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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.

STIMULUS BILL UPDATE

OVERVIEW

On May 18, 2020, the U.S. Health & Human Services (HHS) **announced** it is providing $11 billion in new funding to states, localities, and tribes to support COVID-19 testing. The great majority of the funding will be distributed by the CDC through its Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) **cooperative agreement**. As part of the effort to help states re-open their businesses and communities, the funds will support the development, purchase, and administration of COVID-19 tests, as well as contact tracing / exposure notification activities.

This funding is authorized by the fourth economic stimulus bill that was signed into law on April 24, 2020: **the Paycheck Protection Program and Healthcare Enhancement Act (PPPHCE) Act.** The bill provides $100 billion for the Public Health and Social Services Emergency Fund at HHS, including $25 billion for necessary expenses related to COVID-19 testing -- including "not less than $11 billion for states, localities, tribal organizations." The funds may also be used to conduct surveillance, trace contacts, and other activities related to COVID-19 testing.

FUNDING REQUIREMENTS

Each Governor or official receiving the funding must submit a detailed plan to HHS about their COVID-19 testing and goals for the 2020 calendar year.

This plan must include:

1. Number of tests needed, including diagnostic, serological, and other tests
2. Month-by-month estimates of lab and testing capacity, which includes reporting related to workforce, equipment and supplies, and available tests
3. Description of how resources will be used for testing, including easing of COVID-19 community mitigation policies.

FUNDING RECIPIENTS

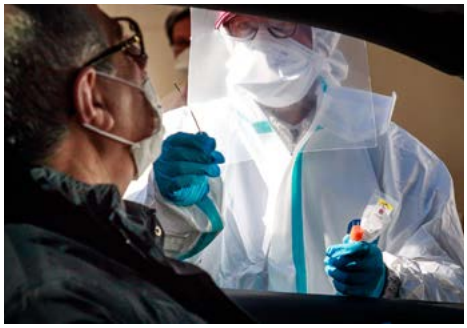
1. **CDC:** a complete list of all recipients of the $10.25 billion in CDC funds can be found **here**; see far right column for HHS testing funds. Funding ranges from $3 million to $800 million, and recipients include:

   a. Most of the 50 states
   b. Cities: New York City, Los Angeles County, Washington DC
   c. Territories: Guam and Puerto Rico

2. **Tribal Organizations:** the IHS director **wrote** to Tribal and Urban Indian Organization (UIO) Leaders announcing how the $750 million in funding will be distributed on May 19, 2020.

LAB INDUSTRY REACTION

This additional funding for states comes after the **lab industry complained** that the largest stimulus bill (**the CARES Act**) failed to prop up lab testing. The American Clinical Laboratory Association (ACLA) recommended that additional funding be directed



to clinical laboratories to meet the continued demand for testing. Part of ACLA's request was to designate funds to cover uncompensated testing for uninsured and under-insured patients, saying that the **existing programs to cover testing** were not benefiting clinical labs. ACLA also noted that the inadequate payment rates and out-of-network providers ordering COVID-19 tests were forcing labs to bear the cost of promised free testing.

On May 11, 2020, ACLA issued another statement after the Trump Administration announced its intention to ramp up funding:

> *"Across the country, laboratories have made significant investments to expand capacity, including purchasing new platforms, retraining staff, and managing the skyrocketing cost of supplies. To continue to make these investments and expand patient access to high-quality testing in every community, laboratories will need designated resources. Without sustainable funding, we cannot achieve sustainable testing."*

ACLA later expressed support for a letter sent by several U.S. House Representatives on June 8th, asking HHS Secretary Azar to direct the funds from the Public Health and Social Services Emergency Fund (PHSSEF) to support the expanded efforts of clinical laboratories.

The Members wrote:

> *"While laboratories are eligible, along with other providers, for these funds, there have been no federal funds specifically designated for the laboratories that have stepped up in this public health crisis and have made significant investments to expand access to COVID-19 testing despite 40-60 percent reductions in regular commercial volume due to the economic lockdowns."*

CDC: OVERVIEW OF TESTING FOR SARS-COV-2

On June 13th, 2020, the CDC published additional guidance regarding testing for SARS-CoV-2. In the guidance document, the CDC provides a summary of considerations and recommendations for testing for SARS-CoV-2. They have developed their recommendations regarding SARS-CoV-2 testing based on what is currently known about this subject.

