

July 27, 2020

COVID-19 TESTING BRIEF

from Avalon Healthcare Solutions

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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

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	165,000	48 hrs priority 4-6 days	Y	Y	300,000	1-3 days
Quest	SC, NC, CBC, VT	Y	Y	130,000	48 hrs priority +6 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	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	7,000	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	500	1-2 days
Precision Genetics	SC, NC	Y	N	3,000	1 day	N	N/A	1,250	2-4 days
PathGroup	NC	Y	Y	2,200	1-2 days	Y	Y	500	1 day
Radeas		Y	Y	2,400	1-2 days	Y	Y	4,000	1 day
LabTech	SC, NC	Y	Y	2,000	1-2 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

THE DEBATE OVER WHO PAYS FOR COVID-19 ANTIBODY TESTING

As discussed in the July 6th edition of the Avalon COVID-19 Brief, payers recently received much-needed clarity about their responsibility for covering COVID-19 lab tests from the federal government. The Tri-Agency Guidance that was published on June 23rd explained that payers do not have to cover claims for tests that are for public health surveillance purposes or back-to-work / back-to-school testingⁱ.



Section 6001 of the Families First Act, as amended by the CARES Act, requires private health insurance plans to cover testing needed to detect or diagnose COVID-19, and the administration of that testing, without cost-sharing, prior authorization, or medical management requirements. The



Trump administration previously confirmed that this includes serological (antibody) tests for COVID-19. This latest guidance issued on June 23rd by the Secretaries of the U.S. Departments of Health & Human Services, Treasury, and Labor made clear that group health plans and insurers are not required to pay for non-diagnostic testing. Some Congressional leaders and the lab industry trade association -- the American Clinical Laboratory Association (ACLA) -- objected to this distinction, preferring that



there be a reliable source of funding to support non-medically necessary testing. Trade associations representing the payer community, like America's Health Insurance Plans (AHIP), Blue Cross Blue Shield Association, and the Alliance for Community Health Plans have all advocated for the inclusion of additional public funding for testing in the next congressional



economic relief package that is anticipated to pass in the next week. On July 21, the National Consumers League, ACLA and AHIP joined nearly 50 health care stakeholders in appealing to congressional leadership for dedicated federal funding for COVID-19 testing. We will monitor the progress of these multi-stakeholder lobbying efforts as the public funding debate continues.

CURRENT INFORMATION ON ANTIGEN TESTING FOR SARS-COV-2



Currently, Avalon's Clinical Advisory Board (CAB) does not recommend the use of antigen-detecting rapid diagnostic tests to guide patient care; instead, Avalon recommends RT-PCR for identifying the presence of SARS-CoV-2, the causative agent of COVID-19, in an individual in an outpatient setting. Avalon's CAB based their decision on the fact that at this time, antigen tests have demonstrated poor analytical performance.

The antigen detection testing relies upon the direct detection of parts of the virus called "antigens"—in this instance, proteins located on the outside of SARS-CoV-2, such as the spike protein (S) or nucleocapsid protein. Typically, rapid antigen diagnostic tests are very fast, easy

to use, and convenient. However, they usually suffer from poor analytical performance compared to molecular tests such as RT-PCR. As of July 20, 2020, there are only two antigen diagnostic tests that received emergency use authorizations (EUA) from FDA: BD Veritor™ System for Rapid Detection of SARS-CoV-2 from Beckton and Dickinson Company



and Sofia 2 SARS Antigen FIA test from Quidel Corporation. The most common limitation of these tests is the need to confirm all negative results with a molecular test, small number of samples tested in their studies and possible cross-reactivities with other viruses not tested. Currently, BD Veritor test demonstrates 84% sensitivity.

Out of 226 frozen samples, only 31 frozen positive samples were tested. On July 17th, 2020 Quidel has updated the performance data for its Sofia SARS Antigen test on its package insert to 96.7%. It is an important improvement from previous Quidel studies that used frozen samples and demonstrated 80% sensitivity with only 5 positive samples tested, however the total number of 30 positive samples used in the current study is still small. Finally, no cross-reactivity for human HKU1 coronavirus causing common cold was tested in either study.

Complete package inserts (IFU's) can be found at:

BD Veritor™ System

Quidel Sofia SARS Antigen FIA

Avalon's policy titled "Coronavirus Testing in the Outpatient Setting" is currently under review, so changes to this policy should be expected if new information becomes available.

