Coronavirus Disease 2019 (COVID-19) / 2019 Novel Coronavirus (2019-nCoV)

Diagnostic Specimen Collection, Packaging and Shipping Guidance for Laboratories and County Health Departments (CHDs)

Version 1.6 | August 18, 2020

Summary

- **Authorization:** Private providers should contact their local county health department (http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/disease-reporting-and-surveillance/surveillance-and-investigation-guidance/_documents/chd-epi-contacts.pdf) for authorization prior to collecting and shipping diagnostic specimens for Coronavirus Disease 2019 (COVID-19) / 2019 novel coronavirus (2019-nCoV) testing to the Florida Department of Health (FDOH), Bureau of Public Health Laboratories (BPHL). Testing requires prior approval before specimen submission.

- **Criteria for Testing:** Patients meeting certain clinical and risk criteria for Coronavirus Disease 2019 (COVID-19) are considered high priority and BPHL will perform testing: https://floridahealthcovid19.gov/county-health-departments/. BPHL, health care facilities, and commercial laboratories will test specimens from high priority individuals, including:
  - Hospitalized patients **with** symptoms
  - Health care workers, workers in congregate living settings, and first responders **with** symptoms
  - Residents in long-term care facilities or other congregate living settings, including correctional and detention facilities and shelters, **with** symptoms.
  - Vulnerable populations who have been determined to be at greater risk for COVID-19
  - Students and teachers **with** symptoms.

  BPHL will also test priority specimens from CHD clinics or FDOH authorized community surveillance testing events.

- **Specimen Collection:** Appropriate specimens should be collected for diagnostic molecular testing. Additional specimens may also be collected upon consultation with epidemiology staff for surveillance or antibody testing. Specimens for molecular testing should be collected as soon as possible, regardless of the time of symptom onset. Preferred specimens include:
  - Upper respiratory tract specimens (oropharyngeal swab collected with a Hologic Aptima Multitest collection kit, nasopharyngeal swab in 1-3 ml of viral transport media (VTM), nasal mid-turbinate swab in 1-3 ml of VTM, anterior nares/nasal swab in 1-3 ml of VTM, or nasopharyngeal wash/aspirate or nasal wash/aspirate in a sterile leak-proof container). Media other than VTM may also be acceptable (see details in Specimen Collection section below).
  - Lower respiratory tract specimens (sputum, in a sterile leak-proof container), for those patients with productive coughs. Induction of sputum is not indicated.

- **Packaging and Shipping:**
  - **Commercial Carrier:** All suspect COVID-19 virus diagnostic specimens must be packaged according to International Air Transport Association (IATA) and U.S. Department of Transportation (USDOT) Packaging Instructions 650 for Biological

substance, Category B agents. This requires specimens be packed in a basic triple packaging system with a primary watertight container with absorbent material, secondary watertight container and an outer shipping package.
    - **Courier:** As above, specimens should be packaged in a basic triple packaging system which consists of a primary watertight container with absorbent material, secondary watertight container and an outer shipping package.

- **Laboratory Requisition:** For FDOH testing events, electronic test orders are required using Mobile LabWare tablets. CHD clinics/collections must also use Mobile LabWare or HMS to create an electronic order. If electronic ordering capability is not possible, complete and include in the package FDOH Form DH1847 (http://www.floridahealth.gov/programs-and-services/public-health-laboratories/forms-publications/index.html, navigate to "Commonly Used BPHL Forms"), including the specimen collection date. **Enter the treating physician information, who will receive the BPHL test report, in the "Health Care Provider Information" section.** In the virology section of the form, include specimen type, write "COVID-19" as the test request next to "Other", include date of symptom onset, and recent travel history (country/territory with dates). Please note that electronic ordering enables BPHL to process the test and report out the result in a timelier manner.

