

If a conflict arises between a Clinical Payment and Coding Policy (“CPCP”) and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. “Plan documents” include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. BCBSIL may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSIL has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act (“HIPAA”) approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing (“UB”) Editor, American Medical Association (“AMA”), Current Procedural Terminology (“CPT®”), CPT® Assistant, Healthcare Common Procedure Coding System (“HCPCS”), ICD-10 CM and PCS, National Drug Codes (“NDC”), Diagnosis Related Group (“DRG”) guidelines, Centers for Medicare and Medicaid Services (“CMS”) National Correct Coding Initiative (“NCCI”) Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

Coronavirus Testing in the Outpatient Setting

Policy Number: CPCPLAB057

Version 1.0

Enterprise Medical Policy Committee Approval Date: January 25, 2022

Plan Effective Date: May 1, 2022

Description

BCBSIL has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

Reimbursement Information:

NOTE 1: Antibody testing for the SARS-CoV-2 (COVID-19) virus provided under an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) during a public health emergency is **NOT** addressed by this policy.

1. Targeted nucleic acid testing, such as RT-PCR, for COVID-19 (SARS-CoV-2) including rapid molecular tests **may be reimbursable** in the following situations:
 - a. Individuals displaying signs and symptoms of possible COVID-19 infection (See **NOTE 2**).

- b. Asymptomatic individuals with known exposure to COVID-19.
 - c. Asymptomatic individuals prior to undergoing immunosuppressive or aerosol-producing procedures.
2. Targeted nucleic acid testing, such as RT-PCR, **may be reimbursable** for detection of severe acute respiratory syndrome (SARS) coronavirus RNA in persons with signs or symptoms of SARS who have traveled to endemic areas or have been exposed to persons with SARS.
 3. Targeted nucleic acid testing, such as RT-PCR, **may be reimbursable** for detection of Middle East respiratory syndrome (MERS) coronavirus RNA in persons with signs or symptoms of MERS who have traveled to endemic areas or have been exposed to persons with MERS.
 4. Host antibody serology testing to support a diagnosis of Multisystem Inflammatory Syndrome in Children (MIS-C) or Multisystem Inflammatory Syndrome in Adults (MIS-A) or Post-Acute Sequelae of SARS-CoV-2 infection (PASC) **may be reimbursable**. (See **NOTES 3 & 4**)
 5. The use of an antigen-detecting diagnostic test in symptomatic individuals, including antigen rapid tests, for SARS-CoV-2, **may be reimbursable**.
 6. Multiplex PCR-based panel testing of up to **5** respiratory pathogens **may be reimbursable** for patients with signs and symptoms of a respiratory tract infection, as evidenced by a compatible clinical syndrome including at least one of the following: temperature of 102 or greater, pronounced dyspnea, tachypnea, or tachycardia.
 7. Antigen panel testing of up to **5** antigens **may be reimbursable** for patients with signs and symptoms of a respiratory tract infection, as evidenced by a compatible clinical syndrome including at least one of the following: temperature of 102 or greater, pronounced dyspnea, tachypnea, or tachycardia.
 8. Whole genome sequencing of paired specimens from distinct lineages (as defined in Nextstrain or GISAID) **is not reimbursable** to diagnose SARS-CoV-2 reinfection.
 9. Antigen panel testing of **6** or more antigens **is not reimbursable**.
 10. Multiplex PCR-based panel testing of **6 or more** respiratory pathogens **is not reimbursable**.
 11. Host antibody serology testing to diagnose an acute suspected COVID-19 (SARS-CoV-2) infection or any other human coronavirus infection **is not reimbursable** (except for MIS-C testing in children or MIS-A testing in adults).
 12. Host antibody serology testing to determine immunity status for any human coronavirus **is not reimbursable**.
 13. Neutralization antibody testing for SARS-CoV-2 **is not reimbursable** for any indications.
 14. Testing for other endemic coronaviruses, such as 229E, NL63, OC43, and HKU1, **is not reimbursable**.

NOTE 2 Signs and symptoms associated with a possible COVID-19 infection can include a fever, cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, sore throat, new loss of taste or smell, nausea, vomiting, diarrhea, conjunctivitis, rash on skin or discoloration of fingers or toes (CDC, 2020k; WHO, 2020g).

Note 3: According to the CDC, evidence of possible MIS-C includes (CDC, 2020g):

- Fever of at least 38.0°C for at least 24 hours
- Multisystem (2 or more) organ involvement
- Laboratory evidence of inflammation, “including, but not limited to, one or more of the following: an elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer, ferritin, lactic acid dehydrogenase (LDH), d-dimer, ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and low albumin (CDC, 2020h)”
- Some children may fulfill full or partial criteria for Kawasaki disease

Note 4: According to the CDC, evidence of possible MIS-A includes (Morris et al., 2020):

- A severe illness requiring hospitalization in a person aged ≥21 years;
- A positive test result for current or previous SARS-CoV-2 infection (nucleic acid, antigen, or antibody) during admission or in the previous 12 weeks;
- Severe dysfunction of one or more extrapulmonary organ systems (e.g., hypotension or shock, cardiac dysfunction, arterial or venous thrombosis or thromboembolism, or acute liver injury);
- Laboratory evidence of severe inflammation (e.g., elevated CRP, ferritin, D-dimer, or interleukin-6);
- Absence of severe respiratory illness (to exclude patients in which inflammation and organ dysfunction might be attributable simply to tissue hypoxia).