COVID-19 TURNAROUND TIME AN ISSUE AGAIN

Both the press and patients are reporting extended turnaround times for COVID-19 diagnostic testing. On their individual websites, both LabCorp and Quest Diagnostics are warning of extended times for the return of results for this testing. LabCorp notes that their turnaround time for non-priority patient testing may extend to 4-6 days. Quest is reporting up to 7 days. It is

important to notice that the labs measure turnaround time from the receipt of the patient specimen in the laboratory to the time that the lab system registers a report. The time necessary to transport the specimen to the lab and the lag in actual receipt of the report or notification by the ordering provider may further extend these turnaround times.

Most of the regional laboratories listed in the chart on [Page 1](#) above are reporting that they can maintain their published turnaround times. However, some labs are reporting that they are experiencing some interruption in the supply chain for necessary testing materials, including swabs and reagents.

QUEST DIAGNOSTICS RECEIVES AN EMERGENCY USE AUTHORIZATION FROM THE FDA FOR “SPECIMEN POOLING”

Quest is the first lab provider to receive FDA authorization for the technique of specimen pooling for COVID-19 testing in the United States.

In pooling, specimens must still be collected into individual vials, but then are combined into small batches or pools by the laboratory. A negative result for a batch means that all patients in that pool are considered negative (If a positive result occurs for the batch, each specimen is retested individually). The technique is an efficient way

to evaluate patients in regions or populations with low rates of disease. Pooling is used routinely in blood banking to screen donated blood for a variety of viruses, among other applications.

With the new pooling EUA, the Quest Diagnostics SARS-CoV-2 RNA (“Quest SARS-CoV-2 rRT-PCR”) test may be used with pooled upper respiratory specimens (nasopharyngeal, mid-turbinate, anterior nares or oropharyngeal swabs). In clinical data presented by Quest to the FDA, none of 3,091

total specimens from a population with a prevalence rate of 1-10 percent, if pooled, would have been incorrectly determined to be negative (95%CI 0.0-0.1%).

The company expects to deploy the technique at its laboratories in Chantilly, VA and Marlborough, Mass., by the end of next week with additional laboratories to follow.

Self-collected specimens that were not observed by a healthcare professional are not eligible for pooling.

CURRENT TRENDS IN COVID-19 AND NON-COVID-19 LABORATORY TESTING

Significant impacts to laboratory testing brought on by the sweeping stay at home orders in April raised concerns regarding changes in testing patterns and impacts to long term health of members who missed necessary testing. As the risk of contracting COVID-19 has not diminished, many people remain at home or pursue more limited lifestyles creating the



potential for negatively impacting patient's health due to insufficient monitoring of patients and reduction their corresponding treatments. Additionally, the reimbursement requirements increase incentives for fraud, waste and abuse associated with COVID-19 testing. In May, the Department of Justice indicted the

president of a laboratory for filing fraudulent claims by bundling allergy panels with COVID-19 tests. Regardless of the rationale for the bundled testing, the relative ratios have remained consistent over the last several weeks.

Avalon routinely analyzes and reviews claims data to ascertain changes in testing patterns. The pandemic introduced an unprecedented change in laboratory testing patterns. COVID-19 testing, which was non-existent in January, includes extraordinary reimbursement changes and exceptional market demand. COVID-19 testing composition (PCR and antibody), concurrent non-COVID-19 lab tests, claim submission times, and overall testing patterns, and which disease categories resisted volume reductions are discussed below. Avalon will continue to review claims and laboratory data to bring useful and actionable insights to our clients and the laboratory industry.

A close-up photograph of a medical bill. The bill is white with black text. The word "BALANCE" is printed in bold. To the right of "BALANCE" is the number "342.62". Below "BALANCE" are several lines of text: "DEDUCTIBLE APPLIED", "CO-PAYMENT", "HOSPITAL DEDUCTIBLE", "EXCEEDS COVERED CHARGES", "EXCEEDS BENEFIT LIMIT", "NON-ELIGIBLE CHARGES", and "TOTAL DUE PROVIDER". To the right of these lines are the numbers "30.80" and "372.62".

The public obtains COVID-19 testing from a variety of sources, and many of those tests are not filed through commercial or government programs but rather are billed to the local, state or federal government for payment. The following analysis solely relies on insurance claims data as the basis for evaluation.

