AVALON HEALTHCARE SOLUTIONS

May 26, 2020

COVID-19 TESTING BRIEF

from Avalon Healthcare Solutions

CONTENTS

FOR MORE INFORMATION, PLEASE CONTACT US:

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

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

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

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

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

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

The capacity of the lab network is relatively unchanged from last week. It is being reported by some news outlets and individual labs that the orders for COVID-19 diagnostic testing are less than the existing test capacity. The American Clinical Lab Association (ACLA) has conveyed that both LabCorp and Quest Diagnostics have current excess capacity. In recent weeks, these labs and many others began marketing this excess capacity, for both diagnostic and antibody testing, directly to employer groups.

On May 19, CMS released pricing for the antibody testing CPT codes 86328 and 86769. The fees are $45.23 and $42.13, respectively. This reimbursement is far above what the usual and customary crosswalk would yield for equivalent testing. This is the result of the lobbying effort of the ACLA.

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)[2]	TURN-AROUND TIME
LabCorp	SC, NC	Y	Y	75,000	1-3 days	Y	Elisa & Chemiluminscence	100,000	1-3 days
Quest	SC, NC, CBC, VT	Y	Y	50,000	1-2 days	Y	Elisa & Chemiluminscence	200,000	1-2 days
BioReference	SC, NC, CBC, VT	Y	Y	35,000	1-2 days	Y	Chemiluminscence	100,000	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	1-2 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	10,000	1-2 days	Y	Chemiluminscence	5,000	2-4 days
MDL (Medical Diagnostic Lab)	SC, NC, CBC, VT	Y	N	5,000	1-2 days	Y	Elisa	1,000	3 days
Neogenomics	SC, NC, CBC, VT	Y	Y	3,400	1-4 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	2,500	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
Luxor	SC	Y	Y	1,000	1-3 days	Y	Elisa	350	1-2 days
Wake Medical Lab Consultants	NC	Y	Y	1,400	1 day	N		N/A	
SMA	CBC	Y	Y	1,000	1 day	Y	TBD	TBD	TBD
Inform Diagnostics	SC, NC, CBC, VT	Y	N	200	1-2 days	N		N/A	

EXPANSION OF "AT-HOME" TESTING

As was previously discussed in this bulletin, LabCorp was the first testing company to gain a Emergency Use Authorization (EUA) for an "at-home" collection device. This test collection method is marketed under LabCorp's Pixel product line. The FDA has recently authorized another similar product produced by the company Everlywell.

Everlywell's COVID-19 Test Home Collection Kit includes sample registration instructions, sample

collection instructions, sample preparation, a nasal swab, saline in a tube, shipping materials, return labels and shipping instructions. It is only authorized for distribution to individuals who meet inclusion criteria based on information provided through an online questionnaire and reviewed by the Physician Wellness Network. Everlywell's nasal swab collection kit is authorized to be utilized with Fulgent's and Assurance's tests.

Startup Hims & Hers announced Wednesday it is now offering FDA-authorized COVID-19 testing kits to order online and administer at home. Men's health startup Vault Health also recently started selling at-home saliva test kits, which rely on a sample of spit in a test tube.

Both companies are distributing a saliva test developed by Rutgers University laboratory, called RUCDR Infinite Biologics, in partnership with Spectrum Solutions and Accurate Diagnostic Labs, which was granted emergency use authorization by the FDA on May 7. This is a diagnostic test (RT-PCR).

There are limitations to saliva tests. The FDA notes that the collection of saliva specimens is limited to patients with symptoms and that negative results should be confirmed by testing an alternative specimen. Saliva tests also may not be able to detect the virus in asymptomatic people.

ALVEO be.well

Alveo Technologies, in collaboration with Janssen Pharmaceuticals, is developing an actual at-home testing platform. The *be.well*™ testing system includes analyzers, nasal swabs, and cartridges for the detection of viral infection diseases, including Respiratory Syncytial Virus (RSV) and SARS-CoV-2. Alveo is utilizing a phased approach to gain authorization from the FDA.

CURRENT NEWS IN EMPLOYER TESTING

A recent survey of employers by the human resources consultancy company Mercer said that just 4% of those responding to a return to workplace questionnaire say that they are planning to conduct serology screening for antibodies to COVID-19. Meanwhile, only 3% of employers say that they plan to screen for the presence of the virus.