- **Documents on this topic dated after the version date, supersede this one.**

- **Shipping to Jacksonville BPHL:**
  Bureau of Public Health Laboratories-Jacksonville
  1217 N. Pearl Street
  Jacksonville, FL 32202
  Attention: Virology/Serology, 2nd Floor Andrade
  For Additional Information: Call the COVID-19 assigned cell phone at 904-855-7665
  Email: JacksonvilleVirology@flhealth.gov

- **Shipping to Miami BPHL:**
  Bureau of Public Health Laboratories-Miami
  1325 NW 14th Ave.
  Miami, FL 33125
  Attention: Virology
  For Additional Information: Call the COVID-19 assigned cell phone at 305-978-2769
  Email: SGBPHL13MiamiVirologyEmail@flhealth.gov

- **Shipping to Tampa BPHL:**
  Bureau of Public Health Laboratories-Tampa
  3602 Spectrum Blvd.
  Tampa, FL 33612
  Attention: Virology
  For Additional Information: Call the COVID-19 assigned cell phone at 813-895-0724
  Email: TampaVirology@flhealth.gov

Authorization

Testing requires prior approval before specimen submission. Private providers should contact their local county health department (http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/disease-reporting-and-surveillance/surveillance-and-investigation-guidance/_documents/chd-epi-contacts.pdf) prior to collecting and shipping any specimens from suspect COVID-19 cases for testing to BPHL.

Criteria for Testing

Patients meeting certain clinical and risk criteria for Coronavirus Disease 2019 (COVID-19) are considered high priority and BPHL will perform testing: https://floridahealthcovid19.gov/county-health-departments/. BPHL, health care facilities, and commercial laboratories will test specimens from High Priority individuals:

- **High Priority:**
  - Hospitalized patients **with** symptoms
  - Health care workers, workers in congregate living settings, and first responders **with** symptoms
  - Residents in long-term care facilities or other congregate living settings, including correctional and detention facilities and shelters, **with** symptoms.
  - Vulnerable populations who have been determined to be at greater risk for COVID-19.
  - Students and teachers **with** symptoms.
- **Priority:** BPHL will test additional specimens from CHD clinics or FDOH authorized community surveillance testing events. Please coordinate specimen submission of such specimens through ESF8. Priority individuals include persons not indicated as High Priority with symptoms of potential COVID-19 infection, including: fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea, and/or sore throat AND persons without symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to: public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to state and local plans. Health care facilities and commercial laboratories will also test specimens from priority individuals.

Specimen Collection

Specimen collection should be performed following proper infection control and use recommended personal protective equipment (PPE), which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown. Specimen collection where a provider is not directly involved (e.g. self-collection and the provider is not within six feet), should be performed following standard precautions while handling specimens; gloves are recommended.

- Upper respiratory tract specimens:

- Oropharyngeal (OP) (e.g., throat) swab collected by a healthcare professional: Hologic Aptima Multitest collection kits are preferred for OP collection and submission.

Only use the provided swab contained in the Multitest kit and place the swab immediately into the provided transport tube containing the provided transport medium. Break the swab shaft at the score line against the side of the tube. Alternatively, place non-Multitest kit OP swabs in a tube containing 1-3 ml of viral transport media (VTM) or universal transport media (UTM). If both NP and OP swabs are collected, combine the swabs at collection into a single tube of VTM or UTM. Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts. Place swabs immediately into sterile tubes containing VTM or UTM.

  - Collection of OP swab: Swab the posterior pharynx, avoiding the tongue, teeth, and gums.
- Nasopharyngeal (NP) swab collected by a healthcare professional: Place NP swab in a tube containing 1-3 ml of VTM or UTM. Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts. Place swabs immediately into sterile tubes containing VTM or UTM.
  - Collection of NP swab: Insert a swab into the nostril parallel to the palate until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Leave the swab in place for a few seconds to absorb secretions.
- Nasal mid-turbinate (NMT) swab collected by a healthcare professional or by a supervised onsite self-collection: Use a flocked tapered swab to swab both nares. Place NMT swabs in a tube containing 1-3 ml of VTM or UTM. Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts. Place swabs immediately into sterile tubes containing VTM or UTM.
- Anterior nares swab (nasal swab, NS) collected by a healthcare professional or by onsite or home self-collection: Use a round foam, flocked, or spun polyester swab to swab both nares. Place NS in a tube containing 1-3 ml of VTM or UTM. Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts. Place swabs immediately into sterile tubes containing VTM or UTM.
- Nasopharyngeal wash/aspirate, or nasal wash/aspirate (NW) collected by a healthcare professional: collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

