AVALON HEALTHCARE SOLUTIONS

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COVID-19 TESTING BRIEF

from Avalon Healthcare Solutions

CONTENTS

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Avalon is the expert in laboratory and medical specialty drug benefit management. Our solutions are driven by evidence-based medical science. Avalon's core program includes full delegation of Routine Testing Management, Genetic Testing Management, Independent Laboratory Network Management, and Medical Specialty Rx Management. Our comprehensive solutions manage all out-patient lab spend across all lab testing types. Avalon helps physicians, consumers, and payers maximize the cost-effective use of diagnostic laboratory tests. Avalon Healthcare Solutions is a registered d/b/a of Avalon Health Services, LLC.

AVALON LABORATORY NETWORK CAPABILITY & CAPACITY REPORT

The current daily capacity for RT-PCR testing exceeds 230,000 tests/day. The following labs have reported their intent to increase capacity:

LabCorp to increase by June:

- RT-PCR capacity increase to 150,000 tests/day
- Antibody capacity increase to 300,000 tests/day

Quest Diagnostics to increase by mid-May:

- Antibody capacity increase to 200,000 tests/day

BioReference Laboratories to increase by June:

- Antibody capacity increase to 400,000 tests/day

LAB	HEALTHPLAN	RT-PCR Y/N	MULTI PLAT-FORMS?	CAPA-CITY (PER DAY)	TURN-AROUND TIME	ANTIBODY TESTING Y/N	METHODOLOGY	CAPA-CITY (PER DAY)	TURN-AROUND TIME
LabCorp	SC, NC	Y	Y	75,000	1-3 days	Y	Elisa & Chemiluminscence	70,000	1-3 days
Quest	SC, NC, CBC, VT	Y	Y	50,000	1-2 days	Y	Elisa & Chemiluminscence	150,000	1-2 days
BioReference	SC, NC, CBC, VT	Y	Y	35,000	1-2 days	Y	Chemiluminscence	100,000	3 days
Sonic CPL (Clinical Pathology Lab)	SC	Y	Y	20,000	1-3 days	Y	Elisa	100,000	24 hrs
Mako Medical Lab	SC, NC	Y	Y	12,000	1-2 days	Y	Elisa & Chemiluminscence	11,000	1 day
Premier Medical Lab	SC	Y	Y	10,000	1-3 days	Y	Elisa	6,000	1-2 days
Eurofins-Diatherix**	SC, NC, CBC, VT	Y	N	5,000	1-2 days	Y	Chemiluminscence	5,000	2-4 days
MDL (Medical Diagnostic Lab)	SC, NC, CBC, VT	Y	N	5,000	1-2 days	Y	Elisa	1,000	3 days
Neogenomics	SC, NC, CBC, VT	Y	Y	3,400	1-4 days	N		N/A	
AIT (American Institute of Tox)	SC, NC, CBC	Y	Y	2,600	1-2 days	N		N/A	
BAKO	SC, NC, CBC, VT	Y	N	2,500	1-2 days	N		N/A	
Precision Genetics	SC, NC	Y	N	2,400	1 day	N		N/A	
PathGroup	NC	Y	Y	2,200	1-2 days	Y	Elisa & Chemiluminscence	500	1 day
LabTech	SC, NC	Y	Y	2,000	1-2 days	Y	Chemiluminscence	3,000	1 day
Luxor	SC	Y	Y	1,000	1-3 days	Y	Elisa	350	1-2 days
Wake Medical Lab Consultants	NC	Y	Y	1,000	1 day	N		N/A	
SMA	CBC	Y	Y	1,000	1-2 days	N		N/A	
Inform Diagnostics	SC, NC, CBC, VT	Y	N	200	1-2 days	N		N/A	

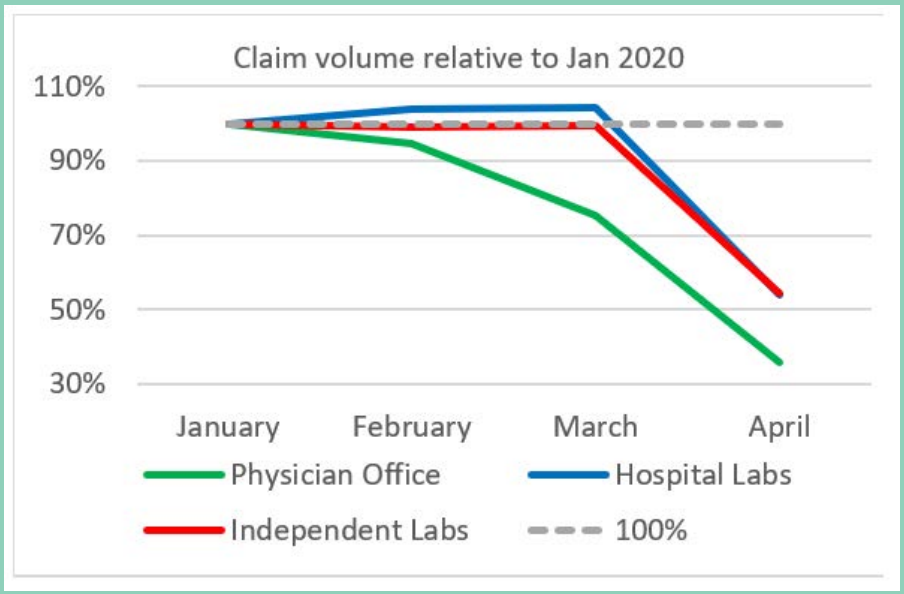
Data from the COVID Tracking Project indicates a current 3-day average (May 11-13) of 338,053 tests performed per day. The Harvard Global Health Initiative suggests that 500,000 to 700,000 tests are needed each day to support the re-opening of the US economy.