Reimbursement

1. AMA standard practice for COVID-19 testing states not to include both the HCPCS and AMA code for same procedure on same DOS and that only one code should be used, therefore only one code per date of service will be reimbursed.
2. Specimen collection codes for coronavirus testing are considered incidental and will not be reimbursed.

Procedure Codes

Codes
86318, 86328, 86408, 86409, 86413, 86769, 86790, 87426, 87428, 87631, 87632, 87633, 87635, 87797, 87798, 87799, 87811, 0115U, 0202U, 0223U, 0224U, 0225U, 0226U, C9803, G2023, G2024, U0001, U0002, U0003, U0004, U0005

References:

AAP. (2021a, October 20). 2019 Novel Coronavirus (SARS-CoV-2 that causes COVID-19) Pandemic. Retrieved from https://redbook.solutions.aap.org/selfserve/ssPage.aspx?SelfServeContentId=rbo_outbreaks_page_3

AAP. (2021b, September 1). COVID-19 Testing Guidance. Retrieved from <https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/covid-19-testing-guidance/>

Abbott_Diagnostics. (2020). BinaxNOW COVID-19 Ag Card. Retrieved from

<https://www.fda.gov/media/141567/download>

Access_Bio. (2020). CareStart COVID-19 Antigen test. Retrieved from <https://www.fda.gov/media/142916/download>

AMA. (2020, 05/14/2020). Serological testing for SARS-CoV-2 antibodies. Retrieved from <https://www.ama-assn.org/delivering-care/public-health/serological-testing-sars-cov-2-antibodies>

ASM. (2021a, January 19). B.1.1.7: What We Know About the Novel SARS-CoV-2 Variant. Retrieved from <https://asm.org/Articles/2021/January/B-1-1-7-What-We-Know-About-the-Novel-SARS-CoV-2-Va>

ASM. (2021b, July 23). How Dangerous is the Delta Variant (B.1.617.2)? Retrieved from <https://asm.org/Articles/2021/July/How-Dangerous-is-the-Delta-Variant-B-1-617-2>

AstraZeneca. (2021, January 29). COVID-19 Vaccine AstraZeneca recommended for use in the EU. Retrieved from <https://www.astrazeneca.com/media-centre/press-releases/2021/covid-19-vaccine-astrazeneca-recommended-for-use-in-the-eu.html>

Backer, J. A., Klinkenberg, D., & Wallinga, J. (2020). Incubation period of 2019 novel coronavirus (2019-nCoV) infections among travellers from Wuhan, China, 20-28 January 2020. *Euro Surveill*, 25(5). doi:10.2807/1560-7917.Es.2020.25.5.2000062

Baum, S. G. (2020). Adult Multisystem Inflammatory Syndrome Associated with COVID-19. *NEJM*. Retrieved from <https://www.jwatch.org/na52622/2020/10/21/adult-multisystem-inflammatory-syndrome-associated-with>

BD_Veritor. (2020). Veritor™ System Retrieved from <https://www.fda.gov/media/139755/download>

Bezerra, M. F., Machado, L. C., De Carvalho, V., Docena, C., Brandão-Filho, S. P., Ayres, C. F. J., . . . Wallau, G. L. (2021). A Sanger-based approach for scaling up screening of SARS-CoV-2 variants of interest and concern. *Infect Genet Evol*, 92, 104910. doi:10.1016/j.meegid.2021.104910

BioFire. (2020, 05/2020). BioFire® Respiratory Panel 2.1 (RP2.1). Retrieved from <https://www.fda.gov/media/137583/download>

BioGerm. (2020). 2019-nCoV nucleic acid detection kit. Retrieved from http://www.biogerm.com/zt.php?class_id=102

BioSpace. (2020, 8/20/20). Quidel to Update Packaging of Point-of-Care Sofia® SARS Antigen Test for COVID-19 to Include Either Nasal or Nasopharyngeal Swabs.

BodiTechMed. (2020). AFIAS COVID-19 Ab. Retrieved from http://www.boditech.co.kr/eng/board/news/board_view.asp?num=30109

Branswell, H. (2020, December 19). A side-by-side comparison of the Pfizer/BioNTech and Moderna vaccines. Retrieved from <https://www.statnews.com/2020/12/19/a-side-by-side-comparison-of-the-pfizer-biontech-and-moderna-vaccines/>

Caturegli, G., Materi, J., Howard, B. M., & Caturegli, P. (2020). Clinical Validity of Serum Antibodies to SARS-CoV-

2 : A Case-Control Study. *Ann Intern Med*, 173(8), 614-622. doi:10.7326/m20-2889

CDC. (2016, February 11). What is whole genome sequencing (WGS)? Retrieved from <https://www.cdc.gov/pulsenet/pathogens/wgs.html>

CDC. (2020a, 03/15/2020). CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Retrieved from <https://www.fda.gov/media/134922/download>

CDC. (2020b, 02/15/2020). Human Coronavirus Types. Retrieved from <https://www.cdc.gov/coronavirus/types.html>

CDC. (2020c, 7/2/2020). Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay. Retrieved from <https://www.fda.gov/media/139744/download>

CDC. (2020d, 07/08/2020). Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19). Retrieved from <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

CDC. (2020e, August 1). Interim Guidelines for COVID-19 Antibody Testing. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html>

CDC. (2020f, October 27). Investigative Criteria for Suspected Cases of SARS-CoV-2 Reinfection (ICR). Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/php/invest-criteria.html>

CDC. (2020g, 5/14/20). Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19). Retrieved from <https://emergency.cdc.gov/han/2020/han00432.asp>

CDC. (2020h, 05/14/2020). Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19). Retrieved from <https://emergency.cdc.gov/han/2020/han00432.asp>

