

**Section 5 - 510(k) Summary**

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JAN 24 2014

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**3. Date Prepared**

November 12, 2013

**4. Device Identification**

Trade/Proprietary Name: Suzhou Beinuo family of Surgical Staplers  
Common/Usual Name: Staple, Implantable  
Classification Name: Implantable staple  
Classification Regulation: 21CFR 878.4750  
Product Code: GDW  
Device Class: Class II  
Classification Panel: General and Plastic Surgery

**5. Predicate Devices**

The Suzhou Frankenman Surgical Staplers (K101378) which includes:

- Disposable Alimentary Canal Staplers;
- Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids;
- Disposable Reloadable Linear Stapler and Reloads; and
- Disposable Reloadable Linear Cutter Stapler and Reloads;

The Frankenman Surgical Staplers are substantially to the Suzhou Beinuo family of surgical staplers. The Suzhou Beinuo surgical staplers are virtually identical to the predicate device(s) described above.

## 6. Device Description

The Suzhou Beinuo Staplers were designed in reference to the general principles of surgical staplers. Each stapler/ instrument is activated by squeezing the handle firmly as far as it will go or by pushing the firing knob as far as it will go. Specifics for each stapler include:

- The Suzhou Beinuo Circular Stapler for Single Use places a circular, double staggered row of titanium staples. Immediately after staple formation, the instrument's central knife blade resects the excess tissue, creating a circular anastomosis. The diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler. Note that there are two product codes for this stapler (SBW and SBCS L). The total length of SBW stapler is 420mm and the total length of SBCS L version is 520mm. The staplers are identical except for the length.
- The Suzhou Beinuo Hemorrhoidal Circular Staplers for Single Use places two circular peripheral lines of alternating and overlapping staples, thereby sealing off the rectal tissue above the anal canal. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal tissue. The diameter of the staple line is determined by the selection of the 32mm or 34mm stapler.
- The Suzhou Beinuo Linear Staplers and Reloads for Single Use places a double(or triple in the case of the SBF 30B) staggered row of titanium staples used for mechanical suturing and closure of tissue. The Linear Stapler is available in 32mm, 46mm, 60mm, and 88mm line lengths for use in various applications. The instrument may be reloaded during a single procedure.
- The Suzhou Beinuo Linear Cutter Staplers and Reloads for Single Use delivers two doubled staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures. The Linear Cutter stapler is available in three staple line lengths (61mm, 81mm, or 101mm). The instrument may be reloaded during a single procedure.

## 7. Intended Use

Suzhou Beinuo surgical staplers are indicated for use as follows:

- **Circular Stapler for Single Use**  
The Suzhou Beinuo Circle Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.

- Hemorrhoidal Circular Stapler for Single Use**  
 The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment of hemorrhoids and anorectal wall defects.
- Linear Stapler and Reloads for Single Use**  
 The Suzhou Beinuo Linear Stapler for Single Use (and reloads) is indicated for the closure of tissue in abdominal, gynecological, and thoracic surgical procedures.
- Linear Cutter Stapler and Reloads for Single Use**  
 The Suzhou Beinuo Linear Cutter Stapler for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, and thoracic surgical procedures.

**8. Comparison of Technological Characteristics**

The following table compares the Suzhou Beinuo family of surgical staplers to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

**Table 5A – Comparison of Characteristics**

<b>Manufacturer</b>	<b>Suzhou Beinuo</b>	<b>Suzhou Frankenman</b>	<b>Significant Differences</b>
<b>510(k) Number</b>	TBD	K101378	n/a
<b>Product Code</b>	GDW	GDW	Identical
<b>Regulation Number</b>	21CFR 878.4750	21CFR 878.4750	Identical
<b>Regulation Name</b>	Implantable staple	Implantable staple	Identical
<b>Indications for Use</b>	<p><b>Circular Stapler for Single Use</b>            The Suzhou Beinuo Circular Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.</p> <p><b>Hemorrhoidal Circular Stapler for Single Use</b>            The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment</p>	<p><b>Disposable Alimentary Canal Stapler</b>            The Frankenman Disposable Alimentary Canal Stapler is used throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic techniques.</p> <p><b>Single Use Circular Stapler for Rectal Prolapse and Hemorrhoid</b>            The Frankenman Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids is a Circular Stapler product, with accessories, that has</p>	<p>Virtually Identical</p> <p>Essentially identical. Suzhou Beinuo indication and the Frankenman indications discuss the same procedures. No safety or efficacy impact to the difference in wording</p>

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
	<p>of hemorrhoids and anorectal wall defects.</p> <p><b>Linear Stapler and Reloads for Single Use</b>            The Suzhou Beinuo Linear Stapler for Single Use (and reloads) is indicated for the closure of tissue in abdominal, gynecological, and thoracic surgical procedures.</p> <p><b>Linear Cutter Stapler and Reloads for Single Use</b>            The Suzhou Beinuo Linear Cutter Stapler for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, and thoracic surgical procedures</p>	<p>application for general surgical treatment of haemorrhoids and anorectal wall defects by means of transanal stapling and resection of mucosal and musculo-mucosal tissue resulting in occlusion of haemorrhoidal inflow, restoring the haemorrhoidal tissue to its normal physiological position.</p> <p><b>Disposable Reloadable Linear Stapler and Reloads</b>            The Frankenman Disposable Reloadable Linear Stapler (and Reloads) is used in the resection or transaction of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.</p> <p><b>Disposable Reloadable Linear Cutter Stapler and Reloads</b>            The Frankenman Disposable Reloadable Linear Cutter Stapler (and Reloads) has application in abdominal, gynecological, thoracic and pediatric surgery transaction, resection, and the creation of anastomoses.</p>	<p>Essentially identical. Suzhou Beinuo Indication and the Frankenman indication discuss the same procedures. No safety or efficacy impact to the difference in wording</p> <p>Essentially identical. Suzhou Beinuo Indication and the Frankenman indication discuss the same procedures. No safety or efficacy impact to the difference in wording</p>
<p><b>Product Descriptions</b></p>	<p><b>Circular Staplers for Single Use</b>            The Circular Stapler for Single Use is a surgical device for the reconstruction of alimentary tract with mechanical method to replace traditional hand operation.            This device is designed on the principal of staplers. It creates side to end, end to end anastomosis in alimentary canal with peripheral double</p>	<p><b>The Frankenman Disposable Alimentary Canal Stapler (i.e., CS Stapler)</b>, is primarily composed of plastic, titanium, and stainless steel and is used for the reconstruction and anastomosis in the alimentary canal. These disposable staplers place a circular, double staggered row of titanium (ISO 5832-2) staples and then resect the excess tissue, creating a circular</p>	<p>The products are virtually identical.</p>

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
	<p>staggered rows of staples, and cut off the residue tissue with the circular cutting blade in the center to ensure a big enough canal for the reconstructed alimentary tract. By squeezing the firing handle, the staples form and the circular knife blade resects the excess tissue, creating a circular anastomosis. The diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler.</p> <p>The Circular Stapler for Single Use is made of plastic particles, pure titanium, aluminum alloy and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. The Circular Stapler for Single Use is used for reconstruction and anastomosis in the alimentary canal. The device has a shelf-life of 3 years.</p> <p><b><u>Hemorrhoidal Circular Stapler for Single Use</u></b></p> <p><b>Product description</b></p> <p>Hemorrhoidal Circular Staplers for Single Use is made of plastic particles, pure titanium, aluminum alloy and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. The product's shelf life is 3 years.</p>	<p>anastomosis. The CS Stapler is activated by squeezing the handle firmly.</p> <p>The outer diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler. The stapler is available in one staple diameter, 0.28mm and two shaft lengths, 420mm and 520mm.</p> <p><b>The Frankenman Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids</b> (i.e., stapled Haemorrhoidopexy (CPH), is primarily manufactured from plastic, titanium, aluminum alloy and stainless steel and is used in the treatment of rectal haemorrhoids and anorectal defects of transanal stapling (otherwise known as <u>staples transanal rectal resection</u> or STARR procedure) and</p>	

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
	<p>Hemorrhoidal Circular Staplers for Single Use is used in the treatment of rectal wall defects and internal hemorrhoids during anorectal surgery. The Beinuo Hemorrhoidal Circular Staplers for Single Use places a circular, double staggered rows of titanium staples, thereby sealing off the rectal mucosa or rectum above the anal canal. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa or rectum. The diameter of the staple line is determined by the selection of the 32mm or 34mm stapler.</p> <p><b><u>Linear Staplers and Reloads for Single Use</u></b></p> <p><b>Product description</b></p> <p>Linear Stapler and Reloads for Single Use are made of plastic particles, titanium and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. Linear Staplers and Reloads for Single Use is used in the closure of incision and stump of inner organs in general surgery. The shelf life is 3 years.</p> <p>The Beinuo Linear Staplers and Reloads for Single Use places a double staggered row of titanium staples (3 rows for white cartridge only) used for mechanical suturing and closure of tissue. The Linear Stapler is available in 32mm,</p>	<p>resection of rectal mucosal and musculo-mucosal tissue resulting in occlusion of haemorrhoidal inflow, restoring the haemorrhoidal tissue to its normal physiological position. Specifically, the rectal mucosa above the anal canal is sealed by the placement of two circular peripheral lines of alternating and overlapping of titanium (ISO 5832-2) staples. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa.</p> <p><b>The Frankenman Disposable Reloadable Linear Stapler</b> is manufactured primarily from plastic, titanium, and stainless steel. Single Use, reloadable linear staplers are used in the process of mechanical suturing and closure of tissue, prior to the removal of excess tissue. Specific surgical procedures where the LS would be used include general, thoracic, gynecological and colorectal surgeries.</p> <p>The LS places a double staggered row of titanium (ISO 5832-2) staples, with the exception of model number LS30W which places three staggered rows of staples. This third row provides additional security for closing vessels where bleeding is a significant risk.</p>	

Manufacturer	Suzhou Beينو	Suzhou Frankenman	Significant Differences
	<p>46mm, 60mm, and 88mm line lengths for use in various applications. The instrument may be reloaded during a single procedure.</p> <p><b><u>Linear Cutter Staplers and Reloads for Single Use</u></b></p> <p><b>Product description</b></p> <p>Linear Cutter Staplers and Reloads for Single Use are made of plastic particles, pure titanium and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. Linear Cutter Staplers and Reloads for Single Use is used in transection, resection and suture in GI, gynecological, thoracic surgeries. The shelf is three years.</p> <p>The Beينو Linear Cutter Staplers and Reloads for Single Use delivers two doubled staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures. The Linear Cutter stapler is available in three staple line lengths (61mm, 81mm, or 101mm). The instrument may be reloaded during a single procedure.</p>	<p>The LS is available in 30mm, 45mm, 60mm, and 90mm staple line lengths for use in various applications and three stapler sizes (2.5, 3.8mm and 4.5mm) to accommodate various tissue thicknesses.</p> <p><b>The Frankenman Disposable Reloadable Linear Cutter Stapler (i.e. LC Stapler)</b></p> <p>The Frankenman LC Disposable Reloadable Stapler delivers two doubled staggered rows of titanium staples and is used to resect and/or anastomose the internal tissues during surgical procedures and reloads are manufactured primarily from plastic, titanium, and stainless steel. The Frankenman Disposable Reloadable Linear Cutter stapler is used for abdominal, gynecological, thoracic, and pediatric surgery for transaction, resection, and the creation of anastomoses</p>	
<b>Basic Principle of Operation</b>	The stapler places a circular, double-staggered row of staples and then resects any excess tissue, creating a circular anastomosis.	Stapler places a circular, double staggered row of staples and then resects the excess tissue, creating a circular anastomosis.	Identical

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
<b>Material</b>	Stainless steel (staplers) & titanium (staples)	Stainless steel (staplers) & titanium (staples)	Identical
<b>Sterile</b>	Yes, radiation sterilized	Yes, radiation sterilized	Identical
<b>Single-Use</b>	Staplers are single use. Staplers + reloads may be reloaded with additional staples during the procedure (single patient – no re-use or re-sterilization).	Staplers are single use. Staplers + reloads may be reloaded with additional staples during the procedure (single patient – no re-use or re-sterilization).	Identical
<b>Shelf Life</b>	36 months based on the sterilization validation of the packaging.	24 months based on sterilization validation of the packaging	The Suzhou Beinuo device has 12 months additional shelf life based on sterilization validation data.
<b>Biocompatibility</b>	Complies with ISO 10993-1 and other pertinent standards	Complies with ISO 10993-1 and other pertinent standards	Identical
<b>Conclusion:</b> The Suzhou Beinuo surgical staple device shares the same indications for use, device operation, overall technical and functional capabilities, meets the same standards and requirements and therefore are substantially equivalent to the predicate device(s). The Suzhou Beinuo device is similar in design and function to the predicate devices for the modes of operation and use.			

## 9. Non-Clinical Performance Data

The Suzhou Beinuo surgical stapler complies with the applicable voluntary standards as shown below:

- Materials of Construction – ISO 5382-2-1999 – Surgical Instruments – Metallic Materials – Part 2 – Unalloyed titanium
- Sterilization –
  - ISO 11737-1: 2006, Sterilization of medical devices -- Microbiological methods – Part 1, Determination of a population of microorganisms on products
  - ISO 11137-1:2006, Sterilization of healthcare products – Radiation – Part 1, Requirements for the development, validation and routine control of a sterilization process for medical devices.
- Biocompatibility – contact materials were tested per the schema in ISO 10993-1. Specifically:
  - AAMI / ANSI / ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)
  - ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. (Biocompatibility)
- Risk Management activities were carried out as described in ISO 14971: 2007, Medical devices -- Application of risk management to medical devices
- Packaging for Terminally Sterilized Devices – ISO 11607:2003, Packaging for Terminally Sterilized Medical Products.

Additionally, the surgical staplers were evaluated to validate physical characteristics (appearance, dimensions, stapler compatibility with the cartridge) and performance characteristics (strength, closure performance). The Suzhou Beinuo staplers were also evaluated for performance testing compared to the analogous Suzhou Frankenman staplers. Evaluation of the two stapler products similar results (in terms of post-operative healing, pain management, anastomotic leakage, and bleeding) as compared to manual suturing and competitors' devices.

Based on this testing, the design and construction of the Suzhou Beinuo and Suzhou Frankenman staplers were determined to be substantially equivalent. The Suzhou Beinuo family of surgical staplers meets all the requirements for overall design, sterilization, biocompatibility, and clinical utility confirming that the output meets the design inputs and specifications. The Suzhou Beinuo surgical staplers passed all testing and supports the claims of substantial equivalence and safe operation.

The Suzhou Beinuo surgical staplers comply with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

#### **10. Clinical Testing**

There was no prospective clinical studies required to support the medical device as the indications for use, technology, materials of construction are virtually identical to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

#### **11. Statement of Substantial Equivalence**

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device.

It has been shown in this 510(k) submission that the difference between the Suzhou Beinuo surgical staplers and the Suzhou Frankenmann surgical staplers do not raise any questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards, demonstrate that the Suzhou Beinuo surgical staplers are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, sterilization, biocompatibility, performance characteristics, and intended use. The Suzhou Beinuo surgical staplers, as designed and manufactured, are determined to be substantially equivalent to the referenced predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-002

January 14, 2014

Suzhou Beinuo Medical Equipment Co., Ltd.  
C/O Emergo Group  
Robert Seiple, RAC, Senior Consultant, QA/RA  
816 Congress Avenue, Suite 1400  
Austin, Texas 78701

Re: K133499

Trade/Device Name: Suzhou Beinuo Family of Surgical Staplers  
Regulation Number: 21 CFR 878.4750  
Regulation Name: Implantable staple  
Regulatory Class: Class II  
Product Code: GDW  
Dated: November 13, 2013  
Received: November 14, 2013

Dear Mr. Seiple:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Binita S. Ashar, MD, MBA, FACS  
2014.01.14 23:40:56 -05'00'

Binita Ashar, MD, MBA, FACS  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)  
K133499

Device Name  
Suzhou Beinuo Surgical Staplers

Indications for Use (Describe)

Suzhou Beinuo surgical staplers are indicated for use as follows:

• Circular Stapler for Single Use

The Suzhou Beinuo Circular Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.

• Hemorrhoidal Circular Stapler for Single Use

The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment of hemorrhoids and anorectal wall defects.

• Linear Stapler and Reloads for Single Use

The Suzhou Beinuo Linear Stapler and Reloads for Single Use (and reloads) is indicated for the closure of tissue in abdominal, gynecological, and thoracic surgical procedures.

• Linear Cutter Stapler and Reloads for Single Use

The Suzhou Beinuo Linear Cutter Stapler and Reloads for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, and thoracic surgical procedures.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**David Krause -S**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-002

January 14, 2014

Suzhou Beinuo Medical Equipment Co., Ltd.  
C/O Emergo Group  
Robert Seiple, RAC, Senior Consultant, QA/RA  
816 Congress Avenue, Suite 1400  
Austin, Texas 78701

Re: K133499

Trade/Device Name: Suzhou Beinuo Family of Surgical Staplers  
Regulation Number: 21 CFR 878.4750  
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Sincerely yours,

Binita S. Ashar, MD, MBA, FACS  
2014.01.14 23:40:56 -05'00'

Binita Ashar, MD, MBA, FACS  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Concurrence & Template History Page**

[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K133499

For Office of Compliance Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197.415881&\\_dad=portal&\\_schema=PORTAL&org=318](http://insideportlets.fda.gov:9010/portal/page?_pageid=197.415881&_dad=portal&_schema=PORTAL&org=318)

For Office of Surveillance and Biometrics Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197.415881&\\_dad=portal&\\_schema=PORTAL&org=423](http://insideportlets.fda.gov:9010/portal/page?_pageid=197.415881&_dad=portal&_schema=PORTAL&org=423)

<b>Digital Signature Concurrence Table</b>	
Reviewer Sign-Off	David Krause for DAH, December 31, 2013
Branch Chief Sign-Off	David Krause, December 31, 2013
Division Sign-Off	Binita Ashar, January 14, 2014

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 <sup>st</sup> page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format

**Indications for Use**

510(k) Number (if known)

K133499

Device Name

Suzhou Beinuo Surgical Staplers

Indications for Use (Describe)

Suzhou Beinuo surgical staplers are indicated for use as follows:

• Circular Stapler for Single Use

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• Hemorrhoidal Circular Stapler for Single Use

The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment of hemorrhoids and anorectal wall defects.

• Linear Stapler and Reloads for Single Use

The Suzhou Beinuo Linear Stapler and Reloads for Single Use (and reloads) is indicated for the closure of tissue in abdominal, gynecological, and thoracic surgical procedures.

• Linear Cutter Stapler and Reloads for Single Use

The Suzhou Beinuo Linear Cutter Stapler and Reloads for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, and thoracic surgical procedures.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**David Krause -S**

K133499

**Section 3 – 510(k) Cover Letter**

U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Mail Center – WO66-G609  
 10903 New Hampshire Avenue  
 Silver Spring, Maryland 20993-0002

FDA CDRH DMC

NOV 14 2013

Received

Dear Sir or Madam:

This document contains a traditional 510(k) submission for Suzhou Beinuo's family of surgical staplers. These include:

- Circular Stapler for Single Use
- Hemorrhoidal Circular Stapler for Single Use
- Linear Stapler and Reloads for Single Use
- Linear Cutter Stapler and Reloads for Single Use

This submission for market clearance, in accordance with Section 510(k) of the Federal Food and Drug Cosmetic Act as amended, and Title 21 CFR, Part 807, this Pre-Market Notification is being submitted at least ninety days prior to the date when Suzhou Beinuo proposes to introduce these surgical staplers into interstate commerce for commercial distribution.

The CD provided with the submission is the official electronic copy of the submission; the eCopy is an exact duplicate of the paper copy.

The following contains the regulatory information for the contents of this submission supporting the device's market clearance.

**Administrative Information**

Date of Submission: November 13, 2013

Submission is Completed By: Emergo Group  
 816 Congress Avenue,  
 Suite 1400  
 Austin, TX 78701

Application Correspondent: Robert Seiple, RAC  
 Senior Consultant QA, Emergo Group  
 Email: [project.management@emergogroup.com](mailto:project.management@emergogroup.com)  
 Cellphone number: 940.390.0961  
 Home office number: 512.327.9997

Submission Sponsor: Suzhou Beinuo Medical Equipment Co., Ltd.  
 158-38 Huashan Rd  
 Suzhou High – New District  
 China, 215129  
 Ms. Liying Huang

114

Office Manager  
Office number: +86 512 66629935

### Device Identification

Type of 510(k) Submission: Traditional

Device Name:

- Circular Stapler for Single Use
- Hemorrhoidal Circular Stapler for Single Use
- Linear Stapler and Reloads for Single Use
- Linear Cutter Stapler and Reloads for Single Use

Regulation Classification: 21 CFR 878.4750 "Implantable Staple - An implantable staple is a staple-like device intended to connect internal tissues to aid healing. It is not absorbable"

Product Code: GDW, Implantable Staple

Class of Device: Class II

Panel: General and Plastic Surgery

Reason for Submission: New device

Multiple Devices: None; this is the only device in the submission

Previous Submissions: None

Confidentiality Requirements: Please keep all parts of the submission confidential

As described for the Frankenman family of surgical staplers, the Suzhou Beinuo surgical staplers operate with the same principles, providing mechanical suturing with aligned rows of titanium staples for tissue fixation and closure. As with the predicate and other surgical staplers, the Suzhou Beinuo staplers are sometimes combined with tissue resection capability using circular or linear traveling blades.

**Design and Use of the Device**

**Table 4A – Principle Factors**

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

All information necessary for a substantial equivalence determination is included herein. Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at 940 390-0961 or by email at [project.management@emergogroup.com](mailto:project.management@emergogroup.com)

Sincerely,



Robert Seiple, RAC  
Senior Consultant, RA/QA

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<b>Section</b>	<b>Description</b>
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## **Section 1 - Medical Device User Fee Cover Sheet (FDA Form 3601)**

**Device Name:** Surgical Staplers

The FDA Form 3601 Medical Device User Fee Sheet is contained in this section.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	PAYMENT IDENTIFICATION NUMBER: <span style="background-color: black; color: red; padding: 2px;">(b)(4) Trade Secret</span> Write the Payment Identification number on your check <b>P d t</b>
---	--

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <http://www.fda.gov/oc/mdufma/cover sheet.html>

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  SUZHOU BEINUO MEDICAL EQUIPMENT CO LTD 816 Congress Avenue Suite 1400 Austin TX 78701 US  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME Melissa Brightwell 2.1 E-MAIL ADDRESS mbrightwell@emergogroup.com 2.2 TELEPHONE NUMBER (include Area code) 512-222-0256 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
--	--

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm>)

Select an application type:

<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 <u>Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
--	---

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA       NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm> for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
---	--

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES       NO

PAPERWORK REDUCTION ACT STATEMENT  
 Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for

reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) Trade Secret  
Process - Product  
Form FDA 3601 (01/2007)

12-Nov-2013

["Close Window"](#) [Print Cover sheet](#)

**Online Payment**

**Step 3: Confirm Payment**

1 | 2 | 3

**Thank you.**  
**Your transaction has been successfully completed.**

**Pay.gov Tracking Information**

**Application Name:** FDA User Fees

(b)(4) Trade Secret Process -  
Product Specs

**Transaction Date and Time:** 11/12/2013 15:37 EST

**Payment Summary**

**Address Information**

**Account Information**

**Payment Information**

(b)(4) Trade Secret Process - Product Specs

## **Section 2 – CDRH Premarket Review Submission Cover Sheet (FDA Form 3514)**

**Device Name:** Surgical Staplers

The CDRH Premarket Review Submission Cover Sheet is contained in this section. Standard Data Report Forms (FDA Forms 3654) for applicable standards are referenced in Section 9 Declaration of Conformity and Summary Reports of this submission.

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission 11/13/2013	User Fee Payment ID Number <b>(b)(4) Trade Secret Process - Product</b>	FDA Submission Document Number (if known)
----------------------------------	--	---

**SECTION A TYPE OF SUBMISSION**

<p><b>PMA</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<p><b>PMA &amp; HDE Supplement</b></p> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<p><b>PDP</b></p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<p><b>510(k)</b></p> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<p><b>Meeting</b></p> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<p><b>IDE</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p><b>Humanitarian Device Exemption (HDE)</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<p><b>Class II Exemption Petition</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p><b>Evaluation of Automatic Class III Designation (De Novo)</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p><b>Other Submission</b></p> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission?  Yes  No (If Yes, please complete Section I, Page 5)

**SECTION B SUBMITTER, APPLICANT OR SPONSOR**

Company / Institution Name Suzhou Beinuo Medical Equipment Co., Ltd.		Establishment Registration Number (if known) tbd	
Division Name (if applicable)		Phone Number (including area code) +86 512 666 299 35	
Street Address 158-38 Huashan Rd.		FAX Number (including area code)	
City Suzhou High - New District	State / Province	ZIP/Postal Code 215129	Country China
Contact Name Ms. Liying Huang			
Contact Title Office Manager		Contact E-mail Address	

**SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)**

Company / Institution Name Emergo Group		Establishment Registration Number (if known)	
Division Name (if applicable)		Phone Number (including area code) 512 327 9997	
Street Address 816 Congress Ave., Suite 1400		FAX Number (including area code)	
City Austin	State / Province Texas	ZIP Code 78701	Country USA
Contact Name Robert Seiple, RAC			
Contact Title Sr. Consultant		Contact E-mail Address Project.management@emergogroup.com	

**SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE**

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (*specify*):

**SECTION D2 REASON FOR APPLICATION - IDE**

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		

Other Reason (*specify*):

**SECTION D3 REASON FOR SUBMISSION - 510(k)**

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
--	---	---

Other Reason (*specify*):

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	GDW	2		3		4		
5		6		7		8		

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K101378	Frankenman Surgical Staplers	Suzhou Frankenman
2			
3			
4			
5			
6			

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification name

Implantable surgical staplers

	Trade or Proprietary or Model Name for This Device	Model Number
1	Suzhou Beinuo Surgical Staplers - Circular Staplers for Single Use	n/a
2	Suzhou Beinuo Surgical Staplers - Hemorrhoidal Circular Staplers for Single Use	n/a
3	Suzhou Beinuo Surgical Staplers - Linear Staplers for Single Use	n/a
4	Suzhou Beinuo Surgical Staplers - Single Use	n/a
5		

FDA document numbers of all prior related submissions (regardless of outcome)

1	NONE	2		3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

- Laboratory Testing     
  Animal Trials     
  Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code GDW	C.F.R. Section (if applicable) 21CFR 878.4750	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery		

Indications (from labeling)

Suzhou Beinuo surgical staplers are indicated for use as follows:  
 Circular Stapler for Single Use - The Suzhou Beinuo Circular Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.  
 Hemorrhoidal Circular Stapler for Single Use - The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment of hemorrhoids and anorectal wall defects. SEE 2ND COPY OF 3514 FOR OTHER TWO INDICATIONS.

**Note:** Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number (if known)

**SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Suzhou Beinuo Medical Equipment Co. Ltd			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) 86 512 666 29935		
Street Address 158-38 Huashan Road			FAX Number (including area code)		
City Suzhou High		State / Province New district	ZIP Code	Country China	
Contact Name Ms. Liying Huang		Contact Title Office Manager		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code)		
Street Address			FAX Number (including area code)		
City		State / Province	ZIP Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code)		
Street Address			FAX Number (including area code)		
City		State / Province	ZIP Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

**SECTION I UTILIZATION OF STANDARDS**

**Note:** Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 5382-2:1999	ISO	ISO 5382-2:1999 - Surgical Instruments - Metallic Materials, Part 2 - Unalloyed Titanium	1999	1
2	ISO 11737-1:2009	ISO	ISO 11737-1:2006 - Sterilization of medical devices - Microbiological methods - Part 1, Determination of a population of microorganisms on products	2006	
3	ISO 11137-1:2006	ISO	ISO 11137-1:2006 - Sterilization of healthcare products - Radiation - Part 1, Requirements for the development, validation, and routine control of a sterilization process for medical devices.	2006	
4	ISO 14971:2007	ISO	ISO 14971:2007, Medical Devices - Application of risk management to medical devices	2007	
5	ISO 11607:2003	ISO	ISO 11607:2003 - Packaging for Terminally Sterilized Medical Products	2003	
6	ISO 10993-5	ISO	ISO 10993-5 - Cytotoxicity Recognition Number 2-153. AAMI / ANSI / ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)	2009	
7	ISO 10993-10	ISO	ISO 10993-10 Third Edition 2010-08-01, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. (Biocompatibility)	2010	

**Please include any additional standards to be cited on a separate page.**

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 Food and Drug Administration  
 Office of Chief Information Officer  
 1350 Piccard Drive, Room 400  
 Rockville, MD 20850

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### Section 3 – 510(k) Cover Letter

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

Dear Sir or Madam:

This document contains a traditional 510(k) submission for Suzhou Beinuo’s family of surgical staplers. These include:

- Circular Stapler for Single Use
- Hemorrhoidal Circular Stapler for Single Use
- Linear Stapler and Reloads for Single Use
- Linear Cutter Stapler and Reloads for Single Use

This submission for market clearance, in accordance with Section 510(k) of the Federal Food and Drug Cosmetic Act as amended, and Title 21 CFR, Part 807, this Pre-Market Notification is being submitted at least ninety days prior to the date when Suzhou Beinuo proposes to introduce these surgical staplers into interstate commerce for commercial distribution.

The CD provided with the submission is the official electronic copy of the submission; the eCopy is an exact duplicate of the paper copy.

The following contains the regulatory information for the contents of this submission supporting the device’s market clearance.

#### Administrative Information

Date of Submission: November 13, 2013

Submission is Completed By: Emergo Group  
816 Congress Avenue,  
Suite 1400  
Austin, TX 78701

Application Correspondent: Robert Seiple, RAC  
Senior Consultant QA, Emergo Group  
Email: [project.management@emergogroup.com](mailto:project.management@emergogroup.com)  
Cellphone number: 940.390.0961  
Home office number: 512.327.9997

Submission Sponsor: Suzhou Beinuo Medical Equipment Co., Ltd.  
158-38 Huashan Rd  
Suzhou High – New District  
China, 215129  
Ms. Liying Huang



Office Manager  
Office number: +86 512 66629935

**Device Identification**

Type of 510(k) Submission: Traditional

Device Name:

- Circular Stapler for Single Use
- Hemorrhoidal Circular Stapler for Single Use
- Linear Stapler and Reloads for Single Use
- Linear Cutter Stapler and Reloads for Single Use

Regulation Classification: 21 CFR 878.4750 “Implantable Staple - An implantable staple is a staple-like device intended to connect internal tissues to aid healing. It is not absorbable”

Product Code: GDW, Implantable Staple

Class of Device: Class II

Panel: General and Plastic Surgery

Reason for Submission: New device

Multiple Devices: None; this is the only device in the submission

Previous Submissions: **None**

Confidentiality Requirements: Please keep all parts of the submission confidential

As described for the Frankenman family of surgical staplers, the Suzhou Beinuo surgical staplers operate with the same principles, providing mechanical suturing with aligned rows of titanium staples for tissue fixation and closure. As with the predicate and other surgical staplers, the Suzhou Beinuo staplers are sometimes combined with tissue resection capability using circular or linear traveling blades.



**Design and Use of the Device**

**Table 4A – Principle Factors**

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

All information necessary for a substantial equivalence determination is included herein. Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at 940 390-0961 or by email at [project.management@emergogroup.com](mailto:project.management@emergogroup.com)

Sincerely,

Robert Seiple, RAC  
Senior Consultant, RA/QA

## Indications for Use

510(k) Number (if known)

Device Name

Suzhou Beinuo Surgical Staplers

Indications for Use (Describe)

Suzhou Beinuo surgical staplers are indicated for use as follows:

- Circular Stapler for Single Use

The Suzhou Beinuo Circular Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.

- Hemorrhoidal Circular Stapler for Single Use

The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment of hemorrhoids and anorectal wall defects.

- Linear Stapler and Reloads for Single Use

The Suzhou Beinuo Linear Stapler and Reloads for Single Use (and reloads) is indicated for the closure of tissue in abdominal, gynecological, pediatric and thoracic surgical procedures.

- Linear Cutter Stapler and Reloads for Single Use

The Suzhou Beinuo Linear Cutter Stapler and Reloads for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, pediatric and thoracic surgical procedures.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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## Section 5 - 510(k) Summary

### 1. Submission Sponsor

Suzhou Beinuo Medical Equipment Co., Ltd.  
158-38 Huashan Road  
Suzhou High – New District  
China, 215129  
Phone: +86 512 66629925  
Fax: +86 512 66626238  
Contact: Ms Liying Huang, Office Manager

### 2. Submission Correspondent

Emergo Group  
Suite 1400  
816 Congress Ave.  
Austin, TX 78701  
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Fax: (512) 327.9998  
Contact: Robert Seiple, RAC, Senior Consultant, QA/RA  
Email: [project.management@emergogroup.com](mailto:project.management@emergogroup.com)

### 3. Date Prepared

November 13, 2013

### 4. Device Identification

Trade/Proprietary Name: Suzhou Beinuo family of Surgical Staplers  
Common/Usual Name: Staple, Implantable  
Classification Name: Implantable staple  
Classification Regulation: 21CFR 878.4750  
Product Code: GDW  
Device Class: Class II  
Classification Panel: General and Plastic Surgery

### 5. Predicate Devices

The Suzhou Frankenman Surgical Staplers (K101378) which includes:

- Disposable Alimentary Canal Staplers;
- Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids;
- Disposable Reloadable Linear Stapler and Reloads; and
- Disposable Reloadable Linear Cutter Stapler and Reloads;

The Frankenman Surgical Staplers are substantially to the Suzhou Beinuo family of surgical staplers. The Suzhou Beinuo surgical staplers are virtually identical to the predicate device(s) described above.

## 6. Device Description

The Suzhou Beinuo Staplers were designed in reference to the general principles of surgical staplers. Each stapler/ instrument is activated by squeezing the handle firmly as far as it will go or by pushing the firing knob as far as it will go. Specifics for each stapler include:

- The Suzhou Beinuo Circular Stapler for Single Use places a circular, double staggered row of titanium staples. Immediately after staple formation, the instrument's central knife blade resects the excess tissue, creating a circular anastomosis. The diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler. Note that there are two product codes for this stapler (SBW and SBCS L). The total length of SBW stapler is 420mm and the total length of SBCS L version is 520mm. The staplers are identical except for the length.
- The Suzhou Beinuo Hemorrhoidal Circular Staplers for Single Use places two circular peripheral lines of alternating and overlapping staples, thereby sealing off the rectal tissue above the anal canal. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal tissue. The diameter of the staple line is determined by the selection of the 32mm or 34mm stapler.
- The Suzhou Beinuo Linear Staplers and Reloads for Single Use places a double(or triple in the case of the SBF 30B) staggered row of titanium staples used for mechanical suturing and closure of tissue. The Linear Stapler is available in 32mm, 46mm, 60mm, and 88mm line lengths for use in various applications. The instrument may be reloaded during a single procedure.
- The Suzhou Beinuo Linear Cutter Staplers and Reloads for Single Use delivers two doubled staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures. The Linear Cutter stapler is available in three staple line lengths (61mm, 81mm, or 101mm). The instrument may be reloaded during a single procedure.

## 7. Intended Use

Suzhou Beinuo surgical staplers are indicated for use as follows:

- **Circular Stapler for Single Use**  
The Suzhou Beinuo Circle Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.

- Hemorrhoidal Circular Stapler for Single Use**  
 The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment of hemorrhoids and anorectal wall defects.
- Linear Stapler and Reloads for Single Use**  
 The Suzhou Beinuo Linear Stapler for Single Use (and reloads) is indicated for the closure of tissue in abdominal, gynecological, pediatric and thoracic surgical procedures.
- Linear Cutter Stapler and Reloads for Single Use**  
 The Suzhou Beinuo Linear Cutter Stapler for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, pediatric and thoracic surgical procedures.

**8. Comparison of Technological Characteristics**

The following table compares the Suzhou Beinuo family of surgical staplers to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

**Table 5A – Comparison of Characteristics**

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
<b>510(k) Number</b>	TBD	K101378	n/a
<b>Product Code</b>	GDW	GDW	Identical
<b>Regulation Number</b>	21CFR 878.4750	21CFR 878.4750	Identical
<b>Regulation Name</b>	Implantable staple	Implantable staple	Identical
<b>Indications for Use</b>	<p><b>Circular Stapler for Single Use</b>                      The Suzhou Beinuo Circular Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.</p> <p><b>Hemorrhoidal Circular Stapler for Single Use</b>                      The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment</p>	<p><b>Disposable Alimentary Canal Stapler</b>                      The Frankenman Disposable Alimentary Canal Stapler is used throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic techniques.</p> <p><b>Single Use Circular Stapler for Rectal Prolapse and Hemorrhoid</b>                      The Frankenman Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids is a Circular Stapler product, with accessories, that has</p>	<p>Virtually Identical</p> <p>Essentially identical. Suzhou Beinuo indication and the Frankenman indications discuss the same procedures. No safety or efficacy impact to the difference in wording</p>

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
	<p>of hemorrhoids and anorectal wall defects.</p> <p><b>Linear Stapler and Reloads for Single Use</b>            The Suzhou Beinuo Linear Stapler for Single Use (and reloads) is indicated for the closure of tissue in abdominal, gynecological, pediatric and thoracic surgical procedures.</p> <p><b>Linear Cutter Stapler and Reloads for Single Use</b>            The Suzhou Beinuo Linear Cutter Stapler for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, pediatric and thoracic surgical procedures</p>	<p>application for general surgical treatment of haemorrhoids and anorectal wall defects by means of transanal stapling and resection of mucosal and musculo-mucosal tissue resulting in occlusion of haemorrhoidal inflow, restoring the haemorrhoidal tissue to its normal physiological position.</p> <p><b>Disposable Reloadable Linear Stapler and Reloads</b>            The Frankenman Disposable Reloadable Linear Stapler (and Reloads) is used in the resection or transection of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.</p> <p><b>Disposable Reloadable Linear Cutter Stapler and Reloads</b>            The Frankenman Disposable Reloadable Linear Cutter Stapler (and Reloads) has application in abdominal, gynecological, thoracic and pediatric surgery transection, resection, and the creation of anastomoses.</p>	<p>Essentially identical. Suzhou Beinuo Indication and the Frankenman indication discuss the same procedures. No safety or efficacy impact to the difference in wording</p> <p>Essentially identical. Suzhou Beinuo Indication and the Frankenman indication discuss the same procedures. No safety or efficacy impact to the difference in wording</p>
<p><b>Product Descriptions</b></p>	<p><b>Circular Staplers for Single Use</b>            The Circular Stapler for Single Use is a surgical device for the reconstruction of alimentary tract with mechanical method to replace traditional hand operation.            This device is designed on the principal of staplers. It creates side to end, end to end anastomosis in alimentary canal with peripheral double</p>	<p><b>The Frankenman Disposable Alimentary Canal Stapler</b> (i.e., CS Stapler, is primarily composed of plastic, titanium, and stainless steel and is used for the reconstruction and anastomosis in the alimentary canal. These disposable staplers place a circular, double staggered row of titanium (ISO 5832-2) staples and then resect the excess tissue, creating a circular</p>	<p>The products are virtually identical.</p>

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
	<p>staggered rows of staples, and cut off the residue tissue with the circular cutting blade in the center to ensure a big enough canal for the reconstructed alimentary tract. By squeezing the firing handle, the staples form and the circular knife blade resects the excess tissue, creating a circular anastomosis. The diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler.</p> <p>The Circular Stapler for Single Use is made of plastic particles, pure titanium, aluminum alloy and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. The Circular Stapler for Single Use is used for reconstruction and anastomosis in the alimentary canal. The device has a shelf-life of 3 years.</p> <p><b><u>Hemorrhoidal Circular Stapler for Single Use</u></b></p> <p><b>Product description</b></p> <p>Hemorrhoidal Circular Staplers for Single Use is made of plastic particles, pure titanium, aluminum alloy and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. The product's shelf life is 3 years.</p>	<p>anastomosis. The CS Stapler is activated by squeezing the handle firmly.</p> <p>The outer diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler. The stapler is available in one staple diameter, 0.28mm and two shaft lengths, 420mm and 520mm.</p> <p><b>The Frankenman Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids</b> (i.e., stapled Haemorrhoidopexy (CPH), is primarily manufactured from plastic, titanium, aluminum alloy and stainless steel and is used in the treatment of rectal haemorrhoids and anorectal defects of transanal stapling (otherwise known as <u>staples transanal rectal resection</u> or STARR procedure) and</p>	

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
	<p>Hemorrhoidal Circular Staplers for Single Use is used in the treatment of rectal wall defects and internal hemorrhoids during anorectal surgery. The Beinuo Hemorrhoidal Circular Staplers for Single Use places a circular, double staggered rows of titanium staples, thereby sealing off the rectal mucosa or rectum above the anal canal. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa or rectum. The diameter of the staple line is determined by the selection of the 32mm or 34mm stapler.</p> <p><b><u>Linear Staplers and Reloads for Single Use</u></b></p> <p><b>Product description</b></p> <p>Linear Stapler and Reloads for Single Use are made of plastic particles, titanium and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. Linear Staplers and Reloads for Single Use is used in the closure of incision and stump of inner organs in general surgery. The shelf life is 3 years.</p> <p>The Beinuo Linear Staplers and Reloads for Single Use places a double staggered row of titanium staples (3 rows for white cartridge only) used for mechanical suturing and closure of tissue. The Linear Stapler is available in 32mm,</p>	<p>resection of rectal mucosal and musculo-mucosal tissue resulting in occlusion of haemorrhoidal inflow, restoring the haemorrhoidal tissue to its normal physiological position. Specifically, the rectal mucosa above the anal canal is sealed by the placement of two circular peripheral lines of alternating and overlapping of titanium (ISO 5832-2) staples. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa.</p> <p><b>The Frankenman Disposable Reloadable Linear Stapler</b> is manufactured primarily from plastic, titanium, and stainless steel. Single Use, reloadable linear staplers are used in the process of mechanical suturing and closure of tissue, prior to the removal of excess tissue. Specific surgical procedures where the LS would be used include general, thoracic, gynecological and colorectal surgeries.</p> <p>The LS places a double staggered row of titanium (ISO 5832-2) staples, with the exception of model number LS30W which places three staggered rows of staples. This third row provides additional security for closing vessels where bleeding is a significant risk.</p>	

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
	<p>46mm, 60mm, and 88mm line lengths for use in various applications. The instrument may be reloaded during a single procedure.</p> <p><b><u>Linear Cutter Staplers and Reloads for Single Use</u></b></p> <p><b>Product description</b></p> <p>Linear Cutter Staplers and Reloads for Single Use are made of plastic particles, pure titanium and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. Linear Cutter Staplers and Reloads for Single Use is used in transection, resection and suture in GI, gynecological, thoracic and pediatric surgeries. The shelf is three years.</p> <p>The Beinuo Linear Cutter Staplers and Reloads for Single Use delivers two doubled staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures. The Linear Cutter stapler is available in three staple line lengths (61mm, 81mm, or 101mm). The instrument may be reloaded during a single procedure.</p>	<p>The LS is available in 30mm, 45mm, 60mm, and 90mm staple line lengths for use in various applications and three stapler sizes (2.5, 3.8mm and 4.5mm) to accommodate various tissue thicknesses.</p> <p><b>The Frankenman Disposable Reloadable Linear Cutter Stapler (i.e. LC Stapler)</b></p> <p>The Frankenman LC Disposable Reloadable Stapler delivers two doubled staggered rows of titanium staples and is used to resect and/or anastomose the internal tissues during surgical procedures and reloads are manufactured primarily from plastic, titanium, and stainless steel. The Frankenman Disposable Reloadable Linear Cutter stapler is used for abdominal, gynecological, thoracic, and pediatric surgery for transaction, resection, and the creation of anastomoses</p>	
<p><b>Basic Principle of Operation</b></p>	<p>The stapler places a circular, double-staggered row of staples and then resects any excess tissue, creating a circular anastomosis.</p>	<p>Stapler places a circular, double staggered row of staples and then resects the excess tissue, creating a circular anastomosis.</p>	<p>Identical</p>

Manufacturer	Suzhou Beinuo	Suzhou Frankenman	Significant Differences
<b>Material</b>	Stainless steel (staplers) & titanium (staples)	Stainless steel (staplers) & titanium (staples)	Identical
<b>Sterile</b>	Yes, radiation sterilized	Yes, radiation sterilized	Identical
<b>Single-Use</b>	Staplers are single use. Staplers + reloads may be reloaded with additional staples during the procedure (single patient – no re-use or re-sterilization).	Staplers are single use. Staplers + reloads may be reloaded with additional staples during the procedure (single patient – no re-use or re-sterilization).	Identical
<b>Shelf Life</b>	36 months based on the sterilization validation of the packaging.	24 months based on sterilization validation of the packaging	The Suzhou Beinuo device has 12 months additional shelf life based on sterilization validation data.
<b>Biocompatibility</b>	Complies with ISO 10993-1 and other pertinent standards	Complies with ISO 10993-1 and other pertinent standards	Identical
<b>Conclusion:</b> The Suzhou Beinuo surgical staple device shares the same indications for use, device operation, overall technical and functional capabilities, meets the same standards and requirements and therefore are substantially equivalent to the predicate device(s). The Suzhou Beinuo device is similar in design and function to the predicate devices for the modes of operation and use.			

## 9. Non-Clinical Performance Data

The Suzhou Beinuo surgical stapler complies with the applicable voluntary standards as shown below:

- Materials of Construction – ISO 5382-2-1999 – Surgical Instruments – Metallic Materials – Part 2 – Unalloyed titanium
- Sterilization –
  - ISO 11737-1: 2006, Sterilization of medical devices -- Microbiological methods – Part 1, Determination of a population of microorganisms on products
  - ISO 11137-1:2006 , Sterilization of healthcare products – Radiation – Part 1, Requirements for the development, validation and routine control of a sterilization process for medical devices.
- Biocompatibility – contact materials were tested per the schema in ISO 10993-1. Specifically:
  - AAMI / ANSI / ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)
  - ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. (Biocompatibility)
- Risk Management activities were carried out as described in ISO 14971: 2007, Medical devices -- Application of risk management to medical devices
- Packaging for Terminally Sterilized Devices – ISO 11607:2003, Packaging for Terminally Sterilized Medical Products.

Additionally, the surgical staplers were evaluated to validate physical characteristics (appearance, dimensions, stapler compatibility with the cartridge) and performance characteristics (strength, closure performance). The Suzhou Beinuo staplers were also evaluated for performance testing compared to the analogous Suzhou Frankenman staplers. Evaluation of the two stapler products similar results (in terms of post-operative healing, pain management, anastomotic leakage, and bleeding) as compared to manual suturing and competitors' devices.

Based on this testing, the design and construction of the Suzhou Beinuo and Suzhou Frankenman staplers were determined to be substantially equivalent. The Suzhou Beinuo family of surgical staplers meets all the requirements for overall design, sterilization, biocompatibility, and clinical utility confirming that the output meets the design inputs and specifications. The Suzhou Beinuo surgical staplers passed all testing and supports the claims of substantial equivalence and safe operation.

The Suzhou Beinuo surgical staplers comply with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

## **10. Clinical Testing**

There was no prospective clinical studies required to support the medical device as the indications for use, technology, materials of construction are virtually identical to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

## **11. Statement of Substantial Equivalence**

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device.

It has been shown in this 510(k) submission that the difference between the Suzhou Beinuo surgical staplers and the Suzhou Frankenmann surgical staplers do not raise any questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards, demonstrate that the Suzhou Beinuo surgical staplers are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, sterilization, biocompatibility, performance characteristics, and intended use. The Suzhou Beinuo surgical staplers, as designed and manufactured, are determined to be substantially equivalent to the referenced predicate devices.

## Section 6 – Truth and Accuracy Statement

**Device Name:** Suzhou Beinuo Surgical Staplers

As Required by 21 CFR 807.87(k), the Truth and Accuracy Statement on company letterhead signed by a responsible person at Suzhou Beinuo is attached in Exhibit 6-1.

## **Section 7 - Class III Certification and Summary**

**Device Name:** Surgical Staplers

**Conclusion:** Not applicable; Class II device

## Section 8 – Financial Certification or Disclosure Statement

**Device Name:** Surgical Staplers

**Conclusion:** Not applicable as clinical trials were not performed with the device.

## Section 9 - Declarations of Conformity and Summary Reports

**Device Name:** Surgical Stapler

The submission is a Traditional 510(k) Submission with no device-specific guidance documents or any declaration of conformity to recognized standards specified by the device regulation. No specific performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act. However, certain voluntary standards and guidance have been used in the design and testing of this device.

### **Materials of Construction:**

The Suzhou Beinuo surgical stapler complies with the applicable voluntary standards for materials of construction as shown below:

- ISO 5382-2:1999 – Surgical Instruments – Metallic Materials – Part 2 – Unalloyed titanium.

### **Sterilization Declaration of Conformity:**

The Suzhou Beinuo devices comply with the applicable voluntary standards of ISO 11137-1:2006 and ISO 11737-1:2006 for sterilization. The sterilization validation reports are included in Section 14 – Sterilization and Shelf Life section of the submission.

- ISO 11737-1: 2006, Sterilization of medical devices -- Microbiological methods – Part 1, Determination of a population of microorganisms on products.
- ISO 11137-1:2006 , Sterilization of healthcare products – Radiation – Part 1, Requirements for the development, validation and routine control of a sterilization process for medical devices.

### **Biocompatibility Declaration of Conformity:**

Patient –contact materials were tested per ISO 10993-1. The following tests were conducted:

- AAMI / ANSI / ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. (Biocompatibility)

### **Risk Management Declaration of Conformity:**

- ISO 14971: 2007, Medical devices -- Application of risk management to medical devices

For the voluntary standards listed above, Suzhou Beinuo certifies that the results from the requisite testing performed meet specified acceptance criteria and the surgical stapler conforms to applicable and relevant portions of each respective standard. The Standard Data Reports, FDA Form-3654 are attached as Exhibit 9-1 through Exhibit 9-8 in order to provide more detailed conformance information for the recognized voluntary standards.

**Packaging Validation:**

Packaging Validation testing of the sterilized product was conducted in conformance with ISO 11607:2003<sup>1</sup> “Packaging for Terminally Sterilized Medical Devices”. FDA recognition # 14-193.

**Summary:**

A number of voluntary standards were utilized to demonstrate conformance to the various requirements. These are listed below:

**Table 9-A – List of Voluntary Standards – FDA Forms 3654:**

ISO 5382-2:1999	8-57	Exhibit 9-1
ISO 11137-1:2006	14-364	Exhibit 9-2
ISO 11737-1:2006	14-327	Exhibit 9-3
ISO 14971:2007	5-40	Exhibit 9-4
ISO 11607-2:2003	14-356	Exhibit 9-5
ISO 10993-5:2009	2-153	Exhibit 9-6
ISO 10993-10:2002	2-174	Exhibit 9-7
ISO 10993-1:2009	2-156	Exhibit 9-8

<sup>1</sup> Note that some of the packaging test reports also reference BS EN 868-1:1997 “Packaging materials and systems for medical devices which are to be sterilized. General requirements and test methods”. This standard has been superseded by ISO 11607 which is listed above.

## Section 10 – Executive Summary

**Device Name:** Suzhou Beinuo Surgical Staplers

**Summary of Device:**

The Suzhou Beinuo Staplers were designed in reference to the general principles of surgical staplers. Each stapler/ instrument is activated by squeezing the handle firmly as far as it will go or by pushing the firing knob as far as it will go. Specifics for each stapler include:

- The Suzhou Beinuo Circular Stapler for Single Use places a circular, double staggered row of titanium staples. Immediately after staple formation, the instrument's central knife blade resects the excess tissue, creating a circular anastomosis. The diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler. Note that there are two product codes for this stapler (SBW and SBCS L). The total length of SBW stapler is 420mm and the total length of SBCS L version is 520mm. The staplers are identical except for the length.



- The Suzhou Beinuo Hemorrhoidal Circular Staplers for Single Use places two circular peripheral lines of alternating and overlapping staples, thereby sealing off the rectal tissue above the anal canal. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal tissue. The diameter of the staple line is determined by the selection of the 32mm or 34mm stapler.



- The Suzhou Beinuo Linear Staplers and Reloads for Single Use places a double (or triple in the case of the SBF 30B) staggered row of titanium staples used for mechanical suturing and closure of tissue. The Linear Stapler is available in 32mm, 46mm, 60mm, and 88mm line lengths for use in various applications. The instrument may be reloaded during a single procedure.



- The Suzhou Beinuo Linear Cutter Staplers and Reloads for Single Use delivers two doubled staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures. The Linear Cutter stapler is available in three staple line lengths (61mm, 81mm, or 101mm). The instrument may be reloaded during a single procedure.



#### Indications for Use:

Suzhou Beinuo surgical staplers are indicated for use as follows:

- **Circular Stapler for Single Use**  
The Suzhou Beinuo Circular Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.
- **Hemorrhoidal Circular Stapler for Single Use**  
The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment of hemorrhoids and anorectal wall defects.
- **Linear Staplers and Reloads for Single Use**  
The Suzhou Beinuo Linear Stapler for Single Use (and reloads) is indicated for the closure of tissue in abdominal, gynecological, pediatric and thoracic surgical procedures.
- **Linear Cutter Staplers and Reloads for Single Use**  
The Suzhou Beinuo Linear Cutter Staplers for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, pediatric and thoracic surgical procedures.

**Table 10-1 Device Comparison Summary – Circular Stapler for Single Use:**

Manufacturer	Suzhou Beinu Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
<b>510(k) Number</b>	TBD	K101378	N/A
<b>Product Code</b>	GDW	GDW	Identical
<b>Regulation Number</b>	21CFR 878.4750	21CFR 878.4750	Identical
<b>Regulation Name</b>	Implantable staple	Implantable staple	Identical
<b>Indications for Use</b>	<p><b>Circular Stapler for Single Use</b></p> <p>The Suzhou Beinu Circle Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.</p>	<p><b>Disposable Alimentary Canal Stapler</b></p> <p>The Frankenman Disposable Alimentary Canal Stapler is used throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic techniques.</p>	Virtually identical
<b>Product Descriptions:</b>	<p><b>Circular Staplers for Single Use</b></p> <p>The Circular Stapler for Single Use is a surgical device for the reconstruction of alimentary tract with mechanical method to replace traditional hand operation. This device is designed on the principal of staplers. It creates side to end, end to end anastomosis in alimentary canal with peripheral double staggered rows of staples, and cut off the residue tissue with the circular cutting blade in the center to ensure a big enough canal for the reconstructed alimentary tract. By squeezing the firing handle, the staples form and the circular knife blade resects the excess tissue, creating a circular anastomosis. The diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm</p>	<p><b>The Frankenman Disposable Alimentary Canal Stapler</b> (i.e., CS Stapler, is primarily composed of plastic, titanium, and stainless steel and is used for the reconstruction and anastomosis in the alimentary canal. These disposable staplers place a circular, double staggered row of titanium (ISO 5832-2) staples and then resect the excess tissue, creating a circular anastomosis. The CS Stapler is activated by squeezing the handle firmly.</p> <p>The outer diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler. The stapler is available in one staple diameter, 0.28mm and two shaft lengths, 420mm and 520mm.</p>	Essentially identical; the products are virtually identical

Manufacturer	Suzhou Beinuo Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
	<p>stapler.</p> <p>The Circular Stapler for Single Use is made of plastic particles, pure titanium, aluminum alloy and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. The Circular Stapler for Single Use is used for reconstruction and anastomosis in the alimentary canal. The device has a shelf-life of 3 years.</p>		
<b>Basic Principle of Operation</b>	The stapler places a circular, double-staggered row of staples and then resects any excess tissue, creating a circular anastomosis.	Stapler places a circular, double staggered row of staples and then resects the excess tissue, creating a circular anastomosis.	Identical
<b>Material</b>	Stainless steel (staplers)& titanium (staples)	Stainless steel (staplers) and titanium (staples)	Identical
<b>Sterile</b>	Radiation sterilized	Radiation sterilized	Identical
<b>Single Use</b>	Single Use	Single Use	Identical
<b>Compliance to voluntary standards</b>	Sterilization (ISO 11137 & 11737), Package Validation (ISO 11607), Materials of Construction (ISO 5382-2 – Titanium), Risk Management (ISO 14971).	Sterilization (ISO 11137 & 11737), Package Validation (ISO 11607), Materials of Construction (ISO 5382-2 – Titanium), Risk Management (ISO 14971).	Identical
<b>Stapler Diameter (mm)</b>	21.5, 25.5, 28.5, 32.5	21.5, 25.5, 28.5, 32.5	Identical
<b>Shaft Sizes (mm)</b>	420 and 520	420 and 520	Identical
<b>Approximate Tissue Closure (mm)</b>	1.0 – 2.0	1.0 – 2.0	Identical
<b>Staple Diameter (mm)</b>	0.3 <sub>-0.03</sub>	0.28	Identical within limits stated
<b>Staple Count</b>	16, 20, 24, 28	16, 20, 24, 28	Identical
<b>Crown Length (mm)</b>	3.8 and 4.0	3.8 and 4.0	Identical
<b>Leg Length (mm)</b>	4.2 and 5.0	4.2 and 5.0	Identical
<b>Lumen Size (mm)</b>	13, 17, 20, 24	13, 17, 20, 24	Identical

**Table 10-2 Device Comparison Summary – Hemorrhoidal Circular Stapler for Single Use**

Manufacturer	Suzhou Beinuo Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
510(k) Number	TBD	K101378	N/A
Product Code	GDW	GDW	Identical
Regulation Number	21CFR 878.4750	21CFR 878.4750	Identical
Regulation Name	Implantable staple	Implantable staple	Identical
Indications for Use	<p><b>Hemorrhoidal Circular Stapler for Single Use</b></p> <p>The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment of hemorrhoids and anorectal wall defects.</p>	<p><b>Single Use Circular Stapler for Rectal Prolapse and Hemorrhoid</b></p> <p>The Frankenman Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids is a Circular Stapler product, with accessories, that has application for general surgical treatment of haemorrhoids and anorectal wall defects by means of transanal stapling and resection of mucosal and musculo-mucosal tissue resulting in occlusion of haemorrhoidal inflow, restoring the haemorrhoidal tissue to its normal physiological position. .</p>	Essential identical; the clinical application is the same
Product Description	<p><b><u>Hemorrhoidal Circular Stapler for Single Use</u></b></p> <p><b>Product description</b></p> <p>Hemorrhoidal Circular Staplers for Single Use is made of plastic particles, pure titanium, aluminum alloy and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. The product’s shelf life is 3 years.</p> <p>Hemorrhoidal Circular Staplers for Single Use is used in the treatment of rectal wall defects and internal hemorrhoids during anorectal surgery. The Beinuo Hemorrhoidal Circular Staplers for Single Use places a circular, double staggered rows of titanium staples, thereby sealing off</p>	<p><b>The Frankenman Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids</b></p> <p>(i.e., stapled Haemorrhoidopexy (CPH), is primarily manufactured from plastic, titanium, aluminum alloy and stainless steel and is used in the treatment of rectal haemorrhoids and anorectal defects of transanal stapling (otherwise known as <u>staples transanal rectal resection</u> or STARR procedure) and resection of rectal mucosal and musculo-mucosal tissue resulting in occlusion of haemorrhoidal inflow, restoring the haemorrhoidal tissue to its normal physiological position. Specifically, the rectal mucosa above the anal canal is sealed by the placement of two</p>	The products are virtually identical

Manufacturer	Suzhou Beinuo Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
	the rectal mucosa or rectum above the anal canal. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa or rectum. The diameter of the staple line is determined by the selection of the 32mm or 34mm stapler.	circular peripheral lines of alternating and overlapping of titanium (ISO 5832-2) staples. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa.	
<b>Principle of Operation</b>	The device places two circular peripheral lines of alternating and overlapping staples, sealing the rectal mucosa above the anal canal. A central circular blade cuts the surplus tissue after sealing to reconstruct the rectal mucosa.	Instrument designed on the principles of surgical staplers. By placement of two circular peripheral lines of alternating and overlapping staples, the rectal mucosa above the anal canal is sealed. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa.	Identical
<b>Material</b>	Stainless steel (staplers)& titanium (staples)	Stainless steel (staplers) and titanium (staples)	Identical
<b>Sterile</b>	Radiation sterilized	Radiation sterilized	Identical
<b>Single Use</b>	Single Use	Single Use	Identical
<b>Compliance to voluntary standards</b>	Sterilization (ISO 11137 & 11737), Package Validation (ISO 11607), Materials of Construction (ISO 5382-2 – Titanium), Risk Management (ISO 14971).	Sterilization (ISO 11137 & 11737), Package Validation (ISO 11607), Materials of Construction (ISO 5382-2 – Titanium), Risk Management (ISO 14971).	Identical
<b>Stapler Diameter (mm)</b>	32.5 and 34.5	32.5 and 34.5	Identical
<b>Approximate Tissue Closure (mm)</b>	0.75 and 1.5	0.75 and 1.5	Identical
<b>Staple Diameter (mm)</b>	0.3 <sub>-0.03</sub>	0.28	Identical within the limits stated
<b>Staple Count</b>	32	32	Identical
<b>Crown Length (mm)</b>	3.8	3.8	Identical
<b>Leg Length (mm)</b>	4.2	4.2	Identical
<b>Lumen Size (mm)</b>	24 and 26	24 and 26	Identical
<b>Volume (cm<sup>3</sup>)</b>	17.17 and 20.60	17.17 and 20.60	Identical
<b>Accessories</b>	Suture threader, anal dilator, anal dilator inner lining, purse string suture anoscope	Suture threader, anal dilator, anal dilator inner lining, purse string suture anoscope	Identical

**Table 10-3 Device Comparison Summary – Linear Stapler and Reloads for Single Use:**

Manufacturer	Suzhou Beinu Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
510(k) Number	TBD	K101378	N/A
Product Code	GDW	GDW	Identical
Regulation Number	21CFR 878.4750	21CFR 878.4750	Identical
Regulation Name	Implantable staple	Implantable staple	Identical
Indications for Use	<p><b>Linear Stapler and Reloads for Single Use</b>            The Suzhou Beinu Linear Stapler for Single Use (and reloads) is indicated for the closure of tissue in abdominal, gynecological, pediatric and thoracic surgical procedures.</p>	<p><b>Disposable Reloadable Linear Stapler and Reloads</b>            The Frankenman Disposable Reloadable Linear Stapler (and Reloads) is used in the resection or transaction of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.</p>	Essential identical; the clinical application is the same
Product Description	<p><b><u>Linear Staplers and Reloads for Single Use</u></b>            Linear Stapler and Reloads for Single Use are made of plastic particles, titanium and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60.            Linear Staplers and Reloads for Single Use is used in the closure of incision and stump of inner organs in general surgery. The shelf life is 3 years.            The Beinu Linear Staplers and Reloads for Single Use places a double staggered row of titanium staples (3 rows for white cartridge only) used for mechanical suturing and closure of tissue. The Linear Stapler is available in 32mm, 46mm, 60mm, and 88mm line lengths for use in various applications. The instrument may be reloaded during a single procedure.</p>	<p><b>The Frankenman Disposable Reloadable Linear Stapler</b> is manufactured primarily from plastic, titanium, and stainless steel. Single Use, reloadable linear staplers are used in the process of mechanical suturing and closure of tissue, prior to the removal of excess tissue. Specific surgical procedures where the LS would be used include general, thoracic, gynecological and colorectal surgeries.            The LS places a double staggered row of titanium (ISO 5832-2) staples, with the exception of model number LS30W which places three staggered rows of staples. This third row provides additional security for closing vessels where bleeding is a significant risk.            The LS is available in 30mm, 45mm, 60mm, and 90mm staple line lengths for use in various applications and three stapler sizes (2.5, 3.8mm and 4.5mm) to accommodate various tissue thicknesses.</p>	The products are virtually identical

Manufacturer	Suzhou Beinuo Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
<b>Principle of Operation</b>	Places a double (or triple in the case of the SBF 30B) staggered row of staples and is available in four sizes/staple line lengths for use in various applications to accommodate various tissues thickness.	Places a double (or triple in the case of the LS30-W) staggered row of staples and is available in four sizes/staple line lengths for use in various applications to accommodate various tissues thickness.	Identical
<b>Material</b>	Stainless steel (staplers)& titanium (staples)	Stainless steel (staplers) and titanium (staples)	Identical
<b>Sterile</b>	Radiation sterilized	Radiation sterilized	Identical
<b>Single Use</b>	Staplers are single use but may be reloaded during a single procedure.	Staplers are single use but may be reloaded during a single procedure.	Identical
<b>Compliance to voluntary standards</b>	Sterilization (ISO 11137 & 11737), Package Validation (ISO 11607), Materials of Construction (ISO 5382-2 – Titanium), Risk Management (ISO 14971).	Sterilization (ISO 11137 & 11737), Package Validation (ISO 11607), Materials of Construction (ISO 5382-2 – Titanium), Risk Management (ISO 14971).	Identical
<b>Stapler Diameter (mm)</b>	0.23 <sub>-0.03</sub> and 0.3 <sub>-0.03</sub>	0.23 and 0.28	Identical within the stated limits
<b>Approximate Tissue Closure (mm)</b>	1.0, 1.5 and 2.0	1.0, 1.5 and 2.0	Identical
<b>Staple Count</b>	13, (23 for SBF 30B)19, 25, 37	13, (23 for LS30W)19, 25, 37	Identical
<b>Crown Length (mm)</b>	3.0 and 3.5	3.0 and 3.5	Identical
<b>Leg Length (mm)</b>	2.5, 3.8, 4.5	2.5, 3.8 4.5	Identical
<b>Staple Line Length (mm)</b>	32, 46, 60, 88	32, 46, 60, 88	Identical
<b>Staple Rows</b>	2,3	2.3	Identical
<b>Maximum # of Firings Possible</b>	8	8	Identical

**Table 10-4 Device Comparison Summary – Linear Cutter Stapler and Reloads for Single Use**

Manufacturer	Suzhou Beinu Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
510(k) Number	TBD	K101378	N/A
Product Code	GDW	GDW	Identical
Regulation Number	21CFR 878.4750	21CFR 878.4750	Identical
Regulation Name	Implantable staple	Implantable staple	Identical
Indications for Use	<p><b>Linear Cutter Stapler and Reloads for Single Use</b>            The Suzhou Beinu Linear Cutter Stapler for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, pediatric and thoracic surgical procedures.</p>	<p><b>Disposable Reloadable Linear Cutter Stapler and Reloads</b>            The Frankenman Disposable Reloadable Linear Cutter Stapler (and Reloads) has application in abdominal, gynecological, thoracic and pediatric surgery transaction, resection, and the creation of anastomoses.</p>	Essential identical; the clinical application is the same
Product Description:	<p><u><b>Linear Cutter Staplers and Reloads for Single Use</b></u>  <b>Product description</b>            Linear Cutter Staplers and Reloads for Single Use are made of plastic particles, pure titanium and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. Linear Cutter Staplers and Reloads for Single Use is used in transection, resection and suture in GI, gynecological, thoracic and pediatric surgeries. The shelf is three years.            The Beinu Linear Cutter Staplers and Reloads for Single Use delivers two doubled staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures. The Linear Cutter stapler is available in three staple line lengths (61mm, 81mm, or 101mm). The instrument may be reloaded during a</p>	<p><b>The Frankenman Disposable Reloadable Linear Cutter Stapler</b> (i.e. LC Stapler            The Frankenman LC Disposable Reloadable Stapler delivers two doubled staggered rows of titanium staples and is used to resect and/or anastomose the internal tissues during surgical procedures and reloads are manufactured primarily from plastic, titanium, and stainless steel. The Frankenman Disposable Reloadable Linear Cutter stapler is used for abdominal, gynecological, thoracic, and pediatric surgery for transaction, resection, and the creation of anastomoses.</p>	The products are virtually identical

Manufacturer	Suzhou Beinuo Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
	single procedure.		
<b>Principle of Operation</b>	This stapler delivers two doubled staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures	This stapler delivers two doubled staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures.	Identical
<b>Material</b>	Stainless steel (staplers)& titanium (staples)	Stainless steel (staplers) and titanium (staples)	Identical
<b>Sterile</b>	Radiation sterilized	Radiation sterilized	Identical
<b>Single Use</b>	Staplers are single use but may be reloaded with additional staples during single procedure.	Staplers are single use but may be reloaded with additional staples during single procedure.	Identical
<b>Compliance to voluntary standards</b>	Sterilization (ISO 11137 & 11737), Package Validation (ISO 11607), Materials of Construction (ISO 5382-2 – Titanium), Risk Management (ISO 14971).	Sterilization (ISO 11137 & 11737), Package Validation (ISO 11607), Materials of Construction (ISO 5382-2 – Titanium), Risk Management (ISO 14971).	Identical
<b>Approximate Tissue Closure (mm)</b>	1.5, 2.0	1.5, 2.0	Identical
<b>Staple Diameter (mm)</b>	0.23 <sub>0.03</sub>	0.23	Identical
<b>Staple Count</b>	60, 80, 100	60, 80 100	Identical
<b>Crown Length (mm)</b>	3.0	3.0	Identical
<b>Leg Length (mm)</b>	3.8, 4.5	3.8, 4.5	Identical
<b>Cut Line (mm)</b>	55, 75, 96	55, 75, 96	Identical
<b>Staple Rows</b>	4	4	Identical
<b>Staple Line</b>	61, 81, 101	61, 81, 101	Identical

**Device Comparison Summary:**

The Suzhou Beinuo devices are virtually identical to the predicate Frankenman staplers, Indications for Use, Principles of Operation, materials of construction, applicable standards and dimensions are identical between the Suzhou Beinuo and Suzhou Frankenman staplers, therefore the Suzhou Beinuo are considered to be safe and effective and have been shown to be substantially equivalent to the predicate device.

**Performance Testing Summary:**

The Suzhou Beinuo meets all the requirements for overall design, sterilization, principles of operation, and package validation. The Suzhou Beinuo staplers passed all testing and supports the claims of substantial equivalence and safe operation. See further discussion below.

## Non-Clinical Performance Data

The Suzhou Beinuo surgical stapler complies with the applicable voluntary standards as shown below:

- Materials of Construction – ISO 5382-2-1999 – Surgical Instruments – Metallic Materials – Part 2 – Unalloyed titanium
- Sterilization –
  - ISO 11737-1: 2006, Sterilization of medical devices -- Microbiological methods – Part 1, Determination of a population of microorganisms on products
  - ISO 11137-1:2006 , Sterilization of healthcare products – Radiation – Part 1, Requirements for the development, validation and routine control of a sterilization process for medical devices.
- Biocompatibility – contact materials were tested per the schema in ISO 10993-1. Specifically:
  - AAMI / ANSI / ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)
  - ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. (Biocompatibility)
- Risk Management activities were carried out as described in ISO 14971: 2007, Medical devices -- Application of risk management to medical devices

Additionally, the surgical staplers were evaluated to validate physical characteristics (appearance, dimensions, stapler compatibility with the cartridge) and performance characteristics (strength, closure performance). The Suzhou Beinuo staplers were also evaluated for performance testing in the clinical setting as compared to the analogous Suzhou Frankenman staplers. This testing of the two stapler products similar results (in terms of post-operative healing, pain management, anastomotic leakage, and bleeding) as compared to manual suturing and competitors' devices.

Based on this testing, the design and construction of the Suzhou Beinuo and Suzhou Frankenman staplers were determined to be substantially equivalent. . The Suzhou Beinuo family of surgical staplers meets all the requirements for overall design, sterilization, biocompatibility, and clinical utility confirming that the output meets the design inputs and specifications. The Suzhou Beinuo surgical staplers passed all testing and supports the claims of substantial equivalence and safe operation.

The Suzhou Beinuo surgical staplers comply with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

## Clinical Testing

There was no prospective clinical testing required to support the medical device as the indications for use, technology, materials of construction are virtually identical to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-

clinical testing detailed in this submission supports the substantial equivalence of the device.

### **Statement of Substantial Equivalence**

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device.

### **Conclusion:**

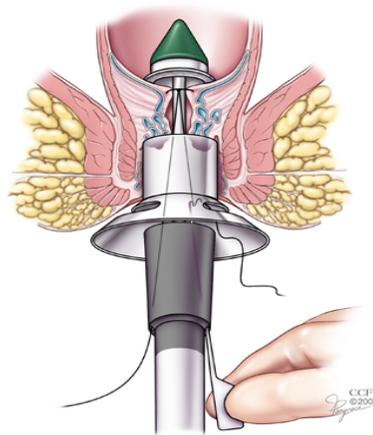
It has been shown in this 510(k) submission that the difference between the Suzhou Beinuo surgical staplers and the Frankenmann surgical staplers do not raise any questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards, demonstrate that the Suzhou Beinuo surgical staplers are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, sterilization, biocompatibility, performance characteristics, and intended use. The Suzhou Beinuo surgical staplers, as designed and manufactured, are determined to be substantially equivalent to the referenced predicate devices.

## Section 11 – Device Description

**Device Name:** Suzhou Beinuo Surgical Staplers

### Description of the Device:

Surgical staplers are specialized staplers used in place of sutures. Examples of how staplers are used include closing skin wounds, creation of anastomoses, general surgical treatment of haemorrhoids and anorectal wall defects (Figure 1), and connecting or removing parts of the esophagus, bowels, stomachs (gastrointestine) or lungs. Stapling is much faster than suturing by hand, and also more accurate and consistent. In the esophagus, bowel, stomach (gastro-intestine) and lung surgery, staplers are primarily used because staple lines are less likely to leak blood, air or bowel contents.



**Figure 1:** Use of Circular Stapler for Surgical Treatment of Hemorrhoids

All surgical staplers operate under the same principle of providing mechanical suturing utilizing aligned rows of titanium staples for fixation and tissue closure. The action of stapling is sometimes combined with tissue resection utilizing circular or linear travelling knife blades.

The Beinuo staplers were designed in reference to the general principles of surgical staplers. Each stapler is activated by squeezing the handle or pushing the firing knob firmly as far as it will go or by pushing the firing knob as far as it will go. The Suzhou Beinuo Family of Staplers includes the:

- The Suzhou Beinuo Circular Stapler for Single Use places a circular, double staggered row of titanium staples. Immediately after staple formation, the instrument's central knife blade resects the excess tissue, creating a circular anastomosis. The diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler. Note that there are two product codes for this stapler (SBW and SBCS L). The

total length of SBW stapler is 420mm and the total length of SBCS L version is 520mm. The staplers are identical except for the staple sizes.

- The Suzhou Beinuo Hemorrhoidal Circular Staplers for Single Use places two circular peripheral lines of alternating and overlapping staples, thereby sealing off the rectal tissue above the anal canal. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal tissue. The diameter of the staple line is determined by the selection of the 32mm or 34mm stapler.
- The Suzhou Beinuo Linear Staplers and Reloads for Single Use places a double(or triple in the case of the SBF 30B) staggered row of titanium staples used for mechanical suturing and closure of tissue. The Linear Stapler is available in 32mm, 46mm, 60mm, and 88mm line lengths for use in various applications. The instrument may be reloaded during a single procedure.
- The Suzhou Beinuo Linear Cutter Staplers and Reloads for Single Use delivers two doubled staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures. The Linear Cutter stapler is available in three staple line lengths (61mm, 81mm, or 101mm). The instrument may be reloaded during a single procedure.

## **Circular Stapler for Single Use**

### **Product description**

#### **Circular Staplers for Single Use**

The Circular Stapler for Single Use is a surgical device for the reconstruction of alimentary tract with mechanical method to replace traditional hand operation.

This device is designed on the principal of staplers. It creates side to end, end to end anastomosis in alimentary canal with peripheral double staggered rows of staples, and cut off the residue tissue with the circular cutting blade in the center to ensure a big enough canal for the reconstructed alimentary tract. By squeezing the firing handle, the staples form and the circular knife blade resects the excess tissue, creating a circular anastomosis. The diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler.

The Circular Stapler for Single Use is made of plastic particles, pure titanium, aluminum alloy and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. The Circular Stapler for Single Use is used for reconstruction and anastomosis in the alimentary canal. The device has a shelf-life of 3 years.

Through selecting qualified material suppliers, controls are applied on the incoming material inspections, manufacturing processes, sterilization process with Cobalt-60 and final inspections. Validation has been applied on sterilization process and internal package. After cytotoxicity test, skin irritation test and skin allergic test, the products have been found to offer no toxicity to cells, no stimulation to skin, and no allergic reaction; they have passed all required tests with regard to Biocompatibility.

### **Product Photo:**



**Drawing and specifications**

(b)(4) Trade Secret Process - Product Specs



1. Anvil 2. Instrument Body 3. Active Handle 4. Safety 5. Adjusting Knob  
 Figure 2: Circular Stapler for Single Use

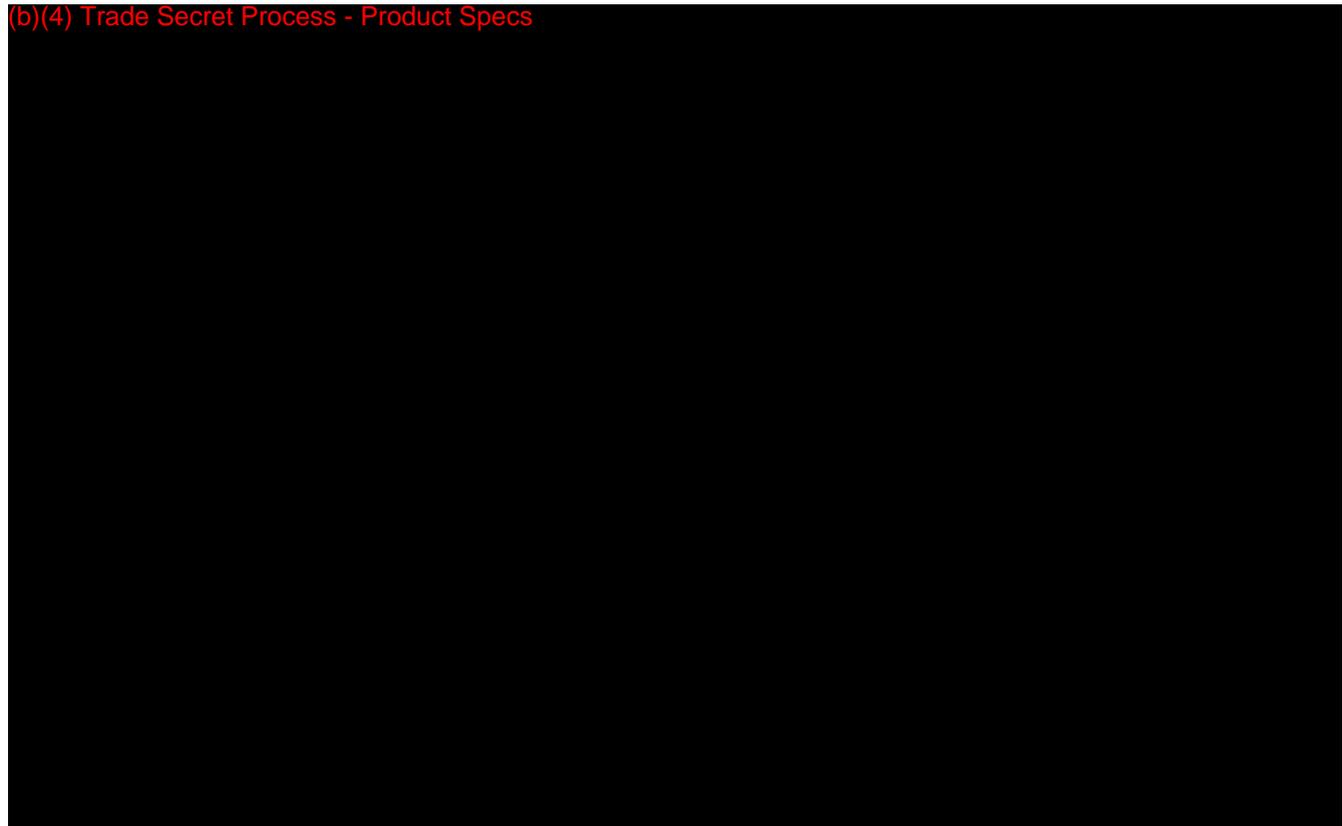
The engineering drawing for the circular stapler is drawing reference SBW-00 and is attached as Exhibit 11 -1.

**Model Number and Specifications for the Beinuo Circular Staplers for Single Use**

Model	Color Code	Lumen Size or Cutting Ø (mm)	Outer Ø (mm)	Staple Count	Staple Diameter (mm)	Crown Length (mm)	Leg Length (mm)	Tissue Closure (mm)	Stapler Length
SBW 21W	Orange	13	21.5	16	φ 0.3 <sub>-0.03</sub>	3.8	4.2	1.0 - 2.0	420mm
SBW 25W	White	17	25.5	20	φ 0.3 <sub>-0.03</sub>	4.0	5.0	1.0 - 2.0	420mm
SBW 28W	Blue	20	28.5	24	φ 0.3 <sub>-0.03</sub>	4.0	5.0	1.0 - 2.0	420mm
SBW 32W	Green	24	32.5	28	φ 0.3 <sub>-0.03</sub>	4.0	5.0	1.0 - 2.0	420mm
SBCS21L	Orange	13	21.5	16	φ 0.3 <sub>-0.03</sub>	3.8	4.2	1.0 - 2.0	520mm
SBCS25L	White	17	25.5	20	φ 0.3 <sub>-0.03</sub>	4.0	5.0	1.0 - 2.0	520mm
SBCS28L	Blue	20	28.5	24	φ 0.3 <sub>-0.03</sub>	4.0	5.0	1.0 - 2.0	520mm
SBCS32L	Green	24	32.5	28	φ 0.3 <sub>-0.03</sub>	4.0	5.0	1.0 - 2.0	520mm

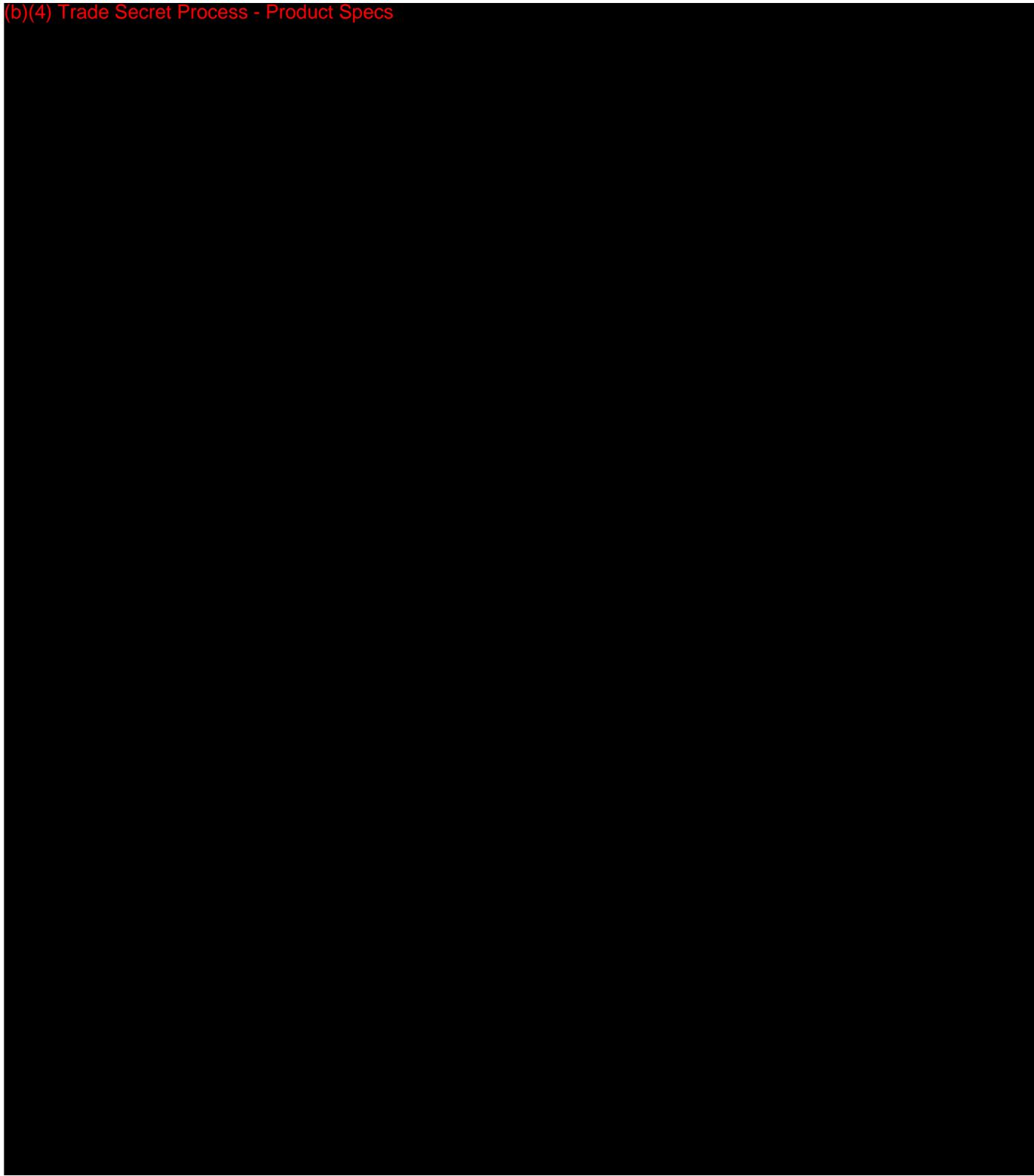
The material specifications for the patient contacting components are summarized below

(b)(4) Trade Secret Process - Product Specs



The following table details components that have no patient contact and describes the function of these components.

(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



## **Hemorrhoidal Circular Stapler for Single Use**

### **Product description**

Hemorrhoidal Circular Staplers for Single Use is made of plastic particles, pure titanium, aluminum alloy and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. The product's shelf life is 3 years.

Hemorrhoidal Circular Staplers for Single Use is used in the treatment of rectal wall defects and internal hemorrhoids during anorectal surgery. The Beinuo Hemorrhoidal Circular Staplers for Single Use places a circular, double staggered rows of titanium staples, thereby sealing off the rectal mucosa or rectum above the anal canal. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa or rectum. The diameter of the staple line is determined by the selection of the 32mm or 34mm stapler.

Through selecting qualified material suppliers, serious controls are applied on incoming material inspections, manufacturing processes, sterilization with Cobalt-60 and final inspections. Validation is applied on sterilization process and small package. After cytotoxicity test, skin irritation test and skin allergic test, the products have been found to offer no toxicity to cells, no stimulation to skin, and no allergic reaction; they have passed all required tests with regard to Biocompatibility.

### **Product Photo:**



**Drawing and specifications**

(b)(4) Trade Secret Process - Product Specs

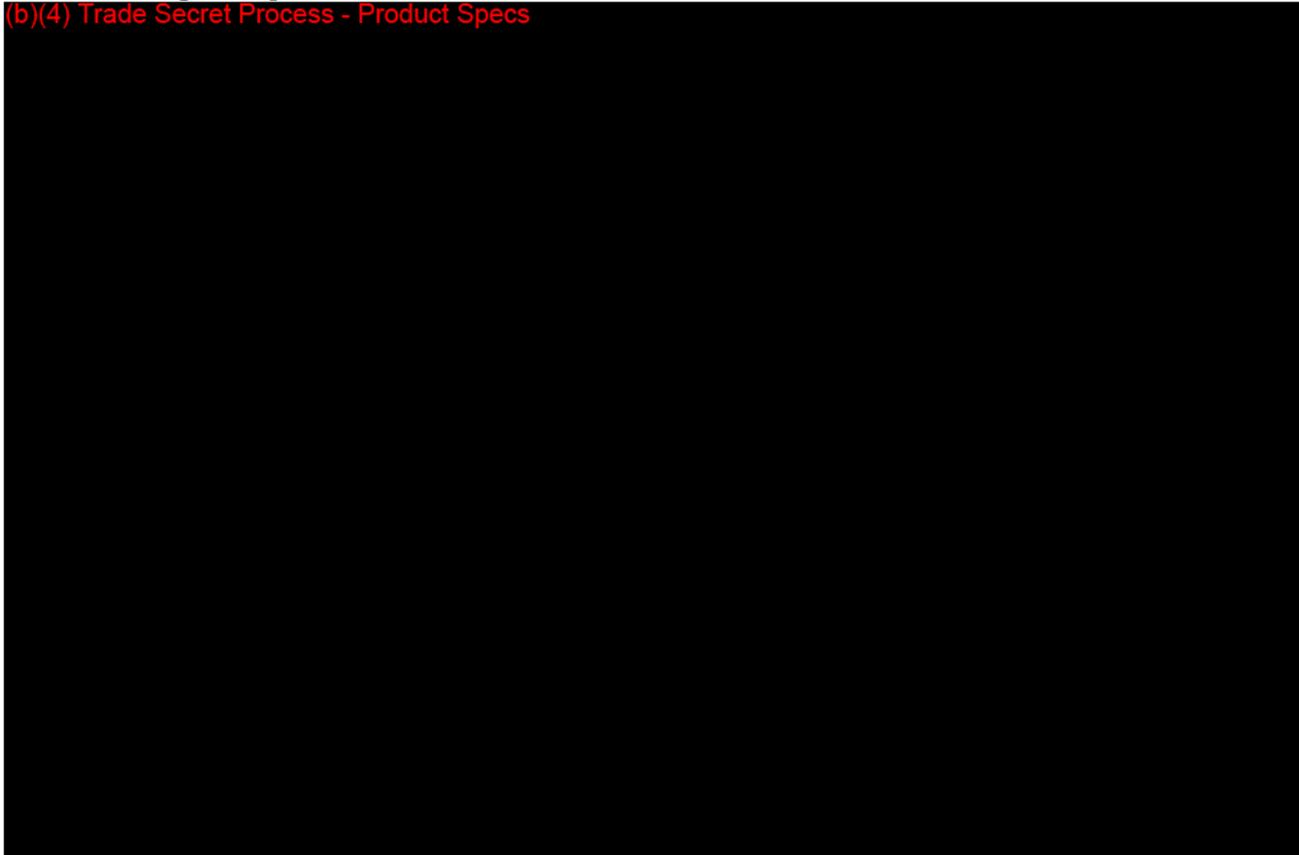


Fig. Hemorrhoidal Circular Staplers for Single Use and accessories

The engineering drawing for the Hemorrhoidal Stapler is drawing reference SBZ-00 and is attached as Attachment 11 -2.

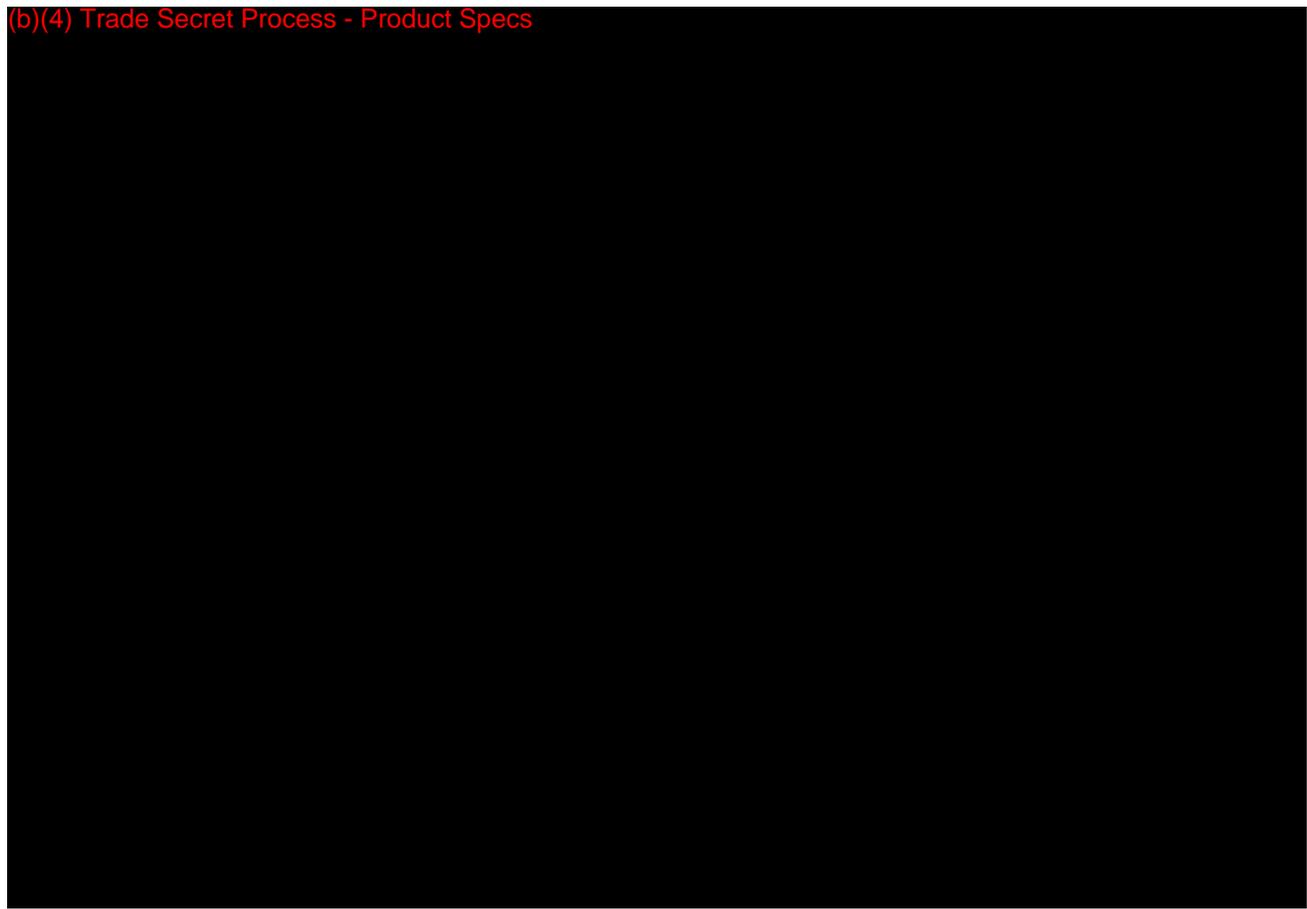
**Specifications**

Model #	Color Code	Lumen Size	Outer Diameter (mm)	Staple Count	Crown Length (mm)	Leg Length (mm)	Tissue Closure (mm)
SBZ 32	White	24	32.5	32	3.8	4.2	0.75-1.5
SBZ 34	Green	26	34.5	32	3.8	4.2	0.75-1.5
Accessories							
	SBZF 32			SBZF 34			
	Applicable for SBZ 32			Applicable for SBZ 34			
Anal Dilator	D1=36.5±0.80			D1=38.5±0.80			

Anal Dilator Inner Lining	D2=33.5±0.80	D2=35.5±0.80
Purse String Suture Anoscope	D3=33.5±0.80	D3=34.5±0.80
Suture Threader	L1=130±1	

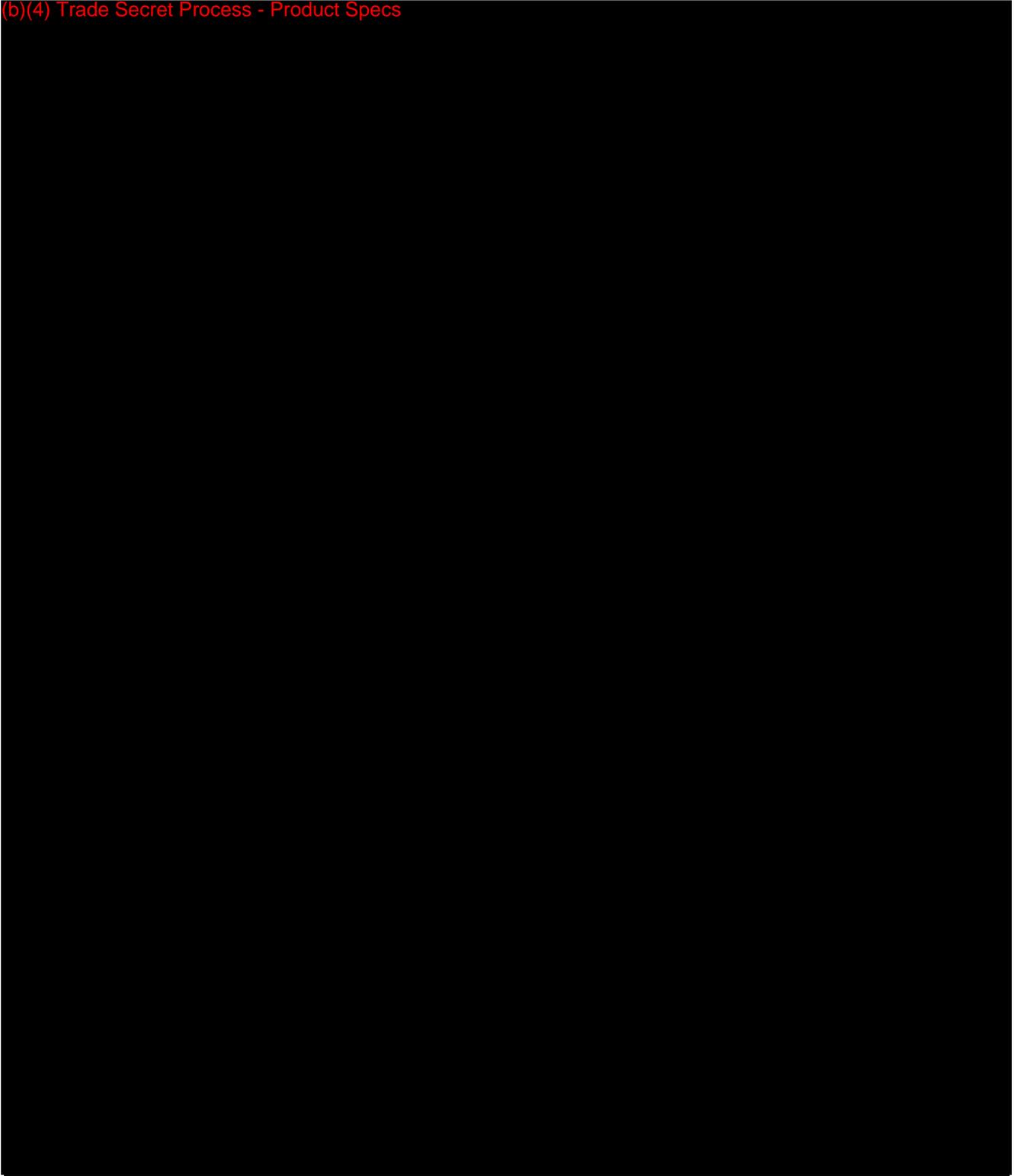
The material specifications for the patient contacting components are summarized below:

(b)(4) Trade Secret Process - Product Specs



The following components have no patient contact and the function of these components.

