AVALON HEALTHCARE SOLUTIONS

May 11, 2020

COVID-19 TESTING BRIEF

from Avalon Healthcare Solutions

CONTENTS

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.

FOR MORE INFORMATION, PLEASE CONTACT US:

Barry S. Davis, Chief Growth Officer
201-218-3425 | barry.davis@avalonhcs.com

Fred Barry, VP, Business Development
714-615-1889 | Fred.Barry@avalonhcs.com

Sara Sabin, VP, Business Development
845-591-4725 | sara.sabin@avalonhcs.com

Joy Harris, Dir. Business Development
813-751-3814 | joydana.harris@avalonhcs.com

Angelo Devita, VP, Business Development
215-872-2202 | Angelo.Devita@avalonhcs.com

AVALON LABORATORY NETWORK CAPABILITY & CAPACITY REPORT

The laboratories with RT-PCR capability and associated capacities have stabilized with a total daily capacity of over 200,000 tests/day. However, Avalon can muster additional RT-PCR testing volume within its managed network as a response to organized collection efforts in which volume estimates are available. With respect to COVID-19 antibody testing, Avalon wishes to remind our readers that the utility of this testing is extremely limited. This issue will be further discussed in this bulletin.

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	65,000	1-2 days	Y	Elisa & Chemiluminscence	100,000	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	30,000	1-2 days	Y	Chemiluminscence	TBD	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	1-3 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	1-3 days	Y	Elisa	500	1-3 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
Wake Medical Lab Consultants	NC	Y	Y	1,000	1 day	N		N/A	
SMA	CBC	Y	Y	500	1 day	N		N/A	
Inform Diagnostics	SC, NC, CBC, VT	Y	N	200	1-2 days	N		N/A	

DIRECT-TO-CONSUMER TESTING (DTC)

The offering of DTC testing for COVID-19 by LabCorp and Quest Diagnostics has resulted in many questions about the veracity of this testing access modality.

It is important to note that DTC testing is not a new marketing tool for laboratories and is allowed in many states. Enclosed with this section are some links to regulatory references.

The following are additional considerations:

- *Some states allow limited DTC testing without a physician order*
- *DTC was originally not intended to be offered as a procedure to be claimed as a medical benefit. The assumption is that the consumer assumes full responsibility for this individually requested testing event.*
- *Given the regulatory environment associated with COVID-19 testing, it is prudent to observe for abuse of this marketing method by labs.*
- *It may be necessary to determine specific policies and contract language that addresses DTC testing in specific.*

REGULATORY REFERENCE WEBSITE LINKS

FDA Direct-to-Consumer Test Site

Visit Site

Direct Access Testing (DAT) & the Clinical Laboratory Improvement Amendments (CLIA) Regulations

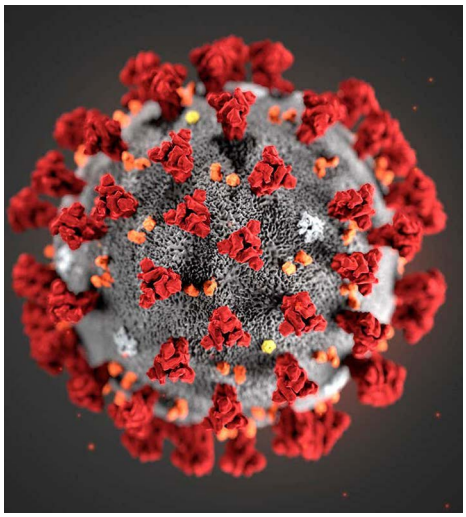
Visit Site

FDA UPDATES POLICY FOR COVID-19 ANTIBODY TESTING

As of the May 4, 2020, policy, manufacturers who have validated their test and notified the FDA that the test has been validated have 10 business days (from the date of the notification or the date of this policy, whichever is later) to prepare and submit an EUA.

During this 10-day period and EUA review period, the test may stay on the market as long as the following information related to the intended use of the test is included on product packaging, labeling and the manufacturer's website:

- *This test has not been reviewed by the FDA.*
- *Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.*
- *Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.*
- *Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43 or 229E.*



The agency has further provided sensitivity and specificity recommendations for serology testing. Clinical agreement data should be provided demonstrating a minimum overall 90 percent positive agreement and overall 95 percent negative agreement. For tests that report specifically IgM and IgG results, a minimum positive percent agreement for IgM of 70 percent and a minimum positive percent agreement for IgG of 90 percent is required, the template states.

