

FDA CDRH DMC

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January 22, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002



Re: 510(k) Notification (21 CFR 807.90(e)) for the ANAM Test System: Military Battery

Dear Reviewer:

The following Traditional 510(k) is submitted in accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, this 510(k) Premarket Notification is being submitted prior to the date when Vista LifeSciences, Inc. proposes to introduce into interstate commerce, for commercial distribution, the ANAM Test System: Military Battery.

This submission contains methods, data, and analysis of these data which the Sponsor considers "Trade Secret", commercially privileged and confidential. In accordance with 21 CFR §20.61, this information may not be disclosed to the public in accordance with Freedom of Information (FOI) Act. In accordance with (21 CFR 807.95); the submitter considers their intent to market the device to be confidential commercial information.

There have been no prior formal correspondence with FDA regarding this submission.

The eCopy provided with this submission is an exact duplicate of the paper copy except that: (1) only the final signed cover letter was provided in paper form and (2) the eCopy includes all content.

The following submission details are provided in accordance with FDA Guidance "Format for Traditional and Abbreviated 510(k)s" issued August 12, 2005:

Device Common Name: Recorder, Attention Task Performance

Device Proprietary Name: ANAM Test System: Military Battery

Applicant: Vista LifeSciences, Inc.
PO Box 4670
Parker CO 80134
Phone: 888.733.8804 Ext. 1
www.vistalifesciences.com

Primary Correspondent: Calley Herzog
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Alternate Correspondent: Donna-Bea Tillman, Ph.D.
 Senior Consultant
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 Email: dtillman@bcg-usa.com
 Phone: 410-531-6542

Classification Regulation: Unclassified, Pre-Amendment

Panel: Neurology

Product Code: LQD

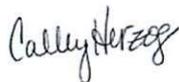
Basis for Submission: new device

Design and Use of the Device:

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

Please do not hesitate to contact me at any time during the review process to answer questions or provide additional information.

Sincerely,



Calley Herzog
 Consultant to Vista LifeSciences, Inc.
 Email: cherzog@bcg-usa.com
 Phone: 720-883-3633

January 22, 2015

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Center for Devices and Radiological Health
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The following submission details are provided in accordance with FDA Guidance "Format for Traditional and Abbreviated 510(k)s" issued August 12, 2005:

Device Common Name: Recorder, Attention Task Performance

Device Proprietary Name: ANAM Test System: Military Battery

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 Senior Consultant
 Biologics Consulting Group, Inc.
 Email: dtillman@bcg-usa.com
 Phone: 410-531-6542

Classification Regulation: Unclassified, Pre-Amendment

Panel: Neurology

Product Code: LQD

Basis for Submission: new device

Design and Use of the Device:

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

Please do not hesitate to contact me at any time during the review process to answer questions or provide additional information.

Sincerely,



Calley Herzog
 Consultant to Vista LifeSciences, Inc.
 Email: cherzog@bcg-usa.com
 Phone: 720-883-3633

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Vista LifeSciences, Inc.

ANAM Test System: Military Battery

510(k) Premarket Notification

January 22, 2015

Submitter: Vista LifeSciences, Inc.
PO Box 4670
Parker CO 80134
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G: References

(Reprints of each references listed in [Section 21](#))

1. MEDICAL DEVICE USER FEE COVER SHEET

FDA User Fee Cover Sheet is provided as *Appendix A1*.

2. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

FDA Form 3514 is provided as *Appendix A2*.

3. **510(K) COVER LETTER**

See separate PDF for final signed cover letter.

4. INDICATIONS FOR USE

Indication Statement:

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's medical or psychological state. Factors that may affect measurement of cognitive performance (such as reaction time and accuracy of responding) include, but are not limited to concussion, head injury, insomnia, post-traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress). ANAM results should be interpreted only by qualified professionals.

FDA Form 3881 is provided as *Appendix A3*.

5. 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for ANAM Test System: Military Battery is provided below.

Device Common Name: Recorder, Attention Task Performance

Device Proprietary Name: ANAM Test System: Military Battery

Applicant: Vista LifeSciences, Inc.
PO Box 4670
Parker CO 80134
Phone: 888.733.8804 Ext. 1
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Prepared by: Calley Herzog
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Phone: 720-883-3633
Fax: 703-548-7457

Date Prepared: **January 22, 2014**

Classification Regulation: Unclassified, Pre-Amendments

Panel: Neurology

Product Code: LQD

Predicate Device: K141865, DANA, AnthroTronix, Inc.

Indication for Use:

ANAM provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's medical or psychological state. Factors that may affect measurement of cognitive performance (such as reaction time and accuracy of responding) include, but are not limited to concussion, head

injury, insomnia, post-traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress). ANAM results should be interpreted only by qualified professionals.

Device Description:

ANAM Test System: Military Battery is a software only device that provides clinicians with objective measurements of cognitive performance in military populations, to aid in the assessment of an individual's medical or psychological state.

The software is downloaded from the Vista LifeSciences website and is for use on a Dell Latitude E6440 Laptop. The laptop is not provided as part of the device, but is purchased separately by the user. Each ANAM battery consists of a collection of pre-selected modules that are administered in a sequential manner.

Specific modules included in the ANAM Test System: Military Battery:

1. Demographics
2. Sleepiness Scale
3. Symptoms Checklist
4. Mood Scale
5. TBI Questionnaire
6. Simple Reaction Time
7. Code Substitution – Learning
8. Procedural Reaction Time
9. Mathematical Processing
10. Matching to Sample
11. Code Substitution – Delayed
12. Simple Reaction Time (R)

Performance Data:

The 510(k) included the results of numerous studies that examined the concurrent validity of ANAM as a clinical tool by documenting correlations with traditional neuropsychological tests. The results of these studies demonstrate that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

Substantial Equivalence:

Both the predicate device and ANAM are intended to “aid in the assessment of an individual’s medical or psychological state”. The predicate device does this by measuring reaction time and accuracy. ANAM also measures reaction time and accuracy, but also provides measures of fundamental neurocognitive functions including response speed,

attention/concentration, immediate and delayed memory, spatial processing, and decision processing speed and efficiency.

The intended use of ANAM is the same as that of the predicate device, namely to aid in the assessment of an individual's medical or psychological state.

A technological comparison is provided in the table below.

	Proposed Device	Predicate Device
510(k) Number	TBD	K141865
Device Name	ANAM Test System: Military Battery	DANA
Submitter	Vista LifeSciences, Inc.	Anthrotronix, Inc.
Classification Regulation	Pre-Amendments, Unclassified	Pre-Amendments, Unclassified
Product Code	LQD – Recorder, Attention Task Performance	LQD – Recorder, Attention Task Performance
Indication	ANAM provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's medical or psychological state. Factors that may affect measurement of cognitive performance (such as reaction time and accuracy of responding) include, but are not limited to concussion, head injury, insomnia, post-traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress). ANAM results should be interpreted only by qualified professionals.	DANA provides clinicians with objective measurements of reaction time (speed and accuracy) to aid in the assessment of an individual's medical or psychological state. Factors that may affect the measurement of reaction time include, but are not limited to concussion, head injury, insomnia, post traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress). DANA also delivers and scores standardized psychological questionnaires. DANA results should be interpreted only by qualified professionals.
Platform	PC: Dell Latitude E6440 Laptop Computer, Windows 7 operating system	Android and Apple mobile devices and mobile operating systems
Use Cases	Measures change over time and/or compares performance with military normative data.	Measures change over time.

	Proposed Device	Predicate Device
Patient Population	Military population	Not specified
Age of Users	18-65 years	Not specified
How Provided	Software only, downloaded	Software only, downloaded
Reporting features	ANAM Performance Report provides summary results in PDF format. Summary and Raw Data available in csv and xml file formats.	DANA report viewable in PDF format. Summary and Raw Data available in csv, xml, and html file formats.
Modules Included in Battery		
Demographics	Yes	Yes
TBI Questionnaire	Yes	No
Sleepiness Scale	Yes	Yes
Symptoms Checklist	Yes	No
Mood Scale	Yes	Yes
Simple Reaction Time	Yes	Yes
Code Substitution – Learning	Yes	Yes
Procedural Reaction Time	Yes	Yes
Mathematical Processing	Yes	No
Matching to Sample	Yes	Yes
Code Substitution - Delayed	Yes	Yes
Simple Reaction Time (Repeated)	Yes	Yes
Memory Search	No	Yes
Spatial Discrimination	No	Yes
Go No Go	No	Yes
PTSD modules	No	Yes

Summary / Conclusion of Substantial Equivalence Rationale

Although there are some differences in the modules between ANAM and the predicate device, and ANAM provides a comparison to a normative database, the performance testing demonstrates that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

6. TRUTHFUL AND ACCURACY STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Quality System Program Manager of Vista LifeSciences, 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)

Lori A. White
(Typed Name)

December 23, 2014
(Date)

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

7. CLASS III SUMMARY AND CERTIFICATION

Not applicable. This is not a Class III device.

**8. FINANCIAL CERTIFICATION AND DISCLOSURE
STATEMENT**

Not applicable. No clinical data is needed to support substantial equivalence of this device.

9. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

A declaration of conformity is not applicable, as this is not an Abbreviated 510(k).

There are no standards referenced in this 510(k), therefore Summary Reports (FDA Form 3654) are not provided.

10. EXECUTIVE SUMMARY

10.1. Device Description

ANAM Test System: Military Battery (also referred to as ANAM Military or ANAM) is a software only device that provides clinicians with objective measurements of cognitive performance in military populations, to aid in the assessment of an individual's medical or psychological state.

The software is downloaded from the Vista LifeSciences website and is for use on a Dell Latitude E6440 Laptop. The laptop is not provided as part of the device, but is purchased separately by the user. The ANAM Test System: Military Battery consists of a collection of pre-selected modules that are administered in a sequential manner.

Specific modules included in the ANAM Test System: Military Battery are:

1. Demographics
2. Sleepiness Scale
3. Symptoms Checklist
4. Mood Scale
5. TBI Questionnaire
6. Simple Reaction Time
7. Code Substitution – Learning
8. Procedural Reaction Time
9. Mathematical Processing
10. Matching to Sample
11. Code Substitution – Delayed
12. Simple Reaction Time (R)

For a more detailed device description, see [Section 11](#).

10.2. Indication for Use Statement

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's medical or psychological state. Factors that may affect measurement of cognitive performance (such as reaction time and accuracy of responding) include, but are not limited to concussion, head injury, insomnia, post-traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress). ANAM results should be interpreted only by qualified professionals.

FDA Form 3881 is provided as *Appendix A3*.

10.3. Reason for 510(k)

This is the first 510(k) submission for the ANAM Test System: Military Battery.

10.4. Substantial Equivalence

The predicate device for which substantial equivalence is established is the DANA, cleared in K141865 by AnthroTronix, Inc. DANA is a mobile based task performance recorder.

The intended use of ANAM is the same as that of the predicate device, namely to aid in the assessment of an individual's medical or psychological state.

Although there are some differences in the modules between ANAM and the predicate device, and ANAM provides a comparison to a normative database, the performance testing provided in Section 18 demonstrates that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

For a more detailed substantial equivalence analysis, see [Section 12](#).

10.5. Sterilization and Shelf Life

As a software only device, sterilization is not applicable and no shelf life is claimed for the device. Storage conditions could not affect safety and effectiveness.

10.6. Biocompatibility

As a software only device, there are no patient contacting components of the device and therefore biocompatibility is not applicable.

10.7. Performance Testing

Performance Testing – Bench

(b)(4) Confidential and Proprietary Information



Performance Testing – Animal

No animal studies were needed or provided in support of this 510(k).

Performance Testing – Clinical

No clinical studies were needed or provided in support of this 510(k).

11. DEVICE DESCRIPTION

11.1. General Description

ANAM Test System: Military Battery is a software only device that provides clinicians with objective measurements of cognitive performance in military populations, to aid in the assessment of an individual's medical or psychological state.

The software and related reference materials are downloaded from the Vista LifeSciences website. The downloaded components of the ANAM Test System: Military Battery include:

- ANAM Military Battery test modules
- ANAM Performance Report (APR)
- ANAM Performance Validity Index Report (Effort Measure)
- ANAM Data and Presentation Tool (ADEPT)
- ANAM Data Converter
- ANAM Administration Manual

The ANAM Test System: Military Battery is for use on a Dell Latitude E6440 Laptop. The laptop is not provided as part of the device, it is purchased separately by the user.

The ANAM Test System: Military Battery takes approximately 20-30 minutes to complete. In clinical and research settings, it is recommended that a professional be present during test administration in order to proctor the test administration and to make relevant behavioral observations related to the examinee's test performance (i.e., distractibility, impulsivity, fatigue, frustration, anxiety, tearfulness, etc.).

11.2. Intended Uses and Testing Paradigms

The ANAM Test System: Military Battery can be used by qualified health professionals to screen for general cognitive impairment within initial triage assessment/decision making or to obtain more refined and detailed information regarding neurocognitive status of individuals 18 to 65 years of age.

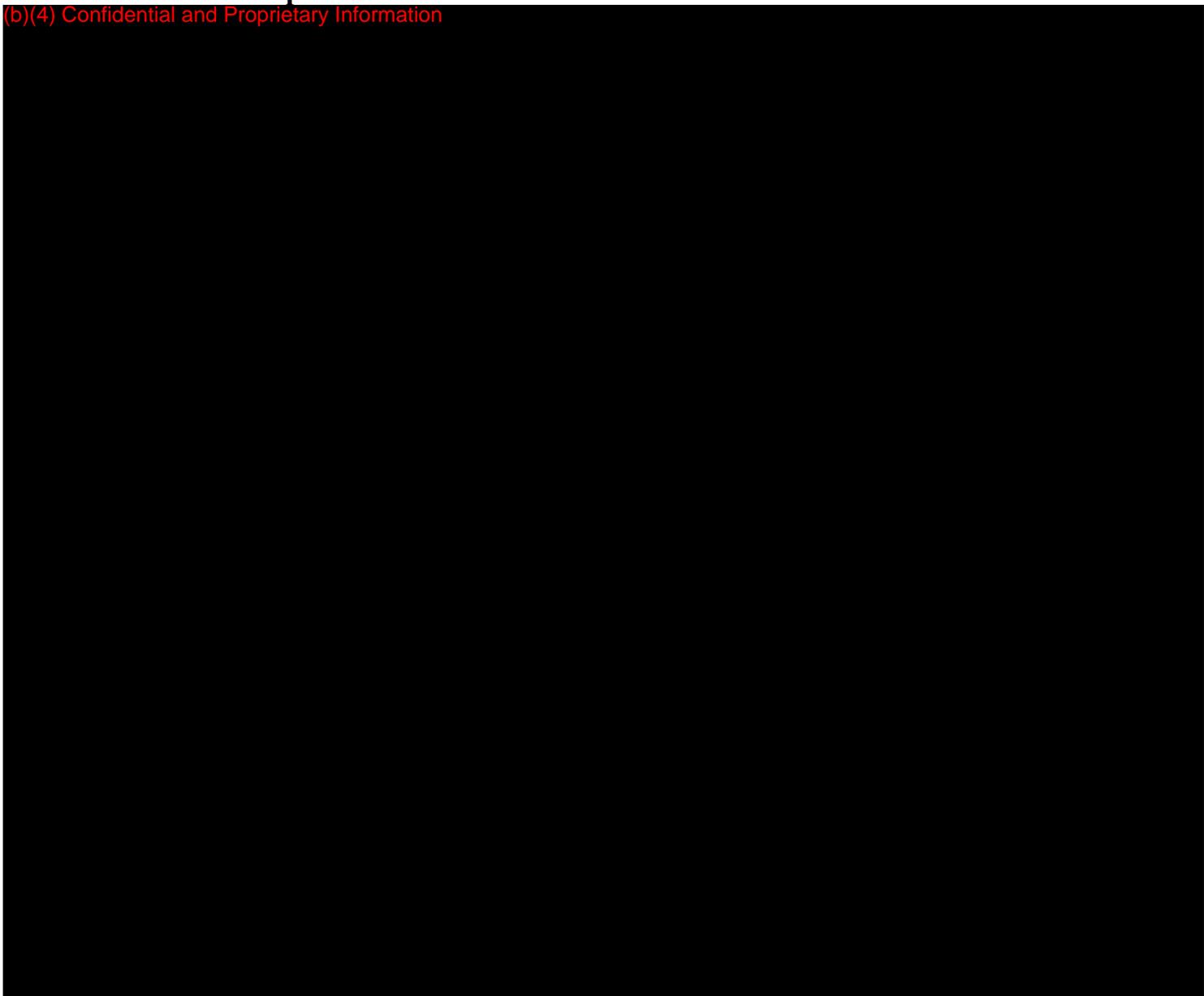
The ANAM Test System: Military Battery provides both absolute and relative information about the examinee's performance. Test performance can be compared to results from a previous testing point or to a pre-existing "baseline" if those data are available. If pre-existing testing data are unavailable, The ANAM Test System: Military Battery will provide a comparison of performance in relationship to a selected normative/reference group. The ANAM Performance Report software program will automatically provide comparisons to selectable reference groups as well as to the examinee's previous testing data, if available.

Testing frequency can vary according to the examinee's needs, the examinee's capability to take the test, other physical injuries or disease processes, and the appropriateness and strategic use of the test by the health professional. Testing frequency following disease or injury may also be determined by clinical management guidelines. In all cases, the frequency of testing should be clinically determined in conjunction with the symptoms associated with the disease or injury and other pertinent medical information.

The ANAM Test System: Military Battery can be *administered* by qualified professionals who have training in psychological testing principles and test administration procedures. This might include primary care providers trained in psychological test administration to assist in initial triage, assessment, or clinical guideline decision making, but this level of assessment activity would not include *clinical interpretation*. The ANAM Test System: Military Battery is a psychological test and the *clinical interpretation* of the test should be conducted by qualified medical professionals with training in psychological testing principles, test administration procedures, and clinical test interpretation. Further, The ANAM Test System: Military Battery should not be used alone to diagnose medical or mental diseases. It is not meant to replace more comprehensive tests or assessment procedures. It is important to use the test results in conjunction with other tests and information about the examinee before making any diagnostic or prescriptive decisions.

11.3. Description of Modules

(b)(4) Confidential and Proprietary Information



12. SUBSTANTIAL EQUIVALENCE DISCUSSION

12.1. Predicate Device

The predicate device for which substantial equivalence is established is the DANA, cleared in K141865 by AnthroTronix, Inc. DANA is a mobile based task performance recorder.

12.2. Indication for Use Comparison

The indications for use of the predicate device are:

DANA provides clinicians with objective measurements of ***reaction time (speed and accuracy)*** to aid in the assessment of an individual's medical or psychological state. Factors that may affect the measurement of reaction time include, but are not limited to concussion, head injury, insomnia, post traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress). DANA also delivers and scores standardized psychological questionnaires. DANA results should be interpreted only by qualified professionals.

The indications for use of the subject device are:

The ANAM Test System: Military Battery provides clinicians with objective measurements of ***cognitive performance in military populations ages 18 to 65 years***, to aid in the assessment of an individual's medical or psychological state. Factors that may affect measurement of cognitive performance (such as reaction time and accuracy of responding) include, but are not limited to concussion, head injury, insomnia, post-traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress). ANAM results should be interpreted only by qualified professionals.

The only difference in the indications is the text shown in bold italics above. The predicate device is indicated for a general population, while ANAM is indicated for a military population. This difference reflects the fact that the normative data provided for ANAM was collected from a military population. The predicate device does not provide norms. The ANAM population is a subset of the predicate device population, so this difference does not raise any new safety or effectiveness issues.

Fundamentally, both the predicate device and ANAM are intended to “aid in the assessment of an individual’s medical or psychological state”. The predicate device does this by measuring reaction time and accuracy. ANAM also measures reaction time and accuracy, but as discussed in ANAM Military Validation (***Appendix F1***), ANAM provides precise, objective, automated measures of fundamental neurocognitive functions including response speed, attention/concentration, immediate and delayed memory, spatial processing, and decision processing speed and efficiency.

12.3. Technological Comparison

The technological characteristics of the subject device are compared to the predicate device in [Table 4](#).

Table 4: Device Comparison Table

	Proposed Device	Predicate Device
510(k) Number	(b)(4) Confidential and Proprietary Information	
Device Name		
Submitter		
Classification Regulation		
Product Code		
Indication		
Platform		

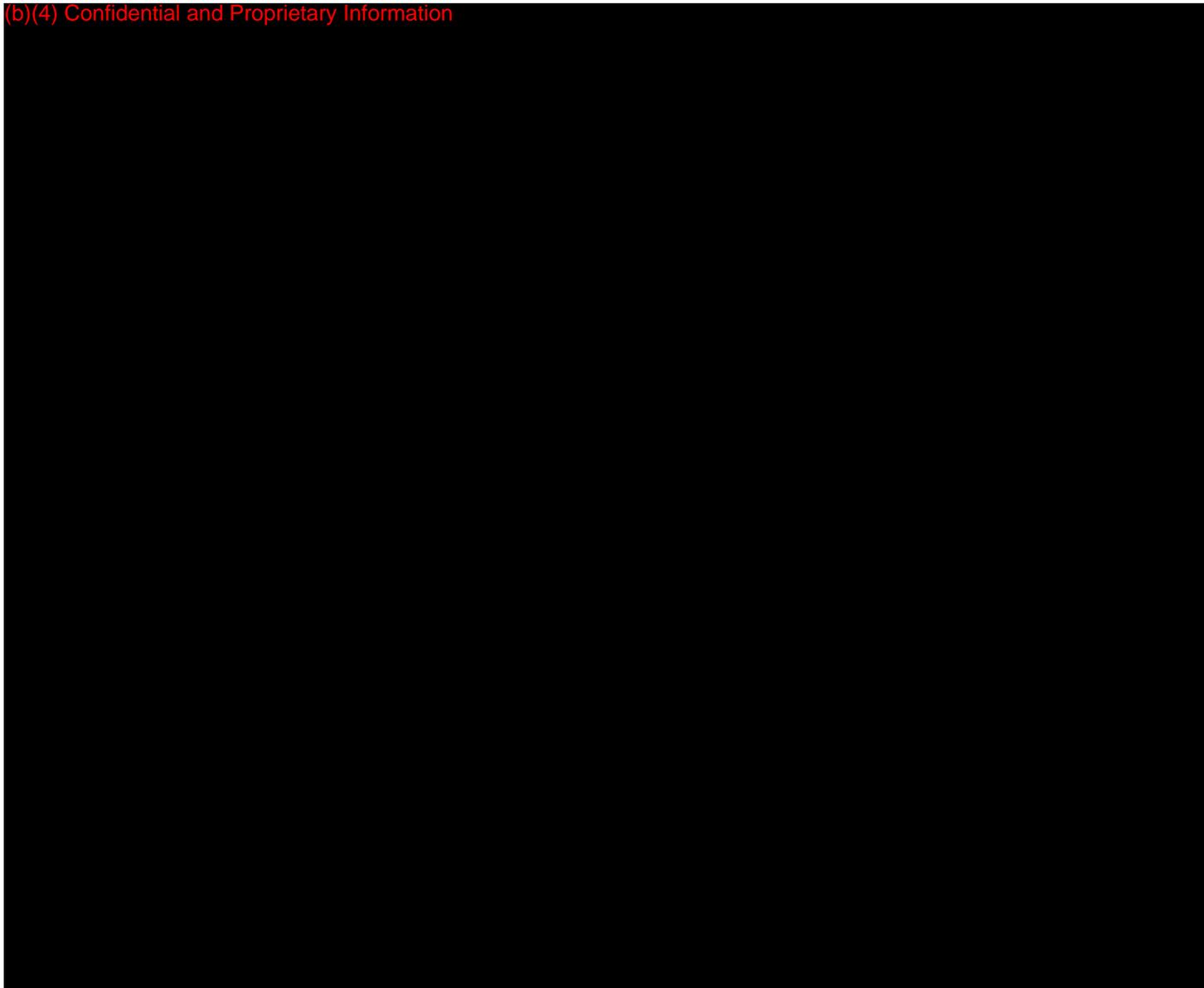
	Proposed Device	Predicate Device
Use Cases	(b)(4) Confidential and Proprietary Information	
Patient Population		
Age of Users		
How Provided		
Reporting features		

Modules Included in Battery

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13. PROPOSED LABELING

Labeling for the ANAM Test System: Military Battery is provided in *Appendix C* and includes:

- ANAM Test System: Military Battery Administration Manual (*Appendix C1*)
- Sample ANAM Performance Report (*Appendix C2*)
- Sample Validity Indicator Report (*Appendix C3*)

14. STERILIZATION AND SHELF LIFE

As a software only device, sterilization is not applicable and no shelf life is claimed for the device. Storage conditions could not affect safety and effectiveness.

15. BIOCOMPATIBILITY

As a software only device, there are no patient contacting components of the device and therefore biocompatibility is not applicable.

16. SOFTWARE

Per FDA Guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff”, the following sections summarize the required software documentation.

16.1. Level of Concern

The software level of concern for ANAM Test System: Military Battery is MODERATE.

This determination was reached by a careful review of the FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff”, (5/11/2005). The following list of questions and answers gives a summary of that decision making process:

Questions for Major Level of Concern

4. Does the Software Device qualify as Blood Establishment Computer Software?
No.
5. Is the Software Device intended to be used in combination with a drug or biologic?
No.
6. Is the Software Device an accessory to a medical device that has a Major Level of Concern?
No.
7. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:
 - a. Does the Software Device control a life supporting or life sustaining function?
No.
 - b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?
No.
 - c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?
No.
 - d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?
No.
 - e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?
No.

Questions for Moderate Level of Concern

1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?

No.

2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?

No.

3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

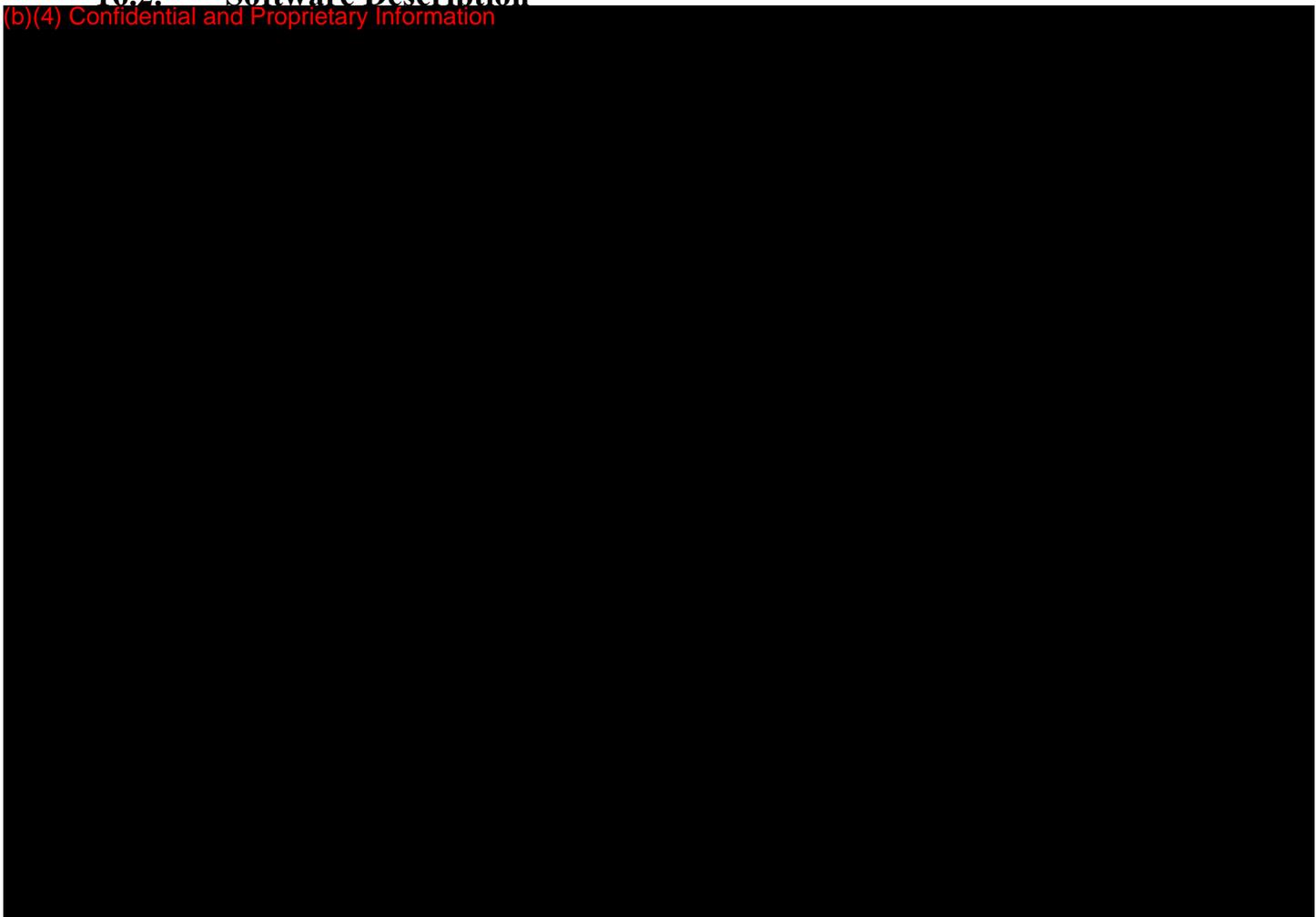
YES.

Level of Concern Rationale:

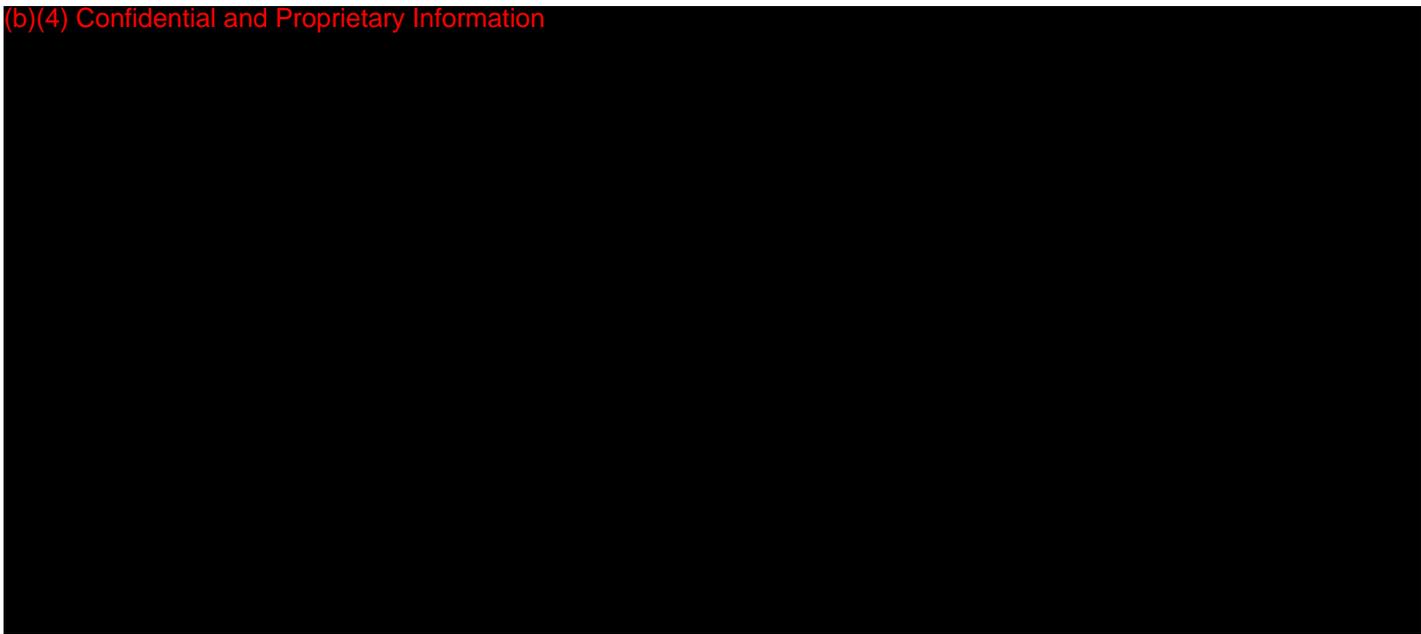
Based on the answers to the above questions the software level of concern for ANAM Test System: Military Battery is MODERATE.

16.2. Software Description

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16.3. Device Hazard Analysis

A Device Hazard Analysis was conducted and took into account all device hazards associated with the use of ANAM Test System: Military Battery. The analysis includes both hardware and software hazards. The hazards are presented in tabular form with a line item for each hazard. The device hazard analysis is provided as *Appendix D1*.

16.4. Software Requirements Specification (SRS)

The complete SRS is provided as *Appendix D2*.

16.5. Architecture Design Chart

The Architecture Design Chart is provided as *Appendix D3*.

16.6. Software Design Specification

The complete Software Design Specification is provided as *Appendix D4*.

16.7. Traceability Analysis

The Traceability Analysis is provided as *Appendix D5*.

16.8. Software Development Environment Description

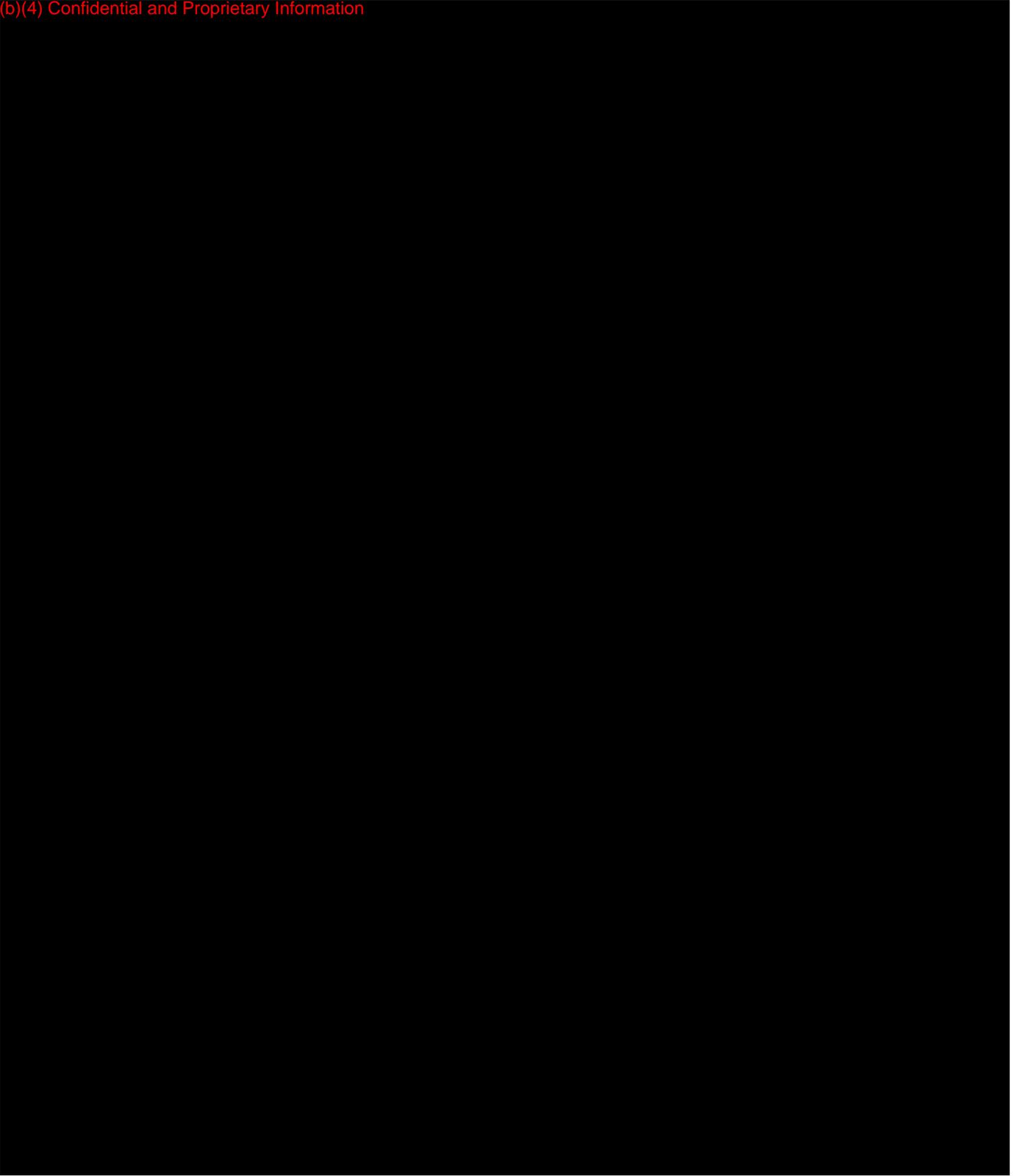
A summary of the software life cycle development plan, including a summary of the configuration management and maintenance activities is provided as *Appendix D6*.

16.9. Verification and Validation Documentation

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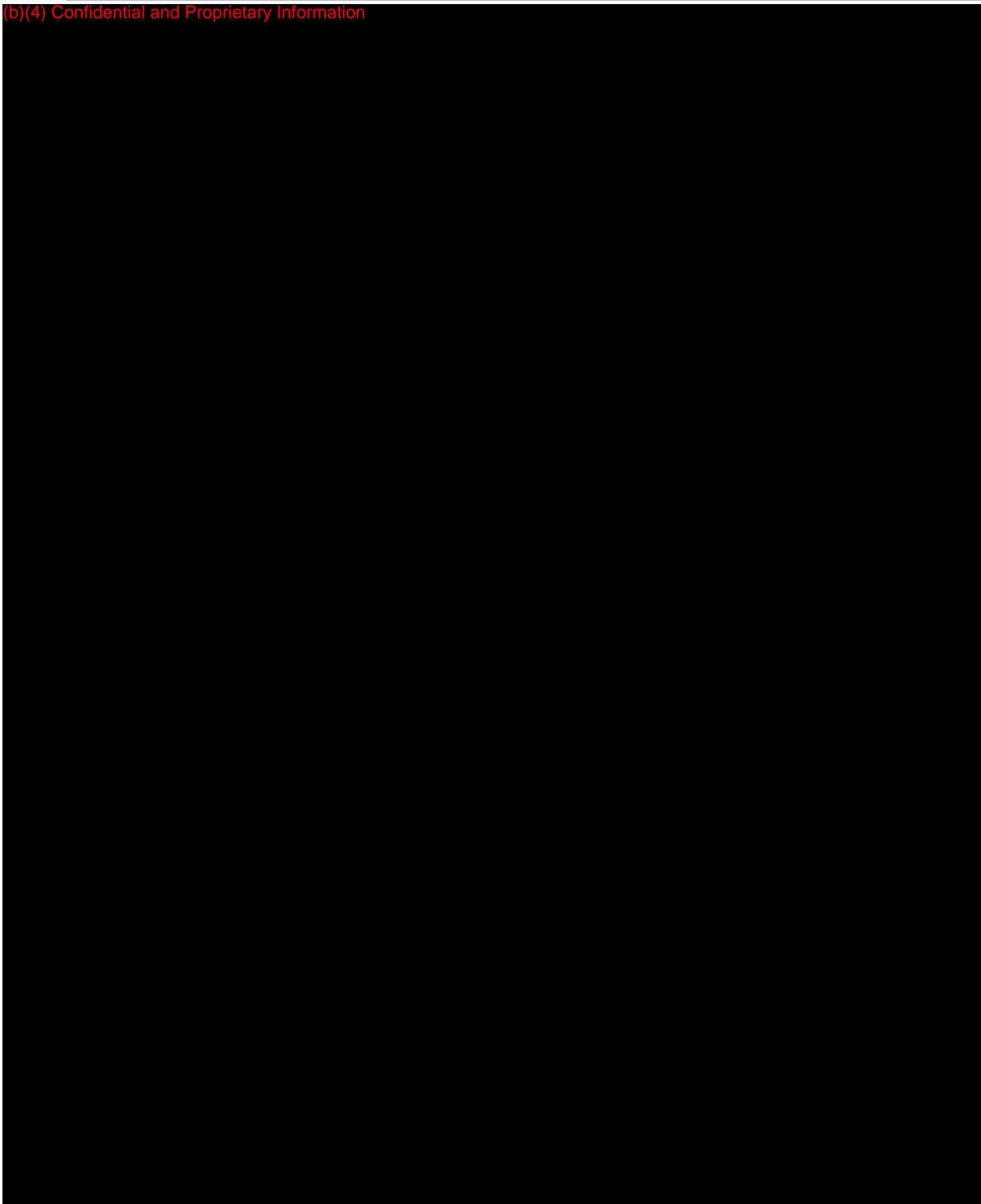
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16.10. Revision Level History

The revision level history is provided in *Appendix D9*. The ANAM Test System: Military Battery software release version that is the subject of this 510(k) is Version 4.3.

16.11. Unresolved Anomalies

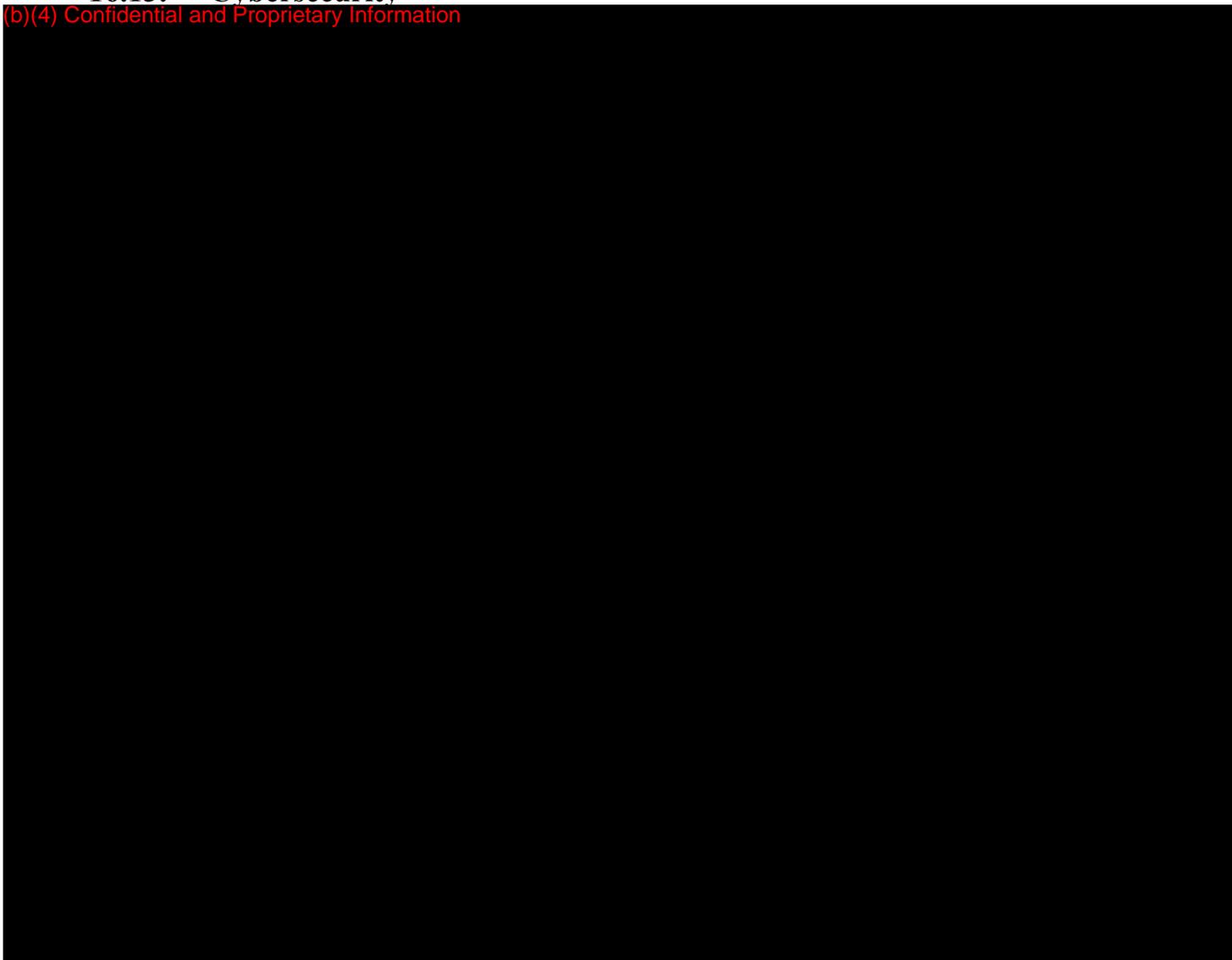
All bugs found during verification testing have been resolved. There are no unresolved anomalies in the release version that is the subject of this 510(k).

16.12. Off-the-Shelf Software

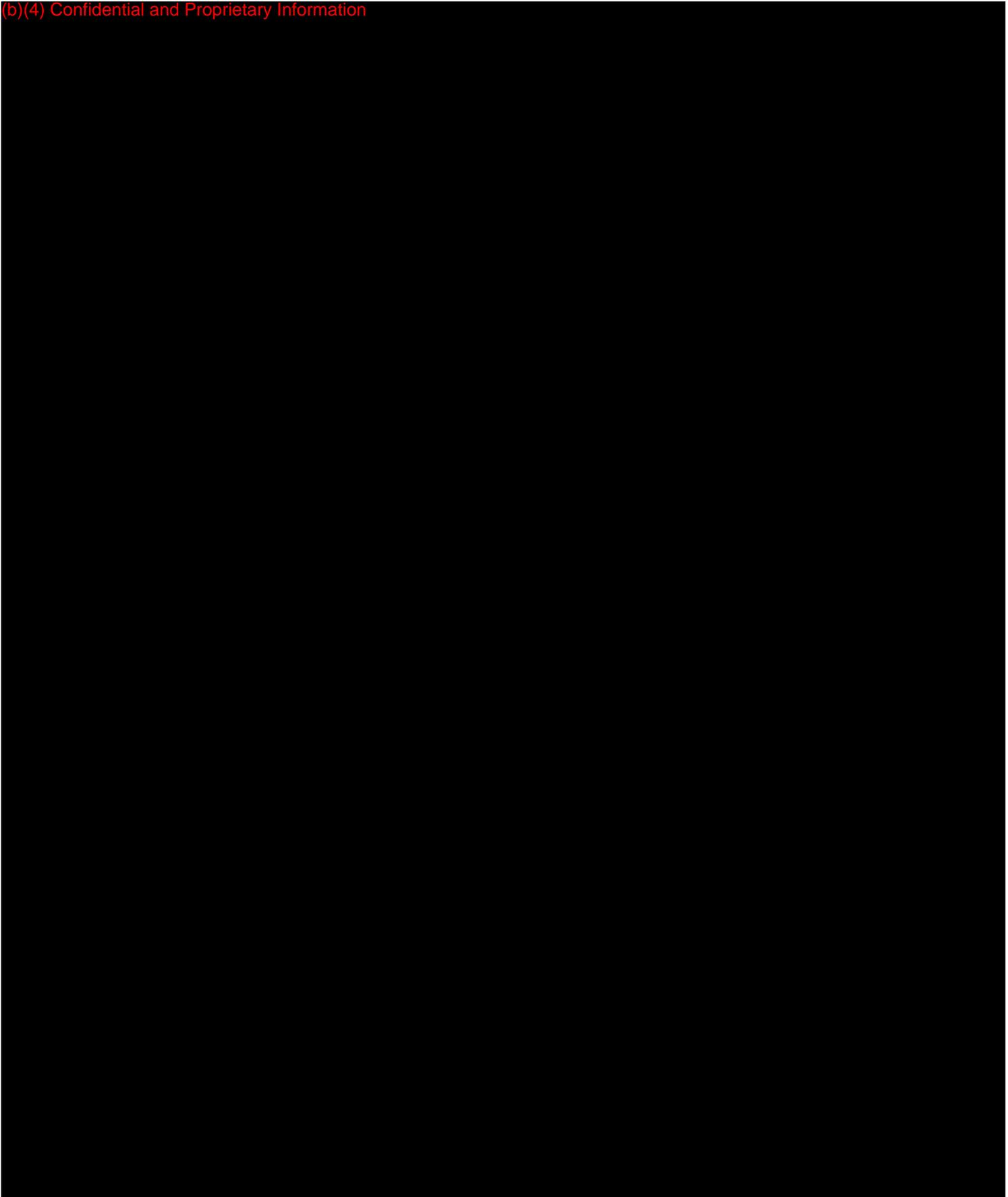
The Basic Requirements from the 1999 FDA Off-the-Shelf Software Guidance are provided as *Appendix D10*.