(b)(4) Trade Secret Process - Product Specs



## **Linear Staplers and Reloads for Single Use**

### **Product description**

Linear Stapler and Reloads for Single Use are made of plastic particles, titanium and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. Linear Staplers and Reloads for Single Use is used in the closure of incision and stump of inner organs in general surgery. The shelf life is 3 years.

The Beinuo Linear Staplers and Reloads for Single Use places a double staggered row of titanium staples(3 rows for white cartridge only) used for mechanical suturing and closure of tissue. The Linear Stapler is available in 32mm, 46mm, 60mm, and 88mm line lengths for use in various applications. The instrument may be reloaded during a single procedure.

Through selecting qualified material suppliers, serious controls are applied on incoming material inspections, manufacturing processes, sterilization with Cobalt-60 and final inspections. Validation is applied on sterilization process and small package. After cytotoxicity test, skin irritation test and skin allergic test, the products have been found to offer no toxicity to cells, no stimulation to skin, and no allergic reaction ; they have passed all required tests with regard to Biocompatibility.

### **Product Photo:**



**Drawing and specifications**

(b)(4) Trade Secret Process - Product Specs



Fig. Linear Stapler and Reload for Single Use

The Engineering Drawing for the Linear Stapler is drawing reference SBF-00 (Exhibit 11-3) and the Linear Stapler Reload is drawing reference SBF -02-00 (Exhibit 11-4).

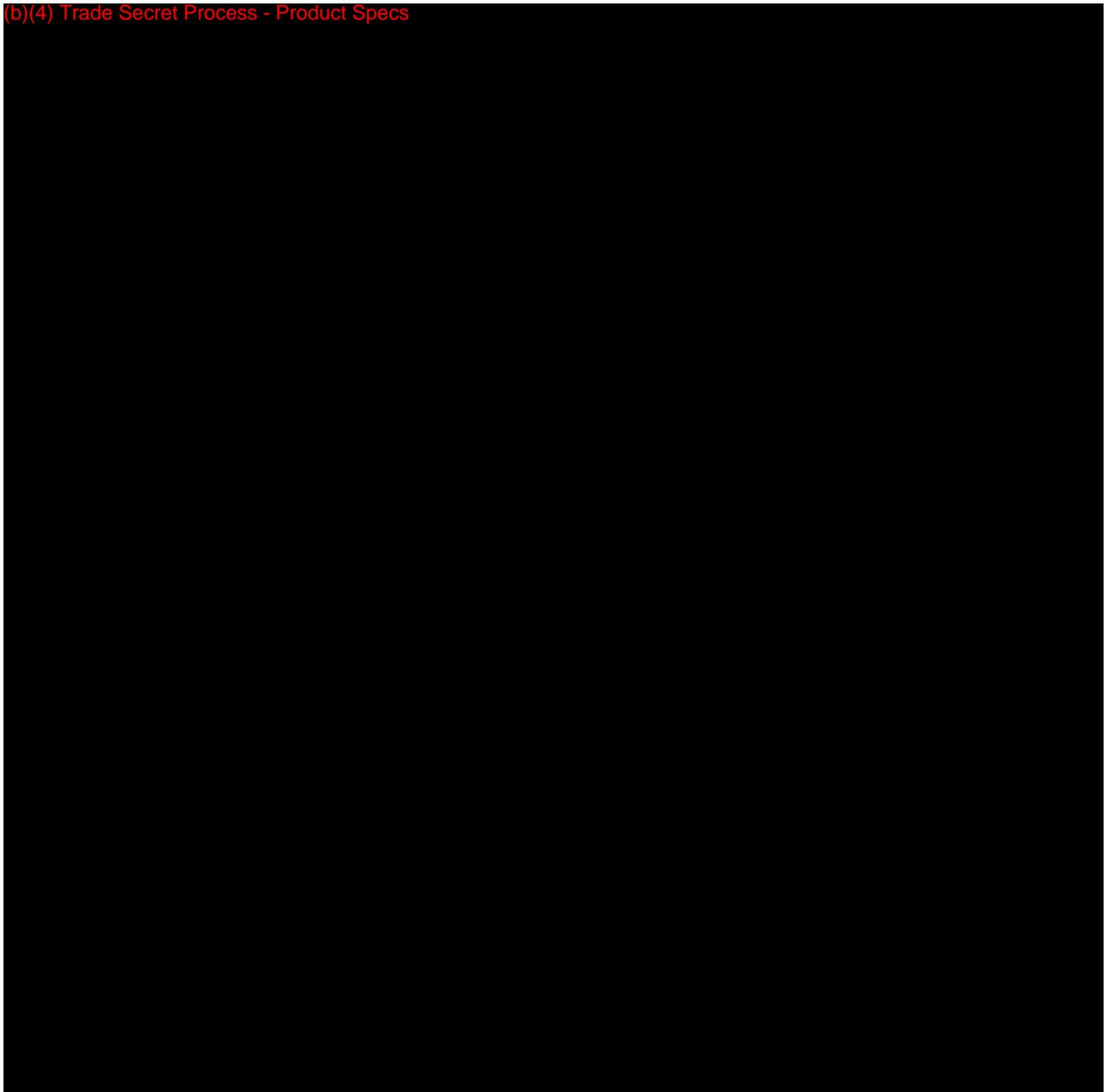
**Specifications:**

Model		Color Code	Staple Line	Staple Rows	Staple Count	Staple Diameter (mm)	Leg Length (mm)	Crown Length (mm)	Tissue Closure (mm)
Linear Stapler	Reload-Cartridge								
SBF 30B	SBFZ 30B	White	32	3	23	$\phi 0.23_{-0.03}$	2.5	3.0	1.0
SBF 30Z	SBFZ 30Z	Blue	32	2	13	$\phi 0.3_{-0.03}$	3.8	3.5	1.5
SBF 30H	SBFZ 30H	Green	32	2	13	$\phi 0.3_{-0.03}$	4.5	3.5	2.0
SBF 45Z	SBFZ 45Z	Blue	46	2	19	$\phi 0.3_{-0.03}$	3.8	3.5	1.5
SBF 45H	SBFZ 45H	Green	46	2	19	$\phi 0.3_{-0.03}$	4.5	3.5	2.0
SBF 60Z	SBFZ 60Z	Blue	60	2	25	$\phi 0.3_{-0.03}$	3.8	3.5	1.5
SBF 60H	SBFZ 60H	Green	60	2	25	$\phi 0.3_{-0.03}$	4.5	3.5	2.0
SBF 90Z	SBFZ 90Z	Blue	88	2	37	$\phi 0.3_{-0.03}$	3.8	3.5	1.5
SBF 90H	SBFZ 90H	Green	88	2	37	$\phi 0.3_{-0.03}$	4.5	3.5	2.0

(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



## **Linear Cutter Staplers and Reloads for Single Use**

### **Product description**

Linear Cutter Staplers and Reloads for Single Use are made of plastic particles, pure titanium and stainless steel, packed in specially designed sterile packs and boxes and sterilized by Cobalt-60. Linear Cutter Staplers and Reloads for Single Use is used in transection, resection and suture in GI, gynecological, thoracic and pediatric surgeries. The shelf is three years.

The Beinuo Linear Cutter Staplers and Reloads for Single Use delivers two doubled staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures. The Linear Cutter stapler is available in three staple line lengths (61mm, 81mm, or 101mm). The instrument may be reloaded during a single procedure.

Through selecting qualified material suppliers, serious controls are applied on incoming material inspections, manufacturing processes, sterilization with Cobalt-60 and final inspections. Validation is applied on sterilization process and small package. After cytotoxicity test, skin irritation test and skin allergic test, the products have been found to offer no toxicity to cells, no stimulation to skin, and no allergic reaction ; they have passed all required tests with regard to Biocompatibility.

### **Product Photo:**



**Drawing and specifications**

(b)(4) Trade Secret Process - Product Specs



(Exhibit 11-5), the Reload for the Linear Cutting Stapler is drawing reference SBQ-01-00  
(Exhibit 11-6).

**Specifications:**

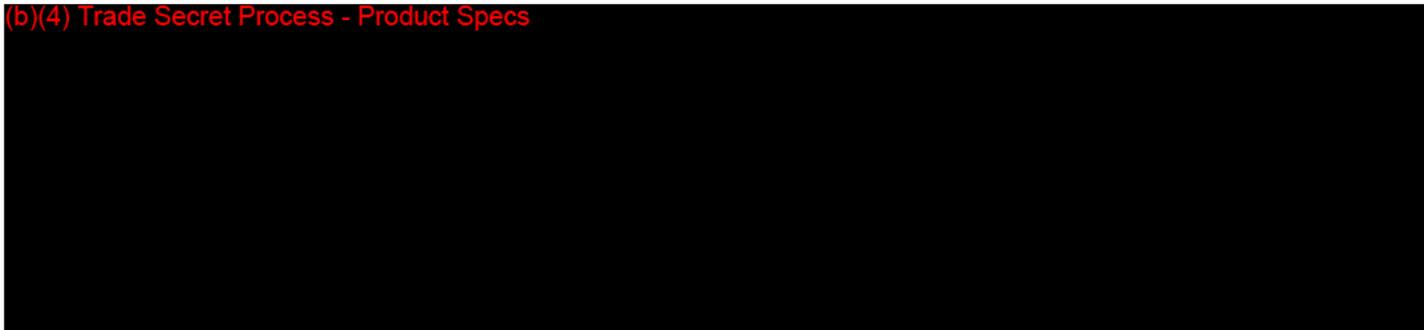
Model		Color Code	Cut Line (mm)	Staple Line	Staple Rows	Staple Count	Staple Diameter (mm)	Leg Length (mm)	Crown Length (mm)	Tissue Closure (mm)
Linear Cutter Stapler	Reload-Cartridge									
SBQ 60ZY	SBQZ 60Z	Blue	55	61	4	60	0.23 <sub>-0.03</sub>	3.8	3.0	1.5
SBQ 60HY	SBQZ 60H	Green	55	61	4	60	0.23 <sub>-0.03</sub>	4.5	3.0	2.0
SBQ 80ZY	SBQZ 80Z	Blue	75	81	4	80	0.23 <sub>-0.03</sub>	3.8	3.0	1.5
SBQ 80HY	SBQZ 80H	Green	75	81	4	80	0.23 <sub>-0.03</sub>	4.5	3.0	2.0
SBQ 100ZY	SBQZ 100Z	Blue	96	101	4	100	0.23 <sub>-0.03</sub>	3.8	3.0	1.5
SBQ 100HY	SBQZ 100H	Green	96	101	4	100	0.23 <sub>-0.03</sub>	4.5	3.0	2.0

(b)(4) Trade Secret Process - Product Specs



The following components have no patient contact and the function of these components.

(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



**Packaging:**

Each surgical staplers is packaged in a Tyvek blister package which is labeled with the identity of the product, lot number, manufacturing date and expiration date. Each stapler is packed in an individual box and the boxes packed in a carton for sterilization. Sterilized staplers are packed 3 boxes to a carton for shipment.

Stapler reloads are packed in blister packages; 12 reloads are packed in a carton.

**Shipping Validation:**

The ability of the Suzhou Beinuo packaging to maintain the components in a satisfactory state during storage and transportation was evaluated by the conduct of a transit test. Drop testing, horizontal impact, and static load stacking testing was conducted to assure that the Suzhou Beinuo product and packaging was appropriate for the anticipated shipping methods. All test results passed; the shipping validation protocol and test reports are attached:

- Exhibit 18-9 – Shipping Validation Protocol
- Exhibit 18-10 – Drop Test Report
- Exhibit 18-11 – Horizontal Impact Test Report
- Exhibit 18-12 – Static Load Stacking Test Report

**Manufacturing Information:**

The device is manufactured in-house and maintains FDA Quality System Regulation compliance, and is certified to ISO 13485.

Brief Explanation of Manufacturing Process

(b)(4) Trade Secret Process - Product Specs



**Summary:**

The Suzhou Beinuo Staplers were designed in reference to the general principles of surgical staplers. The staplers are consistent in indications for use, compliance with relative standards, manufacturing techniques and are judged to be substantially equivalent to the predicate device.

## Section 12 – Substantial Equivalence Discussion

**Device Name:** Surgical Staplers

A copy of the 510(k) summary for the Suzhou Frankenman predicate stapler is included as Exhibit 12-1. The instructions-for-use for the Suzhou Frankenman stapler is included in Exhibit 12-2 to show current marketing information for the predicate device.

**Comparison to Legally Marketed Device:**

**Table 12A – Device Comparison Chart: Similarities and Differences**

Manufacturer	Suzhou Beinuo Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
<b>510(k) Number</b>	TBD	K101378	n/a
<b>Product Code</b>	GDW	GDW	Identical
<b>Regulation Number</b>	21CFR 878.4750	21CFR 878.4750	Identical
<b>Regulation Name</b>	Implantable staple	Implantable staple	Identical
<b>Indications for Use</b>	<p><b>Circular Stapler for Single Use</b>                      The Suzhou Beinuo Circle Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.</p> <p><b>Hemorrhoidal Circular Stapler for Single Use</b>                      The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment of hemorrhoids and anorectal wall defects.</p>	<p><b>Disposable Alimentary Canal Stapler</b>                      The Frankenman Disposable Alimentary Canal Stapler is used throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic techniques.</p> <p><b>Single Use Circular Stapler for Rectal Prolapse and Hemorrhoid</b>                      The Frankenman Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids is a Circular Stapler product, with accessories, that has application for general surgical treatment of haemorrhoids and anorectal wall defects by means of transanal stapling and resection of mucosal and musculo-mucosal tissue resulting in occlusion of haemorrhoidal inflow, restoring the haemorrhoidal tissue to its normal physiological position.</p>	<p>Virtual Identical</p> <p>Essentially identical. Suzhou Beinuo indication and Frankenmann indication discuss the same procedures. No safety or efficacy impact to the difference in wording.</p>

Manufacturer	Suzhou Beinuo Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
	<p><b>Linear Stapler for Single Use</b>            The Suzhou Beinuo Linear Stapler for Single Use (and reloads) is indicated for the closure of tissue in abdominal, gynecological, pediatric and thoracic surgical procedures.</p> <p><b>Linear Cutter Stapler for Single Use</b>            The Suzhou Beinuo Linear Cutter Stapler for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, pediatric and thoracic surgical procedures</p>	<p><b>Disposable Reloadable Linear Stapler and Reloads</b>            The Frankenman Disposable Reloadable Linear Stapler (and Reloads) is used in the resection or transaction of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.</p> <p><b>Disposable Reloadable Linear Cutter Stapler and Reloads</b>            The Frankenman Disposable Reloadable Linear Cutter Stapler (and Reloads) has application in abdominal, gynecological, thoracic and pediatric surgery transaction, resection, and the creation of anastomoses.</p>	<p>Essentially identical. Suzhou Beinuo indication and Frankenmann indication discuss the same procedures. No safety or efficacy impact to the difference in wording.</p> <p>Essentially identical. Suzhou Beinuo indication and Frankenmann indication discuss the same procedures. No safety or efficacy impact to the difference in wording.</p>
<p><b>Product Descriptions:</b></p>	<p><b>Circular Staplers for Single Use</b>            The Circular Stapler for Single Use is a surgical device for the reconstruction of alimentary tract with mechanical method to replace traditional hand operation.            This device is designed on the principal of staplers. It creates side to end, end to end anastomosis in alimentary canal with peripheral double staggered rows of staples, and cut off the residue tissue with the circular cutting blade in the center to ensure a big enough canal for the</p>	<p><b>The Frankenman Disposable Alimentary Canal Stapler (i.e., CS Stapler)</b>, is primarily composed of plastic, titanium, and stainless steel and is used for the reconstruction and anastomosis in the alimentary canal. These disposable staplers place a circular, double staggered row of titanium (ISO 5832-2) staples and then resect the excess tissue, creating a circular anastomosis. The CS Stapler is activated by squeezing the handle firmly. The outer diameter of the staple line is determined by the selection of the 21mm,</p>	<p>The products are virtually identical.</p>

Manufacturer	Suzhou Beinuo Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
	<p>reconstructed alimentary tract. By squeezing the firing handle, the staples form and the circular knife blade resects the excess tissue, creating a circular anastomosis. The diameter of the staple line is determined by the selection of the 21mm, 25mm, 28mm, or 32mm stapler.</p> <p>The Circular Staplers for Single Use have advantages of uniform and reliable anastomosis, good hemostasis and good blood transport. It can not only greatly shorten the operation time, reduce bleeding and injury, but also improve operation quality and reduce complications.</p> <p>The Circular Stapler for Single Use is made of plastic particles, pure titanium, aluminum alloy and stainless steel, packed in specially designed sterile packs and boxes and radiation sterilized (gamma). The Circular Stapler for Single Use is used for reconstruction and anastomosis in the alimentary canal. The device has a shelf-life of 3 years.</p> <p><b><u>Hemorrhoidal Circular Stapler for Single Use</u></b></p>	<p>25mm, 28mm, or 32mm stapler. The stapler is available in one staple diameter, 0.28mm and two shaft lengths, 420mm and 520mm.</p> <p><b>The Frankenman Single Use Circular Stapler for Rectal</b></p>	

Manufacturer	Suzhou Beinuo Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
	<p><b>Product description</b></p> <p>Hemorrhoidal Circular Staplers for Single Use is made of plastic particles, pure titanium, aluminum alloy and stainless steel, packed in specially designed sterile packs and boxes and radiation sterilized (gamma). The product's shelf life is 3 years.</p> <p>Hemorrhoidal Circular Staplers for Single Use is used in the treatment of rectal wall defects and internal hemorrhoids during anorectal surgery. The Beinuo Hemorrhoidal Circular Staplers for Single Use places a circular, double staggered rows of titanium staples, thereby sealing off the rectal mucosa or rectum above the anal canal. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa or rectum. The diameter of the staple line is determined by the selection of the 32mm or 34mm stapler.</p> <p><b><u>Linear Staplers and Reloads for Single Use</u></b></p> <p><b>Product description</b></p> <p>Linear Stapler and Reloads for Single Use are made of plastic particles, titanium and stainless steel, packed in specially</p>	<p><b>Prolapse and Hemorrhoids</b> (i.e., stapled Haemorrhoidopexy (CPH), is primarily manufactured from plastic, titanium, aluminum alloy and stainless steel and is used in the treatment of rectal haemorrhoids and anorectal defects of transanal stapling (otherwise known as <u>staples transanal rectal resection</u> or STARR procedure) and resection of rectal mucosal and musculo-mucosal tissue resulting in occlusion of haemorrhoidal inflow, restoring the haemorrhoidal tissue to its normal physiological position. Specifically, the rectal mucosa above the anal canal is sealed by the placement of two circular peripheral lines of alternating and overlapping of titanium (ISO 5832-2) staples. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa.</p> <p><b>The Frankenman Disposable Reloadable Linear Stapler</b> is manufactured primarily from plastic, titanium, and stainless steel. Single Use, reloadable linear staplers are used in the process of mechanical suturing and closure of tissue, prior to</p>	

Manufacturer	Suzhou Beinuo Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
	<p>designed sterile packs and boxes and sterilized by Cobalt-60. Linear Staplers and Reloads for Single Use is used in the closure of incision and stump of inner organs in general surgery. The shelf life is 3 years.</p> <p>The Beinuo Linear Staplers and Reloads for Single Use places a double staggered row of titanium staples(3 rows for white cartridge only) used for mechanical suturing and closure of tissue. The Linear Stapler is available in 32mm, 46mm, 60mm, and 88mm line lengths for use in various applications. The instrument may be reloaded during a single procedure.</p> <p><b><u>Linear Cutter Staplers and Reloads for Single Use</u></b></p> <p><b>Product description</b></p> <p>Linear Cutter Staplers and Reloads for Single Use are made of plastic particles, pure titanium and stainless steel, packed in specially designed sterile packs and boxes and radiation sterilized gamma). Linear Cutter Staplers and Reloads for Single Use is used in transection, resection and suture in GI,</p>	<p>the removal of excess tissue. Specific surgical procedures where the LS would be used include general, thoracic, gynecological and colorectal surgeries.</p> <p>The LS places a double staggered row of titanium (ISO 5832-2) staples, with the exception of model number LS30W which places three staggered rows of staples. This third row provides additional security for closing vessels where bleeding is a significant risk.</p> <p>The LS is available in 30mm, 45mm, 60mm, and 90mm staple line lengths for use in various applications and three stapler sizes (2.5, 3.8mm and 4.5mm) to accommodate various tissue thicknesses.</p> <p><b>The Frankenman Disposable Reloadable Linear Cutter Stapler (i.e. LC Stapler</b></p> <p>The Frankenman LC Disposable Reloadable Stapler delivers two doubled staggered rows of titanium staples and is used to resect and/or anastomose the internal tissues during surgical procedures and reloads are manufactured primarily from plastic, titanium, and stainless steel. The Frankenman Disposable Reloadable Linear Cutter stapler is used for</p>	

Manufacturer	Suzhou Beinuo Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
	<p>gynecological, thoracic and pediatric surgeries. The shelf is three years.</p> <p>The Beinuo Linear Cutter Staplers and Reloads for Single Use delivers two doubled staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures. The Linear Cutter stapler is available in three staple line lengths (61mm, 81mm, or 101mm). The instrument may be reloaded during a single procedure.</p>	<p>abdominal, gynecological, thoracic, and pediatric surgery for transaction, resection, and the creation of anastomoses</p>	
<b>Basic Principle of Operation</b>	<p>The stapler places a circular, double-staggered row of staples and then resects any excess tissue, creating a circular anastomosis.</p>	<p>Stapler places a circular, double staggered row of staples and then resects the excess tissue, creating a circular anastomosis.</p>	Identical
<b>Materials</b>	<p>Plastic, stainless steel, aluminum alloy and titanium (Titanium per ISO 5832-2)</p>	<p>Plastic, stainless steel and titanium (Titanium per ISO 5832-2)</p>	Identical
<b>Sterile</b>	yes	yes	Identical
<b>Single-Use</b>	<p>Staplers are single use. Staplers + reloads may be reloaded with additional staples during the procedure (single patient – no re-use or re-sterilization)</p>	<p>Staplers are single use. Staplers + reloads may be reloaded with additional staples during the procedure (single patient – no re-use or re-sterilization).</p>	Identical
<b>Shelf Life</b>	<p>36 months years based on the sterilization validation of the packaging.</p>	<p>24 months based on sterilization validation of the packaging</p>	<p>The Suzhou Beinuo device has 12 months additional shelf life based on sterilization validation data</p>
<b>Biocompatibility</b>	<p>Yes- Complies with ISO 10993-1 and other pertinent standards (described in Section 10)</p>	<p>Yes - Complies with ISO 10993-1 and other pertinent standards (described in Section 10)</p>	Identical
<p><b>Conclusion:</b>          The Suzhou Beinuo surgical staple device shares the same indications for use, device operation, overall</p>			

Manufacturer	Suzhou Beinuo Surgical Staplers	Suzhou Frankenman Surgical Staplers	Significant Differences
technical and functional capabilities, meets the same standards and requirements and therefore are substantially equivalent to the predicate device(s). The Suzhou Beinuo device is similar in design and function to the predicate devices for the modes of operation and use.			

The Suzhou Beinuo surgical staple device shares the same indications for use, device operation, overall technical and functional capabilities, meets the same standards and requirements and therefore are substantially equivalent to the predicate device(s). The Suzhou Beinuo device is similar in design and function to the predicate devices for the modes of operation and use.

**Performance Testing Summary:**

Internal verification and validation testing confirms that product specifications are met which are equivalent in design and technological characteristics as the predicate device. The testing results support that the shelf life of the sterilized device, sterilization, and functional testing of the surgical staplers were met for the acceptance of the device. The surgical stapler device passed all testing and supports the claims of substantial equivalence to the predicate device. Section 18 (Non clinical performance bench testing) presents (b) (4) bench test reports where the Suzhou Beinuo devices are directly compared to the Frankenman predicate devices. As detailed in the report, the four versions of the surgical stapler devices are very similar in all respects.

**Table 12B – Performance Summary**

Information or Testing Summarized	Section Located
Proposed Labeling of Device	Section 13
Established Shelf Life	Section 14
Sterilization Validation of Device	Section 14
Biocompatibility Results	Section 15
Non-Clinical Bench Testing	Section 18

**Comparison Discussion:**

The Suzhou Beinuo device has the same intended use and technological characteristics as the predicate device and therefore is substantially equivalent to the predicate device.

## Section 13 – Proposed Labeling

**Device Name:** Suzhou Beinuo Surgical Staplers

### Labeling:

Each version of the Suzhou Beinuo surgical stapler device are provided with an Instruction-for-Use (IFU) that describes the intended use, cautions for use, and instructions for use of the device. IFU's for each of the subject staplers are attached as described in the table below.

The package labels include the information specified in 21 CFR 801 Subpart A and are representative of the planned labels to be used for the surgical stapler's labeling. Draft packaging labeling for the subject staplers are attached as described in the table below.

Each surgical staplers is packaged in a Tyvek blister package which is labeled with the identity of the product, lot number, manufacturing date and expiration date (see Exhibit 13-10). Each stapler is packed in an individual box and the boxes packed in a carton for sterilization. Sterilized staplers are packed 3 boxes to a carton for shipment.

Stapler reloads are packed in blister packages; 12 reloads are packed in a carton.

**Table 13A – Labeling Information**

Product Model	Package Insert (IFU)	Package Label
Circular Stapler	Exhibit 13-1	Exhibit 13-2
Hemorrhoidal circular stapler	Exhibit 13-3	Exhibit 13-4
Linear cutter stapler & reloads	Exhibit 13-5	Exhibit 13-6
Linear stapler & reloads	Exhibit 13-7	Exhibit 13-8
Example Tyvek inner package – all four staplers	Exhibit 13 -9	
Sample package for the Linear Stapler with lot and expiration dating	Exhibit 13-10	

Packaging and labeling of the device will conform to all the regulatory requirements including manufacturer information, product identification, and regulatory statements.

## Section 14 – Sterilization and Shelf Life

**Device Name:** Surgical Staplers

The Suzhoi Beinuo surgical staplers are sterilized with gamma radiation (Cobalt 60). The sterility of the device is assured by using a validated sterilization method qualified in accordance with ISO 11137-1 and ISO 11731-1. The minimum exposure dose of 25kGy was established for routine sterilization. This minimum dose provided a Sterility Assurance Level (SAL) of  $10^{-6}$ . The validation protocols were successfully completed and the test reports are provided further in this section.

### Packaging:

Packaging verification/integrity testing was conducted by (b) (4) [REDACTED]. Test results are discussed below and attached as Exhibits 14-1 through 14-4.

Circular Stapler – (b) (4) [REDACTED]

Test Report Title	Standard(s)	Results
Vacuum Leak Test	ISO 11607-2003	(b)(4) Trade Secret Process - Product Specs
Seal Impermeability and Continuity	EN 868-1:1997	
Agar Contact Attack Test (Microbial Barrier test)	ISO 11607-2003	
Seal Tensile Strength Test	ISO 11607-2003	
Accelerated Aging	ISO 11137:1995 & ISO 11607:2003	

Circular Hemorrhoidal Stapler – (b) (4) [Redacted]  
 [Redacted]:

Test Report Title	Standard(s)	Results
Vacuum Leak Test	ISO 11607-2003	(b)(4) Trade Secret Process - Product Specs
Seal Impermeability and Continuity	EN 868-1:1997	
Agar Contact Attack Test (Microbial Barrier test)	ISO 11607-2003	
Seal Tensile Strength Test	ISO 11607-2003	
Accelerated Aging	ISO 11137:1995 & ISO 11607:2003	

Linear Stapler – (b) (4) [Redacted]

Test Report Title	Standard(s)	Results
Vacuum Leak Test	ISO 11607-2003	(b)(4) Trade Secret Process - Product Specs
Seal Impermeability and Continuity	EN 868-1:1997	
Agar Contact Attack Test (Microbial Barrier test)	ISO 11607-2003	
Seal Tensile Strength Test	ISO 11607-2003	Twelve samples were evaluated to quantify the tensile peel strength. The mean peel strength was 1.41 psi with a standard deviation of 0.15psi.
Accelerated Aging	ISO 11137:1995 & ISO 11607:2003	Test samples remained sterile after 28 days at 60°C.

Linear Cutting Stapler – (b) (4)

Test Report Title	Standard(s)	Results
Vacuum Leak Test	ISO 11607-2003	(b)(4) Trade Secret Process - Product Specs
Seal Impermeability and Continuity	EN 868-1:1997	
Agar Contact Attack Test (Microbial Barrier test)	ISO 11607-2003	
Seal Tensile Strength Test	ISO 11607-2003	
Accelerated Aging	ISO 11137:1995 & ISO 11607:2003	

**Sterilization:**

The Suzhou Beinuo staplers are sterilized by gamma irradiation with a minimum exposure of 25kGy with a Sterility Assurance Level (SAL)  $\leq 10^{-6}$ . Sterilization verification reports are attached (Exhibits 14-5 through 14-8) which demonstrate that the radiation sterilization process was effective. Each stapler and package was tested. All results showed zero growth.

Sterilization Reports are attached demonstrating that the dose mapping of the sterilization load provides the necessary exposure to meet the minimum exposure (modified to account for dosimetry uncertainty). Results are summarized here and attached as Exhibits 14-9 through 14-12.

Product	Exhibit	Dose Range	Dose Uniformity
Circular Stapler	14-9	(b)(4) Trade Secret Process - Product Specs	(b)(4) Trade Secret Process - Product Specs
Hemorroidal Circular Stapler	14-10		
Linear Stapler	14-11		
Linear Cutting Stapler	14-12		

## Shelf Life

A maximum shelf life of 3 years has been assigned to the Suzhou Beinuo staplers, when stored as directed. Each stapler is packaged in a sealed pouch. Stability testing was conducted for 36 months. Tests conducted included: sterility, mechanical performance, and tensile seal strength.

All test reports met acceptance criteria; test reports are attached as follows:

- Exhibit 14-13 – Three year stability – SBF – Linear Stapler
- Exhibit 14-14 – Three year stability – SBW – Circular Stapler
- Exhibit 14-15 – Three year stability – SBQ – Linear Cutter Stapler
- Exhibit 14-16 – Three year stability – SBZ – Hemorrhoidal Circular Stapler

## Package Validation

Package validation testing was conducted for each staplers. Validation testing included a vacuum leak test, dye permeability test, microbial barrier test and tensile seal strength test. This data and the test reports are further discussed in Section 18 – Bench testing.

## Section 15 - Biocompatibility

**Device Name:** Surgical Stapler

### **Discussion Summary:**

The four versions of the device share many common materials; the tables below present the patient-contacting materials for each of the devices (reproduced from Device Description).

### **Circular Staplers for Single Use**

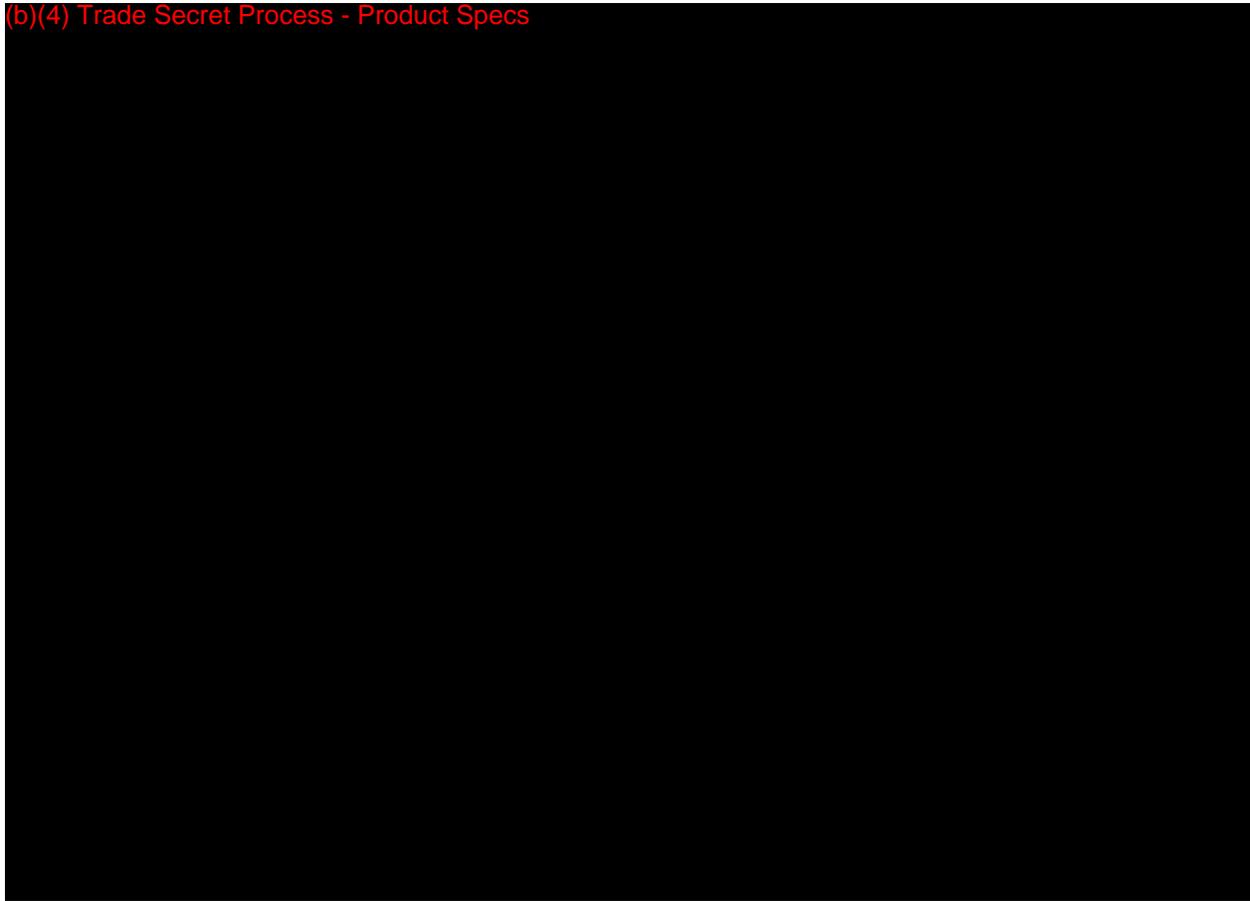
The material specifications for the patient contacting components are summarized below

(b)(4) Trade Secret Process - Product Specs



**Hemorrhoidal Circular Staplers for Single Use**

(b)(4) Trade Secret Process - Product Specs



**Linear Staplers and Reloads for Single Use**

(b)(4) Trade Secret Process - Product Specs



**Linear Cutter Staplers and Reloads for Single Use**

(b)(4) Trade Secret Process - Product Specs



**Patient Contacting Materials**

The biological safety of the Surgical Staplers was evaluated in accordance with ISO 10993-1: 2009. The staplers are considered surface devices with limited contact and were evaluated

for Cytotoxicity (ISO 10993-5) and Sensitization and Irritation (ISO 10993-10). The test report (SDFY 2006-2291) is attached as Exhibit 15-1 (Biocompatibility – all devices).

(b)(4) Trade Secret Process - Product Specs

[Redacted]

re  
*Implants for Surgery - Metallic*

*Materials – Part 2 – Unalloyed Titanium.* All requirements passed; the test report for the Titanium is in Section 18. The cytotoxicity report (SDFY 2006-2292) for the staples is attached in this section (Exhibit 15-2)

The Cytotoxicity testing showed that no cytotoxicity or cell lysis was

(b)(4) Trade Secret  
Process - Product  
Specs

[Redacted]

(b)(4) Trade Secret Process - Product Specs

[Redacted]

(b)(4) Trade Secret Process - Product Specs

[Redacted]

Copies of the surgical stapler material specifications are provided in the Device Description section. The following factors should also be considered in the evaluation of the device:

- The materials of construction and intended use of Suzhou Beinuo surgical staplers are identical to the predicate device.
- The patient-contacting materials used in the surgical staplers have been historically used in this device and many more surgically invasive sterile disposable medical devices over the last decade.
- The intended exposure to the patient is intermittent and limited.
- Test results obtained for Cytotoxicity and Irritation/Sensitization demonstrated that the Suzhou Beinuo devices pass all biocompatibility requirements.

## Section 16 – Software Description

**Device Name: Surgical Staplers**

This section does not apply; the surgical staplers are not electronic devices and contain no software.

## **Section 17 – Electromagnetic Compatibility and Electrical Safety**

**Device Name:** Surgical Staplers

**Discussion Summary:**

Not applicable. The Suzhou Beinuo surgical staplers are manual surgical instruments and contain no electronics, thus EMC and electrical safety do not apply.

## Section 18 – Performance Testing - Bench

**Device Name:** Surgical Staplers

### **Non-Clinical Testing – Summary:**

#### **1. Non-Clinical Testing – Risk Assessment:**

Formal Risk Assessment of the Suzhou Beinuo surgical stapler devices was performed in accordance with ISO 14971:2007, *Medical Devices – Application of Risk Management to Medical Devices*. These analyses were designed to identify potential hazards and failure modes of the device (i.e. system) and assess the risks associated with any potential hazards, as well as identifies hazard control that has been incorporated into the design, and to verify that safety risks have been eliminated or reduced to acceptable levels.

Suzhou Beinuo believes the outcomes of this risk analysis are considered acceptable within the context of ISO 14971:2007, for the intended use (professional Rx use) and that potential risks have been mitigated to their lowest form. The Risk Management reports are attached as follows:

- Exhibit 18-1 – Risk Analysis – Linear Stapler (product code SBF)
- Exhibit 18-2 – Risk Analysis – Linear cutting stapler (product code SBQ)
- Exhibit 18-3 – Risk Analysis – Circular Stapler (product code SBW & SBC) –as discussed previously, the SBC device is identical to the SBW device, it only utilizes longer staples.
- Exhibit 18-4 – Risk Analysis – Circular Hemorrhoidal Stapler (product code SBZ)

#### **2. Non-Clinical Testing - Metallurgy**

Test results for ISO 5382-2 “Implants for Surgery, Metallic Materials, Part 2 – Unalloyed titanium are attached in Exhibit 18-5. The titanium used for the Suzhou Beinuo stapler passed all test criteria.

#### **3. Non-Clinical Testing – Bench Technical Comparison to the Predicate Products**

(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



Shipping Validation:

The ability of the Suzhou Beinuo packaging to maintain the components in a satisfactory state during storage and transportation was evaluated by the conduct of a transit test. Drop testing, horizontal impact, and static load stacking testing was conducted to assure that the Suzhou Beinuo product and packaging was appropriate for the anticipated shipping methods. All test results passed; the shipping validation protocol and test reports are attached:

Exhibit 18-9 – Shipping Validation Protocol

Exhibit 18-10 – Drop Test Report

Exhibit 18-11 – Horizontal Impact Test Report

Exhibit 18-12 – Static Load Stacking Test Report

## Section 19 – Performance Testing - Animal

**Device Name:** Surgical Staplers

**Conclusion:** Not applicable; there was no animal testing performed utilizing the device.

## Section 20 – Performance Testing - Clinical

(b)(4) Trade Secret Process - Product Specs





# 苏州贝诺医疗器械有限公司

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传真(Fax):0512-66626238 邮编(Postal Code):215129 Http://www.beinuomedical.com  
158-38 Huashan Road, Suzhou High-New District, Jiangsu 215129, P.R.China

Suzhou Beinuo Medical Equipment Co., Ltd.  
158-38 Huashan Road  
Suzhou High – New District  
China, 215129

Oct.20, 2013

## Truth and Accuracy Statement

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Management Representative of Suzhou Beinuo, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Liu Qinfang

Date

2013.10.20

Department of Health and Human Services  
 Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
 (To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 5382-2:1999 Surgical Instruments - Metallic Materials, Part 2 Unalloyed titanium

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes     No

FDA Recognition number <sup>3</sup> ..... #8-57

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes     No

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....  Yes     No  
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....  Yes     No

Does this standard include acceptance criteria? .....  Yes     No  
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....  Yes     No  
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....  Yes     No  
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....  Yes     No

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....  Yes     No  
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....  Yes     No  
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....  Yes     No  
 If yes, was the guidance document followed in preparation of this 510k? .....  Yes     No

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 5382-2:1999 – Surgical Instruments – Metallic Materials – Part 2 – Unalloyed titanium.

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER ALL	SECTION TITLE ALL	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11137-1:2006 Sterilization of Health Care Products - Radiation - Part 1: Requirements for Development, Validation and Routin

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #14-328

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
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Title of guidance: \_\_\_\_\_

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<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 11137-1:2006 Sterilization of Health Care Products - Radiation - Part 1: Requirements for Development, Validation and Routine

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER ALL	SECTION TITLE ALL	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11737-1:200 Sterilization of Medical Devices - Microbiological Methods - Part 2: Tests of Sterility Performed in the Definitio

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number<sup>3</sup> ..... #14-327

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

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Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 11737-2:2009 Sterilization of Medical Devices - Microbiological Methods - Part 2: Tests of Sterility Performed in the Definitio

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER ALL	SECTION TITLE ALL	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 14971:2007 Medical devices - Application of risk management to medical devices

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... #5-40

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

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 If yes, was the guidance document followed in preparation of this 510k? .....      

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<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 14971:2007 Medical devices - Application of risk management to medical devices

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER ALL	SECTION TITLE ALL	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

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 (To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11607-2:2006 Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 14-356

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
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 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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SUMMARY REPORT TABLE**

STANDARD TITLE  
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**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER ALL	SECTION TITLE ALL	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Test for in vitro Cytotoxicity

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #2-153

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

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 If no, include the results of testing in the 510(k).

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 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993"

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Test for in vitro Cytotoxicity

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER ALL	SECTION TITLE ALL	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Test for Irritation and Skin Sensitization

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #2-174

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

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Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993"

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Test for Irritation and Skin Sensitization

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER ALL	SECTION TITLE ALL	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-1:2009 - Biological Evaluation of Medical Devices - Part 1: Eval & Testing w/i a risk management process

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #2-156

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

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 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993"

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 10993-1:2009 - Biological Evaluation of Medical Devices - Part 1: Eval & Testing w/i a risk management process

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER ALL	SECTION TITLE ALL	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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10903 New Hampshire Avenue  
Document Control Room –WO66-G609  
Silver Spring, MD 20993-0002

Suzhou Frankenman Medical Equipment Co., Ltd  
% Emergo Group, Inc.  
Jean Asquith  
1705 S. Capital of Texas Highway, Suite 500  
Austin, Texas 78746

JUN 29 2010

Re: K101378

Trade/Device Name: Frankenman Surgical Staplers  
Regulation Number: 21 CFR 878.4750  
Regulation Name: Implantable staple  
Regulatory Class: II  
Product Code: GDW  
Dated: April 12, 2010  
Received: May 21, 2010

Dear Jean Asquith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Page 2 - Jean Asquith

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K101378

Device Name: Frankenman Surgical Staplers

Indications for Use:

Frankenman Staplers are indicated as follows:

- **Disposable Alimentary Canal Stapler**  
The Frankenman Disposable Alimentary Canal Stapler is used throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic techniques.
- **Single Use Circular Stapler for Rectal Prolapse and Hemorrhoid**  
The Frankenman Single Use Circular Stapler for Rectal Prolapse and Hemorrhoids is a Circular Stapler product, with accessories, that has application for general surgical treatment of haemorrhoids and anorectal wall defects by means of transanal stapling and resection of mucosal and musculo-mucosal tissue resulting in occlusion of haemorrhoidal inflow, restoring the haemorrhoidal tissue to its normal physiological position.
- **Disposable Reloadable Linear Stapler and Reloads**  
The Frankenman Disposable Reloadable Linear Stapler (and Reloads) is used in the resection or transaction of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.
- **Disposable Reloadable Linear Cutter Stapler and Reloads**  
The Frankenman Disposable Reloadable Linear Cutter Stapler (and Reloads) has application in abdominal, gynecological, thoracic and pediatric surgery transaction, resection, and the creation of anastomoses.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
 (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)  
 (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

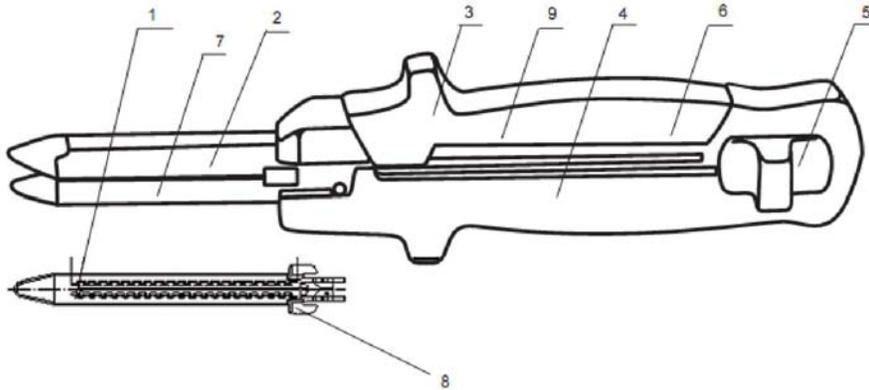
Concurrence of CDRH, Office of Device Evaluation (ODE)

*David Krono for MXM*  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Surgical, Orthopedic,  
 and Restorative Devices

510(k) Number K101378



2、 the product codes and sizes for the instrument and reloading units are as follows:



1 RELOADING UNIT  
 2 ANVIL FORK  
 3 SHOULDERS  
 4 HANDLE - ANVIL HALF  
 5 FIRING KNOB

6 HANDLE - ALIGNMENT/LOCKING LEVER  
 7 CARTRIDGE FORK  
 8 RELOADABLE CARTRIDGE TABS  
 9 CARTRIDGE HALF

Instrument Code	Reloading Unit	Sizes				Number of Staples	Diameter of the staple leg mm
		stapling line length (mm)	Tolerance	H	Tolerance		
LC 60B	LCR 60B	61	± 1	65	± 3	60	φ 0.25 <sub>-0.03</sub>
LC 60G	LCR 60G						
LC 80B	LCR 80B	81					
LC 80G	LCR 80G						
LC 100B	LCR 100B	101					
LC 100G	LCR 100G						

Note: Special sizes of the instrument will be produced according to the contract.

3. The staples of this instrument are manufactured by Titanium according to specification in GB/T13810-1997 (ISO5832-2).
4. This instrument is provided sterile with irradiation of Co60 and for single procedure.

**IV Instructions**

1. This instrument shall be used according to the general instructions of staplers. (Consult other materials for detailed information.)
2. This instrument shall be performed only by surgeons having adequate training of the stapling techniques and/or instructed by experienced persons.
3. Check for the entirety of the package and make sure the instrument has no damages. Do not use the instrument if any damages or suspected damages are seen. Contact the salespersons of our company.
4. Manipulation
  - a) Open the handle and separate the instrument halves. Remove the staple retaining cap.
  - b) Press the anvil fork on one side of the tissue to be transected or into the lumen to be anastomosed.
  - c) Fully open the detachable half of the instrument. Place the cartridge fork on the other side of the tissue or into the other lumen.

- d) Join the instrument halves together by aligning from the back of the instrument.
  - e) Close the handle completely and the instrument is locked.
  - f) Fire the instrument by pushing the firing knob completely forward.
  - g) Completely return the firing knob to its original position.
  - h) Separate the instrument halves. Discard the fired reloading unit from the cartridge jaw and insert a new unit.
5. Examine the staple line for hemostasis. Make additional sutures to stop bleeding if there are bleeding points.
  6. This linear cutter is designed for one patient. Surgeons can reload the instrument with reloading units during one surgical procedure.

#### **V. Precautions**

1. This instrument is provided sterilized by irradiation of Co60. **Do not use the instrument if the package is broken.** If anything contained is broken, contact the salespersons of our company.
2. This device is for single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may lead to device failure which in turn may result in patient injury, illness or death. Also, reprocessing or re-sterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection.
3. **The cartridges used to reload the instrument must be the ones of same type and produced by our company.** No reloads from other companies or from our company is permitted.
4. Check the product codes, expiration date and the entirety of the package before using it.
5. Remove the instrument carefully after firing. Never withdraw the instrument by force.
6. The empty cartridge (without staples) of this instrument is designed to be automatically locked and can not be fired. Make sure the cartridge is not fired before reusing the instrument in case of the instrument failure resulted from firing of the empty cartridge.
7. The instrument shall not be used if it is dropped or wrongly processed.

#### **VI. Package and Storage**

1. This instrument is provided sterilized by irradiation of Co60. The term of validity will be three years from sterilization if the package is not destroyed.
2. Please use the instrument before the expiration date.
3. This instrument shall be stored in dry, shady and cool places, relative humidity  $\leq 80\%$ , drafty and without active gases.

#### **VII. Contraindications**

1. Do not use on ischemic or necrotic tissue.
2. Do not use on pulmonary vessels (including arteries and veins).

#### **VIII. Complications**

1. Infection
2. Split of the staple line
3. Fistulas of the staple line
4. Haemorrhage of the staple line

#### **IX. Warnings and Precautions**

1. This instrument is provided sterilized by irradiation of Co60. **Do not use the instrument if the package is broken.**
2. Do not use the instrument if any damages or suspected damages are seen. Contact the salespersons of our company.
3. This device is for single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may lead to device failure which in turn may result in patient injury, illness or death. Also, reprocessing or re-sterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection.

4. The processing, storage, cleaning and sterilization of the instrument, the surgical procedure and other factors which can not be controlled by our company may influence the usage of this instrument.
5. Pay attention to the removal and reloading of the cartridge. Any carelessness may influence the stapling procedure and damage the instrument.
6. This instrument shall be performed only by surgeons having adequate training of the stapling techniques and/or instructed by experienced persons.
7. Do not try to use the instrument without fully understanding of this instruction. Any carelessness may influence the surgical procedure.
8. Dispose of fired instruments and used reloads according to corresponding instructions. Do not contaminate the environment.

#### **X. Warranty**

1. This instrument is carefully designed and manufactured under appropriate control.
2. The warranty only covers this instrument. Our company does not take direct or indirect responsibility for any incidents and losses caused from the usage of this instrument.
3. Our company does not take responsibility for the reprocessing and re-sterilization of the instrument.

#### **Do not use the instrument if the package is broken.**

Please consult medical literature relative to techniques and appliances or contact with our company if there is anything unclear of this instruction.

**Manufacturer:** Suzhou Frankenman Medical Equipment Co., Ltd.  
**Address:** 88 Jinfeng Road, Suzhou Jiangsu, P. R. China  
**Authorized EC-representative:** Shanghai International Trading Corp. GmbH (Hamburg)  
**Address :** Eiffestrasse 80, 20537 Hamburg, Germany  
**Phone:** +86(512)-6809 0900 +86(512)-6809 9968  
**Post Code:** 215011  
**Web site:** <http://www.frankenman.com>  
**Date:** 2009 first edition

**Circular Staplers for Single Use**  
**INSTRUCTIONS FOR USE**

Before operation, please read the instructions carefully. The contraindication, warning and precautions shall be strictly followed. Otherwise, complication and/or risk may be caused to patient.

This company has entrusted surgeons and engineers to confirm and assess the foreseeable risk, however, this does not mean that there is no any risk in using the product.

This information is designed to assist in using this product. It is not a reference document for surgical stapling techniques.

**I. Indication – For-Use**

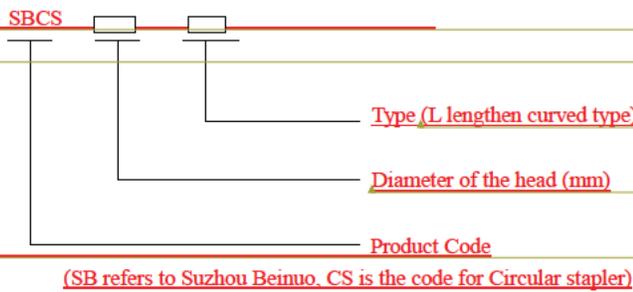
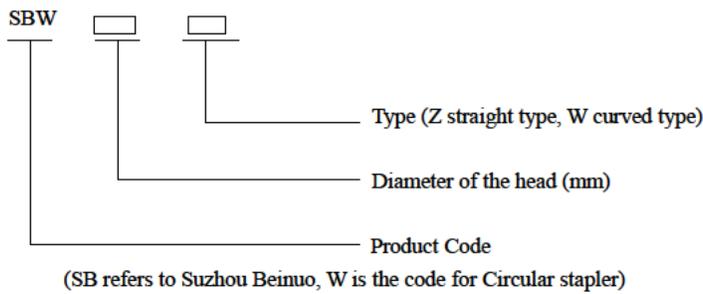
The Suzhou Beinuo Circular Stapler for Single Use is used throughout the alimentary tract for the reconstruction of the alimentary tract and the creation of end-to-end, end-to-side and side-to-side anastomoses.

**II. Principle**

The instrument is designed on the principles of surgical staplers. It delivers a circular, two staggered rows of staples, reconstruct the alimentary tract in surgical procedures by jointing the tissue and resecting the excess tissue with the internal circular blade.

**III. Main technological parameters**

**1 Product marking**



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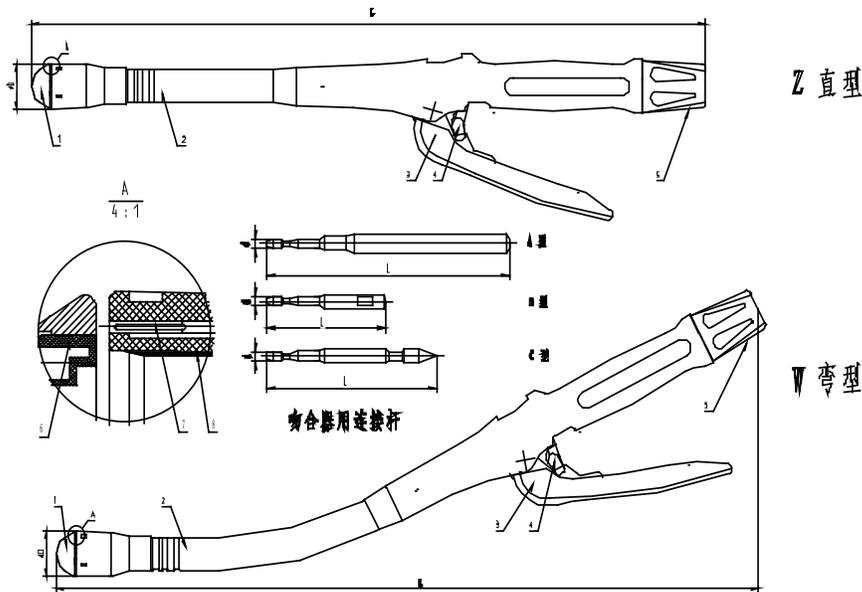
2. Type and size of Circular stapler

Table 1

Basic Dimension

mm

Type	Specification	D	Deviation	Staple Qty.	Staple Dia. (d)	L	Deviation
SBW 21W	21	φ21.5	±0.2	16	φ0.3 <sub>-0.03</sub>	W <sub>i</sub> : -420 Z <sub>i</sub> : -420	±5
SBW 25W	25	φ25.5		20			
SBW 28W	28	φ28.5		24			
SBW 32W	32	φ32.5		28			
SBW 21Z	21	φ21.5		16			
SBW 25Z	25	φ25.5		20			
SBW 28Z	28	φ28.5		24			
SBW 32Z	32	φ32.5		28			
<u>SBCS21L</u>	<u>21</u>	<u>φ21.5</u>	<u>±0.2</u>	<u>16</u>	<u>φ0.3<sub>-0.03</sub></u>	<u>L: 520</u>	<u>±5</u>
<u>SBCS25L</u>	<u>25</u>	<u>φ25.5</u>		<u>20</u>			
<u>SBCS28L</u>	<u>28</u>	<u>φ28.5</u>		<u>24</u>			
<u>SBCS32L</u>	<u>32</u>	<u>φ32.5</u>		<u>28</u>			
Ancillary Trocar/Extended Anvil							
Type	d(mm)	Deviation	l (mm)	Deviation			
A	φ3.5	±0.15	180	±1.5			
B			54				
C			78				



- 1 Detachable anvil    2 Stapler shaft    3 Firing handle    4 Safety  
5 Adjusting knob    6 Cutting washer    7 Staple    8 Cutting blade

**Diagram 1:** Circular Stapler for Single Use

3. The staples adopted by this product are made of TA2 in line with GB/T13810-2007 *Titanium and Titanium Alloy Process Material Used in Surgery Implantation Material* and in conformity with the regulation of ISO5832-2 for Class 2 Pure Titanium.

4. This product is provided sterilized by radiation (Cobalt 60) and is for single procedure use only.

#### IV. Instrument Operation

1. This instrument shall be used according to the general principle of staplers.
2. This instrument shall be performed only by surgeons having adequate training in stapling techniques and/or instructed by experienced persons.
3. Before use, it is necessary to check for the integrity of the package and make sure the instrument has no damage. Do not use the instrument if any damage or suspected damage is noticed in packaging materials and/or product. Contact the sales representative if damage is noticed.
4. Before fire the stapler, please double check the followings:
  - (1) The tissue to be sutured is well retained into the stapler and is compressed effectively
  - (2) The firing indicator is in the firing zone (green zone)
  - (3) The red safety can be rotated for 90 degrees smoothly (If the red safety cannot be turned smoothly, please check the above steps again. Do not turn violently)
5. When the firing handle is squeezed to a certain position, the surgeon will feel reduced trigger pressure and hear a “crunch”, which signifies that firing is finished.
6. After firing, reset the firing handle and turn the red safety back to 90 degrees.
7. After restoring the safety, open the instrument by turning the Adjusting Knob counterclockwise as indicated on the end of the knob by three-quarters to one revolutions to withdraw the stapler.
8. Check the integrity of the donut being cut.
9. Check the completeness of the donut and haemostasis. Un-sutured area or minor bleeding can be controlled by manual sutures timely.
10. Tissue to be sutured should be kept in tension-free state.
11. Operator should reach his/her expectation of effectiveness of treatment as much as possible in the using of this product.
12. The instrument is for single procedure use. One ancillary trocar/extended anvil is supplied together with each stapler, and the ancillary trocar/extended anvil can be changed in the same procedure.

#### V. Precautions

1. The products are provided sterilized by radiation (Cobalt 60). The product is sterile. **Never use any product with damaged packaging.** If any damage is noticed, contact the representative of the company.
2. This instrument is for single procedure use. Do not reuse, reprocess or re-sterilize.
3. Before use, please check and confirm the product model, specification and expiration date. Make sure the package is integrity.
4. When remove the instrument after firing, care shall be used. Do not use any violent force to remove the instrument.
5. Never use the product clinically that is fallen to ground, or damaged or suspected damaged by mistake.

#### VI. Package and storage

1. The products are provided sterilized by radiation (Cobalt 60). The expiry date as indicated on the packaging will be **THREE YEARS** from irradiation if the packaging is not broken

2. Please use the product before the expiration date indicated on the package.
3. This product shall be stored in a dry, cool place with relative humidity no more than 80% without any corrosive gas.

**VII. Contraindications**

1. Do not use the instrument on serious edema tissue.
2. Do not use the instrument on too narrow lumen.
3. Do not use the instrument on too thick or too thin tissue.
4. Do not use the instrument if there is tension on the anastomosis site.

**VIII. Complication**

1. May cause infection.
2. May cause anastomotic stoma tearing.
3. May cause anastomotic stoma fistula.
4. May cause anastomotic stoma hemorrhage.

**IX. Warning**

1. The products are provided sterilized by radiation (Cobalt 60). **Never use any product with damaged packaging.**
2. Do not use any product with any visible damage or suspected damage. Please contact with the representative of this company.
3. This instrument is for single use. Do not reuse, reprocess or re-sterilize.
4. The disposal, storage, cleaning, sterilization of the product, operation procedure and any other factors uncontrolled by the company may directly influence the application result of this product.
5. This product shall be performed only by surgeons having adequate training in stapling techniques and/or instructed by experienced persons.
6. Never try to operate this product before reading the instructions for use thoroughly. Any inadvertent operation may bring the operation with risk.
7. Dispose of all used instruments properly to avoid any pollution to the environment

**X. Guarantees**

1. This company guarantees that the design and production of this product is carried out under reasonable caution and necessary management.
2. The obligation born by this company under this guarantee is limited within the replacement of the product. This company is not directly or indirectly liable for compensation of any loss caused by any accident from the product application.
3. This company is not liable for any loss resulted from any re-use, re-process or re-sterilize of the instrument.

**DO NOT USE THE PRODUCT IF THE PACKAGE IS DAMAGED.**

For the matter not covered, refer to the related medical literature or medical equipment literature, or call (mail) us for consultation.

**Manufacturer:** Suzhou BeiNuo Medical Equipment Co., Ltd.  
**Address :** 158-38 Huashan Road, Suzhou High-New District,

Jiangsu 215129, P.R.China.  
**Tel:** +86-512-66901260  
**Fax:**+86-512-66626238  
**Post Code:** 215129  
**Web site:** www.beinuomedical.com

**Authorized EC-representative:** Shanghai International  
Holding Corp. GmbH (Europe)  
**Address :** Eiffestrasse 80, 20537 Hamburg, Germany  
**Tel:** +49-40-2513175  
**Fax:** +49-40-255726

**Date:** 2012 first edition

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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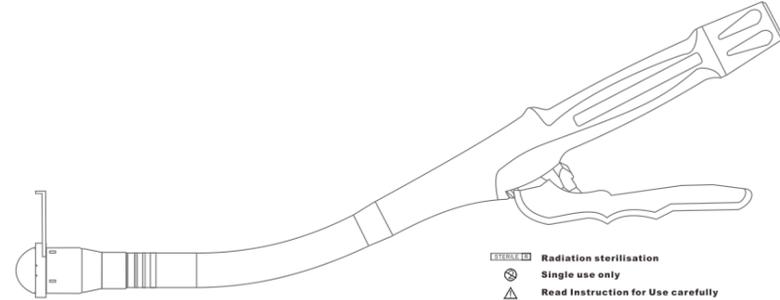
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 Add: Seesferstr. 11B 59519 Moehnesee, Germany  
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 Fax: 0049-2024-878096

 **SUZHOU BEINUO MEDICAL EQUIPMENT CO., LTD.**  
 Add: No 108-38 Huashan Road, Suzhou High-New District, Jiangsu P.R. China  
 Tel: 0512-66620259 66626279  
 Fax: 0512-66626238 P.C: 215129



1PCS

- PRECAUTION**
-  Radiation sterilisation
  -  Single use only
  -  Read Instruction for Use carefully
  -  Recyclable packaging materials
  -  Re-sterilisation is prohibited

 0197

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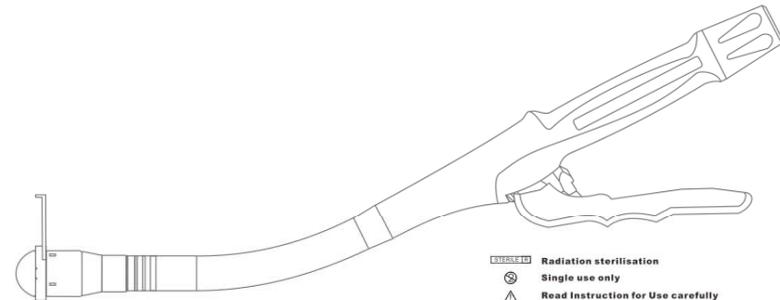
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 0197

# Hemorrhoidal Circular Staplers for Single Use

## Instructions for Use

Before use this product, please read the instructions carefully. The contraindication, warning and precautions shall be strictly followed. Otherwise, complication and/or risk may be caused to patient.

This company has entrusted surgeons and engineers to confirm and assess the foreseeable risk, however, this does not mean that there is no any risk in using the product.

This information is designed to assist in using this product. It is not a reference document for surgical techniques.

### I. Indications-For-Use

The Suzhou Beinuo Hemorrhoidal Circular Stapler for Single Use is a Circular Stapler product, with accessories, that is indicated in anorectal surgical procedures for the treatment of hemorrhoids and anorectal wall defects.

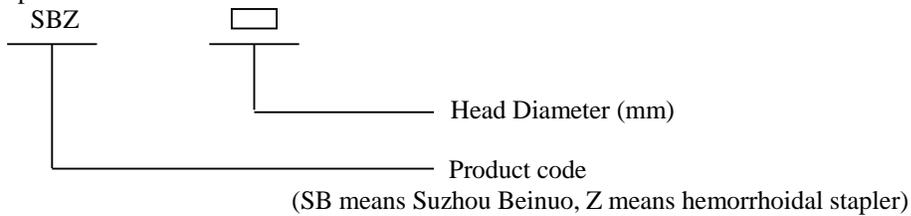
### II. Principle

The Hemorrhoidal Circular Staplers for Single Use is designed on the principles of surgical staplers. It delivers two circular staggered rows of staples, seals off the rectal mucosa in anorectal procedure, and the central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa.

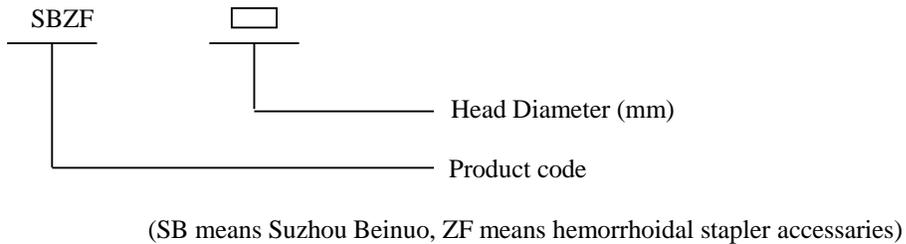
### III. Main technical parameters

#### 1. Product marking

##### 3.1.1 Staplers



##### 3.1.2 Accessories





- Purse string suture anoscope (12) 1
- Suture threader (13) 1

This product is for single procedure use. One set of accessory is supplied together with the stapler, the accessories can be changed during one procedure.

3. Do not use the instrument if any damage or suspected damage is noticed in product, accessories and/or packaging materials. Contact the sales representative if damage is noticed.
4. Using steps of the hemorrhoidal circular stapler for single use:
  - 1) The Anal Dilator (10) and the Inner Lining(11) are introduced into the anus and the Anal Dilator (10) is fixed.
  - 2) Remove the Inner Lining (11), insert the Purse String Anoscope (12) to carry out purse string suture.
  - 3) The purse string suture shall be carried out under the mucous membrane for the entire anal circumference, and be placed 3.5-4 cm above the dentate line.  
**Note: the mucous membrane of the posterior vaginal wall in the female patient should not be sutured.**
  - 4) The hemorrhoidal circular stapler is opened to its maximum position (about 5.5 cm). Its anvil head (1) is introduced beyond the purse-string. Knot the ends of suture and make sure that the tissue be tied up evenly around the Central Rod (2).
  - 5) Draw the suture string out through the lateral conduits(7) of the hemorrhoidal circular stapler with Suture Threader(13), and then knot it with appropriate length which can be hooked by finger.
  - 6) Keep the Anvil Head(1) in line with the axis of Anal Dilator(10), turn the Adjusting Knob(5) to close the stapler, at the same time, pull the tissue with purse-string moderately (pull the purse-string with finger, and draw the prolapsed mucous membrane into the cartridge housing of the stapler in even pace. (Do not pull violently)  
 Note: Maintain the Anvil Head(1) position, and keep the stapler move forwardly when closing the stapler.
  - 7) When red Indicator (3) appears at the Indicating Window(4), stop pulling and maintain.
  - 8) Continue turn the Adjusting Knob (5) until the red Indicator(3) enters into the green zone of the Indicating Window(4), then define the tissue compression position according to the thickness of the mucous membrane (must be in the green zone).
  - 9) Maintain the Anvil Head(1) position, and keep the last scale of the Cartridge Housing Scale (6) of the closed stapler a certain distance with the inner end of the Anal Dilator.
  - 10) Review and check the above steps again (as to female patients, please check the vagina again)
  - 11) Release the red Safety Button(8), and hold the stapler and the handle(9) with two hands (keep the stapler stable) and then fire.
  - 12) Firing is finished with a sound click and a sense of force loss. Keep the firing force for about 20-30 seconds, which helps to reinforce haemostasis.
  - 13) After firing, reset the Handle (9) and restore the Safety Button(8).
  - 14) Rotate (loosen) the Adjusting Knob(5) 3/4-1 revolutions, and then withdraw the hemorrhoidal circular stapler slowly.
  - 15) Check the staple line for bleeding. If bleeding from the staple line occurs, suture with figure "8" stitches. (Absorbable suture is recommended.)
  - 16) Draw the Anal Dilator (10) out and put compound Carraghenates Suppostories and Vaseline gauze into the anal canal.

#### V. Precautions

This product shall be performed only by surgeons having adequate training in stapling and hamorrhoidopexy techniques and/or instructed by experienced persons

1. The product is provided sterilized by radiation (Cobalt 60). The product is sterile. *Never use any product with damaged packaging.* If any damage is noticed, contact the representative of the company.
2. This product is for single procedure use. Do not reuse.
3. Before use, please check and confirm the product model, specification, expiration date and package.
4. When remove the product after firing, care shall be used. Do not use any violent force to remove the product.
5. Never use the product clinically that is fallen to ground, or damaged or suspected damaged

by mistake.

#### **VI. Package and storage**

1. The products are provided sterilized by radiation (Cobalt 60). The expiry date as indicated on the packaging will be **THREE YEARS** from irradiation if the packaging is not broken.
2. Please use the product before the expiration date indicated on the package.
3. This product shall be stored in a dry, cool place with relative humidity no more than 80% without any corrosive gas.

#### **VII. Contraindications**

1. Do not use the product on serious edema tissue.
2. Do not use the product on severe fibrosed hemorrhoids tissue.
3. Do not use the product on hemorrhoids tissue with repeated sclerotherapy.

#### **VIII. Complication**

1. May cause infection.
2. May cause anastomotic stoma tearing.
3. May cause anastomotic stoma hemorrhage.

#### **IX. Warning**

1. The products are provided sterilized by radiation (Cobalt 60). **Never use any product with damaged packaging.**
2. Do not use any product with any visible damage or suspected damage. Please contact with the representative of this company.
3. This product is for single use. Do not reuse, reprocess or re-sterilize.
4. The disposal, storage, cleaning, sterilization of the product, operation procedure and any other factors uncontrolled by the company may directly influence the application result of this product.
5. This product shall be performed only by surgeons having adequate training in stapling techniques and/or instructed by experienced persons.
6. Never try to operate this product before reading the instructions for use thoroughly. Any inadvertent operation may bring the operation with risk.
7. Dispose of all used instruments properly to avoid any pollution to the environment.

#### **X. Guarantees**

1. This company guarantees that the design and production of this product is carried out under reasonable caution and necessary management.
2. The obligation born by this company under this guarantee is limited within the replacement of the product. This company is not directly or indirectly liable for compensation of any loss caused by any accident from the product application.
3. This company is not liable for any loss resulted from any re-use, re-process or re-sterilize of this product.

#### **DO NOT USE THE PRODUCT IF THE PACKAGE IS DAMAGED.**

For the matter not covered, refer to the related medical literature or medical equipment literature, or call (mail) us for consultation.

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**Address :** 158-38 Huashan Road, Suzhou High-New District,  
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**Issuance Date:** 2012 first edition

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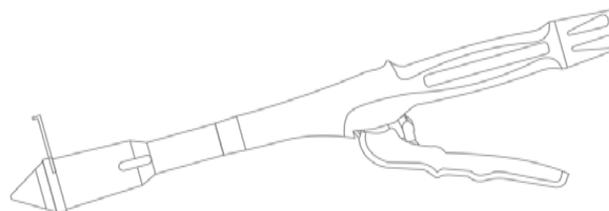
# HEMORRHOIDAL CIRCULAR STAPLER

SBZ 32

# HEMORRHOIDAL CIRCULAR STAPLER

SBZ 32

1PCS



 **SALIE MEDICA GMBH**  
Add: Seeuferstr. 11B 59519 Moehnesee, Germany  
Tel: 0049-2924-8752020(87530)  
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 **SUZHOU BEINUO MEDICAL EQUIPMENT CO., LTD.**  
Add: No. 158-38 Huashan Road, Suzhou High-New District, Jiangsu P.R. China  
Tel: 0512-66626258 66626276  
Fax: 0512-66626238 P.C: 215129

-  Radiation sterilisation
-  Single use only
-  Read instruction for use carefully
-  Recyclable packaging materials
-  Re-sterilisation is prohibited

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HEMORRHOIDAL CIRCULAR STAPLER

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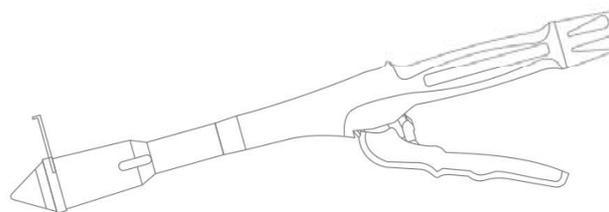
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Add: Seeuferstr. 11B 59519 Moehnesee, Germany  
Tel: 0049-2924-8752020(87530)  
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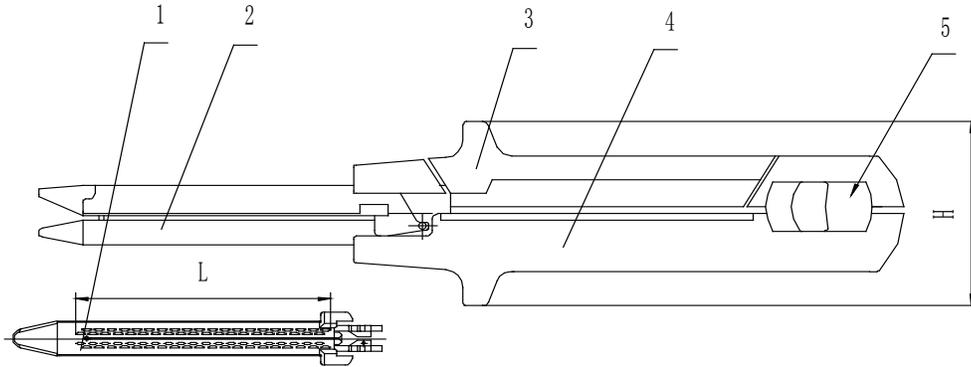
 **SUZHOU BEINUO MEDICAL EQUIPMENT CO., LTD.**  
Add: No. 158-38 Huashan Road, Suzhou High-New District, Jiangsu P.R. China  
Tel: 0512-66626258 66626276  
Fax: 0512-66626238 P.C: 215129

-  Radiation sterilisation
-  Single use only
-  Read instruction for use carefully
-  Recyclable packaging materials
-  Re-sterilisation is prohibited

 0197



2 Type and size of linear cutter stapler and its cartridge



1 Cartridge (optional) 2 Anvil 3 Closing handle 4 Handle 5 Firing Button

**Diagram 1: Linear Cutter Stapler**

Table 1 Basic Dimension mm

Specification	Reloads	Suture length	Deviation	H	Deviation	h	Deviation	Staple	Diameter of staple(d)										
SBQ 60BY	SBQZ 60B	61	±1	65	±3	2.5	±0.2	60	Φ 0.23 <sub>-0.03</sub>										
SBQ 60ZY	SBQZ 60Z					3.8													
SBQ 60HY	SBQZ 60H					4.5													
SBQ 80ZY	SBQZ 80Z	81				±1		65		±3	3.8	±0.2	80	Φ 0.23 <sub>-0.03</sub>					
SBQ 80HY	SBQZ 80H										4.5								
SBQ 100ZY	SBQZ 100Z	101									±1		65		±3	3.8	±0.2	100	Φ 0.23 <sub>-0.03</sub>
SBQ 100HY	SBQZ 100H															4.5			

- The staples adopted by this product are made of TA2 in line with GB/T13810-2007 *Titanium and Titanium Alloy Process Material Used in Surgery Implantation Material* and in conformity with the regulation of ISO5832-2 for Class 2 Pure Titanium.
- This product is provided sterilized by radiation (Cobalt 60) and is for single procedure use only.

**IV. Instrument Operation**

- This instrument shall be used according to the general principle of staplers.
- This instrument shall be performed only by surgeons having adequate training in stapling techniques and/or instructed by experienced persons.
- Before use, it is necessary to check for the integrity of the package and make sure the instrument has no damage. Do not use the instrument if any damage or suspected damage is noticed in packaging materials and/or product. Contact the sales representative if damage is noticed.
- Using steps:
  - Open the Closing handle fully to separate the two halves, remove the staple retaining

- cap;
  - b) Press the Anvil Fork on one side of the tissue to be transected or into the lumen to be anastomosed;
  - c) Fully open the Closing handle. Place the Cartridge Fork on the other side of the tissue or into the other lumen;
  - d) Join the instrument halves together by aligning from the proximal end of the instrument;
  - e) Close the Closing handle completely and the instrument is locked;
  - f) Fire the instrument by pushing the Firing Knob completely forward until the distal end of the Firing Knob reaches the distal red line;
  - g) Completely return the Firing Knob to its original starting position (the proximal red line);
  - h) Separate the instrument halves. Discard the fired cartridge and insert a new unit.
5. Check the staple line for adequate haemostasis. Make additional sutures to stop bleeding when identified.
6. RELOADING INSTRUCTIONS
- a) Open the Closing handle to separate the two halves of the stapler with left hand holding the right handle;
  - b) Grasp the proximal end of the cartridge (cartridge tabs) with right hand and pull up and out to remove the used cartridge;
  - c) To place a new cartridge in the instrument, hold the proximal end tabs of the new cartridge with right hand, with the staple lines facing upwards. When the cartridge is parallel with the stapler and a click is heard, it suggests that the cartridge is successfully loaded.
7. This product is for single procedure use only, one stapler is supplied with a cartridge; however, the cartridge can be reloaded in the same procedure.

## V. Precautions

1. The product is provided sterilized by radiation (Cobalt 60). The product is sterile. **Never use any product with damaged packaging.** If any damage is noticed, contact the representative of the company.
2. This instrument is for single procedure use. Do not reuse, reprocess or re-sterilize.
3. Before use, please check and confirm the product model, specification and expiration date. Make sure the package is integrity.
4. When remove the instrument after firing, care shall be used. Do not use any violent force to remove the instrument.
5. This product is provided with empty cartridge (staples being fired) lock-out mechanism. The stapler can't be fired effectively when no staple is loaded in cartridge. When re-use is needed in the same procedure, please confirm if the cartridge is effectively fired, this will prevent malfunction or damage to the instrument caused by excessive firing force applied to the stapler with empty cartridge.
6. **All Cartridges to be used with the stapler must be the relative cartridges in table 1.** It is prohibited to change with any other brand cartridge or irrelevant cartridge from the company.
7. Never use the product clinically that is fallen to ground, or damaged or suspected damaged by mistake.

## **VI. Package and storage**

1. The products are provided sterilized by radiation (Cobalt 60). The expiry date as indicated on the packaging will be **THREE YEARS** from irradiation if the packaging is not broken
2. Please use the product before the expiration date indicated on the package.
3. This product shall be stored in a dry, cool place with relative humidity no more than 80% without any corrosive gas.

## **VII. Contraindications**

1. Do not use the instruments on serious edema tissue.
2. Do not use the instruments on ischemic or necrotic tissue.
3. Do not use the instruments on too thick or too thin tissue.
4. Do not use the instruments on pulmonary artery or vein.

## **VIII. Complication**

1. May cause infection.
2. May cause anastomotic stoma tearing.
3. May cause anastomotic stoma fistula.
4. May cause anastomotic stoma hemorrhage.

## **IX. Warning**

1. The products are provided sterilized by radiation (Cobalt 60). **Never use any product with damaged packaging.**
2. Do not use any product with any visible damage or suspected damage. Please contact with the representative of this company.
3. This instrument is for single use. Do not reuse, reprocess or re-sterilize.
4. The disposal, storage, cleaning, sterilization of the product, operation procedure and any other factors uncontrolled by the company may directly influence the application result of this product.
5. Pay sufficient attention to the cartridge reloading/unloading in one procedure, any careless may cause risk and/or product damage.
6. This product shall be performed only by surgeons having adequate training in stapling techniques and/or instructed by experienced persons.
7. Never try to operate this product before reading the instructions for use thoroughly. Any inadvertent operation may bring the operation with risk.
8. Dispose of all used instruments properly to avoid any pollution to the environment.

## **X. Guarantees**

1. This company guarantees that the design and production of this product is carried out under reasonable caution and necessary management.
2. The obligation born by this company under this guarantee is limited within the replacement of the product. This company is not directly or indirectly liable for compensation of any loss caused by any accident from the product application.
3. This company is not liable for any loss resulted from any re-use, re-process or re-sterilize of the instrument.

**DO NOT USE THE PRODUCT IF THE PACKAGE IS DAMAGED.**

For the matter not covered, refer to the related medical literature or medical equipment literature, or call (mail) us for consultation.

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**Post Code:** 215129  
**Web site:** www.beinuomedical.com

**Authorized EC-representative:** Shanghai International  
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**Tel:** +49-40-2513175  
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**Date:** 2012 first edition

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

SBQ 80-HY

# LINEAR CUTTER STAPLER

SBQ 80-HY

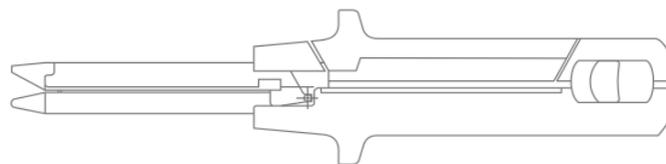
# LINEAR CUTTER STAPLER

SBQ 80-HY

LINEAR CUTTER STAPLER

SBQ 80-HY

1 PCS



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- Re-sterilisation is prohibited**

**CE 0197**

LINEAR CUTTER STAPLER

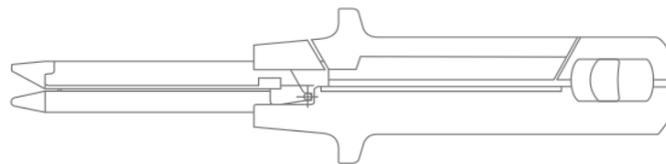
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**CE 0197**

# Linear Stapler for Single Use

## INSTRUCTIONS FOR USE

Before operation, please read the instructions carefully. The contraindication, warning and precautions shall be strictly followed. Otherwise, complication and/or risk may be caused to patient.

This company has entrusted surgeons and engineers to confirm and assess the foreseeable risk, however, this does not mean that there is no any risk in using the product.

This information is designed to assist in using this product. It is not a reference document for surgical techniques.

### I. Indication-For-Use

The Suzhou Beinuo Linear Cutter Stapler and Reloads for Single Use (and reloads) is indicated for use in the resection, transection and anastomosis of tissue in gastrointestinal, gynecological, pediatric and thoracic surgical procedures.

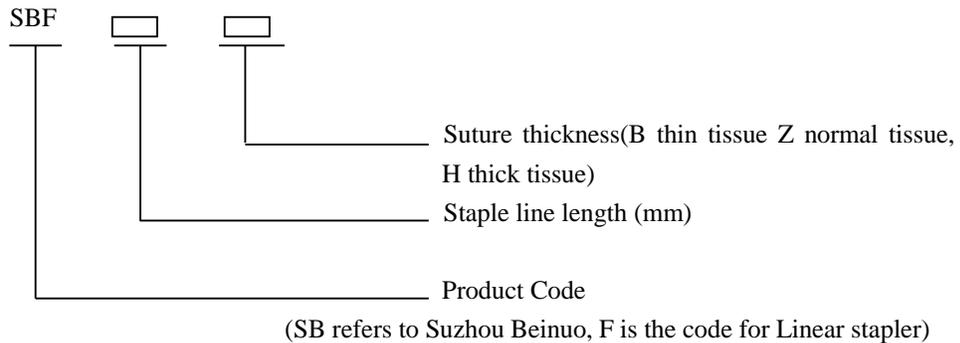
### II. Principle

The instrument is designed on the principles of surgical staplers. It delivers two staggered rows of staples, closes and staples tissue or organ during surgical procedures.

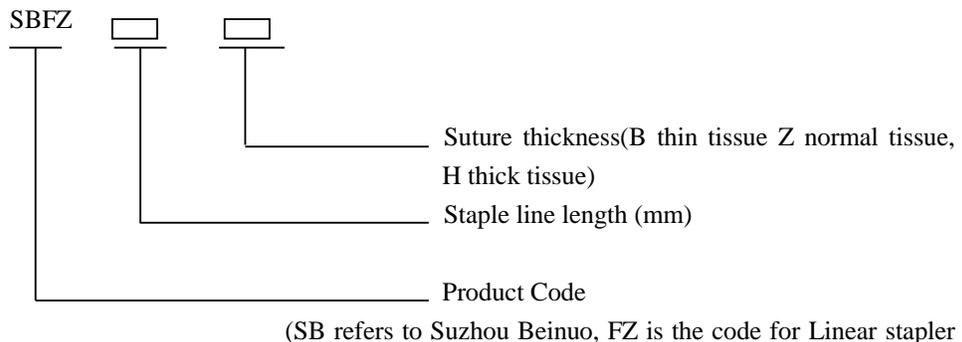
### III. Main technological parameters

#### 1. Product marking

##### 3.1.1 Staplers

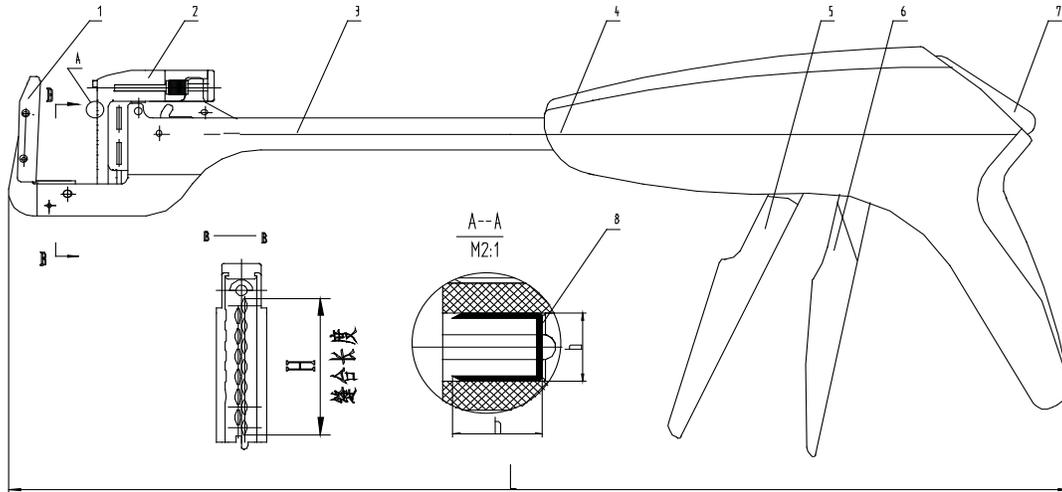


##### 3.1.2 Reloads



reloads, it is the accessory of SBF)

2. Type, specification and size of the product



- |                 |                  |                  |          |
|-----------------|------------------|------------------|----------|
| 1 Anvil         | 2 Cartridge      | 3 Body support   | 4 Handle |
| 5 Firing handle | 6 Closing handle | 7 Release button | 8 Staple |

**Figure1: Linear Stapler for Single Use**

Specification	Reloads	H	Tolerance	h	Tolerance	Staple Qty.	Diameter of staple(d)	L	Tolerance
SBF 30B	SBFZ 30B	32	±1	2.5	±0.2	23	φ0.23 <sub>-0.03</sub>	370	±5
SBF 30Z	SBFZ 30Z			3.8		13			
SBF 30H	SBFZ 30H			4.5		19			
SBF 45Z	SBFZ 45Z	46		3.8		25	37		
SBF 45H	SBFZ 45H			4.5					
SBF 60Z	SBFZ 60Z	60		3.8		37	335		
SBF 60H	SBFZ 60H			4.5					
SBF 90Z	SBFZ 90Z	88		3.8		37	335		
SBF 90H	SBFZ 90H			4.5					

- The staples adopted by this product are made of TA2 in line with GB/T13810-2007 *Titanium and Titanium Alloy Process Material Used in Surgery Implantation Material* and in conformity with the regulation of ISO5832-2 for Class 2 Pure Titanium.
- This product is provided sterilized by radiation (Cobalt 60) and is for single procedure use only.

#### IV. Instrument Operation

1. This instrument shall be used according to the general principle of staplers.
2. This instrument shall be performed only by surgeons having adequate training in stapling techniques and/or instructed by experienced persons.
3. Before use, it is necessary to check for the integrity of the package and make sure the instrument has no damage. Do not use the instrument if any damage or suspected damage is noticed in packaging materials and/or product. Contact the sales representative if damage is noticed.
4. Before fire the stapler, please re-check the following things again:
  - a) The cartridge has been loaded into the instrument body safely;
  - b) Tissue to be sutured is in the permitted suture zone.
5. When the Closing Handle is squeezed to a certain position, the first click can be heard. Meanwhile, the tissue retaining pin in the cartridge will be moved into the anvil hole automatically. The tissue to be sutured will be confined within the jaws, while its position can be adjusted accurately.
6. Adjust the tissue to be stapled within the sapling area.
7. When the Closing Handle is squeezed to the second position, the second click is heard, suggests that the tissue is compressed completely.
8. Pull the Firing Handle to complete the firing. When the Firing Handle is pulled to a certain position, there is a feeling of tension loss and at the same time a click is heard, which signifying that the firing is finished.
9. If cutting is needed, please do it before remove the stapler.
10. Press the release button to reset and withdraw the stapler.
11. The empty cartridge (that is the cartridge has already been fired) will be locked automatically and can not be fired again.
12. Examine the staple line. If bleeding from the staple line occurs, manual sutures may be placed.
13. This instrument is for single procedure use. One cartridge is supplied together with the stapler. The cartridge can be changed during one procedure.
  - a) As described in Figure 1, pull upward to remove the cartridge;
  - b) Load the cartridge supplied in the same internal package;
  - c) Insert the new cartridge along the internal slot;
  - d) When a click is heard, it suggests that the reloading is finished.

#### V. Precautions

1. The product is provided sterilized by radiation (Cobalt 60). The product is sterile. **Never use any product with damaged packaging.** If any damage is noticed, contact the representative of the company.
2. This instrument is for single procedure use. Do not reuse, reprocess or re-sterilize.
3. Before use, please check and confirm the product model, specification and expiration date. Make sure the package is integrity.
4. When remove the instrument after firing, care shall be used. Do not use any violent force to remove the instrument.
5. When change a cartridge, make sure the stapler jaws are maximum opened;
6. **All Cartridges to be used with the stapler must be the relative cartridges in table 1.** It is

- prohibited to change with any other brand cartridge.
7. The retaining pin is designed to separate the tissue to be anastomosed and the normal tissue, its blunt head cannot pierce tissue automatically.
  8. To ensure that the stapler is fired correctly and the tissue is stapled effectively, prerequisites are as follows:
    - a) The tissue retaining pin is seated in the anvil and confines tissue to be sutured within the jaws. Meanwhile, its blunt head can be touched from the reverse side of the anvil;
    - b) Place the tissue to be sutured evenly and lock it until the second position is totally closed;
    - c) Fire completely until: the feeling of tension loss and at the same time a sound click is heard, which signifies that firing is finished
  9. This product is provided with empty cartridge (staples being fired) lock-out mechanism. The stapler can't be fired effectively when no staple is loaded in cartridge. When re-use is needed in the same procedure, please confirm if the cartridge is effectively fired, this will prevent malfunction or damage to the instrument caused by excessive firing force applied to the stapler with empty cartridge.
  10. Never use the product clinically that is fallen to ground, or damaged or suspected damaged by mistake.

