AMERICAN ESOTERIC LABORATORIES
A Sonic Healthcare Company

AEL ALERT- NEW TESTING FOR SARS-CoV-2 (COVID-19) by RT PCR (revision 4)

American Esoteric Laboratories (AEL) is now offering testing for severe acute respiratory syndrome Coronavirus 2(SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19). As your community based laboratory provider, we want to assure you we are prepared to provide the appropriate testing to take care of your patients.

Due to strong market demand and limited supply nationwide, priorities will continue be given to **high risk** patients in accordance to CDC guidelines, epidemic regions, and cluster outbreaks. **Please note that the attached CDC form must be completed with every high risk patient submitted for testing.**

Test order options will be determined to be **high risk or routine**.

- The ordering provider will determine the patient risk level based on CDC Guidelines and clinical judgement.
    - ✓ Criteria to Guide Evaluation of PUI (Persons Under Investigation) for COVID-19: The CDC currently states Clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Decisions on which patients receive testing should be based on the local epidemiology of COVID-19, as well as the clinical course of illness.
    - ✓ Clinicians are strongly encouraged to test for other causes of respiratory illness, including infections such as influenza.
    - ✓ Epidemiologic factors that may help guide decisions on whether to test include: any persons, including healthcare workers, who have had close contact with a laboratory-confirmed COVID-19 patient within 14 days of symptom onset, or a history of travel from affected geographic areas within 14 days of symptom onset.
- **CPT: Effective 3/16/2020 please use 87635.**
- **Positive results will be called to the provider and reported to the state Health Department where the patient resides.**
- Test results from SARS-CoV-2 by RT-PCR test must be accompanied by the following information pertaining to the emergency use, which is required to be made available to healthcare providers and patients.
    - Fact Sheet for Healthcare Providers: https://www.fda.gov/media/134920/download
    - Fact Sheet for Patients: https://www.fda.gov/media/134921/download

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Test Information:

SARS-CoV-2 (COVID-19) by RT-PCR, High Risk
Test code: U696
Also known as COVID-19-HIGH RISK, SARS-COV-2-HIGH RISK, 2019 NOVEL COV-HIGH RISK

- Testing will be performed seven days a week. Expected TAT will be published at 1-3 days but TAT may vary due to increased patient testing demands.
- **Reference Range: Negative / Not Detected**
- Methodology- Real-Time Polymerase Chain Reaction (RT-PCR)
- CPT 87635.

SARS-CoV-2 (COVID-19) by RT-PCR
Test code: U697
Also known as COVID-19, sars-Cov-2, 2019 NOVEL COV

Ordering Recommendations:

U696-For presumptive qualitative detection of nucleic acid from the 2019-Novel Coronavirus (SARS-CoV-2) in upper respiratory specimens collected from the individuals considered at **high risk for infection or with high risk epidemiologic factors.**

U697-For presumptive qualitative detection of nucleic acid from the 2019-Novel Coronavirus (SARS-CoV-2) in upper respiratory specimens.

Tests Contain (LOINC): SARS-CoV-2 Interpretation (94306-8), Naso and Oro SARS-CoV-2 (94316-7), Nasopharyngeal SARS-CoV-2 (94316-7), Oropharyngeal SARS-CoV-2 (94316-7), Other Source SARS-CoV-2 (94316-7), Other Source (31208-2)

Specimen Requirements and Handling for Both Codes:

Sample Type: Upper Respiratory Tract: Nasopharyngeal Swab; Please note that only **one swab** is now necessary for testing.

Handling Instructions:

Nasopharyngeal Swab:
Insert a swab into the nostril parallel to the palate. Leave the swab in place for a few seconds to absorb secretions. Place swab immediately into sterile tube containing 2-3 mL of viral transport media*.

NOTE: Use only synthetic fiber swabs with plastic shafts. Flocked swabs are acceptable. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. **Due to limited testing reagents, it is preferred that one swab is submitted in a single VTM tube.** Refrigerate specimen at 2-8°C and ship overnight on ice pack. If specimen will not reach the laboratory within 72 hours of collection, freeze and ship on dry ice. Please order viral transport media and collection devices from AEL if possible*.

* There are several brands of viral transport media that are available and marketed under different names. They may not specifically be called "Viral transport medium". Viral transport media are designed to maintain viability of viruses, chlamydiae, mycoplasmas and ureaplasmas. These are osmotically balanced and buffered and contain Hank's balanced salt solution with a pH indicator, sucrose as a preservative, protein and gelatin as stabilizers and antimicrobial agents to minimize commensal bacterial and fungus contamination. SRL can perform SARS-CoV-2 testing on any transport media that has these characteristics. **M4RT media must be kept at refrigerated or frozen temperature after collection** because of limited room temperature stability of SARS-CoV-2 samples. Room temperature transport of M4RT media is only appropriate prior to sample inoculation and this is a common cause of confusion with M4RT. Please contact AEL Customer Services for questions around specific products.

Transport: Refrigerated within 72 hours. If specimen will not reach the laboratory within 72 hours of collection, freeze and ship on dry ice.

Specimen Stability: Refrigerated: 72 Hours; Frozen: Not Established

Unsuitable Specimen: Ambient specimens. Swabs not in viral transport media. Calcium alginate swabs. Swabs with wooden shafts.

Sonic Laboratories will continue to work together address this healthcare emergency. Sonic is currently establishing four different testing platforms and methodologies, including the U.S. gold standard CDC/IDT assay, to mitigate any testing supply chain disruptions. Testing capacity will rapidly increase in the next 7-14 days across multiple Sonic laboratories across the country. AEL will communicate testing updates as they occur.

COMPLIANCE STATEMENT**:** This test has not been Food and Drug Administration (FDA) cleared or approved and has been authorized by FDA under an Emergency Use Authorization (EUA). The test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of SARS-CoV-2 under Section 564(b)(1) of the Act, 21 U.S.C. section 360bbb-3(b)(1), unless the authorization is terminated or revoked.
AEL and SRL are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. section 263a, to perform high complexity tests.