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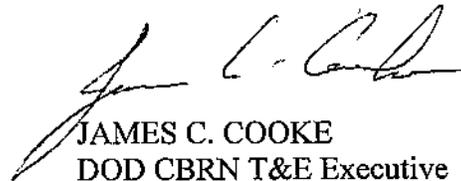
DUSA-TE

MEMORANDUM FOR DISTRIBUTION

SUBJECT: Endorsement of Test and Evaluation (T&E) Capabilities and Methodologies Integrated Process Team (TECMIPT) Test Operations Procedure (TTOP) Test for Cross Contamination During Doffing of Personal Protective Equipment (PPE)

1. Reference: Memorandum, DUSA-TE, and 19 July 10, subject: Chemical and Biological Defense Program (CBDP) Test and Evaluation (T&E) Standards Development Plan.
2. TTOP IP20141201-1.TTOP was developed, coordinated, and approved by interagency stakeholder and members of the Individual Protection Capability Area Process Action Team (CAPAT) in accordance with the reference.
3. I endorse this TTOP as a DOD T&E Standard for gross liquid cross contamination testing during doffing of PPE and encourage its broad use across all test phases. All T&E Standards are for government associated program access and use. They are stored on the TECMIPT website, located at <http://www.amsaa.army.mil/TECMIPT/Standards.html> and on the National Institute of Standards and Technology (NIST) website at <http://www.nist.gov/national-security-standards/tops.cfm>.
4. Further T&E standards will be developed for trace contamination and aerosols.
4. My point of contact for this action is Ms. Deborah Shuping, (703) 545-1119, deborah.f.shuping.civ@mail.mil.

Encl


JAMES C. COOKE
DOD CBRN T&E Executive

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SUBJECT: Endorsement of Test and Evaluation (T&E) Capabilities and Methodologies Integrated Process Team (TECMIPT) Test Operations Procedure (TTOP) Test for Cross Contamination During Doffing of Personal Protective Equipment (PPE)

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DUSA-TE

MEMORANDUM FOR Chemical, Biological, Radiological and Nuclear Defense Test and Evaluation Executive, Office of the Deputy Under Secretary of the Army (DUSA-TE), Taylor Building, Suite 8070, 2530 Crystal Drive, Arlington, VA 22202

SUBJECT: Test and Evaluation Capabilities and Methodologies Integrated Product Team (TECMIPT) Recommendation for the Test Operations Procedure (TTOP) Test for Cross Contamination During Doffing of Personal Protective Equipment (PPE)

1. The Individual Protection (IP) Capability Area Process Action Team (CAPAT), along with interagency stakeholders, completed the TTOP in accordance with DUSA-TE instructions to the TECMIPT, the Standards Development Plan, and the TECMIPT Standard Operating Procedure. All signatory members of the CAPAT have provided their concurrence to the attached TTOP.
2. Based on the concurrence of the CAPAT, I recommend the CBRN Defense T&E Executive endorse this TTOP as a Department of Defense Test and Evaluation Standard

A handwritten signature in black ink, appearing to read "Sean P. O'Brien", is positioned above the printed name.

SEAN P. O'BRIEN
TECMIPT Chair

Encl

TECMIPT Test Operations Procedures (TTOP) Test for Cross Contamination During Doffing of Personal Protective Equipment

Individual Protection Capability Area Process Action Team
(CAPAT)