WHAT ARE THE LIMITATIONS TO TESTING?

A recent survey of laboratories denotes the following hurdles to testing for COVID-19:

- 58% noted a shortage of NP swabs (used in RT-PCR testing)
- 57% noted a shortage of PPE required to protect sample collection personnel
- 47% noted difficulty obtaining reagents or the tests necessary to perform testing

This information is interesting in that it indicates that the collection of subject specimens is the larger hurdle to testing than is the actual performance of the test. Access is also a contributor to the lower daily capacity for testing. Prior to the COVID-19 epidemic in the US, the physician office was the primary "gateway" for laboratory testing. An individual would visit their physician, undergo an exam and if necessary, receive an order for a lab test. The specimen for testing would be collected in the office or the individual would be directed to a lab site where the appropriate specimen would be collected. However, the COVID crisis upset this process in two ways. First, the infectious nature of the virus dictated special precautions for specimen collection. Second, physician offices and lab collection depots were no longer in service. The enclosed chart demonstrates the issue with respect to access to physician office testing.



2020 lab claims originating from each place of service show a significant reduction in April, with physician office labs beginning a steeper drop in March. Each line represents claim volume vs. January 2020, for example, hospital claim volume in April was slightly over 50% of the claim volume in January. 2019 data for the same time period shows laboratory claim volume consistent month-to-month with no reduction (data not shown).

WHERE IS TESTING FOR COVID-19 TAKING PLACE?

The news outlets frequently identify sites where testing is taking place, often in a "drive-in" format where the individual remains in their car and specimens are collected. Typically, these sites are reserved for individuals with symptoms, persons that have been exposed to an infected individual or for frontline healthcare workers. In these cases, there is a medically necessary reason for testing. However, there are additional screening opportunities that are more data driven:

- **Employer testing** to assure the welfare and safety of their employee base (parallel to employee drug screening)
- **Serological surveys**. These are epidemiological or prevalence studies in designated communities funded by federal, state, and local public health entities.

FDA ISSUES FIRST COVID-19 EUA FOR ANTIGEN TESTING

On May 8, 2020, the FDA issued the first Emergency Use Authorization (EUA) for antigen testing for COVID-19. An antigen is a protein, or part of a protein, located on a virus or bacteria that can cause an immune response in an individual. What makes this method of testing distinct from antibody testing is that antigen testing directly measures the presence of the virus in a person whereas antibody testing is measuring the patient's response to an infection. Located on the surface of the virus that causes COVID-19, the SARS-CoV-2 virus, are proteins, such as the spike proteins (S) **(Figure 1)**, while other proteins called the nucleocapsid proteins (N) help package the viral genome. The Quidel Corporation has been granted an EUA for their Sofia®2 SARS Antigen FIA lateral flow immunofluorescent sandwich assay for the qualitative detection of the nucleocapsid (N) protein antigen of SARS-CoV-2 for use in individuals suspected of COVID-19 by their healthcare provider.[3] This test has been approved as a point-of-care (POC) test.[5]

How does this test work? The test detects the N protein of either the SARS-CoV or SARS-CoV-2 virus from an upper respiratory sample (either a nasal swab or nasopharyngeal swab). First, the sample is placed in a reagent tube so that any virus, if present, is broken apart to allow for the N proteins to be exposed. The sample then travels from the sample well, down a test strip—where the term "lateral flow" is derived—where the proprietary reagents will recognize any N proteins and trap them in

