

# Massachusetts State Public Health Laboratory - FAQ

## Coronavirus Disease 2019 (COVID-19)

March 13, 2020

Testing of persons for COVID-19 is available at the MA State Public Health Laboratory (MA SPHL) when a patient meets clinical and epidemiologic criteria. *The Massachusetts Department of Public Health released guidance outlining criteria for use in identifying patients who should be tested for COVID-19 by the MA SPHL. Patients not meeting the criteria in the guidance can be tested through commercial reference laboratories at the clinician's discretion. If you have already collected a specimen different than the preferred below, please send it until you can pivot your staff to our change.* For questions about testing, test results, specimen transport, or control measures, contact MDPH (24/7) at 617-983-6800.

### Where should I obtain collection supplies for specimen collection?

There are commercially available sources for flocked nasopharyngeal (NP) swabs, flocked oropharyngeal (OP) swabs, and transport media appropriate for collection of viral specimens (examples: VTM, UTM, M4). In certain circumstances, collection kits will be made available via MDPH consultation.

### What types of specimens should I collect and submit for COVID-19 testing?

SA single upper respiratory specimen per patient should be submitted: a **single NP swab-preferred by DPH as of 3/13/2020**, OP swab or NP/OP swab, and, if clinically warranted and feasible, lower respiratory specimens; label the primary container with two unique patient identifiers (e.g., name, DOB, and/or MR#) and label the specimen type:

- **Upper respiratory specimen:** for NP AND OP swabs, collect each swab and place both swabs in a **SINGLE** commercially available viral transport media (VTM) tube (*Note- single source NP or OP swabs are still acceptable*) – AND (if available)
- **Lower respiratory specimen:** sputum should be submitted in a sterile, dry screw cap sputum collection cup or other sterile, screw cap container.

Complete the general submission form (SS-PHL-1-18) <https://www.mass.gov/doc/specimen-submission-form/download> **including:** submitting facility, ordering clinician, and patient name, ID (or medical record number), patient address, test request “2019 nCoV PCR”, PUI# (if known), travel history (including dates and locations), signs and symptoms, onset date, and **patient status at time of collection (ER, inpatient, outpatient)**. Refrigerate all samples at 2-8°C prior to and during transport to the MA SPHL within 24 hrs. If the specimen is to be submitted greater than 24 hrs post collection, freeze the specimens at -20°C or below and then ship on dry ice. **Ship as a Category B (UN3373- Biological Substances)**. Specimen collection guidance is available at <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

### What laboratory biosafety guidelines are recommended for COVID-19?

Clinical and laboratory staff should continue to follow the interim laboratory biosafety guidelines recommended by CDC. Facilities should ensure timely communication between clinical and laboratory staff. Biosafety guidelines are found here: <https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html>.

### What if I am a CLIA certified High Complexity Laboratory that has notified FDA of my validated SARS-COV-2 assay status and I need to submit my first 5 positive and first 5 negative samples to a laboratory using the EUA approved assay?

If you have met the FDA guidance released on February 29<sup>th</sup> (<https://www.fda.gov/media/135659/download>) outlining the requirements for an expedited EAU process for your laboratory developed test (LDT), email the MA SPHL Laboratory Director (sandra.smole@state.ma.us) with your CLIA ID# and a request for confirmatory testing of your first 5 positive and first 5 negative samples.

### Where can I find the most current list of EUA authorized tests approved by FDA?

CDC, FDA, and BARDA are working with multiple IVD manufacturers and laboratories to enable additional EUA authorizations for diagnostic testing of COVID-19. Refer to this link for the current list: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019>

### Additional Resources for COVID-19:

Centers for Disease Control and Prevention (CDC) Situation Summary : <https://www.cdc.gov/coronavirus/2019-ncov/summary.html>  
CDC Clinical Criteria for Patients Under Investigation (PUI): <https://www.cdc.gov/coronavirus/2019-ncov/php/guidance-evaluating-pui.html>  
CDC Information for Healthcare Providers: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html>  
CDC Information for Laboratories: <https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html>

**Note:** All information in this fact sheet is subject to update as new information warrants.