*Dr. Jessica Appler, Deputy Undersecretary of the Army-Test and
Evaluation*

CAPAT Review & Concurrence: December 01, 2014

**Test and Evaluation Capabilities and Methodologies
Integrated Process Team (TECMIPT) Participants:**



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REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188			
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9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) Chemical, Biological, Radiological, and Nuclear Defense Test and Evaluation Executive Deputy Undersecretary of the Army- Test and Evaluation ATTN: DUSA-TE/Ms. Deborah Shuping, Taylor Building, Suite 8000, 2530 Crystal Drive, Arlington, VA 22202				10. SPONSOR/MONITOR'S ACRONYM(S) DUSA-TE		
				11. SPONSOR/MONITOR'S REPORT NUMBER(S) IP20141201-1.TTOP		
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14. ABSTRACT This Test and Evaluation Capabilities and Methodologies Integrated Process Team (TECMIPT) Test Operations Procedures (TTOP) provides a test methodology for evaluation of cross contamination resulting from doffing a personal protective equipment (PPE) ensemble. The scope of the methodology within this TTOP focuses on gross liquid contamination of the exterior of a PPE ensemble. The methodology in this TTOP is intended to be used with multiple variants of PPE (e.g., worn by warfighters, emergency responders, healthcare workers) paired with their recommended doffing procedures. Potential use cases for this TTOP include but are not limited to: assessment of doffing procedures in operationally relevant environments, comparison of different PPE ensemble and doffing procedure combinations using the same test conditions, and assessment of training effectiveness for individual PPE users.						
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				SAME AS REPORT	12	Dr. Jessica Appler
a. REPORT UNCLASSIFIED	b. ABSTRACT UNCLASSIFIED	c. THIS PAGE UNCLASSIFIED				19b. TELEPHONE NUMBER 703-545-1088

Individual Protection CAPAT recommends approval of the TTOP. If an organization non-concurs, a dissenting position paper will be attached.

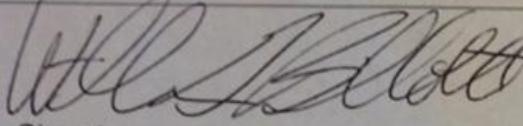
LT Col Kevin Reilly Marine Corps Operational Test & Evaluation Activity	Deirdre Sumpter US Army Test and Evaluation Command/US Army Evaluation Command
 Signature Date 1/12/14	HEAPS.EARL.LEE.12 29303291 Signature Date <small>Digitally signed by HEAPS.EARL.LEE.1229303291 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USA, cn=HEAPS.EARL.LEE.1229303291 Date: 2014.11.20 17:38:57 -05'00'</small>
Jeffery Bobrow Operational Test and Evaluation Force	Grant D. Schaber Air Force Operational Test and Evaluation Center
 Signature Date 18 Nov 14	 Signature Date 24 Nov 14
Laurie K. Richter, Lt Col, USAF Joint Requirements Office for Chemical, Biological, Radiological and Nuclear Defense	Deborah Shuping Deputy Undersecretary of the Army – Test and Evaluation
NOT APPLICABLE Signature Date	 Signature Date 11/25/14
Mark Thomas Joint Program Executive Office of Chemical Biological Defense	Mike Roberts Joint Science and Technology Office
12/2/2014 <input checked="" type="checkbox"/> Mark Thomas <small>Mark Thomas JPED T&E</small>	11/25/2014 <input checked="" type="checkbox"/> Michael Andrew Roberts <small>Michael A. Roberts JSTO IP-CAPAT Representative Signed by: ROBERTS, MICHAEL, A.1228803371</small>
Gabriel Ramos Combating Terrorism Technical Support Office	
ramosg@cttso.gov Signature Date <small>Digitally signed by ramosg@cttso.gov DN: cn=ramosg@cttso.gov Date: 2014.12.03 09:52:03 -05'00'</small>	

Note: It is assumed that a CAPAT member's signature represents an O6 level concurrence from their organization. If the CAPAT representative is not empowered at this level, he must coordinate the signature process within his organization in a timeframe that meets the TECMIPT master schedule. [Reference: Department of Defense (DOD) Chemical, Biological, Radiological, and Nuclear (CBRN) Defense Test and Evaluation (T&E) Standards Establishment Process Implementation Plan (5 November 2014)]

Individual Protection CAPAT recommends approval of the TTOP. If an organization non-concurs, a dissenting position paper will be attached.

Concurrence Sheet (2 of 2): Interagency Partners

William Billotte
National Institute of Standards and Technology



Signature
Date 11/25/2014

Maryann M. D'Alessandro
National Personal Protective Technology
Laboratory
National Institute for Occupational Safety and
Health
Centers for Disease Control and Prevention



Signature
Date 11/26/14

Philip Mattson
Department of Homeland Security



Signature
Date 12/2/2014

Note: Signature of interagency partners represents concurrence of methodology for DoD standards.