CDC. (2020i, 10/21/2020). Overview of Testing for SARS-CoV-2. Retrieved from <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html>

CDC. (2020j, 06/06/2020). Research Use Only 2019-Novel Coronavirus (2019-nCoV) Real-time RT-PCR Primer and Probe Information. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/lab/rt-pcr-panel-primer-probes.html>

CDC. (2020k, 12/22/20). Symptoms of Coronavirus. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>

CDC. (2021a, October 18). COVID Data Tracker Variant Proportions. Retrieved from <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

CDC. (2021b, September 1). Different COVID-19 Vaccines. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html>

CDC. (2021c, September 14). Ending Isolation and Precautions for People with COVID-19: Interim Guidance. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html>

CDC. (2021d, March 8). Guidance for Businesses and Employers: Plan, Prepare, and Respond to Coronavirus Disease 2019. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html>

CDC. (2021e, October 7). Interim Guidance for SARS-CoV-2 Testing in Non-Healthcare Workplaces. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/testing-non-healthcare-workplaces.html>

CDC. (2021f, February 26). Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

CDC. (2021g, September 21). Interim Guidelines for COVID-19 Antibody Testing. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html>

CDC. (2021h, May 11). Johnson & Johnson's Janssen COVID-19 Vaccine. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html>

CDC. (2021i, July 9). Post-COVID Conditions: Information for Healthcare Providers. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/post-covid-conditions.html>

CDC. (2021j, January 6). Specimen Collection: Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19). Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

CDC. (2021k, August 2). Test for Current Infection. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/testing/diagnostic-testing.html>

CDC. (2021l, July 15). Test for Past Infection. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/testing/serology-overview.html>

CDC. (2021m, August 2). Testing for SARS-CoV-2 (COVID-19) Overview. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>

CDC. (2021n, January 13). Understanding How COVID-19 Vaccines Work. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html>

CDC. (2021o, January 27). US COVID-19 Cases Caused by Variants. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html>

CDC. (2021p, April 13). Viral Vector Vaccines. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/viralvector.html>

CDC. (2021q, September 20). What You Need to Know about Variants. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/variants/variant.html>

CDC, & OSHA. (2021a, June 11). Manufacturing Workers and Employers: Interim Guidance from CDC and the Occupational Safety and Health Administration (OSHA). Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-manufacturing-workers-employers.html>

CDC, & OSHA. (2021b, June 11). Meat and Poultry Processing Workers and Employers: Interim Guidance from CDC and the Occupational Safety and Health Administration (OSHA). Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/meat-poultry-processing-workers-employers.html>

Celltrion_USA. (2020). Sampinute COVID-19 Antigen MIA. Retrieved from <https://www.fda.gov/media/143267/download>

Cevik, M., Tate, M., Lloyd, O., Maraolo, A. E., Schafers, J., & Ho, A. (2021). SARS-CoV-2, SARS-CoV, and MERS-CoV viral load dynamics, duration of viral shedding, and infectiousness: a systematic review and meta-analysis. *The Lancet Microbe*, 2(1), E13-E22. doi:10.1016/S2666-5247(20)30172-5

Chan, J. F., Yip, C. C., To, K. K., Tang, T. H., Wong, S. C., Leung, K. H., . . . Yuen, K. Y. (2020). Improved Molecular Diagnosis of COVID-19 by the Novel, Highly Sensitive and Specific COVID-19-RdRp/He1 Real-Time Reverse Transcription-PCR Assay Validated In Vitro and with Clinical Specimens. *J Clin Microbiol*, 58(5). doi:10.1128/jcm.00310-20

Chau, N. V. V., Hong, N. T. T., Ngoc, N. M., Anh, N. T., Trieu, H. T., Nhu, L. N. T., . . . for, O. C.-r. g. (2021). Rapid whole-genome sequencing to inform COVID-19 outbreak response in Vietnam. *The Journal of infection*, 82(6), 276-316. doi:10.1016/j.jinf.2021.03.017

CMS. (2021, October 21). Frequently Asked Questions: SARS-CoV-2 Surveillance Testing. Retrieved from <https://www.cms.gov/files/document/06-19-2020-frequently-asked-questions-covid-surveillance-testing.pdf>

Corman, V. M., Lienau, J., & Witznath, M. (2019). [Coronaviruses as the cause of respiratory infections]. *Internist (Berl)*, 60(11), 1136-1145. doi:10.1007/s00108-019-00671-5

Cucinotta, D., & Vanelli, M. (2020). WHO Declares COVID-19 a Pandemic. *Acta Biomed*, 91(1), 157-160. doi:10.23750/abm.v91i1.9397

Dao Thi, V. L., Herbst, K., Boerner, K., Meurer, M., Kremer, L. P. M., Kirrmaier, D., . . . Anders, S. (2020). A colorimetric RT-LAMP assay and LAMP-sequencing for detecting SARS-CoV-2 RNA in clinical samples. *Sci Transl Med*, 12(556), eabc7075. doi:10.1126/scitranslmed.abc7075

DeBiasi, R. L., Song, X., Delaney, M., Bell, M., Smith, K., Pershad, J., . . . Wessel, D. (2020). Severe COVID-19 in Children and Young Adults in the Washington, DC Metropolitan Region. *J Pediatr*. doi:10.1016/j.jpeds.2020.05.007

Diao, B., Wen, K., Chen, J., Liu, Y., Yuan, Z., Han, C., . . . Wu, Y. (2020). Diagnosis of Acute Respiratory Syndrome Coronavirus 2 Infection by Detection of Nucleocapsid Protein. *medRxiv*, 2020.2003.2007.20032524. doi:10.1101/2020.03.07.20032524

