BlueCross BlueShield of Oklahoma

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. BCBSOK may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSOK 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 Clinical Payment and Coding Policy Committee Approval Date: July 17, 2023

Plan Effective Date: November 1, 2023

Description

BCBSOK 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:

This policy only addressed testing for the purpose of medical decision making in the outpatient setting.

This policy does not address work, school, state, or federally mandated SARS-CoV-2 testing.

1. Targeted nucleic acid testing (e.g., RT-PCR, rapid molecular tests) for COVID-19 (SARS-CoV-2) **may be reimbursable** in any of the following situations:
    a. Individuals displaying signs and symptoms of possible COVID-19 infection (See **NOTE 1**).
    b. Asymptomatic individuals with known exposure to COVID-19, EXCEPT when the individual has had a previous COVID-19 infection within the last 90 days.

2. Targeted nucleic acid testing, (e.g., RT-PCR), **may be reimbursable** for detection of severe acute respiratory syndrome (SARS) coronavirus RNA in individuals with signs or symptoms of SARS and who have traveled to endemic areas or have been exposed to individuals 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 individuals with signs or symptoms of MERS and who have traveled to endemic areas or have been exposed to individuals with MERS.

4. Host antibody serology testing to support a diagnosis of Multisystem Inflammatory Syndrome in Children (MIS-C) (see **NOTE 2**), Multisystem Inflammatory Syndrome in Adults (MIS-A) (see **NOTE 3**), or Post-Acute Sequelae of SARS-CoV-2 infection (PASC) **may be reimbursable**.

5. The use of an antigen-detecting diagnostic test in symptomatic individuals, (e.g., antigen rapid tests), for SARS-CoV-2, **may be reimbursable**.

6. For individuals with signs and symptoms of a respiratory tract infection (see **NOTE** 4), multiplex PCR-based panel testing of up to **5** respiratory pathogens **may be reimbursable**.

7. For individuals with signs and symptoms of a respiratory tract infection (see **NOTE** 4), antigen panel testing of up to **5** antigens **may be reimbursable**.

8. For the diagnosis of SARS-CoV2 reinfection, whole genome sequencing of paired specimens from distinct lineages (as defined in Nextstrain or GISAID) **is not reimbursable**.

9. Multiplex PCR-based panel testing of **6 or more** respiratory pathogens **is not reimbursable**.

10. Antigen panel testing of **6** or more antigens **is not reimbursable.**

11. For all other situations not described above, host antibody serology testing **is not reimbursable.**

12. . In the outpatient setting, SARS-CoV-2 genotyping **is not reimbursable.**

13. For all situations, neutralization antibody testing for SARS-CoV-2 **is not reimbursable.**

14. Testing for other endemic coronaviruses, such as 229E, NL63, OC43, and HKU1, **is not reimbursable**.

NOTE 1: Signs and symptoms associated with a possible COVID-19 infection can include a fever, cough, fatigue, shortness of breath or difficulty breathing, congestion or runny nose, muscle pain, headache,

sore throat, new loss of taste or smell, nausea, vomiting, diarrhea, conjunctivitis, rash on skin or discoloration of fingers or toes (CDC, 2020e; WHO, 2023).

Note 2: According to the CDC, evidence of possible MIS-C includes (CDC, 2021c):

- 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 or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and low albumin (CDC, 2020d)"

Some children may fulfill full or partial criteria for Kawasaki disease.

Note 3: According to the CDC, evidence of possible MIS-A includes (Morris et al., 2020; Patel et al., 2021):

- 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).

Note 4: Signs and symptoms of a respiratory tract infection:

- A temperature greater than 102°F;
- Pronounced dyspnea;
- Tachypnea; or
- Tachycardia.

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

The following is not an all-encompassing code list. The inclusion of a code does not guarantee it is a covered service or eligible for reimbursement.