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1.0 Scope and Application

This Test and Evaluation Capabilities and Methodologies Integrated Process Team (TECMIPT) Test Operations Procedures (TTOP) provides a test methodology for evaluation of cross contamination resulting from doffing a personal protective equipment (PPE) ensemble. Cross contamination includes contamination transfer from a PPE ensemble to personnel (including self contamination), and can include contamination transferred to facilities and/or equipment (e.g. walls, chairs, handles, buckets) associated with the doffing process.

The scope of the methodology within this TTOP focuses on gross liquid contamination of the exterior of a PPE ensemble. It does not assess the effectiveness against contamination with or exposure due to solids, vapors, aerosols, or off gassing resulting from contamination.

The methodology in this TTOP is intended to be used with multiple variants of PPE (e.g., worn by warfighters, emergency responders, healthcare workers) paired with their recommended doffing procedures. The type of PPE ensemble intended to be assessed using this methodology is a full body protection ensemble (e.g., full body, hand, foot, face, and head protection).

Potential use cases for this TTOP include but are not limited to:

- Assessment of doffing procedures in operationally relevant environments
- Comparison of different PPE ensemble and doffing procedure combinations using the same test conditions
- Assessment of training effectiveness for individual PPE users

This document is based on test and evaluation plans developed by Department of Defense components for testing individual and collective protection systems. This TTOP may be combined with the Man-in-Simulant Testing TTOP 10-2-022A, Chemical Vapor and Aerosol System-Level Testing of Chemical/Biological Protective Suits [1], in order to assess contamination during operations prior to doffing as well as contamination during the doffing procedure.

2.0 Word Usage

The following word usage applies:

- The word “shall” signifies a mandatory requirement (where appropriate, a qualifying statement is included to indicate that there may be an allowable exception).
- The word “may” signifies an acceptable method or an example of good practice.
- The word “should” signifies a recommended specification or method.

3.0 Limitations

This TTOP does not evaluate the ability of PPE ensembles to protect individuals from chemical or biological threats during operational use. It should only be used on PPE ensembles that previously have been demonstrated to provide protection in separate test events.

This TTOP only assesses the ability to reduce cross contamination due to removal of gross contamination for any decontamination protocol included in the doffing procedure. It will not evaluate a reduction in cross contamination due to inactivation or other method of rendering safe contamination.

This TTOP provides qualitative evidence using a fluorescent contaminant to track cross contamination, and should not be over-generalized as establishing the safety, or risk, of doffing procedures and decontamination.

This TTOP does not include the specific test procedures used by an individual test organization or facility.

4.0 Test Facilities and Equipment

Test facilities shall develop their own test procedures based on their capabilities and the test objectives. Test procedures shall be based on the test methodology described in this document and should be validated prior to conducting testing.

Test facilities should be accredited to International Organization for Standardization (ISO) 17025 [2] or equivalent standards.

To perform the test methodology listed in this document, a test facility should have as a minimum the following test equipment:

- Fluorescent skin safe contaminant
- Contamination application system
- Ultra violet light source that produces wavelength of light compatible with fluorescent contaminant absorption, and eye protection if required
- Digital image capability
- Operationally representative space to conduct doffing
- Calibrated environmental monitoring equipment

Note that the contamination application equipment may require additional equipment and/or instrumentation to calibrate and operate.

5.0 Health and Safety

Each organization conducting testing described in this TTOP shall comply with all applicable health and safety rules, regulations, and policies governing the organization and any test facilities used. This should be covered in the safety manual of each test facility. Additionally, all required safety releases, safety requirement, and test procedure review shall be completed prior to performing the test outlined in this TTOP.

Fluorescent contaminants and decontamination solutions shall be safe for contact with skin at the concentrations and durations expected, based on the test facility specific test procedure. Test facilities shall ensure that sufficient ventilation is in place for safety as it applies to the potential aerosol hazard to the test officers, test participants, and observers presented by application of the fluorescent contaminant and decontamination solution(s).