#### **VI. Package and storage**

1. The products are provided sterilized by radiation (Cobalt 60). The expiry date as indicated on the packaging will be **THREE YEARS** from irradiation if the packaging is not broken
2. Please use the product before the expiration date indicated on the package.
3. This product shall be stored in a dry, cool place with relative humidity no more than 80% without any corrosive gas.

#### **VII. Contraindications**

1. Do not use the instruments on serious edema tissue.
2. Do not use the instruments on too thick or too thin tissue.
3. Do not use the instruments on ischemic or necrotic tissue.

#### **VIII. Complication**

1. May cause infection.
2. May cause anastomotic stoma fistula.
3. May cause anastomotic stoma hemorrhage.

#### **IX. Warning**

1. The products are provided sterilized by radiation (Cobalt 60). **Never use any product with damaged packaging.**
2. Do not use any product with any visible damage or suspected damage. Please contact with the representative of this company.
3. This instrument is for single procedure use. Do not reuse, reprocess or re-sterilize.
4. The disposal, storage, cleaning, sterilization of the product, operation procedure and any other factors uncontrolled by the company may directly influence the application result of this product.

5. Pay sufficient attention to the cartridge reloading/unloading in one procedure, any careless may cause risk and/or product damage.
6. This product shall be performed only by surgeons having adequate training in stapling techniques and/or instructed by experienced persons.
7. Never try to operate this product before reading the instructions for use thoroughly. Any inadvertent operation may bring the operation with risk.
8. Dispose of all used instruments properly to avoid any pollution to the environment

**X. Guarantees**

1. This company guarantees that the design and production of this product is carried out under reasonable caution and necessary management.
2. The obligation born by this company under this guarantee is limited within the replacement of the product. This company is not directly or indirectly liable for compensation of any loss caused by any accident from the product application.
3. This company is not liable for any loss resulted from any re-use, re-process or re-sterilize of the instrument.

**DO NOT USE THE PRODUCT IF THE PACKAGE IS DAMAGED.**

For the matter not covered, refer to the related medical literature or medical equipment literature, or call (mail) us for consultation.

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**Issuance Date:** 2012 first edition

**Caution:** U.S. Federal law restricts this device to sale by or on the order of a physician.

SBF 60Z

# LINEAR STAPLER

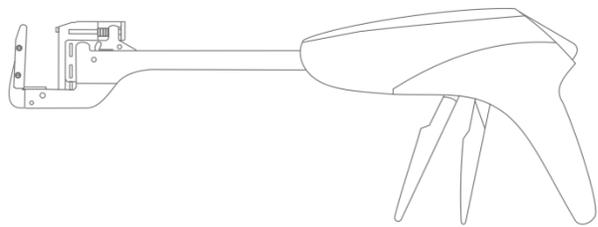
SBF 60Z

LINEAR STAPLER

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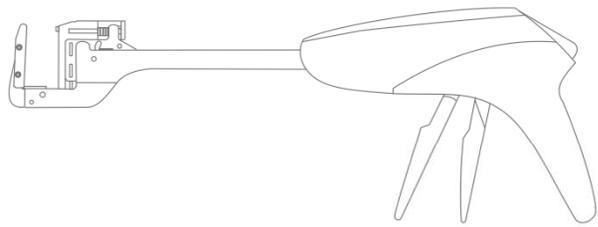
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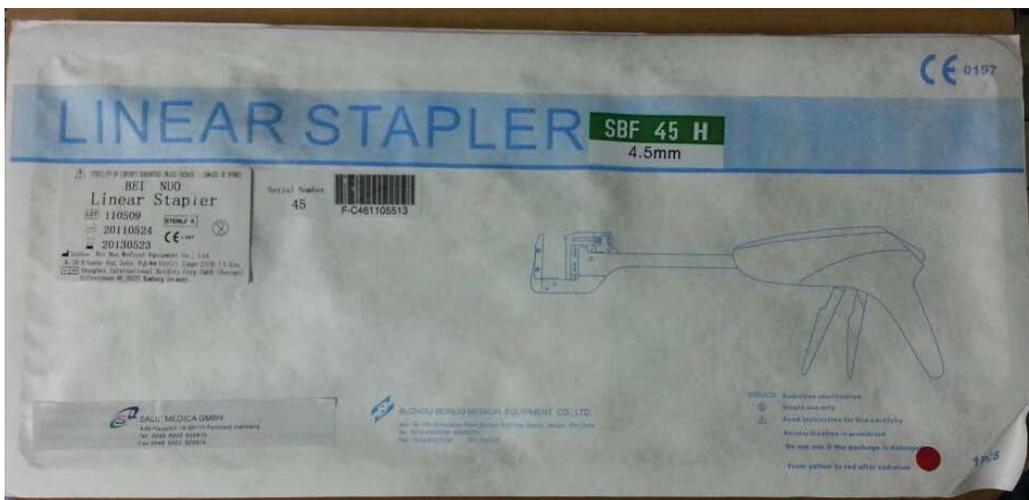
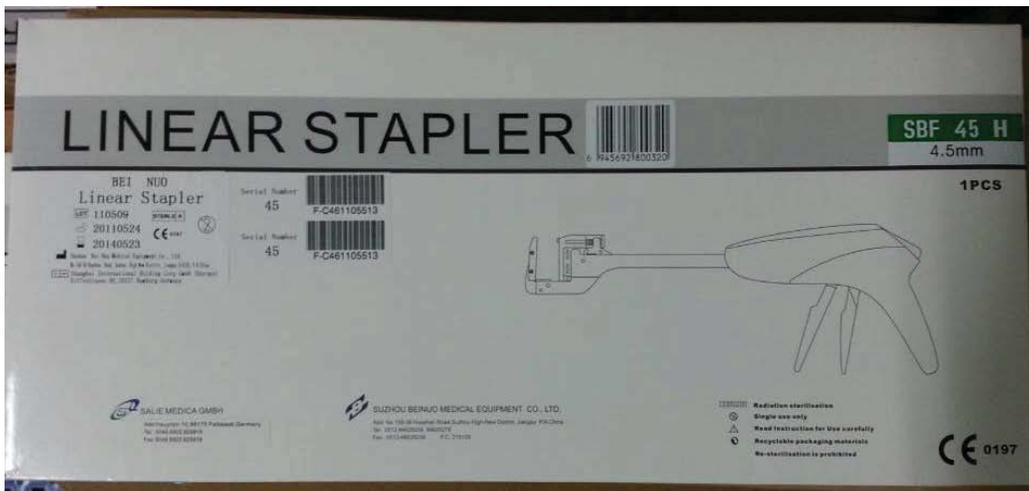
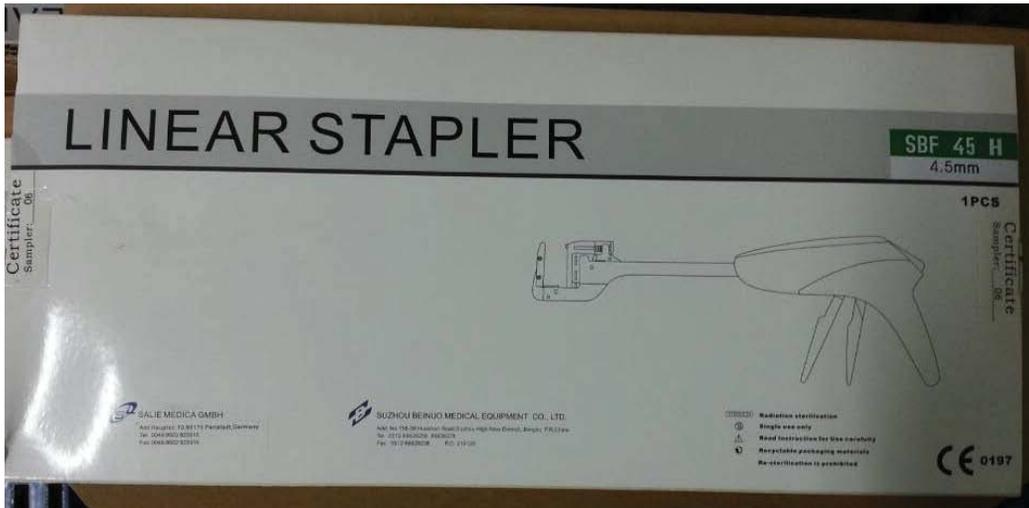
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BeiNuo package sample



STERILITY OF CONTENTS GUARANTEED UNLESS PACKAGE IS DAMAGED OR OPENED

# BEI NUO Linear Stapler

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Shanghai International Holding Corp. GmbH (Europe)  
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Serial Number

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F-C461105513



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SUZHOU BEI

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Tel: 0512-6662629



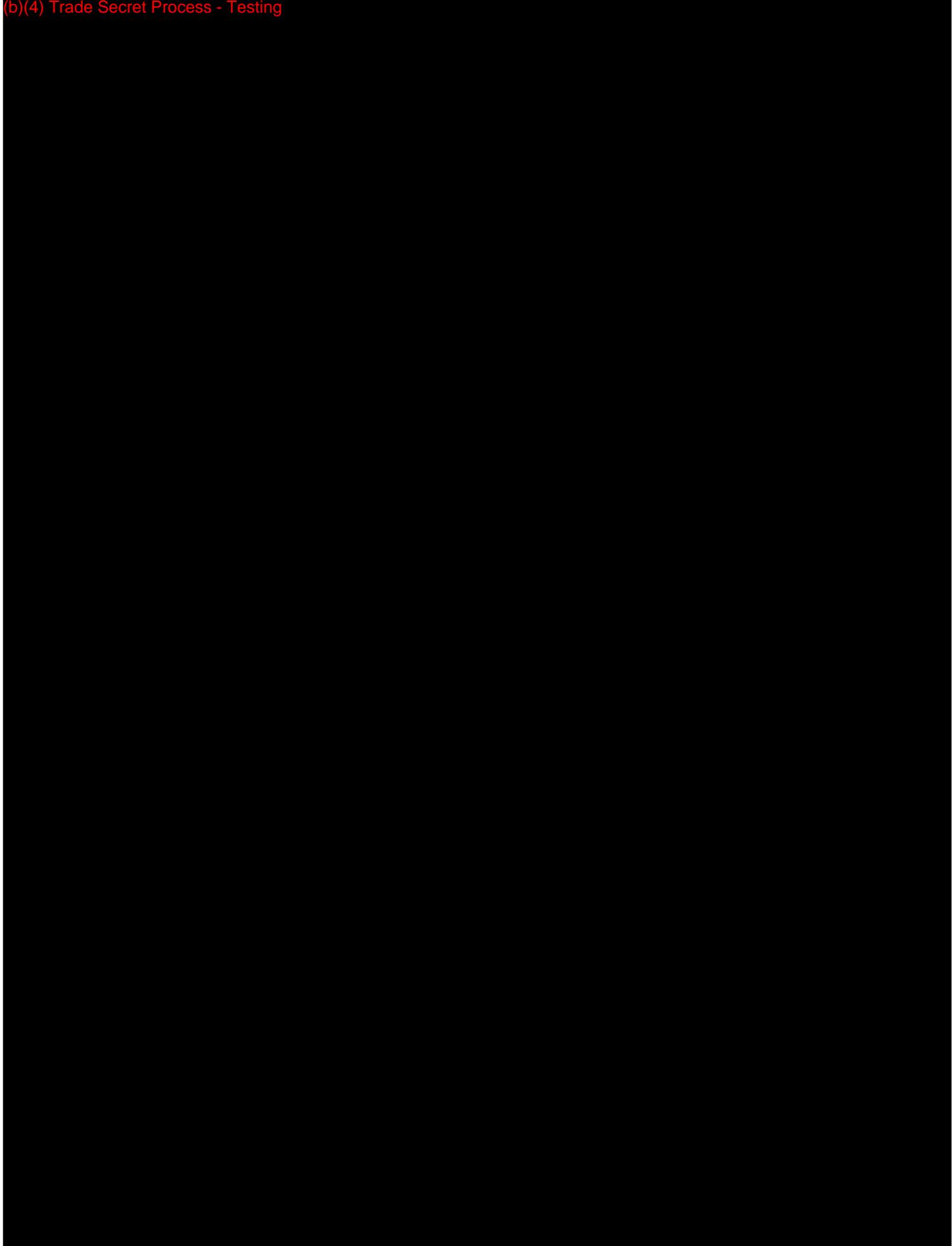
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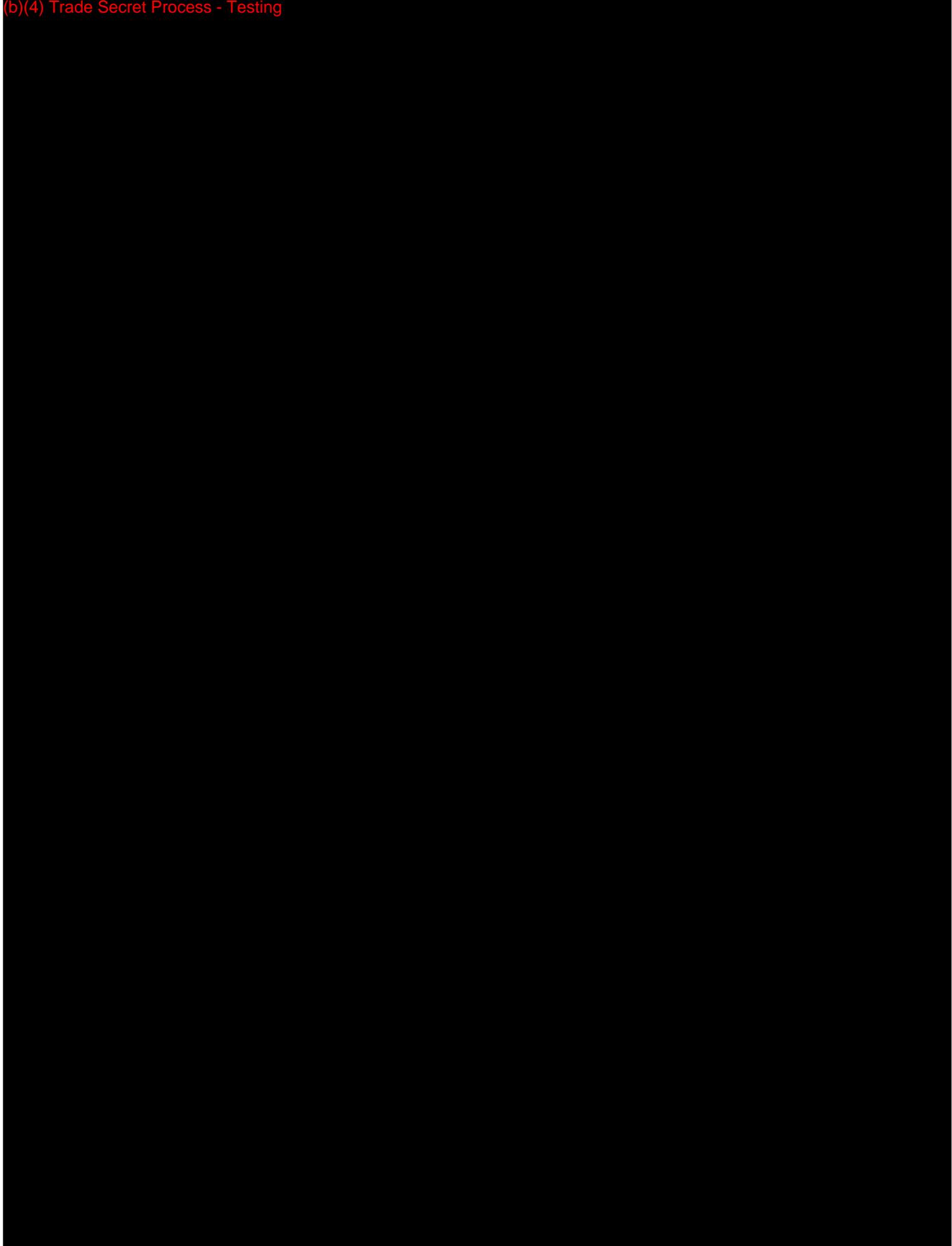
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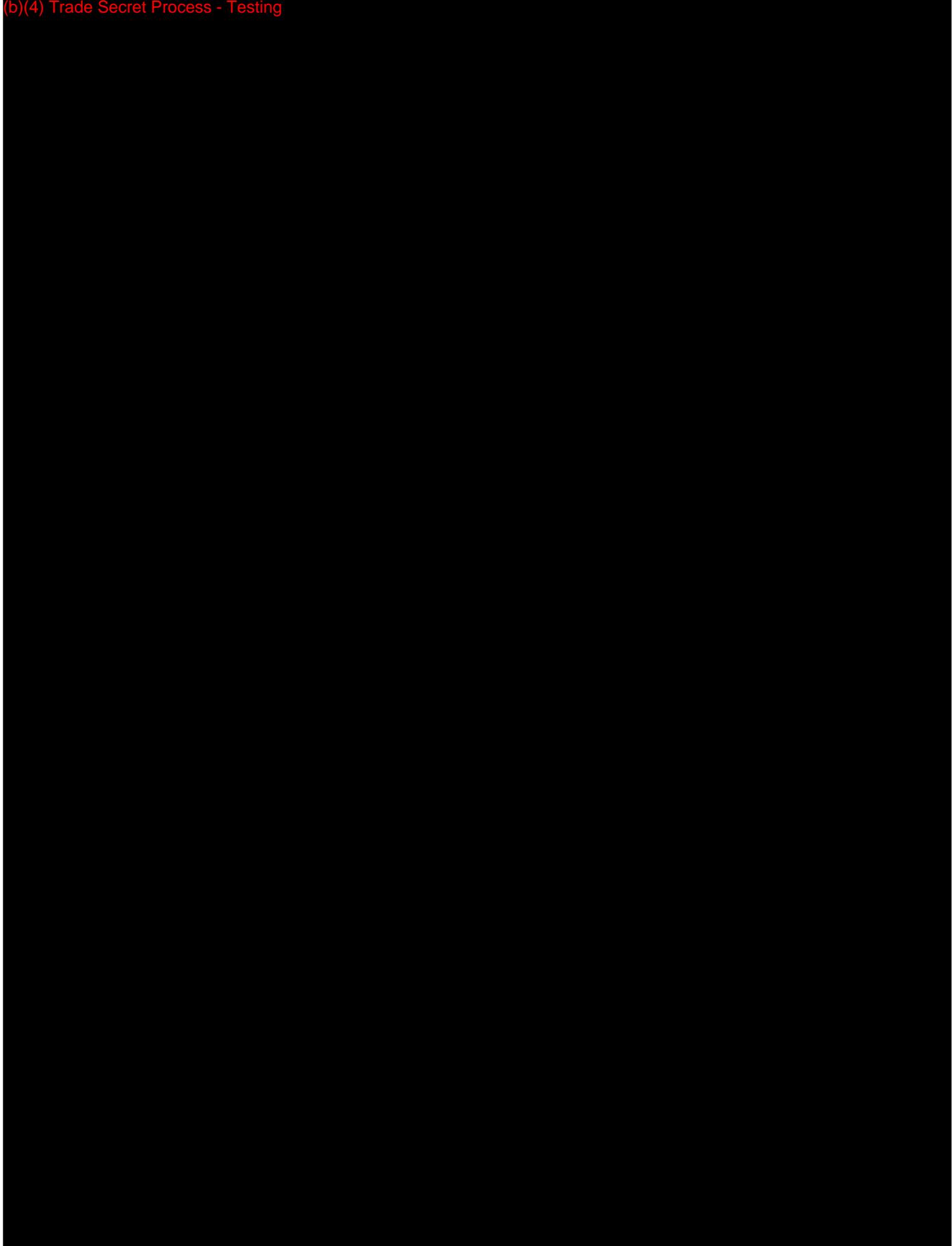
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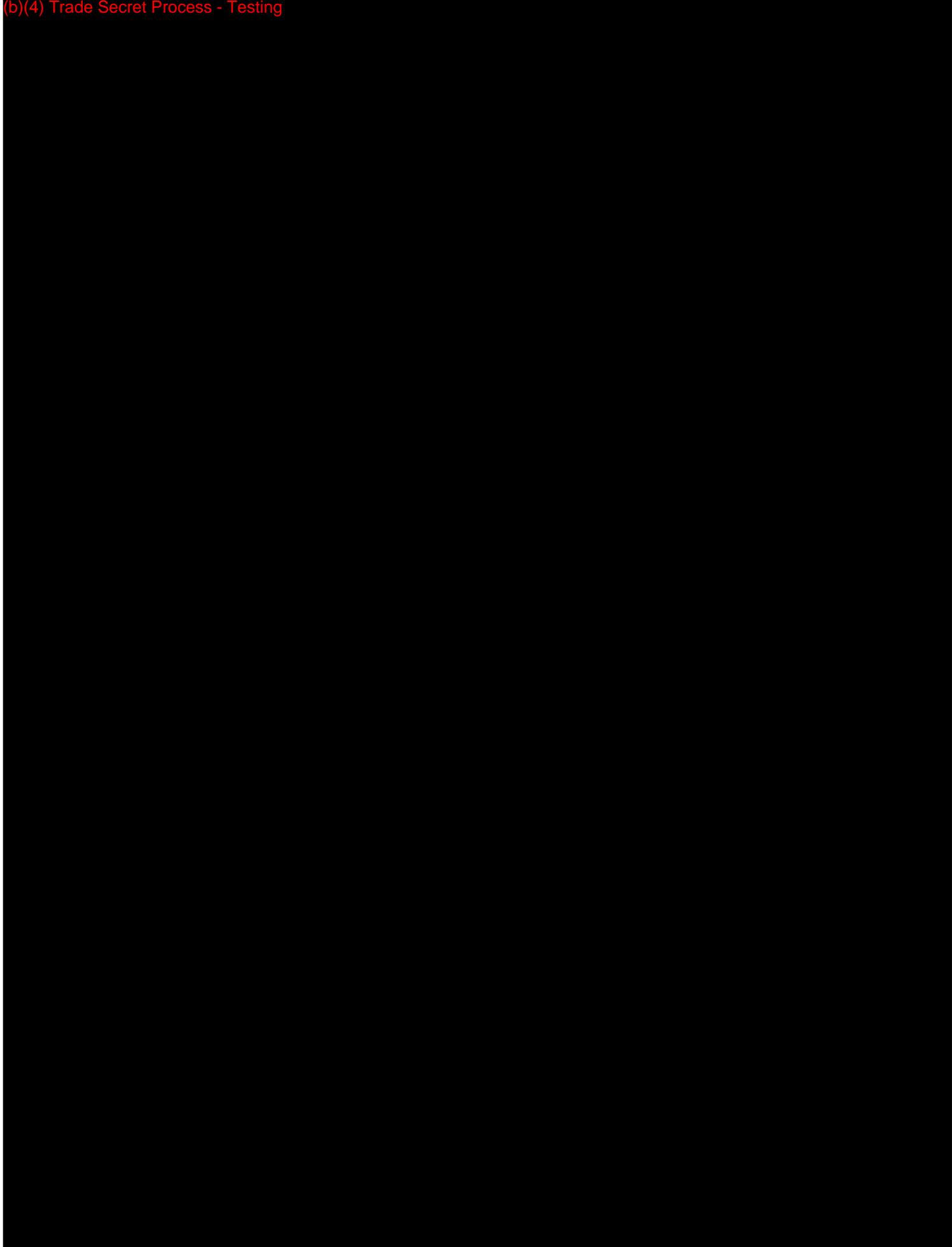


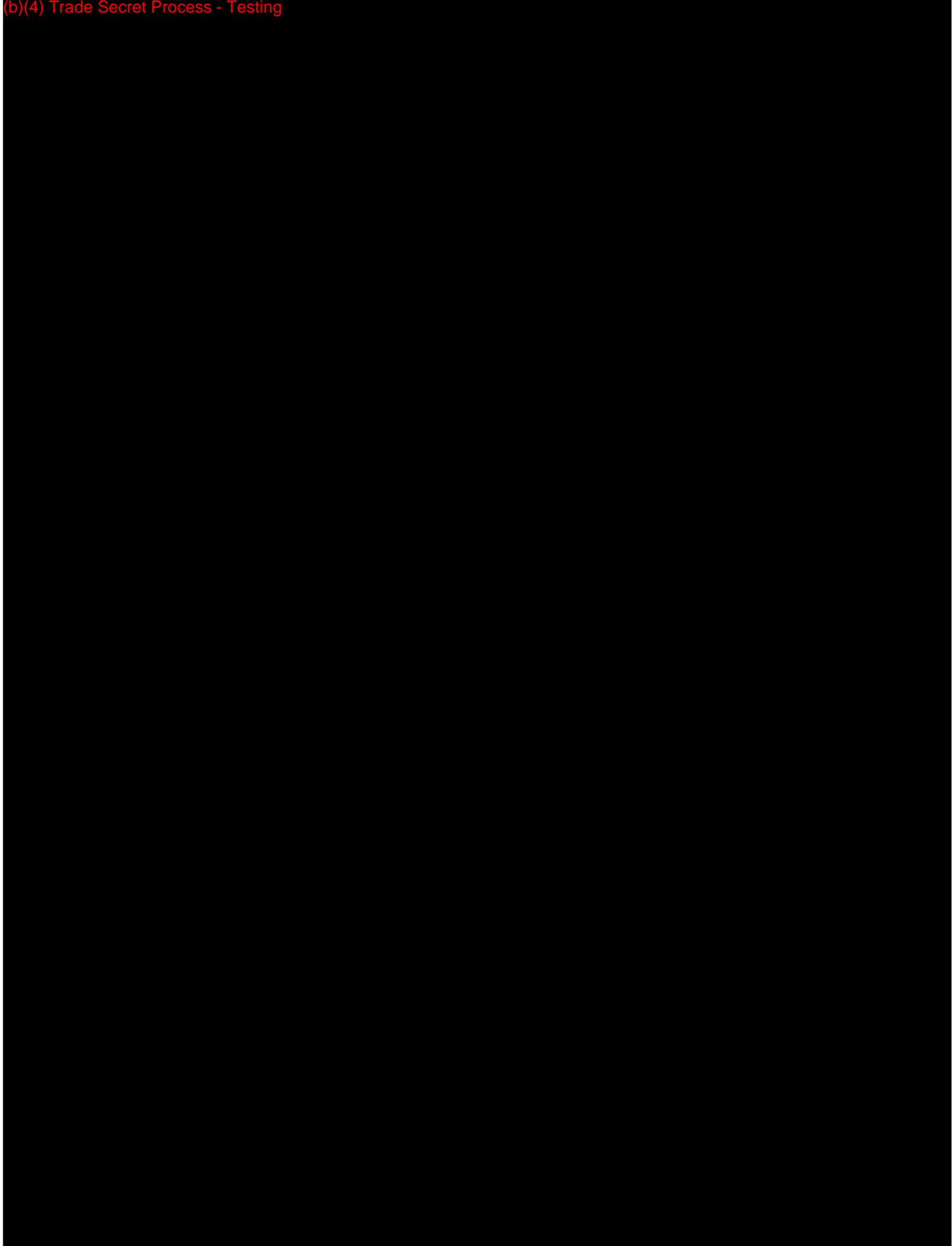
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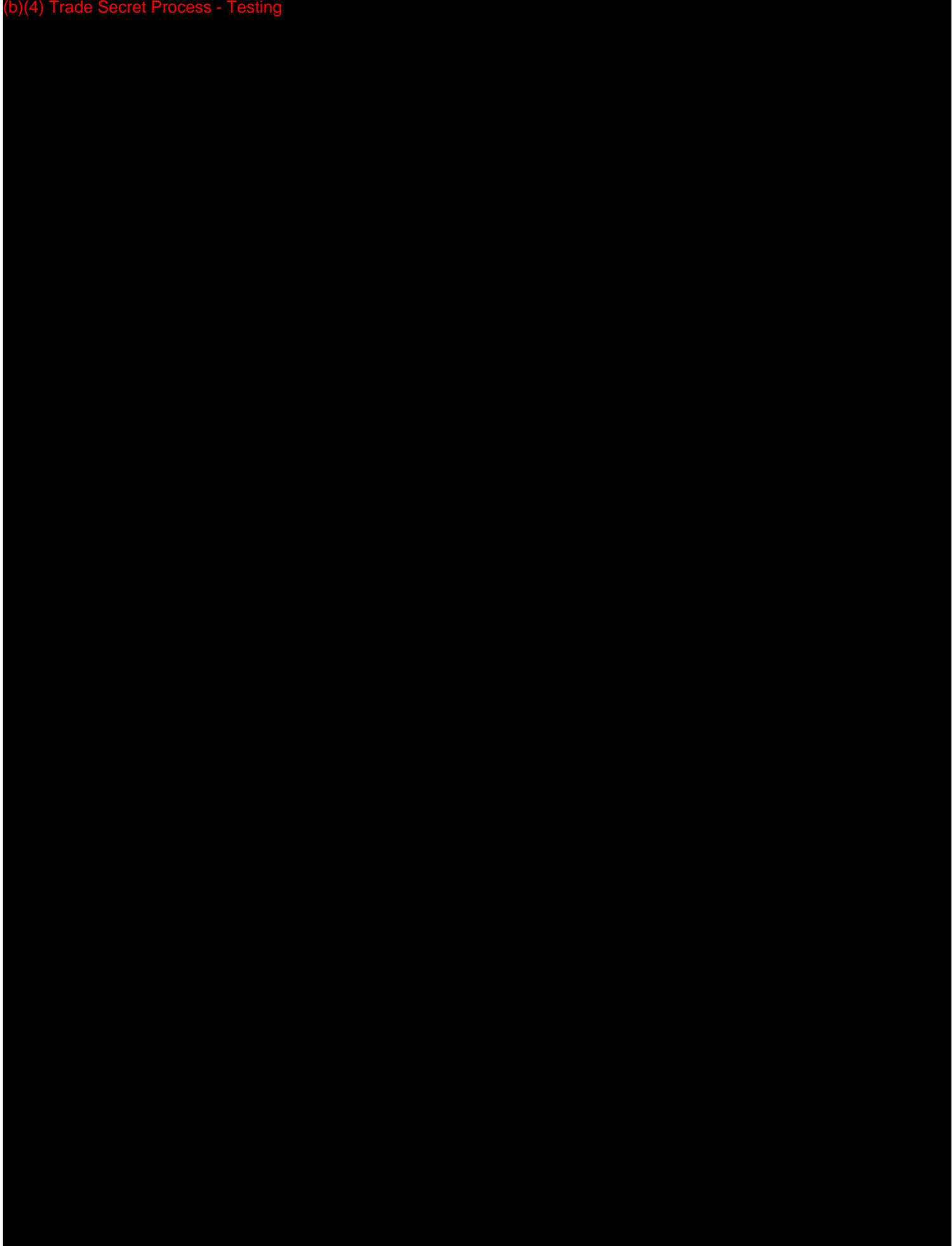


