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PATHOLOGY LABORATORIES
A Sonic Healthcare Clinical Laboratory

Client Communication

Covid RT-PCR Test Update / New Covid Requisition and Patient History Form

Pathology Laboratories, Inc. (PathLabs) is pleased to provide an update as to COVID-19 RT-PCR testing, including a new Test Requisition and Patient History Form, attached for reference.

Most notably, there has been a change in specimen types that are accepted based on ordering recommendations of our Sonic Healthcare USA, Inc. (Sonic) affiliate that performs this COVID RT-PCR testing, Sonic Reference Laboratory (SRL), as further detailed below.

Updated information is shown inside light blue text fields.

Test Name	Test Code	Ordering Recommendation
SARS-COV-2 (COVID-19) BY RT-PCR	39429	For qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens.

Below please find the changes to the Specimen Types:

- **The following upper respiratory specimens will NO LONGER BE ACCEPTED:**
  - Nasal wash/aspirate
  - Nasopharyngeal wash/aspirate
  - Oropharyngeal swab
  - Saliva collected using the Zymo Research DNA/RNA Shield Saliva Collection Kit R1210

- **The following lower respiratory specimens will NO LONGER BE ACCEPTED:**
  - Bronchoalveolar lavage
  - Sputum
  - Tracheal aspirate

- **The following new respiratory specimen WILL BE ACCEPTED:**
  - SalivaDirect™ Compatible Collection Kit (*Please order this new saliva kit through our Supply Department.*)

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Updated Specimen Requirements:

Sample Types:

UPPER RESPIRATORY TRACT ONLY

Nasopharyngeal Swab (NP), Nasal Mid-Turbinate Swab (NT), Nasal Swab, or Saliva.

Container Types:

NP/NT/Nasal Swab:

Use only synthetic fiber swabs with plastic or wire shafts.

Flocked and Blue/Green/White eSwabs are acceptable. Blue/Green (mini-tip) eSwabs are preferred for nasopharyngeal specimen collection.

Swabs should be placed immediately into a sterile transport tube/Viral Transport Media (M4RT, M4, VUTM) or equivalent eSwab collection kit.

Saliva:

Saliva must be collected in a SalivaDirect™ Compatible Collection Kit manufactured by GS Biomark, LLC & Resolution Biomedical, Inc. (CAT No. CV17001). (Order through our Supply Department.)

NOTE: For at least 30 minutes prior to saliva collection, it is important that the patient DOES NOT eat or drink, smoke, chew gum, use nasal spray or brush their teeth.

Handling Instructions: Clearly indicate specimen source on container, manifest, or requisition. Test orders must include additional information required for public health reporting purposes.

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

Specimen Stability: Refrigerated: 72 hours; Frozen: 1 Month

Rejection Criteria: Ambient specimens. Calcium Alginate swabs. Swabs with wooden shafts. Saliva submitted in preservative medium or container not compatible with SalivaDirect™.

Routine Instructions: Include COVID-19 Requisition and Patient History Form or CDC COVID-19 PUI Case Form.

Methodology: Real-Time Polymerase Chain Reaction (RT-PCR) using high throughput technology per CMS-2020-1-R.

Analytic Time: 2-4 DAYS; Tested Sunday through Saturday

Reference Range: Negative

CPT Code: 87635 (alt. code: U0003)

NOTE: CPT codes are provided for information only and are based on Pathology Laboratories' current understanding of Medicare rules and carrier instructions and in accordance with the current issue of Physicians Current Procedural Terminology published by the American Medical Association. Medicare coding may differ from coding used by other third party payers. Questions regarding coding should be confirmed with the payer being billed. Pathology Laboratories cannot accept responsibility for the reimbursement clients may or may not receive based on the procedure codes provided.

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Our on-line Test Directory will be updated for these changes beginning January 7, 2022.

Please review the information and make changes as applicable to your practice/facility. If you have any questions, please contact our Customer Service Department at 419-291-4414 / 833-960-0241 or your Account Executive. Thank you.

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 360bbb3(b)(1), unless the authorization is terminated or revoked sooner. Sonic Reference Laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. section 263a, to perform high complexity tests.

Additional Information:

Coronaviruses (CoVs) are a family of enveloped positive-strand RNA viruses that can infect humans and many different species of birds and mammals, including camels, cattle, cats, and bats. The viruses can cause mild to moderate respiratory illness like the common cold (caused by 229E, NL63, OC43, and HKU1) to more severe respiratory diseases such as Middle East Respiratory Syndrome (caused by MERS-CoV) and Severe Acute Respiratory Syndrome (caused by SARS-CoV) and even death. Zoonotic outbreaks have occurred when SARS-CoV was transmitted from civet cats to humans and MERS-CoV from dromedary camels to humans.