6.0 General Test Procedures

6.1 Standard Test Conditions

Testing shall be carried out under standard test conditions for the environmental parameters listed in Table 1. Standard test conditions listed are representative of documented environmental parameters in approved TTOPS for indoor testing, but they can also be achieved during outdoor testing.

Measurement of each environmental parameter listed in Table 1 should be taken and recorded using calibrated environmental monitoring equipment at least once during each test, and more frequently if environment is not controlled and conditions may change during the course of a test (e.g., outdoors).

Situations may arise where the operational test conditions required are outside the standard test conditions. For these situations, an explanation of the operational test conditions, along with the actual observed values for the environmental parameters, shall be included in the test report.

Table 1: Standard Test Conditions

Environmental Parameter	Standard Test Range
Ambient temperature	15 °C to 30 °C
Relative humidity	50% to 75%
Atmospheric pressure	86 kPa to 106,6 kPa (at 0 °C)

6.2 Training

Prior to testing, all test participants will conduct pre-test training on the decontamination protocols and doffing procedures for the PPE ensemble in use. For each participant, at least two mock trials (without fluorescent contaminant present during contamination application) shall occur. The mock trials should include mock contamination and mock post-contamination assessment, to ensure that the test participants and test officers are proficient at performing test procedures prior to conducting actual trials. Training shall be documented and included in final test report. Materials used in the decontamination process shall be tested for fluorescence during the mock trials to ensure that there will be no interference with test results.

6.3 Fluorescent Contaminant

The fluorescent contaminant should be fluorescent under ultraviolet light but not noticeable to the naked eye during normal lighting conditions. This is necessary in order to identify cross contamination resulting from contaminated PPE during the doffing process. If decontamination is part of the doffing procedure, the contaminant should be able to be removed from the PPE ensemble by the decontamination procedure and not permanently affixed to the PPE. The contaminant and any carrier liquids shall be safe for use directly on the skin in the concentrations used during the test. The basic properties (including but not limited to viscosity and liquid absorbance on PPE ensemble materials) of the fluorescent contaminant shall be assessed and should closely match the properties of the threat expected during the operational use of the PPE ensemble. Guidance on basic properties of bodily fluids can be found in American Society for Testing and Materials (ASTM) F1670M- Standard Test Method for Resistance of

Materials Used in Protective Clothing to Penetration by Synthetic Blood [3]. Examples of potential fluorescent contaminants include Tinopal® CBS-X, a commercial whitener, and Glo Germ™ (<http://www.glogerm.com/index.html>), a product used for testing hand washing procedures. Both can be easily detected using a commercially available blacklight. The inclusion of these products and test equipment is not a specific endorsement of any company or organization, and is provided solely to assist testers in identifying products that have been used in past test events. Manufacturer Safety Data Sheets for each product shall guide required health and safety measures used during testing.

Positive controls assessing detection range for fluorescent contaminant on the participant and undergarment shall be conducted prior to testing, and should be conducted each test day. Drops of known size and concentration may be placed on individual test participants to demonstrate the capability of the minimum detection on each person. If performed after the post-doffing procedure is completed, each person could serve as their own control.

6.4 Contamination Application System

The type of contamination application system required for testing will vary according to the expected operational use of the PPE ensemble. Contamination application systems chosen shall replicate the expected operational exposure to contamination at a minimum, and may replicate a “worst case” exposure.

Prior to testing, characterization of the contamination application system shall be conducted to predetermine the settings needed to deposit the required contamination. Assessment of the contamination application system shall provide record of repeatable contamination prior to the first test. Measures of repeatability shall include, but are not limited to, contamination-to-doffing time, location of application, surface area covered, and coverage density of contamination, with the variability and confidence level included for these measures. Record of repeatability shall be captured through photographs, witness cards, or other means to compare contamination distribution between and across trials. Repeatability may also be assessed during test trials using similar means to assess contamination distribution.

7.0 Test Operating Procedures

7.1 Prior to donning PPE ensemble

Each test participant shall wear a clean garment under PPE that has not been exposed to the fluorescent contaminant. The garment worn under the PPE shall be standardized for the duration of each test and should be a UV neutral material. If a single participant will be tested repeatedly in one day, the participant should shower between trials and have a fresh garment for each trial. Prior to donning the PPE ensemble, a UV light will be used to document whether any fluorescent areas are present on the clothing worn underneath the PPE. Digital photographs and/or videos will be taken to document the “before” state of the participants’ clothing and whether any fluorescent areas were found before any contamination was applied. A hand-recorded data sheet (example Annex A) can be used during testing in addition to digital record.

