Nov 2, 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.

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 CAPACITY & TURNAROUND TIME REPORT

- The current capacity of the Avalon for COVID-19 RT-PCR testing is > 750,000 tests/day
- Nationally there are approximately 1 million COVID-19 tests performed each day
- Turnaround time for all labs is less than 2 days and most labs report excess capacity

LAB	HEALTHPLAN	RT-PCR Y/N	MULTIPLE PLATFORMS	CAPACITY (PER DAY)	TAT	ANTIBODY TESTING Y/N	FDA EUA	CAPACITY (PER DAY)	TAT
LabCorp	SC,NC	Y	Y	200,000	1-2 days	Y	Y	300,000	1-3 days
Quest	SC, NC, CBC, VT	Y	Y	200,000	1-2 days	Y	Y	200,000	1-2 days
BioReference	SC, NC, CBC, VT	Y	Y	70,000	1 day	Y	Y	260,000	3 days
Premier Medical Lab	SC	Y	Y	50,000	1-2 days	Y	Y	50,000	1-2 days
GenetWorx	SC, NC	Y	Y	40,000	2 days	Y		1,000	1 day
Mako Medical Lab	SC, NC	Y	Y	35,000	1-2 days	Y	Y	20,000	1 day
Eurofins-Diatherix	SC, NC, CBC, VT	Y	N	30,000	1-2 days	Y	Y	15,000	2-4 days
AIT (American Institute of Tox)	SC, NC, CBC	Y	Y	20,000	1-2 days	N	Y	15,000	1-2 days
Sonic-CPL	SC	Y	Y	20,000	1-3 days	Y	Y	100,000	1 day
Genesis DX (DNA Analytical)	CBC	Y	Y	16,000	1-2 days	N			
MDL(Medical Diagnostic Lab)	SC, NC, CBC, VT	Y	N	12,000	2-3 days	Y	Y	1,000	3 days
LabTech	SC,NC	Y	Y	10,000	2 days	Y	y	3,000	1 day
Aegis	SC, NC, CBC, VT	Y	Y	10,000	2 days	Y	N	10,000	1 day
AccuReference	CBC	Y	N	10,000	2 days	Y	Y	4,000	2 days
PathGroup	NC	Y	Y	8,000	2-3 days	Y	Y	1000	1 day
Luxor	SC	Y	Y	5,000	1 day	Y	Y	1,000	1-2 days
Transplant Genomics	CBC	Y	N	5,000	1-2 days	Y	Y		1 day
Neogenomics	SC, NC, CBC, VT	Y	Y	5,000	1-4 days	N		NA	
Precision Genetics	SC, NC	Y	N	4,000	1-2 days	Y	Y	1250	2-4 days
BAKO	SC, NC, CBC, VT	Y	N	2,500	1-2 days	N		NA	
Radeas	SC, NC	Y	Y	2,400	1-2 days	Y	Y	4,000	1 day
Wake Medical Lab Consultants	NC	Y	Y	1,500	1 day	Y	Y	4,800	1 day

THE AMERICAN MEDICAL ASSOCIATION PUBLISHES NEW CPT CODES FOR MULTI-VIRUS TESTS INCLUDING COVID-19

On October 7, 2020, the American Medical Association (AMA) released new CPT codes that describe multi-virus panels for the concomitant detection of COVID-19, influenza types A and B and the syncytial respiratory virus. In addition, the CPT Editorial Board revised the description for CPT code 87426 (antigen) and created a new CPT code, 87811. The following are the long descriptors for these codes as published by the AMA:

87636	*Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique*
87637	*Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique*
87426	*The CPT Editorial Panel also revised CPT codes ranging from 87301 to 87430 by removing the undefined term "multi step method" from code descriptors. The revision clarifies the proper reporting for antigen tests that are read by a machine, as compared to those which can be visually interpreted without a machine. This revision affects the newly developed descriptor for CPT code 87426.*
87811	*Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]).* *In accordance with the above revision, the CPT Editorial Panel approved a new category I code, 87811, to report infectious agent antigen detection by immunoassay with direct visual observation.* *Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])*

CMS allows the Medicare Administrative Contractors (MACs) to initially assign reimbursement for new codes. Avalon located the following reimbursement for COVID-19 testing on the First Coast Service Options (FCSO) website. FCSO is the MAC for jurisdiction N, which includes Florida, Puerto Rico and the U.S. Virgin Islands. Avalon does not recommend the use of this information in the pricing of testing for COVID-19. Instead, Avalon recommends each plan check with the MAC that provides Medicare administration for the plan's marketplace.

