Aug 31, 2020

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

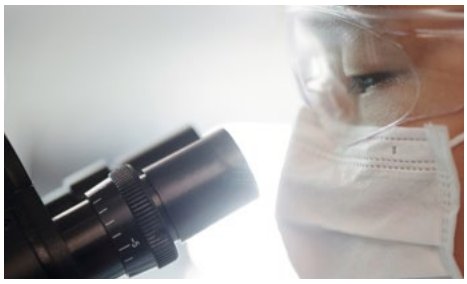
With the addition of new laboratories for COVID-19 testing and increases in daily capacity by the national labs, the daily capacity of the Avalon network now exceeds 600,000 RT-PCR tests/day. Both LabCorp and Quest report that they have cleared the backlog of specimens and are at an average of 1-3 days for non-priority specimens. Quest Diagnostics projects that they will increase their daily capacity of molecular (diagnostic) COVID-19 testing to 185,000 tests/day by Labor Day.

LAB	HEALTHPLAN	RT-PCR Y/N	MULTI PLAT-FORM	CAPA-CITY (PER DAY)	TAT	ANTI-BODY TESTING	FDA EUA	CAPACITY (PER DAY)	TURN-AROUND TIME
LabCorp	SC, NC	Y	Y	200,000	1-3 days	Y	Y	300,000	1-3 days
Quest	SC, NC, CBC, VT	Y	Y	150,000	1 day priority 1-2 day avg	Y	Y	200,000	1-2 days
BioReference	SC, NC, CBC, VT	Y	Y	70,000	1-2 days	Y	Y	260,000	3 days
GenetWorx	SC, NC	Y	Y	40,000	2 days	Y	Y	1,000	1 day
Sonic CPL (Clinical Pathology Lab)	SC	Y	Y	20,000	1-3 days	Y	Y	100,000	1 day
Mako Medical Lab	SC, NC	Y	Y	35,000	1-2 days	Y	Y	20,000	1 day
Premier Medical Lab	SC	Y	Y	20,000	1-3 days	Y	Y	50,000	1-2 days
Eurofins-Diatherix**	SC, NC, CBC, VT	Y	N	30,000	1-2 days	Y	Y	15,000	2-4 days
Aegis	SC, NC, CBC, VT	Y	Y	10,000	1-2 days	N	N/A	N/A	N/A
MDL (Medical Diagnostic Lab)	SC, NC, CBC, VT	Y	N	8,000	1-2 days	Y	Y	1,000	3 days
Neogenomics	SC, NC, CBC, VT	Y	Y	3,400	1-4 days	N	N/A	N/A	N/A
BAKO	SC, NC, CBC, VT	Y	N	2,500	1-2 days	N	N/A	N/A	N/A
Luxor	SC	Y	Y	5,000	1 day	Y	Y	1,000	1-2 days
AccuReference	CBC	Y	Y	5,000	2 days	Y		TBD	
Precision Genetics	SC, NC	Y	N	3,000	1 day	N	N/A	1,250	2-4 days
AIT	SC, NC, CBC	Y	Y	3,000	1-2 days	N	N/A	N/A	N/A
PathGroup	NC	Y	Y	2,200	1-2 days	Y	Y	500	1 day
Radeas	SC, NC	Y	Y	2,400	1-2 days	Y	Y	4,000	1 day
LabTech	SC, NC	Y	Y	2,000	2 days	Y	Y	3,000	1 day
Wake Medical Lab Consultants	NC	Y	Y	1,500	1 day	N	N/A	4,800	1 day
SMA	CBC	Y	Y	1,000	1 day	N	N/A	TBD	TBD
Inform Diagnostics	SC, NC, CBC, VT	Y	N	200	1-2 days	N	N/A	N/A	N/A

COVID-19 TESTING: UNDER CAPACITY AND EXTENDED TURNAROUND TIMES

In the past weeks, there have been many published reports of long waits for COVID-19 diagnostic test results. In this update, we will explore both the reasons for under capacity of COVID-19 testing and some ideas with respect to how the U.S. might mitigate the impact of this national shortage. However, before addressing the causation of under capacity, we need to determine what is the recommended level of COVID-19 testing that should be performed each day in the U.S.

In an August 16 article entitled, "Is Your State Doing Enough Coronavirus Testing?", the NY Times explores both the recommended target for daily testing as well as where testing is

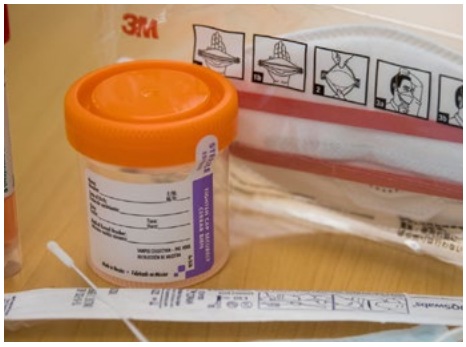


and is not meeting this threshold. The Harvard Global Health Institute has determined that the minimum number of daily COVID-19 tests that should be performed in the U.S. is 1.5 million. This is based on a screening criteria where anyone with flu-like symptoms should be tested plus an additional 10 persons for every positive test. The average number of tests performed in the U.S. during the week of August 10 was 726,000 per day. According to the article, 11 states meet the target for testing, 4 states are near the target and 35 states are well below the target. The article goes on to cite that the rate of positive tests should be at or below 5 percent before a state or country can safely open. The current positive rate in the U.S. is at 9 percent with some states at rates approaching 20 percent.