Codes
86318, 86328, 86408, 86409, 86413, 86769, , 87426, 87428, 87631, 87632, 87633, 87635, , 87798, 87811, 87913, 0115U, 0202U, 0223U, 0224U, 0225U, 0226U, C9803, U0001, U0002

References:

AAP. (2022, February 28). *COVID-19 Testing Guidance*. https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/covid-19-testing-guidance/

AAP. (2023, February 8). *Multisystem Inflammatory Syndrome in Children (MIS-C) Interim Guidance* https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/multisystem-inflammatory-syndrome-in-children-mis-c-interim-guidance/

AMA. (2020, 05/14/2020). *Serological testing for SARS-CoV-2 antibodies*. American Medical Association. Retrieved 05/19/2020 from https://www.ama-assn.org/delivering-care/public-health/serological-testing-sars-cov-2-antibodies

ASA, & APSF. (2022, 12-21-2022). *ASA and APSF Updated Statement on Perioperative Testing for SARS-CoV-2 in the Asymptomatic Patient*. https://www.apsf.org/news-updates/asa-and-apsf-updated-statement-on-perioperative-testing-for-sars-cov-2-in-the-asymptomatic-patient/

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). https://doi.org/10.2807/1560-7917.Es.2020.25.5.2000062

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

BD_Veritor. (2020). *Veritor™ System* 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., Paiva, M. H. S., & 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. https://doi.org/10.1016/j.meegid.2021.104910

BioFire. (2020, 05/2020). *BioFire® Respiratory Panel 2.1 (RP2.1)*. FDA. Retrieved 05/04/2020 from https://www.fda.gov/media/137583/download

BioGerm. (2020). 2019-nCoV nucleic acid detection kit. http://www.bio-germ.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. http://www.boditech.co.kr/eng/board/news/board_view.asp?num=30109

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. https://doi.org/10.7326/m20-2889

CDC. (2016, February 11). *What is whole genome sequencing (WGS)?* 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* FDA. Retrieved 04/30/2020 from https://www.fda.gov/media/134922/download

CDC. (2020b, 02/15/2020). *Human Coronavirus Types*. CDC. Retrieved 05/15/2020 from https://www.cdc.gov/coronavirus/types.html

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

CDC. (2020d, 05/14/2020). *Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19)*. CDC. Retrieved 05/26/2020 from https://emergency.cdc.gov/han/2020/han00432.asp

CDC. (2020e, 12/22/20). *Symptoms of Coronavirus*. Retrieved 2/11/21 from https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

CDC. (2021a, March 8). *Guidance for Businesses and Employers: Plan, Prepare, and Respond to Coronavirus Disease 2019*. Centers for Disease Control and Prevention. Retrieved 8/21/20 from https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html

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

CDC. (2021c, 5/20/21). *Multisystem Inflammatory Syndrome*. CDC. Retrieved 04/19/2022 from https://www.cdc.gov/mis/mis-c/hcp/index.html

CDC. (2022a, 11/14/2022). *CDC's Influenza SARS-CoV-2 Multiplex Assay*. Centers for Disease Control and Prevention. Retrieved 08/21/20 from https://www.cdc.gov/coronavirus/2019-ncov/lab/rt-pcr-panel-primer-probes.html

CDC. (2022b, 09/28/2022). *COVID-19 Testing: What You Need To Know*. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html

CDC. (2022c, September 14). *Ending Isolation and Precautions for People with COVID-19: Interim Guidance*. CDC. Retrieved 08/18/2020 from https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html

CDC. (2022d, July 15). *Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing*. https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

CDC. (2022e, Jan. 24, 2022). *Interim Guidelines for COVID-19 Antibody Testing*. Retrieved 04/20/2022 from https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

CDC. (2022f, January 24). *Interim Guidelines for COVID-19 Antibody Testing*. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

CDC. (2022g, September 28). *Overview of Testing for SARS-CoV-2, the virus that causes COVID-19*. https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

CDC. (2022h, 12/16/2022). *Post-COVID Conditions: Information for Healthcare Providers*. https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/post-covid-conditions.html

CDC. (2023a, 03/16/2023). *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States*. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

CDC. (2023b, 03/21/2023). *Isolations and Precautions for People with COVID-19*. https://www.cdc.gov/coronavirus/2019-ncov/your-health/isolation.html

CDC. (2023c, March 20). *SARS-CoV-2 Variant Classifications and Definitions*. Retrieved April 19, 2022 from https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-classifications.html

CDC, & OSHA. (2020, July 9). *Meat and Poultry Processing Workers and Employers: Interim Guidance from CDC and the Occupational Safety and Health Administration (OSHA)*. Retrieved 08/18/2020 from https://stacks.cdc.gov/view/cdc/90395