COVID-19: ALLOWANCES FOR LABORATORY TEST CODES

CMS has established new codes for laboratory tests for COVID-19. CMS provided pricing for codes U0001 and U0002 but instructed MACs to develop the allowance for the remaining codes. The codes and allowances are as follows:

CODE	ALLOWANCE	CODE	ALLOWANCE	CODE	ALLOWANCE
U0001	$35.92	0225U	$416.78	86413	$42.13
U0002	$51.31	0226U	$42.28	87426	$45.23
U0003	$100.00	0240U	$142.63	87635	$51.31
U0004	$100.00	0241U	$142.63	87636	$142.63
0202U	$416.78	86408	$42.13	87637	$142.63
0223U	$416.78	86409	$105.33	87811	$41.38
0224U	$42.13				

COVID-19 "AT-HOME" TESTING

Avalon has previously discussed the Emergency Use Authorization (EUA) by the FDA for COVID-19 home collection and subsequent testing. Since that time, several companies have received an EUA for this mode of testing. The companies listed below have been assigned an EUA for at home collection and subsequent testing by a qualified facility. Please note that some of the companies listed are manufacturers or distributors of the collection kit and the testing kit. Qualified laboratories may purchase or may be authorized by these manufacturers to utilize their kits. Therefore, it is possible for qualified providers that are not listed here, to utilize this technology and potentially submit claims to the appropriate health plan. At present, there are no approved COVID-19 tests that allow a person to collect a sample and determine a result without the assistance of a qualified provider.

HOME COLLECTION KITS FOR COVID-19 TESTING: MANUFACTURERS AND PROVIDERS WITH EUA

COMPANY NAME	TEST TECHNOLOGY	DELIVERY TYPE
ThermoFisher	RT-PCR	Manufacturer
Clinical Enterprise	RT-PCR	Manufacturer
Eurofins Viracor	RT-PCR	Lab Provider
Color Genomics	RT-LAMP	Lab Provider
Quest Diagnostics	RT-PCR	Lab Provider
Gravity Diagnostics	RT-PCR	Lab Provider
Exact Science	RT-PCR	Lab Provider
LabCorp	RT-PCR	Lab Provider
Infinity BiologiX	RT-PCR	Distributor
Kaiser KPMAS	RT-PCR	Provider
Everlywell	RT-PCR	Distributor

COMPANY NAME	TEST TECHNOLOGY	DELIVERY TYPE
DxTerity Diagnostics	RT-PCR	Lab Provider
QDx Pathology Services	RT-PCR	Lab Provider
PrivaPath/ Let'sGetChecked	RT-PCR	Distributor
Clinical Reference Laboratory	RT-PCR	Lab Provider
Compass Laboratory Services	RT-PCR	Lab Provider
P23 Labs	RT-PCR	Lab Provider
Kroger Health	RT-PCR	Distributor
Phosphorus Diagnostics	RT-PCR	Lab Provider
Fulgent Genetics	RT-PCR	Lab Provider

HEALTHCARE POLICY UPDATE

PUBLIC HEALTH EMERGENCY

On October 2, 2020, HHS Secretary Alex Azar declared an additional 90-day extension of the Public Health Emergency (PHE) effective on October 23, 2020.[1] The announcement came three weeks before the prior emergency declaration was set to expire to allow stakeholders to plan for the continued flexibility of certain health care regulations through January 20, 2021 -- which happens to fall on the inauguration day of the next president.

This is the third 90-day extension of the PHE. The expiration and renewal timelines are important to the healthcare industry and state governments because dozens of COVID-19-related emergency measures will sunset when the PHE expires.

Multiple temporary rules are in place under the PHE, such as requiring medical plans to cover COVID-19 diagnostic testing with no member cost-sharing obligation, Medicare and Medicaid blanket waivers, providing additional time to elect and pay COBRA premiums, and allowing Medicare beneficiaries to see their doctors via virtual visits from anywhere and on any device. Stakeholders should be aware that state governments may have separate timelines associated with state-governed policies, like professional licensure, Medicaid, and commercial insurance rules.

CONTROVERSY OVER THE FDA'S EUA AUTHORITY

Exacerbated by the COVID-19 crisis, an ongoing and long-term controversy about the FDA's authority over laboratory-developed tests (LDTs) is complicating the lab testing market during a challenging time.

At the beginning of the pandemic, FDA announced it would oversee the new diagnostics that were quickly coming to market to serve the emergent need to diagnose the virus. HHS has since rescinded the FDA's authority, forcing laboratories to decide whether to voluntarily seek FDA's blessing for their LDTs. Because the FDA approval process grants labs liability protections during PHEs, the rescission is causing confusion for labs,[2] consternation among policymakers,[3] and will ultimately lead to legislative action by Congress.[4]

FDA Authority of LDTs During PHEs

During PHEs medical countermeasures (MCMs) may be needed to prevent or treat diseases or conditions caused by infectious disease threats, like the COVID-19 virus. MCMs are medical products such as drugs, vaccines, diagnostic tests, and other medical equipment and supplies, needed to respond to emergencies involving such threats. The FDA has traditionally used its EUA authority[5] to quickly expand the availability and use of MCMs needed during public health emergencies.

For years, the FDA has claimed that all in vitro diagnostic (IVD) tests are subject to its regulatory oversight, even as the FDA rarely enforced these requirements for lab-developed tests. When the COVID-19 viral outbreak became a widespread crisis necessitating emergency measures, the FDA announced that every test marketed to screen for or diagnose COVID-19, including lab-developed tests (LDTs), must receive an EUA. In August, HHS rescinded the FDA's authority over LDTs.[6]

PREP Act Immunity From Emergency Medical Countermeasures

The Public Readiness and Emergency Preparedness (PREP) Act[7] gives lab test providers broad immunity from liability claims during a PHE. Specifically, the PREP Act provides immunity "from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure" if the federal government has declared a public health emergency.[8] The PREP Act protection applies only to tests that have received an EUA.