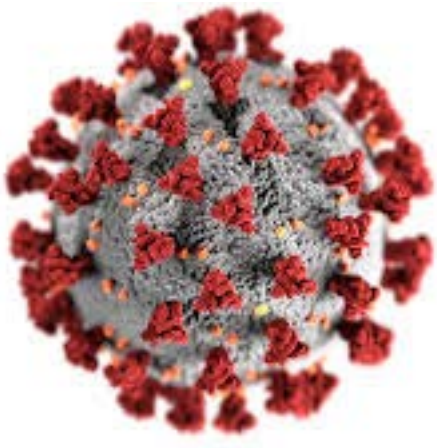


Figure 1: *Illustration of COVID-19. Provided by the Public Health Image Library of the Centers for Disease Control and Prevention (CDC)2, this illustration shows the structures associated with coronaviruses. Proteins, such as the S protein (denoted in red), may be antigens that can possibly be used for direct antigen testing.*

place on the strip. The test requires at least 15 minutes to develop prior to analysis. The strip can then be read by the Sofia®2 system that measures the fluorescent signal from the proprietary reagents. The Sofia®2 system allows the user to have two different modes for analysis—"Walk Away" and "Read Now".

For the "Walk Away" mode, the user will insert the test cassette strip into the system, and the results will be displayed in 15 minutes because the test will be developed while in the instrument. In "Read Now" mode, the user must have already allowed at least 15 minutes for the test to develop prior to inserting it into the instrument. Then, the Sofia®2 system will display the result within one minute.

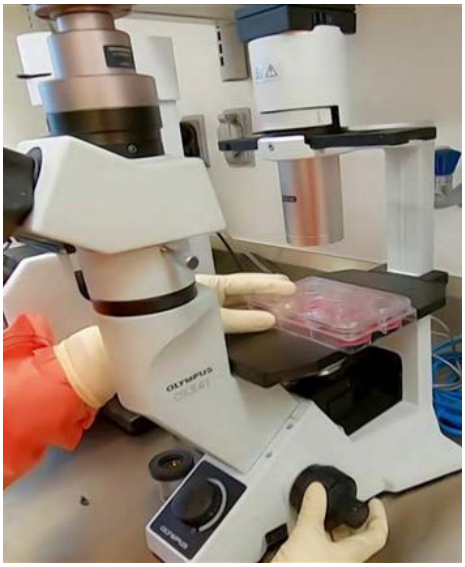
To address the clinical performance, two primary studies were performed. Both studies only used frozen samples. The first study used 143 samples with 80% PPA or Positive Percent Agreement (47/59 of positive samples tested "positive"). They report 100% NPA or Negative Percent Agreement—all 84 negative samples tested "negative". The second study used a total of 48 samples. Again, 80% of the positive samples tested "positive"; however, only a total of five positive samples were included within this second study.

The remaining 43 samples were all negative samples. This study reports a sensitivity of 80.0%, but a 95% confidence interval range of 37.6% - 96.4%. A third supportive study was also performed. In this study, thirty swabs were taken. Twenty of these swabs were spiked with one lower concentration of the virus while the remaining ten swabs were spiked with a higher concentration of the virus. Then, all 30 swabs were tested and compared to 47 control ("unspiked") samples.

In this study, none of the "unspiked" control samples tested "positive" while all 30 of the "spiked" samples, regardless of the concentration, tested positive. Quidel also tested the limit of detection (LoD) of the Sofia®2 SARS Antigen FIA test. LoD is typically measured by determining the TCID50 (median tissue culture infective dose). The TCID50 is the amount where 50% of the cells within a sample are infected.[6]

For the Sofia®2 SARS Antigen FIA test, the LoD for a direct swab sample has a TCID50 of 113 mL whereas it is 850 mL if the initial sample is from a swab sample that has been diluted into 3 mL of reagent. Finally, Quidel also checked this antigen test for possible cross-reactivity with a number of microorganisms and other viruses. It shows no cross-reactivity with any of the microorganisms or viruses tests other than SARS-CoV.

Of note, it does not cross-react with human coronavirus 229e, OC43, NL63, or MERS-CoV (heat-inactivated); however, they did not check for possible cross-reactivity with the other known human coronavirus (HKU1) due to a lack of availability at this time. This is noteworthy since this coronavirus is associated with the common cold.



What are the limitations to the Sofia®2 SARS Antigen FIA test? Limitations include the following:

- This test must be performed using the Sofia®2 system, and the test must be performed accurately following the test procedure. Failure to do so can adversely affect the performance of the test and may invalidate the results.

- A positive test cannot distinguish between a SARS-CoV or a SARS-CoV-2 infection. SARS-CoV is the virus that caused the SARS outbreak of 2003. It should be noted that there is no current outbreak of SARS.

- This test also does not distinguish between "live" (viable) virus and non-viable virus. Consequently, the test results do not necessarily correlate with viral culture results performed on the same sample.

- This test is only for the qualitative use on a sample from either a nasal swab or a nasopharyngeal swab. It has not been approved for use, at this time, on any other sample, such as saliva.