The capacity and turnaround time for COVID-19 testing is being impacted by several factors, many that have been well-publicized, others are not as well known. Below are many of the factors and some additional details:

1. SUPPLY CHAIN

- ***Collection supplies*** (e.g. swabs) in many cases are specific to a manufacturer's test. Also, the transport media is specific as well. As a further example, the swabs utilized for the deep, nasopharyngeal specimen collection are different than the swabs utilized than the swabs employed for an anterior nares collection performed by a healthcare professional or a supervised collection. A



mismatch between the type of swab/sample collected and the test kit results in no results.

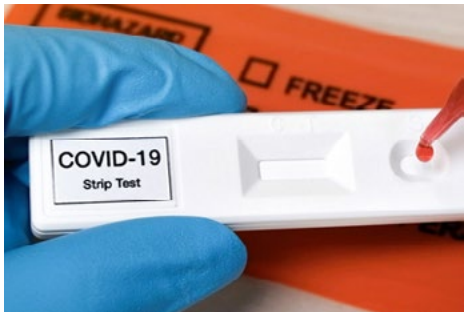
- ***Testing platforms***, that is the instrument on which the testing is performed, are often in short supply thereby hindering a given lab's ability to increase test capacity.
- ***Testing kits*** are often specific to the instrumentation. Therefore, if a lab has a specific platform but the kits are unavailable, then testing capacity is again diminished. Larger labs operate with multiple platforms as a hedge against a backorder of testing kits.
- ***Other testing supplies and reagents*** are frequently out of stock as well. COVID is a global pandemic, and the U.S. is competing with other countries for the same supplies.

2. QUALIFIED PERSONNEL

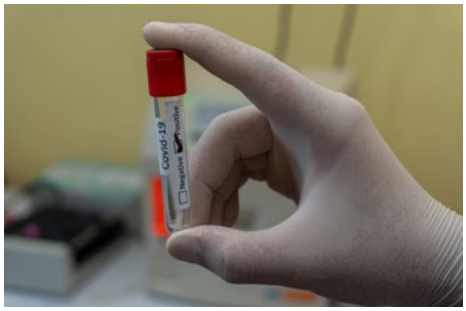
- The U.S. has been experiencing a shortage of medical technology professionals for several years. The COVID epidemic in the country has further exacerbated this issue. One publication placed the vacancy rate at nearly 46%.
- More than a single lab has reported a lack of medical technology professionals as a reason for their lab's under capacity and poor turnaround time.

3. TESTING OF ASYMPTOMATIC PERSONS

- The testing of asymptomatic persons is important to gaining control over the novel coronavirus. However, testing is not a replacement for social distancing or wearing a mask. Given the current deficit for capacity, the testing of asymptomatic persons should be limited to healthcare workers and those that may have been exposed to a person that tested positive for COVID-19.
- Back to work and school is another stress to COVID-19 testing and turnaround time due to the frequency of those tests for an entire employer or campus population.
- Professional sports teams are a controversial element to the COVID testing problem. It is estimated that the current testing for sports teams could account for 10-11% of the current national testing capacity due to frequent, sometimes daily testing of their players and staff.



Space is yet another consideration for test expansion. COVID-19 testing requires space for sample processing, pre-analytical preparation, and actual testing. Most commercial laboratories do not maintain a ready "flex" space for a pandemic. The issue of space is an even greater problem for hospital-based labs in that their internal



"real estate" is typically under compression versus expansion. All these concerns have a real impact on our country's ability to project the minimum test capacity needed to gain control over this virus. Overcoming the current deficit in test capacity will require an approach will require coordination and collaboration of federal, state, and private groups.

The Federal Emergency Management Agency (FEMA) has been tasked with working with states to allocate resources for COVID-19 testing. However, FEMA is buying supplies from

the same vendors as the labs, therefore creating a competition for the same resources. While FEMA does forward the supplies that they purchase to the states, this creates an extension of the supply train and may not always result in an even distribution to those areas with the greatest need. Many states are attempting new strategies to overcome the supply chain challenges. Recently, a group of seven states, led by the governor of Maryland, formed a buying consortium for an initial purchase of three million rapid testing kits. This interstate cooperative purchasing agreement will provide a unique platform to purchase tests and associated supplies in a sustainable and cost-effective manner. In addition, the states will coordinate on policies and protocols regarding rapid antigen testing technology. Other states have taken a direct approach to purchasing testing materials such as Arizona health services department's collaboration with the leading provider of lab services in the state and with a test kit manufacturer. On August 13, HHS invested a combined $6.5M in two U.S. commercial labs with the intention of expanding capacity by up to 4 million additional tests per month.

