

Decision: Accept Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Sreekanth Gutala -S 2013.06.07 13:51:51 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required.
Branch and Division digital signature optional.

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes No N/A Comment

a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
38) If literature is referenced in the submission, submission includes:			<input checked="" type="checkbox"/>	<input type="checkbox"/>
39) For each completed nonclinical (i.e., animal) study conducted			<input checked="" type="checkbox"/>	<input type="checkbox"/>

K. Performance Characteristics - In Vitro Diagnostic Devices Only

(Also see [21 CFR 809.10\(b\)\(12\)](#))

Submission states that the device: (one of the below must be checked)

- is an in vitro diagnostic device.
- is not an in vitro diagnostic device.

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Yes

No

N/A

Comment

F. Shelf Life

26) Proposed shelf life/expiration date stated

✗

27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.

✗

28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.

✗

G. Biocompatibility

If IVD device, select "N/A" and the below criteria will be omitted from checklist.

✗

H. Software

Submission states that the device: (one of the below must be checked)

does contain software/firmware.

✗

does not contain software/firmware.

Information regarding whether the device contains software is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

I. EMC and Electrical Safety

Submission states that the device: (one of the below must be checked)

does require EMC and Electrical Safety evaluation.

✗

does not require EMC and Electrical Safety evaluation.

Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

J. Performance Data - General

If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.

36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.

✗

37)

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Yes

No

N/A

Comment

D. Proposed Labeling (see also 21 CFR part 801)

If *in vitro* diagnostic (IVD) device, criteria 17, 18, & 19 may be omitted.

17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	✗	<input type="checkbox"/>		<input type="checkbox"/>
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	✗	<input type="checkbox"/>		
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	✗	<input type="checkbox"/>		
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	✗	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19) General labeling provisions				<input type="checkbox"/>
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	✗	<input type="checkbox"/>		
b) Labeling includes device common or usual name. (21 CFR 801.61)	✗	<input type="checkbox"/>	<input type="checkbox"/>	
20)				<input type="checkbox"/>
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.	<input type="checkbox"/>	<input type="checkbox"/>	✗	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	✗	<input type="checkbox"/>	<input type="checkbox"/>	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	<input type="checkbox"/>	<input type="checkbox"/>	✗	
21) If the device is an <i>in vitro</i> diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10 .	<input type="checkbox"/>	<input type="checkbox"/>	✗	<input type="checkbox"/>

E. Sterilization

If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.

✗

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(21 CFR 807.87 unless otherwise indicated)

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- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				<input checked="" type="checkbox"/>
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
c) A list and description of each device for which clearance is requested.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments?				
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system			<input checked="" type="checkbox"/>	<input type="checkbox"/>
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
15) Submission includes a comparison of the following for the predicate(s) and subject device				<input type="checkbox"/>
a) Indications for Use	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
b) Technology, including features, materials, and principles of operation	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Yes

No

N/A

Comment

A. Administrative

1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	✗	<input type="checkbox"/>		<input type="checkbox"/>
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	✗	<input type="checkbox"/>		<input type="checkbox"/>
a) Device trade name or proprietary name	✗	<input type="checkbox"/>		
b) Device common name	✗	<input type="checkbox"/>		
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	✗	<input type="checkbox"/>		
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	✗	<input type="checkbox"/>		<input type="checkbox"/>
4) Submission contains 510(k) Summary or 510(k) Statement	✗	<input type="checkbox"/>		<input type="checkbox"/>
a) Summary contains all elements per 21 CFR 807.92 (See also 510(k) Summary Checklist)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b) Statement contains all elements per 21 CFR 807.93	✗	<input type="checkbox"/>	<input type="checkbox"/>	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) See recommended format .	✗	<input type="checkbox"/>		<input type="checkbox"/>
6) Submission contains Class III Summary and Certification. See recommended content .	<input type="checkbox"/>	<input type="checkbox"/>	✗	<input type="checkbox"/>
7) Submission contains clinical data	<input type="checkbox"/>		✗	<input type="checkbox"/>
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	✗	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	✗	<input type="checkbox"/>		<input type="checkbox"/>
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance " Medical Devices: The Pre-Submission Program and Meetings with FDA Staff ." Once finalized, this guidance will represent the Agency's current thinking on this topic.	✗	<input type="checkbox"/>	<input type="checkbox"/>	

B. Device Description

10)				<input type="checkbox"/>
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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3) All pages of the submission are numbered.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments?		

<p>5) Is there a pending PMA for the same device with the same indications for use?</p> <p>If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.</p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<p>Comments? <input style="width: 100%; height: 20px;" type="text"/></p>		
<p>6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?</p> <p>If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm</p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<p>Comments? <input style="width: 100%; height: 20px;" type="text"/></p>		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.

If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.

If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.

If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.



Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K130135 Date Received by DCC: 05/29/2013

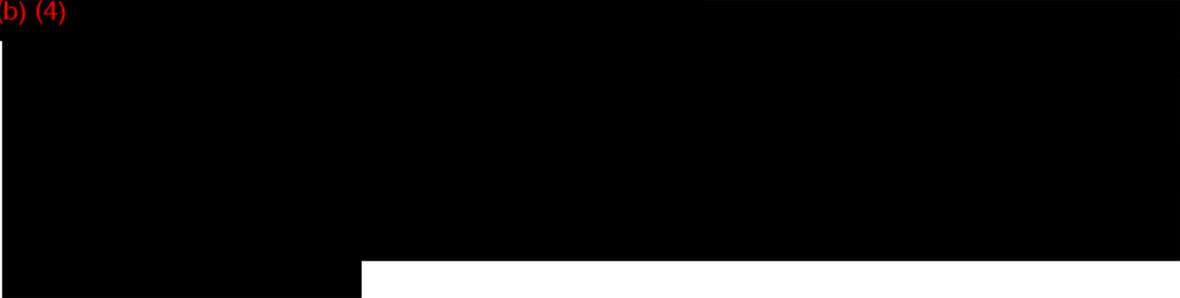
Lead Reviewer: Sreekanth Gutala, Ph.D.

Branch: INCB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions		
Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
<p>1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?</p> <p>If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If the product does not appear to be a device or such a combination product, mark "No."</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments?		
<p>2. Is the application with the appropriate Center?</p> <p>If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If application should not be reviewed by your Center mark "No."</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments?		
<p>3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:</p> <p>a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?</p> <p>b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ?</p> <p>If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.</p>	<input type="checkbox"/>	<input type="checkbox"/>
Comments?		
<p>4) Is this device type eligible for a 510(k) submission?</p> <p>If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments?		

10 (b) (4)



- Dana Products Response: (b) (4)



STUDY 1:

SUMMARY

Exposure Time	Dana Reusable Test Pack	STERITEC TEST PACK
1 minute	28/30	0/30
1.5 minutes	16/30	0/30
2 minutes	9/30	0/30
4 minutes	0/30	0/30

STUDY 2 :

SUMMARY

Exposure Time	Dana Reusable Test Pack	STERITEC TEST PACK
1 minute	29/30	0/30
1.5 minutes	12/30	0/30
2 minutes	5/30	0/30
4 minutes	0/30	0/30

STUDY 3 :

SUMMARY

Exposure Time	Dana Reusable Test Pack	STERITEC TEST PACK
1 minute	28/30	0/30
1.5 minutes	18/30	0/30
2 minutes	9/30	0/30
4 minutes	0/30	0/30

STUDY 4:

SUMMARY

Exposure Time	Dana Reusable Test Pack	STERITEC TEST PACK
1 minute	24/30	0/30
1.5 minutes	17/30	0/30
2 minutes	7/30	0/30
4 minutes	0/30	0/30

STUDY 5 :

SUMMARY

Exposure Time	Dana Reusable Test Pack	STERITEC TEST PACK
1 minute	22/30	0/30
1.5 minutes	12/30	0/30
2 minutes	5/30	0/30
4 minutes	0/30	0/30

STUDY 6:

SUMMARY

Exposure Time	Dana Reusable Test Pack	STERITEC TEST PACK
1 minute	29/30	0/30
1.5 minutes	10/30	0/30
2 minutes	8/30	0/30
4 minutes	0/30	0/30

STUDY 7:

SUMMARY

Exposure Time	Dana Reusable Test Pack	STERITEC TEST PACK
1 minute	21/30	0/30
1.5 minutes	14/30	0/30
2 minutes	6/30	0/30
4 minutes	0/30	0/30

Conclusion: The results show that the samples retained for 1 year after manufacture date showed no drop off in performance (either on first use or after 200 uses) when compared to newly manufactured samples. Therefore, this substantiates the 1 year shelf life claim for the test pack.

Dear Mr. Harry Bala

Enclosed please find FDA comments on your 510(K) K130135 submission.
Please provide the requested information. Please contact me if you have
any additional questions.

-Sreekanth Gutala

SREEKANTH GUTALA, Ph.D.
Sr. Scientific Reviewer
FDA/CDRH/ODE/DAGRID/INCB
WO66, Room 2564
10903 New Hampshire Ave
Silver Spring, MD 20993
Ph: 301-796-7007, Fax: 301-847-8109
Emal: Sreekanth.gutala@fda.hhs.gov<mailto:Sreekanth.gutala@fda.hhs.gov>



**Public Health Service
DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration**

Date: July 24, 2013

Subject: Premarket Notification 510(k) - K130135 Submission

Device Trade Name: Dana Reusable Test Pack

From: Sreekanth Gutala, Ph.D., Reviewer, Infection Control Devices Branch, Division of Anesthesiology, General Hospital, Infection Control and Dental Devices; Office of Device Evaluation, Center for Devices and Radiological Health. Tel: **(301) 796-7007**; Fax: **(301) 847-8109**; email: sreekanth.gutala@fda.hhs.gov

To: Mr. Harry Bala, President, Dana Products, Inc. 7 Corey Drive, South Barrington, IL 60010, USA, Tel: (847) 455- 2881, **Fax:** (847) 455-2886.

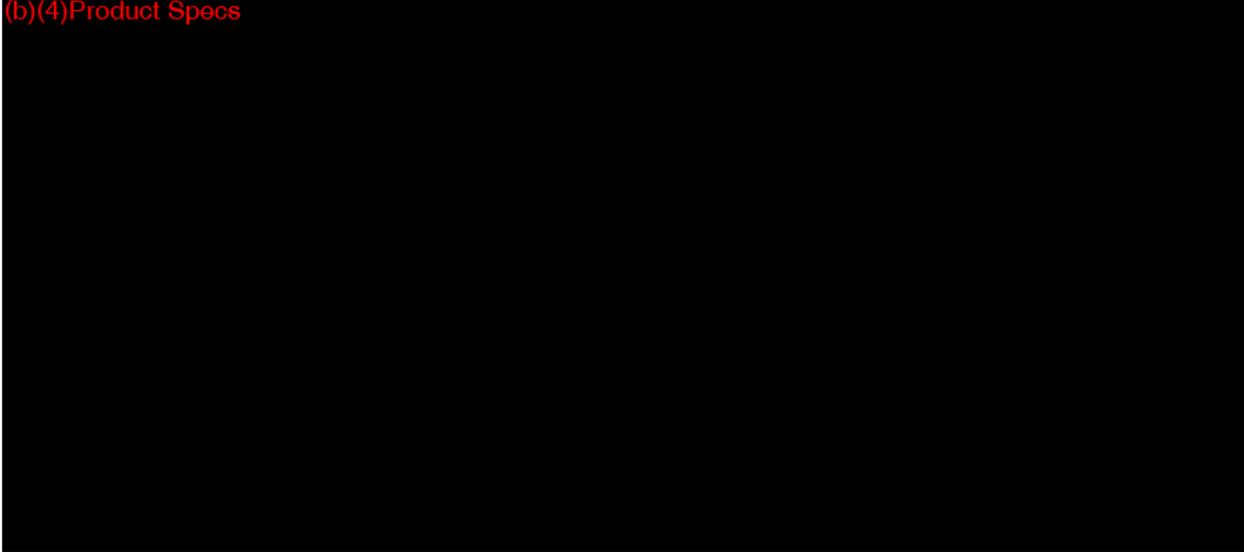
email: bala@voyager.net/bala@danaproducts.com

Dear Mr. Harry Bala

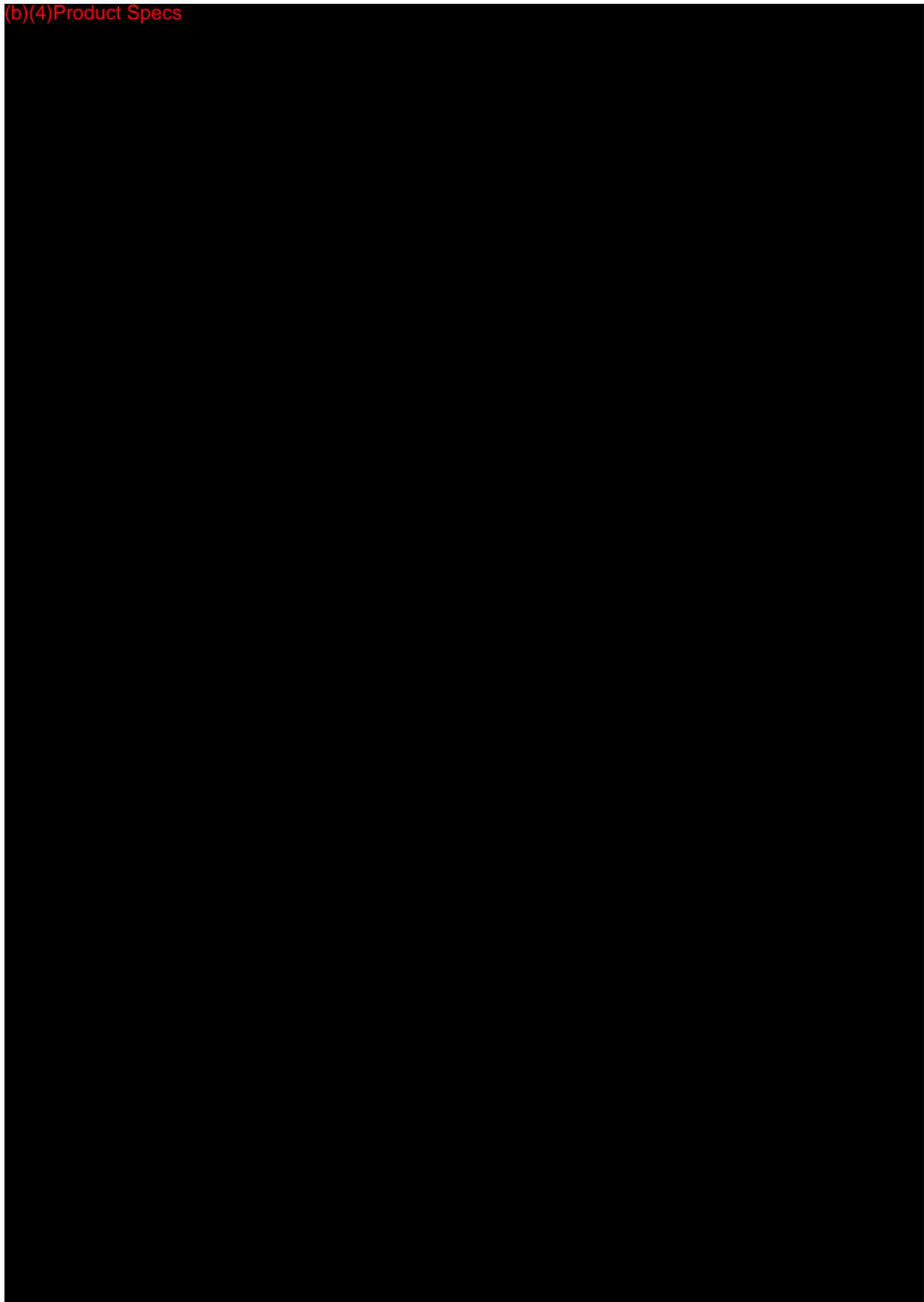
Our review of your **510(k)** submission, K130135, Dana Reusable Test Pack, show areas of deficiency that need to be resolved before we can determine the substantial equivalence of your device. Please provide the following information:

AREAS OF DEFICIENCY:

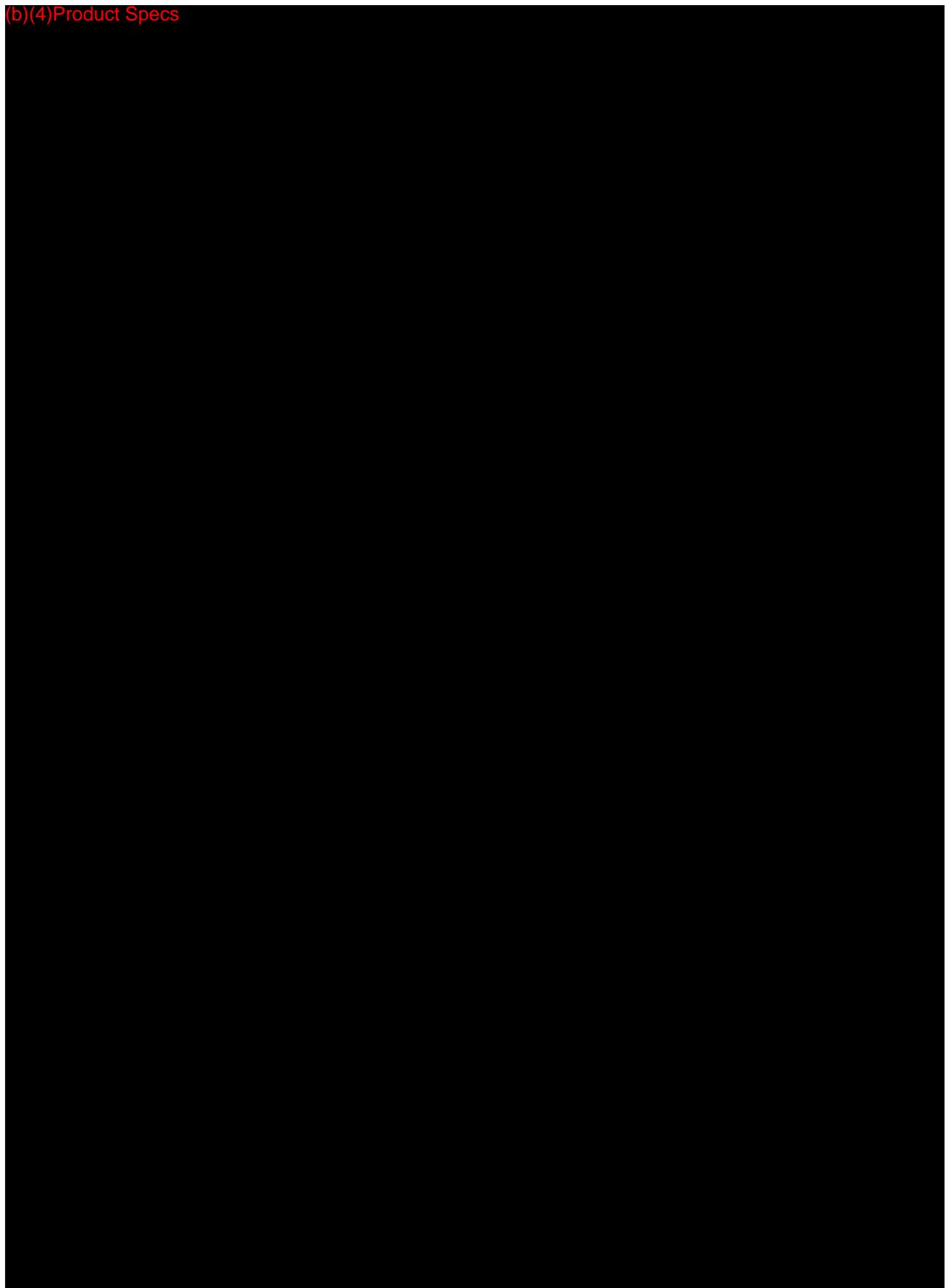
(b)(4)Product Specs



(b)(4)Product Specs



(b)(4)Product Specs



(b)(4)Product Specs



Please provide this information . Your document has been placed on hold pending receipt of the above additional information. The requested information should reference your above 510(k) number and should be submitted in duplicate to the Document Mail Center (DMC) at the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Document Mail Center - WO66-0609
Silver Spring, MD 20993-0002

Correspondence sent to any address other than the above address will not be considered as part of your official 510(k) submission. Therefore, please forward the original copies of all correspondence to the DMC so that we may proceed with the review of your submission. To expedite the processing of you review, you may forward an electronic response to the deficiencies directly to me (Sreekanth Gutala at sreekanth.gutala@fda.hhs.gov). We request that you provide detailed item-by-item responses to the attached request for additional information. The suggested format is to restate the question and/ or comment, state your response to the Agency's request/recommendation and reference the location of appropriate supporting documentation in file.

If you have any questions concerning the content of this letter, please contact me by Tel: (301) 796-7007; Fax: (301) 847-8109 or by e-mail at sreekanth.gutala@fda.hhs.gov.

Sreekanth Gutala, Ph.D.
Scientific Reviewer
FDA/CDRHIODE/DAGIDINCB
W066 Room 2564, 10903 New Hampshire Ave.
Silver Spring, MD 20993
Sreekanth.gutala@fda.hhs.gov

Decision: Accept Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Sreekanth Gutala -S 2013.02.21 09:59:00 -05'00'
Branch Chief Sign-Off (digital signature optional)*	Elizabeth F. Claverie 2013.02.21 10:09:39 -05'00'
Division Sign-Off (digital signature optional)*	Tejashri S. Purohitsheth -S 2013.02.21 10:22:00 -05'00'

* Branch and Division review of checklist and concurrence with decision required.
Branch and Division digital signature optional.

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is not an in vitro diagnostic device.

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- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

J. Performance Data - General

If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.

36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.

✗

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■

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37)

■

a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.

■

■

✗

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.

✗

■

■

c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

■

■

✗

38) If literature is referenced in the submission, submission includes:

✗

■

39) For each completed nonclinical (i.e., animal) study conducted

■

✗

a) Submission includes a study protocol which includes all elements as outlined in [21 CFR 58.120](#).

■

✗

b) Submission includes final study report which includes all elements outlined in [21 CFR 58.185](#).

■

✗

c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation ([21 CFR Part 58](#)), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.

■

✗

Comments?

1. the sponsor did not provide the performance study protocols or report. The sponsor provided very precise data on performance. The sponsor should be asked to provide the detailed study protocols and test reports for the performance studies conducted with the device.
 2. Study did not mention anything about compliance in regards to GLP requirements.

K. Performance Characteristics - In Vitro Diagnostic Devices Only

(Also see [21 CFR 809.10\(b\)\(12\)](#))

■

Submission states that the device: (one of the below must be checked)

■

is an in vitro diagnostic device.

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

G. Biocompatibility

If IVD device, select "N/A" and the below criteria will be omitted from checklist.

Submission states that there: (one of the below must be checked)

are direct or indirect (e.g., through fluid infusion) patient-contacting components.

are no direct or indirect (e.g., through fluid infusion) patient-contacting components.

Information regarding the patient contact status of the device is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present

30) Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration, etc.)

31) Biocompatibility assessment of patient-contacting components

Submission includes:

Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR

a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).

H. Software

Submission states that the device: (one of the below must be checked)

does contain software/firmware.

does not contain software/firmware.

Information regarding whether the device contains software is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

I. EMC and Electrical Safety

Submission states that the device: (one of the below must be checked)

does require EMC and Electrical Safety evaluation.

does not require EMC and Electrical Safety evaluation.

Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

	Yes	No	N/A	Comment
b) Identification of device, and/or accessories, and/or components that are end user sterilized.	✗	☐	☐	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.	✗	☐	☐	
23) If the device, and/or accessory, and/or a component is provided sterile:			✗	☐
24) If the device, and/or accessory, and/or a component is end user sterilized:			☐	✗
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	✗	☐		
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. <i>Note, the sterilization validation report is not required.</i>	✗	☐		
c) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.).	✗	☐		
d) Submission includes sterilization instructions for end user.	✗	☐		
Comments?	1. The subject device is a test pack and package is part of a test pack. This is acceptable.			
25)				☐
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.	☐	☐	✗	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	✗	☐	☐	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	☐	☐	✗	
F. Shelf Life				
26) Proposed shelf life/expiration date stated	✗	☐	☐	☐
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.	☐	☐	✗	☐
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	✗	☐		☐

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

	Yes	No	N/A	Comment
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Comments?	1. The sponsor did not indicate either Rx or Prescription use in its Indications for use and in Labeling also.
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19) General labeling provisions				<input type="checkbox"/>
---------------------------------	--	--	--	--------------------------

a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
---	-------------------------------------	--------------------------	--	--

b) Labeling includes device common or usual name. (21 CFR 801.61)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
---	-------------------------------------	--------------------------	--------------------------	--

20)				<input type="checkbox"/>
-----	--	--	--	--------------------------

a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
--	--------------------------	--------------------------	-------------------------------------	--

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
--	-------------------------------------	--------------------------	--------------------------	--

c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
---	--------------------------	--------------------------	-------------------------------------	--

21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10 .	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
--	--------------------------	--------------------------	-------------------------------------	--------------------------

E. Sterilization

If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.			<input type="checkbox"/>	<input type="checkbox"/>
--	--	--	--------------------------	--------------------------

Submission states that the device and/or accessories are: (one of the below must be checked)

<input type="checkbox"/>	provided sterile
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<input checked="" type="checkbox"/>	provided non-sterile but sterilized by the end user
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<input type="checkbox"/>	non-sterile when used
--------------------------	-----------------------

<input type="checkbox"/>	Information regarding the sterility status of the device is not provided.
--------------------------	---

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

22) Assessment of the need for sterilization information				<input type="checkbox"/>
--	--	--	--	--------------------------

a) Identification of device, and/or accessories, and/or components that are provided sterile.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
---	-------------------------------------	--------------------------	--	--

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

	Yes	No	N/A	Comment
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	<input type="checkbox"/>	<input checked="" type="checkbox"/>		

Comments? 1. The sponsor provided 3 predicates. However, the sponsor listed only one predicate in FDA Form 3514.
 2. The sponsor listed wrong 510(K) number for one predicate (K10300). One digit is missing.
 3. The sponsor did not provide any substantial equivalence section and discussed the similarities and differences of the subject device with predicate(s).

15) Submission includes a comparison of the following for the predicate(s) and subject device				<input checked="" type="checkbox"/>
---	--	--	--	-------------------------------------

a) Indications for Use	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
------------------------	--------------------------	-------------------------------------	--	--

b) Technology, including features, materials, and principles of operation	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
---	--------------------------	-------------------------------------	--	--

Comments? The sponsor did not provide any substantial equivalence section and discussed the similarities and differences of the subject device with predicate(s).
 2. The sponsor did not provide any IFU comparison for the predicates.
 3. The sponsor did not discuss or provide any substantial equivalence comparison table to compare technology features, materials and principles of operation in the submission.

16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
--	--------------------------	-------------------------------------	--------------------------	-------------------------------------

Comments? 1. The sponsor did not provide any analysis or substantial equivalence section and discussed the similarities and differences of the subject device with predicate(s).

D. Proposed Labeling (see also 21 CFR part 801)

If *in vitro* diagnostic (IVD) device, criteria 17, 18, & 19 may be omitted.

17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>
--	-------------------------------------	--------------------------	--	-------------------------------------

a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
--	--------------------------	-------------------------------------	--	--

b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
--	-------------------------------------	--------------------------	--	--

Comments? 1. The name of the subject device is not consistent with that of Indications for use.
 2. The stated indications for use is different from that of labeling. Sponsor discussed this under product description.
 3. Sponsor did not follow labeling requirements for 510(k) premarket submission.

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

<p>- Any "No" answer will result in a "Refuse to Accept" decision.</p> <p>- Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.</p>	Yes	No	N/A	Comment
--	------------	-----------	------------	----------------

a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "[Medical Devices: The Pre-Submission Program and Meetings with FDA Staff](#)." Once finalized, this guidance will represent the Agency's current thinking on this topic.

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Comments?

1. The sponsor did not mention about any prior submissions for the subject device.
2. The sponsor did not fill section F, FDA documents numbers for prior related submissions column on page number 3 of FDA form 3514.

B. Device Description

10)				■
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.	■	■	✗	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	■	■	✗	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				✗
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	■	✗		
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	■	✗		
c) A list and description of each device for which clearance is requested.	✗	■	■	

Comments?

1. The device description is not consistent with the device description in labeling.
2. The device description did not contain principle of operation and mechanism of action to achieve the intended effect.

12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	✗	■	■	■
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system			✗	■

C. Substantial Equivalence Discussion

14) Submitter has identified a predicate device.	✗	■		✗
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online.</i>	■	✗		

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

A. Administrative

1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	✗	☐		☐
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	☐	✗		✗
a) Device trade name or proprietary name	✗	☐		
b) Device common name	☐	✗		
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	✗	☐		
Comments?	1. The device name is not consistent. 2. The sponsor did not provide device common name. 3. The sponsor did not list all the predicate devices on page 3 of FDA form 3514. 4. The sponsor did not provide classification panel on page 3 of FDA form 3514.FDA Form 3514. 5. The sponsor did not fill Indications column on page 3 of FDA form 3514.			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	☐	✗		✗
Comments?	1. The sponsor did not designate with Rx or OTC on the Indications for Use statement. 2. The device name is not consistent on IFU and throughout the submission.			
4) Submission contains 510(k) Summary or 510(k) Statement	✗	☐		☐
a) Summary contains all elements per 21 CFR 807.92 (See also 510(k) Summary Checklist)	☐	☐	☐	
b) Statement contains all elements per 21 CFR 807.93	✗	☐	☐	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) See <i>recommended format</i> .	✗	☐		☐
6) Submission contains Class III Summary and Certification. See <i>recommended content</i> .	☐	☐	✗	☐
7) Submission contains clinical data	☐		✗	☐
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	☐	✗	☐	✗
Comments?	1. The sponsor did not provide the proper standard title. The sponsor did not provide the 'same' standard title on page # 1 and 2 of the FDA Form 3654. 2. The sponsor did not write standard numbers such as ST 8 and ST 79 in the title field on the form 3654.			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	☐	✗		✗

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

		Yes	No
1) Submission contains a Table of Contents		✗	<input type="checkbox"/>
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)		<input type="checkbox"/>	✗
3) All pages of the submission are numbered.		<input type="checkbox"/>	✗
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)		✗	<input type="checkbox"/>
Comments?	<p>1. The sponsor did not give complete information in Table of contents.</p> <p>2. The sponsor did not arrange the submission in a proper order as per table of contents.</p> <p>3. The sponsor did not provide page numbers on all the pages in the submission.</p> <p>4. The sponsor will be asked to refer to 510(k) premarket submission guidelines at : http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134572.htm#link_4</p> <p>5. The sponsor should provide same ecopy and paper copy of the submission.</p>		

<p>5) Is there a pending PMA for the same device with the same indications for use?</p> <p>If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.</p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<p>Comments? <input type="text"/></p>		
<p>6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?</p> <p>If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm</p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<p>Comments? <input type="text"/></p>		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.

If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.

If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.

If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.



Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K130135 Date Received by DCC: 02/07/2013
 Lead Reviewer: Sreekanth Gutala, Ph.D.
 Branch: INCB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed

Yes No

1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?

If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."

Comments?

2. Is the application with the appropriate Center?

If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."

Comments?

3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:

- a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?
- b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ?

If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.

Comments?

4) Is this device type eligible for a 510(k) submission?

If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."

Comments?

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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 number."

Indications for Use

510(k) Number (if known)

K130135

Device Name

Dana Reusable Test Pack

Indications for Use (Describe)

Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SGM Biotech's Self-Contained Biological Indicator Smart-Read EZTest - Steam along with or without SteriScan Integrators.

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)



Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Traditional**

K130135/S001

Date: July 24, 2013
To: The Record
From: Sreekanth Gutala, Ph.D.
Office: ODE Division: DAGRID Branch: INCB
Through: Ms. Elizabeth Claverie, M.S., Branch Chief, ODE/DAGRID/INCB
510(k) Holder: Dana Products, Inc; 7 Corey Dr, South Barrington, IL 60010
Address: 7 Corey Dr, South Barrington, IL 60010
Device Trade Name: Dana Reusable Test Pack
Contact: Harry Bala, President
Phone: 847-455-2881
Fax: 847-455-2886
Email: bala@voyager.net/bala@danaproducts.com

I. Purpose and Submission Summary

The 510(k) holder, Dana Products Inc. would like to introduce the "Dana Reusable Test Pack" into interstate commerce. Dana Products Inc has submitted a pre-market notification 510 (k) K130135, for their device Dana Reusable Test Pack on February 06, 2013 and FDA Document centers received on February 07, 2013. The sponsor has submitted both ecopy and paper copy of the submission and the ecopy is an exactly duplicate of a paper submission. The RTA checklist was completed on February 21, 2013 and it was determined as RTA1 (Refuse to accept). The sponsor was notified by email and the sponsor submitted the revised corrected versions of ecopy and paper copy submission (K130135/S001) on May 24, 2013 and FDA DCC received on May 29, 2013. The RTA checklist was completed again on June 07, 2013 and it was determined as RTAA for the submission K130135/S001. The sponsor claims that, Biological Indicator Test Pack is a Class II device that has a Product Code of JOJ, as described in CFR 880.2800. Dana Products Inc. claims substantial equivalence to SteriTec Products Manufacturing Company inc's, 'SteriTec Biological Test Pack with Instant Readout Integrator, K103000'.

***Conclusion:** After reviewing the submission it was determined that additional information is required to support the determination of substantial equivalence. The submission will be placed on HOLD until all the concerns are resolved.*

510(k) COVERSHEET for DCC

510(k) Number: K 130135

Review Records: DocMan
 Paper *(only applies to original 510(k)s assigned prior to 1/28/2013)*

510(k) in eCopy-only Pilot: Yes No

Interim Decision (RTA1, TH, AI)

RTA1 (refuse to accept – CTS-issued email)

1. Put file on hold shelf.
2. If eCopy-only pilot, not applicable. Nothing should be sent down to DCC.

TH (telephone, email, or fax hold)

1. Put file on hold as of _____ (date of last concurrence in CTS).
2. Issue auto-generated acknowledgement letter from APPS to applicant.
3. Shelf document:
 - a. If paper review records, add copy of the letter to jacketed submission and put file on hold shelf.
 - b. If DocMan review records, put file on hold shelf.
 - c. If eCopy-only pilot, not applicable – no file to put on hold shelf.

AI (AI mailed letter)

1. Put file on hold as of date on attached hold letter.
2. Mail the attached digitally signed and dated hold letter.
3. Shelf document:
 - a. If paper review records, add copy of the letter to jacketed submission and put file on hold shelf.
 - b. If DocMan review records, put file on hold shelf.
 - c. If eCopy-only pilot, not applicable – no file to put on hold shelf.

Final Decision

SE (all SE codes)

NSE (all NSE codes)

Other (DR, EX, FB, NA, ND, NF, OD, PE, etc.) _____ (code)

Add-to-File (ATF)

In lieu of blue cover sheet for ATF, review staff follows the instructions and complete the memo/routing sheet at http://eroom.fda.gov/eRoom/CDRH3/CDRHPreMarketNotification510kProgram/0_3bba7.

DCC refers to that documentation for the close-out code and mails any provided letter.

XVII: Recommendation SE

It is recommended that this 510 (k) submission, K130135/S002, is considered substantially equivalent to the predicate, SteriTec Products Manufacturing Company inc's, 'SteriTec Biological Test Pack with Instant Readout Integrator, K103000'.

Regulation Number: 21 CFR 880.2800

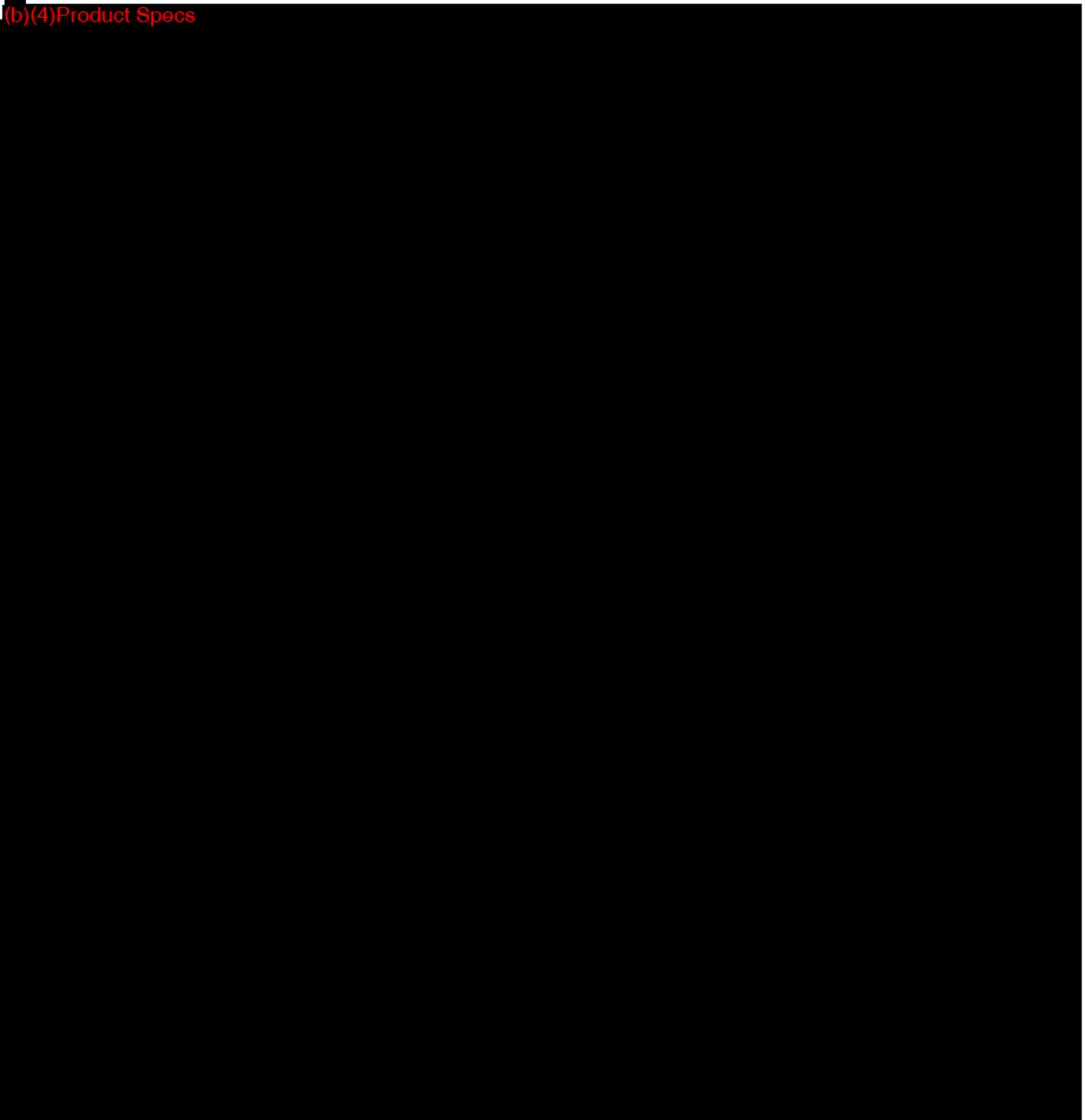
Regulation Name: Indicator, Biological Sterilization Process

Regulatory Class: Class II

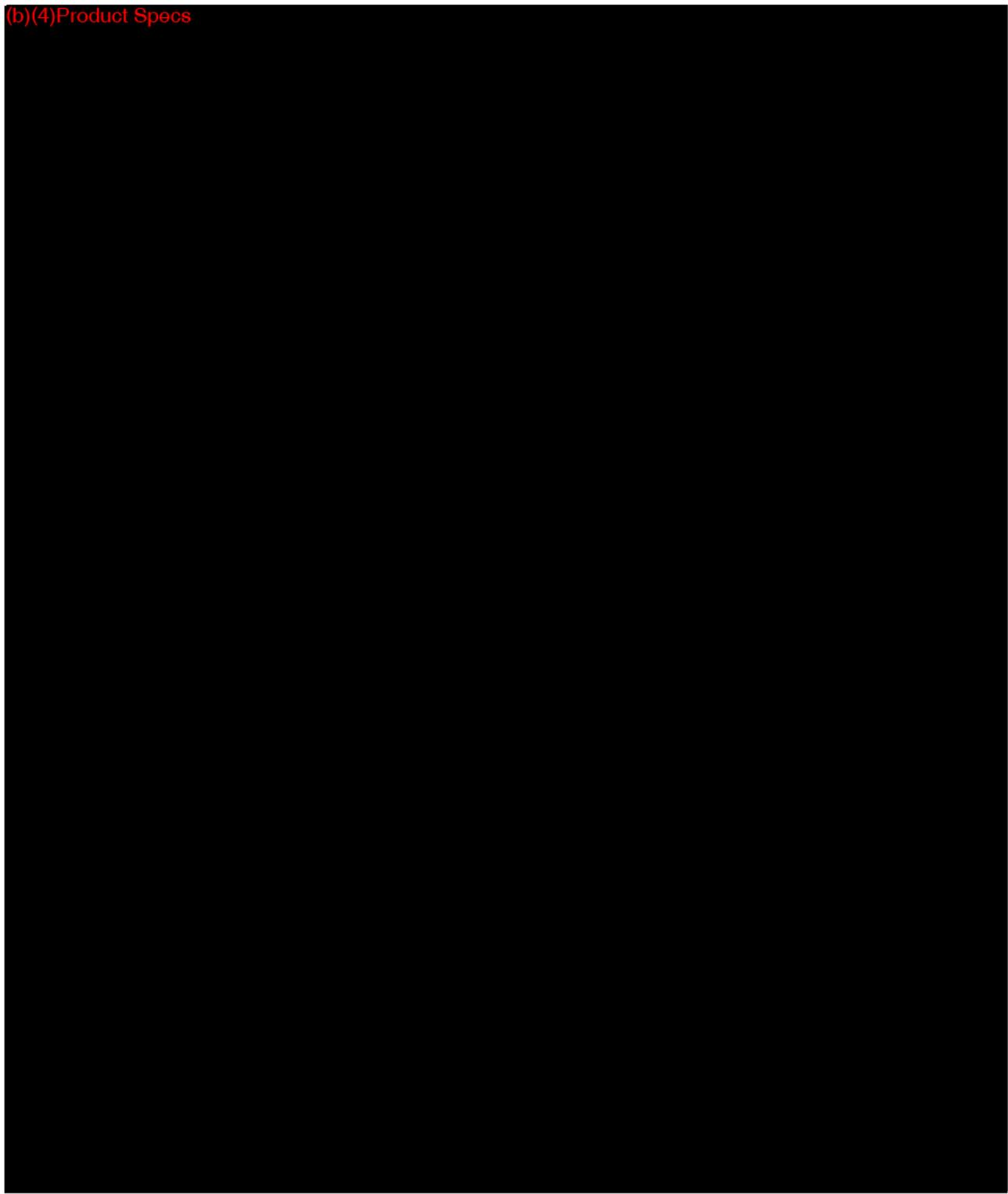
Product Code: JOJ

Digital Signature Concurrence Table	
Reviewer Sign-Off	Sreekanth Gutala -S <small>Digitally signed by Sreekanth Gutala -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000540490, cn=Sreekanth Gutala -S Date: 2013.11.22 10:35:18 -05'00'</small>
Branch Chief Sign-Off	Elizabeth F. Claverie -S 2013.11.22 15:41:47 -05'00'
Division Sign-Off	

(b)(4)Product Specs

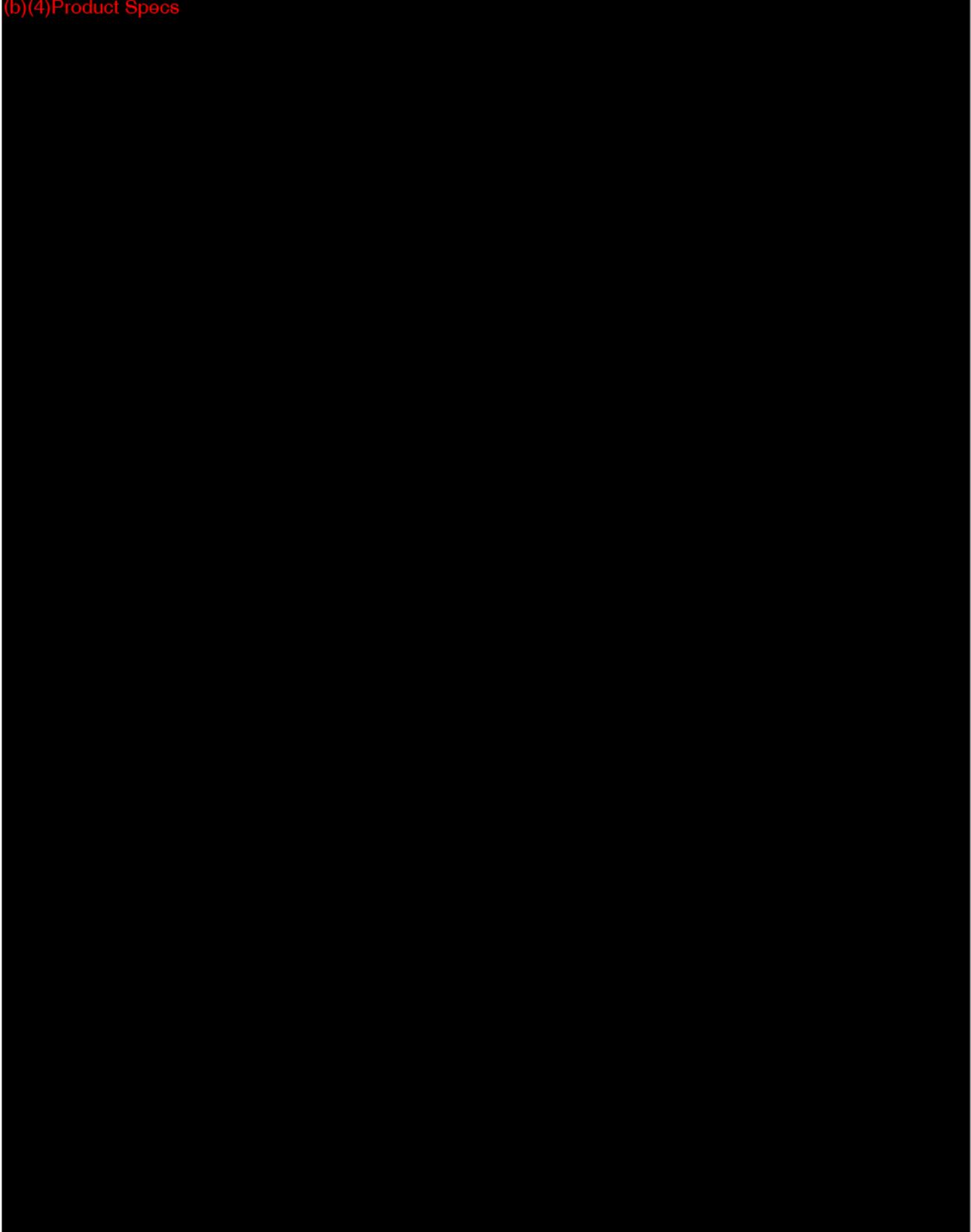


(b)(4)Product Specs



(b)(4)Product Specs

(b)(4)Product Specs



The following is the draft of the labeling that will be applied on each test pack.

Dana Reusable Test Pack

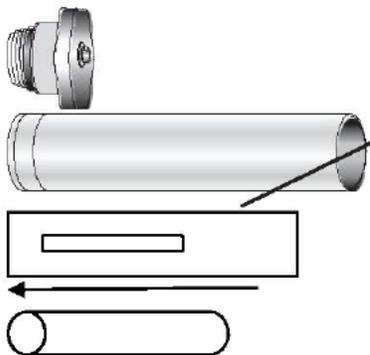
For challenging the steam sterilization process in
healthcare facilities and for routine sterilizer monitoring

Over the counter use

For use only with SGM Smart-Read BI along with or without a SteriScan Integrator

Insert cap end first of BI

Insert first Pellet end of SteriScan Integrator



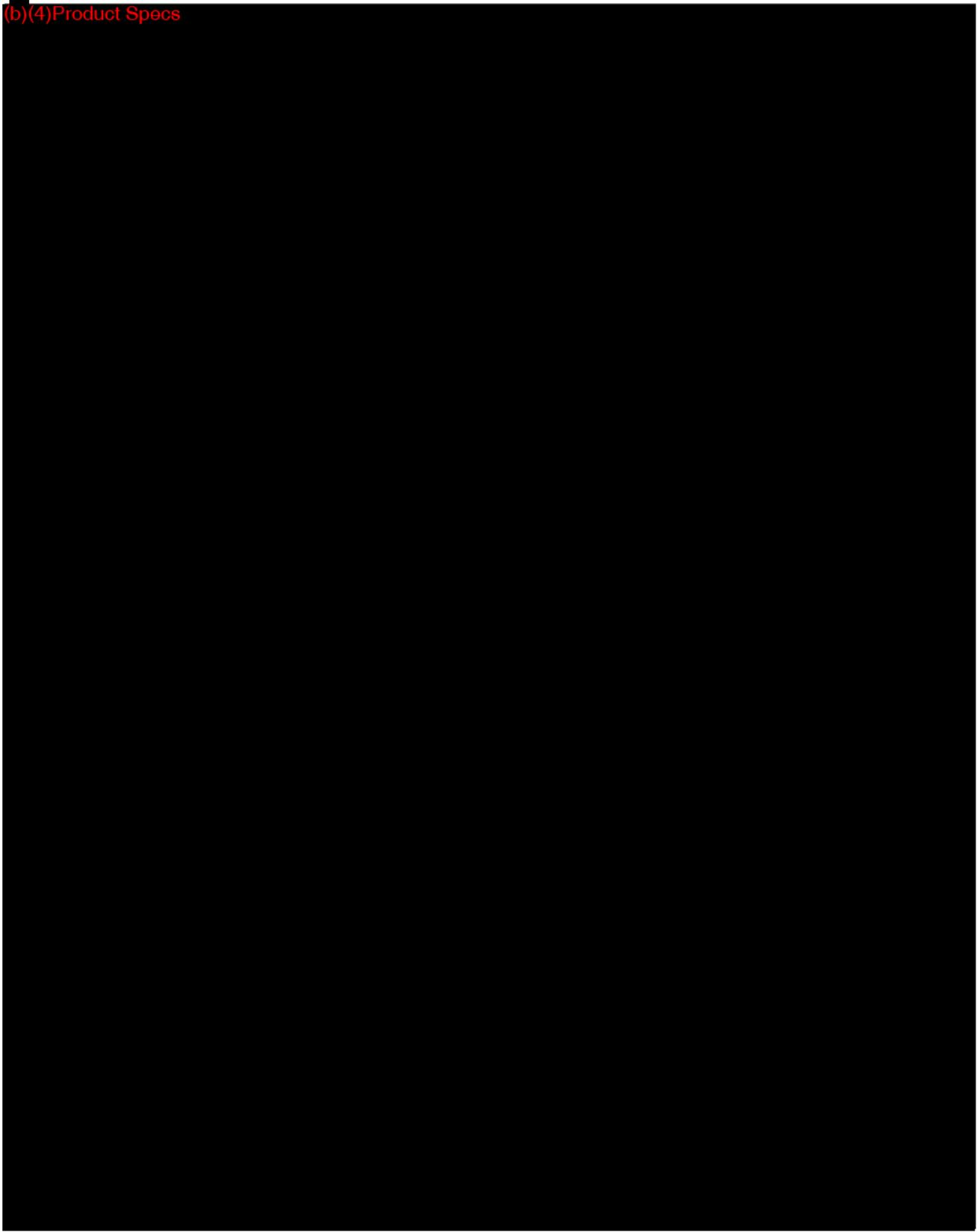
Insert cap end first of BI

Insert first Pellet end of SteriScan Integrator

Dana Products, Inc.
11457 Melrose St.
Franklin Park, IL

Lot Number:
Exp.:

(b)(4)Product Specs





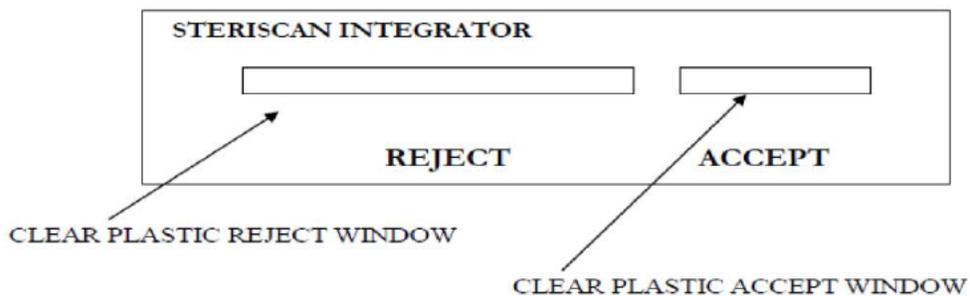
The firm claims that the device entire assembly is insulated. The aluminum chamber is large enough to accommodate a Smart-Read BI and a SteriScan Integrator. For testing, the firm

(b)(4)Product Specs

SteriScan Integrator description:

The SteriScan Integrator that was used in testing for this submission is identical in material, design and construction to the SteriScan Integrator cleared under K012195. The SteriScan Integrator that was used in testing for this submission is also identical to the SteriScan Integrator used in testing of the Dana Reusable Test Pack for use with 3M's 1292 Rapid Readout BI, along with or without a SteriScan Integrator, that was cleared under K092944.

DEVICE TOP VIEW



III. Device Description

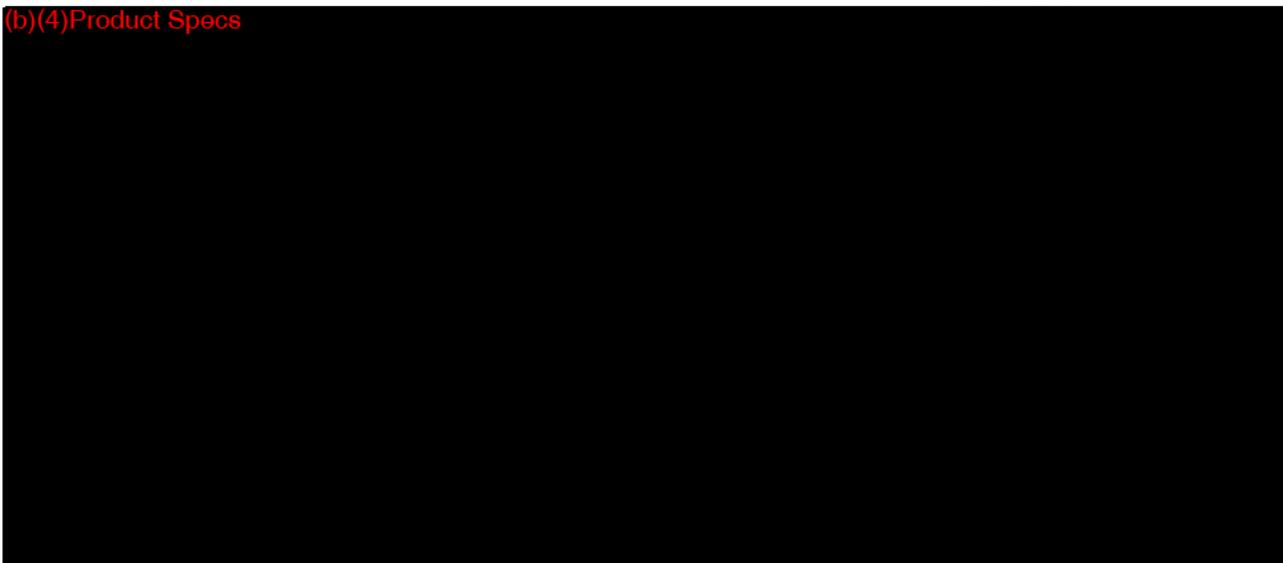
	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?		√	
Is the device sterile?		√	
Is the device reusable (not reprocessed single use)? Are “cleaning” instructions included for the end user?	√		

Product Name: Dana Reusable Test Pack

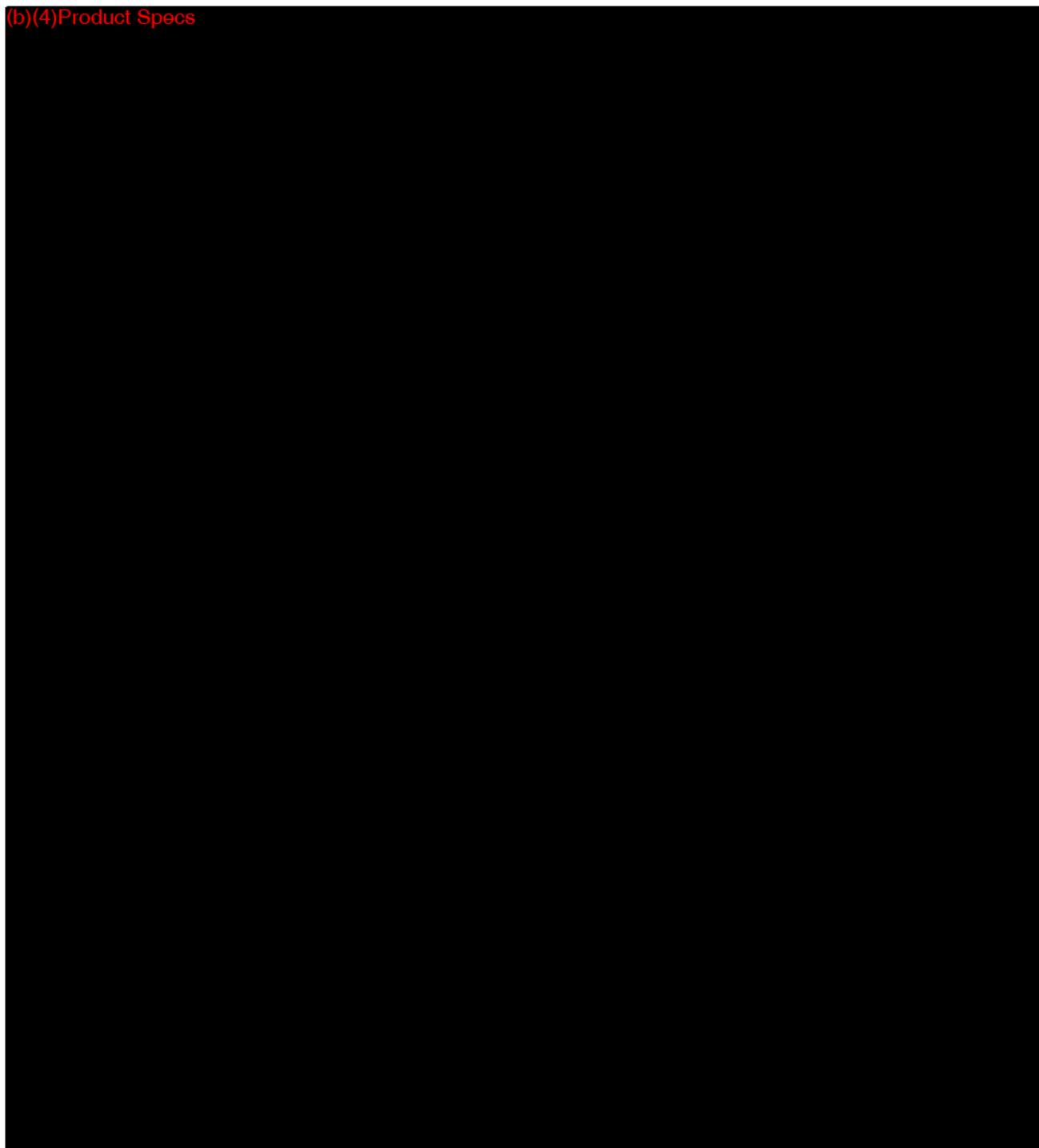
The subject device of this 510(k) submission is manufactured by Dana Products Inc. The subject device, BI Test Pack is a Class II device and regulated under CFR 880.2800 and a Product Code of JOJ. The product is non-sterile and for reusable test pack.