- Negative test results can occur if the viral level is below the lower limit of the test. ***All negative results "should be treated as presumptive and confirmed with an FDA authorized molecular assay, if necessary, for clinical management, including infection control"***[3] [emphasis added]

- Positive test results do not rule out co-infections, and negative results do not "rule in" other non-SARS viral or bacterial infections.

- The clinical performance assays submitted for FDA approval were performed using frozen samples; the test may have a different performance when used with a fresh sample (such as in a point-of-care setting).

- "If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments is required."[3]

- As previously noted, the company did not check this test (as of publication date) for cross-reactivity with human coronavirus HKU1 due to a lack of availability of that strain. This is notable since this particular virus is associated with upper respiratory conditions such as the common cold.

IDSA RELEASES NEW GUIDELINES ON COVID-19 TESTING

The Infectious Diseases Society of America (IDSA) on May 6, 2020, released their guidelines on the diagnosis of COVID-19. At this time, they focus solely on the use of targeted nucleic acid testing, such as RT-PCR, because "[a]t the time of this review, there was little evidence to inform use of serologic testing."[4] The IDSA convened a multidisciplinary panel of experts to review the research and literature on the available diagnostic testing for COVID-19. The panel used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology to assess the evidence of the studies and to make their recommendations.

A primary recommendation implies that diagnostic testing and specimen collection devices are available whereas a contingency recommendation is made for situations where testing and/or personal protective equipment (PPE) are limited.

The panel made 15 recommendations concerning the use of nucleic acid testing as follows:

1. They ***strongly*** recommend using a nucleic acid amplification test (NAAT), such as RT-PCR, in symptomatic patients even when clinical suspicion for COVID-19 is low.

2. They ***strongly*** recommend RNA testing in immunocompromised asymptomatic individuals who are being admitted to the hospital regardless of exposure to COVID-19.

3. They ***strongly*** recommend RNA testing (versus no testing) in asymptomatic individuals before immunosuppressive procedures regardless of a known exposure to COVID-19.

4. They suggest (conditional recommendation) using a nasopharyngeal, mid-turbinate, or nasal swab rather than oropharyngeal swab or saliva sample for testing.

5. They suggest (conditional recommendation) that either a patient or a healthcare provider can collect a nasal or mid-turbinate sample in a symptomatic patient.

6. They make NO recommendation for or against the use of rapid nucleic acid testing (where the test time is within one hour) versus standard RNA testing. They cite a knowledge gap. More research is needed.

7. They suggest (conditional recommendation) RNA testing in asymptomatic individuals who are

either known or suspected to have been exposed to COVID-19.

8. They suggest against (conditional recommendation) RNA testing in asymptomatic individuals with no known contact with COVID-19 who are being hospitalized in areas with low prevalence. They consider a low prevalence rate to be less than 2% of the community.

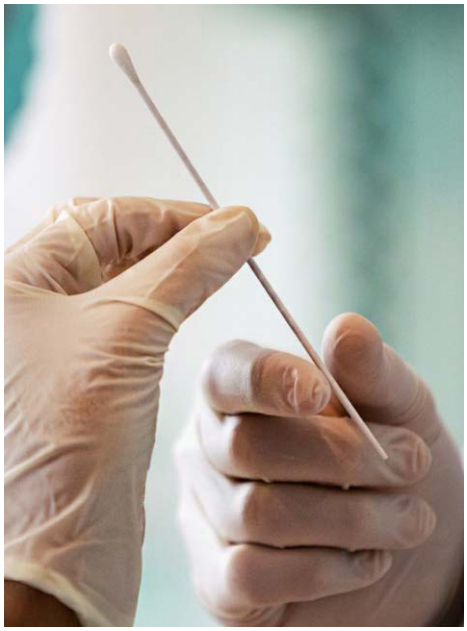
9. They recommend (conditional recommendation) RNA testing in asymptomatic individuals with no known contact with COVID-19 who are being hospitalized in areas with high prevalence of the disease. They consider a high prevalence rate to be 10% or higher. The IDSA does note that if the prevalence rate is between 2% and 9% the decision to test should be dependent on the availability of testing resources.

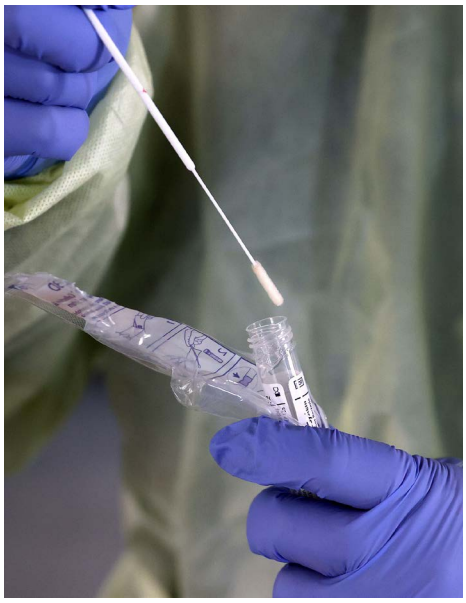
10. They suggest (conditional recommendation) performing only one test in a symptomatic individual and not repeat testing if low clinical suspicion of COVID-19.