The authorization of specimen pooling may offer another avenue to increase testing throughput, especially among asymptomatic populations where the prevalence of the virus is low. The Center for Disease Control's (CDC) website offers the following information about specimen pooling:

CDC GUIDANCE

What is pooling?

Pooling—sometimes referred to as pool testing, pooled testing, or batch testing—means combining respiratory samples from several people and conducting one laboratory test on the combined pool of samples to detect SARS-CoV-2, the virus that causes COVID-19.

Why is pooling used?

Pooling allows laboratories to test more samples with fewer testing materials. It could be useful in scenarios like returning groups of workers to a workplace.

What happens if the pooled test result is negative?

If a pooled test result is negative, then all the samples can be presumed negative with the single test. In other words, all of the people who provided samples can be assumed to test negative for SARS-CoV-2 infection.

What happens if the pooled test result is positive?

If the pooled test result is positive, each of the samples in the pool will need to be tested individually to determine which samples are positive.

When should pooling be used?

Pooling should be used only in areas or situations where the number of positive test results is expected to be low—for example in areas with a low prevalence of SARS-CoV-2 infections.

The following laboratories have received emergency use authorizations (EUA) from the FDA to utilize specimen pooling in a limited manner:

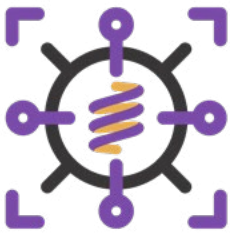
- ***Poplar Healthcare*** has the Poplar SARS-CoV-2 TMA Pooling assay approved 08/03/2020
- ***UCSC*** has the UCSD RCSARS-CoV-2 Assay approved on 07/31/2020
- ***Quest*** has Quest SARS-CoV-2 rRT-PCR (reissued on 07/18/2020 for pooling)
- ***LabCorp*** has their COVID-19 RT-PCR Test (reissued on 07/24/2020 for pooling)

This methodology is currently limited to a pool size of 4-5 samples. An additional limitation is that specimens originating from unsupervised self-collection are not permitted to be included in the pool. In May, officials in Wuhan, China, used a pooling method as part of their efforts to test the vast majority of the city's population, reaching roughly ten million people in just over two weeks. Samples from some 2.3 million people were group tested, with up to 5 samples in a group, and 56 infected people were identified. Additional variations of the pooling method under study in both the U.S. and abroad.

As the capacity for testing increases through both improved supply chain enhancements and through new method development, like specimen pooling, the focus will return to the ability of people to access testing. The HHS.gov publishes a website with a locator of community-based testing. In addition, the increased use of pharmacies as collection sites will offer greater access to testing and may reduce waiting times. One such company, eTrueNorth, manages about 350 test collection sites across the U.S. through retailers such as Kroger and Walmart. Diagnostic testing is not performed at the collection sites nor does eTrueNorth perform testing for COVID-19. Instead, the company outsources the testing to a small network of regional, COVID-capable laboratories. In comparison, Avalon currently manages a laboratory network of over 18 COVID-capable labs with a daily capacity of over 600,000 tests per day. The largest three laboratories in the network comprise over 70 percent of the capacity, and the other laboratories have current capacity and an acceptable turnaround time. Communicating to treating physicians the availability of testing capacity in these laboratories will improve efficiency of COVID testing by aligning demand with unused capacity. Health plans are invited to work with Avalon to coordinate communication to treating providers.

SALIVADIRECT ASSAY

On August 15th, 2020, the U.S. FDA issued an emergency use authorization (EUA) for the SalivaDirect assay from Yale School of Public Health, Department of Epidemiology of



Microbial Diseases. A real-time reverse transcription polymerase chain reaction (rRT-PCR) test, SalivaDirect enables the qualitative detection of nucleic acid from SARS-CoV-2 in saliva collected

without preservatives. This test has demonstrated 94.1% positive agreement and 90.9% negative agreement when compared with TaqPath RT-PCR COVID-19 test and 94.6% positive agreement and 100% negative agreement when compared with modified CDC RT-PCR. It is important to note that cross-reactivity studies performed were limited and studies determining influence of transport on samples quality and testing were not performed. The device description and test principle section of the SalivaDirect assay EUA summary document note the test can be broadly implemented because no preservatives or specialized equipment for nucleic extraction are required and is validated with products from multiple vendors. They do claim that this test is simple and flexible, suggesting that "it is not as affected by supply chain bottlenecks as some other assays." This may be correct for samples collected on-site where the testing is being performed. However, it is unknown how this test will perform for samples that will require transport since stability studies were not performed[1].