- Lower respiratory tract specimens collected by a healthcare professional: Sputum (only for those patients with a productive cough and induction is not indicated): Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.
  - Other acceptable lower respiratory tract specimens:

        - Bronchoalveolar lavage or lower respiratory tract aspirates (when under certain clinical circumstances, e.g. those receiving invasive mechanical ventilation): collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.
- Sources of swabs and transport media: BPHL will accept Hologic Aptima Multitest collection kit OP swabs and examples of acceptable sources of swabs and transport media listed by the US Food and Drug Administration (FDA) (https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2, navigate to the "Testing Supply FAQs" section).
- Alternative swabs and transport media: If Hologic Aptima Multitest collection kits, VTM, or UTM are not available, BPHL will accept liquid Amies transport media or sterile phosphate buffered saline (PBS). The FDA has recommended alternative swabs and transport media if you are having trouble obtaining swabs, VTM or UTM (https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2, navigate to the "Testing Supply FAQs" section). BPHL requests that if an alternative transport media is used, please mark what the alternative is on the collection tube and on the laboratory requisition form.
- BPHL will not accept specimens in snap cap tubes as these pose a biosafety hazard in the laboratory. Please use tight closure screw cab tubes. Please do not parafilm tubes as this creates additional processing time.
- Each specimen must be labeled with at least two patient-specific identifiers. Examples of acceptable identifiers are patient name, date of birth, hospital number, requisition number, accession number, or unique random number.
- If an alternative transport media to Hologic Aptima Multitest collection kits, VTM, or UTM was used, indicate the media type on the tube.
- Place each specimen tube in a separate zip closure bag. If using a tube type that is suspected to leak or has been known to leak (such as the Hardy Diagnostics VTM, Catalog Number R99), stretch a piece of parafilm around the cap in the same direction as the cap closes to create a leakproof seal.
- Refrigerate specimens at 2-8°C prior to shipping and ship overnight to BPHL on frozen gel ice packs. Alternatively, specimens can be driven by car by FDOH personnel if the specimens are high priority. Specimens can be at 2-8°C for up to 72 hours after collection. If a delay in shipping is expected, store specimens at -70°C or below and ship with dry ice.

Packaging requirements: Transport by Commercial Carrier

Package specimens in combination packaging according to International Air Transport Association (IATA) and U.S. Department of Transportation (USDOT) regulations.
NOTE: Per these regulations anyone who handles, offers for transport, or transports specimens must be trained to do so. This document is not a replacement for packaging and shipping training.

- General Packaging Requirements
    - Package the specimens as a Category B agent using IATA/USDOT Packaging Instructions 650 for Category B Agents which requires specimens be packed in a basic triple packaging system with a primary leakproof container with absorbent material, secondary leakproof container and a rigid outer shipping package.
    - Enclose an itemized list of contents between the secondary packaging and the outer packaging.