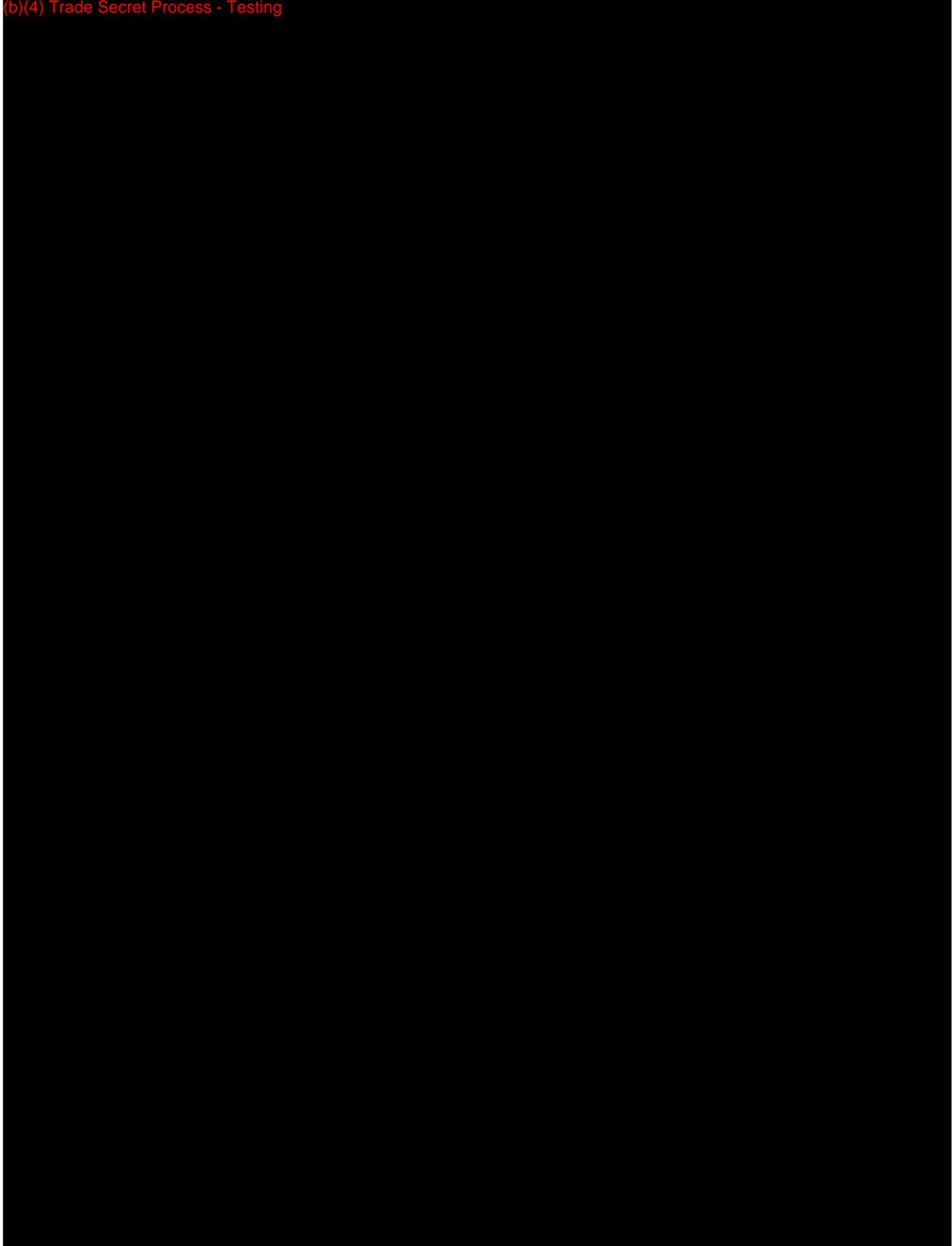


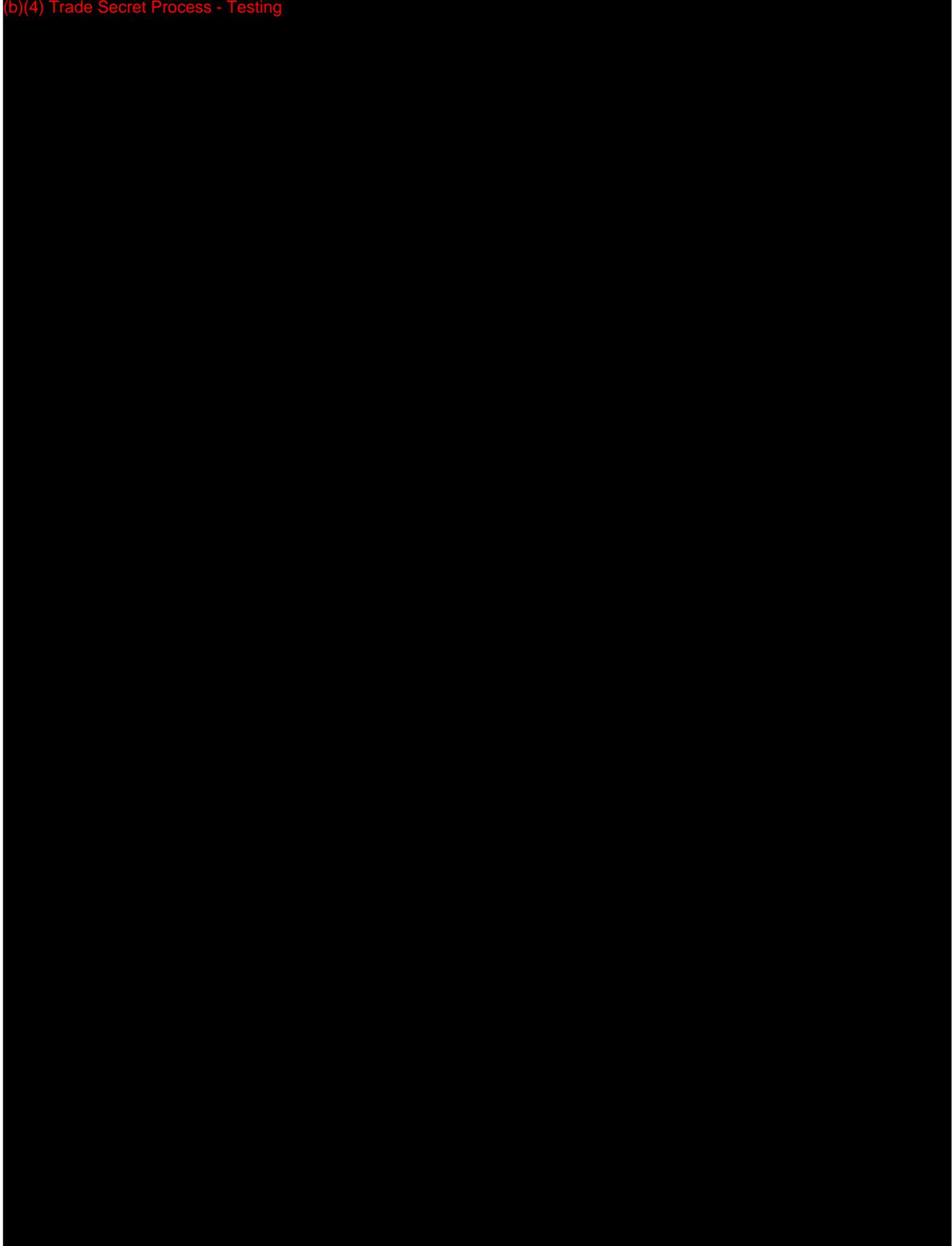


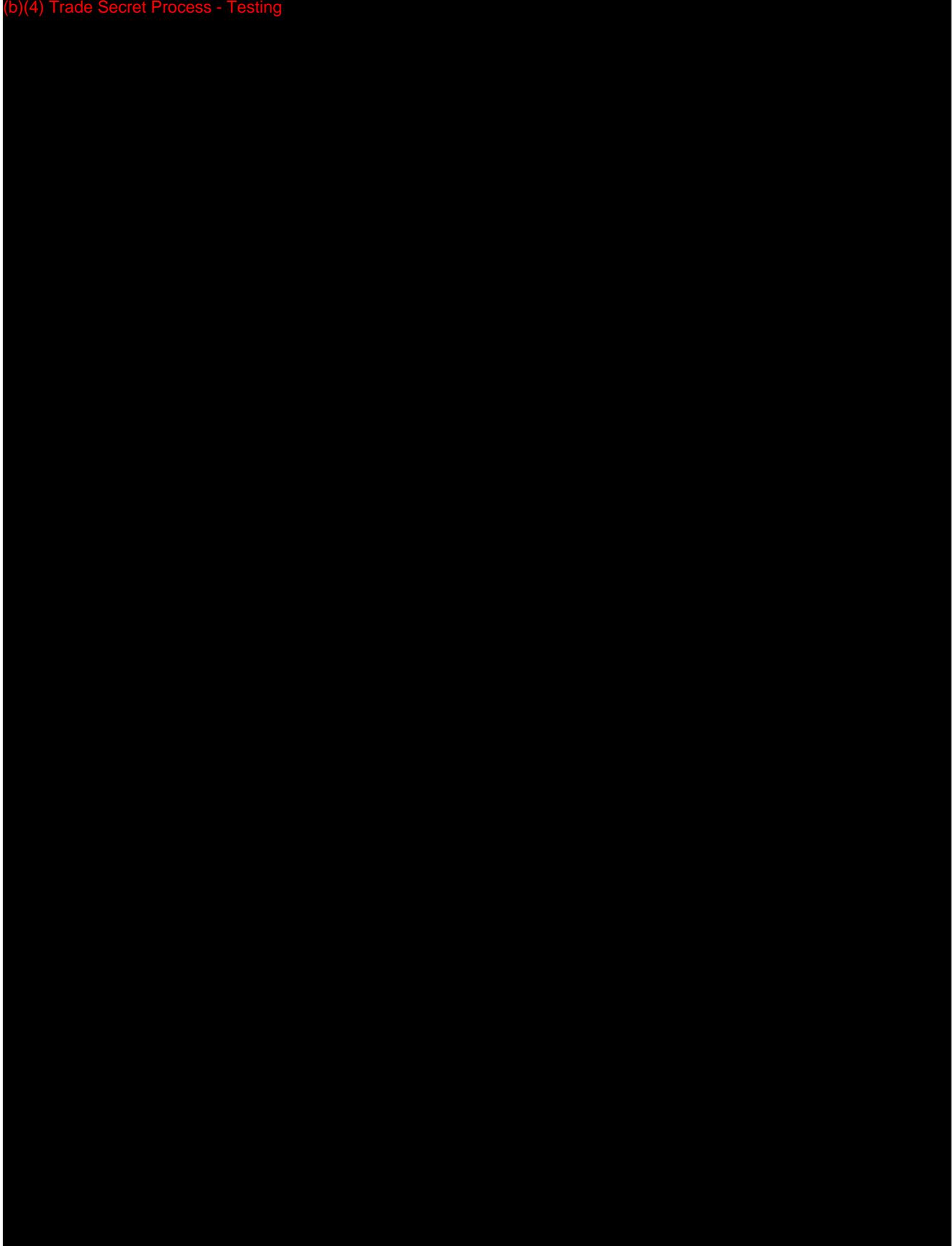


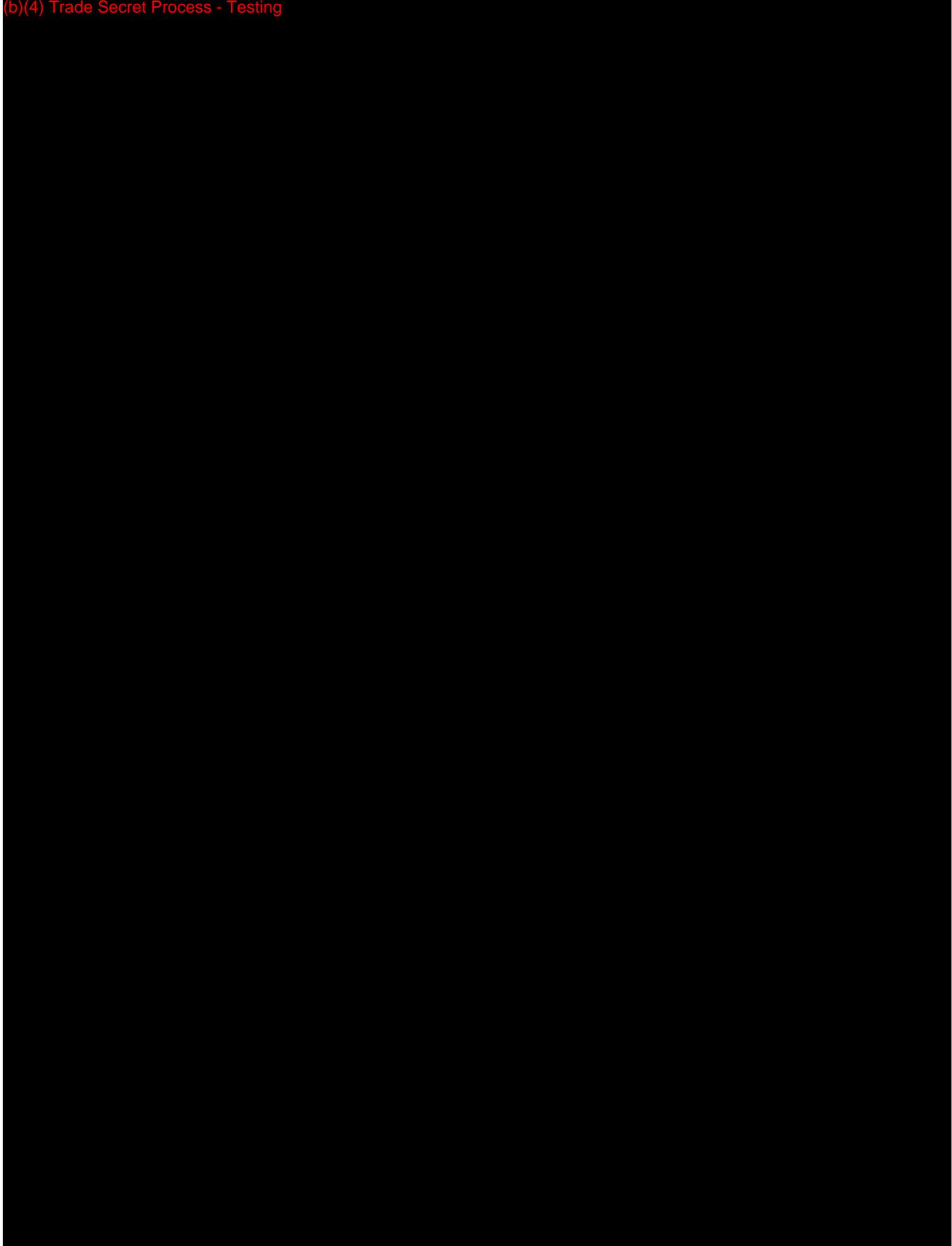


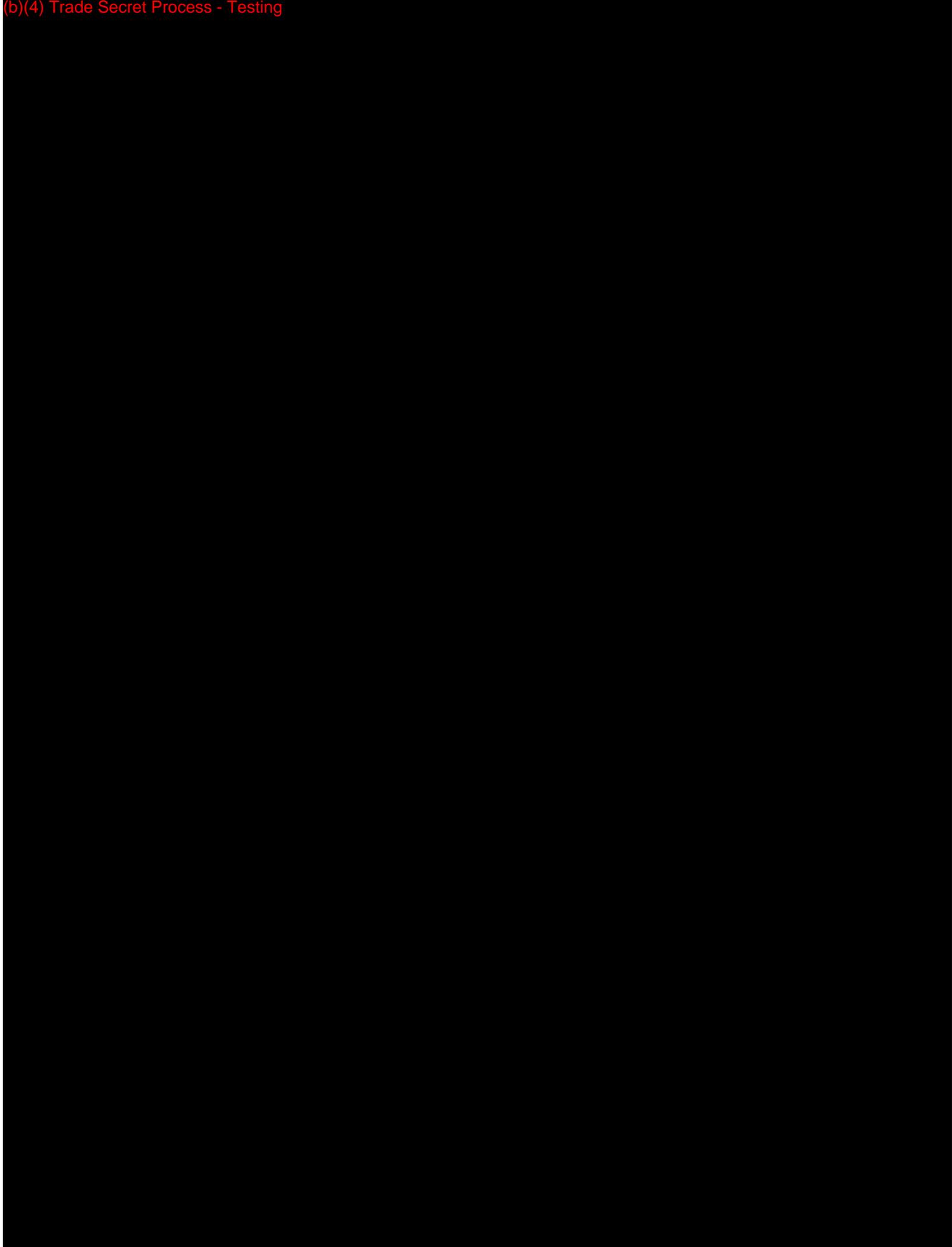


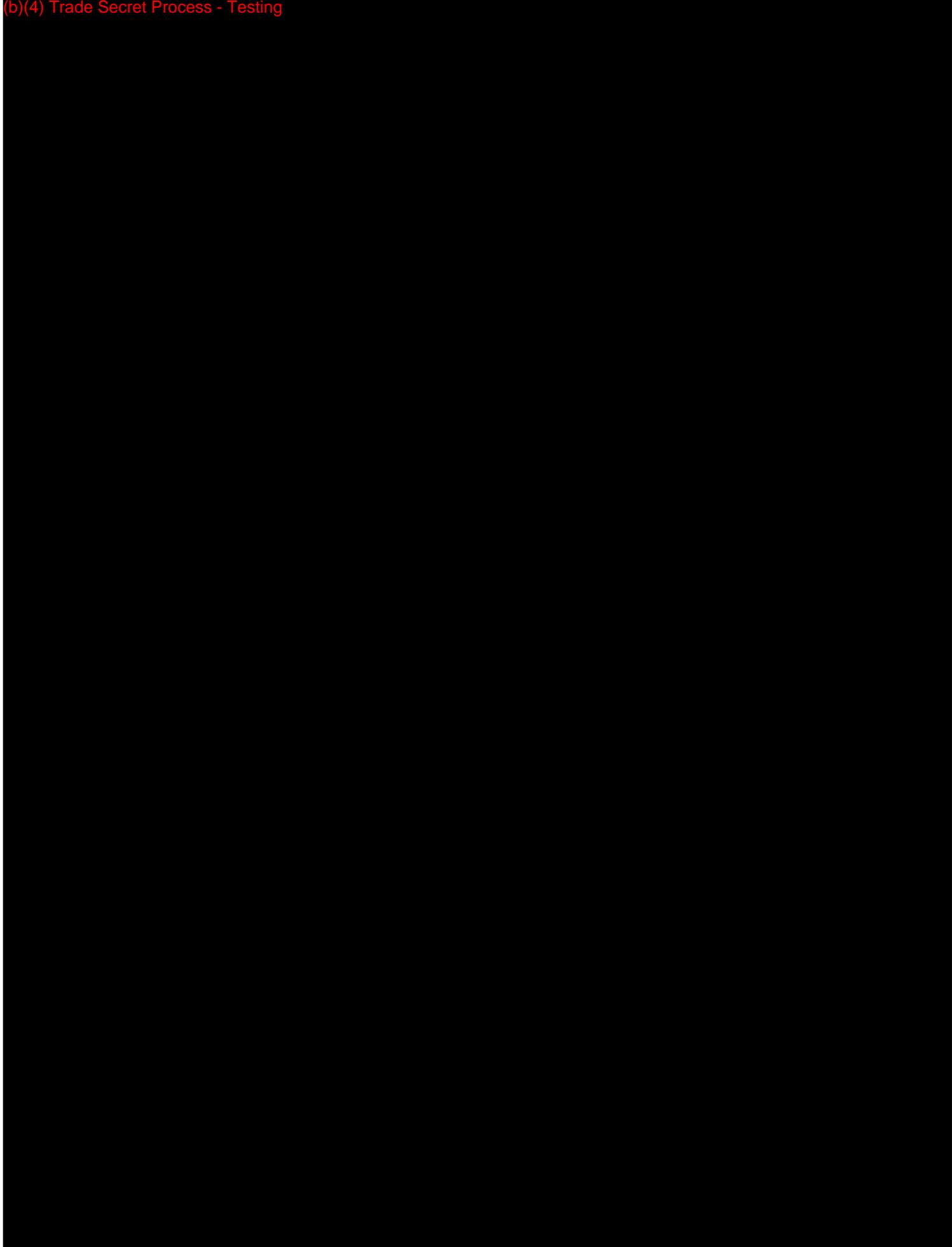


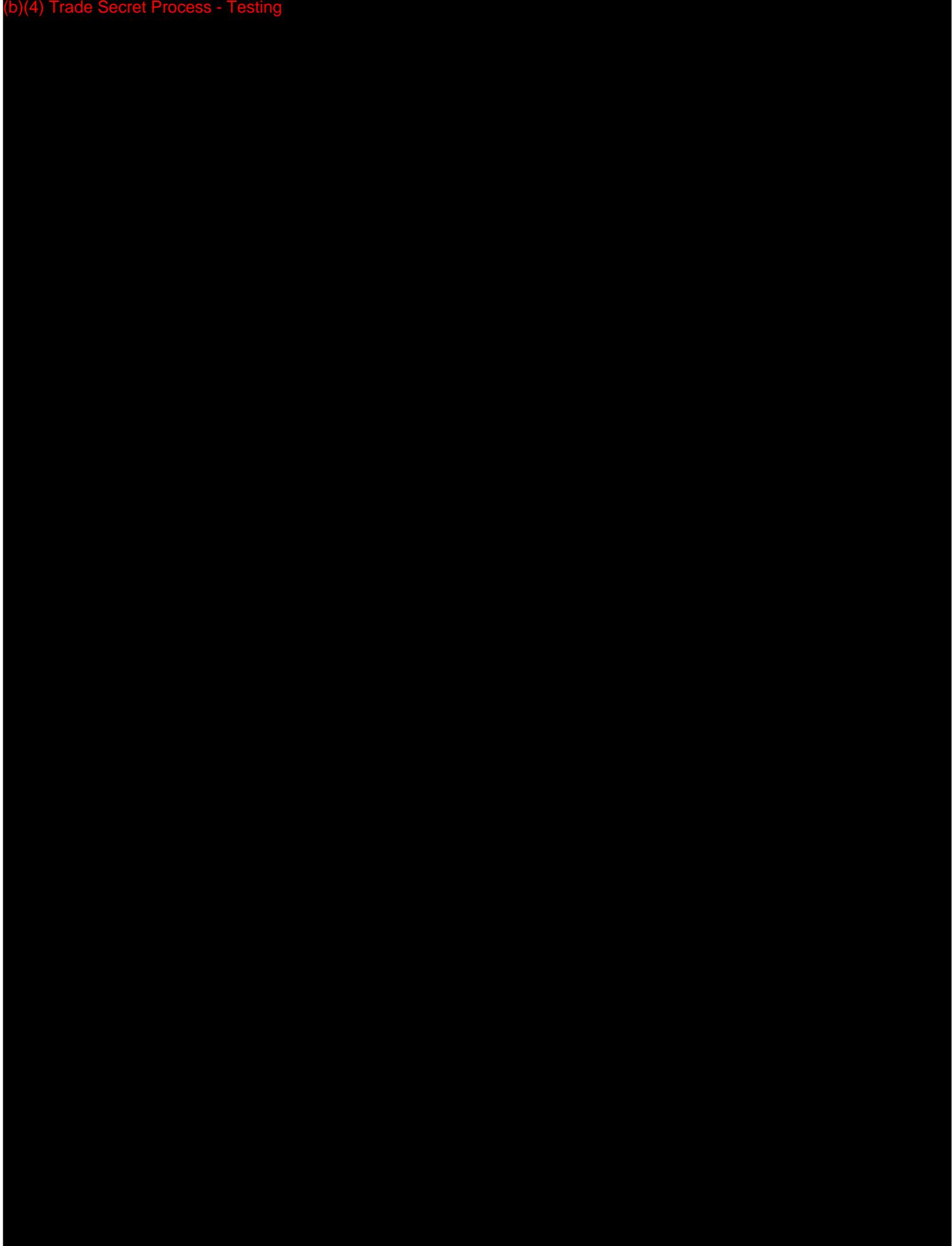


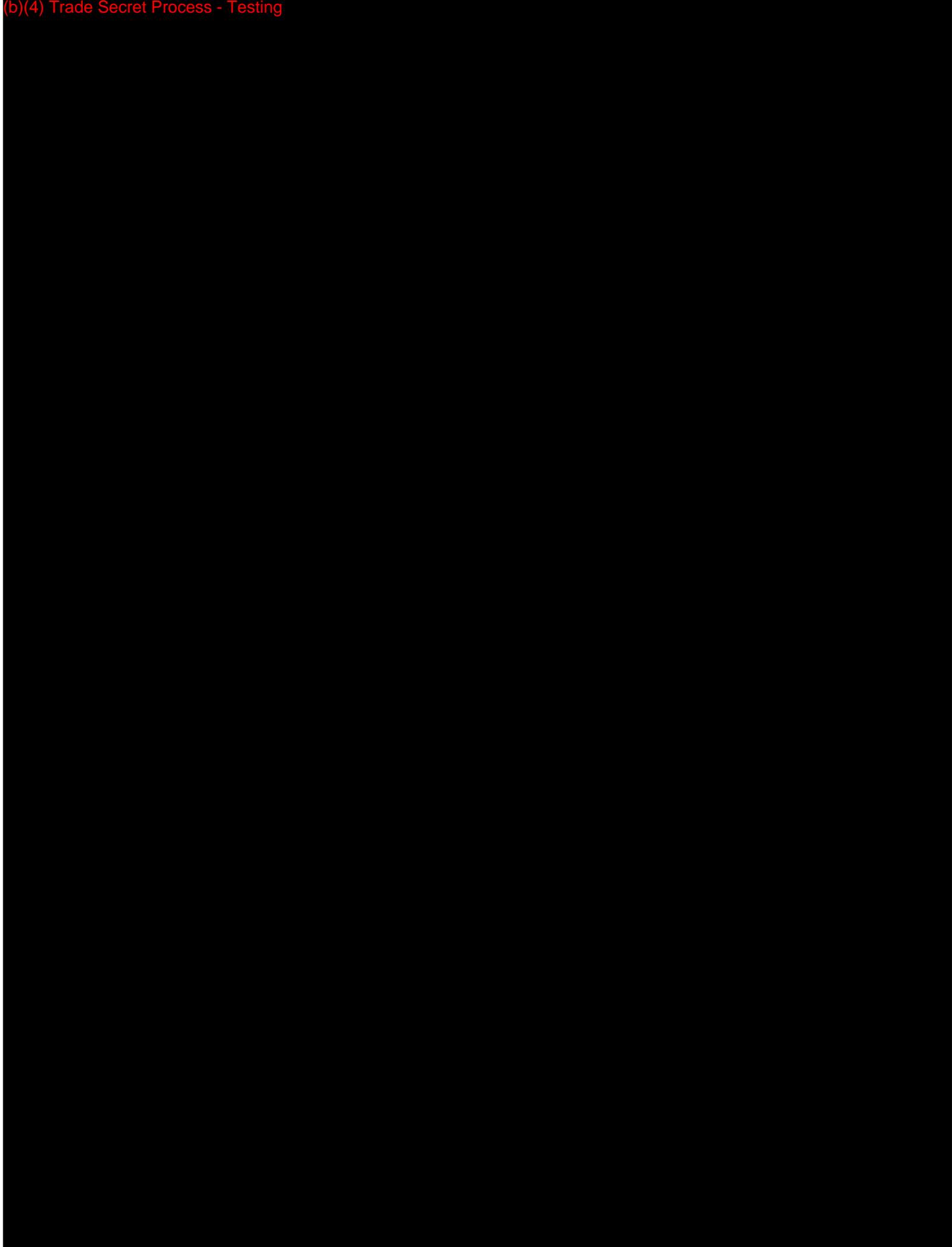


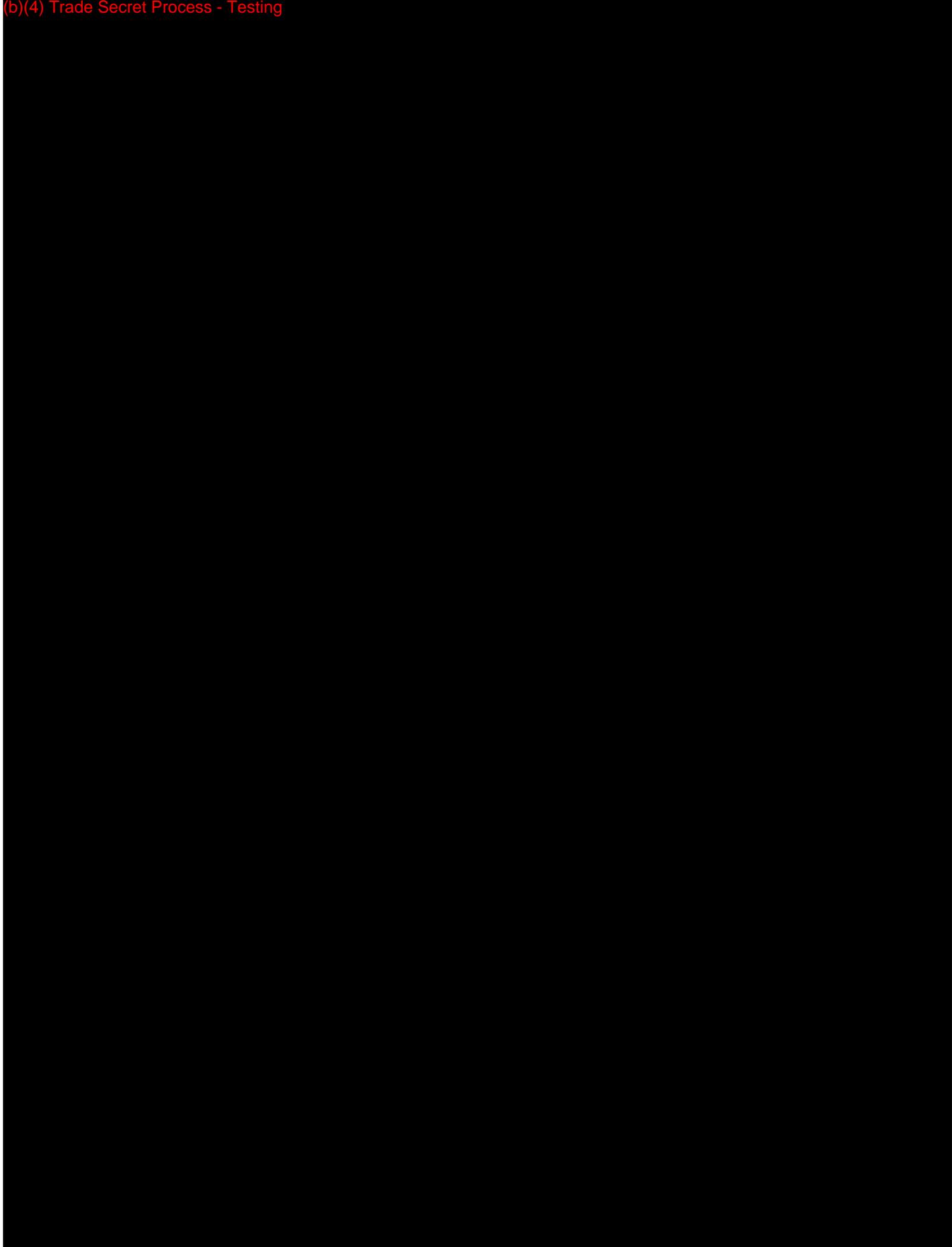


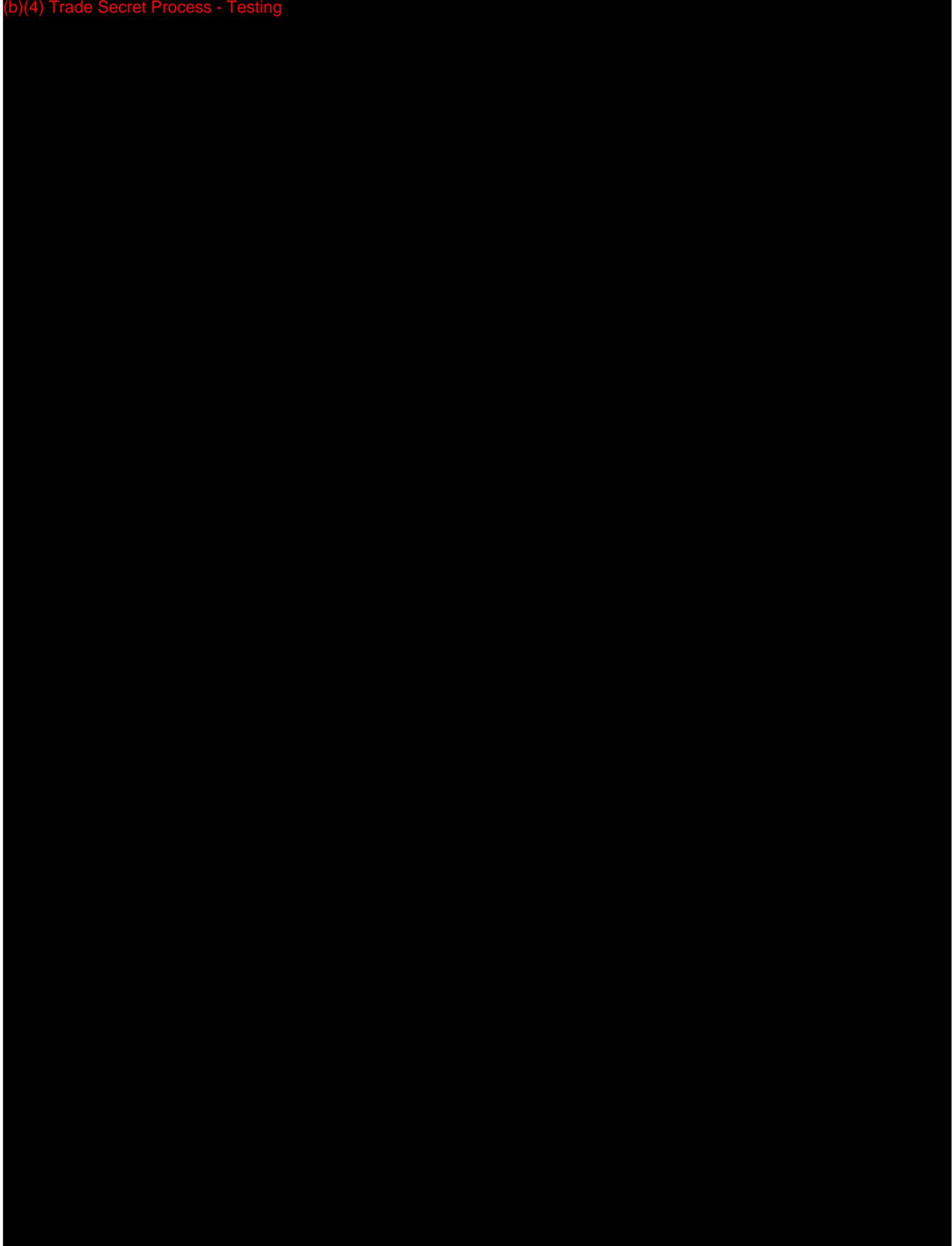


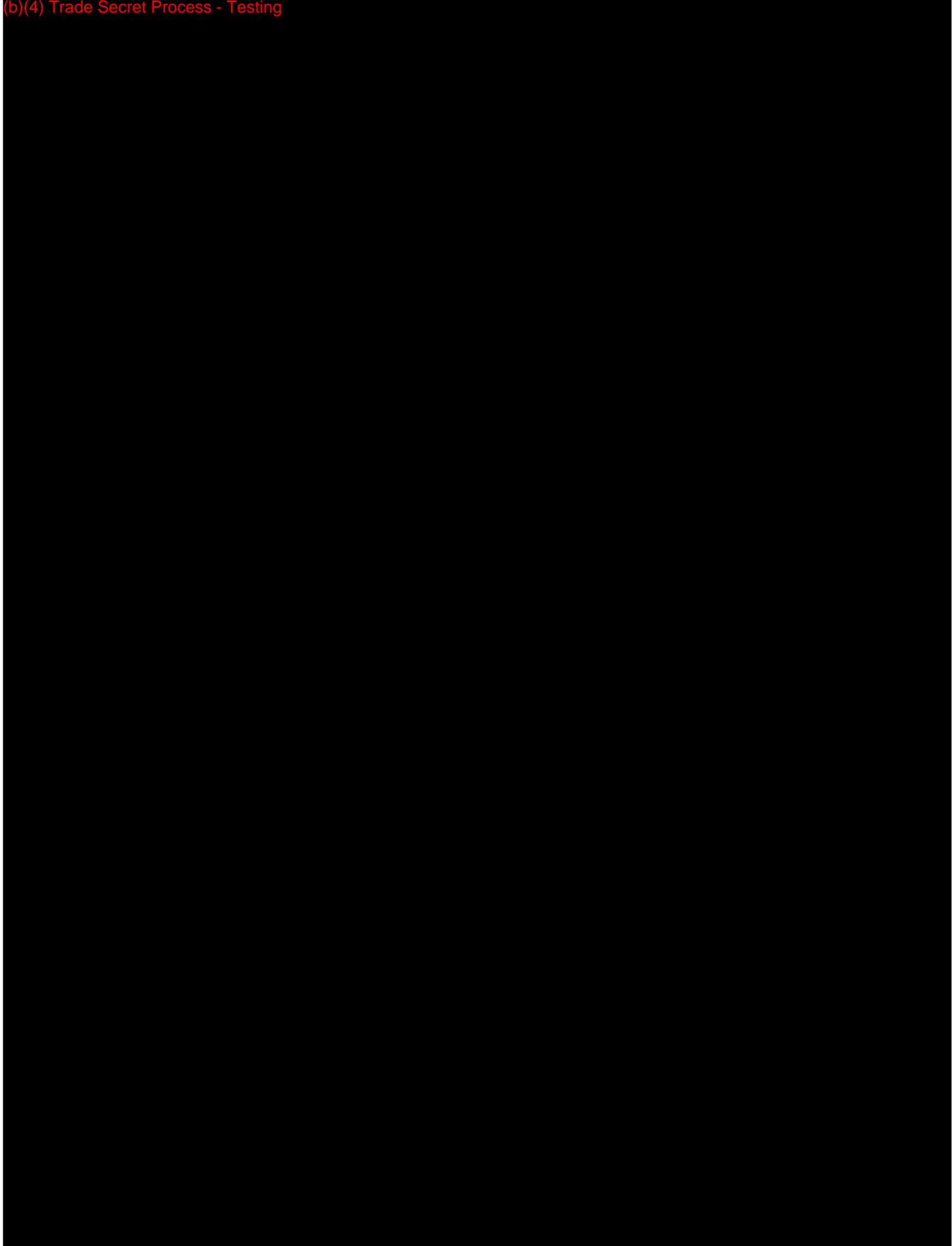


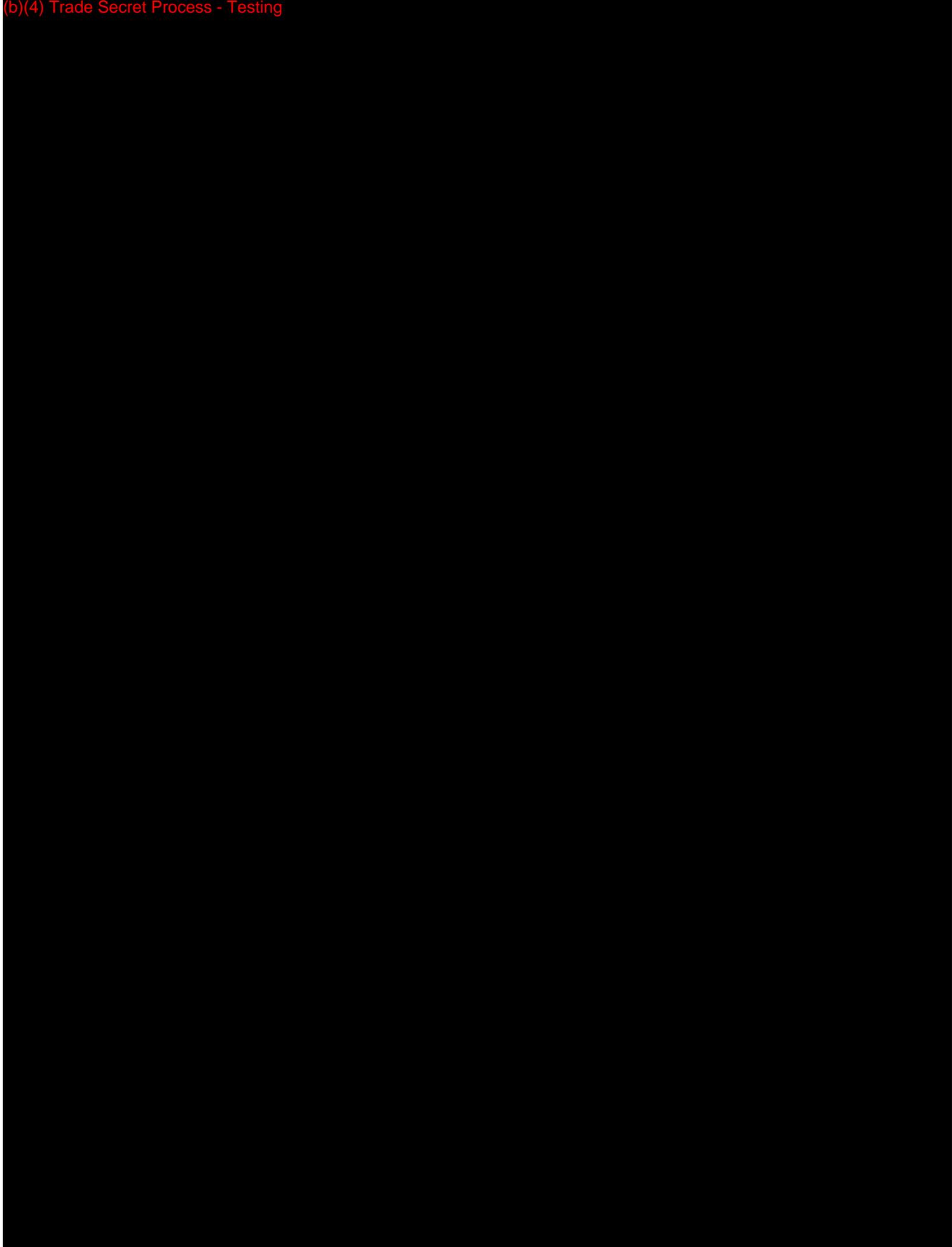


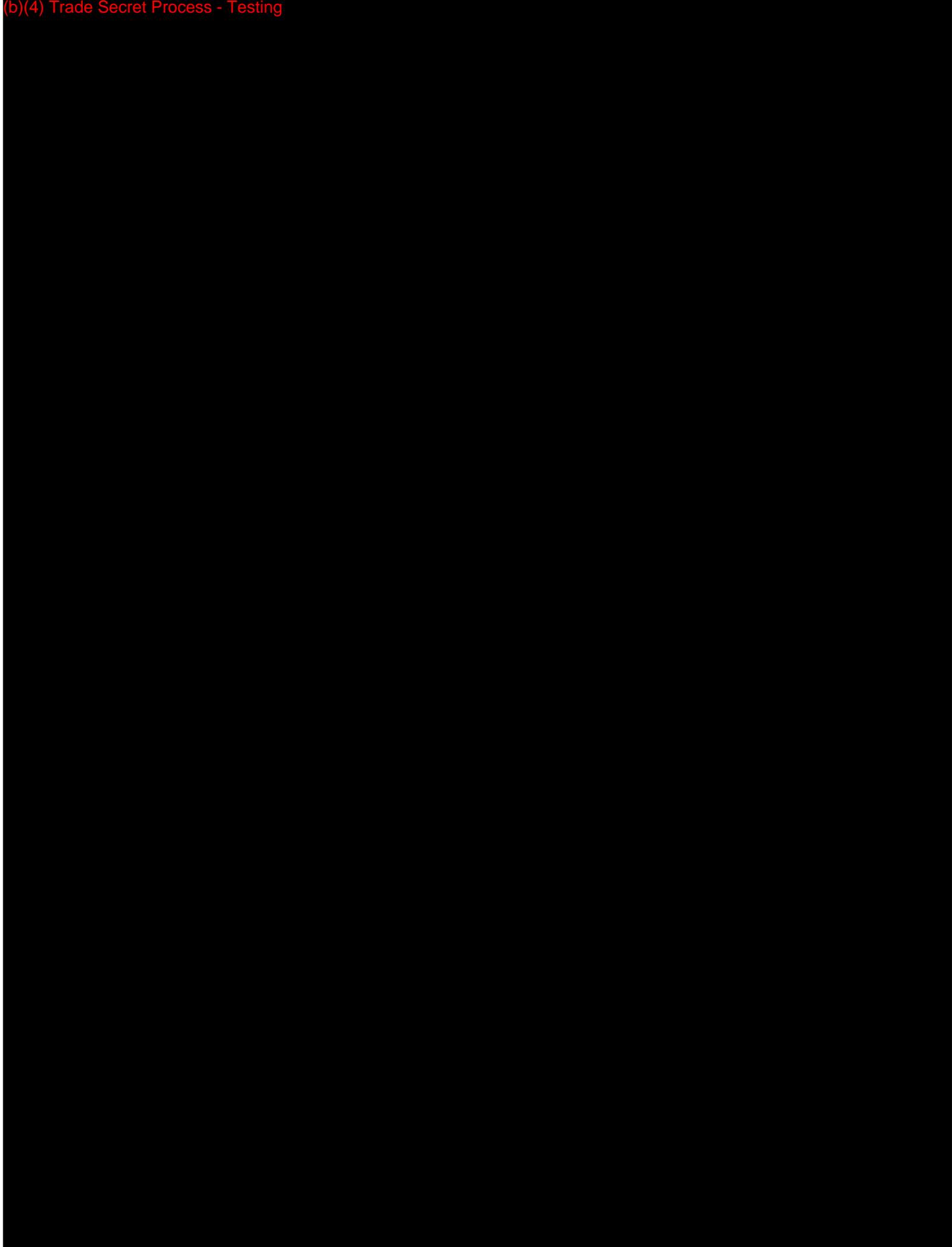


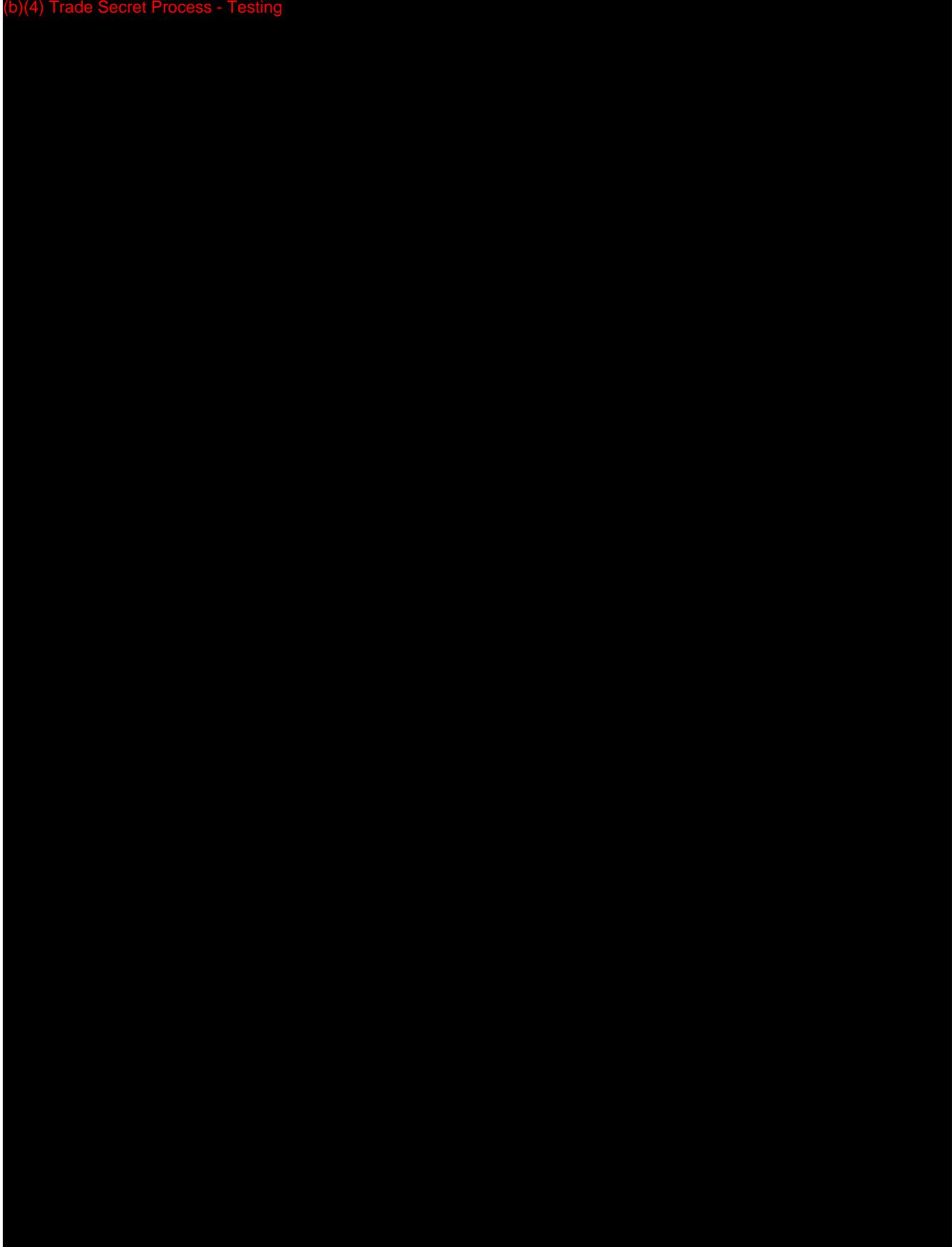


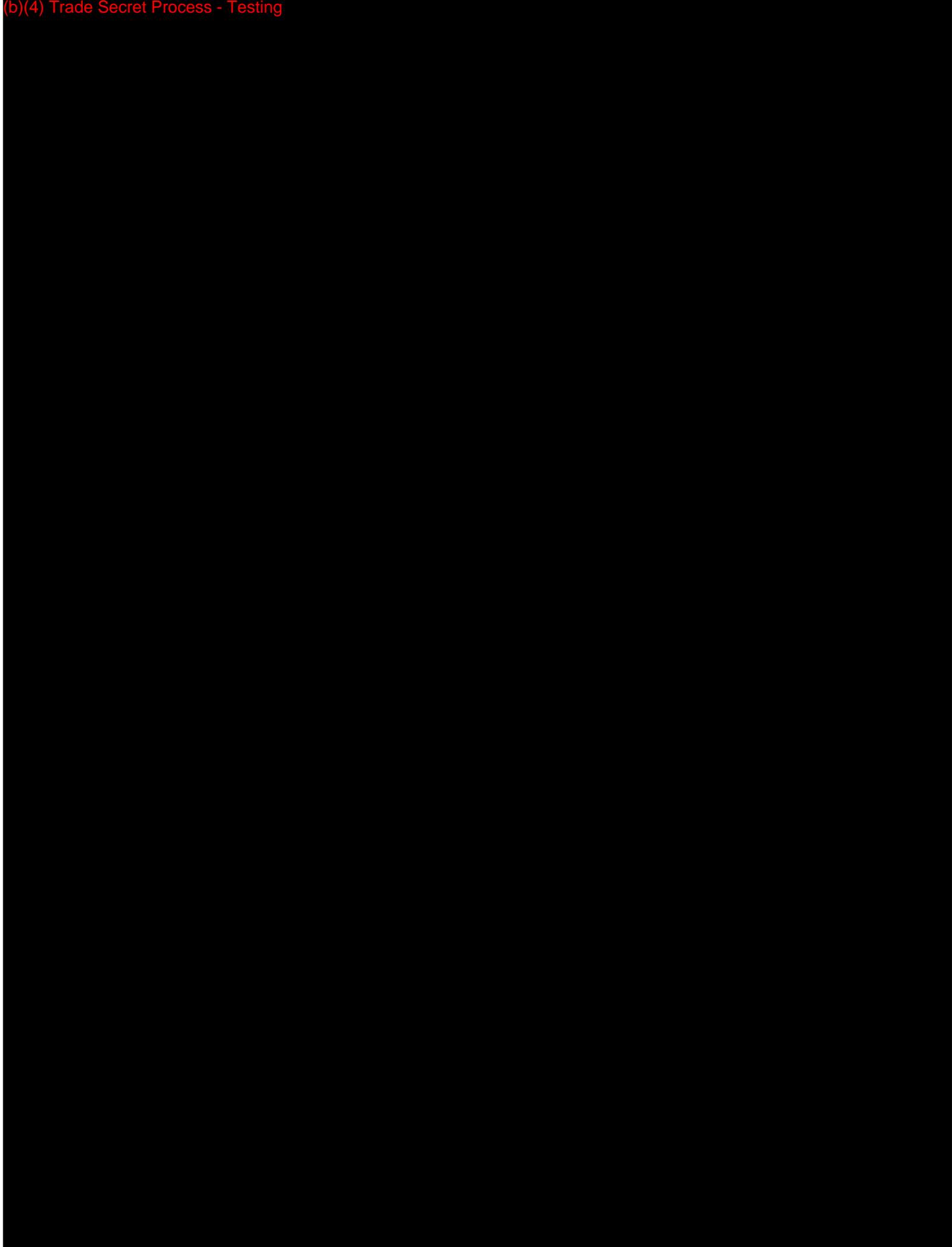


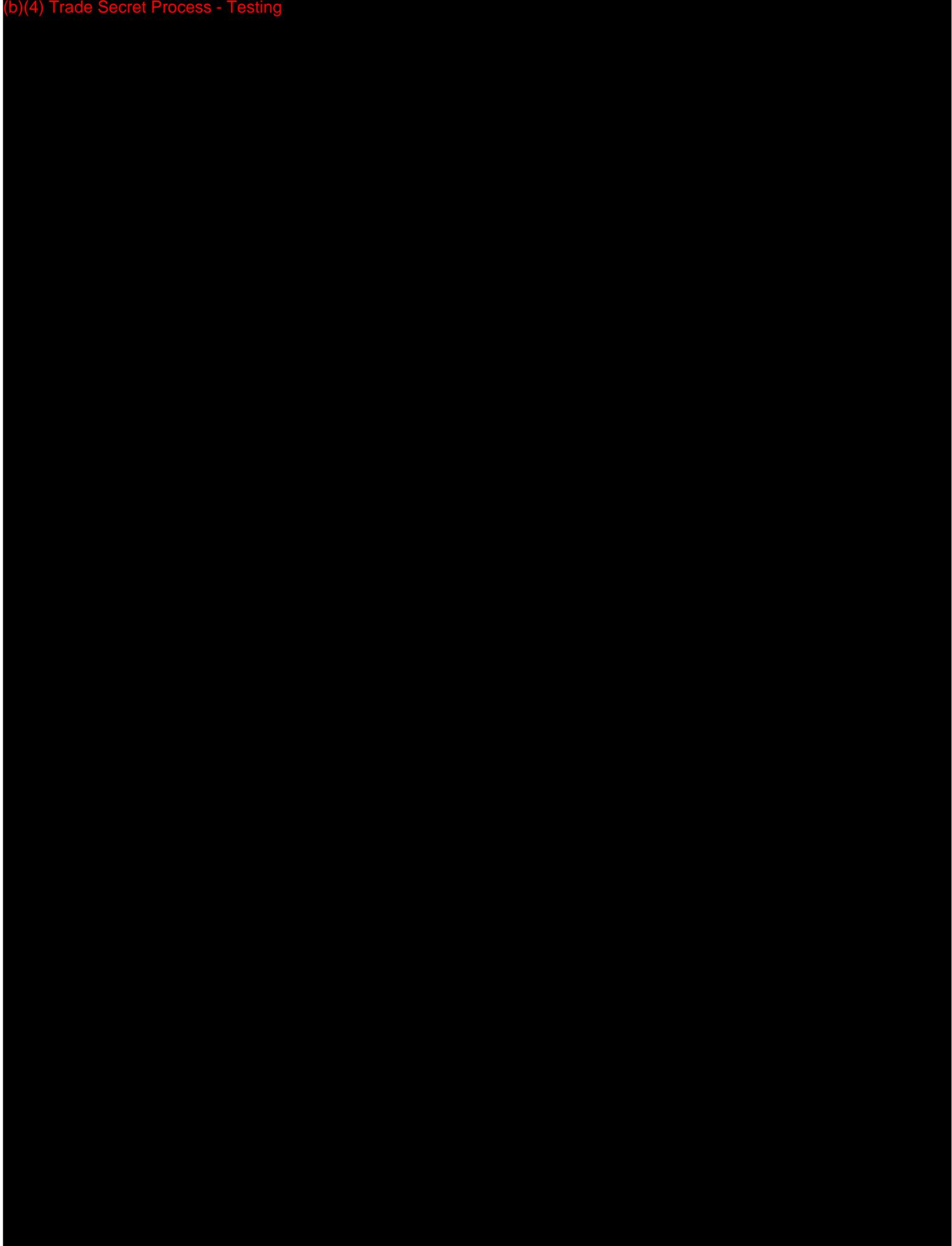


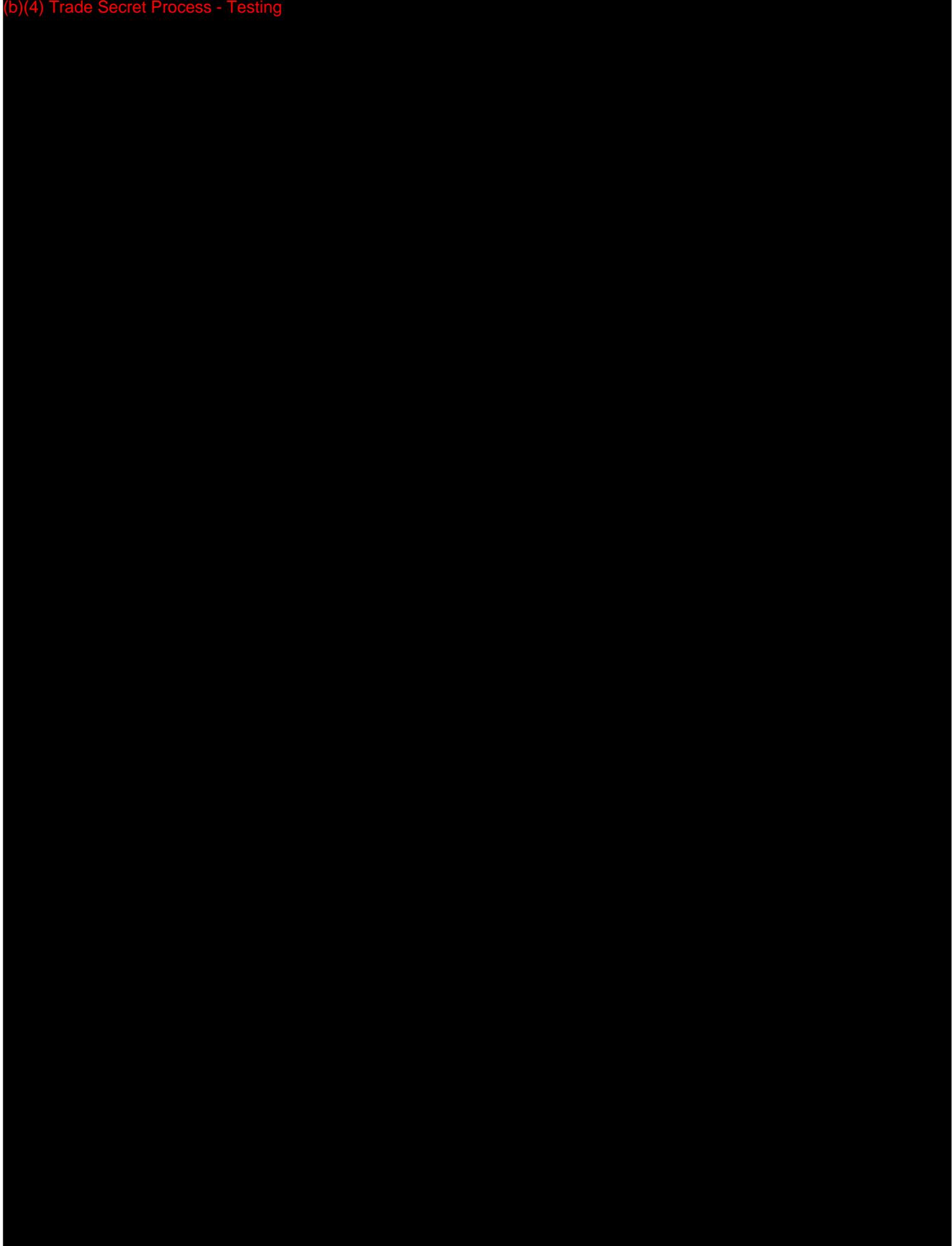


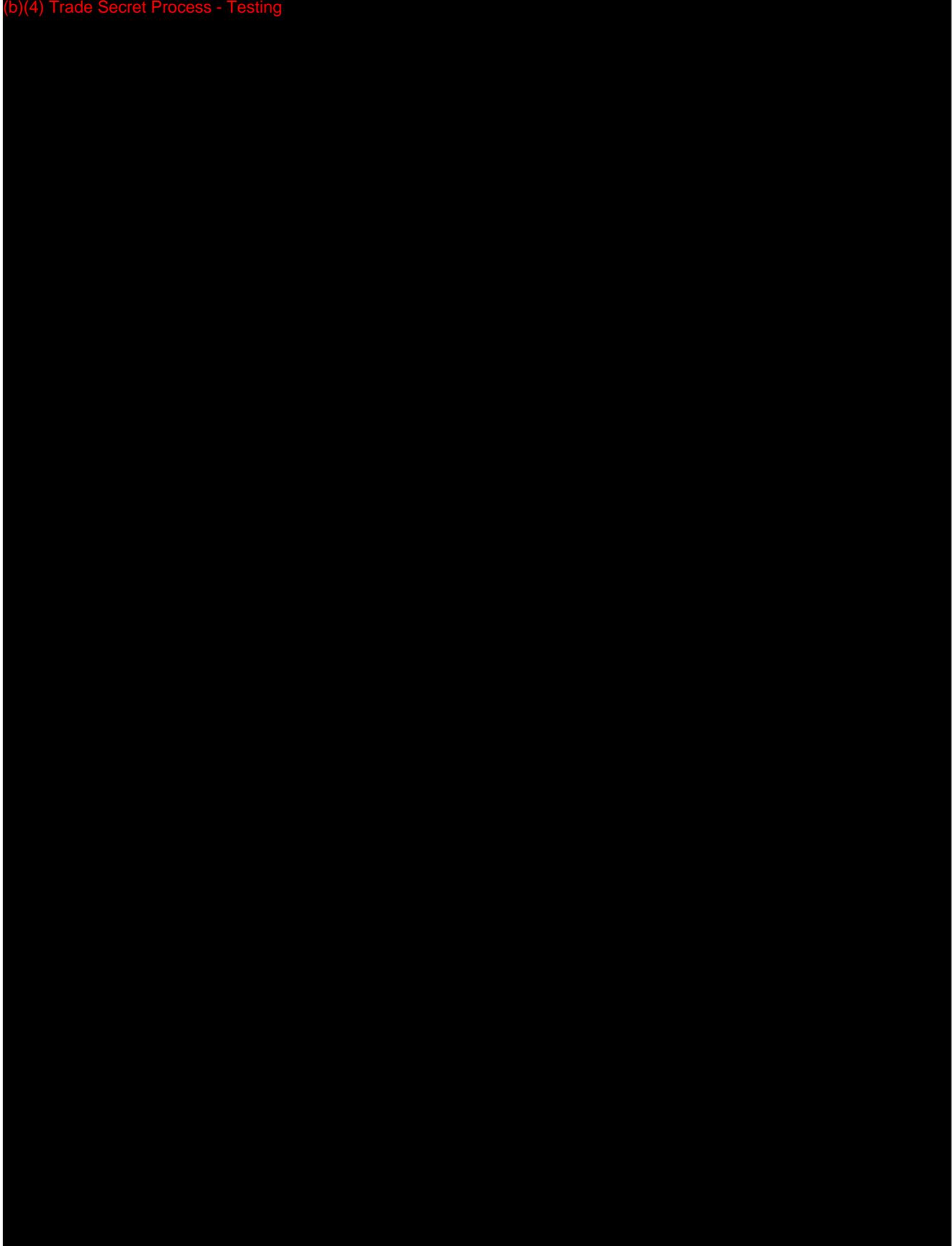


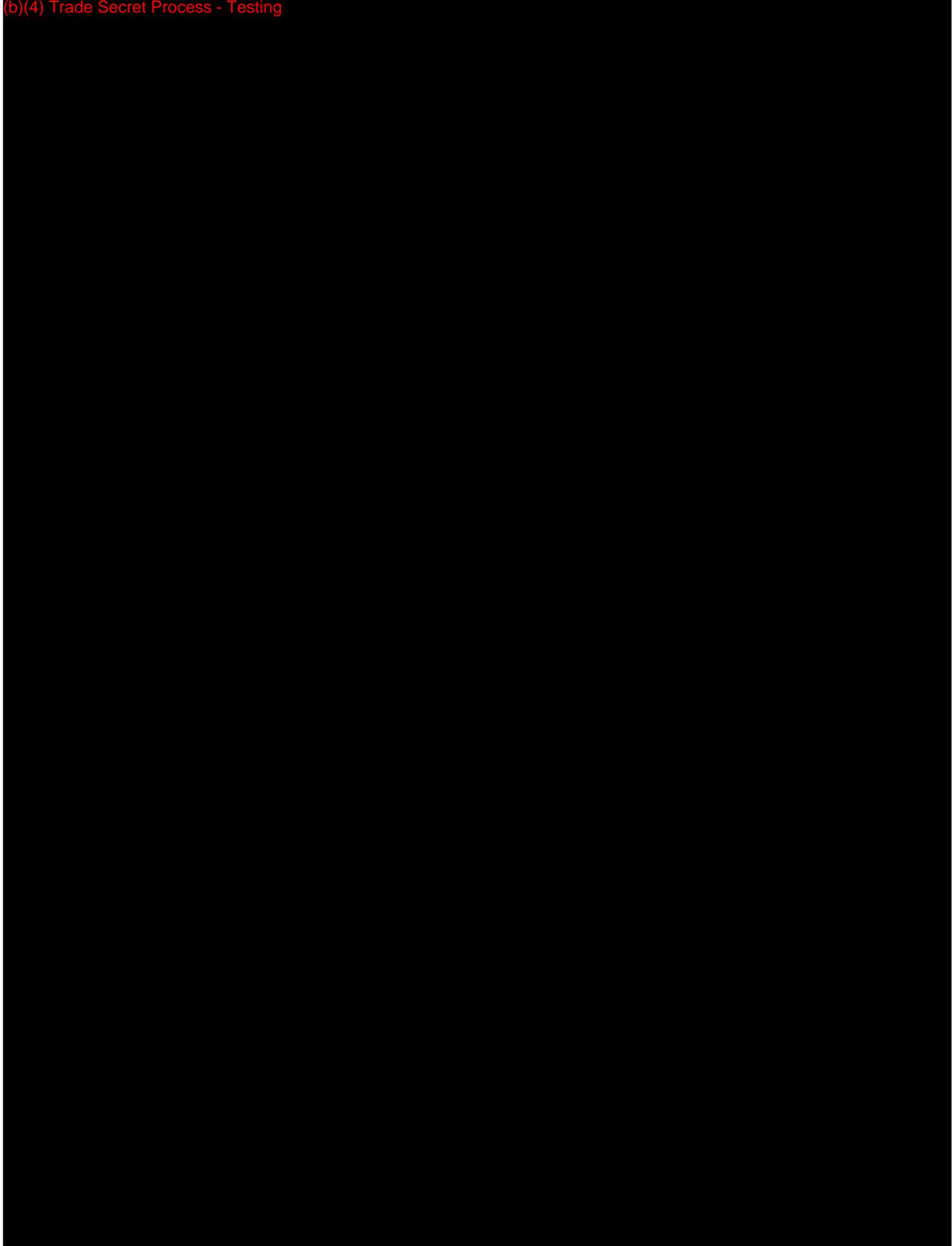


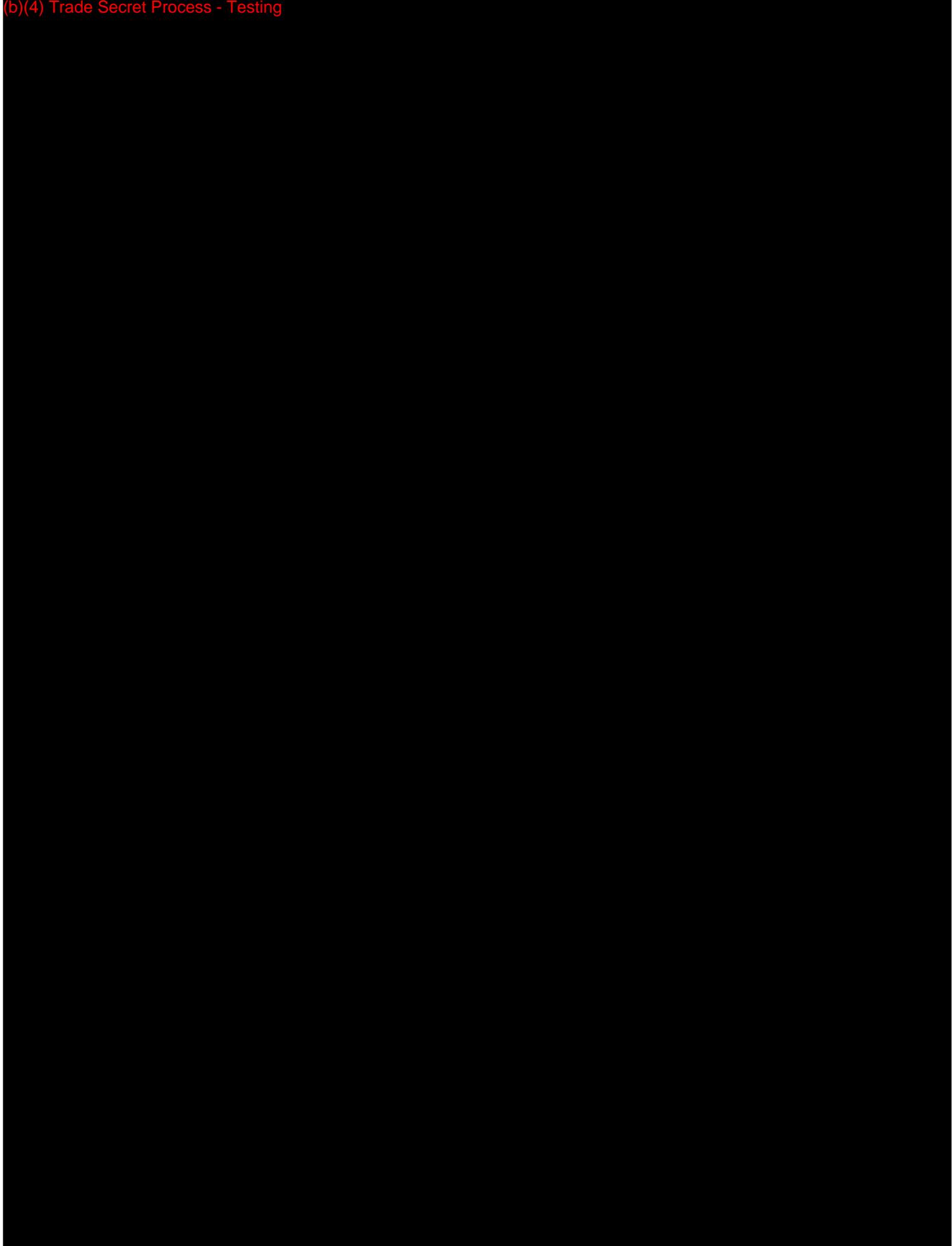


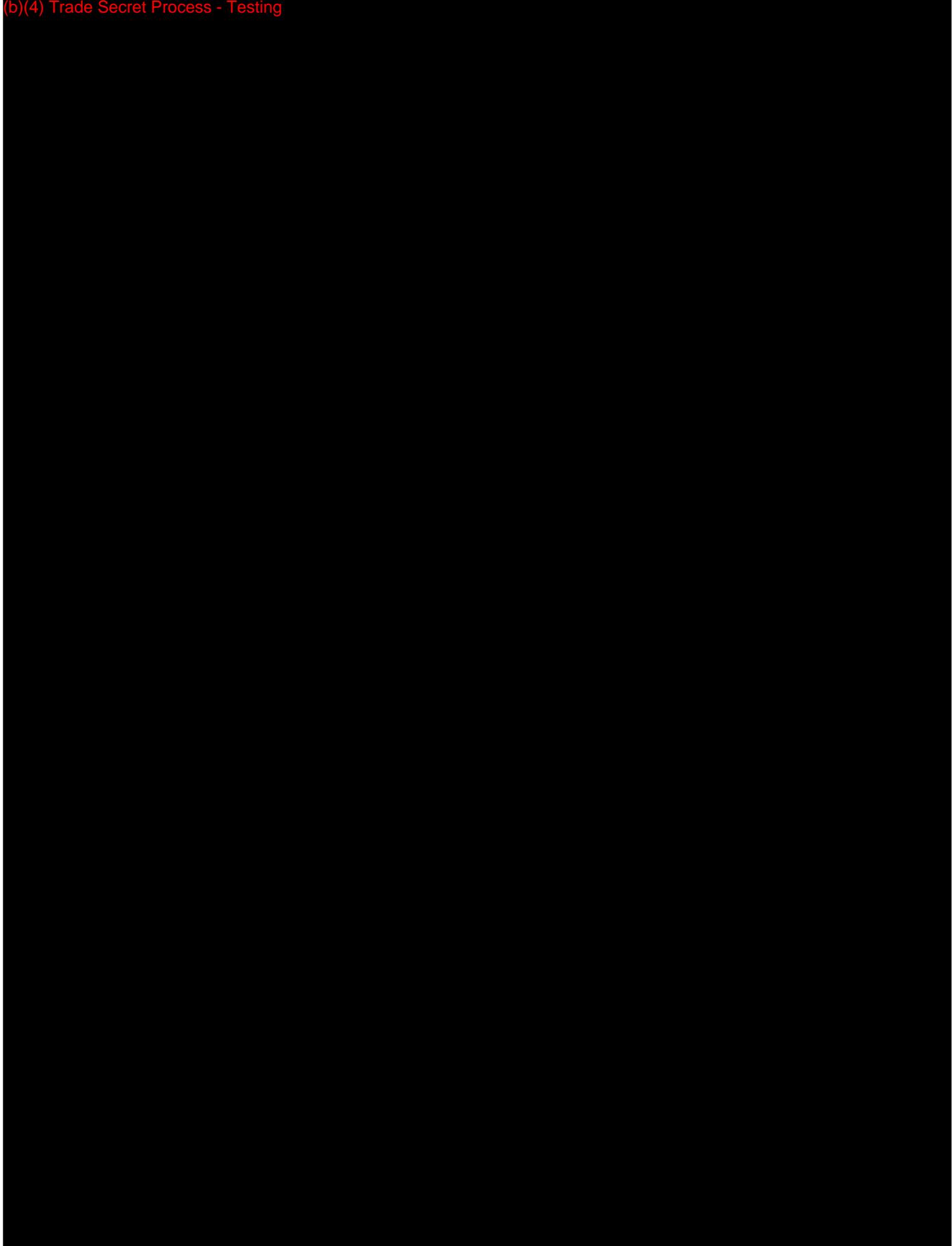


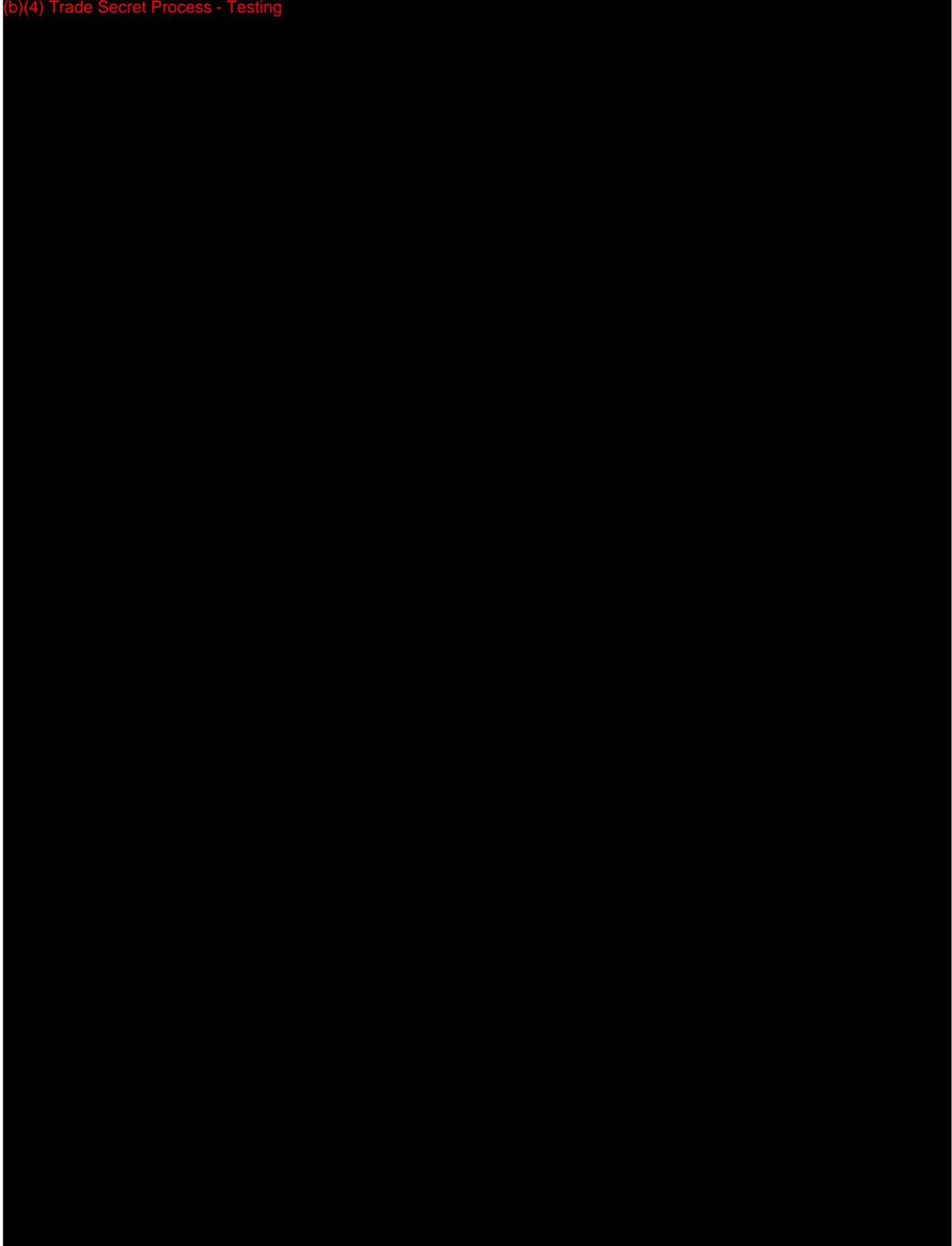


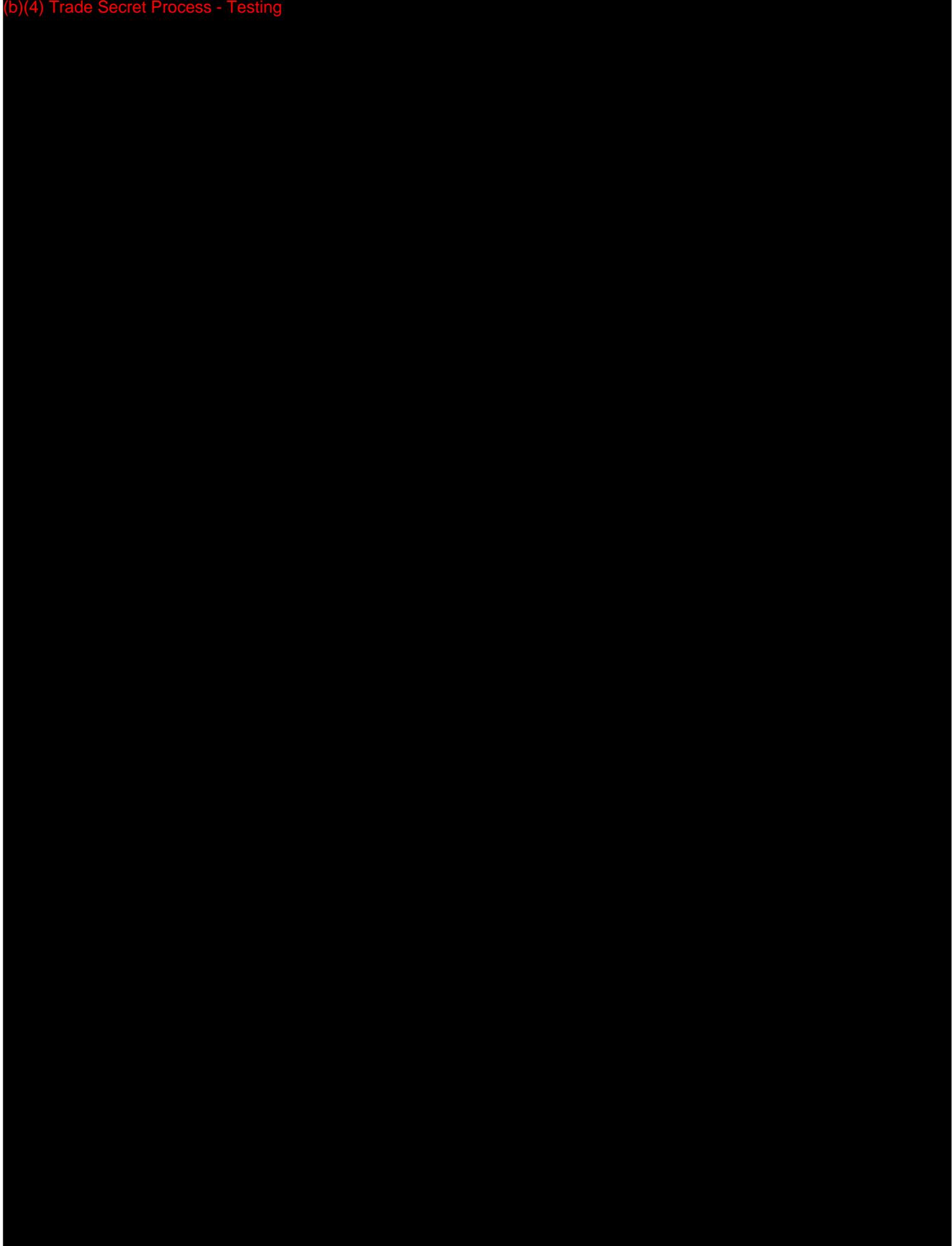


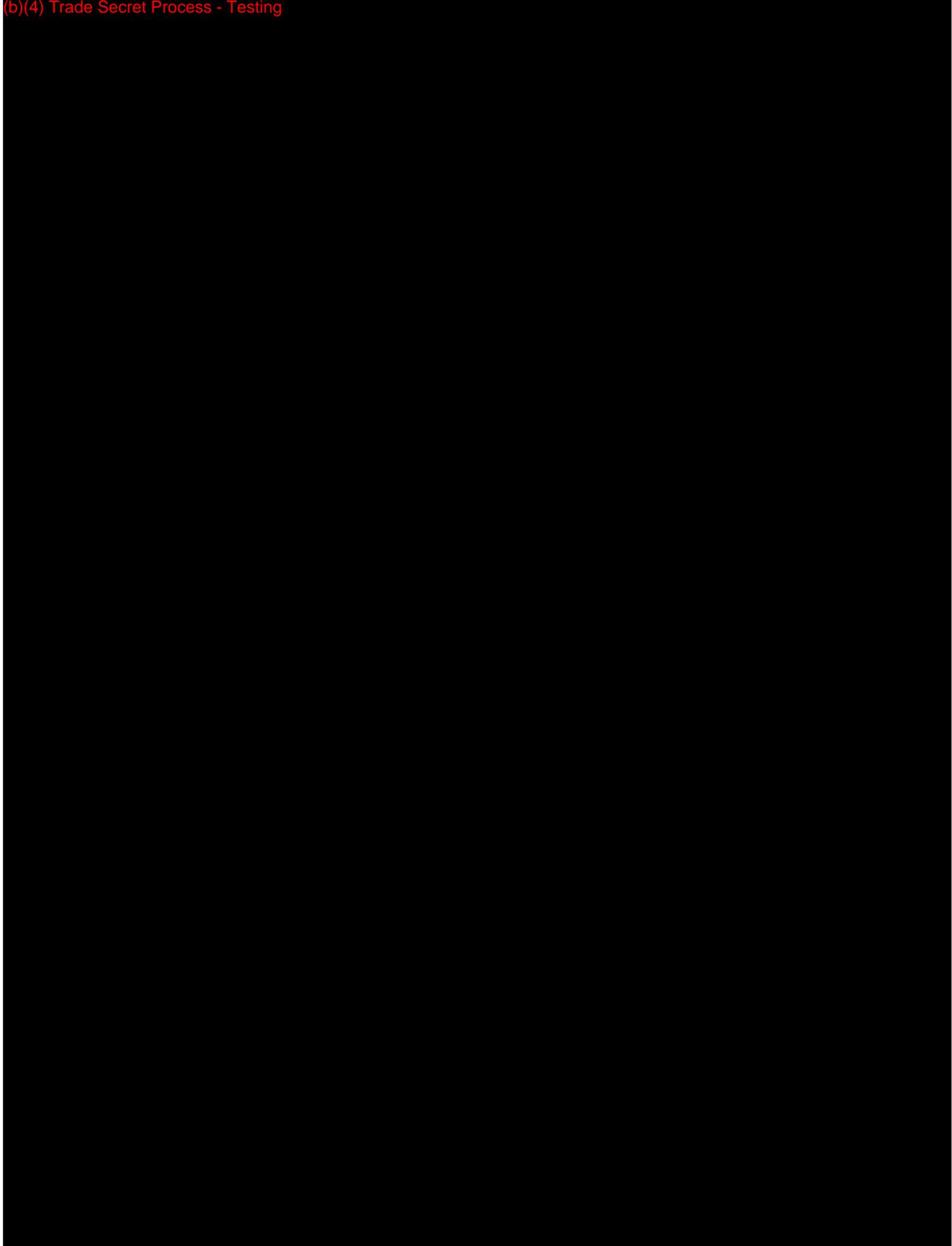


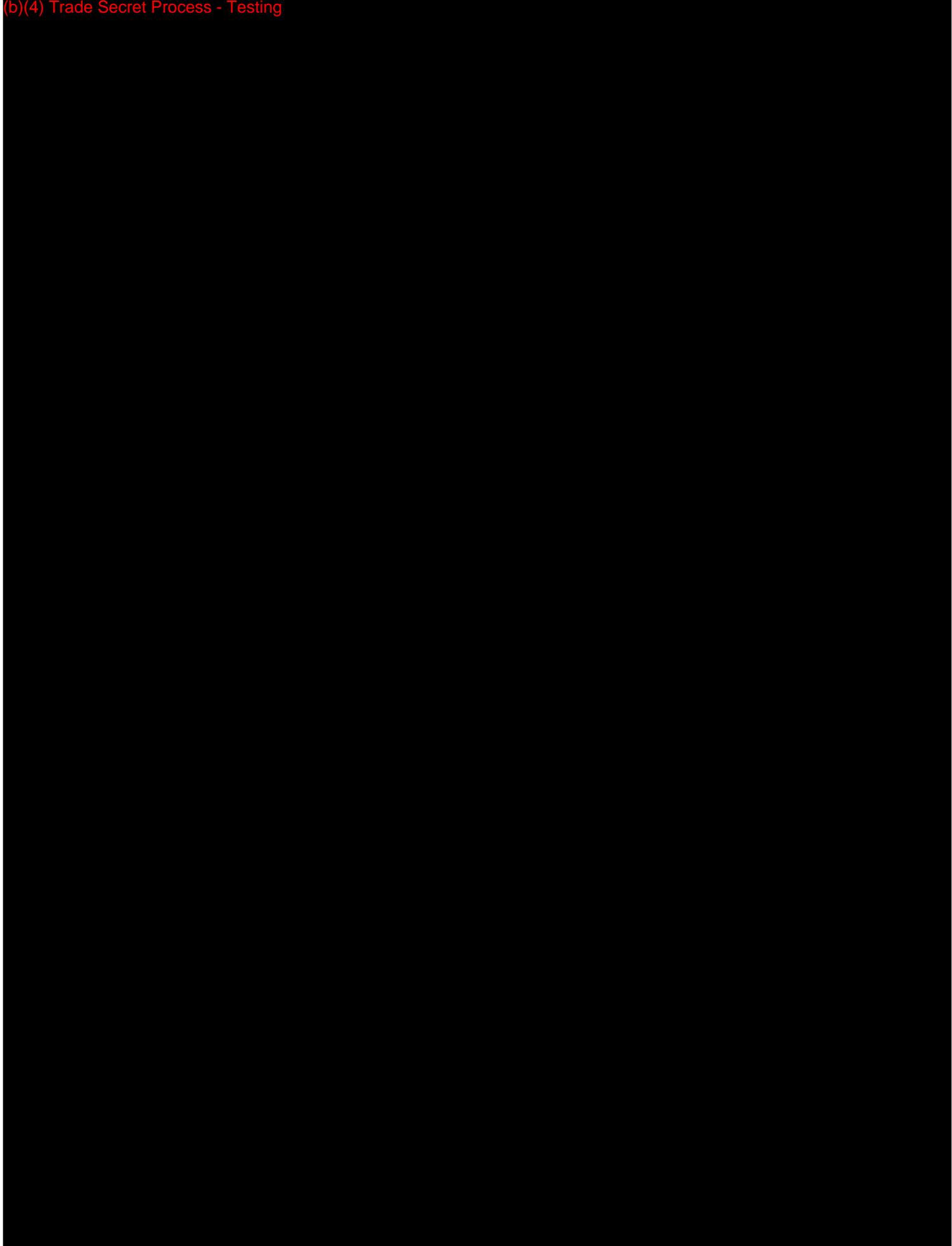


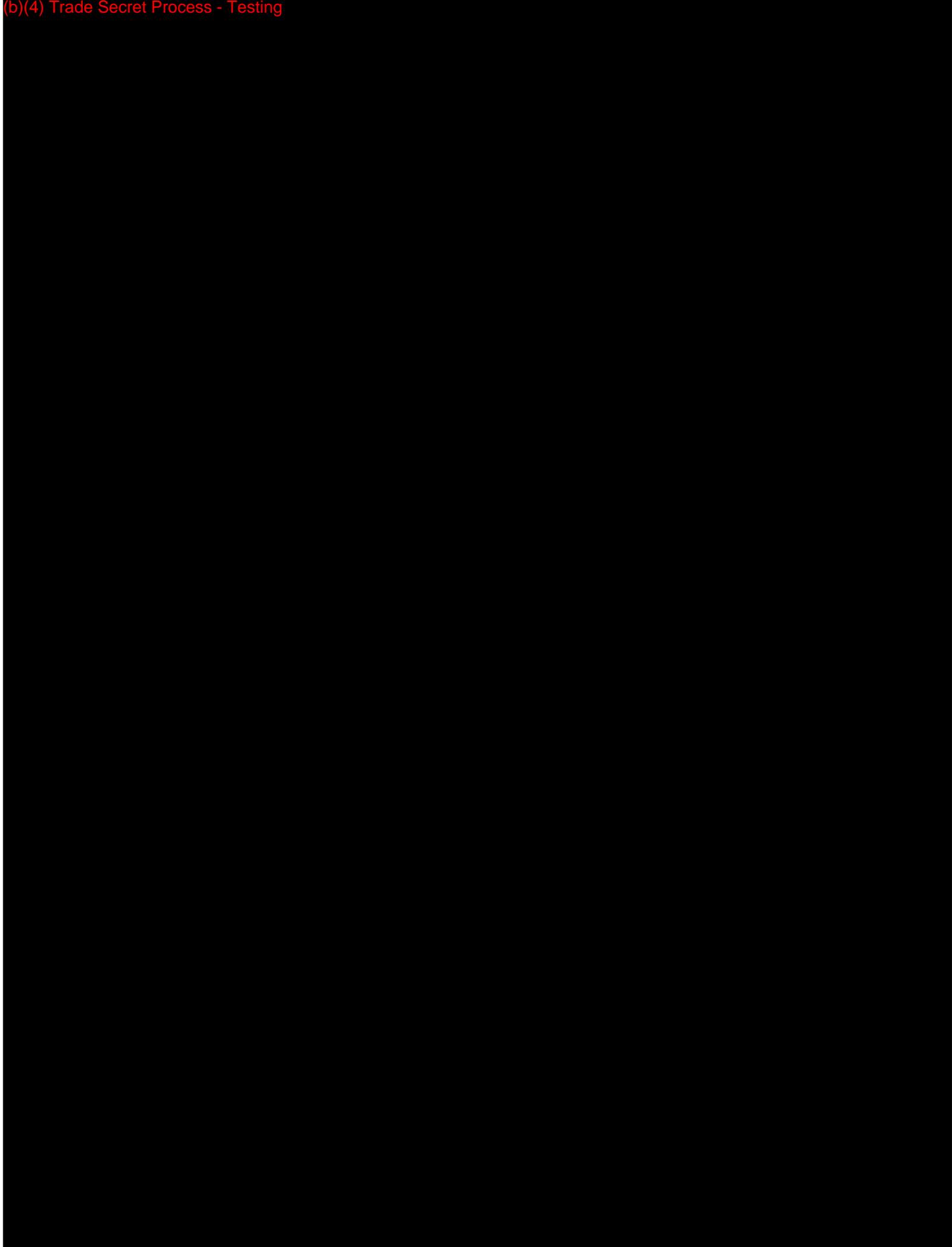


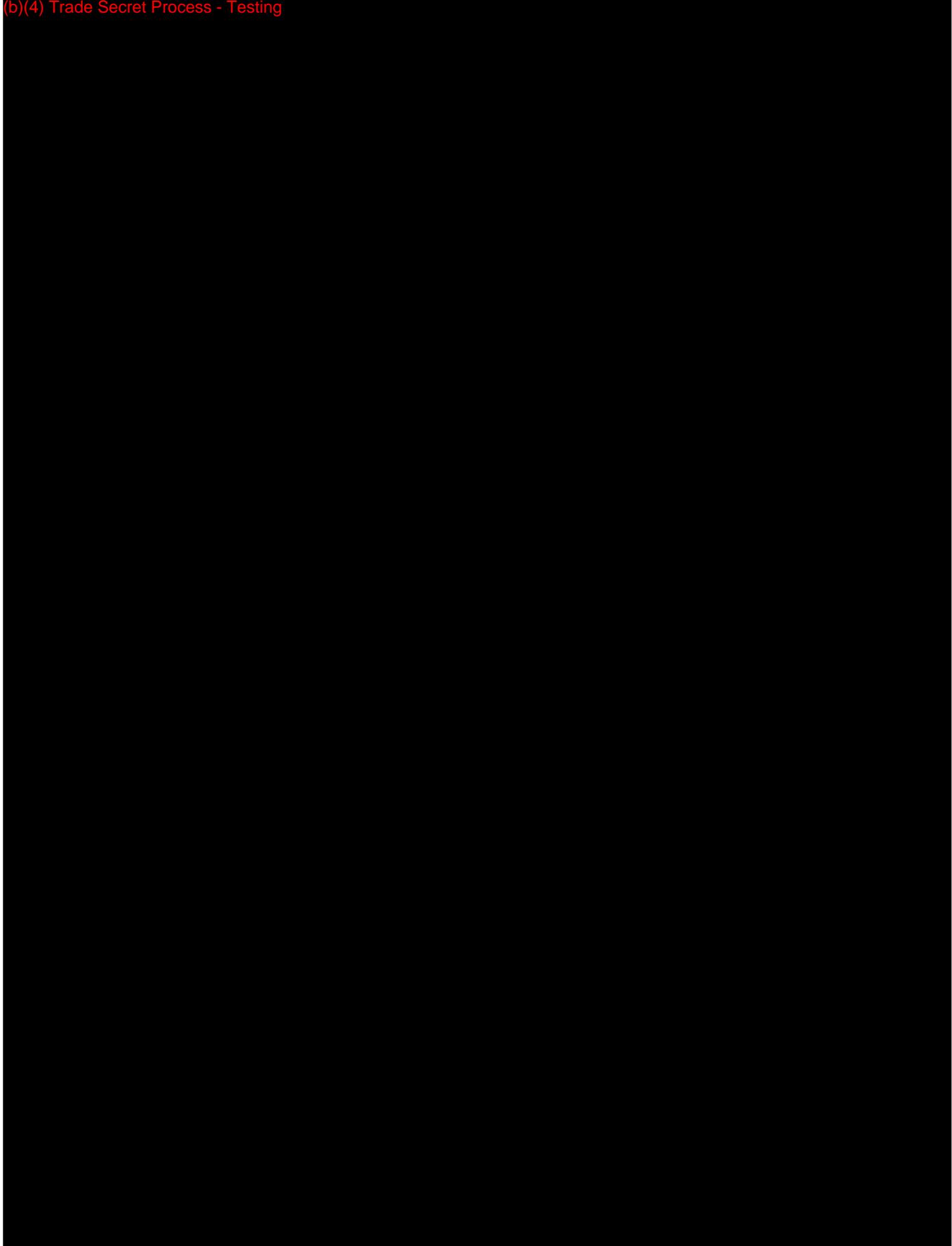


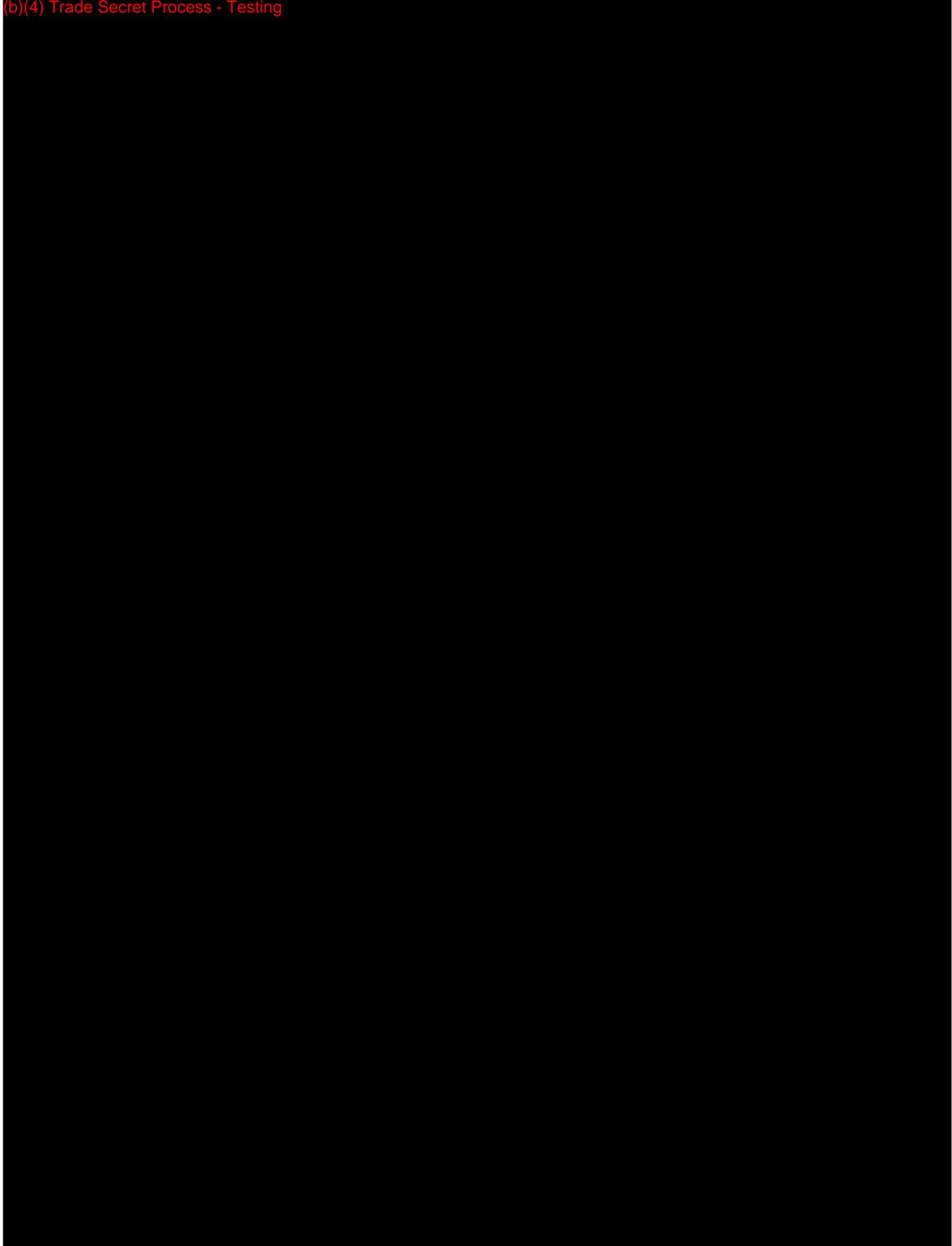


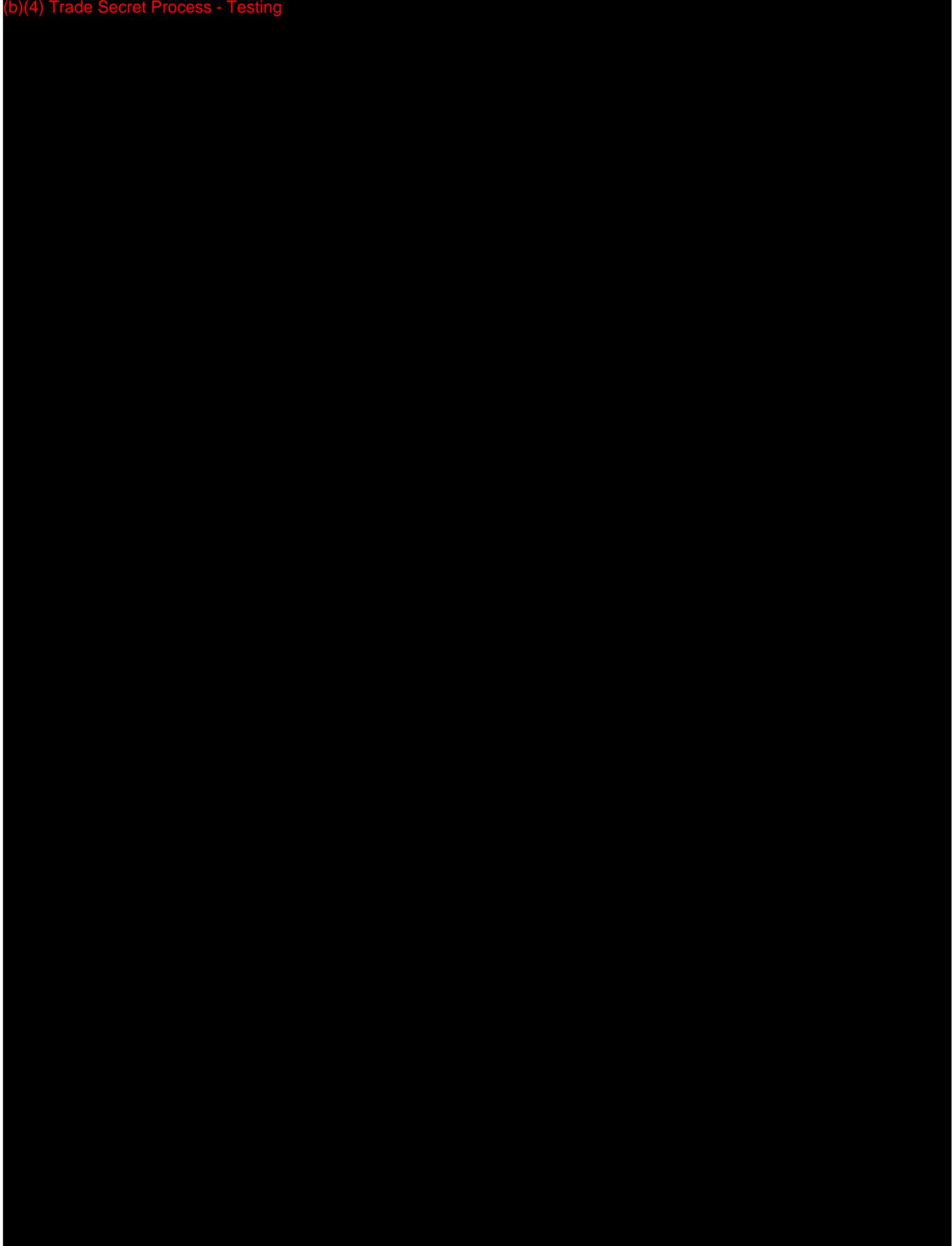


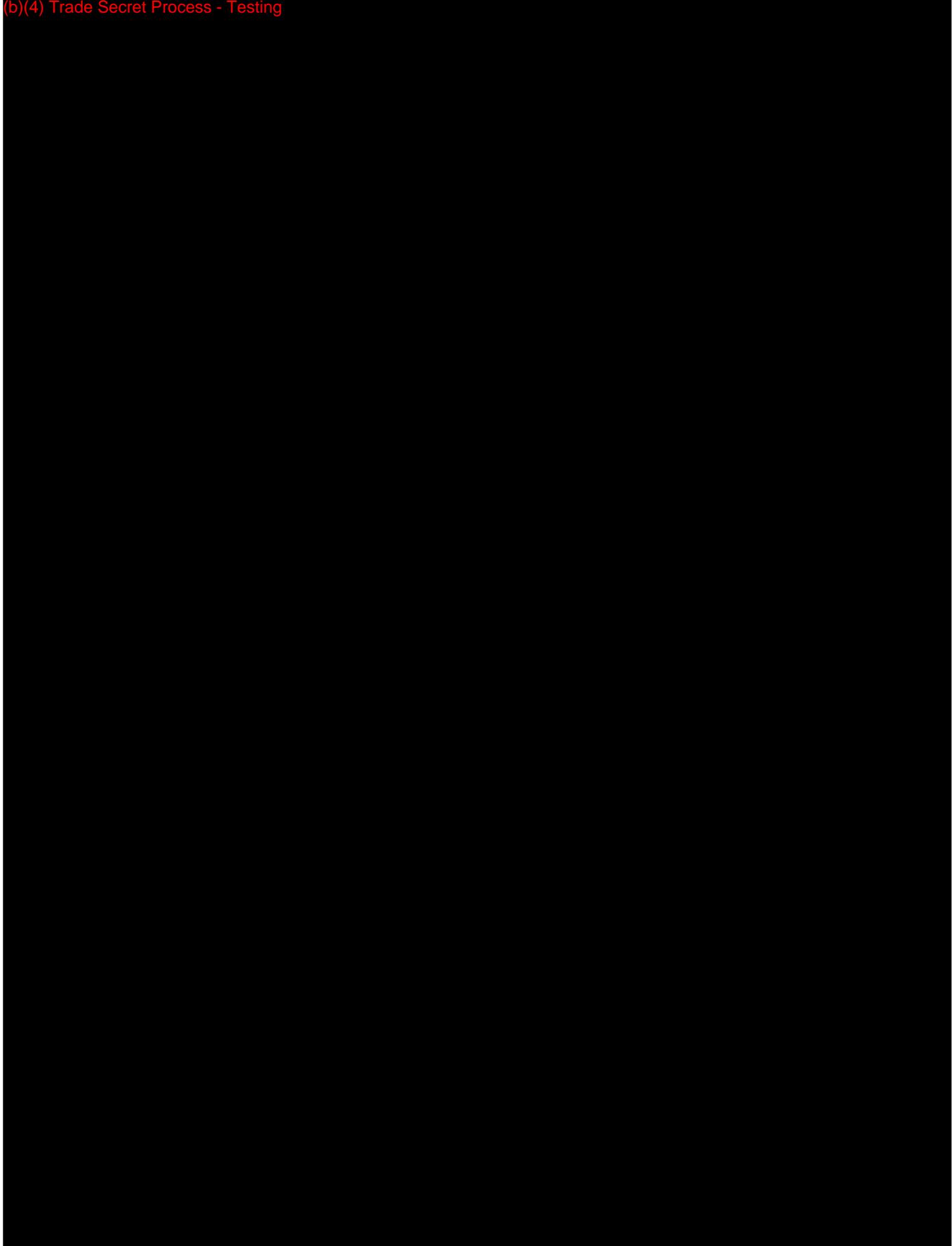


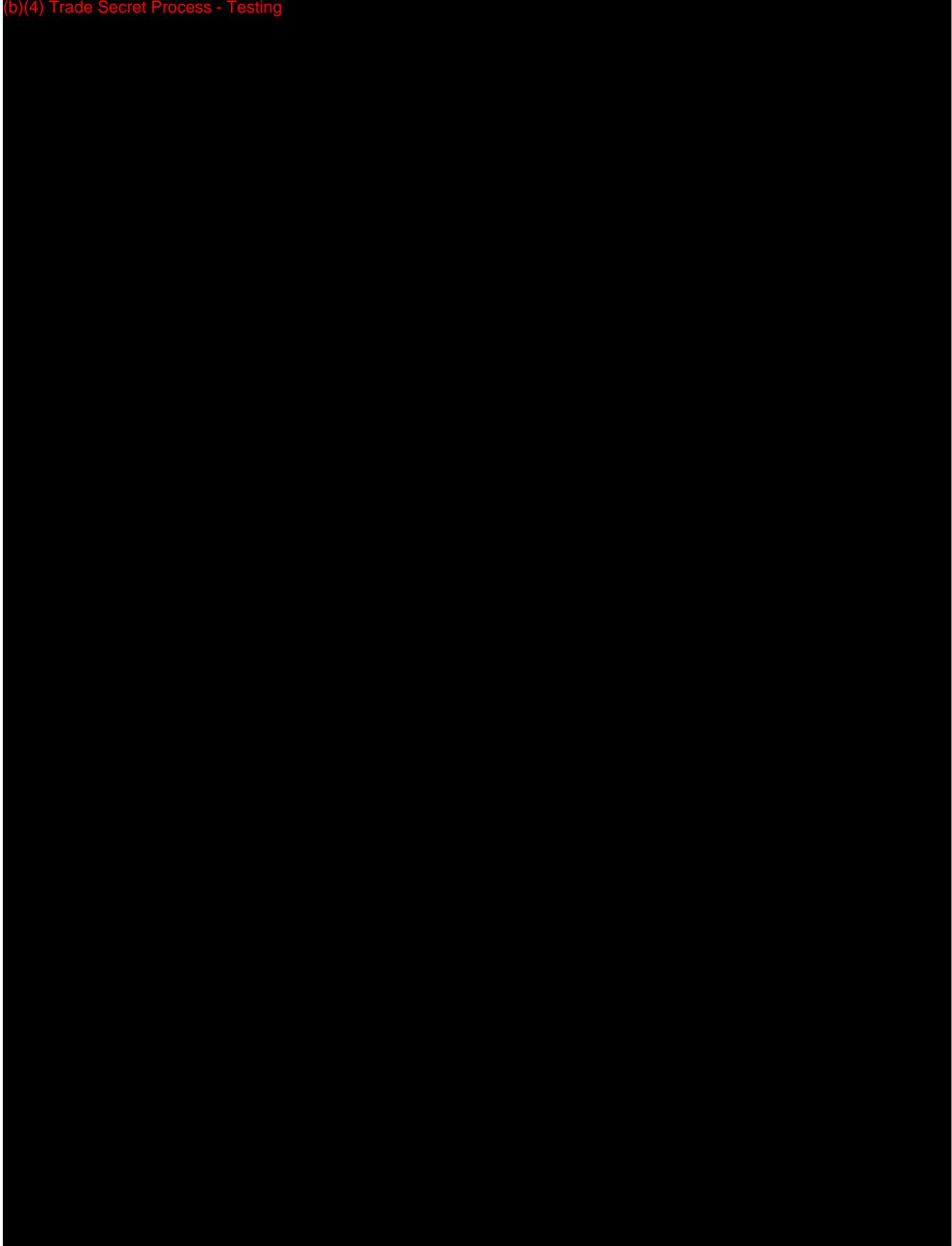


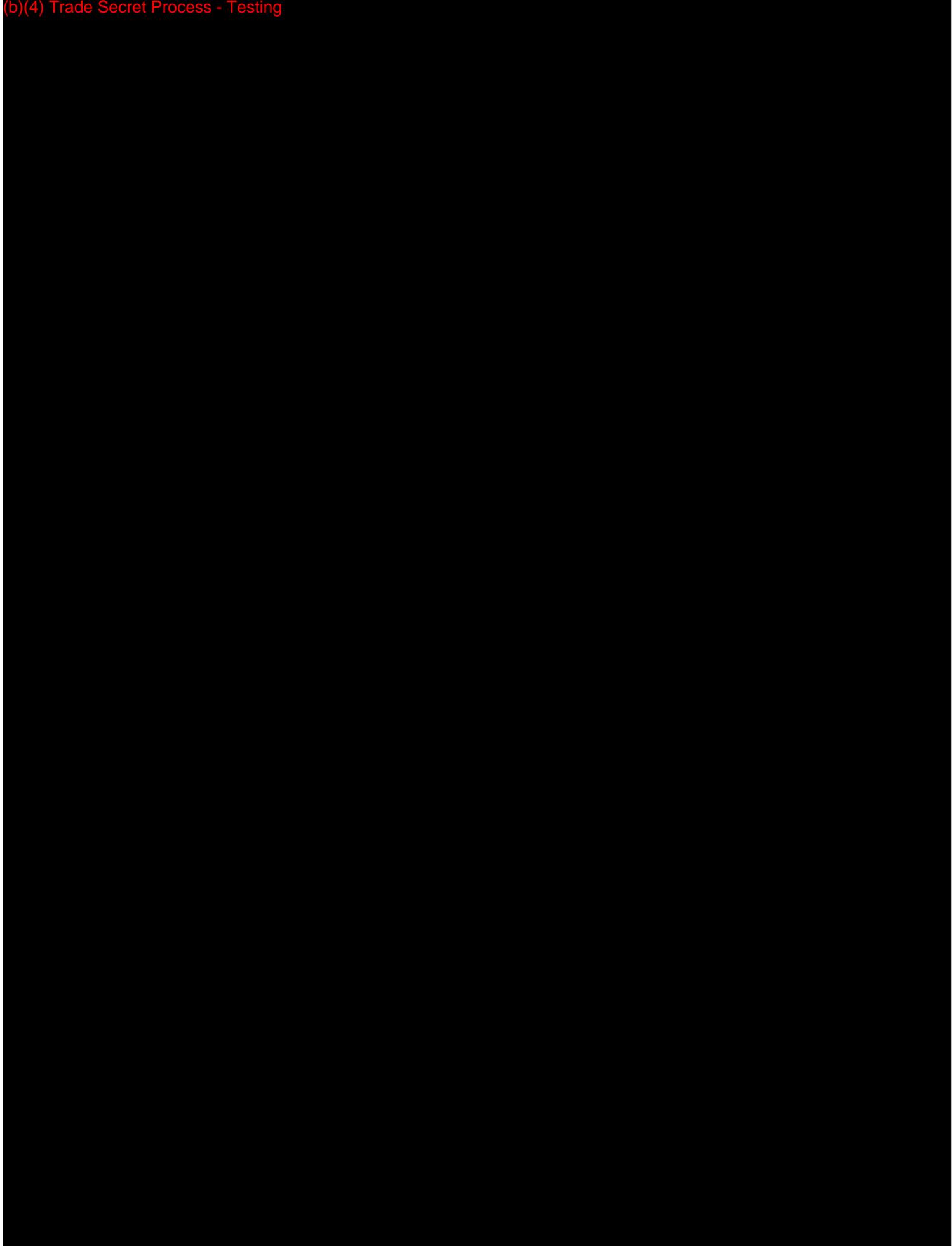


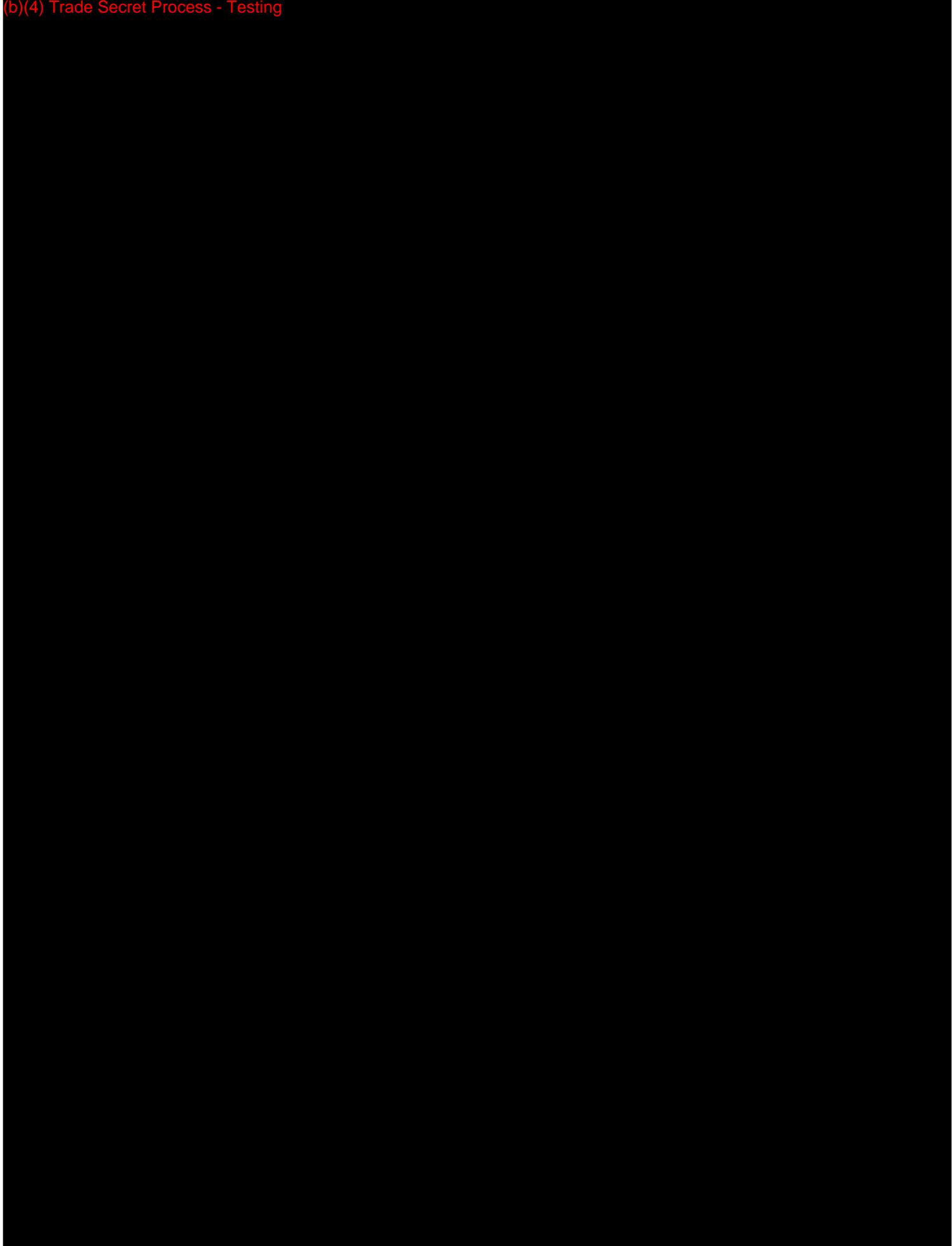