ANTIGEN TESTING FOR SARS-COV-2

At this time, only three antigen diagnostic tests are supported by emergency use authorizations (EUA) from the FDA: BD VeritorTM System for Rapid Detection of SARS-CoV-2 from Beckton and Dickinson Company, Sofia 2 SARS Antigen FIA test from Quidel Corporation, and LumiraDx SARS-CoV-2 Ag Test from LumiraDx UK. Although, Quidel Corporation worked on improving the sensitivity of their test, the number of samples tested remained small and no cross-reactivity for human HKU1 coronavirus causing common cold was tested. On July 17th, 2020 Quidel updated the performance data for the Sofia SARS Antigen test to 96.7%[2]. BD Veritor test demonstrated 84% sensitivity[3] and LumiraDx test demonstrated 97.6% sensitivity. Avalon's Clinical Advisory Board (CAB) does not recommend antigen testing in the policy titled "Coronavirus Testing in the Outpatient Setting" because of the accuracy concerns for the antigen test. Instead, Avalon recommends molecular testing as the gold standard COVID-19 test. The American Academy of Pediatrics concurred with a newly issued recommendation stating "Most CLIA-waived rapid tests have limited specificity and sensitivity and may require follow-up testing. In general, antigen (rapid) tests are not recommended for routine clinical care, although rapid tests may have utility for population-based surveillance"[4]. It is a situation where a common maxim in lab testing applies: "everyone wants a test that is fast, accurate and cheap, but only two of three can be achieved at any one time."

TRENDS IN ANTIGEN AND MOLECULAR COVID-19 TEST ORDERING

The American Medical Association (AMA) issued CPT code 87426 on June 25th, 2020 for coronavirus antigen testing5. As shown on **Figure 1**, the majority of this testing is being done in adult populations (individuals 18 years and older) indicating that there is no evidence yet of a back-to-school testing effect in our data because no significant increase in pediatric testing was noticed. Of note, test ordering has doubled between mid to late July 2020. Avalon will continue to monitor the ordering patterns for antigen testing in relation to COVID-19.

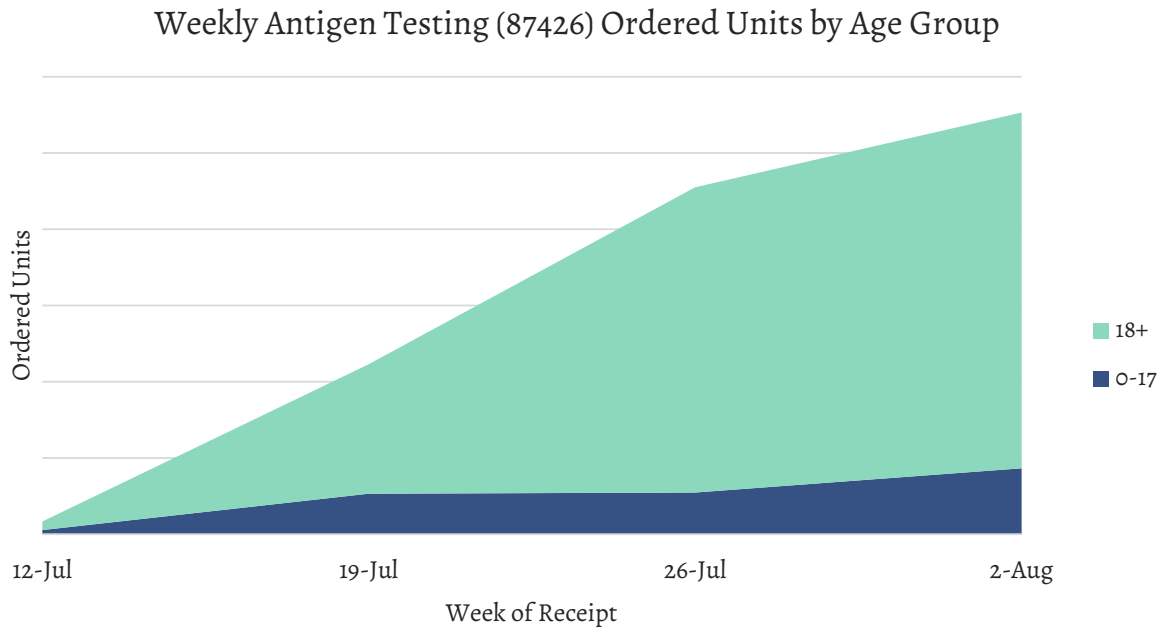


Figure 1: Weekly Antigen Testing (87426) Ordered Units by Age Group

In March 2020, the AMA issued CPT code 87635 specific to PCR testing for COVID-19, and in April 2020, the CMS released two additional codes for dates of service after March 18, 2020: U0003 and U0004. U0003 is specific for high throughput COVID-19 testing, which were priced at nearly twice as much as U0004 and similar to 87635. As it is shown in **Figure 2**, utilization of U0003 almost exponentially increased starting in May, followed by 87635. The utilization of U0004 remained unchanged and was minimally utilized.

