Reimbursement Policy

Coronavirus Testing in the Outpatient Setting

I. Policy Description

Human coronaviruses, first characterized in the 1960s, are named based on the spiked proteins located on their surface. As of 2020, seven coronaviruses are known to infect humans. Four, of which—229E, NL63, OC43, and HKU1—are associated with the common cold. MERS-CoV is the coronavirus that causes Middle East Respiratory Syndrome, or MERS. SARS-CoV is the causative agent of Severe Acute Respiratory Syndrome (SARS), and SARS-CoV-2 is the virus that causes coronavirus disease 2019, or COVID-19 (CDC, 2020, 2024a). As of June 1, 2024, the United States had reported that nearly 1.2 million people have died of COVID-19 (CDC, 2024a). Testing for a possible coronavirus infection can include molecular tests, such as nucleic acid-based testing like reverse transcription polymerase chain reaction (RT-PCR); host antibody testing; and antigen testing.

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

This policy only addresses 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**) MEETS COVERAGE CRITERIA** in any of the following situations:
   a) For individuals displaying signs and symptoms of possible COVID-19 infection (See Note 1).
   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 SARS and who have traveled to endemic areas or who have been exposed to persons with SARS, targeted nucleic acid testing (e.g., RT-PCR) for the detection of severe acute respiratory syndrome (SARS) coronavirus RNA **MEETS COVERAGE CRITERIA**.

Reimbursement Policy

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

4) 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), nucleic acid amplification testing and host antibody serology testing **MEET COVERAGE CRITERIA**.

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

6) For individuals with signs and symptoms of a respiratory tract infection (see Note 4), antigen panel testing of up to 5 antigens **MEETS COVERAGE CRITERIA**.

7) For the diagnosis of SARS-CoV-2 reinfection, whole genome sequencing of paired specimens from distinct lineages (as defined in Nextstrain or GISAID) **DOES NOT MEET COVERAGE CRITERIA**.

8) Antigen panel testing of 6 or more antigens **DOES NOT MEET COVERAGE CRITERIA**.

9) For all other situations not described above, host antibody serology testing **DOES NOT MEET COVERAGE CRITERIA**.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

10) In the outpatient setting, SARS-CoV-2 genotyping **DOES NOT MEET COVERAGE CRITERIA**.

11) For all situations, neutralization antibody testing for SARS-CoV-**2 DOES NOT MEET COVERAGE CRITERIA**.

12) Testing for other endemic coronaviruses, such as 229E, NL63, OC43, and HKU1, **DOES NOT MEET COVERAGE CRITERIA**.

NOTES:

Note 1: 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 (CDC, 2024g).

Note 2: According 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** of 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 3: 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 of 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 or 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, $2^{nd}/3^{rd}$ 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 individuals 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 4: Signs and symptoms of a respiratory tract infection:

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

III. Reimbursement

1) AMA standard practice for COVID-19 testing states not to include both the HCPCS and AMA code for the same procedure on the 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.

IV. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, please visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

The FDA issued an "Immediately in Effect Guidance on policy for diagnostics testing in laboratories certified to perform high complexity testing under CLIA prior to Emergency Use

Authorization for Coronavirus Disease-2019 during the public health emergency" in February 2020 (FDA, 2024c). This policy was updated on May 11, 2020 to state that the "policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act)" (FDA, 2023b). As of October 15, 2021, the FDA had issued 418 different EUAs for COVID-19 testing for either *in vitro* diagnostic products (which includes testing such as point-of-care tests, antibody testing, and antigen testing) or high complexity molecular-based laboratory developed tests (FDA, 2021a).

Moreover, within the HR 748, passed as the CARES Act (or Coronavirus Aid, Relief, and Economic Security Act) as public law 116-136 on March 27, 2020, there are sections concerning coverage and pricing of diagnostic testing for COVID-19 (US, 2020).

In March 2023, the FDA released a "transition plan for medical devices that fall within enforcement policies issued during the coronavirus disease 2019 (COVID-19) public health emergency" and a "transition plan for medical devices issued emergency use authorizations (EUAs) related to coronavirus disease 2019 (COVID-19)." These guidelines are meant to outline the FDA's recommendations during the transition from the COVID-19 pandemic to normal operations (FDA, 2023c, 2023d).

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

V. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
86318	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip)
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
86408	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID19]); screen
86409	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID19]); titer
86413	Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative

Reimbursement Policy

CPT	Code Description
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
87426	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])
87428	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B
87635	Infectious agent detection by nucleic acid (DNA or RNA);severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism
87811	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
87913	Infectious agent genotype analysis by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), mutation identification in targeted region(s)
0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed Proprietary test: COVID-19 Antibody Test Lab/Manufacturer: Mount Sinai Laboratory/Mt Sinai
0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum Proprietary test: Tru-Immune™ Lab/Manufacturer: Ethos Laboratories/GenScript® USA Inc
0408U	Infectious agent antigen detection by bulk acoustic wave biosensor immunoassay, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) Proprietary test: Omnia™ SARS-CoV-2 Antigen Test Lab/Manufacturer: Qorvo Biotechnologies
U0001	CDC Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel

Reimbursement Policy

CPT	Code Description
U0002	Non-CDC laboratory test for 2019-nCoV (COVID-19), any method

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

VI. Evidence-based Scientific 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

Reimbursement Policy

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