ECDC. (2020a, September 15). COVID-19 testing strategies and objectives. Retrieved from https://www.ecdc.europa.eu/sites/default/files/documents/TestingStrategy_Objective-Sept-2020.pdf

ECDC. (2020b, September 29). Testing strategies for SARS-CoV-2. Retrieved from <https://www.ecdc.europa.eu/en/covid-19/surveillance/testing-strategies>

ECDC. (2021, September 8). Diagnostic testing and screening for SARS-CoV-2. Retrieved from <https://www.ecdc.europa.eu/en/covid-19/latest-evidence/diagnostic-testing>

EpitopeDiagnostics. (2020). EDI™ Novel Coronavirus COVID-19 ELISA Kits. Retrieved from <http://www.epitopediagnostics.com/covid-19-elisa>

Espejo, A. P., Akgun, Y., Al Mana, A. F., Tjendra, Y., Millan, N. C., Gomez-Fernandez, C., & Cray, C. (2020). Review of Current Advances in Serologic Testing for COVID-19. *Am J Clin Pathol*, 154(3), 293-304. doi:10.1093/ajcp/aqaa112

FDA. (2020a). ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY SARS-CoV-2 RT-PCR Assay. Retrieved from <https://www.fda.gov/media/141192/download>

FDA. (2020b, 7/29/20). Antibody (Serology) Testing for COVID-19: Information for Patients and Consumers. Retrieved from <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/antibody-serology-testing-covid-19-information-patients-and-consumers>

FDA. (2020c, 7/9/2020). CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay. Retrieved from <https://www.fda.gov/media/139743/download>

FDA. (2020d). Coronavirus (COVID-19) Update: FDA Issues First Emergency Authorization for Sample Pooling in Diagnostic Testing. Retrieved from <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-first-emergency-authorization-sample-pooling-diagnostic>

FDA. (2020e, 04/12/2020). Emergency Use Authorization. Retrieved from <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

FDA. (2020f). Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised). Retrieved from <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>

FDA. (2020g, 05/11/2020). Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency. Retrieved from <https://www.fda.gov/media/135659/download>

FDA. (2021a, May 11). Coronavirus (COVID-19) Update: 10/15/21. Retrieved from <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-101521>

FDA. (2021b, April 22). Illumina COVIDSeq Test. Retrieved from <https://www.fda.gov/media/138778/download>

FDA. (2021c, January 29). In Vitro Diagnostics EUAs. Retrieved from <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

GenMark_Diagnostics. (2020). ePlex Respiratory Pathogen Panel 2. Retrieved from <https://www.fda.gov/media/142902/download>

Griffin, D. (2020, December 31). Viral Load as a Predictor of COVID-19 Patient Outcomes. Retrieved from <https://www.cuimc.columbia.edu/news/viral-load-predictor-covid-19-patient-outcomes>

Guo, L., Ren, L., Yang, S., Xiao, M., Chang, D., Yang, F., . . . Wang, J. (2020). Profiling Early Humoral Response to Diagnose Novel Coronavirus Disease (COVID-19). *Clinical Infectious Diseases*. doi:10.1093/cid/ciaa310

GVN. (2021, <https://gvn.org/covid-19/delta-b-1-617-2/>). Delta Variant (B.1.617.2).

Helix. (2020, 8/6/20). Helix COVID-19 NGSTest. Retrieved from <https://www.fda.gov/media/140917/download>

Henderson, L. A., Canna, S. W., Friedman, K. G., Gorelik, M., Lapidus, S. K., Bassiri, H., . . . Mehta, J. J. (2020). American College of Rheumatology Clinical Guidance for Multisystem Inflammatory Syndrome in Children Associated With SARS-CoV-2 and Hyperinflammation in Pediatric COVID-19: Version 1. *Arthritis Rheumatol*. doi:10.1002/art.41454

Henderson, L. A., Canna, S. W., Friedman, K. G., Gorelik, M., Lapidus, S. K., Bassiri, H., . . . Mehta, J. J. (2020). American College of Rheumatology Clinical Guidance for Pediatric Patients with Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with SARS-CoV-2 and Hyperinflammation in COVID-19. Version 2. *Arthritis Rheumatol*. doi:10.1002/art.41616

Hirotsu, Y., Maejima, M., Shibusawa, M., Nagakubo, Y., Hosaka, K., Amemiya, K., . . . Omata, M. (2020). Comparison of Automated SARS-CoV-2 Antigen Test for COVID-19 Infection with Quantitative RT-PCR using 313 Nasopharyngeal Swabs Including from 7 Serially Followed Patients. *Int J Infect Dis*. doi:10.1016/j.ijid.2020.08.029

Hogan, C. A., Sahoo, M. K., & Pinsky, B. A. (2020). Sample Pooling as a Strategy to Detect Community Transmission of SARS-CoV-2. *JAMA*, 323(19), 1967-1969. doi:10.1001/jama.2020.5445

Hulick, P. (2020, August 21). Next-generation DNA sequencing (NGS): Principles and clinical applications. Retrieved from <https://www.uptodate.com/contents/next-generation-dna-sequencing-ngs-principles-and-clinical-applications>

IDSA. (2020a, December 23). IDSA Algorithm for SARS-CoV-2 Nucleic Acid Testing. Retrieved from <https://www.idsociety.org/globalassets/idsa/practice-guidelines/covid-19/diagnostics/figure-01.png>