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. https://doi.org/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., Fung, A. Y., Ng, A. C., Zou, Z., Tsoi, H. W., Choi, G. K., Tam, A. R., Cheng, V. C., Chan, K. H., Tsang, O. T., & Yuen, K. Y. (2020). Improved Molecular Diagnosis of COVID-19 by the Novel, Highly Sensitive and Specific COVID-19-RdRp/Hel Real-Time Reverse Transcription-PCR Assay Validated In Vitro and with Clinical Specimens. *J Clin Microbiol*, *58*(5). https://doi.org/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., Yen, L. M., Minh, N. N. Q., Phong, N. T., Truong, N. T., Huong, L. T. T., Tu, T. N. H., Hung, L. M., Thanh, T. T., Dung, N. T., Dung, N. T., Thwaites, G., Van Tan, L., & 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. https://doi.org/10.1016/j.jinf.2021.03.017

Churiwal, M., Lin, K. D., Khan, S., Chhetri, S., Muller, M. S., Tompkins, K., Smith, J., Litel, C., Whittelsey, M., Basham, C., Rapp, T., Cerami, C., Premkumar, L., & Lin, J. T. (2021). Assessment of the Field Utility of a Rapid Point-of-Care Test for SARS-CoV-2 Antibodies in a Household Cohort. *Am J Trop Med Hyg*, *106*(1), 156-159. https://doi.org/10.4269/ajtmh.21-0592

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

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

Dao Thi, V. L., Herbst, K., Boerner, K., Meurer, M., Kremer, L. P. M., Kirrmaier, D., Freistaedter, A., Papagiannidis, D., Galmozzi, C., Stanifer, M. L., Boulant, S., Klein, S., Chlanda, P., Khalid, D., Barreto Miranda, I., Schnitzler, P., Kräusslich, H.-G., Knop, M., & Anders, S. (2020). A colorimetric RT-LAMP assay and LAMP-sequencing for detecting SARS-CoV-2 RNA in clinical samples. *Science Translational Medicine*, *12*(556), eabc7075. https://doi.org/10.1126/scitranslmed.abc7075

DeBiasi, R. L., Song, X., Delaney, M., Bell, M., Smith, K., Pershad, J., Ansusinha, E., Hahn, A., Hamdy, R., Harik, N., Hanisch, B., Jantausch, B., Koay, A., Steinhorn, R., Newman, K., & Wessel, D. (2020). Severe COVID-19 in Children and Young Adults in the Washington, DC Metropolitan Region. *J Pediatr*. https://doi.org/10.1016/j.jpeds.2020.05.007

Diao, B., Wen, K., Chen, J., Liu, Y., Yuan, Z., Han, C., Chen, J., Pan, Y., Chen, L., Dan, Y., Wang, J., Chen, Y., Deng, G., Zhou, H., & Wu, Y. (2020). Diagnosis of Acute Respiratory Syndrome Coronavirus 2 Infection by Detection of Nucleocapsid Protein. *medRxiv*, 2020.2003.2007.20032524. https://doi.org/10.1101/2020.03.07.20032524

Dighe, K., Moitra, P., Alafeef, M., Gunaseelan, N., & Pan, D. (2022). A rapid RNA extraction-free lateral flow assay for molecular point-of-care detection of SARS-CoV-2 augmented by chemical probes. *Biosensors and Bioelectronics*, *200*, 113900. https://doi.org/https://doi.org/10.1016/j.bios.2021.113900

ECDC. (2021, May 3). *Guidance for representative and targeted genomic SARS-CoV-2 monitoring*. https://www.ecdc.europa.eu/en/publications-data/guidance-representative-and-targeted-genomic-sars-cov-2-monitoring

ECDC. (2022a, 03/22/2022). *Diagnostic testing and screening for SARS-CoV-2*. European Centre for Disease Prevention and Control. Retrieved 04/18/2022 from https://www.ecdc.europa.eu/en/covid-19/latest-evidence/diagnostic-testing

ECDC. (2022b, December 15). *Testing strategies for SARS-CoV-2*. https://www.ecdc.europa.eu/en/covid-19/surveillance/testing-strategies

EpitopeDiagnostics. (2020). EDI™ Novel Coronavirus COVID-19 ELISA Kits. 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. https://doi.org/10.1093/ajcp/aqaa112