16.13. Cybersecurity

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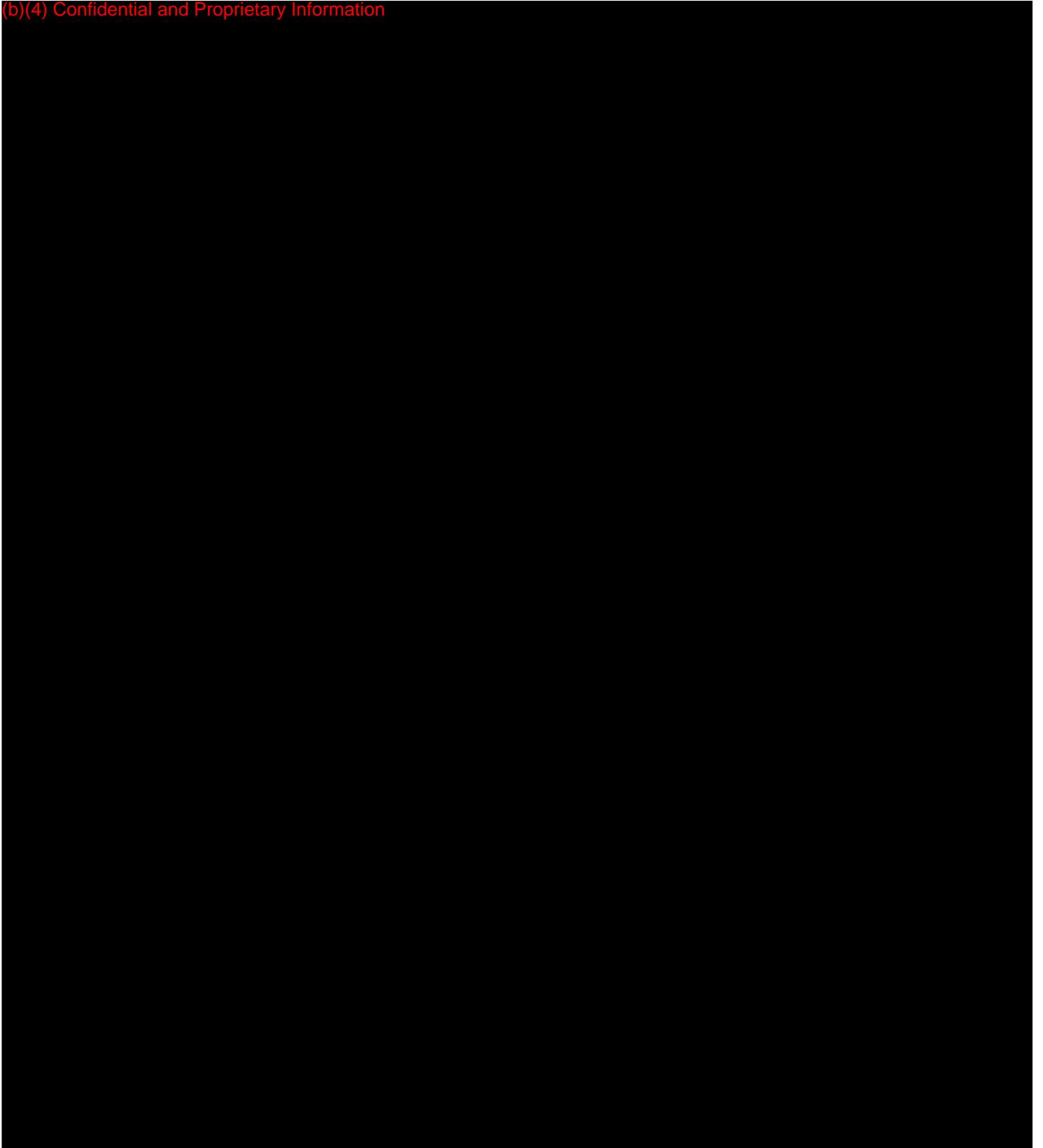
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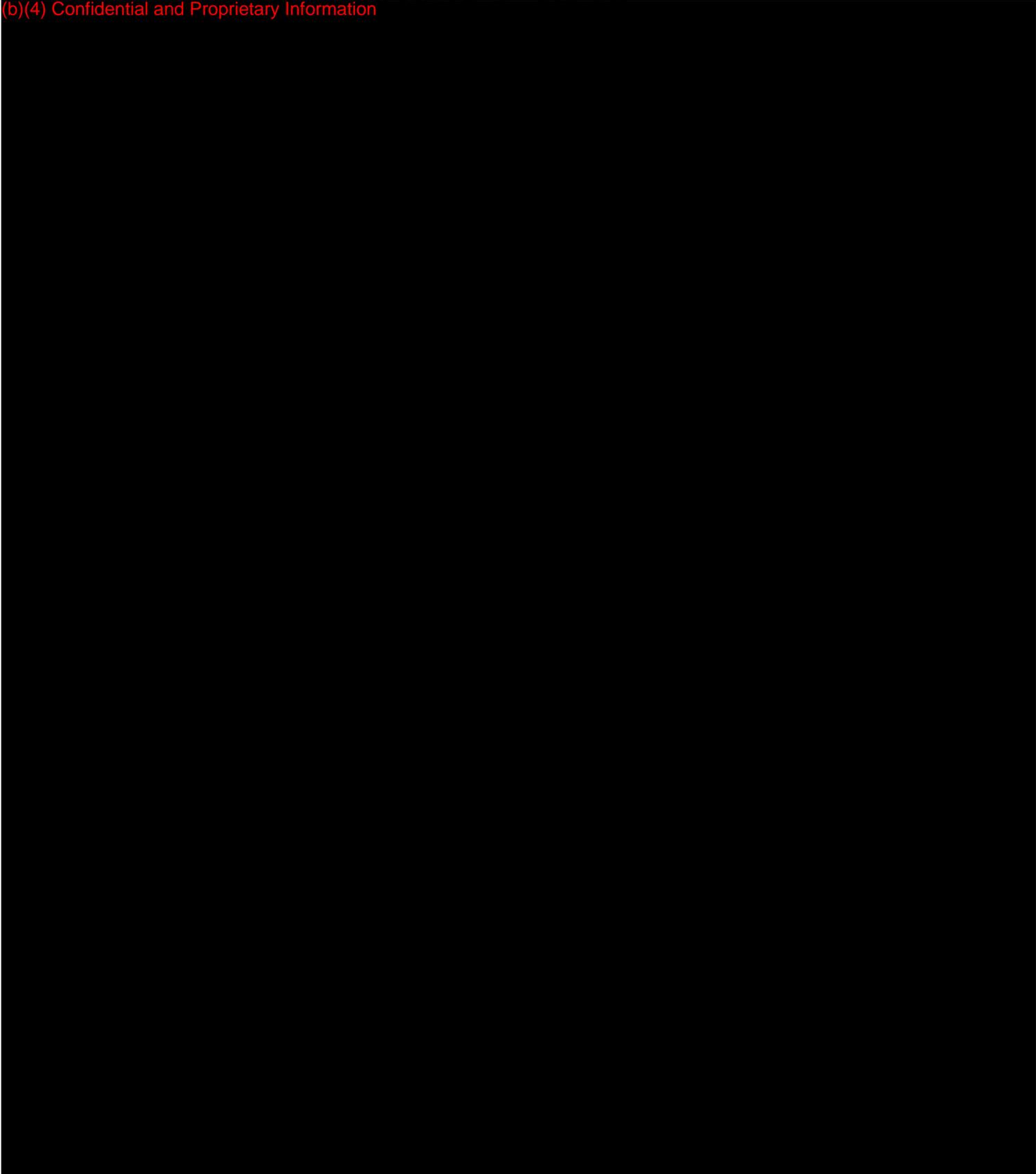
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17. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

As a software only device, electromagnetic compatibility and electrical safety are not applicable.

18. PERFORMANCE TESTING – BENCH

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19. PERFORMANCE TESTING – ANIMAL

Not applicable, animal testing is not required to establish substantial equivalence.

20. PERFORMANCE TESTING – CLINICAL

Not applicable, clinical testing is not required to establish substantial equivalence.

21. REFERENCES

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<p>1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)</p> <p>VISTA PARTNERS DBA VISTA LIFESCIENCES PO Box 4670 PARKER CO Douglas US 80134 US</p> <p>1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****9443</p>	<p>2. CONTACT NAME Lori White</p> <p>2.1 E-MAIL ADDRESS lori.white@vistalifesciences.com</p> <p>2.2 TELEPHONE NUMBER (include Area code) 888-7338804</p> <p>2.3 FACSIMILE (FAX) NUMBER (Include Area code) 202-3153316</p>
<p>3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm)</p> <p><u>Select an application type:</u></p> <p><input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice</p> <p><u>3.1 Select a center</u></p> <p><input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER</p> <p><u>3.2 Select one of the types below</u></p> <p><input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)</p>	
<p>4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)</p>	

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

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

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

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

NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <http://www.fda.gov/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
- This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- The sole purpose of the application is to support conditions of use for a pediatric population
- 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

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8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

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09-Jan-2015

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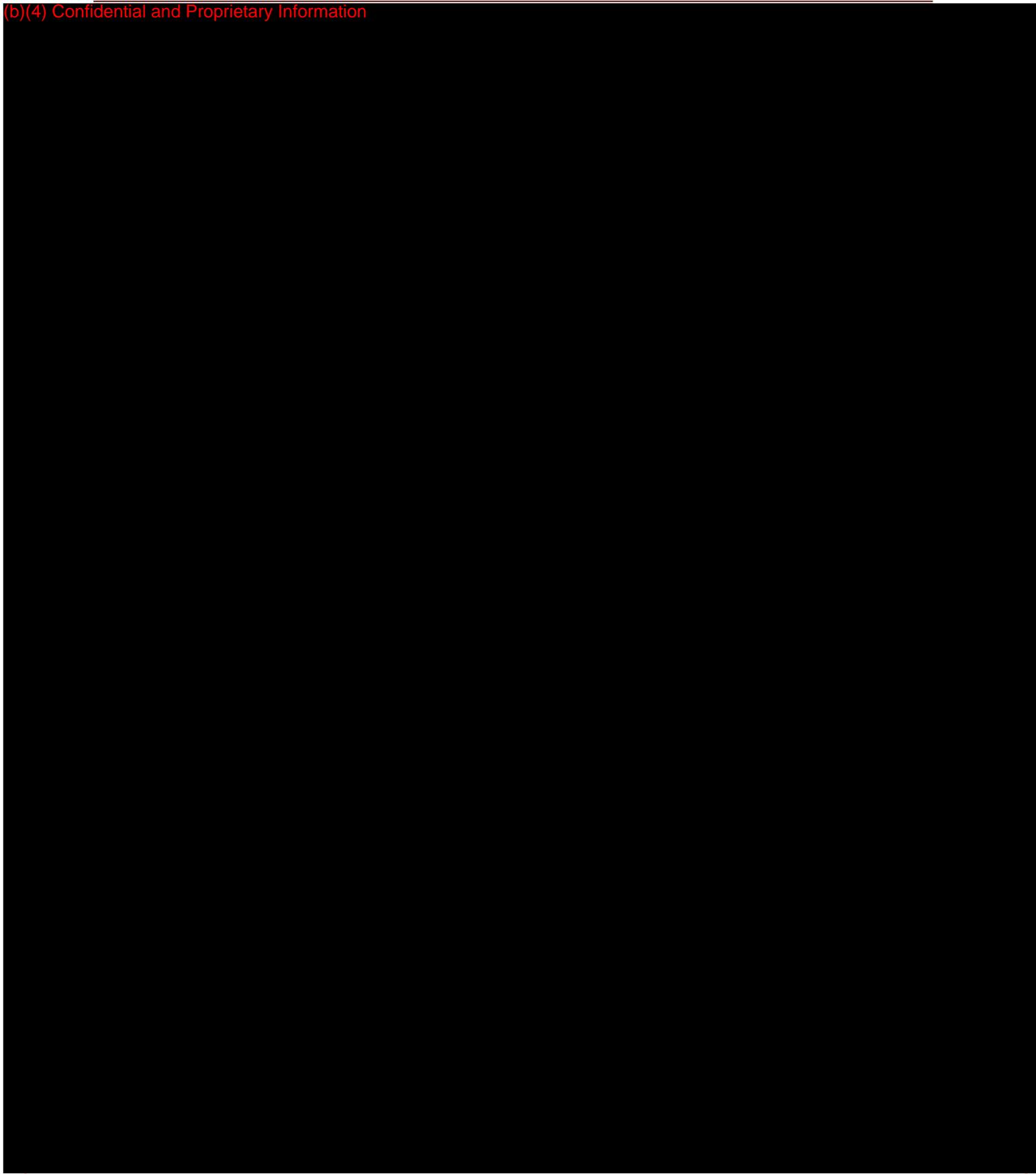
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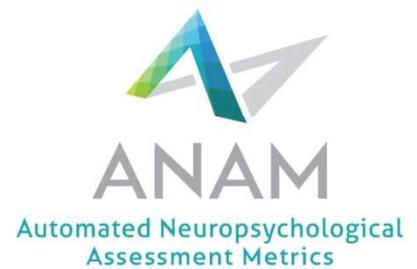
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ANAM Military Battery

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ANAM Test System: Military Battery Norms



ANAM[®] MILITARY BATTERY

Administration Manual





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Tel: 405 325 4444
www.csrc.ou.edu

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Printed in the USA.

Responsible Use of ANAM Military

CAUTION: Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner.

Indications for Use

ANAM provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's medical or psychological state. Factors that may affect measurement of cognitive performance (such as reaction time and accuracy of responding) include, but are not limited to concussion, head injury, insomnia, post-traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress). ANAM results should be interpreted only by qualified professionals.

What is the ANAM Military Battery?

ANAM Military is the Automated Neuropsychological Assessment Metrics (version 4) Military Battery. This battery was previously distributed as the ANAM TBI-Mil Battery. ANAM Military is classified as a psychological test and is regulated and distributed in accordance with the professional and ethical standards articulated by the *Ethical Principles of Psychologists and Code of Conduct* of the American Psychological Association (APA, 2002).

Who is qualified to administer ANAM Military?

ANAM Military can be *administered* by qualified professionals who have training in psychological testing principles and test administration procedures. This might include primary care providers trained in psychological test administration to assist in initial triage, assessment, or clinical guideline decision making, but this level of assessment activity would not include *clinical interpretation*. Test administrators should be supervised by a qualified professional trained in the administration and interpretation of psychological testing (e.g., psychologist or physician).

Who is qualified to interpret scores from ANAM Military?

The ANAM Military battery is a psychological test and the *clinical interpretation* of the test should be conducted by qualified medical professionals with training in psychological testing principles (including understanding of psychometrics), test administration procedures, and clinical test interpretation.

Is ANAM a “diagnostic” test?

ANAM measures cognitive functioning and should not be used alone to diagnose medical or mental diseases, disorders or conditions. It is not meant to replace more comprehensive tests or assessment procedures. ANAM test results should be interpreted in conjunction with information about the test taker and potentially other relevant tests before making diagnostic or prescriptive decisions.

Disclaimer

The use of ANAM does not constitute the practice of medicine or the provision of professional health care advice. The information provided in ANAM is of a general nature and does not represent medical advice, a diagnosis, or prescription for treatment. Only qualified medical professionals should interpret test results. CSRC and the University of Oklahoma are not responsible for any decisions made based on ANAM test results. A qualified medical professional has the sole responsibility for establishing diagnosis and suggesting appropriate treatment.

Preface

Welcome to the Automated Neuropsychological Assessment Metrics (ANAM). ANAM is the latest in an evolutionary line of computer test batteries sponsored by the Department of Defense originating in the late 1970s. This long and distinguished history provides ANAM with a rich foundation in classical laboratory-based human performance assessment technology as well as modern clinical neuropsychological assessment methods and techniques. The result is a computer test battery with remarkable versatility and flexibility to meet a wide range of assessment needs.

The ANAM test system consists of a library of computer-based tests designed for a broad spectrum of clinical and research applications.

ACKNOWLEDGMENTS

Many individuals have contributed to computer test development efforts that have directly culminated in the current ANAM system. Noteworthy among them is Dennis Reeves (then LCDR USN), who creatively managed the transition from early generation computer test batteries through one of the first PC-based systems. The original ANAM[®] (version 1.0) development team included: Fred Hegge, Dennis Reeves, Kathy Winter, Kathy Raynsford, Sam LaCour, Gary Kay, & Tim Elsmore. This effort successfully migrated many tests of core human performance from varied early-generation computer hardware platforms to the IBM PC/Windows-based platform while also implementing some of the first international design specifications (the NATO AGARD Standardized Tests for Research with Environmental Stress, NATO AGARD Working Group 12) for computer-based tests.

The U.S. Army Medical Research and Materiel Command, Fort Detrick, MD, has been the primary organization that has supported the development of ANAM4 and many of its predecessor test batteries. Continuing Dr. Fred Hegge's visionary support of computer-based testing technology to broad-ranging military applications, many others at USAMRMC have been instrumental in continuing the legacy of ANAM4 including COL Karl Friedl, Dr. Stephen Grate, and COL Brian Lukey.

The original software development efforts for ANAM were managed by Kathy Winter of the U.S. Navy Space and Navy Warfare Systems Command (SPAWAR), NAS Pensacola, Florida. Key past and present members of the programming team (in alphabetical order) include Kerry Culligan, Michael Flanagan, Timothy Howard, Samuel LaCour, Phillip Muldoon, and Kathy Raynsford.

Over the years, many other individuals have contributed to the development of ANAM. Notable among them are Dr. Robert Kane, Dr. Joseph Bleiberg, Dr. Alan Lewandowski, and Dr. Jack Spector. Assuredly, there have been many others who have contributed to the evolution and development of ANAM, and their contributions are gratefully appreciated. Portions of this manual were contributed by John Woodard, PhD.

The Cognitive Science Research Center (CSRC; formerly the Center for the Study of Human Operator Performance) at the University of Oklahoma in partnership with Vista LifeSciences, Inc., are jointly responsible for the current management, development, and enhancement of ANAM as well as future ancillary products. ANAM is distributed exclusively by Vista LifeSciences, Inc.

ADDITIONAL RESOURCES

Support and Services

For information regarding licensing or End User License Agreements for ANAM software or if you experience problems with your software installation or operation, please contact Vista LifeSciences, Inc.

Email: support@vistalifesciences.com
Phone: (888) 733-8804 (United States)

Vista LifeSciences and CSRC are committed to helping you get the most out of your ANAM software. Visit the Vista LifeSciences website at <http://www.vistalifesciences.com> where you can learn more about ANAM.

REFERENCING ANAM

Bibliographic citation for ANAM Military

Automated Neuropsychological Assessment Metrics (Version 4) Military Battery [Computer software]. (2015). Denver, CO: Vista LifeSciences, Inc.

Bibliographic citation for this manual

CSRC (2015). *ANAM Military: Administration Manual*. Cognitive Science Research Center, University of Oklahoma, Norman, OK.

TYPOGRAPHICAL CONVENTIONS

This manual uses the following typographical conventions to aid the user in understanding references to specific program objects and other types of information.

Formatting Convention	Type of Information
Courier Bold	Items you must select, such as menu options, command buttons, or items in a list.
<i>Emphasis</i>	Used to emphasize the importance of a point or to reference screen names.
CAPITALS	Names of keys on the keyboard. Example: SHIFT , CTRL , or ALT .
< KEY >+< KEY >	Key combinations for which the user must press and hold down one key and then press another, for example, < ALT >+< F1 >.

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Introduction

The purpose of this document is to present specific guidelines for administering and interpreting the ANAM Military Battery. These guidelines should be strictly followed, with any deviation being clearly noted on the summary outputs or in added comments in the ANAM Performance Report (APR™).

1.1 BRIEF HISTORY OF ANAM®

ANAM is the culmination of a long line of computer-based test systems developed by the Department of Defense and evolved principally from the Unified Tri-Service Cognitive Performance Assessment Battery (UTC-PAB; Englund, Reeves, et al., 1987). The UTC-PAB specifications developed from a set of military batteries including: the U.S. Army Walter Reed Performance Assessment Battery (WRPAB; Thorne, Genser, et al., 1985), the U.S. Air Force Criterion Task Set (CTS; Shingledecker, 1984), the U.S. Navy Performance Evaluation Tests for Environmental Research (PETER; Bittner, Carter, et al., 1986), and the NATO Advisory Group for Aerospace Research and Development Standardized Tests for Research with Environmental Stressors (AGARD-STRES; Reeves, Winter, et al., 1991). WRPAB's original purpose was performance assessment in continuous performance paradigms and determination of efficacy of performance degradation countermeasures. Development of the PETER battery began in 1977 with the objective of identifying traditional cognitive measures suitable for test/retest administration. In a subsequent effort Naval personnel developed the Naval Medical Research Institute Performance Assessment Battery (NMRI-PAB) in an effort to standardize assessment of operational environment effects on military performance. The Harry G. Armstrong Aerospace Medical Research Laboratory developed the CTS to assess mental workload.

In the mid-1980s available tests were evaluated by the Tri-Service Joint Working Group on Drug Dependent Degradation in Military Performance JWGD3-MILPERF with the intent of sponsoring development of neuropsychological performance tests with a major goal of assessing the effect of operational pharmaceuticals on military performance. It was demonstrated that a number of the most sensitive neuropsychological measures were not suitable for use due to practice effects or were not designed for extended baseline studies. The JWGD3-MILPERF transitioned into the Office of Military Performance Assessment Technology (OMPAT). OMPAT led the standardization of computerized operational performance test systems that subsequently developed into the UTC-PAB and, later, ANAM. Prior research studies supported selected modules in the UTC-PAB library because of their construct validity, reliability, and sensitivity. The UTC-PAB proved to be a flexible system and formed the basis for other test batteries, including the NATO AGARD-STRES battery.

ANAM began with the technology first developed by the OMPAT for the AGARD-STRES battery and the UTC-PAB and was improved by program innovations that permitted extraordinary timing accuracy. ANAM also integrated a wider range of performance tests. Further development, including transition from MS-DOS to the MS Windows platform, was directed through the Military Operational Medicine Research Program at the United States Army Medical Research and Materiel Command (USAMRMC). The early versions of ANAM were developed for the MS-DOS operating system with the Windows version of the library beginning in 1995. The success of ANAM in research and clinical applications led to increased pressure for accessibility and usability, as well as a more comprehensive method for developing, managing, distributing, and sustaining ANAM. In 2006, ANAM was licensed to the Center for the Study of Human Operator Performance (C-SHOP; now the Cognitive Science Research Center) at the University of Oklahoma, which has, during the entire developmental period of the DoD batteries beginning in 1984, provided basic research, quality assurance, and human factors engineering support related to computer-based test system development.

After receiving the exclusive license for ANAM, C-SHOP researchers and staff surveyed ANAM users, initiated a quality assurance assessment of the existing ANAM software, and then set about making improvements and innovations in order to produce an enhanced suite of ANAM software products that would provide greater uniformity, capability, and usability. C-SHOP released an improved version of the ANAM test modules (version 4.0 or ANAM4™) in the Fall of 2006. C-SHOP also released a significantly enhanced software tool for ANAM data aggregation and management (the ANAM Data Extraction and Presentation Tool—ADEPT) and completely new software tools including 1) the ANAM Performance

Report (APR), for producing reports of individualized ANAM test performance and 2) the ANAM Effort Measure Program for assisting in the determination of performance validity.

1.2 ABOUT THE ANAM MILITARY BATTERY

The ANAM Military Battery (previously known as the ANAM4 Traumatic Brain Injury-Military version (TBI-Mil) Battery) is a selection of modules from the ANAM library designed to aid in the assessment of general cognitive function. Specific modules for this battery were chosen based on demonstration of their sensitivity to cognitive dysfunction in the broader ANAM literature (see ANAM reference list), due to their sensitivity to the subtle effects of cognitive change, and based on recommendations from a panel of subject matter experts. ANAM Military provides precise, objective, automated measures of fundamental neurocognitive functions including response speed, attention/concentration, immediate and delayed memory, spatial processing, and decision processing speed and efficiency.

Qualities of ANAM Military are consistent with past applications of computer-based testing, with normative work conducted by DVBC, and with the *Clinical Practice Guidelines and Recommendations* published by the Defense and Veterans Brain Injury Center Working Group on the Acute Management of Mild Traumatic Brain Injury in Military Operational Settings (Helmick, 2006).

This manual was specially constructed to provide information regarding the features of ANAM Military. Modules in ANAM Military include the following:

ANAM Military Module List	Domain/Function
Demographics	Examinee Profile
TBI Questionnaire	TBI History
Sleepiness Scale	Sleepiness
Mood Scale	Mood State
Simple Reaction Time	Basic neural processing (speed/efficiency)
Code Substitution – Learning	Associative Learning (speed/efficiency)
Procedural Reaction Time	Processing Speed (choice RT/rule adherence)
Mathematical Processing	Working Memory
Matching to Sample	Visual Spatial Memory
Code Substitution – Delayed	Memory (delayed)
Simple Reaction Time (R)	Basic neural processing (speed/efficiency)

1.3 ANAM APPLICATIONS AND TESTING PARADIGMS

1.3.1 What Does the ANAM Military Battery Provide?

ANAM provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's medical or psychological state. Factors that may affect measurement of cognitive performance (such as reaction time and accuracy of responding) include, but are not limited to concussion, head injury, insomnia, post-traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress). ANAM results should be interpreted only by qualified professionals.

1.3.2 What is the basic ANAM Military testing paradigm?

ANAM Military provides both absolute and relative information about the test taker's performance. Test performance following an injury, event, or intervention can be assessed by comparing a person's test results to a previous testing point or to a pre-existing "baseline" if those data are available. If pre-existing testing data are unavailable, ANAM Military will provide a comparison of performance in relationship to a normative group. The ANAM Performance Report software program will automatically provide comparisons to the selected normative group as well as to the test taker's previous testing data, if available.

1.3.3 When should the ANAM Military test battery be administered?

Testing protocols vary according to the patient's needs, the patient's capability to take the test, other physical injuries or disease processes, and the appropriateness and strategic use of the test by the health professional. Testing frequency following disease or injury may also be determined by clinical management guidelines. In all cases, the frequency of testing should be clinically determined in conjunction with the symptoms associated with the disease or injury and other pertinent medical information.

Installing ANAM

This chapter provides the basic information necessary to install and run the ANAM software.

SPECIAL NOTE: These instructions assume download-based installation procedures with the computer user having full “Administrator privileges.” Because many government or institutional computer systems do not provide users with complete “Administrator privileges”, you may need to contact your local IT support team to obtain permission to install ANAM.

2.1 HARDWARE AND SYSTEM REQUIREMENTS

Platform Requirements

<i>Computer Type:</i>	Dell Latitude E6440 Laptop
<i>Operating System:</i>	Windows 7 Professional SP1
<i>Processor Speed:</i>	2.5 GHz
<i>Processor Type:</i>	Intel Core i5-4200M Processor
<i>RAM:</i>	4 GB
<i>Hard Drive:</i>	320 GB (minimum available disk space 300 MB)
<i>Mouse Device:</i>	USB 2.0 standard two-button; Dell M-UAN DEL with standard mouse pad
<i>Keyboard:</i>	USB 2.0 connected keyboard
<i>Display:</i>	14.0 inch HD (1366x768)
<i>Other Software:</i>	AVG AntiVirus Free Edition 2014 Microsoft .NET Framework v3.5 and v4.0 Adobe Reader 11
<i>Power Supply:</i>	AC power

Available software within the full ANAM Test System includes ANAM, ANAM Performance Report (APR), ANAM Data Extraction and Presentation Tool (ADEPT), and ANAM Effort Measure. All applications have been designed for use on the recommended platform. ANAM should be installed on a local drive – not on a network or shared drive. Windows 7 (SP1) is supported by ANAM. The latest Windows service pack and critical updates must be performed regularly.

The ANAM Test System requires Microsoft .NET Framework versions 3.5 and 4.0 to be installed prior to ANAM installation. In most cases the installation of .NET will happen automatically. In some cases, the computer user may be prompted to provide permission before it is installed.

Microsoft .NET Framework Installation

The Microsoft .NET Framework v3.5 AND v4.0 are required for the ANAM Test System. If versions 3.5 and 4.0 are not installed on your machine, they may be downloaded for free from Microsoft’s website. Download v3.5 at <http://www.microsoft.com/en-us/download/details.aspx?id=65> and v4.0 at <http://www.microsoft.com/en-us/download/details.aspx?id=17718>.

Cybersecurity

Antivirus software should be installed and administered according to manufacturer’s instructions. Scheduled scans must occur during non-business or off-peak hours to mitigate any potential performance impact.

CAUTION: It is important to note that anti-virus software must be temporarily disabled before administering ANAM. AVG provides instructions to its users regarding how to perform this step: <http://www.avg.com/us-en/faq.num-3857>.

Disabling antivirus software temporarily before administering ANAM will provide the best tradeoff between security and performance.

ANAM offers additional security protections including the ability for the user to limit access to reporting and data features by implementing Test Taker User Mode settings (see [4.4.2 ANAM Initial Set-up](#)). It is also recommended that users implement standard security practices including strong passwords, smart cards, or biometric authentication to limit access to PCs with ANAM installed. Hardware should be stored in a secured/locked location when not in use.

Input Devices

ANAM should be administered using a two-button USB-connected mouse and a standard mouse pad.

CAUTION: Use of the mouse tracking-pad and/or buttons built into laptop computers is not recommended. Additionally, Bluetooth and/or wireless mouse devices are not recommended and may result in unreliable comparison to normative groups.

Peripheral Devices and Power Source

CAUTION: ANAM utilizes a highly sensitive timing mechanism to record sub-second response times. Loss of timing accuracy may be cumulative as peripheral devices are added. Therefore, only peripheral devices that are recommended while administering ANAM tests are the keyboard and the USB-connected mouse device. Examples of peripheral devices that are not recommended include printers, scanners, and laptop docking stations to name a few. When the option is available for laptop computers, ANAM should be operated using the AC power cord instead of battery power.

2.2 INSTALLING ANAM

The ANAM Software installation program consists of a series of easy-to follow dialogs that lead you through the installation procedure.

To install ANAM and the support software products, ADEPT, APR, and Effort Measure:

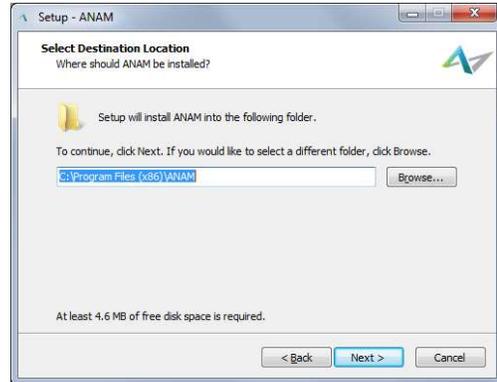
1. Double-click on the installer program provided to you.
2. Click **Next** in the *Installation dialog*.
3. Read the ANAM license agreement and, if you accept the agreement, then click **I Accept...** . If you decline, the software will not install.
4. Click **Next**.



The default installation directory is **C:\Program Files\ANAM**.

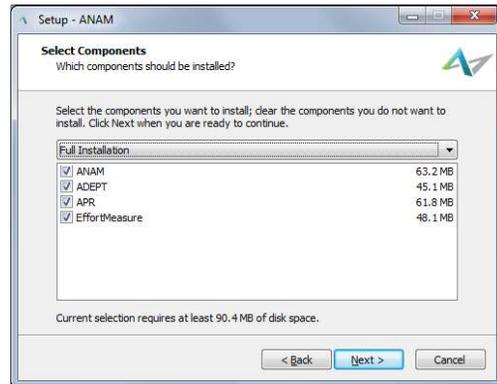
Install location was previously **C:\Program Files\C-SHOP**.

5. Click **Next**.

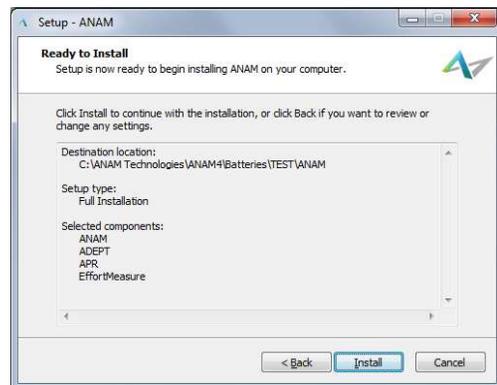


6. Select software to install.

All software packages are selected for installation () by default. If you do not want to install a software package, click on the check box next to it to uncheck it ().

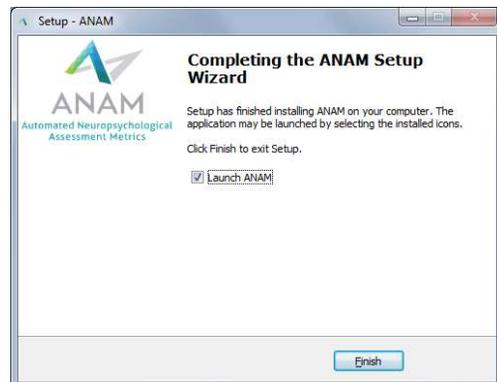


7. Click **Next**.



8. Verify installation settings then Click **Install**.

9. Click **Finish**.



After the ANAM files are copied to your computer, the installation is complete. A desktop icon for the installed product will be created.

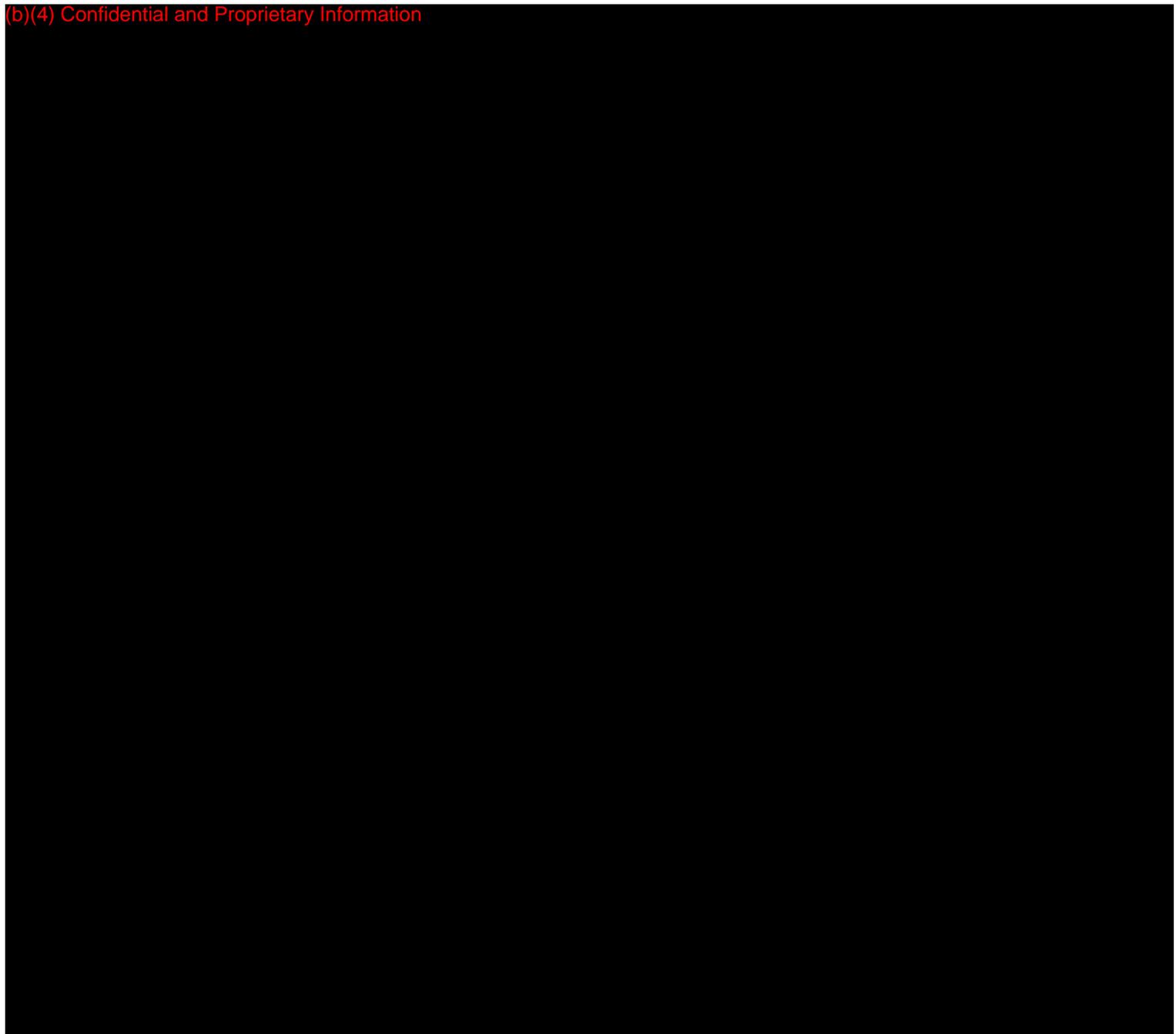


ANAM Military Modules

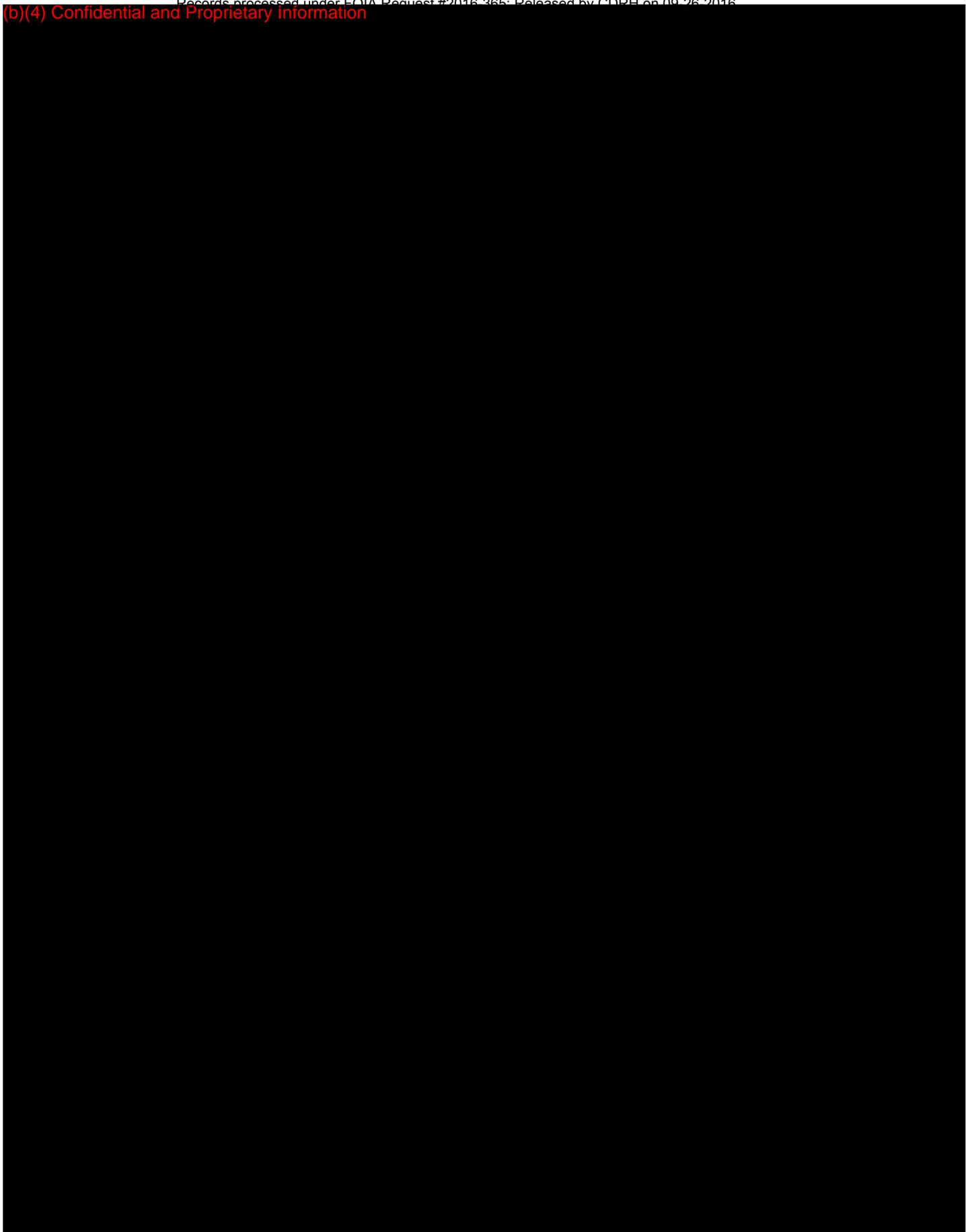
The ANAM Military battery consists of a collection of pre-selected modules that are administered in a sequential manner. Specific modules included in the ANAM Military Battery are described in this chapter.

3.1 ANAM MILITARY MODULE DESCRIPTIONS

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



ANAM Military Test Administration

4.1 USER QUALIFICATIONS

The ANAM Military Battery is a psychological test and should be interpreted by qualified medical professionals with training in psychological test administration and experience in assessment of cognitive functioning. Responsible understanding and interpretation of ANAM Military test scores requires knowledge about and experience with the individual ANAM Military tests, the test scores, and the format of the ANAM Performance Report (APR) and ANAM Performance Validity Indicator Report. Therefore, the reader is strongly advised to understand well the information in other sections of this manual, especially information related to ANAM Military modules ([Chapter 3](#)), the ANAM Performance Report ([Chapter 6](#)), and the ANAM Effort Measure ([Chapter 7](#)).

CAUTION: Interpretation of scores from ANAM Military must only be performed by a licensed psychologist with training in the clinical use of ANAM. Responsible interpretation of ANAM tests should always be considered within the broader framework of information regarding the test taker including: demographic and premorbid factors, behavioral and environmental factors that may impact performance, medical and psychiatric history, details regarding current presenting history, and other possible contributing factors to cognitive functioning.

4.2 GENERAL TEST ADMINISTRATION GUIDELINES

4.2.1 Test Administrators

ANAM Military is to be administered by professionals who have been trained in the proper administration procedures for psychological testing. Furthermore, training of ANAM Military test administrators in standardized procedures helps to reduce variability between test administrations and ensure consistency of test data across administrations.

CAUTION: Test administrators should

- inform themselves and seek appropriate training regarding standard testing procedures, the purposes of the testing, the kinds of tasks involved, the method of administration, and the scoring and reporting of test performance;
- have sufficient experience and training in how to operate equipment;
- ✓ have sufficient training in their specific responsibilities and the administration procedures for the test;
- review test materials, administration sites, and procedures prior to testing session to ensure standard conditions;
- ✓ arrange for appropriate modifications of testing materials and procedures in order to accommodate test takers with special needs; and
- have a clear understanding of test taker rights and responsibilities.

4.2.2 Testing Location

CAUTION: Testing facilities and conditions should be reasonably uniform for all test takers. These extraneous factors can affect the reliability and validity of test results. Whenever possible, ANAM should be administered in a quiet room, free of visual and auditory distractions. A “Do Not Disturb” sign on the exterior door can help to minimize interruptions. Make sure phones are muted and cell phones are OFF rather than set to vibrate.

CAUTION: The test environment should

- ✓ be both physically and psychologically conducive to eliciting the best possible performance of the test taker;
- ✓ be well-lit, well-ventilated, with comfortable room temperature;
- ✓ have a comfortable chair and work surface configuration that allows good visibility of the computer display and comfortable access to the keyboard and mouse;

- ✦ be free of excessive noise, traffic, and other interruptions; and
- ✦ allow privacy and reasonable separation between test takers.

4.2.3 Preparation of the Computer

ANAM Military is a computer-based test battery that uses the computer to present stimuli and collect responses in terms of accuracy and reaction time. Thus, one should consider the computer itself to be a sensitive laboratory instrument used to measure specific aspects of human performance, which will have clinical implications. Therefore, it is crucial to maximize the reliability of measurements made by the computer hardware and software.

CAUTION: ANAM Military is designed to be used with a USB Mouse and a Windows-based laptop. Wireless mice and touchpad/tracking devices should always be avoided. Ideally, the computer that is used to administer ANAM should be dedicated for that purpose. In addition, restricting Internet access to operating system updates only is desirable.

The ANAM software platform is designed to minimize intrusion from the operating system and other competing computer programs. However, to ensure the most accurate collection of millisecond response time, it is highly recommended that all unnecessary programs running along with ANAM be closed prior to initiating testing. Cernich et al. (2007) provide a useful checklist that may be implemented prior to using a computer-based measure in order to reduce the possibility of error.

4.2.4 Examinee Comfort

Examinee positioning and comfort is also important. In order to minimize fatigue or muscle cramps, the examinee should rest his/her hand, wrist, forearm, and elbow comfortably on the table.

CAUTION: In addition, use of a touchpad on a laptop computer should typically be avoided. In addition to having variable timing resolution in timing accuracy with the touchpad, many users may reposition the laptop for comfort in using the touchpad, thereby producing a suboptimal viewing angle.

The screen should be positioned where it is comfortable for the examinee without inducing undue strain on his/her neck. Lighting in the room should be adequate as well. The examinee should also be sitting in a comfortable chair in front of the computer, which is paced on a desk of standard height.

CAUTION: ANAM should NOT be administered using a laptop that is sitting on the lap of the examinee.

ANAM test scores have been shown to be relatively robust to normal variations in ambient lighting, noise, temperature (such as those seen across a variety of deployment preparation sites), but more pronounced variations in such factors, as often found in-theater for example, would be cause for special consideration.

4.3 ANAM TEST ADMINISTRATION

Prior to initiating test administration, administrators should ensure that they are properly trained in psychological test administration and, more specifically, how to administer the ANAM testing battery, as described above. The testing environment and testing computer should also be set up as described above.

CAUTION: It is important to note that administering ANAM is NOT a simple matter of starting the program and letting it run while the examinee performs the various tests. The examinee must be carefully monitored by the examiner throughout the testing session to monitor behavior, motivation, and the examinee's understanding of directions in order to be aware of any possible limitations to performance validity. For example, confusion or inability to follow test instructions may sometimes occur. The examiner should be confident that the examinee understands what is being asked of him/her. If the examiner has questions regarding the examinee's understanding of what he/she is being asked to do, doubt is cast on the validity of the test results.

4.3.1 Testing Session Set-up and Instructions

The examinee should be seated in front of the testing computer and provided an orientation and explanation for the purpose of testing. The examinee should be informed of what to expect and what will be done with their responses once testing is complete. Sample language is as follows:

“You are here are to take ANAM. ANAM is a group of tasks that measure your thinking abilities and how you are feeling right now. Each task will give you instructions about what you will see and how you should answer. If you have questions at any time, please let the examiner know.

You will start with questions that ask how you are feeling right now. Please answer as honestly as you can.

Next, you will take a group of tests that measure your thinking abilities. You will be asked to solve some problems and then respond as quickly as you can.

Once completed, your responses will be saved on the computer. There is no pass/fail on this test, so just try your best.

Remember to always try your best.”

ANAM is designed to accommodate both left- and right-handed test takers. Prior to test administration, the test administrator should query the examinee regarding the hand which they most frequently use to operate a computer mouse (many left-handed individuals still use a computer mouse with their right hand). By default, ANAM is configured for right-handed examinees. Should the examinee indicate that they most often use a computer mouse with their left hand, the administrator should alter the system configuration to accommodate left-handed use (see [4.4.3 Test Settings](#)).