On October 7, 2020, the FDA announced that it will no longer review COVID-related EUA submissions for LDTs.[9] Accordingly, clinical labs that are offering LDTs will not have any liability protection under the PREP Act that do not already have an EUA.

Timeline of EUA-Related Events

The following timeline highlights the sequence of major actions that created the current regulatory uncertainty about FDA oversight of LDTs.

JAN 31, 2020	HHS issued a determination that a PHE exists (a prerequisite to enable the FDA to issue EUAs under Section 564 of the FD&C Act)
FEB 4, 2020	FDA issued a Notice of Declaration under the Public Readiness and Emergency Preparedness Act for medical countermeasures against COVID-19
FEB 29, 2020	FDA issued guidance to allow labs who applied for emergency approval for tests to use them before the FDA completed its review
MARCH 2020	FDA expanded its February Guidance to commercial developers of LDTs; allowed states to oversee tests developed by labs
APRIL 2020	FDA recalled faulty / inaccurate tests and began requiring scientific reviews; issues guidance about serology tests; HHS issues PREP Act immunity notice
MAY 2020	FDA releases EUA Template
JUNE 2020	HHS General Counsel sends memo to FDA questioning its authority to oversee LDTs
AUGUST 2020	HHS rescinds FDA authority over lab tests; declares that LDTs would not be subject to premarket review by the FDA absent formal agency rulemaking
SEPT 2020	HHS issues FAQs on LDTs; FDA leaders author a New England Journal of Medicine article on EUA lessons learned during the pandemic
OCT 7, 2020	At a town hall and in an FAQ , FDA announced that it would no longer review voluntary submissions of COVID-19 LDTs

THE NEXT ECONOMIC STIMULUS BILL

The House Democratic leadership and the White House are reportedly close to reaching a coronavirus stimulus deal, but there will not be enough time to draft and vote on a bill prior to the election.[10]

Throughout the month of October, U.S. House Speaker Nancy Pelosi and Treasury Secretary Steven Mnuchin have been in earnest, last-ditch negotiations aimed at reaching an approximately $2 trillion economic relief package. This follows months of back and forth since the House passed the $3 trillion relief package in May 2020 -- the Health and Economic Recovery Omnibus Emergency Solutions Act or the "HEROES Act"[11] -- without bipartisan support and without any movement by the U.S. Senate on the bill.[12]

The lab testing issue has been a big part of the economic relief package negotiations. Speaker Pelosi noted that Secretary Mnuchin agreed to a "provision on testing with 'minor' changes to the language" of the HEROES Act[13] -- but the White House later made substantive changes.[14]

While it is unclear what the provisions will be in a final bill, the latest proposal[15] clarifies the scope of coverage requirements for COVID-19-related services, calling for health plans to pay for COVID-19 lab tests and related services regardless of medical necessity or provider approval. Specifically, Section 307 of the revised proposal states that group and individual market health plans are to provide coverage of items and services related to COVID-19 testing at no cost-sharing to the individual, regardless of:

- why an individual sought such tests,
- the nature of the clinical assessment that was associated with such tests,

- whether such individual was showing symptoms prior to being furnished such tests,
- whether or not such tests were ordered by a provider;
- the frequency with which such individual is furnished such tests, and
- any other review of the encounters or events that preceded or followed the furnishing of such tests.

The latest bill language also outlines a new lab test price transparency process. The goal is to publicly "name and shame" labs that request exorbitant reimbursement. Specifically, Section 309 of the revised proposal states that the HHS Secretary shall publish on the HHS website "the average cash price for each [lab test] … and a comparison of such average cash price to the reimbursement rate under the Medicare program … and any cash prices … that substantially exceed the average cash price for each such item or service and the name of each provider that charges such prices."

Again, these provisions may change before all parties will agree to make this bill a law. It seems clear, however, that these items will be addressed in some form and that an economic stimulus package is inevitable.[16]

OTHER POLICY UPDATES

As of October 20, the FDA has authorized 282 tests under EUAs; including 220 molecular tests, 56 antibody tests, and 6 antigen tests.

On October 15, CMS announced that starting January 1, 2021, Medicare will pay $100 to laboratories that complete high throughput COVID-19 diagnostic tests within two calendar days of the specimen being collected. Medicare will pay $75 to labs that take longer than two days to complete the tests.

On October 15, the FDA published a guidance document that addresses biotin interference testing for in vitro diagnostic devices. The agency left the 2019 draft guidance largely unchanged.

On October 14, CDC published a new web page on COVID-19 point-of-care testing.

On October 13, the FDA issued guidance on flu tests to address the increased demand of molecular influenza and RSV tests during the pandemic.

LAB ORDERING DATE ANALYSIS

The COVID-19 pandemic has resulted in a significant drop in laboratory testing. This is concerning as at least 70% of medical decisions rely on lab test results. Early on, providers, patients, and payers were confused over how to select the right type of test and when and who to test. There was also a lack of adequate testing capacity and a rapid increase in the number of laboratories providing testing services which added to the confusion.