The sponsor claims that, they seek clearance to market the Dana Reusable Test Pack for use with the Smart-Read BI along with or without a SteriScan integrator. The sponsor claims that, they have previously obtained clearance to market the Dana Reusable Test Pack for use with 3M’s 1292 Rapid Readout Biological Indicator along with or without a SteriScan integrator (K092944). The Dana Reusable Test Pack that was tested with the Smart-Read BI for purposes of this submission is identical in material, design and construction to the Dana Reusable Test Pack that was cleared previously under K092944, except in this case a Smart-Read BI is placed into the Dana Reusable Test Pack instead of a 3M 1292 BI. The Dana Reusable Test Pack consists of an aluminum tube (Ex A –Photo 1 in the submission). One end of the tube has internal thread to receive a removable aluminum plug (Ex A – Photo 2

(b)(4)Product Specs

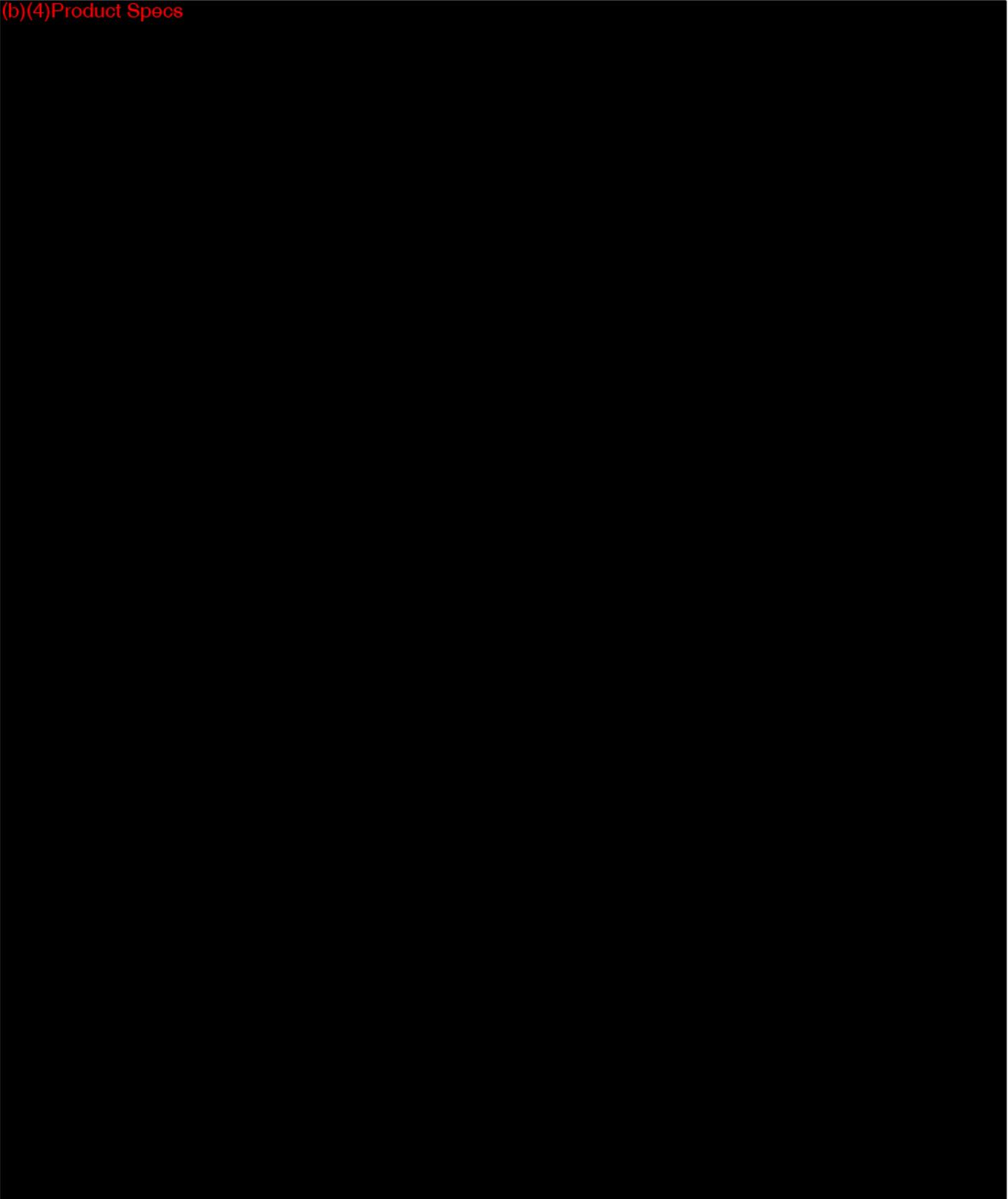


(b)(4)Product Specs



The sponsor included a Declaration of Conformity statement along with executive statement.

(b)(4)Product Specs



to SteriTec Products Manufacturing Company inc's, 'SteriTec Biological Test Pack with Instant Readout Integrator, K103000'.

Summary: *After reviewing the sponsor's additional information, it is recommended that the subject device is considered substantially equivalent to the predicate device.*

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page: OTC use	√		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement	√		
Standards Data Report Form – Form 3654	√		

The applicant provided Indications for Use Statement for the device which is the subject of this submission K130135. The applicant stated that the device is for over-the-counter use. *This is acceptable.*

The applicant provided a dated and signed Truthful and Accuracy Statement. However, the Statement does not include a regulation code. *This is acceptable.*

The sponsor provided the 510(K) statement as per the format as required by 21 CFR 807.93. This is acceptable.

The applicant provided a Medical Device User Fee Cover Sheet, FDA Form 3601. *This is acceptable.*

The applicant provided a CDRH Premarket Review Cover sheet, FDA Form 3514. *This is acceptable.*

The applicant provided a FDA 3654 form for AAMI/ANSI ST79:2010&A1:2010 and AAMI/ANSI ST8:2008 referenced. *This is acceptable.*

STANDARDS REFERENCED:

1. AAMI/ANSI ST79:2010&A1:2010, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
2. AAMI/ANSI ST8:2008, Hospital Steam Sterilizers.

Required Elements for <u>510(k) Statement</u> (21 CFR 807.93)		Yes
	Signed verbatim statement	X

Conclusion:

- Administrative requirements have been met.



Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Traditional**

K130135/S002

Date: November 15, 2013
To: The Record
From: Sreekanth Gutala, Ph.D.
Office: ODE Division: DAGRID Branch: INCB
Through: Ms. Elizabeth Claverie, M.S., Branch Chief, ODE/DAGRID/INCB
510(k) Holder: Dana Products, Inc; 7 Corey Dr, South Barrington, IL 60010
Address: 7 Corey Dr, South Barrington, IL 60010
Device Trade Name: Dana Reusable Test Pack
Contact: Harry Bala, President
Phone: 847-455-2881
Fax: 847-455-2886
Email: bala@voyager.net/bala@danaproducts.com

I. Purpose and Submission Summary

The 510(k) holder, Dana Products Inc. would like to introduce the "Dana Reusable Test Pack" into interstate commerce. Dana Products Inc has submitted a pre-market notification 510 (k) K130135, for their device Dana Reusable Test Pack on February 06, 2013 and FDA Document centers received on February 07, 2013. The sponsor has submitted both ecopy and paper copy of the submission and the ecopy is an exactly duplicate of a paper submission. The RTA checklist was completed on February 21, 2013 and it was determined as RTA1 (Refuse to accept). The sponsor was notified by email and the sponsor submitted the revised corrected versions of ecopy and paper copy submission (K130135/S001) on May 24, 2013 and FDA DCC received on May 29, 2013. The RTA checklist was completed again on June 07, 2013 and it was determined as RTAA for the submission K130135/S001. The sponsor was asked to clarify few deficiencies and the submission was on telephone hold on July 24, 2013. The sponsor responded to FDA deficiencies on October 23, 2013 and FDA DCC received the supplement for the submission, K130135 / S002 on October 24, 2013.

The sponsor claims that, Biological Indicator Test Pack is a Class II device that has a Product Code of JOJ, as described in CFR 880.2800. Dana Products Inc. claims substantial equivalence

XVII: Recommendation

It is recommended that this 510 (k) submission, K130135/S001, be placed on hold (Telephone Hold) pending the receipt of the information requested by e-mail.

Regulation Number: 21 CFR 880.2800

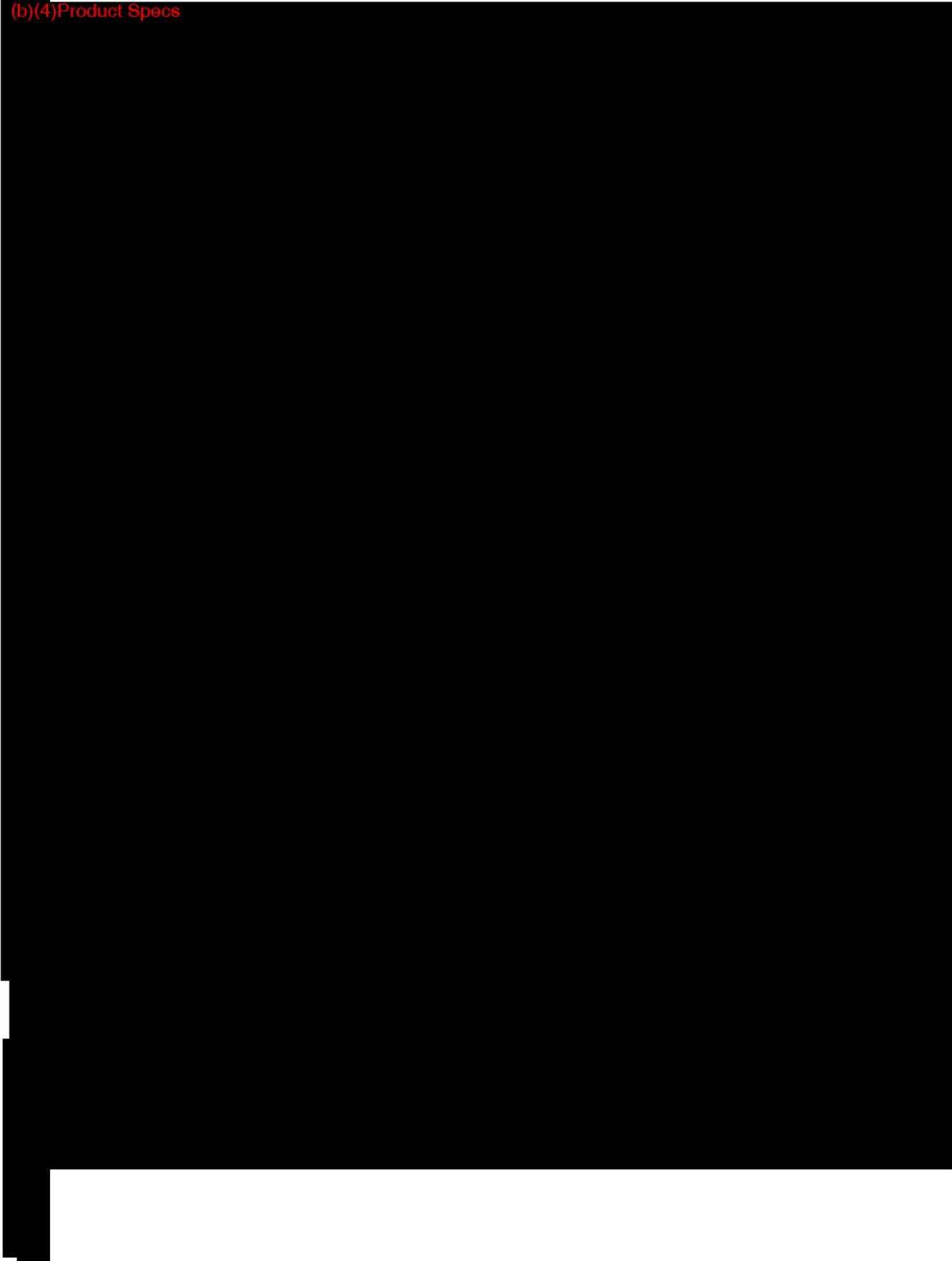
Regulation Name: Indicator, Biological Sterilization Process

Regulatory Class: Class II

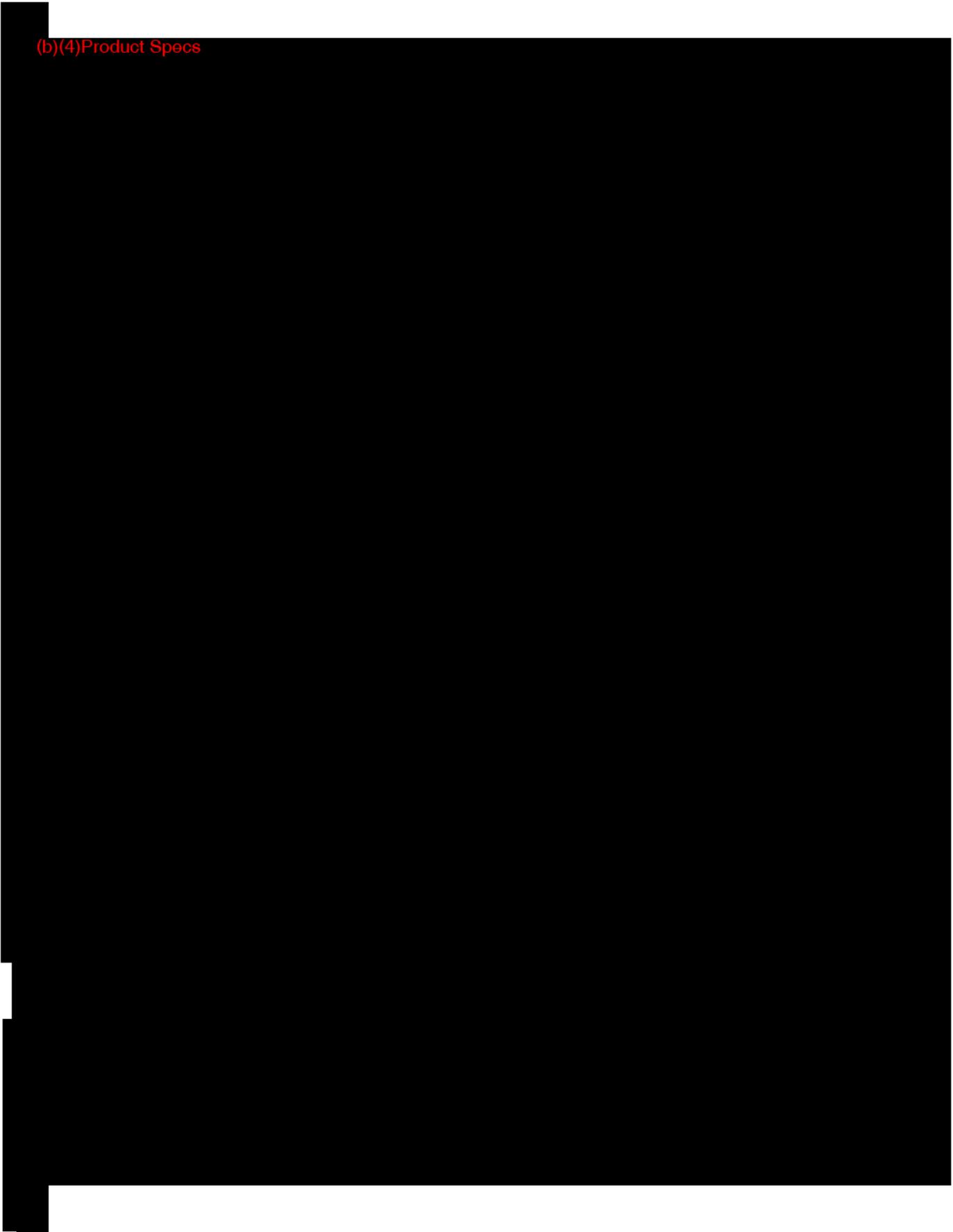
Product Code: JOJ

Other Product Code: FRC

Digital Signature Concurrence Table	
Reviewer Sign-Off	Sreekanth Gutala -S 2013.07.24 14:07:09 -04'00'
Branch Chief Sign-Off	Terrell A. Cunningham -S 2013.07.24 14:43:27 -04'00'
Division Sign-Off	

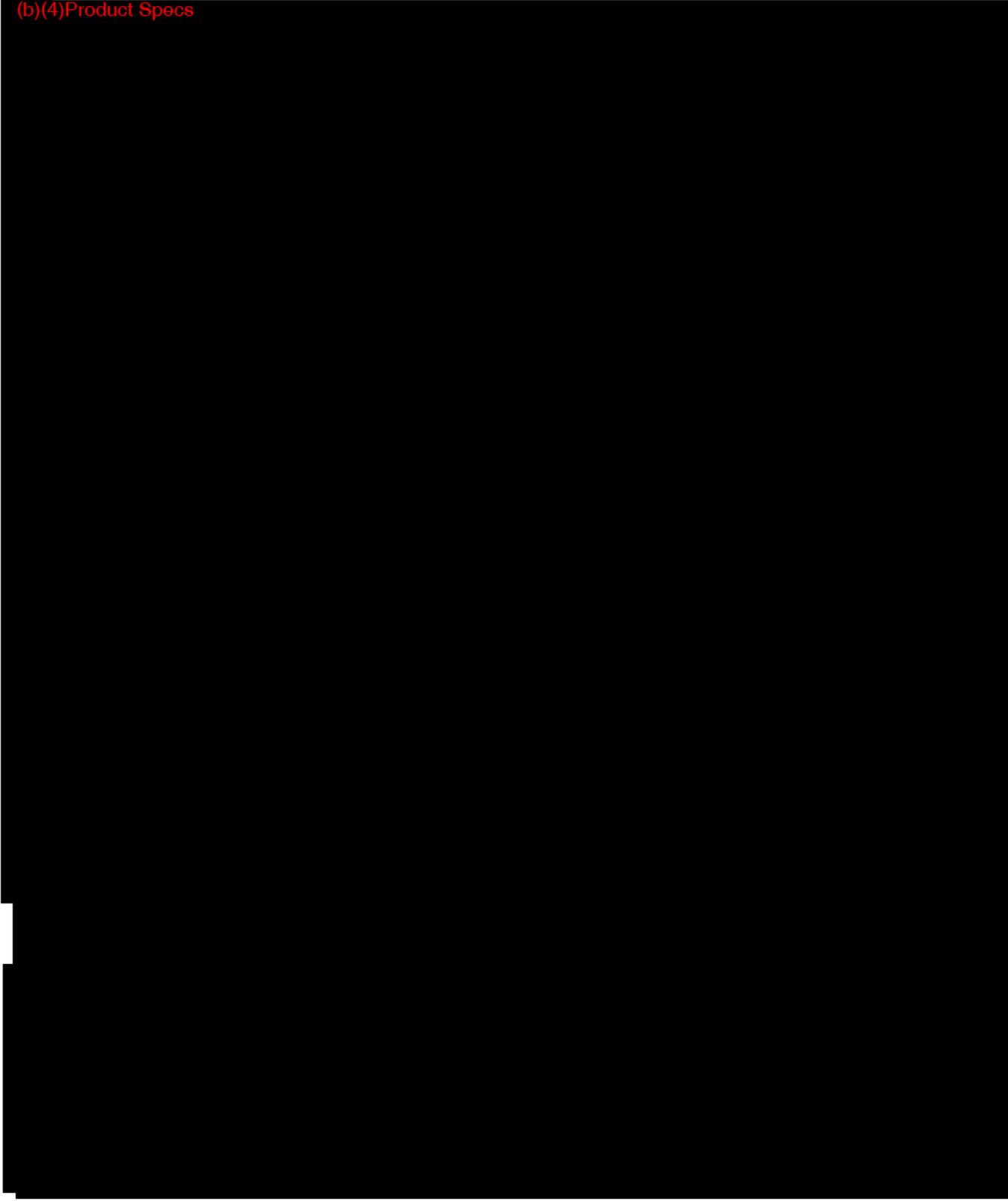


(b)(4)Product Specs



XV: Deficiencies:

(b)(4)Product Specs



XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	✓		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	✓		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		✓	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?		✓	If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision: TH

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
Performance and biocompatibility data is needed to evaluate the safety and effectiveness of the subject device.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed: Refer to Section XV for deficiencies.
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

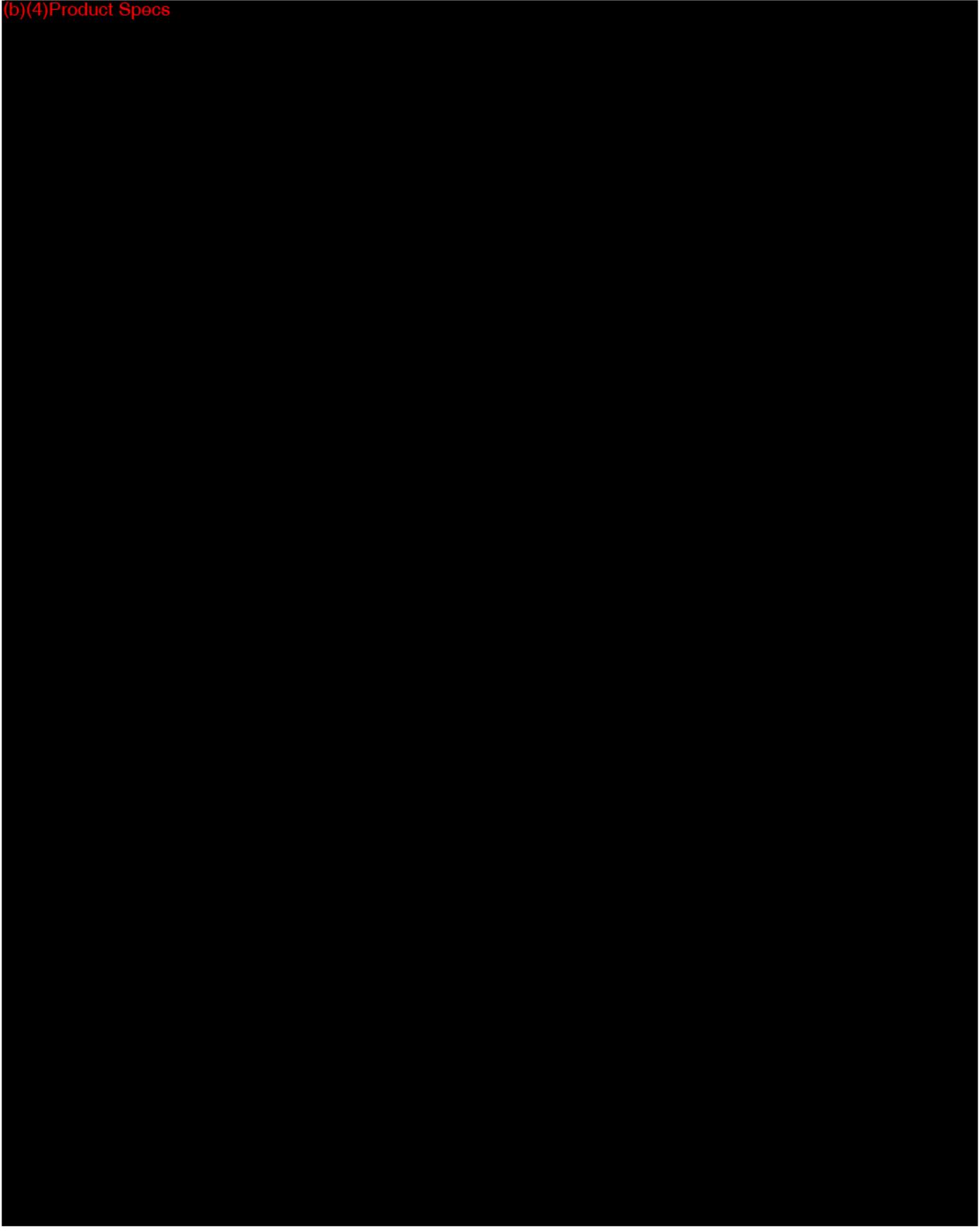
XII. Performance Testing – Animal

Not Applicable to this device.

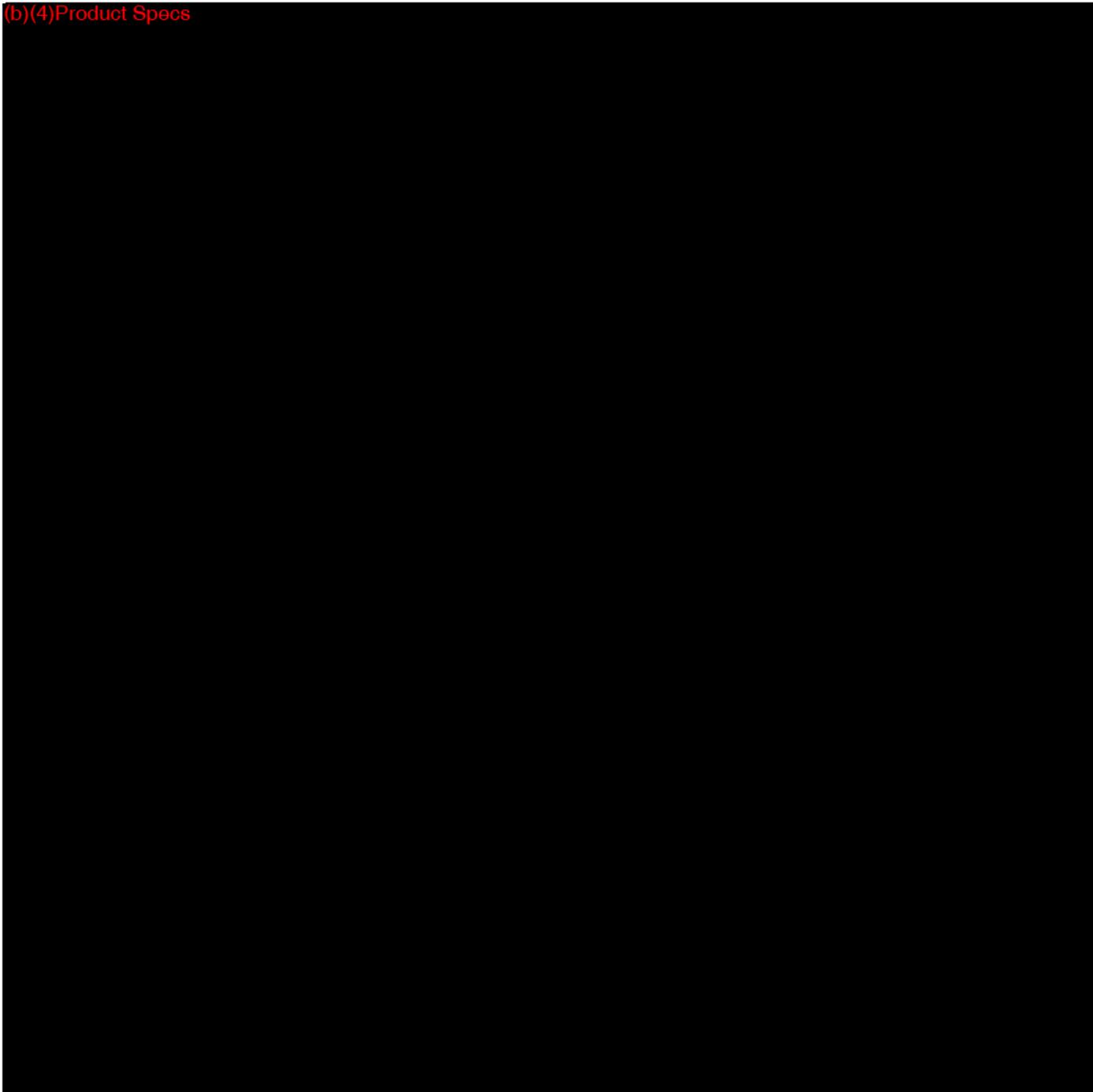
XIII. Performance Testing – Clinical

Not Applicable to this device.

(b)(4)Product Specs

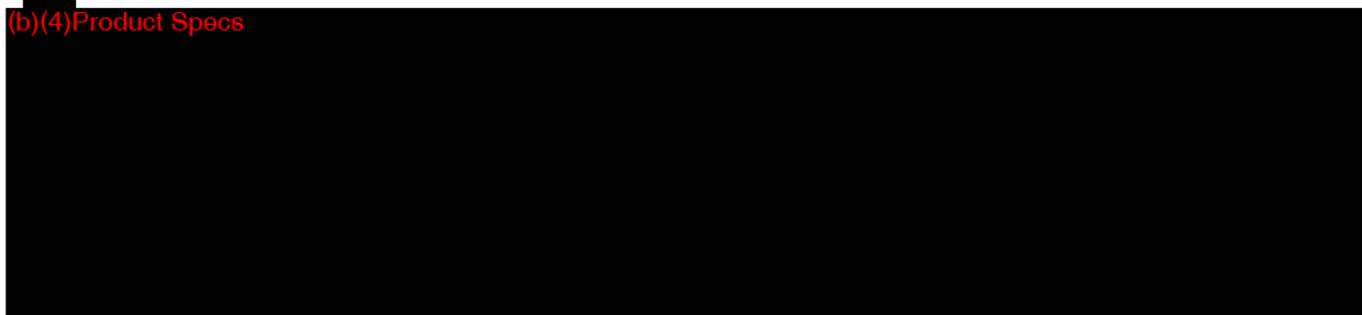


(b)(4)Product Specs

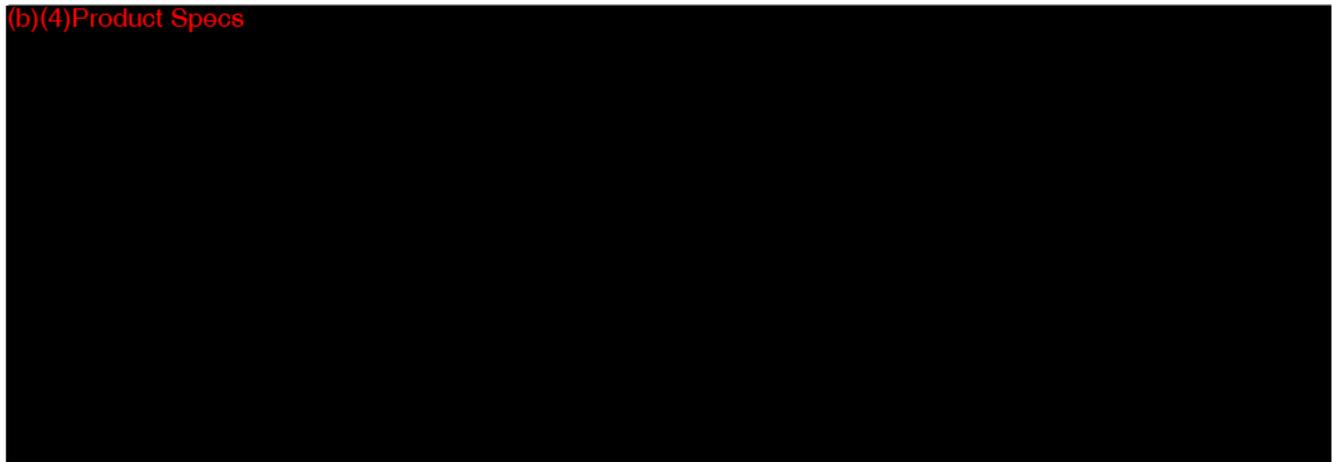


Test Parameters:

(b)(4)Product Specs



(b)(4)Product Specs



IX. Software

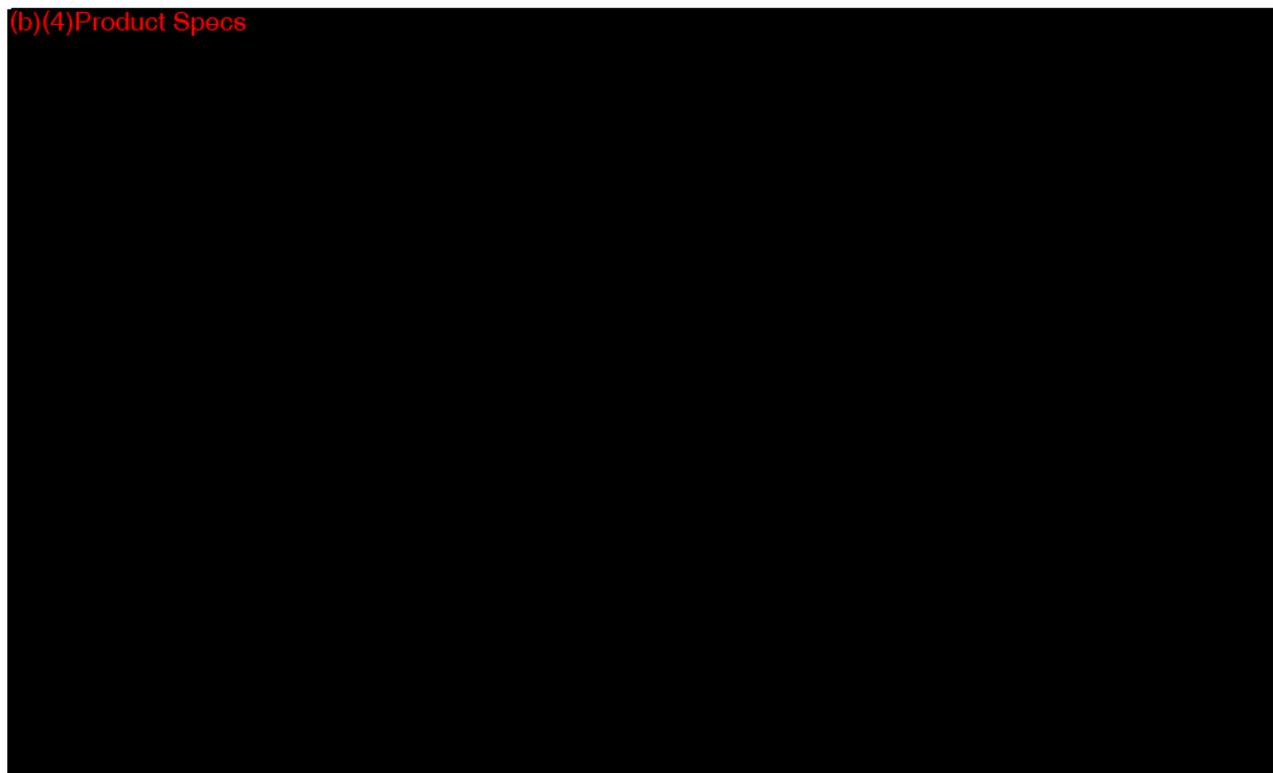
The device has no software. This section is not applicable.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The device has no electrical components. This section is not applicable.

XI. Performance Testing – Bench

(b)(4)Product Specs

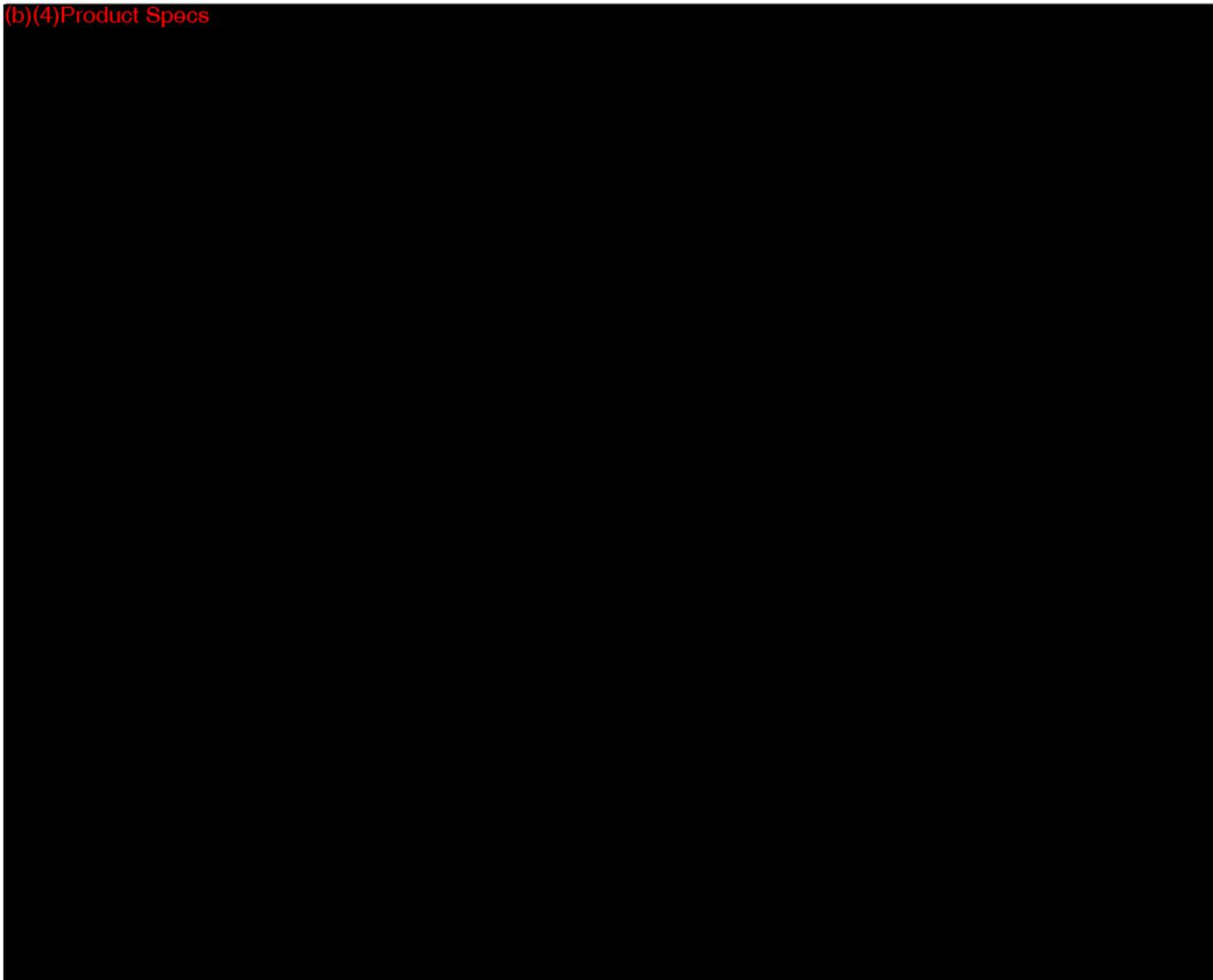


(b)(4)Product Specs

A large black rectangular redaction box covers the majority of the page content, starting below the first redaction code and extending down to the section header for VIII.

VII. Sterilization/Shelf Life/Reuse

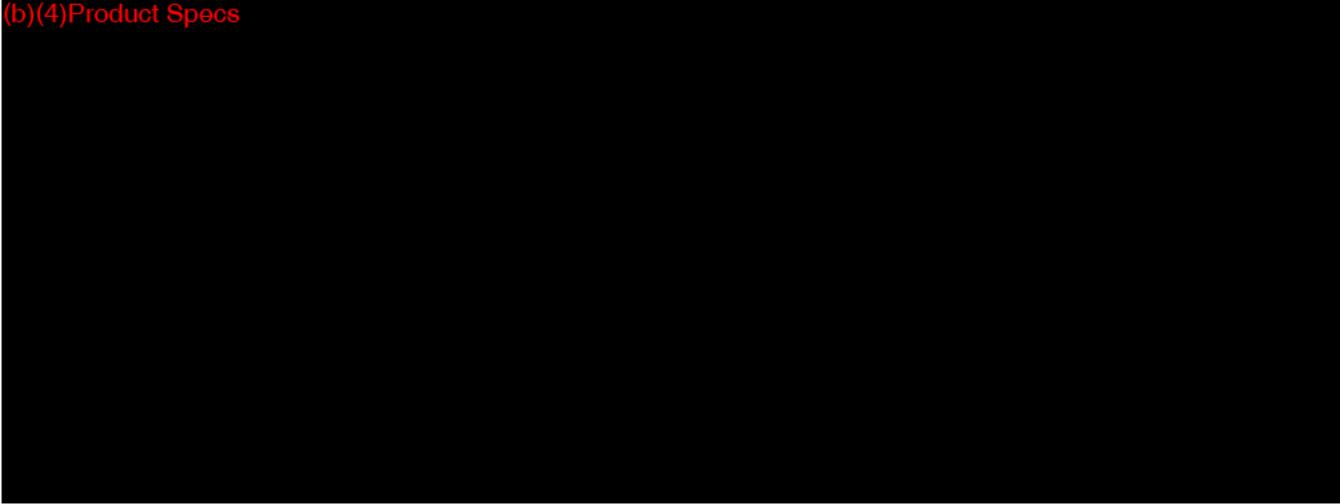
(b)(4)Product Specs

A very large black rectangular redaction box covers the entire body of the section, starting below the section header and extending down to the section header for VIII.

VIII. Biocompatibility

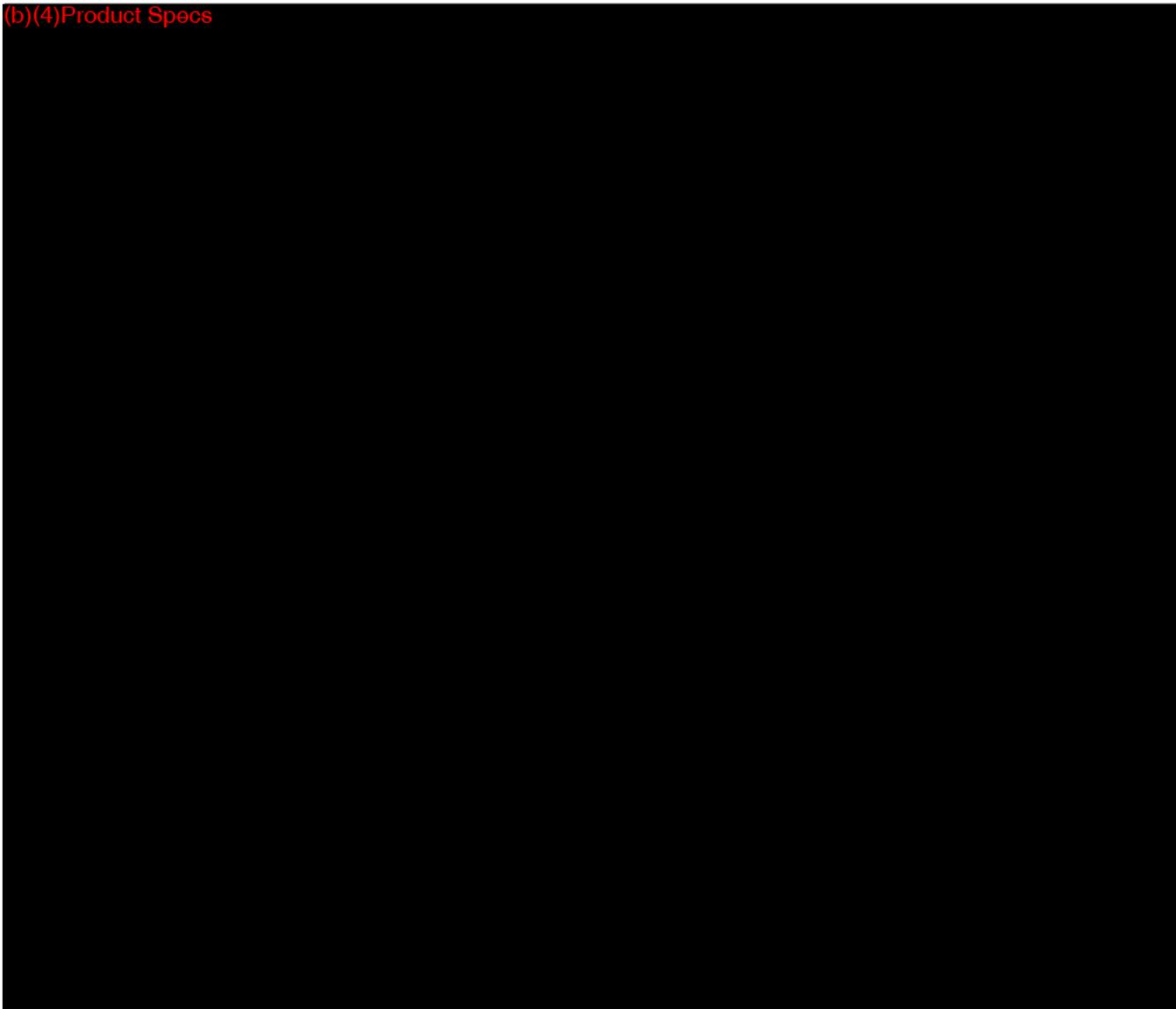
The sponsor did not provide any biocompatibility data.

(b)(4)Product Specs

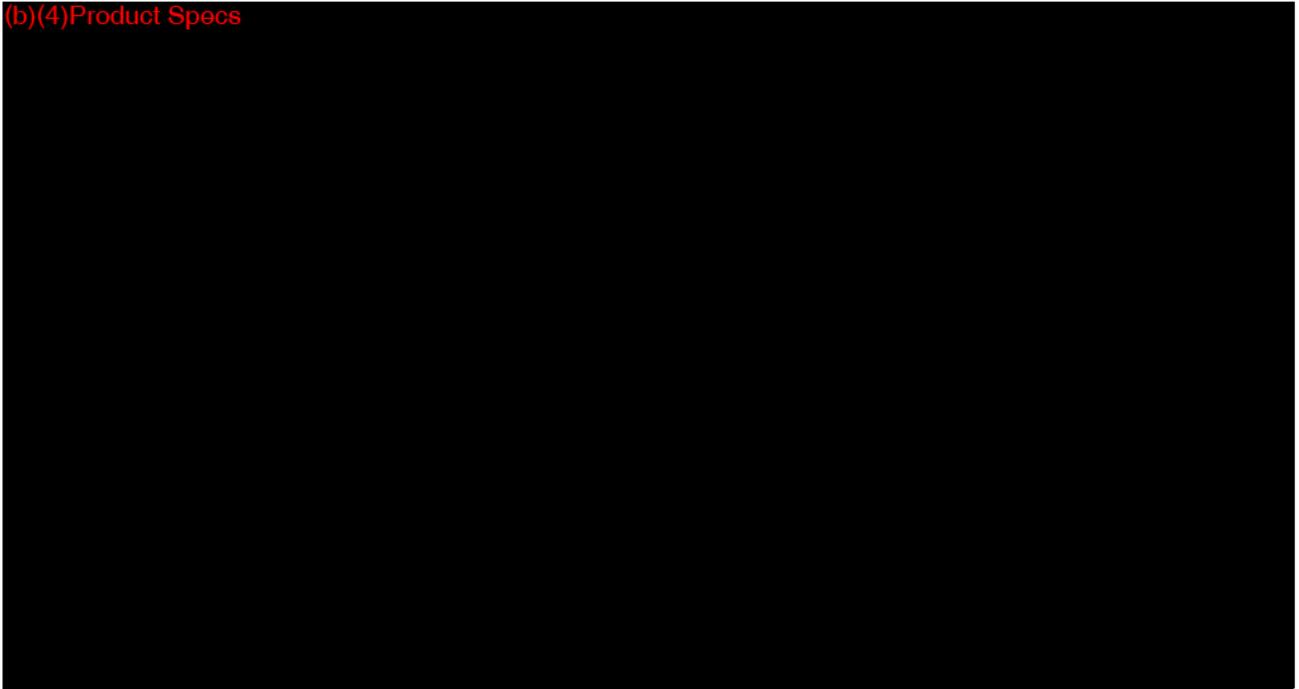


VI. Labeling

(b)(4)Product Specs



(b)(4)Product Specs



IV. Indications for Use (IFU)

The applicant states that the Indications for Use for the device is as follows:

Device Name: Dana Reusable Test Pack

Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SGM Biotech's Self-Contained Biological Indicator Smart-Read EZTest - Steam along with or without SteriScan Integrators.

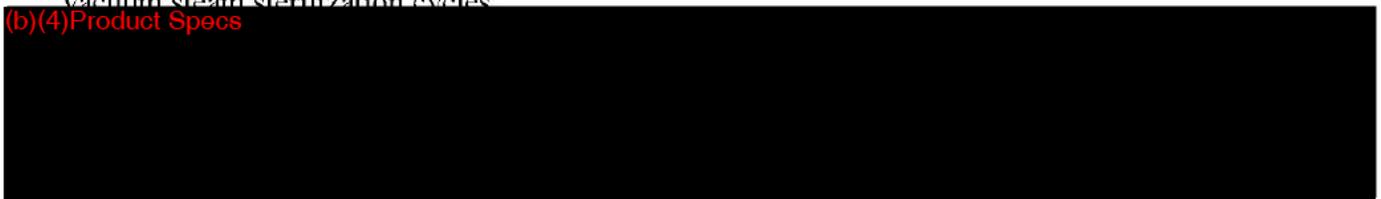
The applicant indicates that the subject device is for over-the-counter use.

Conclusion: The IFU statement provided for the subject device is similar to the previously cleared device for the same sponsor, under K092944. The IFU statement is deemed acceptable.

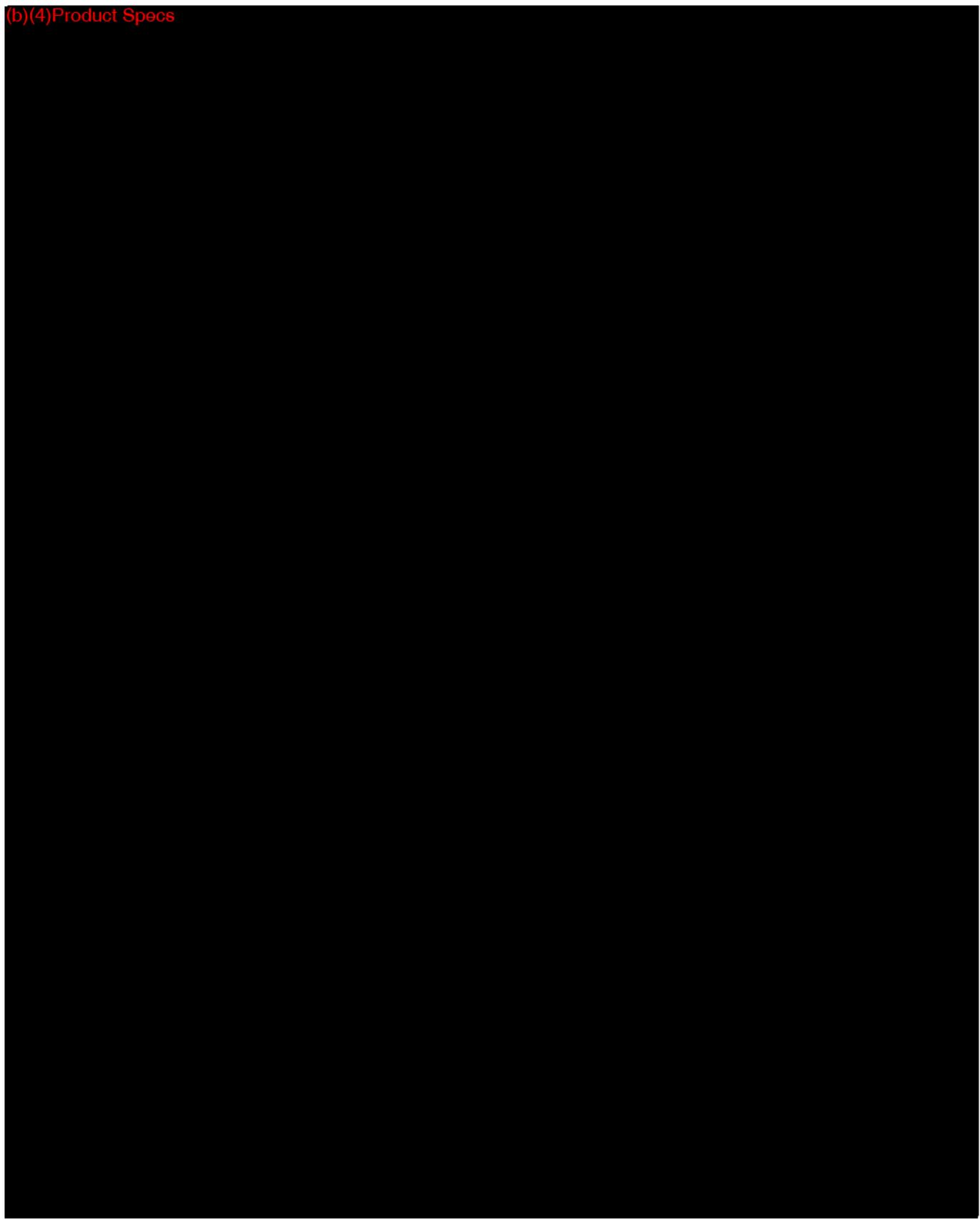
V. Predicate Device Comparison

The predicate device is identified as SteriTec Products Manufacturing Company inc's, 'SteriTec Biological Test Pack with Instant Readout Integrator', cleared under K103000 for monitoring the efficacy of saturated steam sterilization processes operating at 3 minutes or longer at 132°C pre-vacuum steam sterilization cycles.