7.2 Contamination of the PPE ensemble

A clean PPE ensemble shall be donned using the ensemble's standard operating procedure, and each test participant should be examined prior to testing to ensure the fit and application of the PPE was correct. Test participants wearing a clean PPE ensemble shall be contaminated with the fluorescent contaminant simulating expected or worst case operational contamination. The contaminant should be applied in an area separated from the doffing area. The doffing environment shall be monitored with the UV light after the contamination process to determine if any fluorescent areas exist before the start of each doffing trial and digital photographs and/or videos shall be taken to document the "before" state of the doffing environment. The contamination of test participants PPE should be verified using the UV light, and documented using digital photographs and/or videos.

7.3 Cross contamination testing

Test participants in contaminated PPE shall doff their PPE ensemble, including performing decontamination procedures if applicable, according to either their standard operating procedure or the procedure under test. Duration of doffing procedure should be recorded as it may be an essential variable in cross contamination. If cross contamination testing will be used to assess training efficacy or doffing procedure modification, the actual doffing and decontamination procedures should be documented using video recording for additional analysis. This TTOP may be used in conjunction with other test methods that simulate operational activities in a contaminated environment. These methods are outside the scope of this document.

After doffing the PPE ensemble, a UV light will be used by the test officer to document whether there are any fluorescent areas present on the test participant's skin and standardized garment worn underneath the PPE. Digital photographs and/or videos will be taken to document the "after" state of the participants and identify whether any cross contamination occurred. If more than one test participant is involved in the doffing procedure (e.g., buddy doffing, casualty doffing), both test participants shall be examined with the UV light. If environmental cross contamination will be assessed, the PPE doffing environment shall also be monitored with the UV light and contamination documented using digital photographs and/or videos after doffing procedure is complete.

Fluorescence observed after doffing shall be compared to the individual test participant's record of fluorescence prior to donning PPE to determine if it was the result of cross contamination that occurred during the doffing process. If cross contamination is observed, magnitude of contamination should be quantified (i.e., total area contaminated, location weighted area of contamination, or another scoring system, see references [4, 5]). Measurement of contamination may be conducted using swabs or other collection methods and off body analysis of fluorescence. The method of quantification and data requirements necessary to fulfill goals for test (use case specific, e.g., chose a PPE ensemble, modify training procedures) shall be agreed upon prior to start of testing, including any pass/fail metrics, and consistently applied throughout the test. A review of videos recorded during the doffing and decontamination procedures may be used to assist in determining how the cross contamination occurred.

8.0 Data Management

Data management should follow ISO 17025 [2] or equivalent requirements.

9.0 Quality Control/Quality Assurance

Quality control measures shall ensure accuracy for all aspects of conducting the test procedure (e.g., fluorescent contaminant preparation, contaminant application) and collecting the test data (e.g., instrument calibrations, data manipulation).

Quality assurance shall include at a minimum a check or audit of the procedures, including training records, equipment calibration records, validation protocols (with test conditions, number of trials, etc.) and validation criteria. This audit and its results should undergo a peer or panel review process following ISO 17025 [2] or equivalent requirements.

A facility specific validation protocol should be finalized as a result of validating the test method.

10.0 Forms/Data Sheets

Forms and data sheets for data collection should be based on the specific test method of the test facility and test parameters shall be recorded.

11.0 References

The following referenced documents apply to or can supplement the test methodology covered in this document.