For a claim composition analysis, four categories represented the different testing approached: PCR based tests (e.g. U0001, U0004 etc), antibody testing, COVID-19 testing included in a panel (e.g. other respiratory diseases and COVID-19 together), and antigen testing. Figure 1 below shows the percentage of claims each week relative to the peak claim volume by each category. Noticeably, antibody testing spiked in mid-June and has fallen since. Possible explanations include the providers holding claims until uncertainty around reimbursement by payers dissipates or a response to payers holding a negative coverage decision surrounding broad use of antibody testing.

PCR, the definitive 'gold standard' test for active COVID-19 infections, remains close to peak claim volume achieve in late July and represents 84% of all claims submitted to Avalon's clients. Antigen testing steadily increases starting in July and currently accounts for 2% of all COVID-19 claims. Infectious panels including COVID-19 are increasing but remain significantly behind antigen testing in collective volume. Overall, as shown on national testing rates, COVID-19 testing continues to grow in volume. These data cover insurance claim-based testing only. Government funded testing (e.g. drive through collection sites backed by state and local governments), while included in nationally reported volumes are not represented in these analyses.

TEST TYPE	% OF CLAIMS
PCR	84%
Antibody	14%
Antigen	2%
Panel + COVID	0%

TABLE 1: Fraction of total COVID claims since April 2020

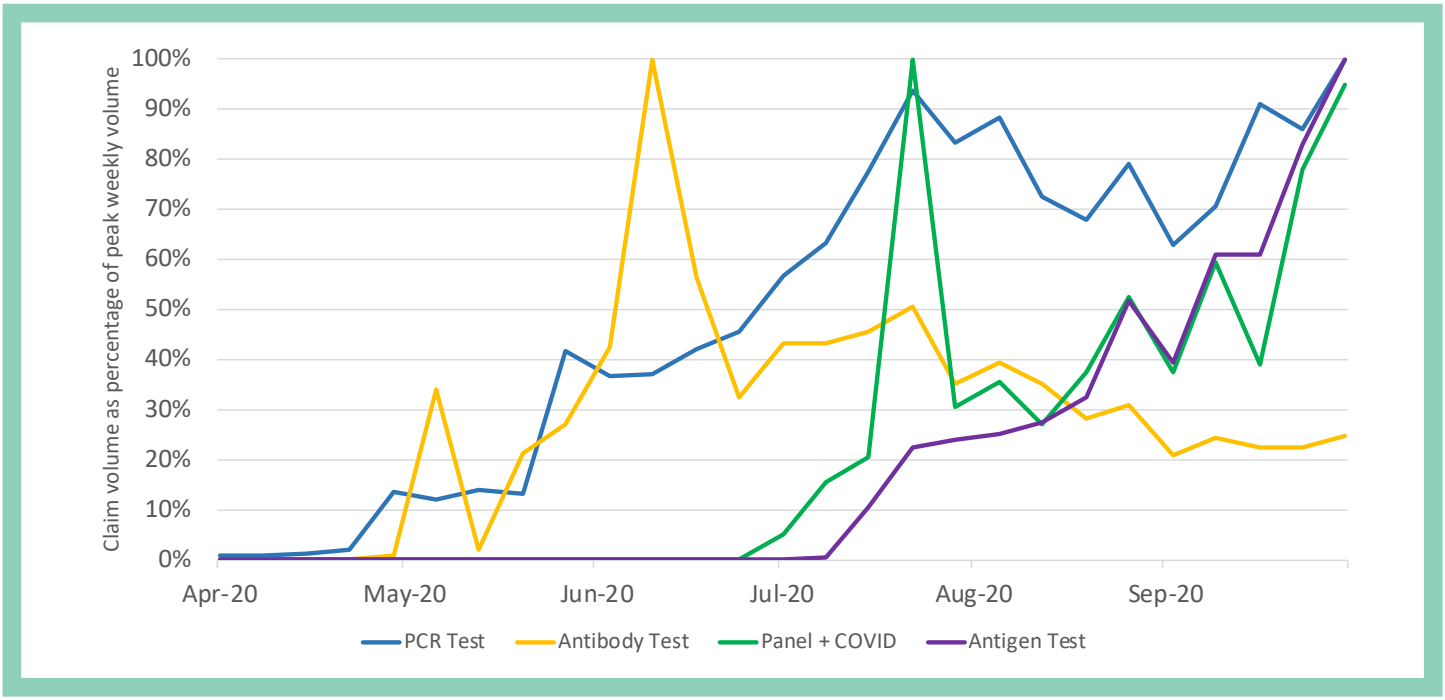

FIGURE 1: Weekly claim volume percentage relative to weekly peak volume by test category

In typical laboratory processes, the submission of a claim immediately follows the issuance of the final report to the physician. Therefore, the time between the date of service and the date of receipt approximates the turnaround time (TAT) for a test. Frequent changes in coding and reimbursement rates, uncertain implications of member cost sharing, limited reagents for tests, and reduced staffing levels in laboratories, among other factors contributed to significant delays between a sample being collected from a patient (date of service) and the submission of the corresponding claim (date of receipt).