IDSA. (2020b, December 23). Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19: Molecular Diagnostic Testing. Retrieved from <https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/>

IDSA. (2020c, December 23). Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19: Molecular Diagnostic Testing. Retrieved from <https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/>

IDSA. (2020d, August 18). Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19: Serologic Testing. Retrieved from <https://www.idsociety.org/practice-guideline/covid-19-guideline-serology/>

JHU. (2021, October 18). COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU). Retrieved from <https://coronavirus.jhu.edu/map.html>

Jones, V. G., Mills, M., Suarez, D., Hogan, C. A., Yeh, D., Bradley Segal, J., . . . Mathew, R. (2020). COVID-19 and Kawasaki Disease: Novel Virus and Novel Case. *Hosp Pediatr*. doi:10.1542/hpeds.2020-0123

- Kawasuji, H., Takegoshi, Y., Kaneda, M., Ueno, A., Miyajima, Y., Kawago, K., . . . Yamamoto, Y. (2020). Transmissibility of COVID-19 depends on the viral load around onset in adult and symptomatic patients. *PLoS One*, 15(12), e0243597. doi:10.1371/journal.pone.0243597
- Kirby, T. (2021). New variant of SARS-CoV-2 in UK causes surge of COVID-19. *The Lancet. Respiratory medicine*, S2213-2600(2221)00005-00009. doi:10.1016/S2213-2600(21)00005-9
- Ko, J. H., Joo, E. J., Park, S. J., Baek, J. Y., Kim, W. D., Jee, J., . . . Peck, K. R. (2020). Neutralizing Antibody Production in Asymptomatic and Mild COVID-19 Patients, in Comparison with Pneumonic COVID-19 Patients. *J Clin Med*, 9(7). doi:10.3390/jcm9072268
- Kontou, P. I., Braliou, G. G., Dimou, N. L., Nikolopoulos, G., & Bagos, P. G. (2020). Antibody Tests in Detecting SARS-CoV-2 Infection: A Meta-Analysis. *Diagnostics (Basel)*, 10(5). doi:10.3390/diagnostics10050319
- Kweon, O. J., Lim, Y. K., Kim, H. R., Kim, M. C., Choi, S. H., Chung, J. W., & Lee, M. K. (2020). Antibody kinetics and serologic profiles of SARS-CoV-2 infection using two serologic assays. *PLoS One*, 15(10), e0240395. doi:10.1371/journal.pone.0240395
- LabCorp. (2020a, 3/16/20). ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY. Retrieved from <https://www.fda.gov/media/136151/download>
- LabCorp. (2020b, 04/20/2020). ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY COVID-19 RT-PCR TEST (LABORATORY CORPORATION OF AMERICA). Retrieved from <https://www.fda.gov/media/136151/download>
- Lambert-Niclot, S., Cuffel, A., Le Pape, S., Vauloup-Fellous, C., Morand-Joubert, L., Roque-Afonso, A. M., . . . Delaugerre, C. (2020). Evaluation of a Rapid Diagnostic Assay for Detection of SARS-CoV-2 Antigen in Nasopharyngeal Swabs. *J Clin Microbiol*, 58(8). doi:10.1128/jcm.00977-20
- Li, M., Wei, R., Yang, Y., He, T., Shen, Y., Qi, T., . . . Zhou, X. (2021). Comparing SARS-CoV-2 Testing in Anterior Nasal Vestibular Swabs vs. Oropharyngeal Swabs. *Front Cell Infect Microbiol*, 11, 653794. doi:10.3389/fcimb.2021.653794
- Li, Y., Yao, L., Li, J., Chen, L., Song, Y., Cai, Z., & Yang, C. (2020). Stability issues of RT-PCR testing of SARS-CoV-2 for hospitalized patients clinically diagnosed with COVID-19. *Journal of medical virology*, 92(7), 903-908. doi:10.1002/jmv.25786
- Lippi, G., Simundic, A. M., & Plebani, M. (2020). Potential preanalytical and analytical vulnerabilities in the laboratory diagnosis of coronavirus disease 2019 (COVID-19). *Clin Chem Lab Med*. doi:10.1515/cclm-2020-0285
- Lisboa Bastos, M., Tavaziva, G., Abidi, S. K., Campbell, J. R., Haraoui, L. P., Johnston, J. C., . . . Ahmad Khan, F. (2020). Diagnostic accuracy of serological tests for covid-19: systematic review and meta-analysis. *BMJ*, 370, m2516. doi:10.1136/bmj.m2516
- Loeffelholz, M. J., & Tang, Y.-W. (2020). Laboratory diagnosis of emerging human coronavirus infections – the state of the art. *Emerging Microbes & Infections*, 9(1), 747-756. doi:10.1080/22221751.2020.1745095
- Lu, Y., Li, L., Ren, S., Liu, X., Zhang, L., Li, W., & Yu, H. (2020). Comparison of the diagnostic efficacy between two

PCR test kits for SARS-CoV-2 nucleic acid detection. *Journal of Clinical Laboratory Analysis*, 34(10), e23554. doi:10.1002/jcla.23554

Ludwig, S., & Zarbock, A. (2020). Coronaviruses and SARS-CoV-2: A Brief Overview. *Anesth Analg*. doi:10.1213/ane.0000000000004845

LumiraDx. (2020). SARS-CoV-2 Ag Test. Retrieved from <https://www.fda.gov/media/141304/download>

Mahase, E. (2020). Covid-19: What have we learnt about the new variant in the UK? *BMJ*, 371, m4944. doi:10.1136/bmj.m4944