Once the test starts, read the test instructions silently as the examinee proceeds from screen to screen, and be aware of whether the examinee bypasses the test instructions too quickly. In these cases, caution the examinee to read the instructions carefully.

If needed, read the instructions to the examinee and answer any clarifying questions the examinee may have. For example, it is fine to reinforce the actual content of directions in the following ways,

- ***“Yes, you hit the button as fast as you can when you see the asterisk”***
- ***“You only hit the button one time.”***
- For the Code Substitution Test, ***“Yes, there will be a memory test later, so try to learn the pairs.”***

However, do not provide information that is not included in the written test instructions, and do not provide information about test taking strategies.

For example **DO NOT** provide the following sorts of statements:

- For the Mathematical Processing subtest, “It is best to add/subtract the first two numbers before attempting the third.”
- For the Code Substitution Test “You should take your time on this test, so that you will remember the symbol/number pairs better on the memory test.”

If an examinee asks whether it is better to perform quickly or accurately, repeat the written directions,

- ***“Make sure that you are fast and accurate.”***

4.3.2 Carefully Observe Behavior During Testing

Carefully follow the examinee's first few button presses, particularly during the practice trials, to determine whether he/she is responding appropriately. Infrequently, the examinee may produce an incorrect response to each item, suggesting that he/she has confused the test instructions. Without any intervention, the examinee may get 0% correct because he/she confused the mouse buttons. In this case, abort the test and restart ANAM (see [4.4.7 Administering a Retest](#)) after explaining the instructions to the examinee and ensuring that he/she understands what to do.

To maintain the integrity of test results, administrators need to be alert to test takers' activities throughout the administration. For example, some individuals may experience difficulty in understanding the instructions. Others may proceed through the battery randomly responding to items. Others may be uncomfortable using a computer, while others may attempt to misuse the computer or attempt to engage their fellow test takers in conversation, competitive activity, or amusement. An alert administrator will be able to correct these situations quickly before they invalidate the test takers' responses. If the administrator believes the integrity of ANAM has been compromised, the battery should be terminated and the test taker should be quietly removed from the testing location. A test proctor log book can be used to record standard information about each test session as well as any abnormalities that may have occurred during the test session.

The most important administration guideline is: **Watch the examinee and his/her responses.**

- Notice whether the examinee is watching the screen or looking away from the screen. Examinees occasionally look away from the screen to follow distractions, or when they are having difficulty with a particular test.
- Watch how the examinee uses the mouse. The examinee's fingers should be resting lightly on the mouse buttons. Try to encourage the examinee not to raise his/her fingers off the mouse, as the added distance traveled to strike the mouse button will increase the examinee's reaction time.



Correct hand/finger position using computer mouse

In general, test administrators should offer aid at any point in the testing when it becomes clear that a test taker is having difficulty understanding the test. Most ANAM tests provide practice trials that help ensure that the test taker understands what is required before the actual test begins. Test administrators should be familiar with potential questions and/or problems that might be encountered during administration and be advised of standard procedures for handling such situations.

4.3.3 Individual versus Group Administration

The above instructions are specific for testing examinees in an individual or one-on-one fashion. There are several testing scenarios, however, that call for testing groups of individuals simultaneously, such as clinic based testing for multiple patients or baseline testing. In group-based testing situations, the above guidelines for testing individuals should continue to be followed. However, additional special set-up and testing guidelines should be considered for group-based testing, including the following:

- There should be ample room between examinees such that they cannot see each other's computer screens and are not distracted by the sound of another's examinee's mouse button responses. Cardboard dividers or other similar partitions can be used to ensure privacy and reduce distractibility.

- The administrator should be seated/positioned in the room such that he/she can observe all examinee's at once. This ensures that the administrator is aware of when an examinee is having trouble with test directions or has other atypical behaviors that require intervention.

4.3.4 Test-Taker Considerations

While ANAM Military provides a stable and robust test system, many factors can impact the valid and useful interpretation of test scores. It is critically important to be aware of a variety of examinee characteristics in order to place the examinee's test results in the proper context, and to ensure the examinee's maximal effort throughout the assessment.

CAUTION: The following section covers several important examinee characteristics that should be considered.

Language

The administration language for ANAM should be the native language of the examinee. Examinees whose native and fluent language is not English should not be given the English version of ANAM. Currently, ANAM Military instructions are only available in English.

State Factors

When possible, the examinee should have had a good night's rest and should refrain from excessive use of alcohol or caffeine for at least 24 hours prior to the administration of ANAM. Be sure to make note of whether or not the examinee is feeling ill on the day of the assessment, as colds, flu, etc. can have an adverse impact on performance.

While ANAM Military test scores are also generally robust to mild transient fluctuations in mood and activity level, significant levels of fatigue, sleep loss, stress, drug/alcohol use or other transient factors may well influence test performance. Consideration of such factors should be included in any test interpretation, with rest and re-testing as one simple, yet often effective, method for assessing the degree to which these factors pose as an influence on test results.

Neurologic Conditions

The examiner should be made aware of any pre-existing neurological conditions, including prior head injury (including concussion), learning disability, attention deficit disorder, reading disabilities, or seizure disorders. This information can be noted in the comments section of the ANAM Performance Report.

Medications

Certain types of medications could have an impact of the examinee's test results, particularly those medications that are sedating or stimulating. The examinee's list of medications, including which were taken the day of testing, should be documented.

Reading Level

The examinee's reading level could impact the ability of the examinee to understand ANAM Military instructions and, thereby, impact performance. ANAM Military instructions have a Flesch-Kincaid Grade Level index of 3.4. Additionally, ANAM Military has a Flesch-Kincaid Reading Ease (RE) score of 87.3. RE scores range from 0 to 100, with higher numbers indicating the text is easier to read.

- Scores between 90.0 and 100.0 are considered easily understandable by the average 5th grader.
- Scores between 60.0 and 70.0 are considered easily understood by 8th and 9th graders.
- Scores between 0.0 and 30.0 are considered easily understood by college graduates.

Despite these estimates of readability, the appropriateness of the test instructions for a given examinee will depend on several factors, including the background knowledge of the examinee and the level of support provided during test administration.

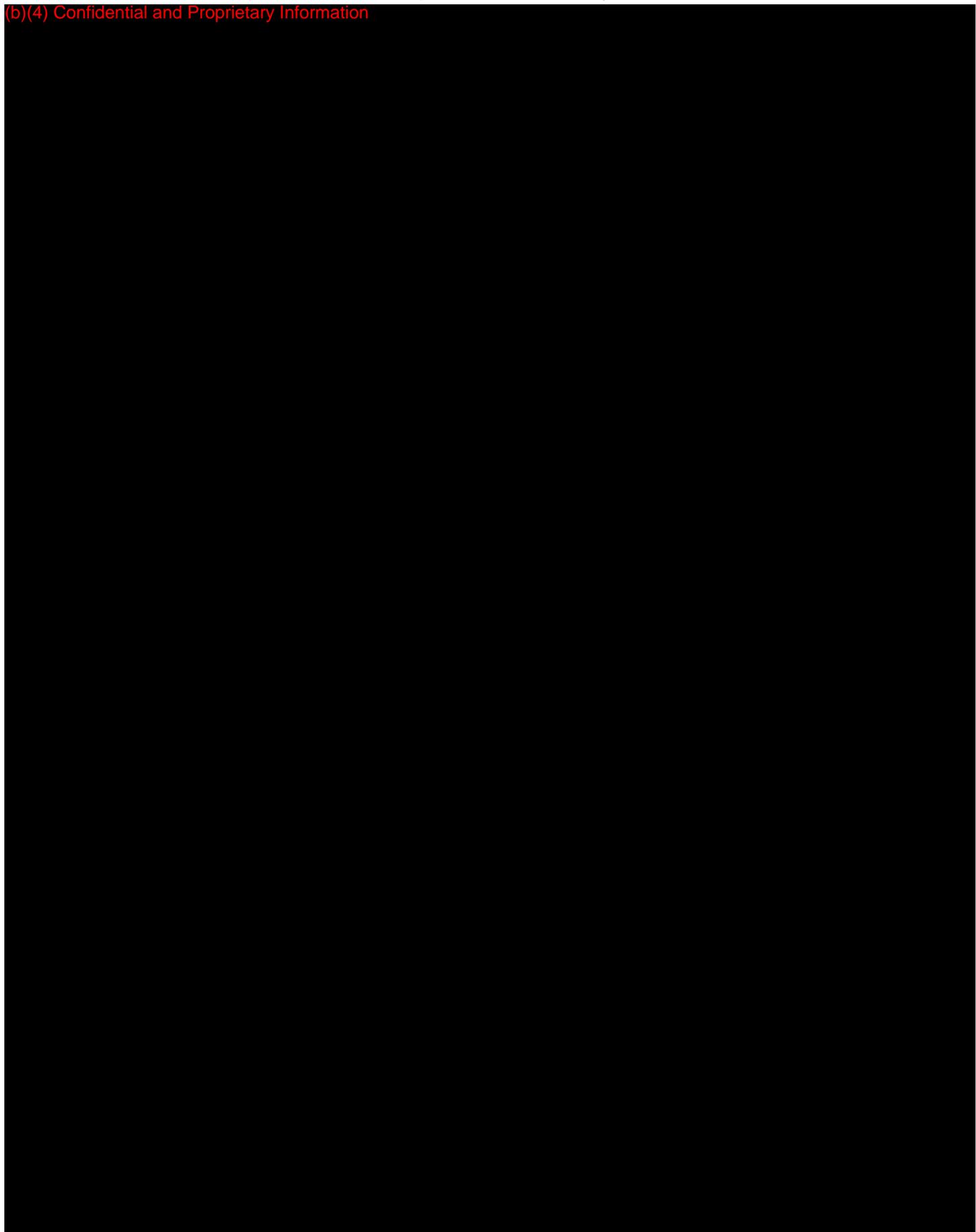
4.4 RUNNING ANAM

Once you have familiarized yourself with the test administration guidelines, you are ready to run ANAM.

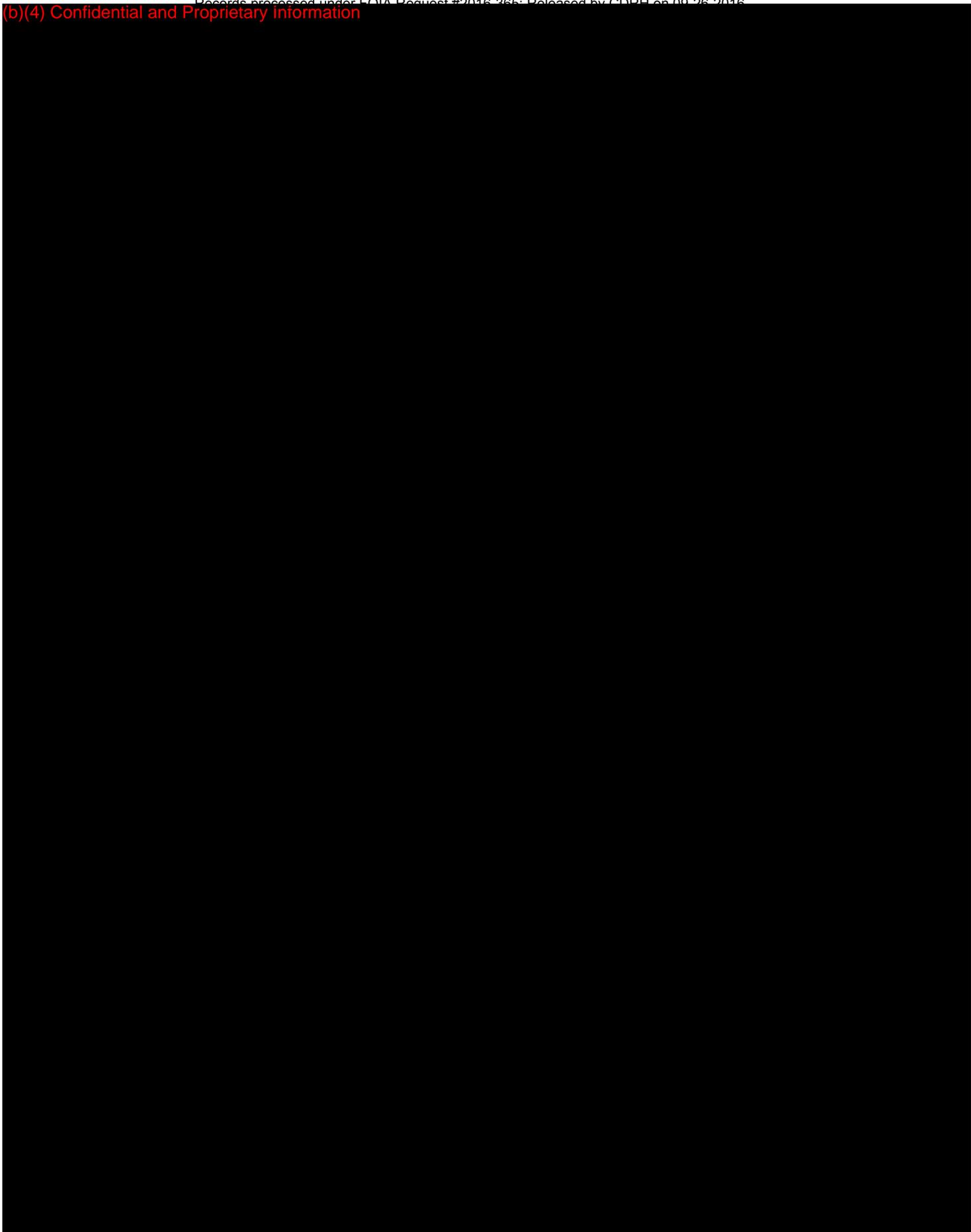
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4.5 SHORTCUTS

The shortcut keys for ANAM functions are the following:

If you need to...	On this screen	Press these keys
Exit a test	Any Test Screen*	ALT + F1
Exit the battery	Any Test Screen*	ALT + F1
Interrupt a battery	Any Test Screen*	ALT + F1
Unlock primary & individual data directories	Battery Selection	ALT + F1
Unlock Session field	Confirmation	ALT + F1
Unlock File Extension & Mouse Hand fields	Test Settings	ALT + F1
Expand Test Settings Screen.	Test Settings	ALT + F2
Continue test after criterion failure	Criterion notice	ALT + F3

*Must be an actual test screen. Shortcut will not work during the instruction screens.

ANAM Data Output and Scores

Data from ANAM is saved at the conclusion of each individual module. If a module is not completed (due to interruption, system failure, or other intentional or unintentional termination) data will not be saved for the incomplete module. However, data will be saved for all other modules in the battery completed up to the point of termination or interruption.

5.1 ANAM DATA OUTPUT

Upon test administration, two data files are generated in two different formats. These are:

- Comma separated files (CSV)
 - Raw Data – individual item/trial information
 - Summary Data – summary statistics computed across all items/trials
- Extensible Markup Language files (XML)
 - Raw Data – individual item/trial information
 - Summary Data – summary statistics computed across all items/trials

The CSV files do not include variable labels. For further information on variable position, labels, order, and calculation, contact Vista LifeSciences, Inc.

5.1.1 Filename format

Data filenames are generated by the ANAM executive program. The filenames are comprised of five components:

1. *File type identifier* – The four different data files generated from each run of an ANAM test are identified by a one letter code. This code will occupy the first character in the data file name.
 - a. R – raw data in CSV format
 - b. Z – raw data in XML format
 - c. S – summary data in CSV format
 - d. X – summary data in XML format
2. *ID* – Corresponds to the ID provided on the *Battery Selection Screen*. The ID component is variable in length and can be any alphanumeric character string.
3. *Type of Administration* – The ID is followed by a ‘p’ or ‘t’ designating a Practice or Test session.
4. *Session number* – Two digits representing the session number which was administered.
5. *File extension* – A three letter extension is attached to the file which serves as an abbreviation code for test identification (see Table 5.1.1).

Table 5.1.1 List of ANAM modules, module names and abbreviations

Module	Module Name	Abbreviation
Code Substitution	codesub	
Learning		.cds
Delayed		.cdd
Demographics	question	.sub
Matching to Sample	mat2samp	.m2s
Mathematical Processing	math	.mth
Mood Scale	question	.moo
Procedural Reaction Time	procrt	.pro
Simple Reaction Time	simplert	.srt/.sr2
Sleepiness Scale	survey	.slp
Symptoms Scale	question	.smt

Example: S32545T01.SRT

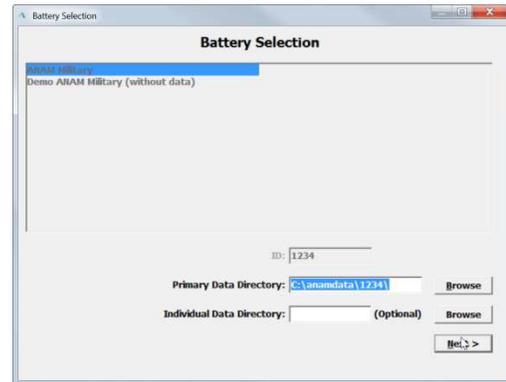
This is a summary data file in CSV format for subject 32545 taking Test Session number 1 of the Simple Reaction Time Test.

5.2 ANAM DATA STORAGE

The default “primary data directory” is displayed on the *Battery Selection screen*. Shown below are two fields to enter a Primary Data Directory and Individual Data Directory. Completed ANAM module data will be stored in the directories as specified in these fields.

The default *Primary Data Directory* in this example is `c:\anamdata\123456789`. The data from all completed modules will be saved in this directory or folder (where 123456789 is the id number of the individual being tested). The default for the *Individual Data Directory* is blank.

By default, the Primary and Individual Data Directory fields are locked. To modify these fields, press **<ALT>+<F1>**, which will unlock the fields and allow you type the desired data directory or navigate to the desired directory by pressing the **Browse** button.



A primary data directory of `c:\anamdata\123456789` is equivalent to a *primary* data directory of `c:\anamdata` combined with an *individual* data directory of 123456789.

To configure ANAM to consistently use a different data directory please see [4.4.2 ANAM Initial Set-up](#).

The default storage location for *converted* ANAM data files is `c:\anamdata-converted`. See [Chapter 10](#) for more information on data conversion.

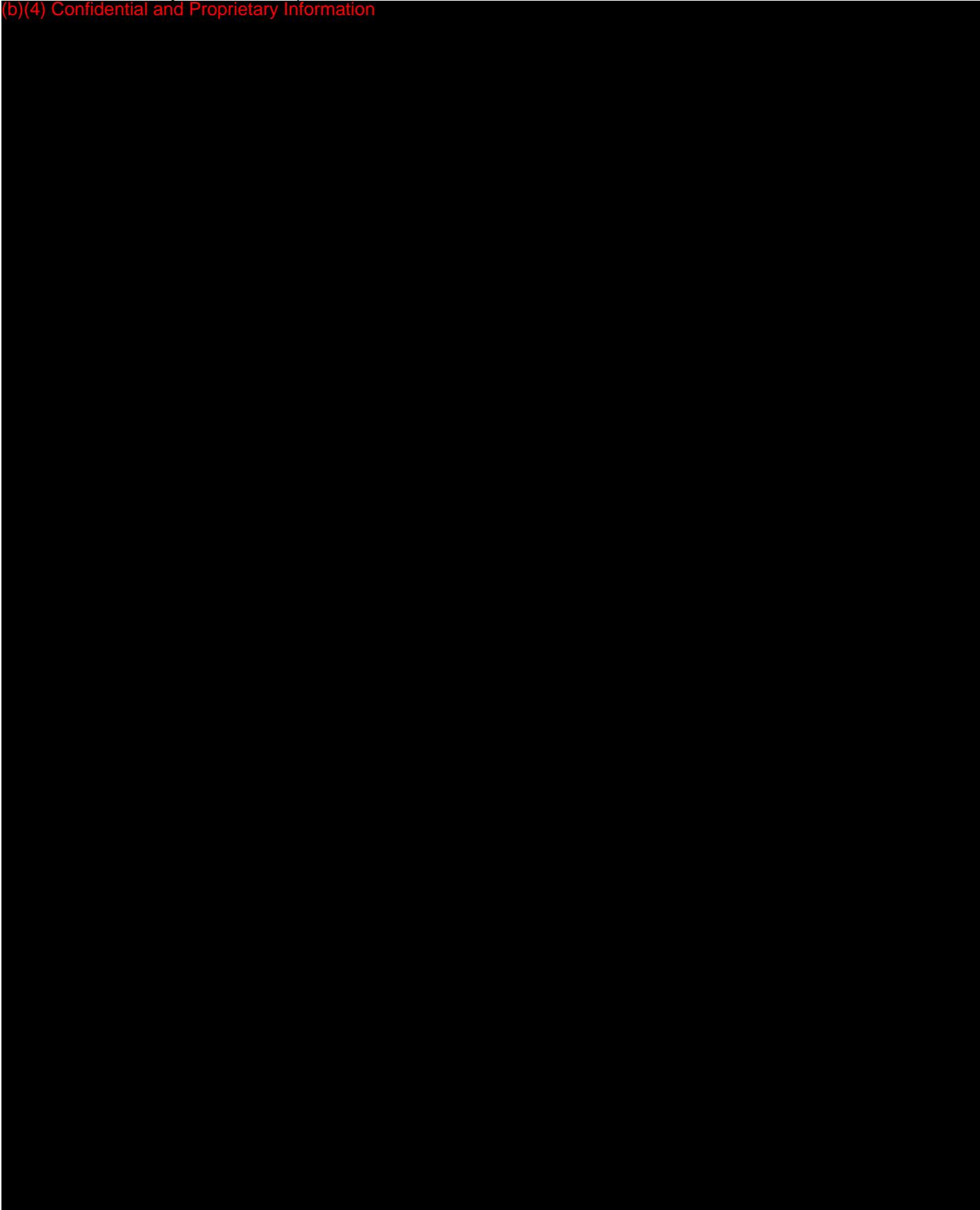
5.3 VIEWING ANAM DATA

Results of ANAM testing are presented on the ANAM Performance Report, or APR. The APR is designed to aid clinical assessment, confirm that subject/patient scores are within a normal range with respect to a reference group, and examine performance history. The APR presents a selected set of scores for each of the ANAM tests administered. These scores are described below for each test in ANAM Military. For more detail regarding the APR, see [Chapter 6](#).

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Calculation of the ANAM Composite Score

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5.4 COMPILING ANAM DATA

The ANAM Data Extraction and Presentation Tool, or ADEPT™, is designed to give users of the ANAM battery of tests a tool for viewing and managing their XML data output. This tool is useful for viewing data from multiple individuals or creating a database for further analysis. For more information on the ADEPT program, see the ANAM Quick Start Guide.

APR: ANAM Performance Report

The ANAM Performance Report, or APR™, provides a summary snapshot of a single ANAM session. The APR is designed to aid clinical assessment, confirm that subject/patient scores are within a normal range with respect to a normative group, and examine performance history.

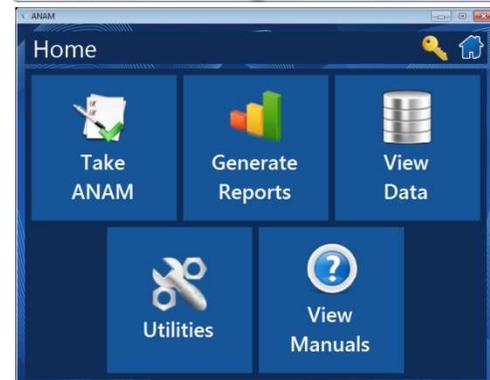
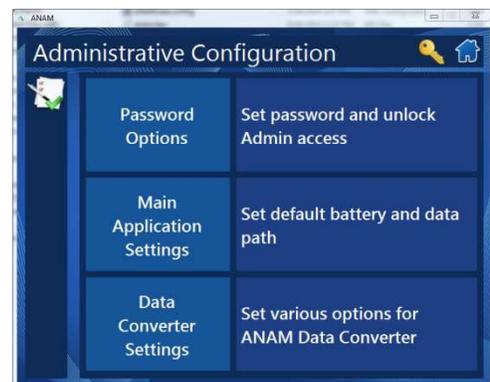
6.1 DATA REQUIREMENTS

The APR program requires summary data files in XML format. This is the standard format for ANAM Military data files. The filenames for these files start with the letter 'X'.

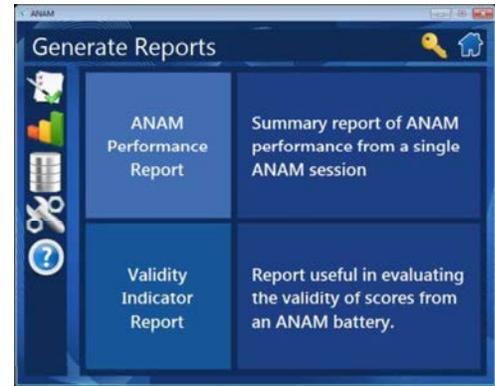
6.2 INSTALLING AND RUNNING APR

If you have received the APR program along with ANAM, it will be automatically installed along with the ANAM software. The default installation directory is `c:\Program Files\ANAM\APR`.

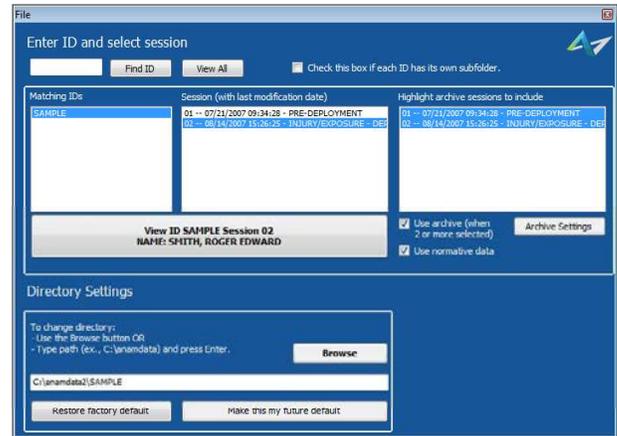
1. To run APR, first unlock administrator mode by clicking on the key (🔑) in the upper-right.
2. Click on **Password Options**.
3. Unlock Administrative Access by entering the password (refer to [4.4.2 ANAM Initial Set-up](#)) and click **Submit** to the right of the field.
4. Click on *Generate Reports*.



- Click on *ANAM Performance Report*.



The software will launch and the *File selection* dialog box will be displayed.



6.3 CREATING A REPORT

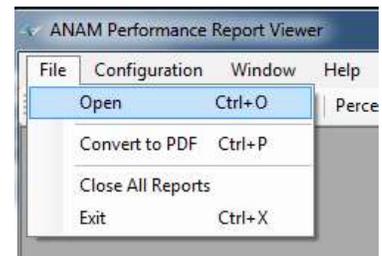
6.3.1 Selecting a Data Folder

The first step in creating a performance report is to locate the data you would like to include in the report.

To open a File selection dialog box

- Click **F**ile from the Main Menu bar.
- Select **O**pen.

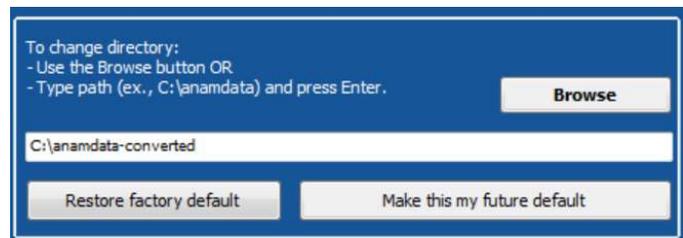
Or, press the Open file button  in the toolbar.



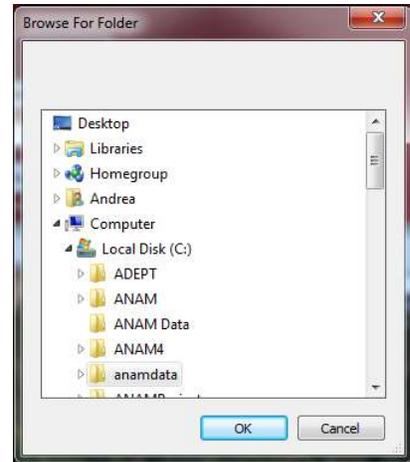
Upon opening, APR will default to searching **C:\anamdata-converted** for valid ANAM data files. If this is the location of your ANAM data files, you can proceed with creating a report.

To change the folder

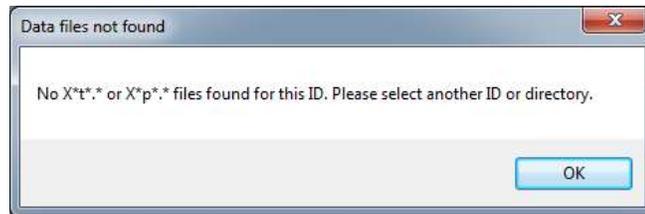
- Click **B**rowse located in the *Directory Settings* section of the File selection dialog box.



2. Navigate to the folder where your data files are located.
3. Click **OK**.



■ If the directory you select has no valid ANAM data files, the following message will appear on the screen:



If you get this message, click **OK** and make sure you select a directory that contains valid XML ANAM data files. The XML summary data files start with the letter 'X'. Generally, this message is generated as a result of the data storage location. If data are stored in subfolders by id (the default), then the box for 'Check the box if each ID has its own subfolder' should be checked. Otherwise, de-select this box to see if the data are stored in a primary data directory that does not include id subfolders.



■ If you would like the selected directory to be set as the default directory for future APR sessions, click **Make this my future default** in the *Directory Settings* section of the File selection dialog box.

If you have selected a directory with valid ANAM data files, the user ID labels for all XML summary data files located in the specified directory will populate the ID box of the Selection Form.

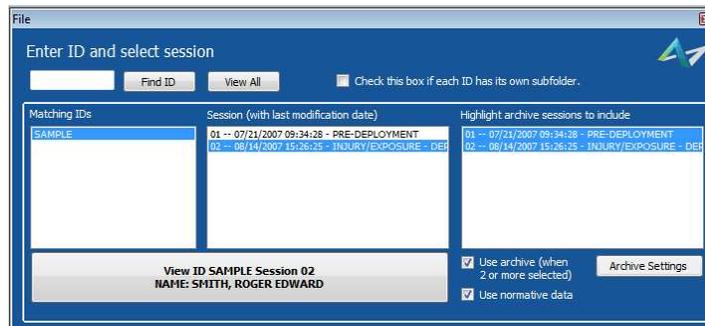
The next step in creating a report is selecting the desired user ID and Session. APR allows you to choose a single user ID and Session for constructing the performance report.

6.3.2 Selecting a User ID

Select a single user ID in the ID selection box by clicking on the ID label. The Session selection box will be updated with all sessions corresponding to the selected user ID. Session number and the last modification date/time will be displayed for each session. The date/time stamp will correspond to the last time data were appended to the file.

6.3.3 Selecting a Session

Select a single Session by clicking on the Session label, and click the **View** button. Alternatively, double-click the Session label and go directly to viewing the report.



6.3.4 Selecting Archive Sessions

When archived ANAM data (e.g., baseline testing) are available for the selected user ID, the APR can plot the current session along with archived sessions for historical comparison. The default sessions that are plotted are determined by the *Archive Settings*. The initial default is to plot the selected session plus the previous three sessions (if available). The default *Archive Settings* provide a starting point. In addition, sessions can be selected or deselected by clicking on the individual session labels in the right-hand archive sessions panel. To exclude the archiving feature from the current report, deselect the **Use archive** checkbox.

6.3.5 Archive Settings

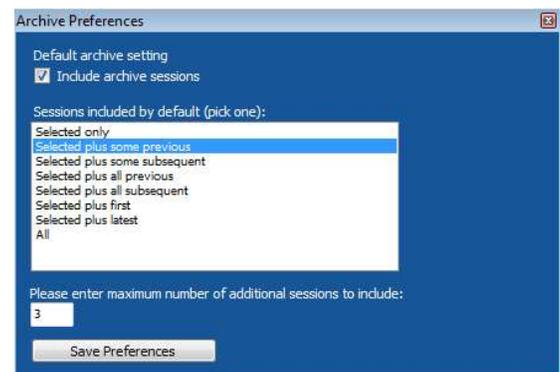
To modify the default settings, click the **Archive Settings** button to open the *Archive Preferences* dialog box.

Suppressing archive plots

To suppress the plotting of archive data by default, deselect the Include archive sessions box in the *Archive Preferences* dialog box.

Setting default archive sessions

To alter the sessions that are included in the archive plot by default, select the desired setting in the *Sessions included by default* selection box. A description of each option is given below.



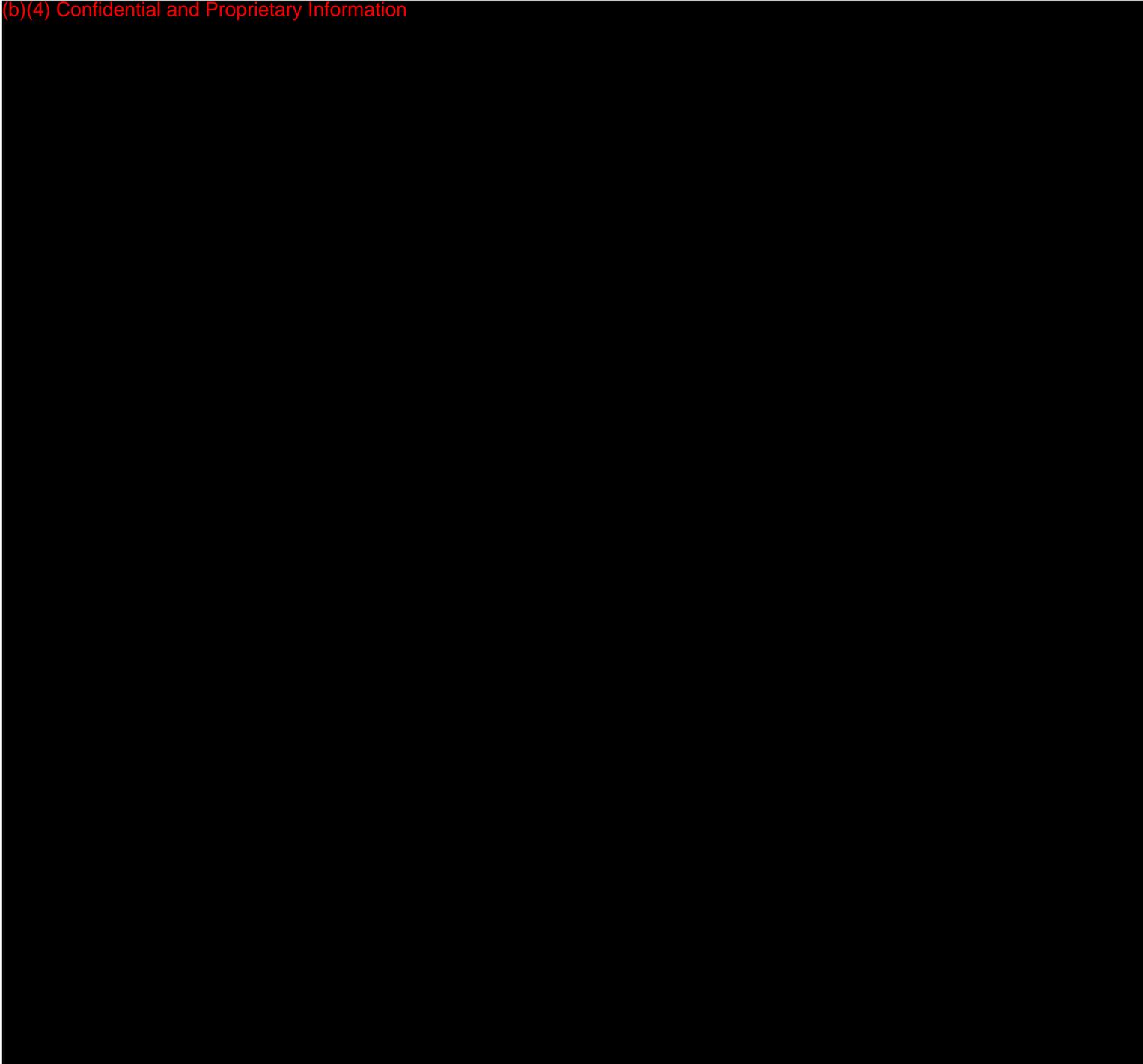
1. **Selected only** - The user must select all archive sessions manually each time a report is generated.
2. **Selected plus some previous** - The selected session plus a number of previous sessions will be included in the report. The number of previous sessions is specified in the additional sessions box in the lower portion of the Archive Preferences dialog box.
3. **Selected plus some subsequent** - The selected session plus a number of subsequent sessions will be included in the report. The number of subsequent sessions is specified in the *additional sessions* box in the lower portion of the Archive Preferences dialog box.
4. **Selected plus all previous** - The selected session plus all previous sessions will be included in the report.
5. **Selected plus all subsequent** - The selected session plus all subsequent sessions will be included in the report.
6. **Selected plus first** - The selected session plus the first available archive session will be included in the report.
7. **Selected plus latest** - The selected session plus the most recent available archive session will be included in the report.
8. **All** - The selected session plus all available archive sessions will be included in the report.

Default: **Selected plus some previous**

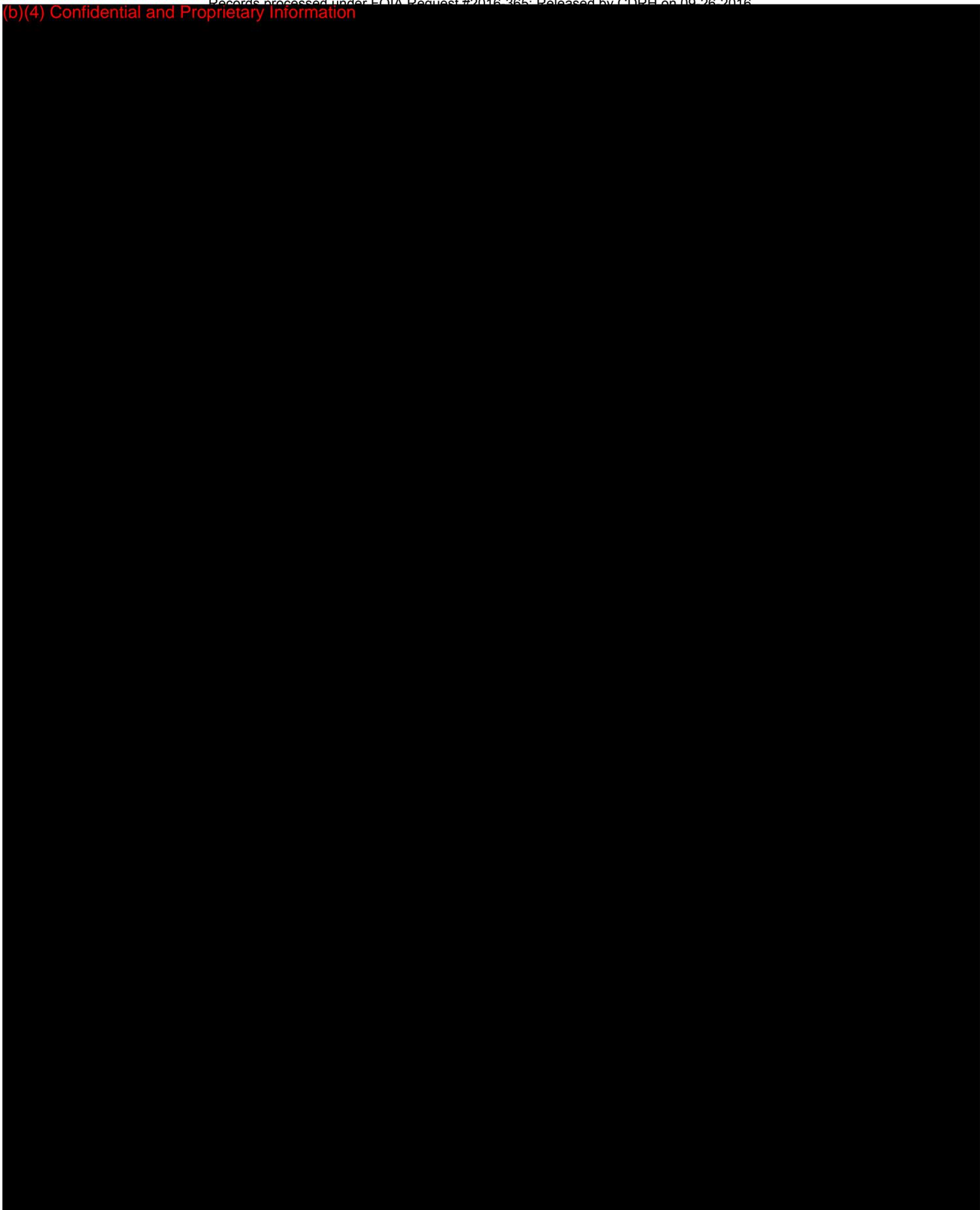
After all desired changes are made to the default archive settings, click the **Save Preferences** button. The selected default options regarding the use of archival data will be implemented in subsequent reports generated by the APR until the defaults are changed.

6.4 REPORT OPTIONS

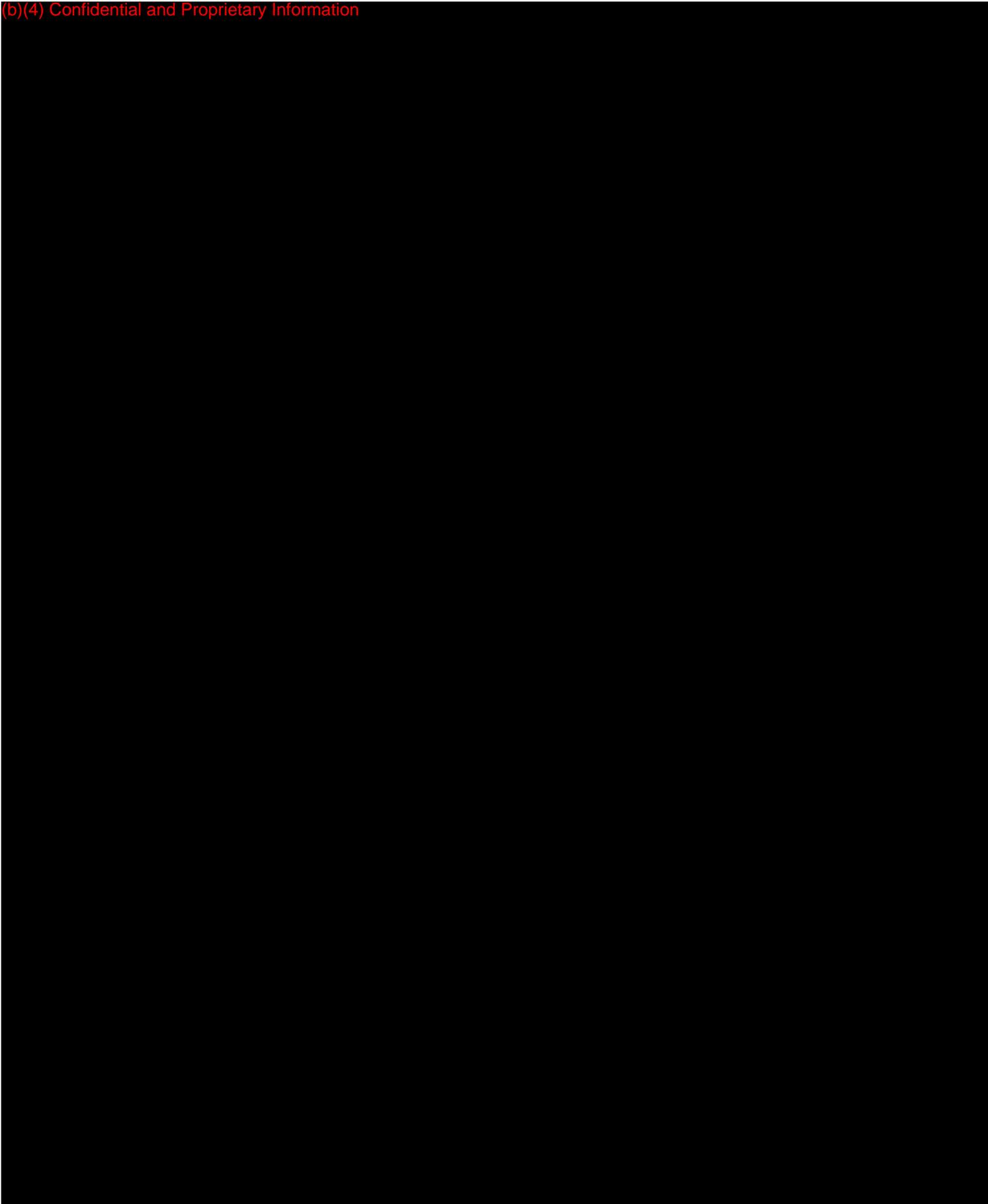
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(b)(4) Confidential and Proprietary Information

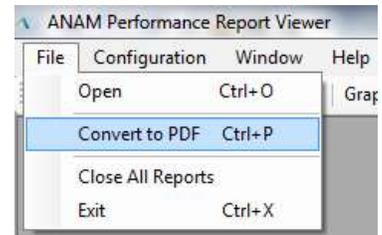


6.5.1 Converting to PDF

To convert a report to PDF

1. Create a report.
2. Click **File** from the Main Menu bar.
3. Select **Convert to PDF**.

Or, press the PDF (printer) button  in the toolbar.

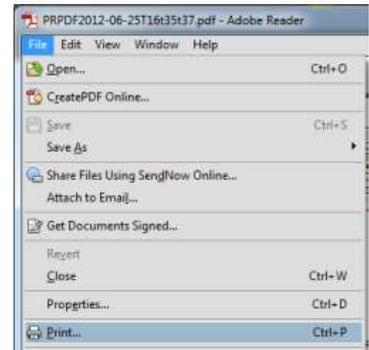


Generating the report may take a moment depending on the number of tests included in the battery and the selected Comparison Group.

6.5.2 Printing a Report

To print the PDF report

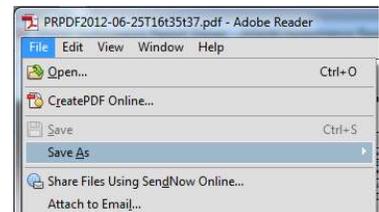
1. Click **File** from the Adobe Reader Main Menu bar.
2. Select **Print**.