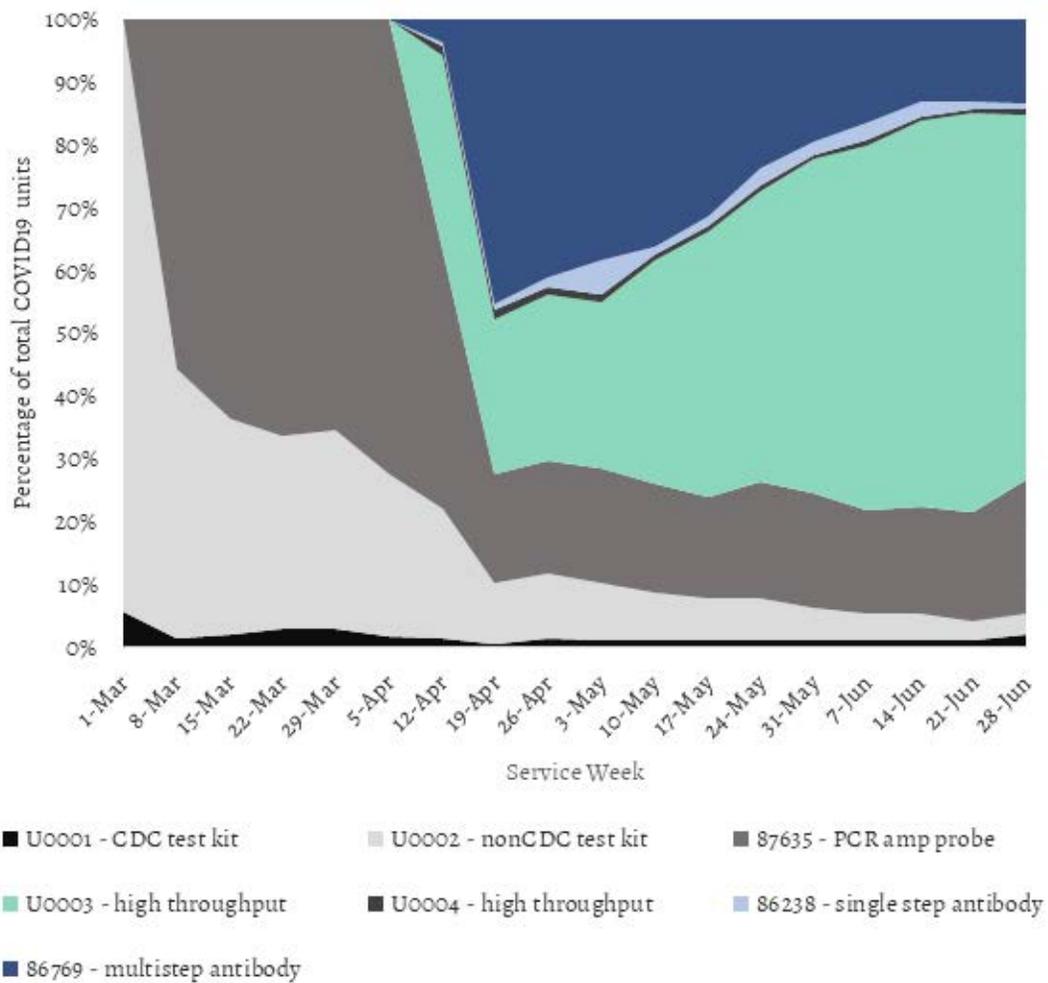
LABORATORY TESTING PATTERNS CHANGE AS REIMBURSEMENT AND CODING AMBIGUITY CHANGES

As COVID-19 spread across the world, governments responded with rapidly changing policies throughout the Spring. As the demand for testing ramped up in the United States and the CDC

tripped up with its own testing kits, CMS issued temporary HCPCS codes, U0001 and U0002, to enable tracking of testing through claims data. Commercial laboratories, initially struggled with FDA red tape, rose to the occasion, and began investing in testing capacity for the novel virus. With the CARES Act stipulation that member cost sharing was waived for COVID-19 tests and associated services, many laboratories withheld submitting claims until plans had implemented necessary claims processing changes. In March, AMA issued