Mak, G. C., Cheng, P. K., Lau, S. S., Wong, K. K., Lau, C. S., Lam, E. T., . . . Tsang, D. N. (2020). Evaluation of rapid antigen test for detection of SARS-CoV-2 virus. *J Clin Virol*, 129, 104500. doi:10.1016/j.jcv.2020.104500

Mandavilli, A. (2021, July 30). C.D.C. Internal Report Calls Delta Variant as Contagious as Chickenpox. Retrieved from <https://www.nytimes.com/2021/07/30/health/covid-cdc-delta-masks.html>

McIntosh, K. (2021, April 2). COVID-19: Clinical features. UpToDate. Retrieved from <https://www.uptodate.com/contents/covid-19-clinical-features>

Miller, J. M., Binnicker, M. J., Campbell, S., Carroll, K. C., Chapin, K. C., Gilligan, P. H., . . . Yao, J. D. (2018). A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2018 Update by the Infectious Diseases Society of America and the American Society for Microbiology. *Clin Infect Dis*, 67(6), e1-e94. doi:10.1093/cid/ciy381

Morell, A., Skvaril, F., Nosedá, G., & Barandun, S. (1973). Metabolic properties of human IgA subclasses. *Clin Exp Immunol*, 13(4), 521-528. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1553728/>

Morris, S. B., Schwartz, N. G., Patel, P., Abbo, L., Beauchamps, L., Balan, S., . . . Godfred-Cato, S. (2020). Case Series of Multisystem Inflammatory Syndrome in Adults Associated with SARS-CoV-2 Infection - United Kingdom and United States, March-August 2020. *MMWR Morb Mortal Wkly Rep*, 69(40), 1450-1456. doi:10.15585/mmwr.mm6940e1

Nackerdien, Z. (2020, December 6). Viral Load Peaks in First Week of COVID-19 Symptom Onset. Retrieved from <https://www.medpagetoday.org/infectiousdisease/covid19/90035>

Nagura-Ikeda, M., Imai, K., Tabata, S., Miyoshi, K., Murahara, N., Mizuno, T., . . . Kato, Y. (2020). Clinical evaluation of self-collected saliva by RT-qPCR, direct RT-qPCR, RT-LAMP, and a rapid antigen test to diagnose COVID-19. *J Clin Microbiol*. doi:10.1128/jcm.01438-20

NIH. (2020, December 28). Phase 3 trial of Novavax investigational COVID-19 vaccine opens. Retrieved from <https://www.nih.gov/news-events/news-releases/phase-3-trial-novavax-investigational-covid-19-vaccine-opens>

NIH. (2021a, October 19). Clinical Spectrum of SARS-CoV-2 Infection. Retrieved from <https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/>

NIH. (2021b, April 21). Testing for SARS-CoV-2 Infection. Retrieved from <https://www.covid19treatmentguidelines.nih.gov/overview/sars-cov-2-testing/>

Okba, N. M. A., Müller, M. A., Li, W., Wang, C., GeurtsvanKessel, C. H., Corman, V. M., . . . Haagmans, B. L. (2020). Severe Acute Respiratory Syndrome Coronavirus 2-Specific Antibody Responses in Coronavirus Disease 2019 Patients. *Emerg Infect Dis*, 26(7). doi:10.3201/eid2607.200841

OSHA. (2020). Guidance on Preparing Workplaces for COVID-19. Retrieved from <https://www.osha.gov/Publications/OSHA3990.pdf>

OSHA. (2021, June 10). Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace. Retrieved from <https://www.osha.gov/coronavirus/safework#workers-who-have-had-covid-19>

Oude Munnink, B. B., Nieuwenhuijse, D. F., Stein, M., O'Toole, Á., Haverkate, M., Mollers, M., . . . The Dutch-Covid-19 response, t. (2020). Rapid SARS-CoV-2 whole-genome sequencing and analysis for informed public health decision-making in the Netherlands. *Nature Medicine*, 26(9), 1405-1410. doi:10.1038/s41591-020-0997-y

Padoan, A., Cosma, C., Sciacovelli, L., Faggian, D., & Plebani, M. (2020). Analytical performances of a chemiluminescence immunoassay for SARS-CoV-2 IgM/IgG and antibody kinetics. *Clin Chem Lab Med*. doi:10.1515/cclm-2020-0443

Palavecino, E. (2015). One Sample, Multiple Results The Use of Multiplex PCR for Diagnosis of Infectious Syndromes. *Clinical Laboratory News*. Retrieved from <https://www.aacc.org/publications/cln/articles/2015/april/one-sample-multiple-results>

Pfefferle, S., Reucher, S., Nörz, D., & Lütgehetmann, M. (2020). Evaluation of a quantitative RT-PCR assay for the detection of the emerging coronavirus SARS-CoV-2 using a high throughput system. *Euro Surveill*, 25(9). doi:10.2807/1560-7917.Es.2020.25.9.2000152

PHE. (2021, February 1). COVID-19: rapid tests for use in community pharmacies or at home. Retrieved from <https://www.gov.uk/government/publications/covid-19-rapid-point-of-care-near-person-testing-for-service-providers/covid-19-summary-guidance-for-service-providers-on-rapid-point-of-care-near-person-tests-for-diagnosis-and-management>

Poplar. (2020). EMERGENCY USE AUTHORIZATION (EUA) SUMMARY OF THE POPLAR SARS-COV-2 TMA POOLING ASSAY. Retrieved from <https://www.fda.gov/media/140792/download>

Qiagen_GmbH. (2020, 03/2020). QIAstat-Dx® Respiratory SARS-CoV2 Panel Instructions for Use (Handbook). Retrieved from <https://www.fda.gov/media/136571/download>

