NEW ASSAY:

Test 907078	**SARS-CoV-2 RNA, QL REAL-TIME RT-PCR (COVID-19)**
Available:	3/11/20

Specimen:	**Preferred -** Upper respiratory specimen: refrigerated nasopharyngeal or oropharyngeal swab in ViroPak Viral Transport Media:
	
	• Nasopharyngeal (Small Swab) – Supply #20012
	• Throat (Large Swab) – Supply #20011
	  ○ Collection supplies may be ordered through your normal process for testing being sent to Sonora Quest Laboratories.
	  ○ Please refer to the attached specimen collection instructions from the CDC and visit www.SonoraQuest.com/coronavirus for additional information.
	
	Alternative - Lower respiratory specimen: 0.85 mL refrigerated bronchial lavage/wash, nasopharyngeal aspirate/wash, sputum, or tracheal aspirate in a plastic, sterile, leak-proof container.
	
	Order SARS-COV-2 test separately from other tests on a separate requisition. Please ensure that the source is written on the specimen container submitted for testing. If leaving specimens in a lock box, placing a frozen ice pack inside will ensure refrigerated specimens stay cool and viable for testing.
	
	NOTE: Samples must be collected by the healthcare provider. Sample collection is not available at Sonora Quest Laboratories Patient Service Centers and will not be performed by any Sonora Quest Laboratories phlebotomists, including in-office phlebotomists and our mobile diagnostic service staff. In-office phlebotomists may accept office collected samples that have been properly capped, labeled and placed in a zip locked specimen bag with the necessary paperwork included.

Stability:	Room temperature: Unacceptable Refrigerated: 72 hours
Method:	Real-time reverse transcriptase polymerase chain reaction (RT RT-PCR)
Reference Ranges:	Not Detected
Setup:	Days, Evenings, & Nights: Sunday – Saturday (Testing will be performed at Quest Diagnostics Infectious Disease in San Juan Capistrano, CA. Samples will be shipped from Sonora Quest to Quest Diagnostics Monday through Saturday morning only).
Reports:	3-5 Days (will vary based on testing demand); Presumptive positive (detected) and inconclusive results will be communicated to clients as critical values.
CPT*:	Pending AMA CPT assignment
Price:	Client: $199.00 Patient: $199.00

Interface Mapping:	**Result Code** 10907078	**Result Name** SARS CoV 2 RNA, RT PCR	
	Ask at order entry question:		
	Result Code 98907078 99907078	**Result Name** Patient Symptomatic? Source:	**Response Options** Y/N Free text
Comments:	This test is intended to be performed only using respiratory specimens collected from individuals who meet Centers for Disease Control and Prevention (CDC) clinical and/or epidemiological criteria for COVID-19 testing. CDC COVID-19 criteria for testing on human specimens are available at CDC's webpage Information for Healthcare Professionals: Coronavirus Disease 2019 (COVID-19) (https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html). A Detected result is considered a presumptive positive test result for COVID-19. This indicates that RNA from SARS-CoV-2 (formerly 2019-nCoV) was detected, and the patient is presumptively infected with the virus and presumed to be contagious. Specimens with Presumptive Positive or Inconclusive results will be referred to the appropriate Public Health laboratory for additional testing. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. A Not Detected (negative) test result for this test means that SARS- CoV-2 RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out the possibility of COVID-19 and should not be used as the sole basis for treatment or patient management decisions. If COVID-19 is still suspected, based on exposure history together with other clinical findings, re-testing should be considered in consultation with public health authorities. This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Infectious Disease. It has not been cleared or approved by FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes. This test is pending the Food and Drug Administration's Emergency Use Authorization.		