It should be noted that high-complexity laboratories (CLIA certification) can still perform their own validation and provide notification to the FDA under the revised policy, following labeling recommendations described in the March 16 policy, and developers of LDTs are still encouraged to seek authorization through an EUA.

CMS ISSUES INTERIM FINAL REGULATIONS IN RESPONSE TO COVID-19 PANDEMIC

Last week the Centers for Medicare and Medicaid Services ("CMS") issued interim final regulations with comment period (the "IFR") that affects a broad cross-section of the American health care industry. The IFR, which is available **online,** implements several waivers and needed flexibilities during the COVID-19 pandemic.

Although this bulletin does not attempt to summarize the entire IFR, your team at Avalon has identified the following IFR provisions that we believe will be of interest to our clients. *Please note: the IFR is open for public comments for 60 days following its publication in the Federal Register.*

SCOPE OF PRACTICE

Allows providers to practice at "the top of their license" during the pandemic: Medicare will now cover diagnostic tests that are supervised by physician assistants, nurse practitioners, and certain others, so long as their state licenses permit as such.

MODIFIED REQUIREMENTS FOR ORDERING COVID-19 DIAGNOSTIC TESTS

Prior to the IFR, Medicare covered diagnostic laboratory tests such as the COVID-19 tests only when ordered by a physician or other appropriate practitioner who is treating the beneficiary, and who uses the results of the test in managing the patient's specific medical condition. The IFR lifts the aforementioned physician order requirement. Of note, CMS stated the following:

… we are amending our regulation at § 410.32(a) to remove the requirement that certain diagnostic tests are covered only based on the order of a treating physician or NPP. Under this interim policy, during the COVID-19 PHE, COVID-19 tests may be covered when ordered by any healthcare professional authorized to do so under state law.

Additionally, because the symptoms for influenza and COVID-19 might present in the same way, during the COVID-19 PHE, we are also removing the same ordering requirements for a diagnostic laboratory test for influenza virus and respiratory syncytial virus, a type of common respiratory virus. CMS will make a list of diagnostic laboratory tests for which we are removing the ordering requirements publicly available. We are removing the treating physician

or NPP ordering requirement for these additional diagnostic laboratory tests only when they are furnished in conjunction with a COVID-19 diagnostic laboratory test as medically necessary in the course of establishing or ruling out a COVID-19 diagnosis or of identifying patients with an adaptive immune response to SARS-CoV-2 indicating recent or prior infection…

…we are amending our regulation at § 410.32(a) to remove the requirement that certain diagnostic tests are covered only based on the order of a treating physician or NPP. Under this interim policy, during the COVID-19 PHE, COVID-19 tests may be covered when ordered by any healthcare professional authorized to do so under state law.

Additionally, because the symptoms for influenza and COVID-19 might present in the same way, during the COVID-19 PHE, we are also removing the same ordering requirements for a diagnostic laboratory test for influenza virus and respiratory syncytial virus, a type of common respiratory virus. CMS will make a list of diagnostic laboratory tests for which we are removing the ordering requirements publicly available.

We are removing the treating physician or NPP ordering requirement for these additional diagnostic laboratory tests only when they are furnished in conjunction with a COVID-19 diagnostic laboratory test as medically necessary in the course of establishing or ruling out a COVID-19 diagnosis or of identifying patients with an adaptive immune response to SARS-CoV-2 indicating recent or prior infection.

APPLICATION OF CERTAIN NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS

CMS clarified that to the extent an NCD or LCD (including articles) would otherwise require a face-to-face or in-person encounter or other implied face-to-face services, those requirements would not apply during the COVID-19 pandemic.

Additionally, CMS clarified that it will not enforce certain clinical indications for coverage across respiratory, home anticoagulation management and infusion pump NCDs and LCDs (including articles). Notably, CMS reiterated the ongoing requirement that items and service for which Medicare reimbursement is sought must be medically necessary:

Some external stakeholders appear to be misinterpreting statements that CMS made in the March 31st COVID-19 IFC as waiving medical necessity requirements; there are now questions as to whether items and services can be furnished or ordered without reason during the PHE for the COVID-19 pandemic. We note there is nothing in guidance or the March 31st COVID-19 IFC, that could be interpreted to permanently or temporarily waive the reasonable and necessary statutory requirement, which is expressed in section 1862(a)(1)(A) of the Act and cannot be waived under the section 1135 PHE waiver authority.