Quidel_Corporation. (2020a). Sofia 2 Flu + SARS Antigen FIA. Retrieved from <https://www.fda.gov/media/142701/download>

Quidel_Corporation. (2020b, 05/2020). Sofia 2 SARS Antigen FIA. Retrieved from <https://www.fda.gov/media/137885/download>

Roberts, M. (2021, January 29). Covid-19: Novavax shows 89% efficacy in UK trials. Retrieved from <https://www.bbc.com/news/uk-55850352>

Ryding, S. (2020, June 24). What is Viral Load? Retrieved from <https://www.news-medical.net/health/What-is-Viral-Load.aspx>

SansureBiotech. (2020, 05-04-2020). Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing). 2019-nCoV IFU. Retrieved from <https://www.fda.gov/media/137651/download>

Scohy, A., Anantharajah, A., Bodéus, M., Kabamba-Mukadi, B., Verroken, A., & Rodriguez-Villalobos, H. (2020). Low performance of rapid antigen detection test as frontline testing for COVID-19 diagnosis. *J Clin Virol*, 129, 104455. doi:10.1016/j.jcv.2020.104455

Seo, G., Lee, G., Kim, M. J., Baek, S. H., Choi, M., Ku, K. B., . . . Kim, S. I. (2020). Rapid Detection of COVID-19 Causative Virus (SARS-CoV-2) in Human Nasopharyngeal Swab Specimens Using Field-Effect Transistor-Based Biosensor. *ACS Nano*, 14(4), 5135-5142. doi:10.1021/acsnano.0c02823

Sri Santosh, T., Parmar, R., Anand, H., Srikanth, K., & Saritha, M. (2020). A Review of Salivary Diagnostics and Its Potential Implication in Detection of Covid-19. *Cureus*, 12(4), e7708. doi:10.7759/cureus.7708

Stewart, C. (2021, September 29). COVID-19 variant B.1.1.7 cases in the UK as of May 19, 2021, by country. Retrieved from <https://www.statista.com/statistics/1208546/covid-19-variant-b117-cases-reported-in-uk-by-country/>

Tang, J. W., Tambyah, P. A., & Hui, D. S. (2020). Emergence of a new SARS-CoV-2 variant in the UK. *J Infect*. doi:10.1016/j.jinf.2020.12.024

Taylor, J., Carter, R. J., Lehnertz, N., Kazazian, L., Sullivan, M., Wang, X., . . . Lynfield, R. (2020). Serial Testing for SARS-CoV-2 and Virus Whole Genome Sequencing Inform Infection Risk at Two Skilled Nursing Facilities with COVID-19 Outbreaks - Minnesota, April-June 2020. *MMWR Morb Mortal Wkly Rep*, 69(37), 1288-1295. doi:10.15585/mmwr.mm6937a3

The_Native_Antigen_Company. (2020, 03/24/2020). Why We Need Antigen and Antibody Tests for COVID-19. Retrieved from <https://thenativeantigencompany.com/why-we-need-antigen-and-antibody-tests-for-covid-19/>

To, K. K. W., Yip, C. C. Y., Lai, C. Y. W., Wong, C. K. H., Ho, D. T. Y., Pang, P. K. P., . . . Yuen, K. Y. (2019). Saliva as a diagnostic specimen for testing respiratory virus by a point-of-care molecular assay: a diagnostic validity study. *Clin Microbiol Infect*, 25(3), 372-378. doi:10.1016/j.cmi.2018.06.009

Tregoning, J. S., Brown, E. S., Cheeseman, H. M., Flight, K. E., Higham, S. L., Lemm, N. M., . . . Pollock, K. M. (2020). Vaccines for COVID-19. *Clinical and experimental immunology*, 202(2), 162-192. doi:10.1111/cei.13517

UCSD. (2020). UCSD RC SARS-CoV-2 Assay Retrieved from <https://www.fda.gov/media/140712/download>

US. (2020, 03/27/2020). H.R. 748 - CARES Act. Retrieved from <https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf>

Van Beusekom, M. (2020, December 8). Phase 3 trials show AstraZeneca COVID vaccine has up to 90% efficacy. Retrieved from <https://www.cidrap.umn.edu/news-perspective/2020/12/phase-3-trials-show-astrazeneca-covid-vaccine-has-90-efficacy>

Verdoni, L., Mazza, A., Gervasoni, A., Martelli, L., Ruggeri, M., Ciuffreda, M., . . . D'Antiga, L. (2020). An outbreak of severe Kawasaki-like disease at the Italian epicentre of the SARS-CoV-2 epidemic: an observational cohort study. *Lancet*. doi:10.1016/s0140-6736(20)31103-x