The blue line in Figure 2 below that depicts a histogram of the TAT relative to peak TAT level early in the pandemic (May) and the extended percentage of claims taking over two weeks for submission demonstrates the culmination of the many factors listed above. Standard TAT times for laboratories, across all places of service and all types of non-genetic tests for outpatient laboratory testing, averages less than seven days. Three months later, while the lab industry claims testing capacity exceeds demand and quicker results to the physician and patient, the surrogate TAT indicates longer than expected durations for test results (orange line). However, the time between receipt date and service date may not accurately represent the true turnaround time for the testing.

Certainly, TAT times associated with rapid testing, where results are provided in minutes to hours, such as point of care PCR and antigen testing, are not represented by the claim based surrogate measurements. Ultimately, the ambiguity of the first three months and the labor and testing shortages have subsided and laboratories are returning to expected performance.

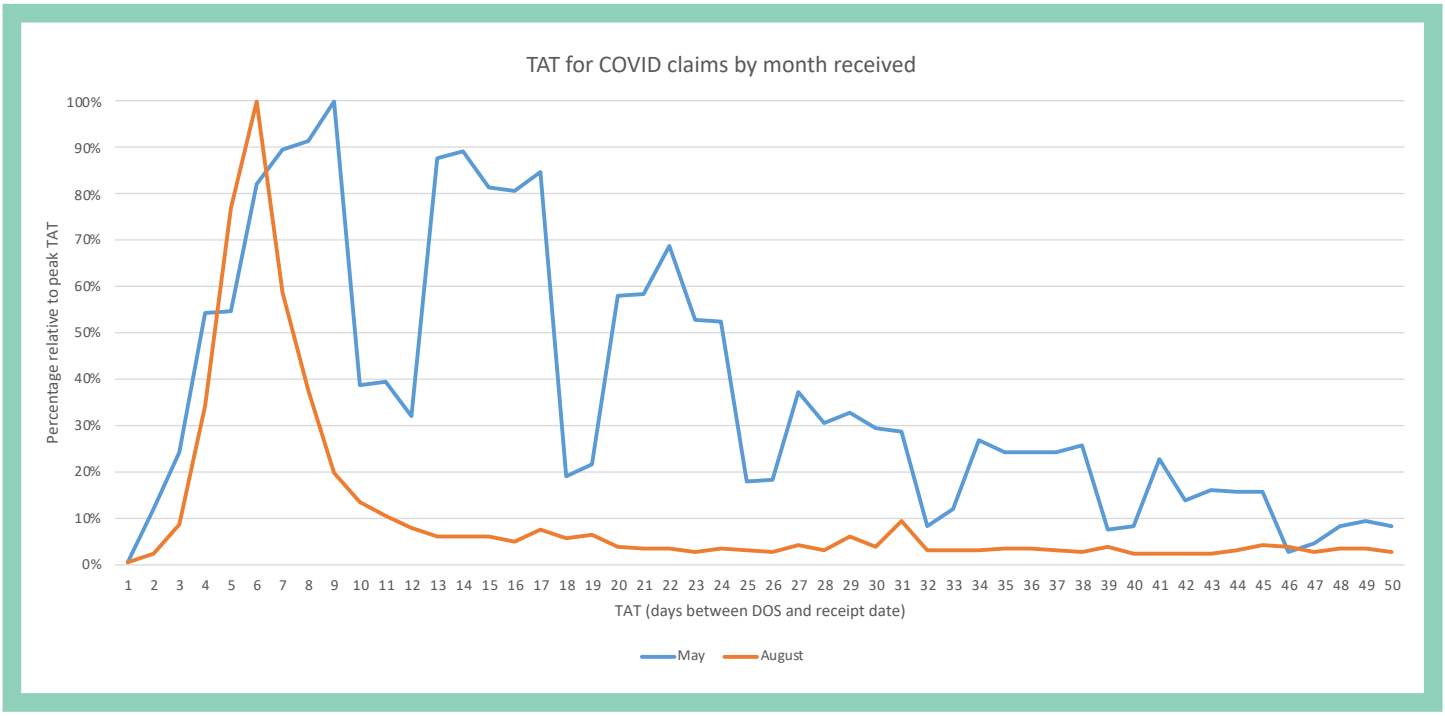

FIGURE 2: Time between COVID date of service and date of claim submission to the health insurance plan