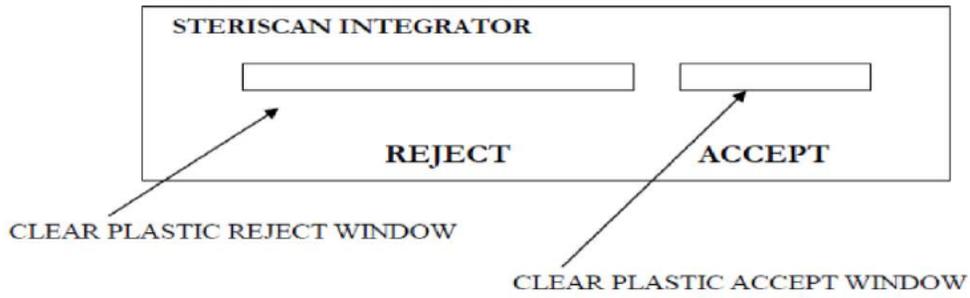
(b)(4)Product Specs



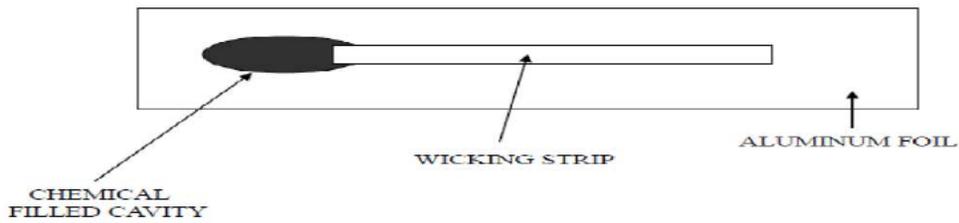
(b)(4)Product Specs



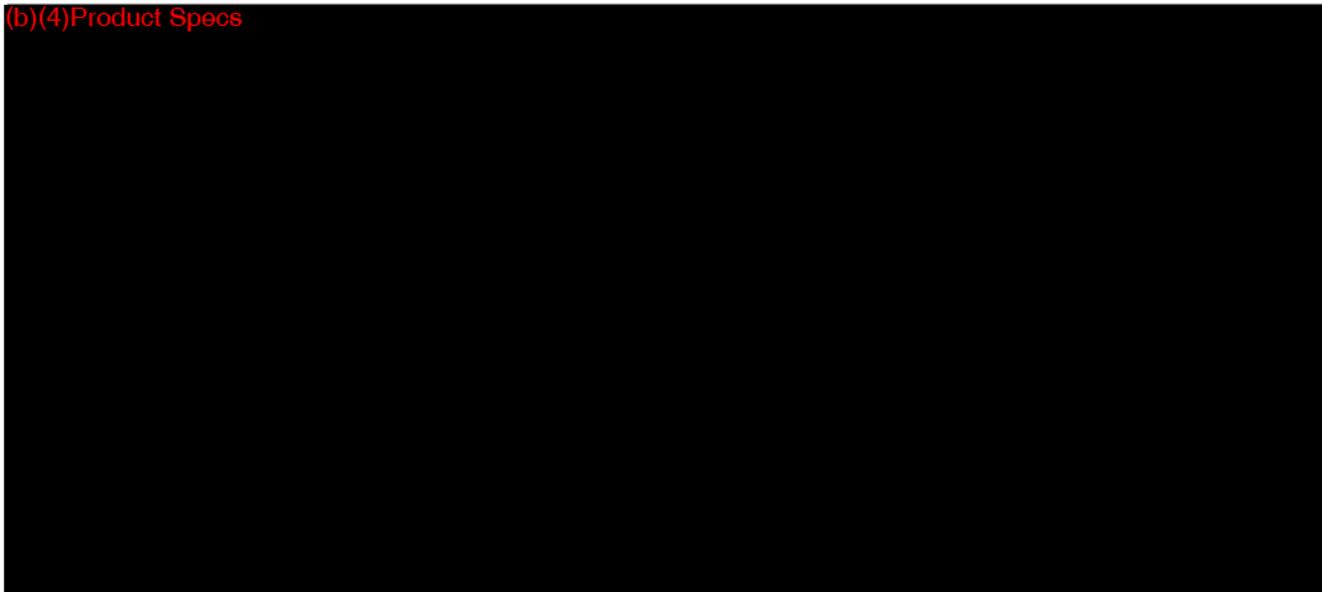
DEVICE TOP VIEW



DEVICE WITHOUT TOP COVER



(b)(4)Product Specs



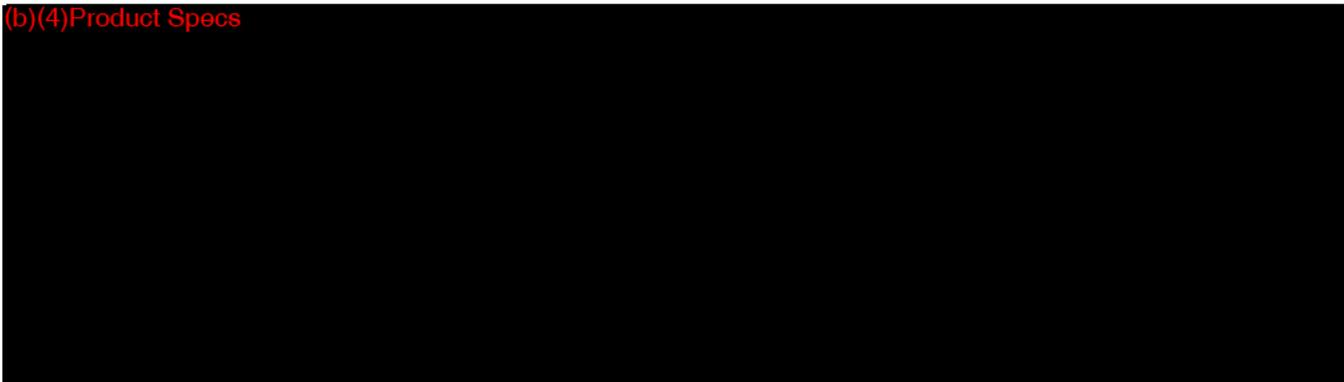
The following table shows dimension and tolerance of individual components:

Smart-Read BI is placed into the Dana Reusable Test Pack instead of a 3M 1292 BI. The Dana Reusable Test Pack consists of an aluminum tube (Ex A –Photo 1 in the submission). One end of the tube has internal thread to receive a removable aluminum plug (Ex A – Photo 2 in the submission). Between knurled aluminum disc and aluminum threaded plug is sandwiched a Teflon disc (Ex A – Photo 3 in the submission). All three are bolted together. The

(b)(4)Product Specs



(b)(4)Product Specs



SteriScan Integrator description:

The SteriScan Integrator that was used in testing for this submission is identical in material, design and construction to the SteriScan Integrator cleared under K012195. The SteriScan Integrator that was used in testing for this submission is also identical to the SteriScan Integrator used in testing of the Dana Reusable Test Pack for use with 3M's 1292 Rapid Readout BI, along with or without a SteriScan Integrator, that was cleared under K092944.

(b)(4)Product Specs

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?		√	
Is the device sterile?		√	
Is the device reusable (not reprocessed single use)? Are “cleaning” instructions included for the end user?	√		

Product Name: Dana Reusable Test Pack

The subject device of this 510(k) submission is manufactured by Dana Products Inc. The subject device, BI Test Pack is a Class II device and regulated under CFR 880.2800 and a Product Code of JOJ. The product is non-sterile and for reusable test pack.

(b)(4)Product Specs

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page: OTC use	√		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement	√		
Standards Data Report Form – Form 3654	√		

The applicant provided Indications for Use Statement for the device which is the subject of this submission K130135. The applicant stated that the device is for over-the-counter use. *This is acceptable.*

The applicant provided a dated and signed Truthful and Accuracy Statement. However, the Statement does not include a regulation code. *This is acceptable.*

The sponsor provided the 510(K) statement as per the format as required by 21 CFR 807.93. This is acceptable.

The applicant provided a Medical Device User Fee Cover Sheet, FDA Form 3601. *This is acceptable.*

The applicant provided a CDRH Premarket Review Cover sheet, FDA Form 3514. *This is acceptable.*

The applicant provided a FDA 3654 form for AAMI/ANSI ST79:2010&A1:2010 and AAMI/ANSI ST8:2008 referenced. *This is acceptable.*

STANDARDS REFERENCED:

1. AAMI/ANSI ST79:2010&A1:2010, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
2. AAMI/ANSI ST8:2008, Hospital Steam Sterilizers.

Required Elements for <u>510(k) Statement</u> (21 CFR 807.93)		Yes
	Signed verbatim statement	X

Conclusion:

- *Administrative requirements have been met.*

The sponsor included a Declaration of Conformity statement along with executive statement.

(b)(4)Product Specs



COVER SHEET MEMORANDUM

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

From: Reviewer Name Sreekanth Gutala, Ph.D.

Subject: 510(k) Number K130135

To: The Record

Please list CTS decision code:

SE

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>)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary or 510(k) Statement (<i>Attach Summary or Statement</i>)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement (<i>Must be present for a Final Decision</i>)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach Form 3654 .)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a combination product?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices .)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
All Pediatric Patients age <= 21	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Infant (29 days to < 2 years)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Child (2 years to <12 years)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Adolescent (12 years to <18 years)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)	<input type="checkbox"/>	<input checked="" type="checkbox"/>

510(k) COVERSHEET for DCC

510(k) Number: K130135/S002

Review Records: DocMan

Paper *(only applies to original 510(k)s assigned prior to 1/28/2013)*

510(k) in eCopy-only Pilot: Yes No

Interim Decision (RTA1, TH, AI):

RTA1 (refuse to accept)

1. Put file on hold shelf

TH (telephone, email or fax hold)

1. Put file on hold as of _____ (date of last concurrence in CTS).

2. Issue auto-generated acknowledgement letter from APPS to applicant.

3. If paper review records, add copy of the letter to jacketed submission and put file on hold shelf.

4. If DocMan review records, put file on hold shelf.

5. If eCopy-only pilot, no further steps.

AI (AI mailed letter)

1. Put file on hold as of date on attached hold letter.

2. Mail the attached digitally signed and dated hold letter.

3. If paper review records, add copy of the letter to jacketed submission and put file on hold shelf.

4. If DocMan review records, put file on hold shelf.

5. If eCopy-only pilot, no further steps.

Final Decision (review finished):

Follow appropriate processing steps

SE (all SE codes)

NSE (all NSE codes)

Other (DR, EX, FB, NA, ND, NF, OD, PE, etc.) _____ (code)

Day 90: November 27th, 2013 Sreekanth Gutala



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 25, 2013

Dana Products, Incorporated
Mr. Harry Bala
President
7 Corey Drive
SOUTH BARRINGTON IL 60010

Re: K130135
Trade/Device Name: Dana Reusable Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: October 23, 2013
Received: October 24, 2013

Dear Mr. Bala:

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 contact 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,


Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin Keith M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K130135

Device Name
Dana Reusable Test Pack

Indications for Use (Describe)

Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SGM Biotech's Self-Contained Biological Indicator Smart-Read EZTest - Steam along with or without SteriScan Integrators.

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)

Elizabeth F. Claverie - S
2013.11.21 22:03:55 - 05:00'



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WQ66-G609
Silver Spring, MD 20993-0002

November 25, 2013

Dana Products, Incorporated
Mr. Harry Bala
President
7 Corey Drive
SOUTH BARRINGTON IL 60010

Re: K130135
Trade/Device Name: Dana Reusable Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
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Dated: October 23, 2013
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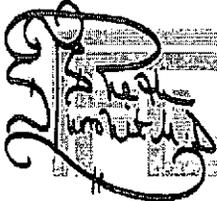
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

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Sincerely yours,


Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin Keith M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental 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: K130135

For Office of Compliance Contact Information:

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

Digital Signature Concurrence Table	
Reviewer Sign-Off	Sreekanth Gutala, Ph.D.
Branch Chief Sign-Off	Elizabeth Claverie-Williams, MS.
Division Sign-Off	 Tejashri Purohit-Sheth, M.D. Clinical Deputy Director DAGRID 2013-11-25 09:22:38 -05'00'

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 st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful..." Replaced incorrect semicolon with a comma.

Indications for Use

510(k) Number (if known)
K130135

Device Name
Dana Reusable Test Pack

Indications for Use (Describe)

Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SGM Biotech's Self-Contained Biological Indicator Smart-Read EZTest - Steam along with or without SteriScan Integrators.

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)

Elizabeth F. Claverie S
2013.11.21 22:03:55 - 05:00'

DANA PRODUCTS, INC.
7 COREY DRIVE
SOUTH BARRINGTON, IL 60010
TEL. 847-455-2881 FAX. 847-455-2886

1253
K130135

FDA CDRH DMC

FEB 07 2013

February 6, 2013

Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - W066-0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Sir or Madam:

K130135 -- eCOPY COVER LETTER

Please see enclosed eCopy of the paper copy submission dated January 17, 2013 (K130135).
The enclosed eCopy is an exact duplicate of the paper copy submitted on January 17, 2013.

Thanking you,

Very Truly Yours,


Harry Bala
President

510k NOTIFICATION

**DANA REUSABLE BOWIE DICK TEST PACK FOR USE WITH
SMART READ BI ALONG WITH OR WITHOUT A STERISCAN
INTEGRATOR**

TABLE OF CONTENTS

1. Medical Device User Fee Cover Sheet (Form FDA 3601)	
2. CDRH Premarket Review Submission Cover sheet	
3. 510(k) Cover letter	-----Pages 1 & 2
4. Indications For Use Statement	-----Page 3
5. 510(k) Statement	-----Page 4
6. Declaration of Conformity, Devise Description	-----Pages 5 -36
Test Results, Shelf-Life and End Point Stability	
Testing and Protocol Proposed Labeling	
7. Truthful and Accuracy Statement	-----Page 37
8. Exhibit A	-----4 pages
9. Exhibit B	-----1 page

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/cdrh/mdufma> for additional information)

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

This application is the first PMA submitted by a qualified small business, including any affiliates

The sole purpose of the application is to support conditions of use for a pediatric population

This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

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)

17-Jan-2013

REP'D \$■■■■■■■■■■

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

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 1-17-2013	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
---------------------------------	---	---

SECTION A TYPE OF SUBMISSION

PMA <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	PMA & HDE Supplement <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	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <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	Meeting <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):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <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 Dana Products, Inc.	Establishment Registration Number (if known) 3007412809		
Division Name (if applicable)	Phone Number (including area code) 847-455-2881		
Street Address 7 Corey Drive	FAX Number (including area code) 847-455-2886		
City South Barrington	State / Province IL	ZIP/Postal Code 60010	Country USA
Contact Name Harry Bala	Contact E-mail Address bala@danaproducts.com		

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

Company / Institution Name	Phone Number (including area code)		
Division Name (if applicable)	FAX Number (including area code)		
Street Address	State / Province	ZIP Code	Country
City	Contact E-mail Address		

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
<input type="checkbox"/> Other Reason (<i>specify</i>):		

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		
<input type="checkbox"/> Other Reason (<i>specify</i>):		

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
<input type="checkbox"/> Other Reason (<i>specify</i>):		

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	
1	2	3	4	<input type="checkbox"/> 510 (k) summary attached	<input type="checkbox"/> 510 (k) statement
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	K10300	1 SteriTec Biological Test Pack with Instant Readout Integrator
2		2 SteriTec Products Manufacturing Company, Incorporated
3		3
4		4
5		5
6		6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name	
Trade or Proprietary or Model Name for This Device	
1	Dana Reusable BI Test Pack
2	
3	
4	
5	
Model Number	
1	
2	
3	
4	
5	

FDA document numbers of all prior related submissions (regardless of outcome)					
1	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	C.F.R. Section (if applicable)	Device Class
JOJ	880.2800	<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II
Classification Panel		<input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Indications (from labeling)		

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

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 Dana Products, Inc.			Establishment Registration Number 3007412809		
Division Name (if applicable)			Phone Number (including area code) 847-455-2881		
Street Address 11457 Melrose Street			FAX Number (including area code) 847-455-2886		
City Franklin Park		State / Province IL		ZIP Code 60131	Country USA
Contact Name Harry Bala		Contact Title President		Contact E-mail Address bala@danaproducts.com	

<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	ST79:2010 & A1:2010	ANSI/AAMI	Comprehensive guide to steam sterilization and sterility assurance in health care facilities	2010	01/01/2010
2	ST8:2008	ANSI/AAMI	Hospital steam sterilizers	2008	1/1/2008
3					
4					
5					
6					
7					

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

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing 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:

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

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.

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

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

Hospital steam sterilizers

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-264

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

Is a summary report ⁴ 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?

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

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

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 ⁶ 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 Chemical Indicators

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

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ 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>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
Comprehensive guide to steam sterilization and sterility assurance in health care facilities

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 5.5	SECTION TITLE BIOLOGICAL PERFORMANCE OF STERILIZERS	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	--	--

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
----------------	---------------	---

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
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

[♦] Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

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

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.

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

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-312

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

Is a summary report ⁴ 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?

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

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

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 ⁶ 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 Chemical Indicators

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

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ 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>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
Comprehensive guide to steam sterilization and sterility assurance in health care facilities

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 10.7	SECTION TITLE ROUTINE STERILIZER EFFICACY MONITORING	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
------------------------	---	--

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
----------------	---------------	---

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
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Paperwork Reduction Act Statement

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

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.

DANA PRODUCTS, INC.
7 COREY DRIVE
SOUTH BARRINGTON, IL 60010
TEL. 847-455-2881 FAX. 847-455-2886

January 17, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center –W066-0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Sir or Madam:

510K Notification (21CFR 807.90 (e))
Traditional Submission
Reusable Challenge Test Pack for Steam Sterilization

I request marketing clearance for our reusable challenge test pack for Biological Indicators and Integrators to be used in steam sterilization. The information on the test pack is as follows:

Device Name: Reusable Biological Indicator and Integrator Test Pack for
Steam Sterilization

Device Classification Name: Indicator, Biological Sterilization Process

Product Code: FRC

Regulation Number: 880.2800

Review Panel: General Hospital

Device Class: 2

Propriety Name: Dana Reusable Test Pack

Establishment Registration Number: 3007412809

Owner Operator Number: 9054259

Performance Standard: ANSI/AAMI ST 79: 2010,
ANSI/AAMI ST 8: 2008

Predicate Device 510(k): SteriTec Biological Test Pack with Instant Readout Integrator
(K10300)
Self-Contained Biological Indicator Smart-Read EZ Test Steam
(K093794)
SteriScan Integrator (K012195)

This submission is prepared in duplicate and it includes adequate information to show substantial equivalence to the predicate device. Our manufacturing facility is located at 11457 Melrose Street, Franklin Park, IL 60131. If you have any questions concerning this submission, please contact:

Harry Bala
Dana Products, Inc.
7 Corey Drive
South Barrington, IL 60010
Tel.: 847-455-2881, Fax: 847-455-2886
Email: bala@voyager.net

Dana Products, Inc. considers this submission confidential and requests that the FDA consider it as such.

Sincerely yours,


Harry Bala
President

Indications for Use

510(k) Number (if known):

Device Name: Reusable Biological Indicator and Integrator Test Pack for Steam Sterilization.

Indications For Use:

Dana reusable challenge test pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SGM Biotech's Self-Contained Biological Indicator Smart-Read EZTest - Steam along with or without SteriScan Integrators.

Prescription Use _____ AND/OR
(Part 21 CFR 801 Subpart D)

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

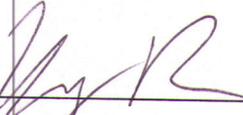
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

510k STATEMENT
(As required by 21 CFR 807.93)

I certify that, in my capacity as the President of Dana Products, Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Signature:  _____

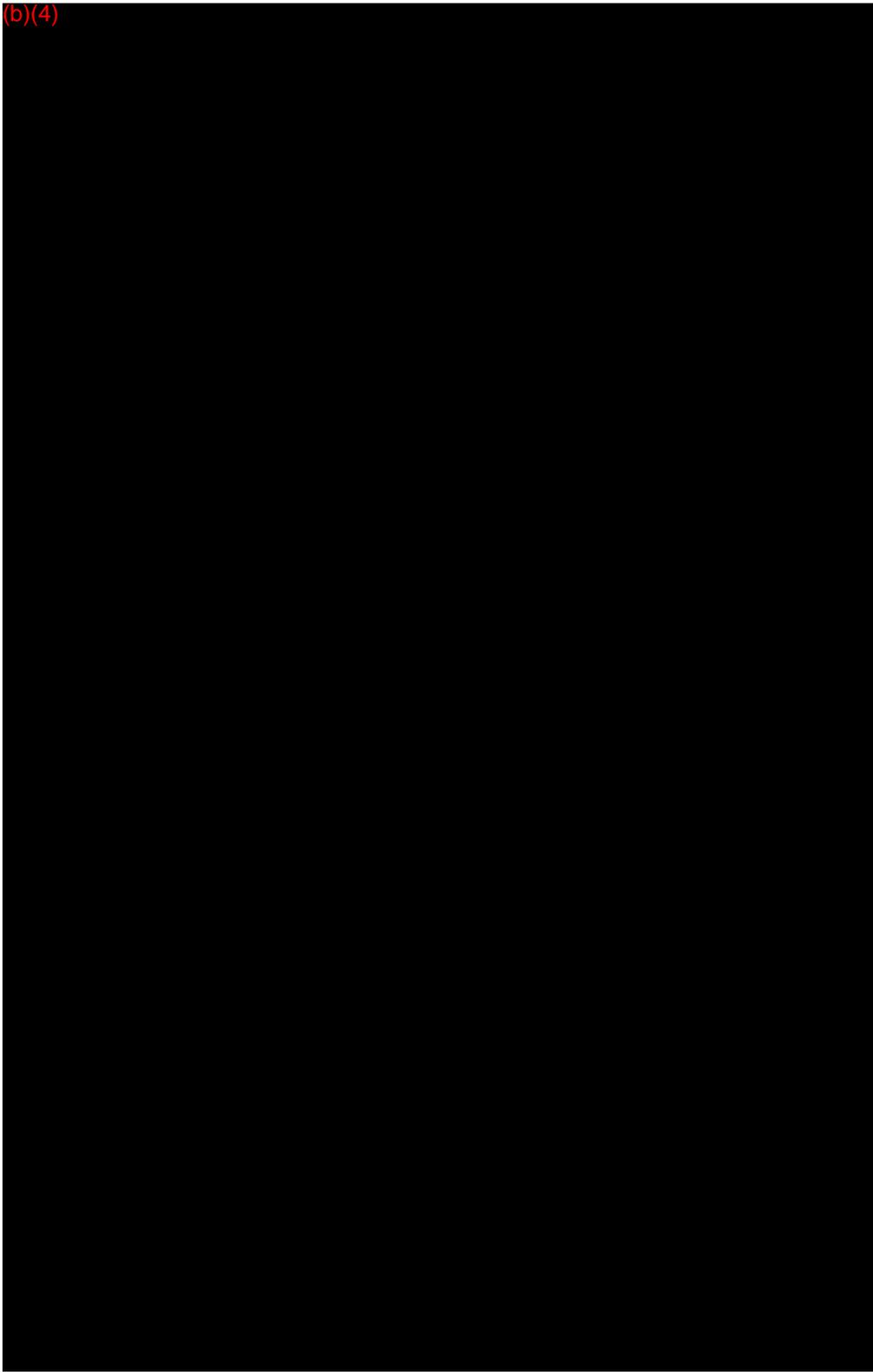
Harry Bala

Date: 1/17/13

510k Number: _____

Information on items used in this study

(b)(4)



Performance Testing:

Predicate device: SteriTec Test pack with Smart-Read BI.

Objective: To show that the Dana Reusable Test Pack is more resistant in a 4 minute 270°F prevac cycle when compared to the SteriTec Test Pack. Both test packs use Smart Read BIs from the same lot.

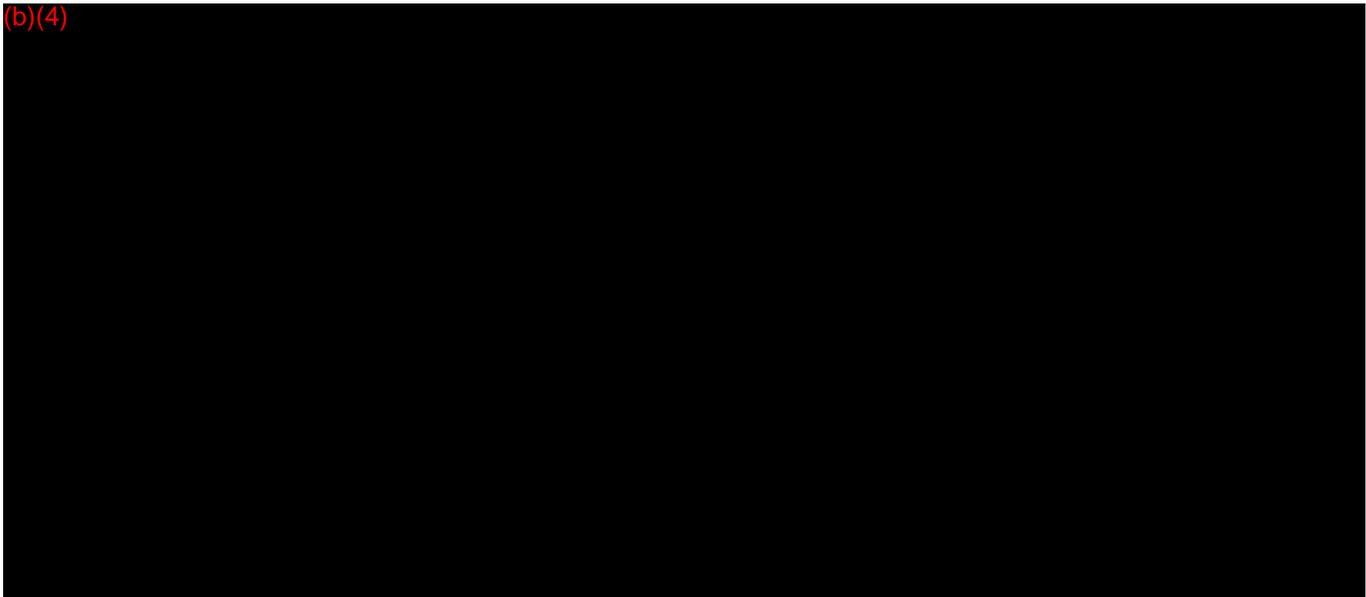
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(b)(4)

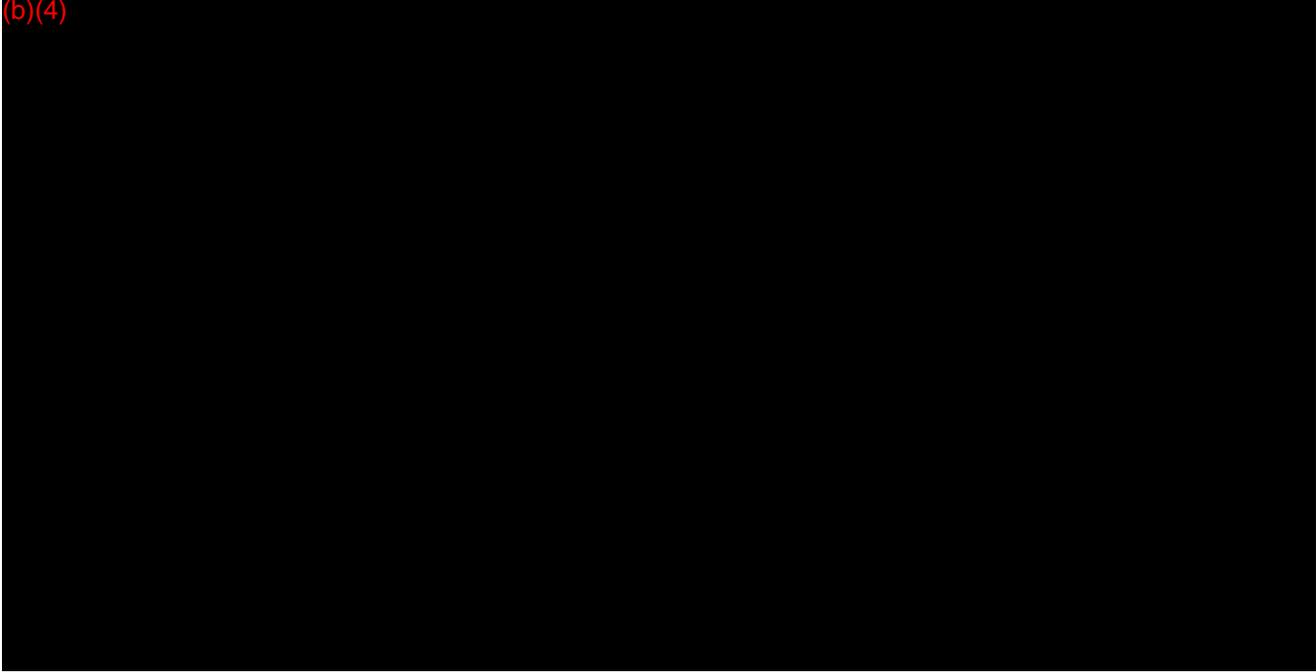


Statement of purpose/ Objective of studies

(b)(4)

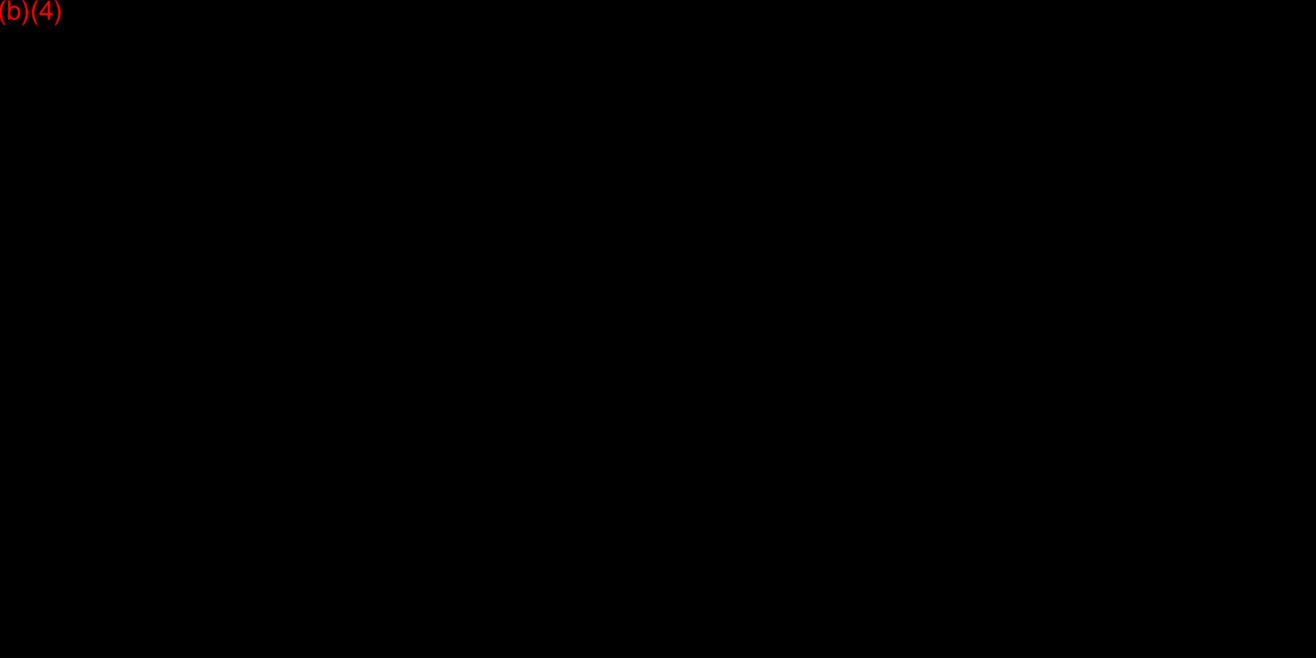


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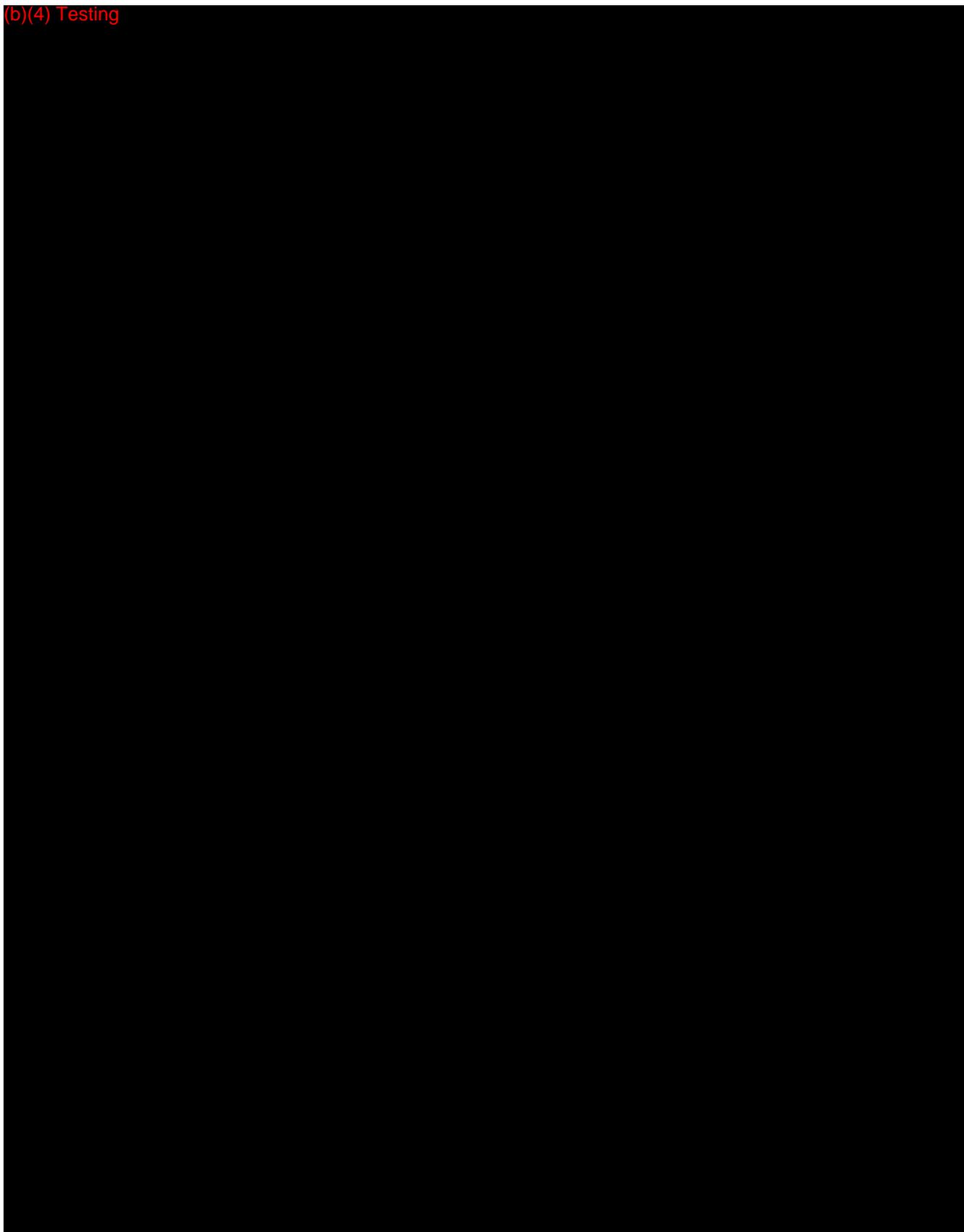


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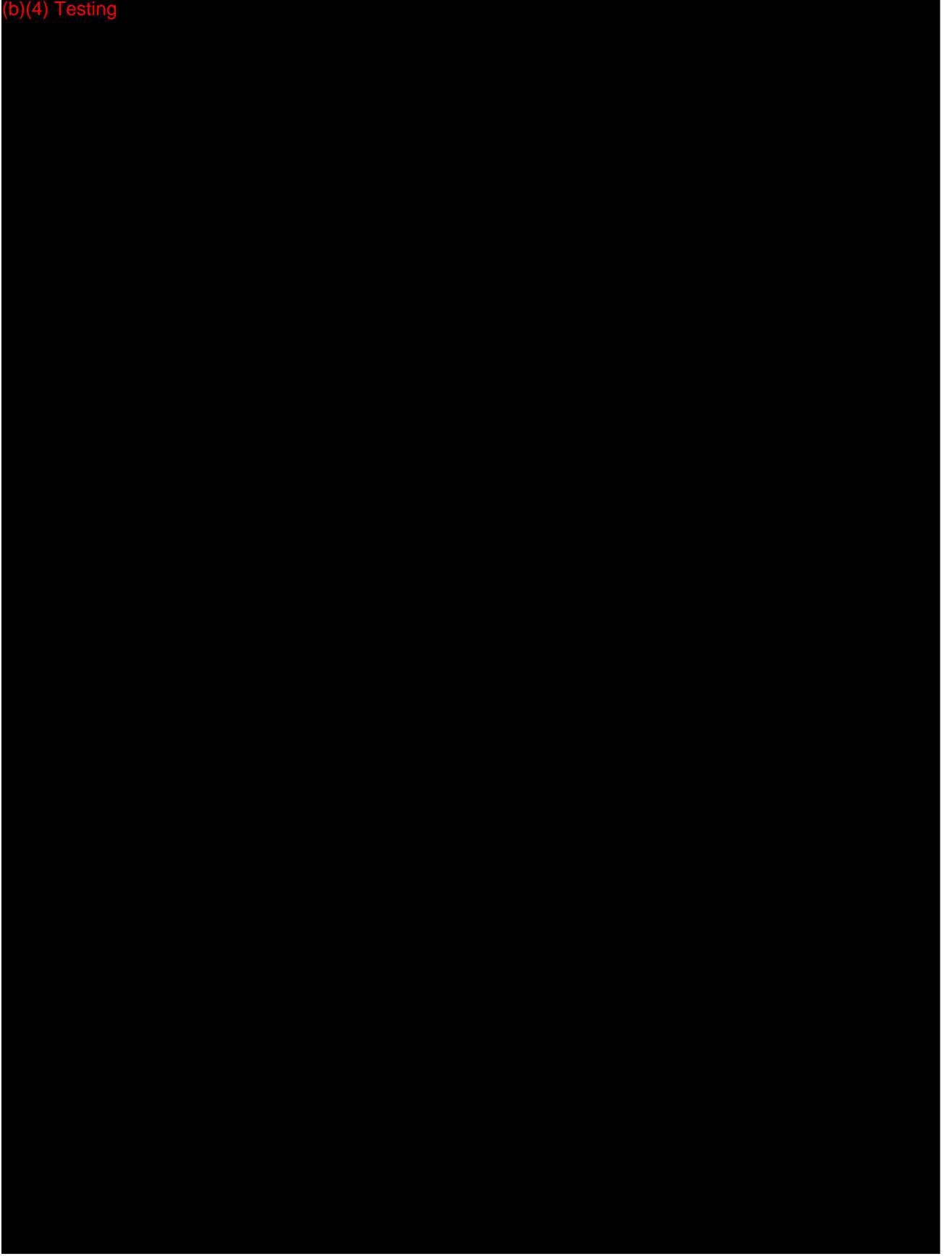
(b)(4)



(b)(4) Testing

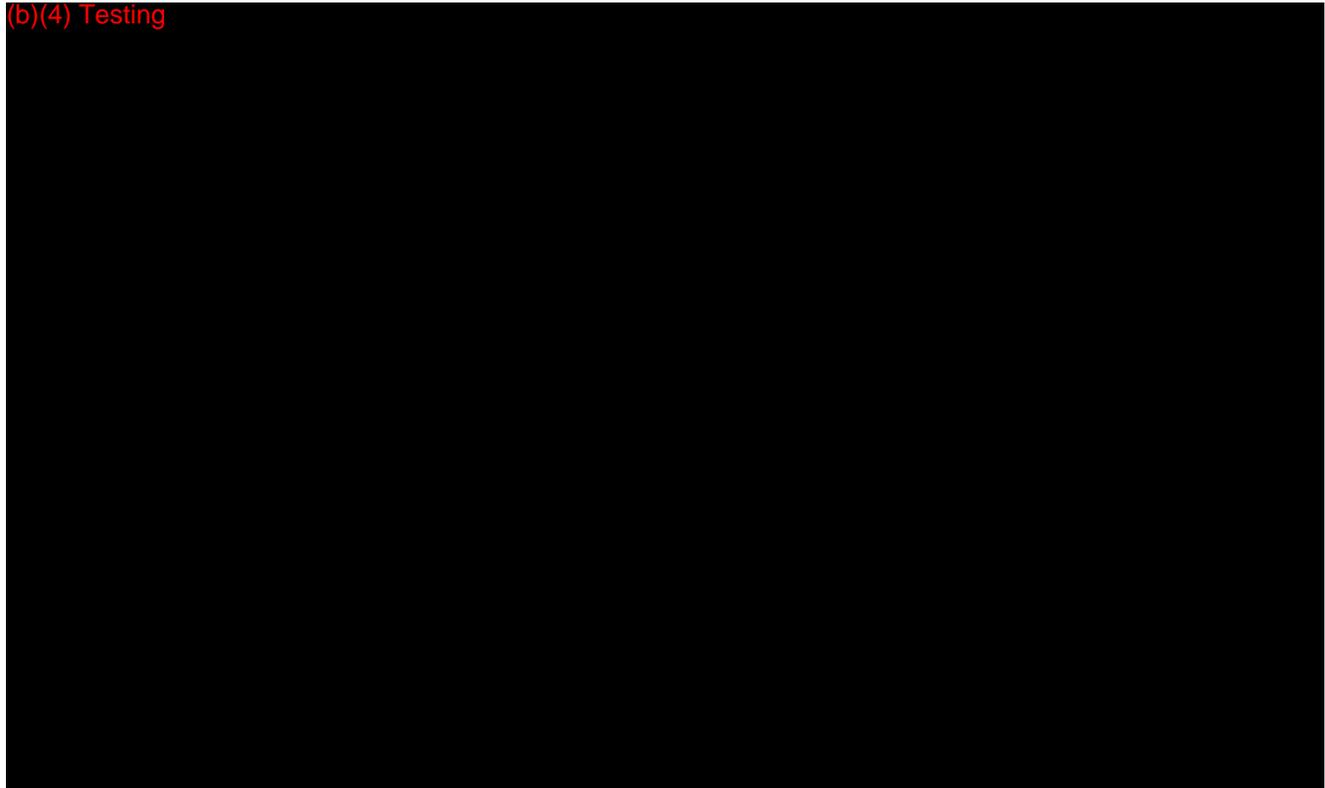


(b)(4) Testing

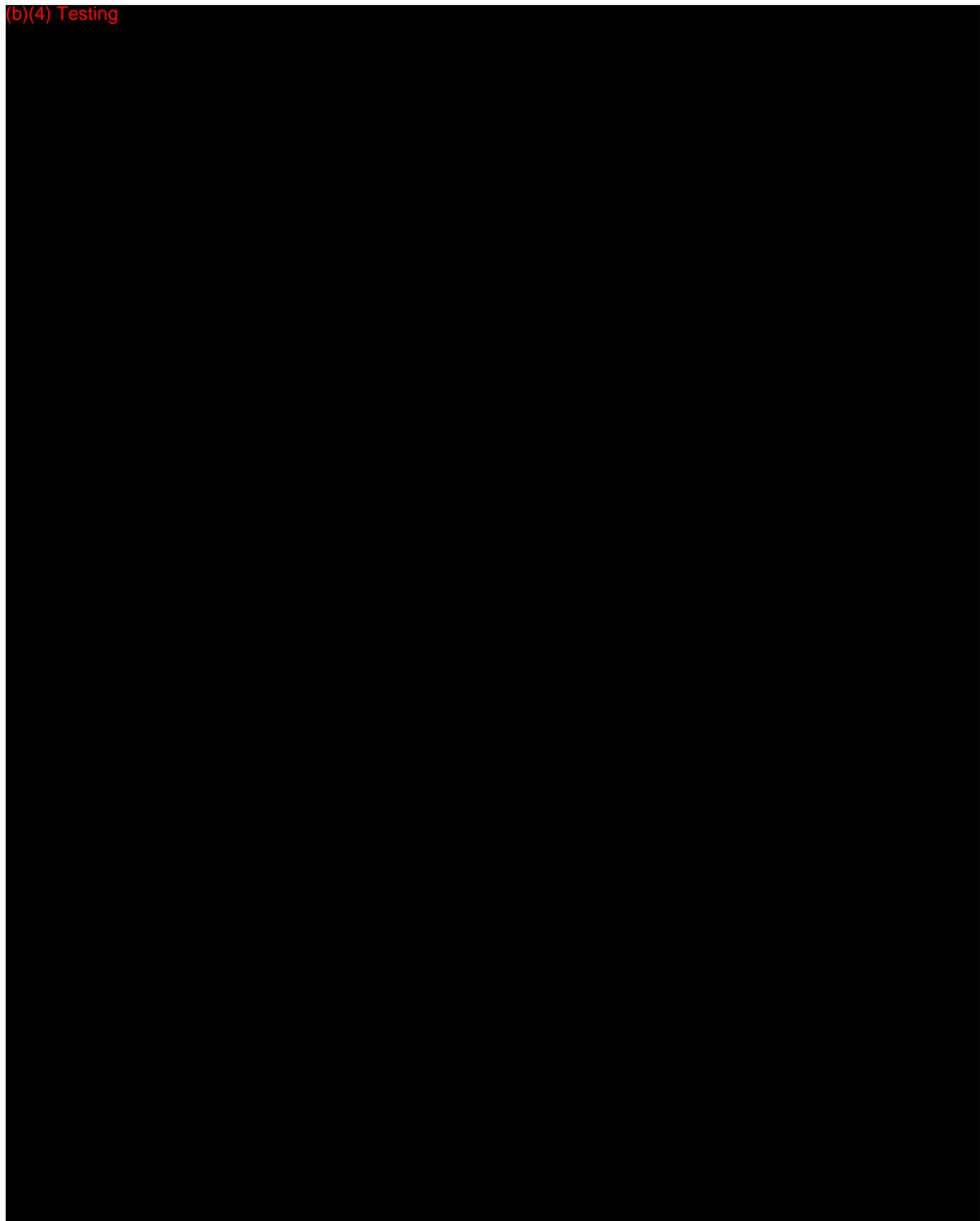


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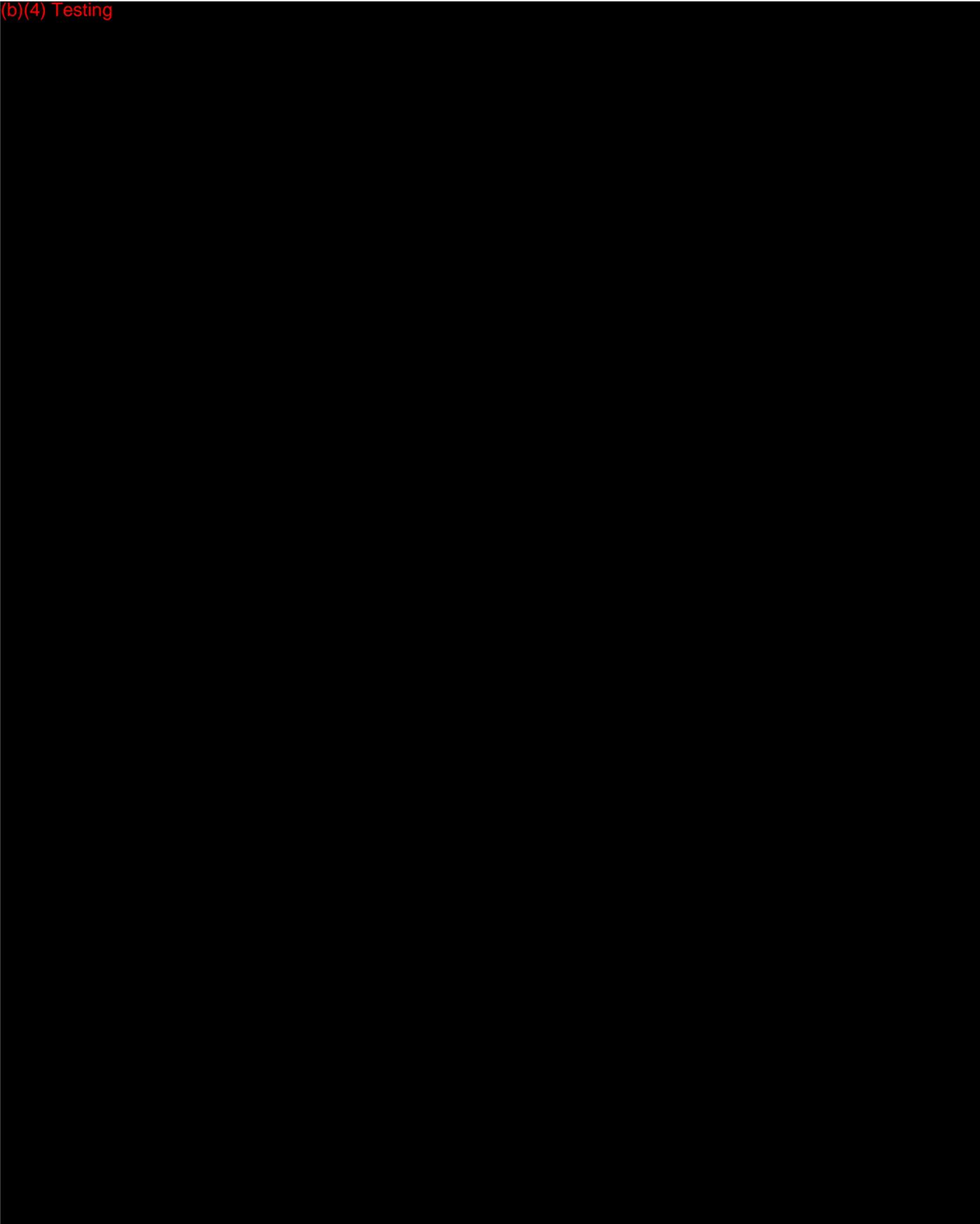
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(b)(4) Testing

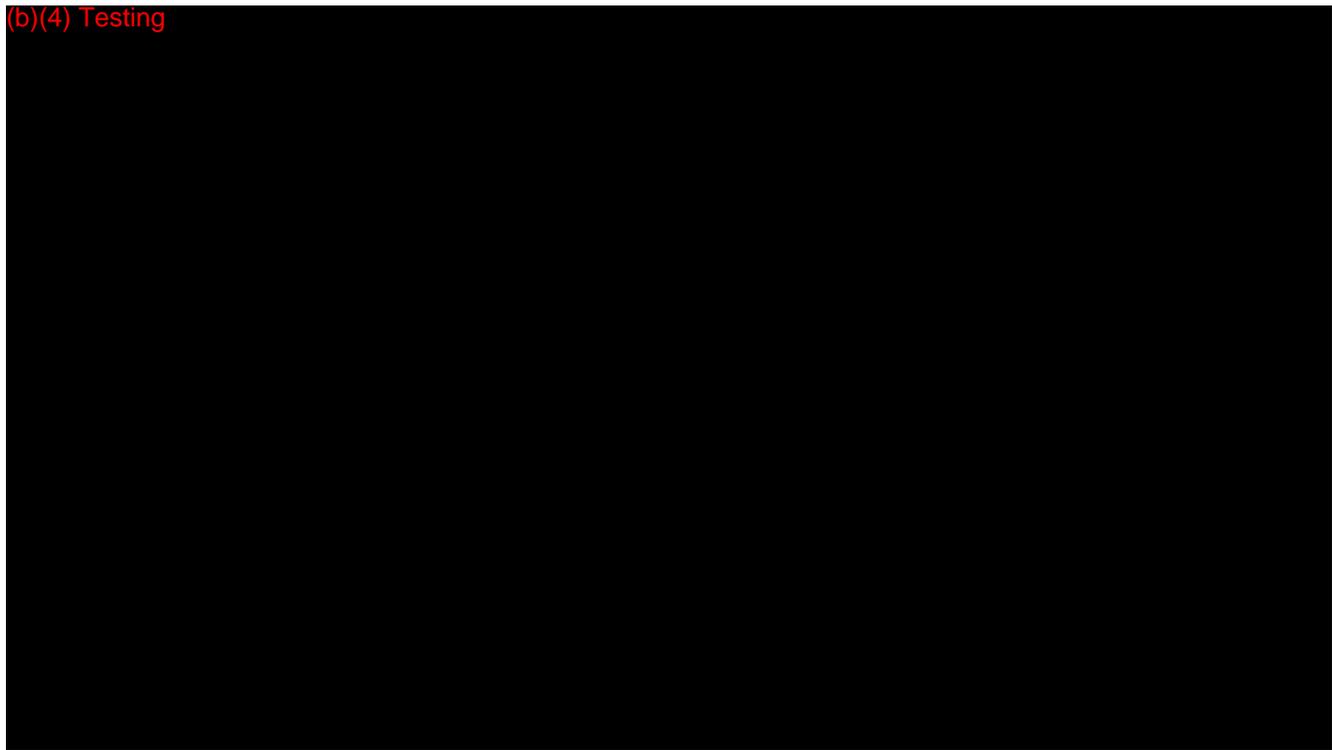


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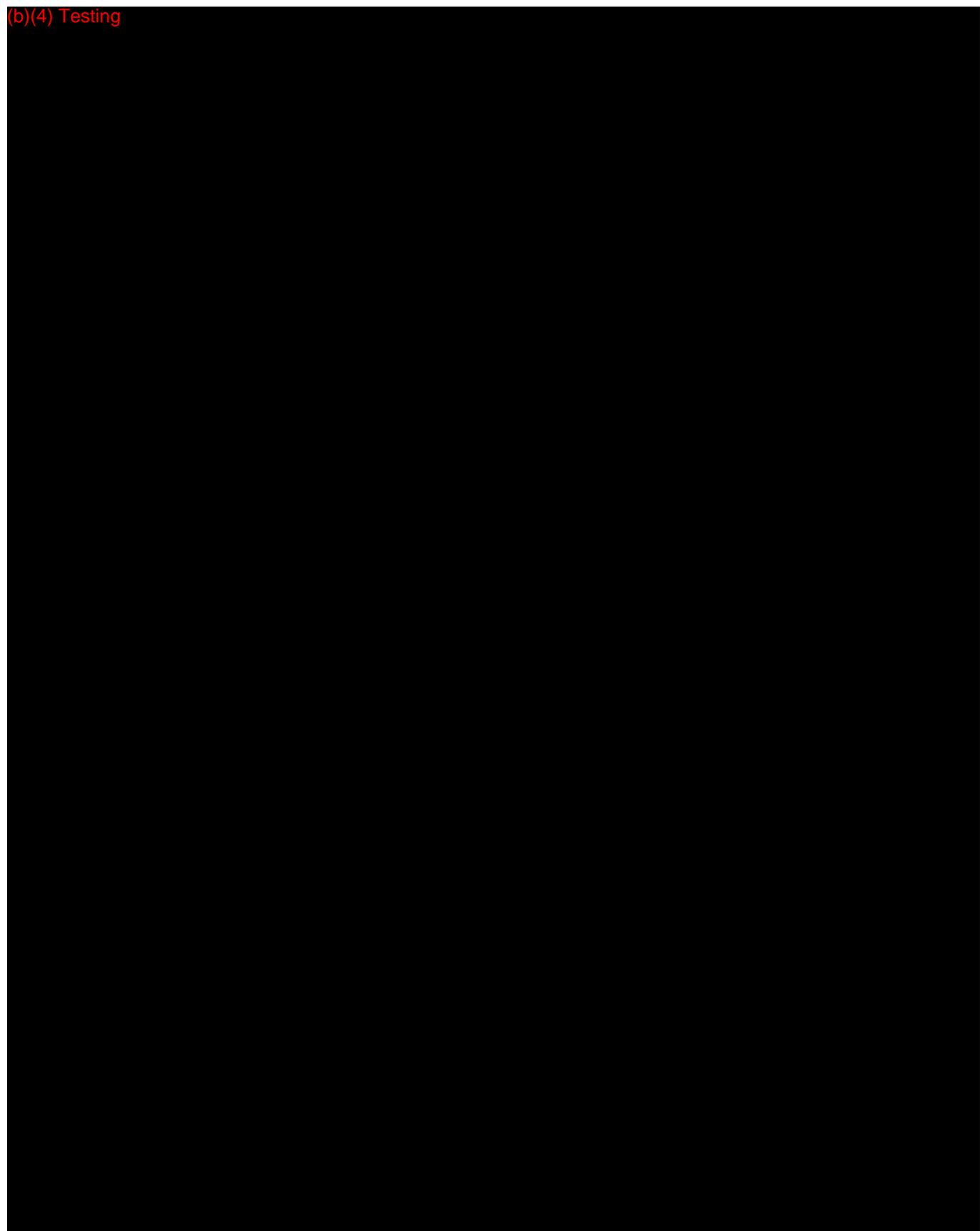


STUDY 3:

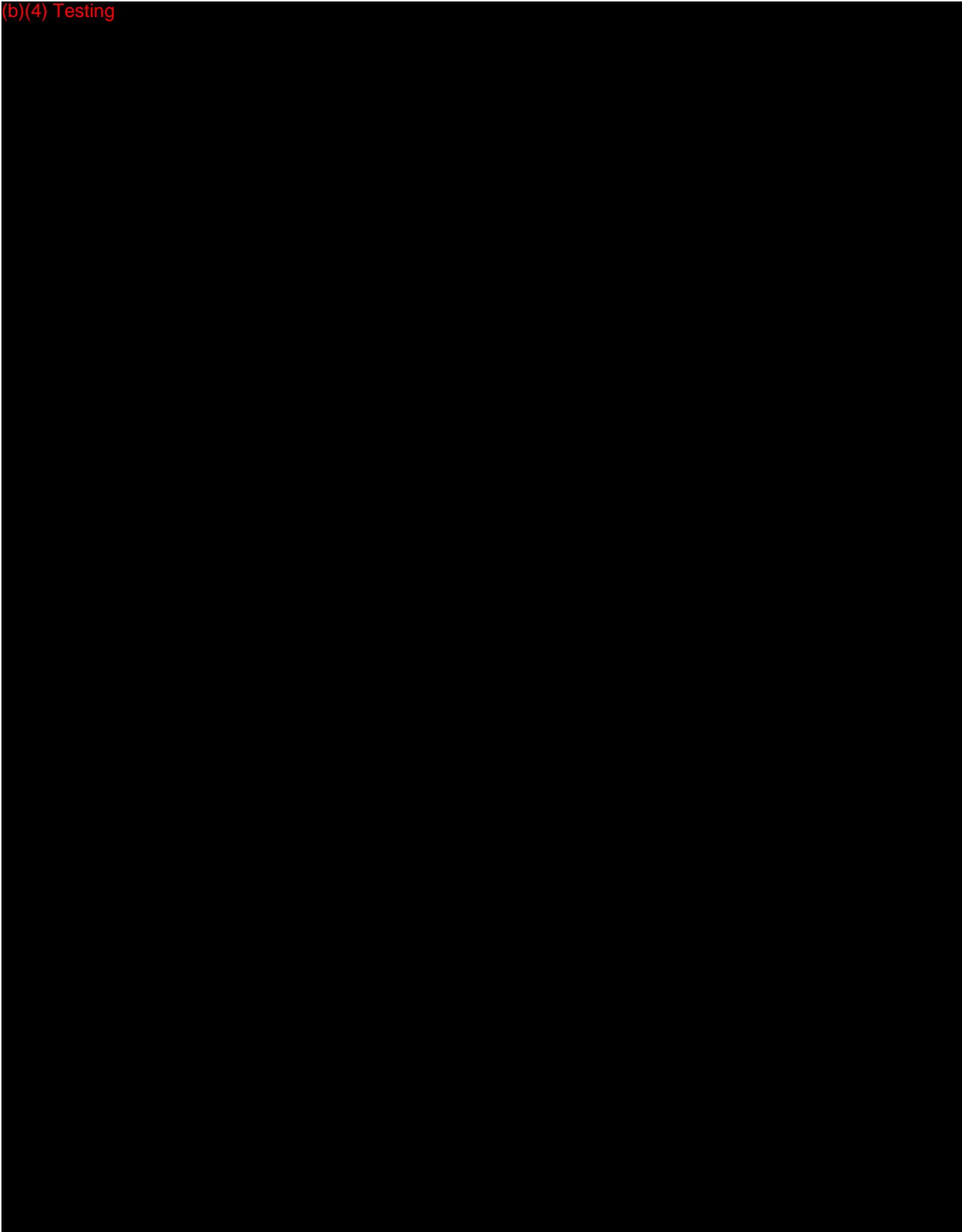
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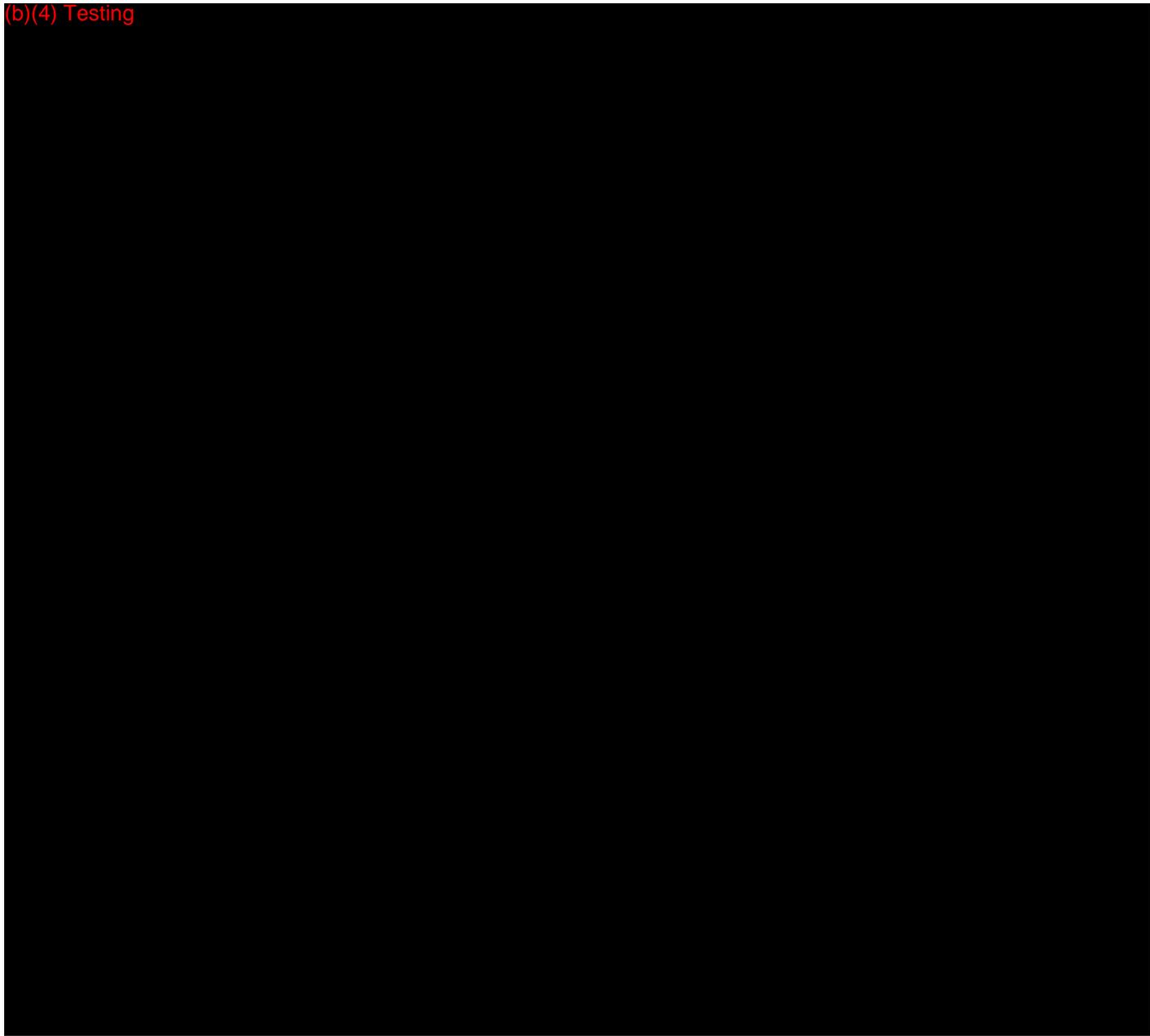
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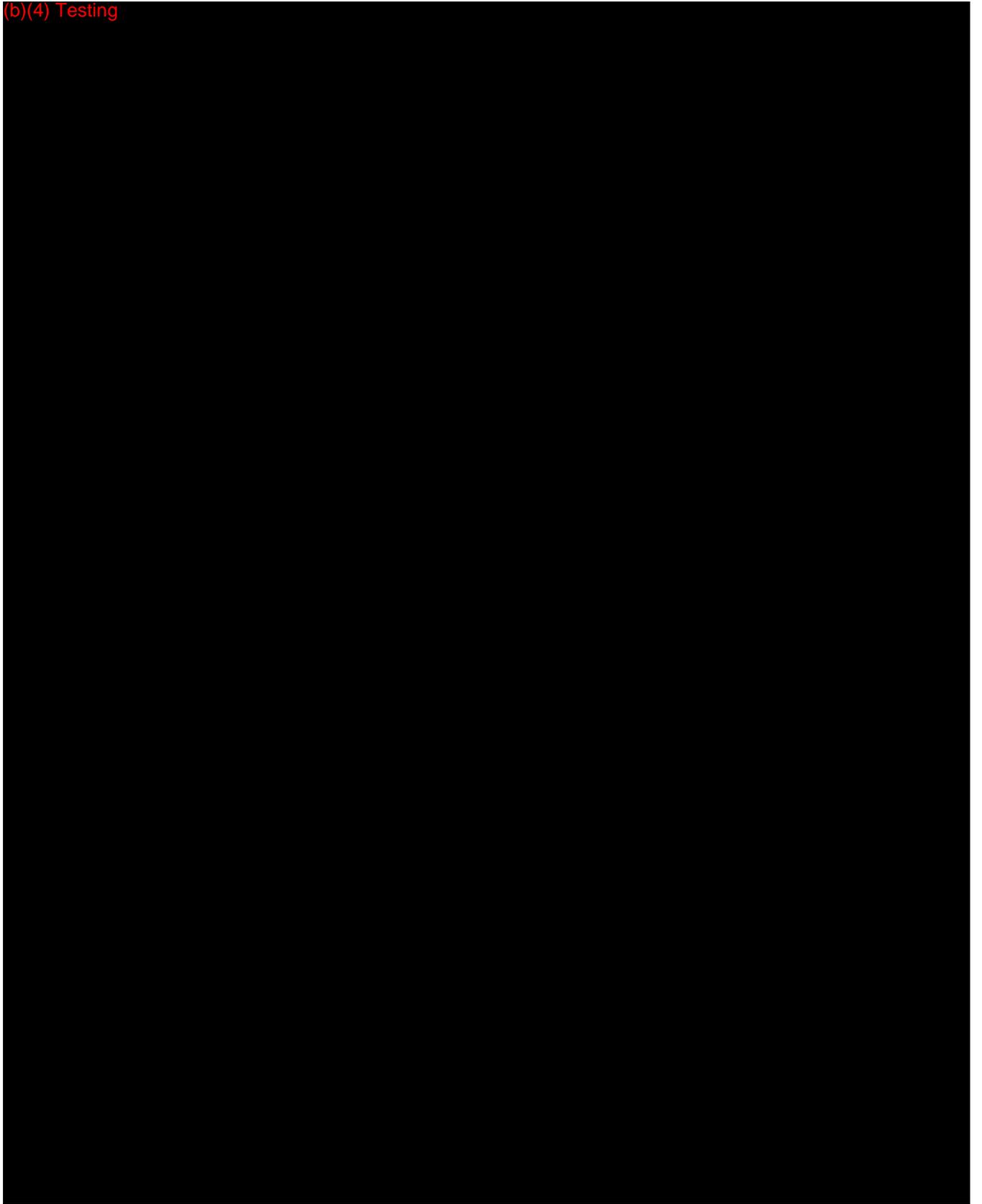
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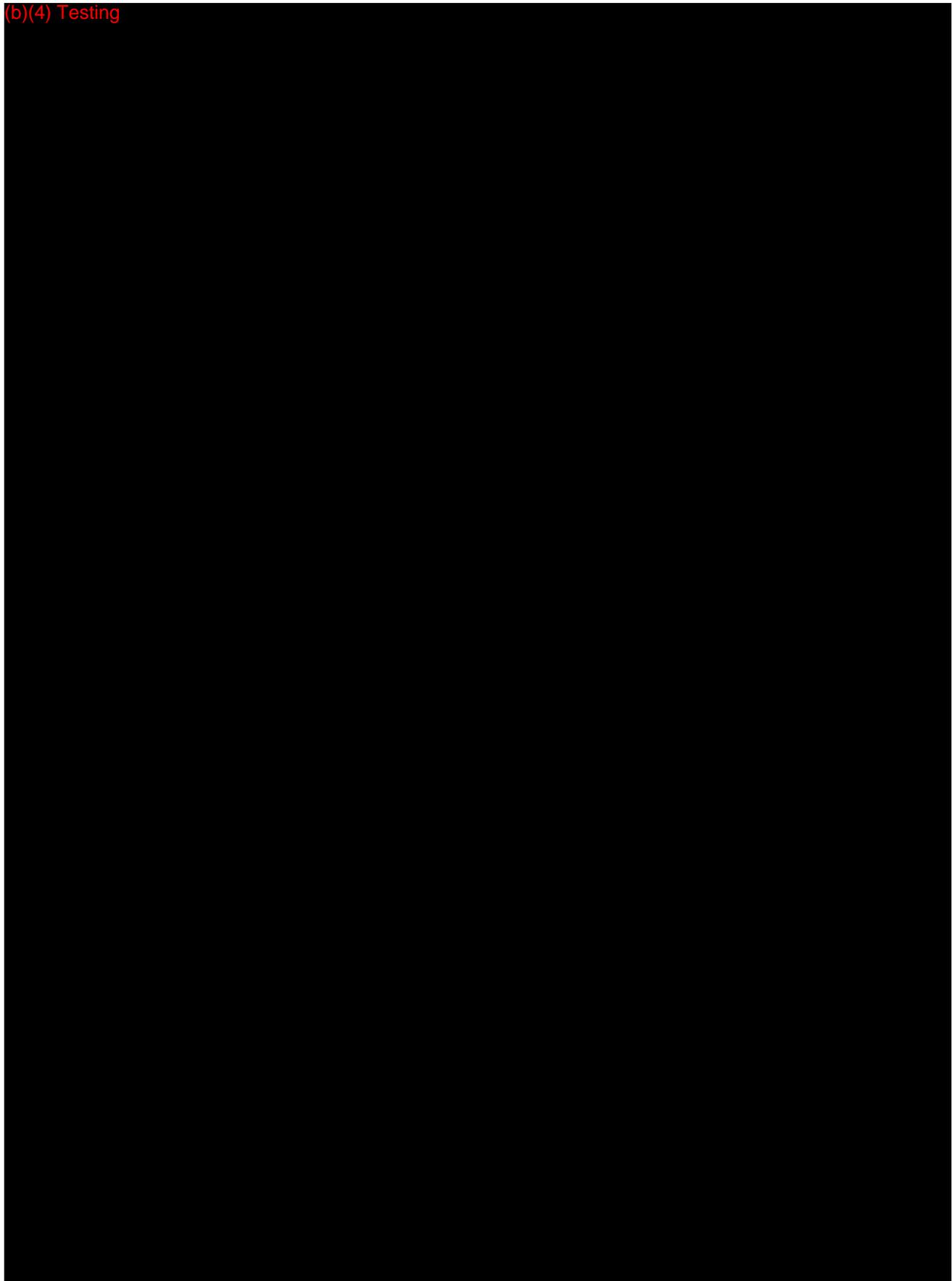
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(b)(4) Testing



(b)(4) Testing

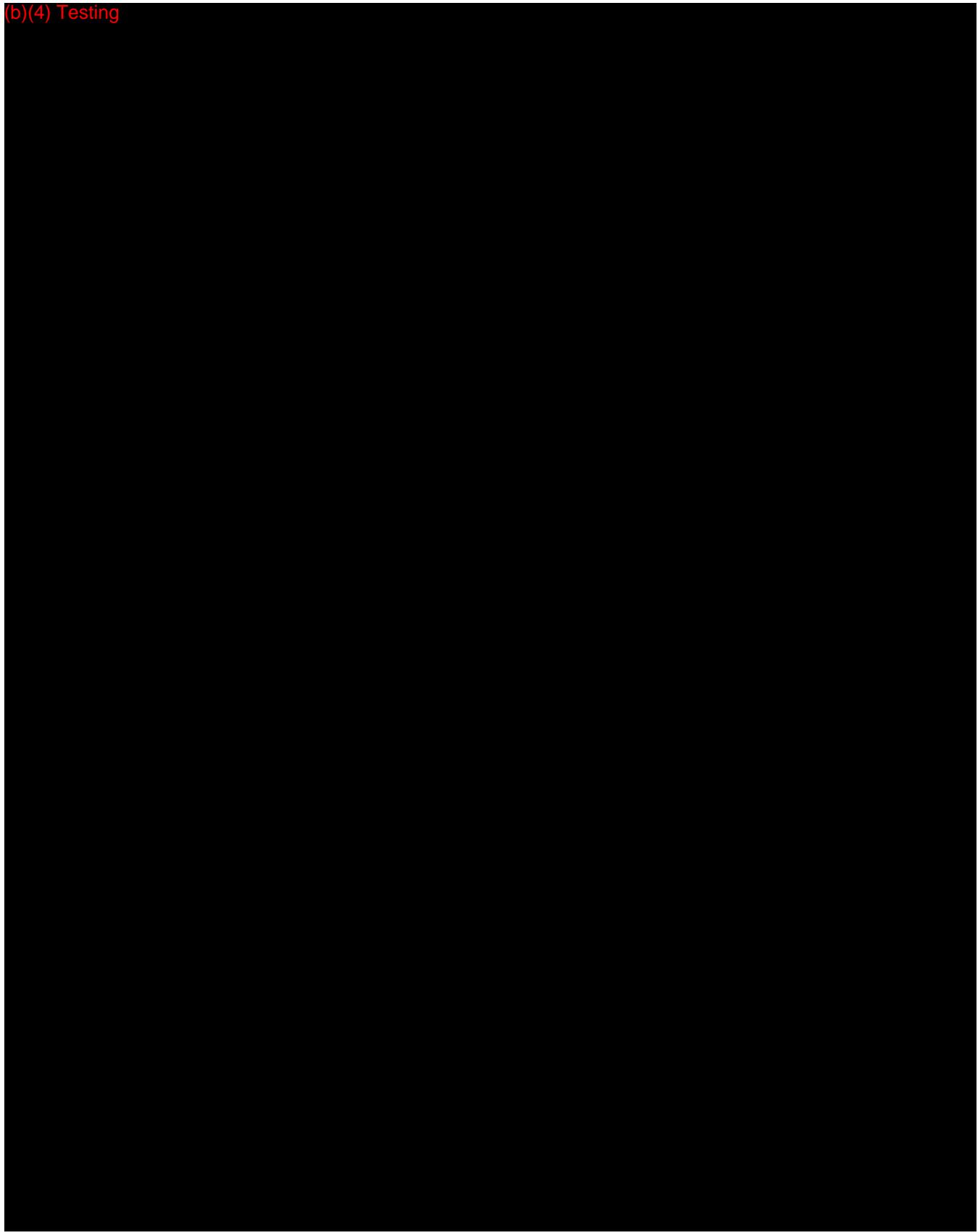


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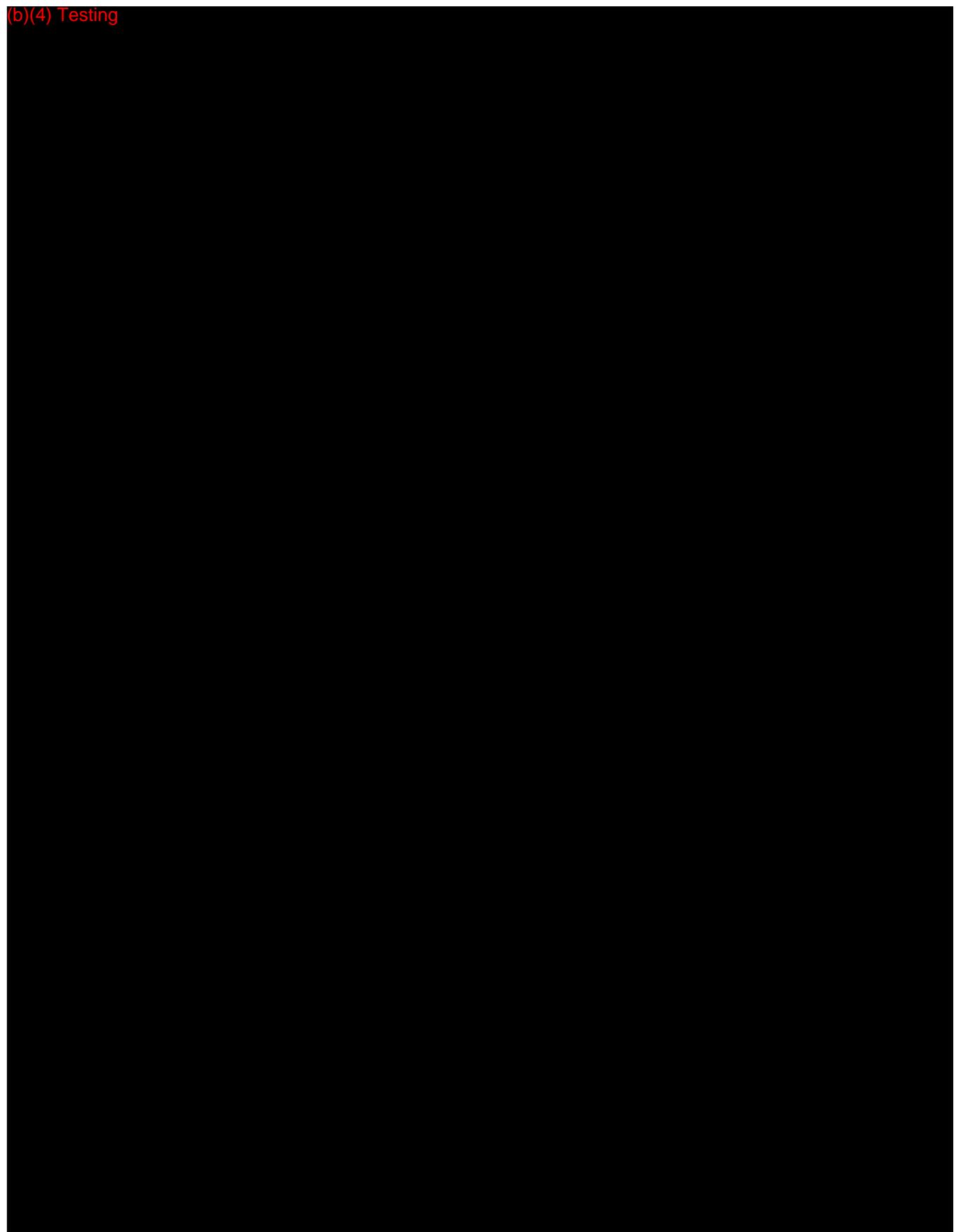
(b)(4) Testing



(b)(4) Testing



(b)(4) Testing

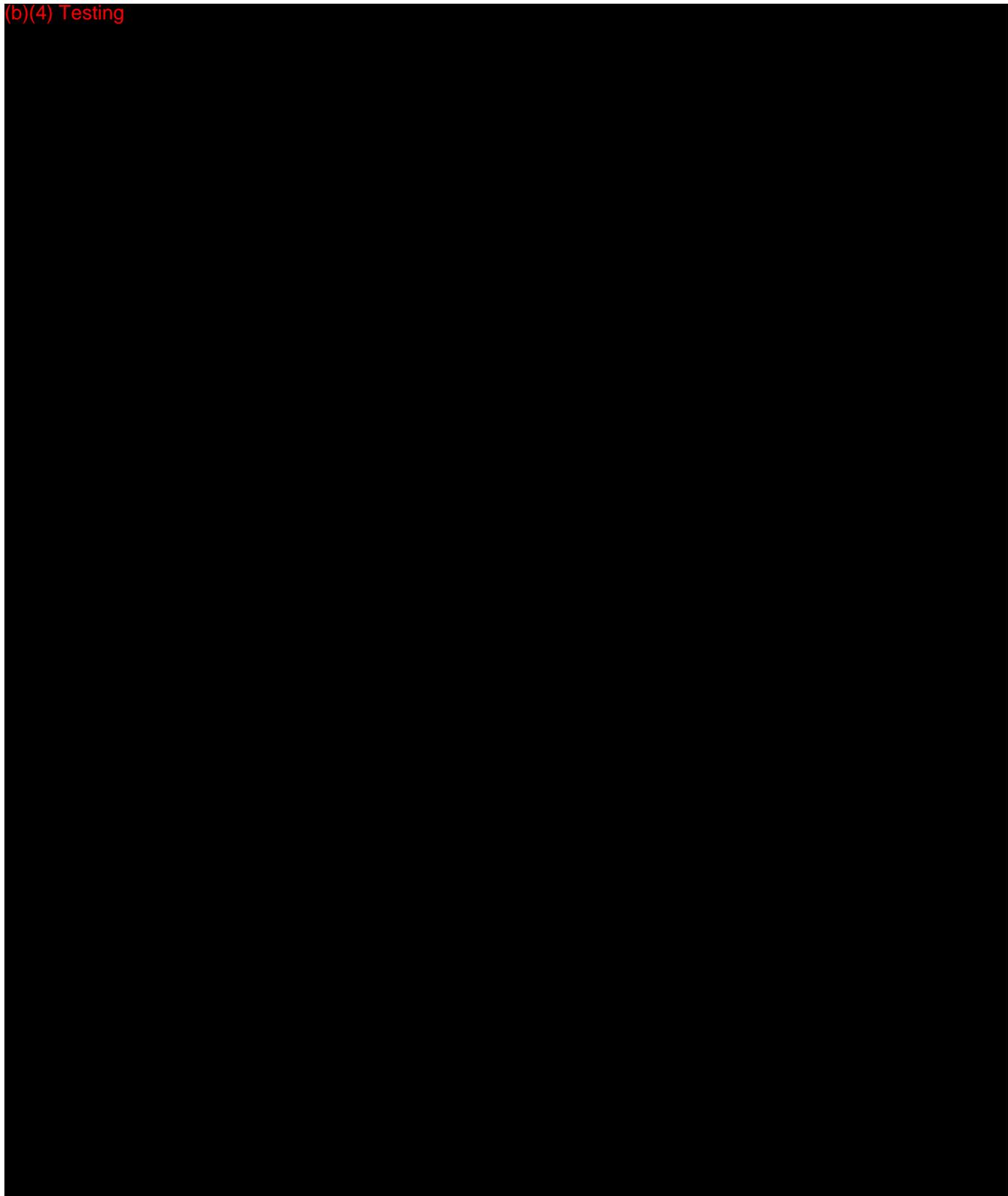


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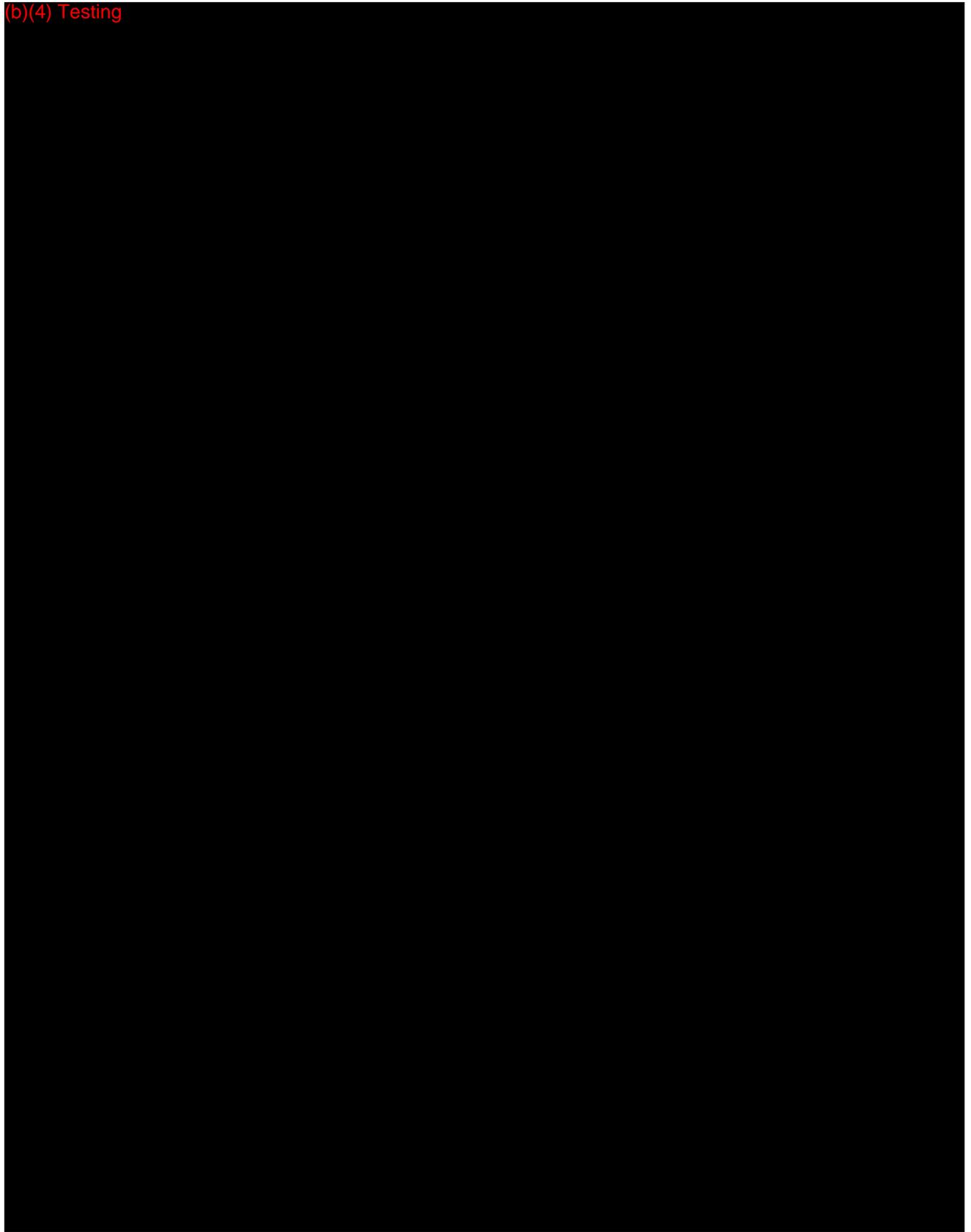
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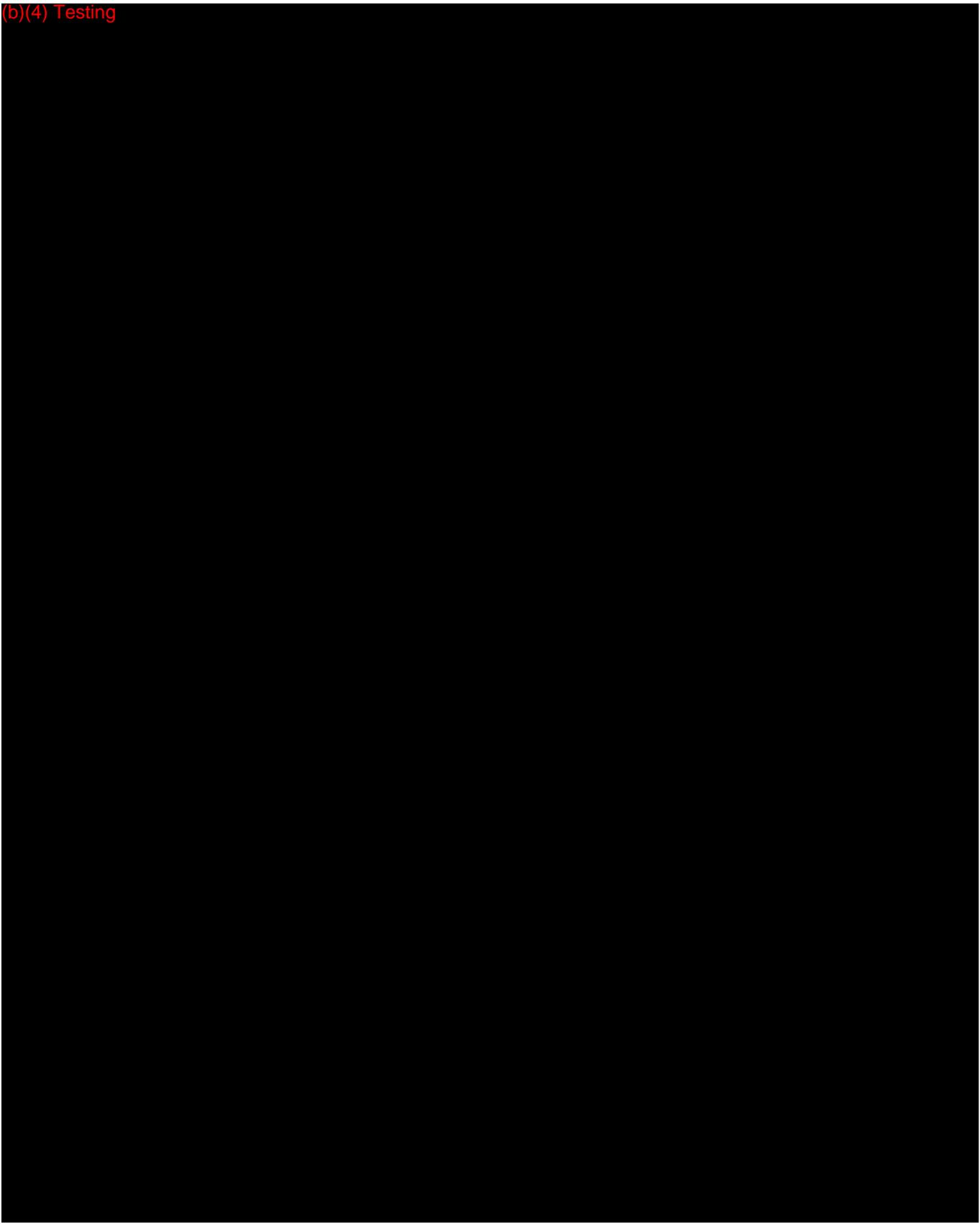
(b)(4) Testing



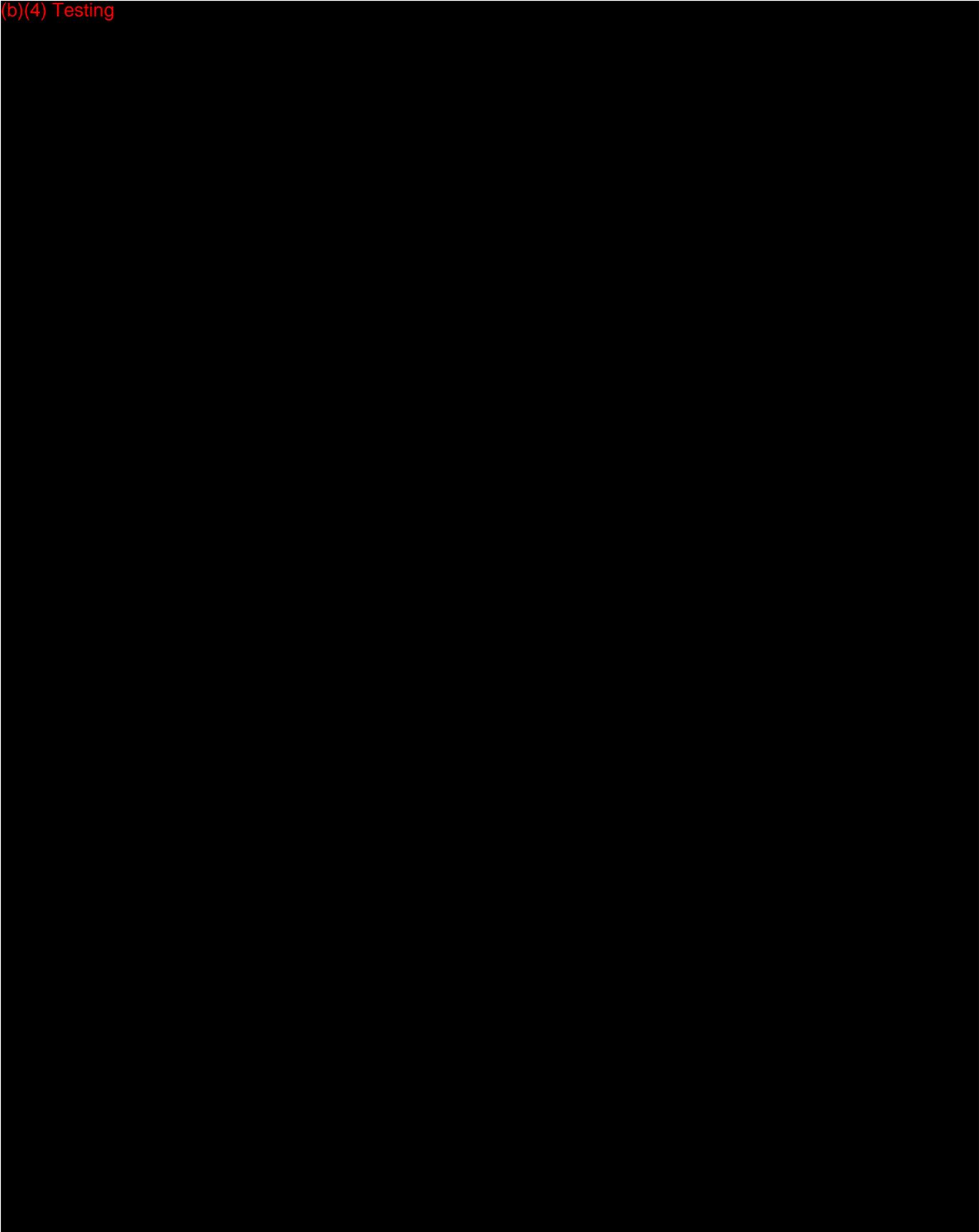
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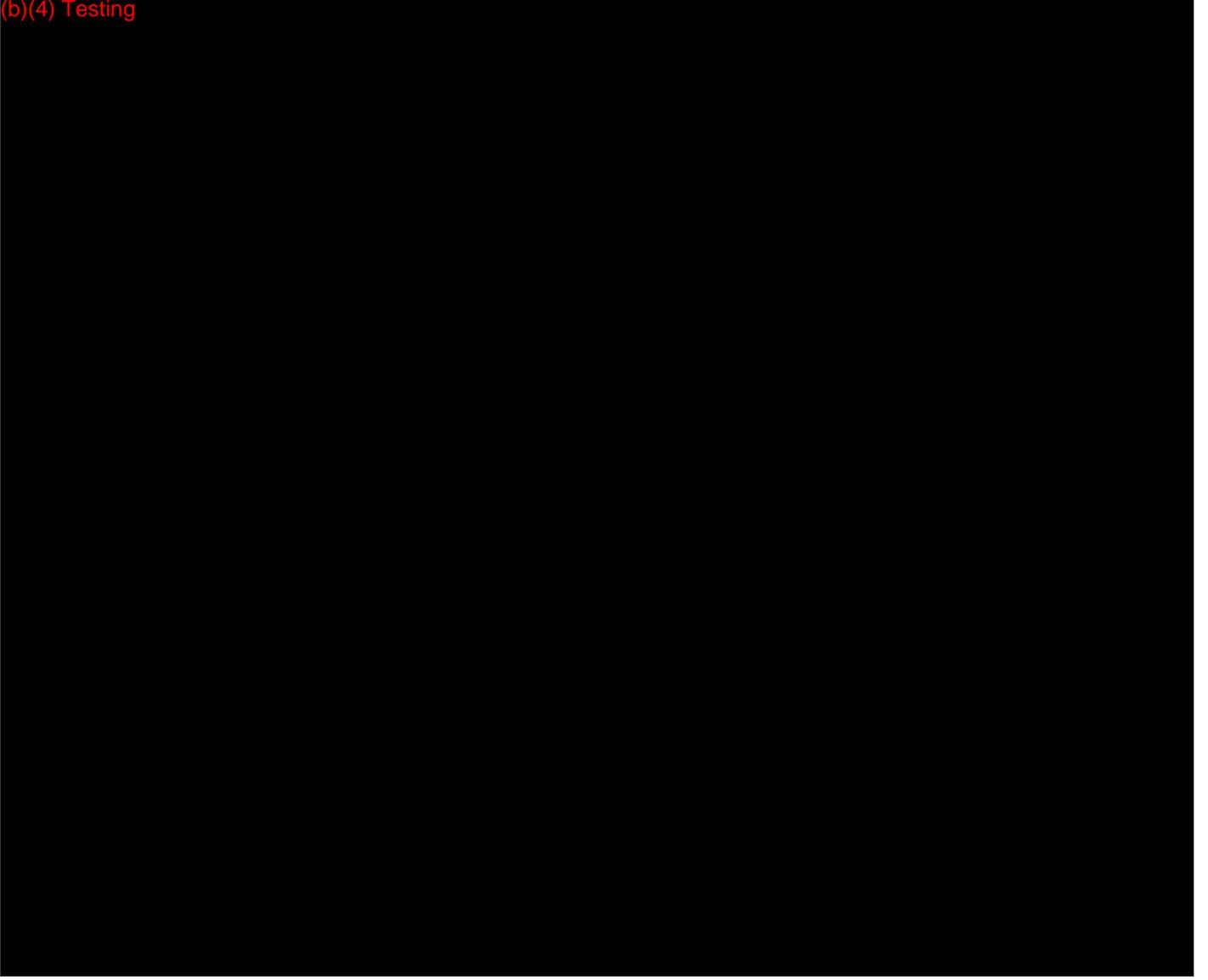
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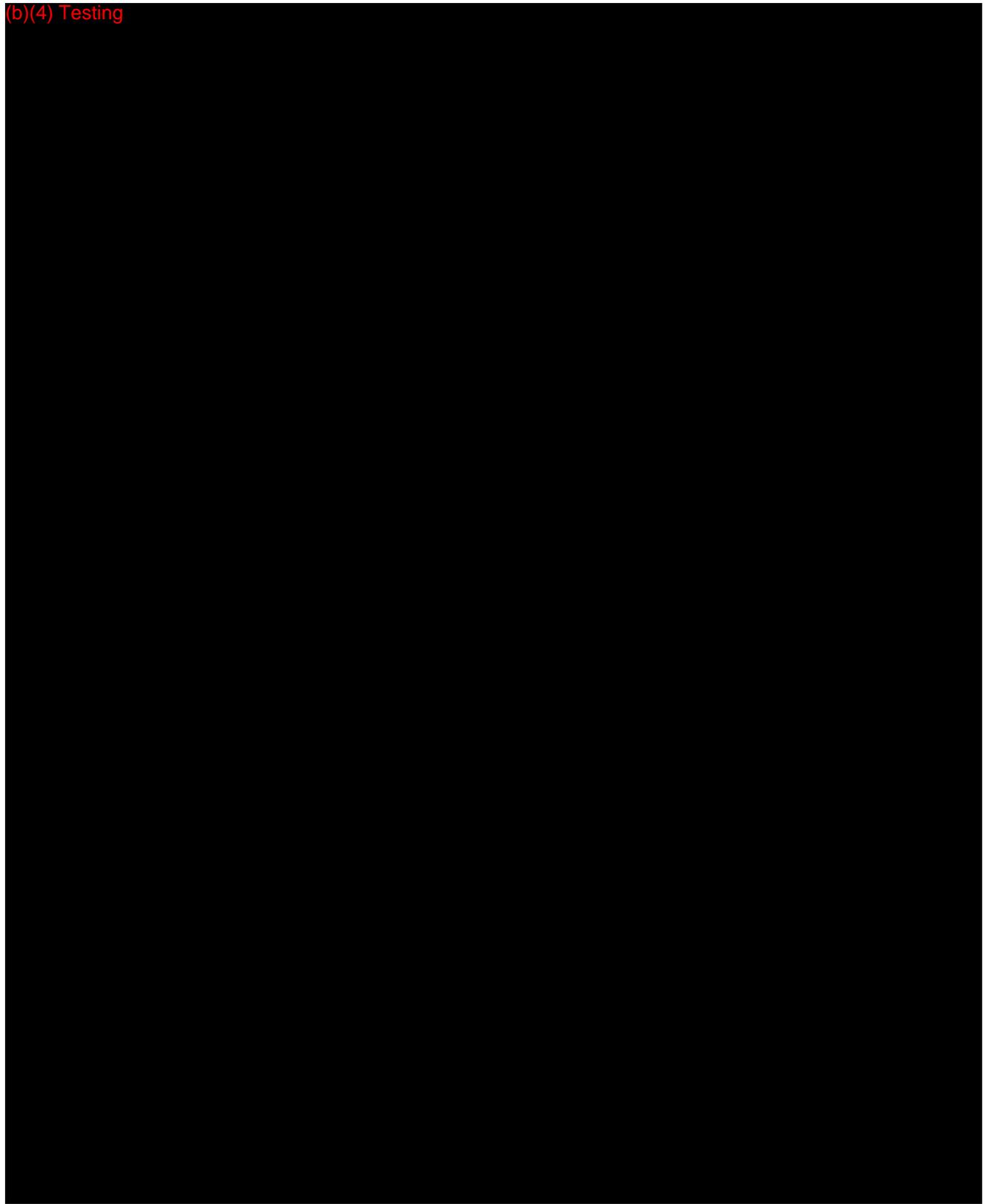
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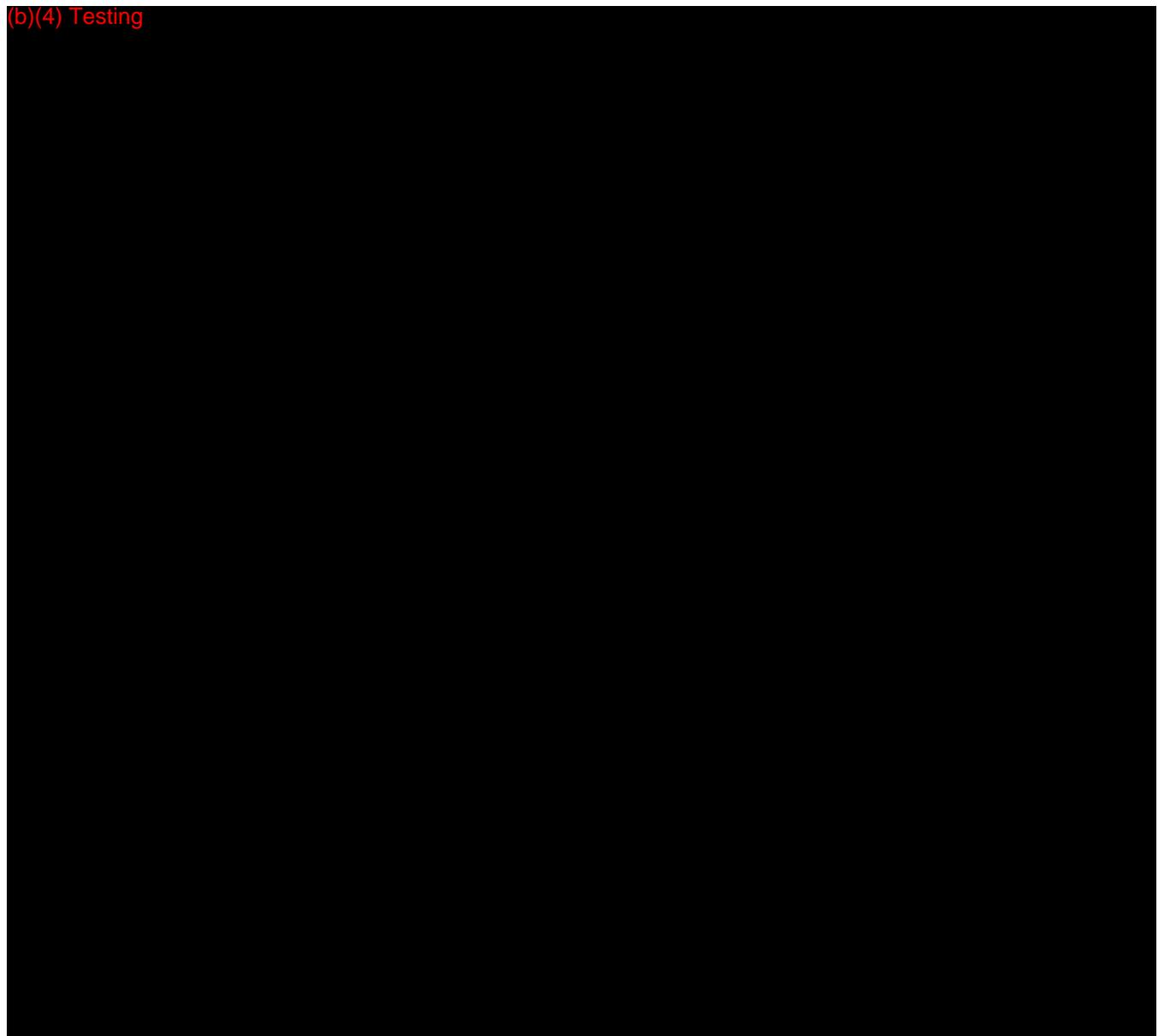
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(b)(4) Testing



(b)(4) Testing



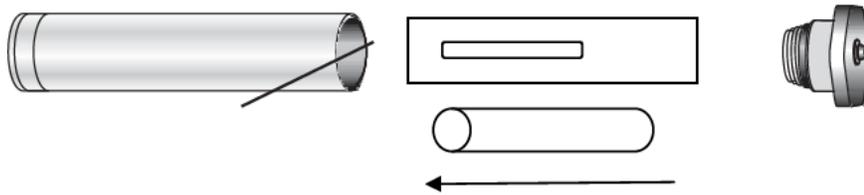
Labeling:

The following is the draft of the labeling that will be applied on each test pack.

Dana Reusable Test Pack

For testing the air removal efficiency
of pre-vacuum steam sterilizers

For use only with SGM Smart-Read BI along with or without a SteriScan Integrator



Insert cap end first of BI
Insert first Pellet end of SteriScan Integrator

Dana Products, Inc.
11457 Melrose St.
Franklin Park, IL

Lot Number:
Exp.:

Instructions for use:

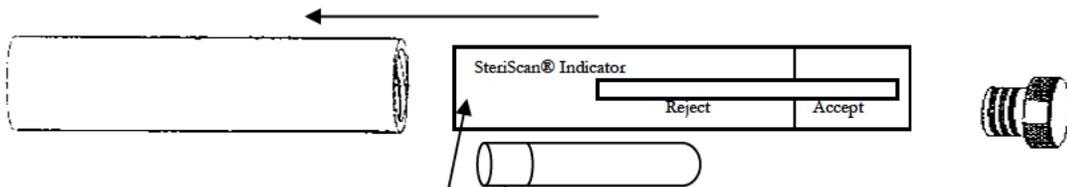
Dana Reusable Test Pack

Product Description:

Dana Reusable Test Pack is designed to challenge the steam sterilization process in healthcare facilities and for routine monitoring of pre-vacuum steam sterilization cycles. It is to be used to monitor 4 minute 270°F (132°C) pre-vacuum steam sterilization cycles when used with an SGM Smart-Read Biological Indicators (BIs) along with or without a SteriScan® Class 5 Integrator.

Direction for Use:

1. To open the device, unscrew the Dana Reusable Test Pack cap.
2. Insert the desired indicator into the chamber as illustrated below.



- Insert **cap end first** of BI into Dana Reusable Test Pack (as shown above).
 - Insert **pellet end first** of the SteriScan® Integrator into Dana Reusable Test Pack (as shown above).
3. To seal the device, screw the Dana Reusable Test Pack cap on tightly.
 4. Place the Dana Reusable Test Pack on the bottom shelf above the drain.
 5. Process the load according to recommended practices.
 6. After completion of the cycle open the sterilizer door and wait at least 5 minutes before removing the Dana Reusable Test Pack.
 7. **Wear gloves and safety glasses when removing the Dana Reusable Test Pack from the sterilizer and at all times when handling and/or removing contents from the Dana Reusable Test Pack after sterilization.**
 8. Do not open the Dana Reusable Test Pack until it has sufficiently cooled off.
 9. After the Dana Reusable Rest Pack has sufficiently cooled off, unscrew the Dana Reusable Test Pack cap.
 10. Remove the BI, and the SteriScan® Class 5 Integrator, as applicable.

11. Follow the instructions provided with the BI and the SteriScan® Steam Sterilization Integrator to read and interpret the results.
12. The BI and the SteriScan® Steam Sterilization Integrator are single use devices. Dispose of these devices after one use per manufacturer's directions.

Storage:

Store at normal room conditions: Temperature 60°F to 85° F Humidity 30 –70%.

Cleaning:

Clean the SteriScan Reusable® Test Pack only with water. Wipe the outside and rinse the inside with water.

Precautions:

1. Use only with 270°F pre-vacuum steam sterilization cycles.
2. Use gloves to handle test pack after sterilization.
3. Wait until the test pack cools off before opening.
4. The manufacturer recommends replacing the Dana Reusable Test Pack six months after first use; however, if there are any visible signs of wear and tear including, for example, discoloration, rusting, cracking, peeling or deformation or any other visible change, discard and replace the Dana Reusable Test Pack immediately.
5. SteriScan® Chemical Indicators are not replacements for Biological Indicators.

Made in USA by
Dana Products
11457 Melrose Street
Franklin Park, IL 60131
847-455-2881

Premarket Notification Truthful and Accurate Statement:
[As Required by 21CFR 807.87(k)]

I certify that, in my capacity as the President of Dana Products, Inc., 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.