    - Package on frozen gel ice packs.
    - If specimens were frozen at -70°C, package with dry ice. The package containing the dry ice must be designed to permit the release of carbon dioxide gas and to prevent the buildup of pressure. The package must be properly marked with the dry ice label, dry ice as the contents, UN1845, and the net weight in kg.
- Inner Packaging Requirements
    - Primary receptacle(s) must be leakproof.
    - Secondary receptacle(s) must be leakproof.
        - Absorbent material must be placed between the primary receptacle(s) and secondary receptacle and be of sufficient quantity to absorb the entire contents of the primary receptacle(s).
    - The primary or secondary receptacle must also be pressure compliant (95kPa).
        - An example of a preferred pressure compliant secondary receptacle is Therapak 95kPa compliant transport bags, Fisher Scientific catalog #22-130-021.
    - BPHL recommends an inner packaging with absorbent material such as one tube or container (the primary leakproof receptacle) and a paper towel placed in a zip closure bag such as a biohazard transport bag with an outer pocket containing the requisition form.
        - Place only one specimen per bag to avoid cross-contamination between specimens if one were to leak.
        - ONLY if using a tube type that is suspected to leak or has been known to leak (such as the Hardy Diagnostics VTM, Catalog Number R99), stretch a piece of parafilm around the cap in the same direction as the cap closes to create a leakproof seal.
        - Multiple zip closure bags are then placed in one pressure compliant bag (the secondary leakproof receptacle).
        - Fully seal all bags, while removing excess air.
    - An itemized list of the contents enclosed between the secondary receptacle and the outer packaging.
    - Include sufficient cushioning between the combined primary-secondary receptacles and the outer package to prevent shifting in transport.
- Outer Packaging Requirements
    - Package must be rigid.
    - Package must be properly labeled with the UN 3373 marking, the shipping name, “Biological Substance, Category B”, and orientation labels.
    - Package must pass required testing.

Packaging Requirements: Transport by Local Courier

Package specimens in combination packaging according to Title 49 of the Code of Federal Regulations or CFR-49 (www.ecfr.gov, browse for Title 49 – Transportation and refer to Part 173 and Subpart 173.6 – Materials of trade exceptions).
NOTE: Per these regulations anyone who handles, offers for transport, or transports specimens must be trained to do so. This document is not a replacement for packaging and shipping training.

- General Packaging Requirements

  - Packaging must coincide with CFR-49 and specimens must be packed in a basic triple packaging system with a primary leakproof container with absorbent material, secondary leakproof container and an outer shipping package.
  - Enclose an itemized list of contents between the secondary packaging and the outer packaging.
  - Package on frozen gel ice packs.
  - If specimens were frozen at -70°C, package with dry ice. The package containing the dry ice must be designed to permit the release of carbon dioxide gas and to prevent the buildup of pressure. The package must be properly marked with the dry ice label, dry ice as the contents, UN1845, and the net weight in kg. The courier needs to ensure ventilation safety procedures or followed during transport.
- Inner Packaging Requirements
  - Primary receptacle(s) must be leakproof.
  - Secondary receptacle(s) must be leakproof.
    - Absorbent material must be placed between the primary receptacle(s) and secondary receptacle and be of sufficient quantity to absorb the entire contents of the primary receptacle(s).
  - BPHL recommends an inner packaging with absorbent material such as one tube or container (the primary leakproof receptacle) and a paper towel placed in a zip closure bag such as a biohazard transport bag with an outer pocket containing the requisition form.
    - Place only one specimen per bag to avoid cross-contamination between specimens if one were to leak.
    - ONLY if using a tube type that is suspected to leak or has been known to leak (such as the Hardy Diagnostics VTM, Catalog Number R99), stretch a piece of parafilm around the cap in the same direction as the cap closes to create a leakproof seal.
    - Multiple zip closure bags are then placed in one large zip closure bag (the secondary leakproof receptacle).
    - Fully seal all bags, while removing excess air.
  - An itemized list of the contents enclosed between the secondary receptacle and the outer packaging.
  - Include sufficient cushioning between the combined primary-secondary receptacles and the outer package to prevent shifting in transport.
- Outer Packaging Requirements
  - Package must be rigid.

Laboratory Requisition

For FDOH testing events, electronic test orders are required using Mobile LabWare tablets. CHD clinics/collections must also use Mobile LabWare or HMS to create an electronic order. If electronic ordering capability is not possible, complete and include in the package FDOH Form DH1847 (http://www.floridahealth.gov/programs-and-services/public-health-laboratories/forms-publications/index.html, navigate to “Commonly Used BPHL Forms”):

- In the “Patient Information” section, record the specimen collection date and patient information (last name, first name, date of birth, county, sex, street address, city, state, and ZIP code).

