AMERICAN ESOTERIC LABORATORIES
A Sonic Healthcare Company

Revised: March 25, 2020

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

American Esoteric Laboratories (AEL) is continuing to perform testing for severe acute respiratory syndrome Coronavirus 2(SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19). We are taking the necessary steps to take care of your patients but as you can imagine the request for testing has grown exponentially. Effective immediately, we will **not require the CDC form** to accompany the HIGH risk orders BUT we ask that you perform a health risk screening prior to ordering the test and continue to test the high risk patients in accordance with CDC guidelines. **Do not test asymptomatic patients that do not follow CDC guidelines** in order to conserve collection devices and testing resources for high risk individuals.

Due to strong market demand and limited supply nationwide, AEL will continue to ration and appropriate supplies as medically necessary.

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: 87635.**
- **You will be notified on positive results. Positive results will also be reported to the state Health Department where the patient resides therefore it is important that we have the patient's current address.**
- **Please do not order these tests STAT. AEL Test TAT is 24-72 hours. Any emergency testing situations will need to be approved by Dr. Matt Dress, AEL Medical Director. Please call 901-405-8200 or 1-900-423-0504 to speak to Dr. Dress regarding a patient.**

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.

Both Tests Contain (LOINC): 94500-6

Specimen Requirements and Handling for Both Codes:

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

- **PLEASE NOTE THAT eSwabs (all colors) ARE NOW ACCEPTABLE SPECIMENS.**
- **PLEASE NOTE THAT IN LIEU OF VIRAL TRANSPORT MEDIA, SPECIMENS MAY BE SUBMITTED IN A SCREW TOP STERILE TUBE WITH 1 ML STERILE SALINE containing a synthetic fiber swab, non-wooden shaft. Stability in saline is 72 hours, refrigerated; Freeze if transport will take longer than 3 days. Please make sure screw top lids are tight as leakage will result in recollect.**

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 or all types of eSwab. 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 or screw top tube in 1 ml sterile saline (stability 72 hours).** 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.

* 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 continuing to establish acceptable collection alternatives as a response to supply shortage 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.