6.5.3 Saving a Report

To save a report

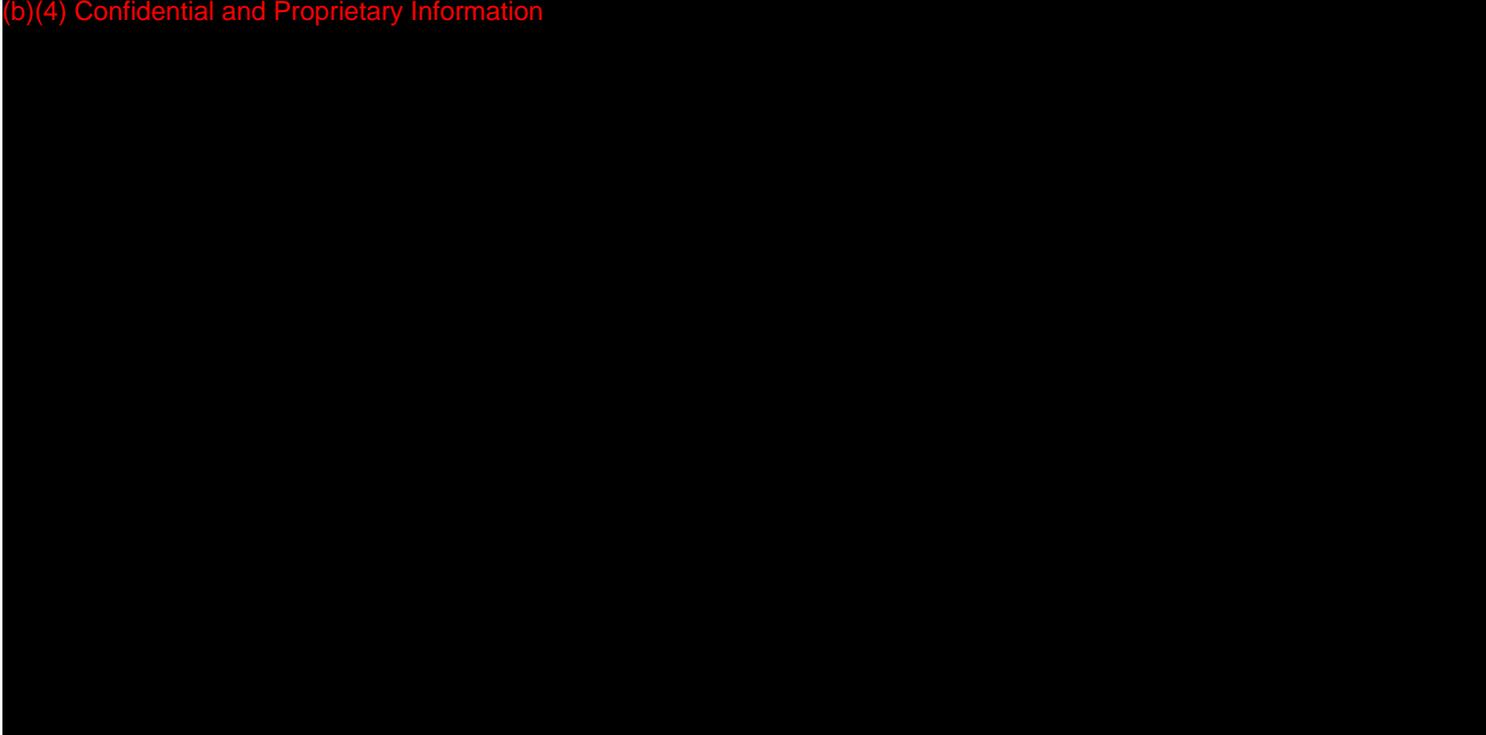
1. Click **File** from the Adobe Reader Main Menu bar.
2. Select **Save a Copy**.



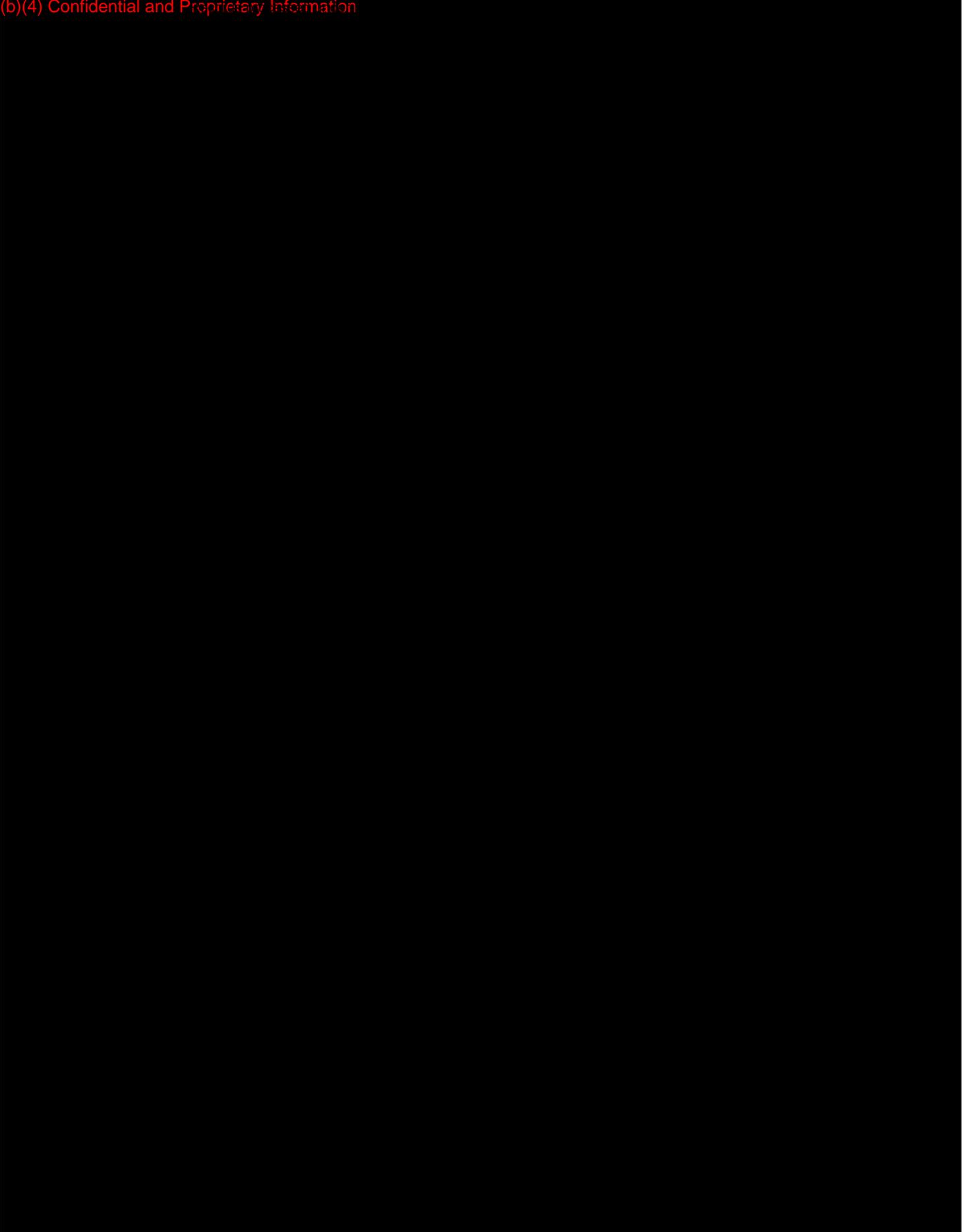
6.6 READING THE REPORT

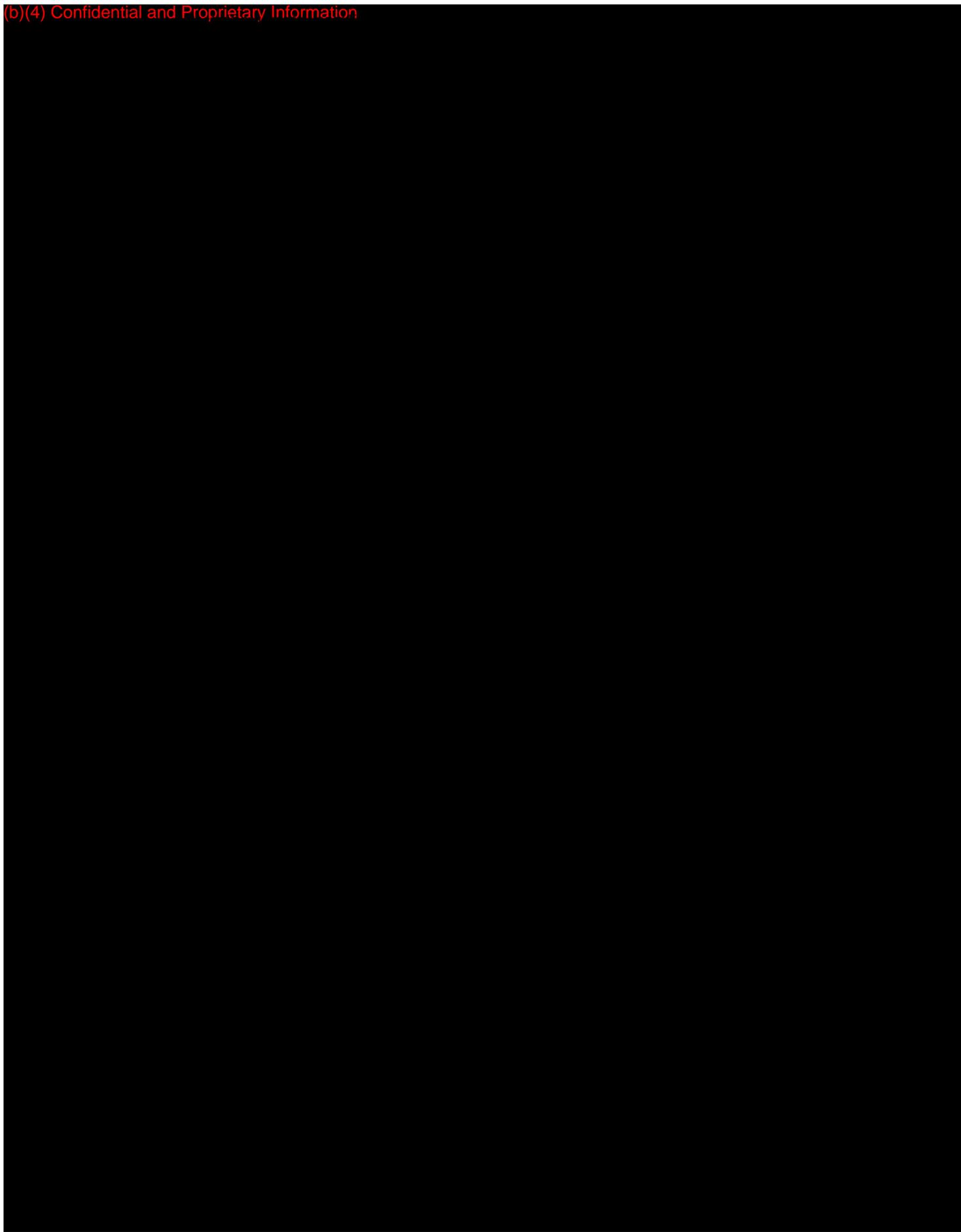
This section provides a section-by-section description of the ANAM Performance Report.

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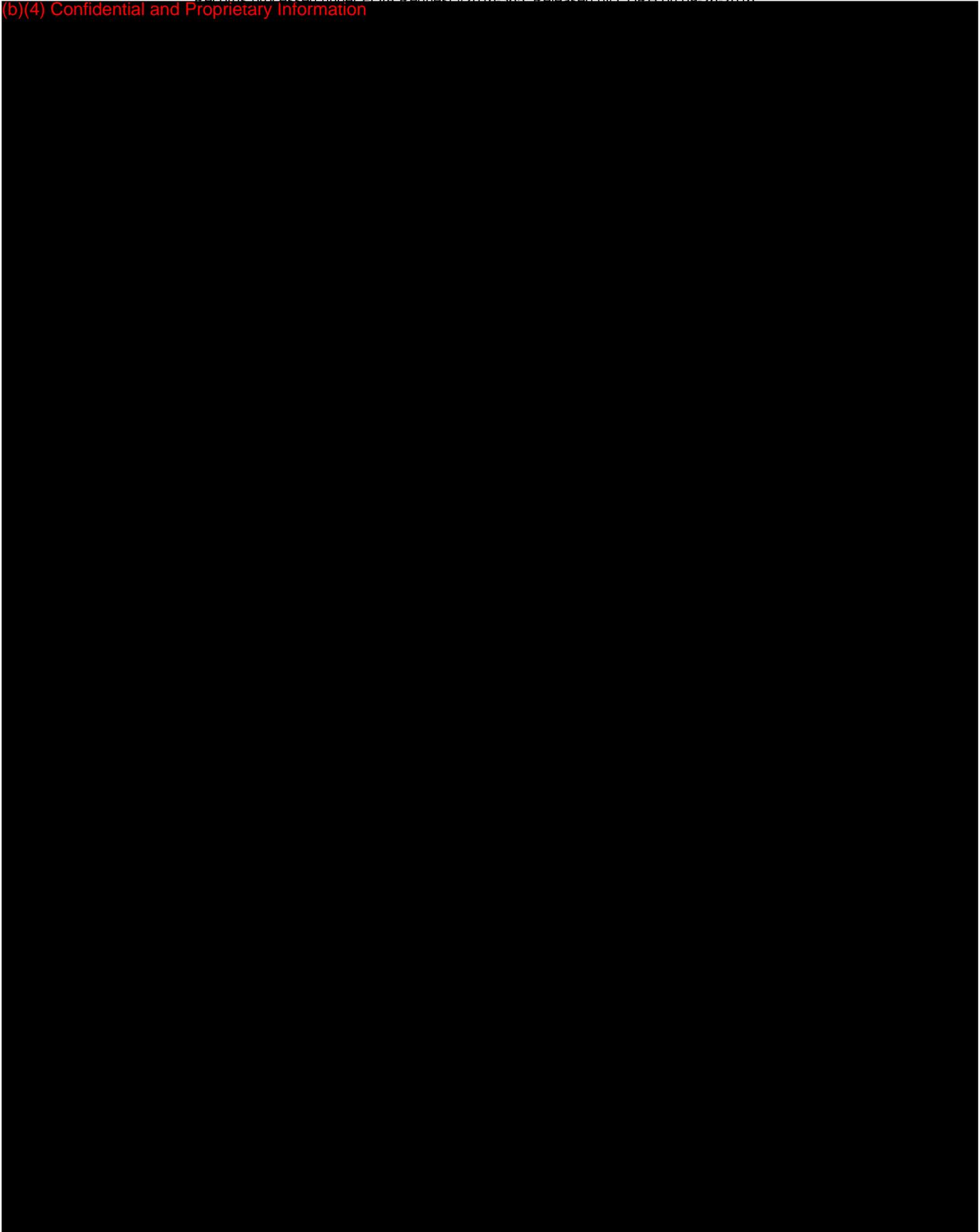


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ANAM Validity Indicator Report

The ANAM Effort Measure is the software program that generates the ANAM Validity Indicator Report (AVIR). The AVIR is designed to provide users of the ANAM test system a tool for evaluating the validity of scores from an ANAM battery by calculating the ANAM Performance Validity Index and highlighting other validity indicators. For further information regarding the ANAM Performance Validity Index calculation, please see the following:

Roebuck-Spencer, T.M., Vincent, A.S, Gilliland, K., Johnson, D.R., & Cooper, D.B. (2013). Initial Clinical Validation of an Embedded Effort Measure Within the Automated Neuropsychological Assessment Metrics (ANAM). *Archives of Clinical Neuropsychology*, 28(7), 700-10.

7.1 DATA REQUIREMENTS

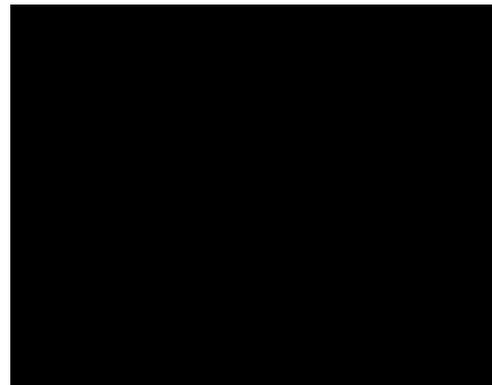
The ANAM Effort Measure program requires raw data files in XML format. This is the standard format for ANAM Military data files. These data files start with the letter 'Z'.

7.2 INSTALLING AND RUNNING ANAM EFFORT MEASURE

The Effort Measure program will be automatically installed as part of the ANAM software. The default installation directory is **c:\Program Files\ANAM\EffortMeasure**.

To run ANAM Effort Measure

1. Open ANAM by double-clicking on the ANAM icon on your desktop or select the ANAM program listed in **Start > All Programs > ANAM**.
2. Unlock administrator mode by clicking on the key () in the upper-right.
3. Click on Password Options.



4. Unlock administrator mode by entering the password (refer to [4.4.2 ANAM Initial Set-up](#)) and click **Submit** to the right of the field.

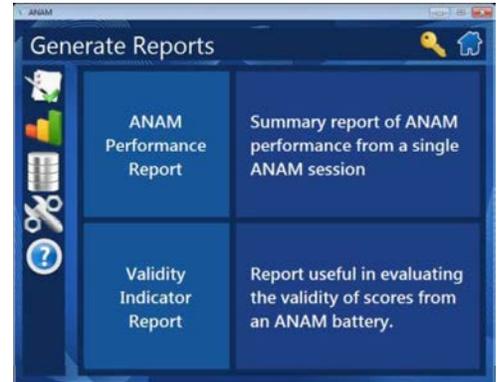
 The image shows the 'Password Options' dialog box within the ANAM application. It has a blue header and contains the following elements:

- Lock Access:** A 'LOCK' button.
- Unlock Access:** A checkbox labeled 'Default to Admin User Mode', a text input field, and a 'Submit' button.
- Change Password:** Three text input fields labeled 'Old', 'New', and 'Repeat New', followed by a 'SUBMIT' button.
- A small 'reset' button is located in the bottom right corner.

5. Click on *Generate Reports*.



6. Click on *Validity Indicator Report*.



7.3 LICENSE INFORMATION

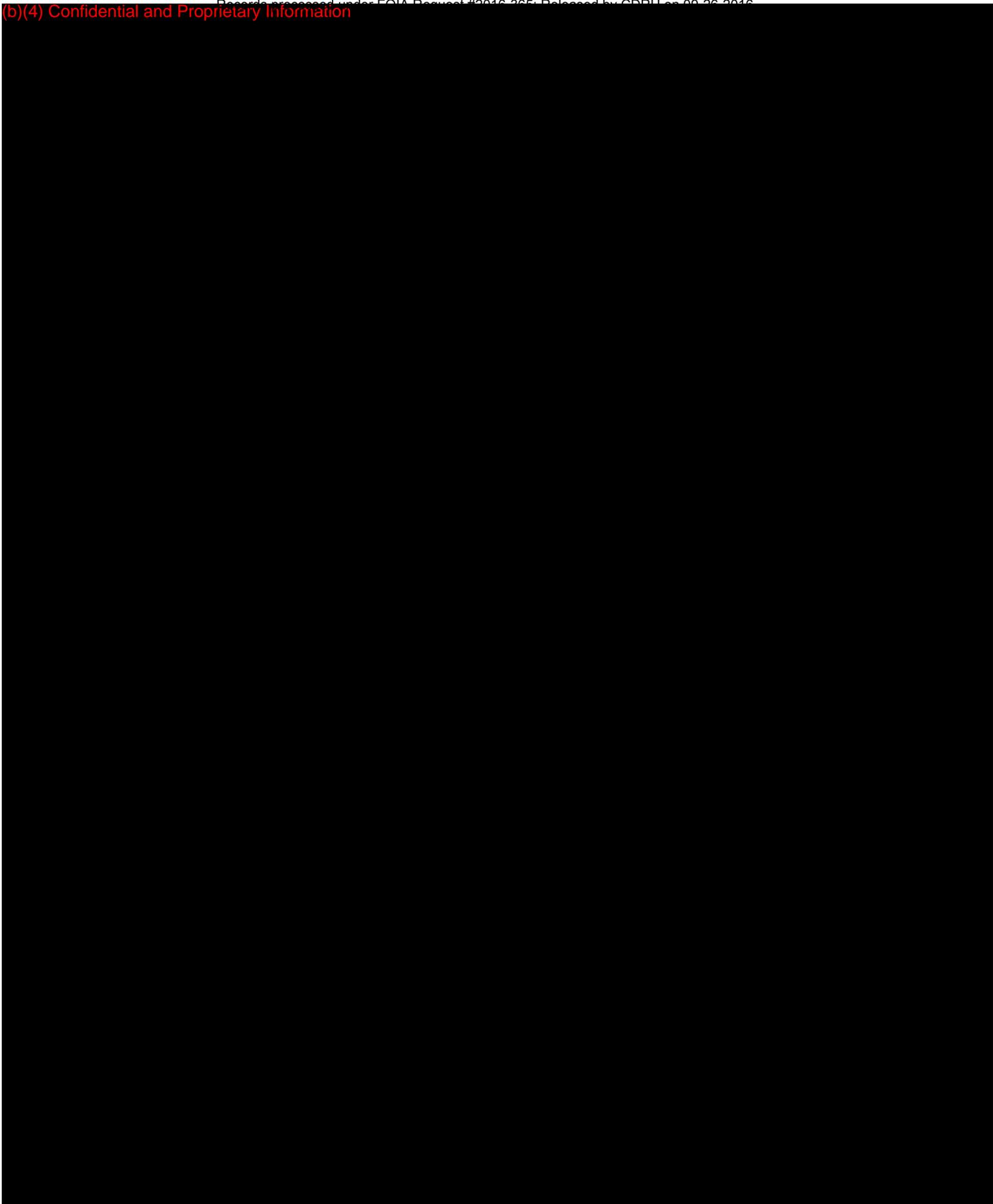
The ANAM Effort Measure program will prompt you to enter a new key upon expiration of your software license. The *License Information* window provides a space to enter a key to extend the expiration date and displays contact information which can be used to contact Vista LifeSciences to extend or re-order this or any ANAM product.



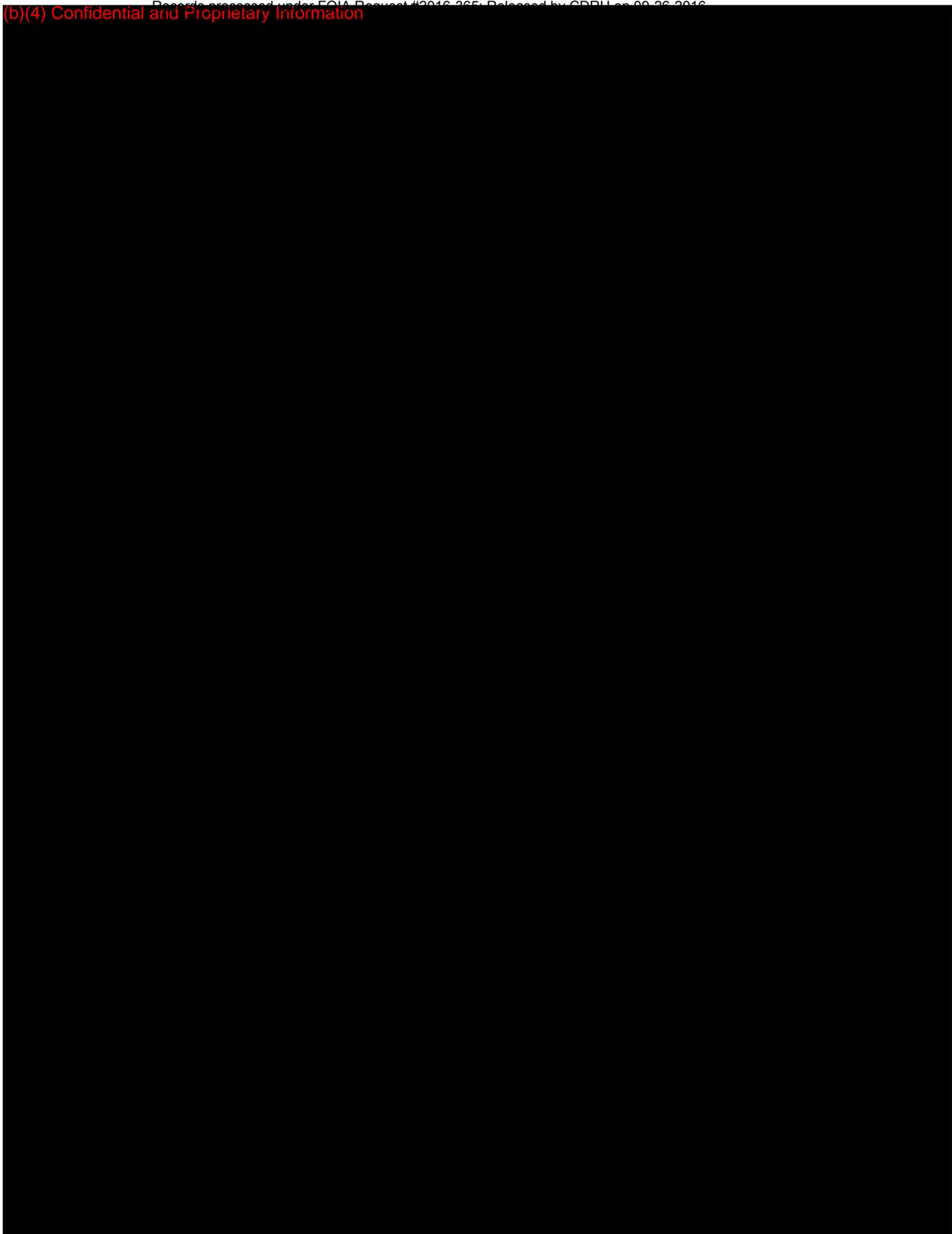
7.4 GENERATING THE ANAM VALIDITY INDICATOR REPORT

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(b)(4) Confidential and Proprietary Information





7.5 SAVING AND PRINTING A REPORT

The ANAM Validity Indicator Report is designed to be stored in portable document format (PDF). This provides tremendous portability and flexibility for storage and printing.

7.5.1 Printing a Report

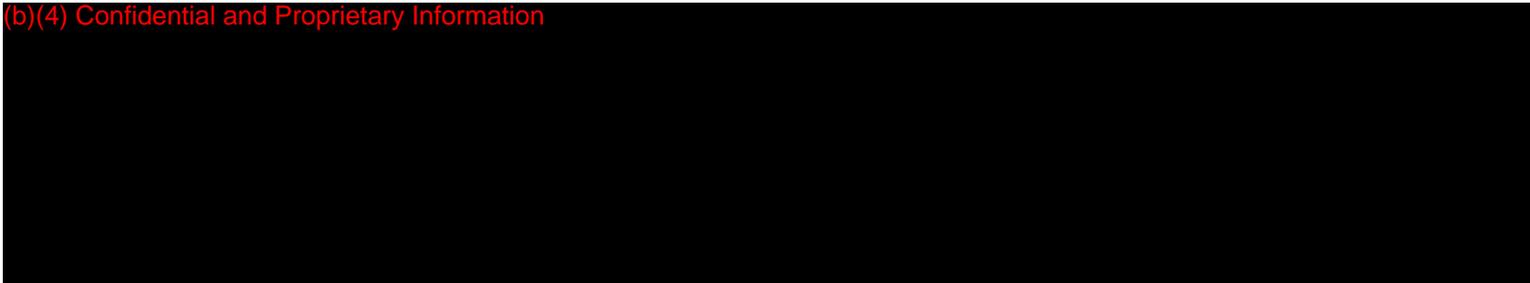
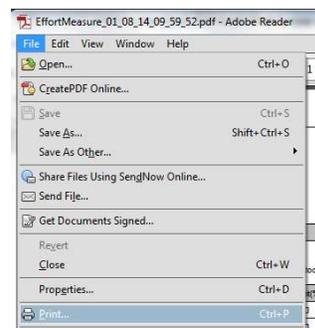
To print the PDF report

1. Click **File** from the Adobe Reader Main Menu bar.
2. Select **Print**.

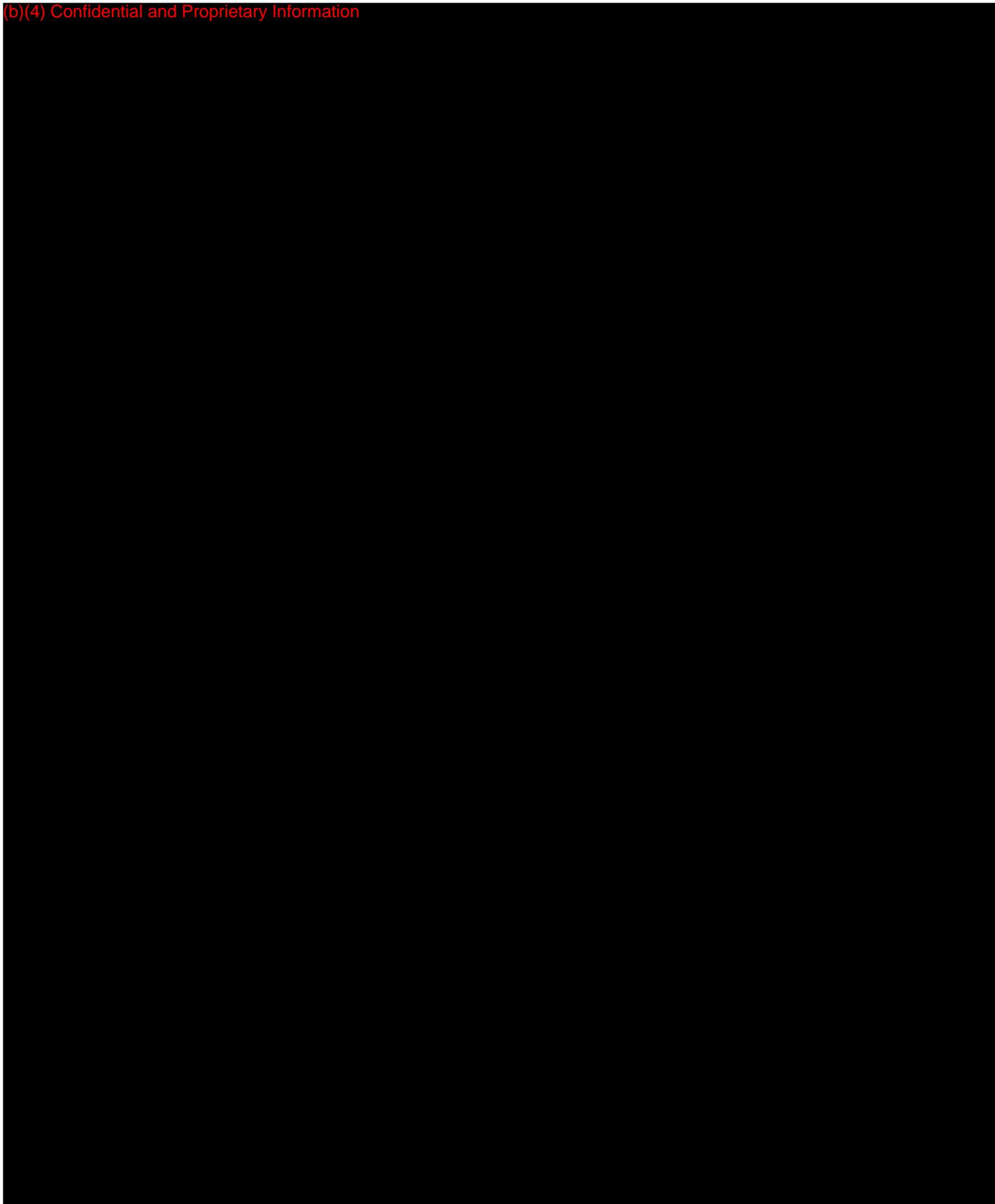
7.5.2 Saving a Report

To save a PDF report

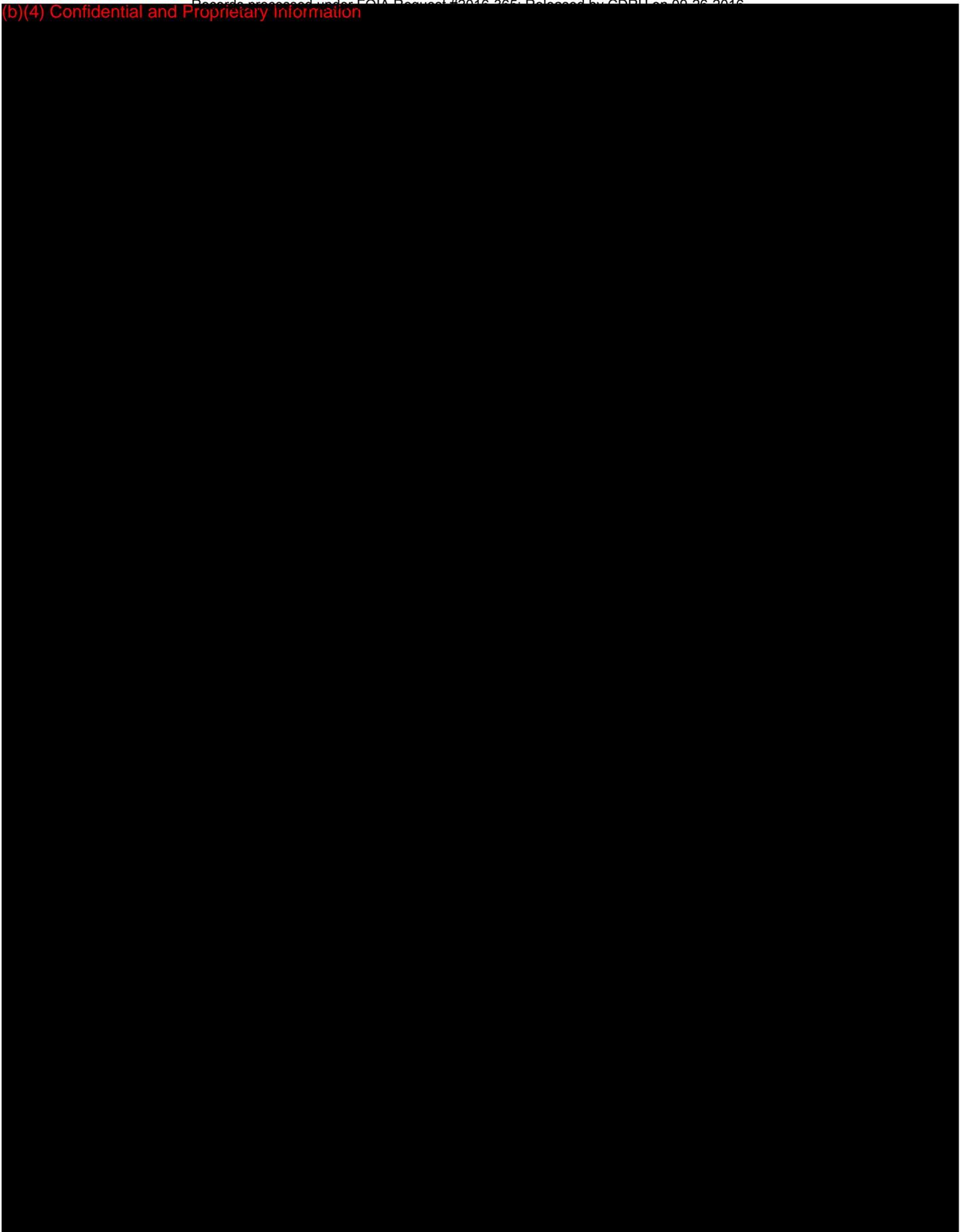
1. Click **File** from the Adobe Reader Main Menu bar.
2. Select **Save As**.



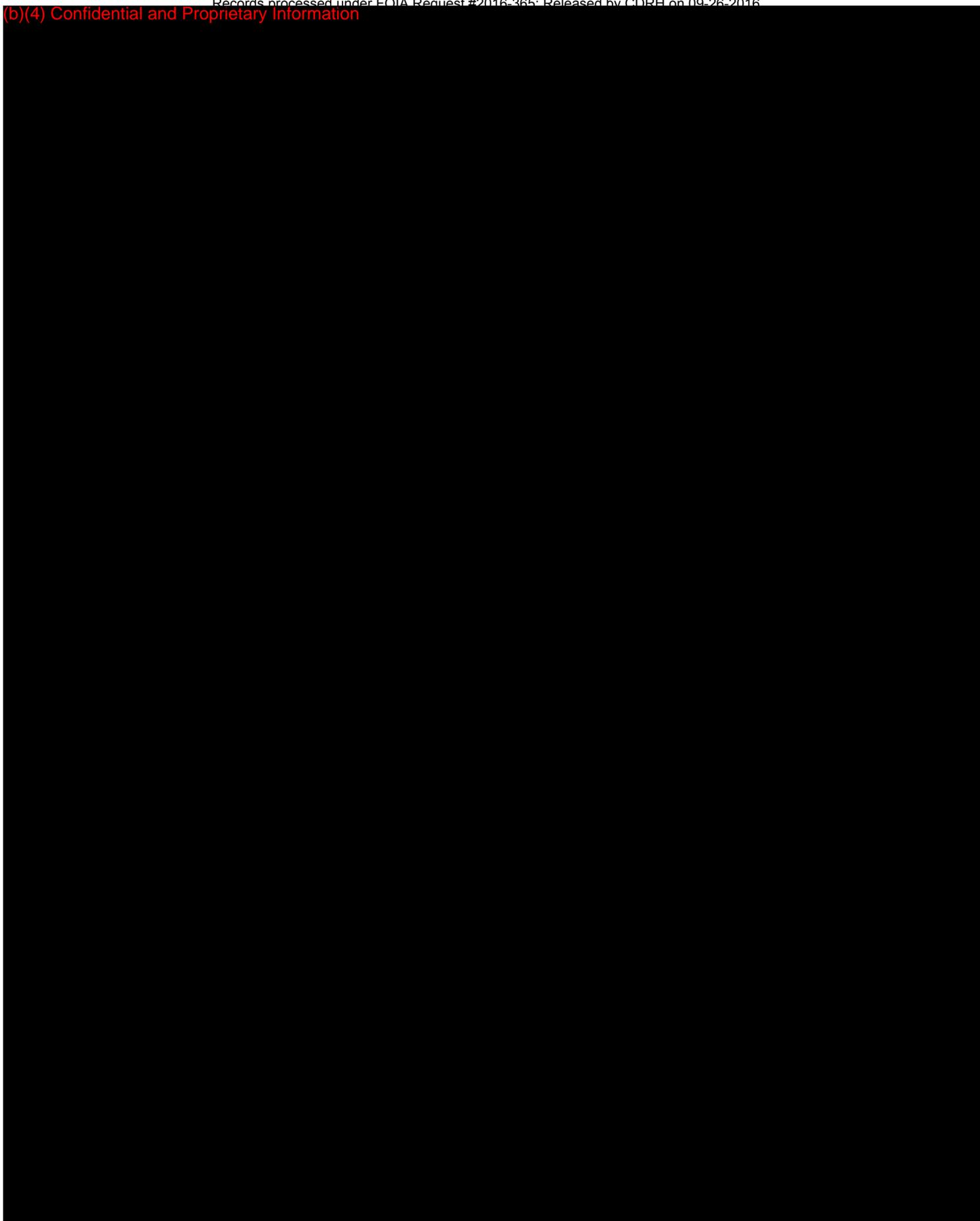
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Interpreting ANAM Military Test Scores

The ANAM Military battery is a psychological test and should be interpreted by qualified medical professionals with training in psychological test administration and psychometric principles and experience in the assessment of cognitive functioning. Responsible understanding and interpretation of ANAM Military test scores requires knowledge about and experiences with the individual ANAM Military tests, the test scores, and the format of the ANAM Performance Report (APR). Therefore, the reader is strongly advised to understand well the information in previous sections of this manual, especially information related to ANAM Military Tests ([Chapter 3](#)), the ANAM Performance Report ([Chapter 6](#)), and the ANAM Validity Indicator Report ([Chapter 7](#)). Responsible interpretation of ANAM tests should always be considered within the broader framework of information regarding the test taker including: demographic and premorbid factors, behavioral and environmental factors that may impact performance, medical and psychiatric history, details regarding current presenting history, and other possible contributing factors to cognitive functioning.

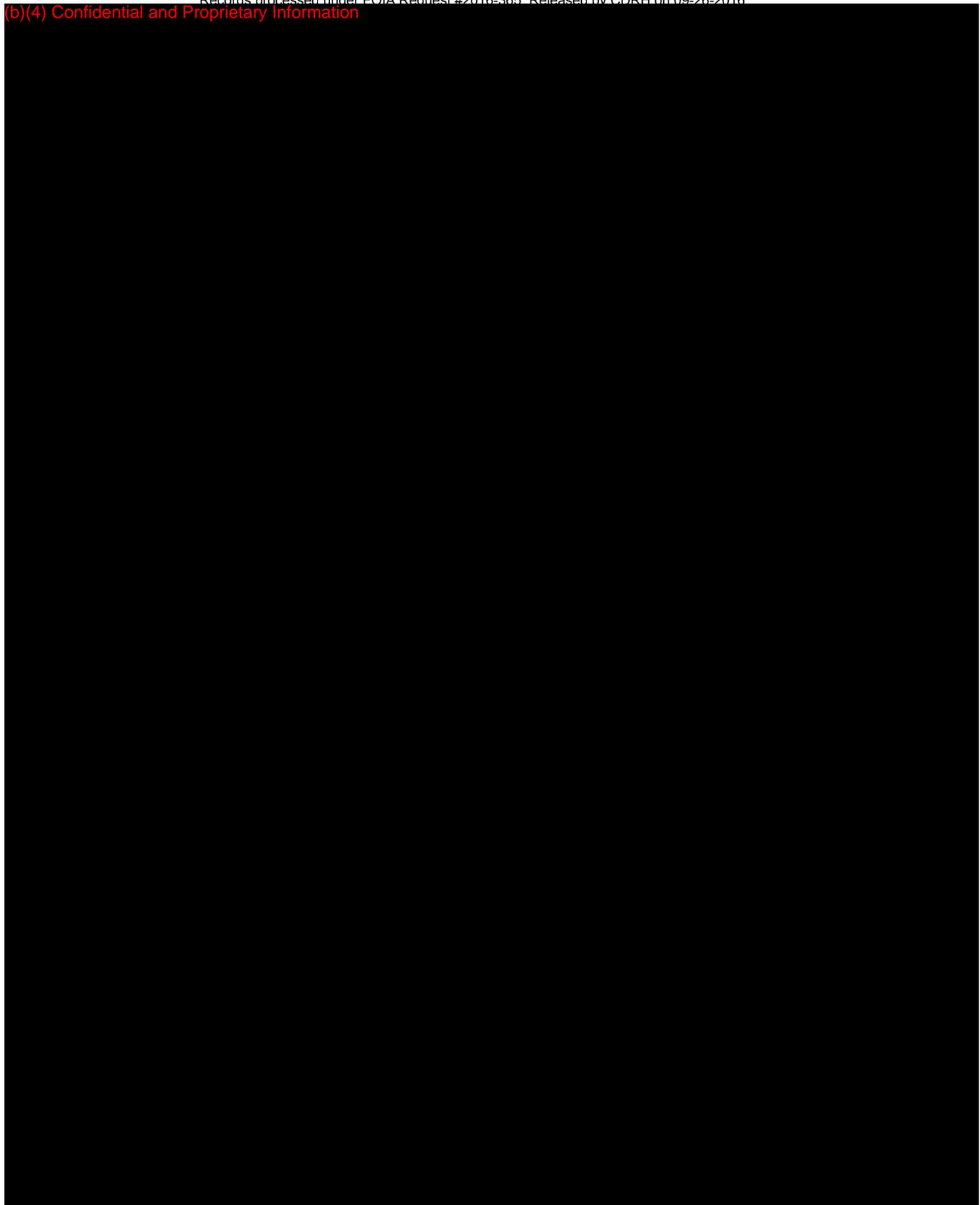
The interpretation of ANAM Military scores includes a multi-faceted examination of individual ANAM test module scores from both comparative (norms-based) and relative (individual-based) perspectives. While the basic principles of interpreting this test are straightforward, ANAM Military is not unlike other psychological tests in that sophisticated use is gained through practice, experience, and an appreciation for the complex relationships among the tests within the battery and the relationship between these tests and the broader framework of information regarding the test taker.

