

D-077 DOD FADL SARS-CoV-2 Pooled Surveillance 1st Version
Sample Submission Guide

DoD FOOD ANALYSIS AND DIAGNOSTIC LABORATORY

STANDARD OPERATING PROCEDURE

SOP D-077 - DOD FADL SARS-CoV-2 POOLED SURVEILLANCE SAMPLE
SUBMISSION GUIDE

Date Prepared: 28 January 2021
Date of Original: 28 January 2021
Schedule for Review: Biennial
Author: LTC Marisol Castaneto
Distribution: Molecular Diagnostic Section

APPROVAL:

Diagnostics Section Supervisor:

Donald A. Beasley

DONALD A. BEASLEY

CPT, MS

27 January 2021

QA Section Chief:

Marisol S. Castaneto

MARISOL S. CASTANETO, PhD

LTC, MS

28 January 2021

Revision History:

Edition Date	Revision (Section & Description)	Reviewer Initials
28 Jan 2021	New Version Created due to New FADL Mission	BD/DAB/MS

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I. PURPOSE

The purpose of this Standard Operating Procedure (SOP), in coordination with Region Health Command - Central (RHC-C) and Army Public Health Center (APHC), DoD Food Analysis & Diagnostic Laboratory (FADL) will conduct SARS-CoV-2 Pooled Surveillance utilizing CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time PCR (CDC-006-00019, Revision: 05 dated 7/13/2020).

II. PRINCIPLE

A. Sample Authorization:

Public Health Command - Central (PHC-C), Food Analysis & Diagnostic Laboratory (FADL) will reject any samples that are submitted without prior coordination. For project coordination, e-mail estimated sampling dates and details to PHC-C FADL at usarmy.jbsa.medcom.mesg.phcc-fadl-cv19@mail.mil

B. Sample Collection:

FADL is **only** accepting nasopharyngeal (NP) swabs. Sampling media includes a synthetic fiber swab (i.e. nylon, Dacron), aluminum or plastic shaft (calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended), sterile transport tube, and viral transport medium (VTM). We cannot accept samples with Amies transport medium, universal transport medium (UTM) or sterile saline.

Following sample collection, immediately place the NP swab into a sterile transport tube containing 2 to 3 ml of VTM. Tightly seal to avoid cross contamination. FADL does not provide sampling kits for SARS-CoV-2 Pooled Surveillance.

Individual samples will be pooled into groups of five (5) or fewer when received at the FADL. For additional information about sampling pools to include positive results implications, refer to Section IV.C Result Interpretation, Appendix A - Packing Requirements for Sample Shipment and CDC guidelines for SARS-CoV-2 collection and handling:

<https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

III. LABELING AND STORAGE

- A. Label each sample with a unique, contributor sample number at the time of collection. This should be performed locally by the sample collector. Do **not** use SSNs or DOD ID numbers for the sample number. DOD ID numbers should be included on the SARS-CoV-2 Pooled Surveillance Submission Form, referenced below in Section IV.A Required Documentation.
- B. Limit sample numbers to no more than 15 characters, using a consecutive numbering system to avoid duplicates and accurately reference the numbers on the laboratory submission form. Use permanent, waterproof ink to write or print the sample numbers and sampling date on a label. Firmly affix the label to the transport tube. Do **not** block manufacturer's label on tube.
- C. Store samples at 2-8°C prior to shipment. Samples **must** be received by the laboratory within 72 hours of collection. If a delay in shipping is expected, store samples at $\leq -70^{\circ}\text{C}$.

NOTE: if samples cannot be stored at $\leq -70^{\circ}\text{C}$, then every effort **must** be made to meet the aforementioned holding time requirements.