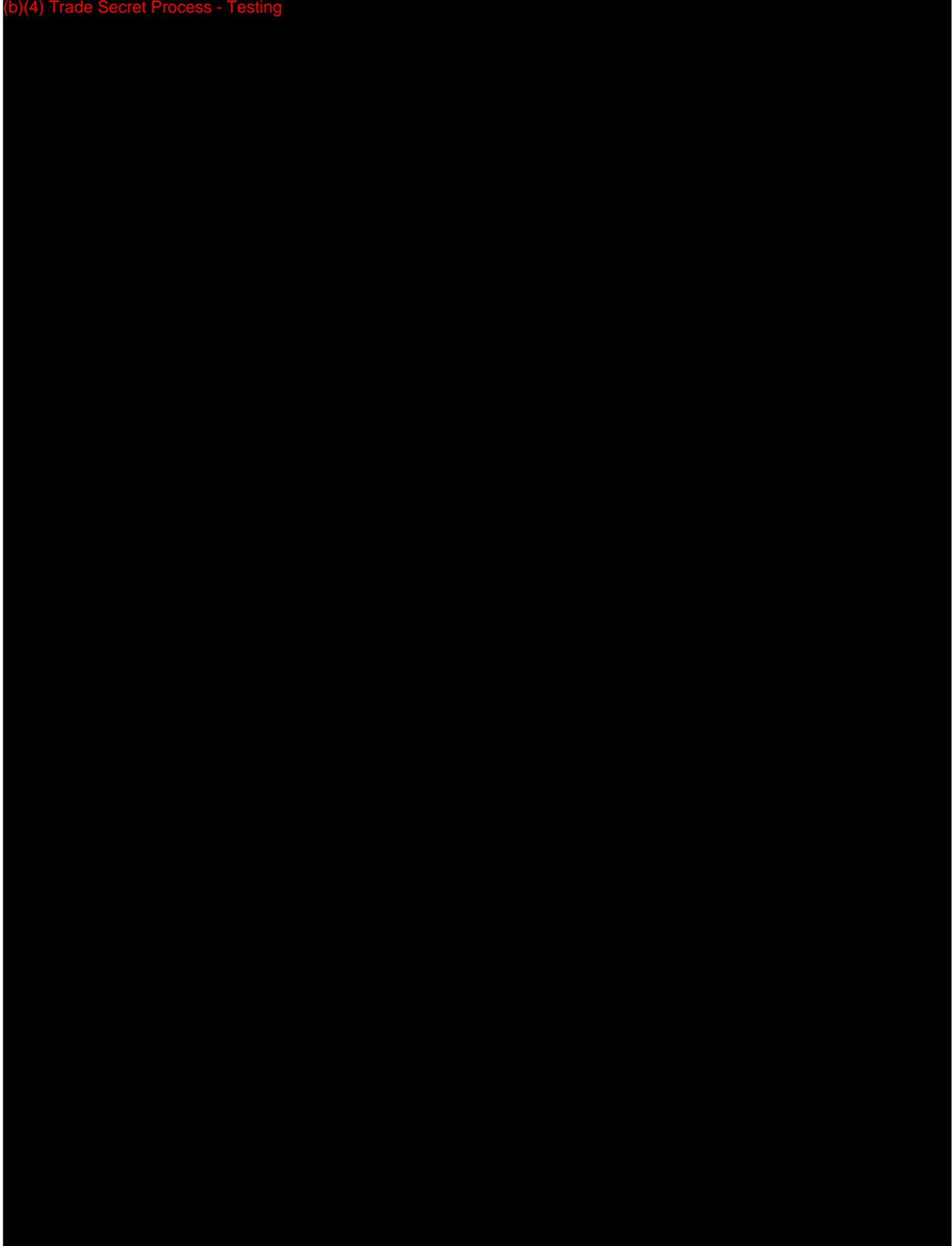


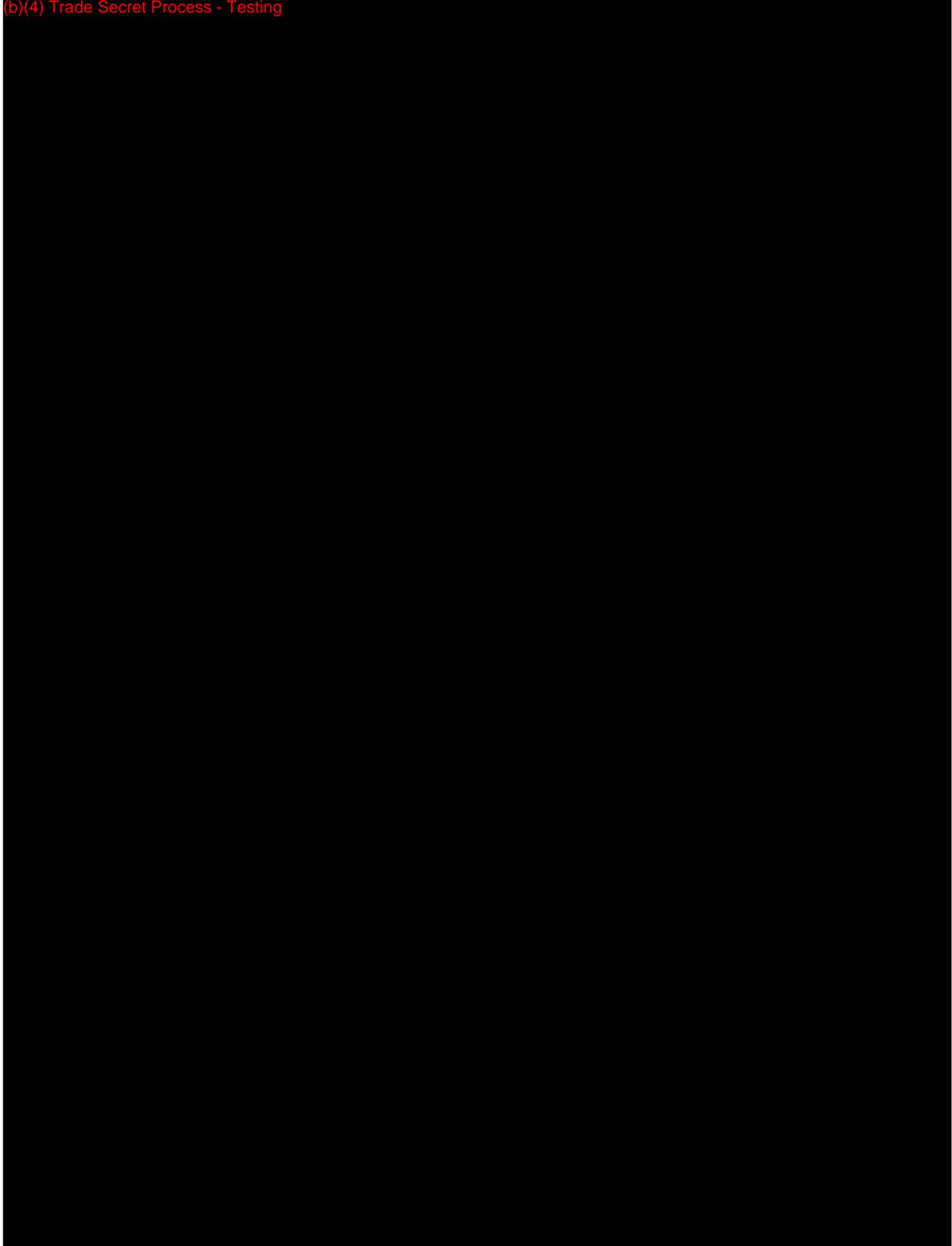


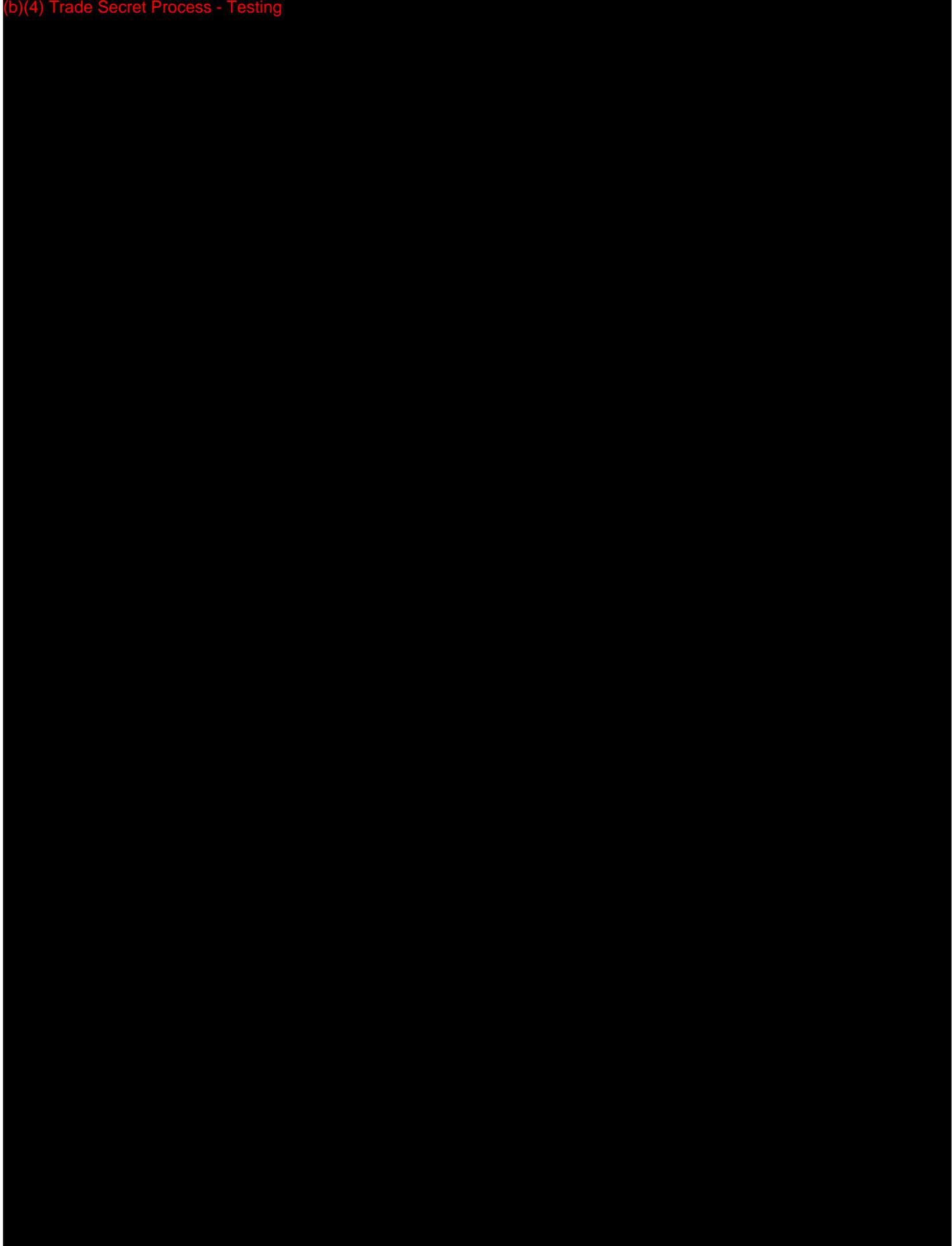


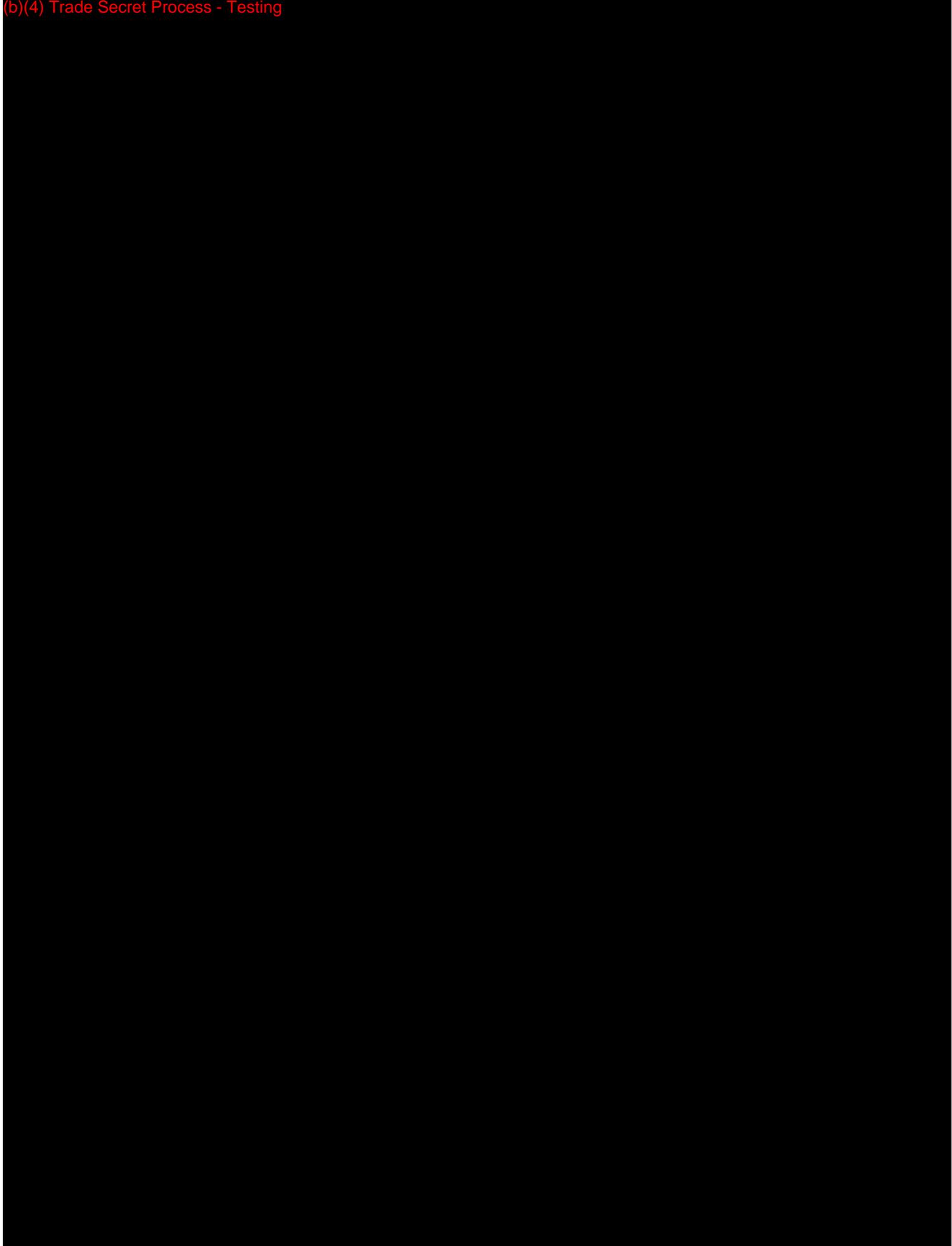


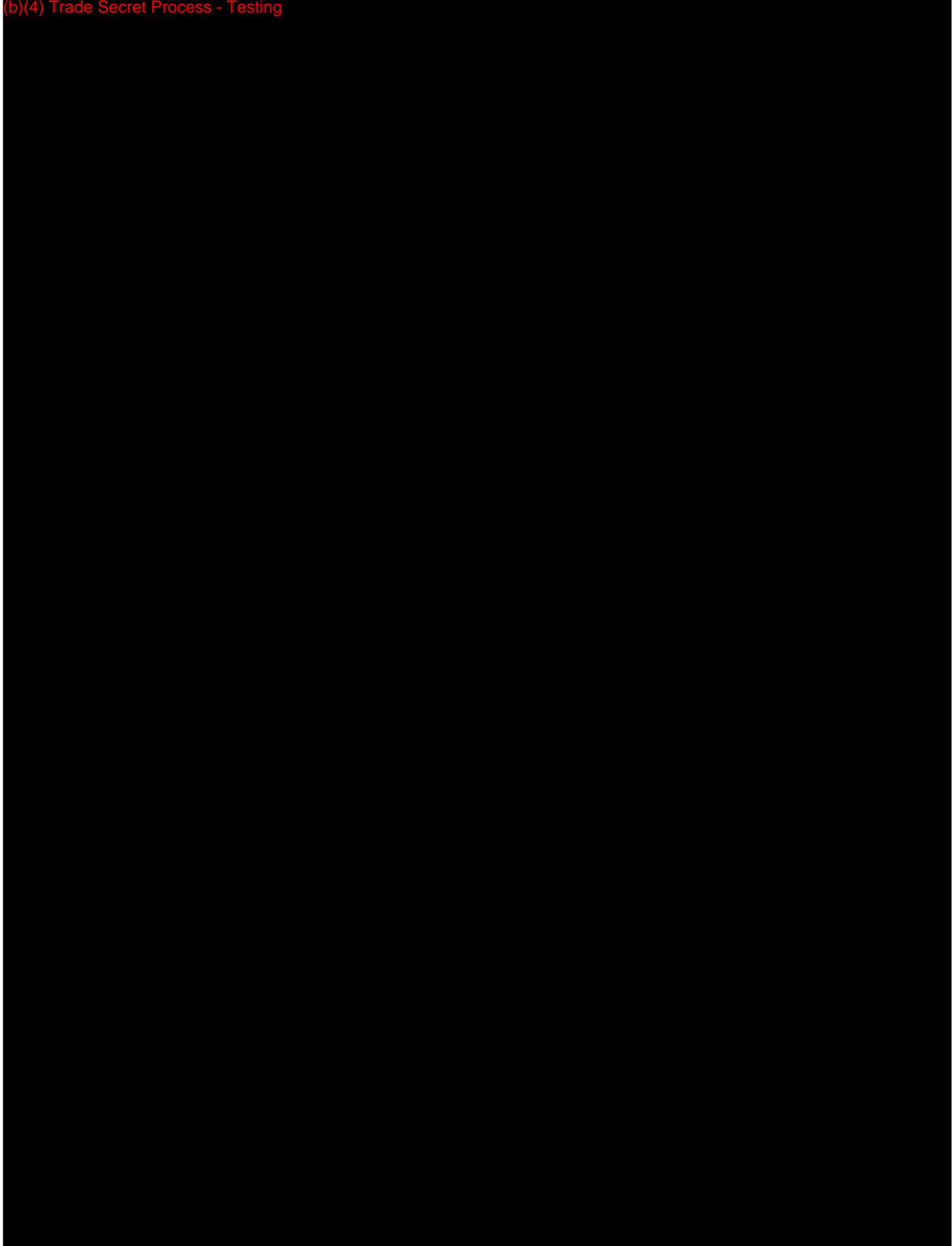


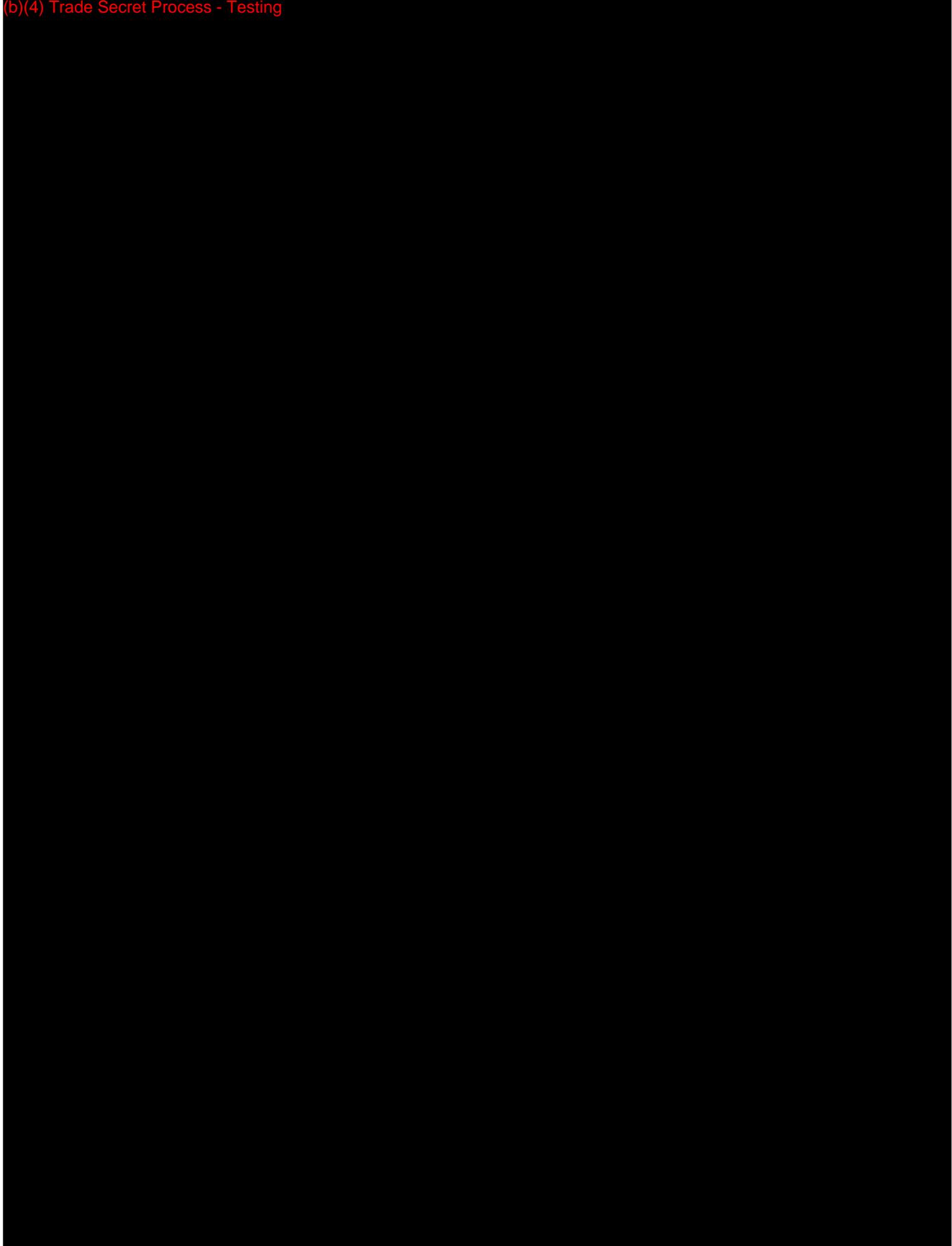


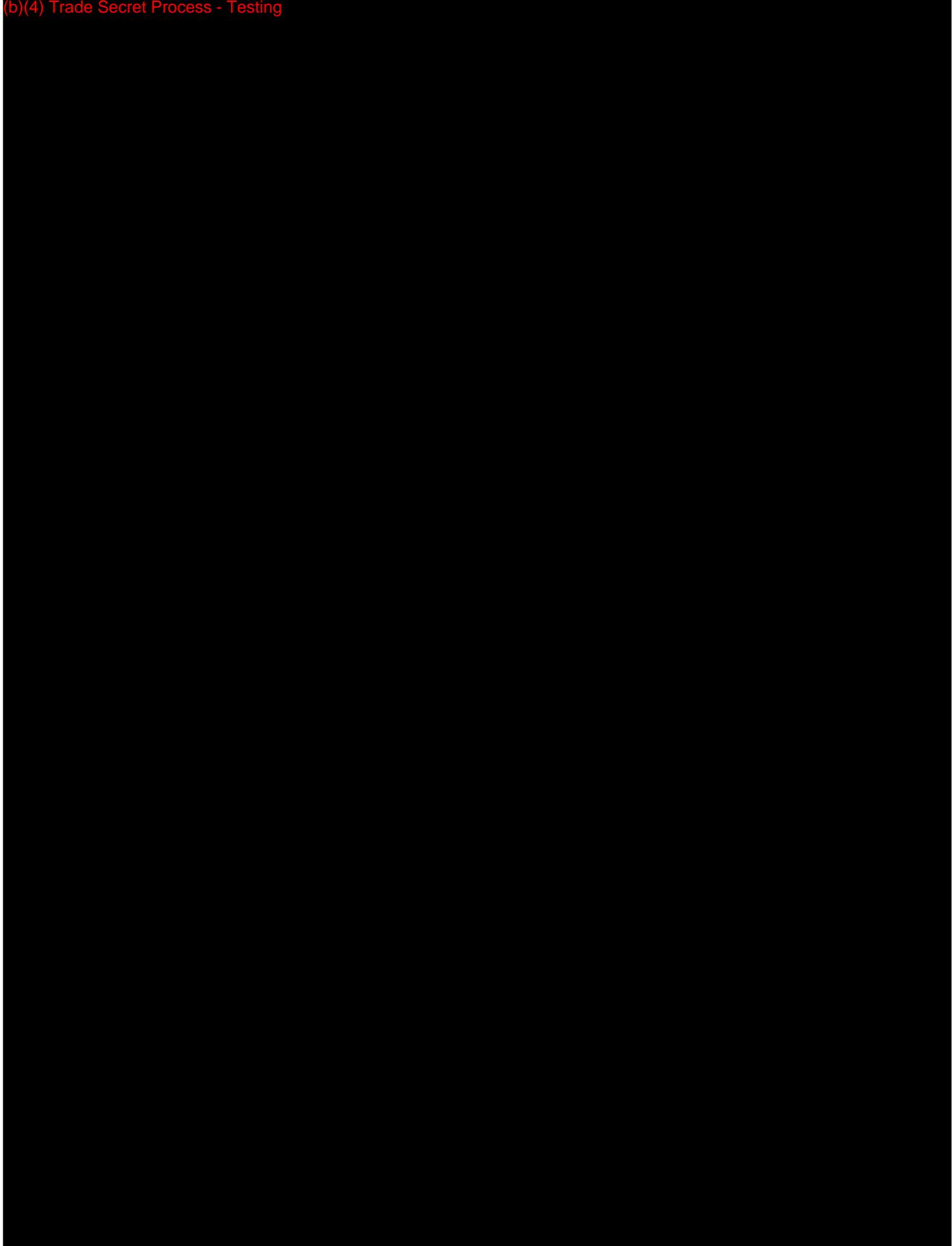


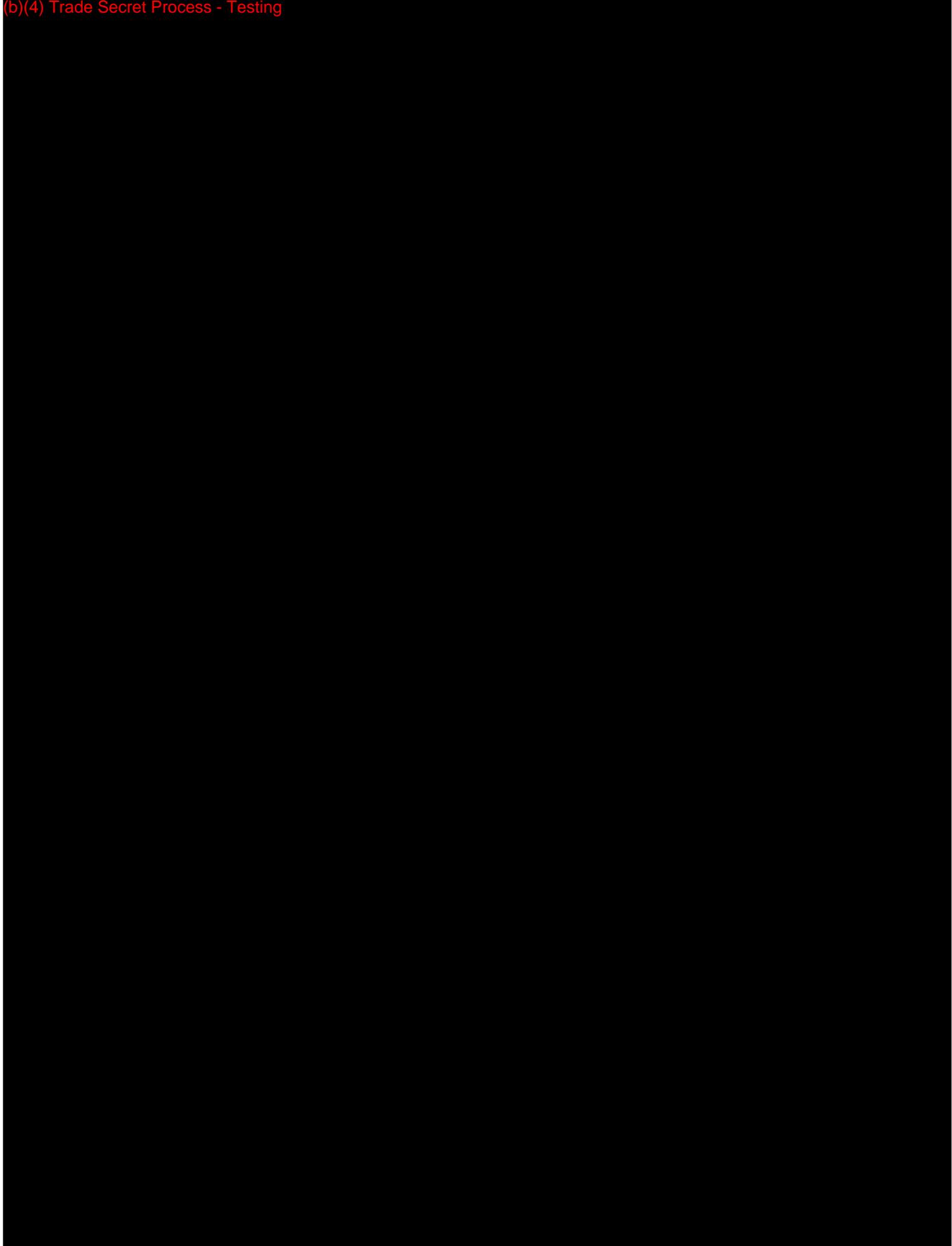


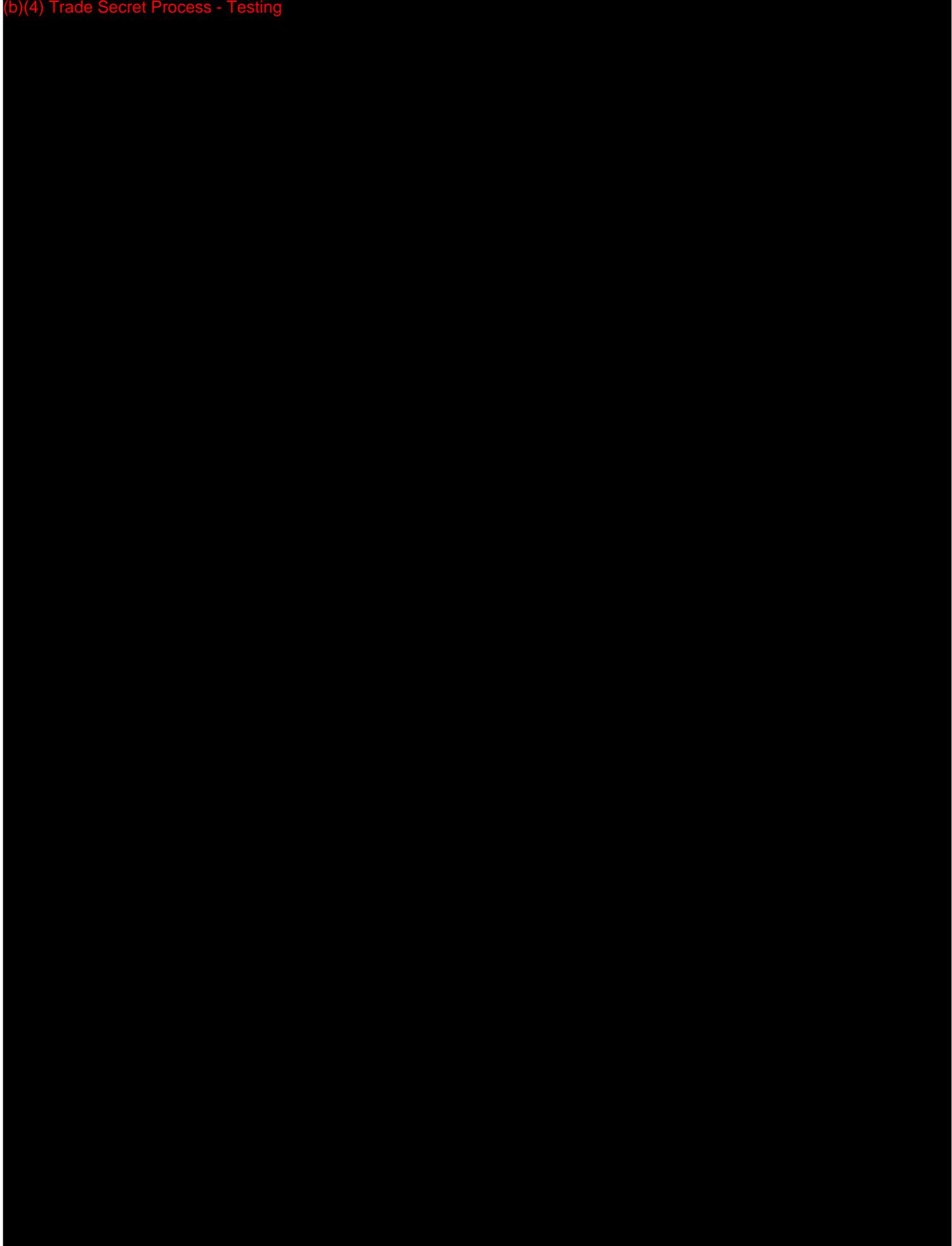


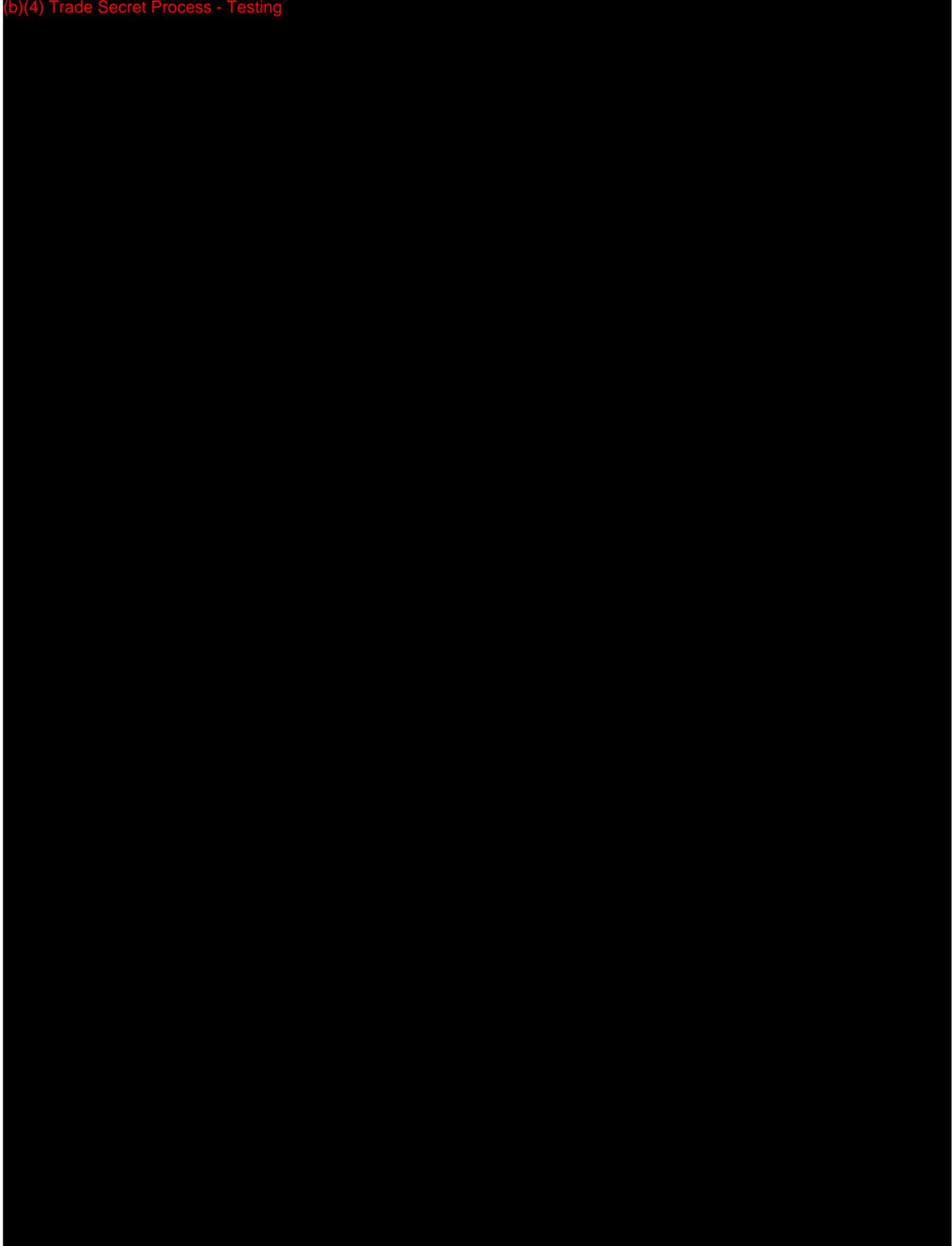


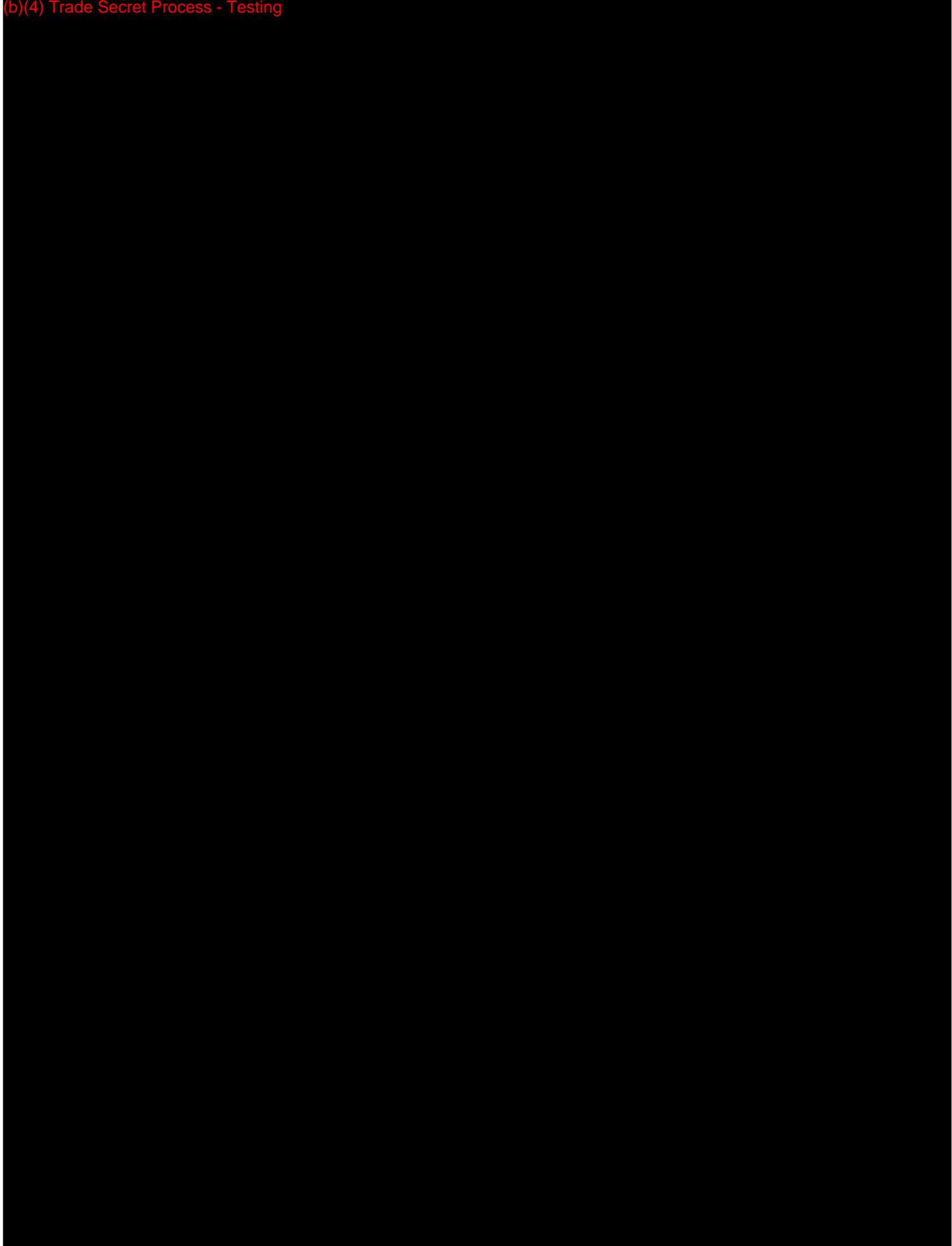


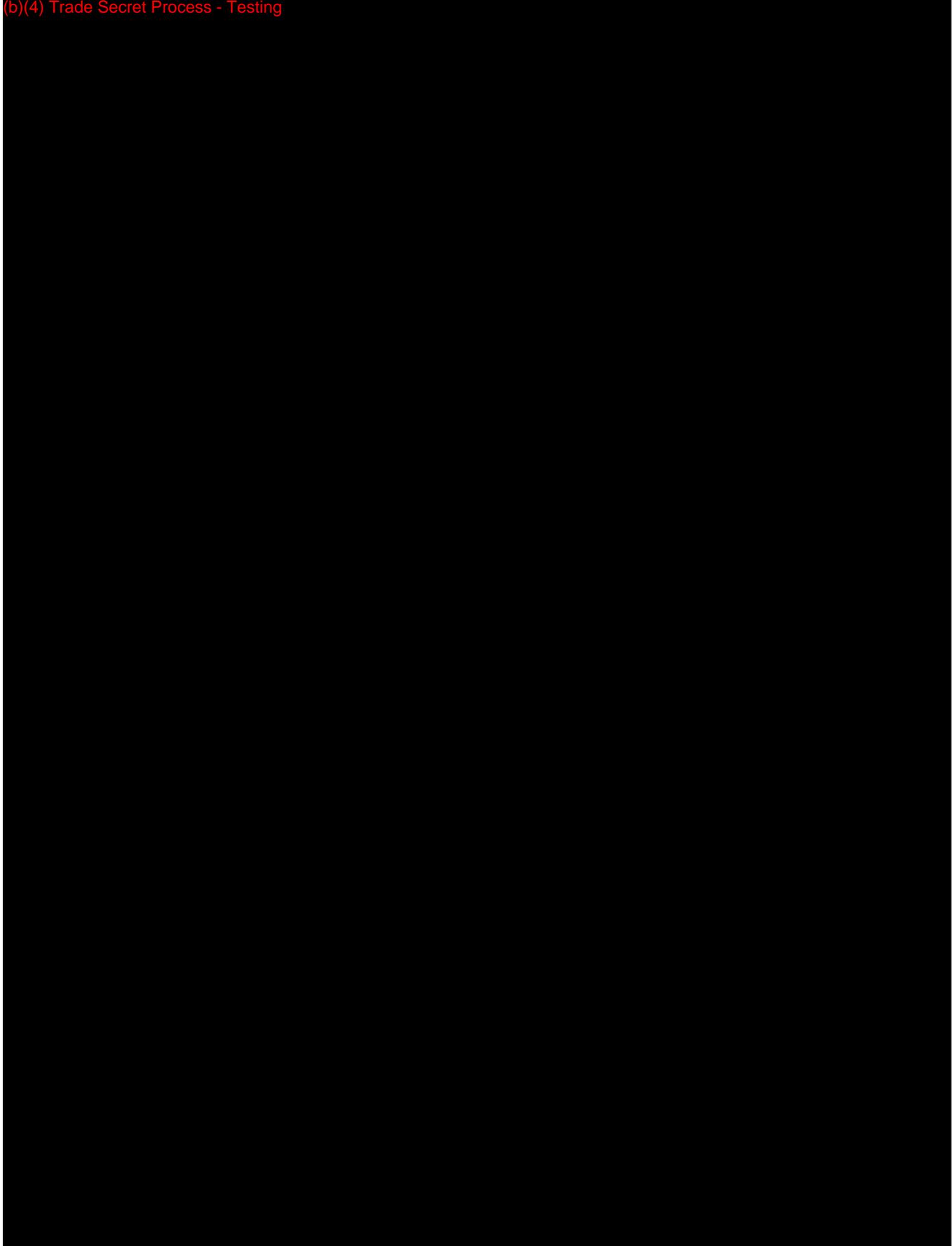


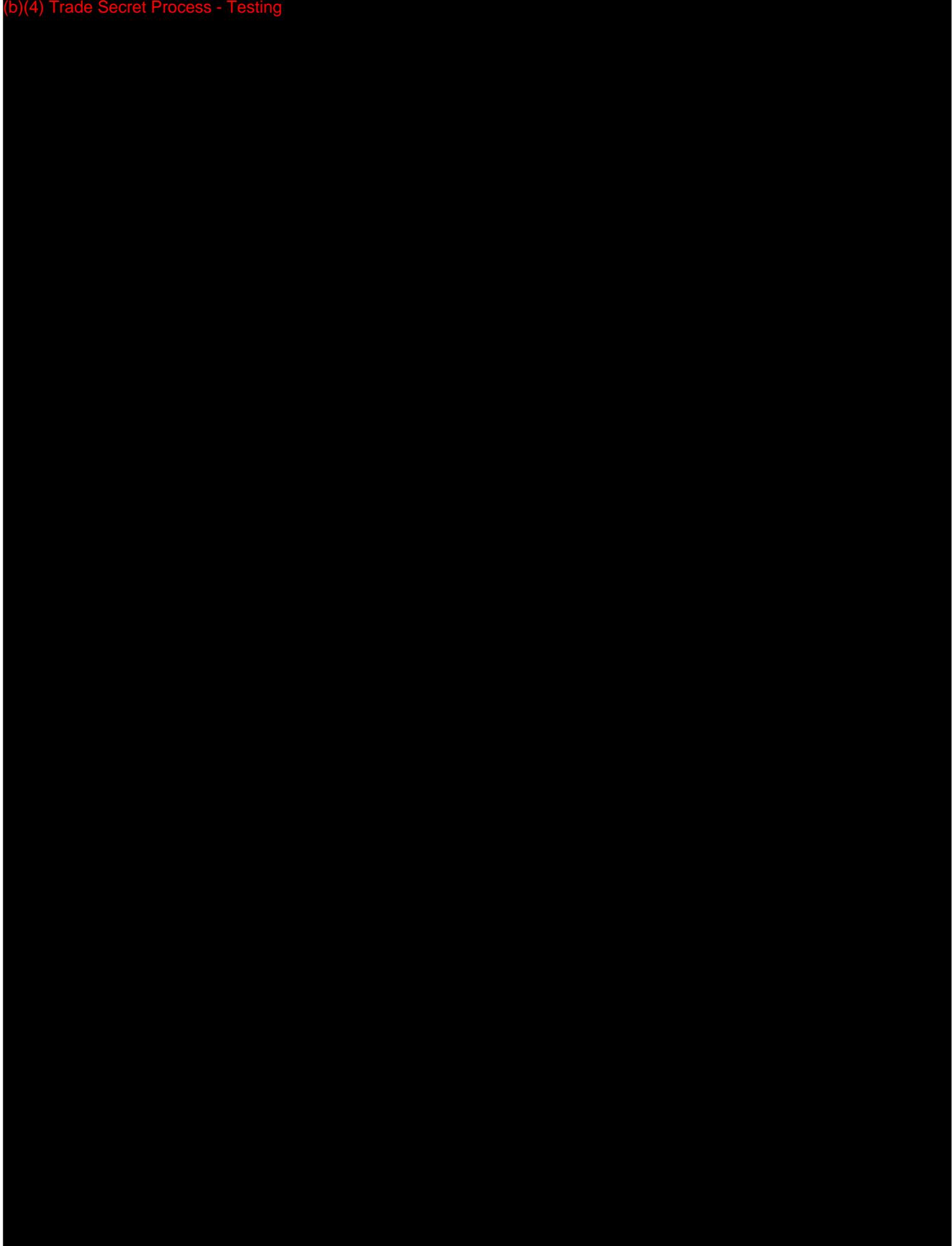


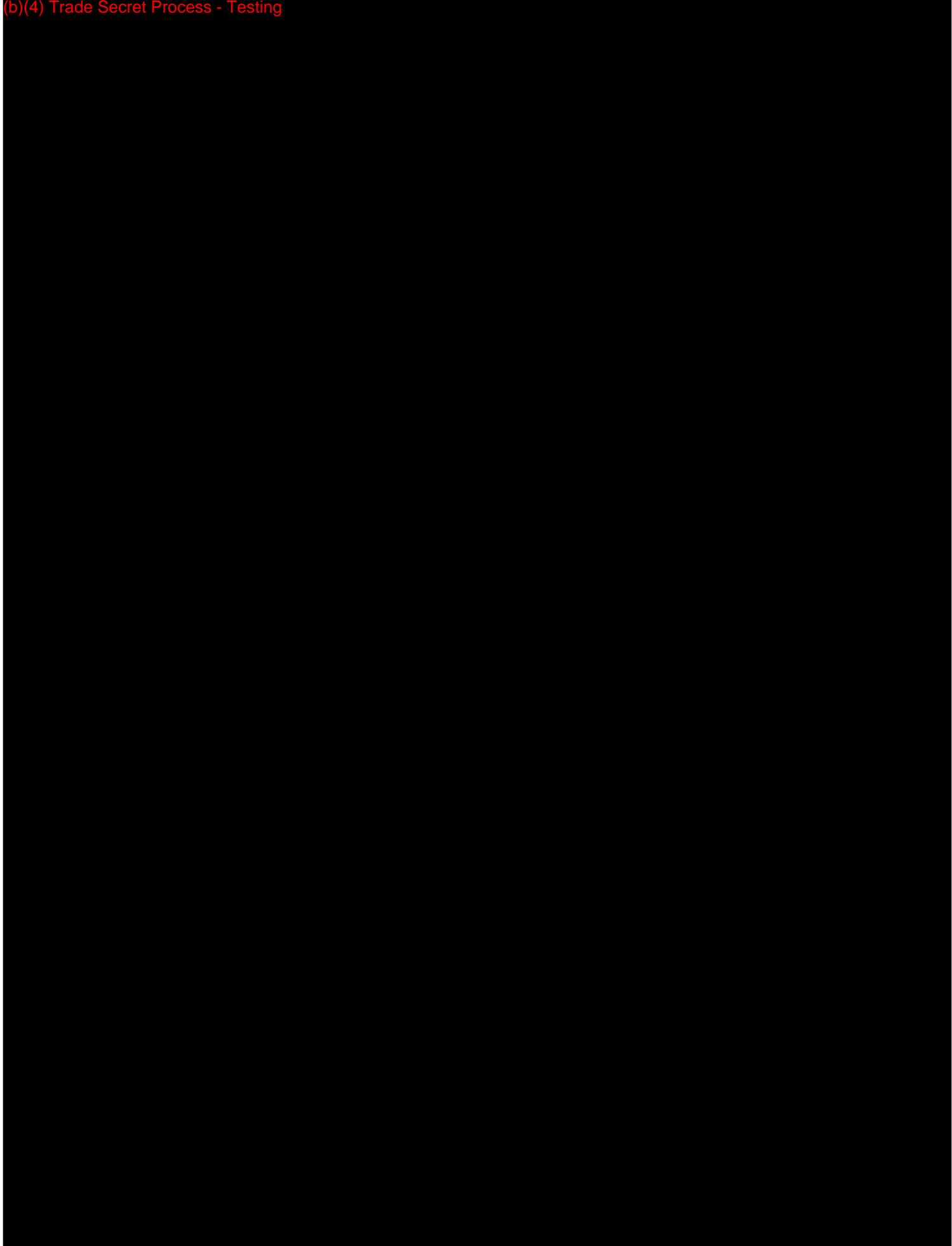


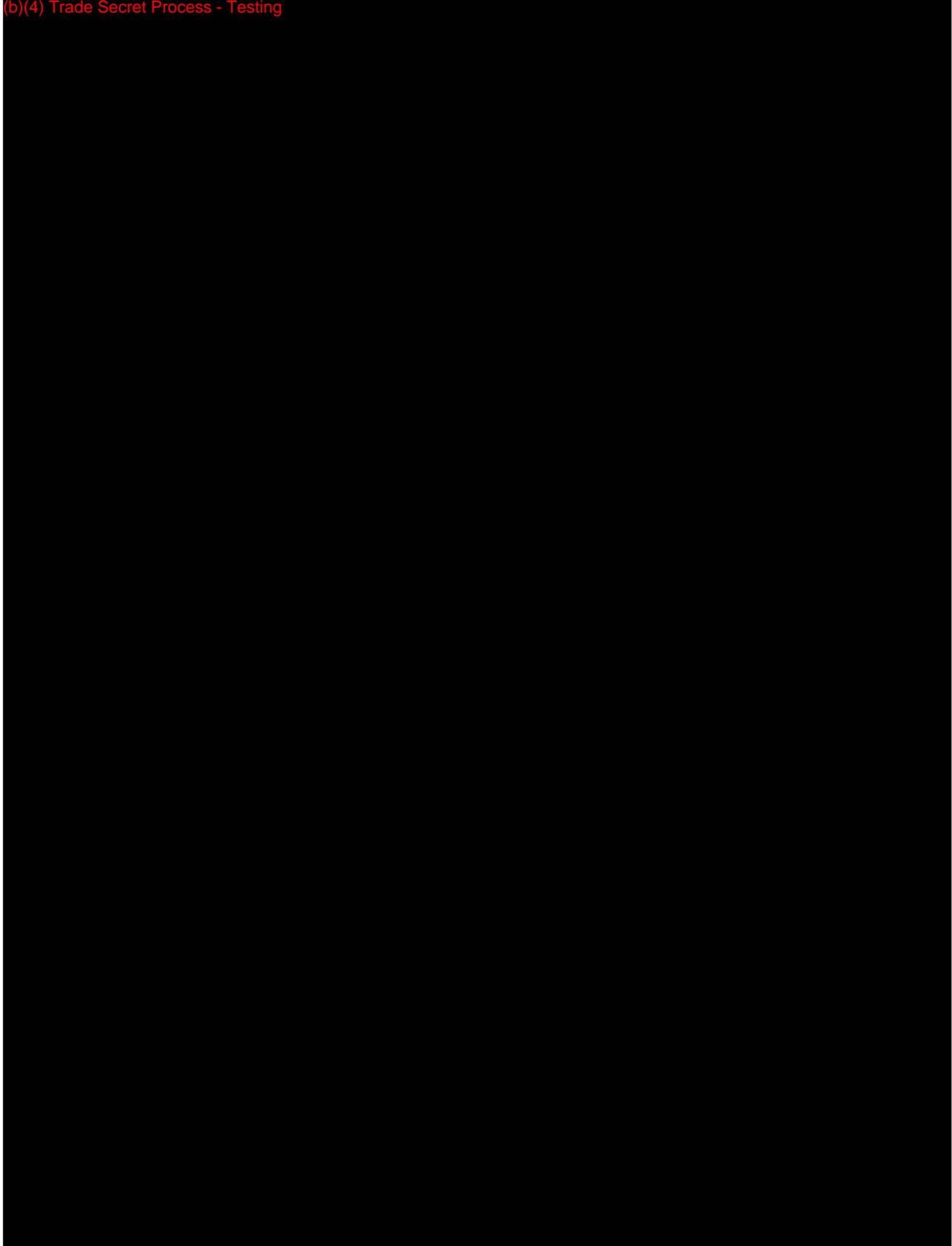


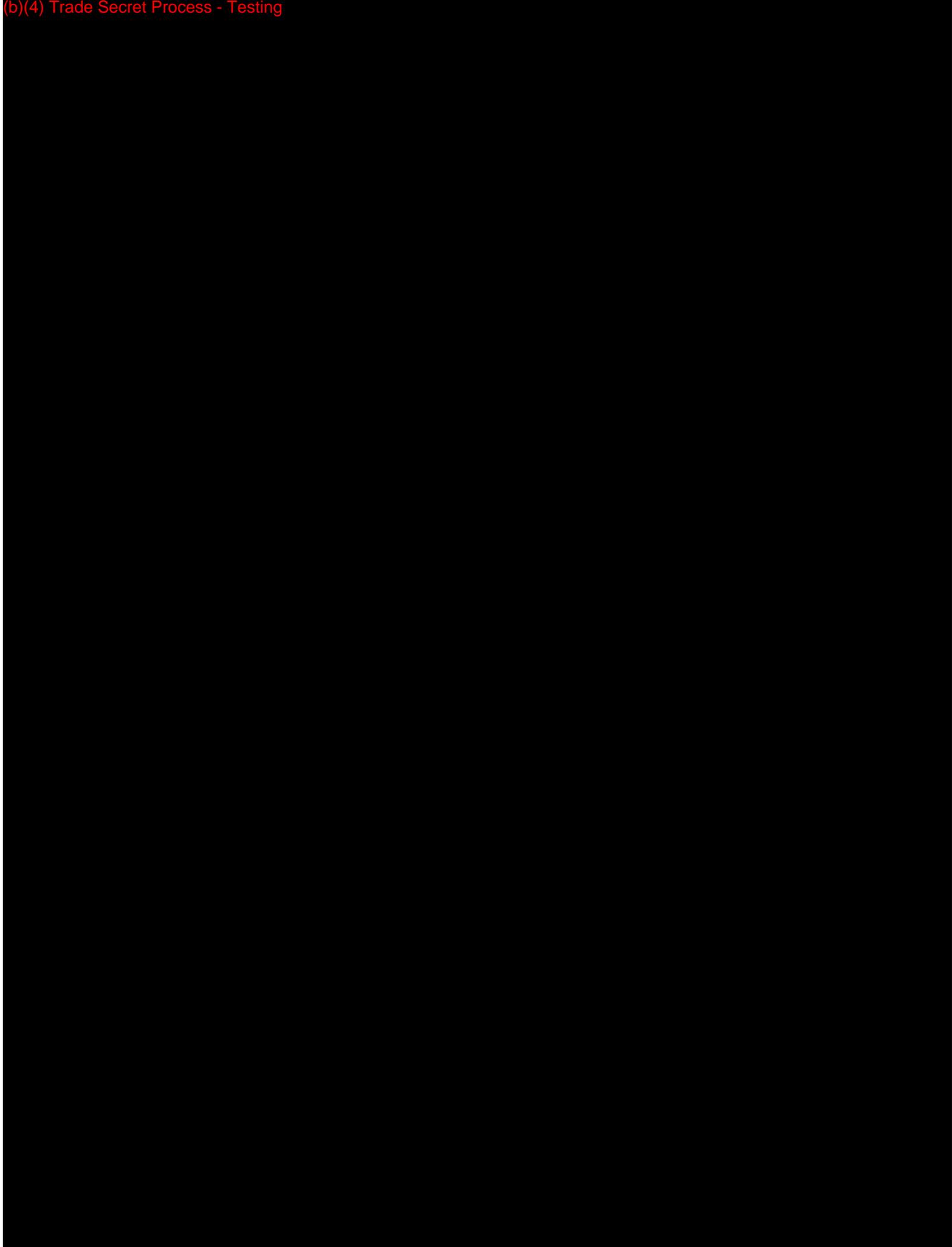




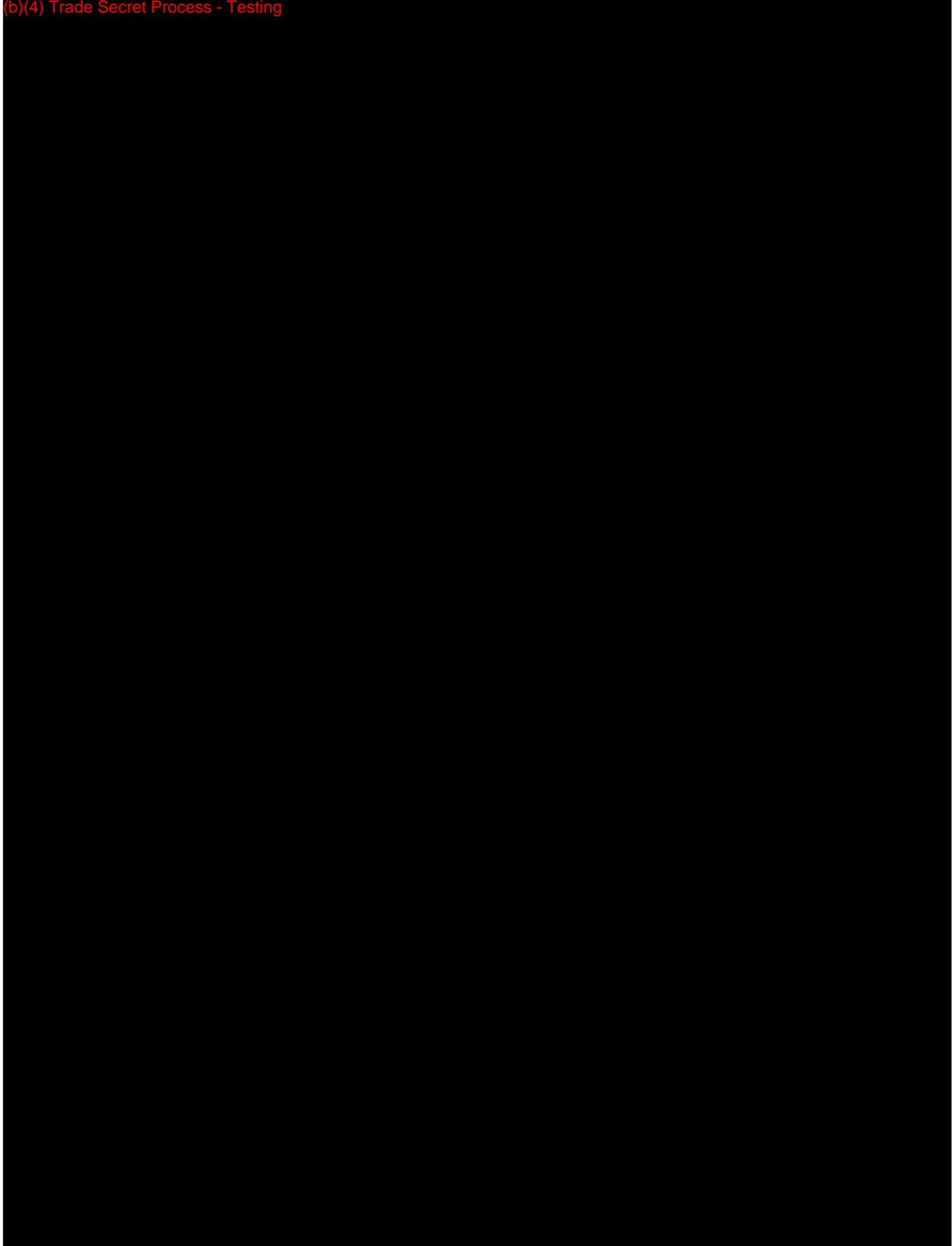


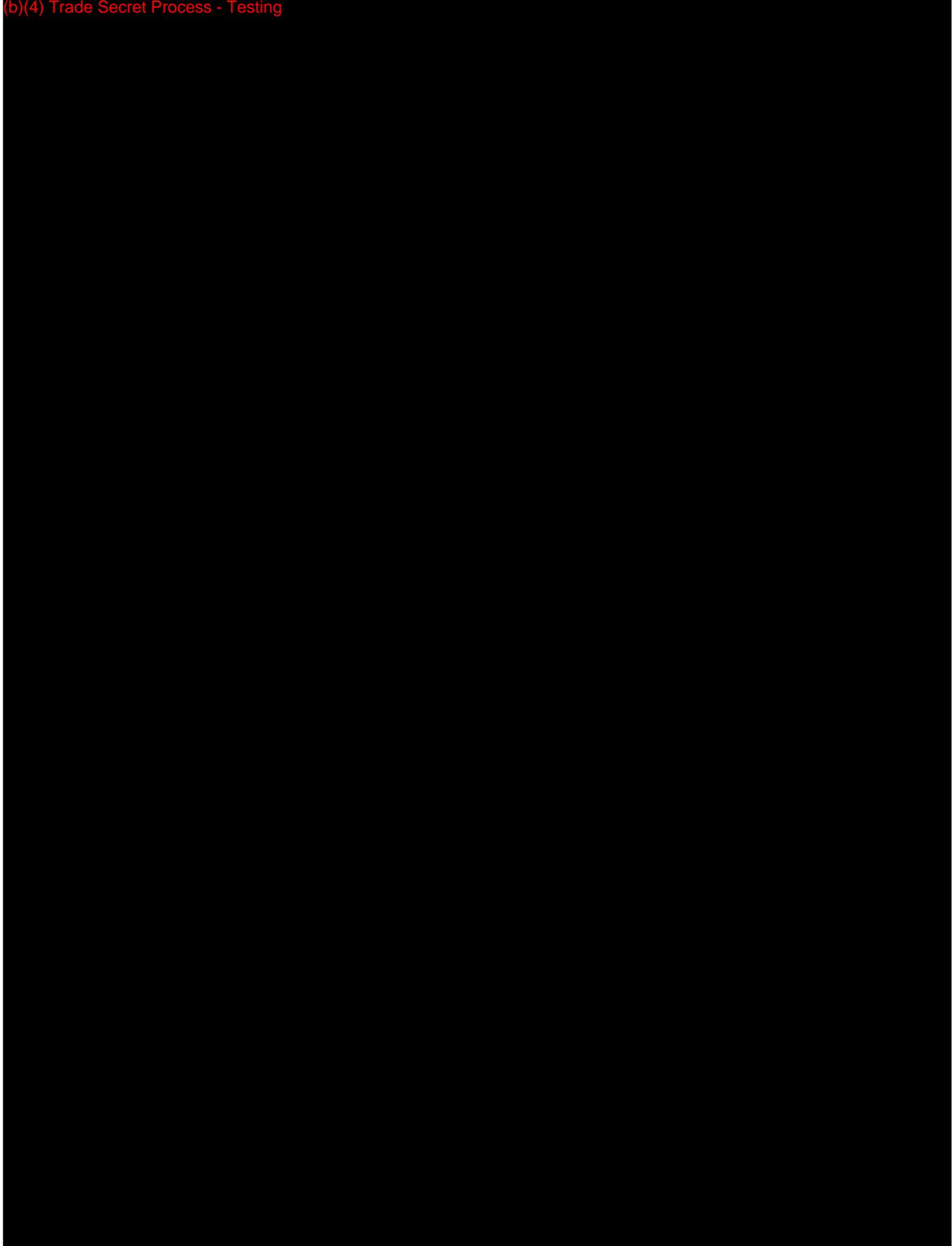


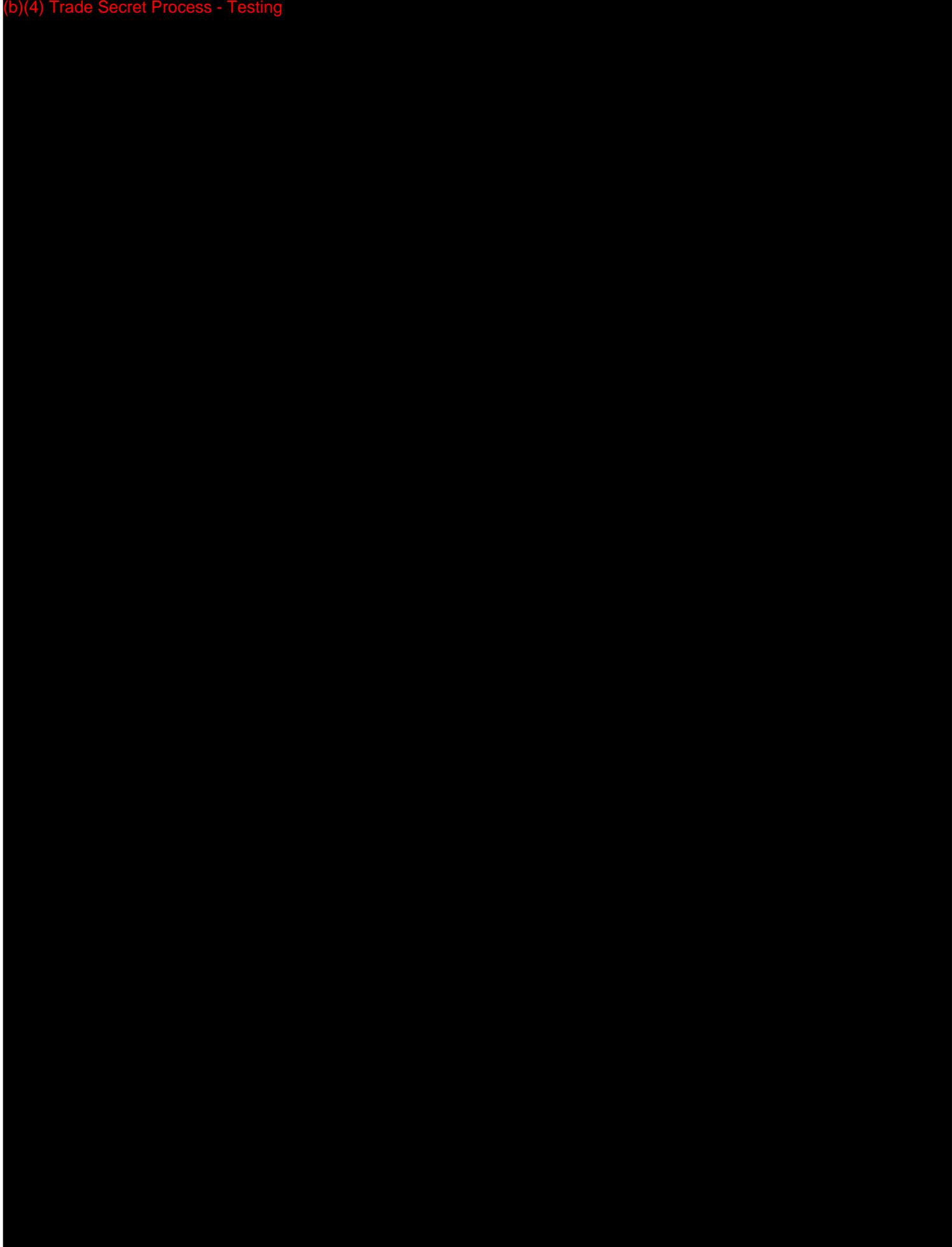


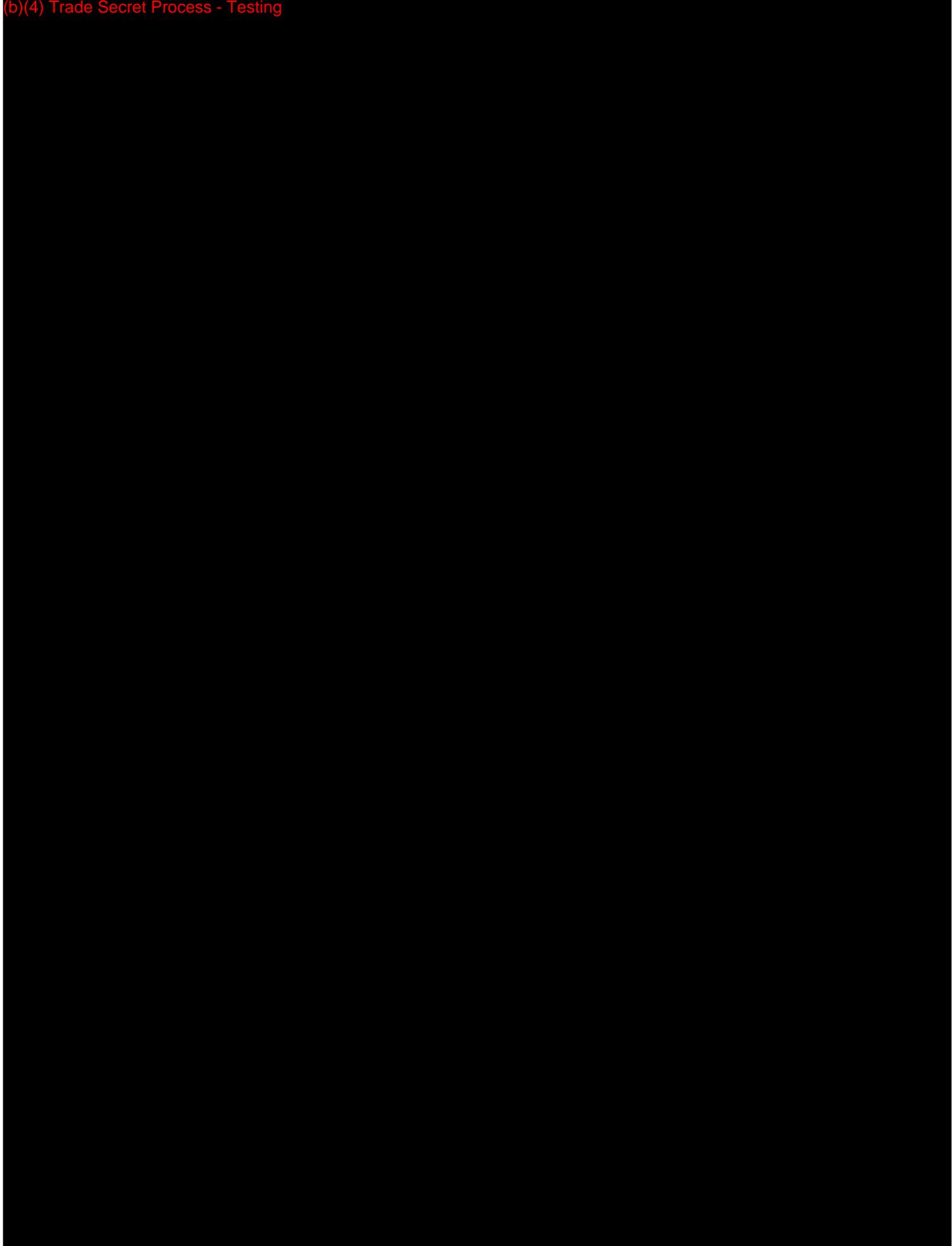


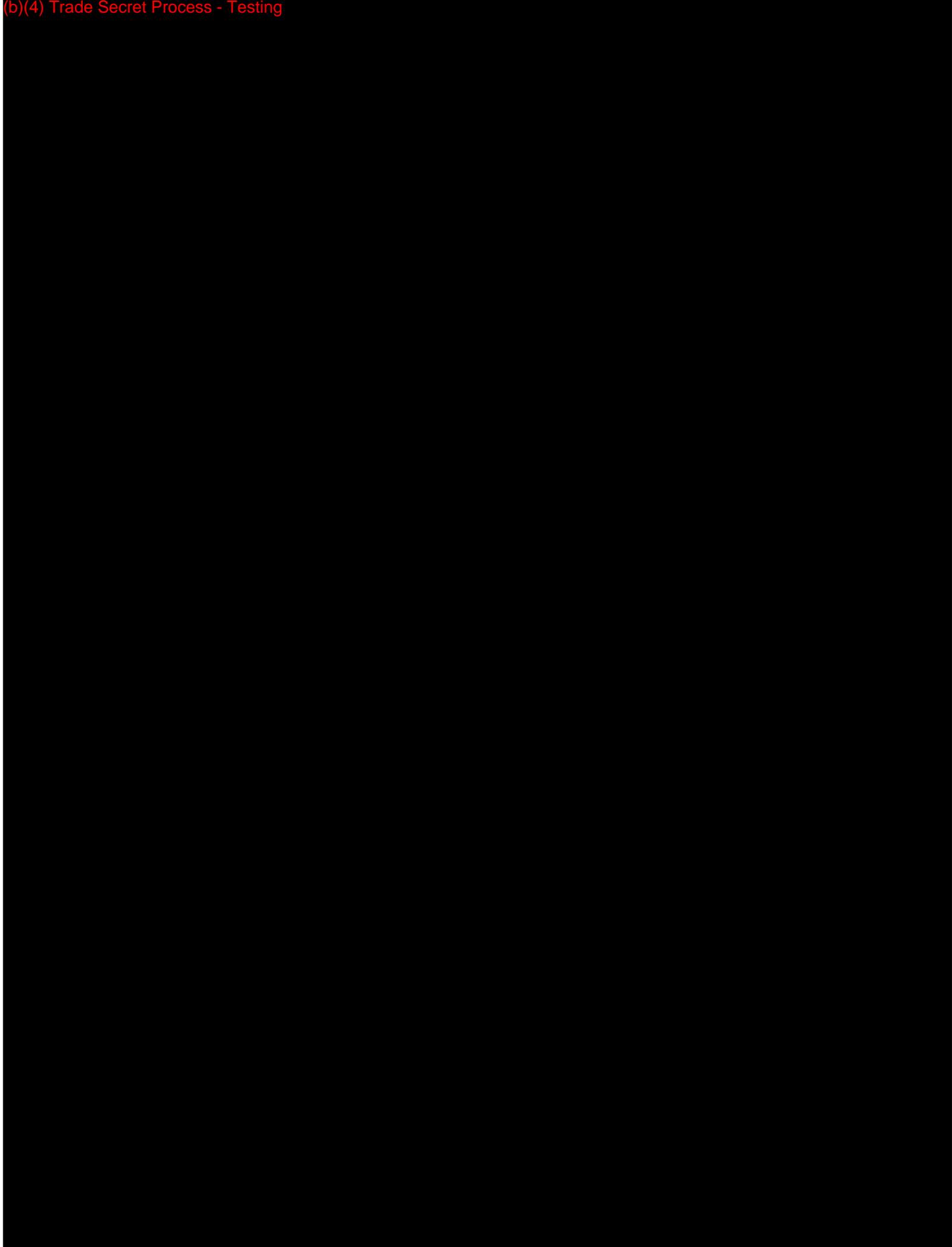


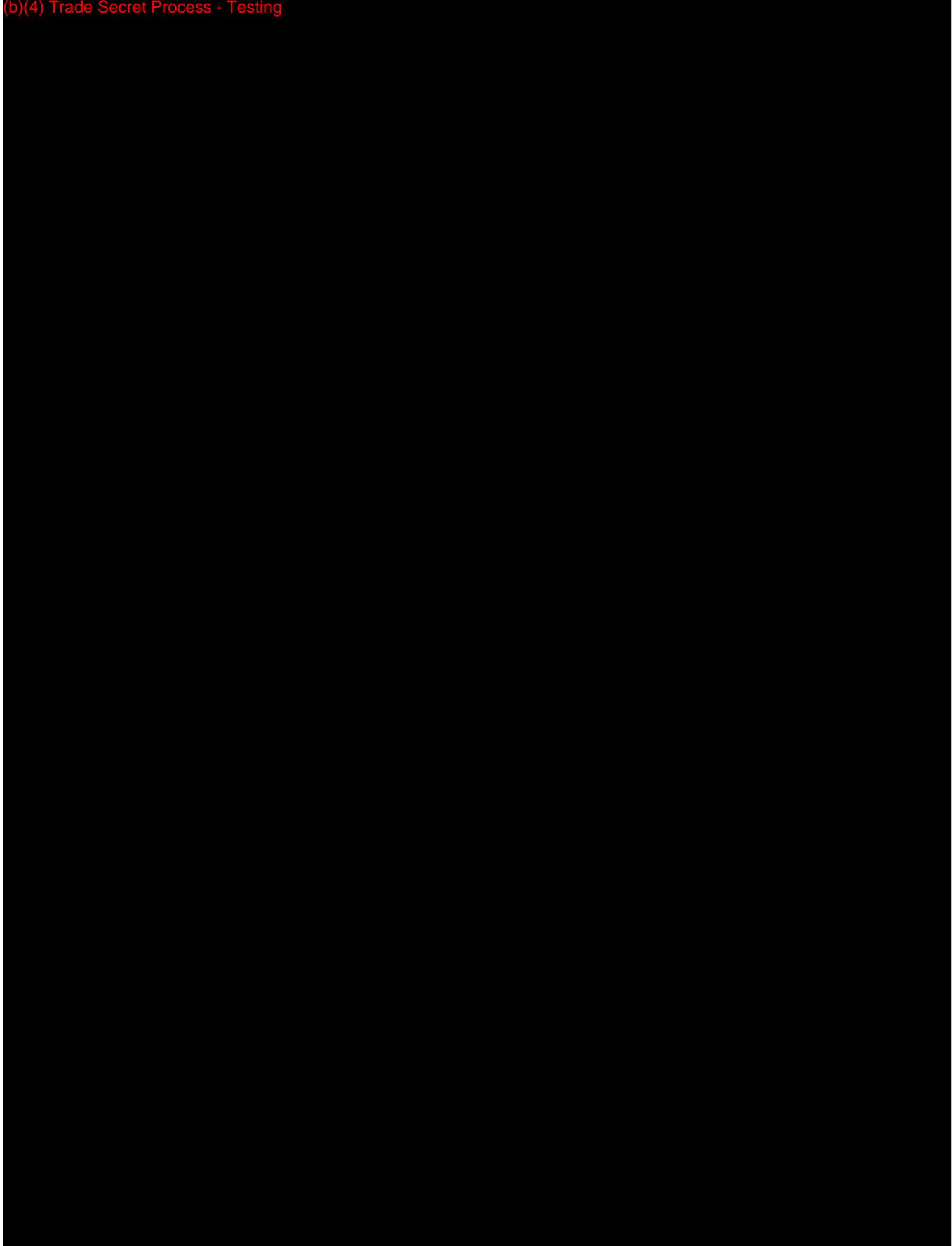


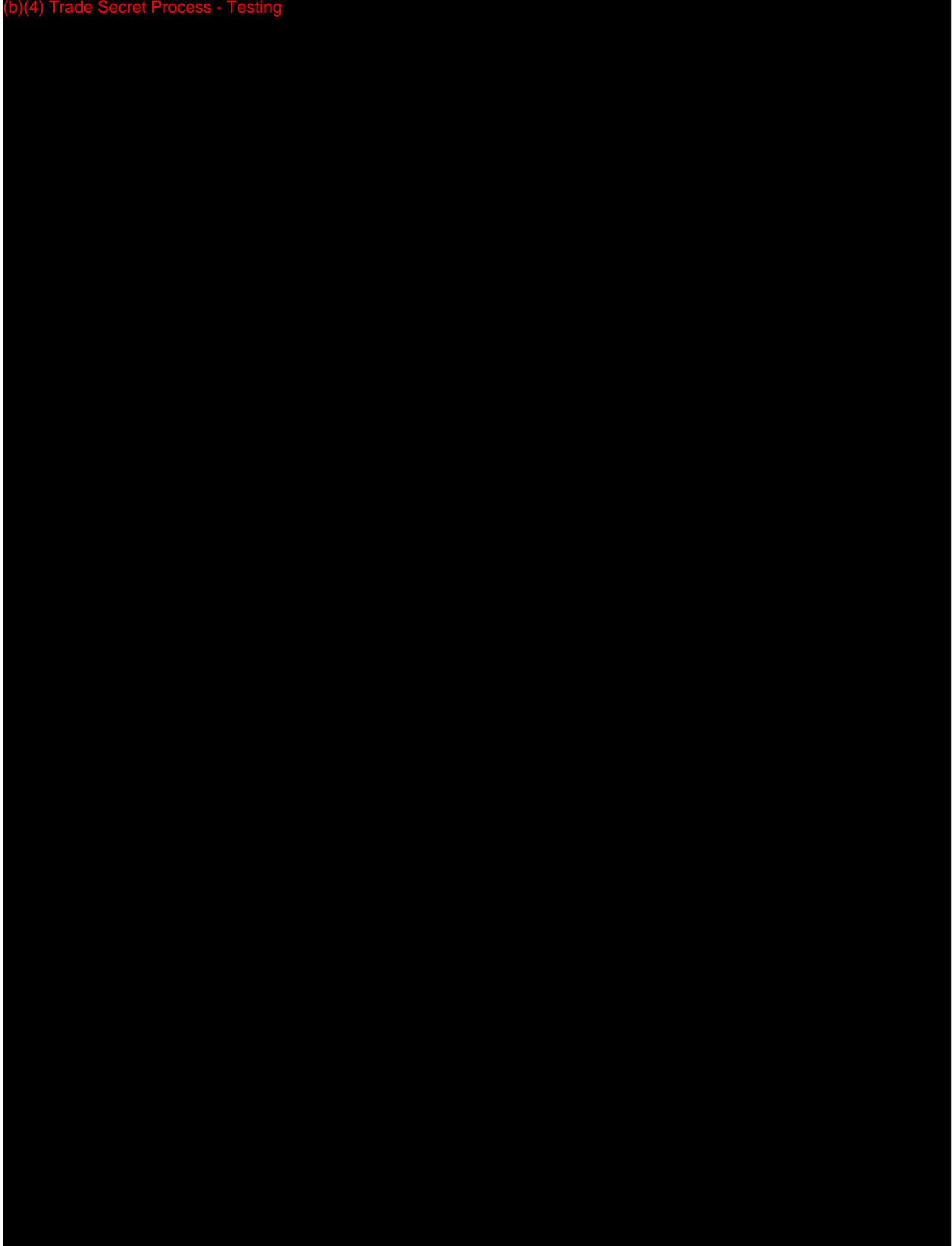


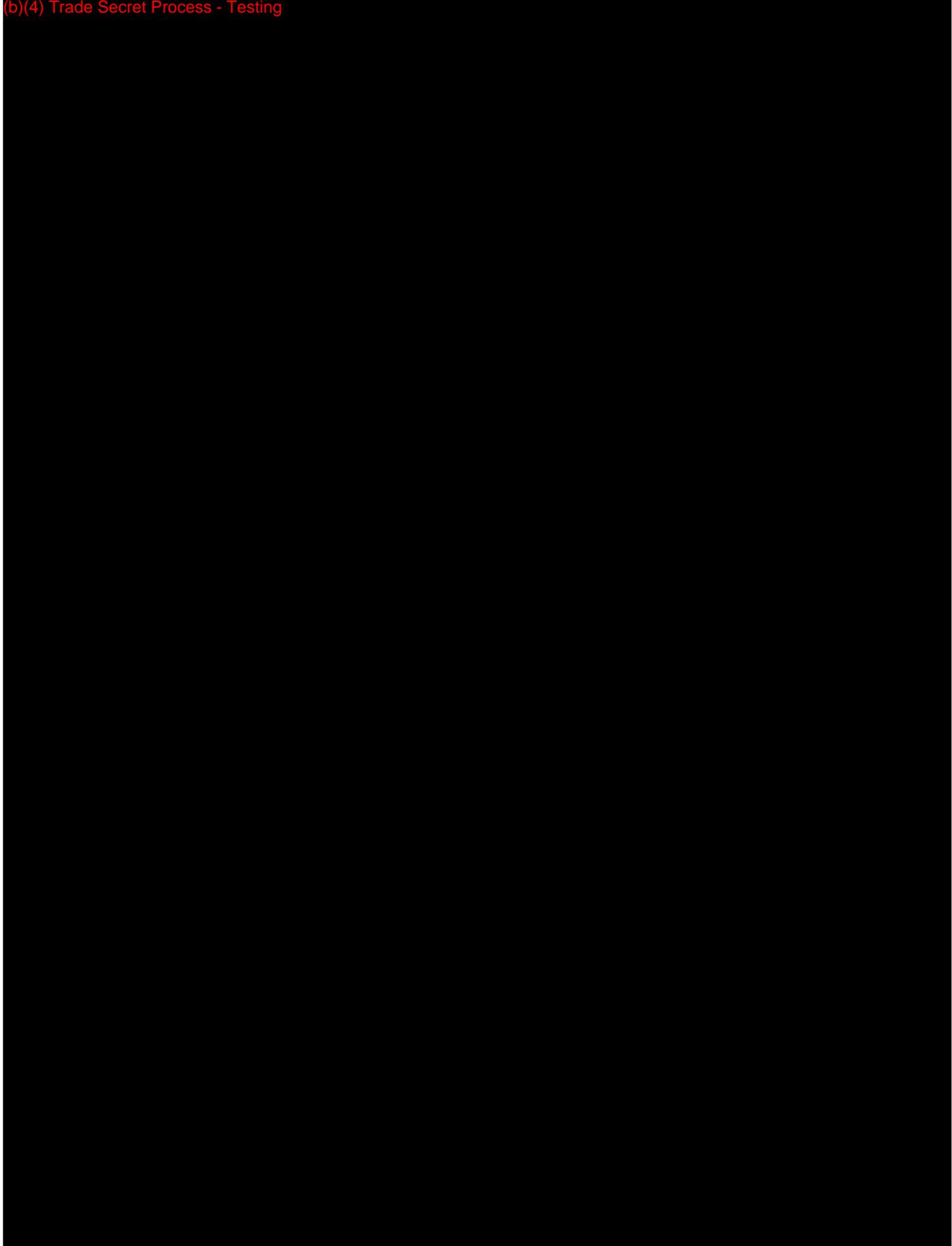


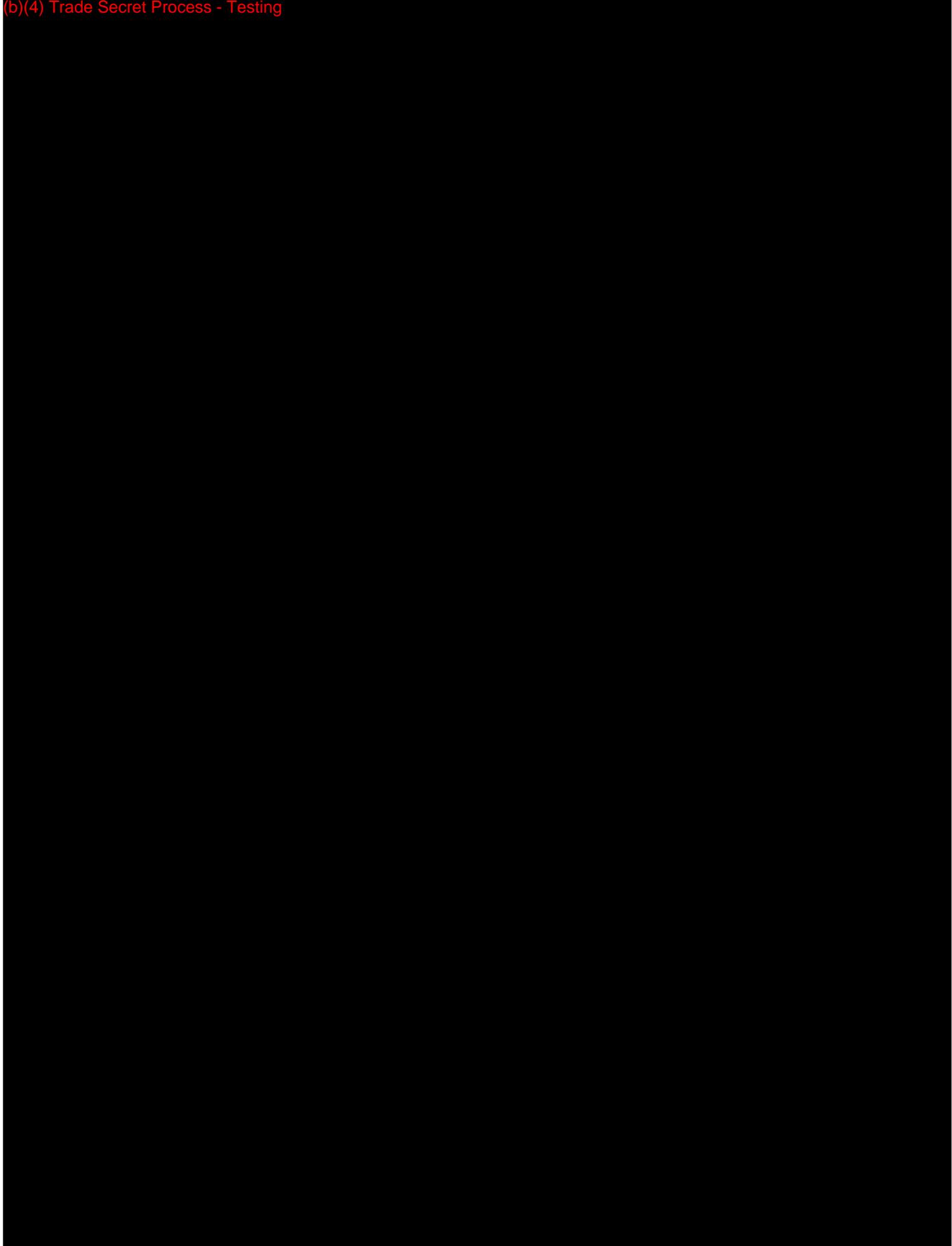


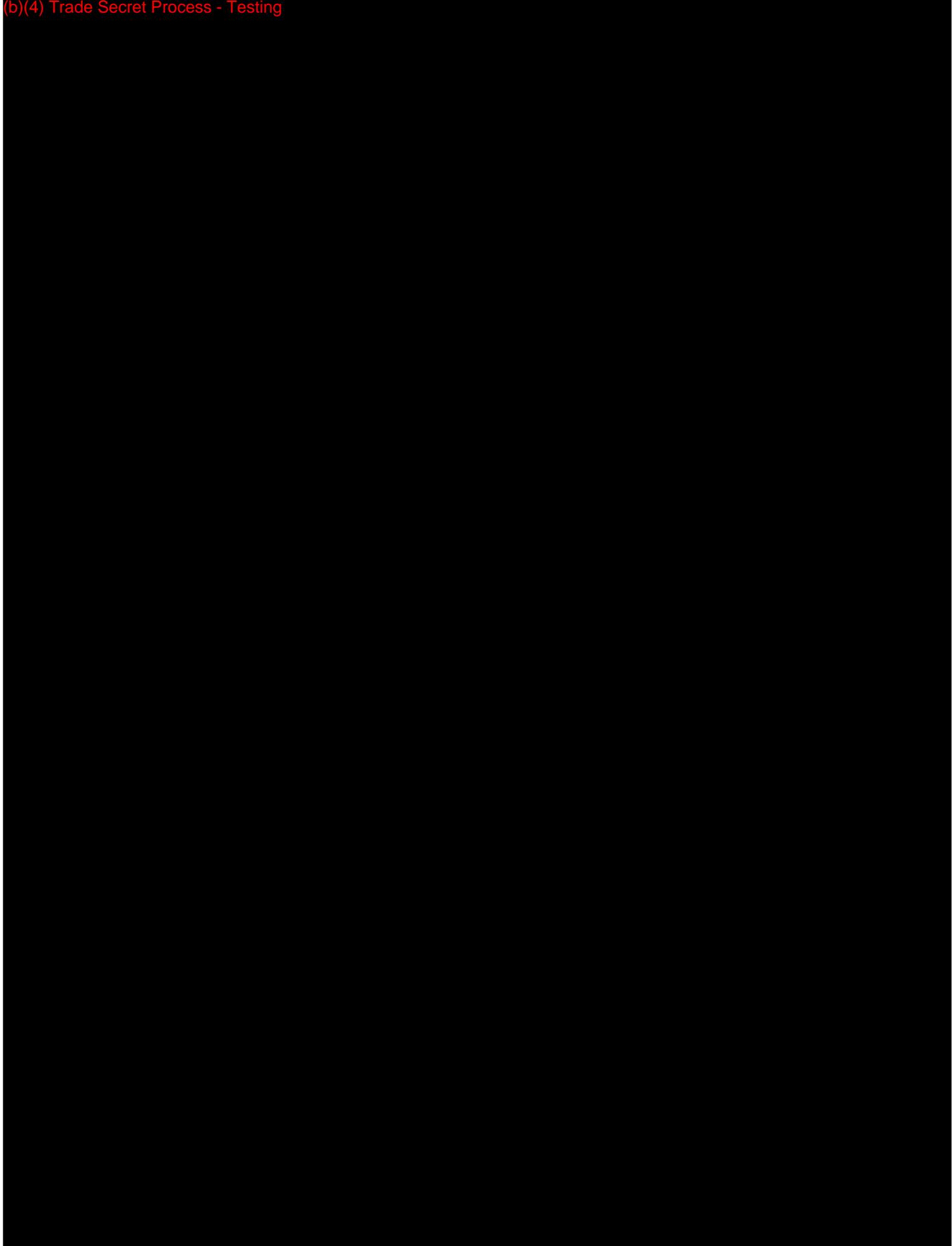


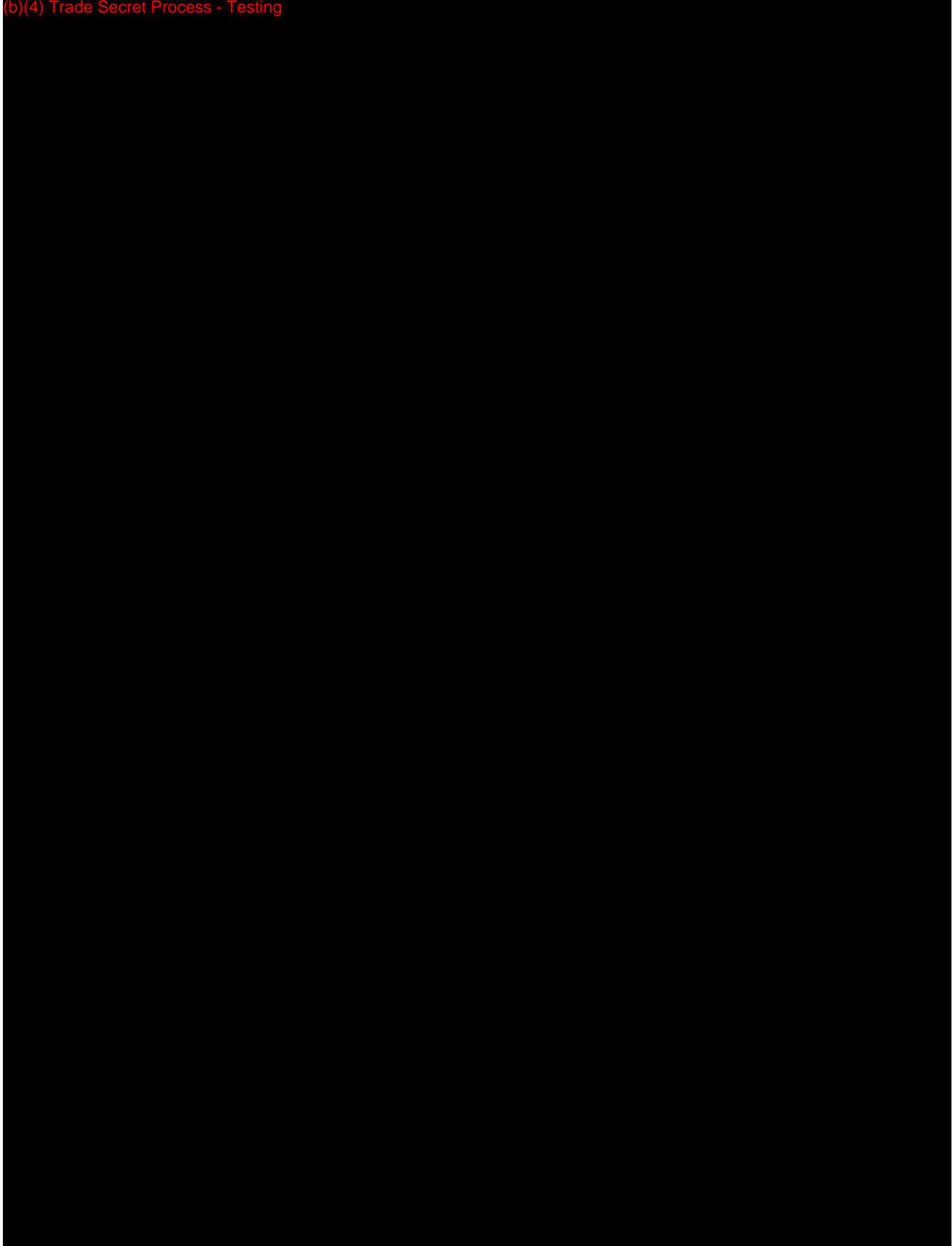


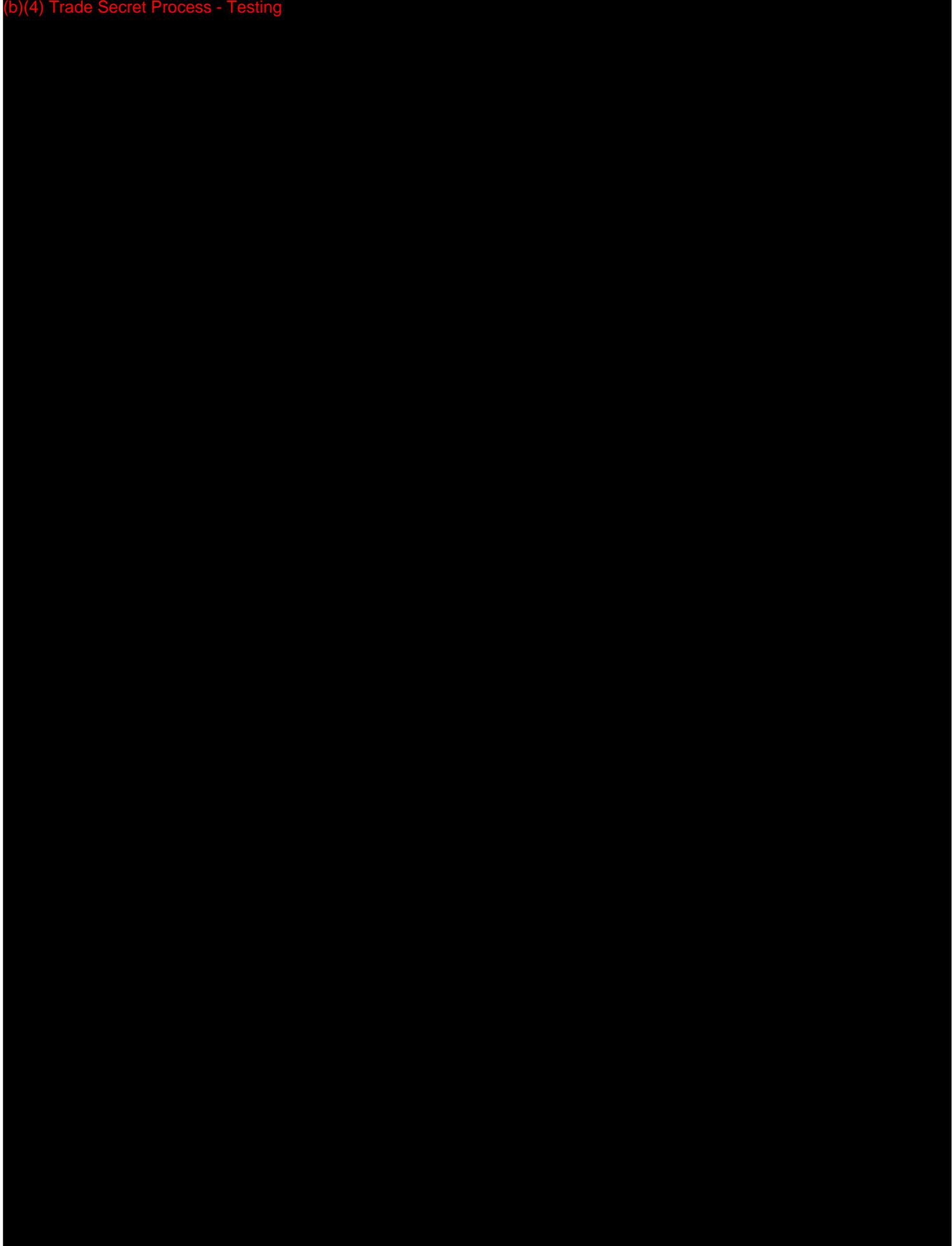


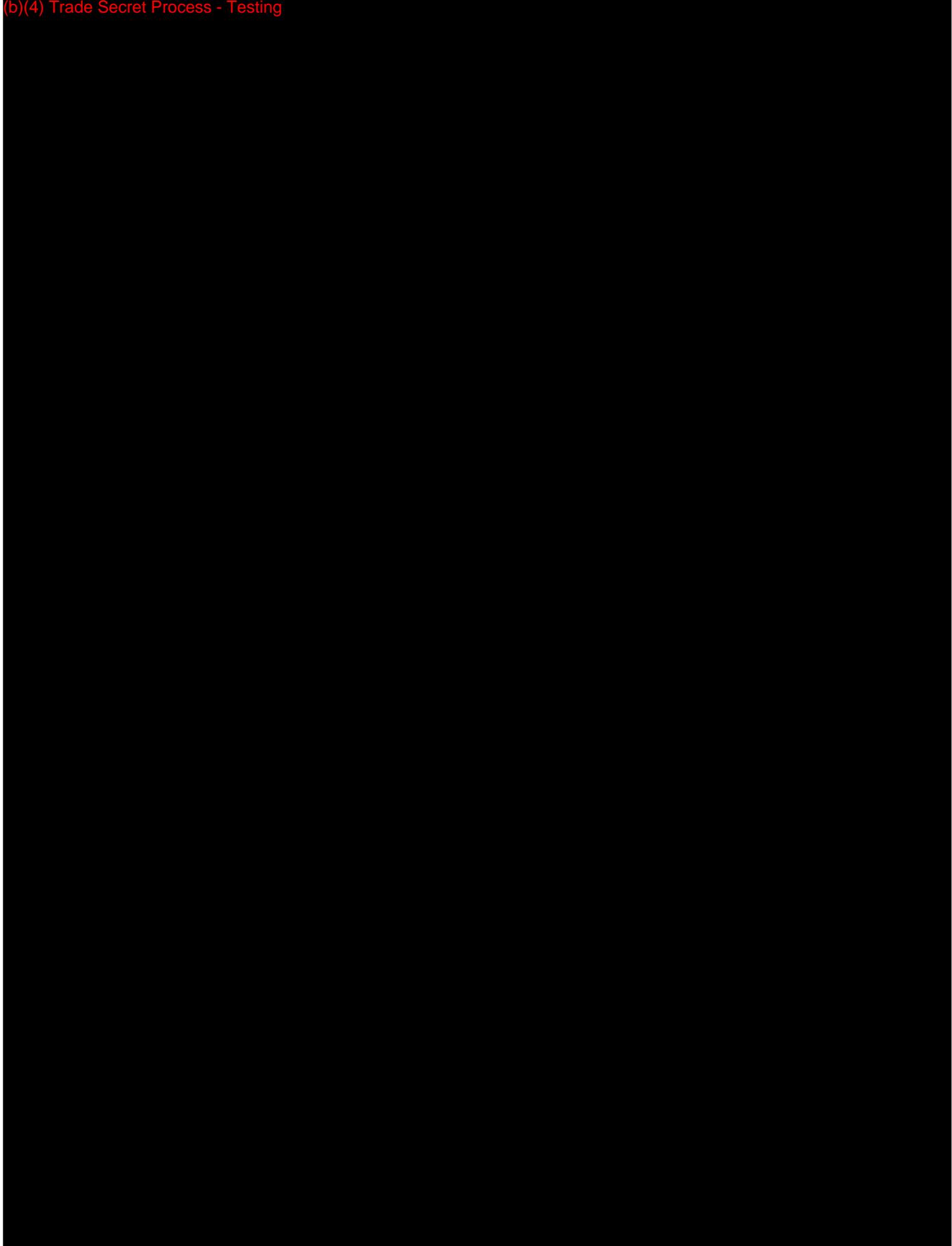


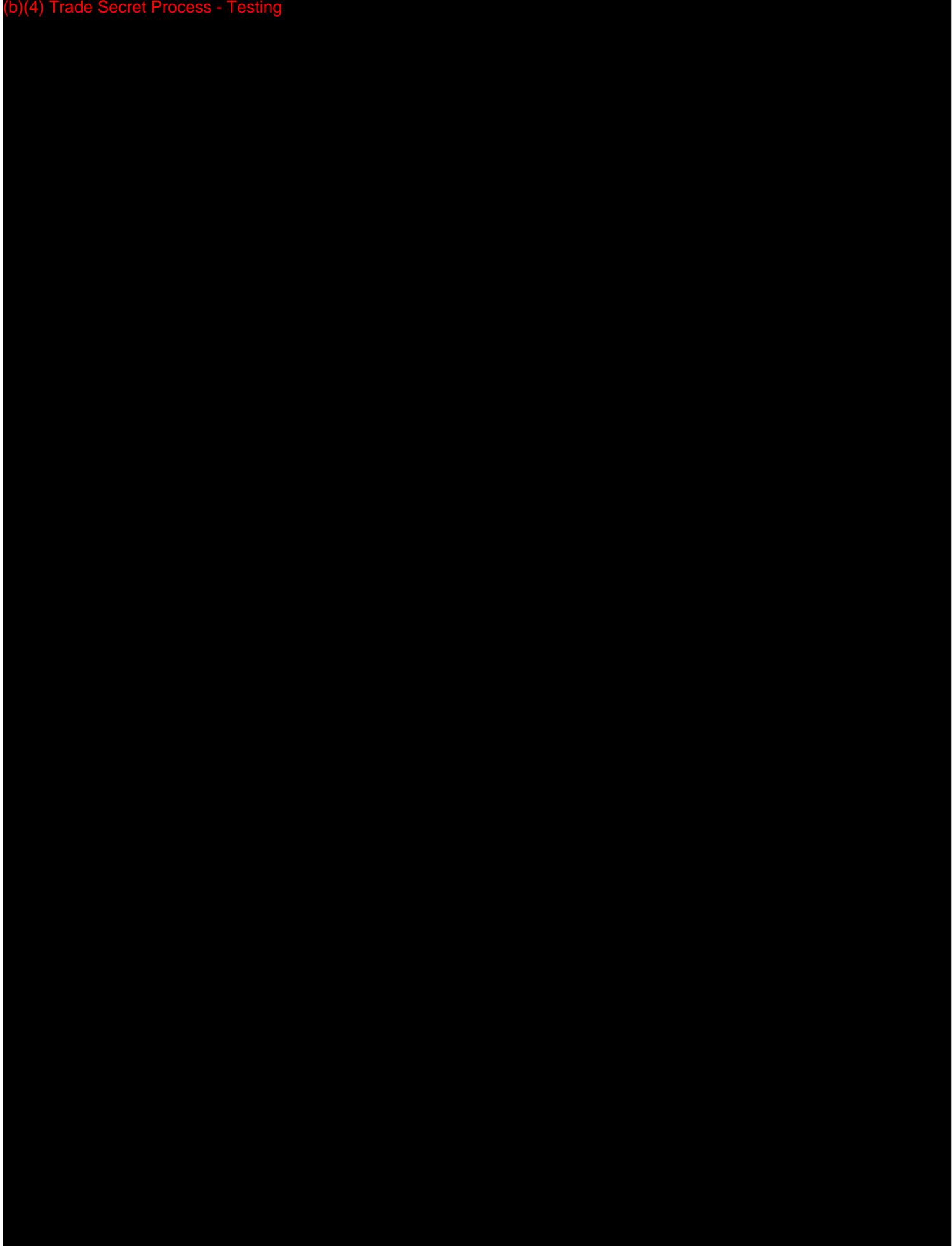


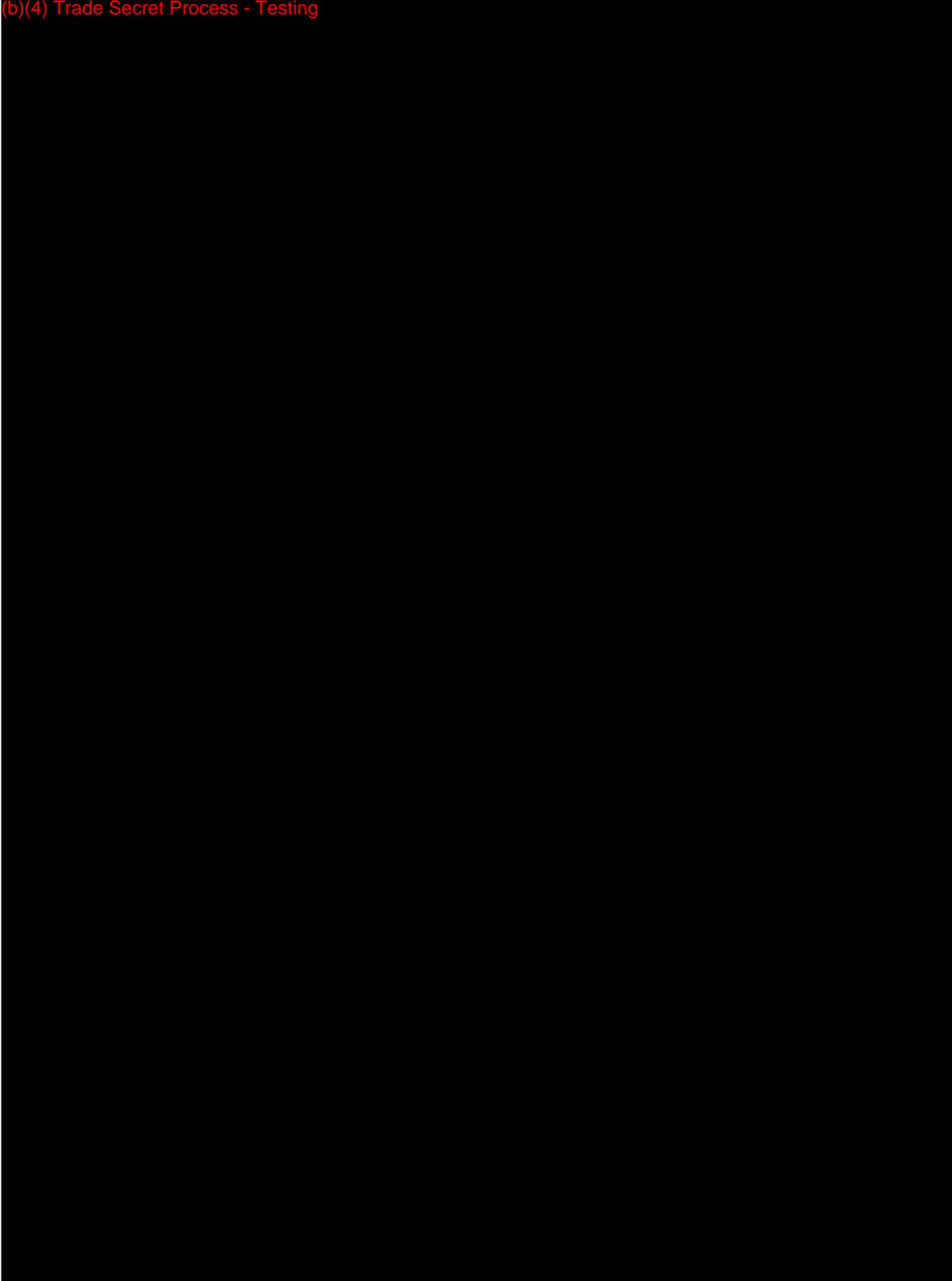


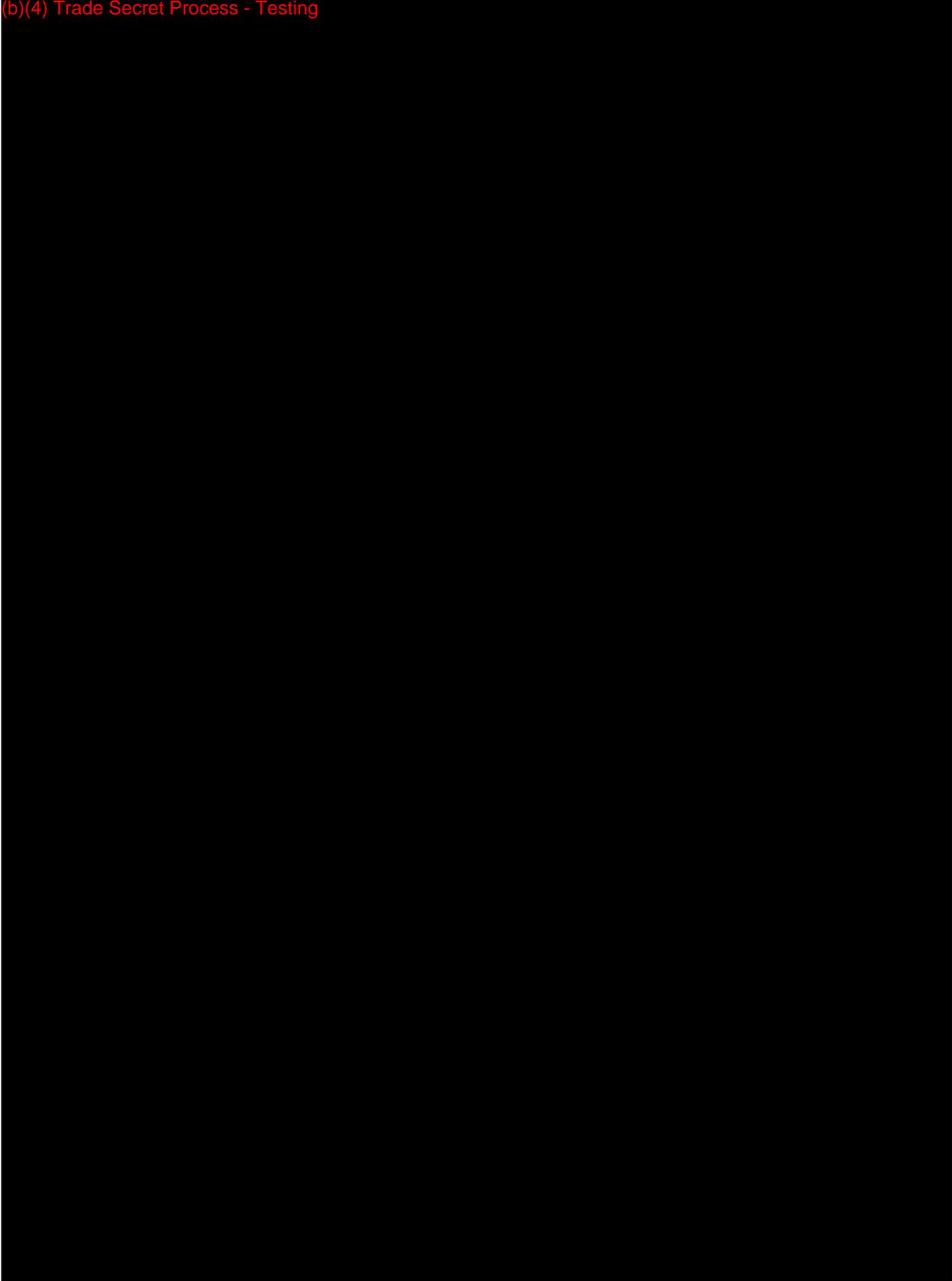


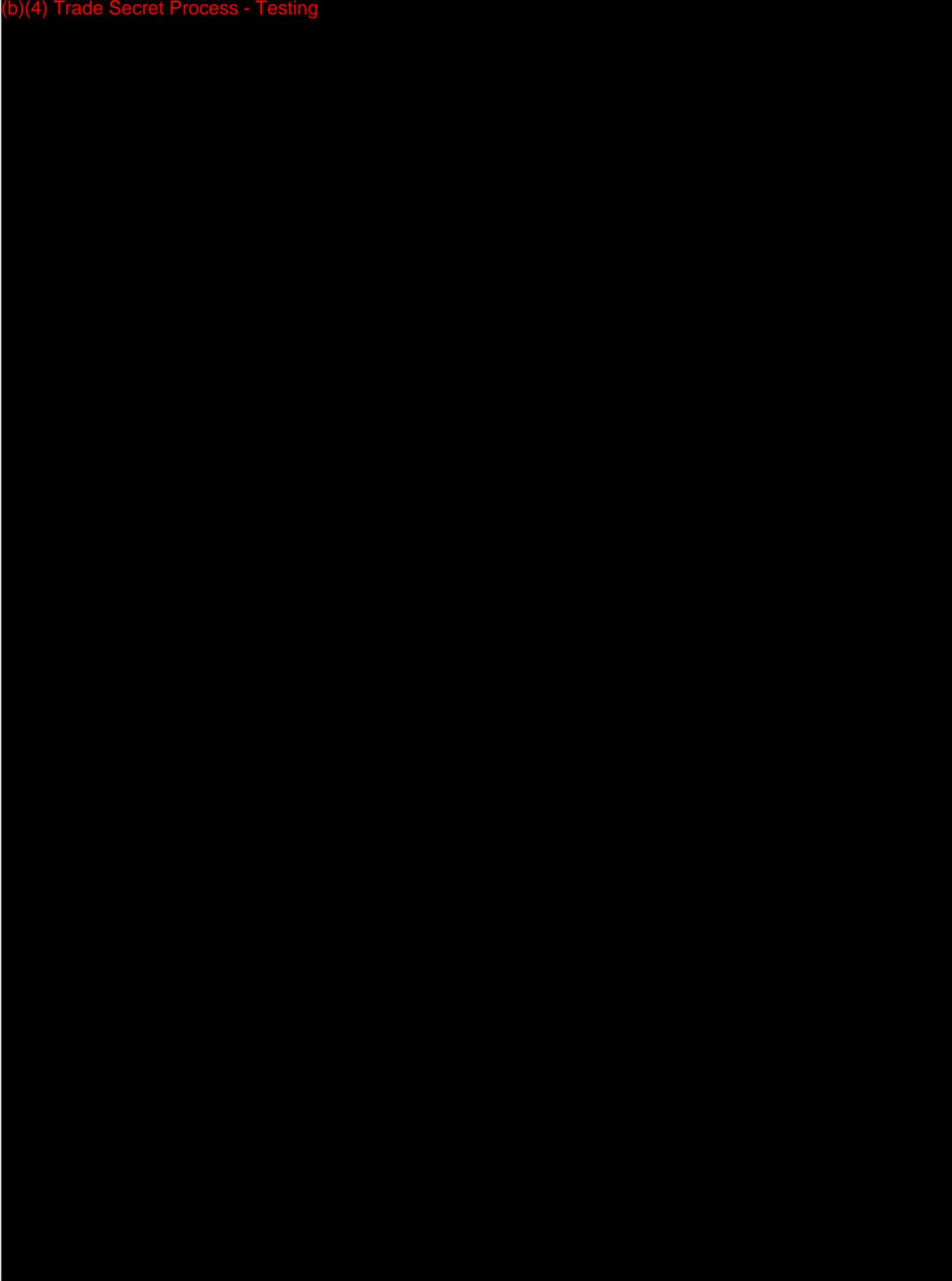