an emergency CPT codes specific to PCR testing for COVID-19, code 87635, and April witnessed another abrupt change in the market, as CMS released two additional codes, U0003 and U0004 – specific for high throughput COVID-19 testing, which were priced at nearly twice the prior codes. Also, in April, AMA released CPT code 86769 specific for serological testing for COVID-19 antibodies. As evidence increased casting doubt on the clinical utility of the serological testing throughout May and June, many plans adopted policies indicating Ab testing

would not be reimbursed. As noted in the previous section, ACLA is advocating for health plans to offer coverage for antibody testing in both medically necessary and non-medically necessary situations. As shown in the graph which depicts the fraction of COVID-19 units by procedure code, throughout all the changes, the labs collectively responded by following the testing methodologies and coding approaches best suited, and most profitable, at the time. As higher throughput technologies received higher reimbursement,



many laboratories with suitable equipment switched from billing low throughput codes. Once antibody testing received a code, labs began billing for antibody tests, and the fraction decreased concurrently with concerns about clinical utility and reimbursement from plans. Stabilization of coding, reimbursement, testing capabilities resulted in a relatively stable test type composition since mid-June.

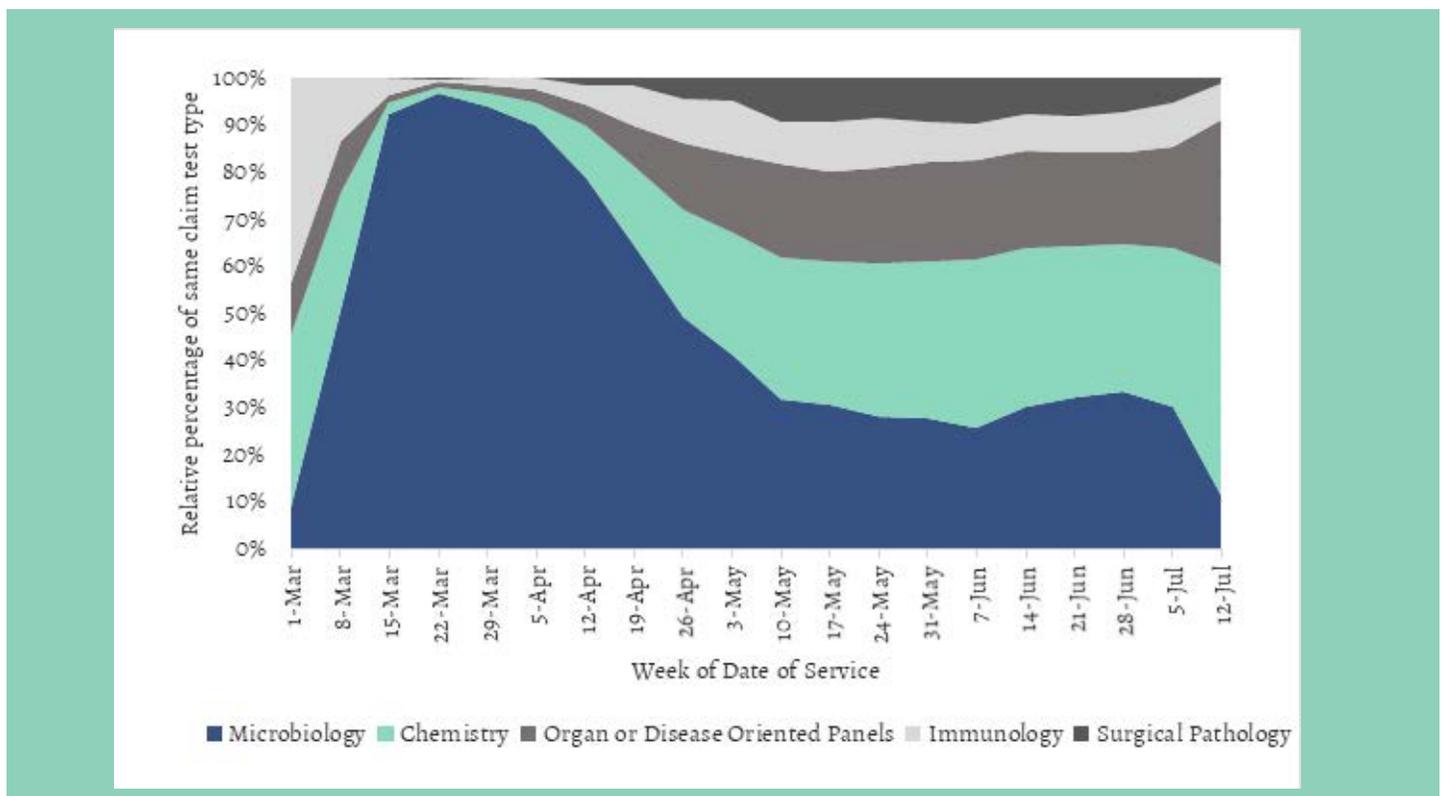
THE COMPOSITION OF CONCURRENT NON-COVID-19 TESTS BILLED WITH COVID-19 TESTS CHANGES