IV. SAMPLE SUBMISSION**A. Required Documentation**

1. Samples **must** be accompanied by a completed FADL Form D-319 - SARS-CoV-2 Pooled Surveillance Submission form. To obtain a copy of this form, please e-mail the laboratory at usarmy.jbsa.medcom.mesg.phcc-fadl-cv19@mail.mil. Forms should be saved locally before filling out. In addition to the hard-copy accompanying the sample, e-mail the completed form and include "COVID-19" along with the sampling date and location in the subject line. If sample was delayed and samples were stored at $\leq -70^{\circ}\text{C}$, the storage details (starting and ending dates) **must** be included in the body of the e-mail.
2. The submitter(s) listed on the SARS-CoV-2 Pooled Surveillance Submission form will be the Point(s) of Contact (POC) for any questions regarding the samples. The final report for the sample results

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will be sent to the POC's e-mail address listed on FADL Form D-319.

3. As per the Department of Defense (DoD) Directive 5124.02 and DoD Instruction 1000.30 - Reduction of Social Security Number (SSN) Use Within DoD", PHC-C - FADL **must** avoid collecting SSNs and therefore, will not process samples using SSNs. Samples can be submitted with DoD ID# in the relevant column on the COVID-19 Surveillance Testing Submission form.

B. Shipping Instructions

1. Ship Samples to:

DoD Food Analysis and Diagnostic Laboratory
(FADL)

ATTN: COVID-19 Testing

2899 Schofield Road, Suite 2630

JBSA Fort Sam Houston, Texas 78234-7583

2. COVID-19 samples **must** be shipped overnight to PHC-C FADL on ice packs or with dry ice.
 - a. Samples **must** be received by the laboratory within 72 hours after collection unless stored at $\leq -70^{\circ}\text{C}$.
 - b. Samples received outside of temperature or holding time requirements may **not** be analyzed; the POC will be contacted for further instructions.

NOTE: If you wish for PHC-C FADL to return your shipping container, please include a return shipping label.

3. Human samples being tested for SARS-CoV-2 (agent of COVID-19) are designated as Biological Substances, Category B, UN3373 for shipping purposes. Shipments of human respiratory samples **must** comply with 49 CFR 173.199 Department of Transportation Regulations by highway and commercial air dangerous goods regulations by air. Refer to Appendix A for detailed instructions for Sample.

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C. Result Interpretation

1. **Not Detected:** SARS-CoV-2 was **not** detected for sample pool. Corresponds to a presumptive negative result for all individual samples within the respective sample pool.
2. **Positive:** SARS-CoV-2 was detected in the sample pool. Corresponds to a presumptive positive result for at least one (1) individual sample within the respective sample pool. All individuals comprising this pool, known only by the submitting unit, will require a second diagnostic test to determine individual COVID-19 infection status. This test will need to be performed in a clinical setting; confirmatory testing is **not** performed by PHC-C FADL.
3. **Inconclusive:** SARS-CoV-2 was detected in the sample pool, but could not be confirmed. This result should be presumed to be positive. All individuals comprising this pool, known only by the submitting unit, will require a second diagnostic test determine individual COVID-19 infection status. This test will need to be performed in a clinical setting; confirmatory testing is **not** performed by PHC-C FADL.
4. **Invalid:** A sample pool result of "Invalid" indicates that no human cells and or virus was detected within the sample. Sampling procedure possibly failed to sample the individual(s) properly. Consider collecting a new sample from this individual or group of individuals.

D. Contact Information

For any questions pertaining to the DoD FADL SARS-CoV-2 Pooled Surveillance Program e-mail PHC-C FADL at usarmy.jbsa.medcom.mesg.phcc-fadl-cv19@mail.mil or call 210-778-9511.

V. APPENDICES

- A. **Appendix A - Packing Requirements for Sample Shipment**
- B. **Appendix B - Packing Specifications for Category B Infectious Substances**