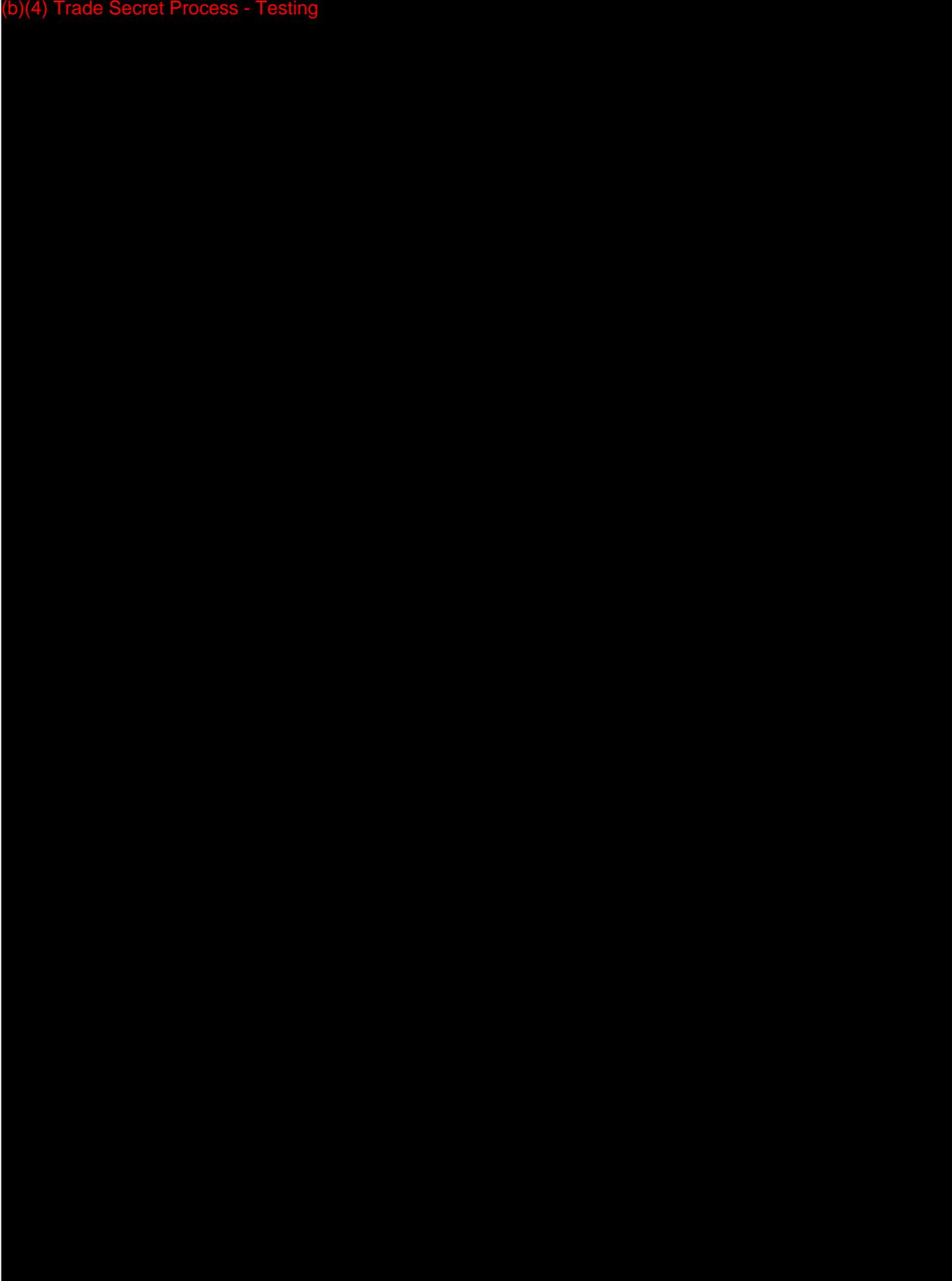


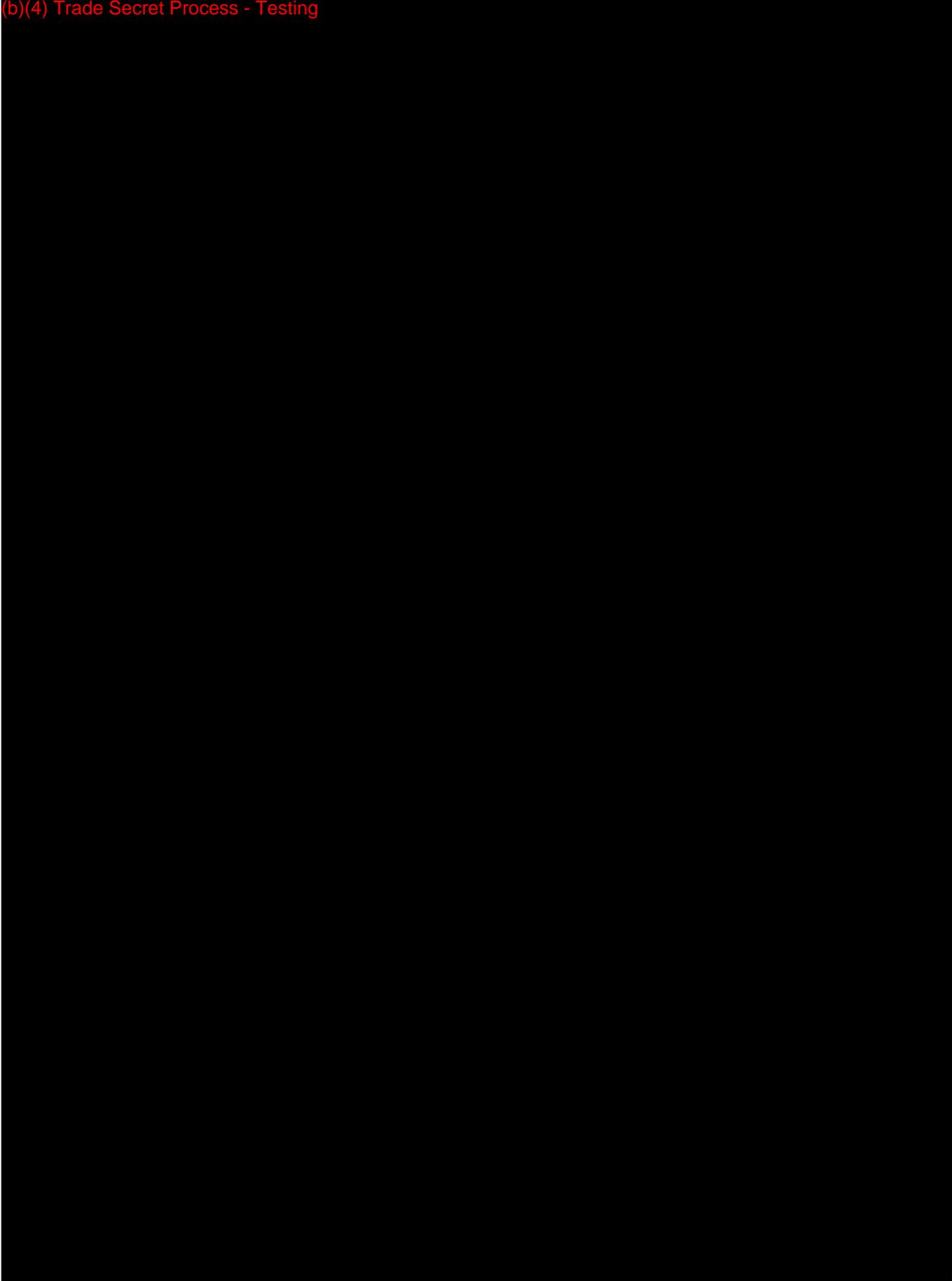


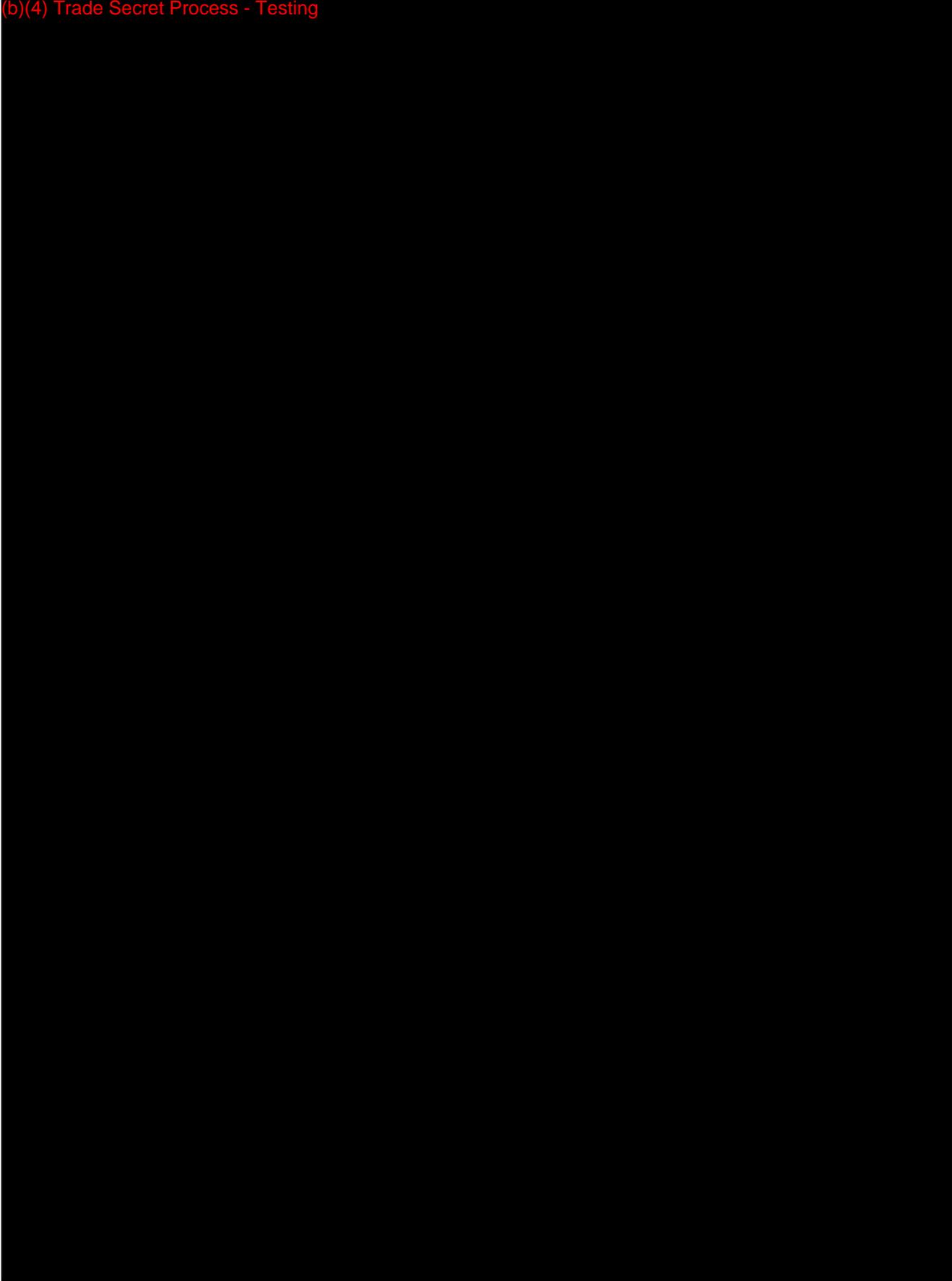


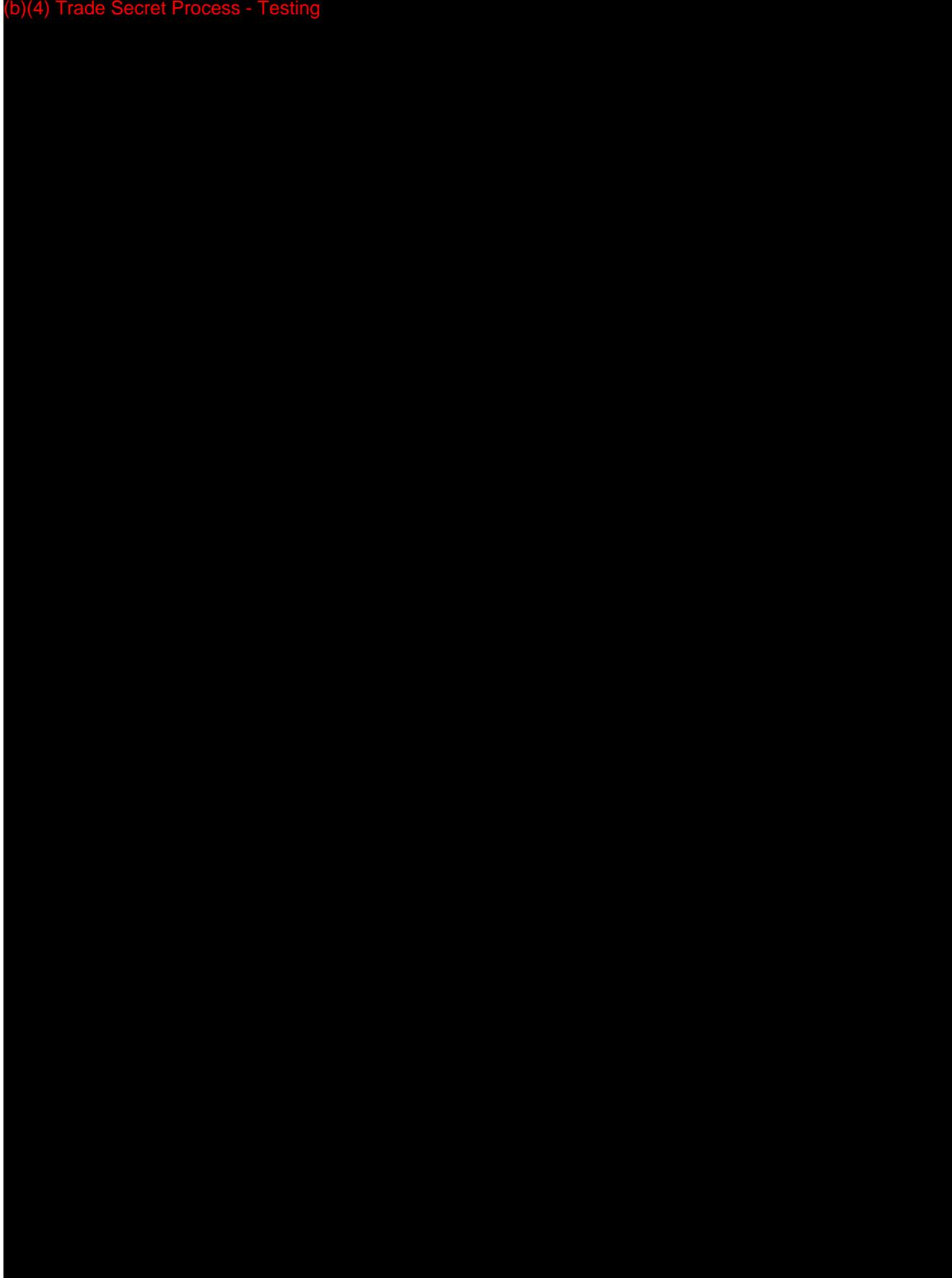


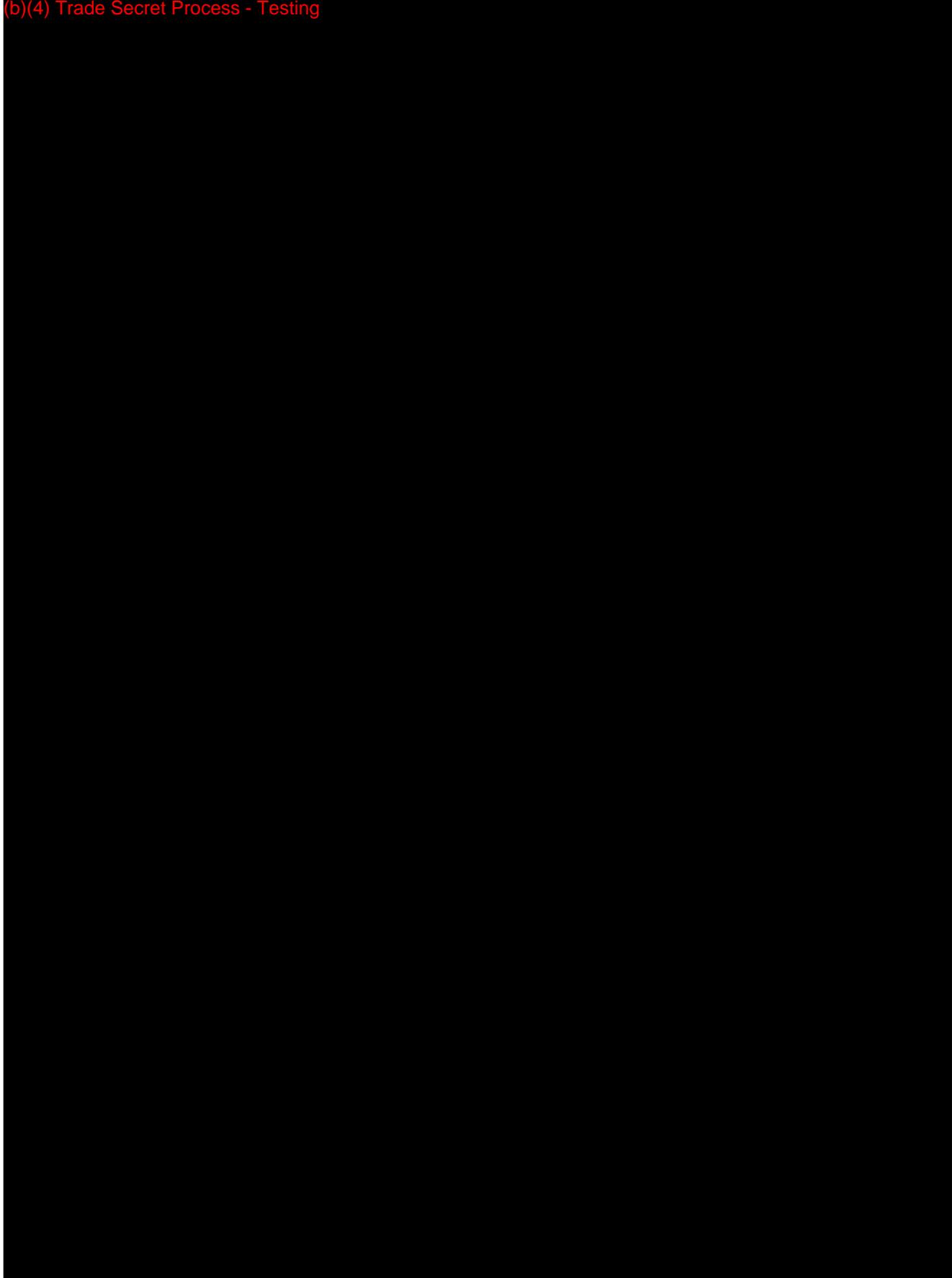


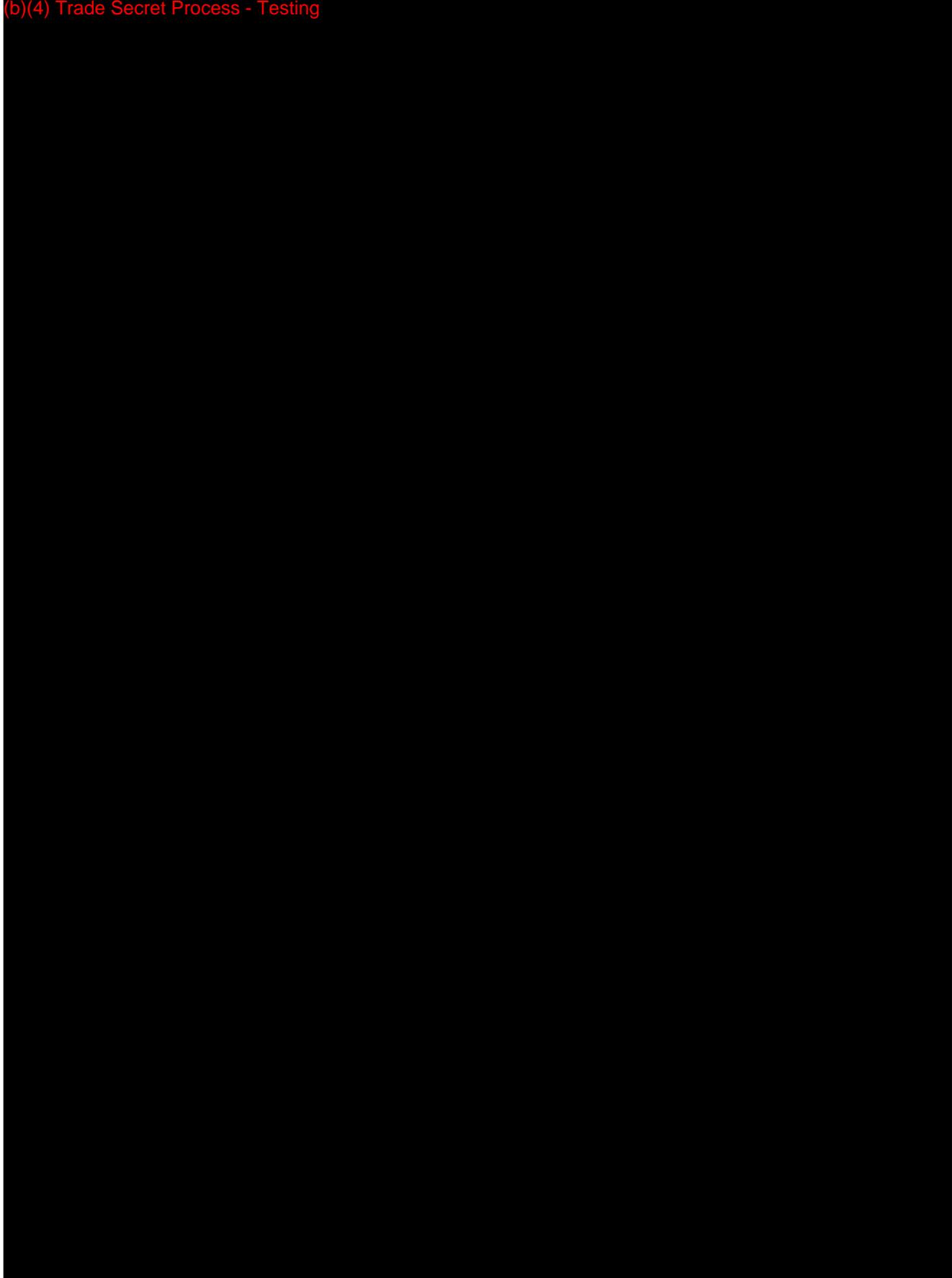


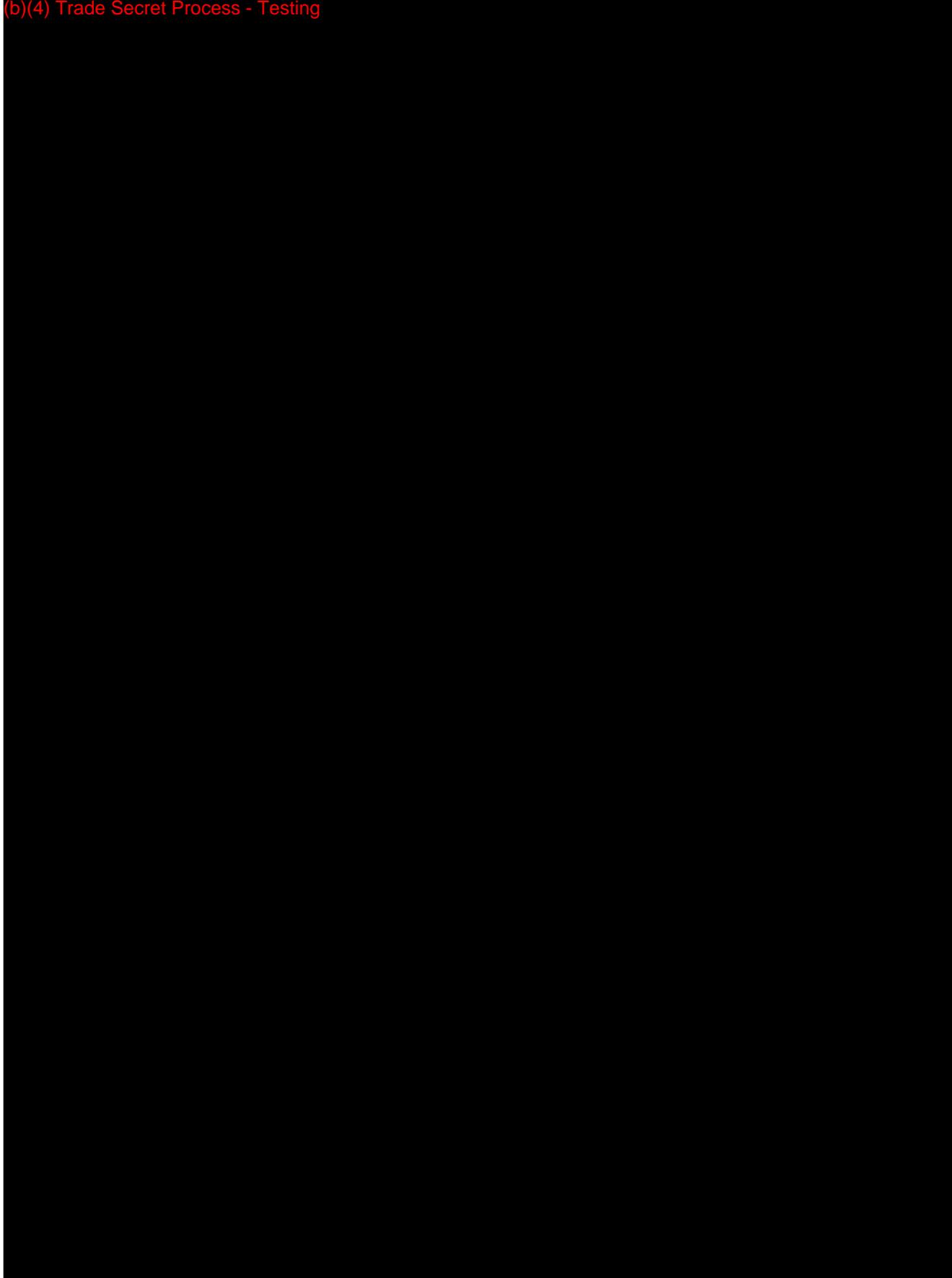


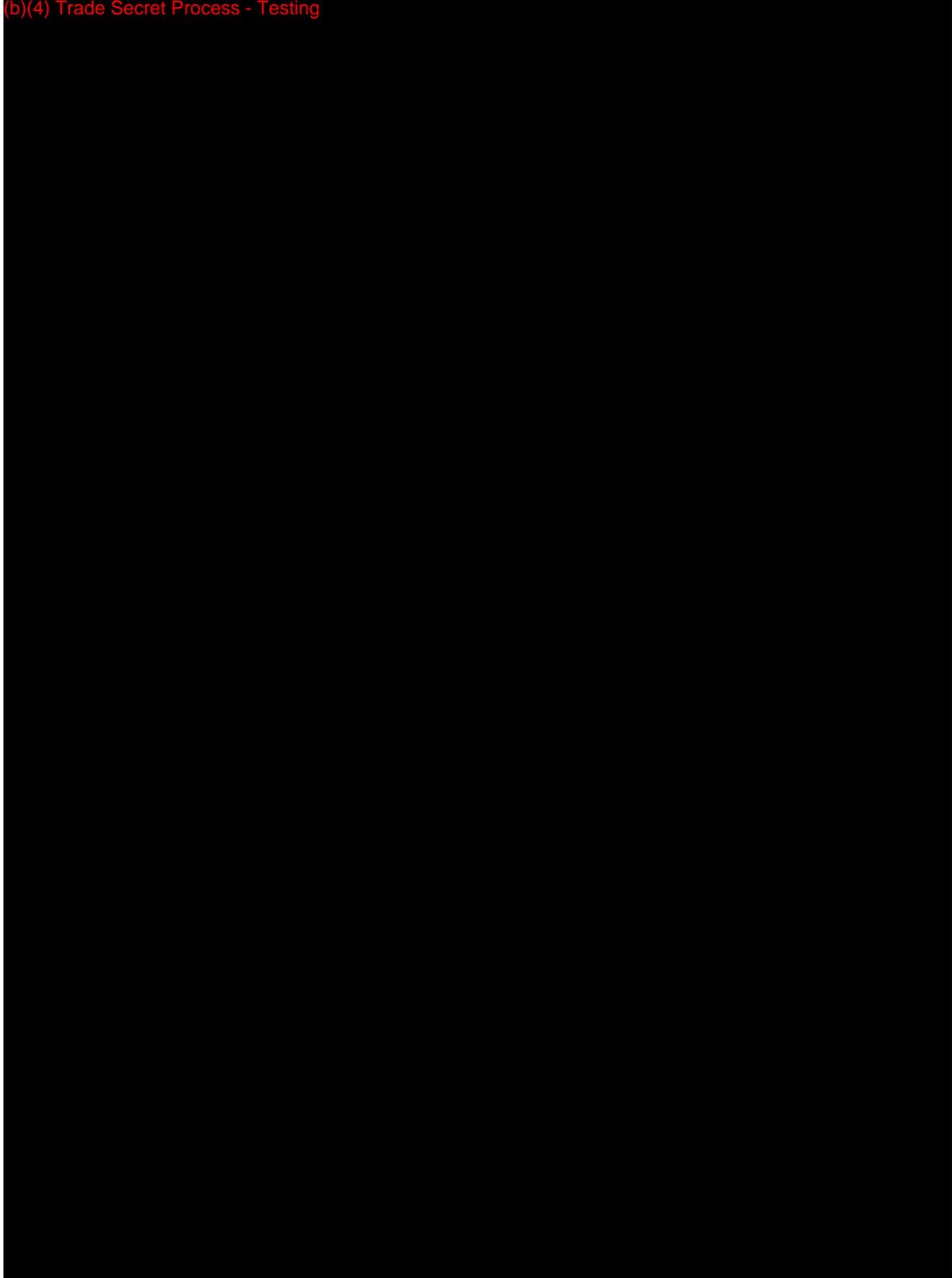


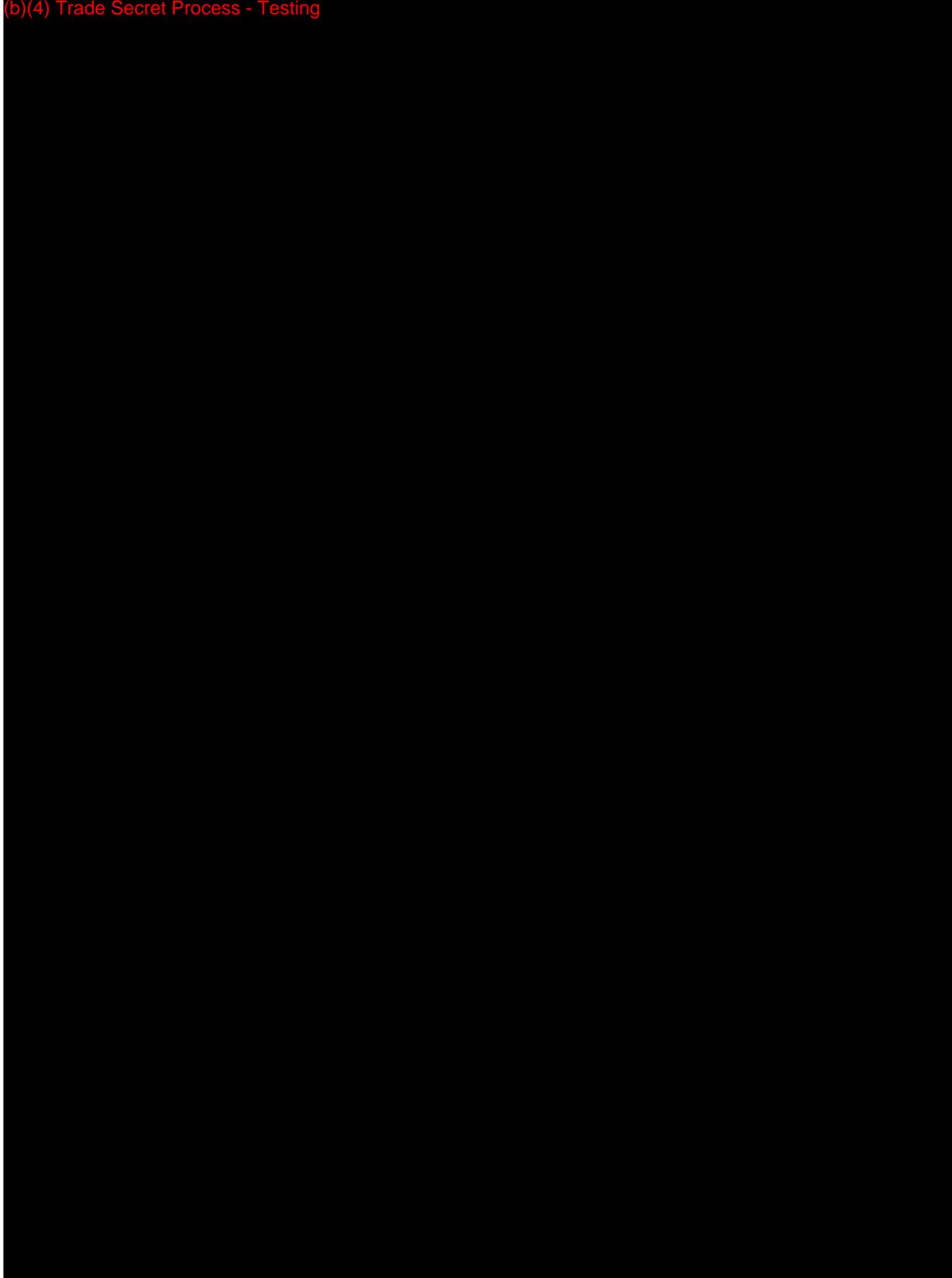




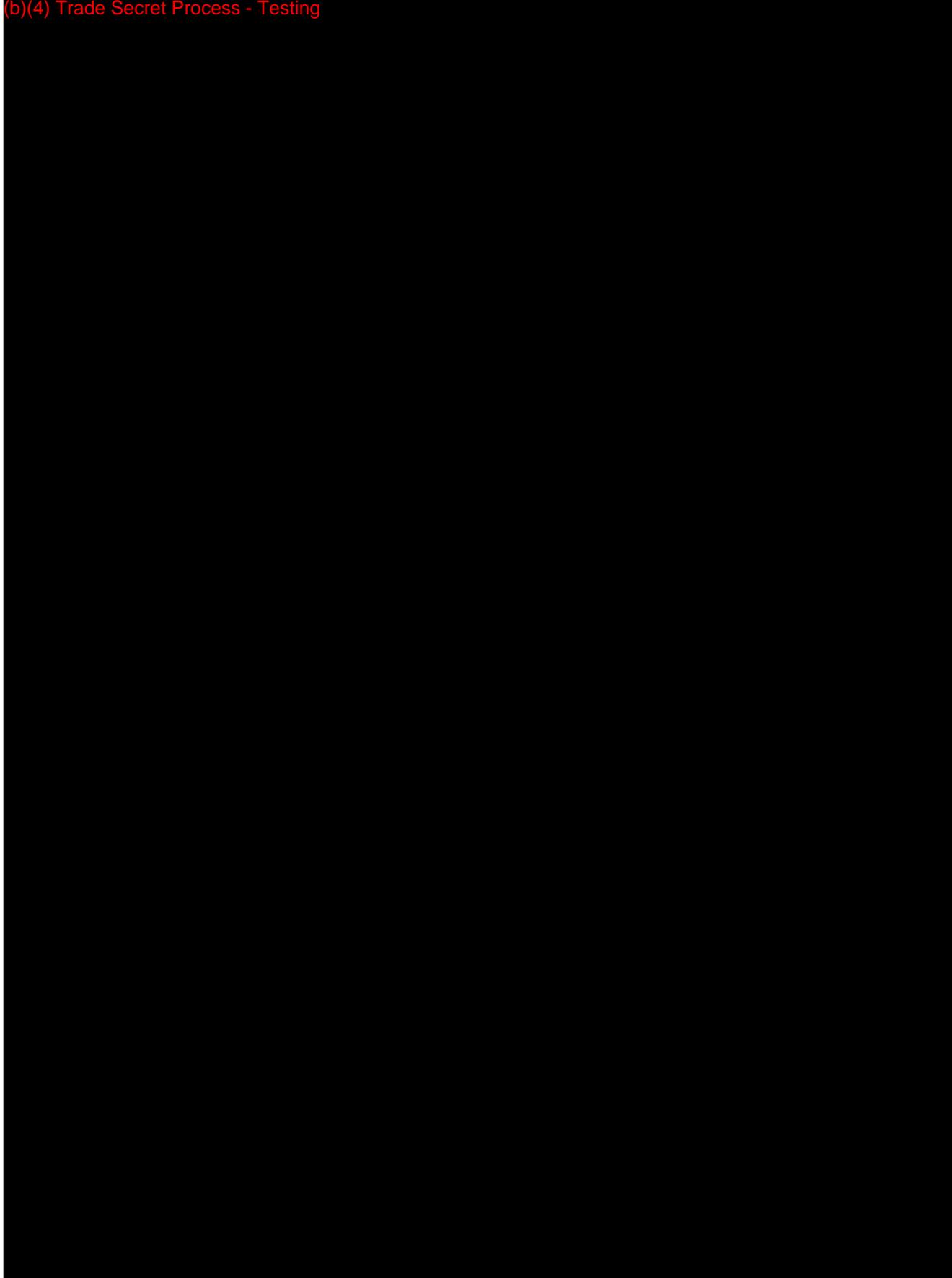




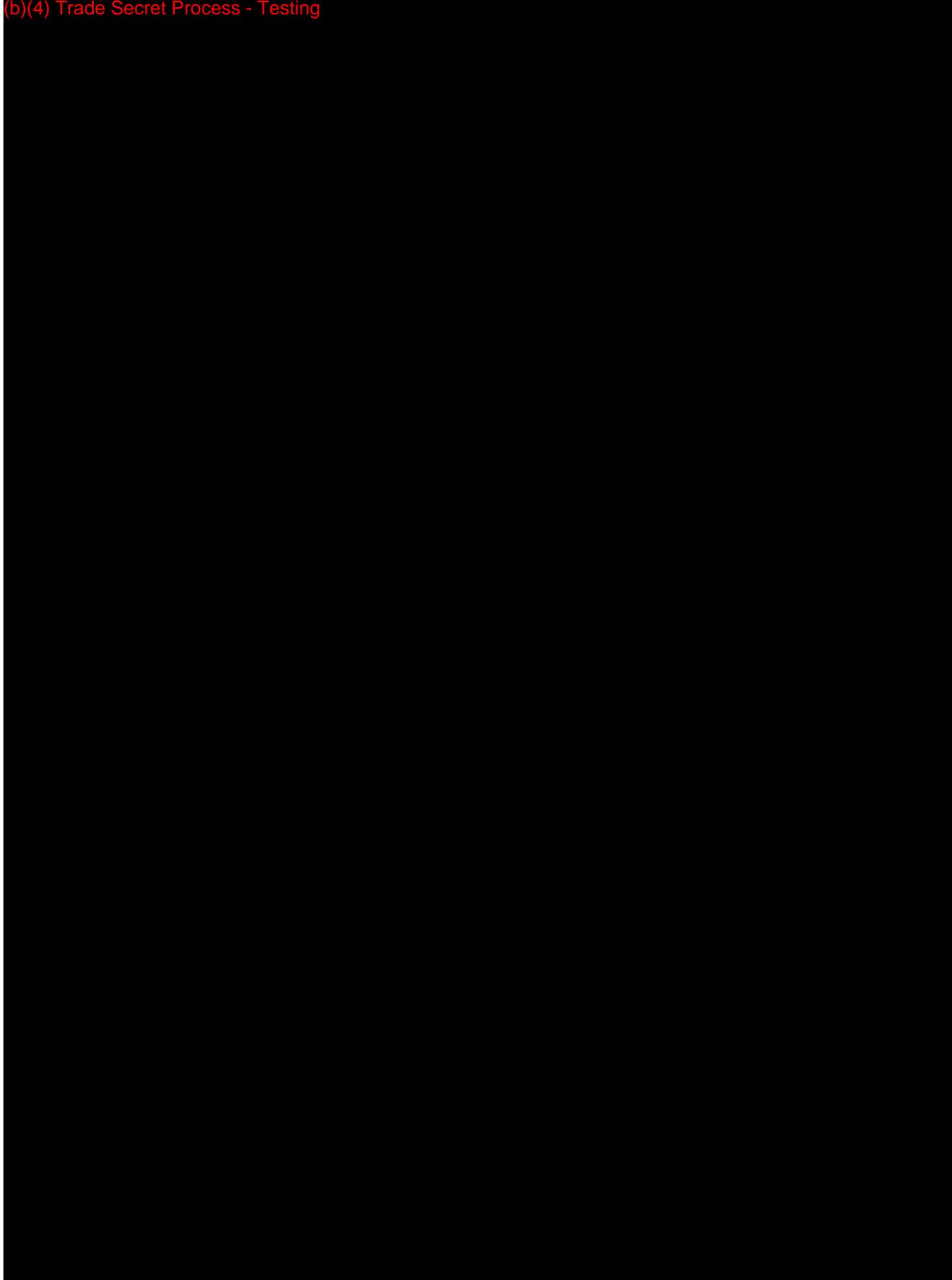


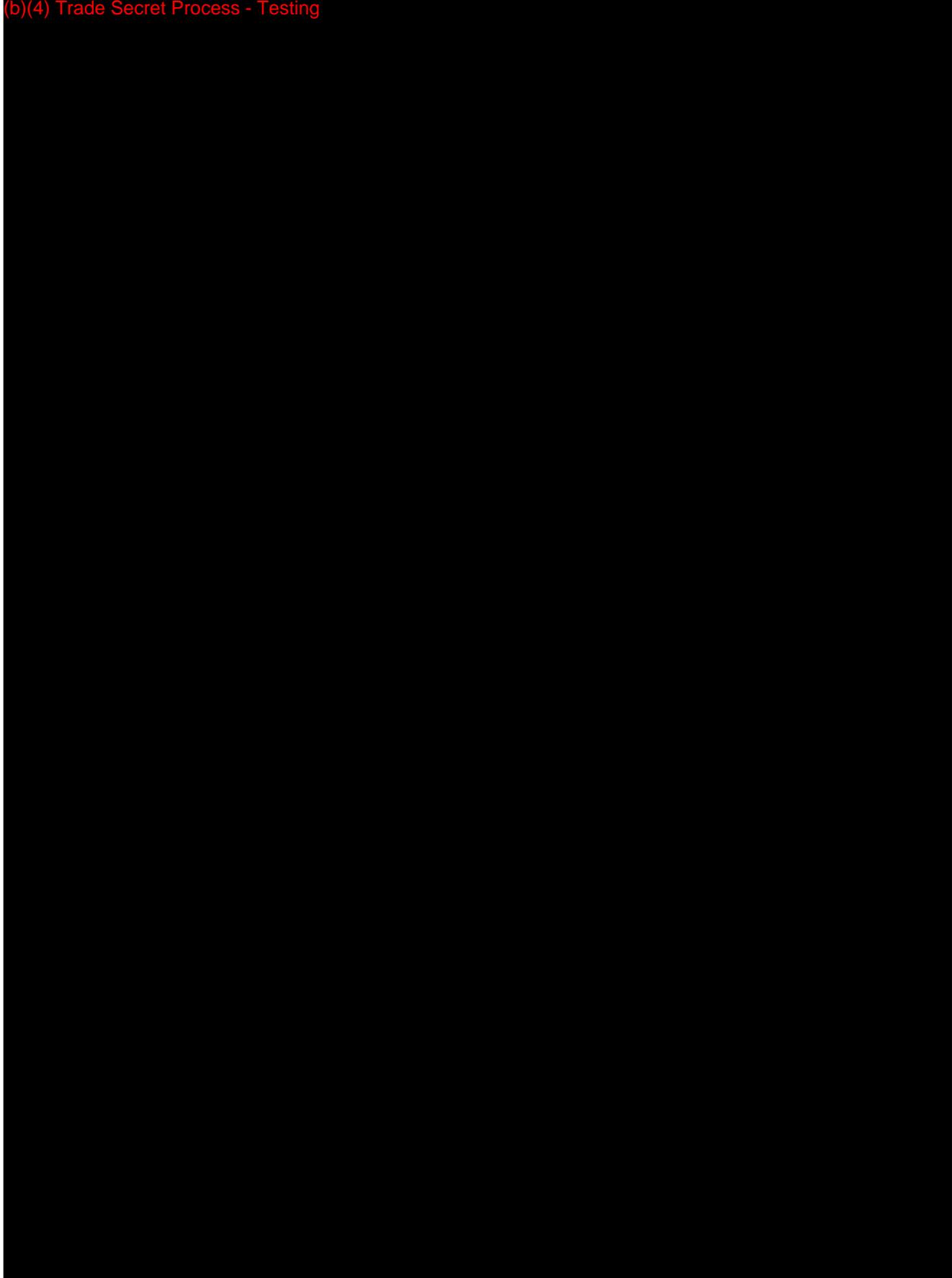












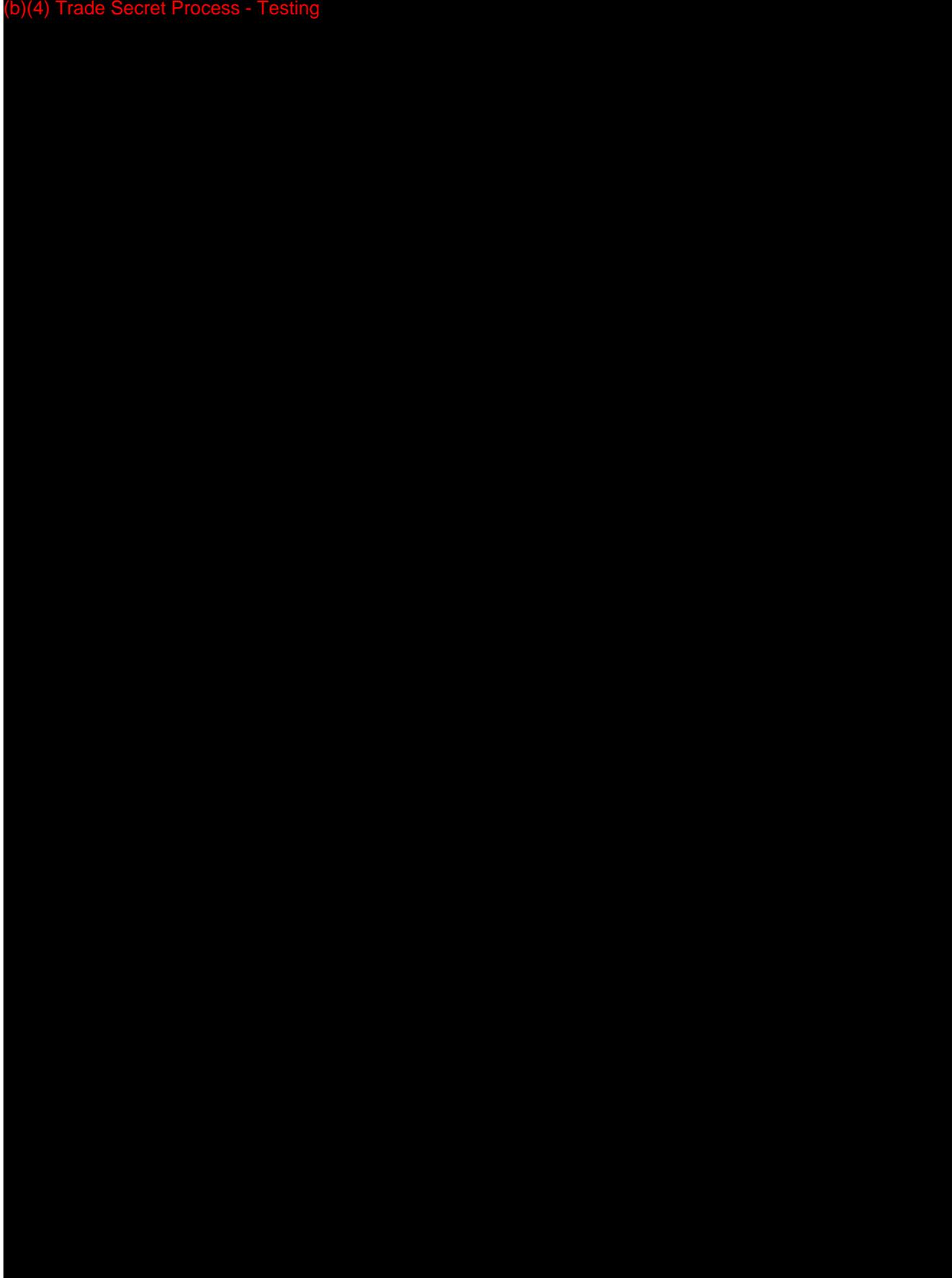








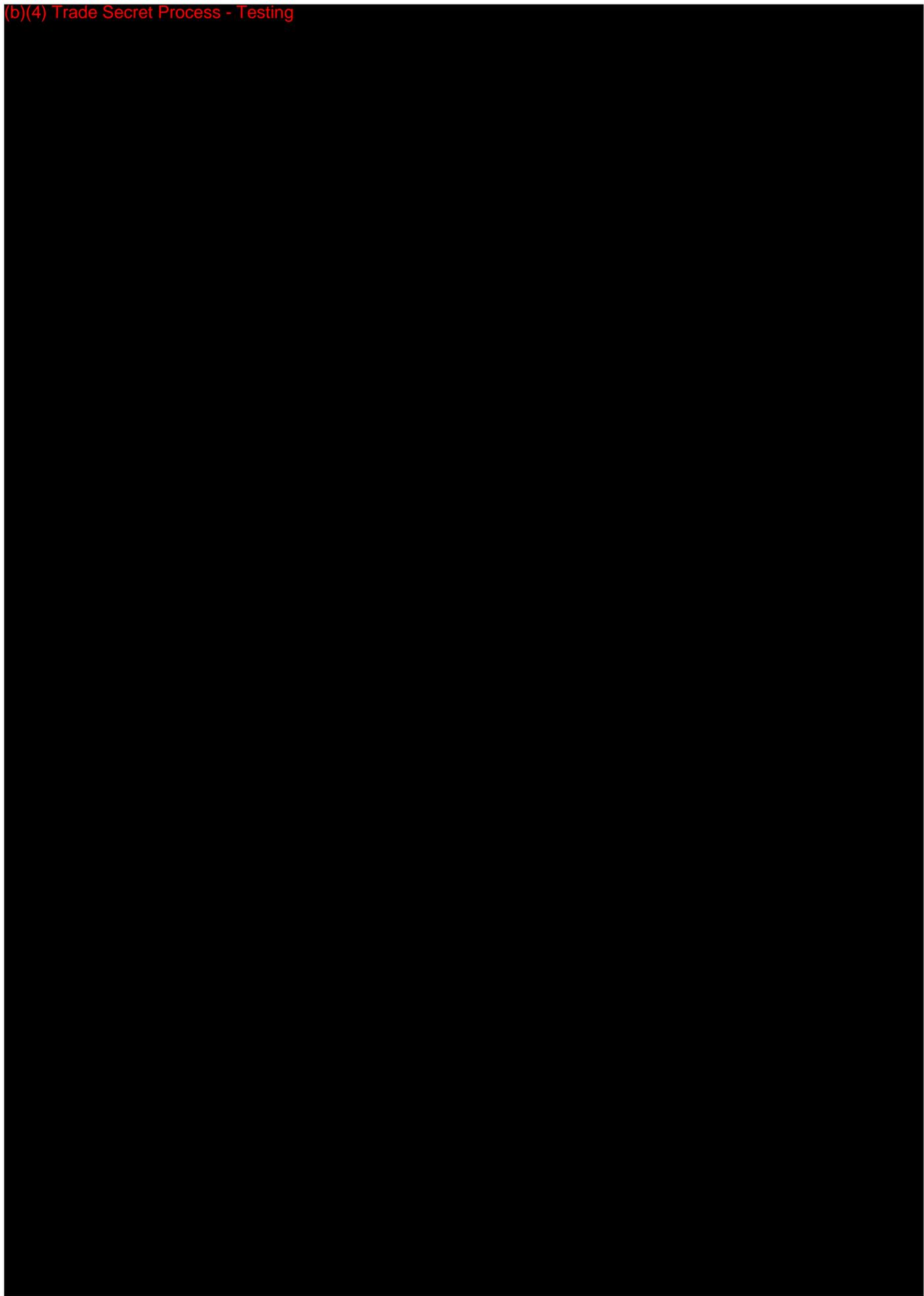


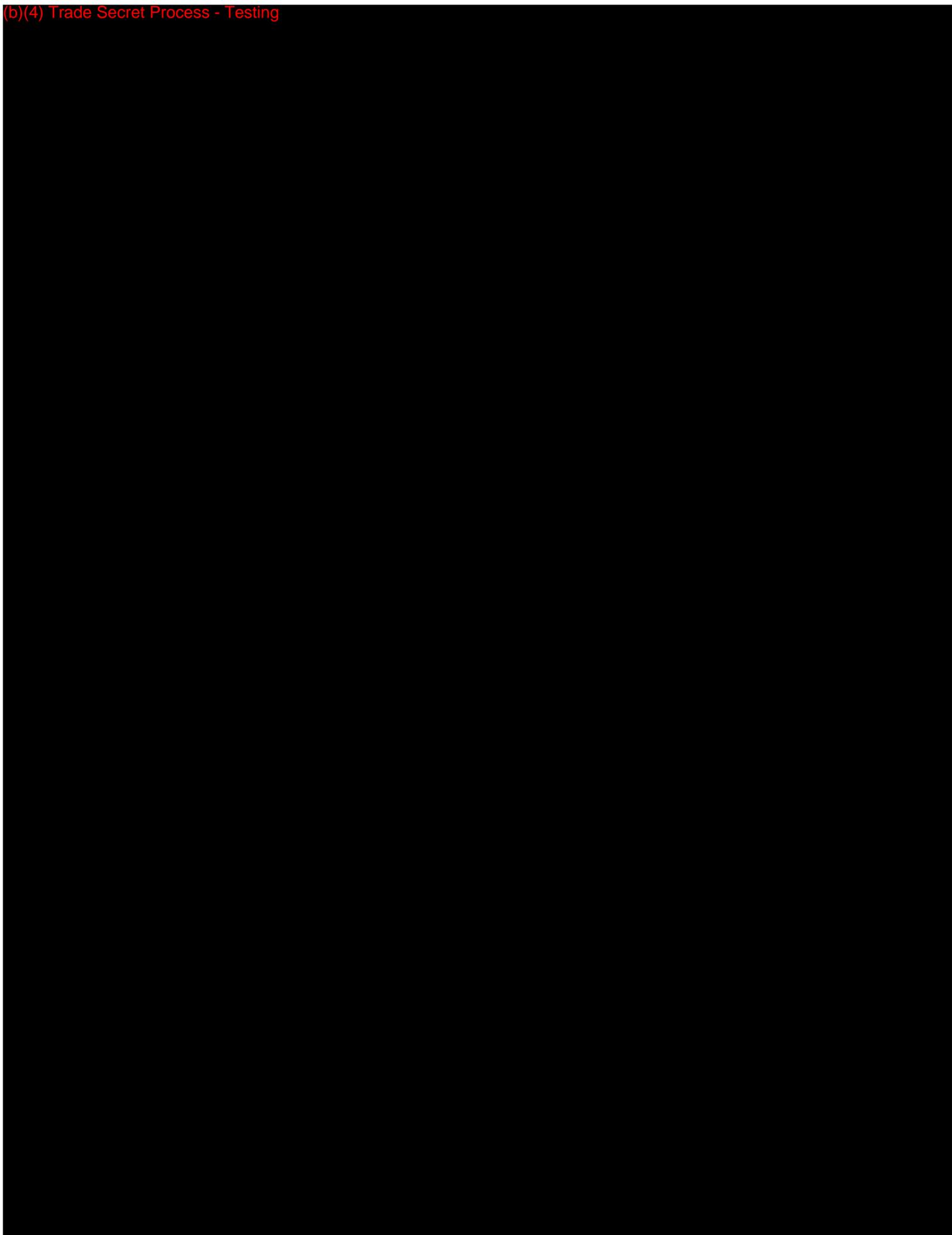


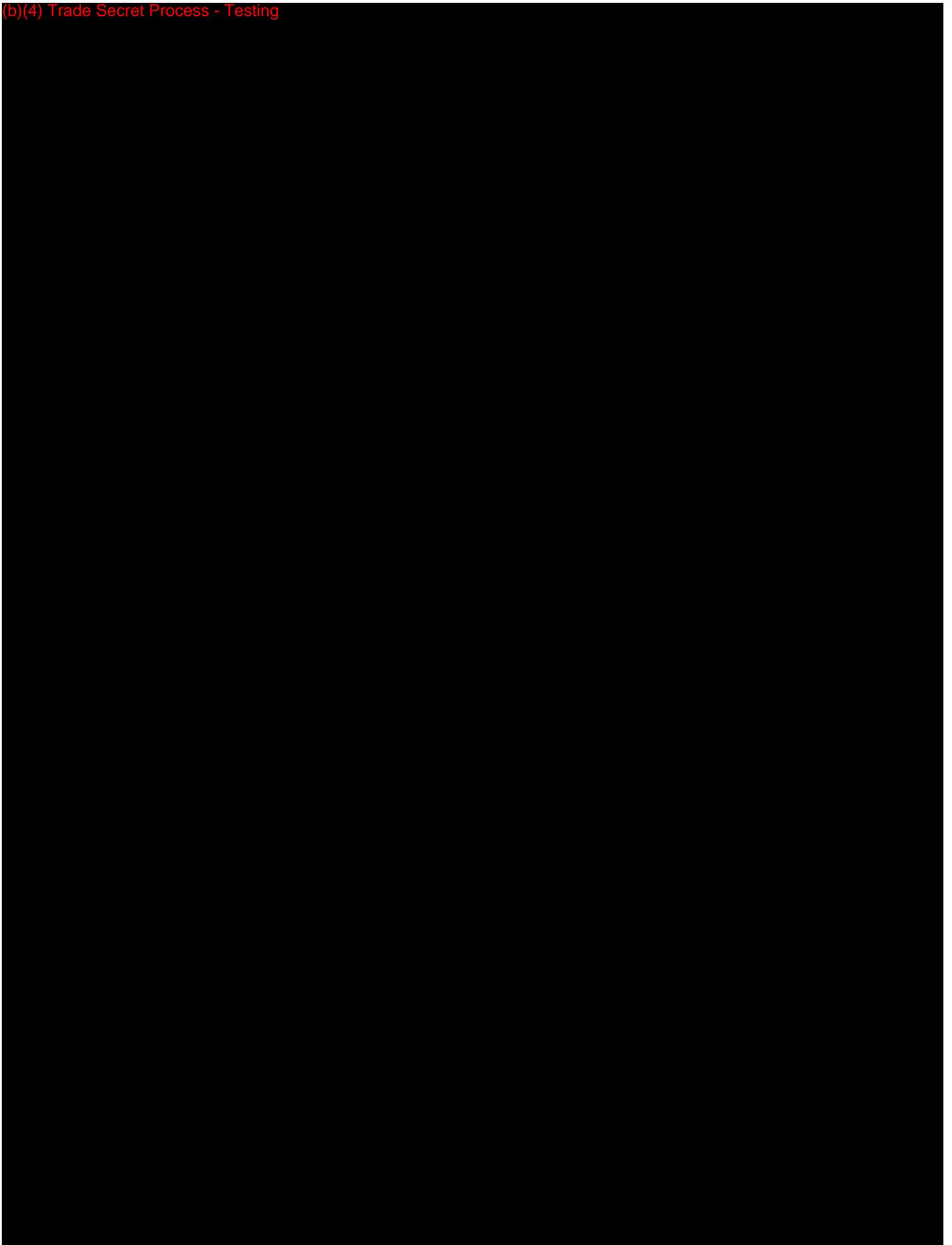




(b)(4) Trade Secret Process - Testing







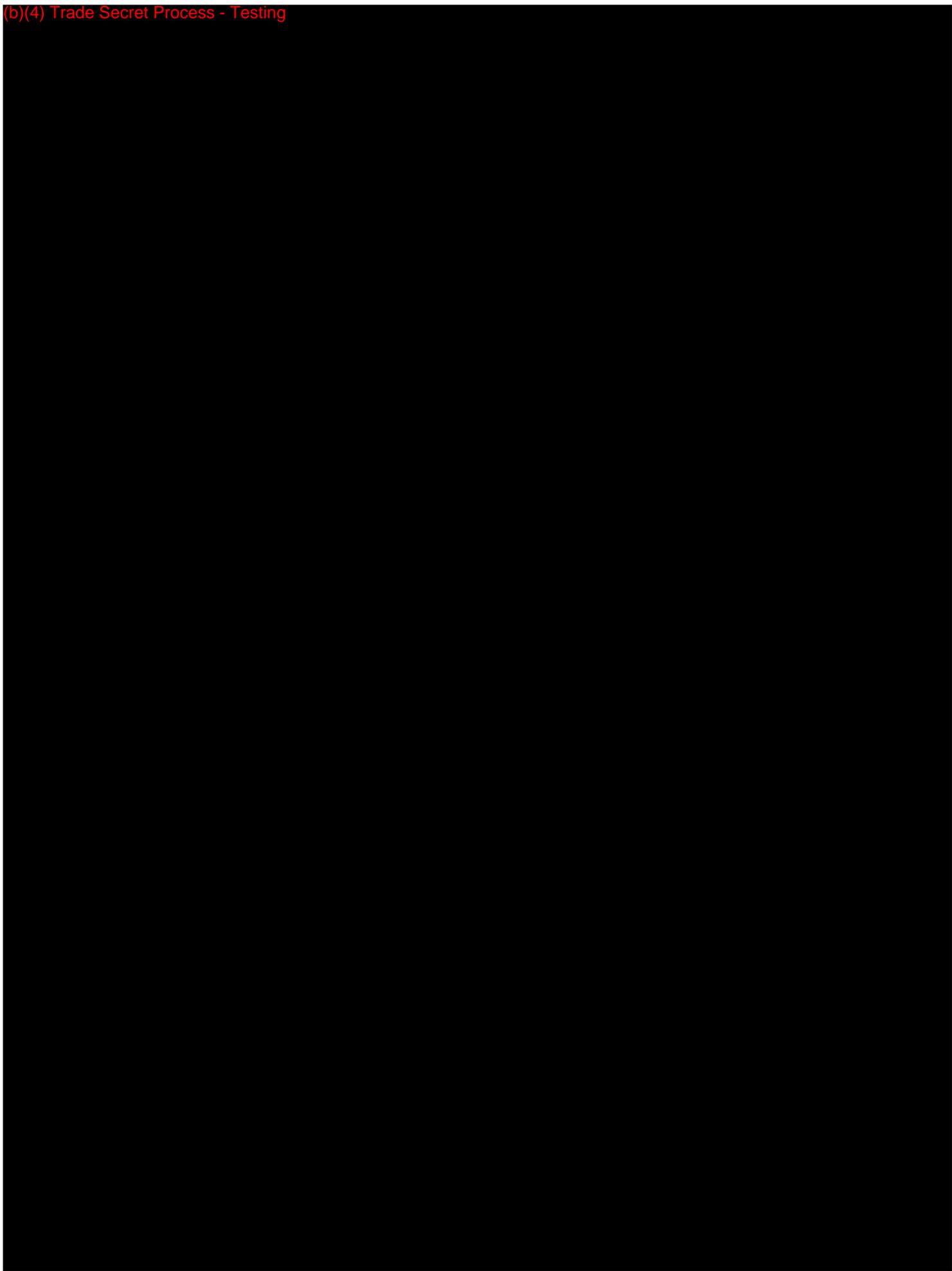






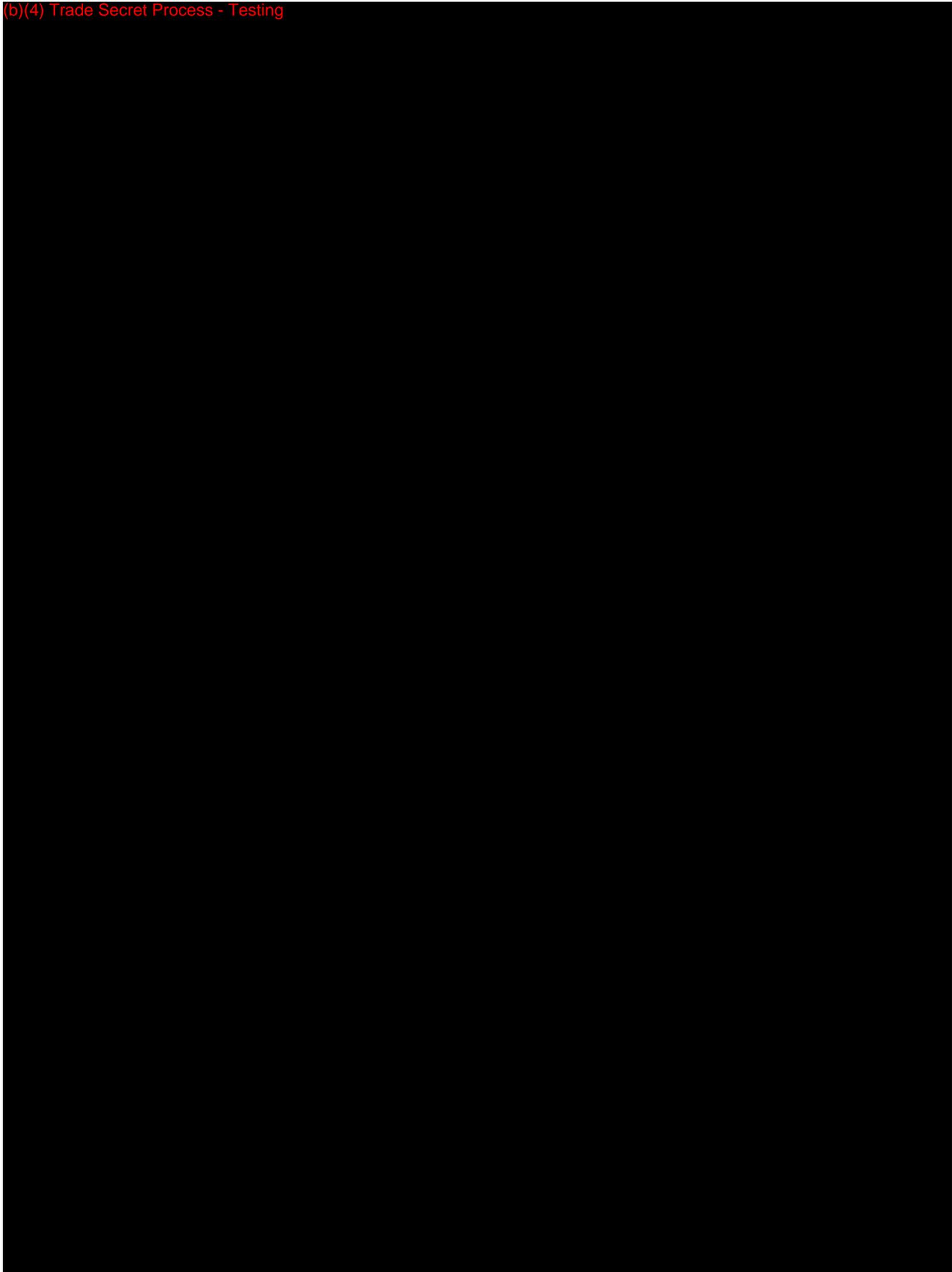




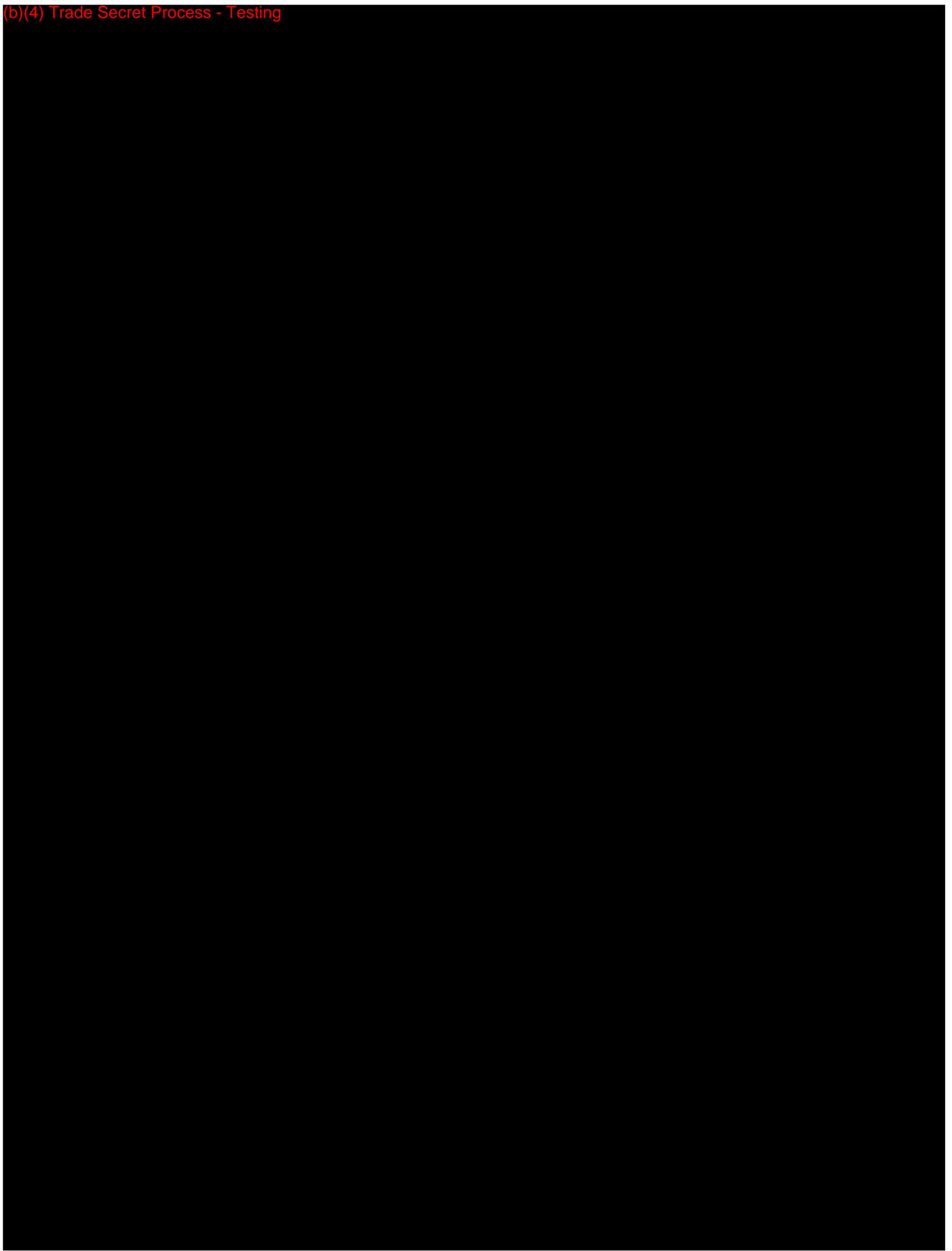




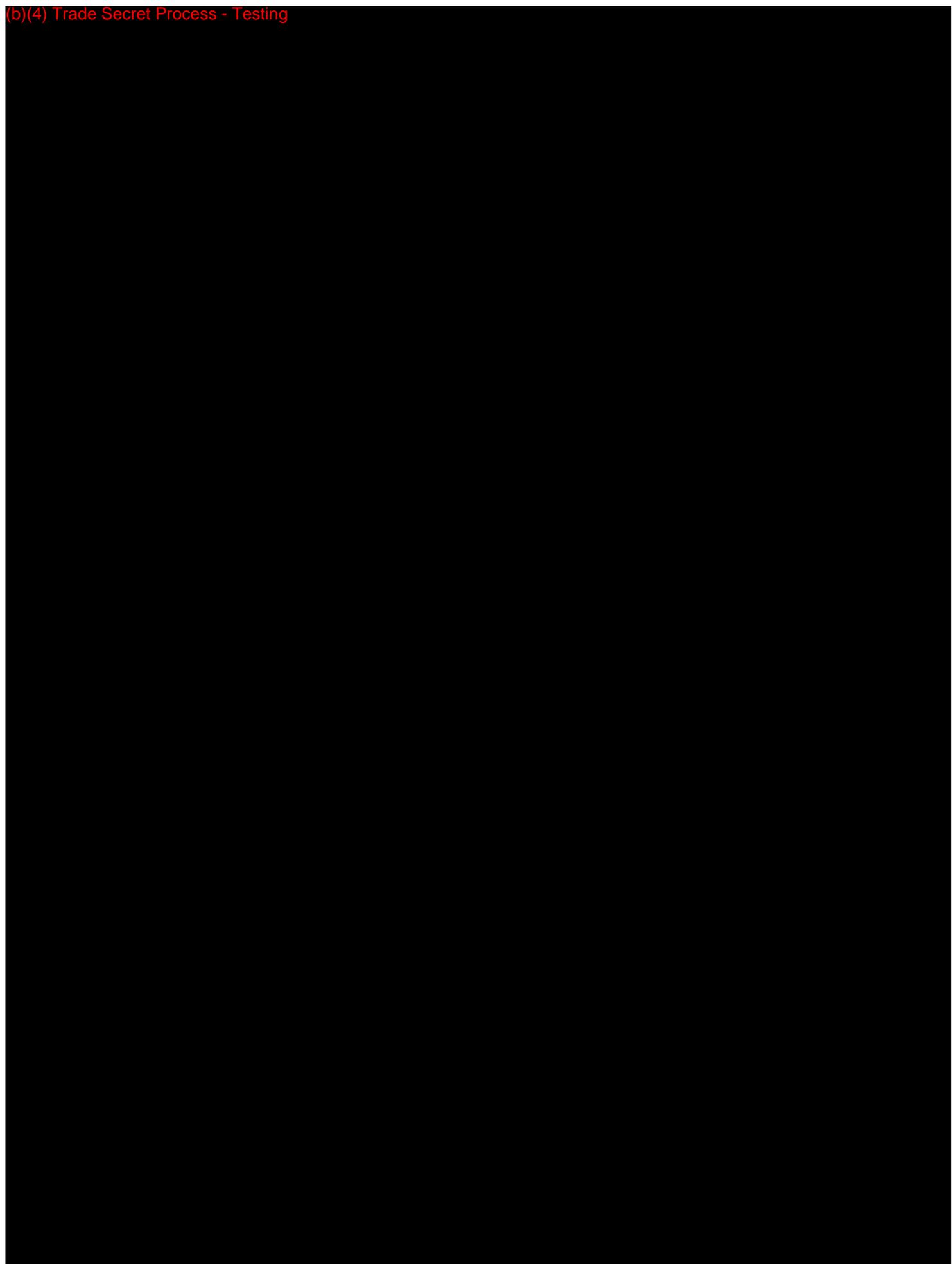






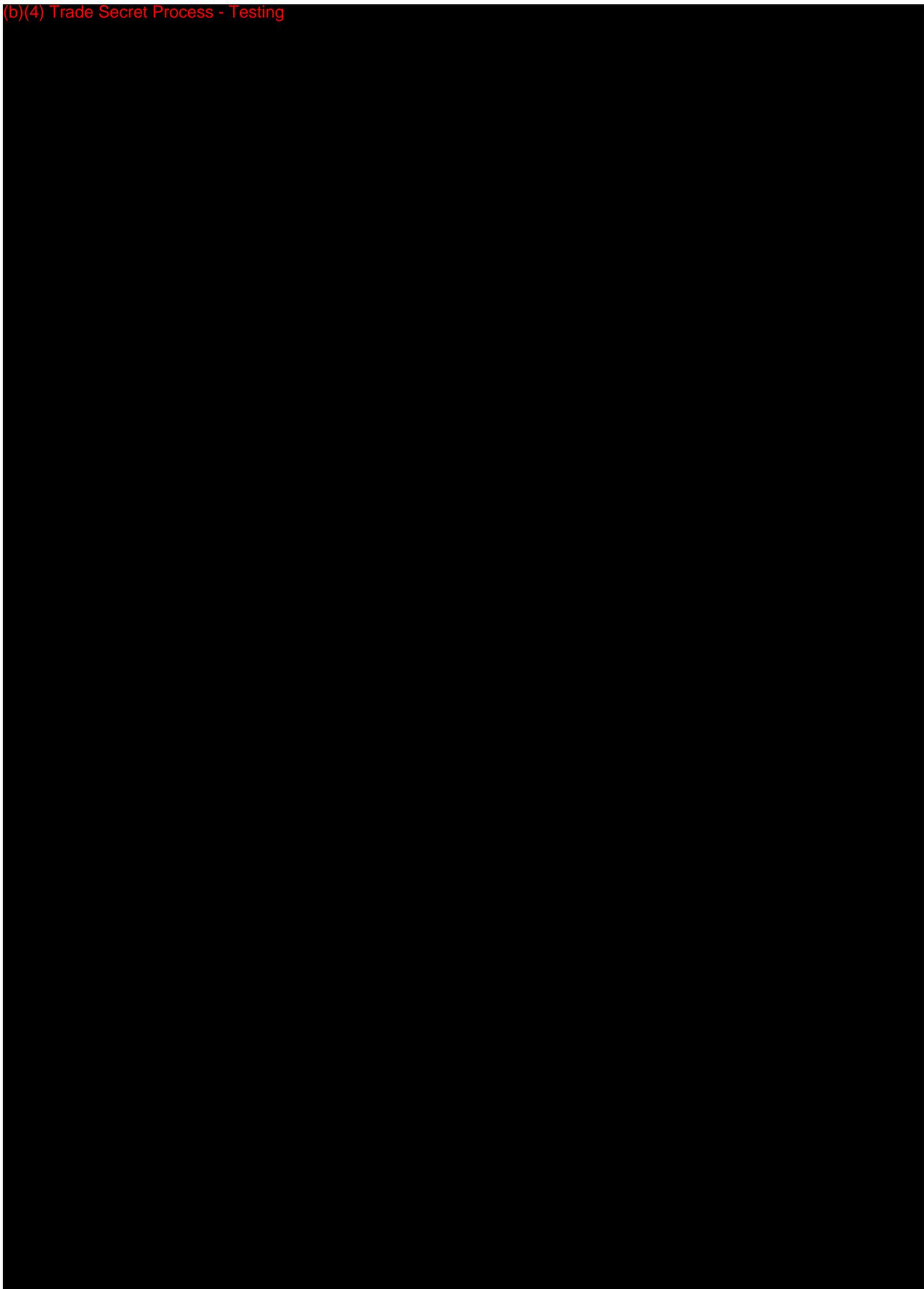


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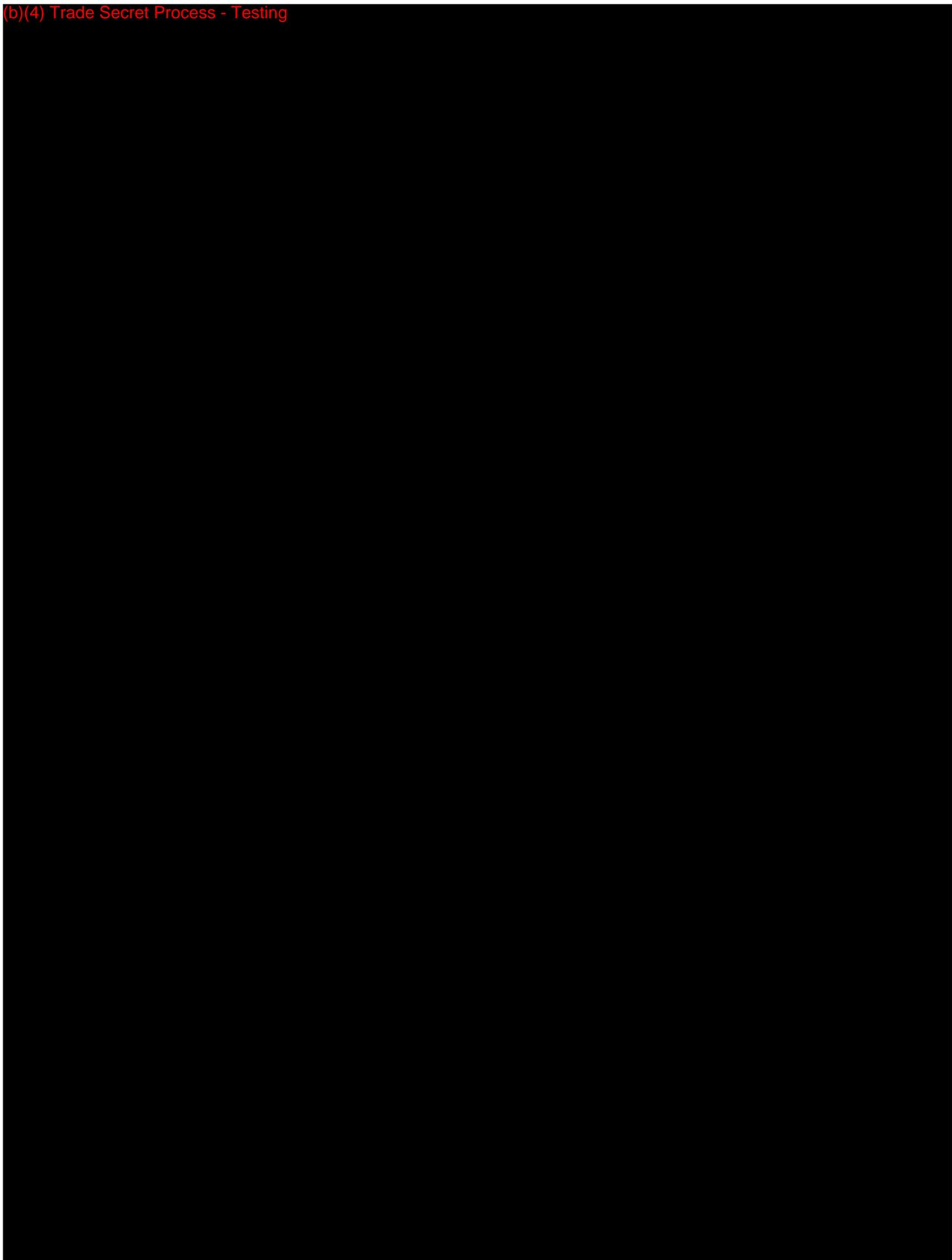


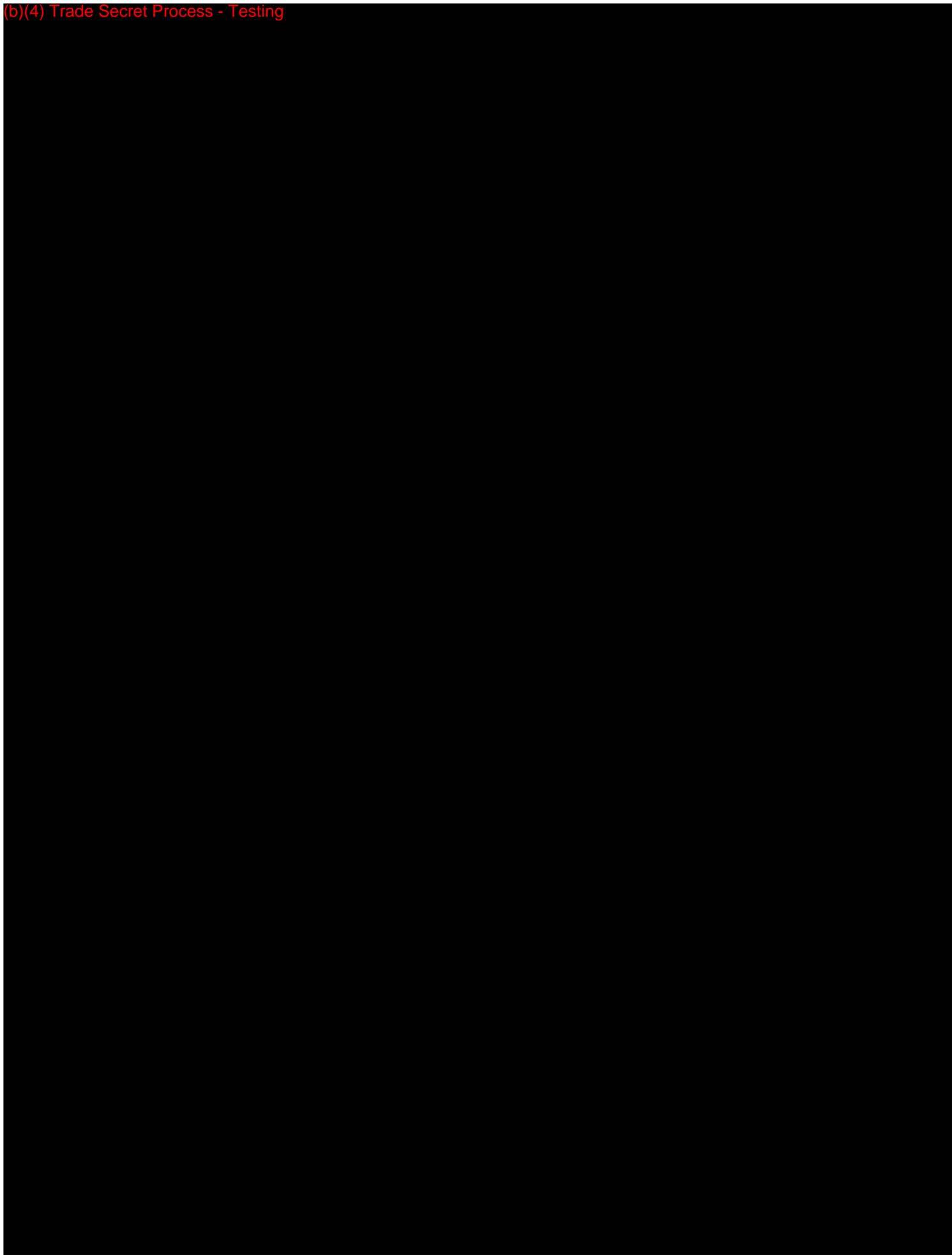






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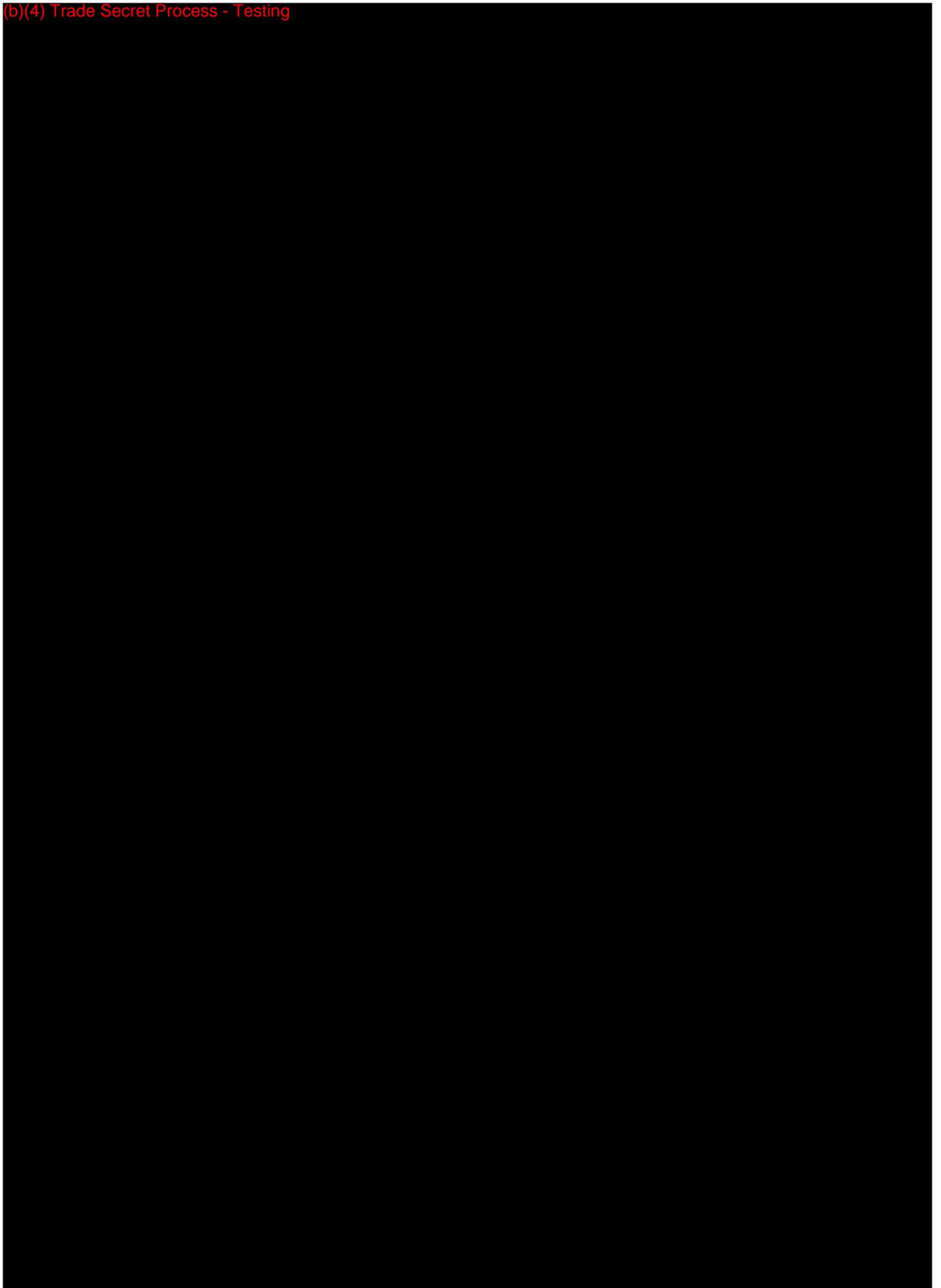




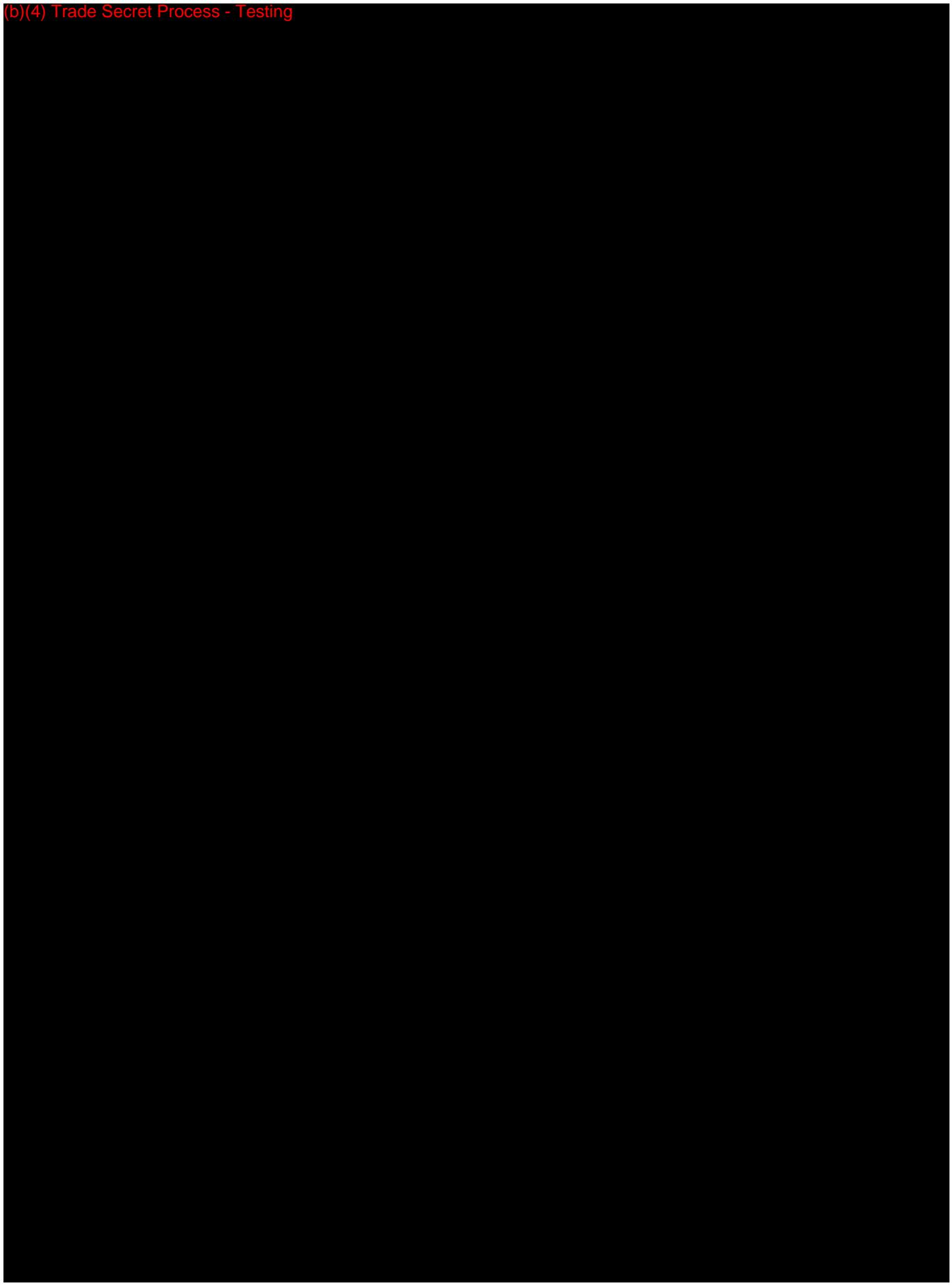


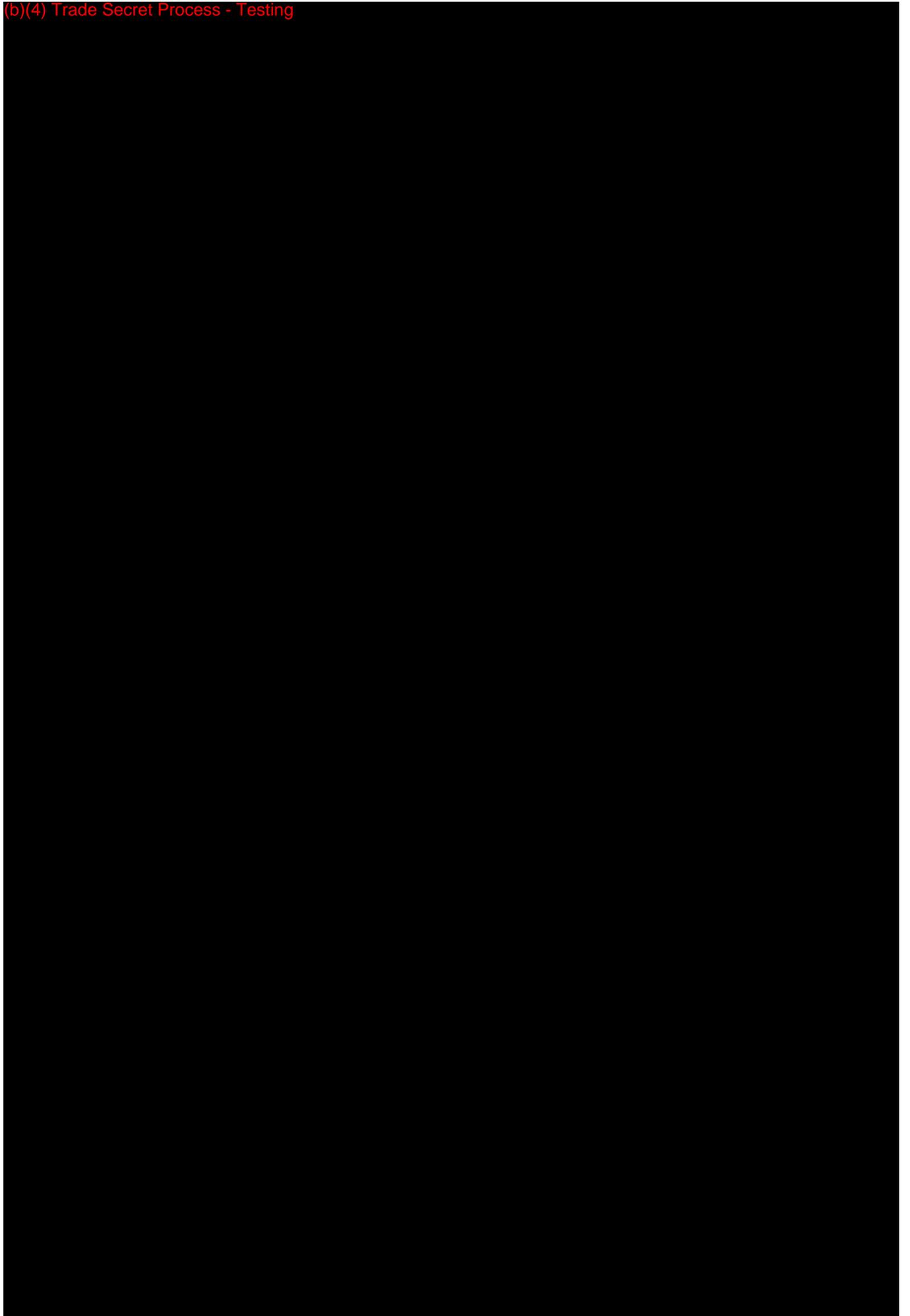




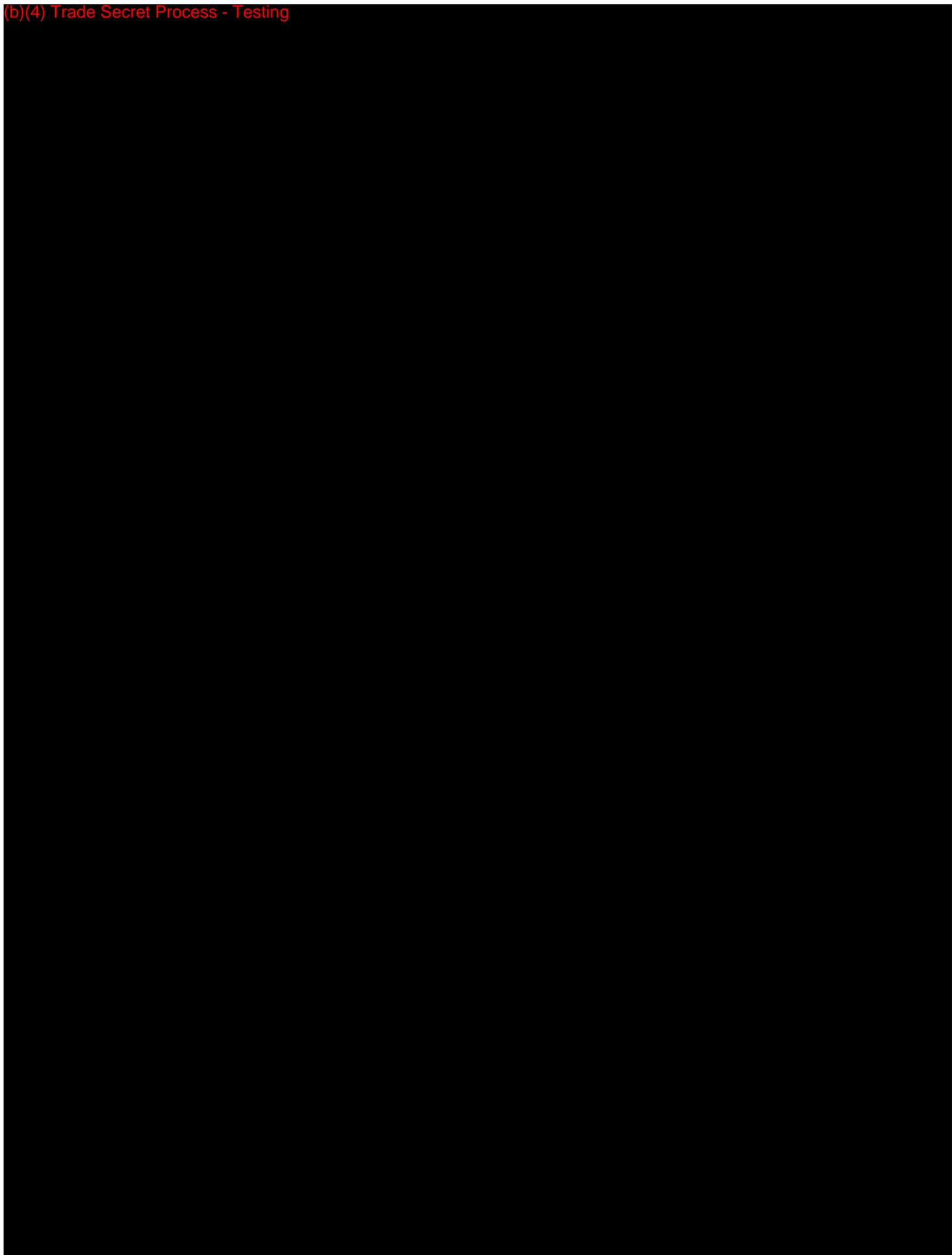


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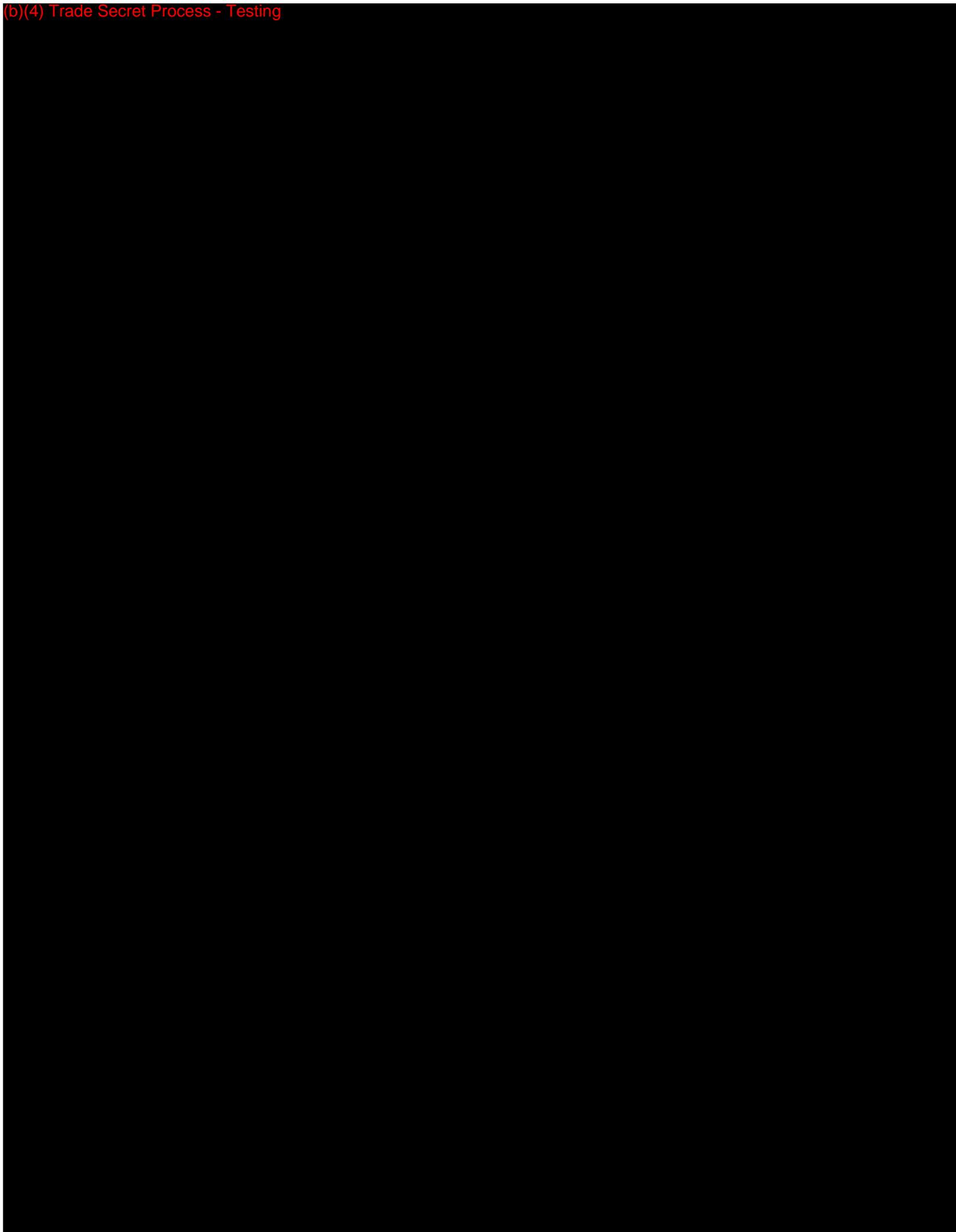




