If a conflict arises between a Clinical Payment and Coding Policy 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. Blue Cross and Blue Shield of New Mexico may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSNM 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 approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing Editor, American Medical Association, Current Procedural Terminology, CPT® Assistant, Healthcare Common Procedure Coding System, ICD-10 CM and PCS, National Drug Codes, Diagnosis Related Group guidelines, Centers for Medicare and Medicaid Services National Correct Coding Initiative 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

Approval Date: January 23, 2025

Plan Effective Date: April 15, 2025

Description

The Plan 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, (e.g., RT-PCR, rapid molecular tests), for COVID-19 (SARS-CoV-2) including rapid molecular tests **may be reimbursable** in the following situations:
    a. For individuals displaying signs and symptoms of possible COVID-19 infection (See **NOTE 2**).
    b. For 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. For individuals with signs or symptoms of sever acute respiratory syndrome (SARS) who have traveled to endemic areas or who have been exposed to persons with SARS, targeted nucleic acid testing, such as RT-PCR for the detection of SARS coronavirus RNA, **may be reimbursable**.

3. For individuals with signs and symptoms of Middle East respiratory syndrome (MERS) who have traveled to endemic areas or who have been exposed to persons with MERS, targeted nucleic acid testing, such as RT-PCR for the detection of MERS coronavirus RNA **may be reimbursable.**

4. To support a diagnosis of multisystem inflammatory syndrome in children (MIS-C) (see **Note 3)** multisystem inflammatory syndrome in adults (MIS-A) (see **Note 4**) or post-acute sequelae of SARS-CoV-2 infection (PASC), nucleic acid amplification testing and host antibody serology testing **may be reimbursable**.

5. For symptomatic individuals, antigen-detecting diagnostic tests for SARS-CoV-2 (e.g., antigen rapid tests) once every 48 hours **may be reimbursable**.

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

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

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

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

10. 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 fever, cough, fatigue, shortness of breath or difficulty breathing, congestion or runny nose, chills, muscle or body aches, headache, sore throat, new loss of taste or smell, nausea, vomiting, and diarrhea, conjunctivitis, (CDC, 2024g).

Note 3: According to the CDC, (CDC, 2024e) MIS-C is defined as an illness that is found in a person less than 21 years of age when **all** the following conditions are met:

- Subjective or documented fever of at least 38°C;
- Clinical severity requiring hospitalization;
- Evidence of systemic inflammation indicated by elevated C-reactive protein (CRP);
- New onset of manifestations in at least two of the following categories:
    - Cardiac involvement indicated by one of the following:
        - Left ventricular ejection fraction <55%,
        - Coronary artery dilatation, aneurysm, or ectasia,
        - Elevated troponin.
    - Mucocutaneous involvement indicated by one of the following:
        - Rash,
        - Inflammation of the oral mucosa,
        - Conjunctivitis or conjunctival injection,
        - Extremity findings (e.g., erythema or edema of the hands or feet).
    - Shock.
    - Gastrointestinal involvement indicated by one of the following:
        - Abdominal pain,
        - Vomiting,
        - Diarrhea.
    - Hematologic involvement indicated by one of the following:
        - Platelet count <150,000 cells/μL.
        - Absolute lymphocyte count.

Note 4: According to the CDC, (CDC, 2024e), MIS-A is defined as an illness that is found in a person 21 years of age or older when all the following conditions are met:

- Hospitalization for 24 hours or more;
- Subjective or documented fever of at least 38°C for one of the following:
    - 24 or more hours prior to hospitalization;
    - Within the first 3 days of hospitalization.

- No alternative diagnosis (e.g., bacterial sepsis).
- At least **three** of the following (occurring prior to hospitalization of within the first three days of hospitalization), with at least one being a primary clinical criterion:
    - Primary clinical criteria:
        - Severe cardiac illness (e.g., myocarditis, pericarditis, coronary artery dilation/aneurysm, new-onset right or left ventricular dysfunction, 2nd/3rd degree A-V block, ventricular tachycardia.
        - Rash **and** non-purulent conjunctivitis.
    - Secondary clinical criteria:
        - New-onset neurologic signs and symptoms (e.g., encephalopathy in an individual without prior cognitive impairment, seizures, meningeal signs, peripheral neuropathy including Guillain-Barré syndrome).
        - Shock or hypotension not attributable to medical therapy.
        - Abdominal pain, vomiting or diarrhea.
        - Thrombocytopenia.
- Evidence of SARS CoV-2 infection;
- Evidence of systemic inflammation (elevated CRP, ferritin, interleukin-6, erythrocyte sedimentation rate, or procalcitonin).

Note 5: Signs and symptoms of a respiratory tract infection:

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

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, 87635, 87798, 87811, 0224U, 0226U, 0408U, 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, May 14, 2020). *Serological testing for SARS-CoV-2 antibodies*. American Medical Association. https://www.ama-assn.org/delivering-care/public-health/serological-testing-sars-cov-2-antibodies

ASA, & APSF. (2022, December 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). *BioFire® Respiratory Panel 2.1 (RP2.1)*. FDA. https://www.fda.gov/media/137583/download

BioGerm. (2024). 2019-nCoV nucleic acid detection kit. https://www.bio-germ.com/

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. (2024). 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. (2020, Febuary 15). *Human Coronavirus Types*. CDC. Retrieved 05/15/2020 from https://archive.cdc.gov/#/details?url=https://www.cdc.gov/coronavirus/types.html

CDC. (2024a, June 13, 2024). *About COVID-19*. https://www.cdc.gov/covid/about/index.html