Signature:  _____

_____ Harry Bala _____

Date 1/17/2013 _____

510k Number: _____

EXHIBIT A

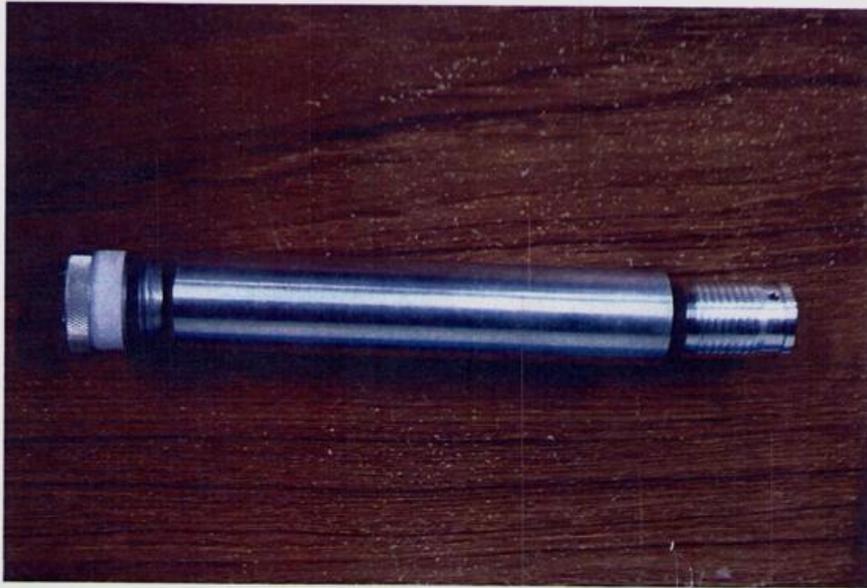


PHOTO - 1



PHOTO 2



PHOTO-3



PHOTO 4

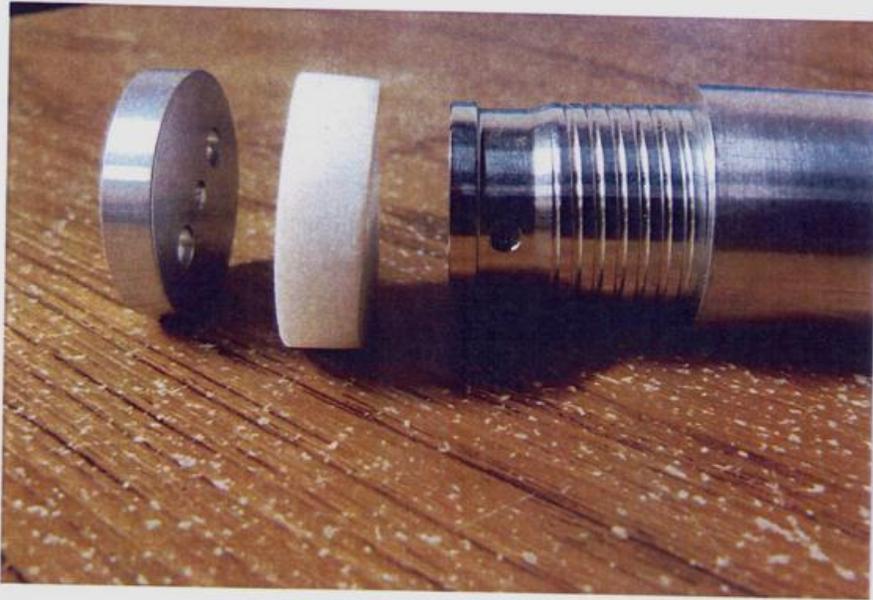


PHOTO-5

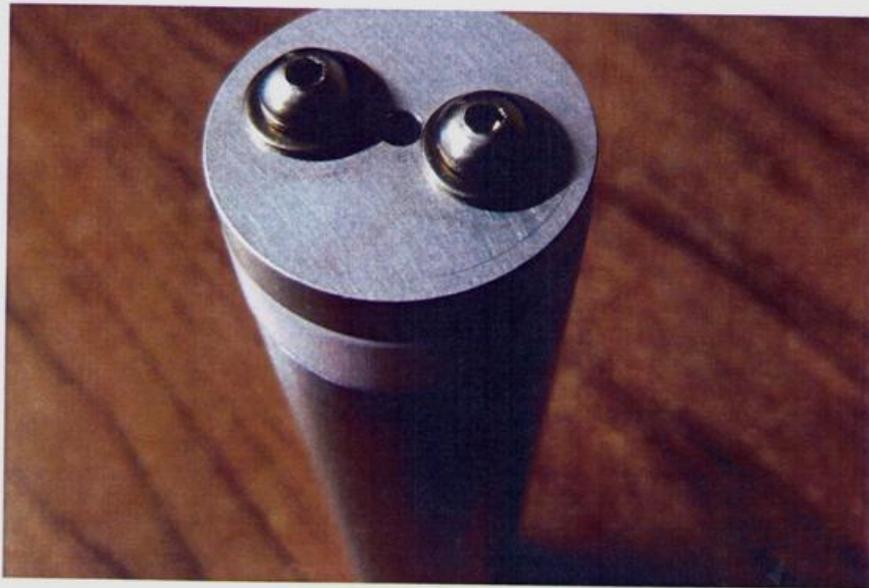


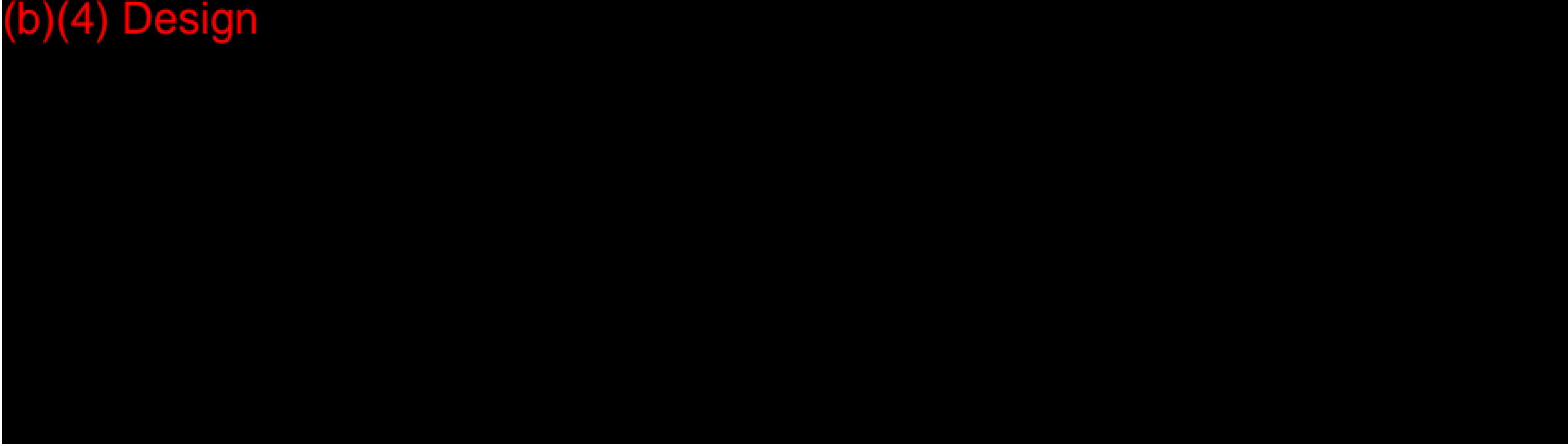
PHOTO 6



PHOTO 7

EXHIBIT B

(b)(4) Design



Barlow, Lenny *

From: Barlow, Lenny *
Sent: Friday, November 29, 2013 11:27 AM
To: 'bala@danaproducts.com'
Cc: DCCLetters
Subject: k130135 Correspondence
Attachments: k130135.pdf



COVER SHEET MEMORANDUM

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

From: Reviewer Name Sreekanth Gutala, Ph.D.
Subject: 510(k) Number K130135
To: The Record

Please list CTS decision code: SE

- 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	
510(k) Summary or 510(k) Statement (<i>Attach Summary or Statement</i>)	X	
Truthful and Accurate Statement (<i>Must be present for a Final Decision</i>)	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		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Regulation Number: 21 CFR 880.2800
Class: II
Product Code: JOJ
Additional Product Codes:

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

Branch Chief Sign-Off	 Elizabeth F. Claverie -S 2013.11.22 15:45:12 -05'00'
Division Sign-Off	 Tejashri Purohit-Sheth, M.D. Clinical Deputy Director DAGRID 2013.11.25 09:00:13 -05'00'

DANA PRODUCTS, INC. **K130135-8001**
7 COREY DRIVE
SOUTH BARRINGTON, IL 60010
TEL. 847-455-2881 FAX. 847-455-2886

May 24, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center -W066-0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC

MAY 29 2013

Received

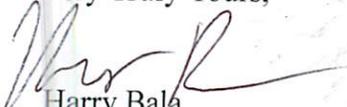
Dear Sir or Madam:

K130135 -- eCOPY COVER LETTER

Please see enclosed eCopy of the enclosed paper copy relating to K130135. **The enclosed eCopy is an exact duplicate of the enclosed paper copy.**

Thanking you,

Very Truly Yours,


Harry Bala
President



DANA PRODUCTS, INC.
7 COREY DRIVE
SOUTH BARRINGTON, IL 60010
TEL. 847-455-2881 FAX. 847-455-2886

May 24, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center –W066-0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

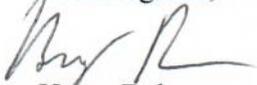
Dear Sir or Madam:

510(k) Number: K 130135 Dana Reusable Test Pack– Your Refuse to Accept dated February 21, 2013

The submission referenced above has been revised (and is attached hereto) in accordance with the comments provided by FDA in the annotated RTA checklist regarding submission K130135. In order to aid in review of the amended submission, preceding the attached revised submission are descriptions of revisions made to the submission in response to issues raised in the RTA checklist. In lieu of submitting only revised sections, the amended submission is attached full for the sake of ease of review. I have made every effort to address the issues you have raised. Please let me know if you require additional information or changes.

Thank you.

Best Regards,

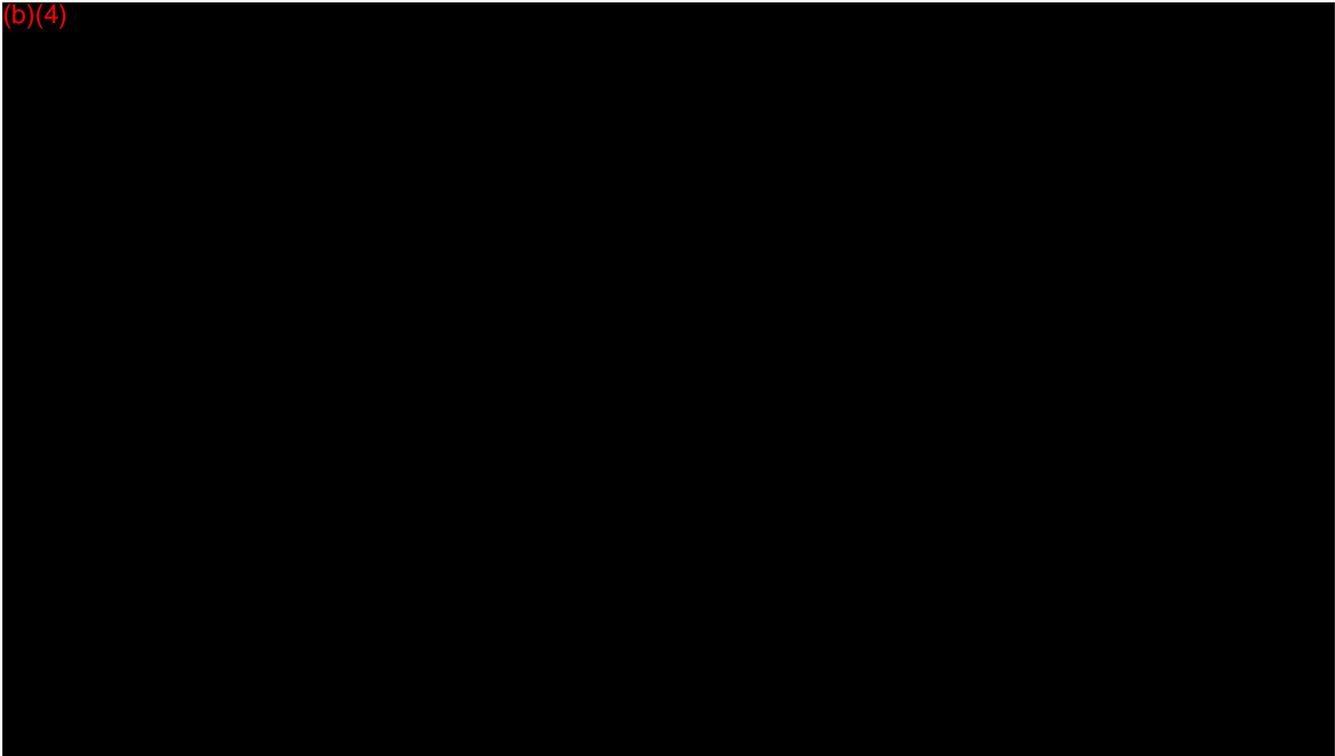

Harry Bala
President

K130135 – RTA CHECKLIST RESPONSE

The submission has been revised and resubmitted in accordance with the comments provided by FDA in the annotated RTA checklist regarding submission K130135. In order to aid review of the amended submission, below are descriptions of revisions made to the submission in response to issues raised in the RTA checklist. In lieu of submitting only revised sections, the amended submission is attached full for the sake of ease of review.

ORGANIZATIONAL ELEMENTS: 2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.); 3) All pages of the submission are numbered.

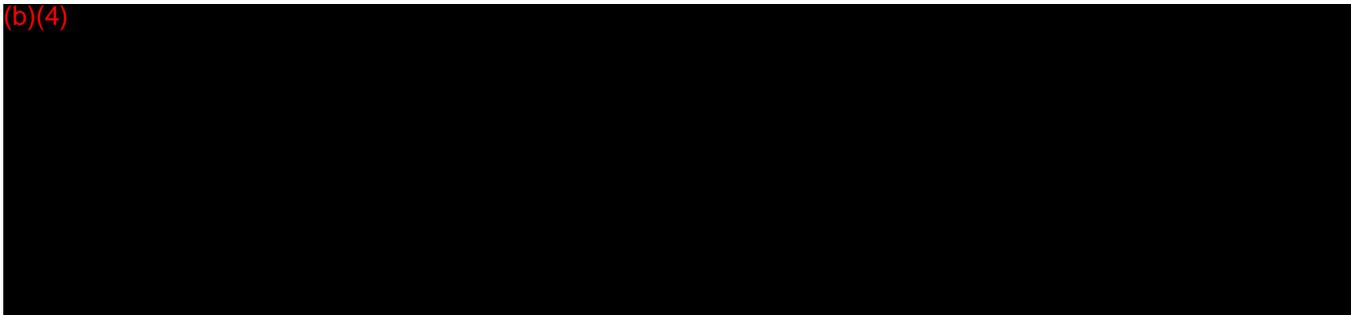
(b)(4)



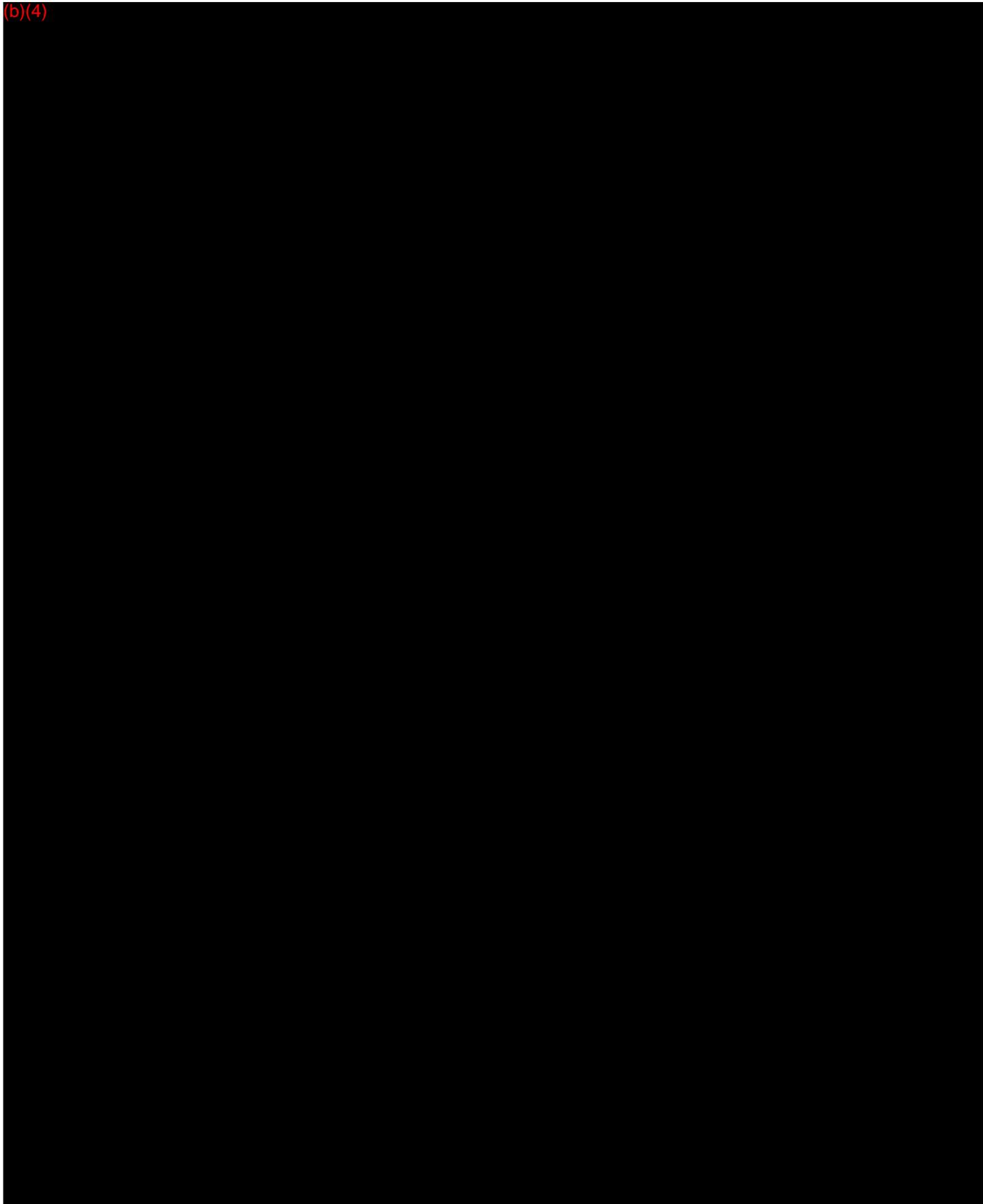
A. ADMINISTRATIVE.

2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter): b) Device common name.

(b)(4)



(b)(4)

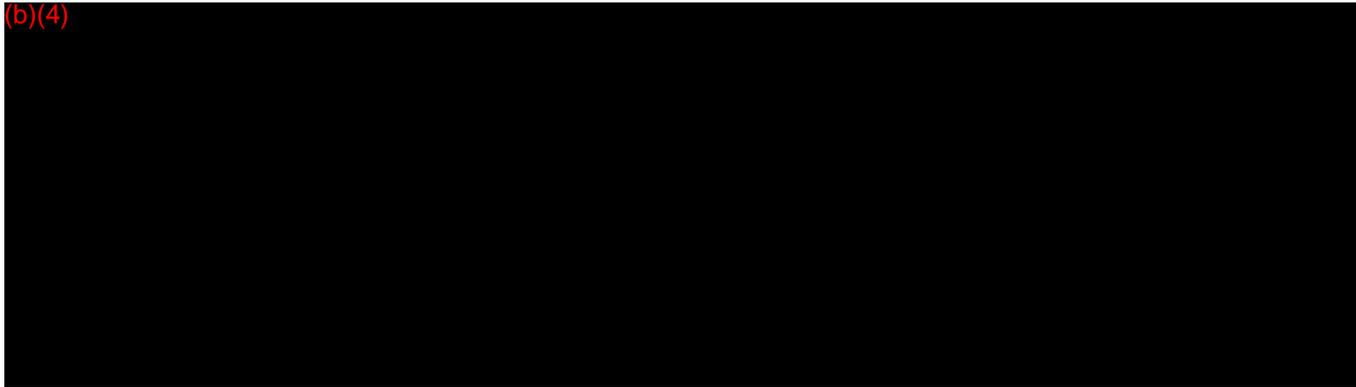


B: DEVICE DESCRIPTION

11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:

- a) A description of the principle of operation and mechanism of action for achieving the intended effect.
- b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.

(b)(4)

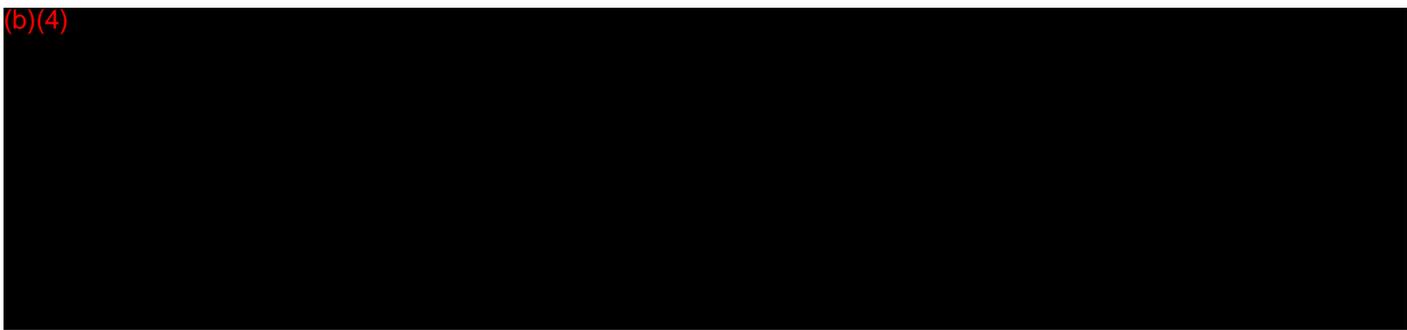


C. SUBSTANTIAL EQUIVALENCE DISCUSSION

14) Submitter has identified a predicate device.

- a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. Information regarding documenting preamendment status is available online.
- b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.

(b)(4)



(b)(4)

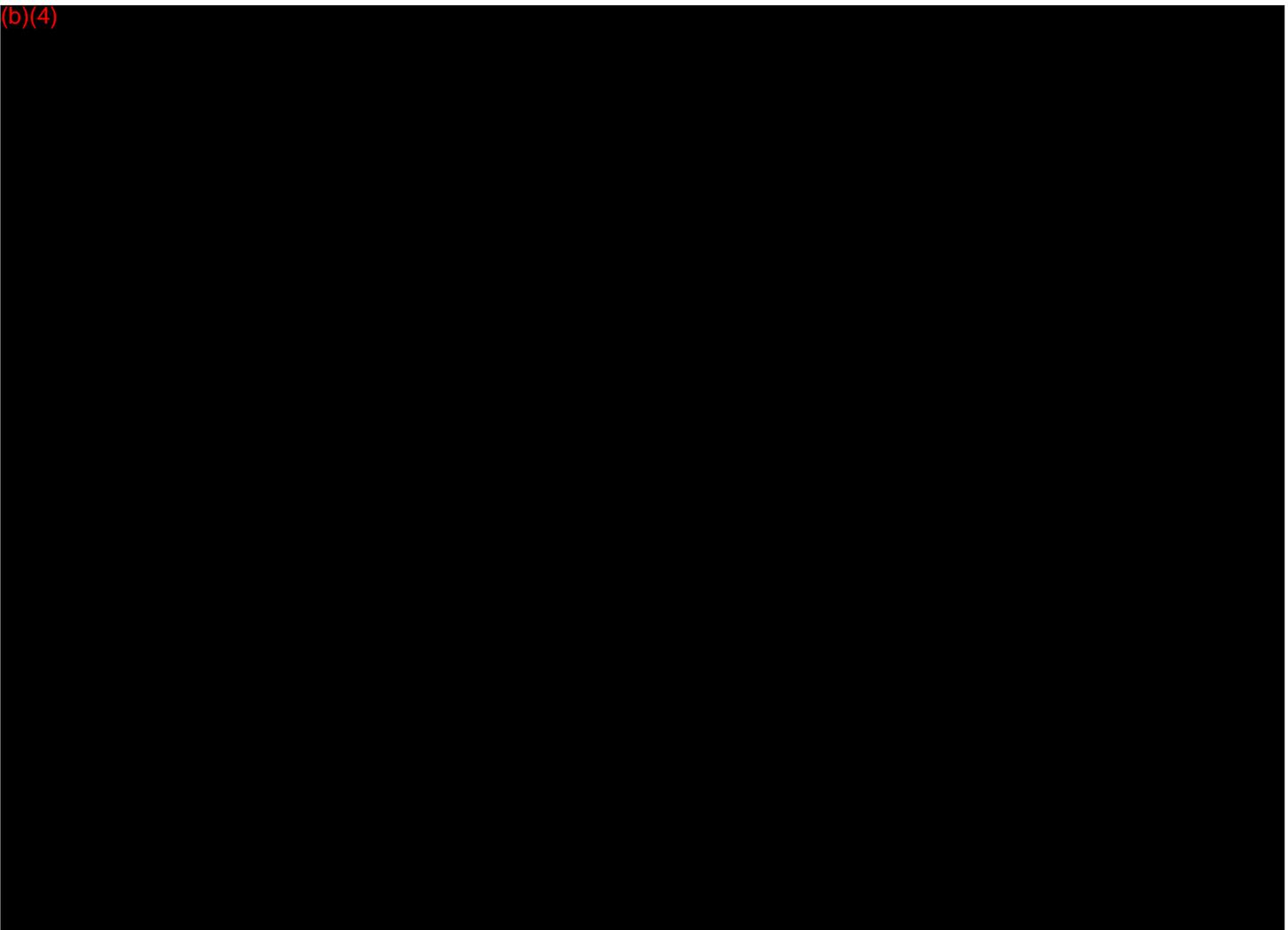
A large black rectangular redaction box covering the top portion of the page.

15) Submission includes a comparison of the following for the predicate(s) and subject device

a) Indications for Use

b) Technology, including features, materials, and principles of operation

(b)(4)

A large black rectangular redaction box covering the majority of the page content below the list items.

D. PROPOSED LABELING

17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.

a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).

(b)(4)



J: PERFORMANCE DATA GENERAL

39) For each completed nonclinical (i.e., animal) study conducted

a) Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120.

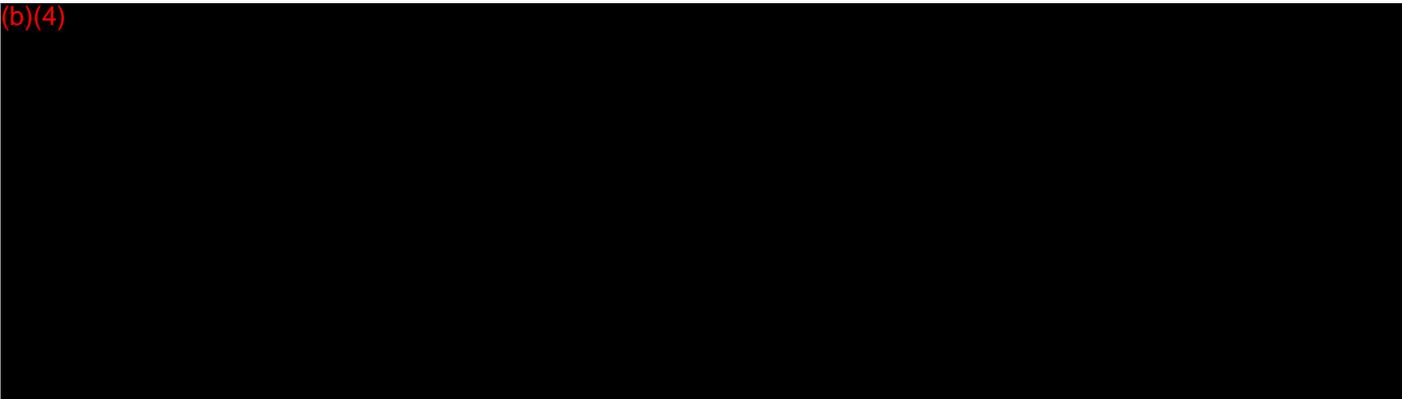
b) Submission includes final study report which includes all elements outlined in 21 CFR 58.185.

c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.

(b)(4)

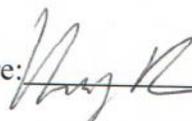


(b)(4)



Premarket Notification Truthful and Accurate Statement:
[As Required by 21CFR 807.87(k)]

I certify that, in my capacity as the President of Dana Products, Inc., 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.

Signature:  _____
Harry Bala

Date 5/24/2013

510k Number: 130135

510k NOTIFICATION

**DANA REUSABLE TEST PACK FOR USE WITH
SMART READ BI ALONG WITH OR WITHOUT A STERISCAN
INTEGRATOR**

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2. CDRH Premarket Review Submission Cover sheet	
3. FDA Form 3654 (ANSI/AAMI ST8:2008: Hospital steam sterilizers)	
4. FDA Form 3654 (ANSI/AAMI ST79:2010 & A1:2010: Comprehensive guide to steam sterilization and sterility assurance in health care facilities)	
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6. Indications For Use Statement	-----Page 3
7. 510(k) Statement	-----Page 4
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14. Truthful and Accuracy Statement	-----Page 40
15. Exhibit A	-----A1-A4
16. Exhibit B	-----B1

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/cdrh/mdufma> for additional information)

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

This application is the first PMA submitted by a qualified small business, including any affiliates

The sole purpose of the application is to support conditions of use for a pediatric population

This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

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)

17-Jan-2013

REP'D \$■■■■■■■■■■

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 FOOD AND DRUG ADMINISTRATION
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
 OMB No. 0910-0120
 Expiration Date: December 31, 2013
 See OMB Statement on page 5.

Date of Submission 1-17-2013	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
---------------------------------	--------------------------------------	---

SECTION A TYPE OF SUBMISSION

PMA <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	PMA & HDE Supplement <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	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <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	Meeting <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):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <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 Dana Products, Inc.	Establishment Registration Number (if known) 3007412809		
Division Name (if applicable)	Phone Number (including area code) 847-455-2881		
Street Address 7 Corey Drive	FAX Number (including area code) 847-455-2886		
City South Barrington	State / Province IL	ZIP/Postal Code 60010	Country USA
Contact Name Harry Bala			
Contact Title President		Contact E-mail Address bala@danaproducts.com	

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

Company / Institution Name			
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 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			
<input type="checkbox"/> Other Reason (<i>specify</i>):					

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					
<input type="checkbox"/> Other Reason (<i>specify</i>):					

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			
<input type="checkbox"/> Other Reason (<i>specify</i>):					

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	
1	JOJ	2		3	
4		5		6	
7		8		9	
				<input type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K103000	1 SteriTec Biological Test Pack with Instant Readout Integrator	1 SteriTec Products Manufacturing Company, Incorporated
2		2	2
3		3	3
4		4	4
5		5	5
6		6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

	Trade or Proprietary or Model Name for This Device	Model Number
1	Dana Reusable Test Pack	1
2		2
3		3
4		4
5		5

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

1	K092944	2	K102761	3	K110253	4	K103321	5	K120592	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 JOJ	C.F.R. Section (if applicable) 880.2800	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Sterilization Process Indicator		

Indications (from labeling)
 Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SGM Biotech's Self-Contained Biological Indicator Smart-Read EZTest - Steam along with or without SteriScan Integrators.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

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 Dana Products, Inc.		Establishment Registration Number 3007412809			
Division Name (if applicable)		Phone Number (including area code) 847-455-2881			
Street Address 11457 Melrose Street		FAX Number (including area code) 847-455-2886			
City Franklin Park		State / Province IL	ZIP Code 60131	Country USA	
Contact Name Harry Bala		Contact Title President		Contact E-mail Address bala@danaproducts.com	

<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	ST79:2010 & A1:2010	ANSI/AAMI	Comprehensive guide to steam sterilization and sterility assurance in health care facilities	2010	01/01/2010
2	ST8:2008	ANSI/AAMI	Hospital steam sterilizers	2008	1/1/2008
3					
4					
5					
6					
7					

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

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing 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:

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

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.

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

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ANSI/AAMI ST8:2008: Hospital steam sterilizers

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-264

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

Is a summary report ⁴ 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?

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

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

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 ⁶ 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 Chemical Indicators

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

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ 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>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ANSI/AAMI ST8:2008: Hospital steam sterilizers

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 5.5	SECTION TITLE BIOLOGICAL PERFORMANCE OF STERILIZERS	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	--	--

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
----------------	---------------	---

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
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

[♦] Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

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

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.

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

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ANSI/AAMI ST79:2010 & A1:2010: Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-312

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

Is a summary report ⁴ 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?

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

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

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 ⁶ 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 Chemical Indicators

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

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ 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>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ANSI/AAMI ST79:2010 & A1:2010: Comprehensive guide to steam sterilization and sterility assurance in health care facilities

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 10.7	SECTION TITLE ROUTINE STERILIZER EFFICACY MONITORING	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
------------------------	---	--

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
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

[♦] Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

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

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.

DANA PRODUCTS, INC.
7 COREY DRIVE
SOUTH BARRINGTON, IL 60010
TEL. 847-455-2881 FAX. 847-455-2886

January 17, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center –W066-0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Sir or Madam:

510K Notification (21CFR 807.90 (e))
Traditional Submission
Dana Reusable Test Pack for Steam Sterilization

I request marketing clearance for our reusable challenge test pack for Biological Indicators and Integrators to be used in steam sterilization. The information on the test pack is as follows:

Device Trade Name: Dana Reusable Test Pack
Device Common Name: Process Challenge Device
Device Classification Name: Indicator, Biological Sterilization Process
Product Code: FRC
Regulation Number: 880.2800
Review Panel: General Hospital
Device Class: 2

Propriety Name: Dana Reusable Test Pack

Establishment Registration Number: 3007412809

Owner Operator Number: 9054259

Performance Standard: ANSI/AAMI ST 79: 2010,
ANSI/AAMI ST 8: 2008

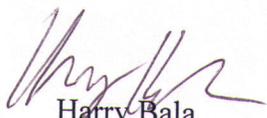
Predicate Device 510(k): SteriTec Biological Test Pack with Instant Readout Integrator
(K103000)

This submission is prepared in duplicate and it includes adequate information to show substantial equivalence to the predicate device. Our manufacturing facility is located at 11457 Melrose Street, Franklin Park, IL 60131. If you have any questions concerning this submission, please contact:

Harry Bala
Dana Products, Inc.
7 Corey Drive
South Barrington, IL 60010
Tel.: 847-455-2881, Fax: 847-455-2886
Email: bala@voyager.net

Dana Products, Inc. considers this submission confidential and requests that the FDA consider it as such.

Sincerely yours,


Harry Bala
President

Indications for Use

510(k) Number (if known):
Device Name: Dana Reusable Test Pack

Indications For Use:

Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SGM Biotech's Self-Contained Biological Indicator Smart-Read EZTest - Steam along with or without SteriScan Integrators.

Prescription Use _____ AND/OR
(Part 21 CFR 801 Subpart D)

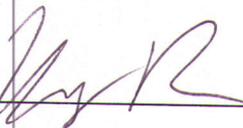
Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510k STATEMENT
(As required by 21 CFR 807.93)

I certify that, in my capacity as the President of Dana Products, Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Signature: 

Harry Bala

Date: 1/17/13

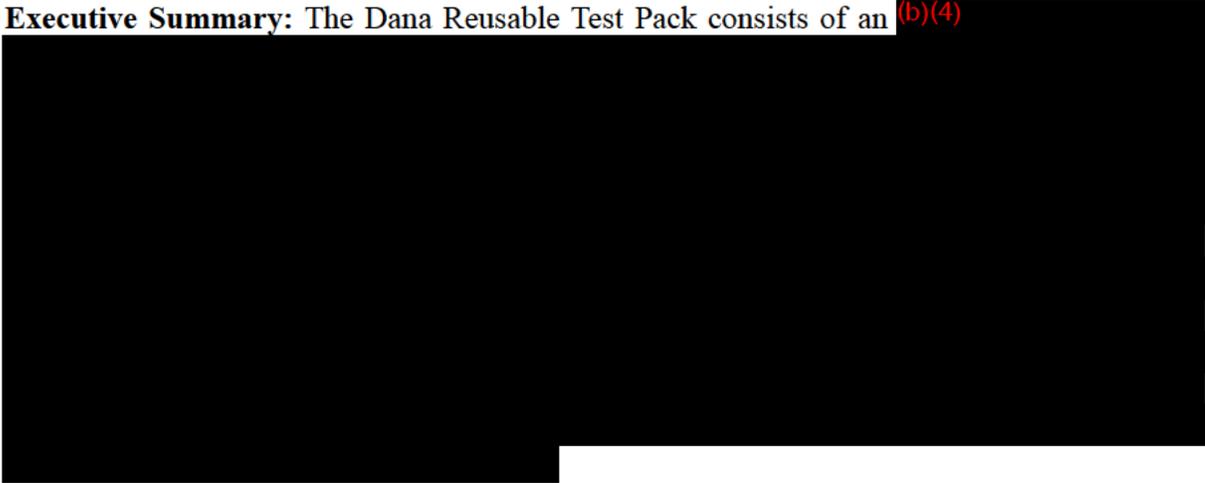
510k Number: _____

DECLARATION OF CONFORMITY / EXECUTIVE SUMMARY

Declaration of conformity: The Dana Reusable Test Pack, when used with SGM's Smart-Read EZTest BI ("Smart-Read BI"), conforms to the Standard set for a BI challenge test pack using (b)(4)



Executive Summary: The Dana Reusable Test Pack consists of an (b)(4)



DEVICE DESCRIPTION

Dana Reusable Test Pack Description: In this submission, we are seeking clearance to market the Dana Reusable Test Pack for use with the Smart-Read BI along with or without a SteriScan integrator. We have previously obtained clearance to market the Dana Reusable Test Pack for use with 3M’s 1292 Rapid Readout Biological Indicator along with or without a SteriScan integrator (K092944). The Dana Reusable Test Pack that was tested with the Smart-Read BI for purposes of this submission is identical in material, design and construction to the Dana Reusable Test Pack that was cleared previously under K092944, except in this case a Smart-Read BI is placed into the Dana Reusable Test Pack instead of a 3M 1292 BI. The Dana Reusable Test Pack consists of an aluminum tube (Ex A –Photo 1). One end of the tube has internal thread to receive a removable aluminum plug (Ex A – Photo 2). Between knurled aluminum disc and aluminum threaded plug is sandwiched a Teflon disc (Ex A – Photo 3). All three are bolted together. The (b)(4)

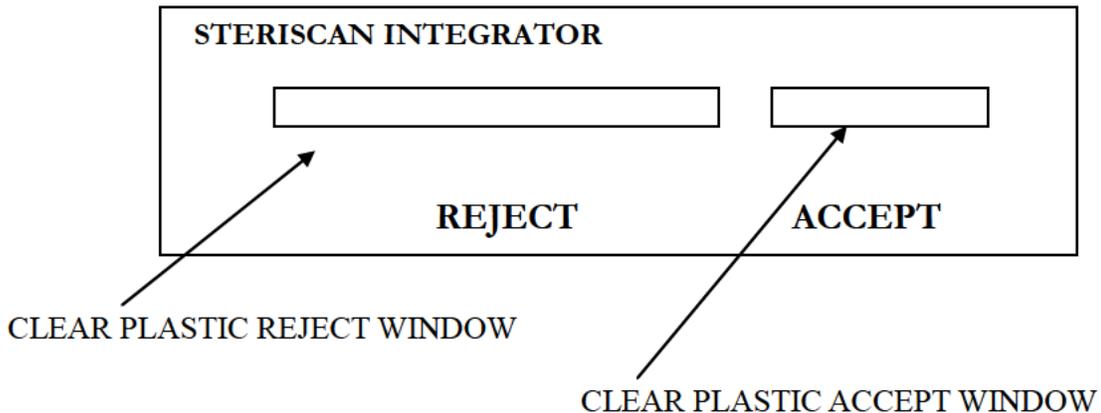
This ensures that this end of the device can be totally sealed. The bore at the other end of the tube is machined so that the aluminum cap (Ex A – Photo 4) can be permanently press fitted into it. The cap has a very shallow spiral with a radial hole at one end to facilitate steam entry. The spiral extends all the way to the other end of the cap. The radial hole and the spiral provide the torturous path challenge for air removal and steam penetration. A Teflon disc (Ex A – Photo 5 & 6) is bolted to the end of the press cap. The Teflon disc acts as an insulator preventing any heat transfer to the interior of the assembly. (b)(4)

The assembly is shown in Ex A – Photo 7.

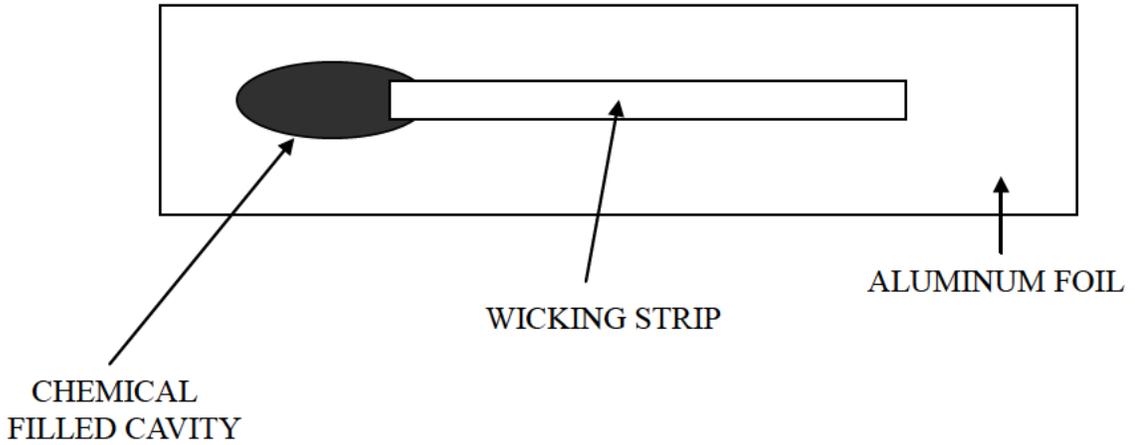
SteriScan Integrator Description:

The SteriScan Integrator that was used in testing for this submission is identical in material, design and construction to the SteriScan Integrator cleared under K012195. The SteriScan Integrator that was used in testing for this submission is also identical to the SteriScan Integrator used in testing of the Dana Reusable Test Pack for use with 3M’s 1292 Rapid Readout BI, along with or without a SteriScan Integrator, that was cleared under K092944.

DEVICE TOP VIEW



DEVICE WITHOUT TOP COVER

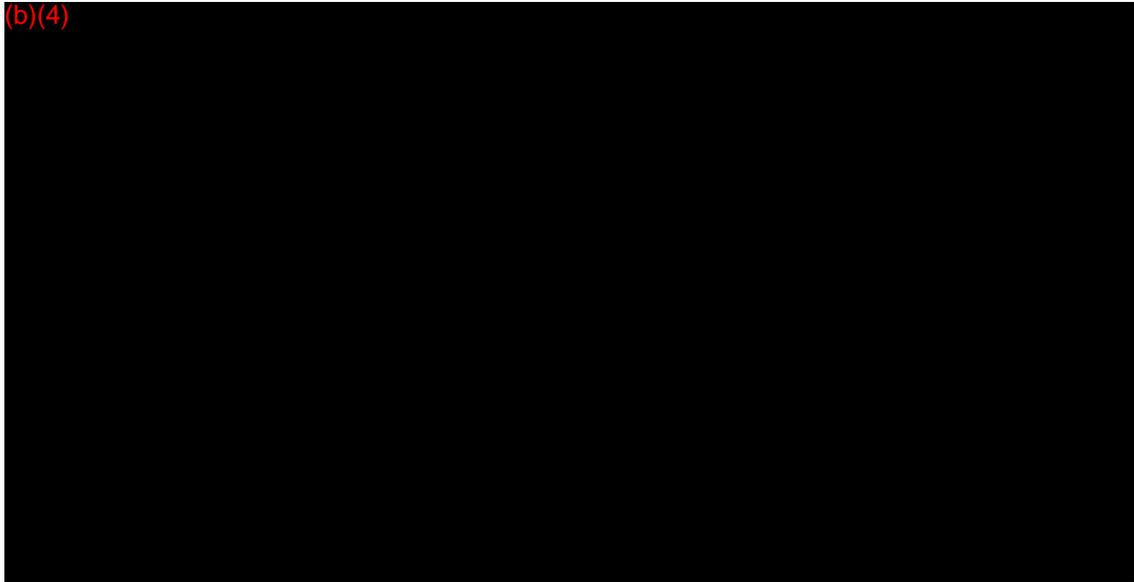


The SteriScan Integrator (b)(4)
The aluminum foil is coated with (b)(4). Aluminum foil has
an (b)(4)

Exhibit B shows the fully dimensioned drawing of the finished indicator. The following table shows dimension and tolerance of individual components:

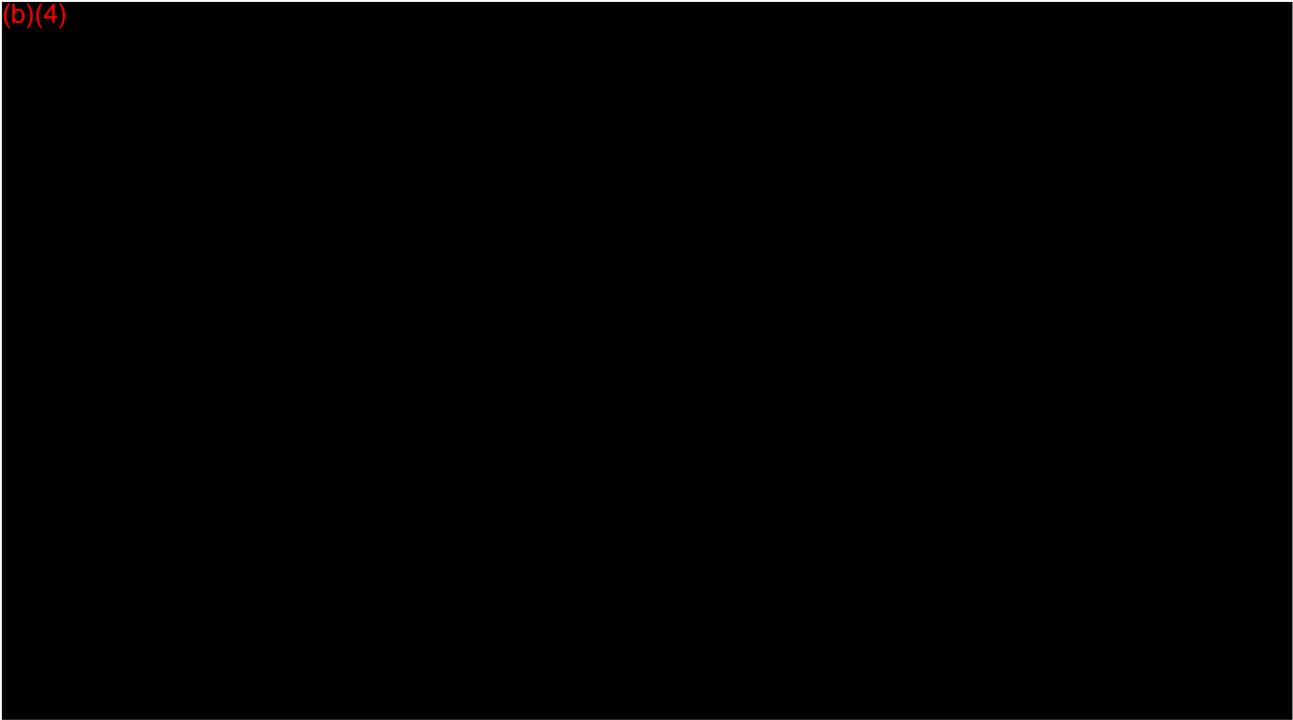
Material	Dimension	Tolerance
(b)(4)		

(b)(4)



Functionality of Dana Reusable Test Pack with the Smart-Read BI and SteriScan Integrator:

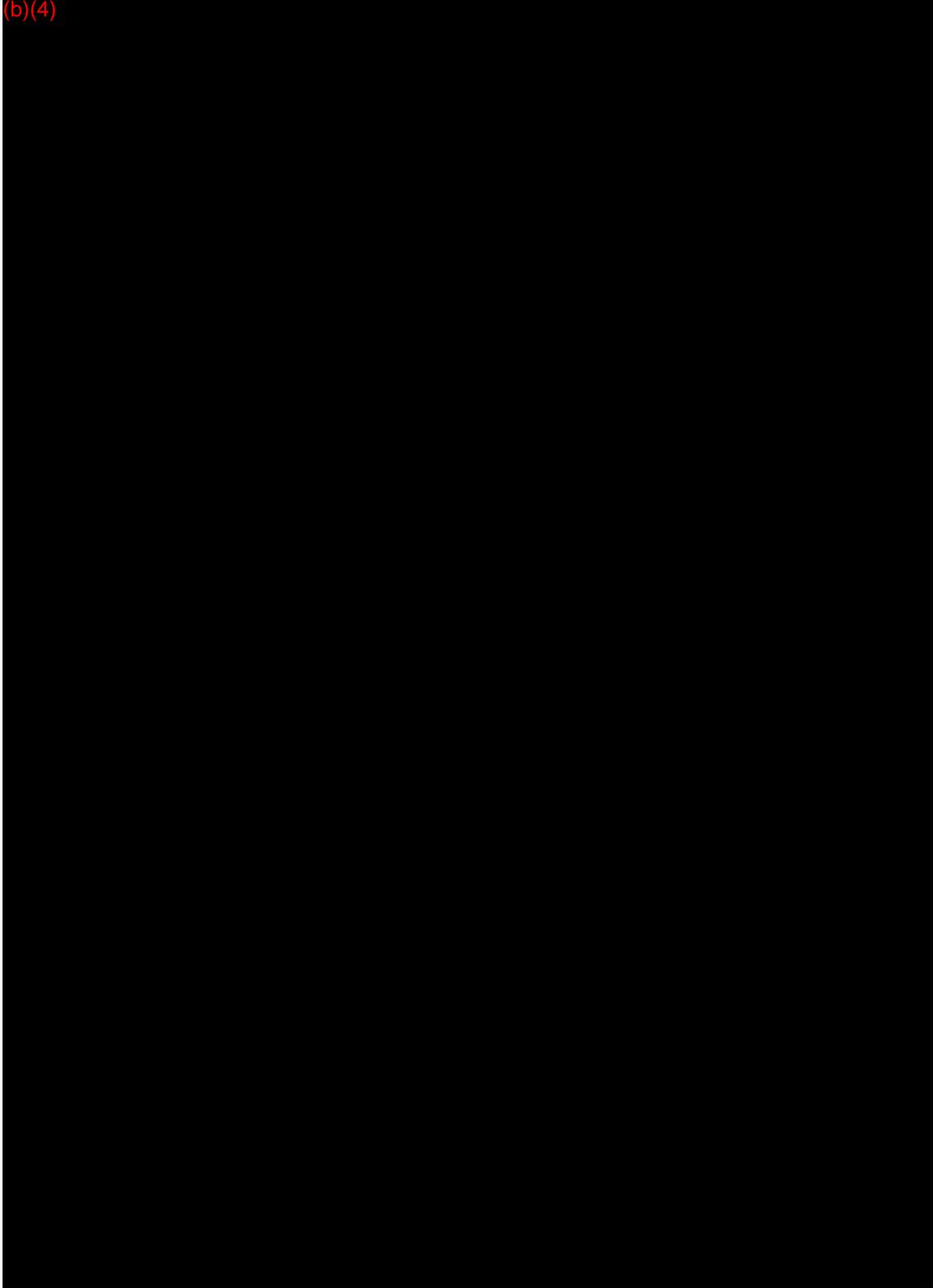
(b)(4)



PERFORMANCE TESTING

Information on items used in this study

(b)(4)



Predicate device: SteriTec Test Pack with Smart-Read BI.

Objective: To show that the Dana Reusable Test Pack is more resistant in a 4 minute 270°F prevac cycle when compared to the SteriTec Test Pack. Both test packs use Smart Read BIs from the same lot.