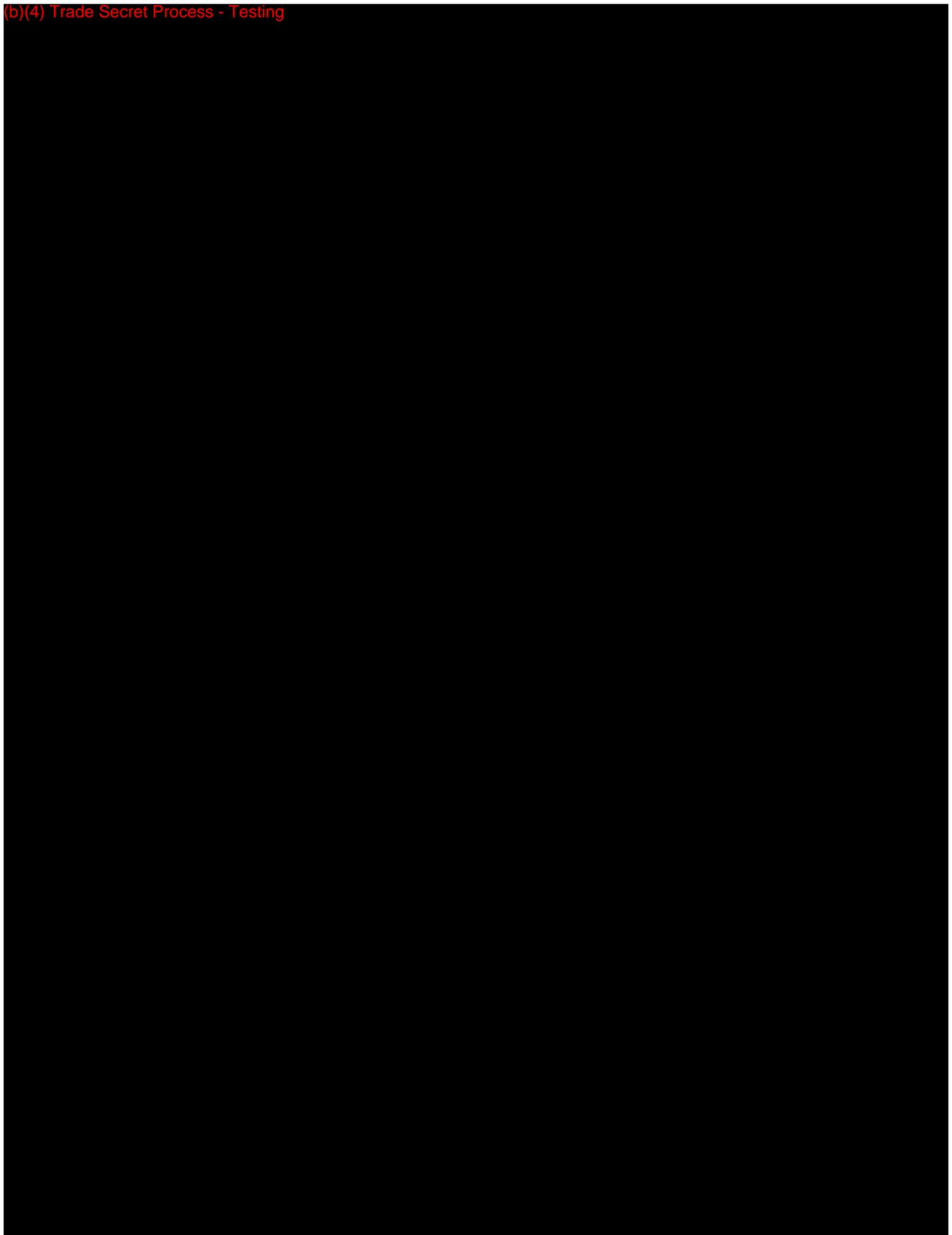
(b)(4) Trade Secret Process - Testing



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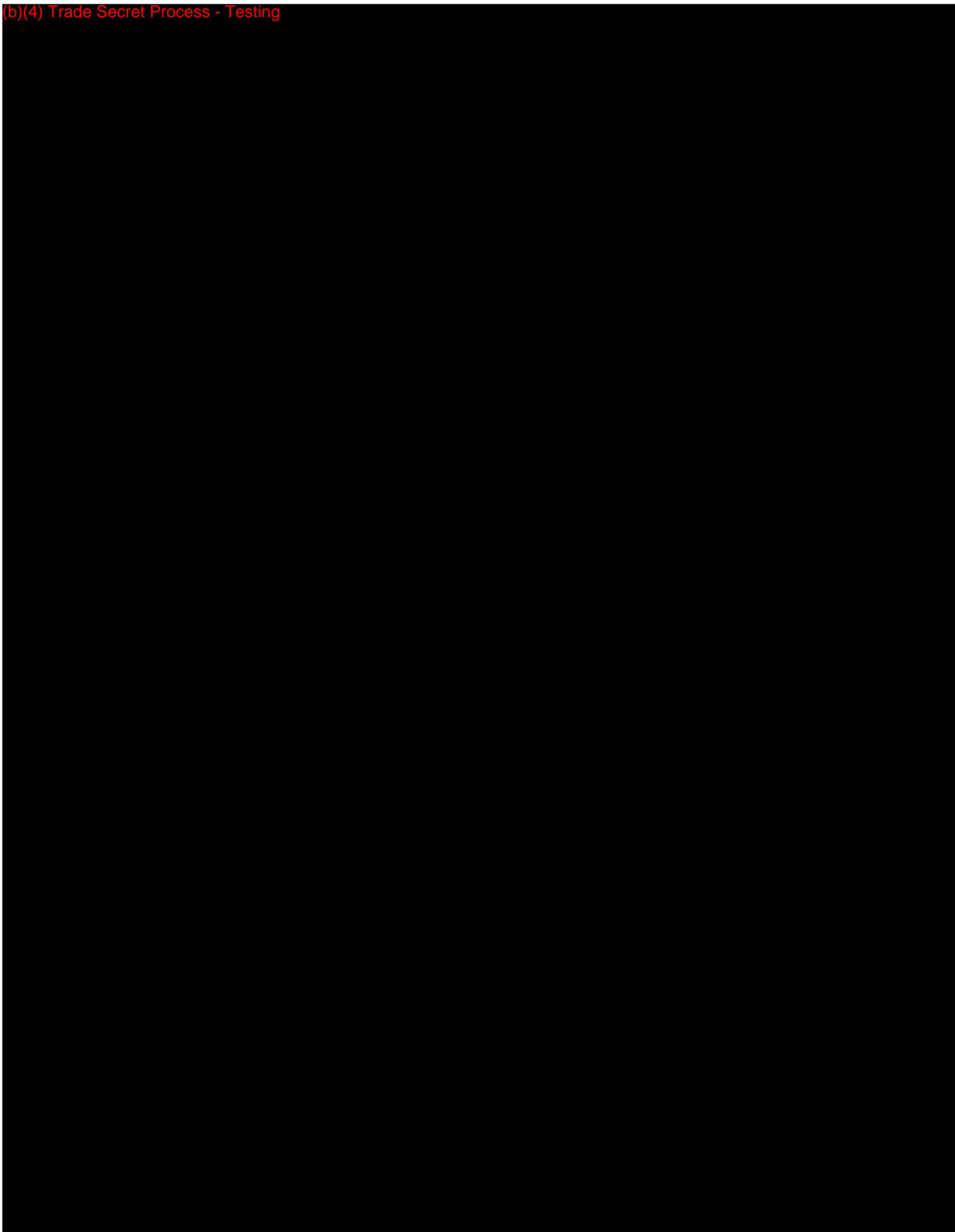


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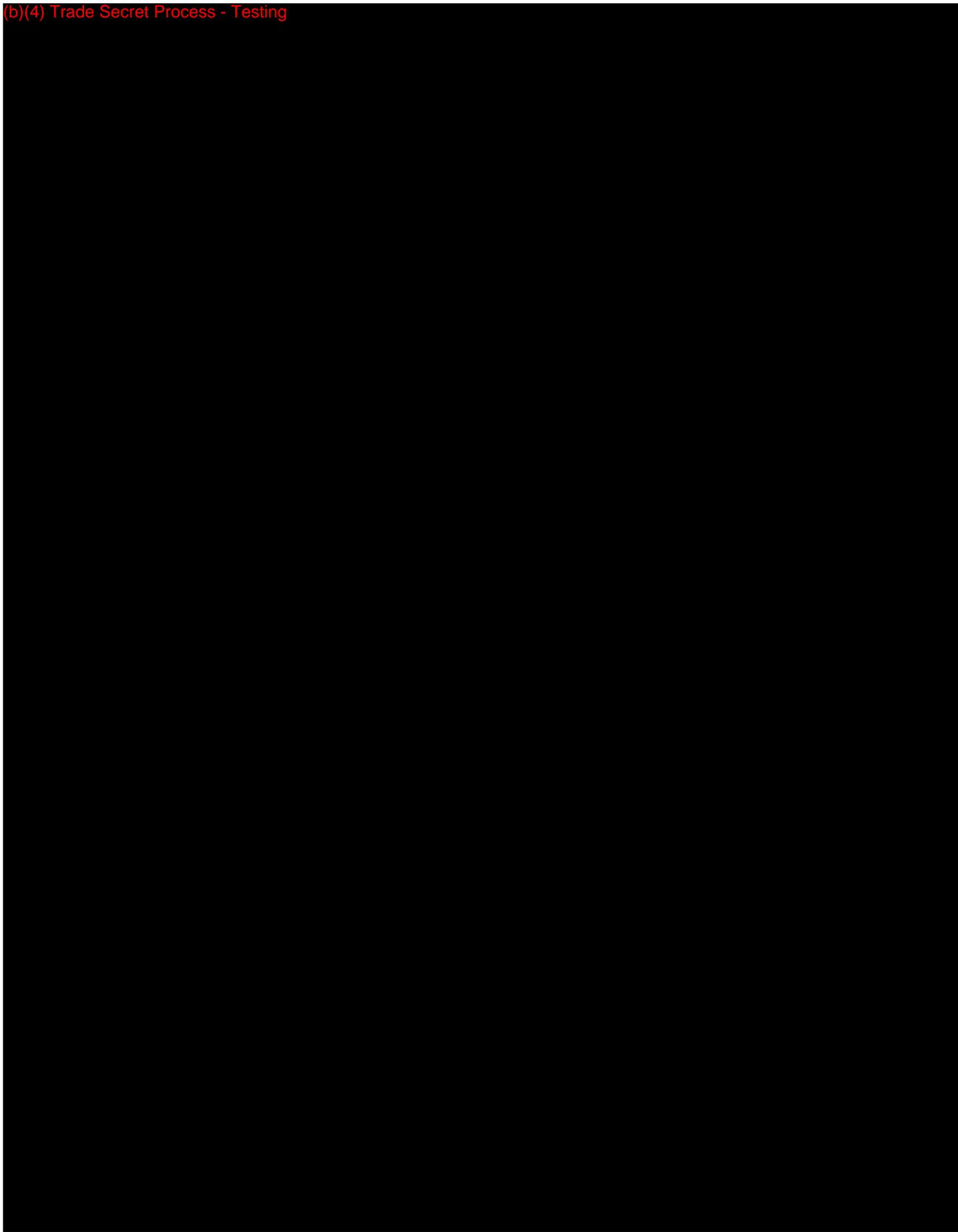




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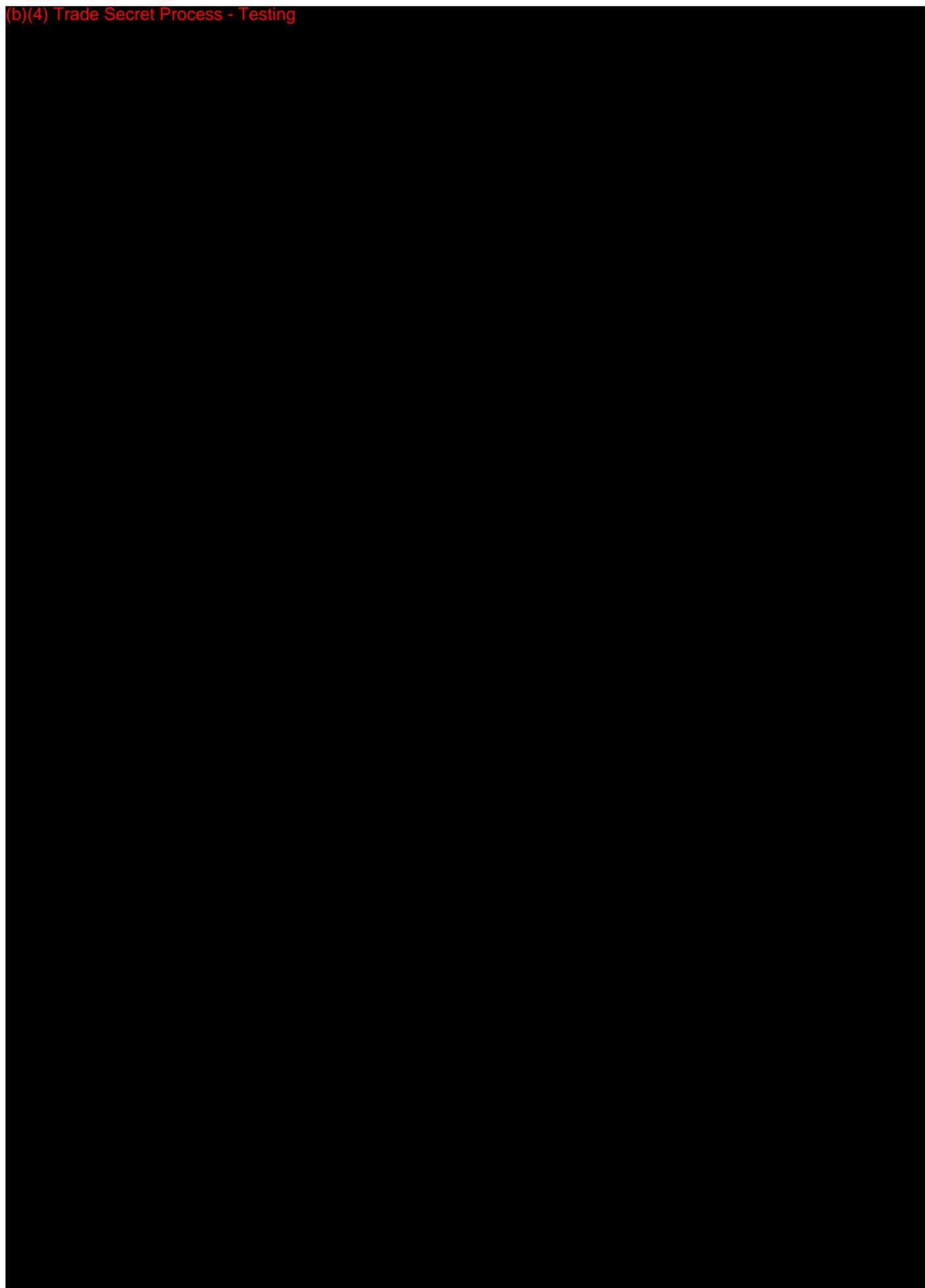


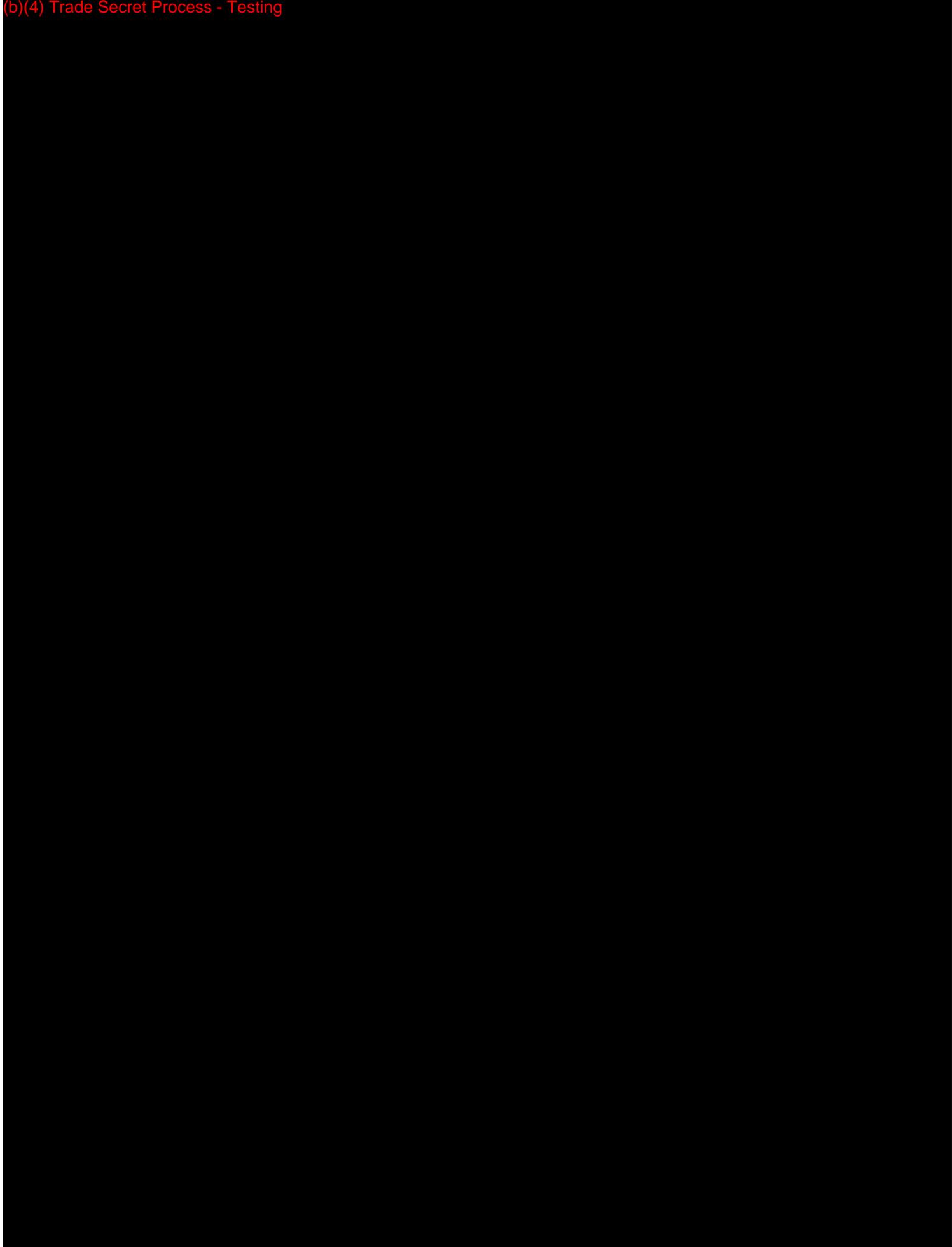
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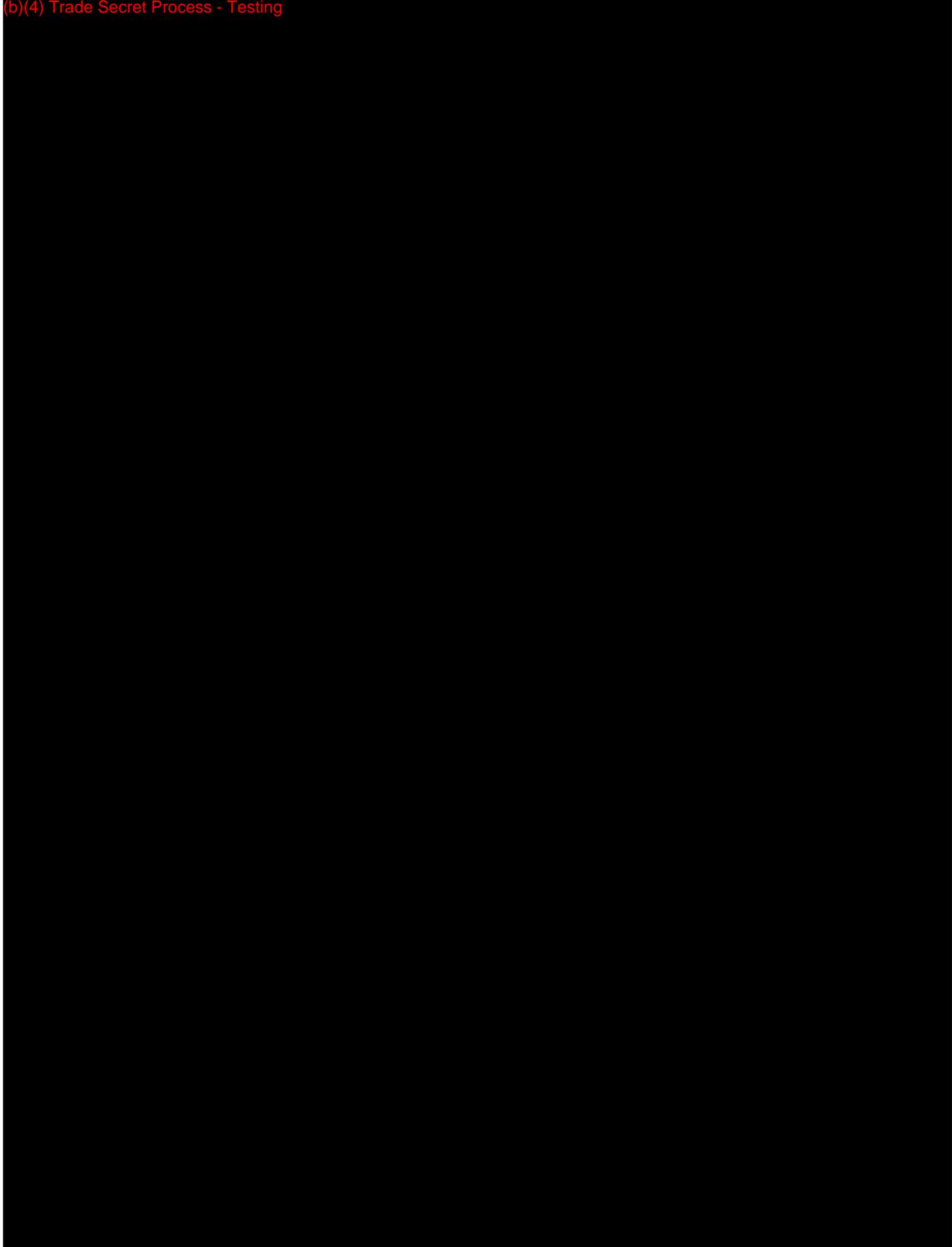