11. The suggest (conditional recommendation) repeat testing of an initial negative result in a symptomatic individual be performed only if there is an intermediate or high clinical suspicion of COVID-19.

12. For hospitalized patients, they suggest (conditional recommendation) initially collecting an upper respiratory tract sample. Then, collect the lower respiratory tract sample if the initial upper respiratory tract sample result is negative but suspicion of a COVID-19 infection is still high.

13. They suggest (conditional recommendation) RNA testing in asymptomatic individuals without known exposure to COVID-19





who are undergoing major time-sensitive surgeries.

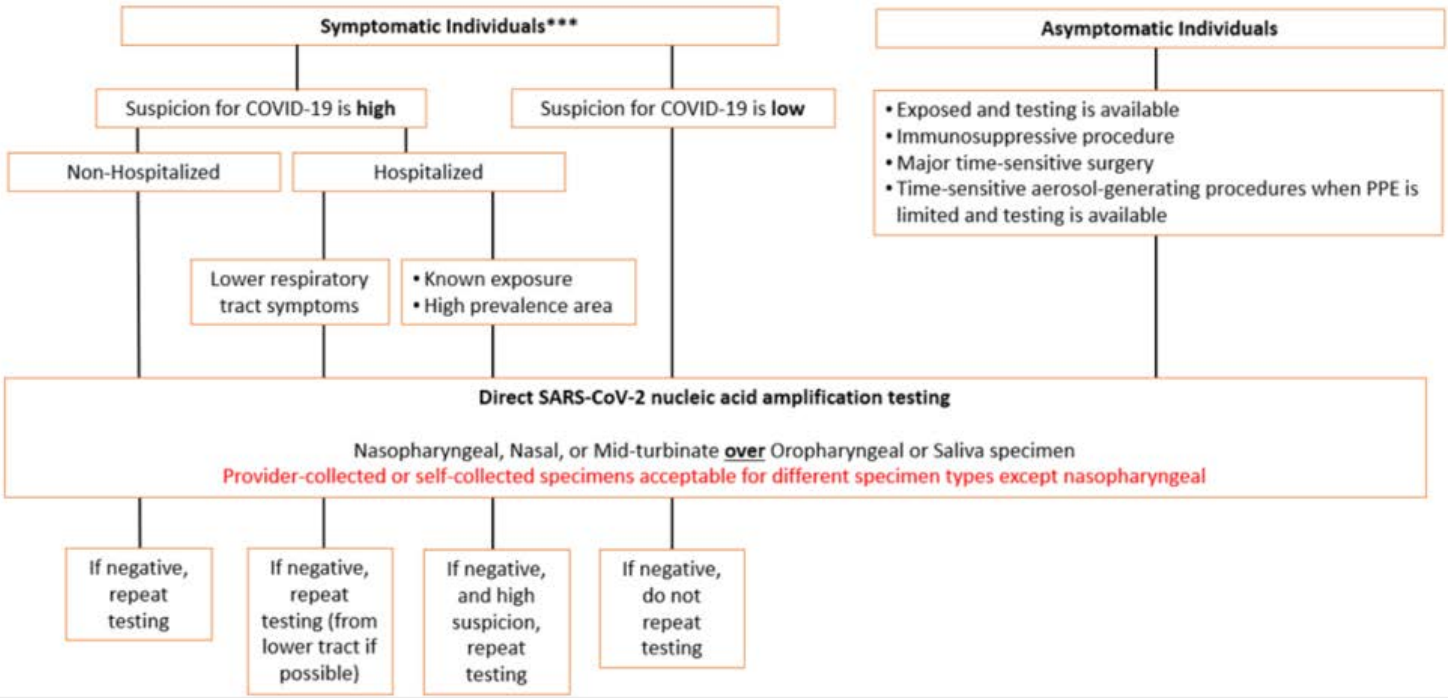
14. They suggest (conditional recommendation) RNA testing in asymptomatic individuals without known exposure to COVID-19 who are undergoing time-sensitive aerosol-generating procedures, such as a bronchoscopy, when PPE is available.

15. Likewise, they suggest (conditional recommendation) RNA testing in asymptomatic individuals without known exposure to COVID-19 who are undergoing time-sensitive aerosol-generating procedures when PPE is limited and testing is available. For this recommendation, the IDSA gives greater detail due to restrictions in availability of PPE. They also note that their recommendation does not address the need for repeat testing if patients require multiple procedures over time.