The most recently identified severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2; previously named 2019 novel coronavirus or 2019-nCoV) is the causative agent of Coronavirus Disease 2019 (COVID-19). Since its emergence at the end of 2019 in Wuhan City, Hubei Province of China, the virus has caused an ongoing pandemic outbreak of COVID-19 and a major global public health emergency. Reference the following link for up to date information regarding the number of patients infected globally by the SARS-CoV-2 virus: **Coronavirus COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU).**

The virus is believed to be transmitted via respiratory droplets, similar to the spread of influenza virus. The incubation period for COVID-19 is described to be 2-14 days following exposure, with most cases showing symptoms in approximately 4-5 days. The manifestation of COVID-19 ranges from mild disease characterized primarily by fever, dry cough, dyspnea, and bilateral infiltrates on chest imaging to critical illness such as respiratory failure, shock, or multi-organ dysfunction. Specifically, Chinese CDC reported approximately 81% of SARS-CoV-2 infections were mild (no or mild pneumonia), 14% were severe, and 5% were critical. The case fatality of SARS-CoV-2 was around 2% to 3% compared to around 35% for MERS-CoV and around 9.5% (774 deaths; 8,000 cases) for SARS-CoV. In a meta-analysis of 27 studies up to September 2020, the COVID-19 infection fatality rate was estimated to increase exponentially by age; 0.002% at age 10, 0.01% at age 25, 0.4% at age 55, 1.4% at age 65, 4.6% at age 75, 15% at age 85, and >25% at age >=90 years. Asymptomatic SARS-CoV-2 infections have been well documented, but their frequency varies widely across studies.

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Detection of SARS-CoV-2 virus is crucial in the diagnosis of illness, patient management, infection prevention and control, and disease epidemiology and surveillance information. Molecular assays, such as RT-PCR, are sensitive, rapid, and reliable diagnostics that can accurately identify SARS-CoV-2 RNA in clinical samples.

SRL utilizes RT-PCR testing methodologies from multiple manufacturers. All of the testing methodologies have received FDA Emergency Use Authorization (EUA). The patient report describes the method utilized. Testing is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (such as nasopharyngeal, nasal mid-turbinate, nasal, or saliva) collected from individuals who meet CDC criteria for COVID-19 testing. This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

CDC's clinical criteria for COVID-19 testing is frequently updated as additional information becomes available. The most recent information on COVID-19 can be found at: **https://www.cdc.gov/coronavirus/2019-nCoV/index.html**.

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:

SalivaDirect™ by Yale School of Public Health, Department of Epidemiology of Microbial Diseases:

Fact Sheet for Healthcare Providers

Fact Sheet for Patients

TaqPath COVID-19 Combo Kit by Thermo Fisher Scientific, Inc. :

Fact Sheet for Healthcare Providers

Fact Sheet for Patients

References:

1. Centers for Disease Control and Prevention. (2020). CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. Retrieved from **https://www.fda.gov/media/134922/download**
2. Centers for Disease Control and Prevention. (2020). Coronavirus Disease 2019 (COVID-19) Guidelines for Clinical Specimens. Retrieved from **https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html**
3. Coronavirus disease (COVID-2019) situation reports **https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports**
4. Dong E, Du H, Gardner L. An interactive web-based dashboard to track COVID-19 in real time. Lancet Infect Dis; published online Feb 19 2020. https://doi.org/10.1016/S1473-3099(20)30120-1 **https://www.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6**
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6. Wu Z, McGoogan JM. Characteristics of and Important Lessons from the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases from the Chinese Center for Disease Control and Prevention. JAMA. 2020;10.1001/jama.2020.2648. doi:10.1001/jama.2020.2648.
7. Pan Y, Zhang D, Yang P, Poon LLM, Wang Q. Viral load of SARS-CoV-2 in clinical. Lancet Infect Dis. 2020;S1473-3099(20)30113-4. doi:10.1016/S1473-3099(20)30113-4.
8. Zou L, Ruan F, Huang M, et al. SARS-CoV-2 Viral Load in Upper Respiratory Specimens of Infected Patients. N Engl J Med. 2020;10.1056/NEJMc2001737. doi:10.1056/NEJMc2001737
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10. Guarner, J. Three Emerging Coronaviruses in Two Decades: The Story of SARS, MERS, and Now COVID-19, American Journal of Clinical Pathology, aqaa029, **https://doi.org/10.1093/ajcp/aqaa029**
11. Levin AT, Hanage WP, Owusu-Boaitey N, Cochran KB, Walsh SP, Meyerowitz-Katz G. Assessing the age specificity of infection fatality rates for COVID-19: systematic review, meta-analysis, and public policy implications. Eur J Epidemiol. 2020;35(12):1123.

Other Offerings for Molecular Detection of Other Common Causes of Respiratory Illness:

PathLabs' Test Code 39439, COVID19/INFLUENZA A/B, NAAT performed by another Sonic affiliated reference laboratory, **Clinical Pathology Laboratories**, which includes Influenza A, Influenza B, and SARS-CoV-2. All tests are performed by PCR.

PathLabs' Test Code 39082, RESPIRATORY PATHOGEN PANEL (RPP) performed by **SRL** for detection of respiratory viruses and bacteria, which includes: Influenza A, Influenza A H1, Influenza A H3, Influenza B, RSV A, RSV B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, Human Rhinovirus/Enterovirus, Human Metapneumovirus, Adenovirus, Coronavirus 229E, Coronavirus NL63, Coronavirus OC43, Coronavirus HKU1, Human Bocavirus, Chlamydophila pneumoniae, and Mycoplasma pneumonia.

PathLabs' Test Code 38934, RESPIRATORY VIRUS PANEL PCR performed by **Warde Medical Laboratory**, which includes Adenovirus, Enterovirus, Influenza A, Influenza B, RSV, Rhinovirus, Parainfluenza 1, Parainfluenza 2, and Parainfluenza 3.

PathLabs' Test Code 37353, BORDETELLA PERT/PARAPERTUSSIS - PCR performed by **SRL**, which includes Bordetella pertussis and B. parapertussis testing.