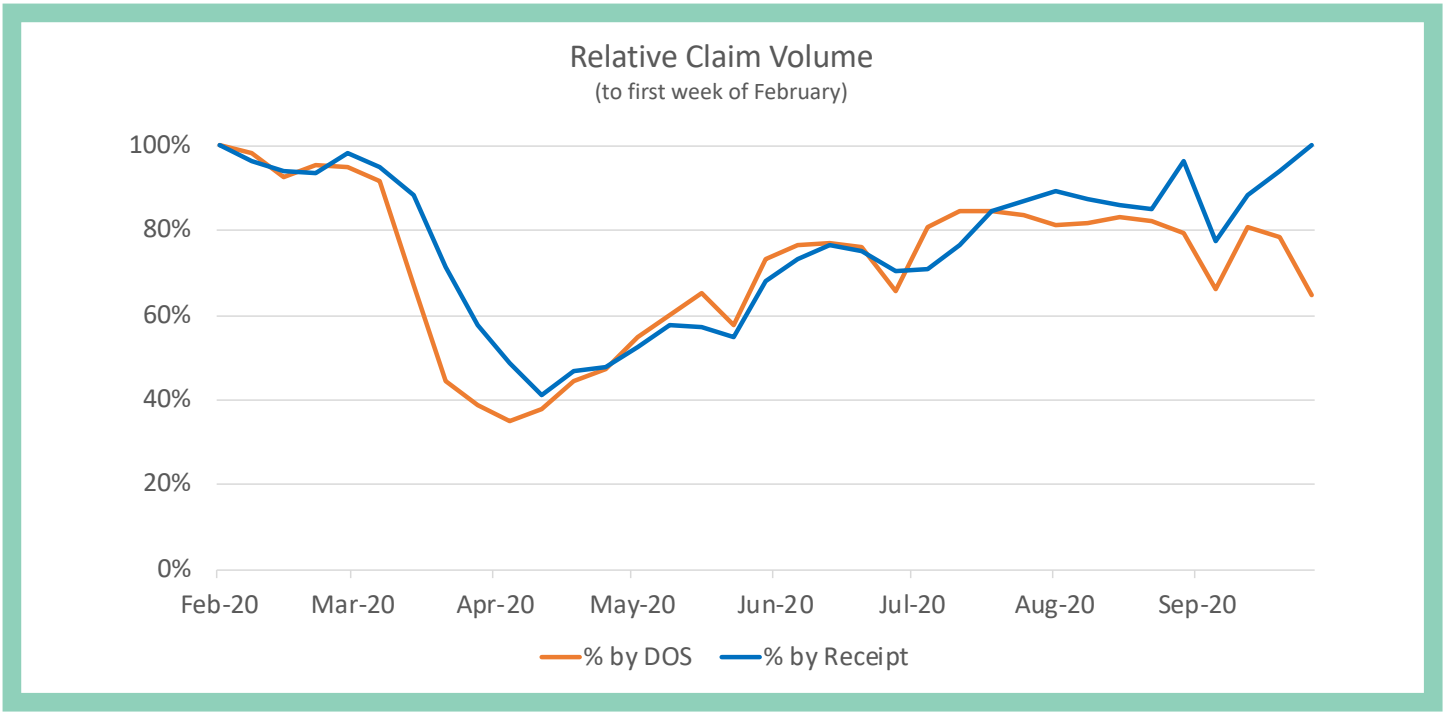

FIGURE 3: Weekly claim volume trend over time

To further discern the trends for specific of types of patients and tests, we evaluated subsets of the total trends over time.

Figures 4A-4C below depict three different types of patients and the corresponding weekly claim volume over time. The blue lines depict the groups weekly claim volume, and the dashed orange lines shows the overall trend as shown in Figure 3 (by receipt date). As mentioned previously, healthy individuals reduced testing more than other groups in the early stages of the pandemic. General medical visits include these healthy patients, and the group as a whole surpassed the overall trend materially commencing in August, potentially indicating a "catching up" from deferred visits or an increase in demand due to COVID concerns.

Contrasting general medical visits, diabetic patients dropped similarly to the total population, but rebounded faster. Since some diabetics require more frequent monitoring, their faster return to normal levels suggests fewer longer-term complications. As could be expected for patients with neoplasms, trending levels remained above or equal to the total trending and may be entering a "catch up" period as well.