- Villaverde, S., Domínguez-Rodríguez, S., Sabrido, G., Pérez-Jorge, C., Plata, M., Romero, M. P., . . . Epidemiological Study of, C.-i. C. o. t. S. S. o. P. W. G. (2021). Diagnostic Accuracy of the Panbio Severe Acute Respiratory Syndrome Coronavirus 2 Antigen Rapid Test Compared with Reverse-Transcriptase Polymerase Chain Reaction Testing of Nasopharyngeal Samples in the Pediatric Population. *The Journal of pediatrics*, 232, 287-289.e284. doi:10.1016/j.jpeds.2021.01.027
- Wang, F., Huang, S., Gao, R., Zhou, Y., Lai, C., Li, Z., . . . Liu, L. (2020). Initial whole-genome sequencing and analysis of the host genetic contribution to COVID-19 severity and susceptibility. *Cell Discovery*, 6(1), 83. doi:10.1038/s41421-020-00231-4
- Wang, R., Qian, C., Pang, Y., Li, M., Yang, Y., Ma, H., . . . Wang, Y. (2020). opvCRISPR: One-pot visual RT-LAMP-CRISPR platform for SARS-cov-2 detection. *Biosensors and Bioelectronics*, 172, 112766. doi:https://doi.org/10.1016/j.bios.2020.112766
- WHO. (2020a, 03/13/2020). Clinical management of severe acute respiratory infection when COVID-19 is suspected. Retrieved from [https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-\(ncov\)-infection-is-suspected](https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected)
- WHO. (2020b, 09/11/20). Diagnostic testing for SARS-CoV-2. Retrieved from <https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2>
- WHO. (2020c). Emergencies. Retrieved from <https://www.who.int/emergencies/diseases/en/>
- WHO. (2020d, 04/24/2020). "Immunity passports" in the context of COVID-19. Retrieved from <https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19>
- WHO. (2020e, 2020). Middle East respiratory syndrome coronavirus (MERS-CoV). Retrieved from <https://www.who.int/emergencies/mers-cov/en/>
- WHO. (2020f, 05/15/2020). Multisystem inflammatory syndrome in children and adolescents with COVID-19. Retrieved from <https://www.who.int/publications-detail/multisystem-inflammatory-syndrome-in-children-and-adolescents-with-covid-19>
- WHO. (2020g, 04/17/2020). Q&A on coronaviruses (COVID-19): What are the symptoms of COVID-19? Retrieved from <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q-a-coronaviruses>
- WHO. (2020h). SARS (Severe Acute Respiratory Syndrome). Retrieved from <https://www.who.int/ith/diseases/sars/en/>
- WHO. (2021a, October 6). Antigen-detection in the diagnosis of SARS-CoV-2 infection. Retrieved from <https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays>
- WHO. (2021b, October 18). Coronavirus disease (COVID-19) Pandemic. Retrieved from <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>
- WHO. (2021c, January 25). COVID-19 Clinical management: living guidance. Retrieved from

<https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-1>

Wise, J. (2020). Covid-19: New coronavirus variant is identified in UK. *BMJ*, 371, m4857. doi:10.1136/bmj.m4857

Woof, J. M., & Kerr, M. A. (2006). The function of immunoglobulin A in immunity. *The Journal of Pathology*, 208(2), 270-282. doi:10.1002/path.1877

Wright, D., & CMS. (2020, 05/18/2020). Nursing Home Reopening Recommendations for State and Local Officials. Retrieved from <https://www.cms.gov/files/document/nursing-home-reopening-recommendations-state-and-local-officials.pdf>

Wright, D., & CMS. (2021, March 10). Nursing Home Reopening Recommendations for State and Local Officials. Retrieved from <https://www.cms.gov/files/document/nursing-home-reopening-recommendations-state-and-local-officials.pdf>

Wu, F., Liu, M., Wang, A., Lu, L., Wang, Q., Gu, C., . . . Huang, J. (2020). Evaluating the Association of Clinical Characteristics With Neutralizing Antibody Levels in Patients Who Have Recovered From Mild COVID-19 in Shanghai, China. *JAMA Intern Med*. doi:10.1001/jamainternmed.2020.4616

Wulff, N. H., Tzatzaris, M., & Young, P. J. (2012). Monte Carlo simulation of the Spearman-Kaerber TCID50. *J Clin Bioinforma*, 2(1), 5. doi:10.1186/2043-9113-2-5

Xiao, D. A. T., Gao, D. C., & Zhang, D. S. (2020). Profile of Specific Antibodies to SARS-CoV-2: The First Report. *J Infect*. doi:10.1016/j.jinf.2020.03.012

Yang, X., Yu, Y., Xu, J., Shu, H., Xia, J., Liu, H., . . . Shang, Y. (2020). Clinical course and outcomes of critically ill patients with SARS-CoV-2 pneumonia in Wuhan, China: a single-centered, retrospective, observational study. *Lancet Respir Med*, 8(5), 475-481. doi:10.1016/s2213-2600(20)30079-5

Yau, F., Ferreira, R., Kamali, R., Bird, P. W., Halliwell, R., Patel, H., . . . Tang, J. W. (2021). Clinical utility of a rapid 'on-demand' laboratory-based SARS-CoV-2 diagnostic testing service in an acute hospital setting admitting COVID-19 patients. *Clin Infect Pract*, 12, 100086. doi:10.1016/j.clinpr.2021.100086

Yelin, I., Aharony, N., Shaer Tamar, E., Argoetti, A., Messer, E., Berenbaum, D., . . . Kishony, R. (2020). Evaluation of COVID-19 RT-qPCR test in multi-sample pools. *Clin Infect Dis*. doi:10.1093/cid/ciaa531

Zhang, Y. V., Wiencek, J., Meng, Q. H., Theel, E. S., Babic, N., Sepiashvili, L., . . . the, A. C. S. T. T. F. (2021). AACC Practical Recommendations for Implementing and Interpreting SARS-CoV-2 EUA and LDT Serologic Testing in Clinical Laboratories. *Clinical Chemistry*. doi:10.1093/clinchem/hvab051

Zhao, J., Yuan, Q., Wang, H., Liu, W., Liao, X., Su, Y., . . . Zhang, Z. (2020). Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. *Clinical Infectious Diseases*. doi:10.1093/cid/ciaa344

Policy Update History:

5/1/2022	New policy
----------	------------