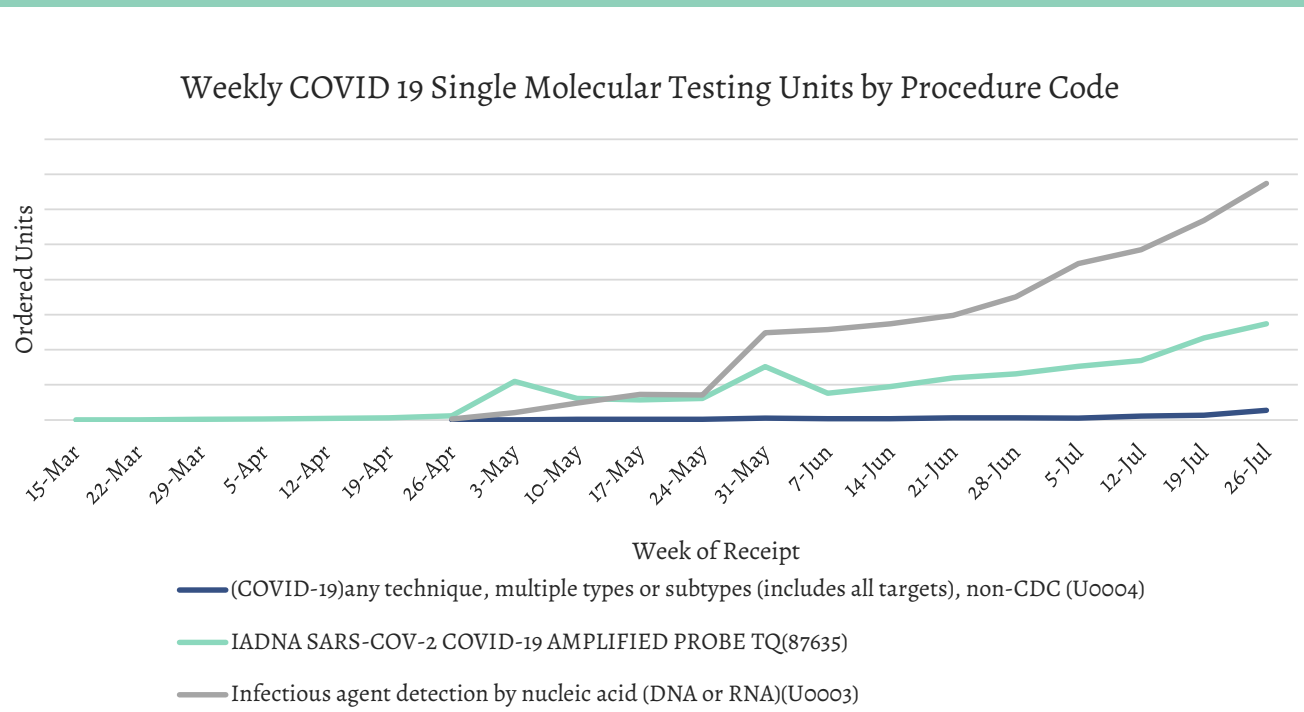


Figure 2: Weekly COVID-19 Single Molecular Testing Units by Procedure Code

RESPIRATORY PATHOGEN PANELS

Avalon's Clinical Advisory Board does not recommend large respiratory panels testing. Currently, a few large respiratory pathogen panels have received FDA EUAs and have a PLA code issued such as BioFire® FilmArray® Respiratory Panel 2.1-22 respiratory pathogens (PLA code 0202U; 22 targets), QIAstat-Dx Respiratory SARS-CoV-2 Panel (PLA code 0223U; 22 targets), and ePlex® Respiratory Pathogen Panel 2 (PLA code 0225U; 21 targets) from GenMark Diagnostics, Inc[5]. Additionally, one large pathogen panel has also been approved, the NxTAG CoV Extended Panel Assay, from Luminex Molecular Diagnostic Inc. (EUA issued 3/27/2020, high complexity, best appropriate CPT code is 86733 for 18 respiratory targets and individual codes for 2 bacterial targets,

Chlamydophila pneumoniae and Mycoplasma pneumoniae). Testing for a long list of pathogens is wasteful when only COVID-19 infection is suspected, and it can increase the rate of false positive and negative results possibly leading to medical errors.

Some clinical situations warrant multiplex nucleic acid testing. With the flu season approaching, small targeted respiratory pathogen panels can be very helpful. On July 2nd, 2020, The U.S. FDA granted EUA for the CDC's diagnostic multiplex assay for flu and COVID-19 simultaneous detection. The CDC's Influenza SARS-CoV-2 (Flu SC2) assay is a multiplex nucleic acid test that detects and differentiates RNA from SARS-CoV-2, Influenza A virus, and Influenza B virus in upper or lower respiratory specimens[6]. Other companies also announced that they are going to develop similar tests. On June 9th, 2020, Cepheid announced development of a four-in-one combination test for SARS-CoV-2, Flu A, Flu B, and RSV[7]. On August 13th, Quidel announced that they are also planning to develop a combination assay with coronavirus and flu soon[8]. Avalon's coronavirus policy recommends testing for a small panel of respiratory pathogens.