Influenza Specimen Collection

	Nasopharyngeal Swab	Nasopharyngeal/Nasal Aspirate	Nasopharyngeal/Nasal Wash	Deep Nasal Swab	Combined Nasal & Throat Swab
Materials	• Sterile Dacron/nylon swab • Viral transport media tube *(should contain 1-3 ML of sterile viral transport medium)*	• Sterile suction catheter/suction apparatus • Viral transport media tube *(should contain 1-3 ML of sterile viral transport medium)*	• Sterile suction catheter/suction apparatus • Sterile normal saline	• Sterile polyester swab *(aluminum or plastic shaft preferred)* • Viral transport media tube *(should contain 1-3 ML of sterile viral transport medium)*	• 2 dry sterile polyester swabs *(aluminum or plastic shafts preferred)* • Viral transport media tube *(should contain 1-3 ML of sterile viral transport medium)*
Procedure	**1** Tilt patient's head back 70 degrees. **2** Insert swab into nostril. (Swab should reach depth equal to distance from nostrils to outer opening of the ear.) Leave swab in place for several seconds to absorb secretions. **3** Slowly remove swab while rotating it. (Swab both nostrils with same swab.) **4** Place tip of swab into sterile viral transport media tube and snap/cut off the applicator stick.	**1** Attach catheter to suction apparatus. **2** Tilt patient's head back 70 degrees. **3** Insert catheter into nostril. (Catheter should reach depth equal to distance from nostrils to outer opening of ear.) **4** Begin gentle suction. Remove catheter while rotating it gently. **5** Place specimen in sterile viral transport media tube. *Note: NP aspirate may not be possible to conduct in infants*	**1** Attach catheter to suction apparatus. **2** Tilt patient's head back 70 degrees. **3** Insert several drops of sterile normal saline into each nostril. **4** Insert catheter into nostril. (Catheter should reach depth equal to distance from nostrils to outer opening of ear.) **5** Begin gentle suction. Remove catheter while rotating it gently. **6** Place specimen in sterile viral transport media tube. *Note: NP aspirate may not be possible to conduct in infants*	**1** Tilt patient's head back 70 degrees. **2** While gently rotating the swab, insert swab less than one inch into nostril (until resistance is met at turbinates). **3** Rotate the swab several times against nasal wall and repeat in other nostril using the same swab. **4** Place tip of the swab into sterile sterile viral transport media tube and cut off the applicator stick.	**1** Tilt patient's head back 70 degrees. **2** While gently rotating the swab, insert swab less than one inch into nostril (until resistance is met at turbinates). **3** Rotate the swab several times against nasal wall and repeat in other nostril using the same swab. **4** Place tip of the swab into sterile viral transport media tube and cut off the applicator stick. **5** For throat swab, take a second dry polyester swab, insert into mouth, and swab the posterior pharynx and tonsillar areas. (Avoid the tongue.) **6** Place tip of swab into the same tube and cut off the applicator tip.

Packing:

- Label the specimen on viral transport media tube and ensure cap on tube is tightly sealed. (Do not use a pencil or pen for labeling, as they can rub off or smear. Instead, use a bar code or permanent marker).
- Fill out paperwork in accordance with state health department guidelines.
- Include a frozen cold pack with the specimen(s).
- Pack specimens in accordance with U.S. Department of Transportation regulations regarding shipment of biological substances, see **www.cdc.gov/flu/professionals/diagnosis/index.htm.**

Storing:

- Specimens should be placed into sterile viral transport media and immediately placed on refrigerant gel packs or at 4 degrees Celsius (refrigerator) for transport to the state public health laboratory.
- Keep specimens refrigerated (2-8 degrees Celsius, 26-46 degrees Fahrenheit) prior to shipping.

Shipping:

- Ship specimens for testing as soon as possible.
- If delivery will be delayed for more than 3-4 days, specimen should be frozen at -70 degrees Celsius (-94 degrees Fahrenheit).
- Ensure specimen will be received by the public health laboratory during normal business hours.

Considerations:

- A nasopharyngeal (NP) swab is the optimal upper respiratory tract specimen collection method for influenza testing. However, such specimens cannot be collected from infants and many older patients may not allow an NP specimen to be collected. Alternatively, a combined nasal and throat swab specimen or aspirate specimens can provide good influenza virus yield.
- Some influenza tests are approved only for use with certain kinds of respiratory tract specimens, so follow guidelines provided by test. Also, some tests (e.g., rapid influenza diagnostic tests) are only approved for certain kinds of respiratory tract specimens.
- For best results (i.e., highest influenza virus yield), collect respiratory tract specimens within four days of illness onset.
- Most sensitive and accurate tests for influenza virus detection are molecular or nucleic acid amplification tests (RT-PCR).
- Negative test results obtained from rapid influenza diagnostic tests (RIDTs) **that detect influenza viral antigens** do not exclude influenza virus infection in patients with signs and symptoms of influenza. A negative test result could be a false negative and should not preclude further diagnostic testing (such as RT-PCR) and starting empiric antiviral treatment.
- A surgical mask and gloves are recommended at a minimum for all procedures. For some patients and procedures, additional precautions may be indicated, see Standard Precautions at **www.cdc.gov/hicpac/2007IP/2007ip_part4.html#a4**.

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