Besides the 15 recommendations, the IDSA panel also released their algorithm for SARS-CoV-2 Nucleic Acid Testing. This algorithm, as seen in Figure 2, separates individuals into symptomatic and asymptomatic groups.

The IDSA notes that testing should be prioritized for symptomatic patients first. When resources are sufficient, then testing for selected asymptomatic individuals can be considered. Regardless, the preferred testing methodology is direct SARS-CoV-2 nucleic acid amplification testing, such as RT-PCR.

ISDA ALGORITHM FOR SARS COV-2 NUCLEIC ACID TESTING



***Note: Testing should be prioritized for symptomatic patients first. When resources are adequate, testing for selected asymptomatic individuals should also be considered.

Figure 2: *IDSA Algorithm for SARS-CoV-2 Nucleic Acid Testing.1 The Infectious Diseases Society of America (IDSA) released their algorithm for nucleic acid testing for COVID-19. According to the IDSA guidelines, testing priority should first be given to symptomatic patients; if resources are available, then testing asymptomatic individuals can be considered. Regardless, patients undergoing time-sensitive immunosuppressive procedures should be tested.*[4]

MAKING SENSE OF CODING POSSIBILITIES TO TRACK COVID-19 CLAIMS FOR COST SHARING REQUIREMENTS AND FWA

The passing of the FFCRA (March 18th) and CARES Acts[7] (March 27th) mandated no cost sharing for covered members and consequently produced an acute need for identification of services and procedures related to diagnosing COVID 19. The rapid pace of legal changes and uncertainty associated with coding complicates compliance.

Additionally, detection of Fraud, Waste and Abuse (FWA) utilizing systematic methods would benefit from standardization of coding in claims data sets.

In response to COVID-19, many organizations began announcing codes to assist health care systems to properly classify clinical situations of patients and associated services. The World Health Organization (WHO) released emergency ICD10 designations, CMS and AMA produced procedure codes for testing, CDC released guidelines for sample collection, WHO outlined coding and reporting requirements, and CMS drafted coding requirements to name a few.

Additionally, with the legislated no cost share requirements, the CS procedure code modifier has been resurrected to assist in COVID-19 claim identification. Plans are racing to ensure proper identification of claims and services to remain in compliance and appropriately apply the cost sharing exemptions without creating overly broad pathways to reimbursement. Inevitably, unscrupulous providers are attempting to take advantage of the changes for their own financial gain.[8] While the CARES Act and related guidance are quiet on application of FWA, we don't believe the government intended to condone services and payments outside of medical necessity. The health plans have an obligation to address FWA and should be prepared to ascertain questionable claims and systemic abuse and waste, and standardized coding of claims is the foundation any post process analytical evaluation to detect FWA.

Ultimately, the health plans will need to establish their own policies specifying appropriate coding methods and the types of services included in "related services" as outlined in the Agency's FAQ.[9] The following provides an overview of the available codes and some considerations when building policies.

DIAGNOSIS CODES

The WHO maintains the ICD10 guidelines and published recommendations for coding and reporting.[10] Specifically, prior to a definitive diagnosis, the provider should document signs and symptoms consistent with COVID-19 infections and if appropriate utilize **Z20.828**. Standard coding best practices utilize the most specific diagnosis codes relevant to the clinical situation. Some signs and symptoms of COVID-19 include, but not limited to, fever, cough, shortness of breath, headache, etc.[11]

Z03.818 – Encounter for observation for suspected exposure to other biological agents ruled out

Z20.828 – Contact with and (suspected) exposure to other viral communicable diseases

Z11.59 – Encounter for screening for other viral diseases

U07.1 – COVID-19, virus identified

For individuals who may have had exposure to COVID-19 and subsequently ruled out, use **Z03.818**. If the individual had been exposed to the virus (via someone who is confirmed or suspected of viral infection) and test results are negative or unknown, **Z20.828** is the recommended ICD10 code.

Screening of asymptomatic individuals who have not knowingly been exposed to the virus, should use **Z11.59** when the test results are unknown or negative. Once a presumptive positive or definitive diagnosis of COVID-19 has been reached, the diagnosis code **U07.1** should be used.[12]

PROCEDURE CODES

Briefly, three types of tests can be performed to ascertain COVID-19 current or prior infection. PCR based testing, which measures the amount of viral RNA, is definitive for an active, current infection with great certainty and is considered the current gold standard. Antibody testing measures the body's response to current or prior COVID-19 testing but is not recommended to be used for determination of an active infection and does not assess future immunity. Antigen testing assesses the amount of viral surface proteins in the patient's blood providing a different method from PCR for measuring active disease.