Interestingly, our data in **Figure 3** shows that there was an increase in respiratory virus testing of 3-5 targets represented by CPT code 87631; however, respiratory virus testing of 12-25 targets, represented by CPT code 87633, was the most requested test. There was no increase in respiratory virus testing of 6-11 targets represented by CPT code 87632. Our data also indicates that single COVID-19 molecular tests are only requested with this testing between 2-4% of the time. In addition, no claims were received for 0223U; however, for the week of 7/19/2020-7/26/2020, orders almost tripled for 0202U, as shown in **Figure 4**. The question remains regarding practice patterns of stacking multiple individual pathogen codes to represent these large pathogen panels, possibly without COVID-19 testing specific codes to maximize reimbursement.

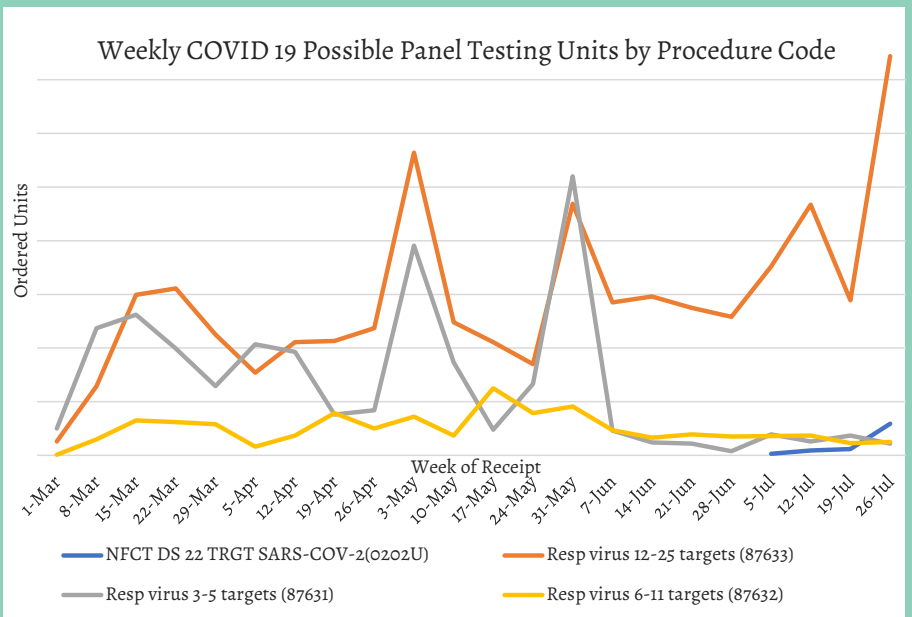


Figure 3: Weekly COVID-19 Possible Panel Testing Units by Procedure Code

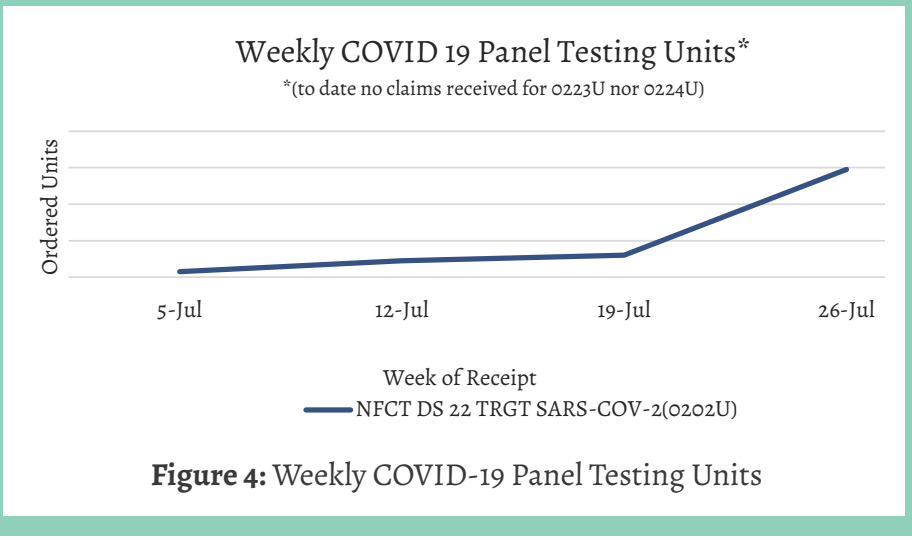


Figure 4: Weekly COVID-19 Panel Testing Units

COVID-19 RELATED TESTING: NEUTRALIZING ANTIBODY

On August 10th, 2020, the AMA issued codes representing neutralizing antibody tests such as 86408 for screen test, 86409 for titer test, and 0226U code for Tru-Immune™, Ethos Laboratories, GenScript USA Inc[5]. Interestingly, as of now, none of these tests have received FDA EUAs. On their website, GenScript notes that their test is for research use only and indicates that, "This kit would be instrumental in vaccine and therapeutic development as it is suitable for all antibody isotypes and can be used to determine neutralizing antibodies in animal models without modification. The kit will also help in current COVID-19 investigations of sero-prevalence, assessment of herd immunity, longevity of protective immunity, efficacy of different vaccine candidates as well as tracking infection in animals"[9].