Currently, the CDC recommends viral tests (i.e., nucleic acid or antigen tests) to diagnose an acute infection. And, they do not recommend testing the same individual more than once within a 24-hour period. In addition, the CDC recommends using either an authorized nucleic acid or antigen detection assay that has received an FDA EUA to test persons with symptoms. They do recommend testing for all close contacts of persons with SARS-CoV-2 infection and for all neonates born to women with COVID-19, regardless of symptoms. In general, the CDC does not have a specific recommendation for testing asymptomatic population without clinical reasons, but they encourage facilities to work with local, territorial, and state departments to determine if testing will be

needed and to develop a strategy for it. The CDC also recommends using one of several possible approaches to determine resolution of infection with SARS-CoV-2 such as test-based or symptom-based strategies.

Regarding antibody testing, the CDC does not currently recommend its use as the sole basis for diagnosis of an acute infection, and antibody tests are not authorized by the FDA for such diagnostic purposes. The CDC states that antibody testing may be useful to support clinical assessment of persons presenting late in their infection as an adjunct to viral testing and in those suspected to have post-infectious syndrome caused by SARS-CoV-2, such as multisystem inflammatory syndrome in children (MIS-C). According to the CDC, further research is needed to determine how antibody testing can be used and if it can predict immunity or if these tests may have utility in infection control decisions. The CDC states that antibody tests can help with public health surveillance for SARS-CoV-2.

Finally, the CDC document provides many links to other documents issued by the CDC that provide full details about each topic discussed in the current guidance. This guidance can be found **here.**

FDA ISSUES EUA FOR NON-SARS-COV-2 TEST

On June 2, 2020, the FDA issued the first EUA under the HHS Public Health Emergency for COVID-19 for a test that is not directly related to SARS-CoV-2, the virus that causes COVID-19. The Elecsys IL-6 test from Roche Diagnostics is an electrochemiluminescence immunoassay (or ECLIA) that quantitatively measures the amount of interleukin-6 (IL-6) in human serum or plasma.[1]

IL-6 is a non-specific inflammatory marker involved in a number of processes, including the immune response and tissue injury.[2] IL-6 is produced in response to many conditions—it is **NOT** specific to COVID-19.

The Elecsys IL-6 test indirectly measures the amount of IL-6 using an antibody "sandwich" method where one antibody binds to any IL-6 in the sample. The sample is then washed to remove any excess antibodies, and then a second particle that recognizes the antibody is added so that it can bind, forming a "sandwich". This "sandwich" generates a signal that the analyzer reads to calculate the amount of IL-6 in the original sample.

The Elecsys IL-6 test can be used with the cobas e 411, e 601, e 602, and e 801 analyzers. The reported sensitivity of this test is 84% (with a 95% confidence interval [or 95%CI] of 60 – 97%). The specificity of this test is 63% (with a 95%CI of 44 – 80%).[1]

The current FDA EUA for the Elecsys IL-6 test does include a warning, stating the following, "This test has not been FDA cleared or approved; [t]his test has been authorized by FDA under an EUA for authorized laboratories…only to assist in identifying severe inflammatory response, when used as an aid in determining the risk of intubation with mechanical ventilation in confirmed COVID-19 patients…"[1]

AVALON LABORATORY NETWORK CAPABILITY & CAPACITY REPORT

The testing capacity for the network remains stable. Most laboratories report that they continue to have some excess capacity with both the diagnostic (PCR) as well as the serological (antibody) testing for COVID-19. On June 9th, Citi Research estimated one national laboratory's utilization rates for COVID-19 testing was at 82% and 11% for PCR and serological testing, respectively.