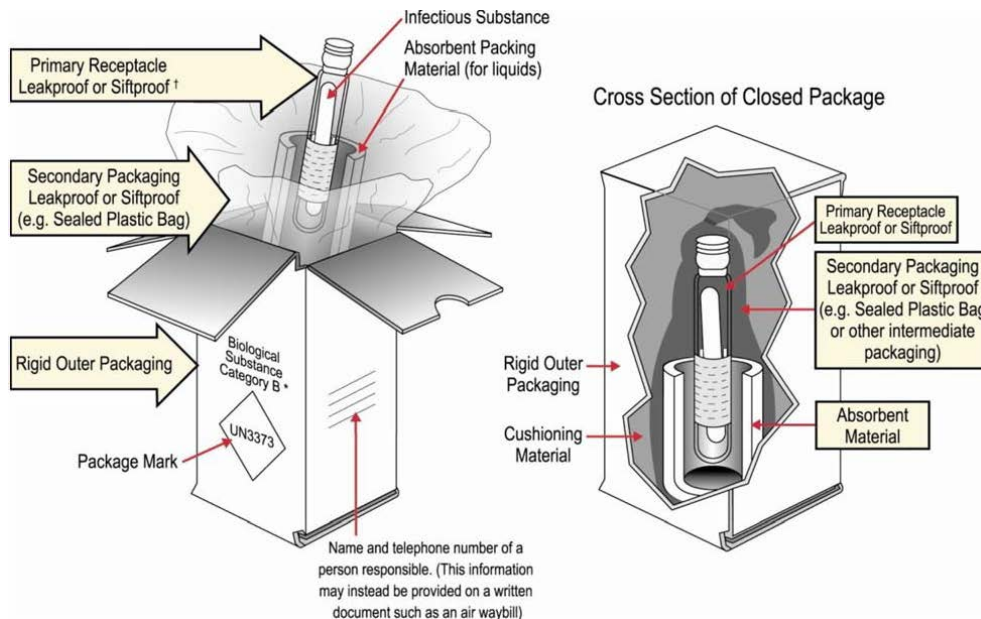
C. Appendix C - Biological Substances for Category B

APPENDIX A: Packing Requirements for Sample Shipment

All shipments of biological materials (Category A, Category B, and exempt materials) must be triple packaged. Standard triple containment packaging consists of a sealed, leak-proof primary receptacle placed within a sealed, leak-proof secondary container that has sufficient absorbent material. The secondary packaging and its contents are then secured in a rigid outer packaging with sufficient cushioning material to minimize shifting during transport. The outer shipping packaging must be durable and capable of passing an UN-approved 1.2m drop test and display the required marking and labeling. This style of packaging provides safety for the public and those handling and receiving packages. Proper classification, packaging, marking, labeling, and other appropriate precautions are essential for public safety. Regulations assign ultimate responsibility for the shipment's safety with the shipper.

Category B infectious substances are assigned the identification number UN3373. Examples include cultures of low to moderate consequence pathogens, and diagnostic or clinical specimens from humans or animals, that may harbor a pathogen (in other words, more than a low probability of containing a pathogen).

The CDC provides the following diagram for packaging UN3373 Category B substance, which can also be applied to multiple samples within the same package:



**APPENDIX B: Packaging Specifications for Category B
Infectious Substances**

1. Utilize a leak proof primary receptacle.
2. Utilize a leak proof secondary container.
3. Place absorbent material between the primary receptacle and secondary packaging (enough absorbent to absorb the entire contents of the primary receptacles).
4. Provide absorbent materials in between primary receptacles.
5. For air shipments, the primary receptacles may not exceed 1L and each package may not exceed 4L.
6. For shipments of liquid by air, the primary or secondary container must be capable of withstanding a pressure of 95 kPa (13.8 psi) and temperatures between (-40 °F to 130 °F). Plastic bags can be used as secondary containers for liquids, but they must be of sufficient strength to pass the 95 kPa pressure test. Researchers who have questions should contact their safety office to have packaging evaluated or see an example of a 95 kPa rated secondary plastic bag or solid walled container.
7. Secure secondary packaging in rigid outer packaging (at least four (4) inches in width).
8. Enclose a list of contents in between the secondary and outer rigid shipping container.
9. The packaging must be capable of passing the drop tests specified by the DOT from a height of four feet, without leaking its contents.
10. Place the name and phone number of a "Responsible Person" on the outer container. This must be available during normal business hours to answer questions about the package.
11. Include the UN3373 mark.

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12. The outside of the packaging must also include the shipping name "Biological Substance, Category B" in letters at least 6 mm high.

NOTE: Most commercially available Category B shipping labels include both the UN3373 mark with the proper shipping name on the same label.