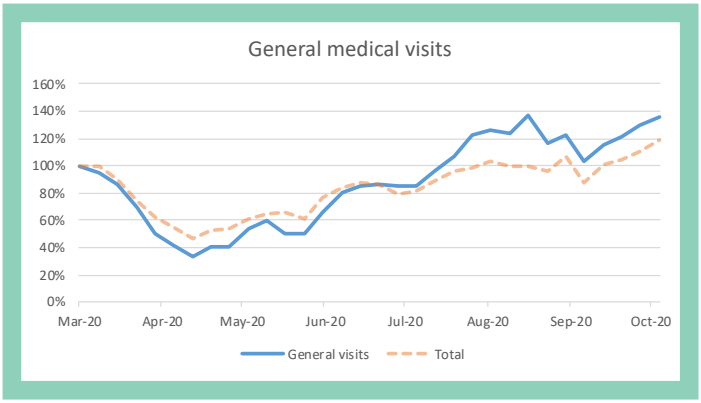

FIGURE 4A: Weekly claim volume trend over time - General medical visits

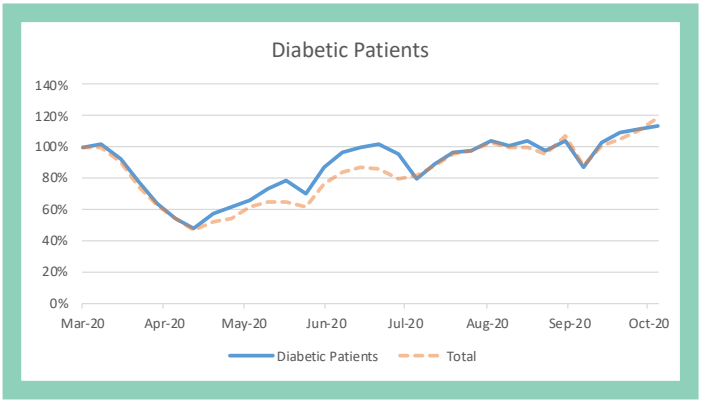

FIGURE 4B: Weekly claim volume trend over time - Diabetic Patients

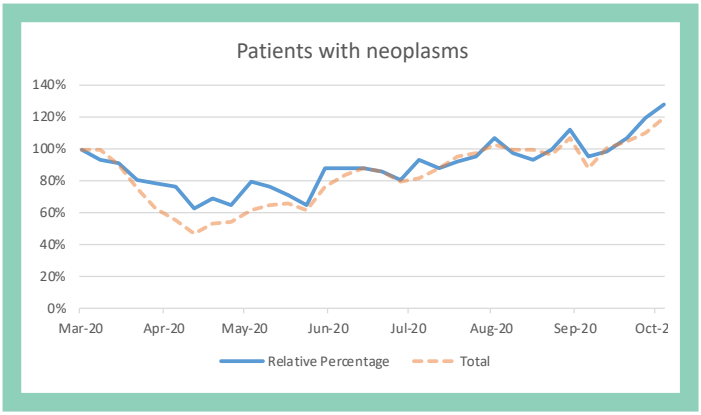

FIGURE 4C: Weekly claim volume trend over time - Patients witih neoplasms

Chemistry and Organ and Disease Oriented Panels are two high volume types of test categories which include such workhorse tests as hemoglobin A1c, free thyroxine, vitamin D, Comprehensive Metabolic Panel, Lipid Panel and General Health Panel. In each category, the changes in weekly claim volume over time (Figures 5A-5C below) are primarily driven by the changes in these two categories. Interestingly, the two categories are slightly over the total trend implying a drop in tests from other categories. For comparison, molecular pathology, an important but lower volume testing category, often used in clinical situations for cancer and preconception genetic testing, showed minimal reduction in claim volume throughout the spring and summer.

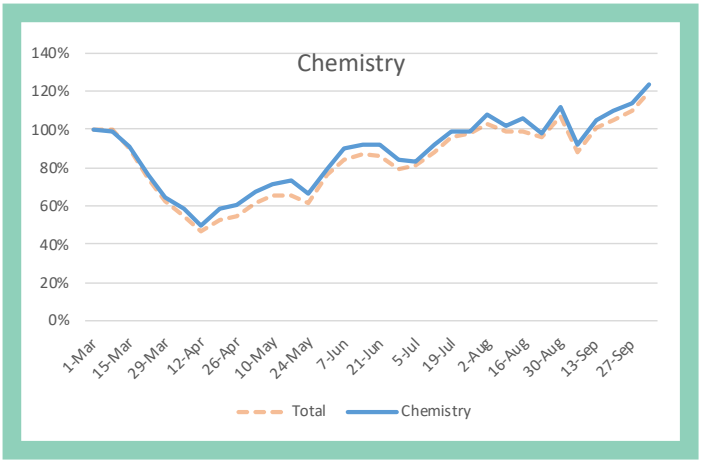

FIGURE 5A: Weekly claim volume trends over time - Chemistry

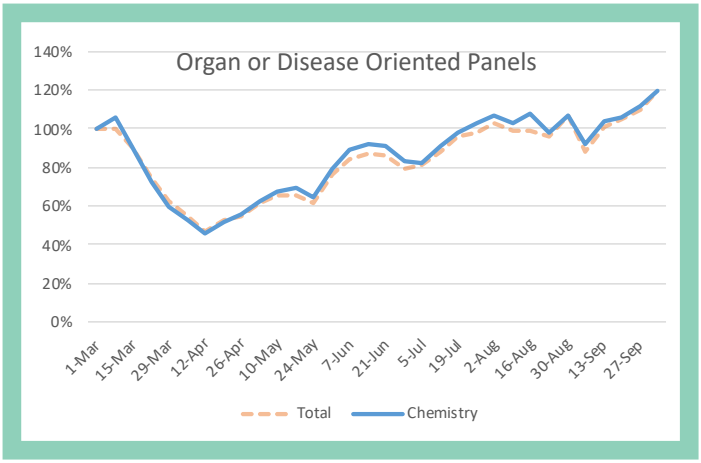

FIGURE 5B: Weekly claim volume trends over time - Organ or Disease Oriented Panels