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

FDA. (2020b, 7/9/2020). *CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay*. https://www.fda.gov/media/139743/download

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

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

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

FDA. (2022a, 02/24/2022). *Antibody (Serology) Testing for COVID-19: Information for Patients and Consumers*. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/antibody-serology-testing-covid-19-information-patients-and-consumers

FDA. (2022b). *Coronavirus (COVID-19) Update: FDA Authorizes First COVID-19 Diagnostic Test Using Breath Samples*. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-covid-19-diagnostic-test-using-breath-samples

FDA. (2022c, 04/14/2022). *Emergency Use Authorization*. Retrieved 04/20/2022 from https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

FDA. (2022d, January 29). *In Vitro Diagnostics EUAs*. https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

FDA. (2022e). *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*. FDA. Retrieved 04/20/2022 from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised

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

Greninger, A. L., Dien Bard, J., Colgrove, R. C., Graf, E. H., Hanson, K. E., Hayden, M. K., Humphries, R. M., Lowe, C. F., Miller, M. B., Pillai, D. R., Rhoads, D. D., Yao, J. D., & Lee, F. M. (2022). Clinical and Infection Prevention Applications of Severe Acute Respiratory Syndrome Coronavirus 2 Genotyping: An Infectious Diseases Society of America/American Society for Microbiology Consensus Review Document. *Clin Infect Dis*, *74*(8), 1496-1502. https://doi.org/10.1093/cid/ciab761

Griffin, D. (2020, December 31). *Viral Load as a Predictor of COVID-19 Patient Outcomes*. 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., Dela Cruz, C. S., Wang, Y., Wu, C., Xiao, Y., Zhang, L., Han, L., Dang, S., Xu, Y., Yang, Q.-W., Xu, S.-Y., Zhu, H.-D., Xu, Y.-C., Jin, Q., . . . Wang, J. (2020). Profiling Early Humoral Response to Diagnose Novel Coronavirus Disease (COVID-19). *Clinical Infectious Diseases*. https://doi.org/10.1093/cid/ciaa310

Helix. (2020, 8/6/20). *Helix COVID-19 NGS Test*. Retrieved 8/20/20 from https://www.fda.gov/media/140917/download

Henderson, L. A., Canna, S. W., Friedman, K. G., Gorelik, M., Lapidus, S. K., Bassiri, H., Behrens, E. M., Ferris, A., Kernan, K. F., Schulert, G. S., Seo, P., MB, F. S., Tremoulet, A. H., Yeung, R. S. M., Mudano, A. S., Turner, A. S., Karp, D. R., & 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*. https://doi.org/10.1002/art.41454

Henderson, L. A., Canna, S. W., Friedman, K. G., Gorelik, M., Lapidus, S. K., Bassiri, H., Behrens, E. M., Ferris, A., Kernan, K. F., Schulert, G. S., Seo, P., Son, M. B. F., Tremoulet, A. H., Yeung, R. S. M., Mudano, A. S., Turner, A. S., Karp, D. R., & 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*. https://doi.org/10.1002/art.41616

Henderson, L. A., Canna, S. W., Friedman, K. G., Gorelik, M., Lapidus, S. K., Bassiri, H., Behrens, E. M., Kernan, K. F., Schulert, G. S., Seo, P., Son, M. B. F., Tremoulet, A. H., VanderPluym, C., Yeung, R. S. M., Mudano, A. S., Turner, A. S., Karp, D. R., & Mehta, J. J. (2022). American College of Rheumatology Clinical Guidance for Multisystem Inflammatory Syndrome in Children Associated With SARS–CoV-2 and Hyperinflammation in Pediatric COVID-19: Version 3. *Arthritis & Rheumatology*, *74*(4), e1-e20. https://doi.org/https://doi.org/10.1002/art.42062

Hirotsu, Y., Maejima, M., Shibusawa, M., Nagakubo, Y., Hosaka, K., Amemiya, K., Sueki, H., Hayakawa, M., Mochizuki, H., Tsutsui, T., Kakizaki, Y., Miyashita, Y., Yagi, S., Kojima, S., & 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*. https://doi.org/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. https://doi.org/10.1001/jama.2020.5445