13. Utilize orientation arrows on opposite sides of the package if the net quantity of liquid Category B infectious substances is greater than 50 ml.

14. Utilizing refrigerants such as dry ice, requires additional marking and labeling.

Marking Specifications for Category B Infectious Substances

All hazardous material packages must include the following basic markings:



APPENDIX C - BIOLOGICAL SUBSTANCES, CATEGORY B

Per 49 CFR Part 173.199, the name and telephone number of a person who is either knowledgeable about the material being shipped and has comprehensive emergency response and incident mitigation information for the material, or has immediate access to a person who possesses such knowledge and information, must be included on a written document (such as an air waybill or lading) or on the outer packaging.

Refrigerants

Per National and International requirements, a packaging containing inner packaging of Category B infectious substances may not contain other hazardous materials except refrigerants (e.g. dry ice or liquid nitrogen), anticoagulants used to stabilize blood or plasma, or small quantities of Class 3, Class 8, Class 9, or other materials in Packing Groups II and III used to stabilize or prevent degradation of the sample, provided the quantity of such materials does not exceed 30 ml (1 ounce) or 30 g (1 ounce) in each inner packaging. Such preservatives are not subject to the requirements of 49 CFR Subchapter C.

For refrigerated substances, place ice, dry ice or pre-frozen packs between the secondary leak-proof receptacle and the outer packaging. To prevent the inner packaging from shifting due to melting ice, use a leak-proof outer packaging with interior supports.

If dry ice is used, the outer packaging must permit the release of carbon dioxide gas and the provisions of 49 CFR Part 173.217 in addition to Part 173.199 must be followed. You may also place the completed package of samples in an overpack and place the refrigerant in the overpack around the completed packages. The overpack must permit the release of the carbon dioxide gas and be marked with the word "Overpack" to indicate it is an overpack. The markings and labels from the completed packages must also be marked on the overpack.

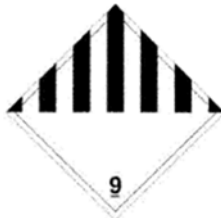
It is important to make advanced arrangements between the shipper and the carrier to ensure proper ventilation and adherence to safety procedures are followed if dry ice is used as the refrigerant.

If the quantity of the dry ice does not exceed 2.5 kg (5.5 pounds) per package, mark the package with the words "Carbon dioxide, solid" or "Dry ice", the net weight of the dry ice, and an indication that the material being refrigerated is used

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for diagnostic treatment purposes (e.g. frozen medical specimens). This amount is exempt from all other dangerous goods requirements.

If the amount of dry ice exceeds 2.5 kg (5.5 pounds) per package, you **must** add a Class 9 Miscellaneous Label to the outer package along with the UN identification number (UN1845), the words "Carbon dioxide, solid" or "Dry ice", and the net quantity of the dry ice.



49 CFR Part 172.446 - Class 9 Miscellaneous Label

Safety Guidance for the use of Dry Ice (if applicable):

1. Never place dry ice inside a sealed transport container (leak proof secondary container). Dry ice must be placed within an outer shipping container or storage container that allows venting or release of CO₂ gas to avoid pressurization. Sealing dry ice within a leak proof container can result in bursting or exploding a container, which can release its contents and/or create a serious physical hazard.
2. When shipping dry ice, use a vented container of sufficient strength to hold the amount of dry ice needed to preserve the shipment. The outside of the packages must contain the dry ice label. The net quantity of dry ice within the shipment must be included on the UN 1845 dry ice label in kilograms (kg). The maximum allowable net quantity of dry ice allowed per package is 200 kg. (This is also the maximum quantity of dry ice allowed in the cargo hold of an aircraft.) The shipment of dry ice does not require a Shipper's Declaration. However, if shipping dry ice with a hazardous material that requires a Shipper's Declaration, include the dry ice on the form as well.

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3. If transporting dry ice by air, include the following information on the air waybill under the "Nature and Quantity of Dangerous Goods" section --- UN1845, the words "Carbon dioxide, solid" or "Dry ice", the number of packages containing dry ice, and the net quantity of the dry ice in kilograms.