Test Parameters:

(b)(4)

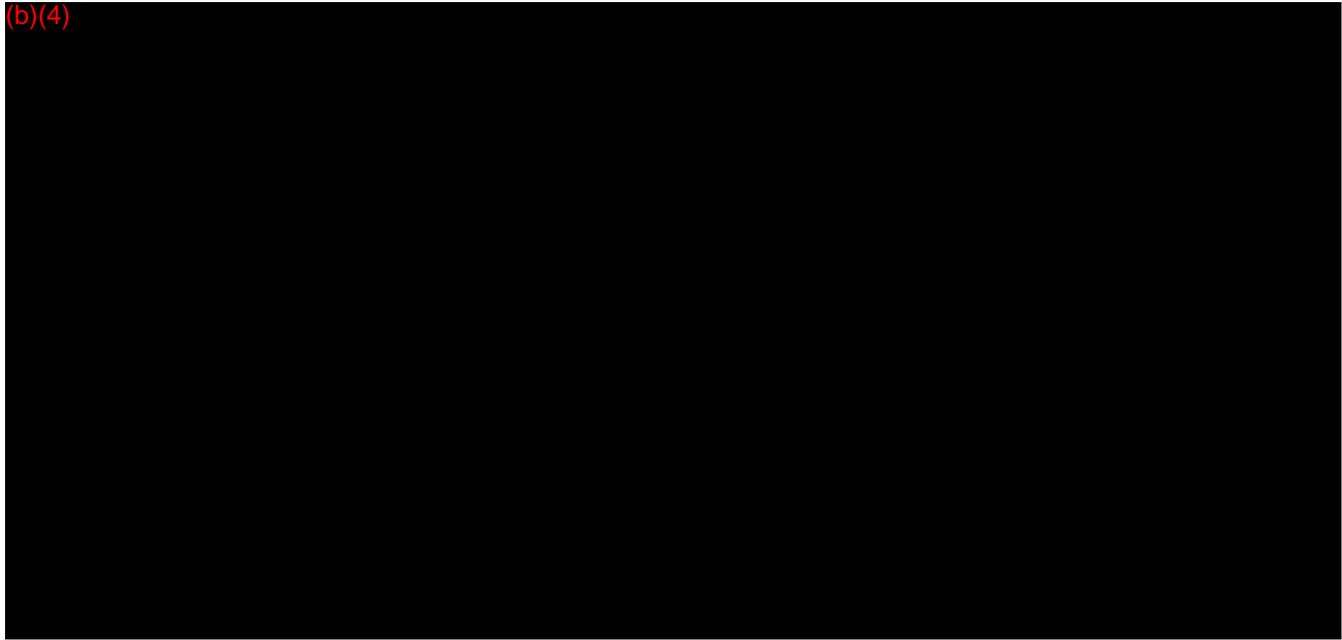


Statement of purpose/ Objective of studies

(b)(4)

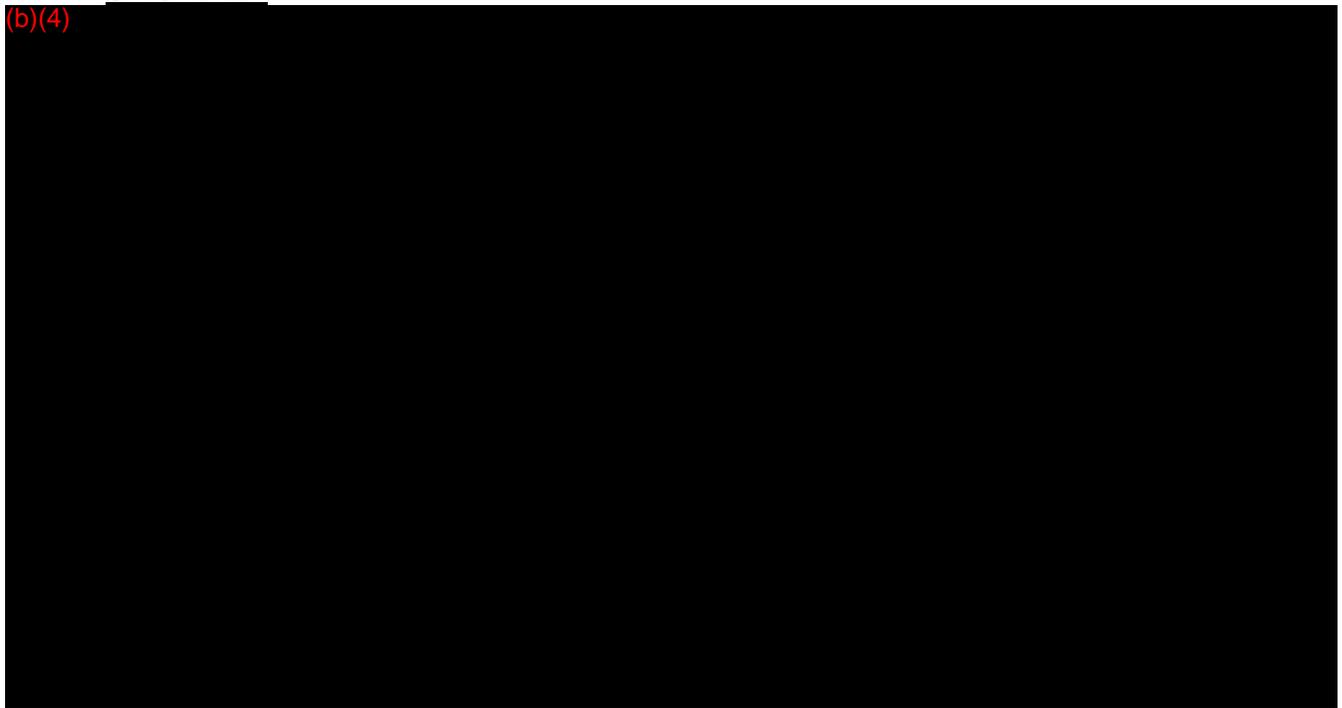


(b)(4)

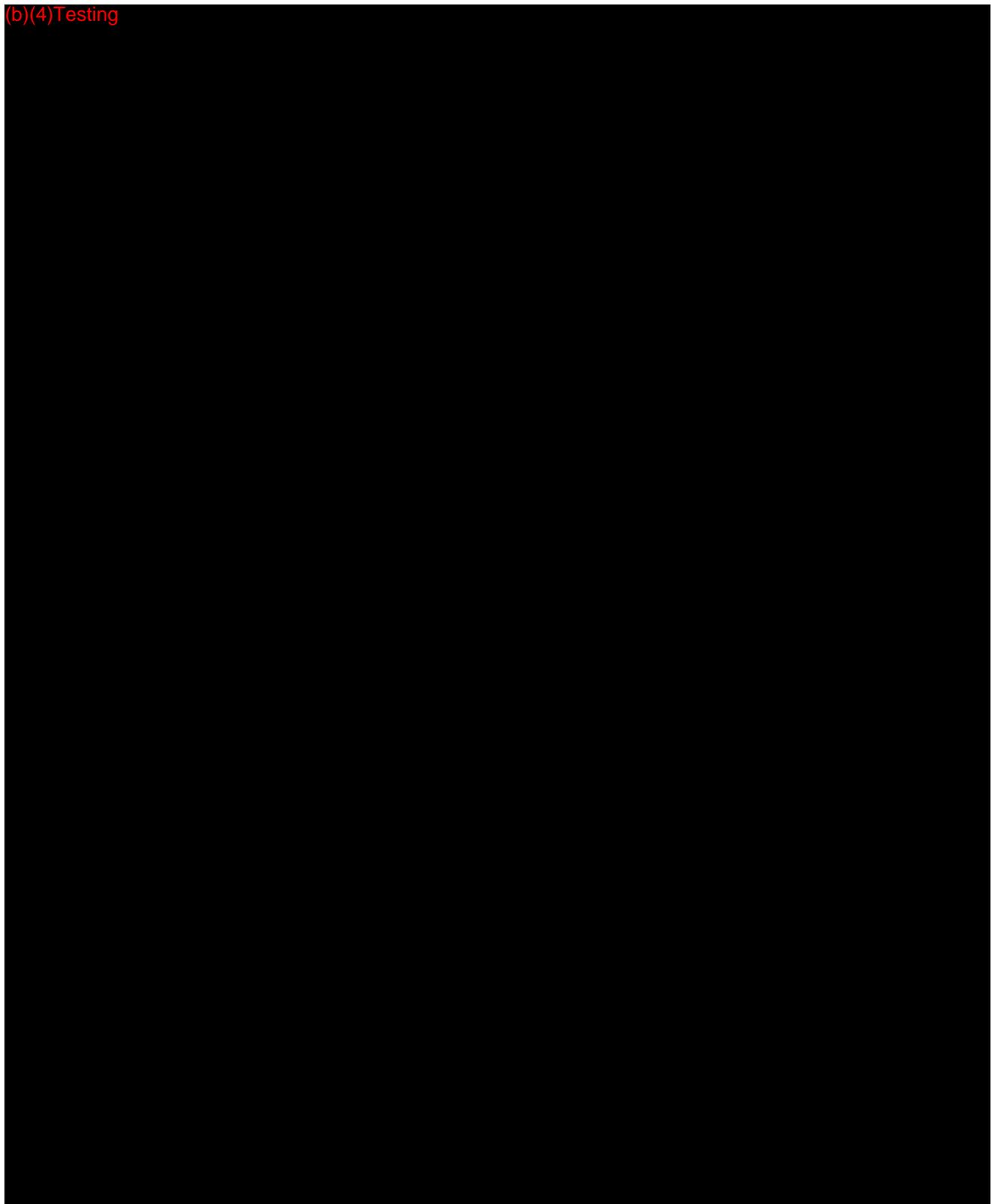


STUDY 1:

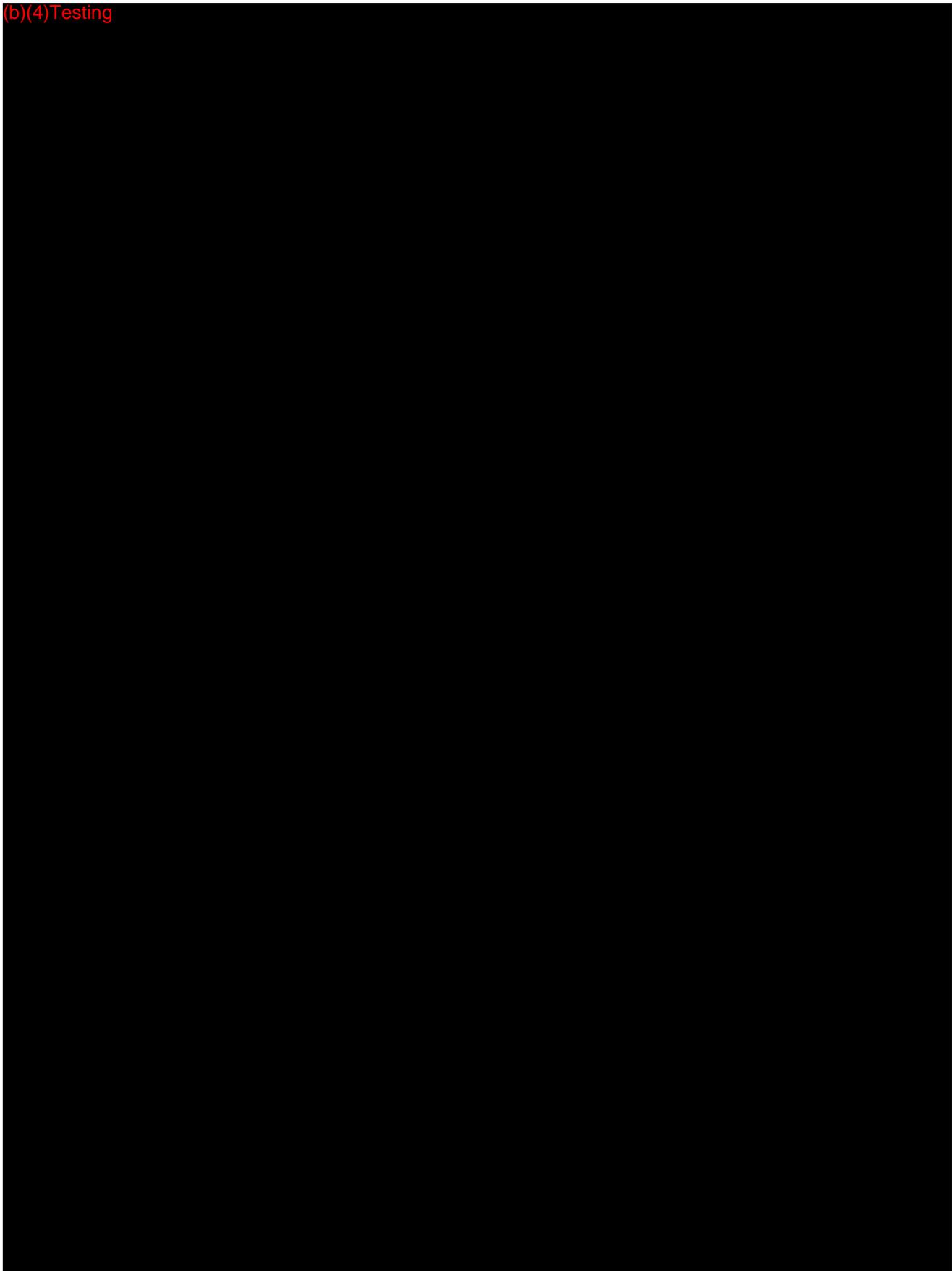
(b)(4)



(b)(4) Testing



(b)(4)Testing

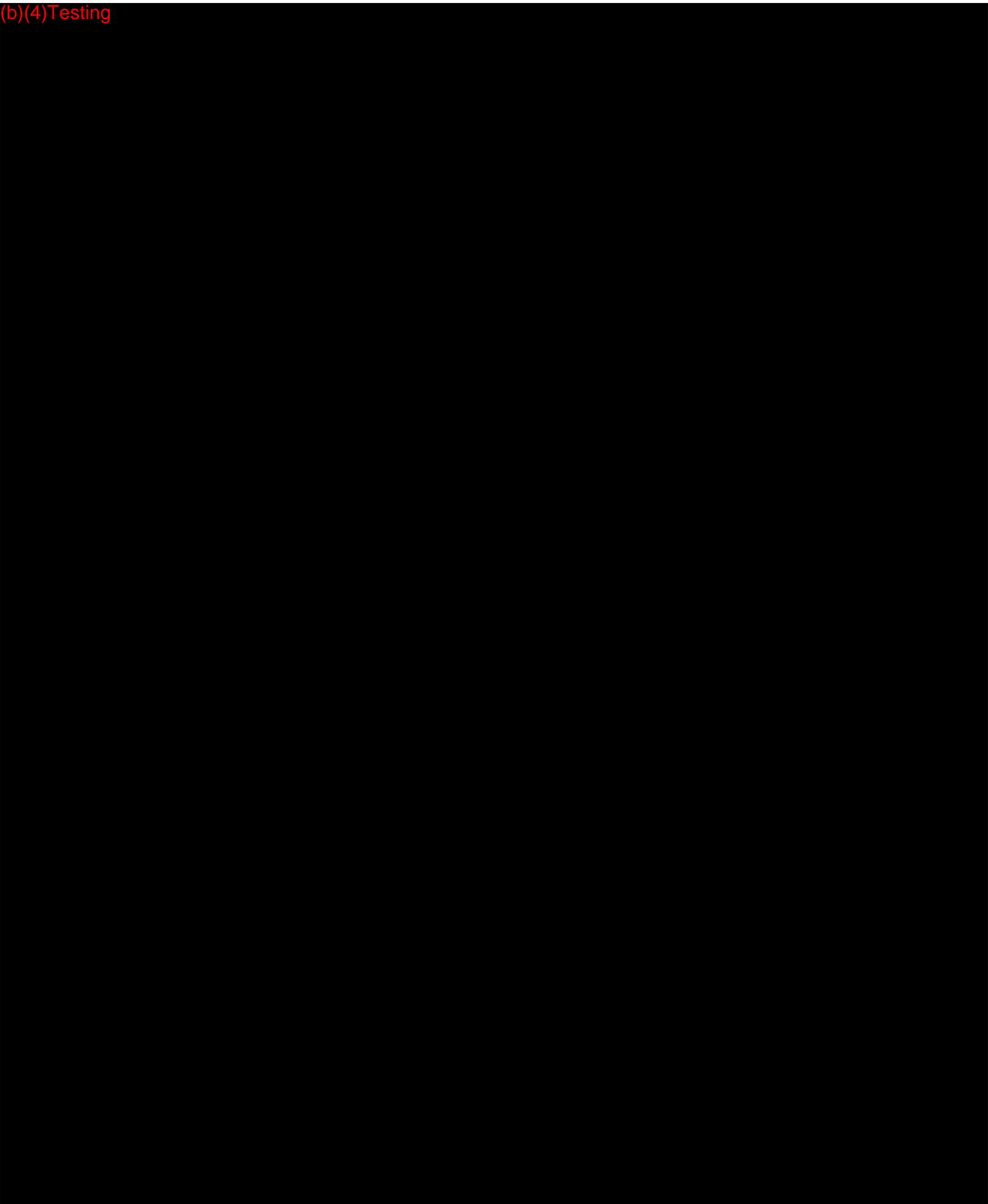


STUDY 2:

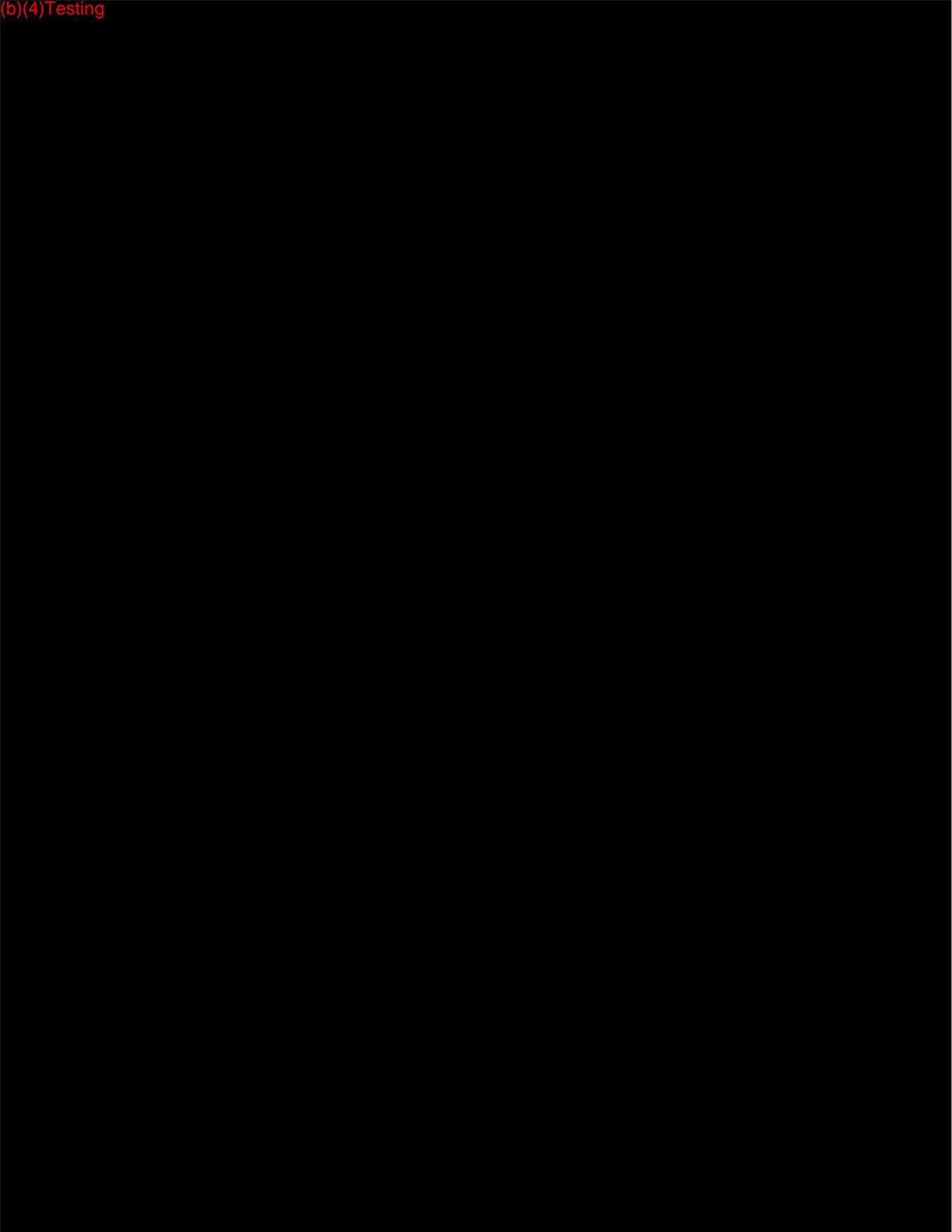
(b)(4) Testing



(b)(4)Testing



(b)(4) Testing

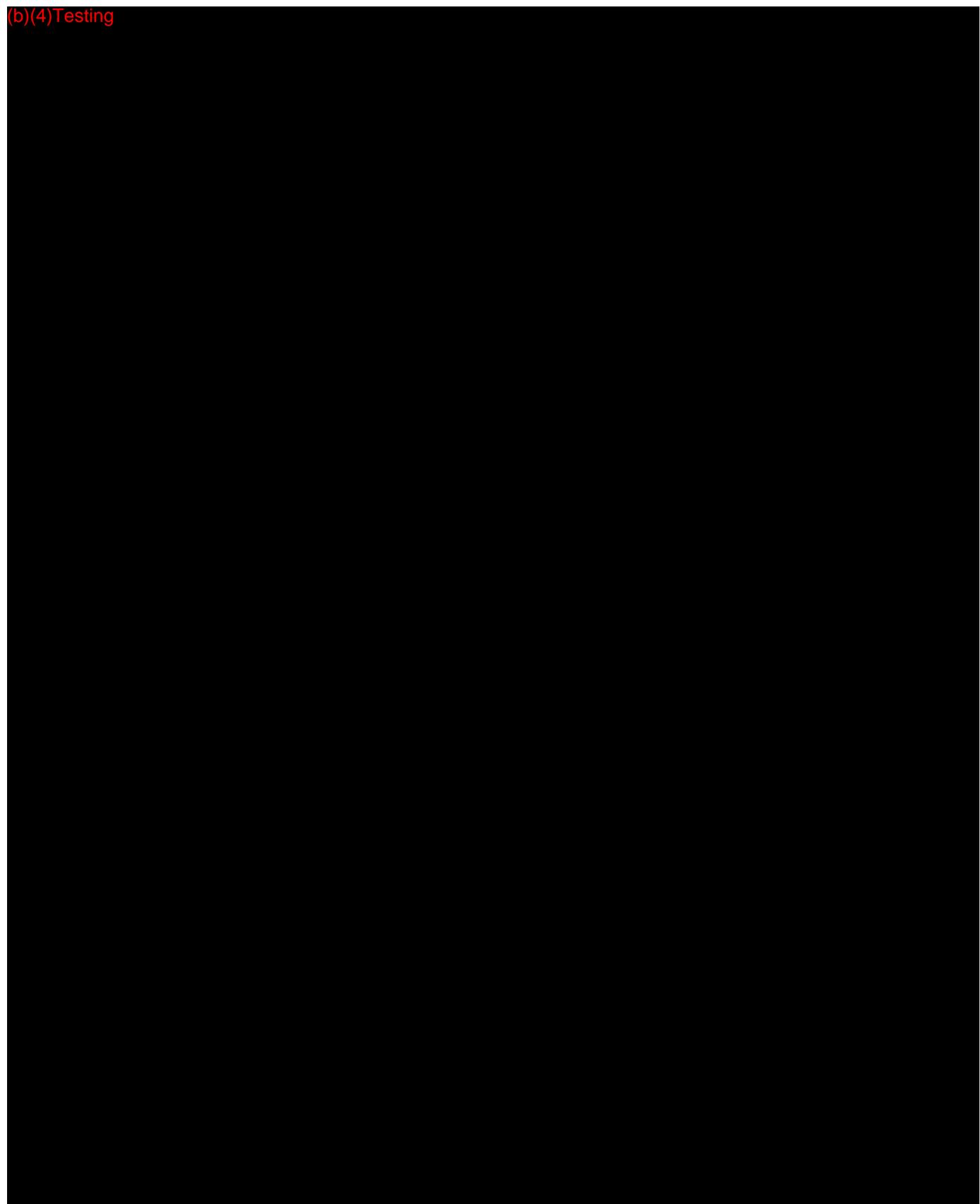


STUDY 3:

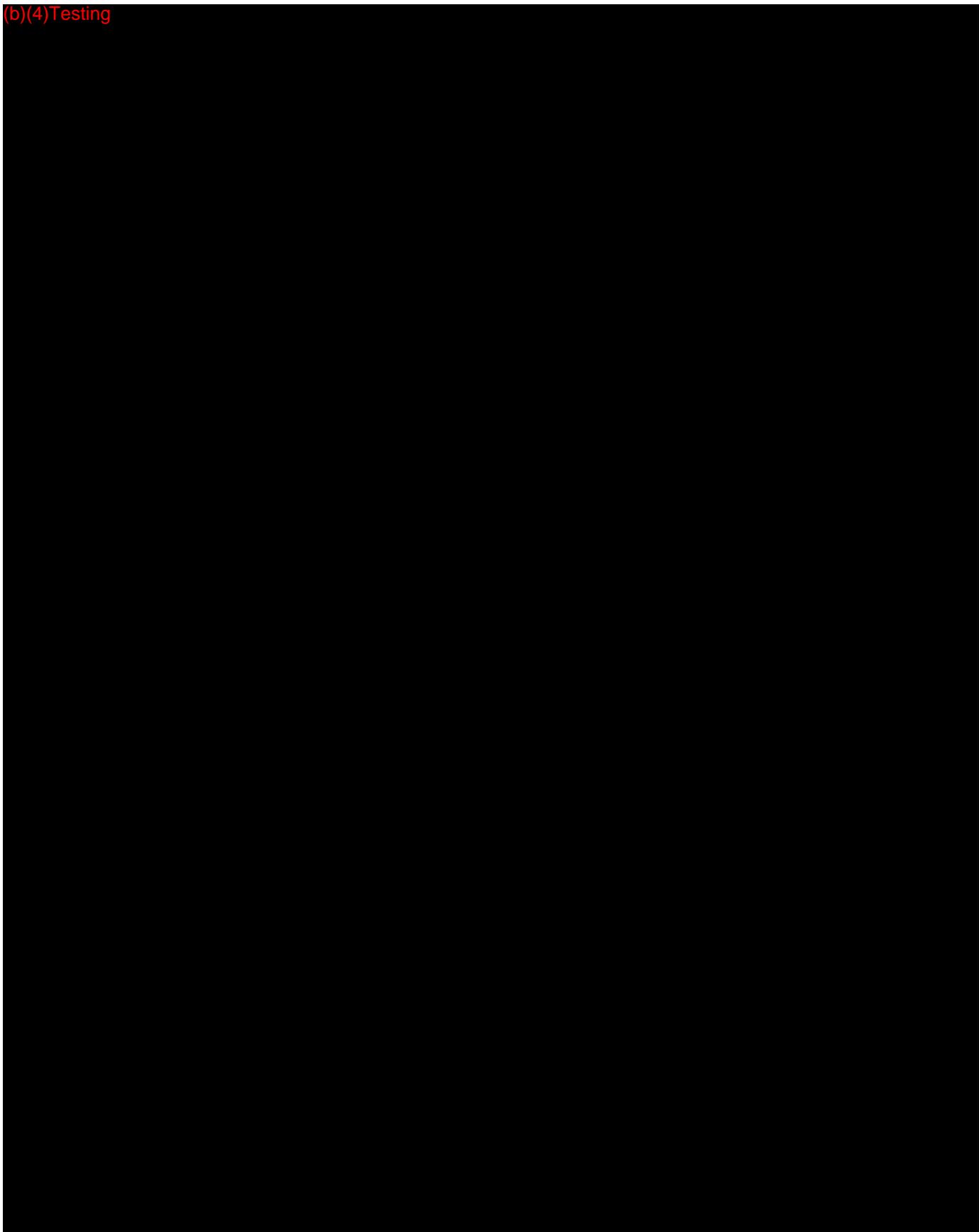
(b)(4) Testing



(b)(4)Testing



(b)(4) Testing

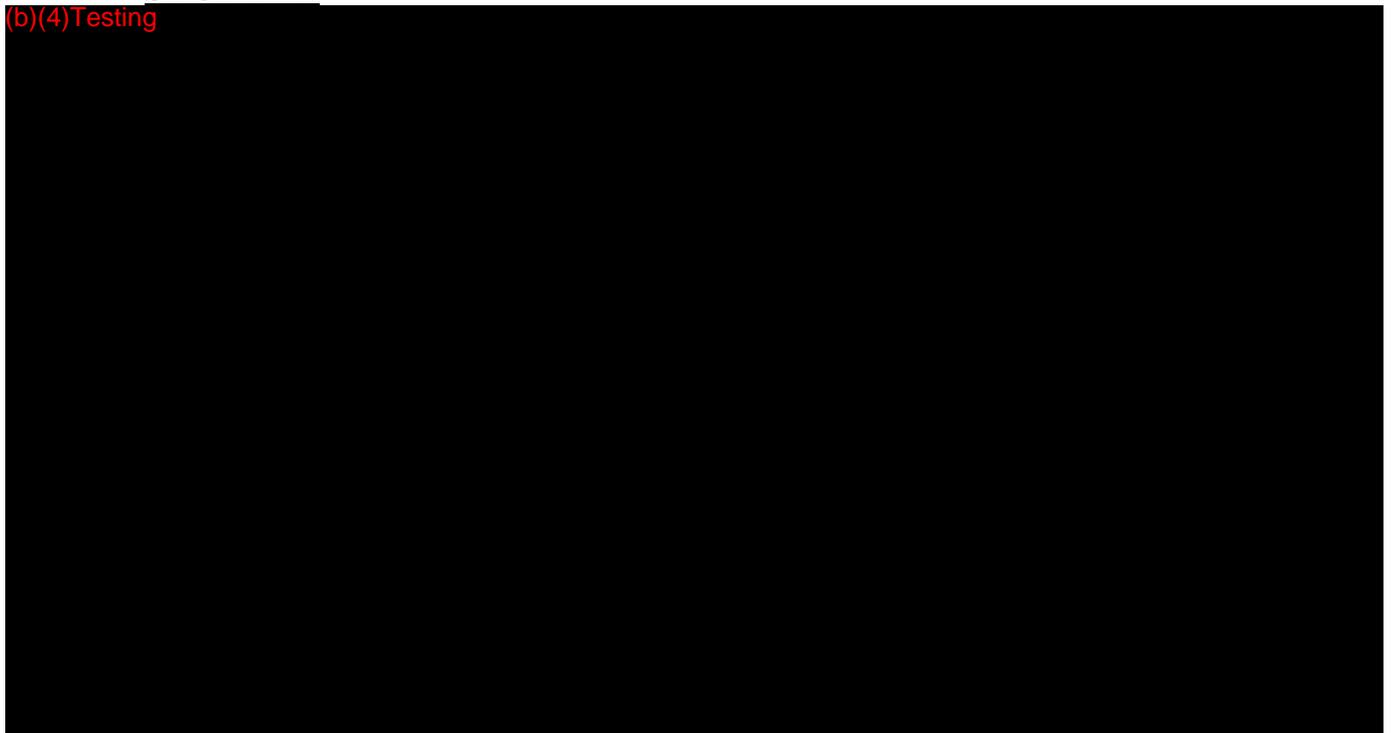


(b)(4) Testing



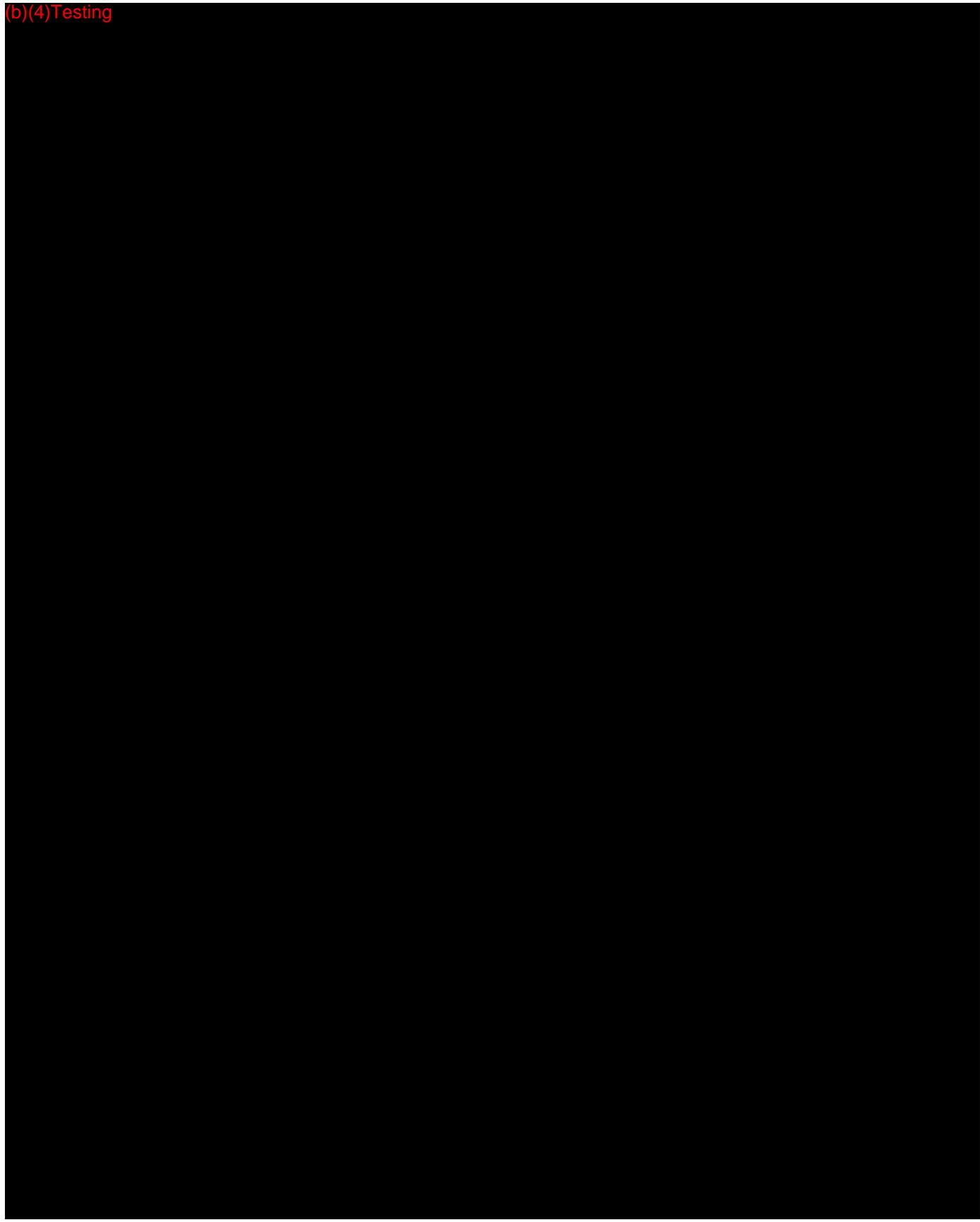
STUDY 4:

(b)(4) Testing



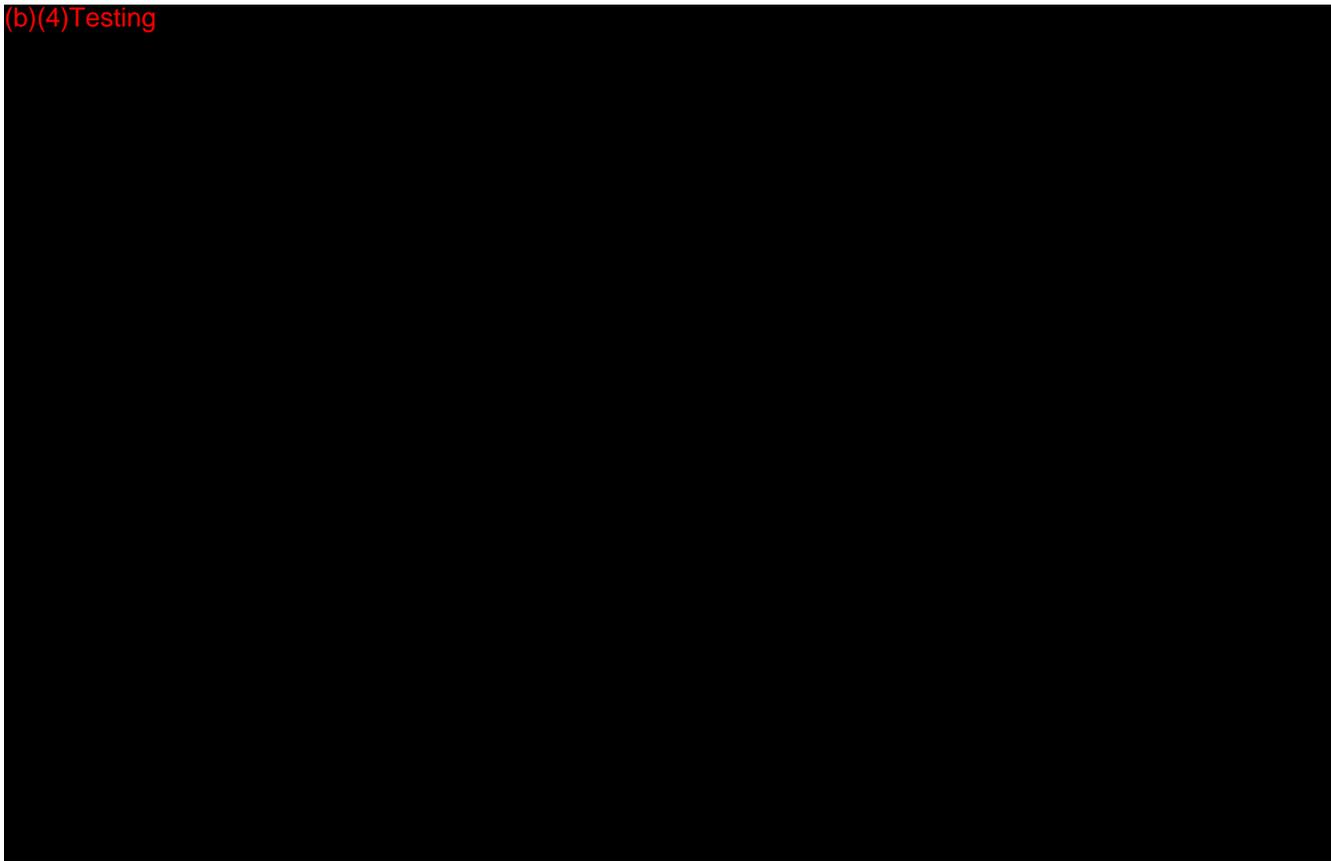
(b)(4) Testing

(b)(4)Testing

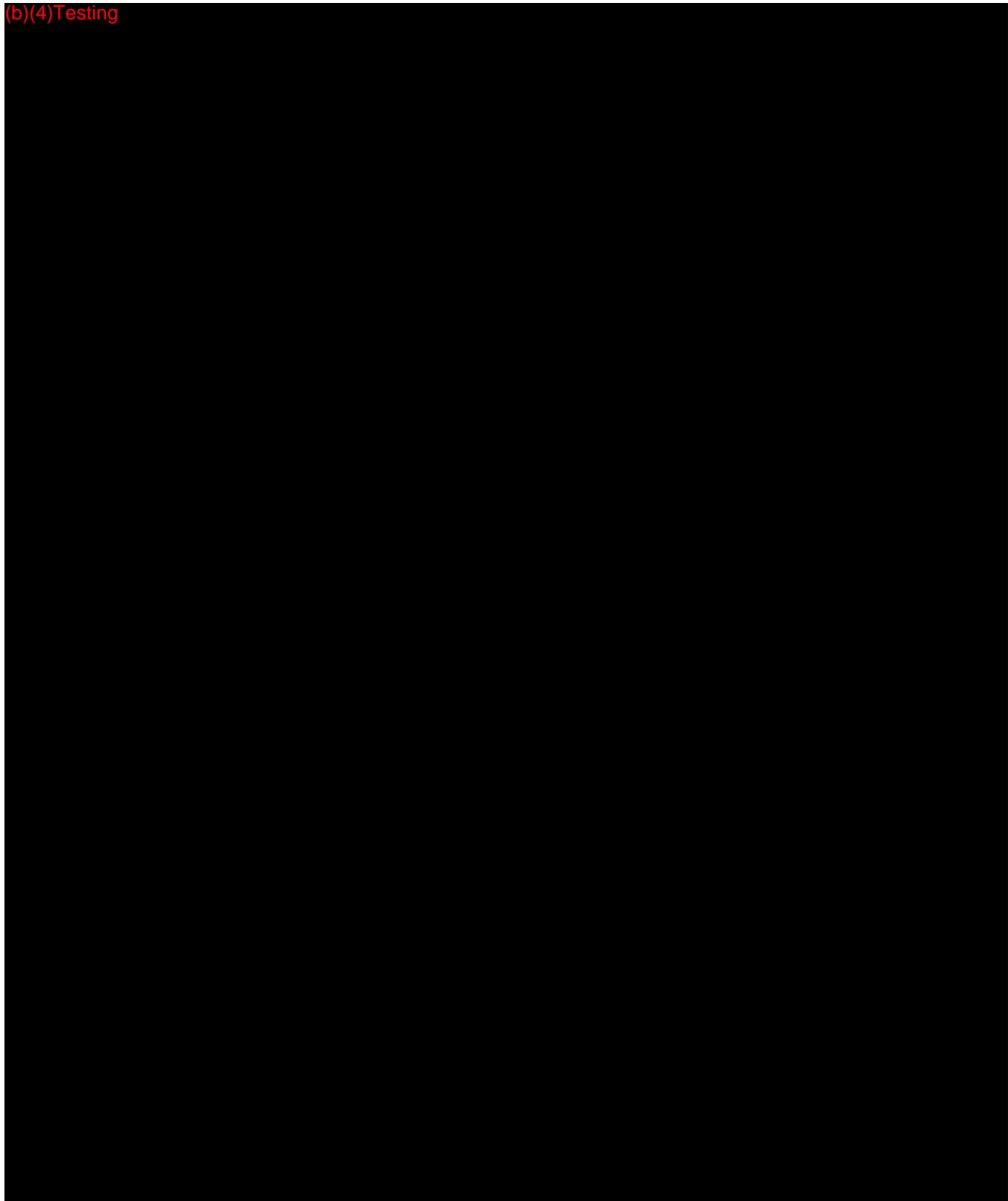


STUDY 5:

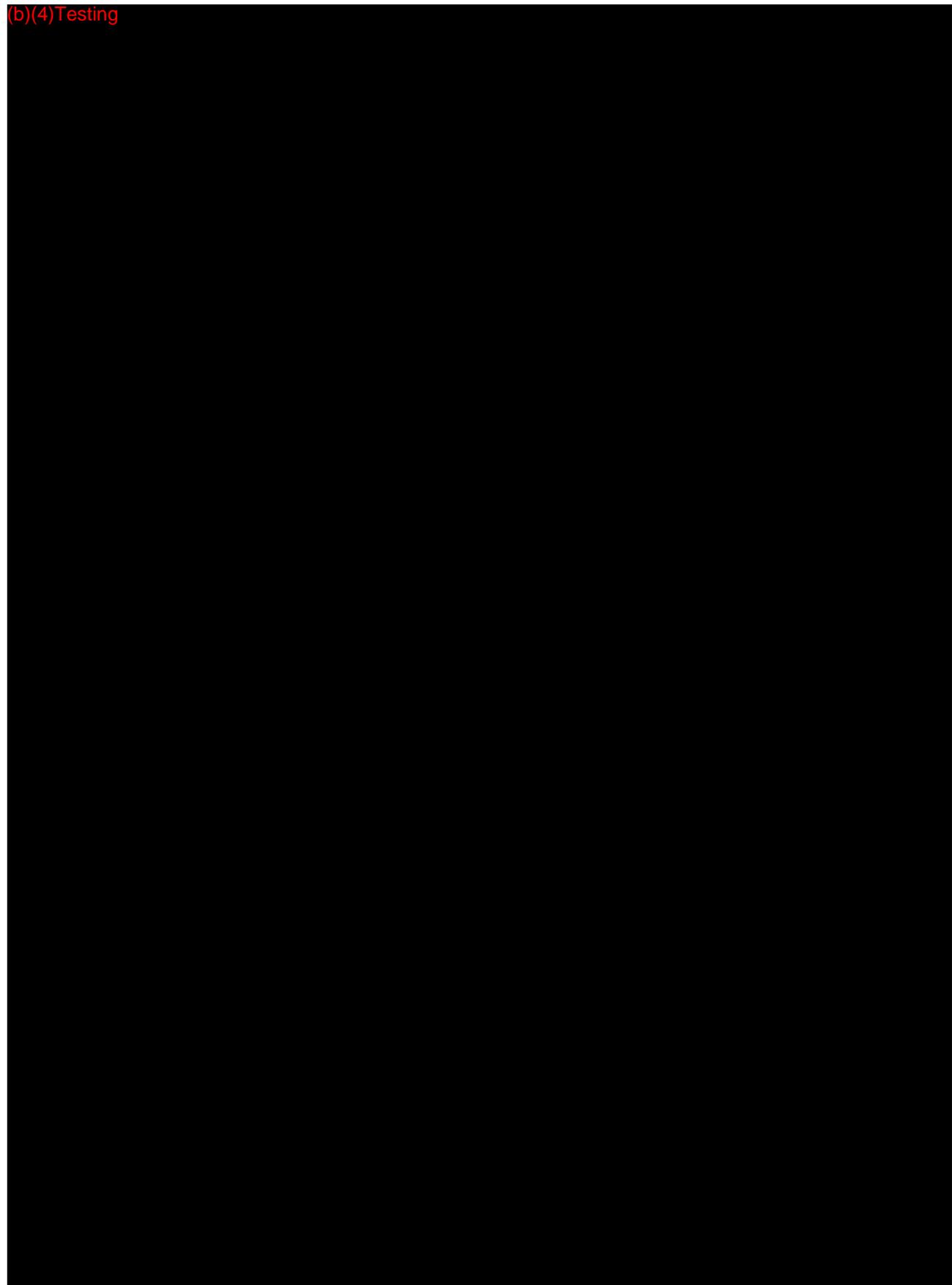
(b)(4) Testing



(b)(4) Testing



(b)(4) Testing

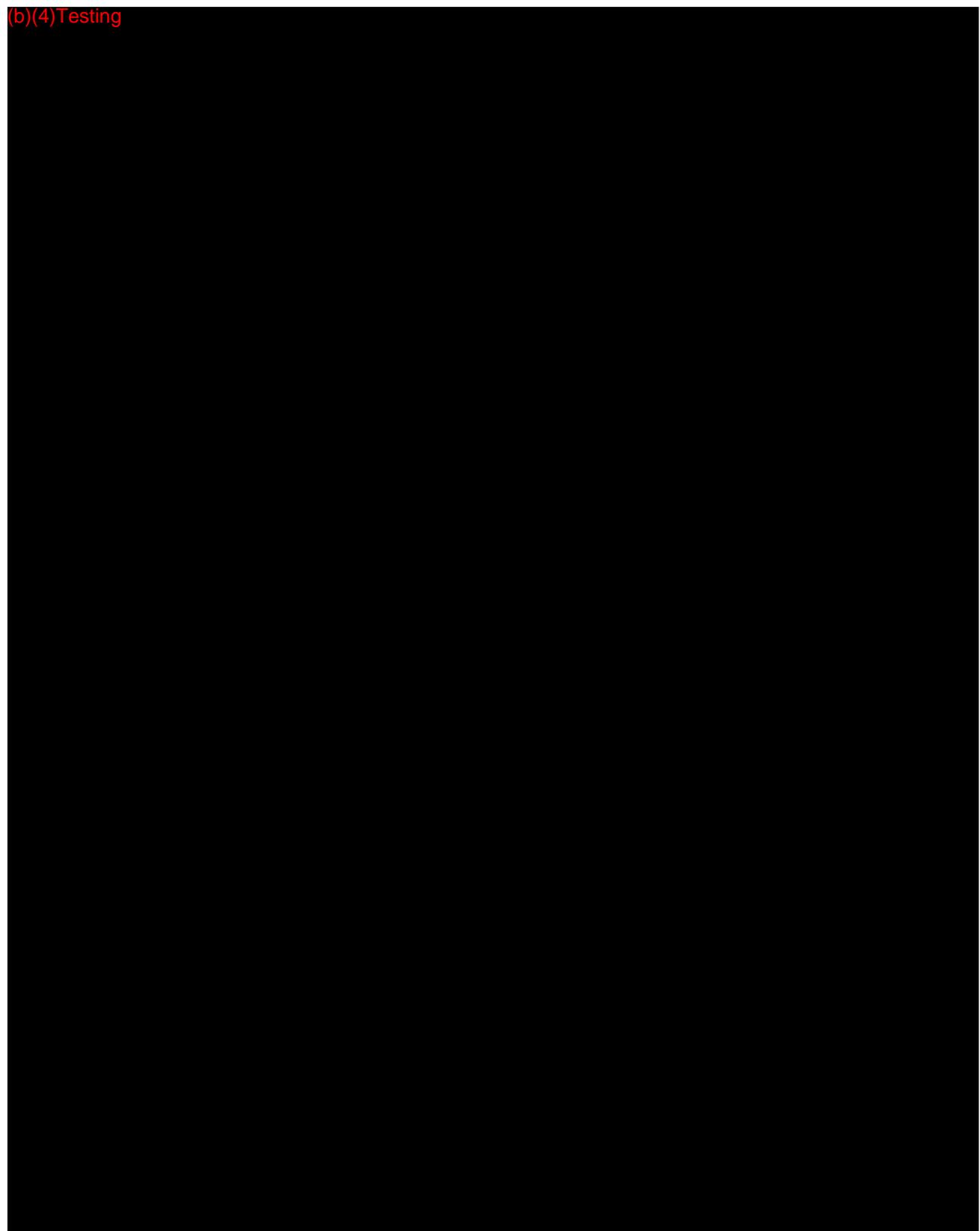


STUDY 6:

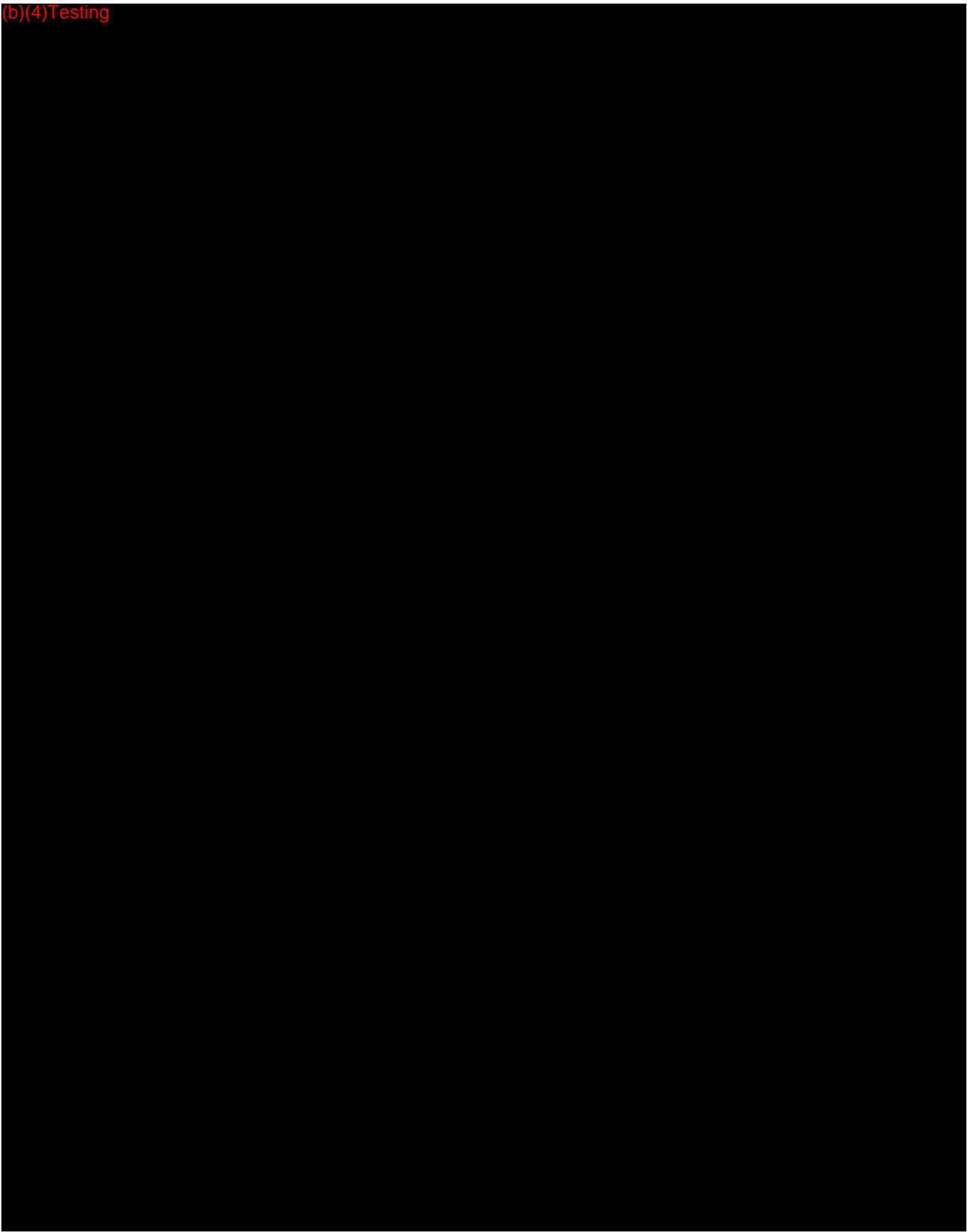
(b)(4) Testing



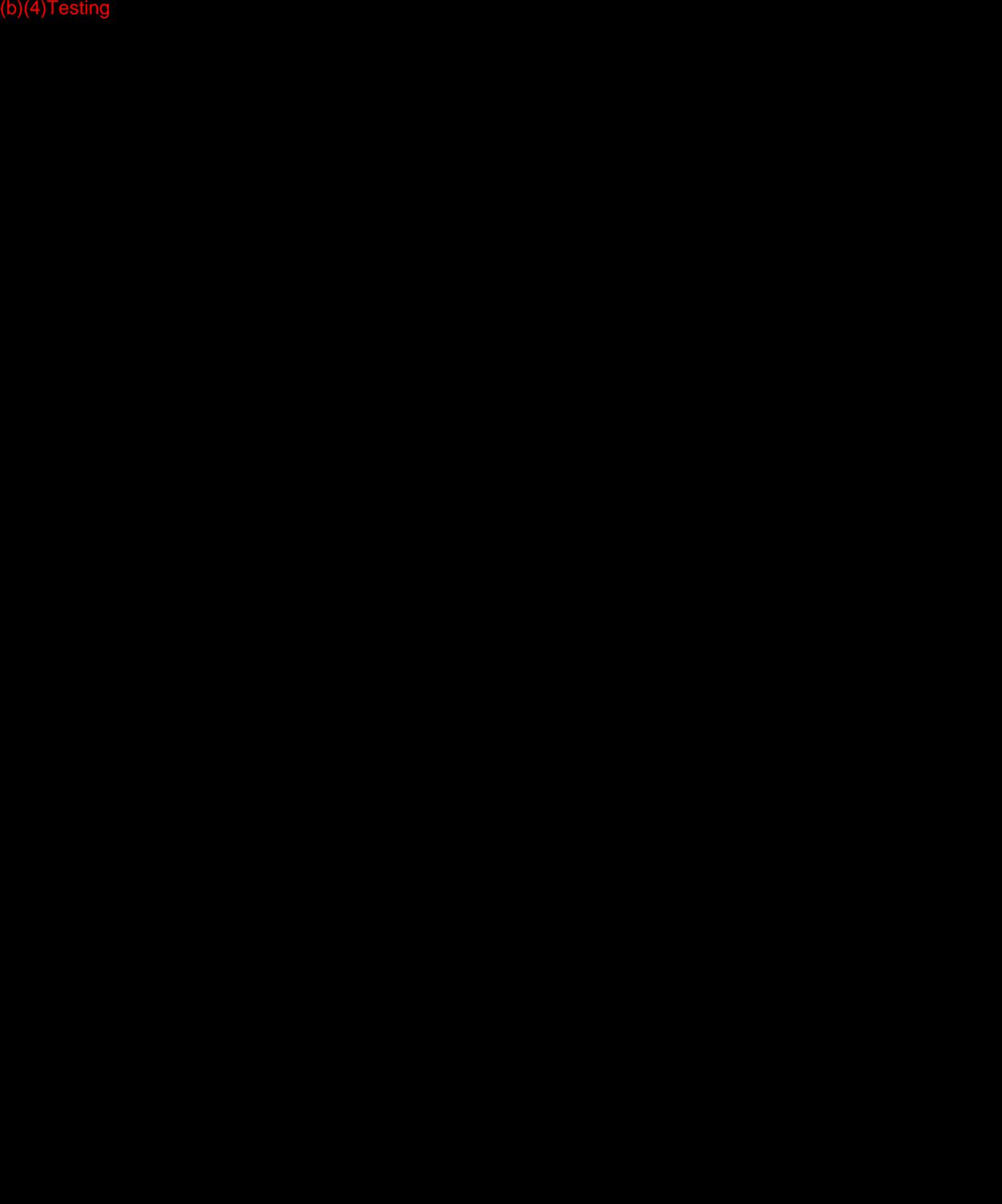
(b)(4) Testing



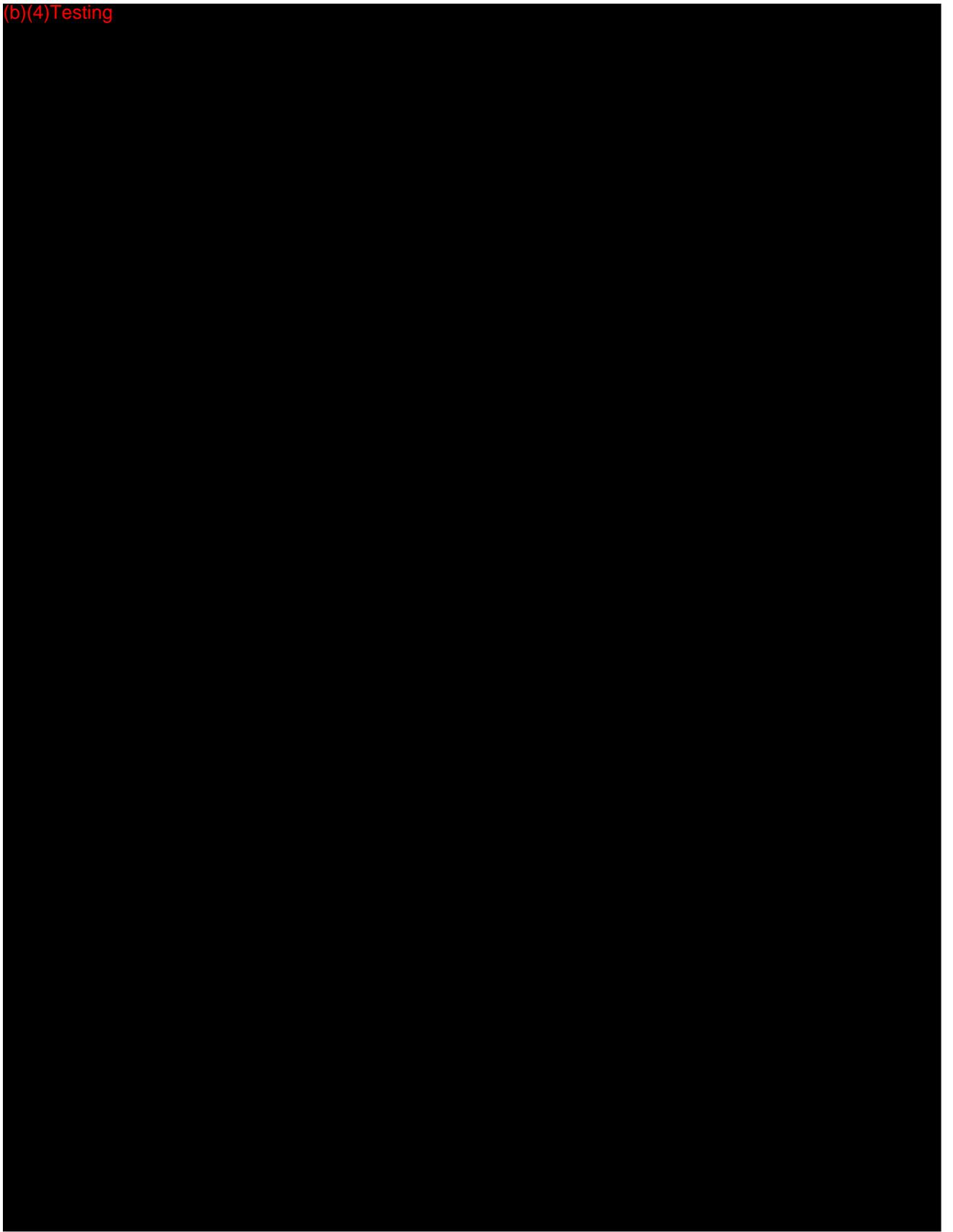
(b)(4) Testing



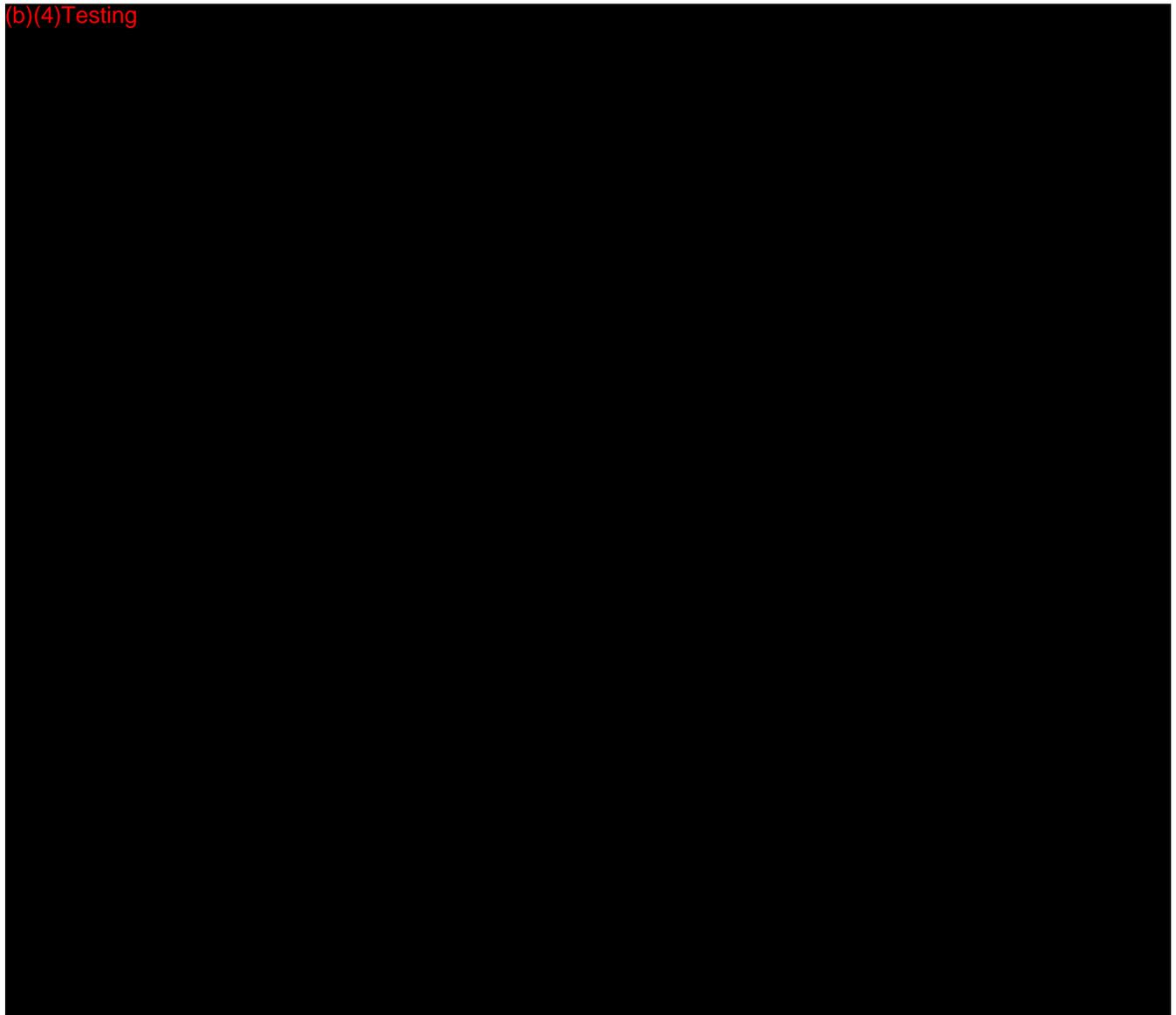
(b)(4) Testing



(b)(4) Testing

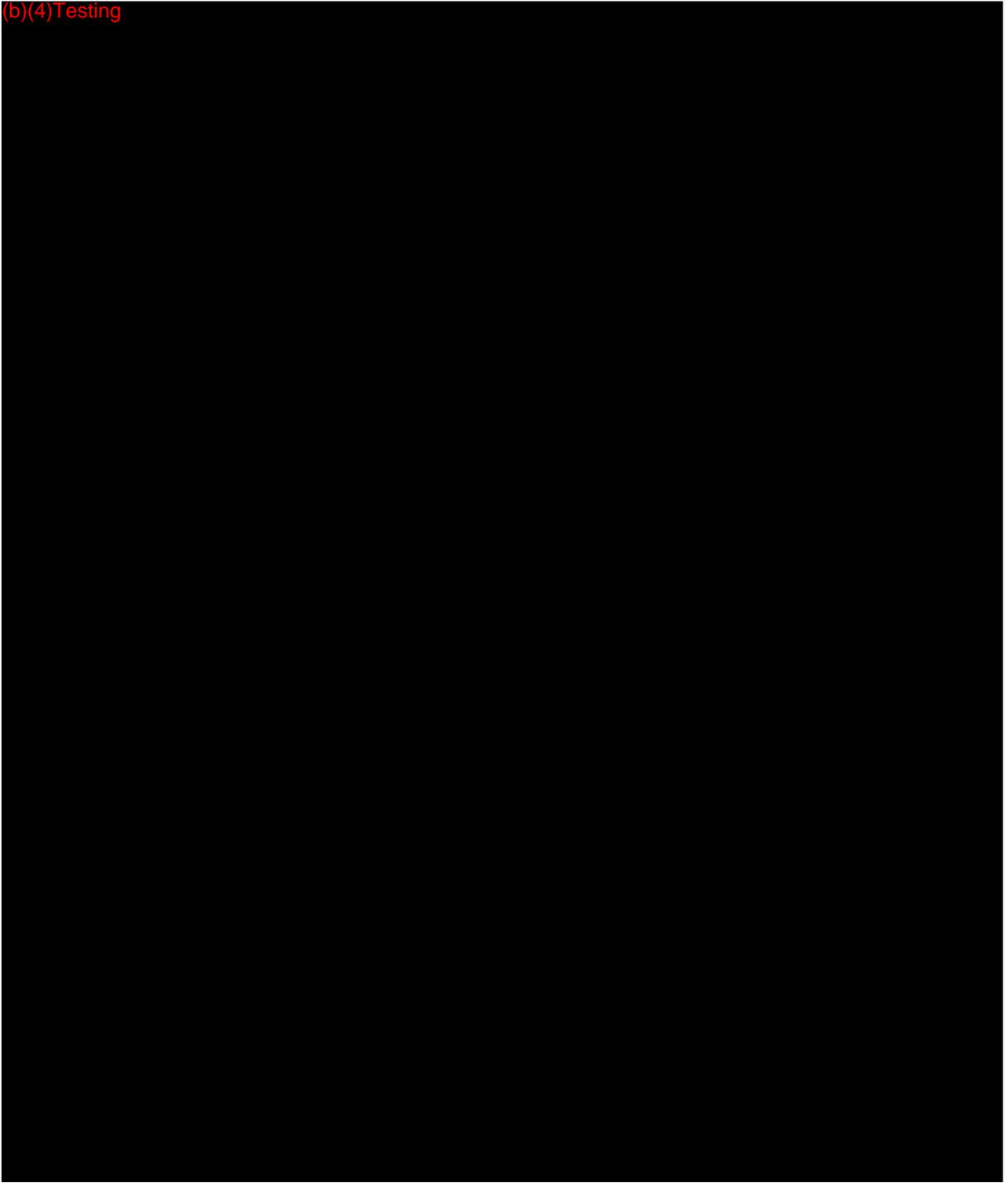


(b)(4)Testing

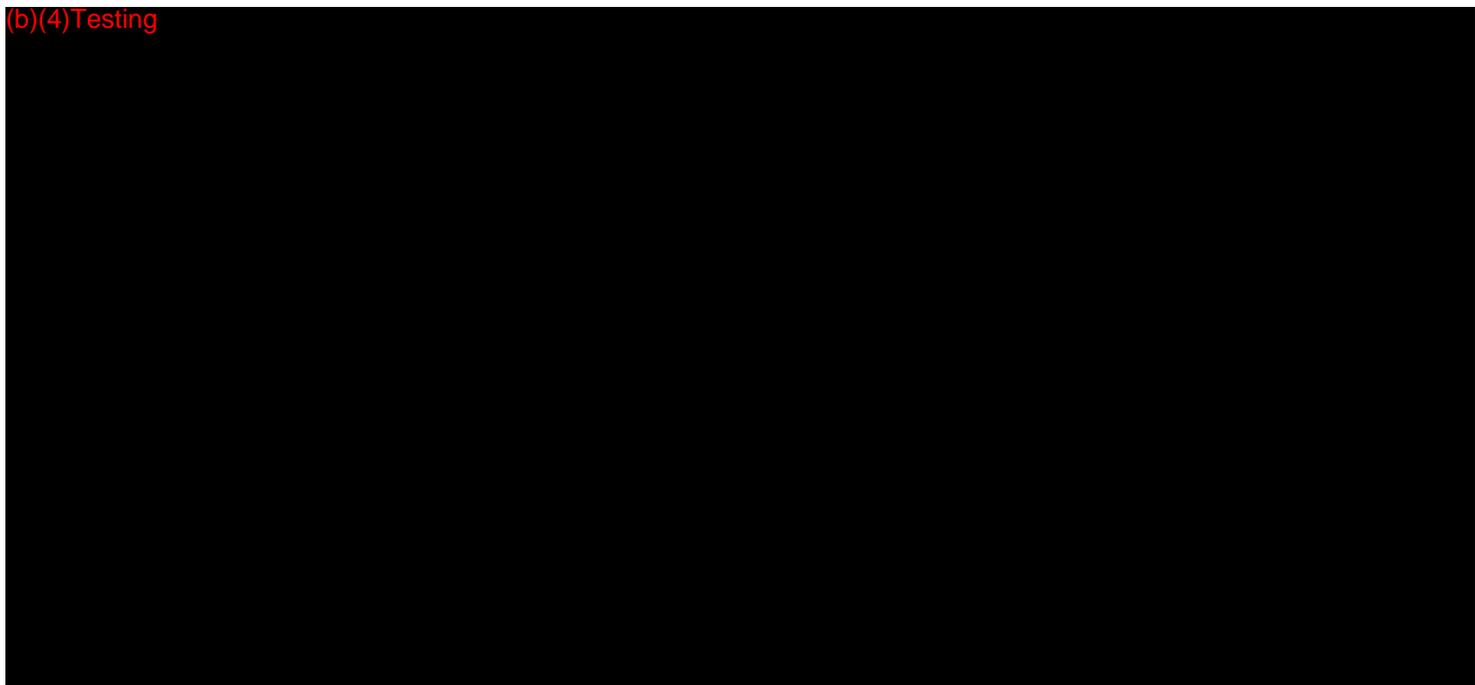


Performance of SteriScan Integrator

(b)(4) Testing



(b)(4) Testing



SHELF LIFE AND REUSE LIFE DISCUSSION

Shelf and Reuse Life: The individual parts and finished assemblies of the Dana Reusable Test Packs were manufactured one year ago. Initially, we will claim a shelf life of one year. Afterwards, we will test the retained samples every six months and adjust the expiration date accordingly.