Hulick, P. (2022, August 10). *Next-generation DNA sequencing (NGS): Principles and clinical applications*. Wolters Kluwer. 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*. IDSA. Retrieved 05/13/2020 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*. IDSA. Retrieved 05/13/2020 from https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/

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

JHU. (2022, November 11). *COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)*. Johns Hopkins University. https://coronavirus.jhu.edu/map.html

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

Kawasuji, H., Takegoshi, Y., Kaneda, M., Ueno, A., Miyajima, Y., Kawago, K., Fukui, Y., Yoshida, Y., Kimura, M., Yamada, H., Sakamaki, I., Tani, H., Morinaga, Y., & Yamamoto, Y. (2020). Transmissibility of COVID-19 depends on the viral load around onset in adult and symptomatic patients. *PLOS ONE*, *15*(12), e0243597. https://doi.org/10.1371/journal.pone.0243597

Ko, J. H., Joo, E. J., Park, S. J., Baek, J. Y., Kim, W. D., Jee, J., Kim, C. J., Jeong, C., Kim, Y. J., Shon, H. J., Kang, E. S., Choi, Y. K., & 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). https://doi.org/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). https://doi.org/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. https://doi.org/10.1371/journal.pone.0240395

LabCorp. (2020a, 3/16/20). *ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY*. Retrieved 8/21/20 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)*. FDA. Retrieved 04/26/2020 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., Le Goff, J., & Delaugerre, C. (2020). Evaluation of a Rapid Diagnostic Assay for Detection of SARS-CoV-2 Antigen in Nasopharyngeal Swabs. *J Clin Microbiol*, *58*(8). https://doi.org/10.1128/jcm.00977-20

Li, M., Wei, R., Yang, Y., He, T., Shen, Y., Qi, T., Han, T., Song, Z., Zhu, Z., Ma, X., Lin, Y., Yuan, Y., Zhao, K., Lu, H., & Zhou, X. (2021). Comparing SARS-CoV-2 Testing in Anterior Nasal Vestibular Swabs vs. Oropharyngeal Swabs. *Front Cell Infect Microbiol*, *11*, 653794. https://doi.org/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. https://doi.org/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*. https://doi.org/10.1515/cclm-2020-0285

Lisboa Bastos, M., Tavaziva, G., Abidi, S. K., Campbell, J. R., Haraoui, L. P., Johnston, J. C., Lan, Z., Law, S., MacLean, E., Trajman, A., Menzies, D., Benedetti, A., & Ahmad Khan, F. (2020). Diagnostic accuracy of serological tests for covid-19: systematic review and meta-analysis. *Bmj*, *370*, m2516. https://doi.org/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. https://doi.org/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. https://doi.org/10.1002/jcla.23554

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

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

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

Mawhorter, M. E., Nguyen, P., Goldsmith, M., Owens, R. G., Baer, B., & Raman, J. D. (2022). Diagnostic yield and costs associated with a routine pre-operative COVID-19 testing algorithm for asymptomatic patients prior to elective surgery. *Am J Clin Exp Urol*, *10*(5), 341-344.

Mboumba Bouassa, R.-S., Tonen-Wolyec, S., Veyer, D., Péré, H., & Bélec, L. (2022). Analytical performances of the AMPLIQUICK® Respiratory Triplex assay for simultaneous detection and differentiation of SARS-CoV-2, influenza A/B and respiratory syncytial viruses in respiratory specimens. *PLOS ONE*, *17*(1), e0262258. https://doi.org/10.1371/journal.pone.0262258

McIntosh, K. (2023, March 23). *COVID-19: Clinical features*. Wolter Kluwer. Retrieved 08/19/2020 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., Gonzalez, M. D., Jerris, R. C., Kehl, S. C., Patel, R., Pritt, B. S., Richter, S. S., Robinson-Dunn, B., Schwartzman, J. D., Snyder, J. W., Telford, S., 3rd, Theel, E. S., Thomson, R. B., Jr., Weinstein, M. P., & 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. https://doi.org/10.1093/cid/ciy381

Morell, A., Skvaril, F., Noseda, G., & Barandun, S. (1973). Metabolic properties of human IgA subclasses. *Clinical and experimental immunology*, *13*(4), 521-528. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1553728/