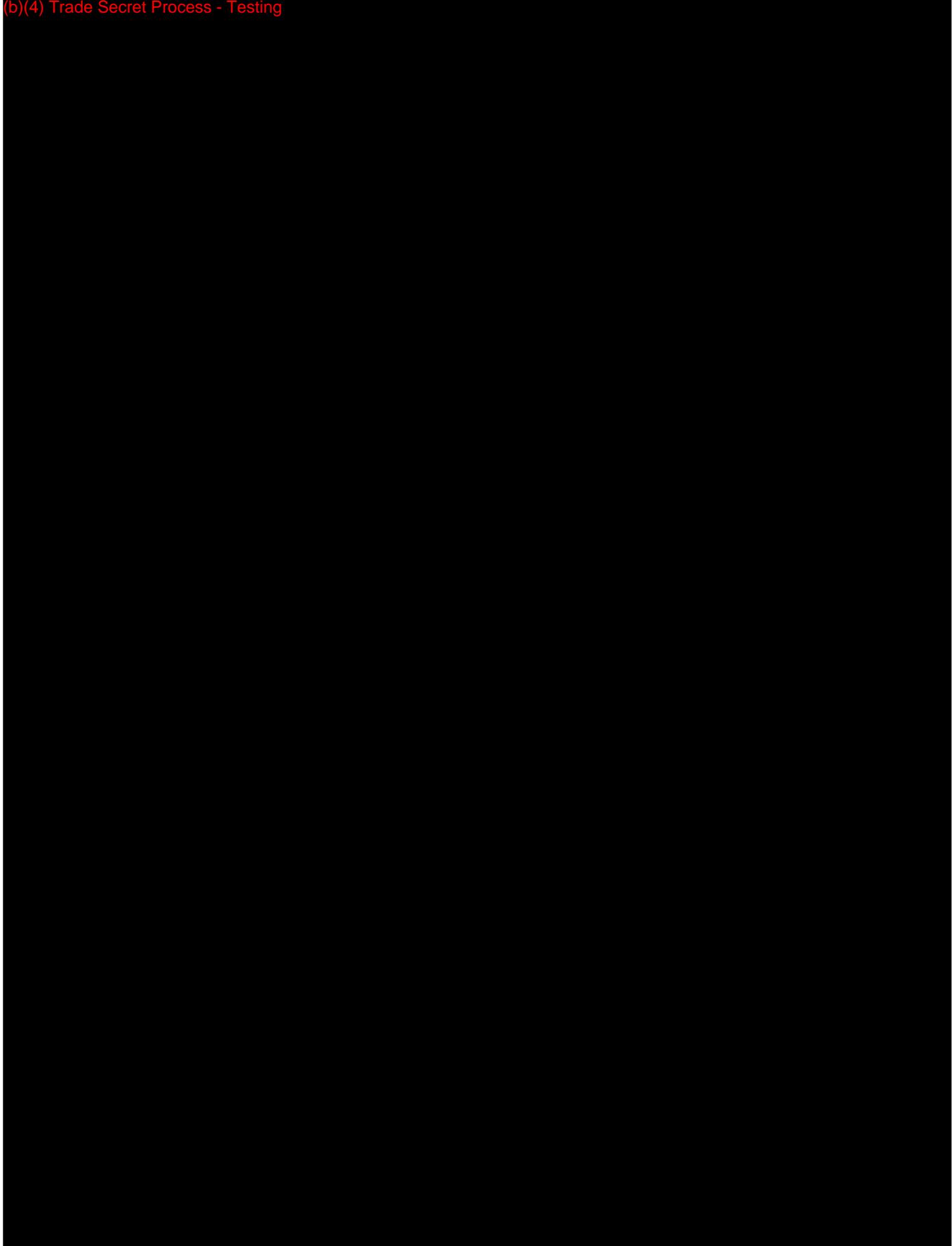


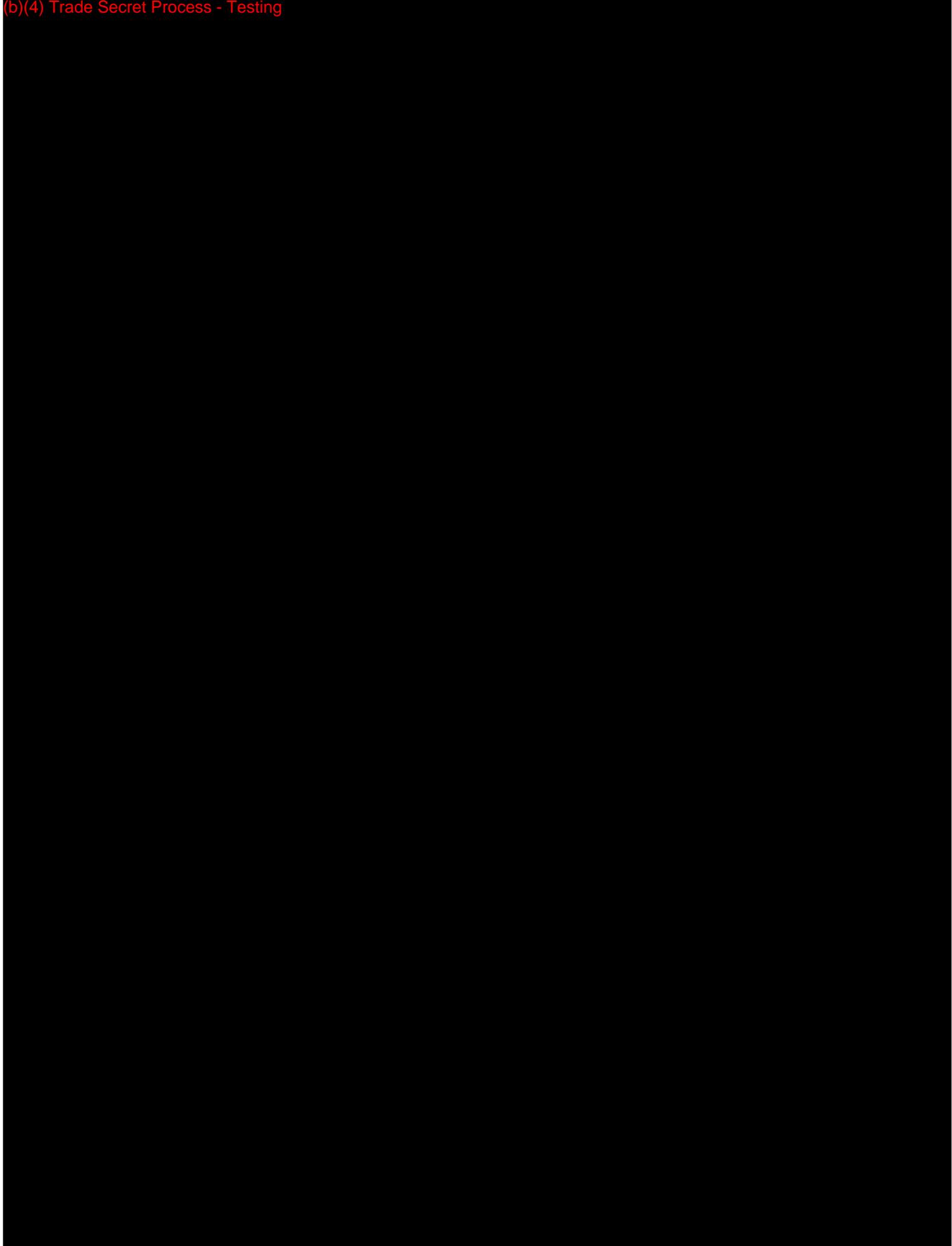
(b)(4) Trade Secret Process - Testing

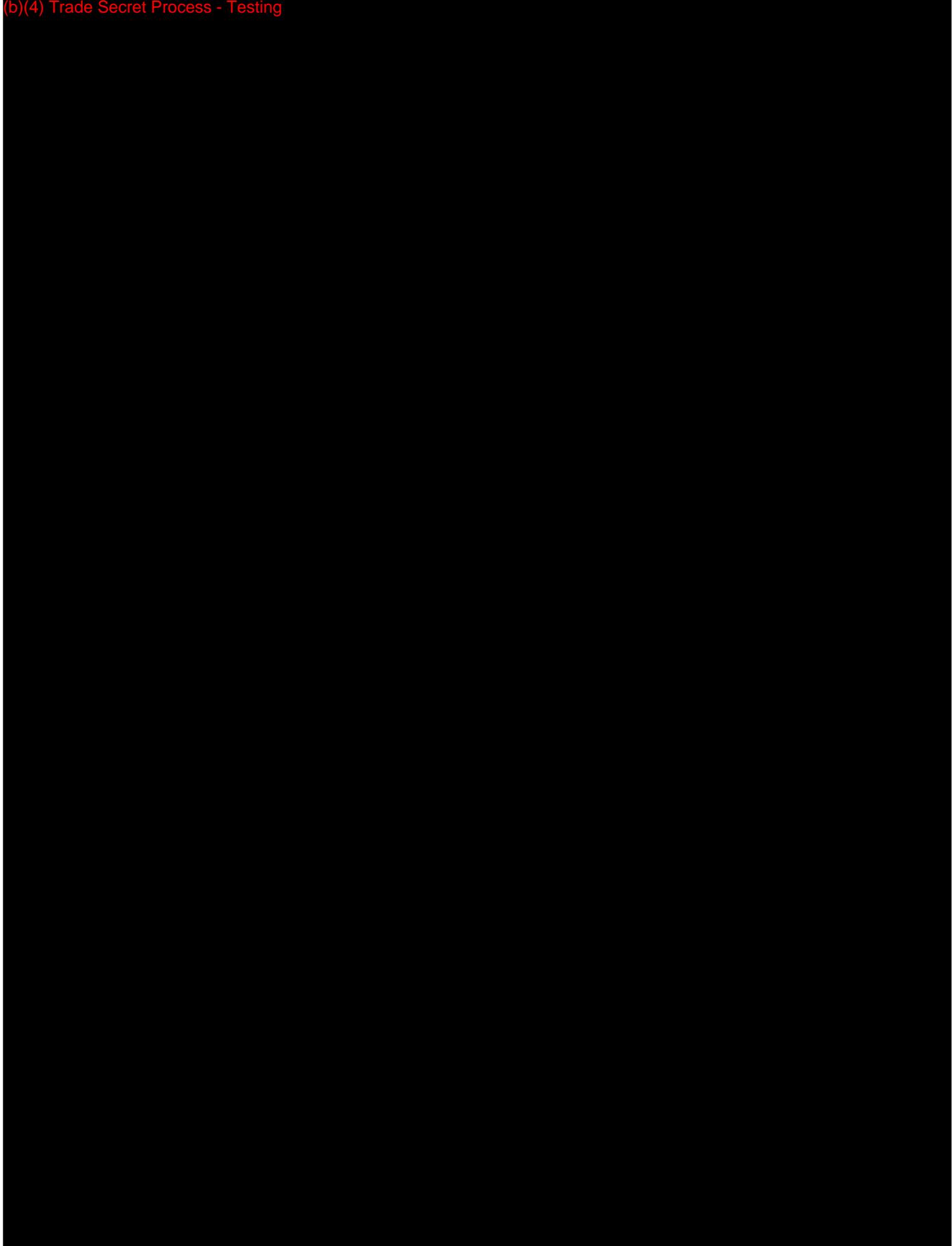


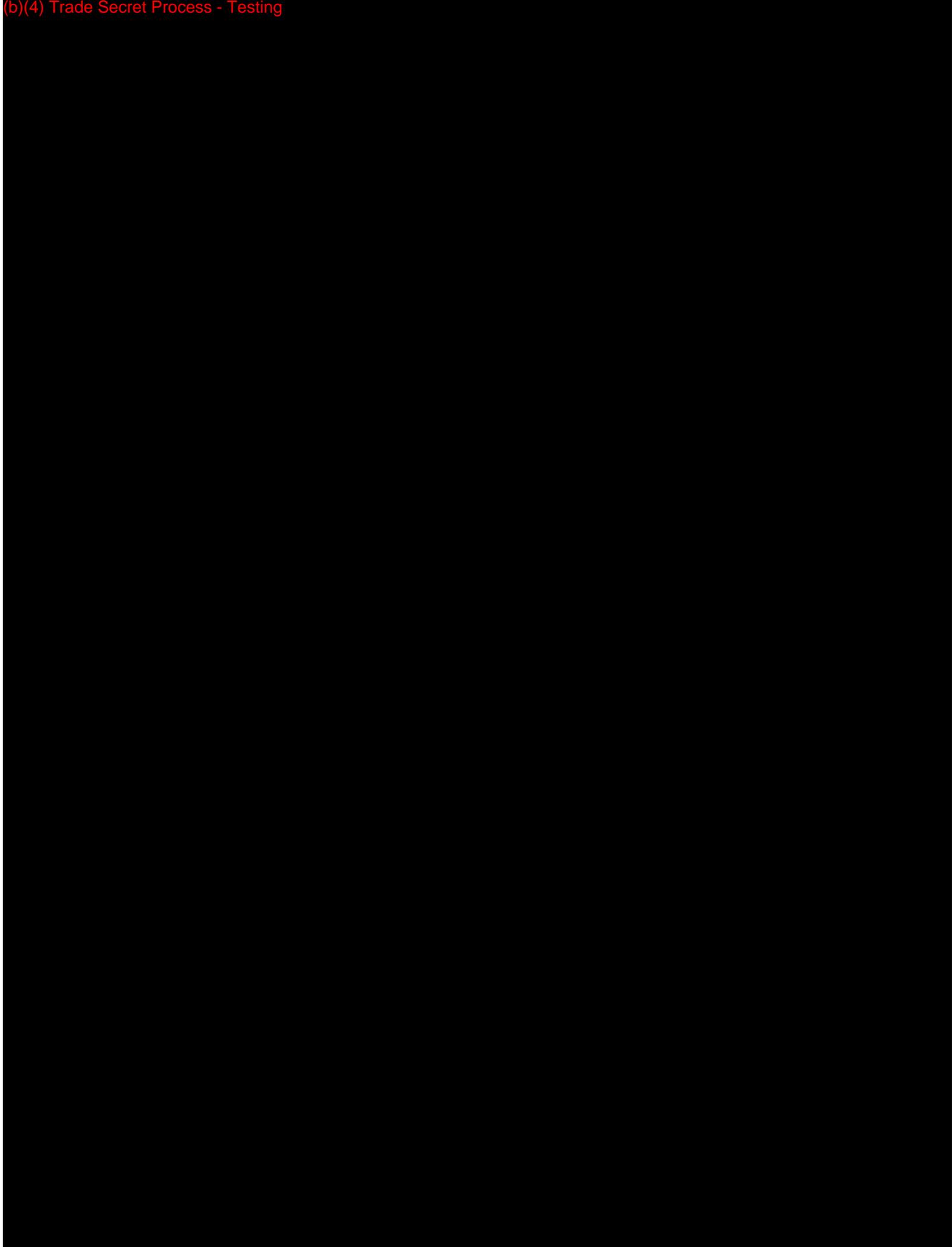


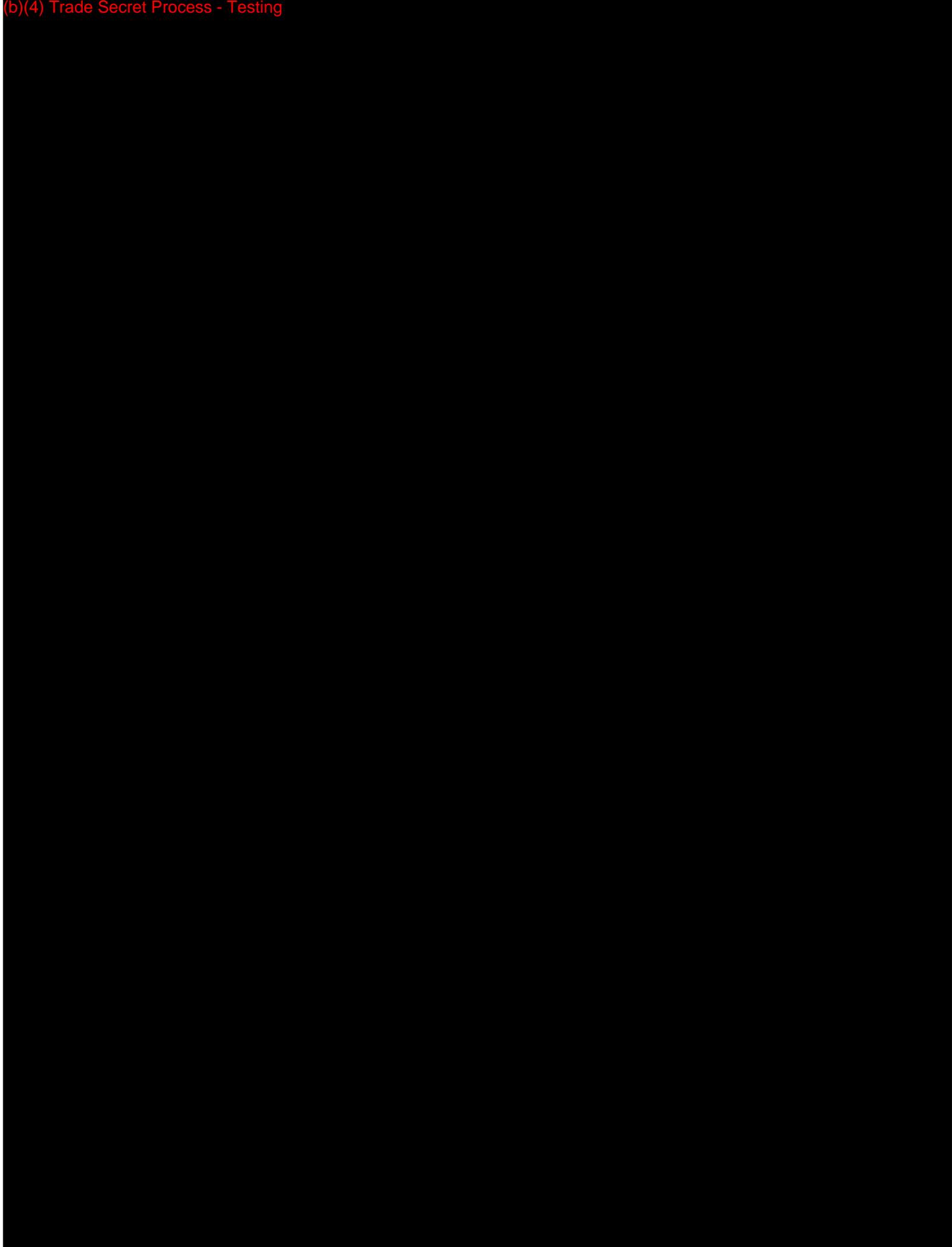


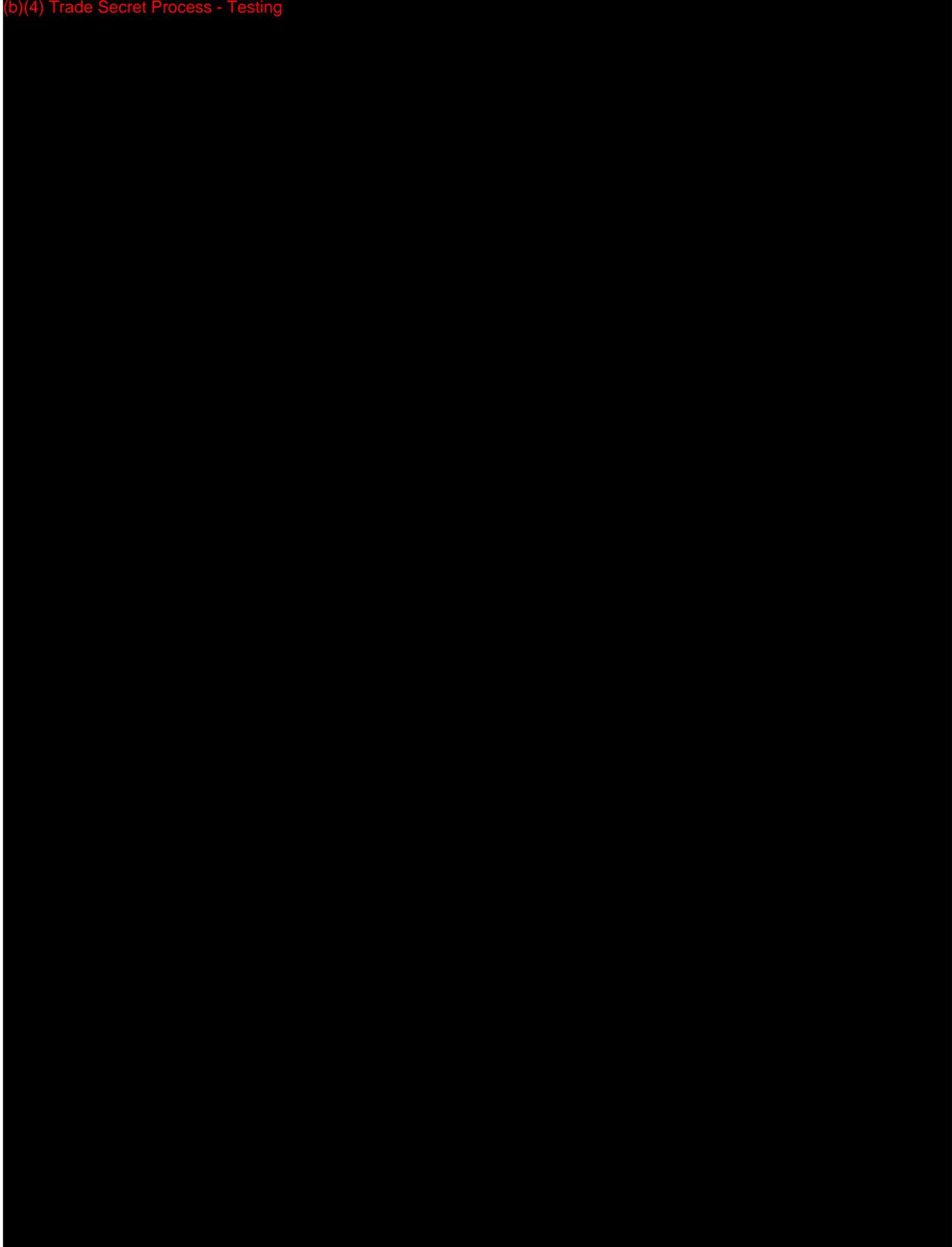


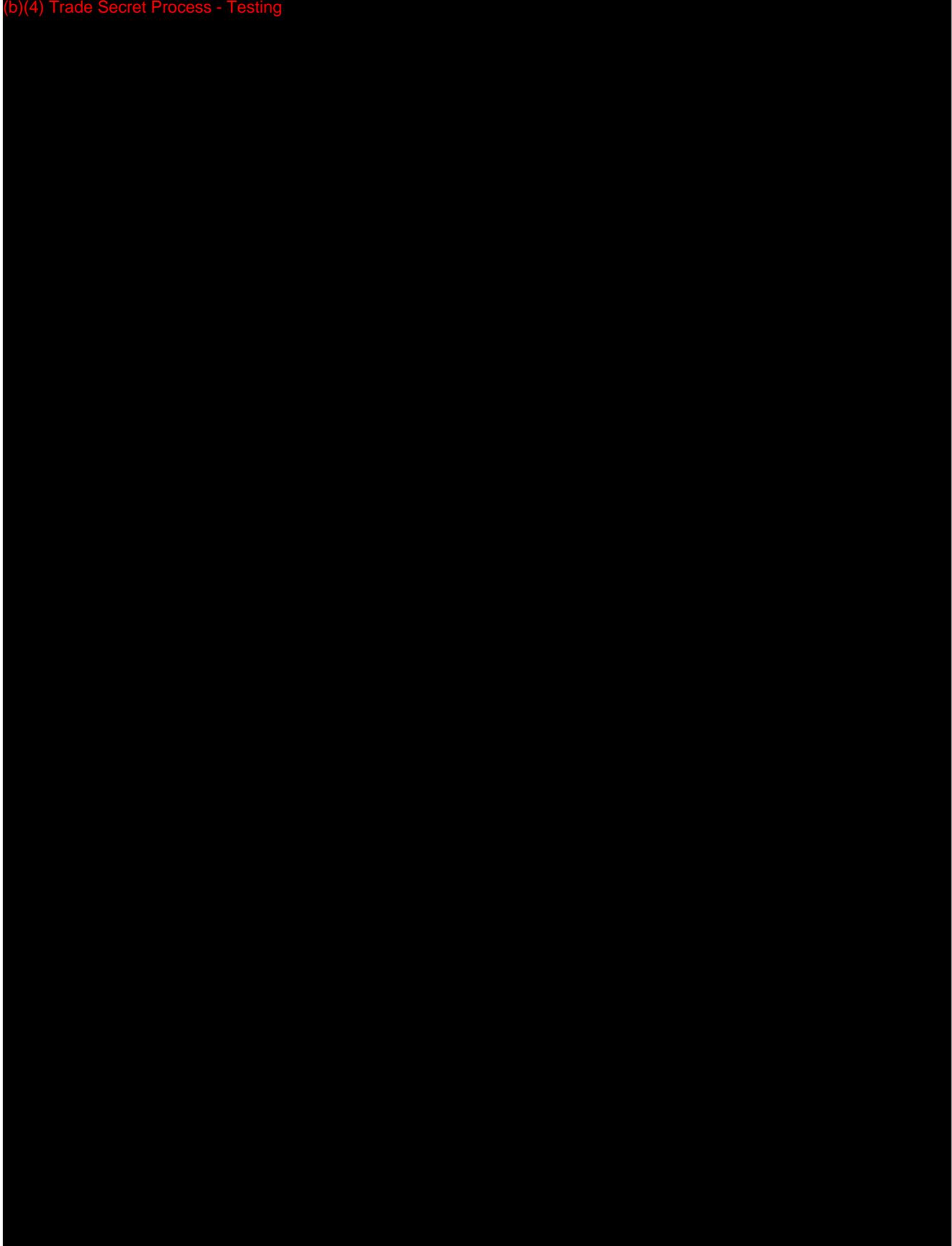


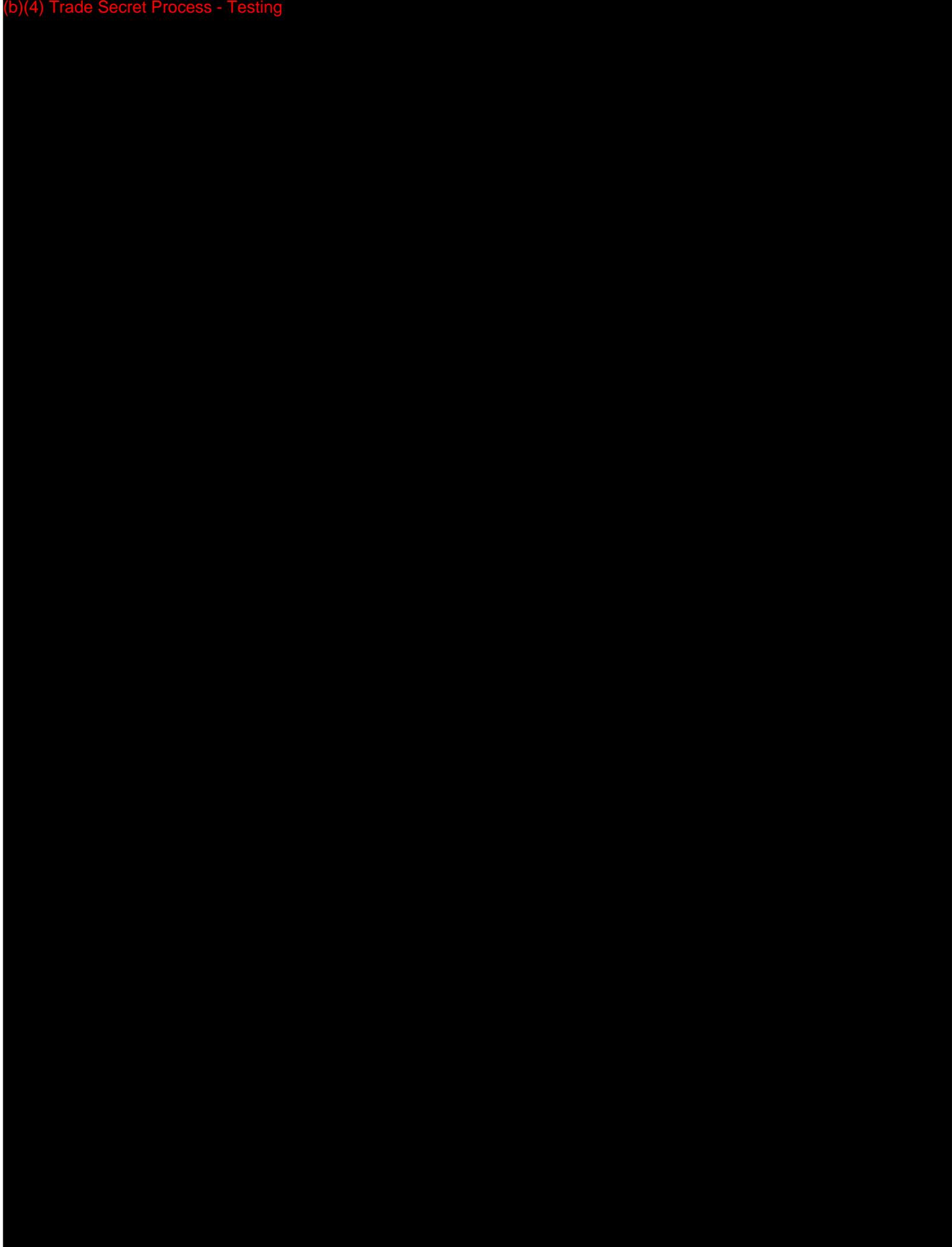


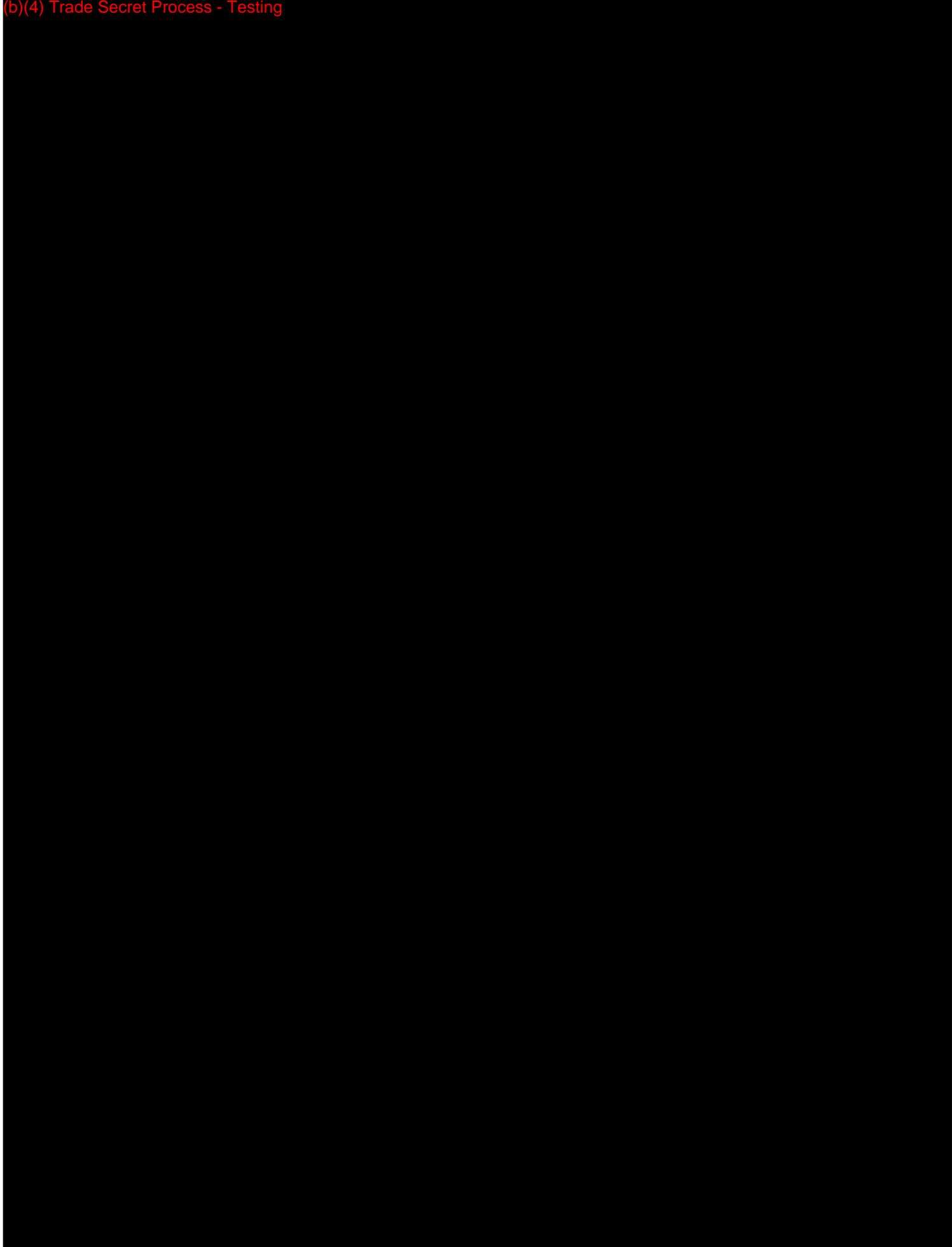


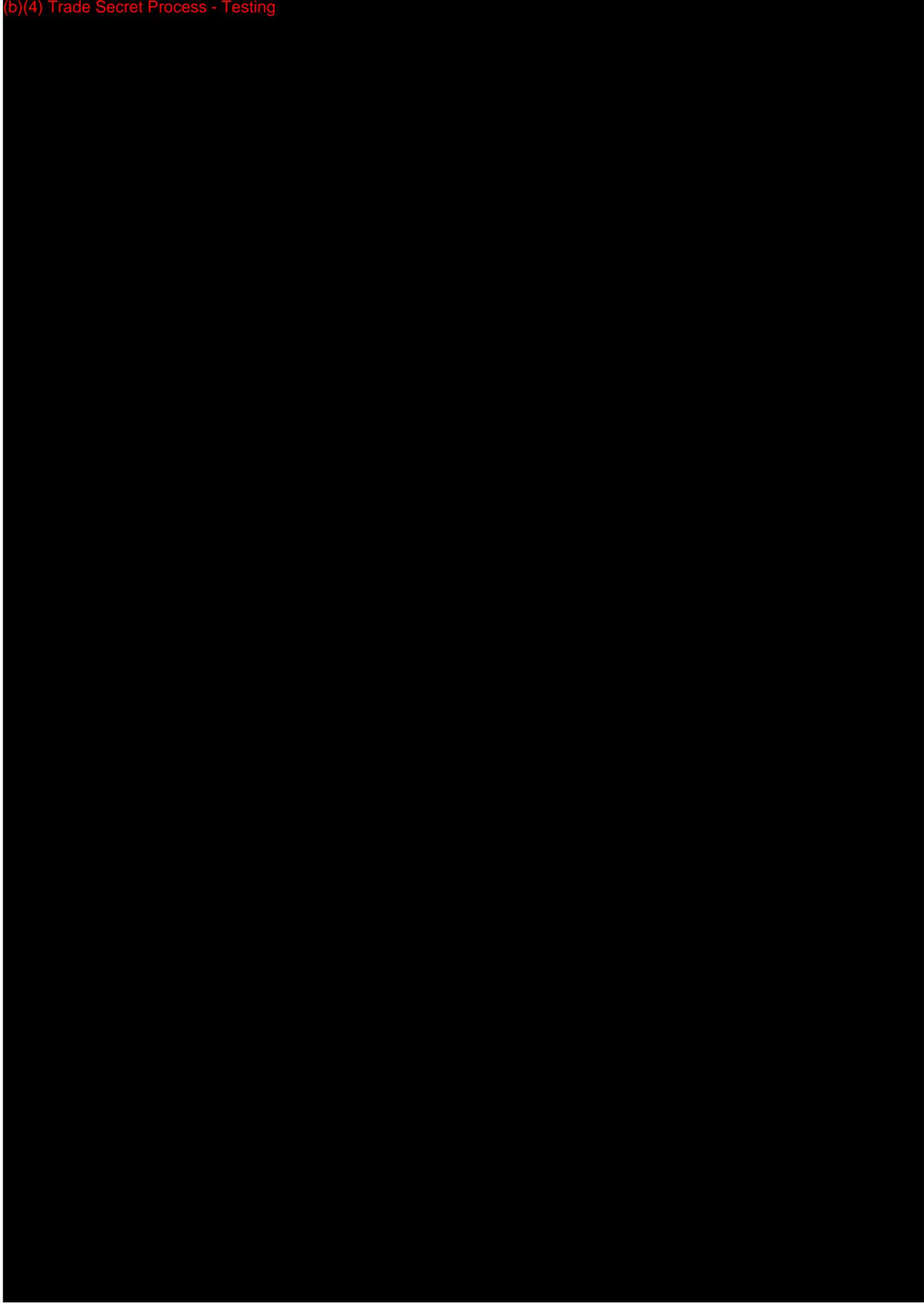


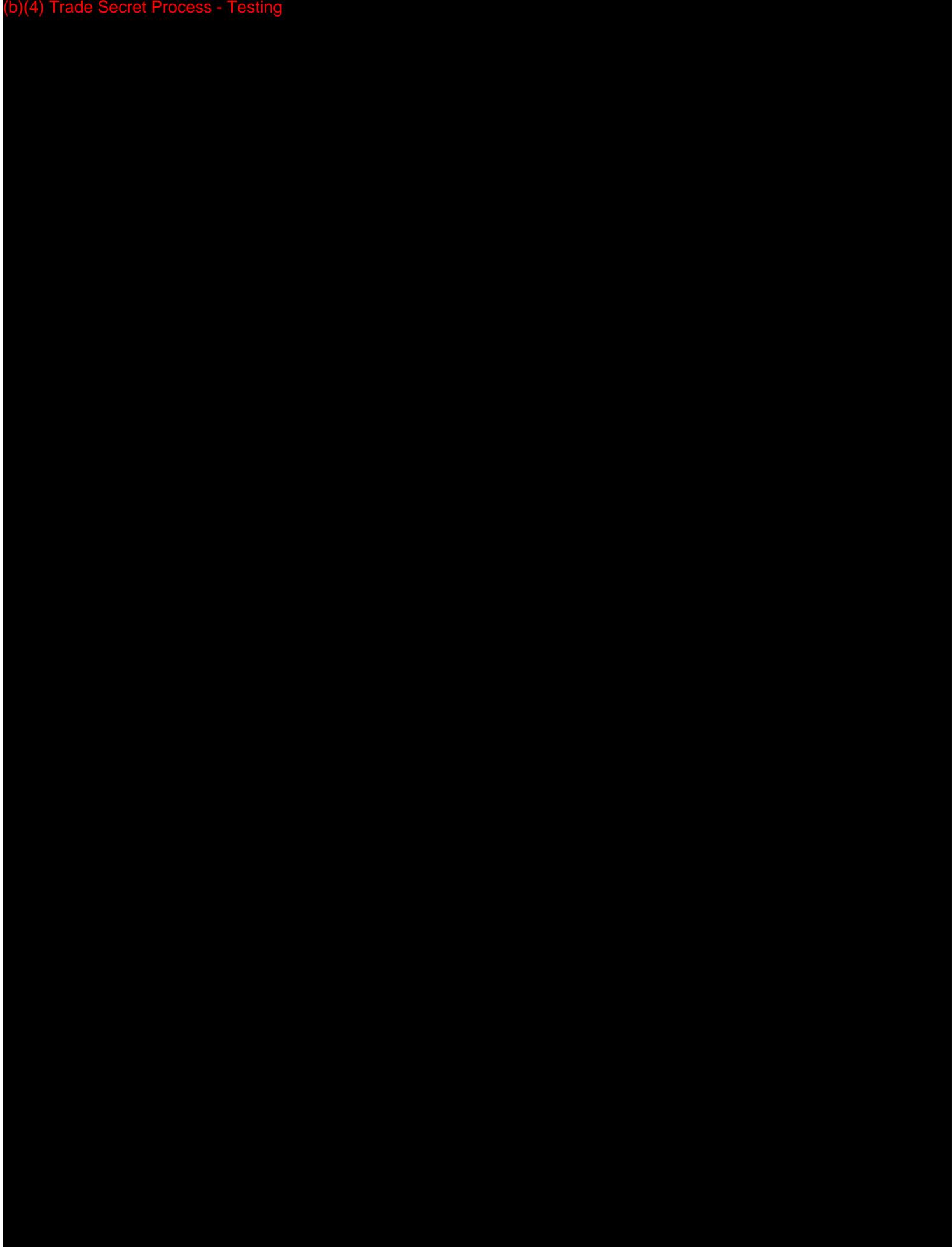


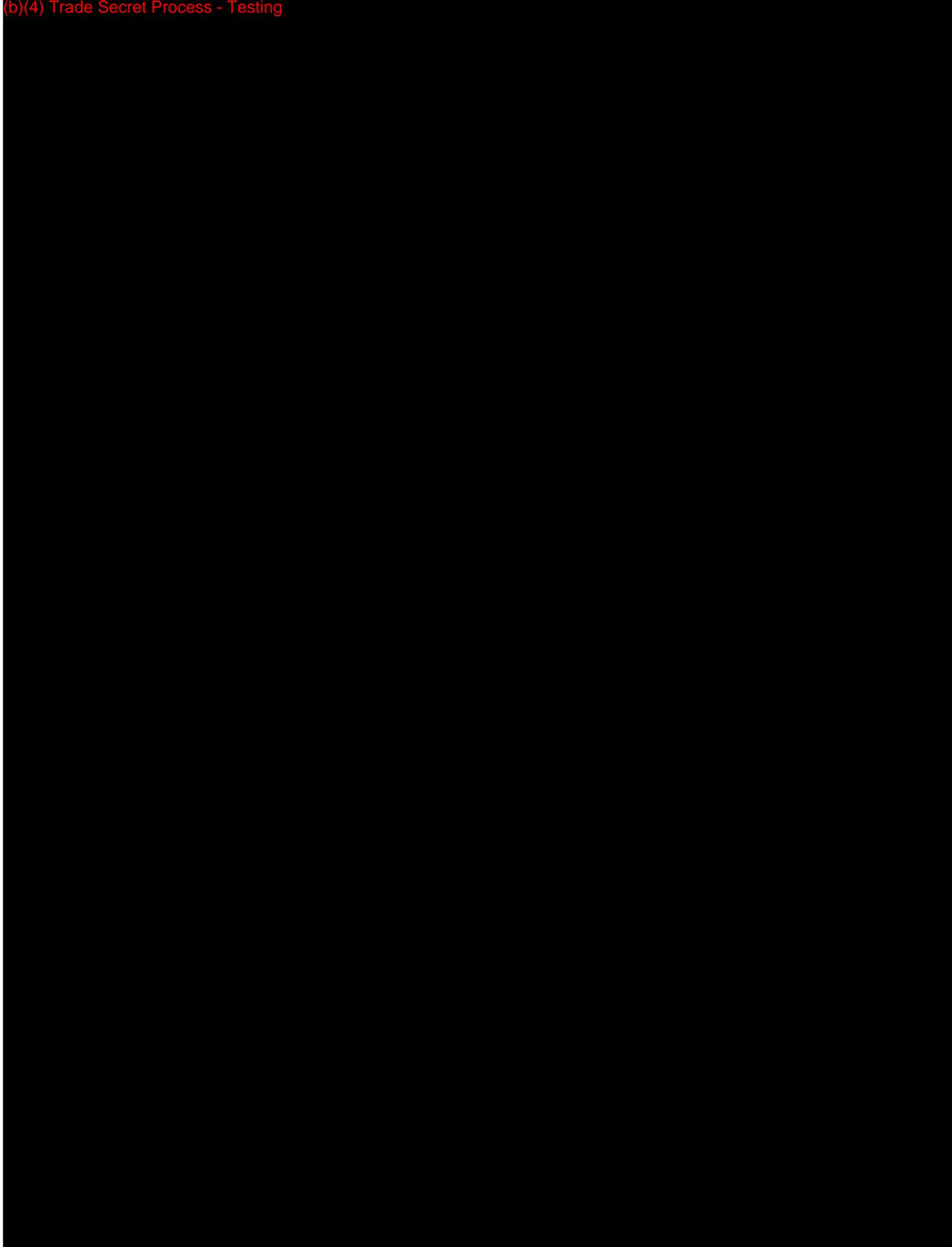


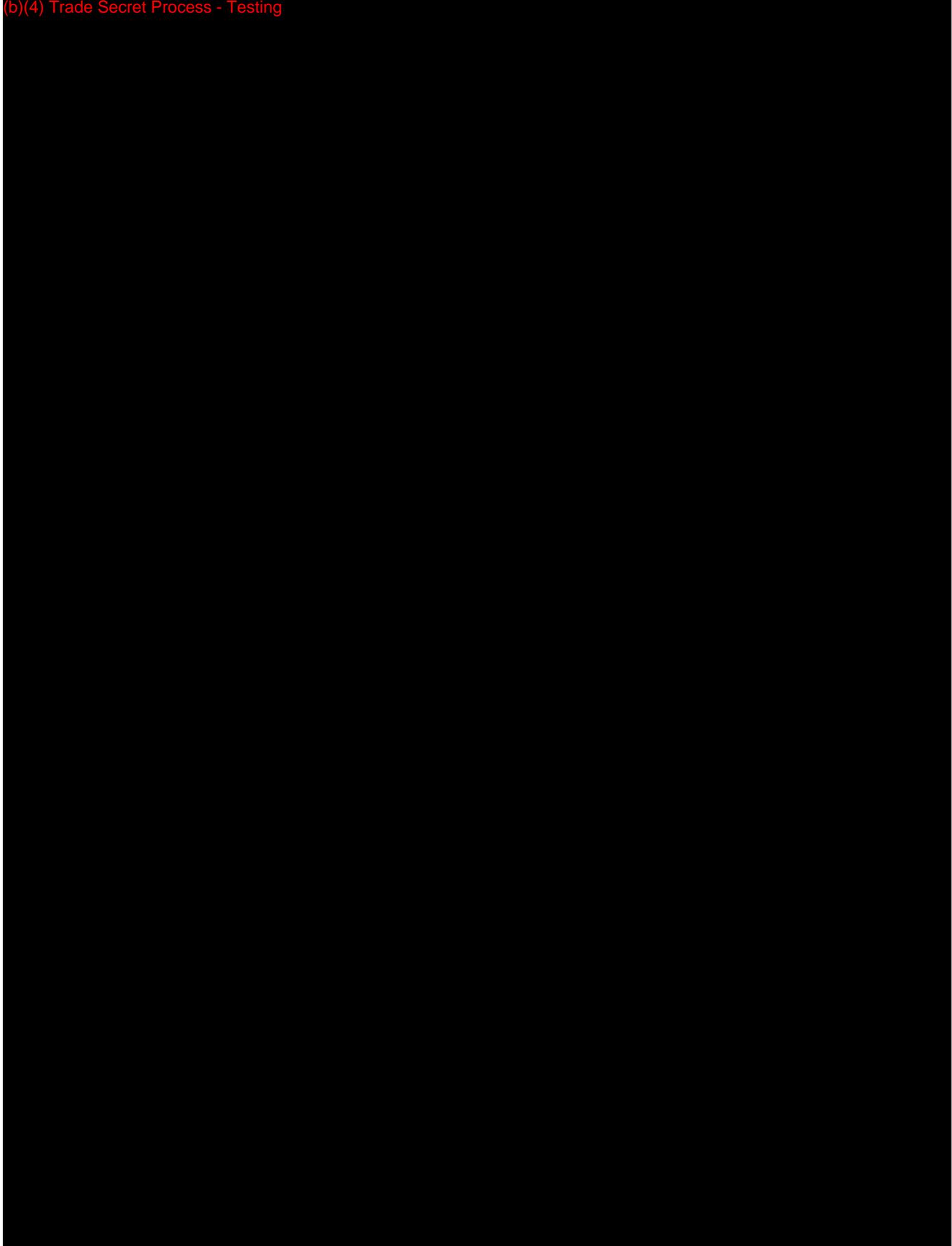


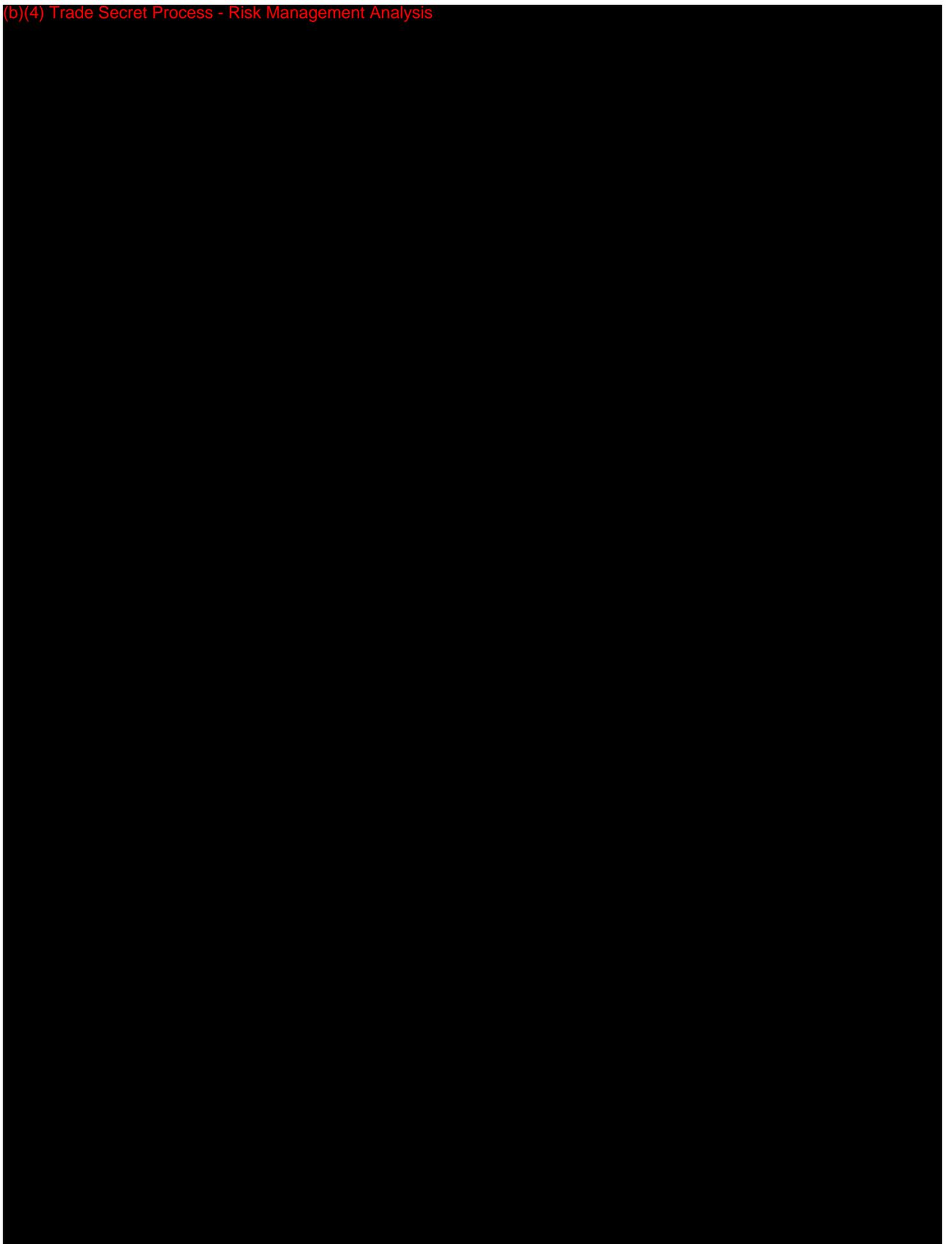


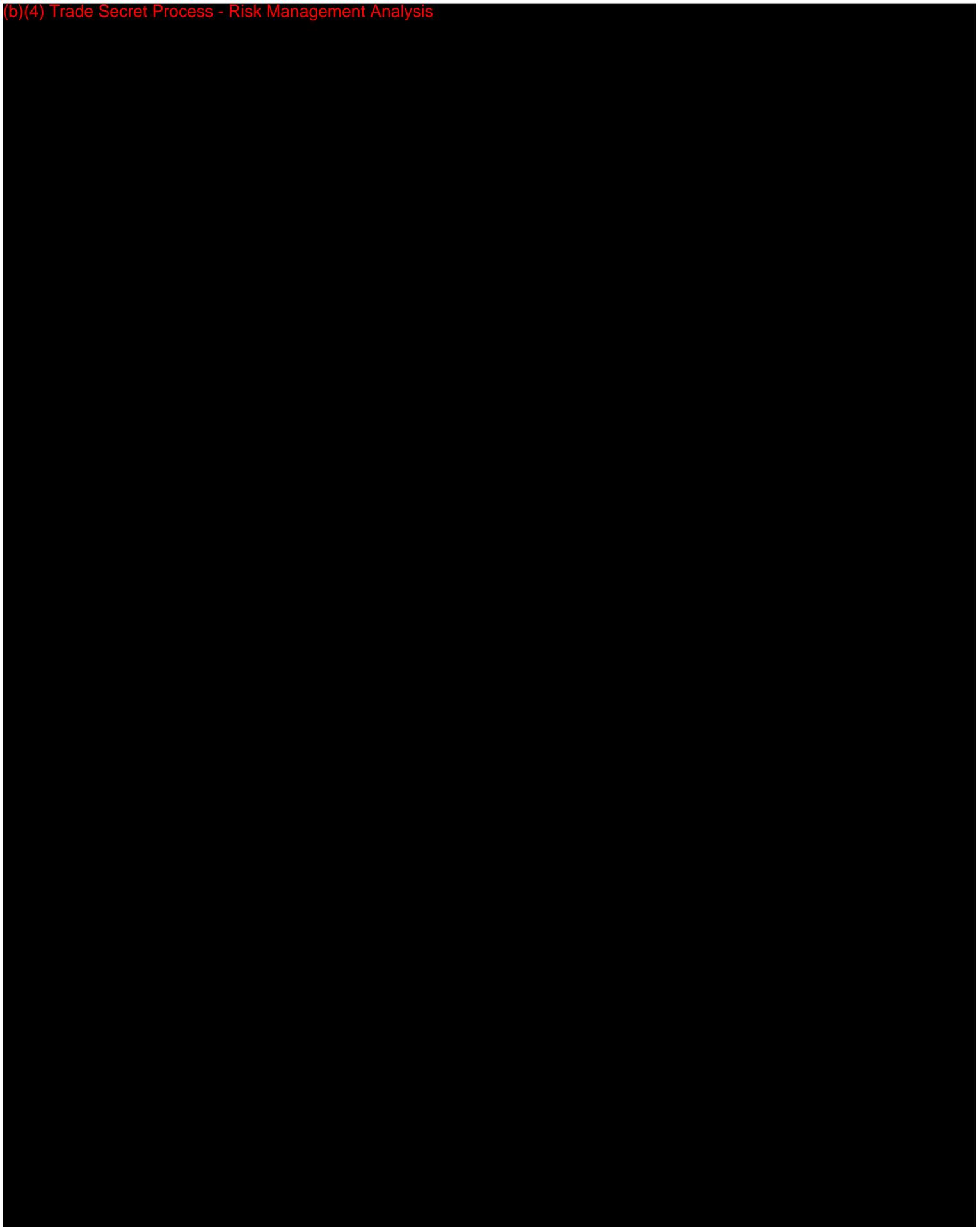


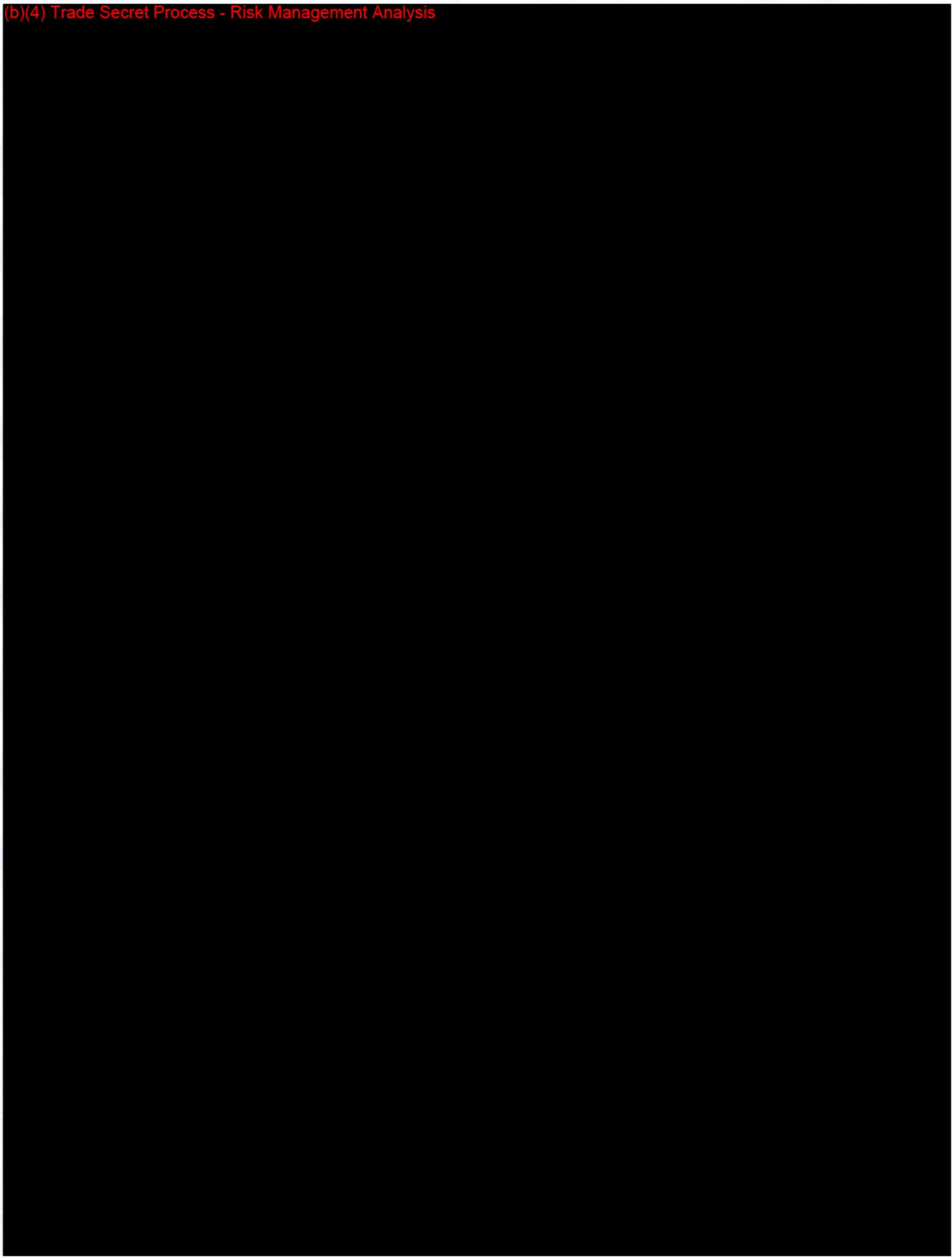












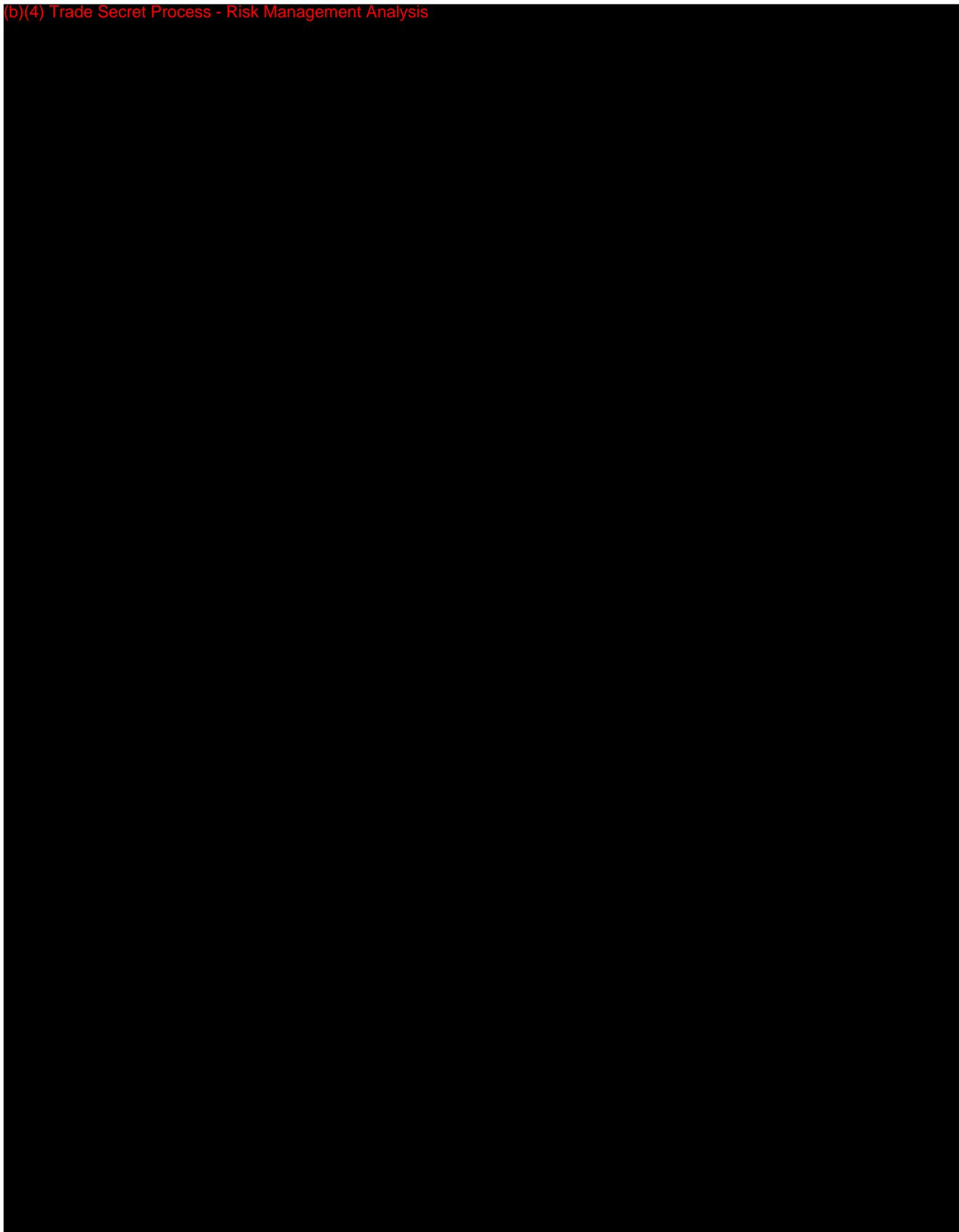












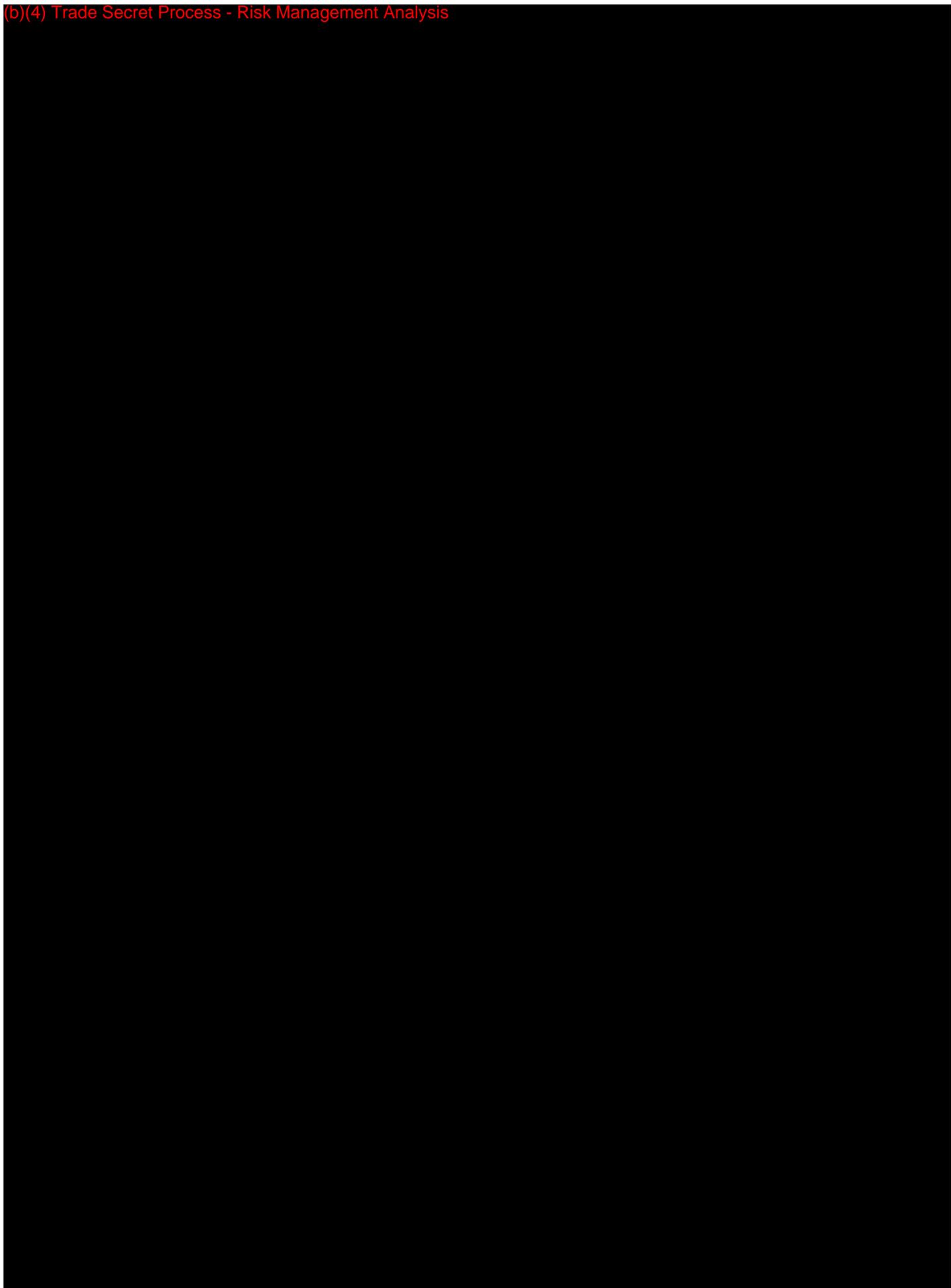




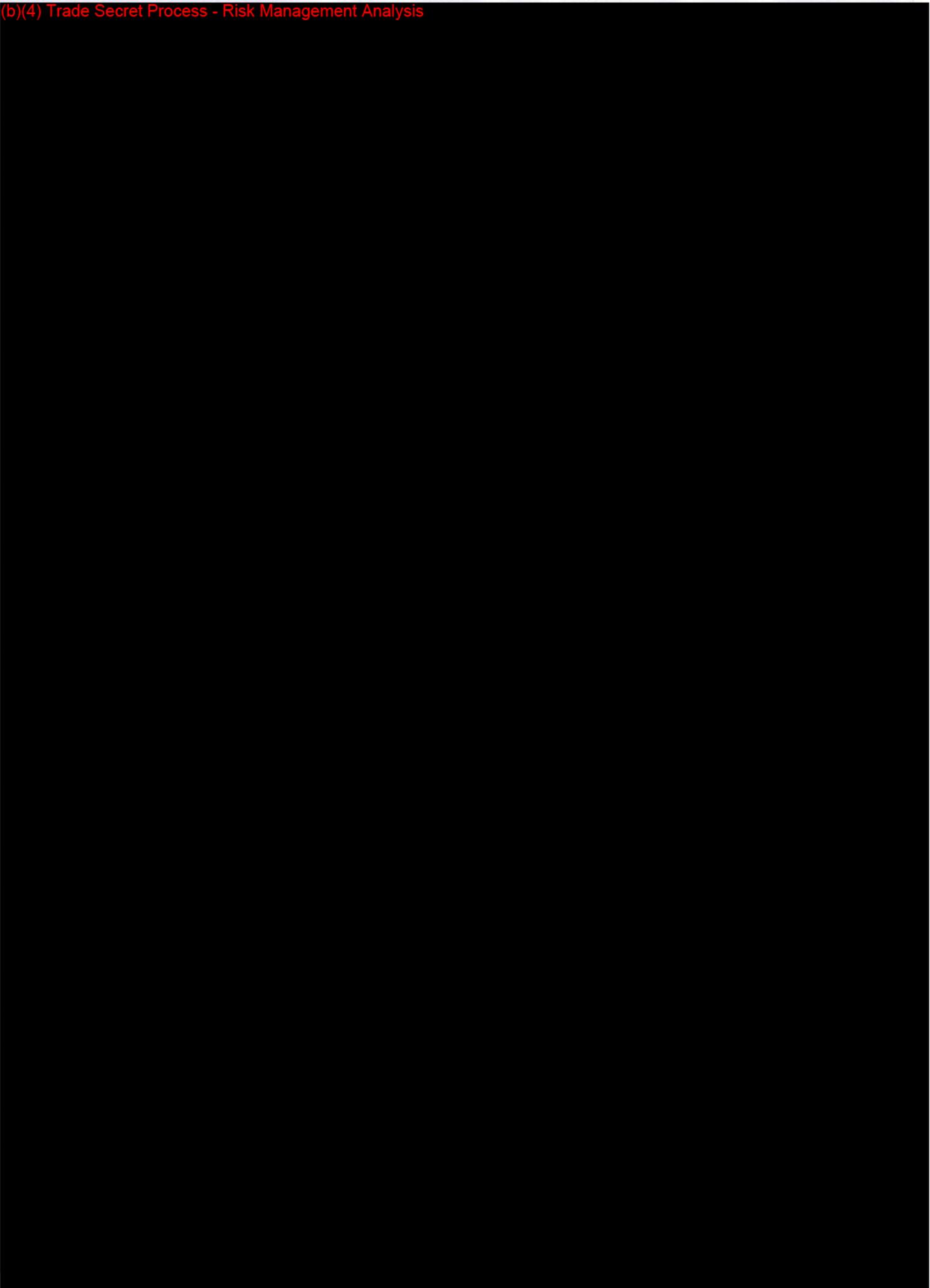


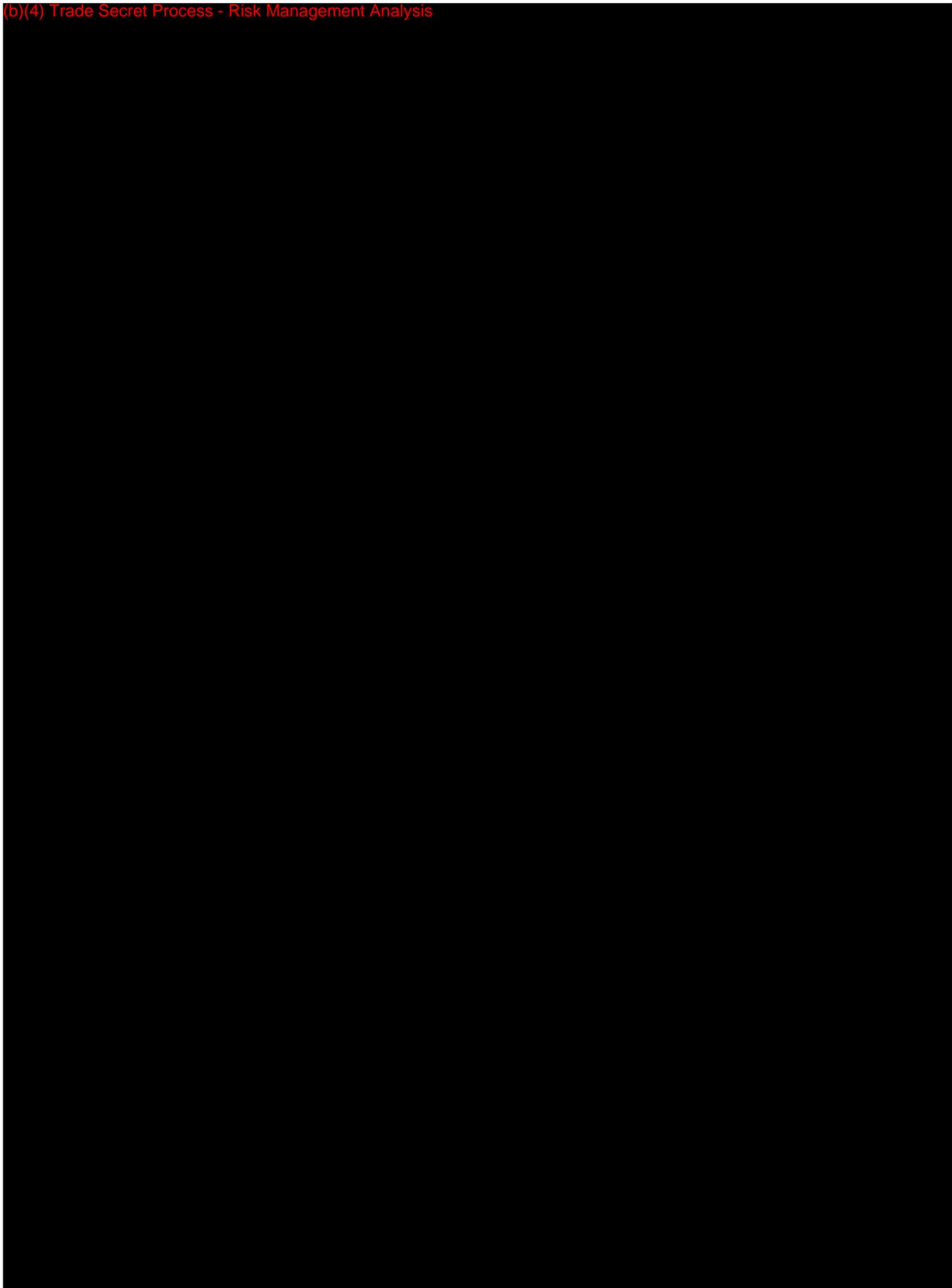




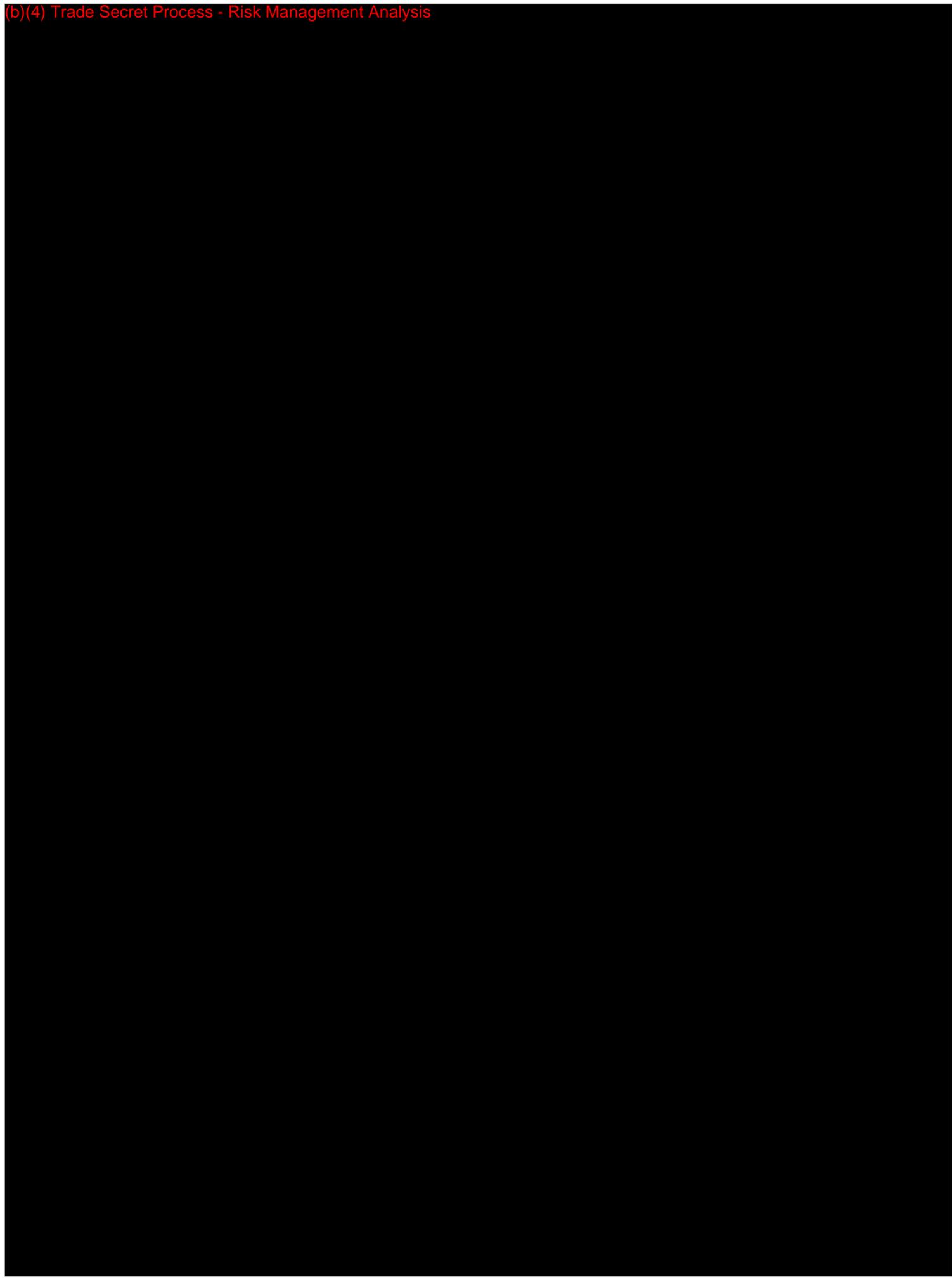














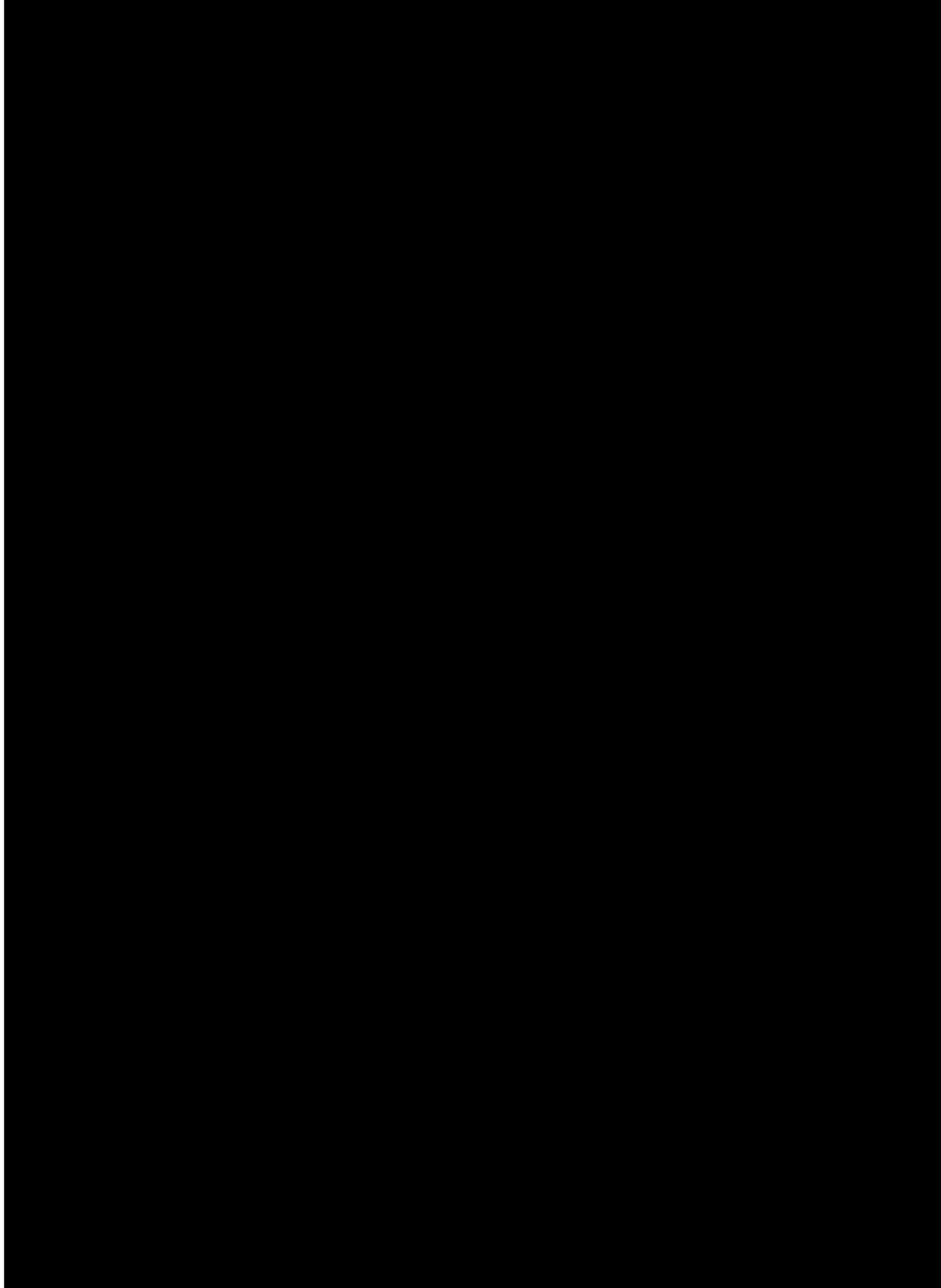


























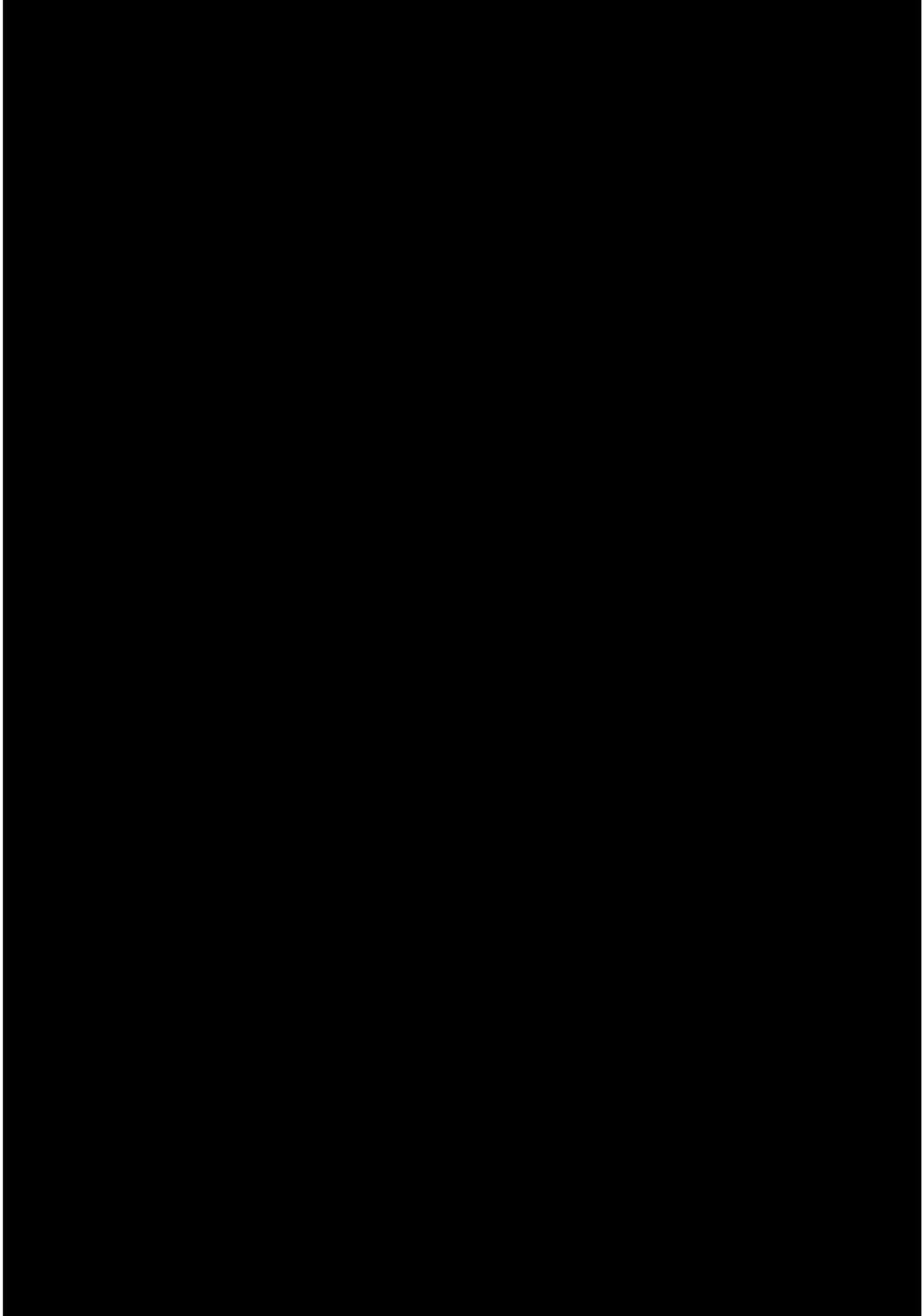












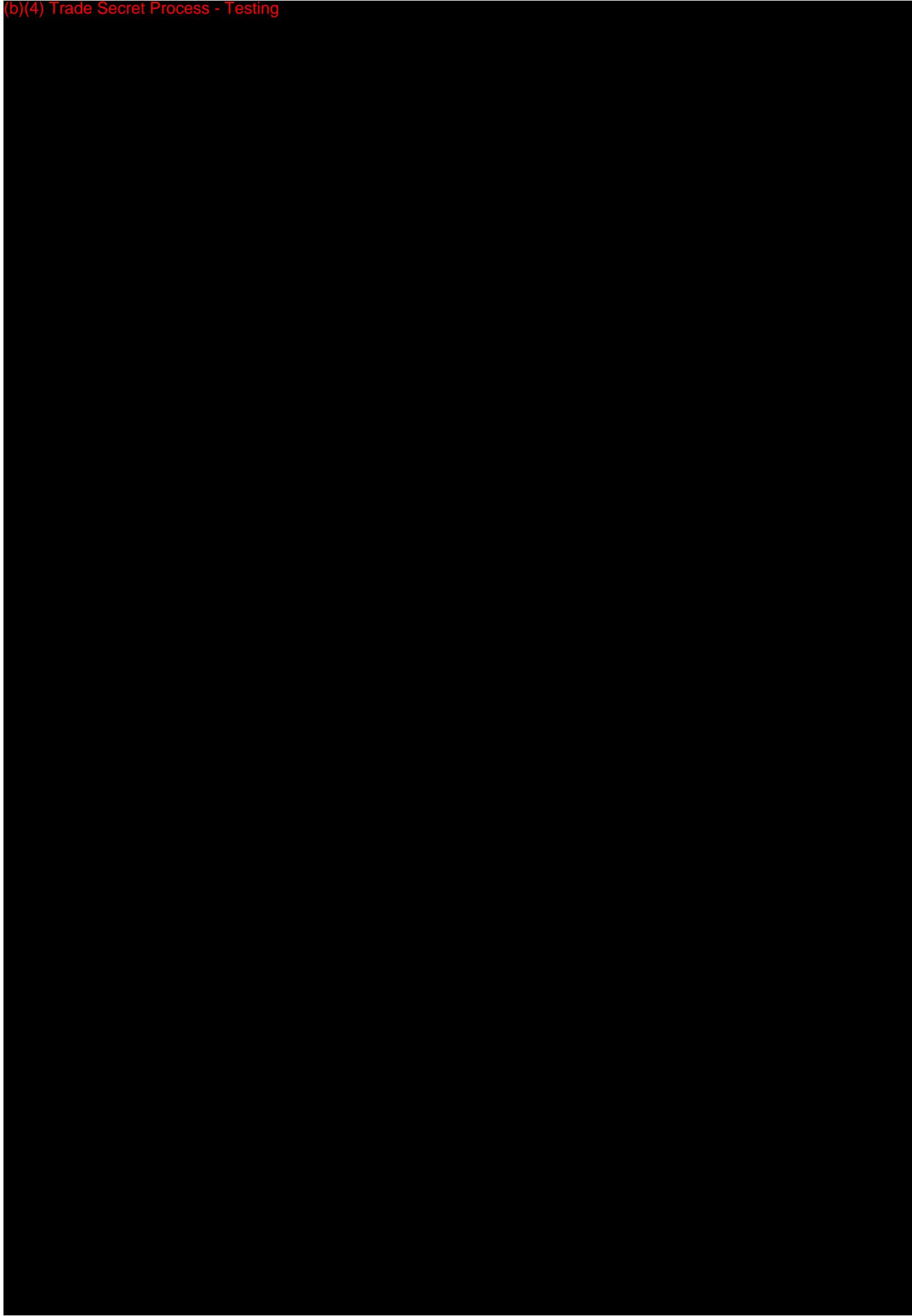


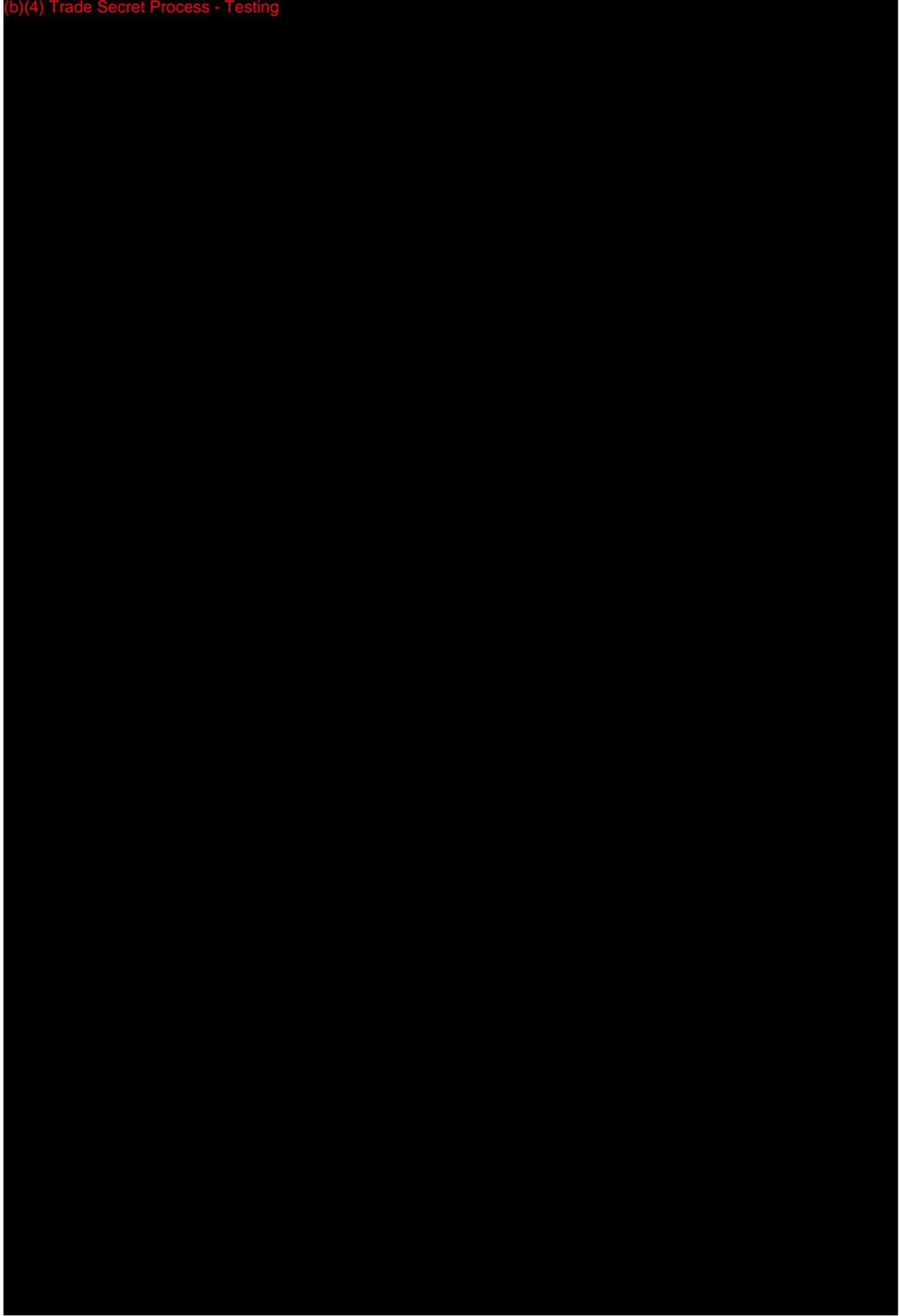


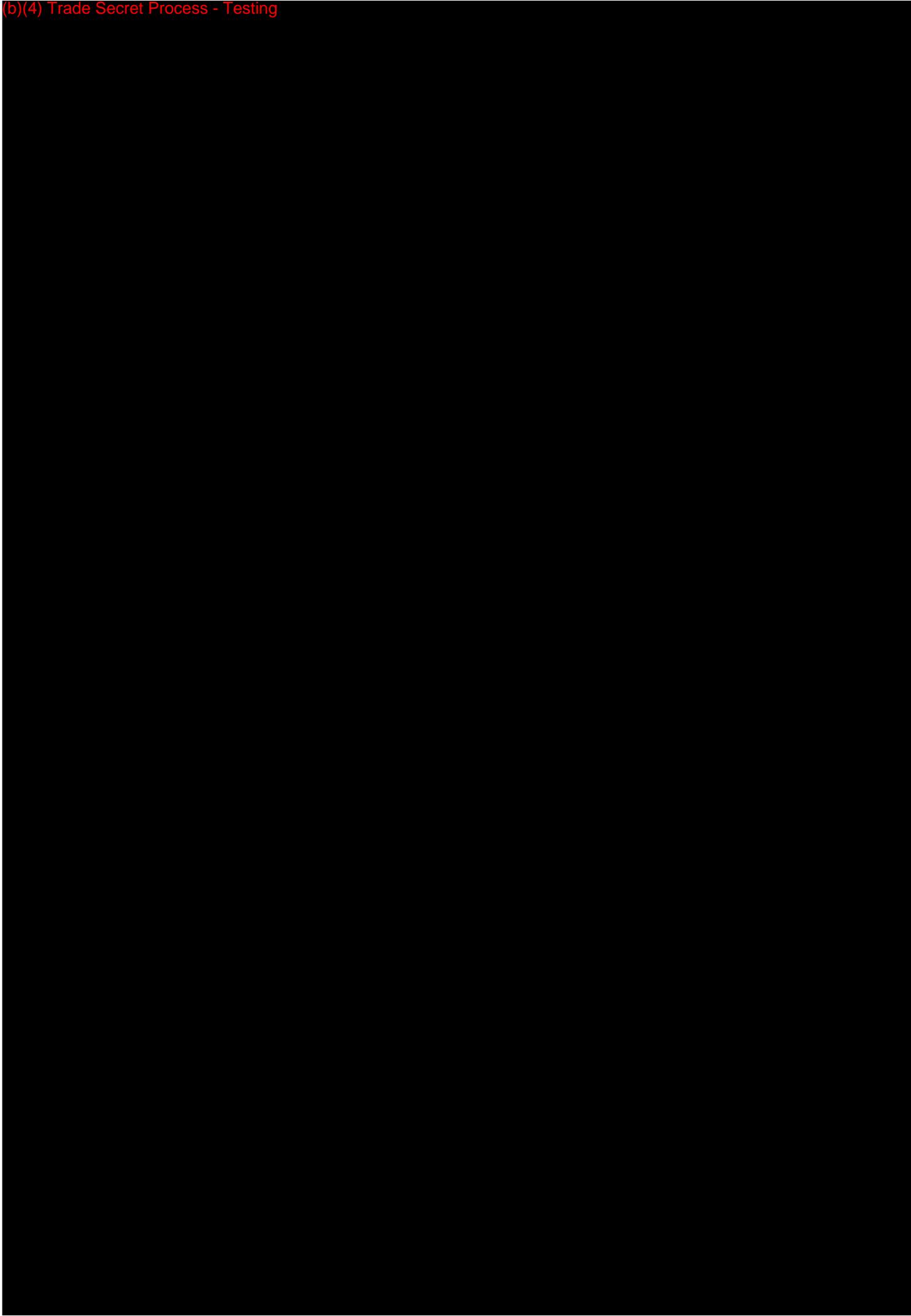


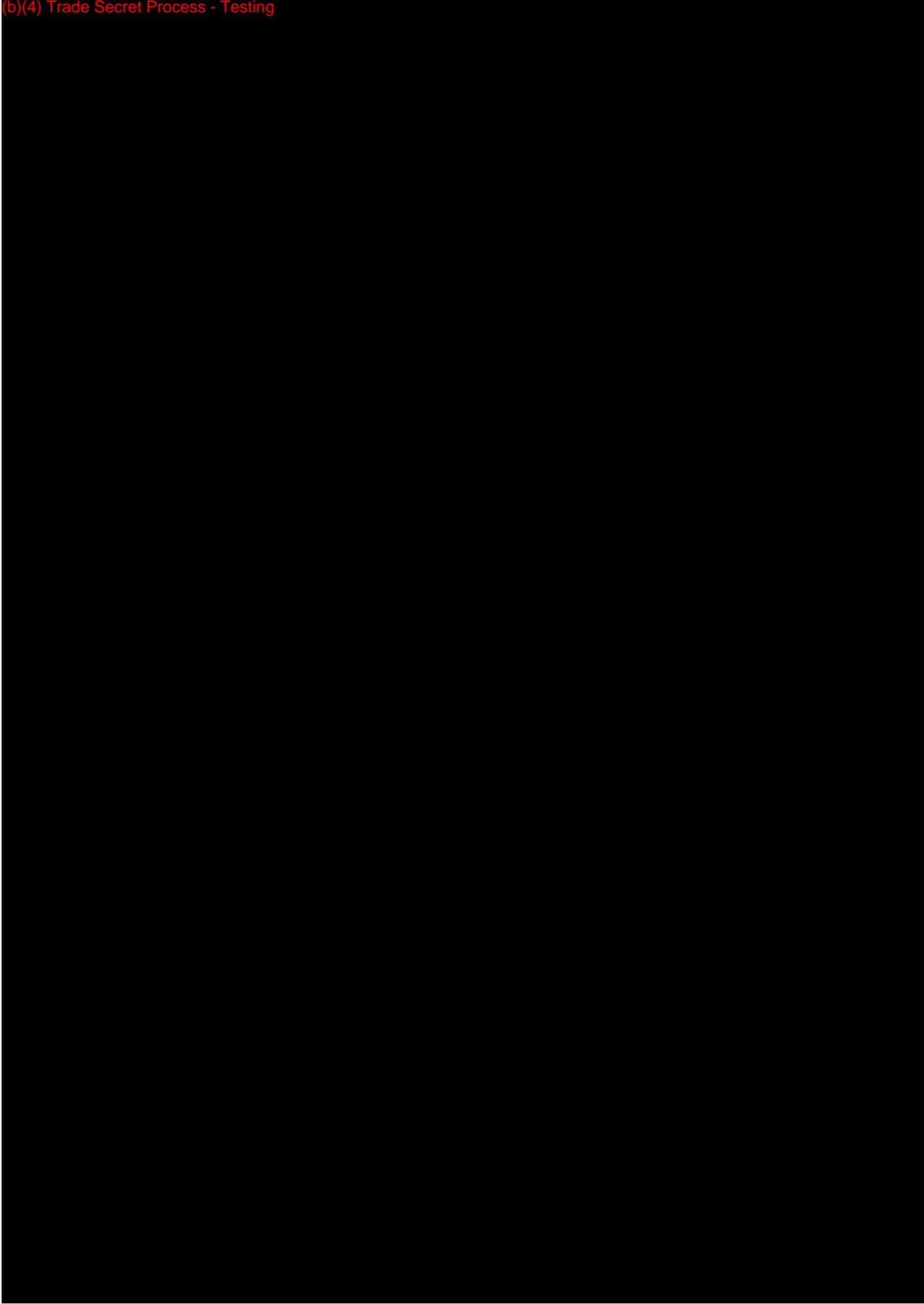


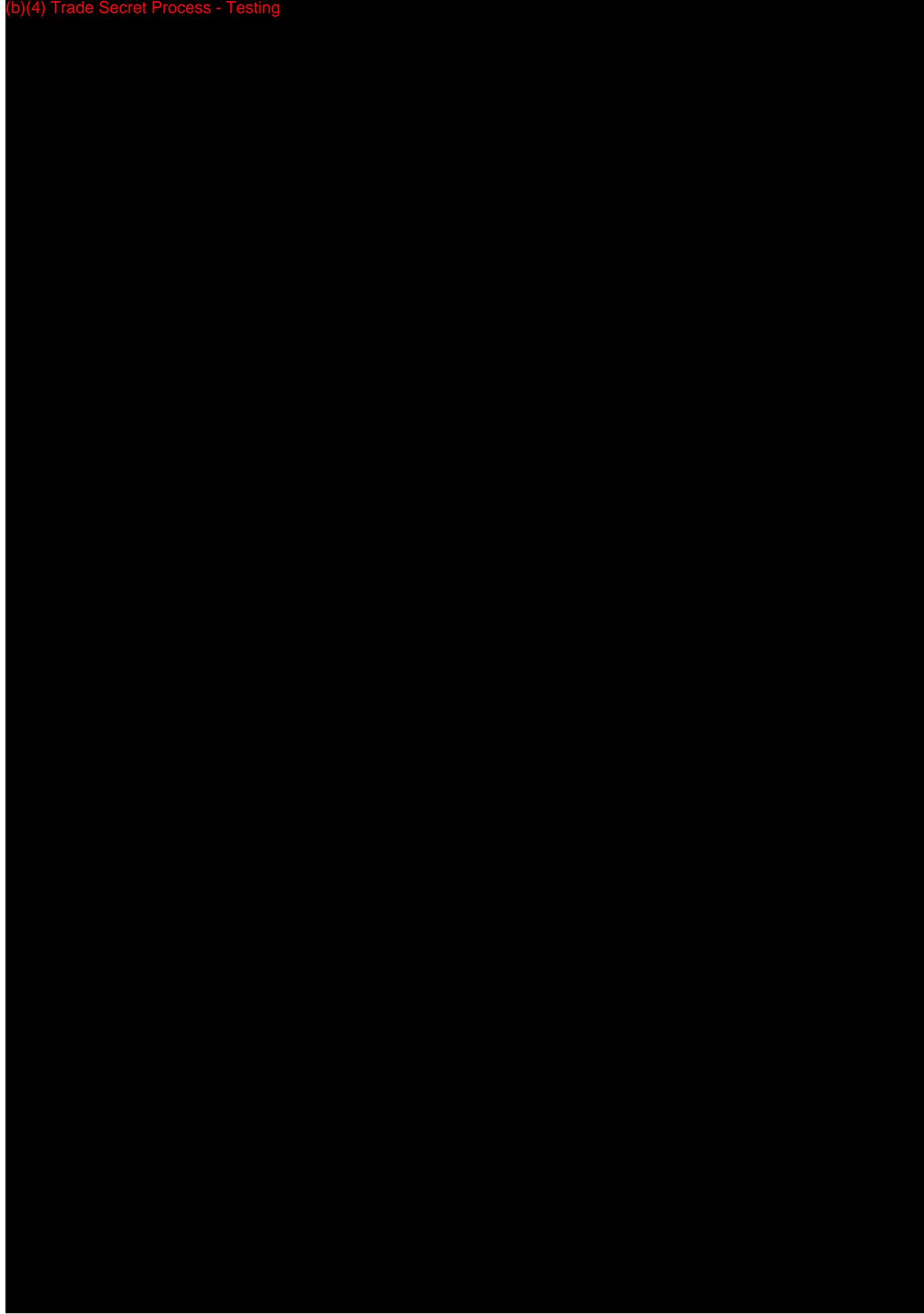


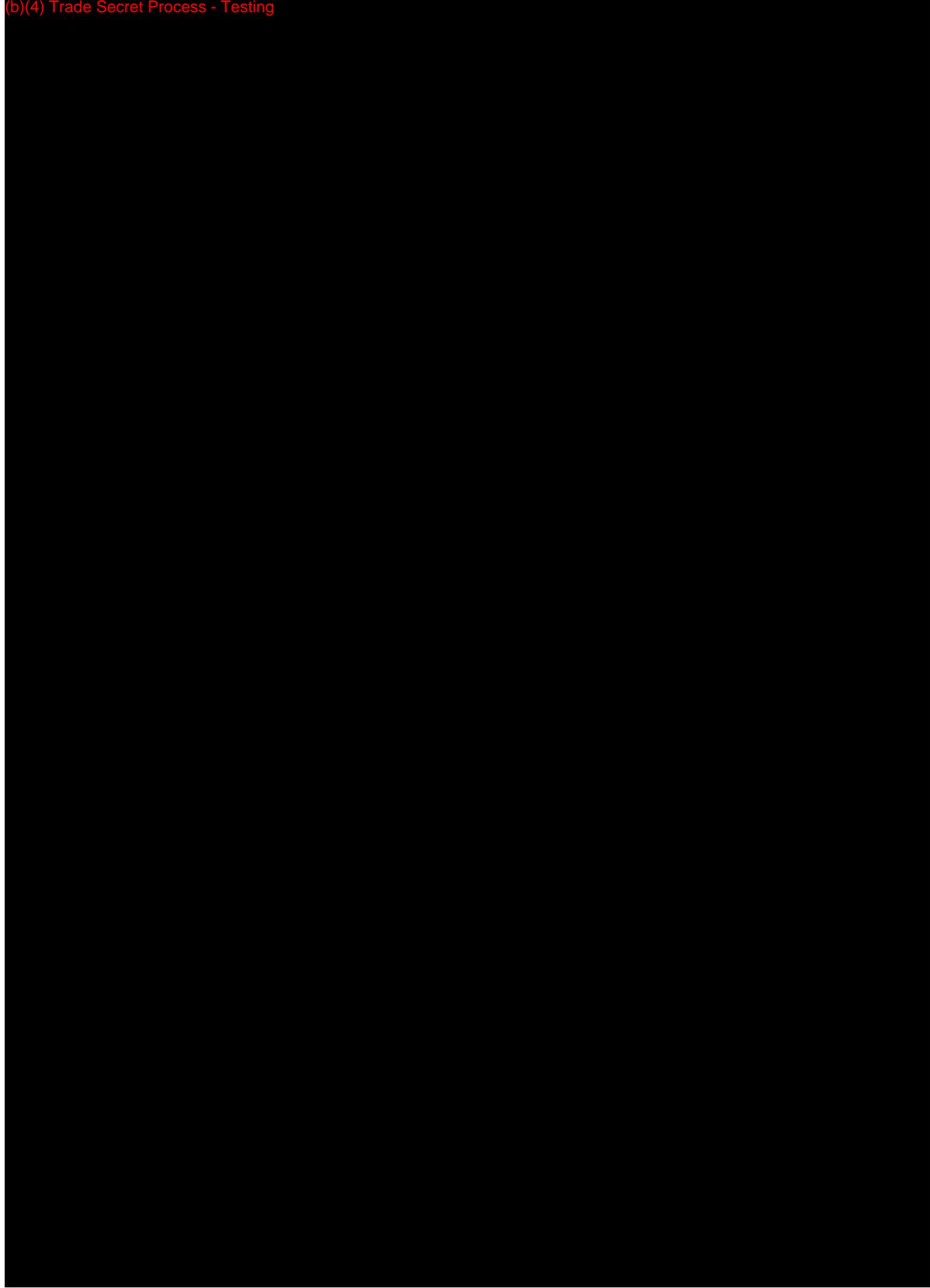








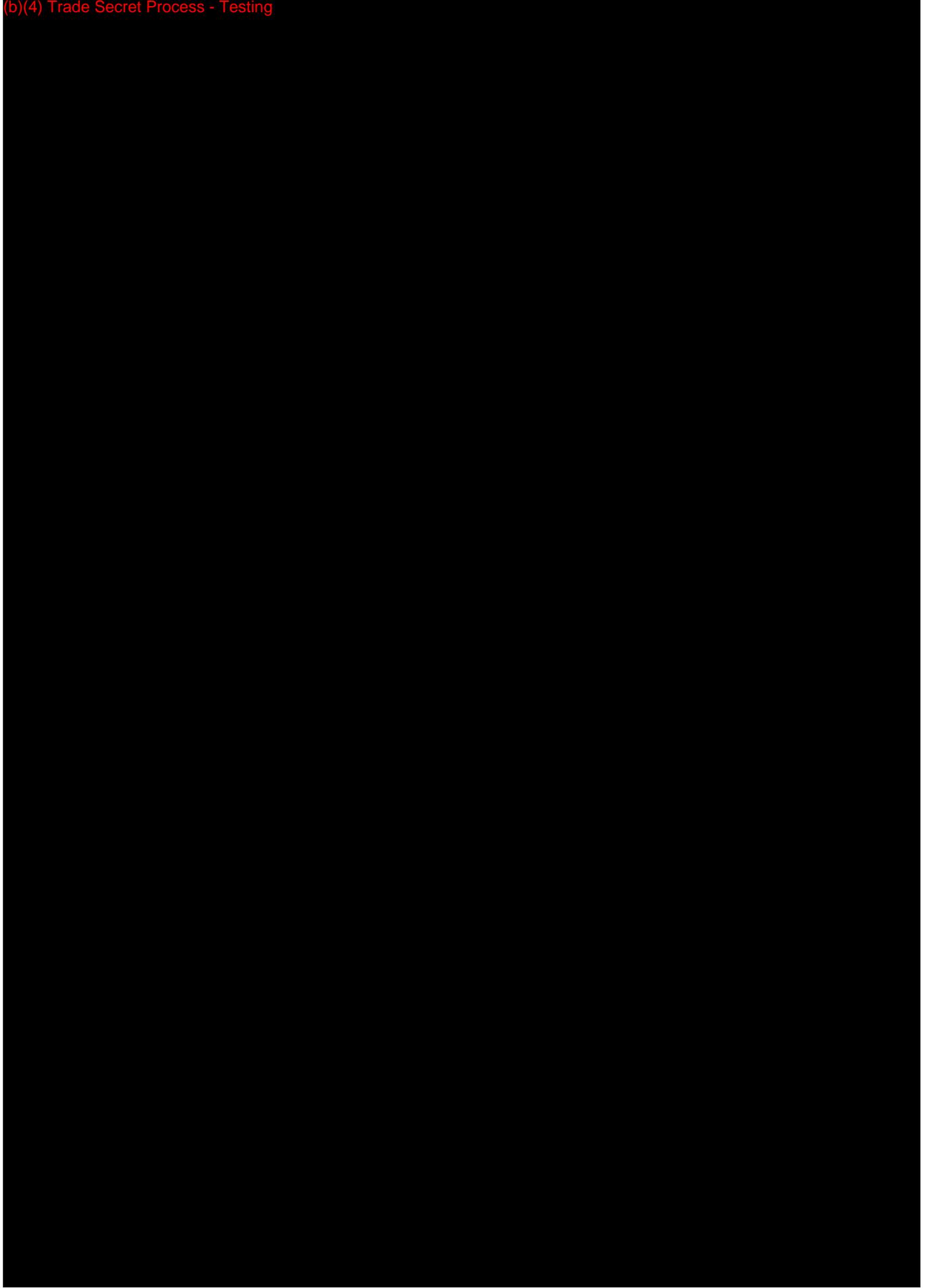


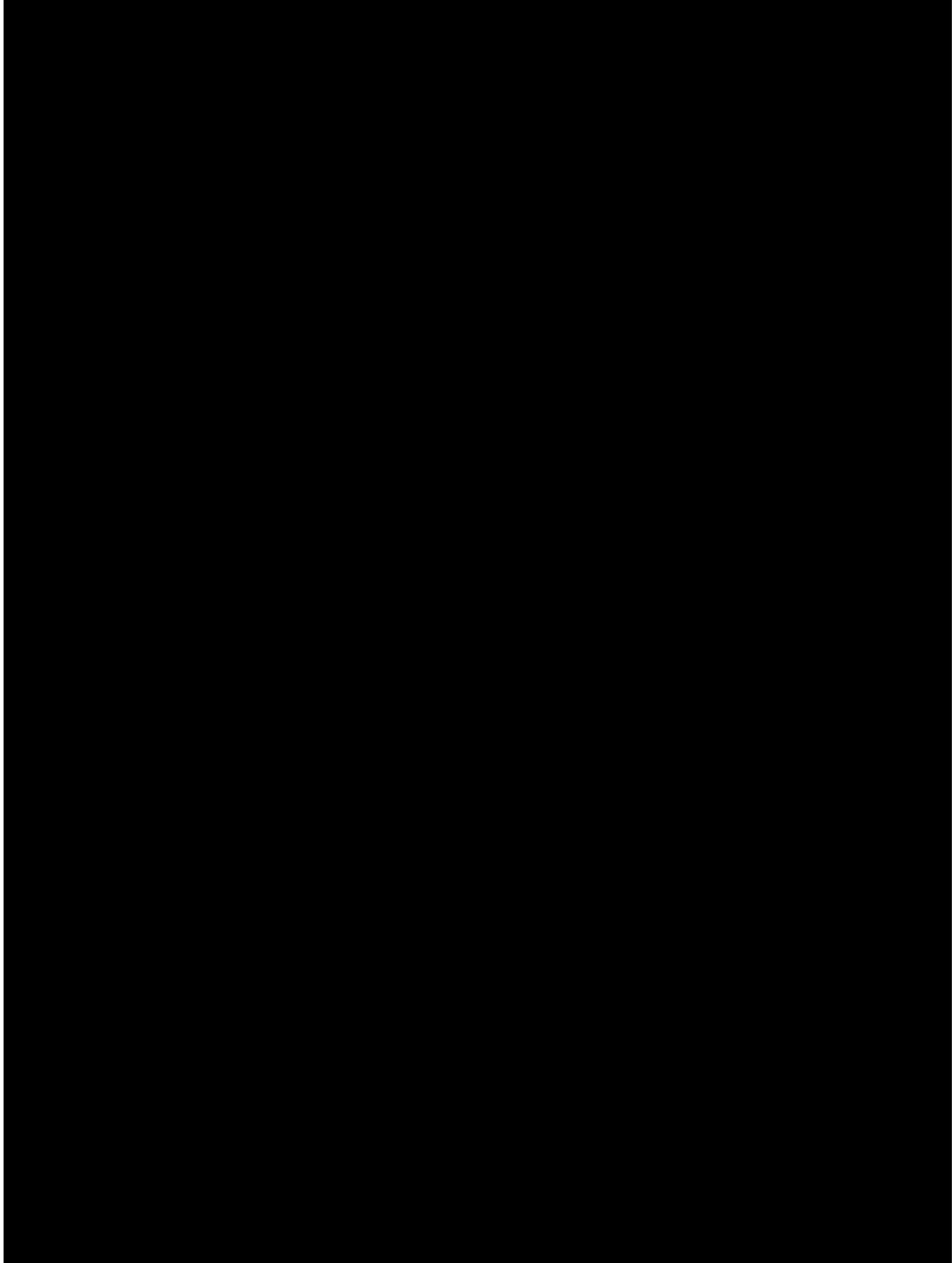


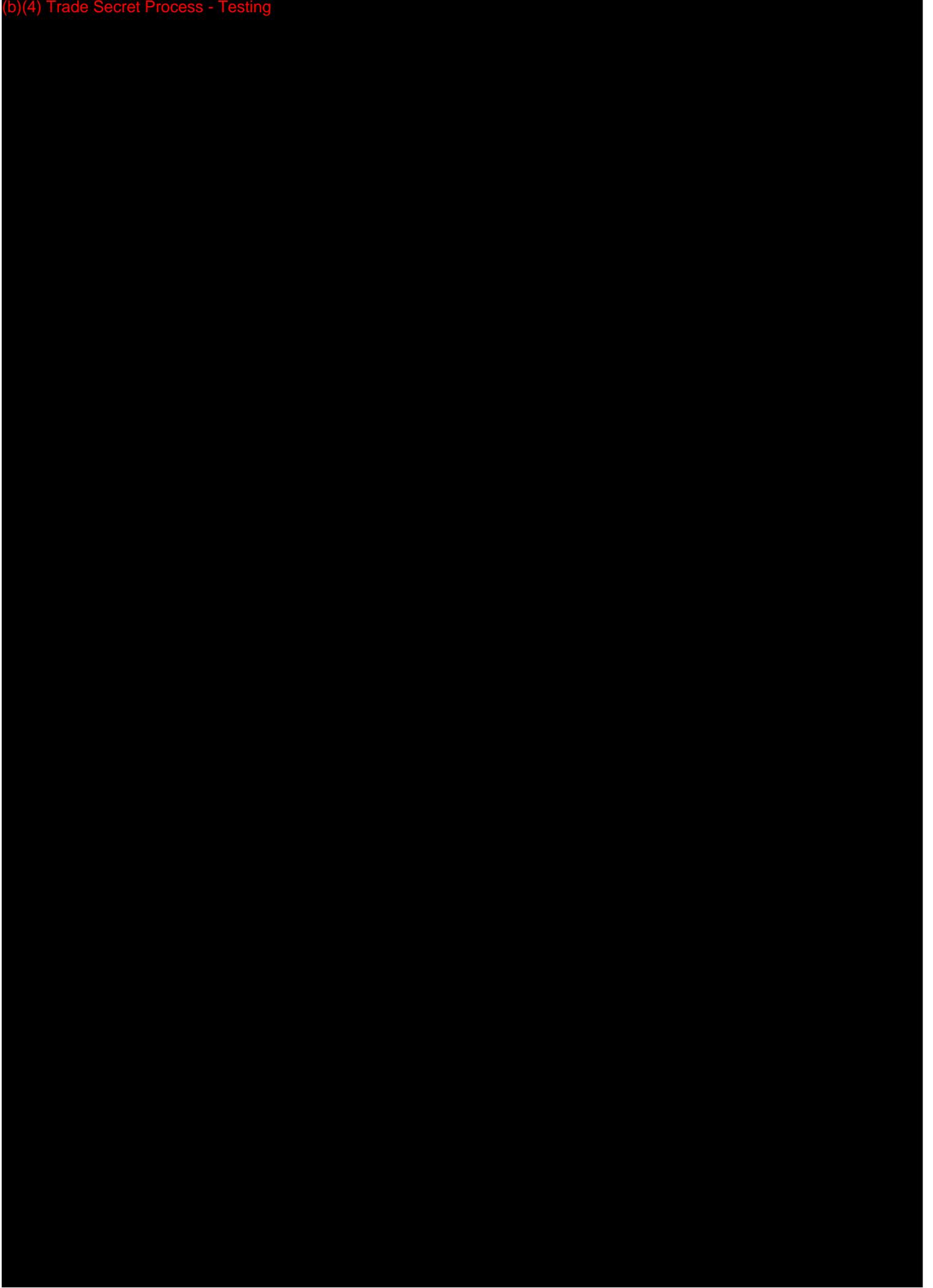


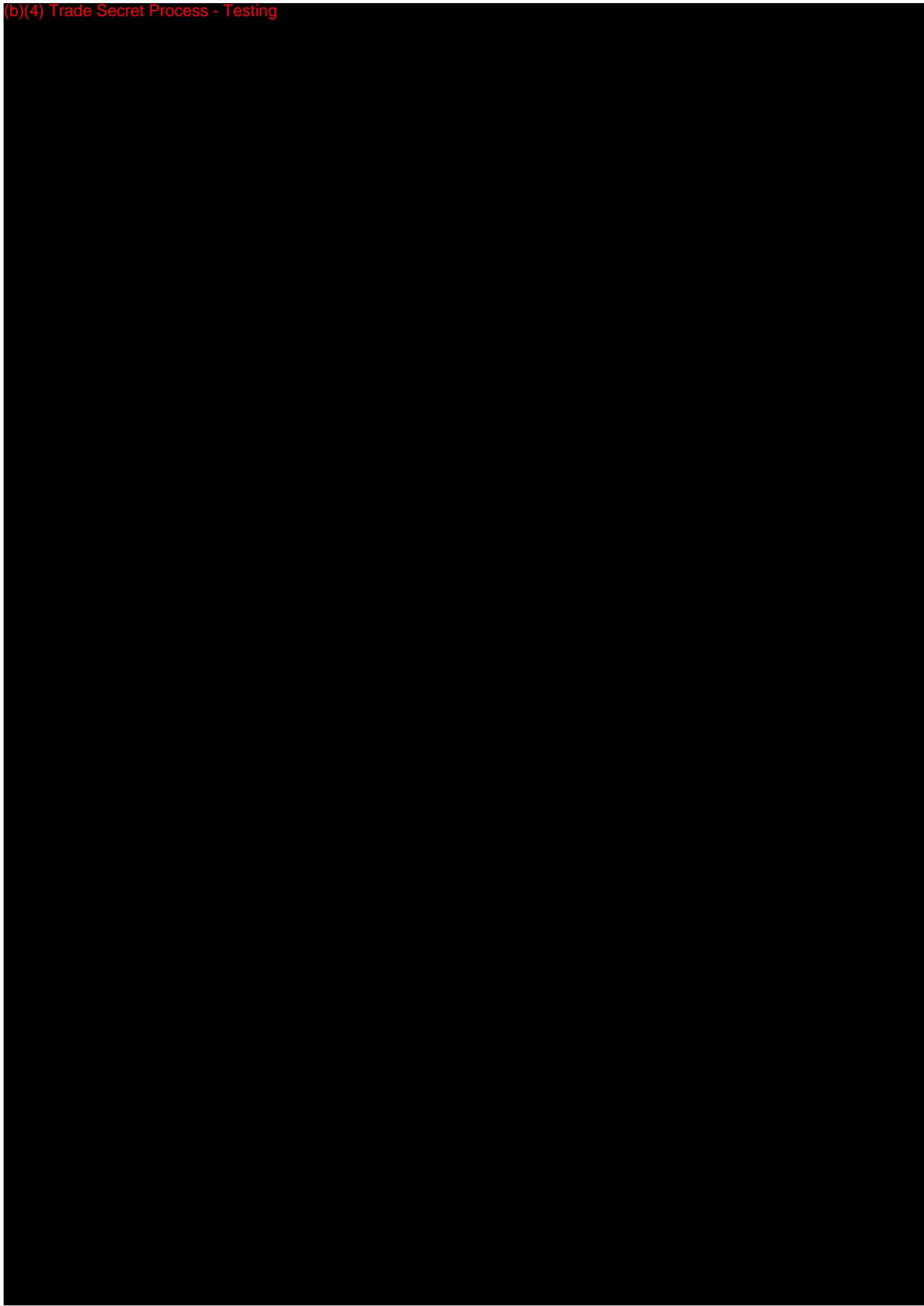


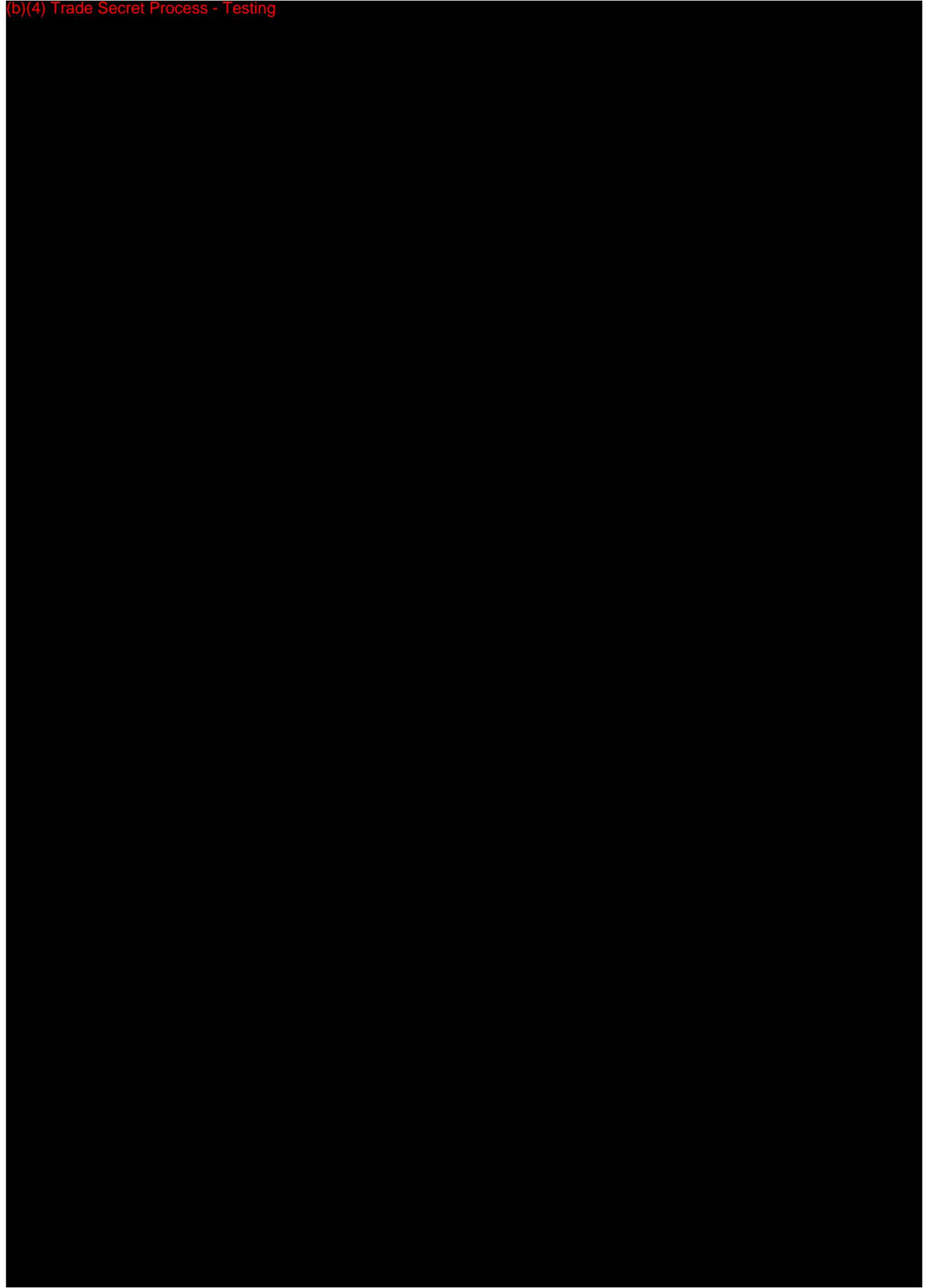


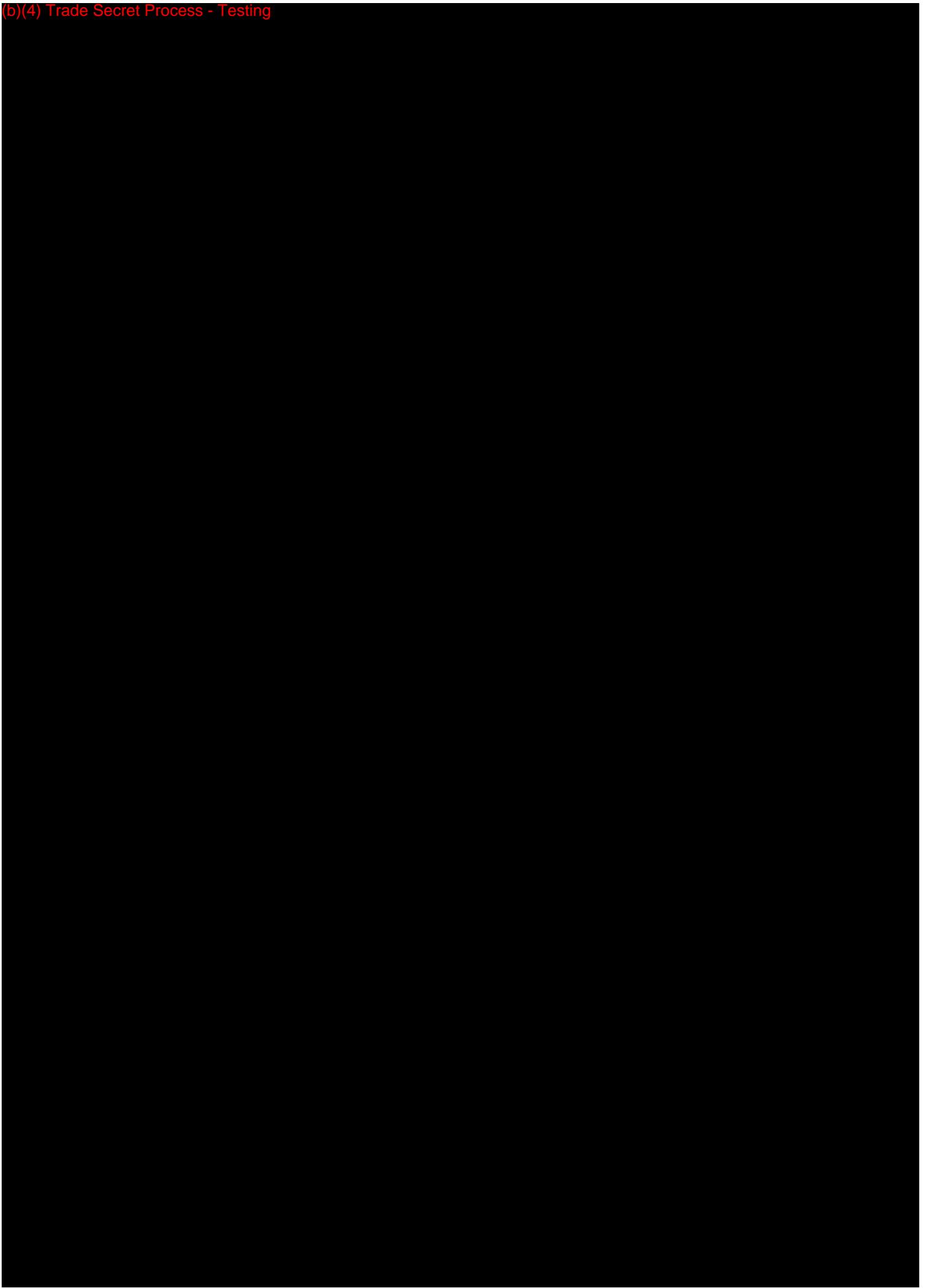








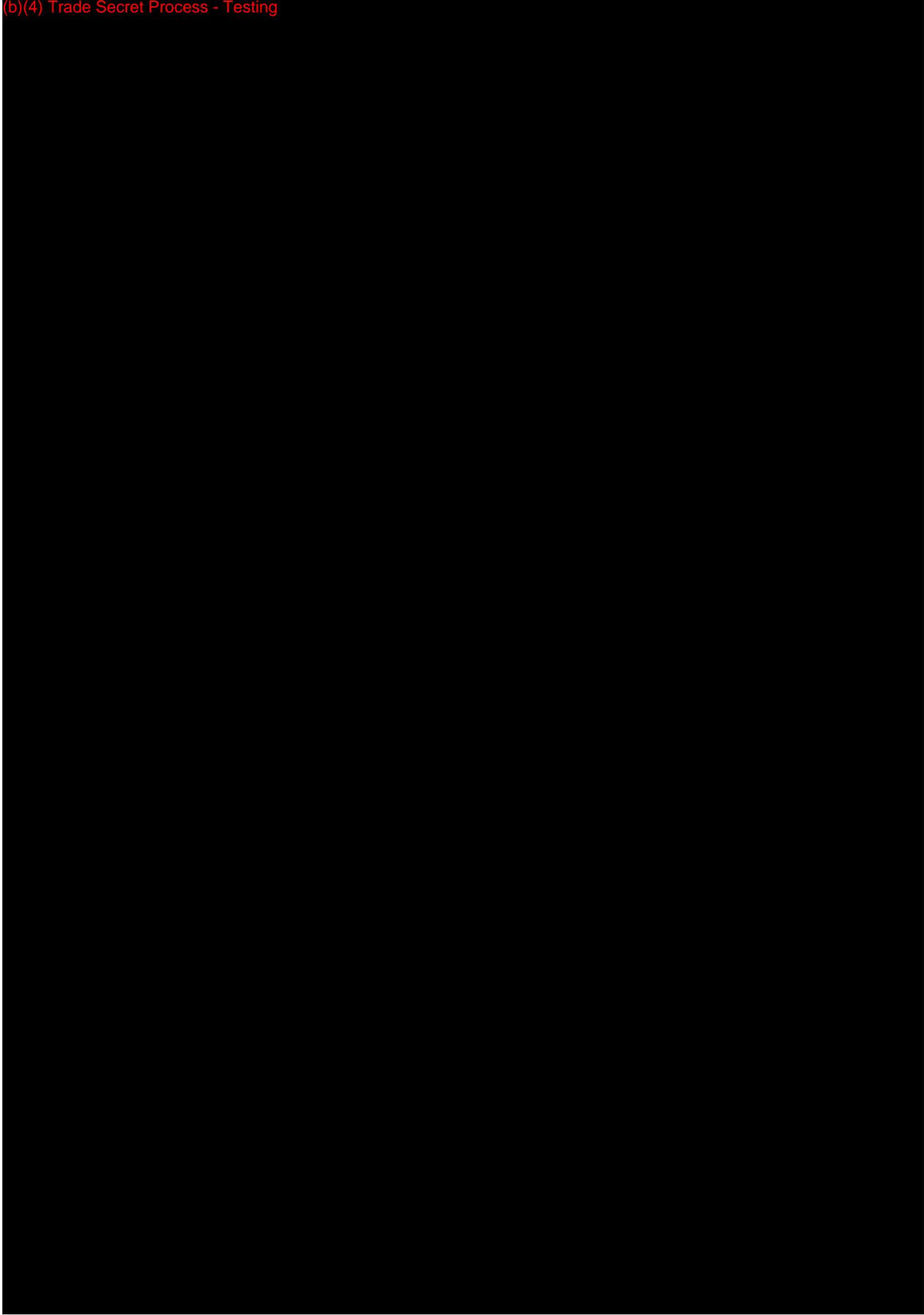




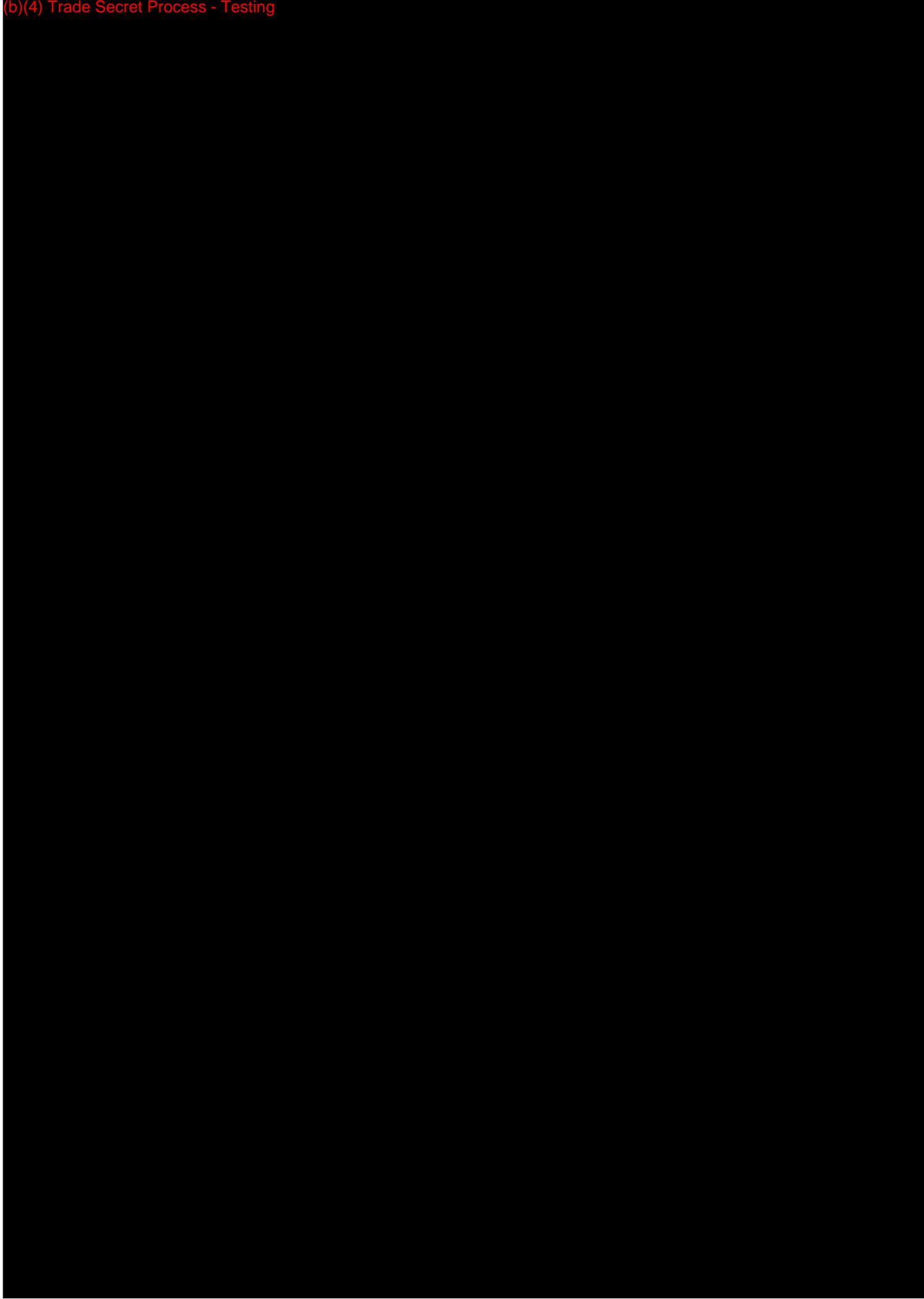


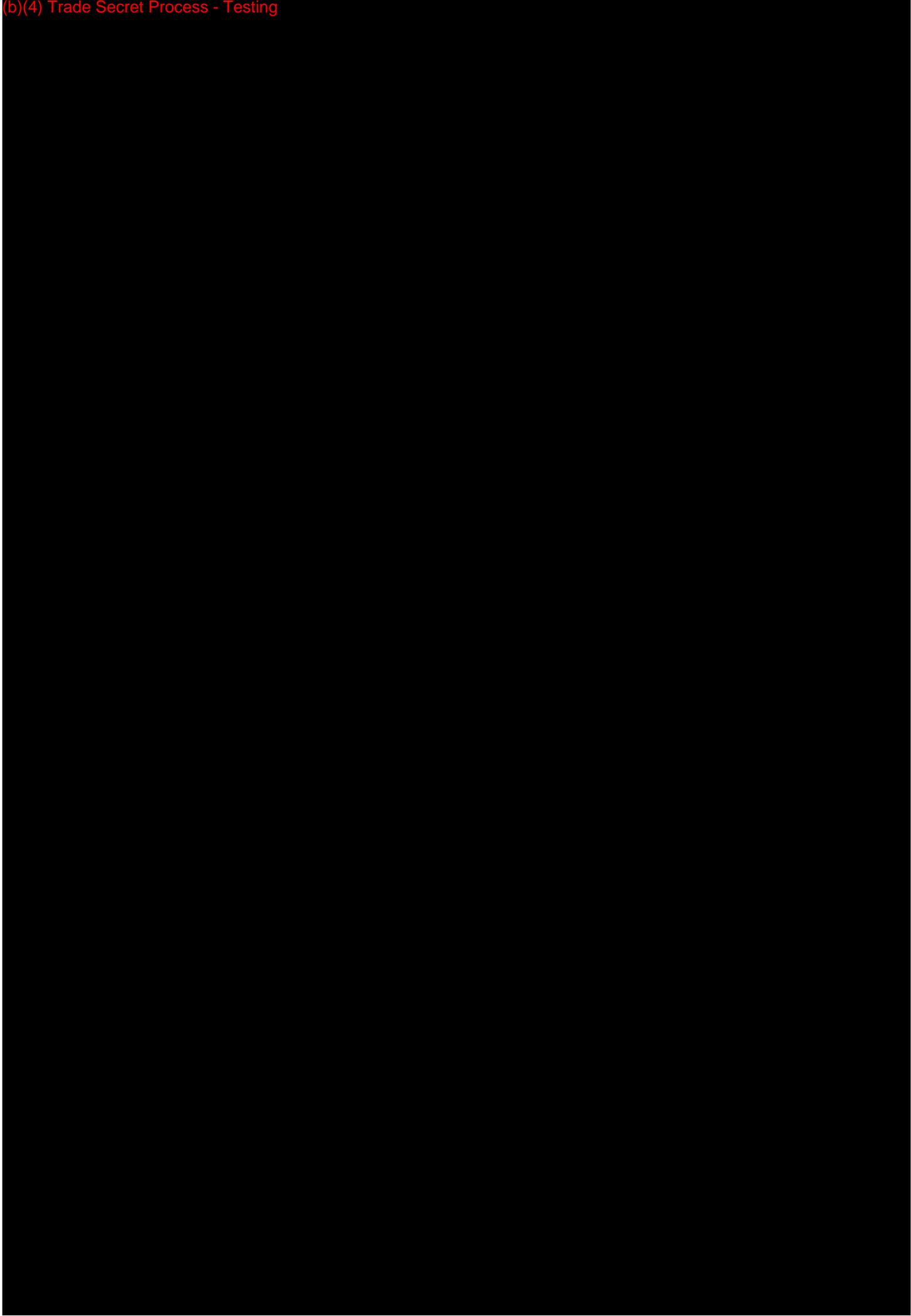


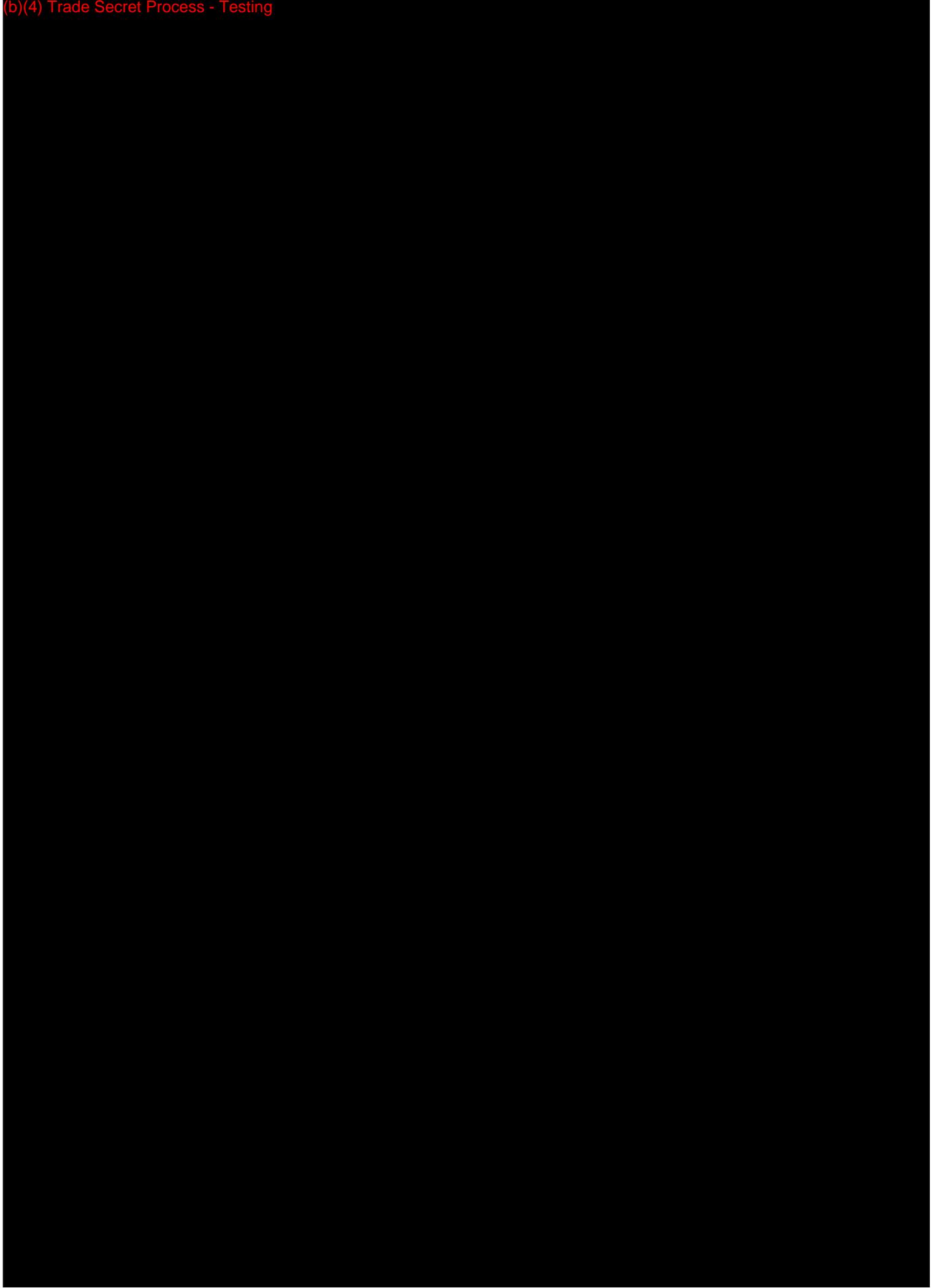






















DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with  
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

**SPONSOR / APPLICANT / SUBMITTER INFORMATION**

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Suzhou Beinuo	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
3. ADDRESS (Number, Street, State, and ZIP Code) Suzhou Beinuo Medical Equipment Co., Ltd. 158-38 Huashan Rd Suzhou High – New District, China 215129	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 86 512 666 26278 (Fax) 86 512 66626238

**PRODUCT INFORMATION**

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)  
**FOR DEVICES:** Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)  
(Attach extra pages as necessary)

Surgical Staplers: Circular Stapler for Single Use, Hemorrhoidal Circular Stapler for Single Use, Linear Stapler & Reloads for Single use,

Linear Cutter Stapler & Reloads for Single Use

**APPLICATION / SUBMISSION INFORMATION**

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES  
 IND  NDA  ANDA  BLA  PMA  HDE  510(k)  PDP  Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

**CERTIFICATION STATEMENT / INFORMATION**

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.  
**Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Liu Qinfang (Title) Management Representative
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 158-38 Huashan Rd Suzhou High – New District, China 215129	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 86 512 666 26278 (Fax) 86 512 666 26238
	15. DATE OF CERTIFICATION Oct 20, 2013

### Instructions for Completion of Form FDA 3674

#### Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

**Box A** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

**Box B** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

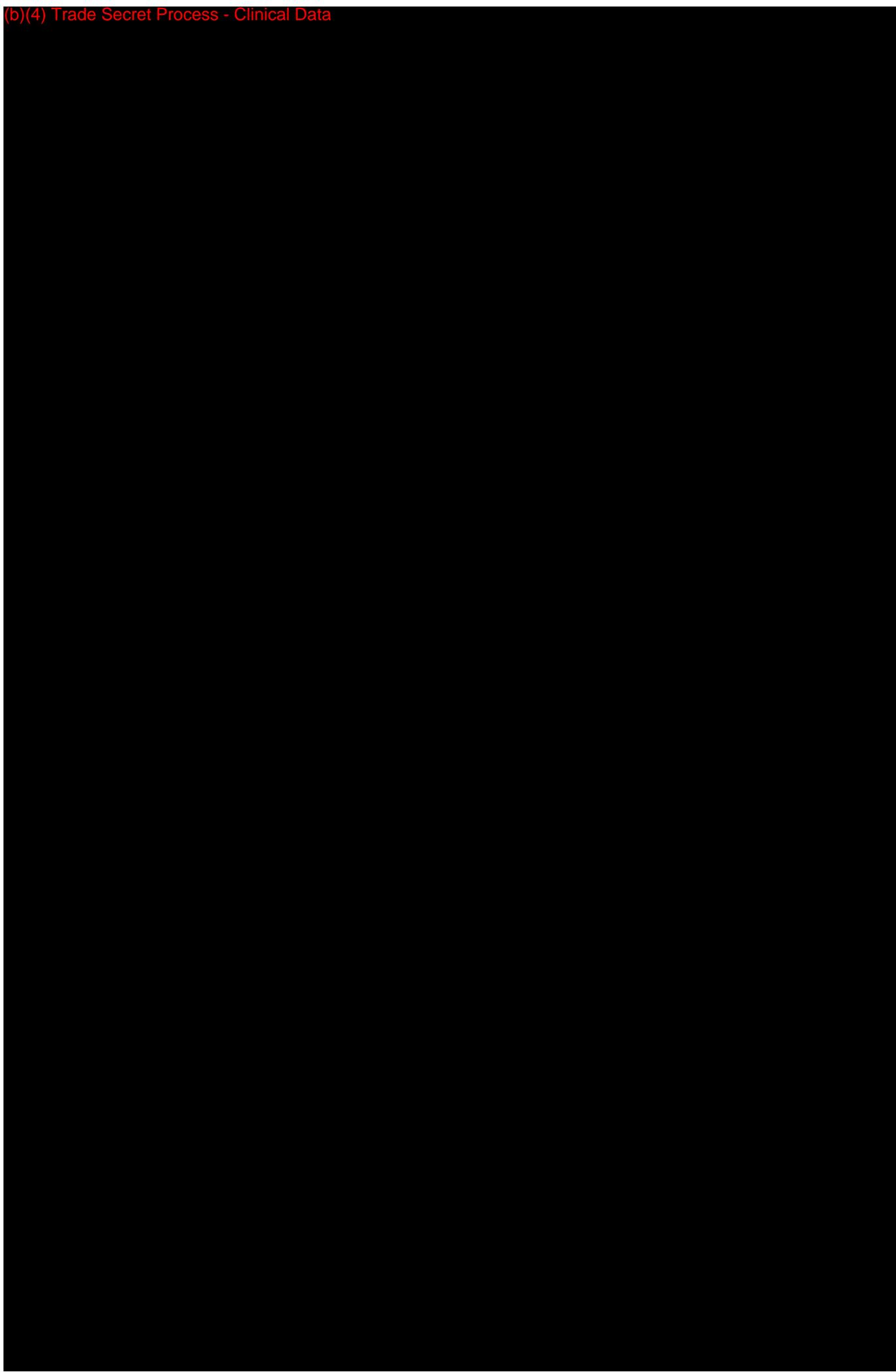
**Box C** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

#### Paperwork Reduction Act Statement

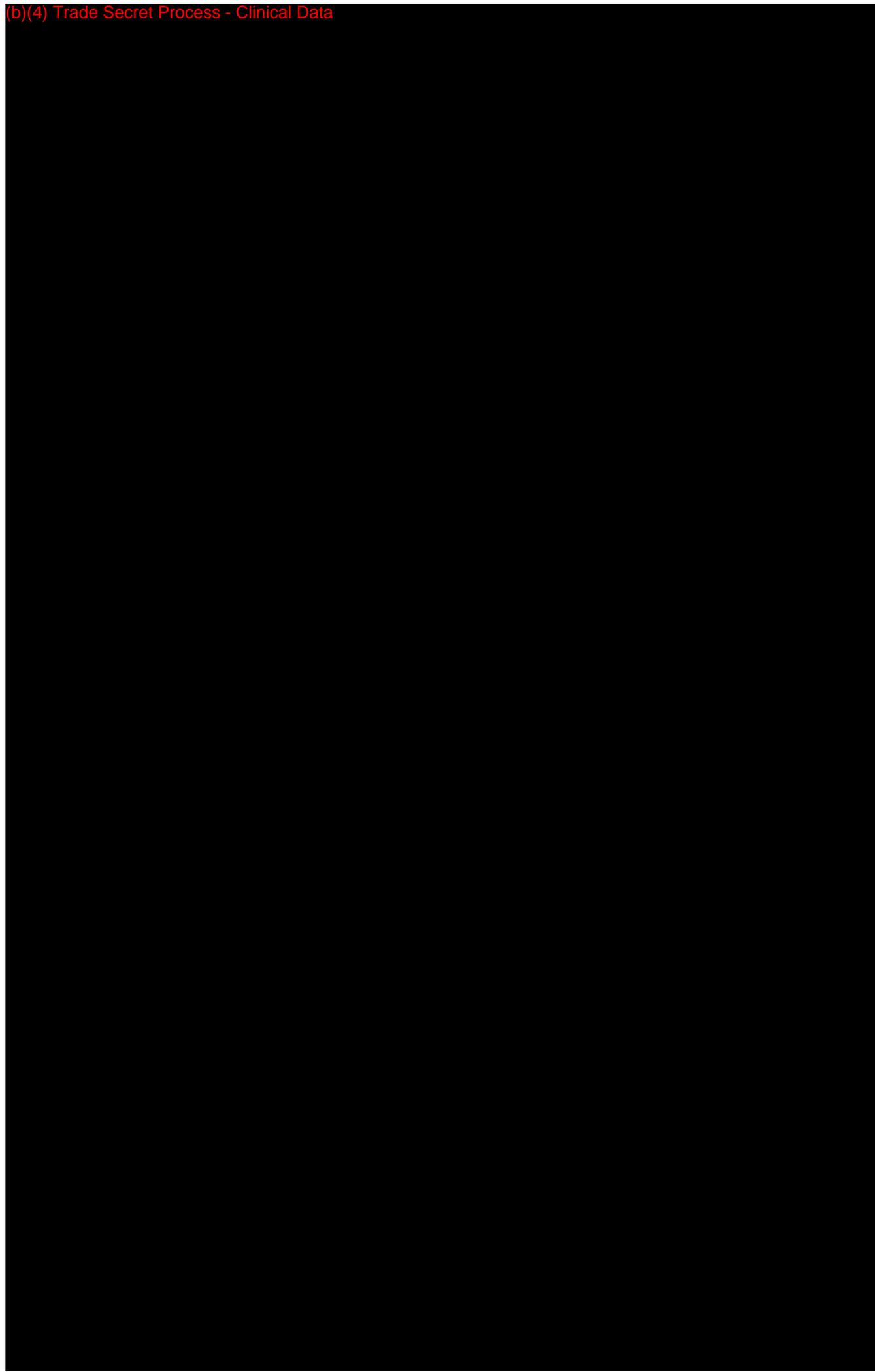
Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

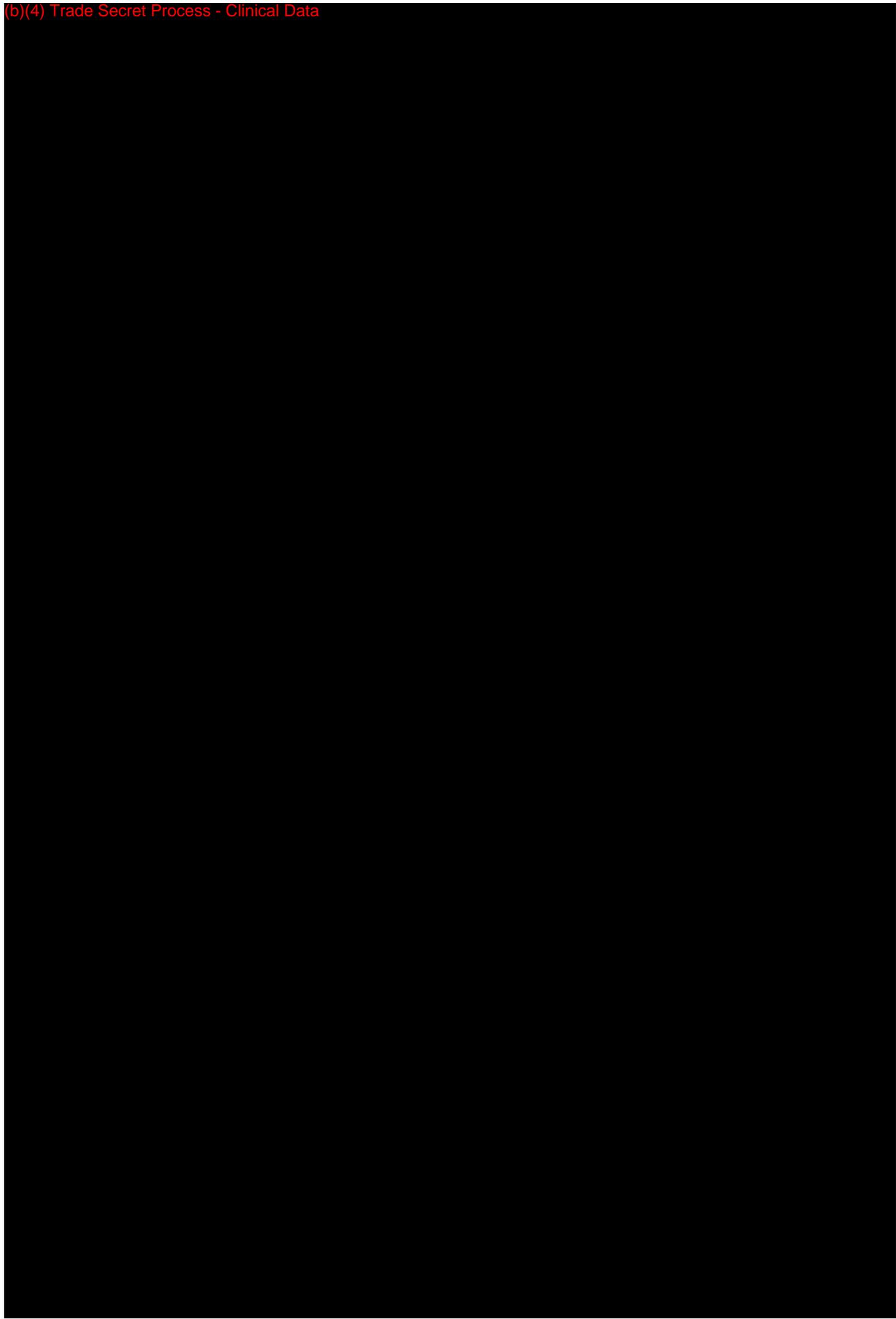
Department of Health and Human Services  
Food and Drug Administration  
Office of the Chief Information Officer (HFA-250)  
5600 Fishers Lane  
Rockville, MD 20857

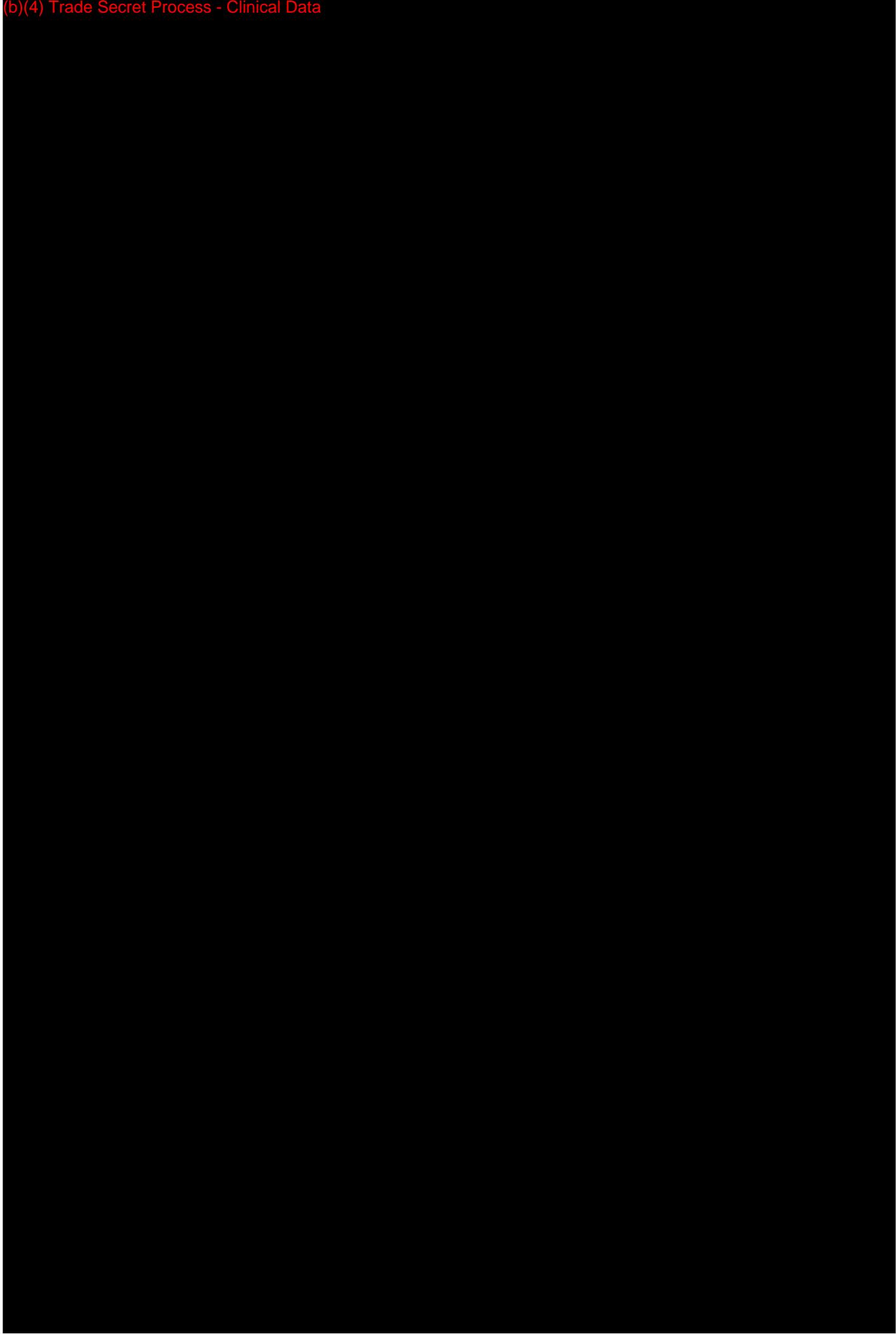
*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.*

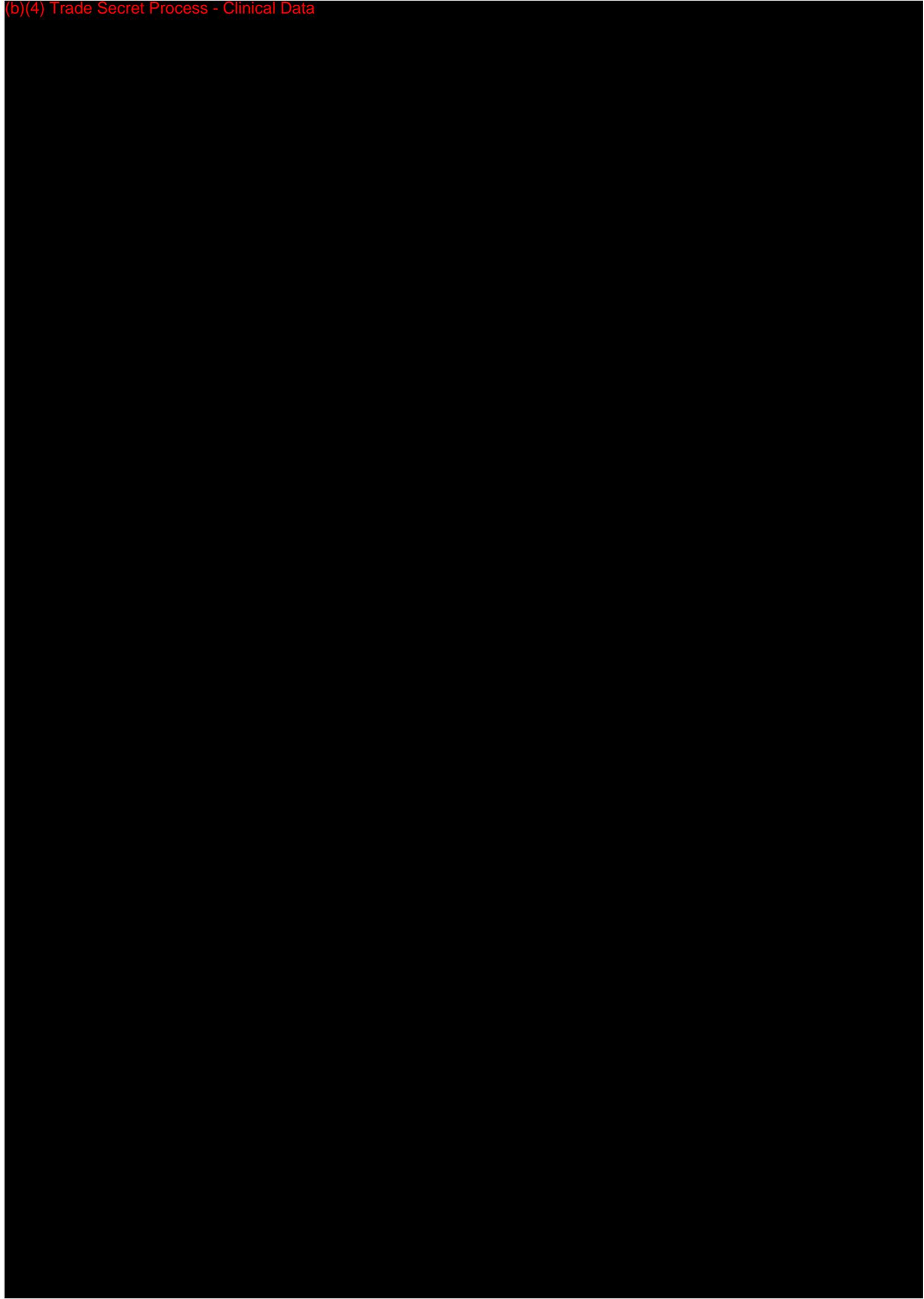
















# COVER SHEET MEMORANDUM

Food and Drug Administration  
Office of Device Evaluation &  
Office of In Vitro Diagnostics and  
Radiological Health

**From:** Reviewer Name Della Hammond  
**Subject:** 510(k) Number K133499  
**To:** The Record

**Please list CTS decision code:** SE - Substantially Equivalent

- Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page ( <i>Attach IFU</i> )	X	X
510(k) Summary or 510(k) Statement ( <i>Attach Summary or Statement</i> )	X	X
Truthful and Accurate Statement ( <i>Must be present for a Final Decision</i> )	X	X
Is the device Class III?	.	X
Does firm reference standards? (If yes, please attach <u>Form 3654</u> .)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See <u>Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices</u> .)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology		×
Is this device subject to the Tracking Regulation? ( <a href="#">Medical Device Tracking Guidance</a> )		×

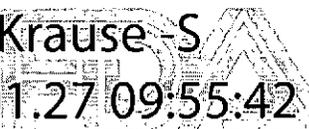
**Regulation Number:** 878.4750

**Class:** II

**Product Code:** GDW

**Additional Product Codes:**

**Digital Signature Concurrence Table**  
(Not all signatures may be required)

Branch Chief Sign-Off	David Krause - S 2014.01.27 09:55:42 -05'00' 
Division Sign-Off	David Krause - S 2014.01.27 09:56:05 -05'00' 