PROCEDURE CODE	SHORT DESCRIPTION AND USAGE	EFFECTIVE DATE
U0001	PCR based testing - utilizing test kits from the CDC to perform the testing	4/1/20
U0002	SPCR based testing – utilizing laboratory developed kits (non-CDC), non-amplified probe	4/1/20
87635	Amplified probe PCR testing	3/13/20
U0003	Amplified probe using high throughput technology	4/14/20
U0004	High throughput technology using any technique	4/14/20
86328	Antibody test - Single step method (e.g. reagent strip) for the detection of COVID-19	4/10/20
86769	Antibody test – Multistep method (e.g. analyzer) for the detection of COVID-19	4/10/20
87299	Infectious agent antigen detection by immunofluorescent technique; not otherwise specified	
G2023	Specimen collection from individuals who cannot leave their home	3/1/20
G2024	Specimen collection at a skilled nursing facility or by a lab on behalf of a home health agency	3/1/20

As of the publication date, only one antigen testing kit, Quidel Corporation, was commercially available[13] (FDA EUA issued on May 8, 2020) and with clinical validity much less than PCR-based testing.[14] However, developments will occur in this area and potentially broaden the capacity and reduce the cost of testing.

PCR TESTING CODES

In February, CMS announced two codes related to COVID-19 testing, **U0001** and **U0002** with the notice that claims would be accepted with these codes on April 1, 2020. **U0001** specified tests that were performed

using test kits obtained from the CDC. **U0002** indicated tests kits that were developed by a non-CDC laboratory and interestingly, the analytical requirements were non-amplified probe only.

On March 13, 2020, the American Medical Association released **87635** for PCR based testing using an

amplified probe. On April 14, 2020, CMS released to additional codes for high throughput technologies, **U0003**, amplified probes using high throughput technology, and **U0004**, any technique using high throughput technology.

AB TESTING CODES

On April 10, AMA released two codes, **86328** and **86769**, for Ab testing specific to COVID-19. The codes are non-specific to the type of antibody detected (i.e. IgG or IgM can be billed with either) and therefore if two antibodies are tested, the code and be billed twice. Single step methods should bill **86328**, while multistep methods should bill **86769**.

ANTIGEN TESTING CODES

Antigen tests will not have been received as claims at the time of this publication, however, two codes are anticipated to be used until AMA releases a specific COVID-19 antigen code. **U0002** is suitable for antigen testing as the methodology for the assay is not limited to PCR by the CMS code description. However, the closest AMA code is **87299** which is a non-specific antigen testing code.

SAMPLING CODES

In addition to testing codes, CMS released two codes specific to sample collection: **G2023** and **G2024**. These codes are specific for independent laboratories collecting samples from individuals who are home bound **(G2023)**, in a skilled nursing facility **(G2024)**[15] or on behalf of a home health agency **(G2024)**.

Some commercial plans are considering these codes to be incorporated into the service and not separately reimbursable. The sampling codes are part of an interim final rule promulgated by CMS published on May 8, 2020 in the Federal Register. While they are effective, they are subject to a 60-day comment period.

PLA CODES

PLA (Proprietary Laboratory Analyses) codes allow for manufacturers or laboratories to more specifically identify their tests. As of this publication, one laboratory, BioFire, has submitted a request for a PLA code to include a bundle COVID-19 and 21 other respiratory pathogens.[16]

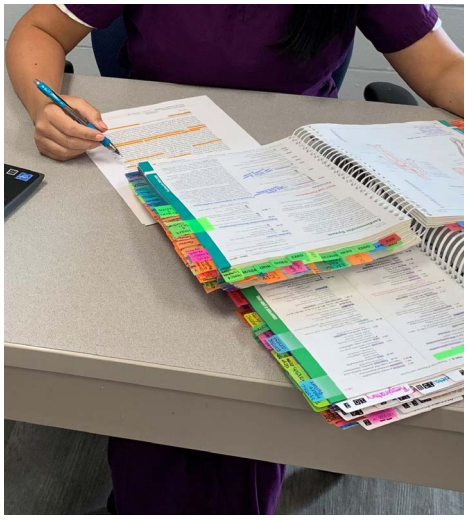
PROCEDURE CODE MODIFIERS

Two modifiers are relevant for COVID-19 claims. Modifier 59 indicates additional samples were tested on the same date of service and therefore should both be billable events. Initially, swabs for both throat and nose were collected and processed separately, and subsequently, two tests were performed. CDC changed their recommendation for sample collection to sample the throat only, and if throat and nose are collected, then combine both into a single sample tube.

Based on this, a single sampler per date of service is sufficient, and modifier 59's importance has been reduced. However, during early stages of the outbreak, some claims may legitimately represent both samples and therefore two tests.

