SARS-CoV-2 Virus Detection using RT-PCR

Laboratory Submission Information Sheet

**Reporting of suspect case to Maine CDC**
- Yes: SARS-CoV-2 is a Notifiable Condition. If you have not already done so, please report confirmed cases to the Maine CDC via the disease reporting line: 1-800-821-5821 (24hrs/day 7 days/week.)

**Required To Submit Laboratory Specimen**
- Not at this time. Positives may need to be submitted at some point in the future.

**Required Information**
- Information on requisition must include: suspected organism, patient name, DOB, date of collection, specimen source or type, submitter name and contact information.
- **Important:** all specimens must be labeled with at least the patient name and be accompanied by HETL COVID-19 submission form.

**Specimen Requirements**
- Due to changing CDC and FDA guidance please see page 2 for Specimen Requirements.
- The order of specimen preference is: Nasopharyngeal swabs, Nasal swabs, and then Oropharyngeal (throat) swabs.

**Collection Instructions**
- Collect specimens in leak proof containers.
- Specimens can be stored at 2-4°C for up to 72 hours after collection. Send specimens on ice packs.
- If a delay in shipping is expected, store specimens at -70°C or lower and send on dry ice.

**Turn Around Time**
- Unknown if sent to Federal CDC
- 24-48 hours, depending on number of specimens in queue, if testing performed at HETL.

**Unacceptable Conditions**
- Specimens not kept at 2-4°C (≤ 4 days) or frozen at -70°C or below.
- Incomplete specimen labeling or documentation.
- Inappropriate specimen type.
- Insufficient specimen volume.
- Dry Swabs
- Swabs with wooden shafts, calcium alginate or cotton tips

**Results**
- Results will be reported to the submitter as stated on requisition via mail or fax, Maine CDC infectious disease epidemiology, and Federal CDC. Results are for the presumptive identification of SARS-CoV-s RNA. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions.

**Laboratory Testing Fee**
- There is no cost for SARS-CoV-2 Virus Detection using Real-Time RT-PCR test when approved by the Maine CDC.

**Applicable CPT Codes**
- U0002

**Additional Information**
- Bacteriology at 207-287-1704, Virology, Respiratory, Arbovirus, and Serology at 207-287-1722
- Molecular Biology, Sequencing, and Foodborne at 207-287-5769
- Mycobacterium and Rabies at 207-287-1706
Updated Guidance for COVID-19 Testing

Summary:


Summary of Changes for COVID-19 Testing and Specimen Collection:

Specimen Type and Priority (April 15, 2020)

All testing for SARS-CoV-2 should be conducted in consultation with a healthcare provider. Specimens should be collected as soon as possible once a decision has been made to pursue testing, regardless of the time of symptom onset. The guidance below addresses options for collection of specimens.

For initial diagnostic testing for SARS-CoV-2, CDC recommends collecting and testing an upper respiratory specimen. The following are acceptable specimens:

- A nasopharyngeal (NP) specimen collected by a healthcare professional; or
- An oropharyngeal (OP) specimen collected by a healthcare professional; or
- A nasal mid-turbinate swab collected by a healthcare professional or by a supervised onsite self-collection (using a flocked tapered swab); or
- An anterior nares (nasal swab) specimen collected by a healthcare professional or by onsite or home self-collection (using a flocked or spun polyester swab); or
- Nasopharyngeal wash/aspirate or nasal wash/aspirate (NW) specimen collected by a healthcare professional.

Swabs should be placed immediately into a sterile transport tube containing 2-3mL of either viral transport medium (VTM), Amies transport medium, or sterile saline, unless using a test designed to analyze a specimen directly, (i.e., without placement in VTM), such as some point-of-care testsexternal icon. If VTM is not available, see the standard operating procedure for public health labs to create viral transport mediumpdf icon in accordance with CDC’s protocol.

The NW specimen and the non-bacteriostatic saline used to collect the specimen should be placed immediately into a sterile transport tube.

Testing lower respiratory tract specimens is also an option. For patients who develop a productive cough, sputum should be collected and tested for SARS-CoV-2. The induction of sputum is not recommended. When under certain clinical circumstances (e.g., those receiving invasive mechanical ventilation), a lower respiratory tract aspirate or bronchoalveolar lavage sample should be collected and tested as a lower respiratory tract specimen.

FDA has changed the required media in which specimens can be transported. (March 15, 2020)

Acceptable media include:

- Liquid Amies-based transport media.
  - Supplies:
    - E-Swab by Copan (Catalogue # 481C and 482C) with regular or flex minitip applicator
    - Opti-Swab by Puritan (Catalogue # LA-117), swab included in kit (Catalog#3317-H).
  - Storage: Up to 72 hours at 4°C, or frozen for longer storage.

- Dry swab in saline
Supplies:
- Copan: 501CS01, 503CS01, 516CS01, 518CS01 and 534CS01

Storage: Up to 72 hours at 4°C, or frozen for longer storage.

The Maine Health and Environmental Testing Laboratory (HETL) will no longer be running a respiratory viral panel with all submitted COVID-19 specimens.
  - HETL will perform test for respiratory viruses, including as a panel, when indicated on the HETL specimen submission form, which can be found at mainepublichealth.gov/lab.

For more information:
- Maine CDC’s COVID-19 website www.maine.gov/dhhs/coronavirus or by calling Maine CDC at 1-800-821-5821.

Maine Center for Disease Control and Prevention
Updated Guidance for COVID-19 Testing