8.1 LEVELS OF INTERPRETATION

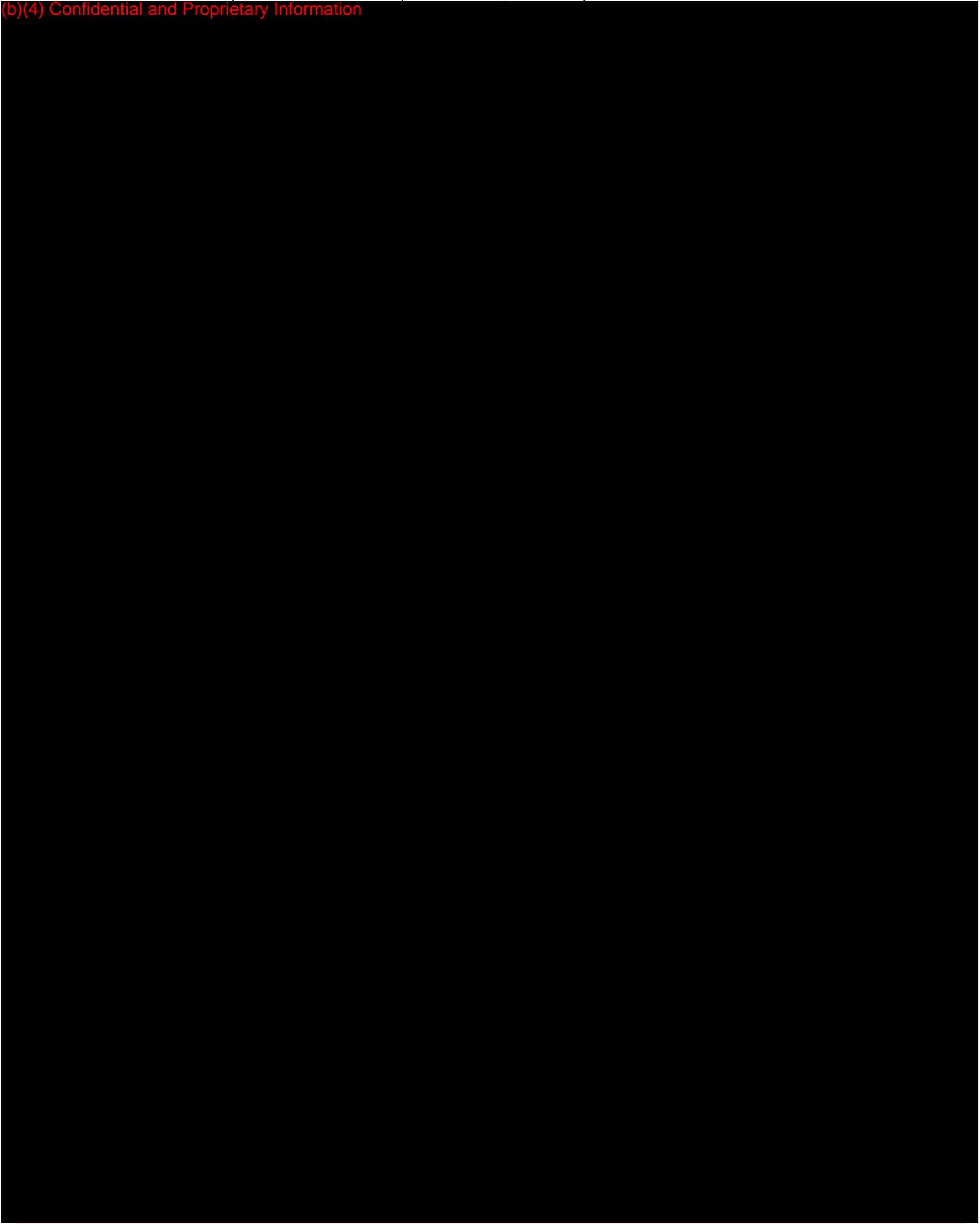
(b)(4) Confidential and Proprietary Information



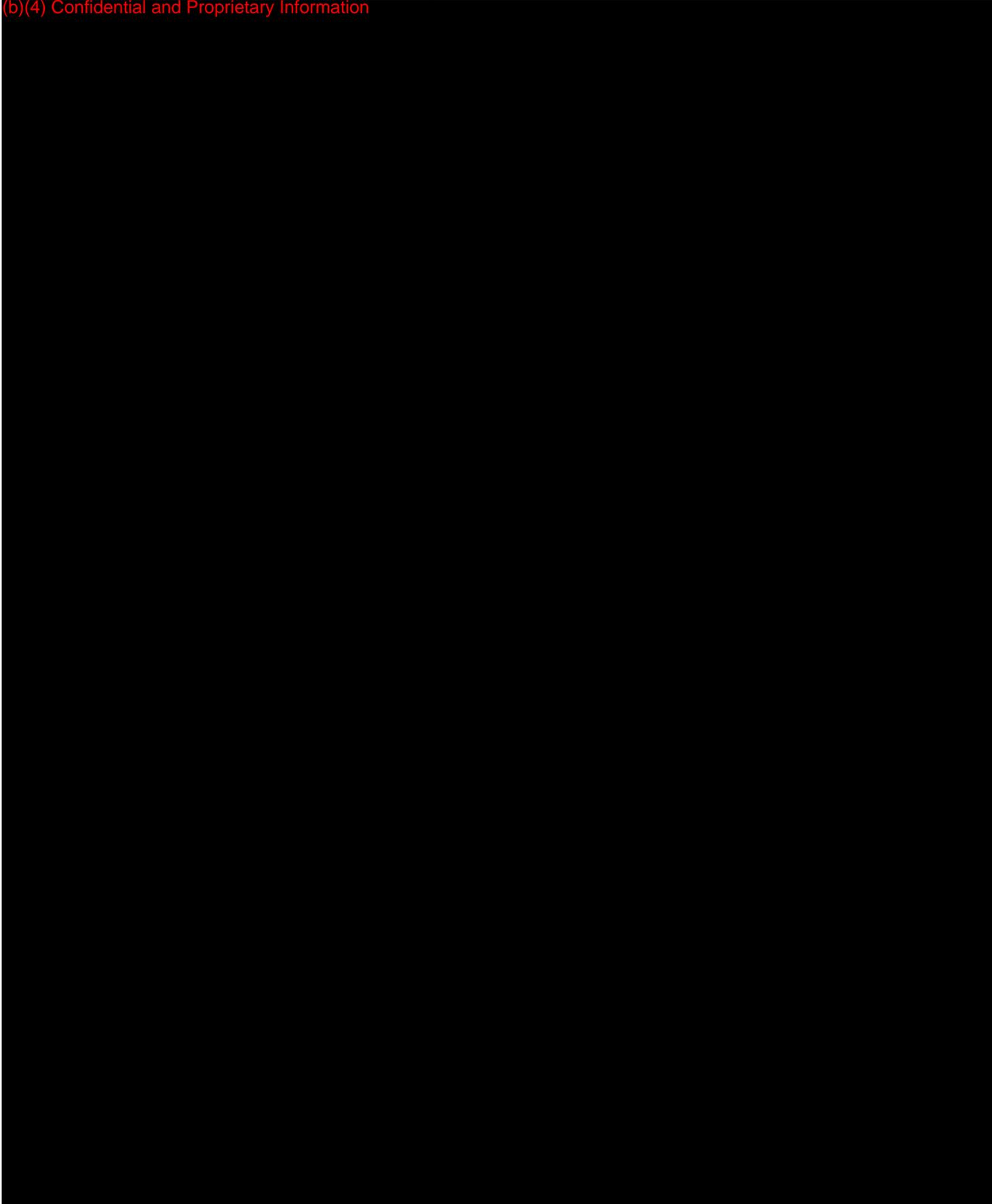
(b)(4) Confidential and Proprietary Information



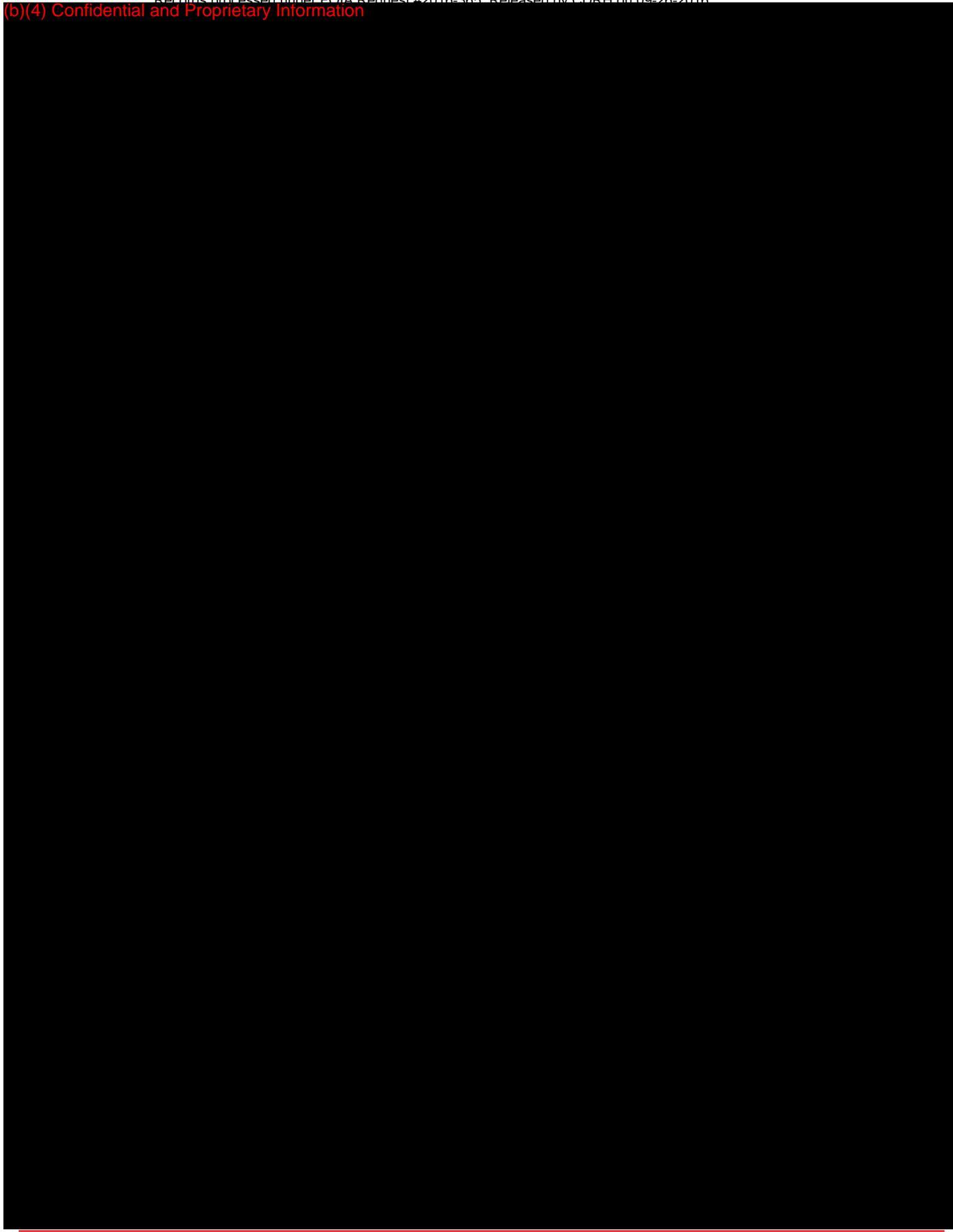
(b)(4) Confidential and Proprietary Information

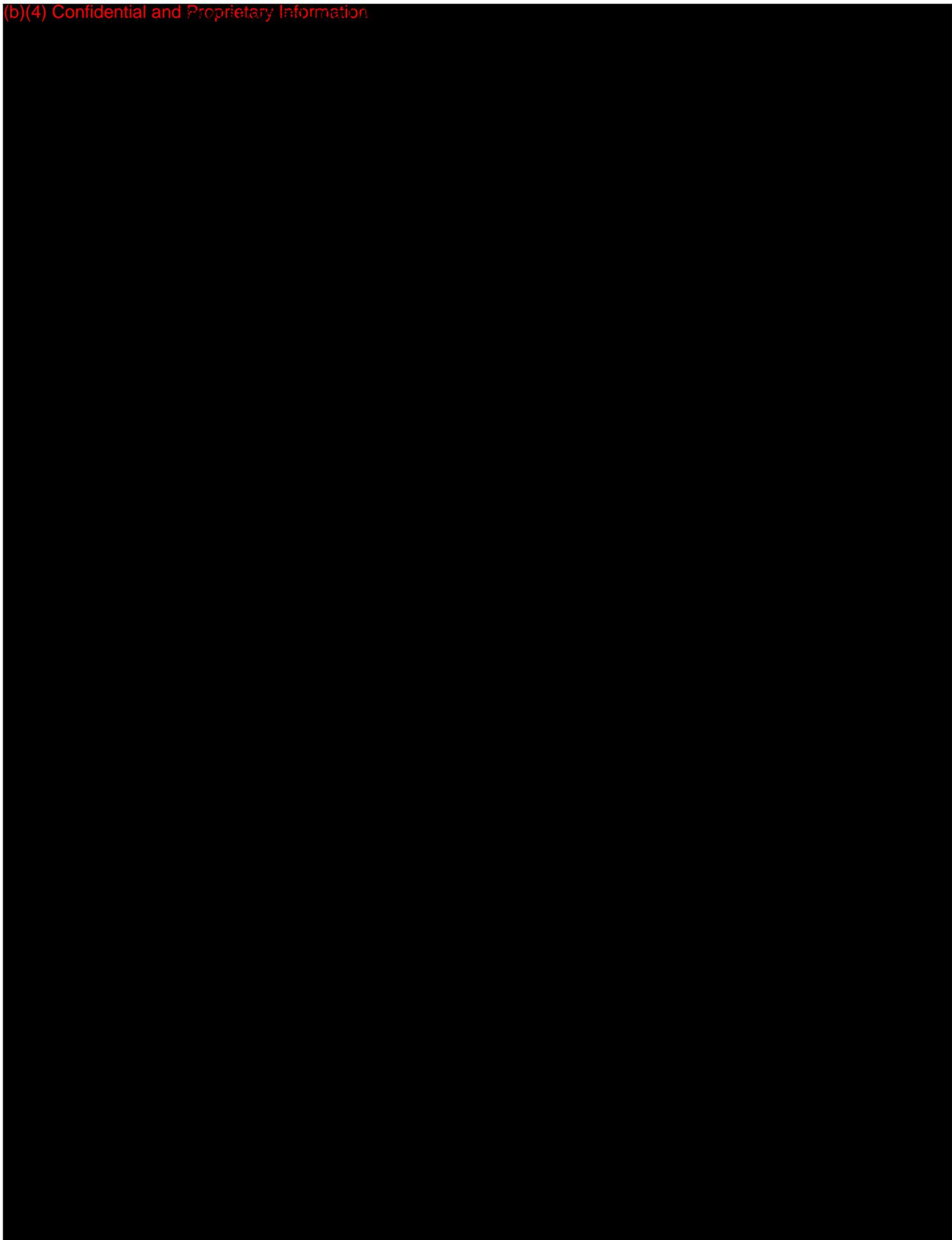


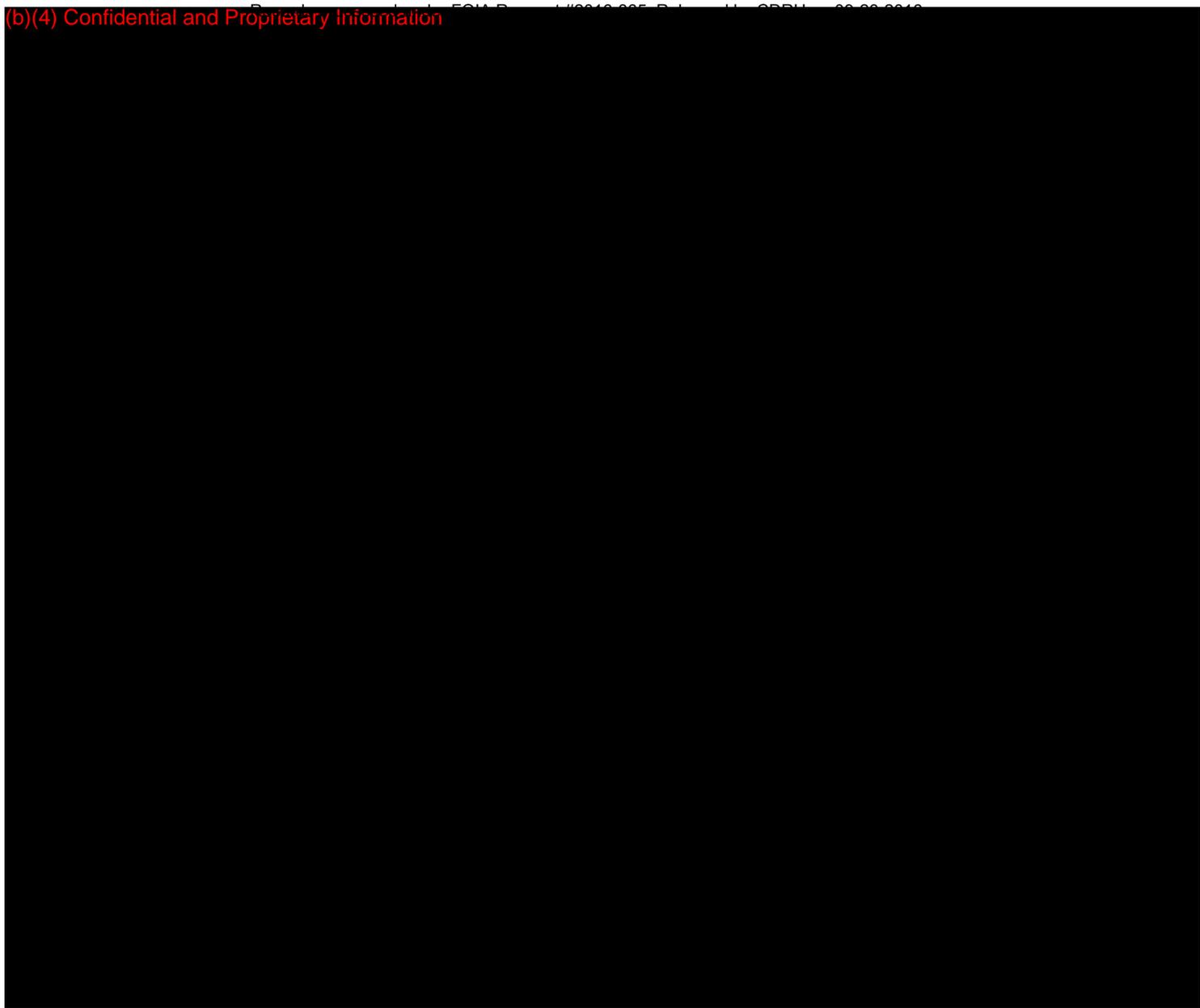
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Psychometric Properties

9.1 RELIABILITY AND STABILITY OF TEST SCORES

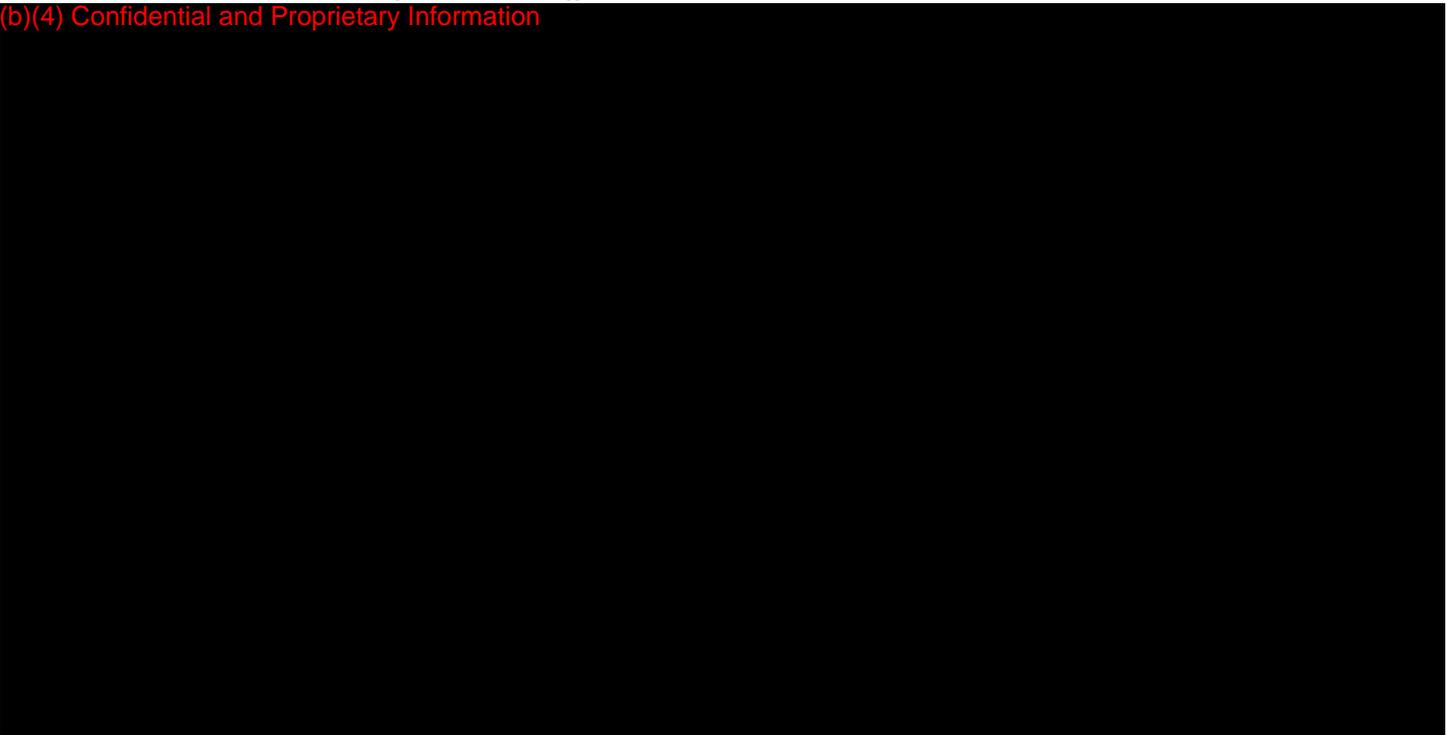
ANAM test development followed the principle of identifying relatively discrete cognitive, perceptual, neuropsychological, or human performance domains, then implementing a simple but effective test of that domain while minimizing factors that might add error variance (e.g., response modality). ANAM was specifically designed to meet the needs of researchers and clinicians assessing neuropsychological function in long-term (6 to 12 months), short-term (daily to weekly), and within sessions repeated measures assessment (hours; Reeves, Spector, Kane, Wood, Bleiberg, & Hegge, 1997). The system has a pseudo-randomization procedure that permits creation of near-limitless alternate forms from stimuli sets, thus allowing tests to be used for performance monitoring and in repeated-measures designs. While great effort has been taken to minimize practice effects in ANAM, like similar computerized neuropsychological tests, practice effects do exist and should be accounted for in research studies and clinical decision making.

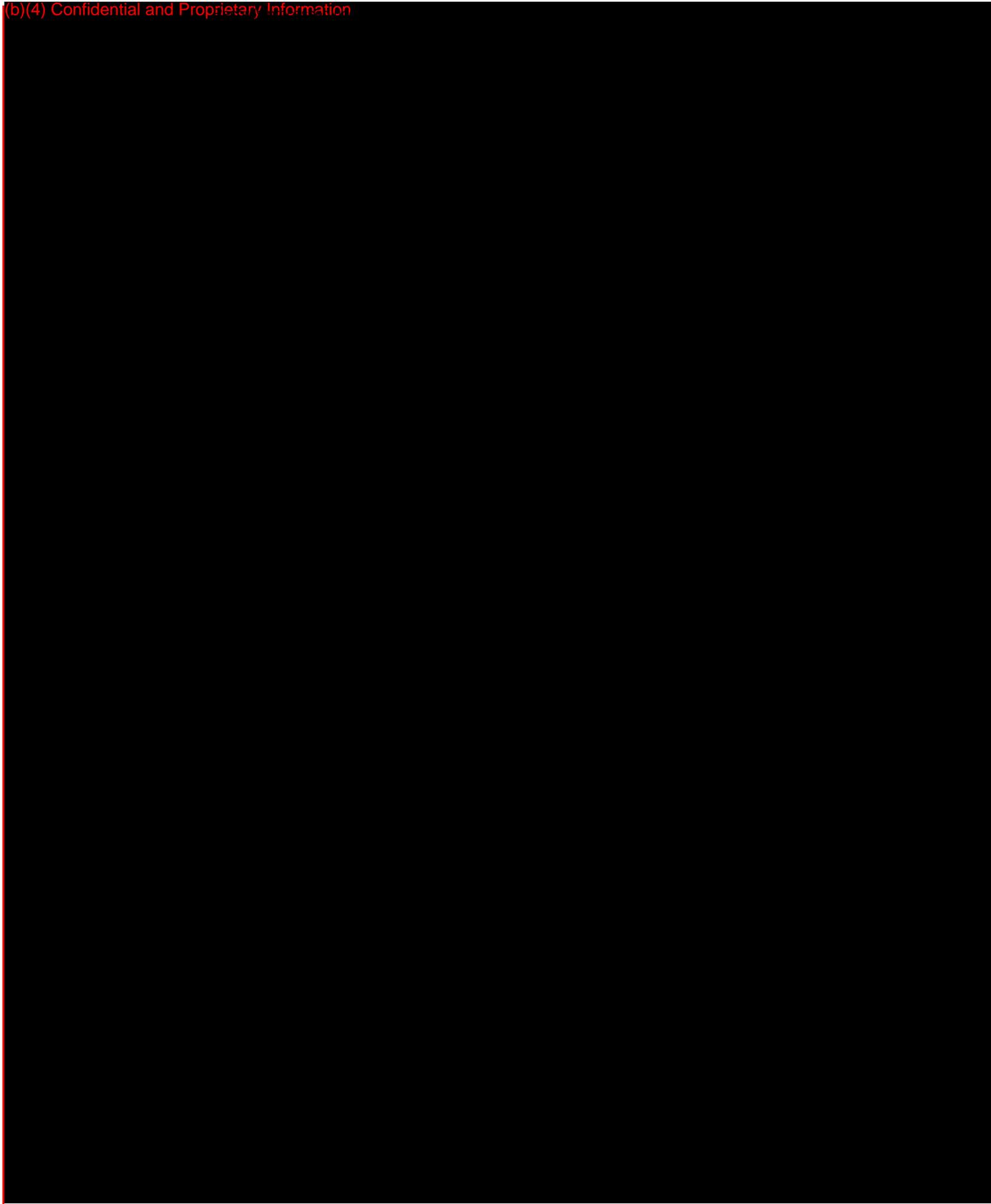
Several studies have examined the test-retest reliability of ANAM tests. Rather than pure test-retest reliability where an identical item set is used in multiple administrations, it is most likely that the published estimates represent alternate forms reliability (with varying delay intervals). The ANAM test system automatically detects when an individual has been previously assessed and will iterate to a new stimulus set, unless otherwise specified. Alternate forms reliability coefficients represent both the temporal stability of the test and the consistency of response to different sets of items (Anastasi & Urbina, 1997).

While steeped in a rich history of development and use in research laboratories, ANAM has evolved into a useful tool for clinical endeavors. While there are many commonalities between clinical and research testing protocols, it is often the case the test strategy employed in each is quite different. For example, a typical research paradigm might involve multiple administrations of ANAM over a relatively short time span (hours or days) while in a typical clinical paradigm longer test-retest intervals (6 to 12 months) are the standard.

9.1.1 Test-Retest Reliability and Practice Effects with Short Retest Intervals

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9.1.2 Test-Retest Reliability and Practice Effects with Long Retest Intervals

In contrast to many research studies where shorter retest intervals are common, *clinical protocols* tend to employ test administration models where longer test-retest intervals (6 to 12 months) are the standard. In these settings, ANAM may be administered to establish a baseline followed by testing upon injury, illness, or exposure some months or years from the baseline administration. The test-retest reliability and the nature of any practice or learning effects would be expected to follow a different course in this scenario.

Practice Effects (long intervals)

While the nature of the practice effects may be different, it should be noted that Daniel and colleagues (1999) demonstrated improvements that persisted over time (4 months) in a sample of high school athletes tested pre- and post-football season.

Vincent et al. (2012) examined the practice effects for ANAM Military (previously known as ANAM TBI-Mil) over a one-year interval in a large military sample (N = 8,002) with a relatively long test-retest interval (M = 396 days; SD = 78, min = 90, max = 489). Statistically significant differences were observed on all tests from session 1 to session 2 (see Table 4). These differences reflected *improved* performance for five of the seven tests. Additionally, for all but one test (i.e., Code Substitution – Delayed Memory), the overall change observed was less than five percent of baseline performance, and effect sizes were in the range of minimal to small. Specifically, for the two tests showing a decline in performance, the effect sizes were small. Thus, statistically significant findings are most likely due to the large sample sizes in this study and over-powered statistics.

Table 3. *Table of Throughput means (SEM) for a subset of ANAM Military tests in a military sample*

Test	Time 1:		Time 2:		Cohen's <i>d</i>
	Baseline (T1)	Post-Deployment (T2)	T2-T1		
Simple Reaction Time	234.4 (0.3)	241.1 (0.3)	6.7 (0.3)*		.23
Simple Reaction Time (R)	233.7 (0.3)	237.9 (0.4)	4.3 (0.4)*		.13
Procedural Reaction Time	100.4 (0.2)	104.5 (0.2)	4.1 (0.2)*		.28
Code Substitution–Learning	53.7 (0.1)	52.7 (0.1)	-1.0 (0.1) [†]		.10
Code Substitution–Delayed Memory	44.2 (0.2)	50.8 (0.2)	6.6 (0.2)*		.42
Matching to Sample	35.1 (0.1)	35.7 (0.1)	0.6 (0.1)*		.06
Mathematical Processing	21.6 (0.1)	20.7 (0.1)	-0.9 (0.1) [†]		.13
ANAM Composite Score	-0.04 (.01)	0.19 (.01)	0.22 (0.01)*		.22

*Significant improvement at $p < .0001$ using paired t-test.

[†]Significant decline at $p < .0001$ using paired t-test.

sem – standard error of measurement

Test-retest reliability

Several studies have addressed this using an alternate forms paradigm. Short et al. (2007) present preliminary data on the test-reliability of ANAM tests in 135 healthy volunteers. Several techniques for reliability estimation were explored yielding reliability estimates ranging from .50 to .94 for processing efficiency across a selection of ANAM tests, while reliability estimates for reaction time ranged from .37 to .93. Cernich, Reeves, Sun, and Bleiberg (2007) reported test-retest reliabilities ranging from .38 to .87 (average test-retest interval 166.5 days) in a sample of United States military academy cadets.

Vincent et al. (2012) also examined test-retest reliabilities. For this study, test-retest reliability ranged from 0.41 to 0.74 (see Table 5), with higher reliability coefficients corresponding to a composite score and tests with the highest cognitive demands (e.g., Mathematical Processing and Code Substitution – Learning). The lowest reliabilities were observed for the Simple Reaction Time and Procedural Reaction Time tests. These tests represent the most basic tests of processing speed, and normal “healthy” subjects will perform near ceiling levels according to the biological limits of response time. The lower ICC values for these tests likely reflect this restricted range of performance. Notably, overall test-retest reliabilities were comparable to those reported

for other traditional neuropsychological tests measuring processing speed over similar test-retest intervals (Strauss, Sherman, & Spreen, 2006). The effect of test-retest interval was also examined. Few differences were observed, but reliability estimates appeared to be the highest for the shortest test-retest interval. However, these reliability estimates are still likely to be attenuated given the relatively long interval between test sessions (e.g., the shortest interval was approximately three months with the majority of individuals having a test-retest interval that exceeded one year).

Table 4. *Test-retest reliability (1-year interval) estimates for ANAM Military tests in a military sample*

Test	Total Sample		Retest Interval Grouping (days)		
	Range		90-188	189-365	366-489
	Mean	M = 396	M = 150	M = 270	M = 432
	Std Dev	SD = 78	SD=28	SD = 42	SD = 17
	N	(N = 8,002)	(n=244)	(n=1,360)	(n=6,398)
Simple Reaction Time		.43 (.39, .46)	.34 (.22, .45)	.48 (.44, .52)	.42 (.38, .46)
Simple Reaction Time (R)		.41 (.39, .43)	.40 (.29, .50)	.48 (.43, .52)	.39 (.37, .42)
Procedural Reaction Time		.45 (.40, .50)	.39 (.27, .50)	.45 (.37, .52)	.46 (.40, .50)
Code Substitution–Learning		.74 (.72, .75)	.75 (.68, .80)	.76 (.74, .78)	.73 (.71, .75)
Code Substitution–Delayed Memory		.56 (.41, .66)	.55 (.40, .69)	.57 (.38, .69)	.55 (.41, .66)
Matching to Sample		.58 (.57, .60)	.63 (.54, .70)	.62 (.59, .65)	.57 (.56, .59)
Mathematical Processing		.71 (.69, .73)	.75 (.68, .80)	.75 (.72, .77)	.69 (.67, .71)
ANAM Composite Score		.68 (.63, .72)	.66 (.56, .74)	.70 (.66, .74)	.67 (.62, .72)

ICC – Intraclass correlation; CI – Confidence Interval

In summary, ANAM provides a consistent measure of cognitive functioning across many samples of healthy and clinical populations. Reliability estimates are consistent with those reported for other computer-based tests.

9.2 BASE RATES

Base rates of performance across tests in ANAM Military suggest that it is rare for a healthy individual to perform more than 2 SDs (corresponding to ‘Clearly Below Average’) below the mean on 2 or more tests or more than 1.3 SDs (corresponding to ‘Below Average’) below the mean on 3 or more tests (Table 5) (Vincent, Roebuck-Spencer, Gilliland, et al., 2012). These base rates are comparable to data from traditional neuropsychological tests. Heaton et al. (1996) showed that 28% of individuals perform > 2 SD below the mean on at least 1 of 25 tests in the Halstead-Reitan Battery, and 72% scored > 1 SD below the mean on 2 tests. Similarly, Schretlen et al. (2008) showed 11-24% perform > 2 SDs below the mean on 2 or more tests from a battery of 25-43 tests with 75% scoring >1 SD below the mean on 2 or more tests from a different set of 25 tests. While these rates are highly contingent on the number of tests in a given battery, overall, ANAM Military appears to be comparable to traditional testing in this area.

Table 5. *Proportion of Healthy Individuals Obtaining One or More ‘Below Average’ or ‘Clearly Below Average’ Scores Across the ANAM Military Battery*

Number of Tests	‘Below Average’ % ≥ 1.3 SD	‘Clearly Below Average’ % ≥ 2 SD
0	71.0	89.4
1	19.6	8.3
2	6.5	1.8
3	2.1	0.4
4	0.6	0.1
5	0.14	0.02
6	0.01	0.0
7	0	0.0

Vincent et al. (2012) examined the frequency of presumably healthy individuals (military sample) demonstrating a clinically significant *change* based on surpassing Reliable Change Index thresholds. Rates for individuals demonstrating meaningful declines in performance depended on the cut-point definition (see Table 6). For instance, when the most lenient cut-point was used (i.e., RCI-based decline for at least *one* ANAM test), 12.4% of the sample demonstrated a decline in ANAM performance at session 2. Using a more moderate, and recommended, cut-point of RCI-based change

on *two or more* ANAM tests, 2.3% of the sample demonstrated a meaningful decline in performance. Finally, it was very rare (< 1%) that meaningful declines in ANAM performance were observed for the most conservative cut-point (i.e., RCI-based change on *four or more* tests). Taken together, these data provide guidelines for cut-points for determining meaningful change in ANAM performance and provide base-rates of atypical performance (i.e., potential false positives) in a healthy, non-injured sample of active-duty military personnel. Interestingly, the rates of atypical performance on ANAM in this presumably healthy sample are consistent with or lower than rates of atypical performance reported for traditional neuropsychological batteries.

Table 6. Base rates of significant performance declines from pre- to post-deployment based on RCI analyses

Reliable Decline Present on	% of Individuals
0 tests	87.6%
1 test	10.1%
2-3 tests	2.0%
4 or more tests	<1%

RCI – Reliable Change Index

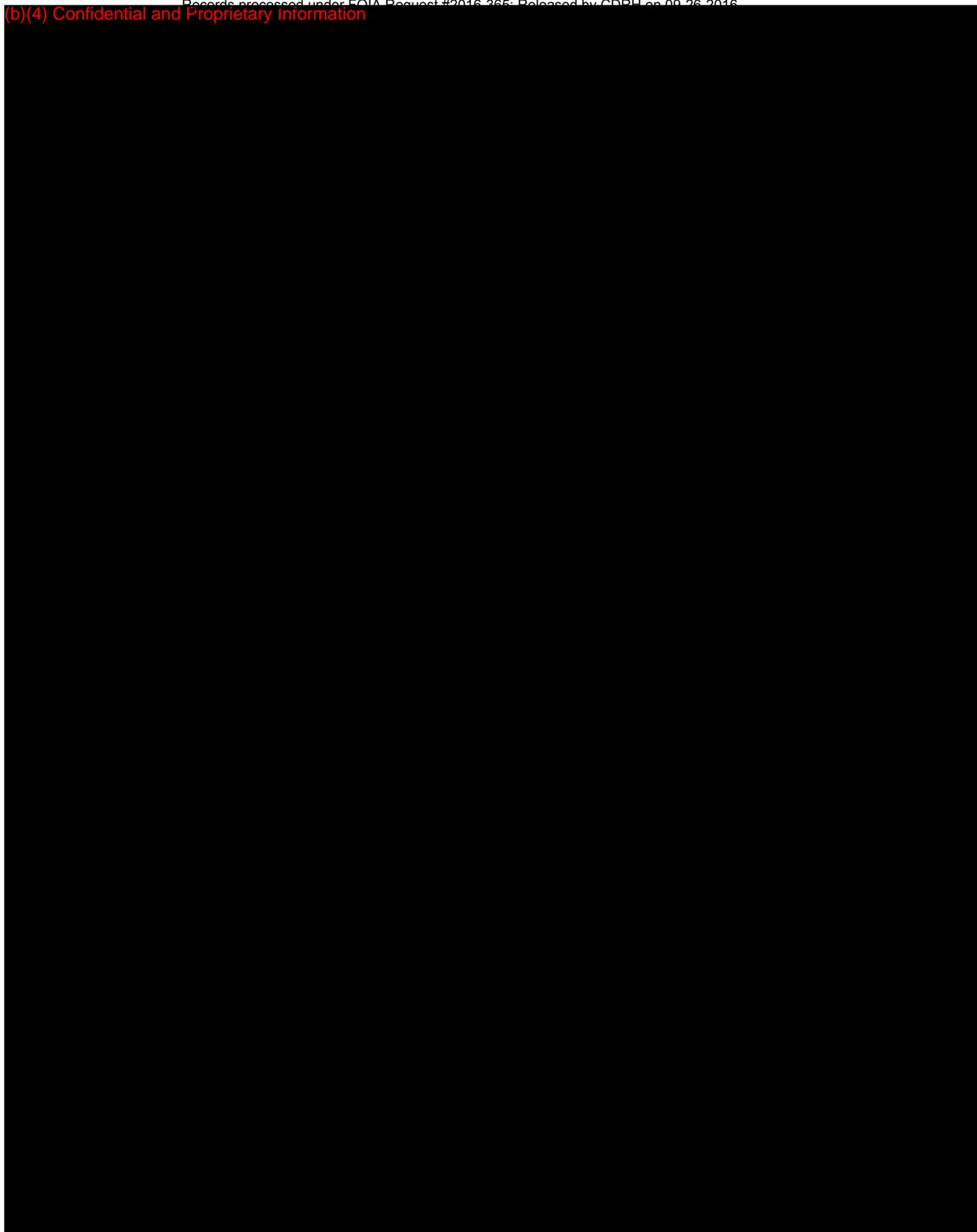
ANAM Data Converter

The ANAM Data Converter is designed to adjust ANAM data for consistency with normative data.

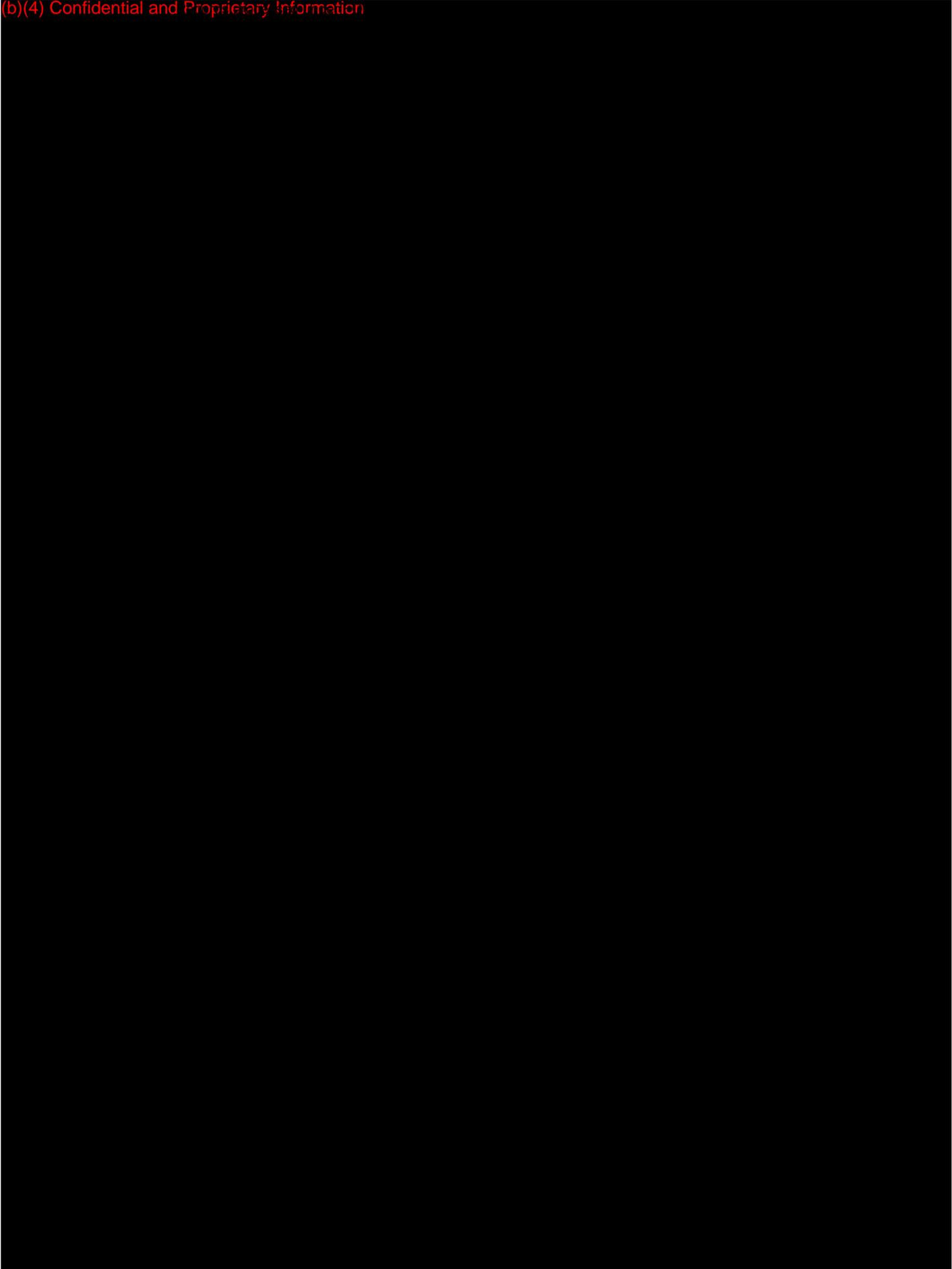
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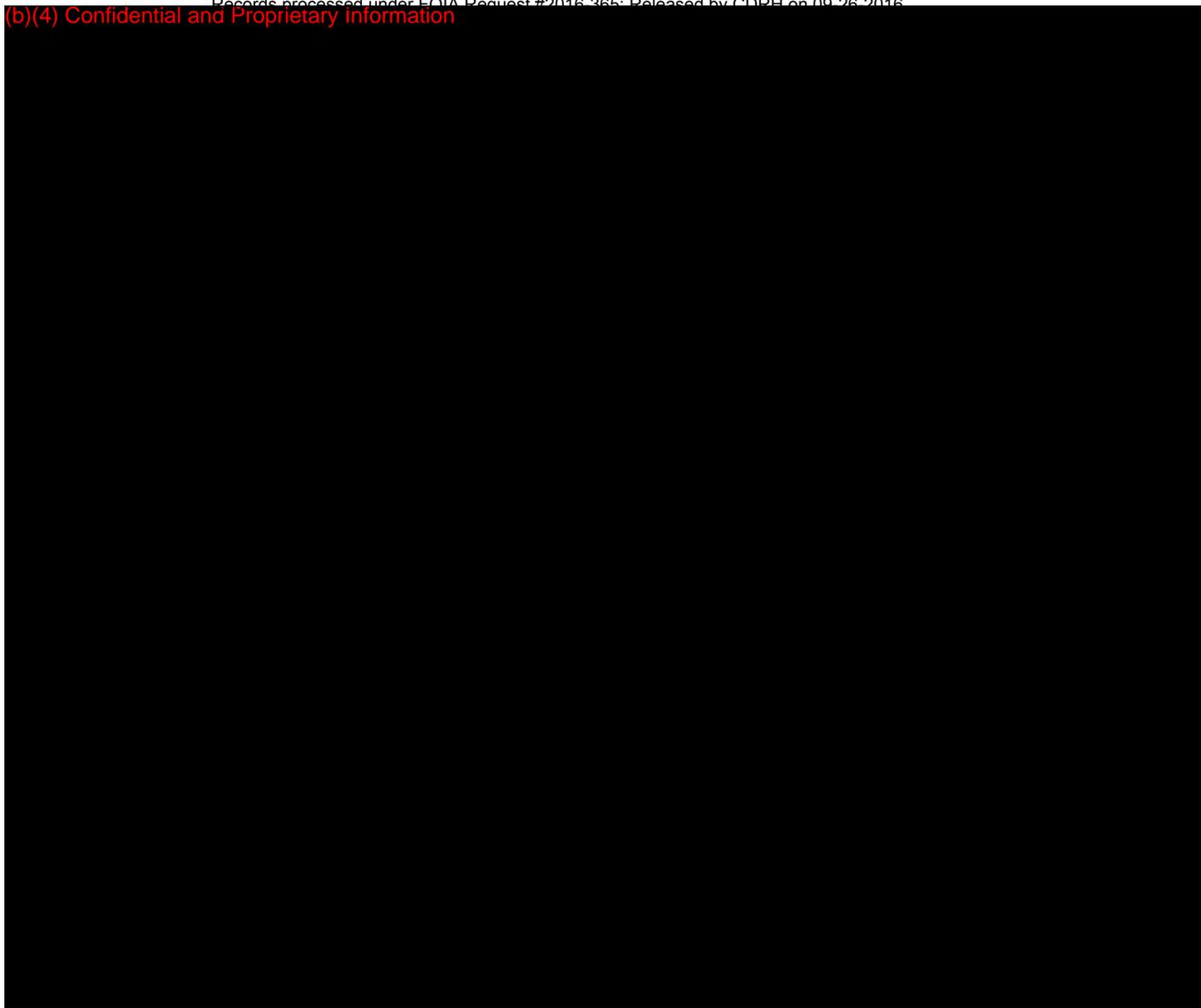
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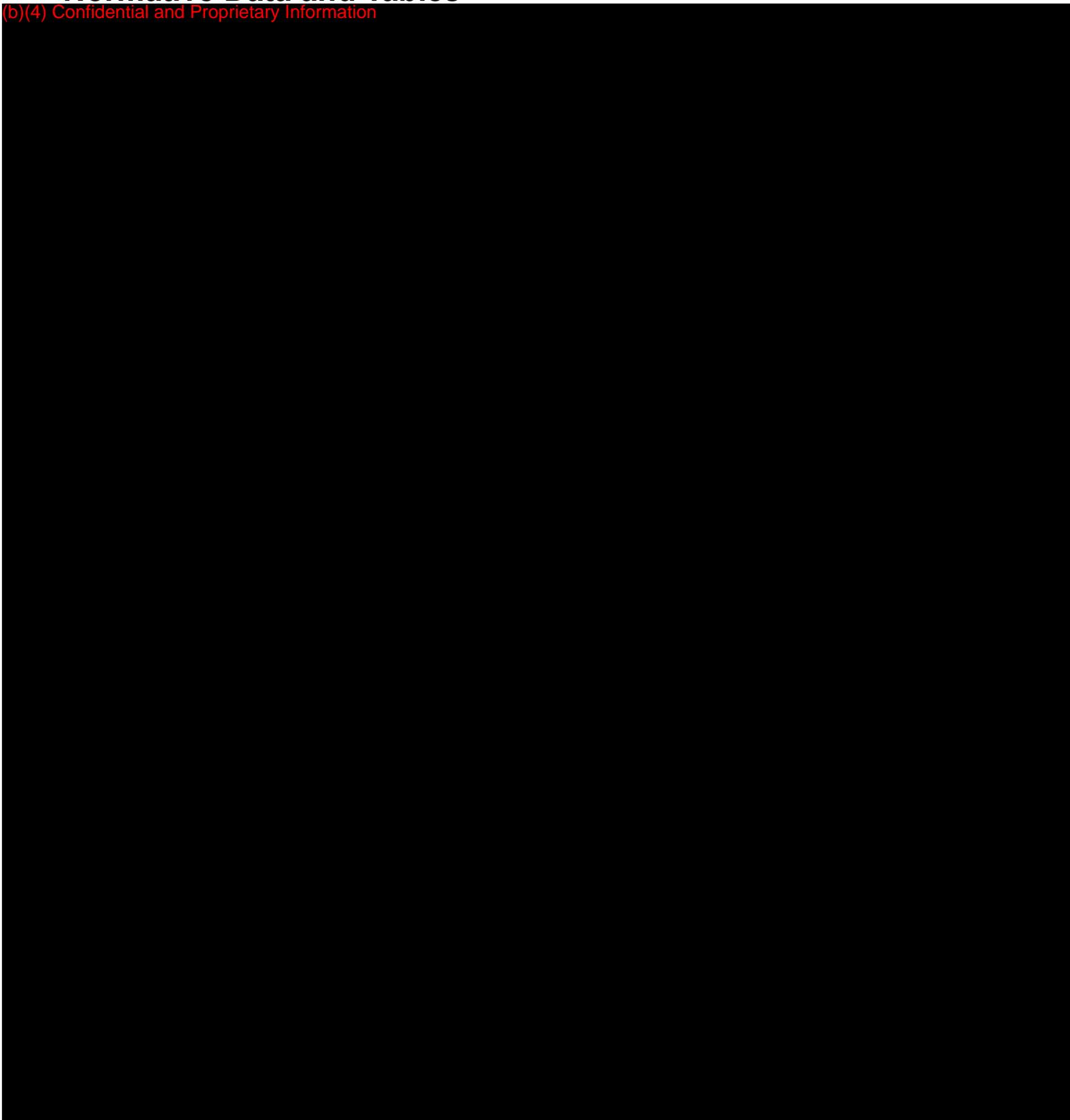


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Normative Data and Tables

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ANAM Test System

Military Battery

SOFTWARE REQUIREMENT SPECIFICATION

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ANAM Test System

Military Battery

SOFTWARE DESIGN SPECIFICATION

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Vista LifeSciences, Inc.

SOFTWARE DEVELOPMENT ENVIRONMENT DESCRIPTION

ANAM

Approver Name	Title	Date
Mickey Lutz	Chief Operating Officer	11/1/2014

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	Status: Final	Doc Number: 001
	Doc Type: Plan	Page 1 of 8

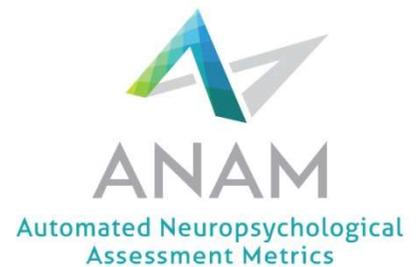
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Verification Plan for ANAM Test System: Military Version November 2014 Product Release

ANAM

Approver Name	Title	Date/Updated
Lori White	Quality System Program Mngr.	11/24/14
Lori White	Quality System Program Mngr.	Updated 1/15/15

ANAM Test System: Military Battery Validation



JUL 31 2015

Received

July 30, 2015

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center - W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002



K150154/51

Re: K150154 – ANAM Test System: Military Battery

Dear Dr. Gutowski:

In response to your request for additional information dated March 25, 2015, Vista LifeSciences is providing the following additional information.