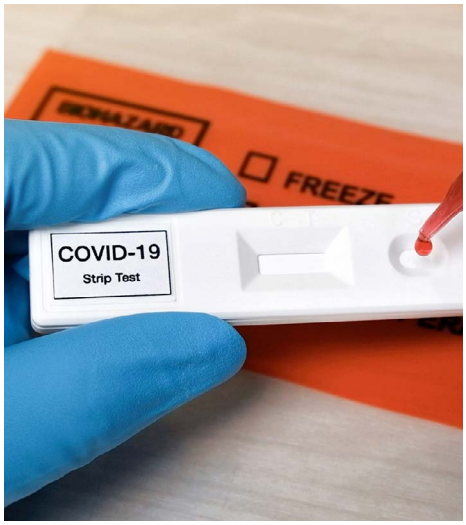
Modifier CS represents "cost sharing", and per CMS guidelines[17], is a requirement on individual lines of a claim if the service represented at the line is to be exempted from member responsibility for services rendered after March 18, 2020. Further, providers are recommended to resubmit prior claims with the CS modifier if those services meet the standards for exemption from member cost sharing.

While CMS is requiring the use of the CS modifier on Medicare claims, several commercial health plans have adopted the same rules to make tracking of claims for cost share exemption to be readily identifiable.



IDENTIFICATION OF COVID CLAIMS

Collectively, claims with COVID-19 related services should be identifiable by several methods. Prior to diagnosis, the WHO[18] is recommending coding for signs and symptoms and, as appropriate, ICD10 code **Z20.828**. However, the signs and symptoms overlap with other clinical conditions, and therefore alone do not necessarily ensure the services



rendered leading to a COVID-19 diagnostic test. To add further confusion, claims utilizing **Z11.59** do not necessarily imply a test was conducted for COVID-19.

Once the member has been diagnosed with COVID-19, claims should have the ICD10 code **U07.1** as the primary diagnosis, unless the member is pregnant, in which case **U07.1** is secondary to the primary diagnosis code of either **O98.5** or **O98.51**.

In both pre-diagnosis and post-diagnosis situations, not all services provided on the claim may be considered related services and therefore subject to legislative obligations for no cost sharing. The CS modifier, which is specific to individual, line level services (as compared to the entire claim), would appropriately designate services as COVID-19 related rather than non-COVID-19 related services. Additionally, as noted, use of CS could better differentiate COVID related services from other unrelated services.

In summary, the WHO's codes and instructions regarding coding and recording COVID-19 cases are not aligned with the requirements to identify claims and services leading to and associated with COVID-19 testing. Therefore, the best approach to ensuring standardized coding of claims, proper assignment of cost sharing requirements, necessitates that plans publish a policy outlining

acceptable COVID-19 services and the expected coding to designate the services as COVID-19 related. The importance of compliance necessitates a concerted, persistent program for educating ordering providers.

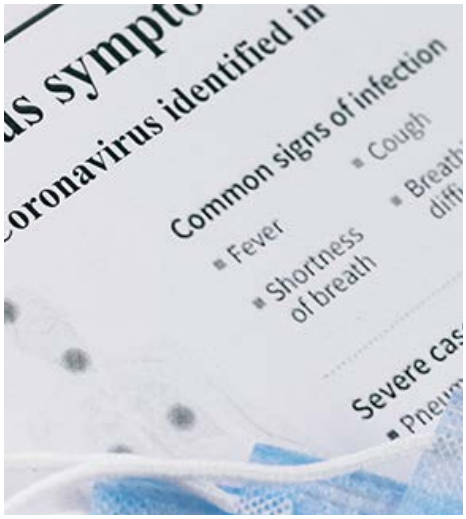
OPPORTUNITIES FOR IDENTIFICATION OF FRAUD, WASTE, AND ABUSE

Despite the flurry of changes and lack of standards for billing, several options exist for detection of FWA and can be implemented as either interventional (e.g. claim denials) or surveillance and post-payment analytics.

Coding specifications or application of good clinical science should be employed. Many of the procedure codes should be or are mutually exclusive, and therefore, simultaneous billing on a claim, especially routinely by a provider, should raise concern. Definitions of the codes and agency guidelines[19] also provide limits on the number of samples that should be performed per date of service. Inappropriate use of the CS modifier for services unrelated to COVID-19 or inappropriate clinical situations (e.g. constipation, allergy status to penicillin, etc.) may indicate abusive testing practices.

Additionally, systematic analytical analysis of claims data can rapidly detect patterns of FWA, such as inappropriate bundling of additional tests or services, designating unrelated services to the cost sharing exemption requirements, or tests performed without and FDA Emergency Use Authorization.

Once identified, the plans standard protocols for educating providers to adjust behavior or further investigative activities up to and including involvement of law enforcement should be followed. As with any period of uncertainty, bad actors will attempt to take advantage of the situation.



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