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	110,000	1-3 days	Y	Y	300,000	1-3 days
Quest	SC, NC, CBC, VT	Y	Y	105,000	1-2 days	Y	Y	200,000	1-2 days
BioReference	SC, NC, CBC, VT	Y	Y	35,000	1-2 days	Y	Y	100,000	3 days
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	12,000	1-2 days	Y	Y	20,000	1 day
Premier Medical Lab	SC	Y	Y	10,000	1-3 days	Y	Y	6,000	1-2 days
Eurofins-Diatherix**	SC, NC, CBC, VT	Y	N	10,000	1-2 days	Y	Y	5,000	2-4 days
MDL (Medical Diagnostic Lab)	SC, NC, CBC, VT	Y	N	5,000	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
Precision Genetics	SC, NC	Y	N	2,500	1 day	N	N/A	1,200	N/A
PathGroup	NC	Y	Y	2,200	1-2 days	Y	Y	500	1 day
LabTech	SC, NC	Y	Y	2,000	1-2 days	Y	Y	3,000	1 day
Luxor	SC	Y	Y	5,000	1 day	Y	Y	500	1-2 days
Wake Medical Lab Consultants	NC	Y	Y	1,400	1 day	N	N/A	N/A	N/A
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

NEWS FROM THE LABS

LABORATORY LOBBYING EFFORTS

The response to the COVID-19 pandemic included many stakeholders, both inside and outside of the healthcare environment. The contribution of the laboratory industry was important in both the speed in the scaling of testing capacity, but also the collaboration by and among the private sector and federal and state authorities to improve access to quality testing. The American Clinical Laboratory Association (ACLA) largely coordinates the laboratory industry's lobbying efforts, such as the recent COVID-19 pricing.

Included are some recent postings from the ACLA website that demonstrate the input of the laboratory industry to the regulatory agencies.

ACLA Letter to CDC on Antibody Guidance

In this letter, ACLA expresses the lab industry's concern that the current CDC guidance with respect to COVID-19 antibody testing may limit access to necessary testing. Access the full letter **here**.

Following an April 29 ACLA letter to HHS, Lawmakers Call on HHS to Designate Resources for Clinical Laboratories

In a letter to HHS, 30 lawmakers urge Secretary Azar to determine funds that will aid laboratories to expand COVID-19 testing capacity. Access the full letter **here**.

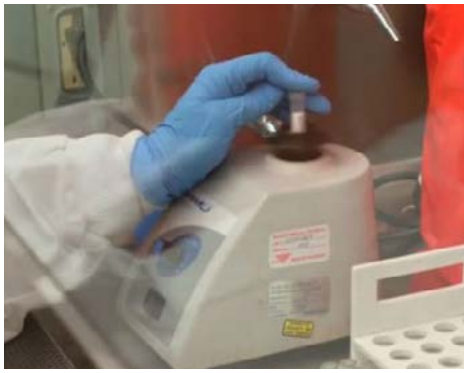
ACLA Serologic Testing White Paper

Excerpt: "Without adequate funding, laboratories would face the same roadblocks with SARS-CoV-2 serologic testing as they have with COVID-19 diagnostic testing. Reimbursement rates may be just a fraction of the cost to perform the testing. Yet, a laboratory that loses money on every test it performs is not likely to offer the test at all." Access the full letter **here**.

PRICE GOUGING

Winston Churchill is credited with the quote, "Never let a good crisis go to waste". This seems to be a guiding principle for those willing to turn any catastrophe into a profit taking scheme. The lab industry has proven not to be exempt from this scourge. The NY Times ran an article on June 16 entitled, **"Most Coronavirus tests cost $100. Why did one cost $2315?"**

A Texas lab was exposed for charging $2315 for COVID-19 diagnostic testing and in some cases, over



$6000. The CARES Act requires health plans to fully cover the cost of out-of-network covered testing. However, the law also requires that providers post their cash price on their website. In the case of the lab exposed in the NY Times article, the website now reflects a price of $150.

Avalon has researched several laboratories that have been reported as charging well above the CMS price of $100. Most of the labs reviewed have not posted a cash price for their COVID-19 testing. Health plans should coalesce around this issue. Price gouging should be reported to federal and state authorities. Offenders should evaluated for federal program exclusion. Lawmakers should be notified so that future crisis legislation can avoid these issues.

Avalon can assist your plan in identifying providers whose activities suggest illegal price gouging.

REFERENCES

[1] Roche_Diagnostics. Elecsys IL-6. 2020; https://www.fda.gov/media/138595/download. Accessed 06/19/2020, 2020.

[2] Tanaka T, Narazaki M, Kishimoto T. IL-6 in inflammation, immunity, and disease. Cold Spring Harb Perspect Biol. 2014;6(10):a016295.