Morris, S. B., Schwartz, N. G., Patel, P., Abbo, L., Beauchamps, L., Balan, S., Lee, E. H., Paneth-Pollak, R., Geevarughese, A., Lash, M. K., Dorsinville, M. S., Ballen, V., Eiras, D. P., Newton-Cheh, C., Smith, E., Robinson, S., Stogsdill, P., Lim, S., Fox, S. E., . . . 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. https://doi.org/10.15585/mmwr.mm6940e1

Nackerdien, Z. (2020, December 6). *Viral Load Peaks in First Week of COVID-19 Symptom Onset*. Retrieved January 31 from https://www.medpagetoday.org/infectiousdisease/covid19/90035

Nagura-Ikeda, M., Imai, K., Tabata, S., Miyoshi, K., Murahara, N., Mizuno, T., Horiuchi, M., Kato, K., Imoto, Y., Iwata, M., Mimura, S., Ito, T., Tamura, K., & 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*. https://doi.org/10.1128/jcm.01438-20

NIH. (2023a, March 6). *Clinical Spectrum of SARS-CoV-2 Infection*. National Institutes of Health. https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/

NIH. (2023b, March 6). *Testing for SARS-CoV-2 Infection*. National Institutes of Health. 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., Lamers, M. M., Sikkema, R. S., de Bruin, E., Chandler, F. D., Yazdanpanah, Y., Le Hingrat, Q., Descamps, D., Houhou-Fidouh, N., Reusken, C., Bosch, B. J., Drosten, C., Koopmans, M. P. G., & Haagmans, B. L. (2020). Severe Acute Respiratory Syndrome Coronavirus 2-Specific Antibody Responses in Coronavirus Disease 2019 Patients. *Emerg Infect Dis*, *26*(7). https://doi.org/10.3201/eid2607.200841

Oude Munnink, B. B., Nieuwenhuijse, D. F., Stein, M., O'Toole, Á., Haverkate, M., Mollers, M., Kamga, S. K., Schapendonk, C., Pronk, M., Lexmond, P., van der Linden, A., Bestebroer, T., Chestakova, I., Overmars, R. J., van Nieuwkoop, S., Molenkamp, R., van der Eijk, A. A., GeurtsvanKessel, C., Vennema, H., . . . 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. https://doi.org/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*. https://doi.org/10.1515/cclm-2020-0443

Palavecino, E. (2015). *One Sample, Multiple Results The Use of Multiplex PCR for Diagnosis of Infectious Syndromes*. Retrieved 11/1 from https://www.aacc.org/publications/cln/articles/2015/april/one-sample-multiple-results

Patel, P., DeCuir, J., Abrams, J., Campbell, A. P., Godfred-Cato, S., & Belay, E. D. (2021). Clinical Characteristics of Multisystem Inflammatory Syndrome in Adults: A Systematic Review. *JAMA Network Open*, *4*(9), e2126456-e2126456. https://doi.org/10.1001/jamanetworkopen.2021.26456

Peacock, W. F., Soto-Ruiz, K. M., House, S. L., Cannon, C. M., Headden, G., Tiffany, B., Motov, S., Merchant-Borna, K., Chang, A. M., Pearson, C., Patterson, B. W., Jones, A. E., Miller, J., Varon, J., Bastani, A., Clark, C., Rafique, Z., Kea, B., Eppensteiner, J., . . . Young, S. (2022). Utility of COVID-19 antigen testing in the emergency department. *Journal of the American College of Emergency Physicians Open*, *3*(1), e12605. https://doi.org/https://doi.org/10.1002/emp2.12605

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). https://doi.org/10.2807/1560-7917.Es.2020.25.9.2000152

Poljak, M., Korva, M., Gašper, N. K., Komloš, K. F., Sagadin, M., Uršič, T., Županc, T. A., Petrovec, M., & McAdam, A. J. (2020). Clinical Evaluation of the cobas SARS-CoV-2 Test and a Diagnostic Platform Switch during 48 Hours in the Midst of the COVID-19 Pandemic. *Journal of Clinical Microbiology*, *58*(6), e00599-00520. https://doi.org/doi:10.1128/JCM.00599-20

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

Qiagen_GmbH. (2020, 03/2020). *QIAstat-Dx® Respiratory SARS-CoV2 Panel Instructions for Use (Handbook)*. FDA. Retrieved 04/27/2020 from https://www.fda.gov/media/136571/download