As you know, the original 510(k) for the ANAM Test System: Military Battery (ANAM) identified the DANA (K141865) as the predicate device for ANAM. In a letter dated March 25, 2015, FDA informed Vista that it appeared that ANAM had a different intended use than DANA, and thus could not be used as a predicate device. In response, Vista submitted a PreSub with a submission issues meeting request (Q150445) and met with FDA on May 12, 2015, to discuss how to move forward. At that meeting, FDA indicated that there would be new information made available in the coming weeks that could affect the K150154 submission. However, FDA was unable to provide further details at that time.

On June 5, 2015, FDA published its decision to approve the *de novo* request for the Cognivue device [DEN130033]. FDA subsequently informed us that the Cognivue could be an appropriate predicate device for ANAM. Therefore, we are modifying the 510(k) submission to identify the Cognivue device as the predicate for ANAM. To support this change, we are providing the following updated sections of the 510(k):

- Section 5: 510(k) Summary
- Section 10: Executive Summary
- Section 12: Substantial Equivalence Discussion
- Revised Appendices F1 and F2

Because of the differences in indications for use and outcome measures, it is not possible to directly compare ANAM to the Cognivue device. Therefore, we believe that the previously submitted Performance Testing section demonstrates that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device. However, please note that we have modified the conclusion sections of the reports that were provided as Appendices F1 and F2 of the original submission. These are now provided as **Attachments D & E** of this response and only the conclusion sections have been edited to reflect the new predicate device. No other modifications were made to these reports.

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Please contact me if you have any questions regarding this response at 720-883-3633 or cherzog@bcg-usa.com.

Sincerely,



Calley Herzog
Consultant to Vista LifeSciences, Inc.

List of Attachments:

- A – Revised Section 5: 510(k) Summary
- B – Revised Section 10: Executive Summary
- C – Revised Section 12: Substantial Equivalence Discussion
- D – Revised Appendix F1: ANAM Military Battery Validation
- E – Revised Appendix F2: ANAM Performance Validity Index Performance

July 30, 2015

Food and Drug Administration
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- C – Revised Section 12: Substantial Equivalence Discussion
- D – Revised Appendix F1: ANAM Military Battery Validation
- E – Revised Appendix F2: ANAM Performance Validity Index Performance

510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for ANAM Test System: Military Battery is provided below.

Device Common Name: Computerized Cognitive Assessment Aid

Device Proprietary Name: ANAM Test System: Military Battery

Applicant: Vista LifeSciences, Inc.
PO Box 4670
Parker CO 80134
Phone: 888.733.8804 Ext. 1
www.vistalifesciences.com

Contact: Lori White
Quality Systems Program Manager
Vista LifeSciences, Inc.
PO Box 4670
Parker CO 80134
Phone: 888.733.8804 Ext. 1
Email: lori.white@vistalifesciences.com

Prepared by: Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington St. Suite 100
Alexandria, VA 22314
Email: cherzog@bcg-usa.com
Phone: 720-883-3633
Fax: 703-548-7457

Date Prepared: July 30, 2015

Classification Regulation: 882.1470

Panel: Neurology

Product Code: PKQ

Predicate Device: DEN130033, Cerebral Assessment Systems Cognivue

Indication for Use:

ANAM provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's medical or psychological state. Factors that may affect measurement of cognitive performance (such as reaction time and accuracy of responding) include, but are not limited to concussion, head injury,

insomnia, post-traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress). ANAM results should be interpreted only by qualified professionals.

Device Description:

ANAM Test System: Military Battery is a software only device that provides clinicians with objective measurements of cognitive performance in military populations, to aid in the assessment of an individual's medical or psychological state.

The software is downloaded from the Vista LifeSciences website and is for use on a Dell Latitude E6440 Laptop. The laptop is not provided as part of the device, but is purchased separately by the user. Each ANAM battery consists of a collection of pre-selected modules that are administered in a sequential manner.

Specific modules included in the ANAM Test System: Military Battery:

1. Demographics
2. Sleepiness Scale
3. Symptoms Checklist
4. Mood Scale
5. TBI Questionnaire
6. Simple Reaction Time
7. Code Substitution – Learning
8. Procedural Reaction Time
9. Mathematical Processing
10. Matching to Sample
11. Code Substitution – Delayed
12. Simple Reaction Time (R)

Performance Data:

The 510(k) included the results of numerous studies that examined the concurrent validity of ANAM as a clinical tool by documenting correlations with traditional neuropsychological tests. The results of these studies demonstrate that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

Substantial Equivalence:

Both devices are computerized assessment aids that use an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. In addition to perceptual and memory function, ANAM may be used as an adjunctive tool for evaluating additional functions including: visuomotor reaction time and processing speed, simple decision making, visual scanning, associative learning, visual-spatial processing, and attention.

	Proposed Device	Predicate Device
510(k) Number	K150154	DEN130033
Device Name	ANAM Test System: Military Battery	Cognivue
Submitter	Vista LifeSciences, Inc.	Cerebral Assessment Systems
Classification Regulation	Computerized Cognitive Assessment Aid	Computerized Cognitive Assessment Aid
Product Code	PKQ	PKQ
Indication	ANAM provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's medical or psychological state. Factors that may affect measurement of cognitive performance (such as reaction time and accuracy of responding) include, but are not limited to concussion, head injury, insomnia, post-traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress). ANAM results should be interpreted only by qualified professionals.	Cognivue is an adjunctive tool for evaluating perceptual and memory function in individuals aged 55-95 years old.
Platform	PC: Dell Latitude E6440 Laptop Computer, two button USB connected mouse, and Windows 7 operating system.	Computer, monitor, rotatory manipulandum, printer, and mouse/keyboard are provided on a device cart.
Use Cases	Reports individual test results and compares changes in individual tests over time and/or against military normative data.	Reports individual test results and compares overall performance to a cut-off.

	Proposed Device	Predicate Device
Patient Population	Military population	Adults
Age of Users	18-65 years	55-95 years
How Provided	Software only, downloaded	Software is pre-installed on computer hardware provided by the manufacturer.
Reporting features	ANAM Performance Report (APR) provides raw scores and standard scores (calculated with the military normative database) for each test within the battery. APR also yields the ANAM Composite Score (ACS) summarizing performance across the test battery.	Cognivue Performance Profile report yields a single output measure that is an average score of the four perception scores and four memory scores.
Psychometric Properties	ANAM demonstrates construct validity with traditional neuropsychological tests.	Cognivue demonstrates construct validity with traditional neuropsychological tests.
Results Interpretation	ANAM does not provide a recommendation that the patient is impaired vs. unimpaired. Clinical interpretation of the results includes comparison with the normative database. ANAM provides raw scores, standard scores, and reliable change indices for each test.	Cognivue provides an average score that is categorized as unimpaired, impaired, or intermediate/indeterminate based on comparison with a normative database. Sub-tests may not be evaluated individually.

Summary / Conclusion of Substantial Equivalence Rationale

Although there are some differences in the modules between ANAM and the predicate device, and ANAM provides a comparison to a normative database, the performance testing demonstrates that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

10. EXECUTIVE SUMMARY

10.1. Device Description

ANAM Test System: Military Battery (also referred to as ANAM Military or ANAM) is a software only device that provides clinicians with objective measurements of cognitive performance in military populations, to aid in the assessment of an individual's medical or psychological state.

The software is downloaded from the Vista LifeSciences website and is for use on a Dell Latitude E6440 Laptop. The laptop is not provided as part of the device, but is purchased separately by the user. The ANAM Test System: Military Battery consists of a collection of pre-selected modules that are administered in a sequential manner.

Specific modules included in the ANAM Test System: Military Battery are:

1. Demographics
2. Sleepiness Scale
3. Symptoms Checklist
4. Mood Scale
5. TBI Questionnaire
6. Simple Reaction Time
7. Code Substitution – Learning
8. Procedural Reaction Time
9. Mathematical Processing
10. Matching to Sample
11. Code Substitution – Delayed
12. Simple Reaction Time (R)

For a more detailed device description, see [Section 11](#).

10.2. Indication for Use Statement

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's medical or psychological state. Factors that may affect measurement of cognitive performance (such as reaction time and accuracy of responding) include, but are not limited to concussion, head injury, insomnia, post-traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of

psychological states (e.g. fatigue and stress). ANAM results should be interpreted only by qualified professionals.

FDA Form 3881 is provided as *Appendix A3*.

10.3. Reason for 510(k)

This is the first 510(k) submission for the ANAM Test System: Military Battery.

10.4. Substantial Equivalence

The predicate device for which substantial equivalence is established is the Cognivue, which was approved by de novo DEN130033 as a Computerized Cognitive Assessment Aid.

The intended use of ANAM is the same as that of the predicate device, namely to aid in the assessment of an individual's medical or psychological state.

Although there are some differences in the modules between ANAM and the predicate device, and ANAM provides a comparison to a normative database, the performance testing provided in Section 18 demonstrates that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

For a more detailed substantial equivalence analysis, see [Section 12](#).

10.5. Sterilization and Shelf Life

As a software only device, sterilization is not applicable and no shelf life is claimed for the device. Storage conditions could not affect safety and effectiveness.

10.6. Biocompatibility

As a software only device, there are no patient contacting components of the device and therefore biocompatibility is not applicable.

10.7. Performance Testing

Performance Testing – Bench

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Performance Testing – Animal

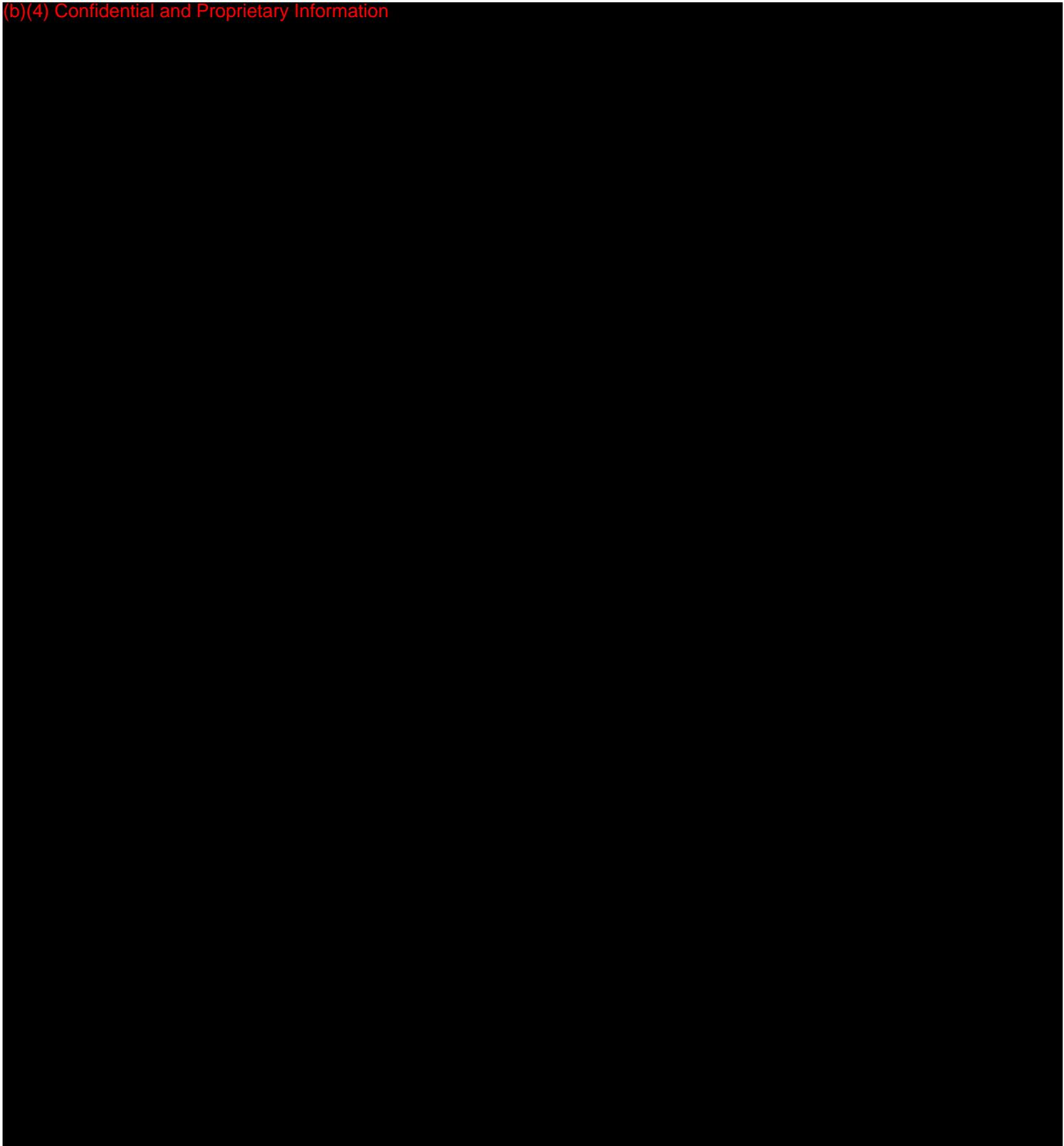
No animal studies were needed or provided in support of this 510(k).

Performance Testing – Clinical

No clinical studies were needed or provided in support of this 510(k).

12. SUBSTANTIAL EQUIVALENCE DISCUSSION

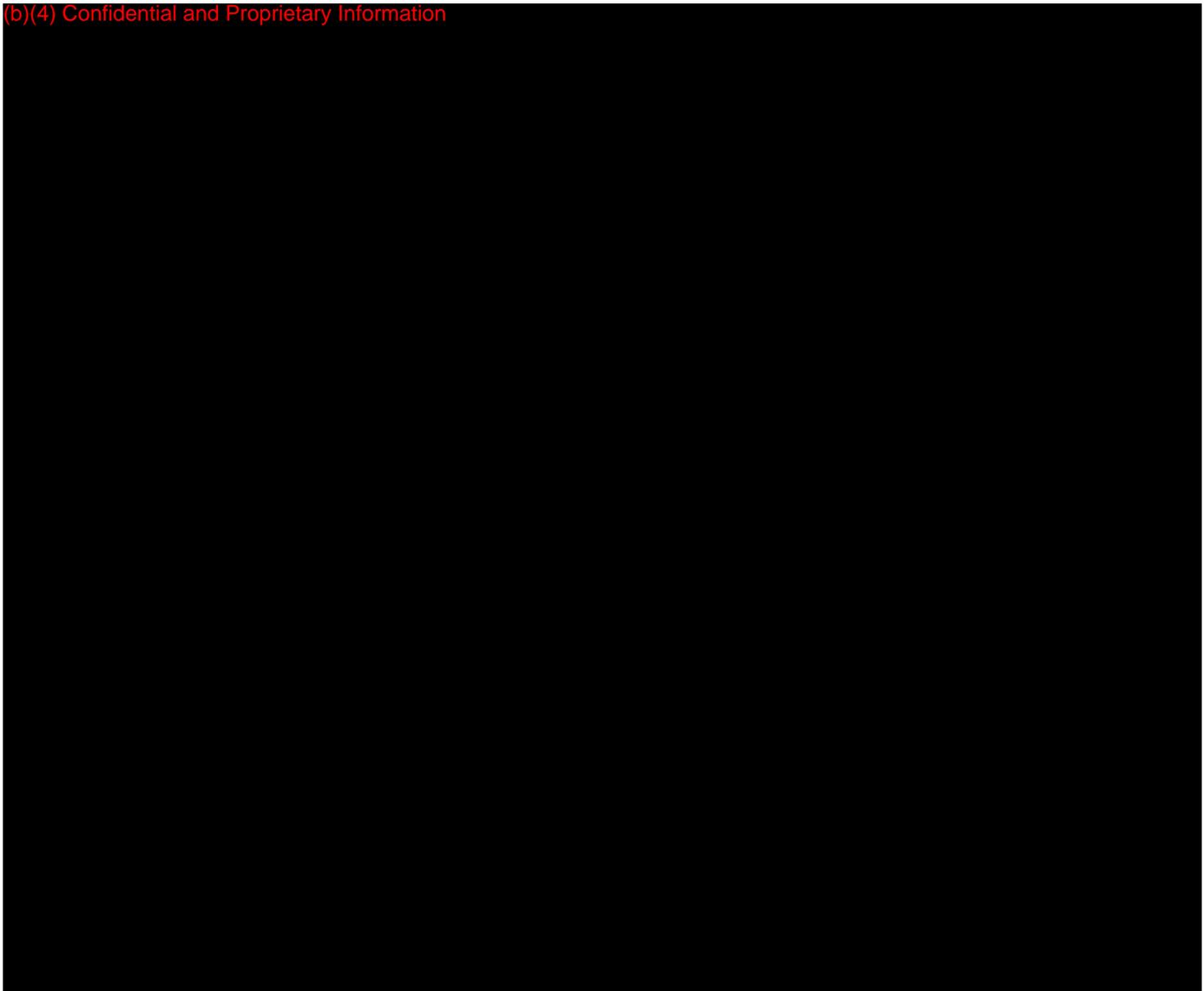
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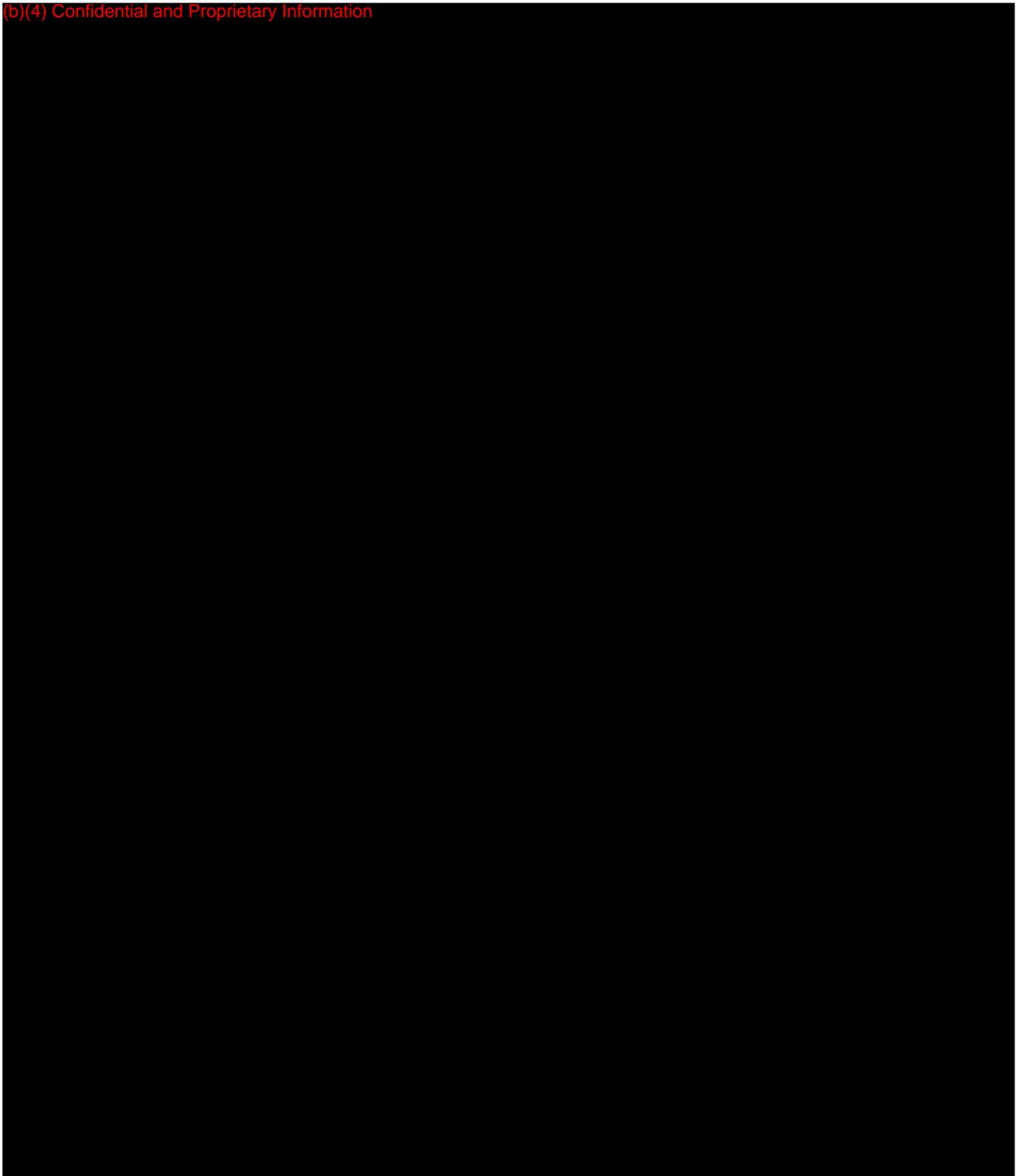
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(b)(4) Confidential and Proprietary Information



- CONFIDENTIAL -

Page 3

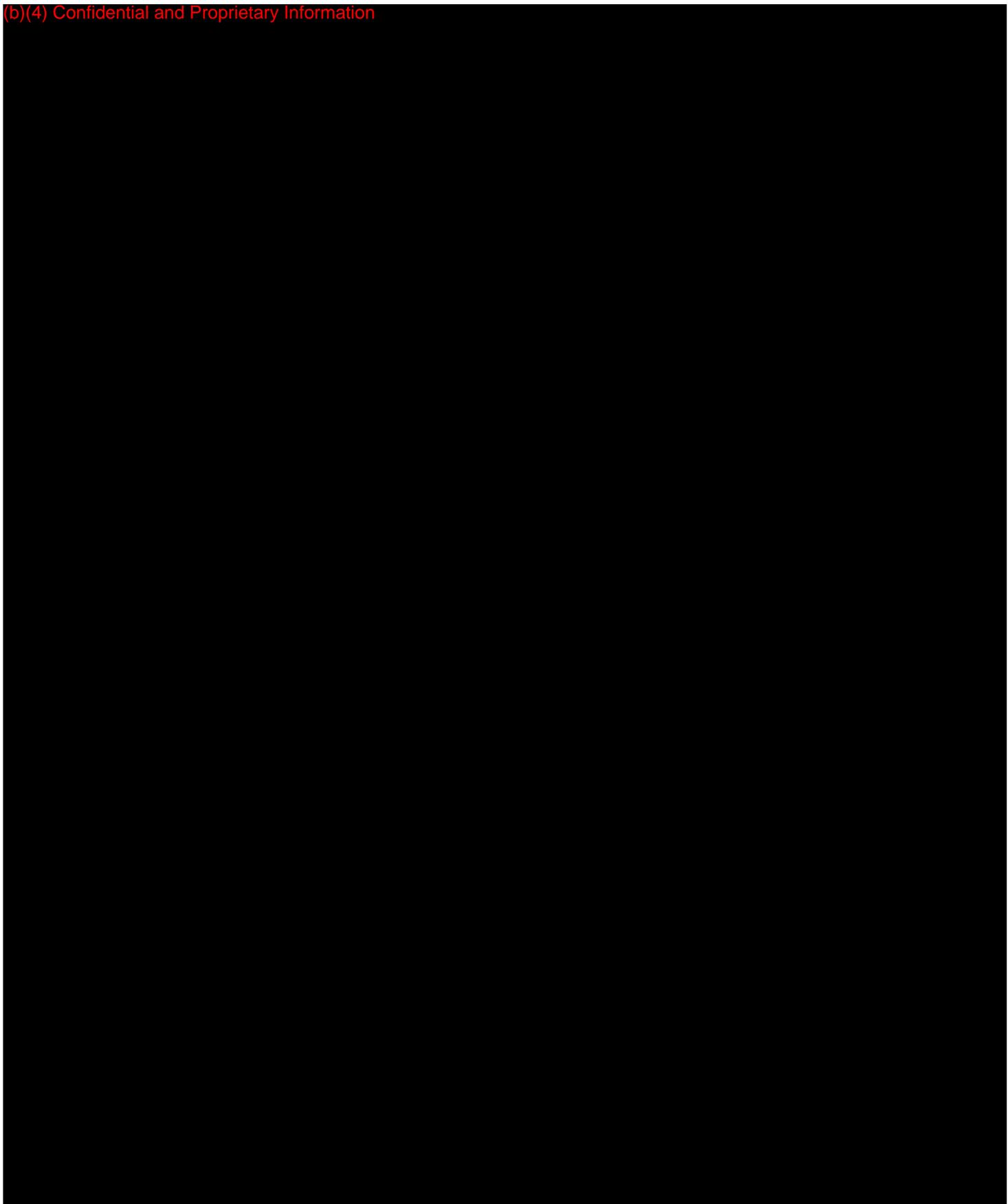
(b)(4) Confidential and Proprietary Information



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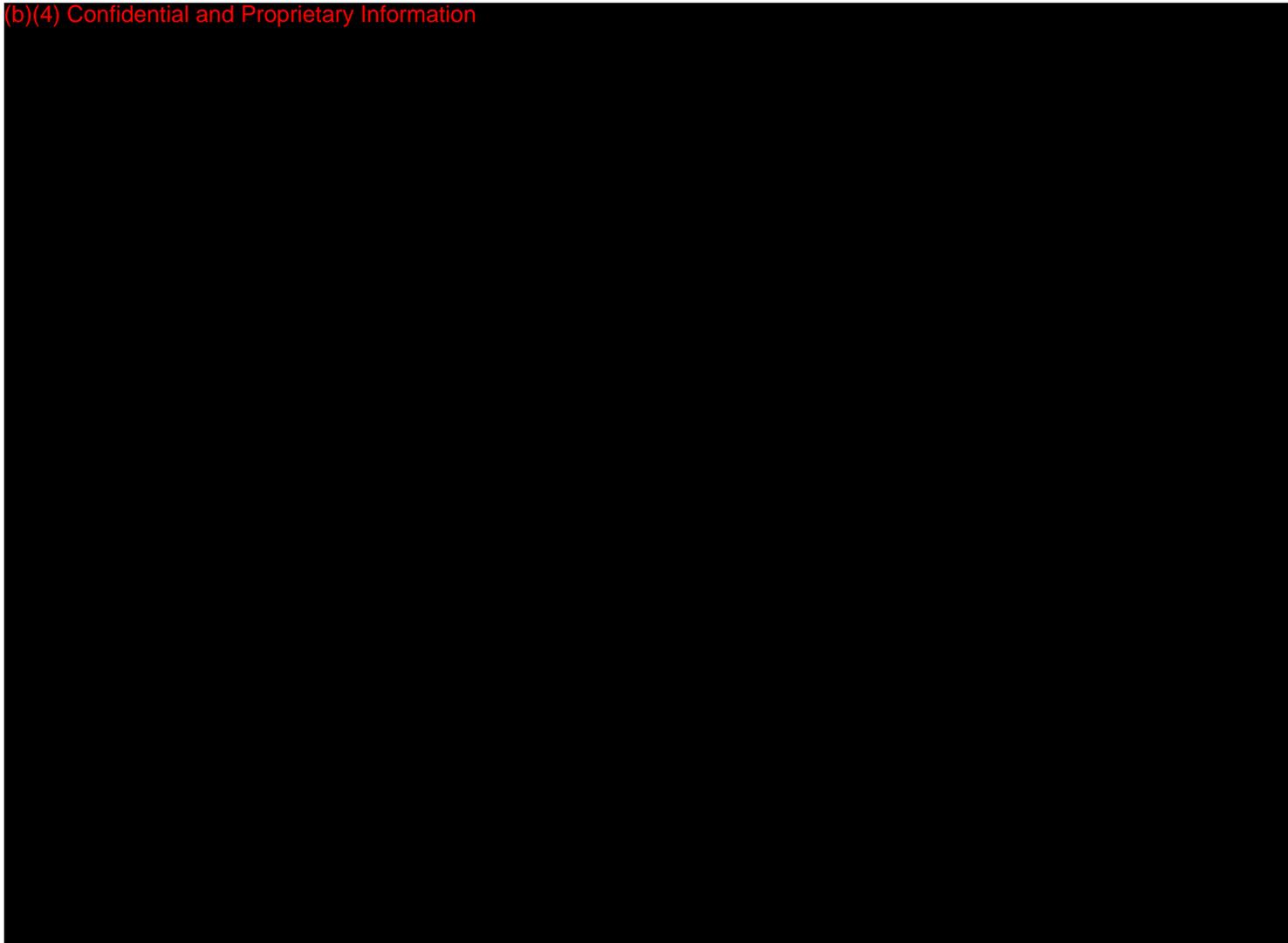
(b)(4) Confidential and Proprietary Information



- CONFIDENTIAL -

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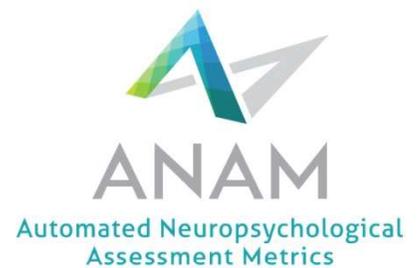
(b)(4) Confidential and Proprietary Information



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Page 6

ANAM Test System: Military Battery Validation



510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for ANAM Test System: Military Battery is provided below.

Device Common Name: Computerized Cognitive Assessment Aid

Device Proprietary Name: ANAM Test System: Military Battery

Applicant: Vista LifeSciences, Inc.
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Contact: Lori White
Quality Systems Program Manager
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Email: lori.white@vistalifesciences.com

Prepared by: Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
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Alexandria, VA 22314
Email: cherzog@bcg-usa.com
Phone: 720-883-3633
Fax: 703-548-7457

Date Prepared: July 30, 2015

Classification Regulation: 882.1470

Panel: Neurology

Product Code: PKQ

Predicate Device: DEN130033, Cerebral Assessment Systems Cognivue

Indication for Use:

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.

Device Description:

ANAM Test System: Military Battery is a software only device that provides clinicians with objective measurements of cognitive performance in military populations, to aid in the assessment of an individual's level of cognitive function.

The software is downloaded from the Vista LifeSciences website and is for use on a Dell Latitude E6440 Laptop. The laptop is not provided as part of the device, but is purchased separately by the user. Each ANAM battery consists of a collection of pre-selected modules that are administered in a sequential manner.

Specific modules included in the ANAM Test System: Military Battery:

1. Demographics
2. Sleepiness Scale
3. Symptoms Checklist
4. Mood Scale
5. TBI Questionnaire
6. Simple Reaction Time
7. Code Substitution – Learning
8. Procedural Reaction Time
9. Mathematical Processing
10. Matching to Sample
11. Code Substitution – Delayed
12. Simple Reaction Time (R)

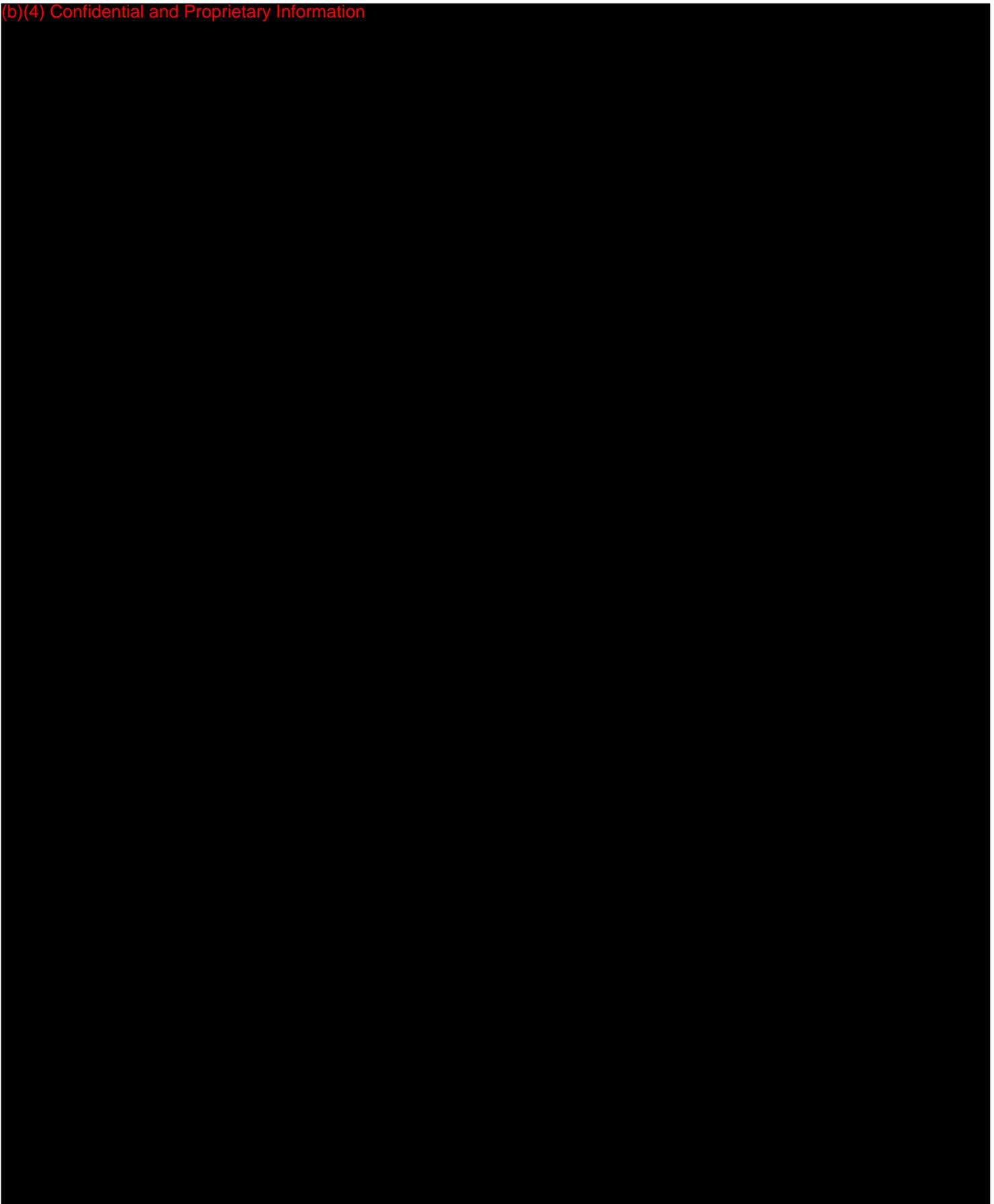
Performance Data:

The 510(k) included the results of numerous studies that examined the concurrent validity of ANAM as a clinical tool by documenting correlations with traditional neuropsychological tests. The results of these studies demonstrate that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

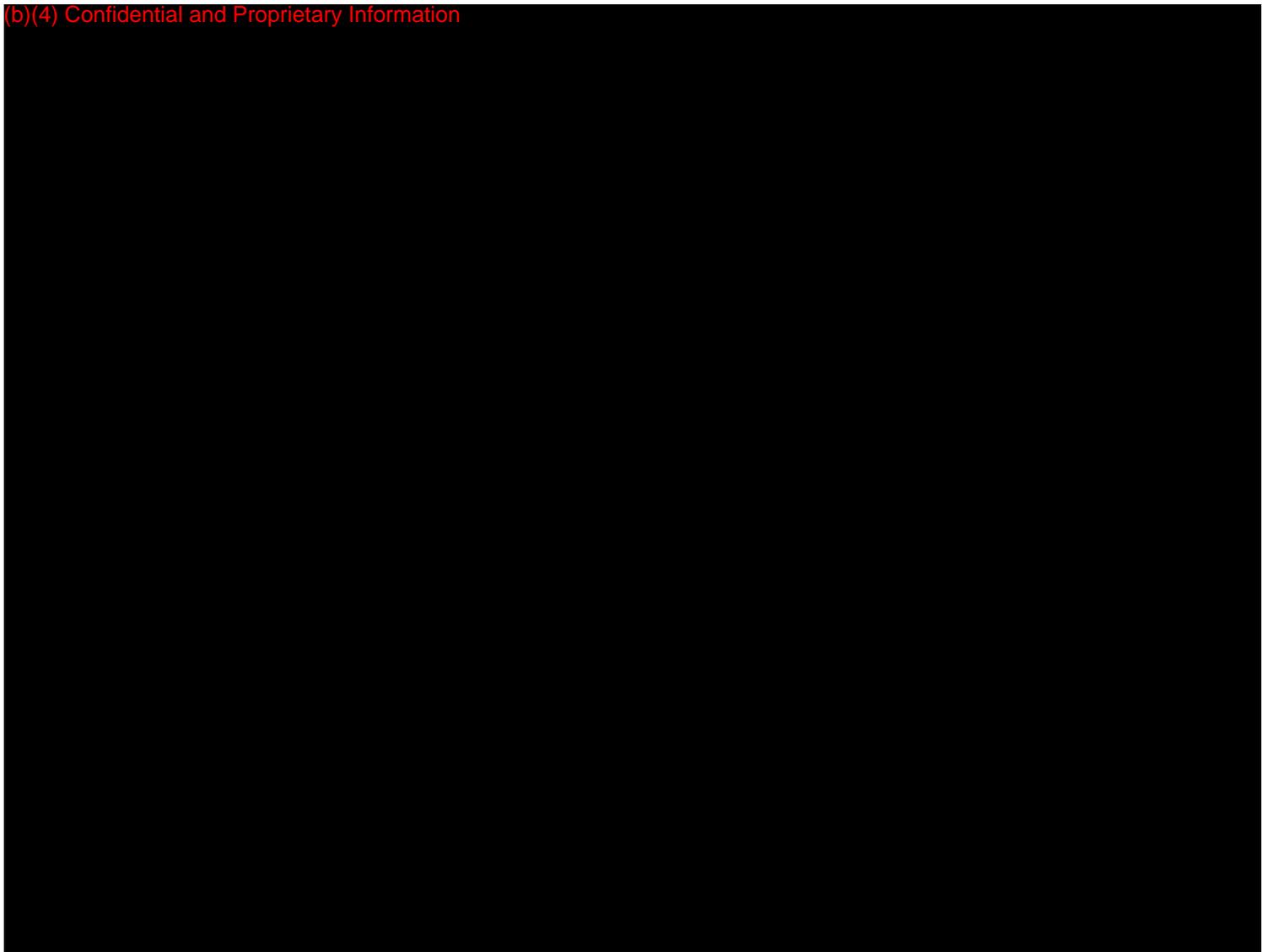
Substantial Equivalence:

Both devices are computerized assessment aids that use an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. In addition to perceptual and memory function, ANAM may be used as an adjunctive tool for evaluating additional functions including: visuomotor reaction time and processing speed, simple decision making, visual scanning, associative learning, visual-spatial processing, and attention.

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Summary / Conclusion of Substantial Equivalence Rationale

Although there are some differences in the modules between ANAM and the predicate device, and ANAM provides a comparison to a normative database, the performance testing demonstrates that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

510(K) SUMMARY

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Device Proprietary Name: ANAM Test System: Military Battery

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Prepared by: Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington St. Suite 100
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Product Code: PKQ

Predicate Device: DEN130033, Cerebral Assessment Systems Cognivue

Indication for Use:

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.

Device Description:

ANAM Test System: Military Battery is a software only device that provides clinicians with objective measurements of cognitive performance in military populations, to aid in the assessment of an individual's level of cognitive function.

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Specific modules included in the ANAM Test System: Military Battery:

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Performance Data:

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	Proposed Device	Predicate Device
510(k) Number	K150154	DEN130033
Device Name	ANAM Test System: Military Battery	Cognivue
Submitter	Vista LifeSciences, Inc.	Cerebral Assessment Systems
Classification Regulation	Computerized Cognitive Assessment Aid	Computerized Cognitive Assessment Aid
Product Code	PKQ	PKQ
Indication	The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.	Cognivue is an adjunctive tool for evaluating perceptual and memory function in individuals aged 55-95 years old.
Platform	PC: Dell Latitude E6440 Laptop Computer, two button USB connected mouse, and Windows 7 operating system.	Computer, monitor, rotatory manipulandum, printer, and mouse/keyboard are provided on a device cart.
Use Cases	Reports individual test results and compares changes in individual tests over time and/or against military normative data.	Reports individual test results and compares overall performance to a cut-off.

	Proposed Device	Predicate Device
Patient Population	Military population	Adults
Age of Users	18-65 years	55-95 years
How Provided	Software only, downloaded	Software is pre-installed on computer hardware provided by the manufacturer.
Reporting features	ANAM Performance Report (APR) provides raw scores and standard scores (calculated with the military normative database) for each test within the battery. APR also yields the ANAM Composite Score (ACS) summarizing performance across the test battery.	Cognivue Performance Profile report yields a single output measure that is an average score of the four perception scores and four memory scores.
Psychometric Properties	ANAM demonstrates construct validity with traditional neuropsychological tests.	Cognivue demonstrates construct validity with traditional neuropsychological tests.
Results Interpretation	ANAM does not provide a recommendation that the patient is impaired vs. unimpaired. Clinical interpretation of the results includes comparison with the normative database. ANAM provides raw scores, standard scores, and reliable change indices for each test.	Cognivue provides an average score that is categorized as unimpaired, impaired, or intermediate/indeterminate based on comparison with a normative database. Sub-tests may not be evaluated individually.

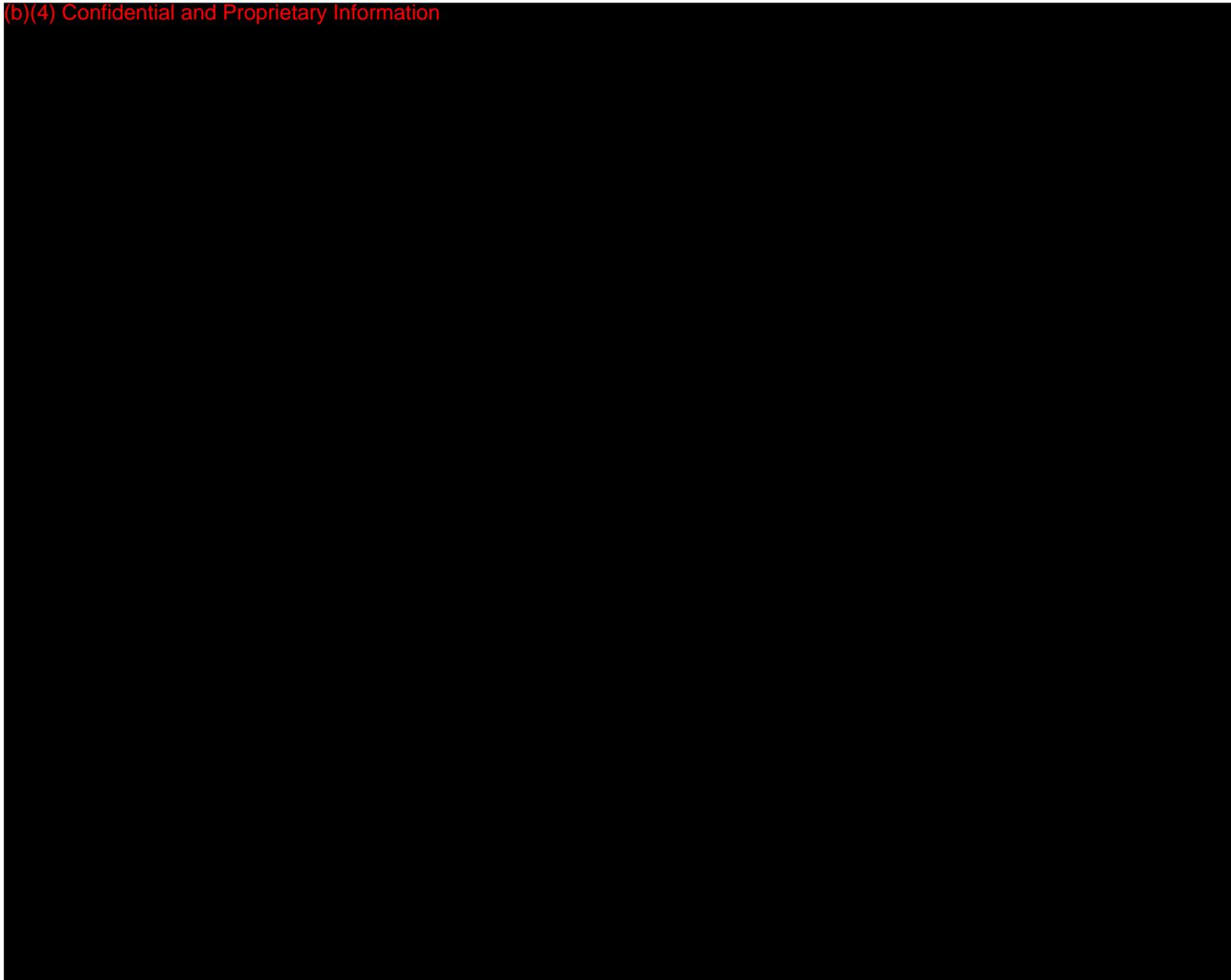
Summary / Conclusion of Substantial Equivalence Rationale

Although there are some differences in the modules between ANAM and the predicate device, and ANAM provides a comparison to a normative database, the performance testing demonstrates that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

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This is a summary data file in CSV format for subject 32545 taking Test Session number 1 of the Simple Reaction Time Test.

5.2 ANAM DATA STORAGE

The default “primary data directory” is displayed on the *Battery Selection screen*. Shown below are two fields to enter a Primary Data Directory and Individual Data Directory. Completed ANAM module data will be stored in the directories as specified in these fields.

The default *Primary Data Directory* in this example is `c:\anamdata\123456789`. The data from all completed modules will be saved in this directory or folder (where 123456789 is the id number of the individual being tested). The default for the *Individual Data Directory* is blank.

By default, the Primary and Individual Data Directory fields are locked. To modify these fields, press **<ALT>+<F1>**, which will unlock the fields and allow you type the desired data directory or navigate to the desired directory by pressing the **Browse** button.



 A primary data directory of `c:\anamdata\123456789` is equivalent to a *primary* data directory of `c:\anamdata` combined with an *individual* data directory of 123456789.

To configure ANAM to consistently use a different data directory please see [4.4.2 ANAM Initial Set-up](#).

The default storage location for *converted* ANAM data files is `c:\anamdata-converted`. See [Chapter 10](#) for more information on data conversion.