- [1] TTOP 10-2-022A, Chemical Vapor and Aerosol System-Level Testing of Chemical/Biological Protective Suits.
http://www.amsaa.army.mil/TECMIPT/docs/TTOP_10-2-022A.pdf
- [2] ISO 17025: General requirements for the competence of testing and calibration laboratories.
- [3] Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood. ASTM F1670 / F1670M - 08(2014)e1.
- [4] Aragón, Aurora, et al. "Assessment of dermal pesticide exposure with fluorescent tracer: a modification of a visual scoring system for developing countries." *Annals of Occupational Hygiene* 50.1 (2006): 75-83.
- [5] Aragón, Aurora, et al. "Reliability of a visual scoring system with fluorescent tracers to assess dermal pesticide exposure." *Annals of Occupational Hygiene* 48.7 (2004): 601-606.

12.0 Abbreviations

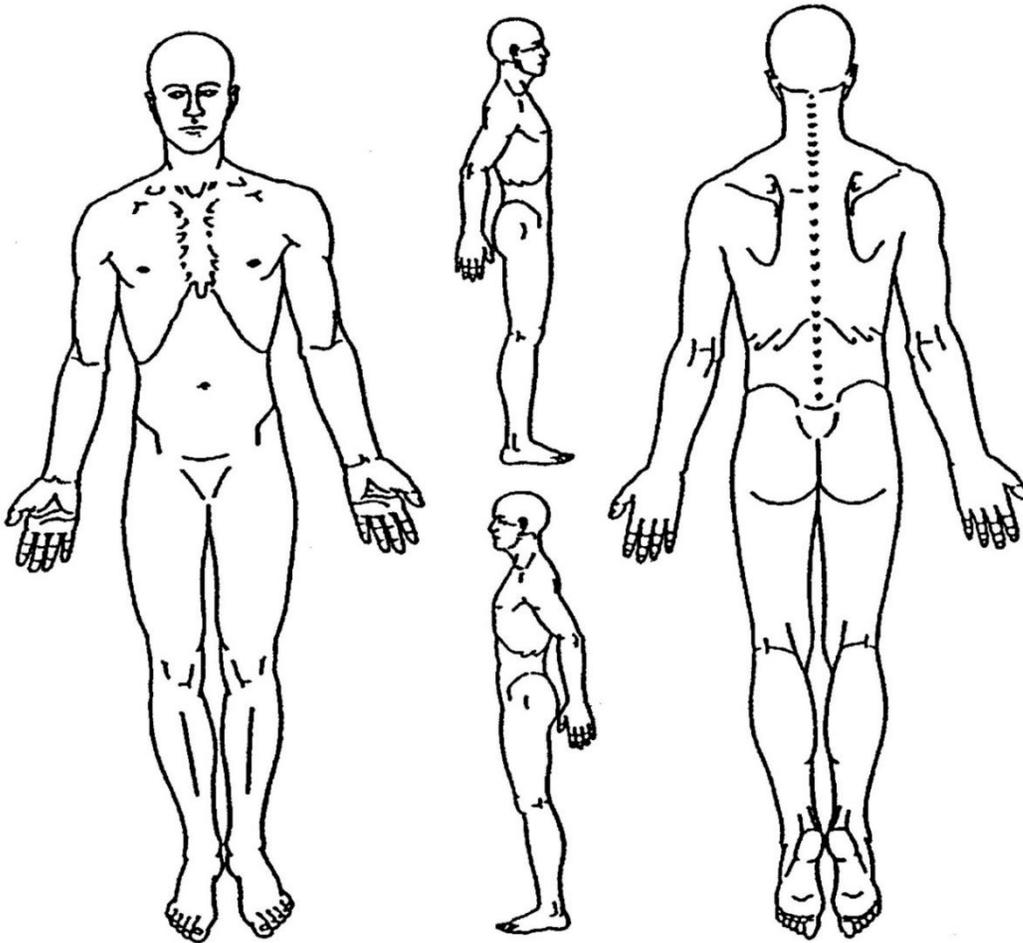
ASTM	American Society for Testing and Materials
CAPAT	Capability Area Process Action Team
DoD	Department of Defense
ISO	International Organization for Standardization
PPE	Personal Protective Equipment
TECMIPT	Test and Evaluation Capabilities and Methodologies Integrated Process Team
TTOP	TECMIPT Test Operations Procedures
UV	Ultraviolet

Annex A – Sample of Contamination Record Data Sheet

Test Number: _____

Sample ID: _____

Sample Location: _____



Comments: _____