Quidel_Corporation. (2020, 05/2020). *Sofia 2 SARS Antigen FIA*. FDA. Retrieved 05/12/2020 from https://www.fda.gov/media/137885/download

Ryding, S. (2020, June 24). *What is Viral Load?* Retrieved January 31 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)*. 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. https://doi.org/10.1016/j.jcv.2020.104455

Seo, G., Lee, G., Kim, M. J., Baek, S. H., Choi, M., Ku, K. B., Lee, C. S., Jun, S., Park, D., Kim, H. G., Kim, S. J., Lee, J. O., Kim, B. T., Park, E. C., & 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. https://doi.org/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. https://doi.org/10.7759/cureus.7708

Talbot, T. R., Hayden, M. K., Yokoe, D. S., Malani, A. N., Amer, H. A., Kalu, I. C., Logan, L. K., Moehring, R. W., Munoz-Price, S., Palmore, T. N., Weber, D. J., Wright, S. B., & Trustees, S. B. o. (2023). Asymptomatic screening for severe acute respiratory coronavirus virus 2 (SARS-CoV-2) as an infection prevention measure in healthcare facilities: Challenges and considerations. *Infect Control Hosp Epidemiol*, *44*(1), 2-7. https://doi.org/10.1017/ice.2022.295

Taylor, J., Carter, R. J., Lehnertz, N., Kazazian, L., Sullivan, M., Wang, X., Garfin, J., Diekman, S., Plumb, M., Bennet, M. E., Hale, T., Vallabhaneni, S., Namugenyi, S., Carpenter, D., Turner-Harper, D., Booth, M., Coursey, E. J., Martin, K., McMahon, M., . . . 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. https://doi.org/10.15585/mmwr.mm6937a3

The_Native_Antigen_Company. (2020, 03/24/2020). *Why We Need Antigen and Antibody Tests for COVID-19*. The Native Antigen Company. Retrieved 04/21/2020 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., Ng, A. C. K., Leung, K. H., Poon, R. W. S., Chan, K. H., Cheng, V. C. C., Hung, I. F. N., & 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. https://doi.org/10.1016/j.cmi.2018.06.009

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

US. (2020, 03/27/2020). *H.R.748 - CARES Act*. Retrieved 05/19/2020 from https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf

Verdoni, L., Mazza, A., Gervasoni, A., Martelli, L., Ruggeri, M., Ciuffreda, M., Bonanomi, E., & 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*. https://doi.org/10.1016/s0140-6736(20)31103-x

Villaverde, S., Domínguez-Rodríguez, S., Sabrido, G., Pérez-Jorge, C., Plata, M., Romero, M. P., Grasa, C. D., Jiménez, A. B., Heras, E., Broncano, A., Núñez, M. D. M., Illán, M., Merino, P., Soto, B., Molina-Arana, D., Bermejo, A., Mendoza, P., Gijón, M., Pérez-Moneo, B., . . . 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. https://doi.org/10.1016/j.jpeds.2021.01.027

Wang, F., Huang, S., Gao, R., Zhou, Y., Lai, C., Li, Z., Xian, W., Qian, X., Li, Z., Huang, Y., Tang, Q., Liu, P., Chen, R., Liu, R., Li, X., Tong, X., Zhou, X., Bai, Y., Duan, G., . . . 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. https://doi.org/10.1038/s41421-020-00231-4

Wang, R., Qian, C., Pang, Y., Li, M., Yang, Y., Ma, H., Zhao, M., Qian, F., Yu, H., Liu, Z., Ni, T., Zheng, Y., & Wang, Y. (2020). opvCRISPR: One-pot visual RT-LAMP-CRISPR platform for SARS-cov-2 detection. *Biosensors and Bioelectronics*, *172*, 112766. https://doi.org/https://doi.org/10.1016/j.bios.2020.112766

WHO. (2020a, 09/11/20). *Diagnostic testing for SARS-CoV-2*. Retrieved 11/08/20 from https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2

WHO. (2020b, 04/24/2020). *"Immunity passports" in the context of COVID-19*. World Health Organization. Retrieved 04/25/2020 from https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19

WHO. (2020c, 05/15/2020). *Multisystem inflammatory syndrome in children and adolescents with COVID-19*. World Health Organization. Retrieved 05/18/2020 from https://www.who.int/publications-detail/multisystem-inflammatory-syndrome-in-children-and-adolescents-with-covid-19