Except as expressly permitted by statute, we remind physicians, practitioners and suppliers that most items and services must be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member to be paid under Part A or Part B of Title XVIII. Physicians, practitioners, and suppliers are required to continue documenting the medical necessity for all services. Accordingly, the medical record must be sufficient to support payment for the services billed (that is, the services were actually provided, were provided at the level billed, and were medically necessary).

COVID-19 SEROLOGY TESTING

CMS clarified that FDA-authorized COVID-19 serology tests fall under the Medicare benefit category of diagnostic laboratory test, and therefore, are "coverable" by Medicare. The AMA has issued two CPT codes for COVID-19 antibody testing; 86328 and 86769.

PAYMENT FOR COVID-19 SPECIMEN COLLECTION TO PHYSICIANS, NON-PHYSICIAN PRACTITIONERS, AND HOSPITALS

CMS clarified that "physicians and NPPs' may use CPT code 99211 to bill for services furnished incident to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID-19 testing." Meanwhile, CMS has created a new code, CPT code C9803 under the outpatient prospective payment system for hospital outpatient departments to bill for a clinic visit dedicated to specimen collection.

NEW AVALON CLINICAL ADVISORY BOARD RECOMMENDATIONS

Recently, Avalon's Clinical Advisory Board (CAB) released COVID-19 Testing in the Outpatient Setting-Avalon Clinical Advisory Board Recommendations containing three general recommendations on testing based on the current scientific literature:

1. Avalon recommends nucleic acid testing, such as RT-PCR, to identify or diagnose COVID-19.

2. Avalon does not recommend host antibody testing to diagnose a current COVID-19 infection, to screen the general population (including people who have no symptoms of a COVID-19 infection), or to determine the immunity at this time.

3. Avalon does not recommend using antigen-detecting rapid diagnostic tests at this time.

Currently, nucleic acid testing is the only testing that is used to identify or diagnose COVID-19, and it should be used only for this purpose.

WHO SHOULD BE TESTED?

The CDC provided some guidance for who should be tested, and it generally includes persons with symptoms, but states and local health departments might have a different guidance. The nucleic acid test will tell if a person has the COVID-19 virus present in their body because it detects the virus itself. If the person was sick but has recovered, then the amount of virus has decreased and can no longer be detected by this test. So, nucleic acid testing cannot be used to determine if a person had COVID-19 and has recovered.

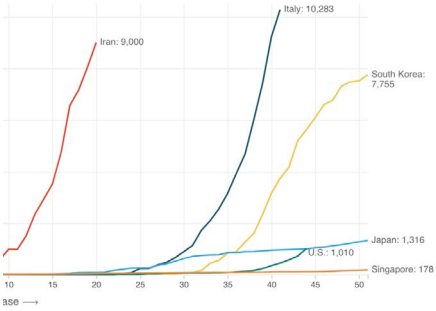
Present studies still show that antibodies form in response to an infection; however, each person's response is unique. There is a lot that we still do not know about this virus and when the antibodies are produced in response to this virus.

Some studies have reported differing results of when antibodies form, what levels are produced, and how long they last. Even the CDC, in the updated guidelines released on May 5, 2020, does not recommend using antibody testing

to diagnose an acute infection. The CDC recommends this because the antibody test cannot directly tell if a sick person has a COVID-19 acute infection. The antibody test does not directly detect if the virus is present in the body or not, and there is still much to learn about what is happening with antibodies in that person.

Additional research is needed to know whether or not the presence of antibodies confer immunity to a future COVID-19 infection or how long this immunity would last. So, antibody testing cannot be used to determine if a person is immune to future infections, meaning that this test is unable to tell if a person that recovered from a COVID-19 infection may or may not get sick again with COVID-19.

A positive test indicates a possible previous exposure to the virus, but a negative result does not necessarily indicate that someone has not been exposed. Possible examples of a false-negative include mishandling a test, the patient has antibody levels below the detection limit of the test, or the test was taken in the time period prior to the patient developing antibodies to the virus. We still need to learn a lot about the antibody production in the person who is sick with a COVID-19 infection. Thus, what is the possible clinical utility of antibody testing? For right now, the CDC and other governmental health agencies may use antibody testing data to help aid in possible surveillance strategies for statistical analysis and to see



how the disease is spreading in the U.S.

As for a rapid antigen test, additional research is required to show that this test meets the accuracy and reliability needed as a point-of-care test. The FDA has not issued an EUA for a rapid antigen test as of May 6, 2020.

PLEASE SEE THE WHITEPAPER INCLUDED WITH THIS WEEK'S BULLETIN:

COVID-19 Testing in the Outpatient Setting:
Avalon Clinical Advisory Board Recommendations