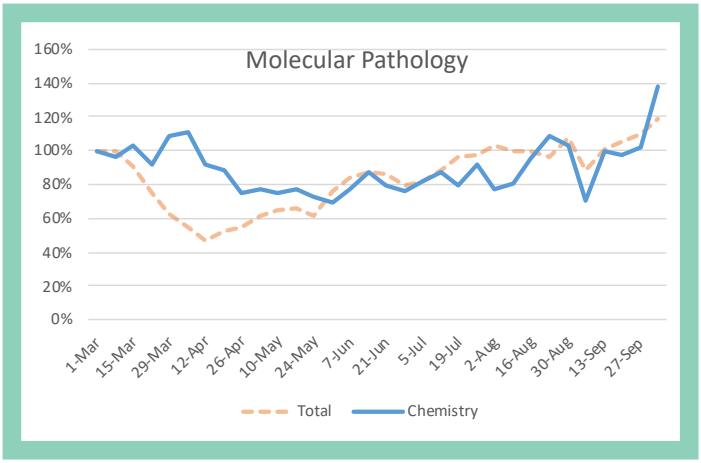

FIGURE 5C: Weekly claim volume trends over time - Molecular Pathology

A further analysis showed that microbiology testing volume dropped overall and has not returned to pre-pandemic total weekly claim volume (Figure 6). Tests for flu testing, sexually transmitted diseases and streptococcus contribute greatly to the total microbiology test volume. Interestingly, sexually transmitted diseases followed the total weekly claim volume trend. However, influenza and streptococcus testing dropped precipitously to a fraction of the levels in January. In typical years, flu testing drops to near zero over the summer months and begins to tick upwards commencing in August (data not shown). While a delay of flu testing to later in September is atypical, previous years have shown similar patterns.

Collectively, the above trends show a promising return of outpatient laboratory testing, which bodes well for patient screening and disease management. While various experts opine various predictions of COVID-19 over the winter months, Avalon will share data-based insights and trends to assist with health plans' decision making.

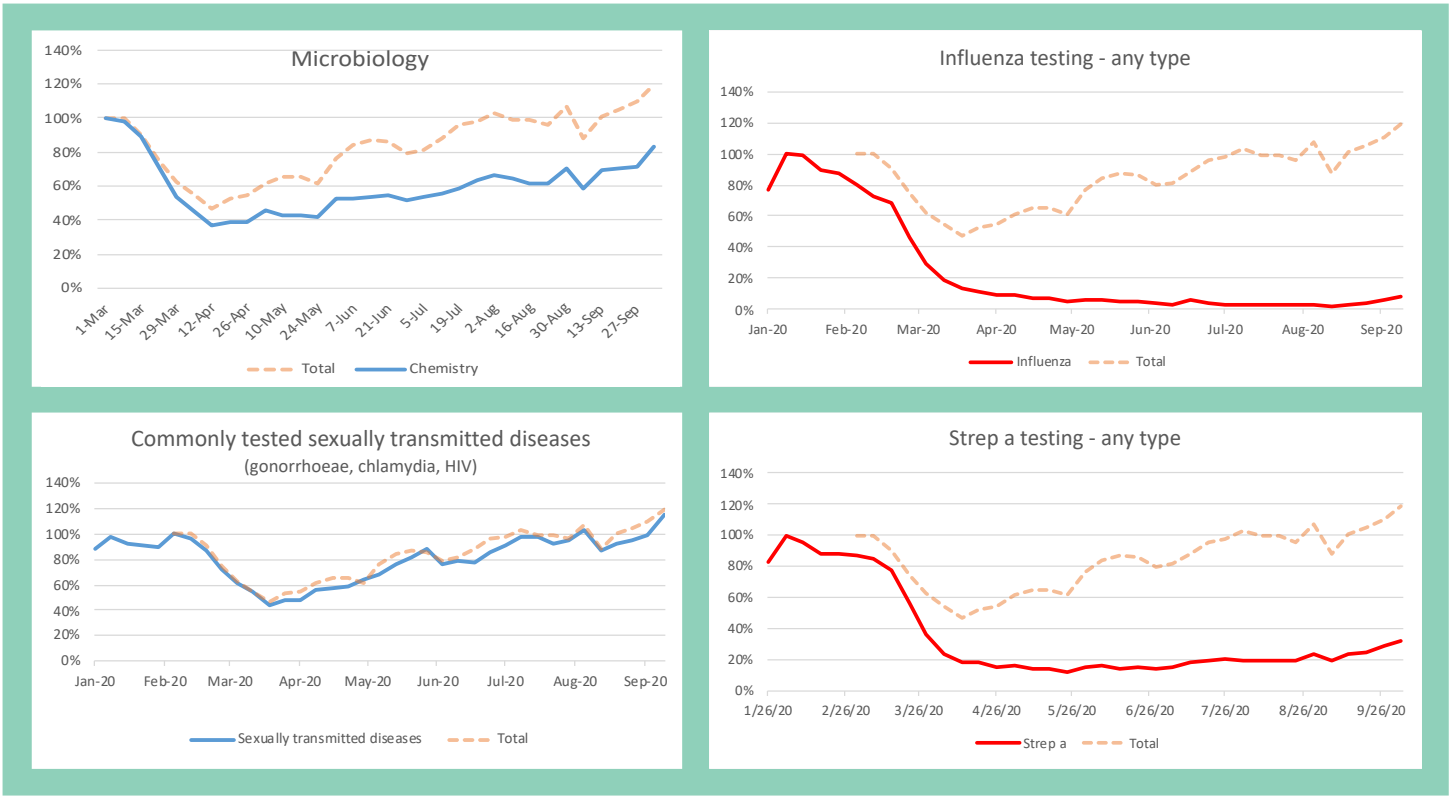

FIGURE 6: Weekly claim volume trends over time of selected microbiology tests

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