WHO. (2021a, October 6). *Antigen-detection in the diagnosis of SARS-CoV-2 infection*. World Health Organization. Retrieved 11/08/2020 from https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays

WHO. (2021b, November 2021). *COVID-19 Clinical management: living guidance*. World Health Organization. Retrieved April 19 from https://apps.who.int/iris/bitstream/handle/10665/349321/WHO-2019-nCoV-clinical-2021.2-eng.pdf

WHO. (2021c). COVID-19 natural immunity. file:///C:/Users/AHCS8330/Downloads/WHO-2019-nCoV-Sci-Brief-Natural-immunity-2021.1-eng.pdf

WHO. (2022a, November 11). *Coronavirus disease (COVID-19) Pandemic*. World Health Organization. https://www.who.int/emergencies/diseases/novel-coronavirus-2019

WHO. (2022b, 2022). *Middle East respiratory syndrome coronavirus (MERS-CoV)*. World Health Organization. Retrieved 08/19/2020 from https://www.who.int/emergencies/mers-cov/en/

WHO. (2022c). *SARS (Severe Acute Respiratory Syndrome)*. World Health Organization. Retrieved 04/19/2022 from https://www.who.int/ith/diseases/sars/en/

WHO. (2023, March 28). *Coronavirus disease (COVID-19)*. Retrieved 05/20/2020 from https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19

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

Wu, F., Liu, M., Wang, A., Lu, L., Wang, Q., Gu, C., Chen, J., Wu, Y., Xia, S., Ling, Y., Zhang, Y., Xun, J., Zhang, R., Xie, Y., Jiang, S., Zhu, T., Lu, H., Wen, Y., & 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*. https://doi.org/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. https://doi.org/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*. https://doi.org/10.1016/j.jinf.2020.03.012

Yang, X., Yu, Y., Xu, J., Shu, H., Xia, J., Liu, H., Wu, Y., Zhang, L., Yu, Z., Fang, M., Yu, T., Wang, Y., Pan, S., Zou, X., Yuan, S., & 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. https://doi.org/10.1016/s2213-2600(20)30079-5

Yau, F., Ferreira, R., Kamali, R., Bird, P. W., Halliwell, R., Patel, H., Nicoara, D. C., Woltmann, G., & 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. https://doi.org/10.1016/j.clinpr.2021.100086

Yelin, I., Aharony, N., Shaer Tamar, E., Argoetti, A., Messer, E., Berenbaum, D., Shafran, E., Kuzli, A., Gandali, N., Shkedi, O., Hashimshony, T., Mandel-Gutfreund, Y., Halberthal, M., Geffen, Y., Szwarcwort-Cohen, M., & Kishony, R. (2020). Evaluation of COVID-19 RT-qPCR test in multi-sample pools. *Clin Infect Dis*. https://doi.org/10.1093/cid/ciaa531

Zhang, Y. V., Wiencek, J., Meng, Q. H., Theel, E. S., Babic, N., Sepiashvili, L., Pecora, N. D., Slev, P., Cameron, A., Konforte, D., & 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*. https://doi.org/10.1093/clinchem/hvab051

Zhao, J., Yuan, Q., Wang, H., Liu, W., Liao, X., Su, Y., Wang, X., Yuan, J., Li, T., Li, J., Qian, S., Hong, C., Wang, F., Liu, Y., Wang, Z., He, Q., Li, Z., He, B., Zhang, T., . . . Zhang, Z. (2020). Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. *Clinical Infectious Diseases*. https://doi.org/10.1093/cid/ciaa344

Policy Update History:

7/17/2023	Document updated with literature review. The following changes were made to Reimbursement Information: Removed 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. Added: This policy only addressed testing for the purpose of medical decision making in the outpatient setting. This policy does not address work, school, state, or federally mandated SARS-CoV-2 testing. From #1, removed c: Asymptomatic individuals prior to undergoing immunosuppressive or aerosol-producing procedures. Added 12: In the outpatient setting, SARS CoV-2 genotyping is not reimbursable. Revised Notes accordingly; added Note 4 for signs and symptoms of a respiratory tract infection. Other changes made for clarity. References revised.
11/1/2022	New policy