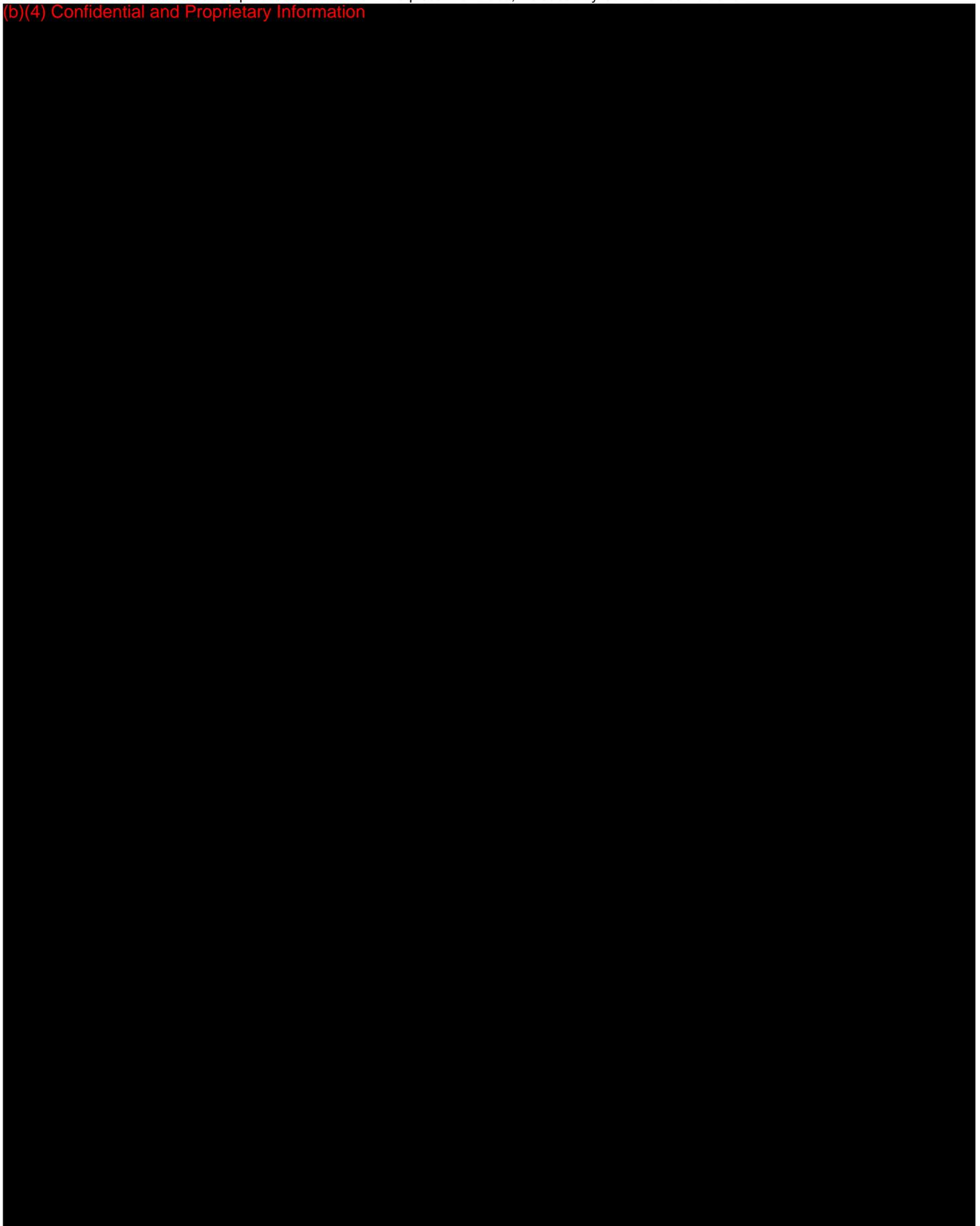
5.3 VIEWING ANAM DATA

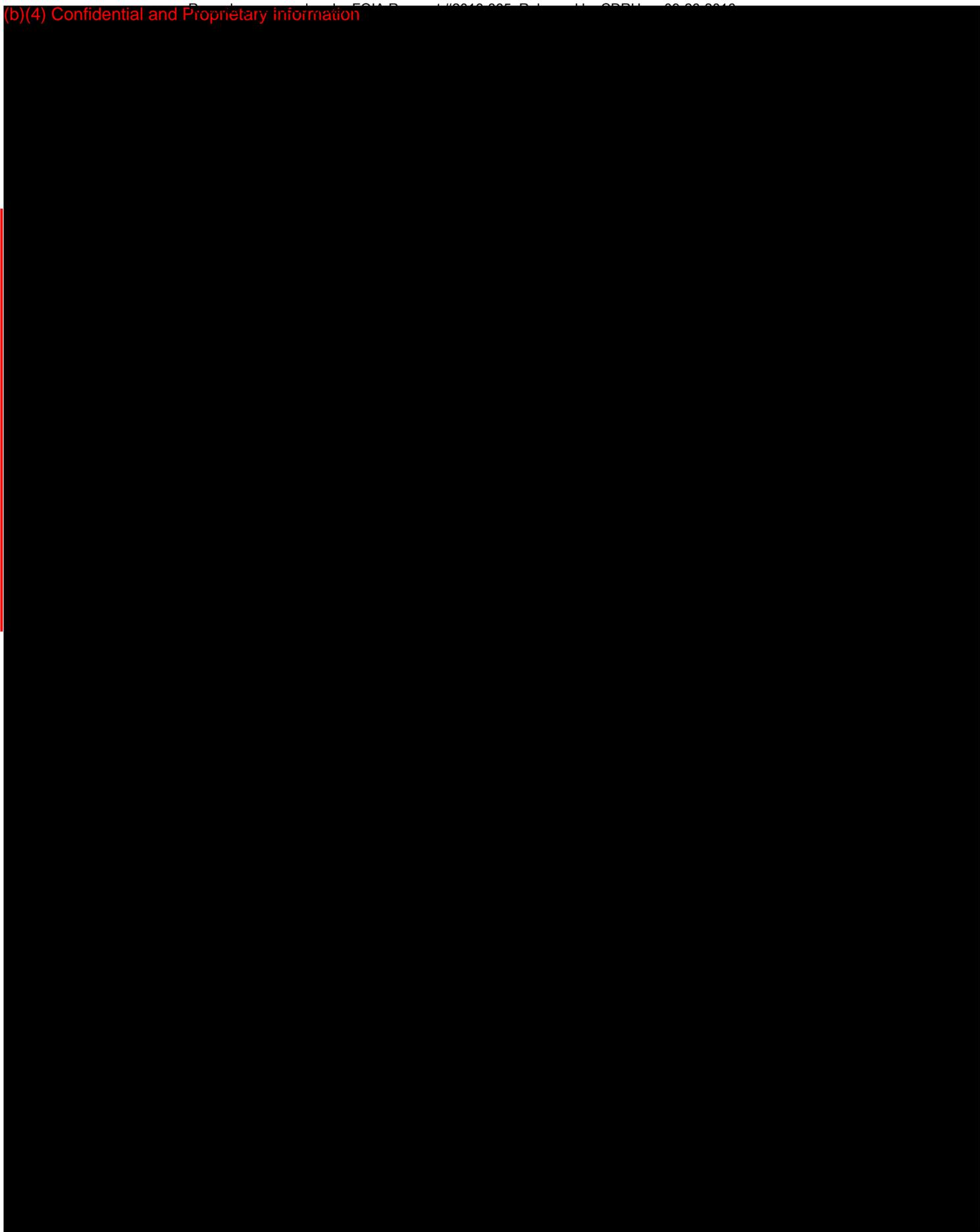
Results of ANAM testing are presented on the ANAM Performance Report, or APR. The APR is designed to aid clinical assessment, confirm that subject/patient scores are within a normal range with respect to a reference group, and examine performance history. The APR presents a selected set of scores for each of the ANAM tests administered. These scores are described below for each test in ANAM Military. For more detail regarding the APR, see [Chapter 6](#).

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Calculation of the ANAM Composite Score

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1.2 ABOUT THE ANAM MILITARY BATTERY

The ANAM Military Battery (previously known as the ANAM4 Traumatic Brain Injury-Military version (TBI-Mil) Battery) is a selection of modules from the ANAM library designed to aid in the assessment of general cognitive function. Specific modules for this battery were chosen based on demonstration of their sensitivity to cognitive dysfunction in the broader ANAM literature (see ANAM reference list), due to their sensitivity to the subtle effects of cognitive change, and based on recommendations from a panel of subject matter experts. ANAM Military provides precise, objective, automated measures of fundamental neurocognitive functions including response speed, attention/concentration, immediate and delayed memory, spatial processing, and decision processing speed and efficiency.

Qualities of ANAM Military are consistent with past applications of computer-based testing, with normative work conducted by DVBC, and with the *Clinical Practice Guidelines and Recommendations* published by the Defense and Veterans Brain Injury Center Working Group on the Acute Management of Mild Traumatic Brain Injury in Military Operational Settings (Helmick, 2006).

This manual was specially constructed to provide information regarding the features of ANAM Military. Modules in ANAM Military include the following:

ANAM Military Module List	Domain/Function
Demographics	Examinee Profile
TBI Questionnaire	TBI History
Sleepiness Scale	Sleepiness
Mood Scale	Mood State
Simple Reaction Time	Basic neural processing (speed/efficiency)
Code Substitution – Learning	Associative Learning (speed/efficiency)
Procedural Reaction Time	Processing Speed (choice RT/rule adherence)
Mathematical Processing	Working Memory
Matching to Sample	Visual Spatial Memory
Code Substitution – Delayed	Memory (delayed)
Simple Reaction Time (R)	Basic neural processing (speed/efficiency)

1.3 ANAM APPLICATIONS AND TESTING PARADIGMS

1.3.1 What Does the ANAM Military Battery Provide?

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.

1.3.2 What is the basic ANAM Military testing paradigm?

ANAM Military provides both absolute and relative information about the test taker's performance. Test performance following an injury, event, or intervention can be assessed by comparing a person's test results to a previous testing point or to a pre-existing "baseline" if those data are available. If pre-existing testing data are unavailable, ANAM Military will provide a comparison of performance in relationship to a normative group. The ANAM Performance Report software program will automatically provide comparisons to the selected normative group as well as to the test taker's previous testing data, if available.

1.3.3 When should the ANAM Military test battery be administered?

Testing protocols vary according to the patient's needs, the patient's capability to take the test, other physical injuries or disease processes, and the appropriateness and strategic use of the test by the health professional. Testing frequency following disease or injury may also be determined by clinical management guidelines. In all cases, the frequency of testing should be clinically determined in conjunction with the symptoms associated with the disease or injury and other pertinent medical information.

Responsible Use of ANAM Military

CAUTION: Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner.

Indications for Use

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.

What is the ANAM Military Battery?

ANAM Military is the Automated Neuropsychological Assessment Metrics (version 4) Military Battery. This battery was previously distributed as the ANAM TBI-Mil Battery. ANAM Military is classified as a psychological test and is regulated and distributed in accordance with the professional and ethical standards articulated by the *Ethical Principles of Psychologists and Code of Conduct* of the American Psychological Association (APA, 2002).

Who is qualified to administer ANAM Military?

ANAM Military can be *administered* by qualified professionals who have training in psychological testing principles and test administration procedures. This might include primary care providers trained in psychological test administration to assist in initial triage, assessment, or clinical guideline decision making, but this level of assessment activity would not include *clinical interpretation*. Test administrators should be supervised by a qualified professional trained in the administration and interpretation of psychological testing (e.g., psychologist or physician).

Who is qualified to interpret scores from ANAM Military?

The ANAM Military battery is a psychological test and the *clinical interpretation* of the test should be conducted by qualified medical professionals with training in psychological testing principles (including understanding of psychometrics), test administration procedures, and clinical test interpretation.

Is ANAM a “diagnostic” test?

ANAM measures cognitive functioning and should not be used alone to diagnose medical or mental diseases, disorders or conditions. It is not meant to replace more comprehensive tests or assessment procedures. ANAM test results should be interpreted in conjunction with information about the test taker and potentially other relevant tests before making diagnostic or prescriptive decisions.

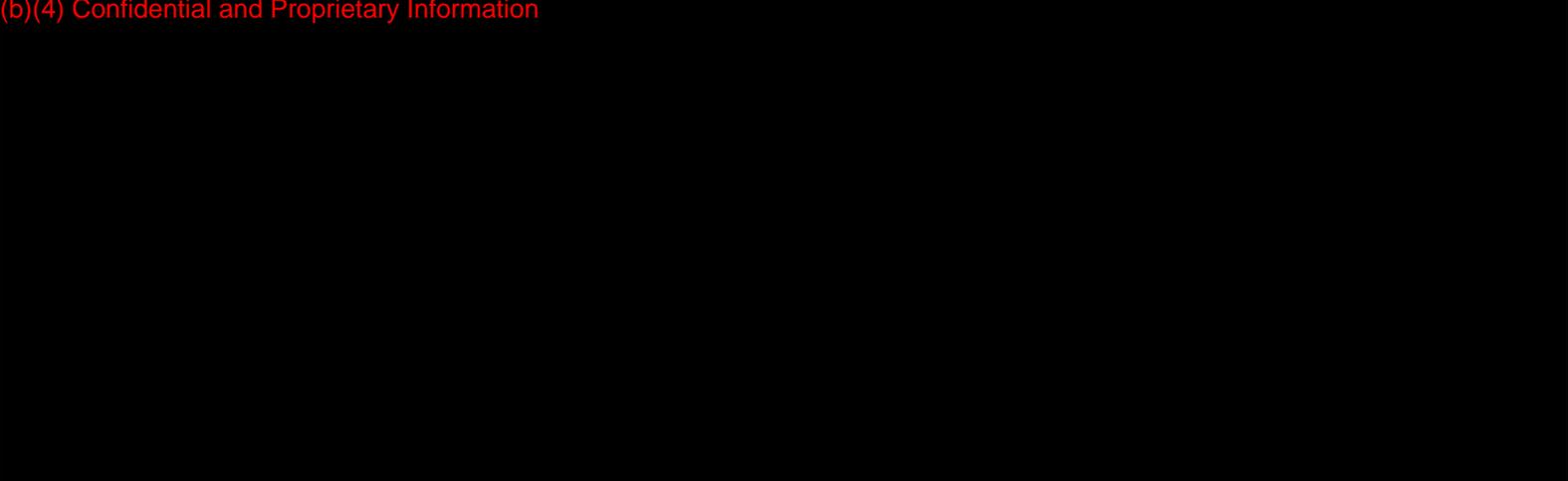
Disclaimer

The use of ANAM does not constitute the practice of medicine or the provision of professional health care advice. The information provided in ANAM is of a general nature and does not represent medical advice, a diagnosis, or prescription for treatment. Only qualified medical professionals should interpret test results. CSRC and the University of Oklahoma are not responsible for any decisions made based on ANAM test results. A qualified medical professional has the sole responsibility for establishing diagnosis and suggesting appropriate treatment.

Hello Calley,

We are in the process of reviewing the updated ANAM submission. Given the short time frame, I will be contacting you to bring up any issues as they arise so you may receive multiple emails from me.

(b)(4) Confidential and Proprietary Information



Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
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Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&E=&S=E>



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

March 25, 2015

Vista Lifesciences, Inc.
% Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington St. Suite 100
Alexandria, Virginia 22314

Re: K150154

Trade/Device Name: ANAM Test System: Military Battery

Dated: January 22, 2015

Received: January 23, 2015

Dear Ms. Herzog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device. Based on our review of your submission, it appears that your device has a new indication, providing objective measurements of cognitive performance rather than objective measurements of reaction time, that alters the diagnostic effect, impacting safety and effectiveness, and is therefore a new intended use.

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(b)(4) Confidential and Proprietary Information



You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, you should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in this request within 180 calendar days of the date of this request. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

For further information regarding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

The requested information should reference your above 510(k) number and should be submitted in duplicate to:

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

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or other electronic media, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>. In addition, we strongly encourage you to visit FDA's eSubmitter website at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm> in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the deficiencies in this letter, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note, however, that a Submission Issue Q-Sub does not take the place of a formal response to this letter. As noted above, FDA will consider this 510(k) to be withdrawn if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in this AI request within 180 calendar days of the date of this request.

If you have any minor clarification questions concerning the contents of the letter, please contact Stacie Gutowski at 240-402-6032. If you need information or assistance concerning the IDE regulations or 510(k) policy, please contact the Division of Industry and Consumer Education (DICE) 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,

Timothy Marjenin
Chief
Neurostimulation Devices Branch
Division of Neurological and Physical Medicine
Office of Device Evaluation
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH AND HUMAN SERVICES

M E M O R A N D U M

Food and Drug Administration
Office of Device Evaluation

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

K150154

Date: March 20, 2015
To: The Record
From: Stacie Gutowski

Office: ODE
Division: DNPMD

510(k) Holder: Vista LifeSciences, Inc.
Device Name: ANAM Test System: Military Battery
Contact: Calley Herzog, Senior Consultant
Phone: 720-883-3633
Fax: 703-548-7457
Email: cherzog@bcg-usa.com

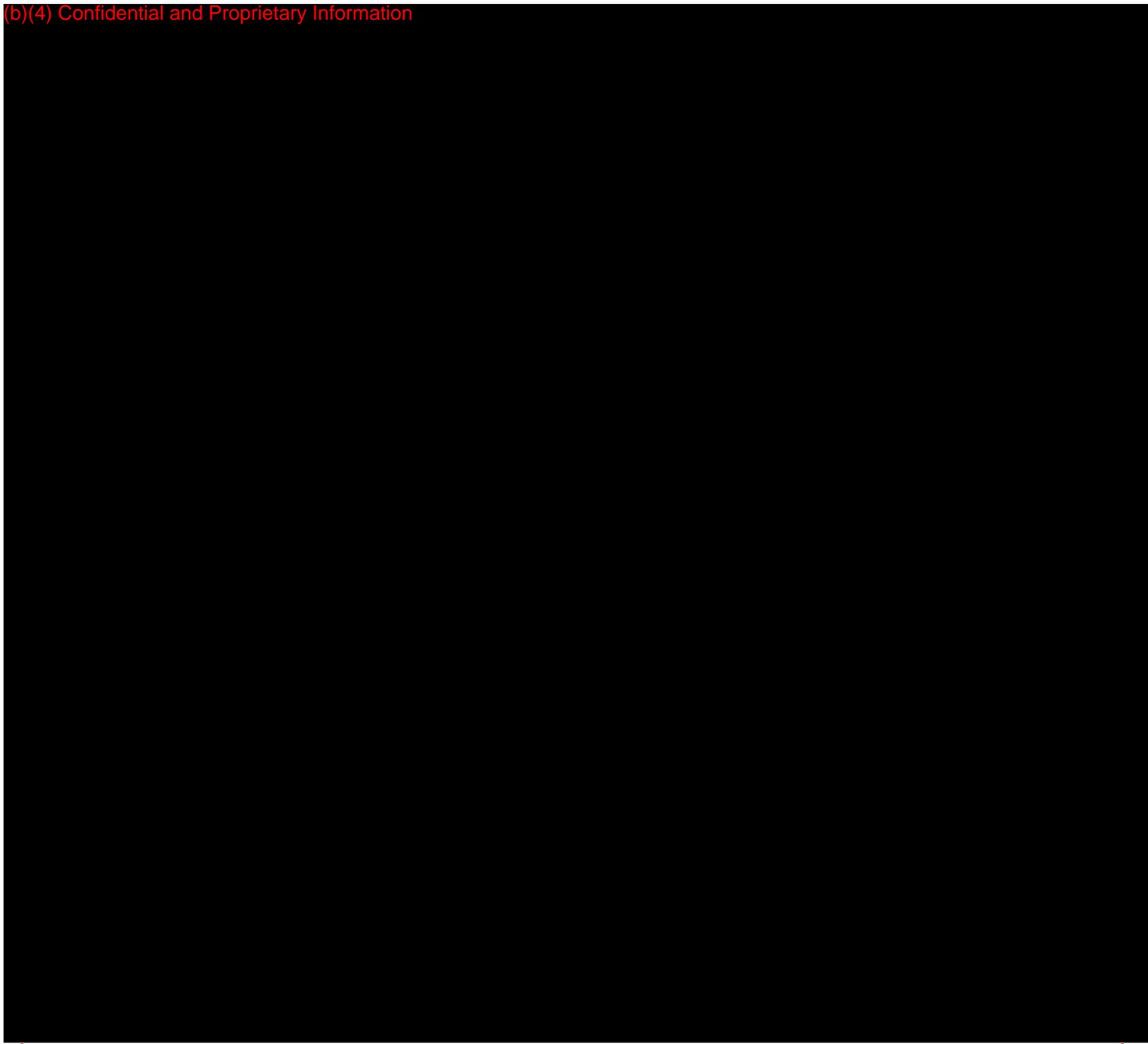
I. Purpose and Submission Summary

The 510(k) holder would like to introduce the ANAM Test System: Military Battery into interstate commerce and have it considered a class II device. The ANAM Test System is software-only device which uses a digital test battery to obtain objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's medical or psychological state.

(b)(4) Confidential and Proprietary Information

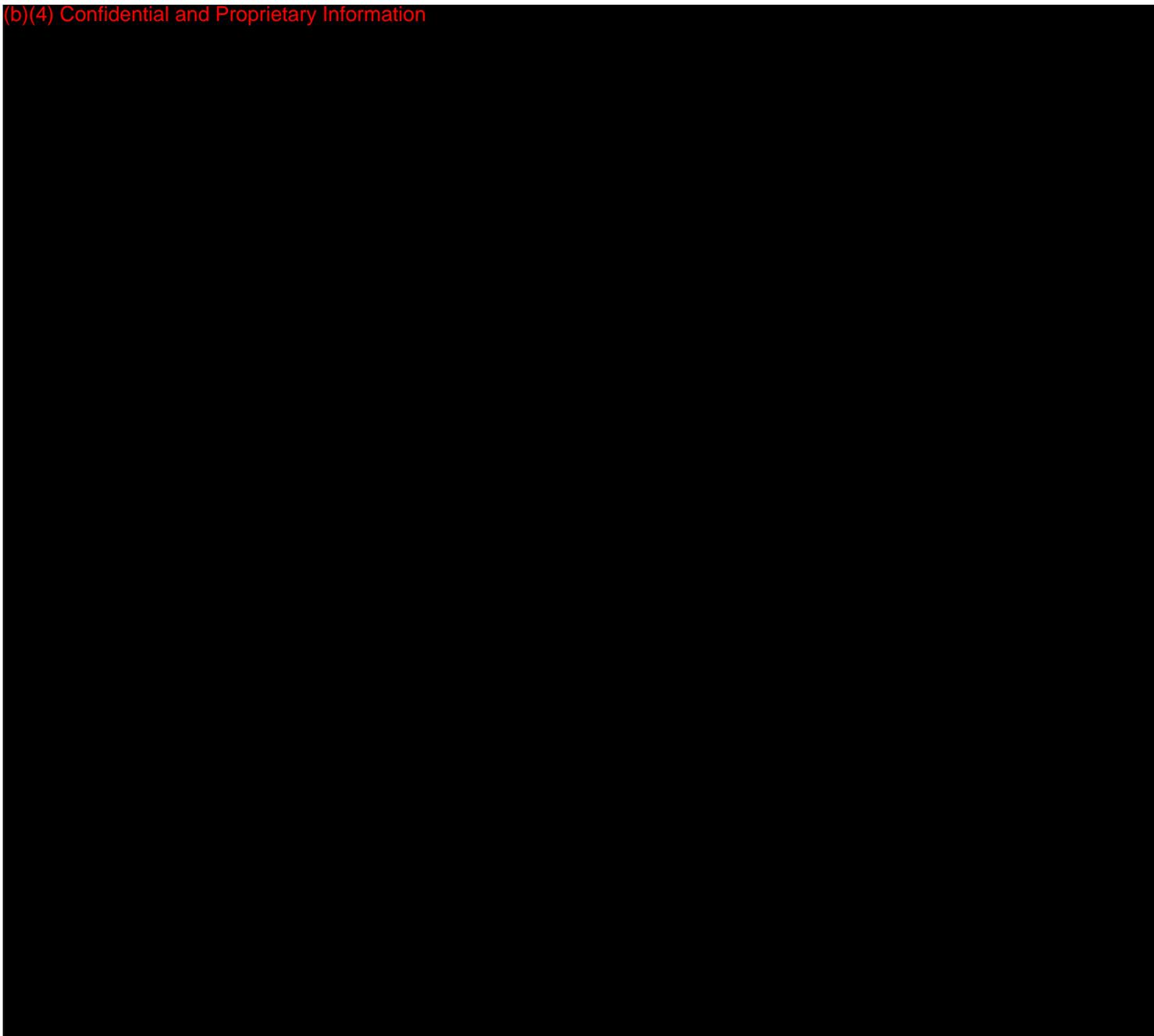
	Yes	No	N/A
Indications for Use page	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

(b)(4) Confidential and Proprietary Information



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

(b)(4) Confidential and Proprietary Information



IV. Indications for Use

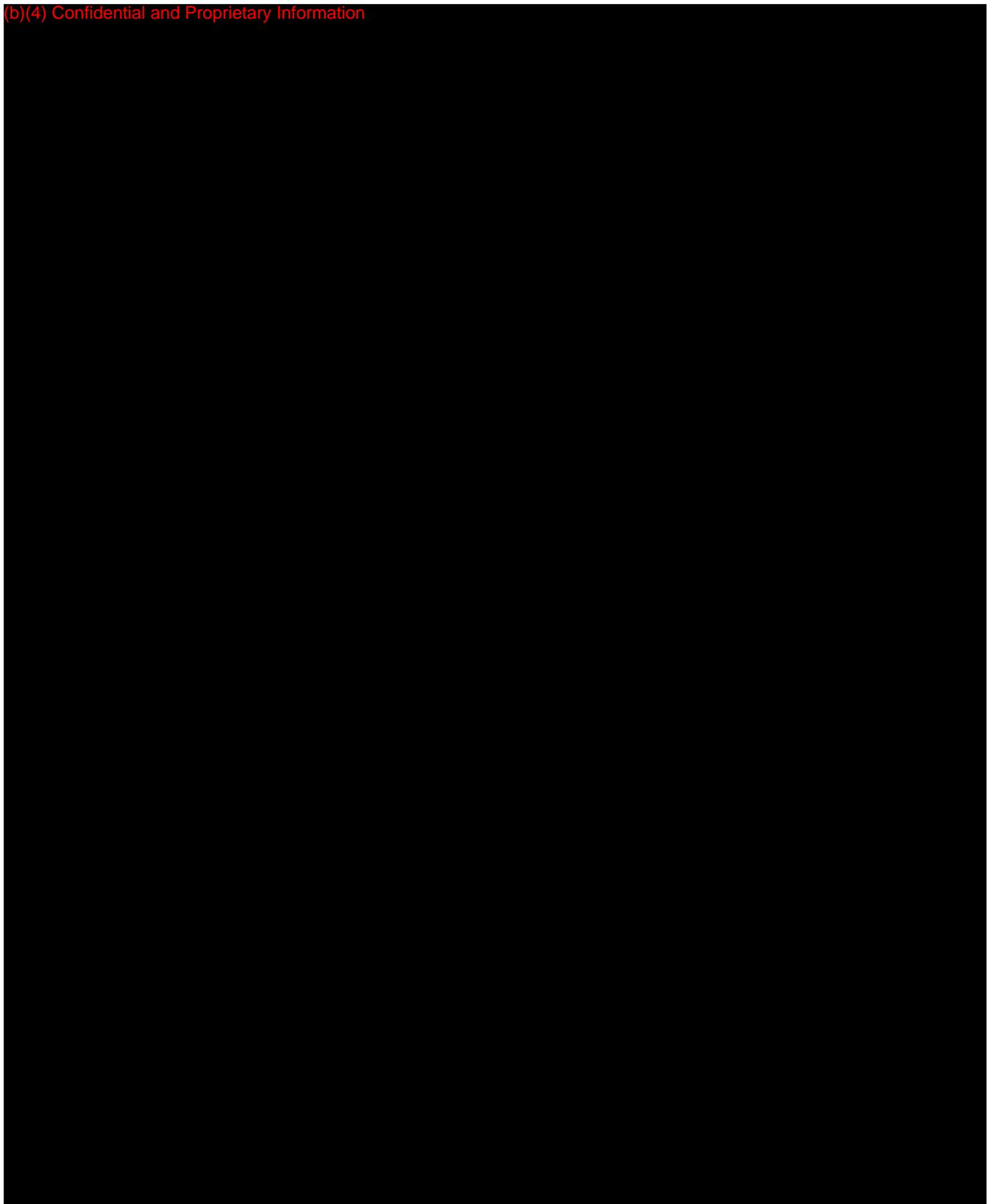
Subject Device (K150154)

ANAM provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's medical or psychological state. Factors that may affect measurement of cognitive performance (such as reaction time and accuracy of responding) include, but are not limited to concussion, head injury, insomnia, post-traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress). ANAM results should be interpreted only by qualified professionals.

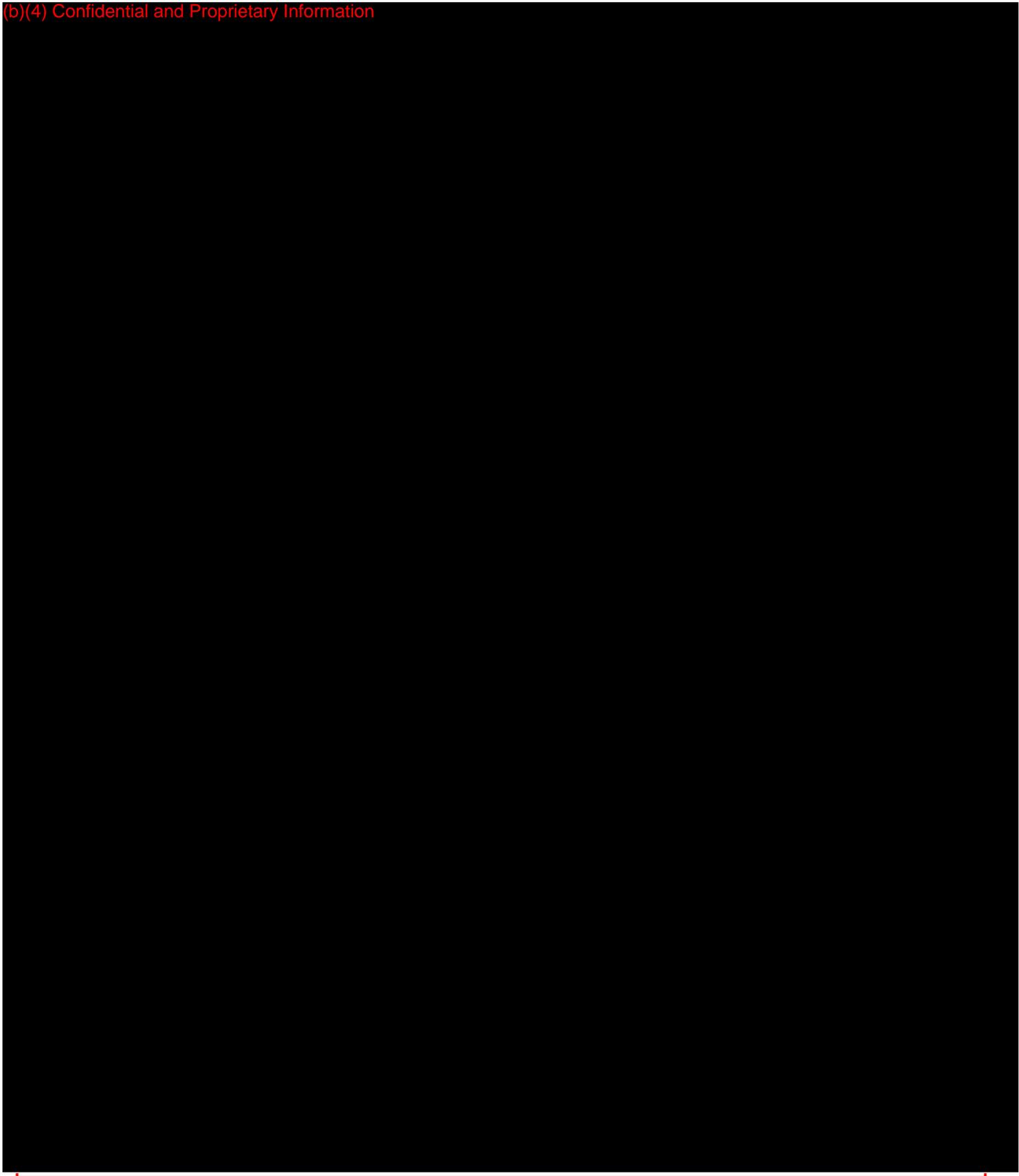
Prescription

Over-the-Counter

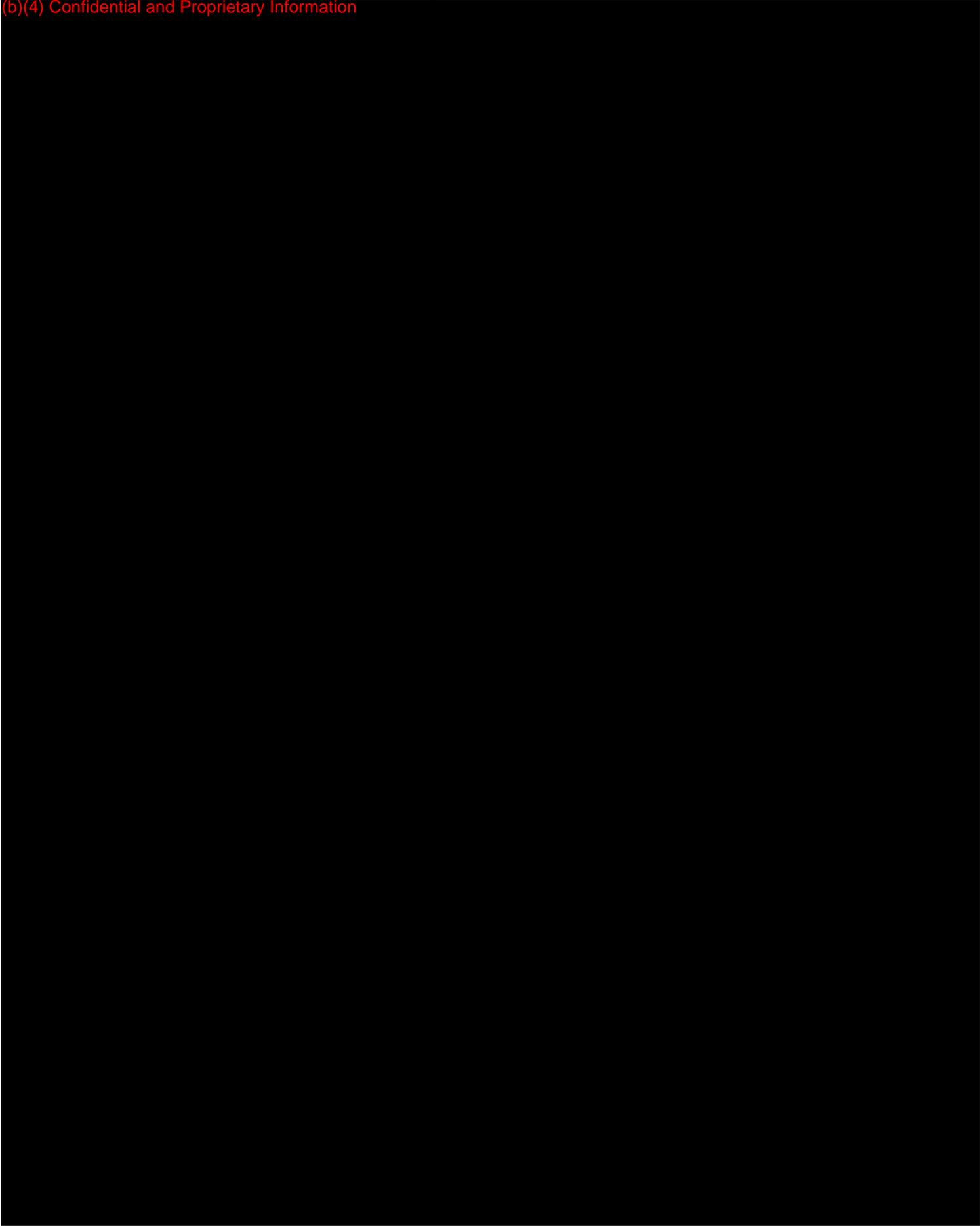
(b)(4) Confidential and Proprietary Information



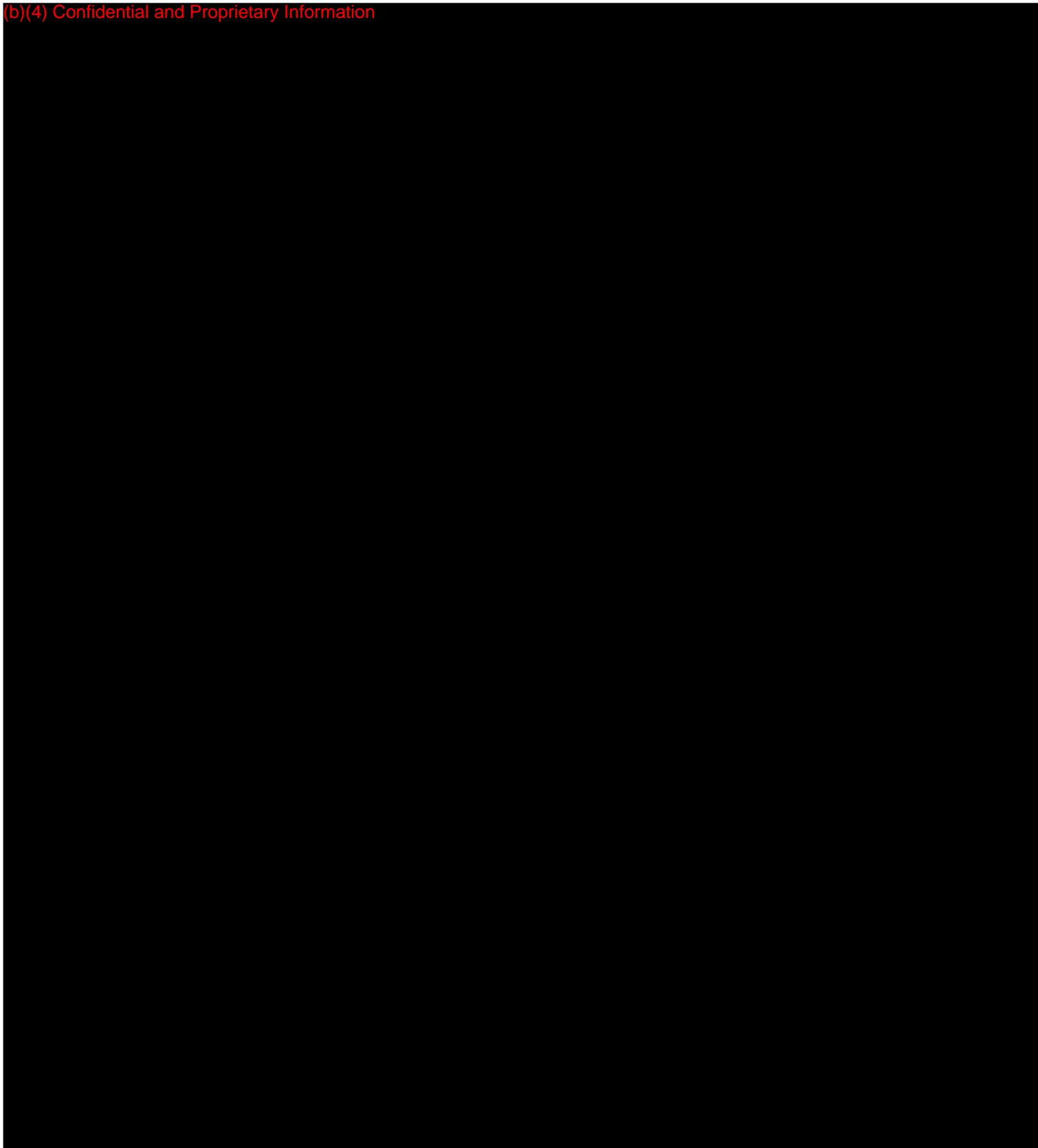
(b)(4) Confidential and Proprietary Information



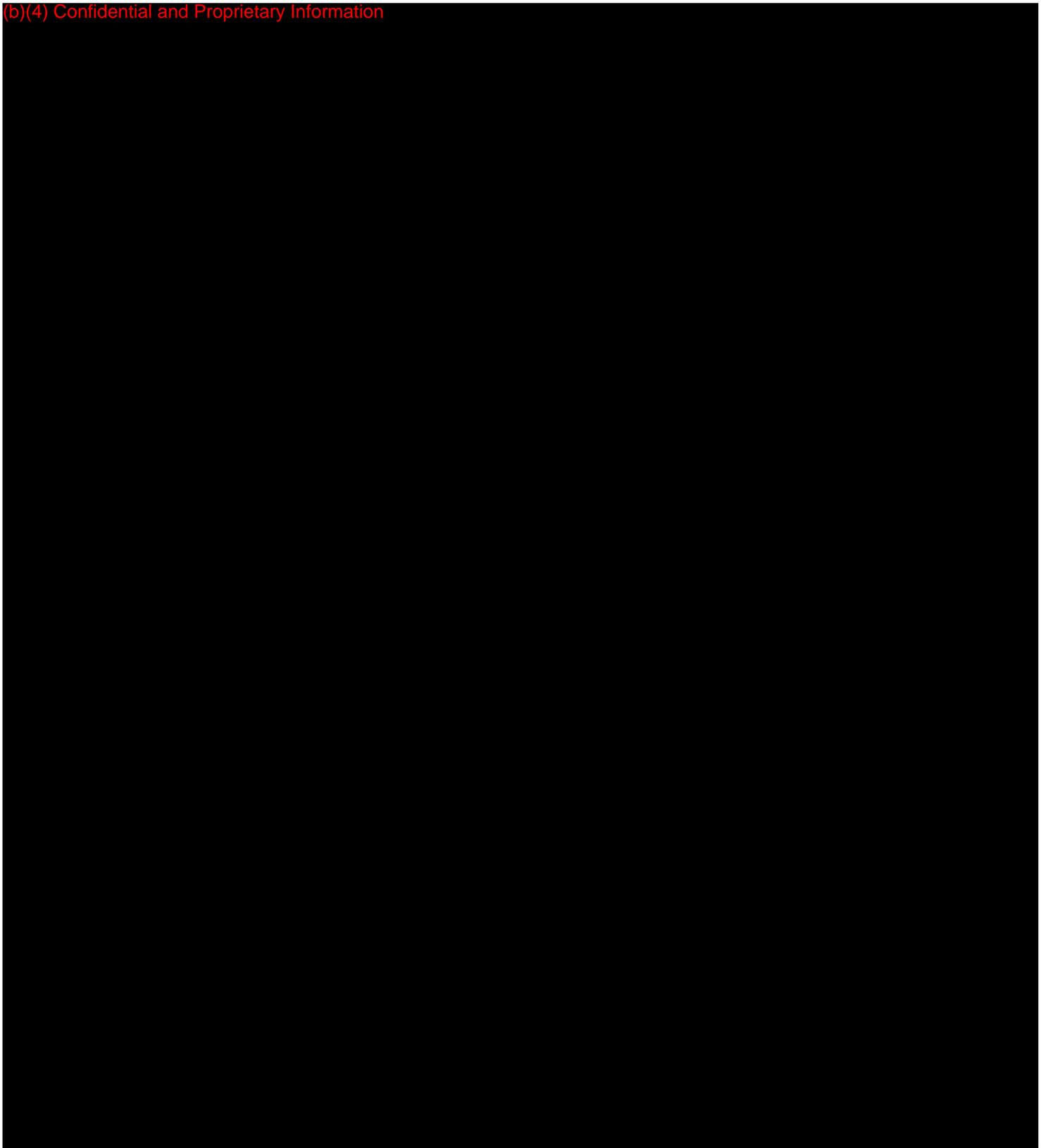
(b)(4) Confidential and Proprietary Information



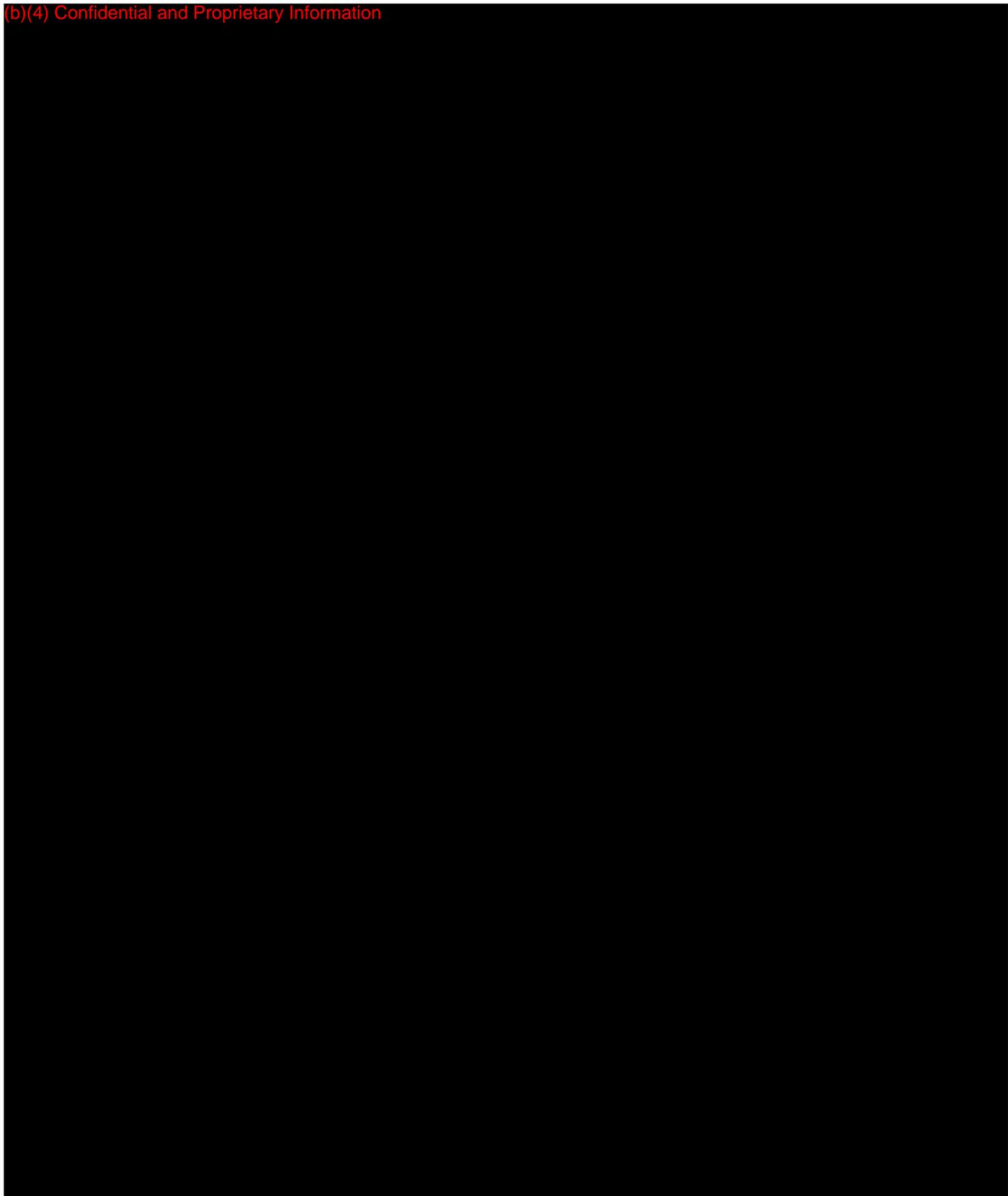
(b)(4) Confidential and Proprietary Information



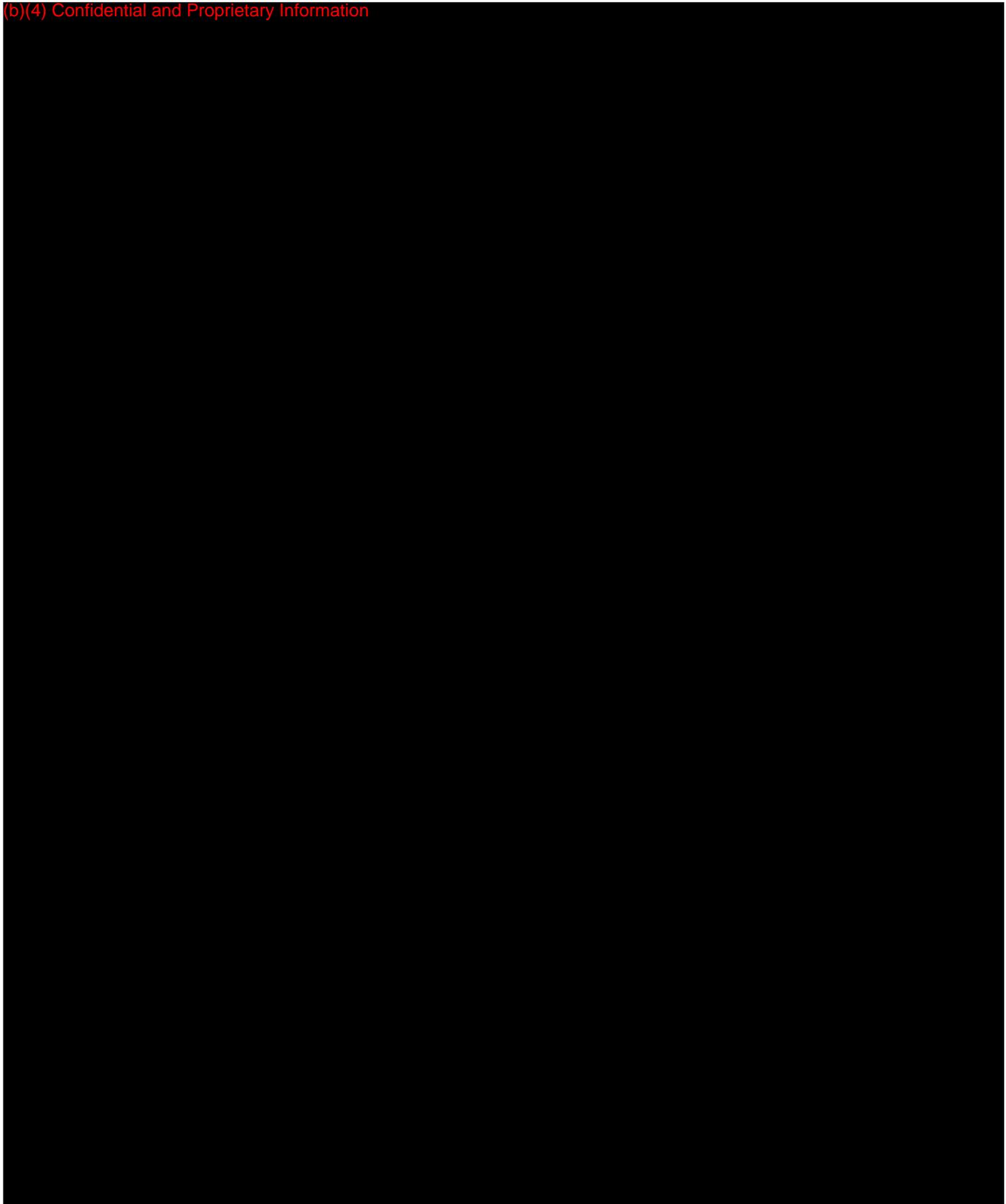
(b)(4) Confidential and Proprietary Information



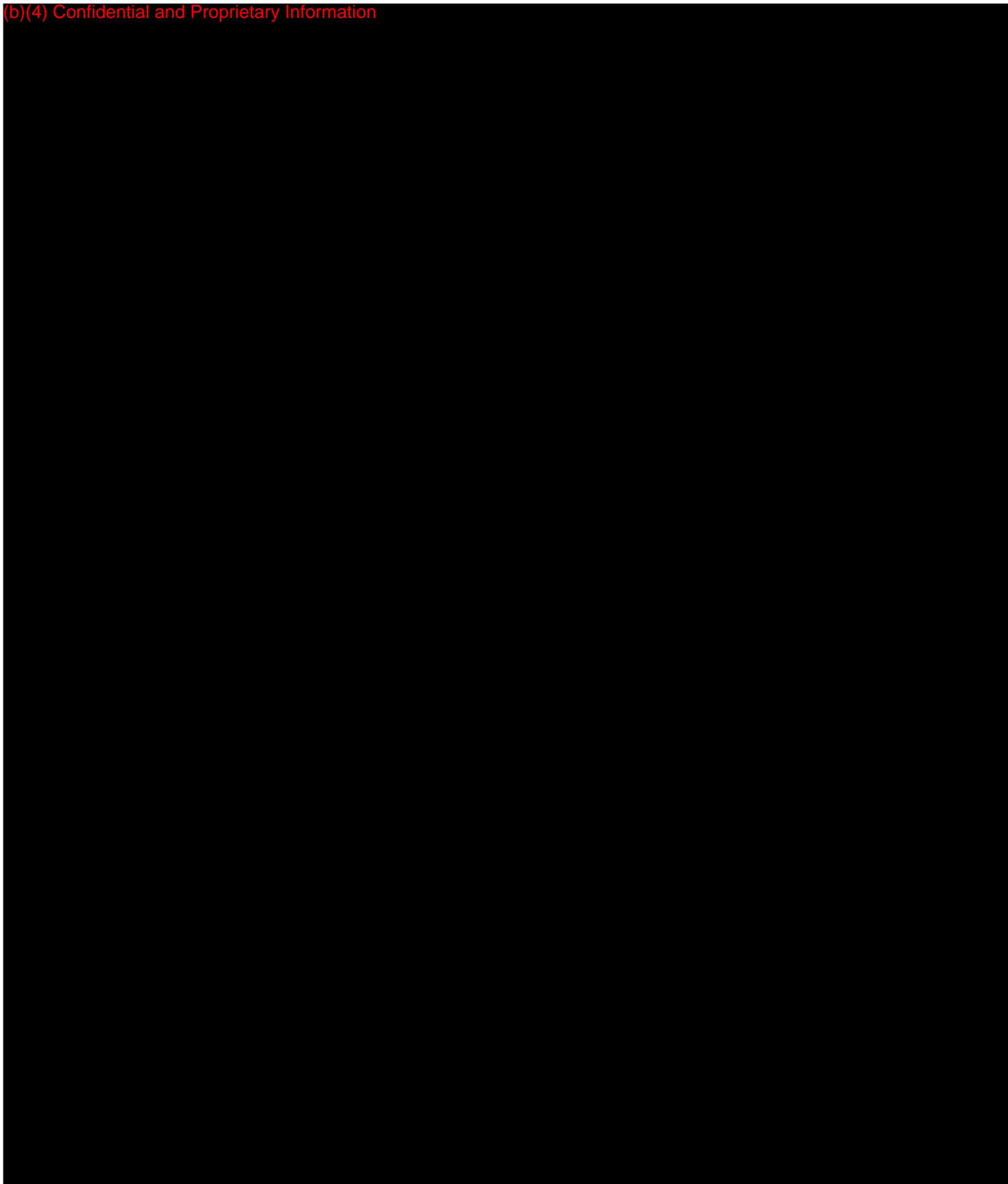
(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



Regulation Number: 21 CFR

Regulation Name:
Regulatory Class: Class II
Product Code:

XVII. Attachments

(b)(4) Confidential and Proprietary Information



510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for ANAM Test System: Military Battery is provided below.