    - It is important that the patient-specific identifiers on this form match the two identifiers on each specimen.
- **Record the name and phone number of the treating physician who will receive the BPHL test report in the "Health Care Provider Information" section.**
    - If a patient is positive for COVID-19, the local county health department epidemiologist will also directly notify the treating physician using the contact information recorded on this form.
- In the "Virology" section of the form:
    - Indicate the specimen type. If an alternative transport media to VTM or UTM was used, also indicate the type of media.
    - Write "COVID-19" as the test request next to "Other."
    - Record date of symptom onset.
    - Record recent travel history (country/territory with dates), or indicate the patient had no recent travel.

Ship to Locations

Ship specimens to the appropriate BPHL (see table below). Addresses for each location can be found on page 2. Deliver or ship samples immediately, at least by next day mid-morning delivery. If driving the samples, please use the closest BPHL. If shipping overnight, please ship to your designated BPHL per the below table. If using a courier established by BPHL, the courier will deliver to the appropriate BPHL location on their route.

Counties	Ship to
Alachua, Baker, Bradford, Brevard, Clay, Columbia, Dixie, Duval, Flagler, Franklin, Gadsden, Gilchrist, Hamilton, Jefferson, Lafayette, Leon, Liberty, Madison, Marion, Nassau, Orange, Putnam, Seminole, St. Johns, Suwannee, Taylor, Union, Volusia, Wakulla	Jacksonville BPHL
Broward, Collier, Dade, Glades, Hendry, Indian River, Lee, Martin, Monroe, Okeechobee, Palm Beach, St. Lucie	Miami BPHL
Bay, Calhoun, Charlotte, Citrus, Desoto, Escambia, Gulf, Hardee, Hernando, Highlands, Hillsborough, Holmes, Jackson, Lake, Levy, Manatee, Okaloosa, Osceola, Pasco, Pinellas, Polk, Santa Rosa, Sarasota, Sumter, Walton, Washington	Tampa BPHL
Specimens from community surveillance testing events	Coordinate through ESF8 to ensure rapid turnaround time

Laboratory Notification and/or Questions:

On shipment of specimens for a suspect COVID-19 patient to BPHL or if you have questions related to laboratory testing, please notify the following respective BPHL laboratory locations. For commercially shipped specimens, provide a shipping tracking number.

- Jacksonville
  - Email to JacksonvilleVirology@flhealth.gov or call the COVID-19 assigned cell phone at 904-855-7665
- Miami
  - Email to SGBPHL13MiamiVirologyEmail@flhealth.gov or call the COVID-19 assigned cell phone at 305-978-2769
- Tampa
  - Email to TampaVirology@flhealth.gov or call the COVID-19 assigned cell phone at 813-895-0724
- For emergency notification outside the hours of 8:00 AM to 5:00 PM, Monday through Friday or on holidays contact 866-FLA-LABS (866-352-5227).
- For any non-laboratory related or other questions, a COVID-19 Call Center has been set up to answer questions by calling 866-779-6121 or email COVID-19@flhealth.gov. The Call Center is available 24/7.

Test Reporting:

- If a patient is positive for COVID-19, the local county health department epidemiologist will directly notify the treating physician using the contact information recorded on the laboratory requisition form.
- By default, BPHL test reports are sent to the treating physician recorded on the laboratory requisition form by US Mail. A facility can change their delivery mechanism from US Mail to automatic faxing by following the instructions at http://www.floridahealth.gov/programs-and-services/public-health-laboratories/_documents/BPHL_SecureFaxForm_RequestForAutoFaxing.pdf. After successful completion, the facility will receive reports automatically to the fax number provided at the time of test report generation in the BPHL Laboratory Information Management System (LIMS).
- To obtain test reports electronically, please request access to the BPHL WebLIMS Portal by following the instructions at http://www.floridahealth.gov/programs-and-services/public-health-laboratories/weblims-ra.html. Once authenticated as an authorized user, you can view and print all test reports for your facility as soon as they are generated by logging in at https://weblims.floridapublichealthlab.com. Note that reports can be accessed via WebLIMS in addition to automatic faxing.
- If you require an urgent test report, please call 904-855-7665 or email covid-lab-reports@flhealth.gov Monday through Sunday, 7:00 AM to 7:00 PM.