Neutralizing antibody tests are used to determine the functional ability of antibodies to prevent infection or to determine immunity. These tests must be performed in specialized laboratories with the appropriate biosafety level depending on the test. For example, virus neutralization tests require biosafety level 3 laboratories because serum or plasma is incubated with live SARS-CoV virus or recombinant reporter expressing SARS-CoV-2 proteins. In the case of pseudovirus neutralization tests, recombinant pseudovirus expressing the S-protein of SARS-CoV-2 is utilized; this type of test requires biosafety level 2 laboratories.

TRENDS IN COVID-19 ANTIBODY TEST ORDERING

The antibody testing area is rapidly evolving. At this moment, there is no clinical utility for antibody testing, except as an aid in the diagnosis of multisystem inflammatory syndrome in children (MIS-C) according to Avalon's CAB and many professional guidelines. There are 41 antibody tests that received FDA EUAs, and some AMA CPT codes were issued. Avalon's data indicates that there was modest use of 86328, and almost a three time increase in testing 86769 after Memorial Day (**Figure 5**). Antibody testing appears to be utilized as a screening test since it is used in association with many screening tests such as lipid panels, as shown in **Figure 6**.

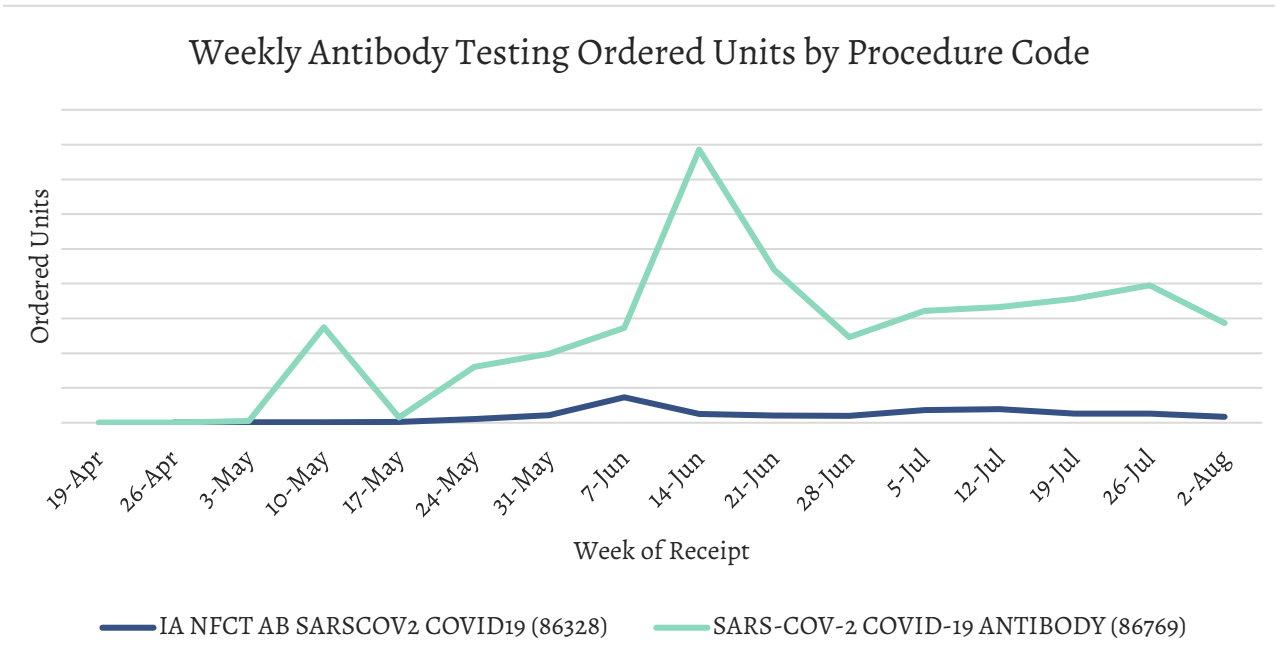


Figure 5: Weekly Antibody Testing Ordered Units by Procedure Code

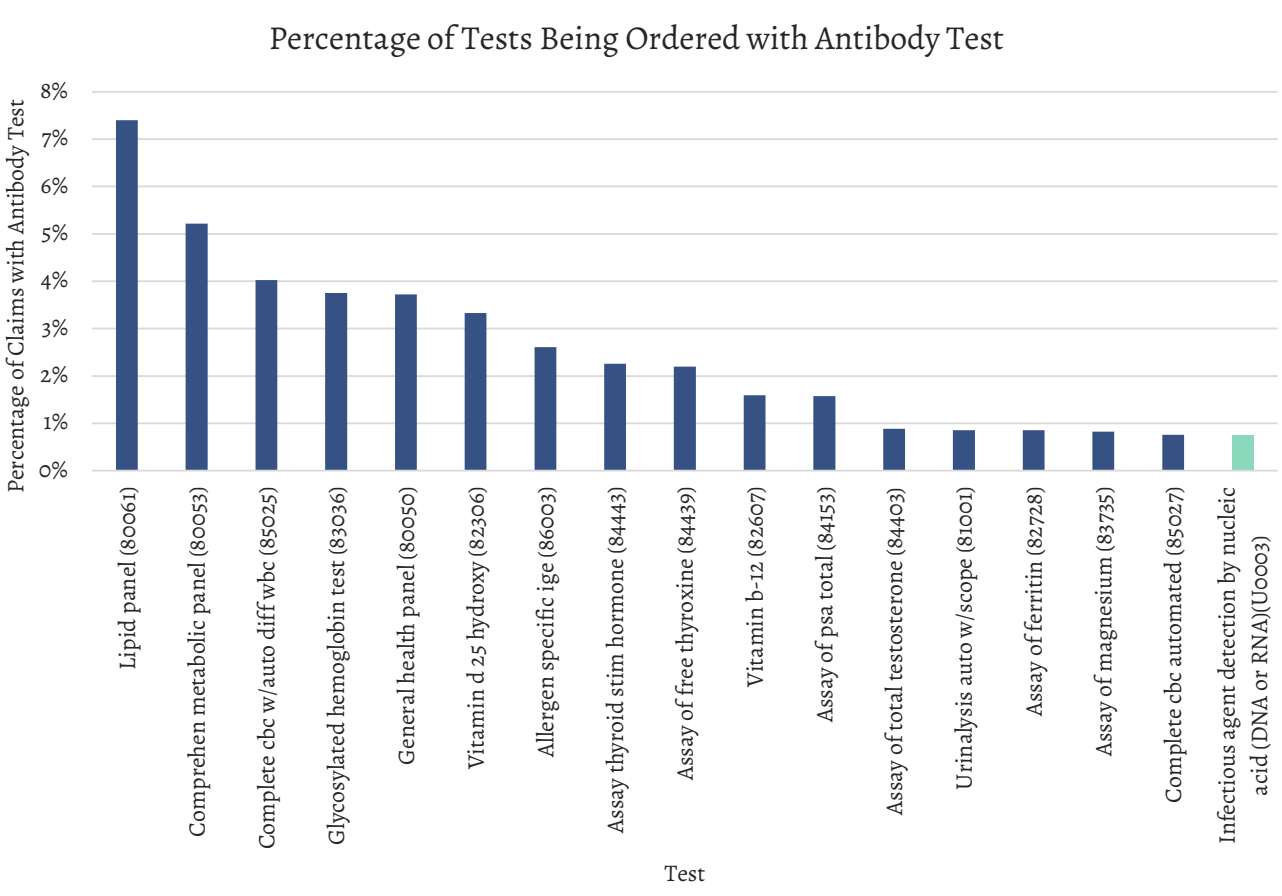


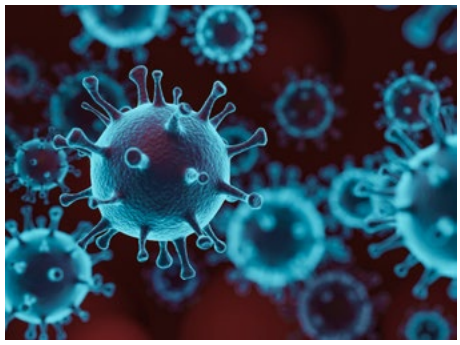
Figure 6: Percentage of Tests Being Ordered with Antibody Test

CENTERS FOR DISEASE CONTROL AND PREVENTION-UPDATED GUIDANCE ON SARS-COV-2 (COVID-19) TESTING