Device Common Name: Computerized Cognitive Assessment Aid

Device Proprietary Name: ANAM Test System: Military Battery

Applicant: Vista LifeSciences, Inc.
PO Box 4670
Parker CO 80134
Phone: 888.733.8804 Ext. 1
www.vistalifesciences.com

Contact: Lori White
Quality Systems Program Manager
Vista LifeSciences, Inc.
PO Box 4670
Parker CO 80134
Phone: 888.733.8804 Ext. 1
Email: lori.white@vistalifesciences.com

Prepared by: Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington St. Suite 100
Alexandria, VA 22314
Email: cherzog@bcg-usa.com
Phone: 720-883-3633
Fax: 703-548-7457

Date Prepared: July 30, 2015

Classification Regulation: 882.1470

Panel: Neurology

Product Code: PKQ

Predicate Device: DEN130033, Cerebral Assessment Systems Cognivue

Indication for Use:

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.

Device Description:

ANAM Test System: Military Battery is a software only device that provides clinicians with objective measurements of cognitive performance in military populations, to aid in the assessment of an individual's level of cognitive function.

The software is downloaded from the Vista LifeSciences website and is for use on a Dell Latitude E6440 Laptop. The laptop is not provided as part of the device, but is purchased separately by the user. Each ANAM battery consists of a collection of pre-selected modules that are administered in a sequential manner.

Specific modules included in the ANAM Test System: Military Battery:

1. Demographics
2. Sleepiness Scale
3. Symptoms Checklist
4. Mood Scale
5. TBI Questionnaire
6. Simple Reaction Time
7. Code Substitution – Learning
8. Procedural Reaction Time
9. Mathematical Processing
10. Matching to Sample
11. Code Substitution – Delayed
12. Simple Reaction Time (R)

Performance Data:

The 510(k) included the results of numerous studies that examined the concurrent validity of ANAM as a clinical tool by documenting correlations with traditional neuropsychological tests. The results of these studies demonstrate that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

Substantial Equivalence:

Both devices are computerized assessment aids that use an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. In addition to perceptual and memory function, ANAM may be used as an adjunctive tool for evaluating additional functions including: visuomotor reaction time and processing speed, simple decision making, visual scanning, associative learning, visual-spatial processing, and attention.

	Proposed Device	Predicate Device
510(k) Number	K150154	DEN130033
Device Name	ANAM Test System: Military Battery	Cognivue
Submitter	Vista LifeSciences, Inc.	Cerebral Assessment Systems
Classification Regulation	Computerized Cognitive Assessment Aid	Computerized Cognitive Assessment Aid
Product Code	PKQ	PKQ
Indication	The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.	Cognivue is an adjunctive tool for evaluating perceptual and memory function in individuals aged 55-95 years old.
Platform	PC: Dell Latitude E6440 Laptop Computer, two button USB connected mouse, and Windows 7 operating system.	Computer, monitor, rotatory manipulandum, printer, and mouse/keyboard are provided on a device cart.
Use Cases	Reports individual test results and compares changes in individual tests over time and/or against military normative data.	Reports individual test results and compares overall performance to a cut-off.

	Proposed Device	Predicate Device
Patient Population	Military population	Adults
Age of Users	18-65 years	55-95 years
How Provided	Software only, downloaded	Software is pre-installed on computer hardware provided by the manufacturer.
Reporting features	ANAM Performance Report (APR) provides raw scores and standard scores (calculated with the military normative database) for each test within the battery. APR also yields the ANAM Composite Score (ACS) summarizing performance across the test battery.	Cognivue Performance Profile report yields a single output measure that is an average score of the four perception scores and four memory scores.
Psychometric Properties	ANAM demonstrates construct validity with traditional neuropsychological tests.	Cognivue demonstrates construct validity with traditional neuropsychological tests.
Results Interpretation	ANAM does not provide a recommendation that the patient is impaired vs. unimpaired. Clinical interpretation of the results includes comparison with the normative database. ANAM provides raw scores, standard scores, and reliable change indices for each test.	Cognivue provides an average score that is categorized as unimpaired, impaired, or intermediate/indeterminate based on comparison with a normative database. Sub-tests may not be evaluated individually.

Summary / Conclusion of Substantial Equivalence Rationale

Although there are some differences in the modules between ANAM and the predicate device, and ANAM provides a comparison to a normative database, the performance testing demonstrates that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for ANAM Test System: Military Battery is provided below.

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Device Proprietary Name: ANAM Test System: Military Battery

Applicant: Vista LifeSciences, Inc.
PO Box 4670
Parker CO 80134
Phone: 888.733.8804 Ext. 1
www.vistalifesciences.com

Contact: Lori White
Quality Systems Program Manager
Vista LifeSciences, Inc.
PO Box 4670
Parker CO 80134
Phone: 888.733.8804 Ext. 1
Email: lori.white@vistalifesciences.com

Prepared by: Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington St. Suite 100
Alexandria, VA 22314
Email: cherzog@bcg-usa.com
Phone: 720-883-3633
Fax: 703-548-7457

Date Prepared: July 30, 2015

Classification Regulation: 882.1470

Panel: Neurology

Product Code: PKQ

Predicate Device: DEN130033, Cerebral Assessment Systems Cognivue

Indication for Use:

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	Proposed Device	Predicate Device
510(k) Number	K150154	DEN130033
Device Name	ANAM Test System: Military Battery	Cognivue
Submitter	Vista LifeSciences, Inc.	Cerebral Assessment Systems
Classification Regulation	Computerized Cognitive Assessment Aid	Computerized Cognitive Assessment Aid
Product Code	PKQ	PKQ
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Although there are some differences in the modules between ANAM and the predicate device, and ANAM provides a comparison to a normative database, the performance testing demonstrates that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.



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

Vista Lifesciences, Inc.
% Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington St. Suite 100
Alexandria, Virginia 22314

Re: K150154

Trade/Device Name: ANAM Test System: Military Battery

Dated: January 22, 2015

Received: January 23, 2015

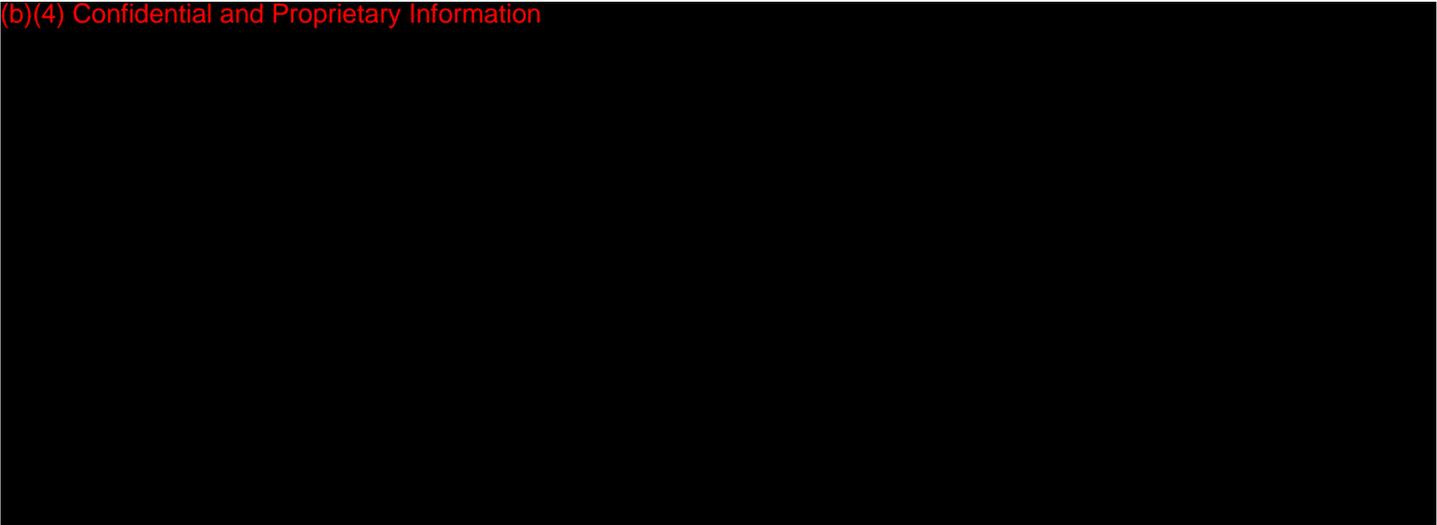
Dear Calley Herzog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device. Based on our review of your submission, we are not aware of a legally marketed preamendments device labeled or promoted for providing clinicians with objective measurement of cognitive performance.

Based on this determination, we believe that your 510(k) would likely be found not substantially equivalent and result in your device to be classified by statute into class III (Premarket Approval), under Section 513(f) of the Federal Food, Drug, and Cosmetic Act (Act).

Because we have completed our first review of your 510(k) submission, we are providing you with an opportunity to respond to this letter so you may attempt to address the regulatory issue identified above. Please be advised that an inadequate resolution of this issue in your next response will likely result in a not substantially equivalent determination. Please also be advised that a substantive review of your 510(k) submission, including performance data, has not been conducted at this time.

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



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(AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, you should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in this request within 180 calendar days of the date of this request. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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The requested information should reference your above 510(k) number and should be submitted in duplicate to:

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

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For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>. In addition, we strongly encourage you to visit FDA's eSubmitter website at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm> in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the deficiencies in this letter, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note, however, that a

Page 4 - Calley Herzog

Submission Issue Q-Sub does not take the place of a formal response to this letter. As noted above, FDA will consider this 510(k) to be withdrawn if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in this AI request within 180 calendar days of the date of this request.

If you have any minor clarification questions concerning the contents of the letter, please contact Stacie Gutowski at 240-402-6032. If you need information or assistance concerning the IDE regulations or 510(k) policy, please contact the Division of Industry and Consumer Education (DICE) 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,

Timothy Marjenin
Chief
Neurostimulation Devices Branch
Division of Neurological and Physical Medicine
Office of Device Evaluation
Center for Devices and Radiological Health



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

August 28, 2015

Vista Lifesciences, Inc.
c/o Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington St. Suite 100
Alexandria, Virginia 22314

Re: K150154

Trade/Device Name: ANAM Test System: Military Battery
Regulation Number: 21 CFR 882.1470
Regulation Name: Computerized Cognitive Assessment Aid
Regulatory Class: Class II
Product Code: PKQ
Dated: July 30, 2015
Received: July 31, 2015

Dear Ms. Herzog:

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

Page 2 - Calley Herzog

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



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

August 28, 2015

Vista Lifesciences, Inc.
c/o Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington St. Suite 100
Alexandria, Virginia 22314

Re: K150154

Trade/Device Name: ANAM Test System: Military Battery
Regulation Number: 21 CFR 882.1470
Regulation Name: Computerized Cognitive Assessment Aid
Regulatory Class: Class II
Product Code: PKQ
Dated: July 30, 2015
Received: July 31, 2015

Dear Ms. Herzog:

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

Page 2 - Calley Herzog

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



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

August 28, 2015

Vista Lifesciences, Inc.
c/o Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington St. Suite 100
Alexandria, Virginia 22314

Re: K150154

Trade/Device Name: ANAM Test System: Military Battery
Regulation Number: 21 CFR 882.1470
Regulation Name: Computerized Cognitive Assessment Aid
Regulatory Class: Class II
Product Code: PKQ
Dated: July 30, 2015
Received: July 31, 2015

Dear Ms. Herzog:

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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

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<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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<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K150154

Device Name
ANAM Test System: Military Battery

Indications for Use (Describe)

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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."

510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for ANAM Test System: Military Battery is provided below.

Device Common Name: Computerized Cognitive Assessment Aid

Device Proprietary Name: ANAM Test System: Military Battery

Applicant: Vista LifeSciences, Inc.
PO Box 4670
Parker CO 80134
Phone: 888.733.8804 Ext. 1
www.vistalifesciences.com

Contact: Lori White
Quality Systems Program Manager
Vista LifeSciences, Inc.
PO Box 4670
Parker CO 80134
Phone: 888.733.8804 Ext. 1
Email: lori.white@vistalifesciences.com

Prepared by: Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington St. Suite 100
Alexandria, VA 22314
Email: cherzog@bcg-usa.com
Phone: 720-883-3633
Fax: 703-548-7457

Date Prepared: July 30, 2015

Classification Regulation: 882.1470

Panel: Neurology

Product Code: PKQ

Predicate Device: DEN130033, Cerebral Assessment Systems Cognivue

Indication for Use:

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.

Device Description:

ANAM Test System: Military Battery is a software only device that provides clinicians with objective measurements of cognitive performance in military populations, to aid in the assessment of an individual's level of cognitive function.

The software is downloaded from the Vista LifeSciences website and is for use on a Dell Latitude E6440 Laptop. The laptop is not provided as part of the device, but is purchased separately by the user. Each ANAM battery consists of a collection of pre-selected modules that are administered in a sequential manner.

Specific modules included in the ANAM Test System: Military Battery:

1. Demographics
2. Sleepiness Scale
3. Symptoms Checklist
4. Mood Scale
5. TBI Questionnaire
6. Simple Reaction Time
7. Code Substitution – Learning
8. Procedural Reaction Time
9. Mathematical Processing
10. Matching to Sample
11. Code Substitution – Delayed
12. Simple Reaction Time (R)

Performance Data:

The 510(k) included the results of numerous studies that examined the concurrent validity of ANAM as a clinical tool by documenting correlations with traditional neuropsychological tests. The results of these studies demonstrate that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

Substantial Equivalence:

Both devices are computerized assessment aids that use an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. In addition to perceptual and memory function, ANAM may be used as an adjunctive tool for evaluating additional functions including: visuomotor reaction time and processing speed, simple decision making, visual scanning, associative learning, visual-spatial processing, and attention.

	Proposed Device	Predicate Device
510(k) Number	K150154	DEN130033
Device Name	ANAM Test System: Military Battery	Cognivue
Submitter	Vista LifeSciences, Inc.	Cerebral Assessment Systems
Classification Regulation	Computerized Cognitive Assessment Aid	Computerized Cognitive Assessment Aid
Product Code	PKQ	PKQ
Indication	The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.	Cognivue is an adjunctive tool for evaluating perceptual and memory function in individuals aged 55-95 years old.
Platform	PC: Dell Latitude E6440 Laptop Computer, two button USB connected mouse, and Windows 7 operating system.	Computer, monitor, rotatory manipulandum, printer, and mouse/keyboard are provided on a device cart.
Use Cases	Reports individual test results and compares changes in individual tests over time and/or against military normative data.	Reports individual test results and compares overall performance to a cut-off.

	Proposed Device	Predicate Device
Patient Population	Military population	Adults
Age of Users	18-65 years	55-95 years
How Provided	Software only, downloaded	Software is pre-installed on computer hardware provided by the manufacturer.
Reporting features	ANAM Performance Report (APR) provides raw scores and standard scores (calculated with the military normative database) for each test within the battery. APR also yields the ANAM Composite Score (ACS) summarizing performance across the test battery.	Cognivue Performance Profile report yields a single output measure that is an average score of the four perception scores and four memory scores.
Psychometric Properties	ANAM demonstrates construct validity with traditional neuropsychological tests.	Cognivue demonstrates construct validity with traditional neuropsychological tests.
Results Interpretation	ANAM does not provide a recommendation that the patient is impaired vs. unimpaired. Clinical interpretation of the results includes comparison with the normative database. ANAM provides raw scores, standard scores, and reliable change indices for each test.	Cognivue provides an average score that is categorized as unimpaired, impaired, or intermediate/indeterminate based on comparison with a normative database. Sub-tests may not be evaluated individually.

Summary / Conclusion of Substantial Equivalence Rationale

Although there are some differences in the modules between ANAM and the predicate device, and ANAM provides a comparison to a normative database, the performance testing demonstrates that ANAM provides a reliable measure of cognitive function, and is therefore substantially equivalent to the predicate device.

DIVISION 510(k) MILESTONE WORKSHEET

Records processed under FOIA request #2016-365; Released by CDRH on 09-26-2016.

**For New TRADITIONAL/ABBREVIATED
510(k) Submissions and Response to RTA1**

Div./Branch:

DNPMD/NSDB

510(k) No. K150154
 Device ANAM test System: Military Battery
 Sponsor/Applicant Vista LifeSciences, Inc.
 Lead Reviewer _____
 Date In for Lead Reviewer _____

Enter the receipt and due dates (from CTS) in these boxes (MM/DD/YYYY or M/D/YY)

DCC Receipt Date: First day → **Friday, January 23, 2015**
 Unadjusted FDA due date → **Thursday, April 23, 2015**

Refuse-to-Accept Review (decision required by Day 15)

	Milestone	Adjusted Milestone Date
Lead Reviewer Recommendation into CTS	Day 8	Friday, January 30, 2015 *
BC Concurrence on RTA	Day 9	Friday, January 30, 2015 *
DDD Concurrence on RTA	Day 10	Monday, February 02, 2015
MDUFA III RTA Auto-Email (Date NOT adjusted)	Day 15	Saturday, February 07, 2015

Substantive Review (Note: This begins only after file is ACCEPTED, which should be no later than day 16)

	Milestone	Adjusted Milestone Date
Assign consults	Day 11	Tuesday, February 03, 2015
<i>If "potential NSE" anticipated, discuss with BC/DDD</i>	Day 30	Friday, February 20, 2015 *
Consulting Reviews to lead reviewer	Day 39	Tuesday, March 03, 2015
<i>Discuss proposed SI recommendation with BC¹</i>	Day 42	Friday, March 06, 2015

For SI Recommendation of Telephone Hold (TH) Email or Additional Information (AI) Letter:

	Milestone	Adjusted Milestone Date
TH or AI and File To BC	Day 45	Monday, March 09, 2015
File Placed on Hold	Day 50	Friday, March 13, 2015 *
MDUFA III SI Due Date	Day 60	Tuesday, March 24, 2015

For SI Recommendation of "Proceed Interactively" (PI) (Note: for PI, you are REQUIRED to interact with the sponsor prior to forwarding a final recommendation to your BC. PI means that you will NOT put the file on hold.)

	Milestone	Adjusted Milestone Date
Lead Reviewer: PI Recommendation in CTS	Day 50	Friday, March 13, 2015 *
BC Concurrence on PI recommendation in CTS	Day 55	Thursday, March 19, 2015
DDD Concurrence on PI Recommendation in CTS	Day 60	Tuesday, March 24, 2015
Send final information requests to sponsor ¹	Day 70	Friday, April 03, 2015
Receive responses to final requests from sponsor ¹	Day 77	Friday, April 10, 2015
Consulting reviews to lead reviewer	Day 79	Friday, April 10, 2015 *
Final Letter and File to BC	Day 83	Thursday, April 16, 2015
Final Letter and File to DDD	Day 85	Friday, April 17, 2015 *
Issue Final Letter	Day 86	Friday, April 17, 2015 *
FDA Due Date (Adjusted for holidays and weekends)	Day 90	Thursday, April 23, 2015
Brief Management on Close-out Plan	Day 92	Friday, April 24, 2015 *
Missed MDUFA Decision (MMD)	Day 101	Monday, May 04, 2015

* Milestone dates that would have fallen on a holiday or weekend will adjust automatically, and will be noted with a "*"

¹ Office Suggested Target



FOOD AND DRUG ADMINISTRATION MEMORANDUM

Center for Devices and Radiologic Health
Office of Device Evaluation
Division of Neurological and Physical Medicine Devices
10903 New Hampshire Avenue
Silver Spring, MD 20993

**510(k) Clinical Consultation
K150154/S001**

DATE: August 21, 2015

TO: Stacie Gutowski, Ph.D., Biomedical Engineer/Lead Reviewer
ODE/DNPMD/NSDB

FROM: Peter G. Como, Ph.D., Neuropsychologist/Clinical Reviewer
ODE/DNPMD/NSDB

SUBJECT: K150154/S001

DEVICE : ANAM Test System: Military Battery

SPONSOR : Vista LifeSciences, Inc.

(b)(4) Confidential and Proprietary Information

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

M E M O R A N D U M

Food and Drug Administration
Office of Device Evaluation

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

K150154/S001

Date: August 25, 2015
To: The Record
From: Stacie Gutowski

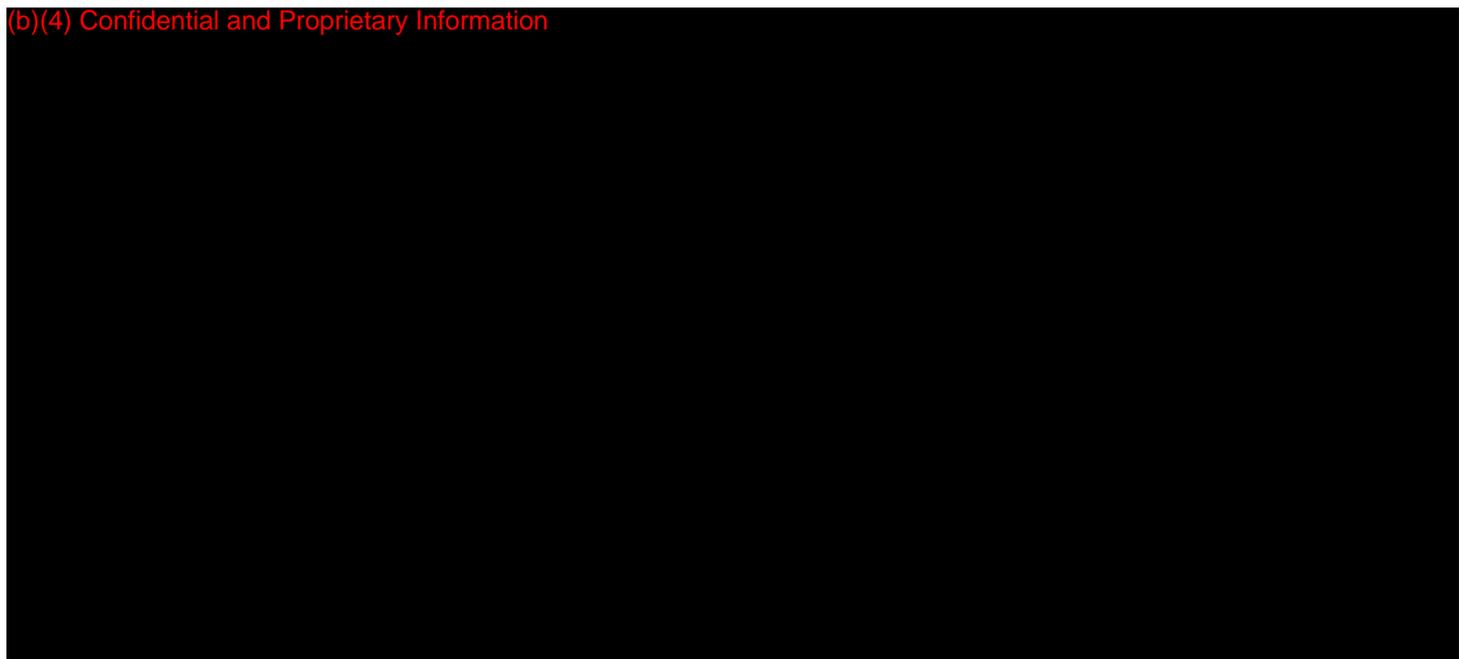
Office: ODE
Division: DNPMD

510(k) Holder: Vista LifeSciences, Inc.
Device Name: ANAM Test System: Military Battery
Contact: Calley Herzog, Senior Consultant
Phone: 720-883-3633
Fax: 703-548-7457
Email: cherzog@bcg-usa.com

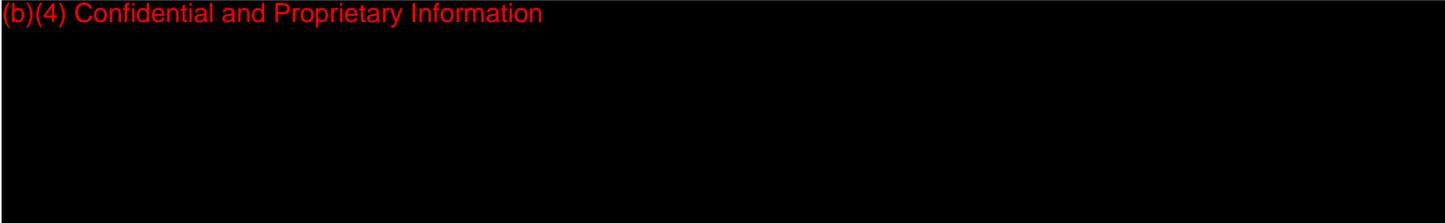
I. Purpose and Submission Summary

The 510(k) holder would like to introduce the ANAM Test System: Military Battery into interstate commerce and have it considered a class II device. The ANAM Test System is software-only device which uses a digital test battery to obtain objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's medical or psychological state.

(b)(4) Confidential and Proprietary Information



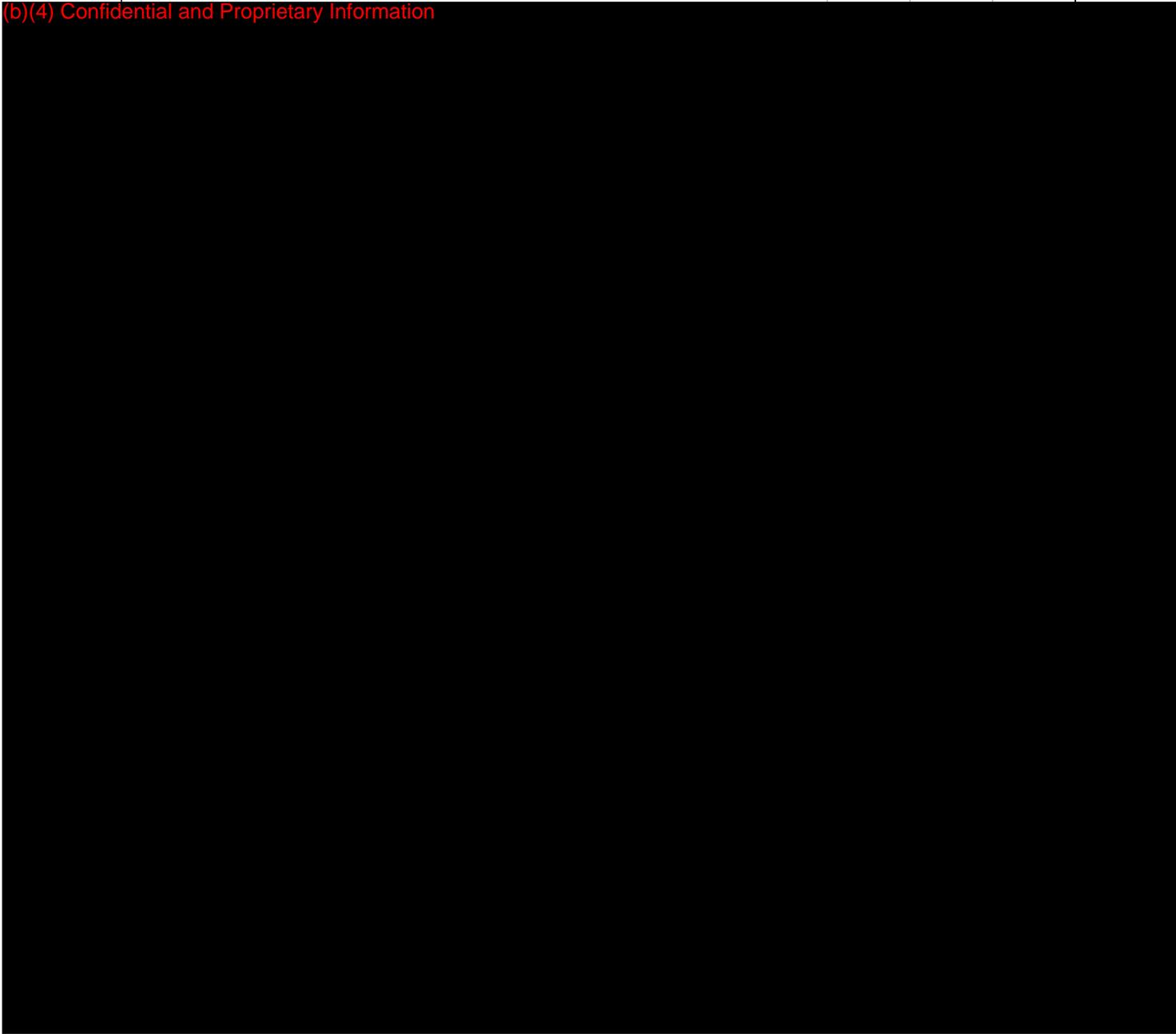
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II. Administrative Requirements

	Yes	No	N/A
Indications for Use page	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

(b)(4) Confidential and Proprietary Information



Date: August 21, 2015

From: Bipasa Biswas, Mathematical Statistician,
Division of Biostatistics, OSB

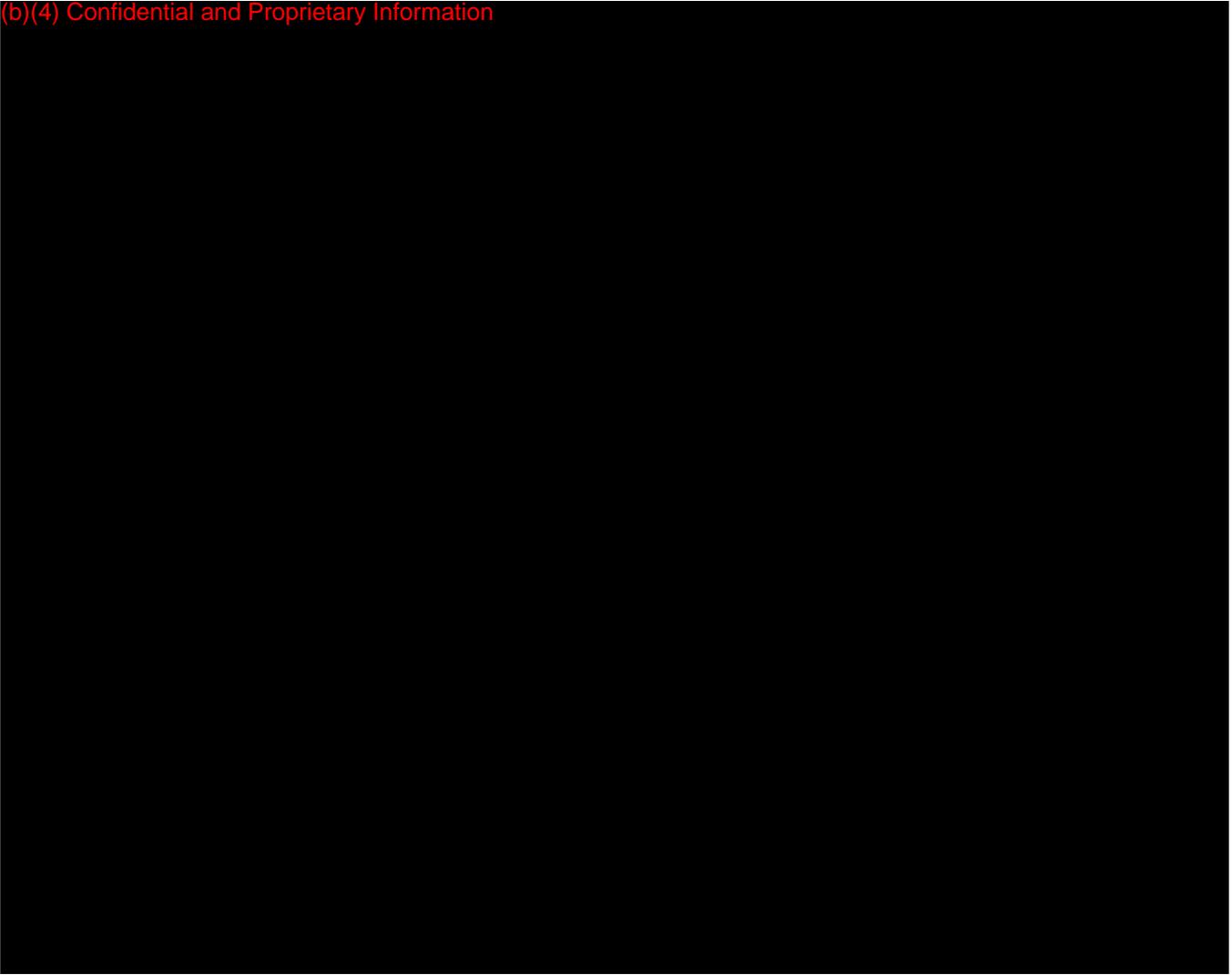
Subject: Statistical review of 501(k) K150154/S001–ANAM Test System by VISTA Lifesciences Inc.

To: Stacie Gutowski
NSDB, DNPMD, ODE.

Scope

The review focuses on Revised Appendix F1 and F2, and the ANAM Test System Military Battery Administration Manual. The statistical analyses could not be checked but only the results and proposed analyses as there was no electronic data set provided with the submission.

(b)(4) Confidential and Proprietary Information



Dear Ms. Herzog,

I am writing to inform you of a newly granted de novo for Cognivue, a Class II Computerized Cognitive Assessment Aid, which is relevant to your recent submission to FDA (K150154), and is described below:

(b)(4) Confidential and Proprietary Information



Cognivue approval order:

http://www.accessdata.fda.gov/cdrh_docs/pdf13/DEN130033.pdf

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

White Oak Building #66, Room 1436

10903 New Hampshire Avenue

Silver Spring, MD 20993

Phone: 240-402-6032

E-mail: Stacie.Gutowski@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=462&F=&S=F>

Hello Calley and Donna-Bea,

We are finalizing the paperwork for K150154, and we noticed in the updated 510(k) Summary that the IFU was updated on the first page but the comparison table still has the old IFU. Could you please update the 510(k) Summary with the new IFU in the comparison table and send to me ASAP?

Sincerely,

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

White Oak Building #66, Room 1436

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov

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From: Donna-Bea Tillman [mailto:dtillman@bcg-usa.com]

Sent: Friday, August 21, 2015 3:57 PM

To: Gutowski, Stacie; Calley Herzog

Cc: k150154@docs.fda.gov

Subject: RE: FDA contact regarding K150154

Stacie:

The Administration Manual is too big to email in its entirety (it is 21Mbytes). We have attached a revised Section 5.3.1 that address your request to provide greater clarity regarding what the standard deviation unit score represents and how the end user may interpret this score. The highlighted text is the new information.

We have also provided:

- Updated Indications for Use Form
- Updated 510(k) Summary
- Updated pages from the labeling that indicate the new indications for use (pages ii and 10)

Please let us know if there is anything else you need.

Donna-Bea

Donna-Bea Tillman, Ph.D, FRAPS | Senior Consultant (Devices), Biologics Consulting Group | 400 N. Washington St., Suite 100, Alexandria, VA 22314 | 410.531.6542 | dtillman@bcg-usa.com | www.biologicsconsulting.com/

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From: Gutowski, Stacie [mailto:Stacie.Gutowski@fda.hhs.gov]

Sent: Friday, August 21, 2015 3:25 PM

To: Calley Herzog <cherzog@bcg-usa.com>; Donna-Bea Tillman <dtillman@bcg-usa.com>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Cc: k150154@docs.fda.gov Records processed under FOIA Request #2016-365; Released by CDRH on 09-26-2016.

Subject: RE: FDA contact regarding K150154

Hello Calley,

Please go ahead and update the IFU form and the 510(k) Summary with the updated IFU. Additionally, the Manual and any other associated labeling will need to be updated as well. I sent a another email this afternoon regarding the need for a better explanation of the Composite Score, and this will also need to be addressed in the updated labeling. Please let me know if you have any questions, and thank you for your prompt response to my email this morning.

Stacie Gutowski, Ph.D.

Biomedical Engineer

ODE/DNPMD/NSDB

White Oak Building #66, Room 1436

10903 New Hampshire Avenue

Silver Spring, MD 20993

(240) 402-6032

Stacie.Gutowski@fda.hhs.gov

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From: Calley Herzog [<mailto:cherzog@bcg-usa.com>]

Sent: Friday, August 21, 2015 12:53 PM

To: Gutowski, Stacie; Donna-Bea Tillman

Cc: k150154@docs.fda.gov

Subject: RE: FDA contact regarding K150154

Hi Stacey,

I have discussed this request with the Vista team and we agree with the modification you have proposed. Would you like me to go ahead and update the administrative documents or wait for further clarifications or requests from you?

Calley A. Herzog

Senior Consultant, Medical Devices, RAC

Biologics Consulting Group, Inc.

Phone: 720-883-3633

Fax: 703-548-7457

cherzog@bcg-usa.com

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From: Gutowski, Stacie [<mailto:Stacie.Gutowski@fda.hhs.gov>]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Sent: Friday, August 19, 2016 8:19 AM
Processed under FOIA Request #2016-365; Released by CDRH on 09-26-2016.

To: Calley Herzog <cherzog@bcg-usa.com>; Donna-Bea Tillman <dtillman@bcg-usa.com>

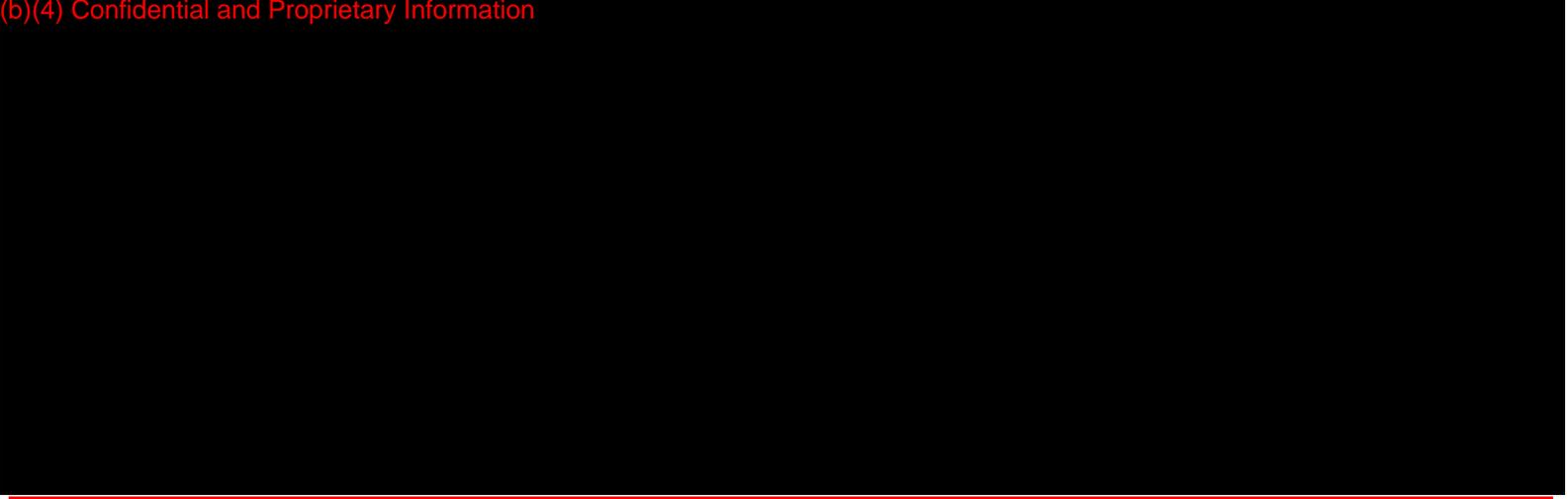
Cc: k150154@docs.fda.gov

Subject: FDA contact regarding K150154

Hello Calley,

We are in the process of reviewing the updated ANAM submission. Given the short time frame, I will be contacting you to bring up any issues as they arise so you may receive multiple emails from me.

(b)(4) Confidential and Proprietary Information



Sincerely,
Stacie Gutowski, Ph.D.
Biomedical Engineer
ODE/DNPMD/NSDB
White Oak Building #66, Room 1436
10903 New Hampshire Avenue
Silver Spring, MD 20993
(240) 402-6032
Stacie.Gutowski@fda.hhs.gov

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Indications for Use

510(k) Number (if known)

K150154

Device Name

ANAM Test System: Military Battery

Indications for Use (Describe)

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@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)

K150154

Device Name

ANAM Test System: Military Battery

Indications for Use (Describe)

The ANAM Test System: Military Battery provides clinicians with objective measurements of cognitive performance in military populations ages 18 to 65 years, to aid in the assessment of an individual's level of cognitive functioning. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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
PRAStaff@fda.hhs.gov

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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) #: K150154 Date Received by DCC: January 23, 2015

Lead Reviewer: Stacie Gutowski, Ph.D.

Branch: NSDB Division: DNPMD 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>	X	
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>	X	
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>		
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>	X	
Comments?		

<p>5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.</p>		×
<p>Comments?</p>		
<p>6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? 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>		×
<p>Comments?</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.

Organizational Elements

Records processed under FOIA Request # 2016-0305, Released by CDRH on 09-26-2016.

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

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

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
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A. Administrative

1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 (See also 510(k) Summary Checklist)	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) See recommended format .	X			
6) Submission contains Class III Summary and Certification. See recommended content .			X	
7) Submission contains clinical data			X	
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.			X	
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.	X			
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.			X	

B. Device Description

10)				
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Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

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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 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.			X	
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.			X	
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.	X			
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.	X			
c) A list and description of each device for which clearance is requested.	X			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
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>	X			
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.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
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))	X			

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.

<ul style="list-style-type: none"> - 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
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D. Proposed Labeling (see also 21 CFR part 801)

If *in vitro* diagnostic (IVD) device, criteria 17 & 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.	X			
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).	X			
b) Submission includes directions for use that <ul style="list-style-type: none"> - 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 	X			
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]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
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.			X	
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.			X	
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.			X	
21) If the device is an <i>in vitro</i> diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10 .			X	

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

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
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provided sterile

provided non-sterile but sterilized by the end user

✗ non-sterile when used

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

a) Identification of device, and/or accessories, and/or components that are provided sterile.

✗

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.

✗

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.

✗

G. Biocompatibility

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

✗

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
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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.

32) Submission includes a statement of software level of concern and rationale for the software level of concern.	X			
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33) All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices , or the submitter has provided an alternative approach with a rationale.	X			
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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.	X			
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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.			X	
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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.			X	
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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
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.			X	
38) If literature is referenced in the submission, submission includes:				
a) Legible reprints or a summary of each article.	X			
b) Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	X			
39) For each completed nonclinical (i.e., animal) study conducted			X	
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.				
X is not an in vitro diagnostic device.				

Decision: Accept Refuse to Accept
Records processed under FOIA Request #2016-365; Released by CDRH on 09-26-2016.

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	Stacie M. Gutowski -S 2015.02.02 10:22:27 -05'00'
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.