Throughout March and into April, testing volumes throughout the country remained relatively low compared to the current testing capacity. Initially, in March, most

of the concurrent tests ordered in conjunction with COVID-19 tests related to infectious disease testing. Presumably, physicians were looking to rule out, or rule in, other viral or bacterial infections to ensure appropriate patient treatments.

Interestingly, over time the composition of concurrent tests changed to include more chemistry, disease focused panels (e.g. metabolic panel), immunological testing, and surgical pathology. As more publications presented information regarding the consequences of COVID-19 infections, physicians may have ordered blood work (e.g. CBC, lipid panels, metabolic panels) to preemptively probe the condition of the patient. Alternatively, patients

may have been seeking care for COVID-19 and unrelated ailments more expected timeframes. The histogram shows the number of claims and the associated difference between the date of receipt and the date of services. The minimal claim volume from March (red) averaged 65 days. Claims with dates of service in June are speeding through the system much faster than previous months and are becoming more indicative of the laboratory providers test turnaround time. In the next few months, the service to receipt metric will again closely represent laboratory test turnaround times and therefore, as increases in the metric are observed, this may indicate which laboratories are reaching their testing capacity limits simultaneously.



DELAYS IN COVID-19 CLAIM FILINGS ARE DECREASING

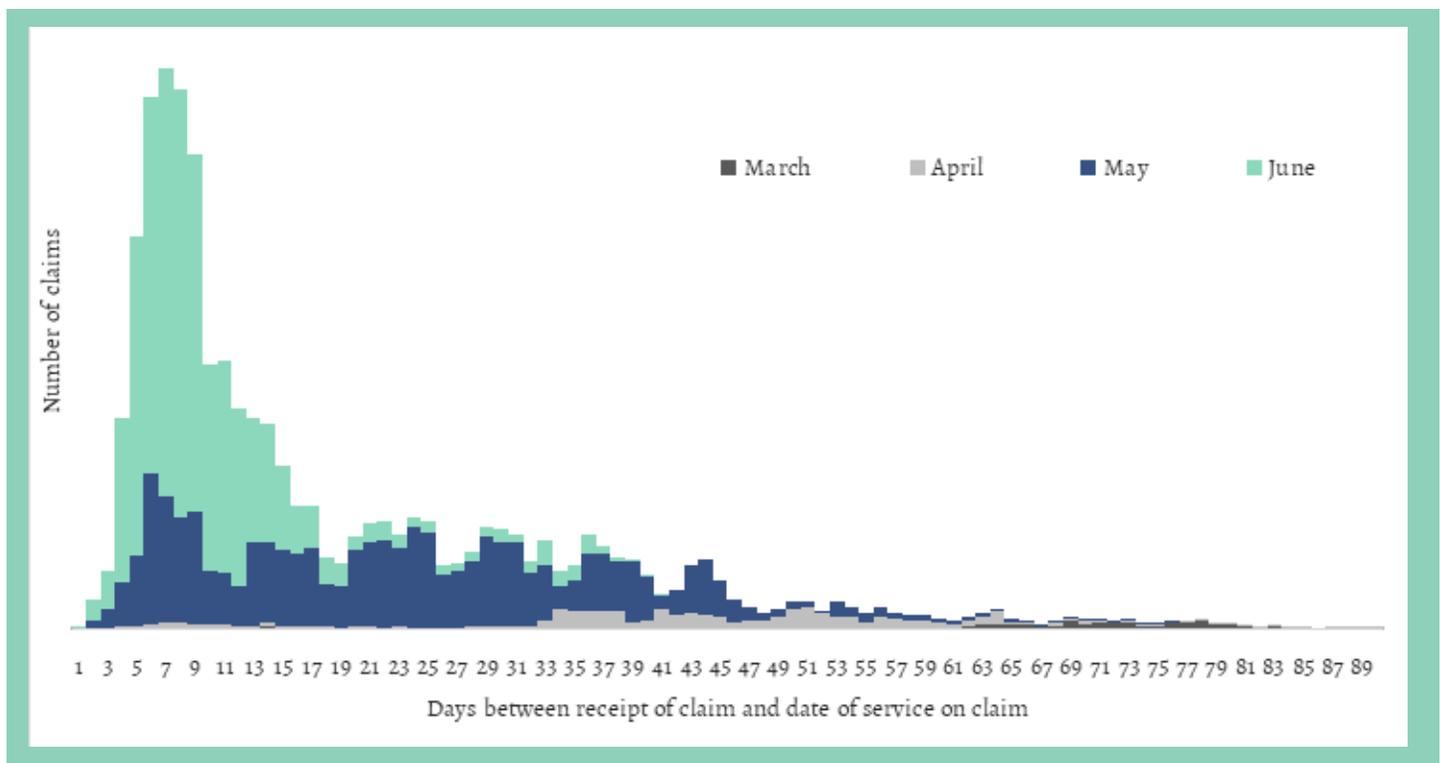
Prior to the COVID-19 pandemic, health plans could assume that the receipt date of a claim corresponded closely with the laboratory issuing a final report to the ordering physician because reimbursement requires the laboratory service be complete. However, COVID-19 claims were purposefully held by the providers due to ambiguity on coding or reimbursement, as well as awaiting the plans to configure their claims systems to account for the members cost share waiver. As those hinderances no longer impede claims processing, laboratory claims flow has been reduced in line with expected timeframes. The histogram shows the number of claims and the associated difference between