On Monday, August 24th, 2020 the Centers for Disease Control (CDC) revised a document titled "Overview of Testing for SARS-CoV-2 (COVID-19)". In this document, the CDC provided a summary of considerations and recommendations for SARS-CoV-2 testing. The revisions were made to clarify when people needed to be tested and what actions should be taken by COVID-19 tested individuals.

The CDC stated "You will need to be tested" for individuals working or living in a nursing home or long-term care facility.

In general, the CDC did not recommend testing asymptomatic individuals that have or have not been in close contact with COVID-19 infected individuals or when their contact status was unknown with a few exceptions. The CDC recommended that testing might be needed in some situations such as for symptomatic individuals per health care provider's advice. Or, when an asymptomatic individual has been in close contact (within 6 feet) of a COVID-19 infected person for at least 15 minutes and belongs to a vulnerable group such as "an elderly person or an individual with underlying health conditions". The COVID-19 testing recommendation was also given for a critical infrastructure worker, health care worker, and first responder per "employer's guidelines".



In cases when an individual tested positive or had mild symptoms and did not get tested, the CDC recommended to "self-isolate for at least 10 days after symptoms onset and at least 24 hours after the resolution of any fever

(without the use of fever-reducing medications)." The CDC did not recommend repeating testing if an individual tested positive for COVID-19.

Finally, the CDC highlighted that testing advice from state and local health officials regarding COVID-19 should be followed.

The CDC's complete guidance regarding COVID-19 testing can be found **here**.

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