



**SARS-CoV-2 Virus Detection using Real Time RT-PCR**  
***Laboratory Submission Information Sheet***

Reporting of suspect case to Maine CDC	<ul style="list-style-type: none"> <li>• 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.)</li> </ul>
Required To Submit Laboratory Specimen	<ul style="list-style-type: none"> <li>• Clinical laboratories are required to submit positive isolates or clinical specimens, as requested by Maine CDC to the <i>Maine Health and Environmental Testing Laboratory</i> for typing.</li> </ul>
Required Information	<ul style="list-style-type: none"> <li>• Information on requisition must include: suspected organism, patient name, DOB, date of collection, specimen source or type, submitter name and contact information.</li> <li>• <b>Important: all specimens must be labeled with at least the patient name and be accompanied by HETL COVID-19 submission form.</b></li> </ul>
Specimen Requirements	<ul style="list-style-type: none"> <li>• Nasopharyngeal (NP) specimen collected by a healthcare provider; or</li> <li>• Oropharyngeal (OP) specimen collected by a healthcare provider; or</li> <li>• Nasal mid-turbinate swab collected by a healthcare provider or by a supervised onsite self-collection (using a flocked tapered swab); or</li> <li>• Anterior nares (nasal swab) specimen collected by a healthcare provider or by onsite self-collection (using a flocked or spun polyester swab)</li> <li>• The Aptima Multitest Swab Specimen Collection Kit may be used for the collection of OP and nasal swab samples.</li> </ul>
Collection Instructions	<ul style="list-style-type: none"> <li>• Collect specimens in leak proof containers.</li> <li>• Specimens can be stored at 2-4°C for up to 72 hours after collection. Send specimens on ice packs.</li> <li>• If a delay in shipping is expected, store specimens at -70°C or lower and send on dry ice.</li> </ul>
Turn Around Time	<ul style="list-style-type: none"> <li>• Unknown if sent to Federal CDC</li> <li>• 24-72 hours, depending on number of specimens in queue, if testing performed at HETL.</li> </ul>
Unacceptable Conditions	<ul style="list-style-type: none"> <li>• Specimens not kept at 2-4°C (≤4 days) or frozen at -70°C or below.</li> <li>• Incomplete specimen labeling or documentation.</li> <li>• Inappropriate specimen type.</li> <li>• Insufficient specimen volume.</li> <li>• Dry Swabs, Swabs with wooden shafts, calcium alginate or cotton tips</li> </ul>
Results	<ul style="list-style-type: none"> <li>• Results will be reported to the submitter as stated on requisition via fax or through the lab portal, Maine CDC infectious disease epidemiology, and Federal CDC. Results are for the identification of SARS-CoV-2 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.</li> </ul>
Laboratory Testing Fee	<ul style="list-style-type: none"> <li>• There is no cost at this time for SARS-CoV-2 Virus Detection using Real-Time RT-PCR test when approved by the Maine CDC.</li> </ul>
Applicable CPT Codes	<ul style="list-style-type: none"> <li>• U0002</li> </ul>
Additional Information	<ul style="list-style-type: none"> <li>• Bacteriology at 207-287-1704, Virology, Respiratory, Arbovirus, and Serology at 207-287-1722</li> <li>• Molecular Biology, Sequencing, and Foodborne at 207-287-5769</li> <li>• Mycobacterium and Rabies at 207-287-1706</li> </ul>



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## Updated Guidance for COVID-19 Testing

### Summary:

On May 22, 2020, the U.S. Center for Disease Control and Prevention (U.S. CDC) and the U.S. Food and Drug Administration (FDA) issued new guidance for collection, handling, and testing clinical specimens from persons for Coronavirus Disease 2019 (COVID-19). These new guidance can be found at <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html> and <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>.

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

#### Specimen Type and Priority (May 22, 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 provider; or
- An oropharyngeal (OP) specimen collected by a healthcare provider; or
- A nasal mid-turbinate swab collected by a healthcare provider or by a supervised onsite self-collection (using a flocked tapered swab); or
- An anterior nares (nasal swab) specimen collected by a healthcare provider or by onsite self-collection (using a flocked or spun polyester swab)

Collect NP swab, nasal swab, and OP swab specimens according to standard technique using a polyester-, rayon-, or nylon-tipped swab. Immediately place the swab specimen into 1mL of VTM, UTM, saline, Liquid Amies or STM. The Aptima Multitest Swab Specimen Collection Kit may be used for the collection of OP and nasal swab samples.

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

Acceptable media include:

##### 1. Swab Specimen collection

- a. Collect NP swab, nasal swab, and OP swab specimens according to standard technique using a polyester-, rayon-, or nylon-tipped swab. Immediately place the swab specimen into 3mL of VTM or UTM. Swab specimens may alternatively be added to saline, Liquid Amies or STM. The Aptima Multitest Swab Specimen Collection Kit may be used for the collection of OP and nasal swab samples.
- b. The following types of VTM/UTM were verified for use.
  - i. Remel MicroTest M4, M4RT, M5 or M6 formulations
  - ii. Copan Universal Transport Medium
  - iii. BD Universal Viral Transport Medium

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).



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- Storage: Up to 72 hours at 4°C, or frozen for longer storage.
- Dry swab in saline
  - Supplies:
    - Puritan: 25-3317-H, 25-3316-U, 25-3316-H, 25-3317-U, 25-3318-U, 25-3318-H, 25-3319-H, 25-3320-U, 25-3320-U EMB 100MM, 25-3320-U EMB 80MM, 25-3320-H and 25-3320-H EMB 80MM
    - Copan: 501CS01, 503CS01, 516CS01, 518CS01 and 534CS01
  - Storage: Up to 72 hours at 4°C, or frozen for longer storage.
- A respiratory viral panel cannot be run using the Aptima MultiTest Collection Kit. If other respiratory virus testing is wanted, please contact the Maine Health and Environmental Testing Laboratory (HETL) prior to collection of sample.
  - HETL can perform test for respiratory viruses, including as a panel, when indicated on a separate HETL specimen submission form, which can be found at [mainepublichealth.gov/lab](http://mainepublichealth.gov/lab).

**For more information:**

- Maine CDC's COVID-19 website [www.maine.gov/dhhs/coronavirus](http://www.maine.gov/dhhs/coronavirus) or by calling Maine CDC at **1-800-821-5821**.
  - U.S. CDC's COVID-19 website <https://www.cdc.gov/coronavirus/2019-nCoV/index.html>
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