We are claiming the Dana Reusable Test Pack as a reusable device which the manufacturer recommends replacing six months after first use; however, if there are any visible signs of wear and tear including, for example, discoloration, rusting, cracking, peeling or deformation or any other visible change, the Dana Reusable Test Pack should be discarded and replaced immediately.. We have enclosed test data to substantiate our claim. We will continue to test to validate the reuse life with the retained samples.

SUBSTANTIAL EQUIVALENCE DISCUSSION

Intended Use:

Predicate: For routine monitoring of steam sterilization cycles.

Device in this submission: For routine monitoring of steam sterilization cycles.

Indications for use:

Predicate: SteriTec Smart-Read® Biological Test Pack with Instant Readout Integrator is designed specifically for testing of 3 minutes or longer at 1320C (270°F) in pre-vacuum steam sterilizers. The test pack consists of a self-contained biological indicator containing *Geobacillus stearothermophilus* inside a small package of porous and nonporous materials, simulating the biological indicator 16 towel test packs defined by ANSI/AAMI ST7S. When used as directed, the Chemical Integrator Record Card gives visible indication that sterilizing conditions were met.

Device in this submission: Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SGM Biotech's Self-Contained Biological Indicator Smart-Read EZTest - Steam along with or without SteriScan Integrators.

Used in:

Predicate: In health care facilities.

Device in this submission: In health care facilities.

Design and Performance:

Predicate: The test pack consists of a self-contained biological indicator containing *Geobacillus stearothermophilus* inside a small package of index cards, intended to simulate the biological indicator 16 towel test packs defined by ANSI/AAMI ST7S. When used as directed, the Chemical Integrator Record Card gives visible indication that sterilizing conditions were met.

Device in this submission: Consists of a totally insulated aluminum chamber and can be sealed with a screw cap. This device when used with the SmartRead BI can effectively challenge the 4 minute 270°F steam sterilization cycle. The steam penetration and air removal is through a torturous path built into the insulated chamber. Materials used in the construction of the chamber are Aluminum, Teflon, Polypropylene tube and silicon rubber.

(b)(4) Testing



(b)(4) Testing



PROPOSED LABELING

Labeling:

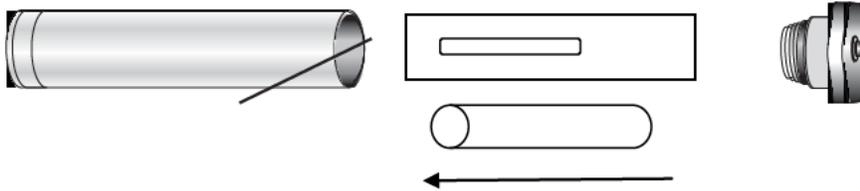
The following is the draft of the labeling that will be applied on each test pack.

Dana Reusable Test Pack

For testing the air removal efficiency
of pre-vacuum steam sterilizers

Over the counter use

For use only with SGM Smart-Read BI along with or without a SteriScan Integrator



Insert cap end first of BI

Insert first Pellet end of SteriScan Integrator

**Dana Products, Inc.
11457 Melrose St.
Franklin Park, IL**

**Lot Number:
Exp.:**

Instructions for use:

Dana Reusable Test Pack

Product Description:

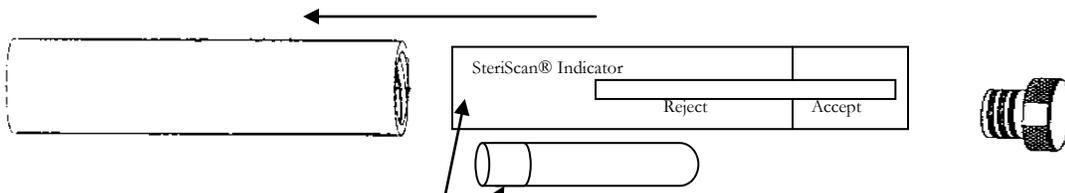
Dana Reusable Test Pack is designed to challenge the steam sterilization process in healthcare facilities and for routine monitoring of pre-vacuum steam sterilization cycles.

Indications for Use:

Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SGM Biotech's Self-Contained Biological Indicator Smart-Read EZTest - Steam along with or without SteriScan Integrators.

Direction for Use:

1. To open the device, unscrew the Dana Reusable Test Pack cap.
2. Insert the desired indicator into the chamber as illustrated below.



- Insert **cap end first** of BI into Dana Reusable Test Pack (as shown above).
 - Insert **pellet end first** of the SteriScan® Integrator into Dana Reusable Test Pack (as shown above).
3. To seal the device, screw the Dana Reusable Test Pack cap on tightly.
 4. Place the Dana Reusable Test Pack on the bottom shelf above the drain.
 5. Process the load according to recommended practices.
 6. After completion of the cycle open the sterilizer door and wait at least 5 minutes before removing the Dana Reusable Test Pack.

7. **Wear gloves and safety glasses when removing the Dana Reusable Test Pack from the sterilizer and at all times when handling and/or removing contents from the Dana Reusable Test Pack after sterilization.**
8. Do not open the Dana Reusable Test Pack until it has sufficiently cooled off.
9. After the Dana Reusable Rest Pack has sufficiently cooled off, unscrew the Dana Reusable Test Pack cap.
10. Remove the BI, and the SteriScan® Class 5 Integrator, as applicable.
11. Follow the instructions provided with the BI and the SteriScan® Steam Sterilization Integrator to read and interpret the results.
12. The BI and the SteriScan® Steam Sterilization Integrator are single use devices. Dispose of these devices after one use per manufacturer's directions.

Storage:

Store at normal room conditions: Temperature 60°F to 85° F Humidity 30 –70%.

Cleaning:

Clean the SteriScan Reusable® Test Pack only with water. Wipe the outside and rinse the inside with water.

Precautions:

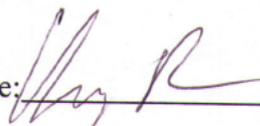
1. Use only with 270°F pre-vacuum steam sterilization cycles.
2. Use gloves to handle test pack after sterilization.
3. Wait until the test pack cools off before opening.
4. The manufacturer recommends replacing the Dana Reusable Test Pack six months after first use; however, if there are any visible signs of wear and tear including, for example, discoloration, rusting, cracking, peeling or deformation or any other visible change, discard and replace the Dana Reusable Test Pack immediately.
5. SteriScan® Chemical Indicators are not replacements for Biological Indicators.

Made in USA by
Dana Products
11457 Melrose Street
Franklin Park, IL 60131
847-455-2881

Premarket Notification Truthful and Accurate Statement:
[As Required by 21CFR 807.87(k)]

I certify that, in my capacity as the President of Dana Products, Inc., 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.

Signature: _____



Harry Bala

Date 1/17/2013

510k Number: _____

EXHIBIT A

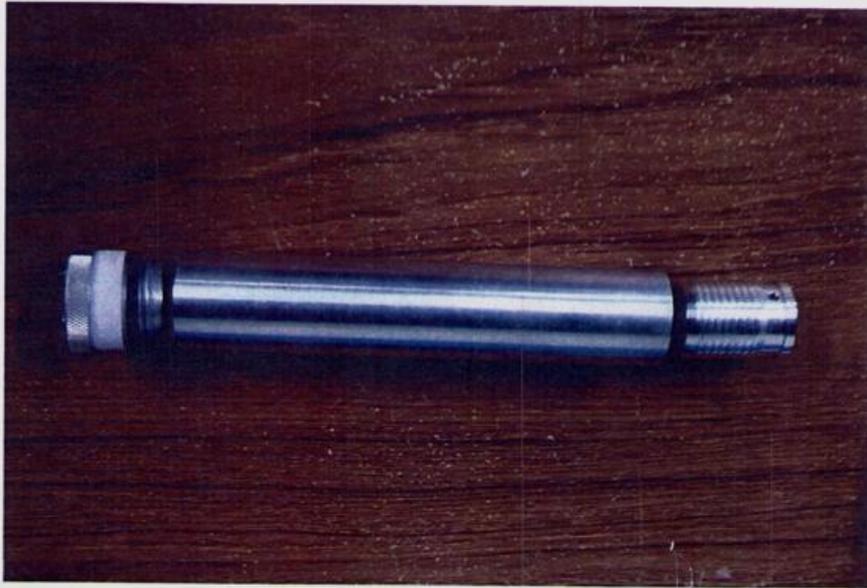


PHOTO - 1



PHOTO 2

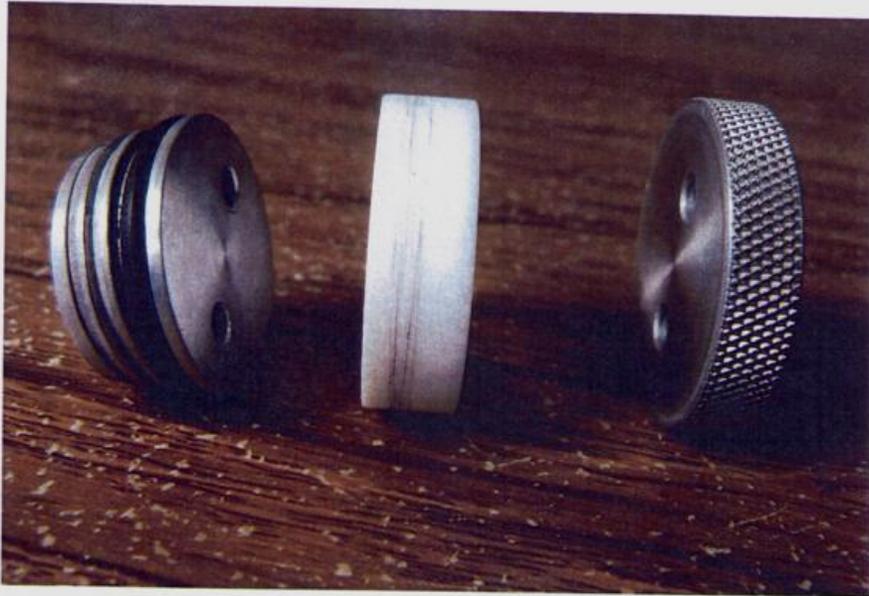


PHOTO-3



PHOTO 4

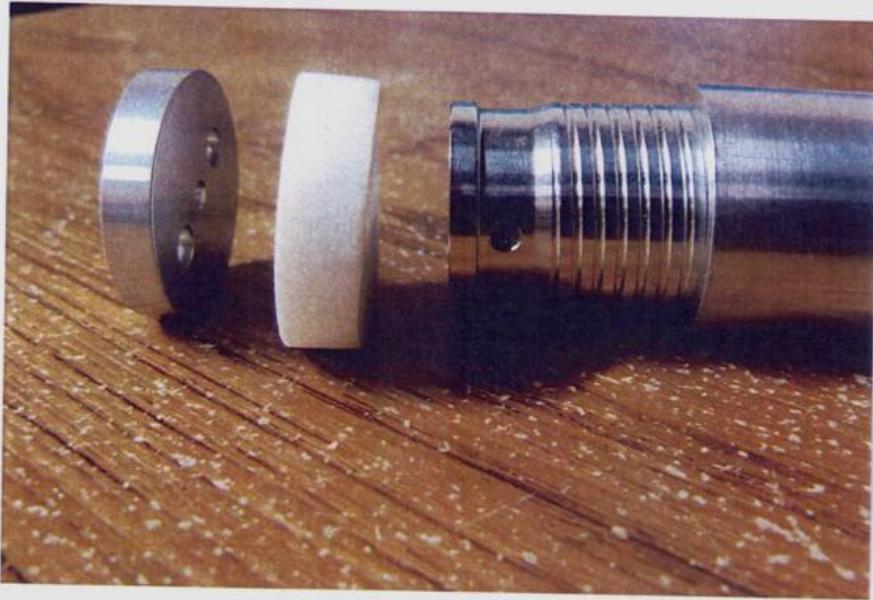


PHOTO-5

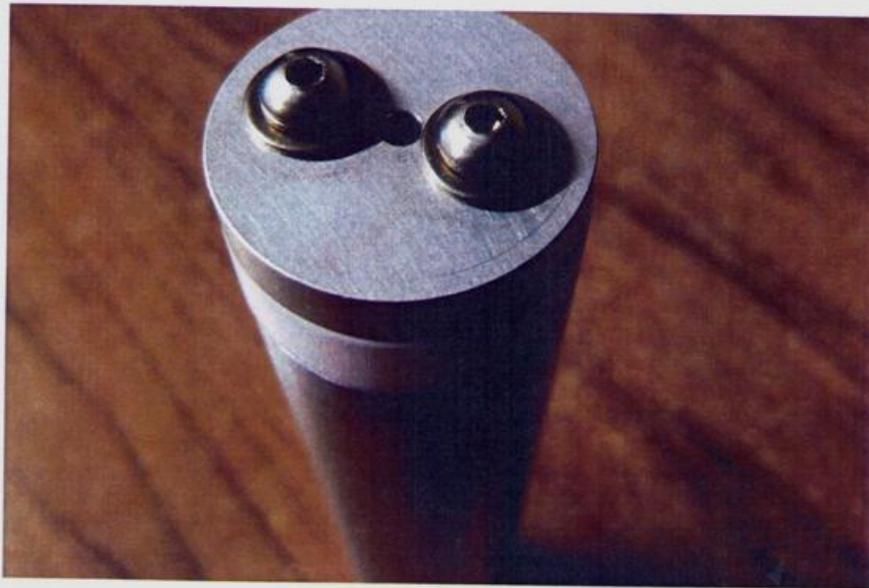


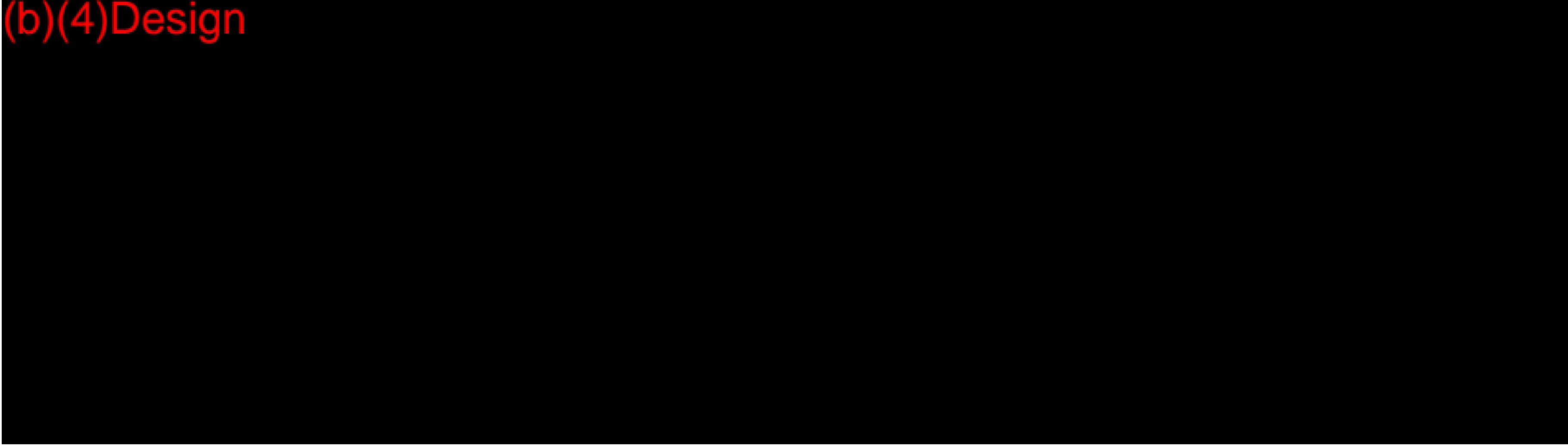
PHOTO 6



PHOTO 7

EXHIBIT B

(b)(4) Design



K130135/5002

DANA PRODUCTS, INC.
7 COREY DRIVE
SOUTH BARRINGTON, IL 60010
TEL. 847-455-2881 FAX. 847-455-2886

October 23, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center -W066-0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC
OCT 24 2013
Received

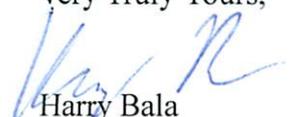
Dear Sir or Madam:

510(k) Number: K 130135 Dana Reusable Test Pack for Use with SGM Smart Read BI-
Your request for additional information dated July 24, 2013

Following is the additional information you requested in your letter dated July 24, 2013. I have made every effort to produce all of the information you have requested.

Thanking you,

Very Truly Yours,


Harry Bala
President

9

DANA PRODUCTS, INC.
7 COREY DRIVE
SOUTH BARINGTON, IL 60010
TEL. 847-455-2881 FAX. 847-455-2886

October 23, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center –W066-0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

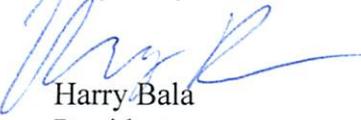
Dear Sir or Madam:

K130135 -- eCOPY COVER LETTER

Please see enclosed eCopy of the enclosed paper copy relating to K130135. **The enclosed eCopy is an exact duplicate of the enclosed paper copy.**

Thanking you,

Very Truly Yours,


Harry Bala
President

DANA PRODUCTS, INC.
7 COREY DRIVE
SOUTH BARRINGTON, IL 60010
TEL. 847-455-2881 FAX. 847-455-2886

October 23, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center –W066-0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

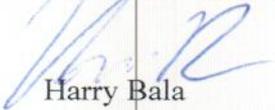
Dear Sir or Madam:

**510(k) Number: K 130135 Dana Reusable Test Pack for Use with SGM Smart Read BI-
Your request for additional information dated July 24, 2013**

Following is the additional information you requested in your letter dated July 24, 2013. I have made every effort to produce all of the information you have requested.

Thanking you,

Very Truly Yours,


Harry Bala
President

Required Elements for a Declaration of Conformity to a Recognized Standard

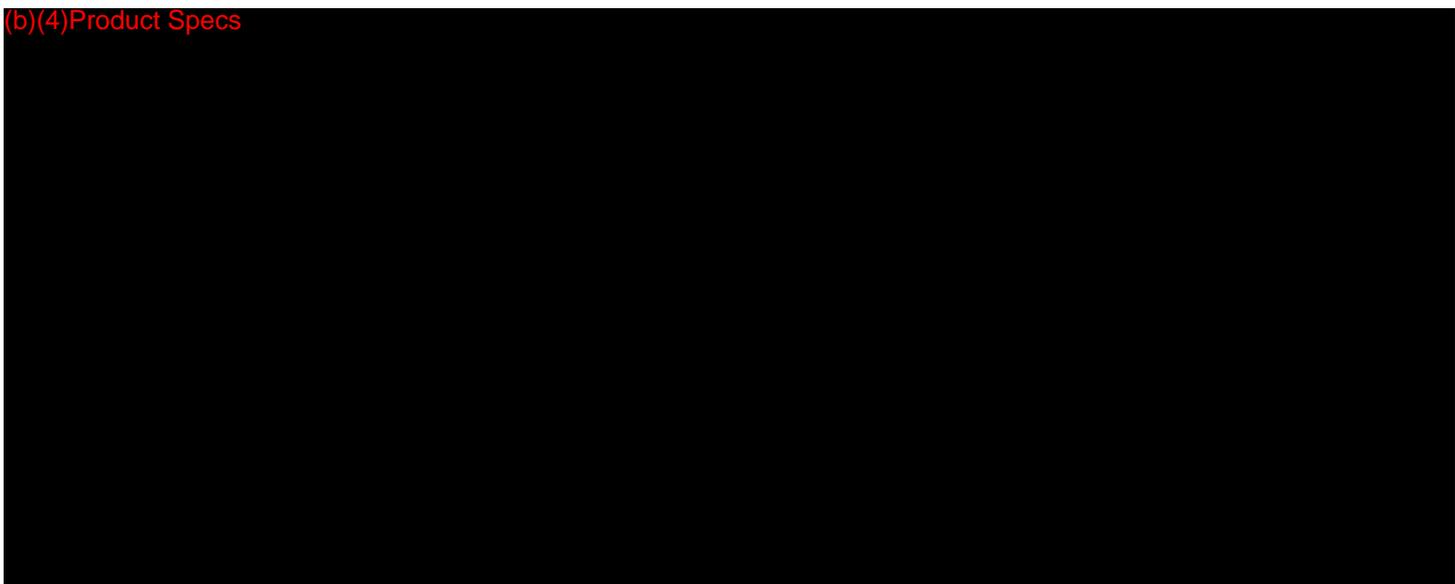
Required Element	Present	Inadequate or Missing
a. An identification of the applicable recognized consensus standards that were met.	See A below	
b. A statement, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below.	See B below	
c. An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review (e.g. An identification of an alternative series of tests that were performed).	See C below	
d. An identification, for each consensus standard, of any requirements that were not applicable to the device.	See D below	
e. A specification of any deviations from each applicable standard	See E below	

that were applied.		
f. A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference.	See F below	
g. The name and address of the testing laboratory and/or certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations.	See G below	

Set forth below is the revised Declaration of Conformity Statement:

Declaration of conformity: The Dana Reusable Test Pack, when used with SGM’s Smart-Read EZTest BI (“Smart-Read BI”), conforms to the recognized consensus standard set for a BI challenge test pack using 16 surgical towels in section 10.7 of ANSI/AAMI ST79: 2010 (**fulfills requirement A above**). The Dana Reusable Test Pack was more resistant than the SteriTec Biological Test Pack with Instant Readout Integrator (“SteriTec Test Pack”) (each SteriTec Test Pack contains a Smart-Read BI) when tested in an FDA approved Steam Sterilizer and 270°F Prevac cycle for use in healthcare facilities. For comparative purposes in a given test, the Smart-Read BI used in the Dana Reusable Test Pack was from the same lot as the one in the SteriTec Test Pack. The SteriTec Test Pack was validated against the AAMI 16 towel pack. Comparative testing was done with just the one Dana Reusable Test Pack and one SteriTec Test Pack placed directly over the drain but in an otherwise empty Sterilizer. This is the worst sterilizer load condition (per sec. 5.5 of ANSI/AAMI ST-8). For each consensus standard, all requirements were met (**fulfills requirement B above**). The standard was not adapted for application to the device under review (**fulfills requirement C above**). There were no requirements that were not applicable to the device (**fulfills requirement D above**). There were no deviations from each applicable standard that was applied (**fulfills requirement E above**). There are no differences between the tested device and the device to be marketed (**fulfills requirement F above**). Neither a testing laboratory nor certification body was involved in determining the conformance of the device with applicable consensus standards (**fulfills requirement G above**).

(b)(4)Product Specs

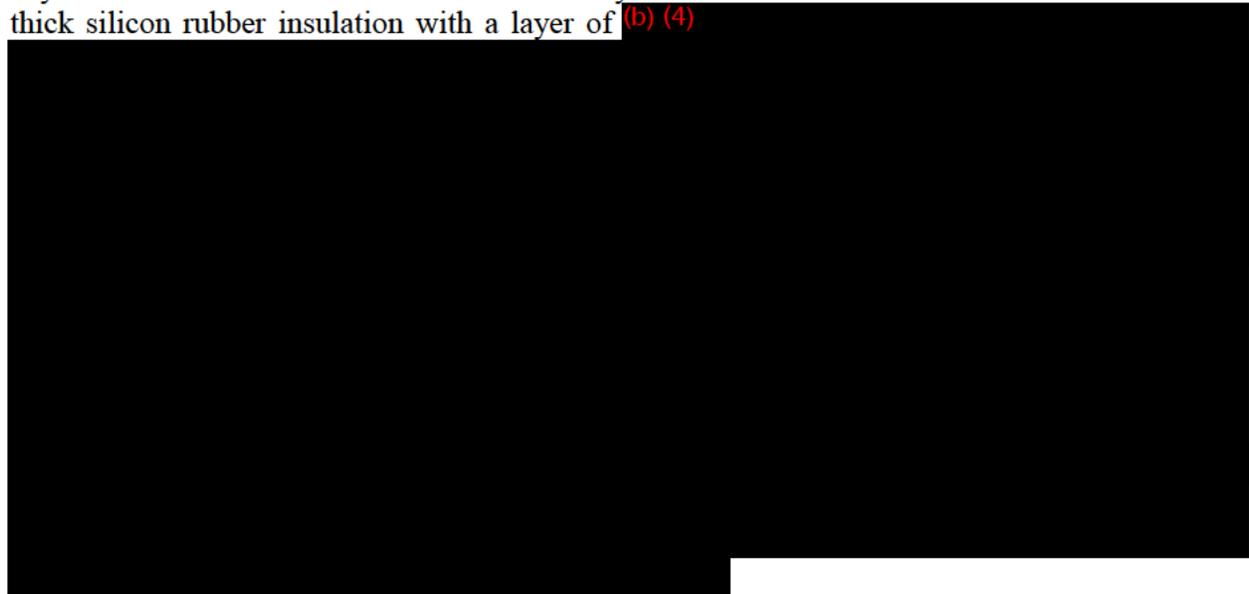


- **Dana Products Response:** Please see below revised Executive Summary:

Executive Summary:

Concise Description of Device, Including Indicators for Use:

Concise Device Description: The Dana Reusable Test Pack consists of an aluminum chamber that can be sealed at one end using a removable aluminum plug. The other end has a permanently pressed in aluminum cap with a precision machined spiral that provides the torturous path for air removal and for steam penetration. The entire assembly is insulated. The aluminum chamber is large enough to accommodate a Smart-Read BI and a SteriScan Integrator. The Dana Reusable Test Pack consists of an aluminum tube. One end of the tube has internal thread to receive a removable aluminum plug. Between knurled aluminum disc and aluminum threaded plug is sandwiched a Teflon disc. All three are bolted together. The Teflon disc acts as an insulator preventing any heat transfer to the interior of the assembly. The 15° taper next to the thread in the tube seats the seal ring from the plug. This ensures that this end of the device can be totally sealed. The bore at the other end of the tube is machined so that the aluminum cap can be permanently press fitted into it. The cap has a very shallow spiral with a radial hole at one end to facilitate steam entry. The spiral extends all the way to the other end of the cap. The radial hole and the spiral provide the torturous path challenge for air removal and steam penetration. A Teflon disc is bolted to the end of the press cap. The Teflon disc acts as an insulator preventing any heat transfer to the interior of the assembly. The aluminum tube is covered with 1/16 inch thick silicon rubber insulation with a layer of (b) (4)



Indications for Use: Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SGM Biotech's Self-Contained Biological Indicator Smart-Read EZTest - Steam along with or without SteriScan Integrators.

Device Comparison Table:

	SteriTec Test Pack	Dana Reusable Test Pack
Intended Use	For routine monitoring of steam sterilization cycles.	For routine monitoring of steam sterilization cycles.
Indications for Use	SteriTec Smart-Read® Biological Test Pack with Instant Readout Integrator is designed specifically for testing of 3 minutes or longer at 132°C (270°F) in pre-vacuum steam sterilizers. The test pack consists of a self-contained biological indicator containing <i>Geobacillus stearothermophilus</i> inside a small package of porous and nonporous materials, simulating the biological indicator 16 towel test packs defined by ANSI/AAMI ST7S . When used as directed, the Chemical Integrator Record Card gives visible indication that sterilizing conditions were met.	Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SGM Biotech’s Self-Contained Biological Indicator Smart-Read EZTest - Steam along with or without SteriScan Integrators.
Used in	In health care facilities.	In health care facilities.
Design and Materials Used	The test pack consists of a self-contained biological indicator containing <i>Geobacillus stearothermophilus</i> inside a small package of index cards, intended to simulate the biological indicator 16 towel test packs defined by ANSI/AAMI ST7S. When used as directed, the Chemical Integrator Record Card gives visible indication that sterilizing conditions were met.	Consists of a totally insulated aluminum chamber and can be sealed with a screw cap. This device when used with the SmartRead BI can effectively challenge the 4 minute 270°F steam sterilization cycle. The steam penetration and air removal is through a torturous path built into the insulated chamber. Materials used in the construction of the chamber are Aluminum, Teflon, (b)(4)Product Specs
Performance	(b) (4)	

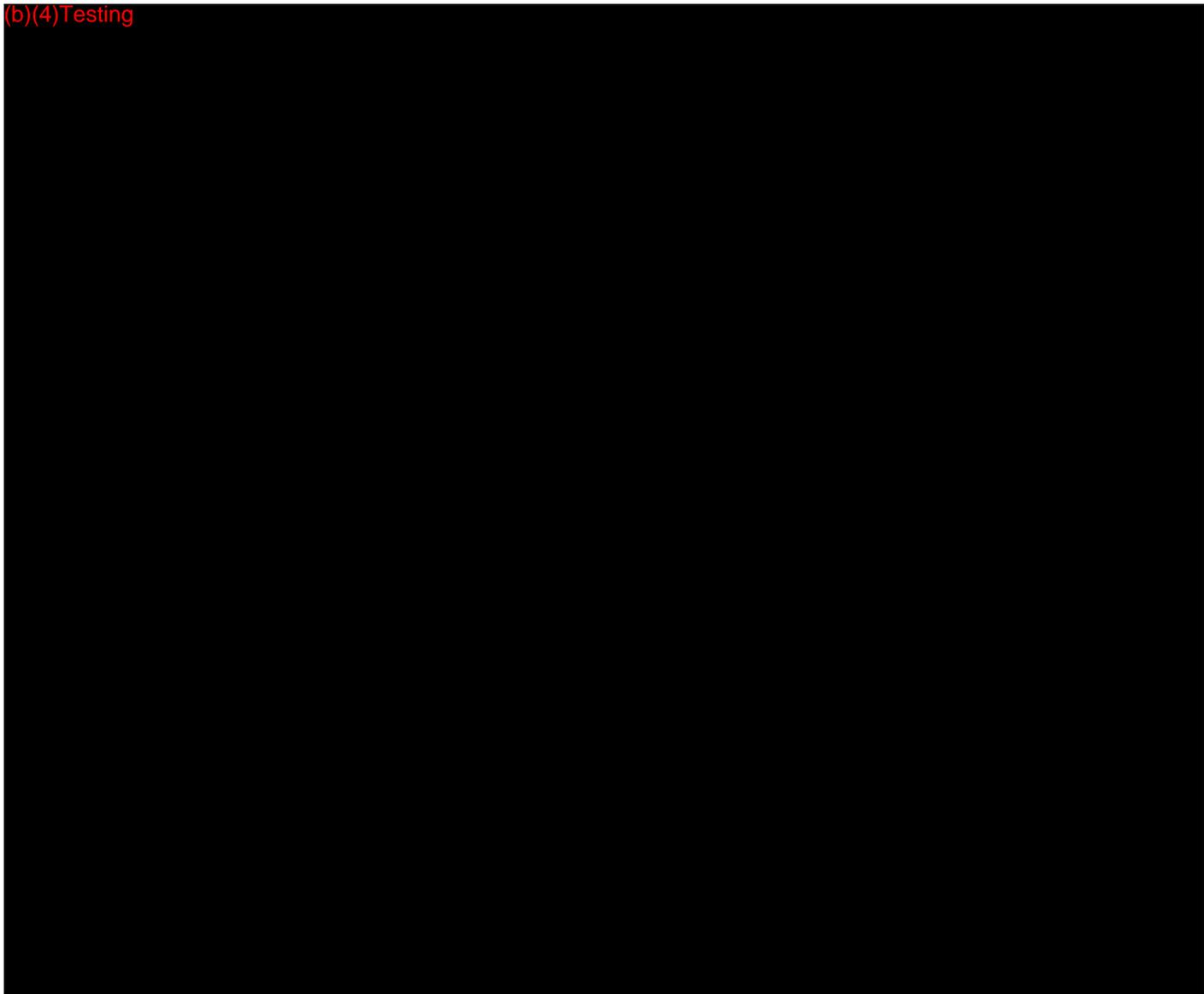
(b) (4)



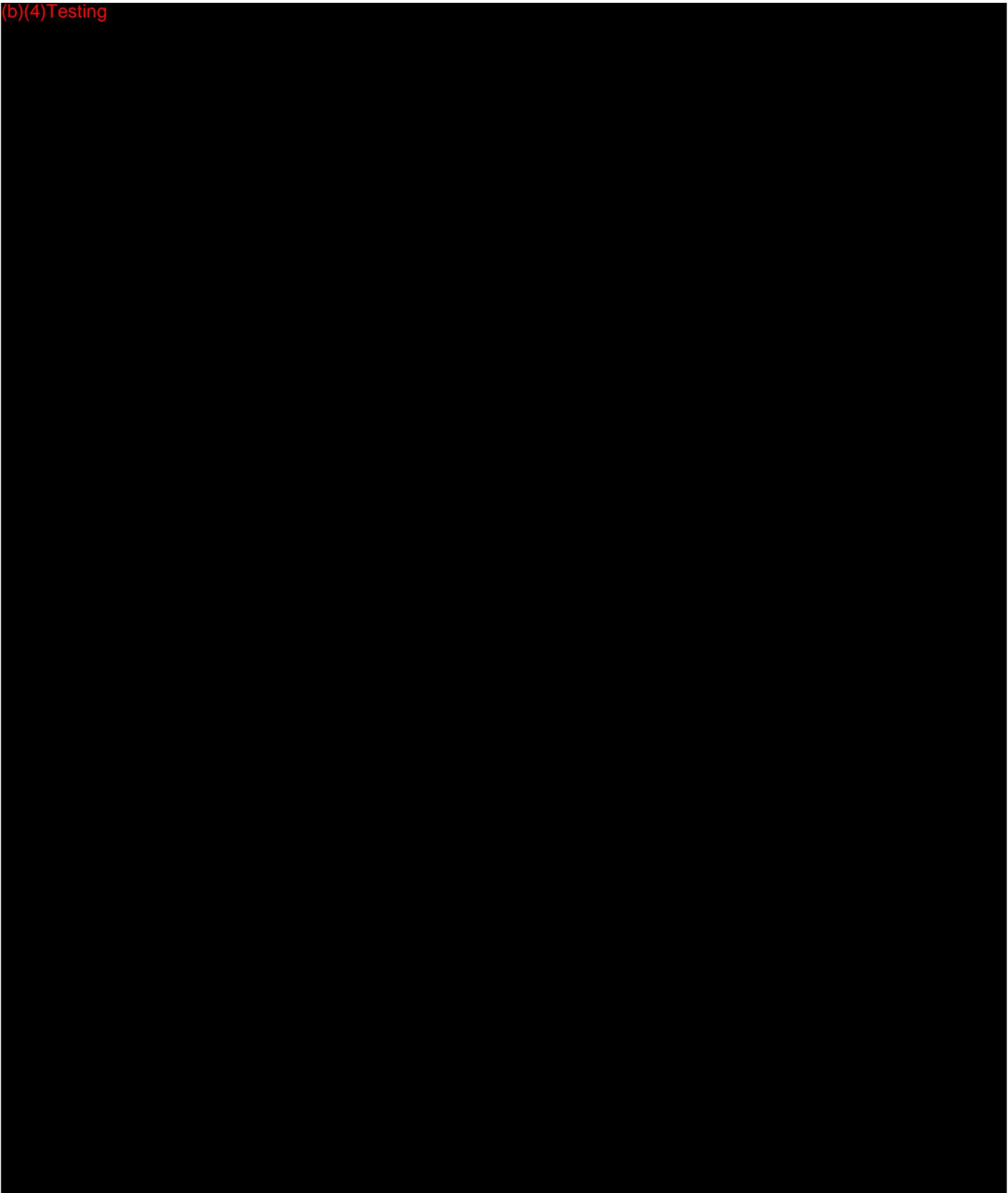
Detailed summary of the performance tests for the device and conclusion:

The following studies were conducted and will be presented in the submission. **Detailed summaries of these studies are set forth below.**

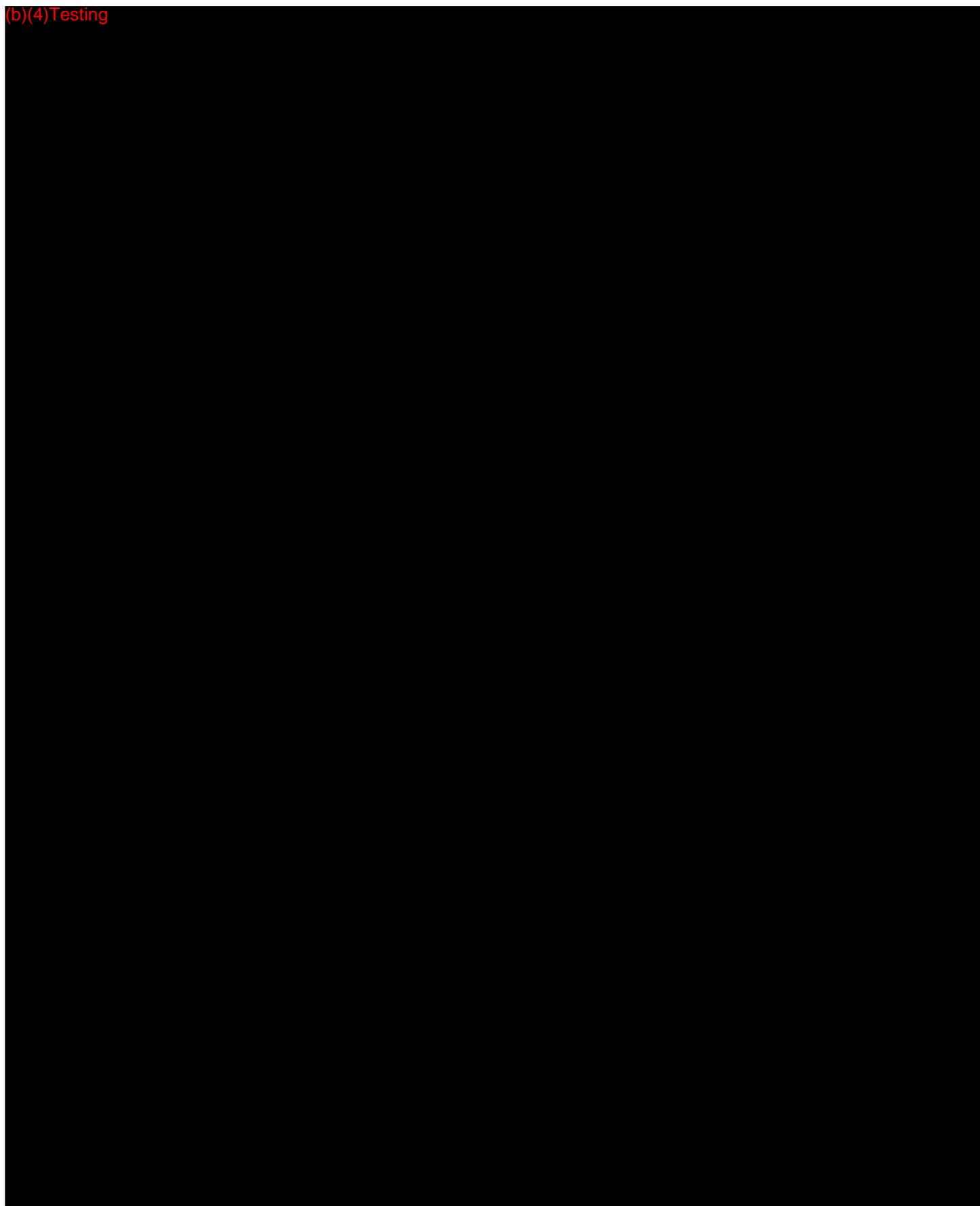
(b)(4) Testing



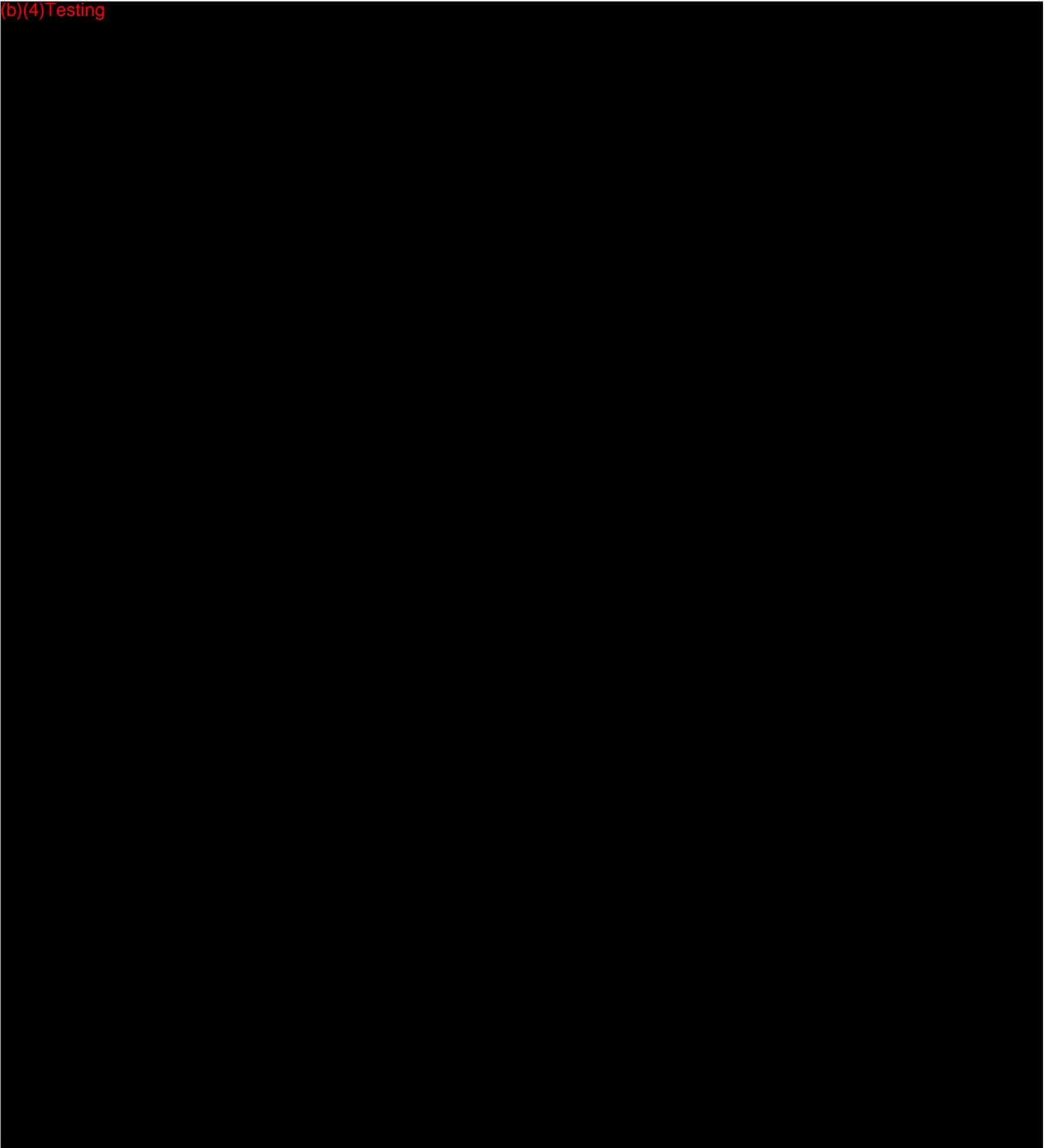
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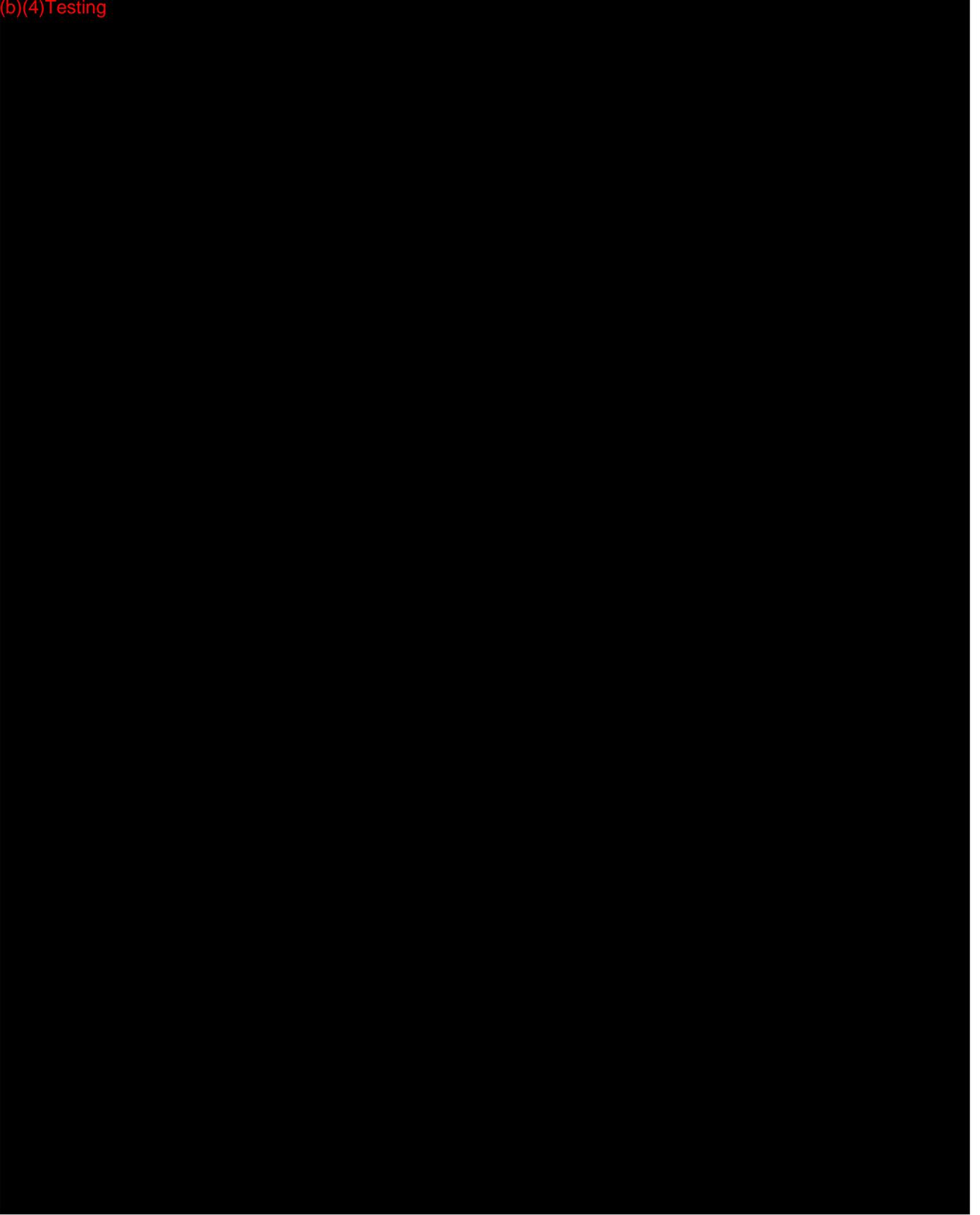
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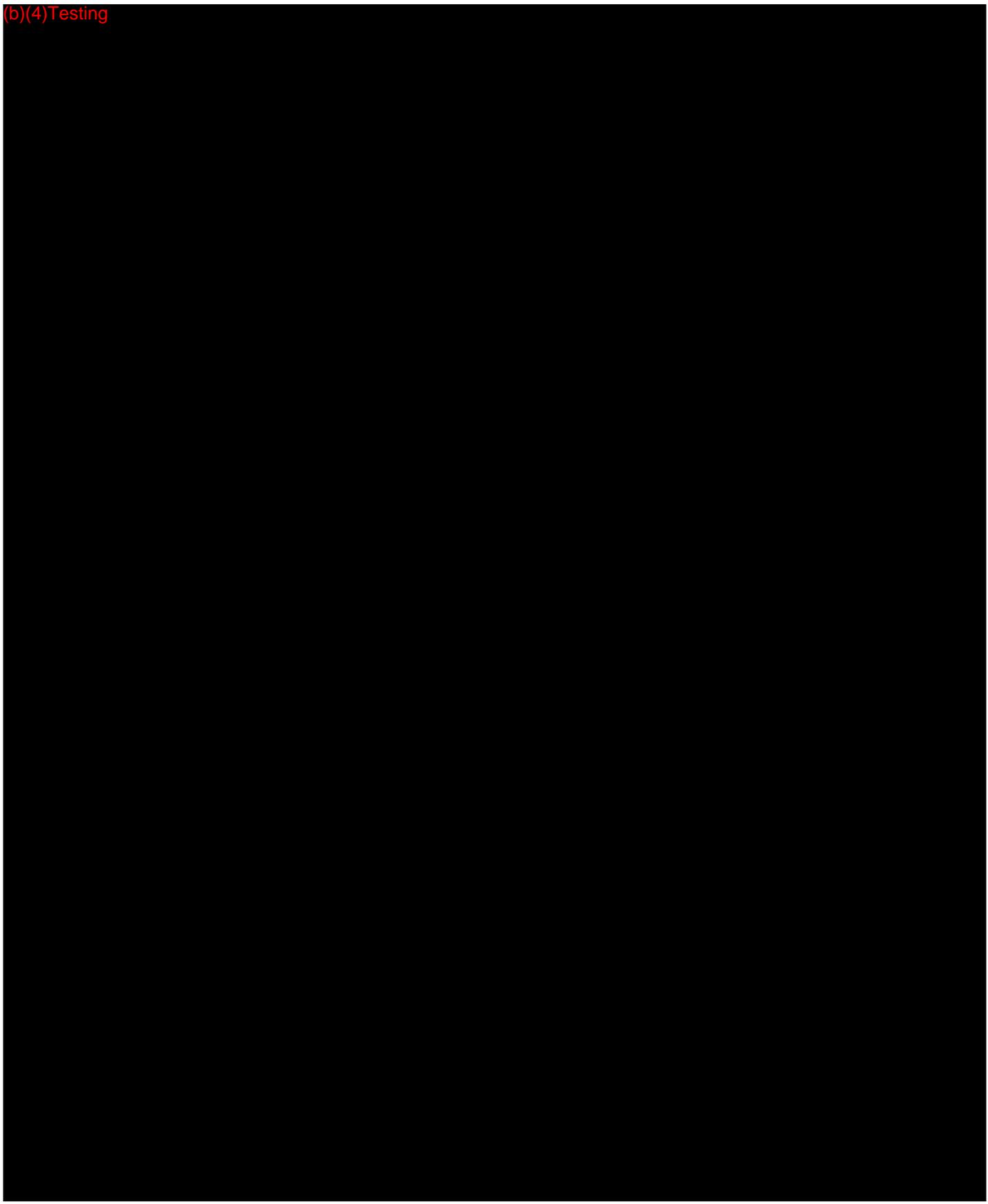
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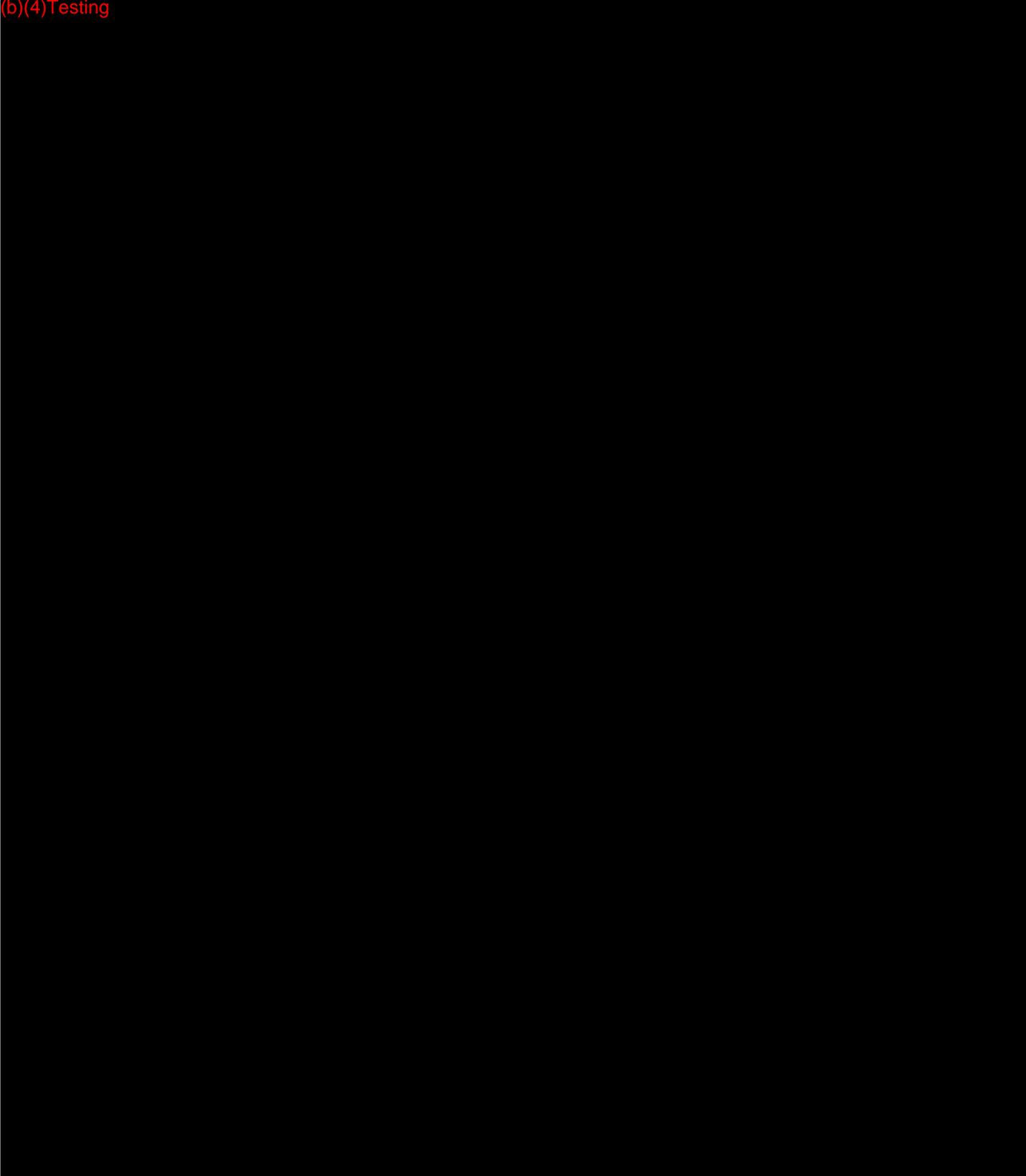
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(b)(4)Testing