TOP 10 CONCURRENT LABORATORY TESTS	FRACTION OF CONCURRENT TESTS
Detect agent nos dna amp (87798)	12%
Complete cbc w/auto diff wbc (85025)	5%
M.pneumon dna amp probe (87581)	4%
Comprehen metabolic panel (80053)	4%
Lipid panel (80061)	3%
Metabolic panel total ca (80048)	2%
Tissue exam by pathologist (88305)	2%
Influenza assay w/optic (87804)	2%
Complete cbc automated (85027)	2%
General health panel (80050)	2%

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MONTH	AVERAGE CLAIM TAT (DAYS)
March	65
April	44
May	23
June	10

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COVID-19 AND NON-COVID-19 TRENDS: TESTING PARTIALLY RECOVERS

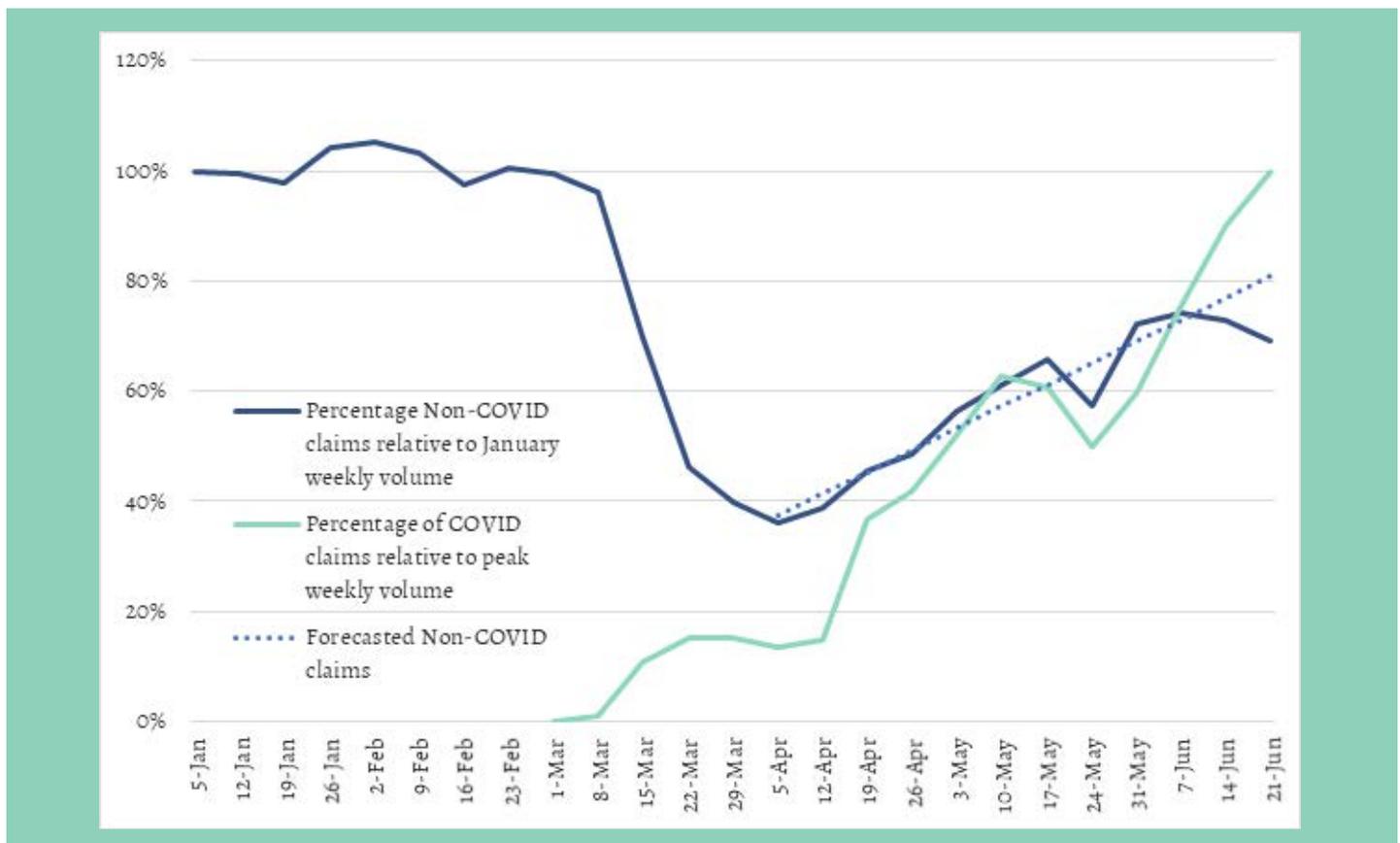
The steep drop in testing observed in April was troublesome as the longer the duration, the more patients would not be receiving the necessary care and treatment for conditions. Long durations without seeing physicians can result in more severe manifestations of diseases. Fortunately, the precipitous drop in laboratory testing has been steadily recovering since the April low. As governments rescinded stay at home orders throughout May and early June, patients began returning for care and receiving laboratory tests. Concurrently, the testing of COVID-19 has increased as the risk of contagion remains

high, especially as social distancing measures are lifted or ignored by subsets of the population.

Forecasting the current trend shows a return to January levels by August. Numerous factors could influence the return of patients to their physicians. However, continued opening of the economy and increased usage of masks to prevent disease spread may provide more comfort to patients and result in a return to prior testing levels. The surging cases of COVID-19 may necessitate the return of stay at home orders or further prevent patients from office visits.