CDC. (2024b, January 8, 2024). *About Whole Genome Sequencing*. https://www.cdc.gov/pulsenet/php/wgs/

CDC. (2024c, October 31, 2024). *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. (2024d, July 11, 2024). *Long COVID Basics*. https://www.cdc.gov/covid/long-term-effects/

CDC. (2024e, May 29, 2024). *Multisystem Inflammatory Syndrome: Case Definitions and Reporting*. https://www.cdc.gov/mis/hcp/case-definition-reporting/index.html

CDC. (2024f, August 29, 2024). *Overview of Testing for SARS-CoV-2*. https://www.cdc.gov/covid/hcp/clinical-care/overview-testing-sars-cov-2.html

CDC. (2024g, June 25, 2024). *Symptoms of COVID-19*. https://www.cdc.gov/covid/signs-symptoms/

CDC. (2024h, August 24, 2024). *Testing for COVID-19*. https://www.cdc.gov/covid/testing/index.html

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/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). Considerations for the use of antibody tests for SARS-CoV-2 – first update. https://www.ecdc.europa.eu/en/publications-data/use-antibody-tests-sars-cov-2
ECDC. (2022b, December 15). *Testing strategies for SARS-CoV-2*. https://www.ecdc.europa.eu/en/covid-19/surveillance/testing-strategies
ECDC. (2023, 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
EpitopeDiagnostics. (2024). 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. (2020). *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. (2021c, August 5). *Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay*. https://www.fda.gov/media/139744/download
FDA. (2023a, November 8). *In Vitro Diagnostics EUAs*. https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
FDA. (2023b). *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
FDA. (2023c). Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease
FDA. (2023d). Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease

FDA. (2024a, July 1). *ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY SARS-CoV-2 RT-PCR Assay*. https://www.fda.gov/media/141192/download

FDA. (2024b, August 6). *CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay*. https://www.fda.gov/media/139743/download

FDA. (2024c, August 27). *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

Fox, T., Geppert, J., Dinnes, J., Scandrett, K., Bigio, J., Sulis, G., Hettiarachchi, D., Mathangasinghe, Y., Weeratunga, P., Wickramasinghe, D., Bergman, H., Buckley, B. S., Probyn, K., Sguassero, Y., Davenport, C., Cunningham, J., Dittrich, S., Emperador, D., Hooft, L., . . . Deeks, J. J. (2022). Antibody tests for identification of current and past infection with SARS-CoV-2. *Cochrane Database Syst Rev*, *11*(11), Cd013652. https://doi.org/10.1002/14651858.CD013652.pub2

Gandhi, R. (2024, March 19). *COVID-19: Clinical features*. Wolter Kluwer. Retrieved 08/19/2020 from https://www.uptodate.com/contents/covid-19-clinical-features

GenMark Diagnostics. (2024). 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/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. (2024, October 25 2024). *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. (2023). *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. (2024, Febuary 9). *Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19: Serologic Testing*. https://www.idsociety.org/practice-guideline/covid-19-guideline-serology/

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. (2022a, June 21). *ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY*. Retrieved 8/21/20 from https://www.fda.gov/media/136151/download
LabCorp. (2022b, June 21). *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

Morell, A., Skvaril, F., Noseda, G., & Barandun, S. (1973). Metabolic properties of human IgA subclasses. *Clin Exp Immunol*, *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

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. (2024a, May 20). *Clinical Spectrum of SARS-CoV-2 Infection*. National Institutes of Health. https://medlineplus.gov/covid19coronavirusdisease2019.html

NIH. (2024b, April 1). *Testing for SARS-CoV-2 Infection*. National Institutes of Health. https://medlineplus.gov/covid19testing.html

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

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. (2021, July). *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. (2022, March 25). *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. (2022). Use of SARS-CoV-2 antigen-detection rapid diagnostic tests for COVID-19 self-testing. https://www.who.int/publications/i/item/WHO-2019-nCoV-Ag-RDTs-Self_testing-2022.1

WHO. (2023, November 11). *Coronavirus disease (COVID-19) Pandemic*. World Health Organization. https://www.who.int/emergencies/diseases/novel-coronavirus-2019

WHO. (2024a, 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. (2024b). *SARS (Severe Acute Respiratory Syndrome)*. World Health Organization. Retrieved 04/19/2022 from https://www.who.int/ith/diseases/sars/en/

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:

Approval Date	Effective Date; Summary of Revisions
01/23/2025	04/15/2025; Document updated with literature review. The following changes were made to Reimbursement Information: Added rapid molecular tests as testing option in #1; removed 1c: for asymptomatic individuals prior to undergoing immunosuppressive or aerosol-producing procedures; added NAAT as an acceptable test option for MIS-A and MIS-C in #4; updated #5 to include once every 48 hour frequency; removed #7 and #9 as they are appropriately managed in CPCPLAB045 Pathogen Panel Testing; removed #8 for genotyping. Updated Note 2 with updated CDC signs and symptoms of COVID-19; updated Note 3 and Note 4 with updated CDC clinical requirements for suspected MIS-C and MIS-1. Removed codes 86790, 87631, 87632, 87633, 87797, 87799, 0115U, 0202U, 0223U, 0225U, C9803. References revised.
03/15/2024	Document updated with literature review. Reimbursement information unchanged. References revised; some added, others removed. Removed codes G2023, G2024, U0003, U0004, U0005.
03/01/2024	Added code 0408U. No other changes made.
11/01/2023	Document updated with literature review. Reimbursement information revised for clarity. References revised; some added, others removed.
11/01/2022	New policy