(b)(4) Testing

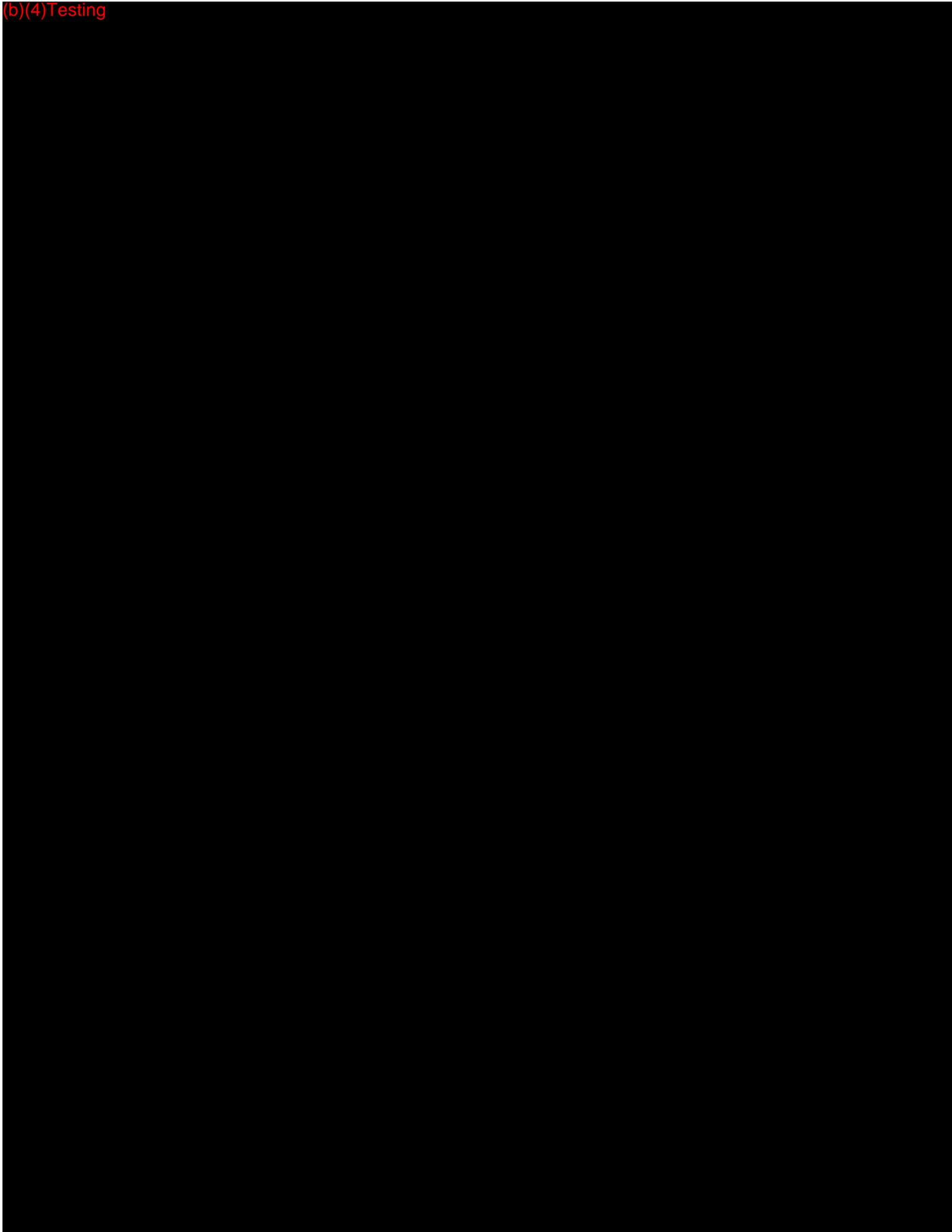


(b)(4)Testing

Performance of SteriScan Integrator Inside of Dana Reusable Test Pack

(b)(4)Testing

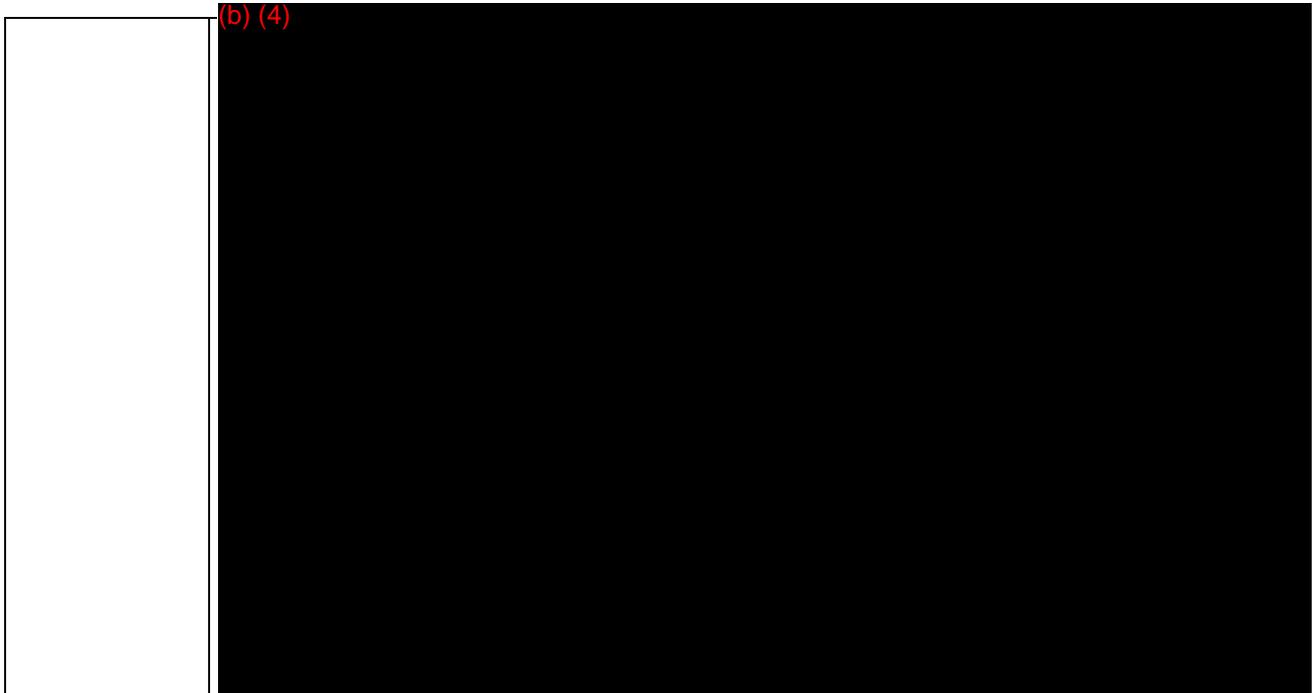
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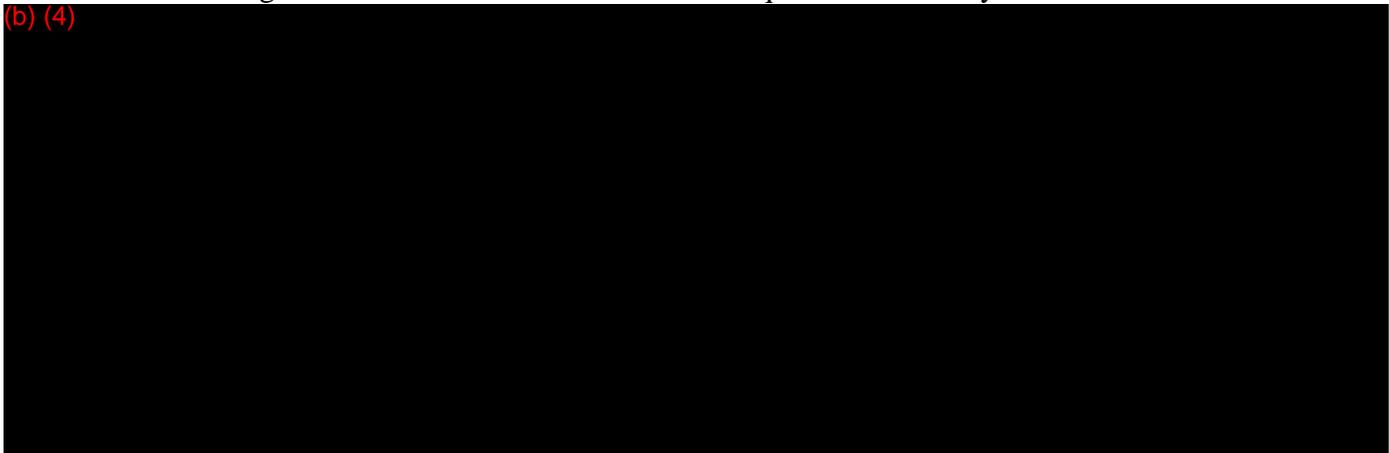
(b)(4) Testing

- **Dana Products Response:** Please see below revised substantial equivalence comparison in the form of a side-by-side comparison table set forth below:

	SteriTec Test Pack	Dana Reusable Test Pack
Intended Use	For routine monitoring of steam sterilization cycles.	For routine monitoring of steam sterilization cycles.
Indications for Use	SteriTec Smart-Read® Biological Test Pack with Instant Readout Integrator is designed specifically for testing of 3 minutes or longer at 132°C (270°F) in pre-vacuum steam sterilizers. The test pack consists of a self-contained biological indicator containing <i>Geobacillus stearothermophilus</i> inside a small package of porous and nonporous materials, simulating the biological indicator 16 towel test packs defined by ANSI/AAMI ST7S . When used as directed, the Chemical Integrator Record Card gives visible indication that sterilizing conditions were met.	Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SGM Biotech's Self-Contained Biological Indicator Smart-Read EZTest - Steam along with or without SteriScan Integrators.
Used in	In health care facilities.	In health care facilities.
Design and Materials Used	The test pack consists of a self-contained biological indicator containing <i>Geobacillus stearothermophilus</i> inside a small package of index cards, intended to simulate the biological indicator 16 towel test packs defined by ANSI/AAMI ST7S. When used as directed, the Chemical Integrator Record Card gives visible indication that sterilizing conditions were met.	Consists of a totally insulated aluminum chamber and can be sealed with a screw cap. This device when used with the SmartRead BI can effectively challenge the 4 minute 270°F steam sterilization cycle. The steam penetration and air removal is through a torturous path built into the insulated chamber. Materials used in the construction of the chamber are Aluminum, Teflon, (b) (4)
Performance	(b) (4)	(b) (4)



Summary of Substantial Equivalence Discussion: The results of these evaluations showed that the Dana Reusable Test Pack exceeds the performance of the SteriTec Test Pack and is thus substantially equivalent to the predicate device in terms of its intended use, physical properties and technological characteristics. There are no new questions of safety or effectiveness.



- **Dana Products Response:** Please see labeling below:

Labeling:

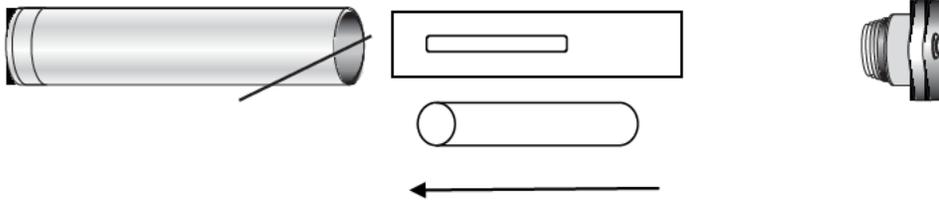
The following is the draft of the labeling that will be applied on each test pack.

Dana Reusable Test Pack

For challenging the steam sterilization process in
healthcare facilities and for routine sterilizer monitoring

Over the counter use

For use only with SGM Smart-Read BI along with or without a SteriScan Integrator



Insert cap end first of BI
Insert first Pellet end of SteriScan Integrator

Dana Products, Inc.
11457 Melrose St.
Franklin Park, IL

Lot Number:
Exp.:

(b) (4)

Instructions for use:

Dana Reusable Test Pack

Product Description:

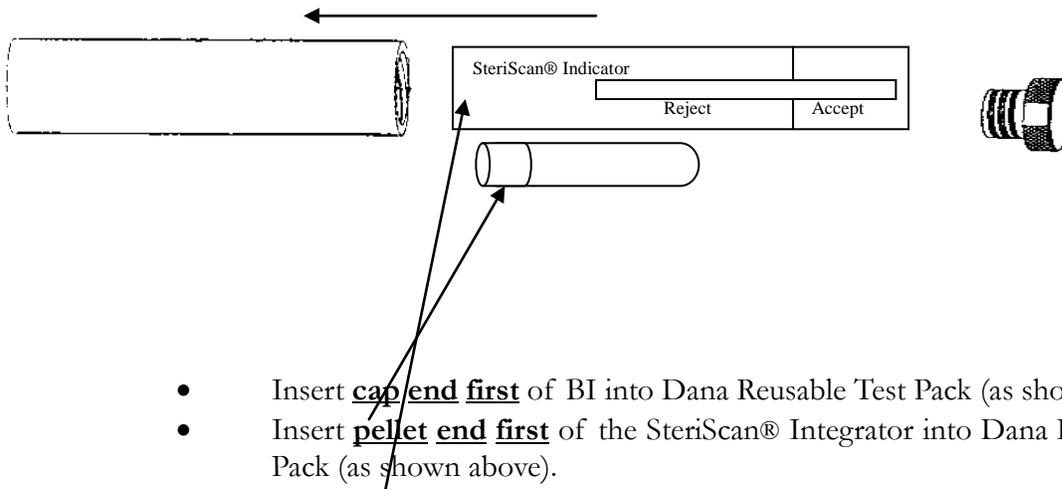
Dana Reusable Test Pack is designed to challenge the steam sterilization process in healthcare facilities and for routine monitoring of pre-vacuum steam sterilization cycles.

Indications for Use:

Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SGM Biotech's Self-Contained Biological Indicator Smart-Read EZTest - Steam along with or without SteriScan Integrators.

Direction for Use:

1. To open the device, unscrew the Dana Reusable Test Pack cap.
2. Insert the desired indicator into the chamber as illustrated below.



- Insert **cap end first** of BI into Dana Reusable Test Pack (as shown above).
 - Insert **pellet end first** of the SteriScan® Integrator into Dana Reusable Test Pack (as shown above).
3. To seal the device, screw the Dana Reusable Test Pack cap on tightly.
 4. Place the Dana Reusable Test Pack on the bottom shelf above the drain.
 5. Process the load according to recommended practices.
 6. After completion of the cycle open the sterilizer door and wait at least 5 minutes before removing the Dana Reusable Test Pack.
 7. **Wear gloves and safety glasses when removing the Dana Reusable Test Pack from the sterilizer and at all times when handling and/or removing contents from the Dana Reusable Test Pack after sterilization.**
 8. Do not open the Dana Reusable Test Pack until it has sufficiently cooled off.
 9. After the Dana Reusable Rest Pack has sufficiently cooled off, unscrew the Dana Reusable Test Pack cap.
 10. Remove the BI, and the SteriScan® Class 5 Integrator, as applicable.
 11. Follow sterilizer manufacturer instructions when using the Dana Reusable Test Pack
 12. Follow the instructions provided with the BI and the SteriScan® Steam Sterilization Integrator to read and interpret the results.
 13. Follow the instructions provided with the BI incubator when incubating BI.

14. The BI and the SteriScan® Steam Sterilization Integrator are single use devices. Dispose of these devices after one use per manufacturer's directions.

Storage:

Store at normal room conditions: Temperature 60°F to 85° F Humidity 30 –70%.

Cleaning:

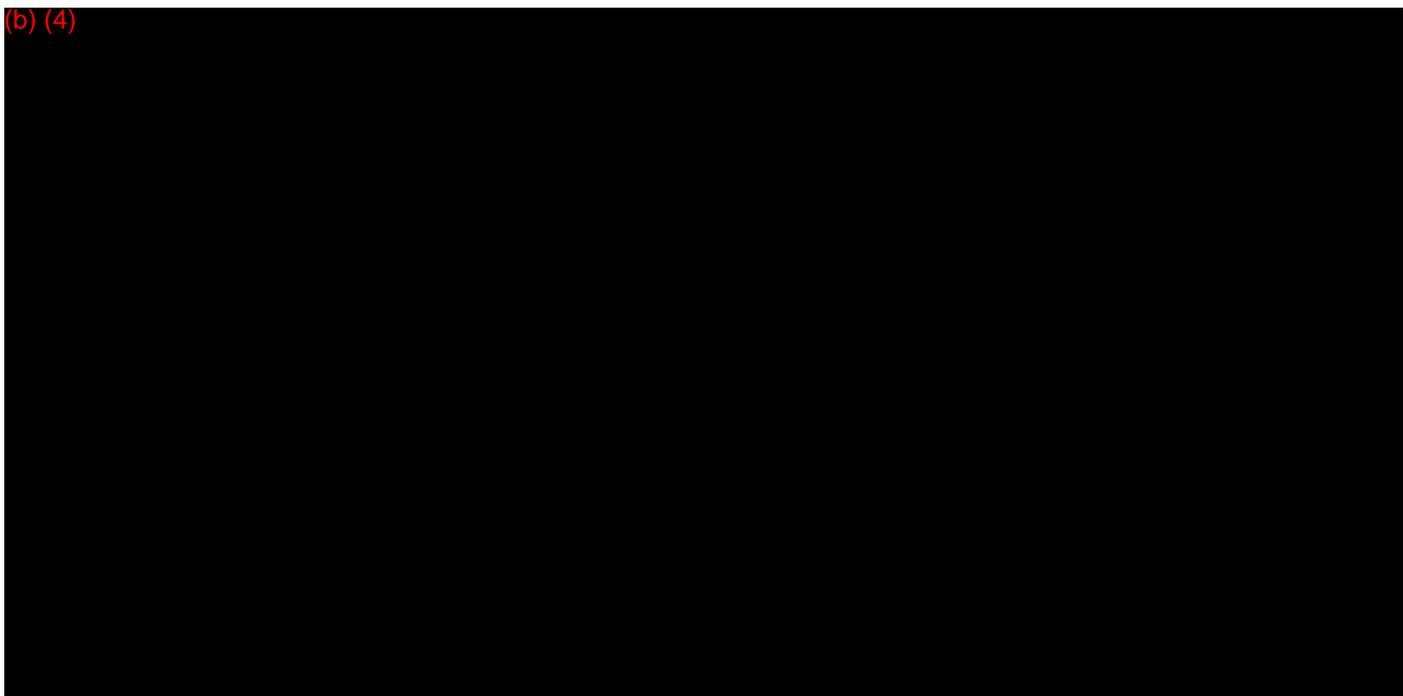
Clean the SteriScan Reusable® Test Pack only with water. Wipe the outside and rinse the inside with water.

Precautions:

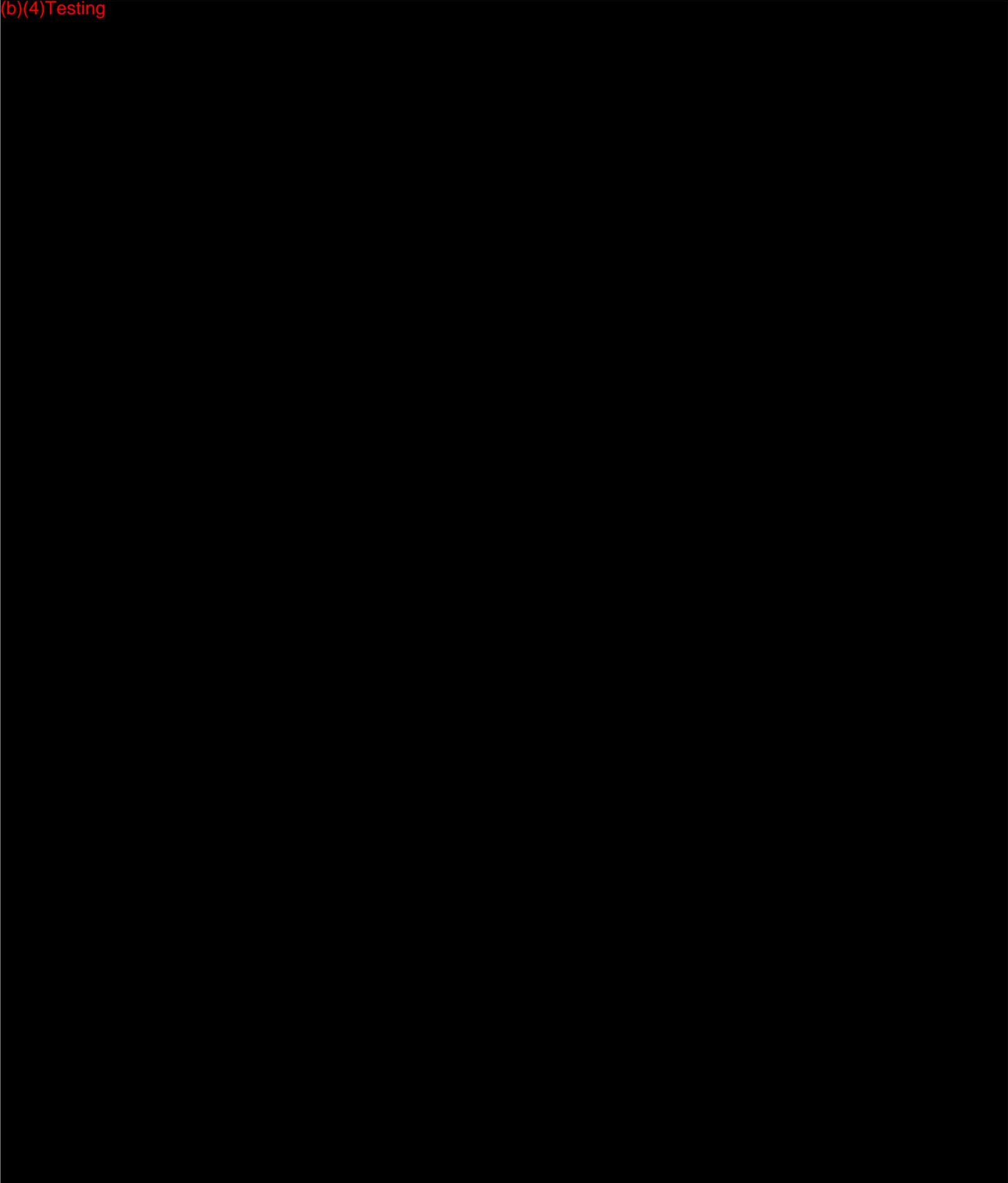
1. Use only with 270°F pre-vacuum steam sterilization cycles.
2. Use gloves to handle test pack after sterilization.
3. Wait until the test pack cools off before opening.
4. The manufacturer recommends replacing the Dana Reusable Test Pack six months after first use; however, if there are any visible signs of wear and tear including, for example, discoloration, rusting, cracking, peeling or deformation or any other visible change, discard and replace the Dana Reusable Test Pack immediately.
5. SteriScan® Chemical Indicators are not replacements for Biological Indicators.

Made in USA by
Dana Products
11457 Melrose Street
Franklin Park, IL 60131
847-455-2881

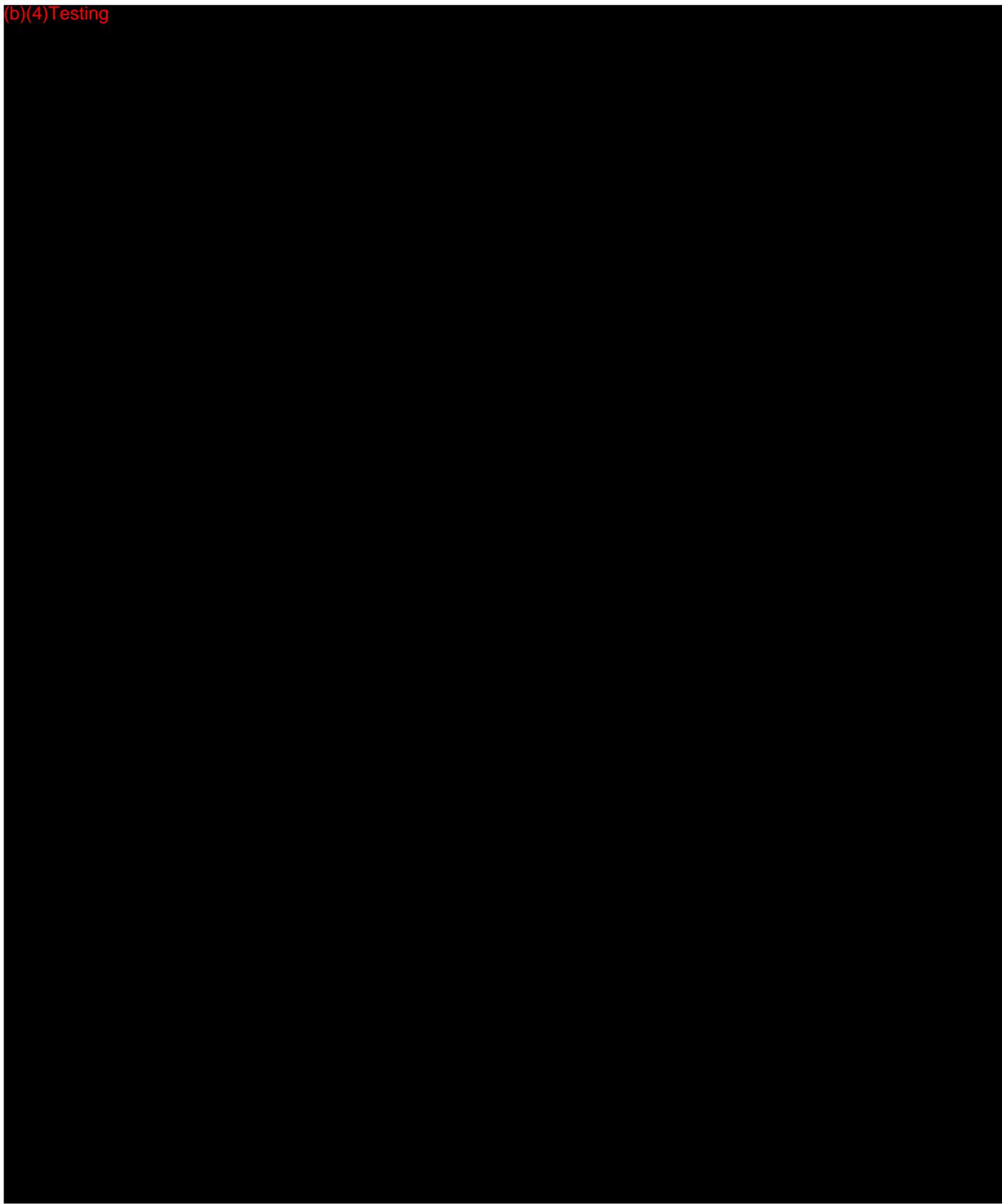
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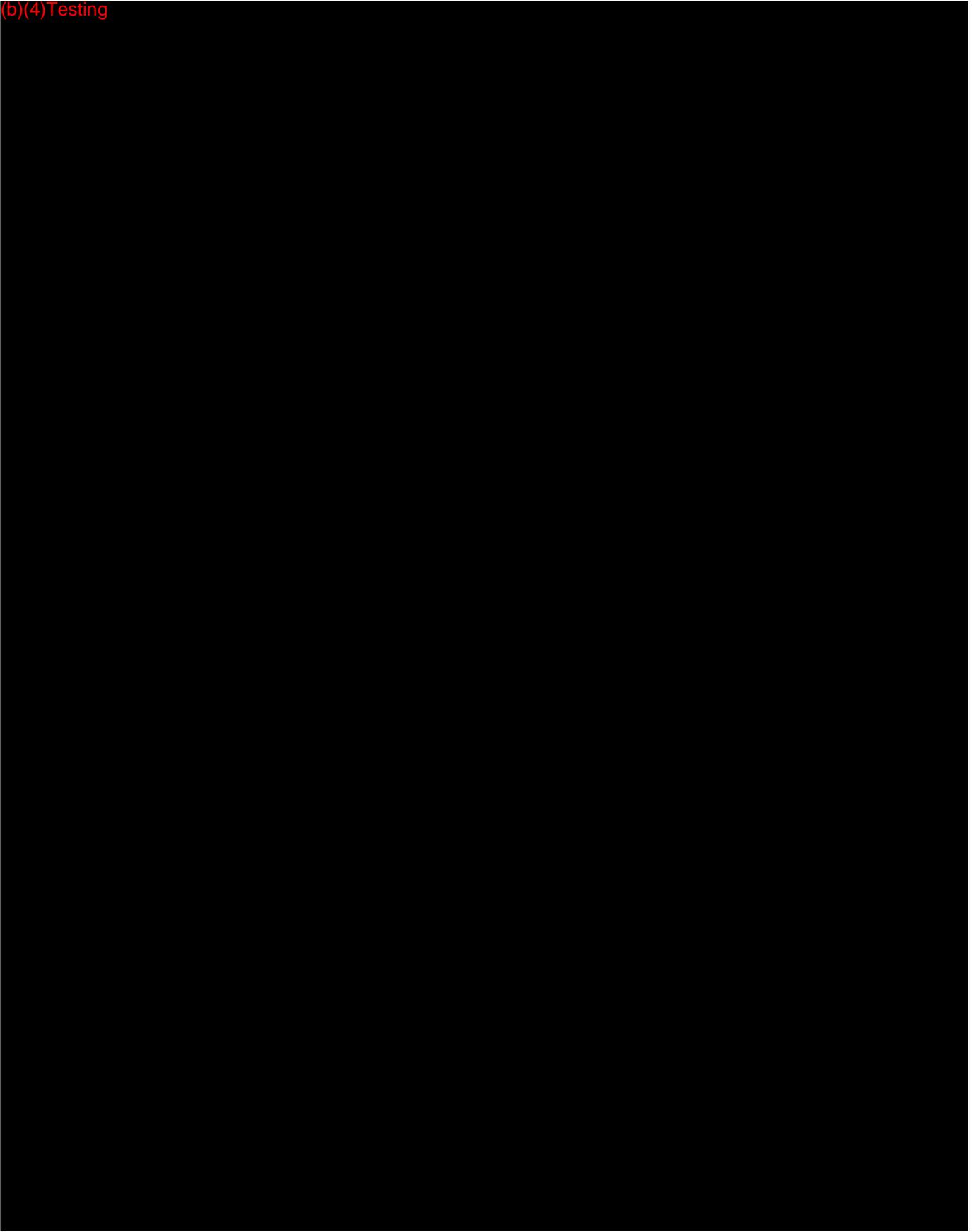
(b)(4) Testing



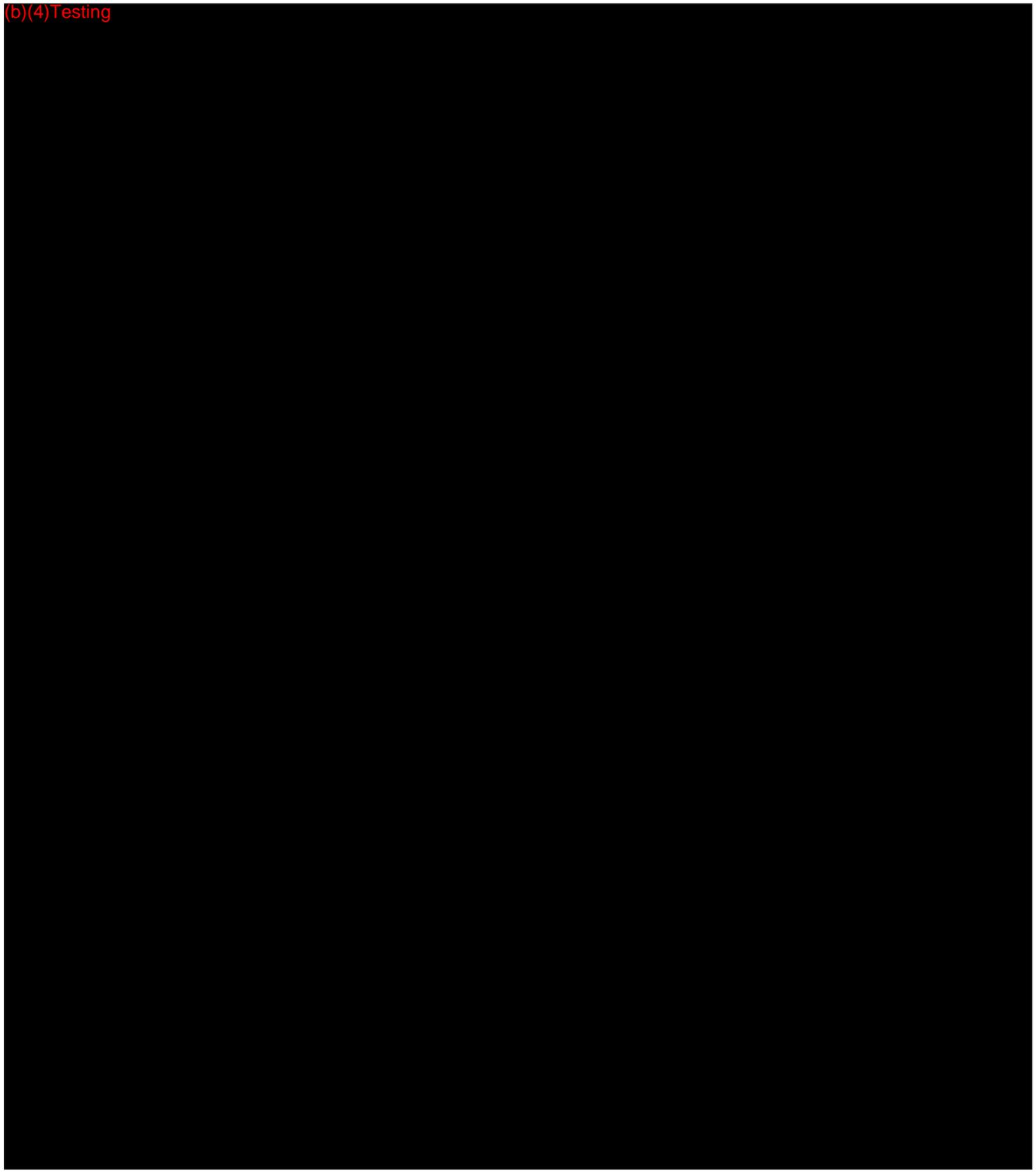
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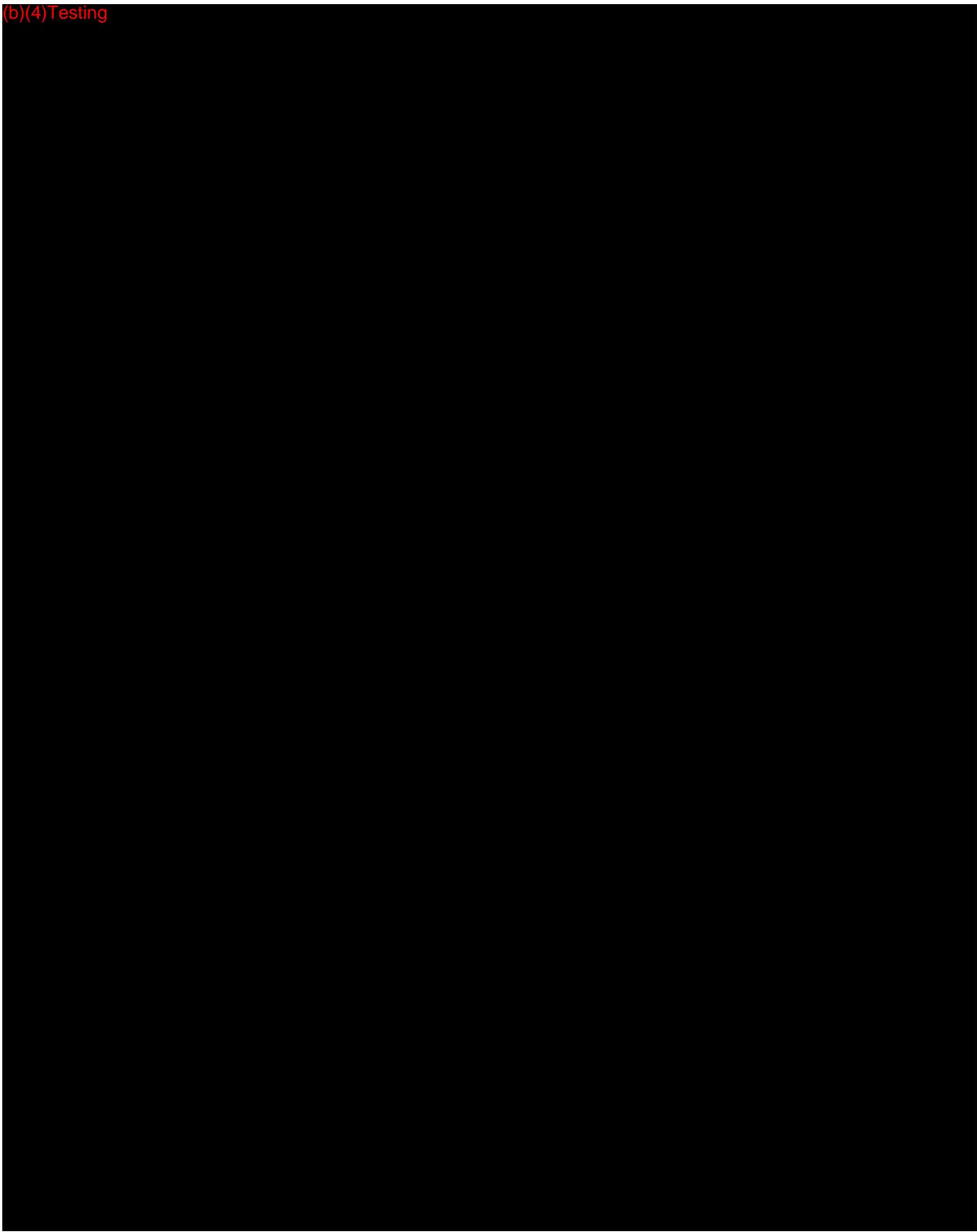
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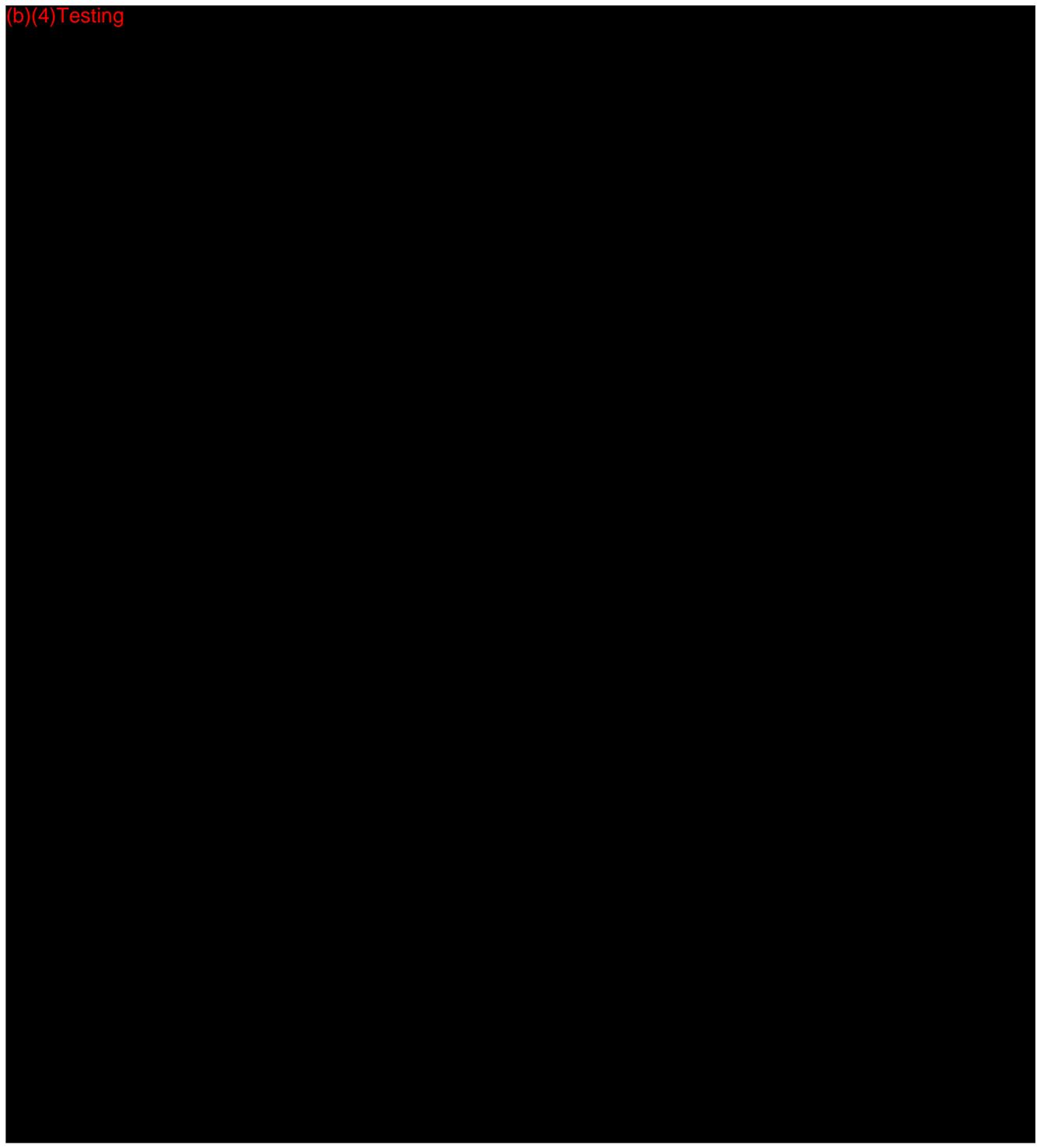
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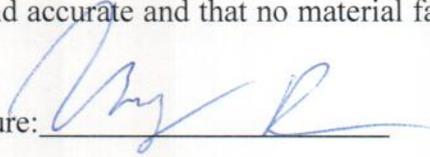


(b)(4) Testing



Premarket Notification Truthful and Accurate Statement:
[As Required by 21CFR 807.87(k)]

I certify that, in my capacity as the President of Dana Products, Inc., 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.

Signature: 

Harry Bala

Date 10/23/2013

510k Number: K130135

EXHIBIT A

DANA PRODUCTS, INC.
11457 MELROSE STREET
FRANKLIN PARK, IL 60131
TEL. 847-455-2881 FAX. 847-455-2886

**Material Safety Data Sheet
SteriScan Integrator**

7/10/2010

1. Composition /Information on Ingredients

Aluminum Foil
Steam sensitive chemical
Filter paper
Adhesive
Polypropylene cover
Paper overlay

Hazards Identification

HMIS Classification
Health Hazard 1
Flammability 0
Physical hazard 0

NFPA Rating

Health Hazard: 1
Fire: 0
Reactivity Hazard: 0

Cytotoxicity Test Result Result of Product and Contents

The Grade 0 response from the sample preparation meets assay acceptance requirements of no more than Grade 2 reactivity (Ref. USP)

Accidental release of sealed contents

In case of skin contact: Wash with soap and water.
In case of contact with instruments: Clean instruments and sterilize.

Handling

Do not cut or puncture the product, which may release contents.

DANA PRODUCTS, INC.
11457 MELROSE STREET
FRANKLIN PARK, IL 60131
TEL. 847-455-2881 FAX. 847-455-2886

9/22/2011

**Material Safety Data Sheet
SteriScan Reusable Test Pack**

Composition /Information on Ingredients

Machined aluminum
Machined teflon
Silicon over-mold
Stainless steel screws and washers
Viton o-rings
FEP shrink tubing

Hazards Identification

HMIS Classification
Health Hazard 0
Flammability 0
Physical hazard 0

NFPA Rating

Health Hazard: 0
Fire: 0
Reactivity Hazard: 0

Cytotoxicity Test Result Result of Product and Contents

The Grade 0 response from the sample preparation meets assay acceptance requirements of no more than Grade 2 reactivity (Ref. USP)

Handling

Wear gloves when removing product from sterilizer as it may be hot.

EXHIBIT B

REORDER NO.: SRSP

STEAM

Smart-Read
EZTEST[®] **BIOLOGICAL**
TEST PACK
WITH INSTANT READOUT INTEGRATOR

For monitoring **STEAM** sterilizers at 132°C (270°F).
Store at room temperature. Keep away from sterilants.
Contains **Smart-Read EZTest[®]** self-contained biological indicator and
Instant Readout Integrator card.
Smart-Read EZTest[®] for use with the **Smart-Well[™]** Incubator.

M E S A Manufactured For:

Mesa Labs
10 Evergreen Drive
Bozeman, MT 59715 USA
L A B S www.MesaLabs.com



10⁶ BIOLOGICAL TEST PACK WITH INSTANT READOUT INTEGRATOR

Reorder No: SRSP6/05 & SRSP6/25

INDICATIONS FOR USE:

Smart-Read® EZTest® Biological Test Pack with Instant Readout Integrator is designed specifically for biological testing of 132°C (270°F) pre-vacuum steam sterilizers. The test pack consists of a self-contained biological indicator containing *Geobacillus stearothermophilus* inside a small package of porous and nonporous materials, simulating the biological indicator 16 towel test packs defined by ANSI/AAMI ST79. When used as directed, the Chemical Integrator Record Card gives visible indication that sterilizing conditions were met.

COLOR CHANGE

Biological Media: Purple to Yellow

Smart-Read EZTest Label Chemical Indicator: Blue to Black
Record Card: Purple to Green.

CRITICAL PARAMETERS (in a standard hospital steam sterilizer)

Steam sterilization cycle functioning at 132°C (270°F) for 3 minutes or longer

RECORD CARD STATED VALUES (As determined in a steam sterilization resistometer.)
132°C (270°F) – 5.5 minutes

INSTRUCTIONS FOR USE

1. Load the sterilizer as normal.
2. Place the biological test pack flat on the lowest shelf near the door.
3. Process the load, normal cycle.
4. Remove the pack from the sterilizer and allow to cool at room temperature for 10 minutes.
5. Open the pack and remove the **Smart-Read EZTest Indicator**. Activate and incubate in the **Smart-Well™ Incubator**. If sterilization failure occurs, **Smart-Read** will provide positive biological evidence of that failure within 5 hours of incubation. A positive test must be immediately confirmed by the operator visually observing the color change to yellow. To meet the USFDA/RIT protocol the biological indicator must be further incubated for a total of 10 hours.
6. Remove and examine the Instant Readout Integrator Card.
7. When the chemical integrator 'PASS' changes color from purple to green, it indicates correct exposure conditions of temperature, time and steam. Biological spores should be killed under the same exposure conditions.

INCUBATION

Smart-Read EZTest biological indicators are designed to be used with the **Smart-Well incubator** which is calibrated to maintain 60°C ± 2°C (140°F ± 36°F). To activate the media, place the indicator in an upright position in the crushing chamber located on the **Smart-Well incubator**. Slowly pull forward to break the glass ampoule and release the media. Tap the EZTest BI to remove any bubbles within the plastic tube. Then immediately place the exposed activated indicator in an incubator cell, 1-10. The "C" cell is intended for an unexposed positive control BI (see also Use of Controls).

DISPOSAL

Dispose of all used biological indicators in accordance with your institution's policy. Incinerate or autoclave any positive cultures at 121°C (250°F) for no less than 30 minutes.

INTERPRETATION

Instant Readout Integrator Card: An Integrator Card printed with a Chemical Integrator is contained within the Process Challenge Device (PCD) to demonstrate that the PCD was exposed to proper sterilization conditions of steam, time, and temperature. If the chemical integrator is PURPLE, it has not been exposed to the proper conditions. If the indicator is GREEN (endpoint), the pack has been exposed to proper sterilization conditions and therefore, biological kill should be achieved. Record data on the Integrator Card.

Biological Indicator:

1. LEDs located in front of each cell display the current status of the cell: amber = test in progress; red = test positive; green = test negative. The appearance of a yellow color in the media indicates bacterial growth. No color change from purple indicates adequate sterilization. All incubation results MUST be visually confirmed by the operator.
2. Act on a yellow BI as soon as the color change is noted. Notify appropriate personnel. Always retest the sterilizer with several **Smart-Read EZTest** biological indicators throughout the test load. **Smart-Read EZTest** biological indicators can be subcultured if identification of positive growth is desired. Recommended subculturing procedure techniques are available upon request from SGM Biotech.
3. If sterilization failure occurs, **Smart-Read** will provide positive biological evidence of that failure within 5 hours of incubation. A positive test must be immediately confirmed by visually the operator observing the color change to yellow. To meet the USFDA/RIT protocol the biological indicator must be further incubated for a total of 10 hours.
4. A printout will be generated from the **Smart-Well incubator** containing results of incubation of **Smart-Read EZTest** BIs.

SAFETY PRECAUTIONS

CAUTION: the PCD will be hot and should be opened carefully to avoid thermal injury.

STORAGE

Store at normal room temperature, 50°-100°F (10°-38°C) and 10-70% Relative Humidity. Do not store near sterilants or other chemicals.

EXPIRY DATE

The expiry date is printed on the product packaging.

LOT NUMBER

A unique identification code, LOT, is printed on each Record Card, Biological Indicator label, and boxing/packaging labels.

INTERFERING SUBSTANCES OR CONDITIONS

There are NO KNOWN INTERFERING SUBSTANCES OR CONDITIONS that could affect the intended use of the indicator or adversely affect the indicator performance.

RELEASE OF TOXIC SUBSTANCES

The indicator releases NO KNOWN TOXIC SUBSTANCES in sufficient quantities to cause either a health hazard, or a hazard to the intended properties of the product being sterilized before, during or after the sterilization process.

DECLARATION OF CONFORMITY

The **Smart-Read Biological Test Pack** is equivalent in function and performance to the standard AAMI Challenge Test Pack as outlined in the ANSI/AAMI ST79. All biological indicators used in the **Smart-Read Biological Test Packs** are manufactured according to quality systems in compliance with ISO 11138. The INSTANT READOUT INTEGRATOR is compliant with the FDA requirements for chemical indicators.



10 Evergreen Drive, Bozeman, MT 59715
(406) 585-9535 * www.sgmbiotech.com

EXHIBIT C

DANA PRODUCTS, INC.
11457 MELROSE STREET
FRANKLIN PARK, IL 60131
TEL. 847-455-2881 FAX. 847-455-2886

**Material Safety Data Sheet
SteriScan Integrator**

7/10/2010

1. Composition /Information on Ingredients

Aluminum Foil
Steam sensitive chemical
Filter paper
Adhesive
Polypropylene cover
Paper overlay

Hazards Identification

HMIS Classification
Health Hazard 1
Flammability 0
Physical hazard 0

NFPA Rating

Health Hazard: 1
Fire: 0
Reactivity Hazard: 0

Cytotoxicity Test Result Result of Product and Contents

The Grade 0 response from the sample preparation meets assay acceptance requirements of no more than Grade 2 reactivity (Ref. USP)

Accidental release of sealed contents

In case of skin contact: Wash with soap and water.
In case of contact with instruments: Clean instruments and sterilize.

Handling

Do not cut or puncture the product, which may release contents.

DANA PRODUCTS, INC.
11457 MELROSE STREET
FRANKLIN PARK, IL 60131
TEL. 847-455-2881 FAX. 847-455-2886

9/22/2011

**Material Safety Data Sheet
SteriScan Reusable Test Pack**

Composition /Information on Ingredients

Machined aluminum
Machined teflon
Silicon over-mold
Stainless steel screws and washers
Viton o-rings
FEP shrink tubing

Hazards Identification

HMIS Classification
Health Hazard 0
Flammability 0
Physical hazard 0

NFPA Rating

Health Hazard: 0
Fire: 0
Reactivity Hazard: 0

Cytotoxicity Test Result Result of Product and Contents

The Grade 0 response from the sample preparation meets assay acceptance requirements of no more than Grade 2 reactivity (Ref. USP)

Handling

Wear gloves when removing product from sterilizer as it may be hot.

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