PATIENTS WITH SIGNIFICANT HEALTH PROBLEMS GENERALLY CONTINUED TO RECEIVE CARE

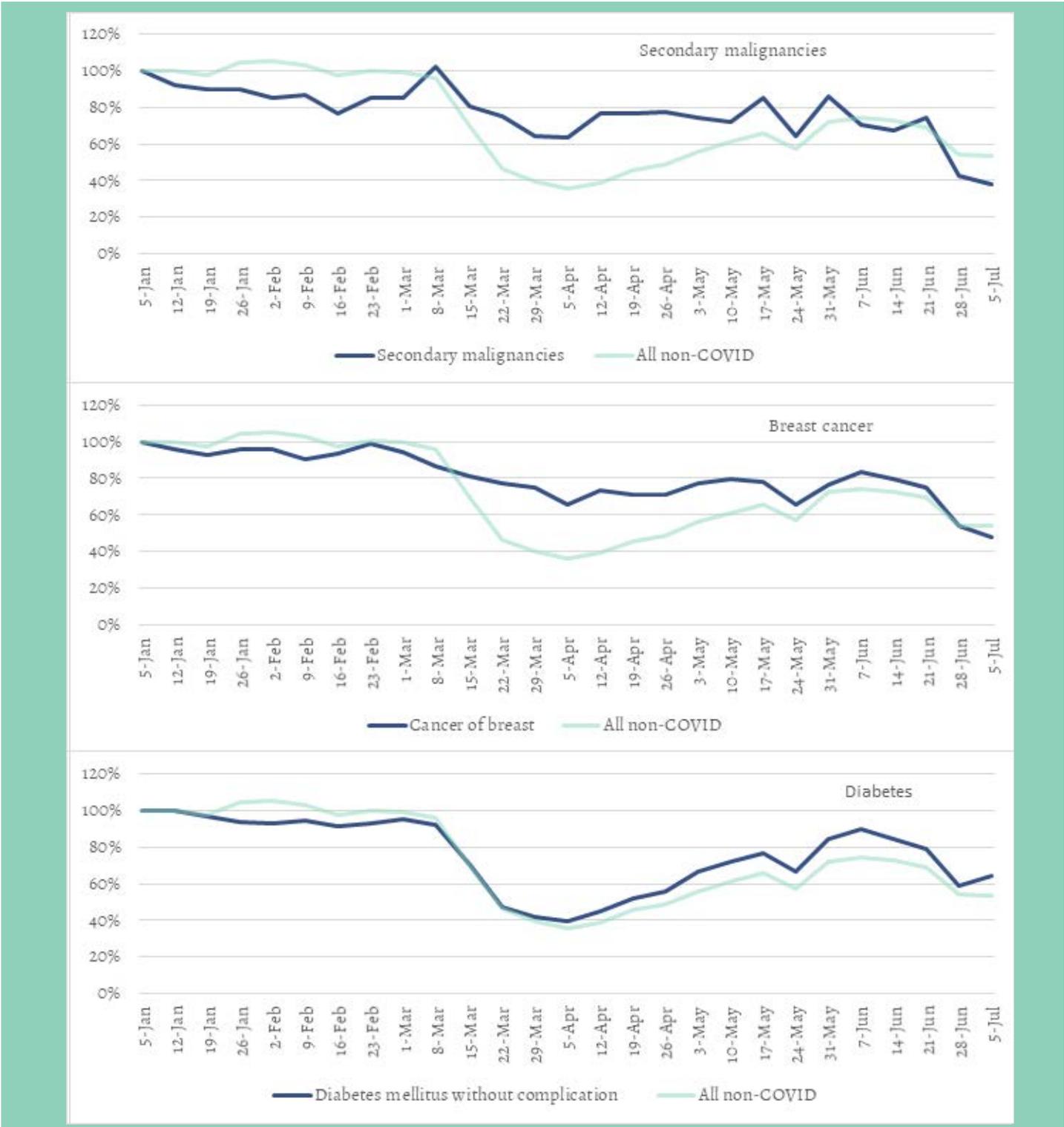
With the material drop in laboratory testing, concerns grew regarding the health status of patient under active care for severe and acute diseases as well as patients which would normally have undergone surveillance or screening for conditions. Collectively, the absence of testing and monitoring patients who need care, especially over prolonged periods, may correspond to more advanced diagnoses in the future. The graphs depict the relative changes in weekly testing volumes over time compared to the week of January 5th, 2020. The aqua line represents the changes in total testing. The blue lines represent the changes in claim volume for disease states using the AHRQ



clinical classification software methodology. Overall, patients with claims associated with severe diseases with potentially acute timelines, such as breast cancer or secondary malignancies, showed less decline in testing compared

to the overall testing drop. As a contrast, diabetes monitoring showed a similar decline to the general testing trend. Across many disease categories, severe diseases showed a smaller decrease in testing compared to chronic diseases.

While positive signs that critical patients generally maintained their care, the longer-term trends of missed surveillance or deferred treatments in other areas of healthcare should be monitored to evaluate the potential for future risks in the health status of patients.



REFERENCES

¹ Q5. Is COVID-19 testing for surveillance or employment purposes required to be covered under section 6001 of the FFCRA?

No. Section 6001 of the FFCRA requires coverage of items and services only for diagnostic purposes as outlined in this guidance. Clinical decisions about testing are made by the individual's attending health care provider and may include testing of individuals with signs or symptoms compatible with COVID-19, as well as asymptomatic individuals with known or suspected recent exposure to SARS-CoV-2, that is determined to be medically appropriate by the individual's health care provider, consulting CDC guidelines as appropriate. ¹³ However, testing conducted to screen for general workplace health and safety (such as employee "return to work" programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition is beyond the scope of section 6001 of the FFCRA.

ⁱⁱ Accessed on 7/23/20 - <https://www.jdsupra.com/legalnews/doj-brings-covid-19-related-fraud-77830/>