3%

OF EMPLOYERS SURVEYED SAY THEY PLAN TO SCREEN FOR COVID-19

"Many employers … are realizing that antibody testing isn't going to be a silver bullet and really isn't going to bring them any value," said David Zieg, a lead consultant on clinical services at Mercer.

The Big Three automotive manufacturers intend to offer diagnostic tests to workers, not antibody tests. Officials at the Detroit carmakers indicated they have chosen not to implement antibody testing because it was not clear what the antibody tests show. Amazon.com Inc's on-site testing plan, now in development, does not include antibody testing.

The CDC website includes a section giving guidance to employers entitled, **"Interim Guidance for Businesses and Employers Responding to the Coronavirus Disease 2019"**. This interim guidance is intended to help prevent workplace exposures to COVID-19 in non-healthcare settings.

While the CDC does list the following key guidance to prevent and reduce the transmission of the virus among employees, it does not list lab testing:

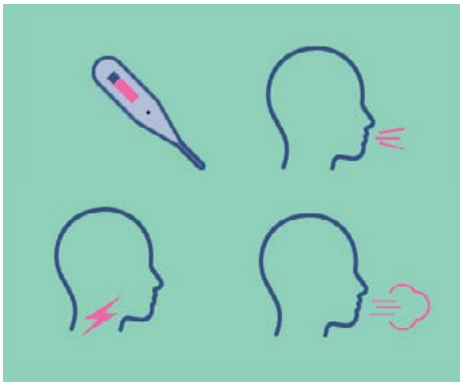
- Actively encourage sick employees to stay home
- Consider conducting daily in-person or virtual health checks
- Identify where and how workers might be exposed to COVID-19 at work
- Separate sick employees
- Take action if an employee is suspected or confirmed to have COVID-19 infection
- Educate employees about steps they can take to protect themselves at work and home
- For employees who commute to work using public transport, offer special considerations

However, for employees identified as infected and subsequently in isolation, in their guidance, **CDC recommends 2 strategies to return to work or discontinue isolation**:

FOR PERSONS WITH COVID-19 UNDER ISOLATION

The decision to discontinue home isolation for persons with confirmed or suspected COVID-19 should be made in the context of local circumstances. Options include a symptom-based (i.e., time-since-illness-onset and time-since-recovery strategy) or a test-based strategy. Of note, there have been reports of prolonged detection of RNA without direct correlation to viral culture.

SYMPTOM-BASED STRATEGY



Persons with COVID-19 who have symptoms and were directed to care for themselves at home may discontinue isolation under the following conditions:

- At least 3 days (72 hours) have passed since recovery defined as resolution of fever without the use of fever-reducing medications and improvement in respiratory symptoms (e.g., cough, shortness of breath); and,
- At least 10 days have passed since symptoms first appeared.

TEST-BASED STRATEGY

Previous recommendations for a test-based strategy remain applicable; however, a test-based strategy is contingent on the availability of ample testing supplies and laboratory capacity as well as convenient access to testing. Persons who have COVID-19 who have symptoms and were directed to care for themselves at home may discontinue isolation under the following conditions:

- Resolution of fever without the use of fever-reducing medications, and
- Improvement in respiratory symptoms (e.g., cough, shortness of breath), and
- Negative results of an FDA Emergency Use Authorized COVID-19 molecular assay for detection of SARS-CoV-2 RNA from at least two consecutive respiratory specimens collected ≥24 hours apart (total of two negative specimens)

*See **Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)**.*

Of note, there have been reports of prolonged detection of RNA without direct correlation to viral culture.

If this survey and the CDC recommendations are any indication, mass employee testing should not be expected. However, interested employers should be directed to a laboratory that is utilizing FDA-authorized testing to perform these services. Avalon can assist the health plan in locating a laboratory to meet the employers' testing needs.

THE AMA AND ANTIBODY TESTING

The AMA has issued **guidance** on serological testing for SARS-CoV-2 antibodies that outlines three major limitations to the tests that physicians must understand to properly order them and interpret their results.

"Given that we do not yet have scientific evidence showing if, when and for how long individuals might become immune to COVID-19, physicians and the general public should not use antibody testing to consider anyone immune to the disease—doing so may lead individuals to falsely assume they can stop physical distancing and further the spread of illness.," said AMA President Patrice A. Harris, MD, MA.

"Although many are using these tests to determine whether an individual had COVID-19, we encourage physicians to only use antibody tests authorized by the Food and Drug Administration [FDA] and only for the purposes of population-level studies, evaluating recovered individuals for convalescent plasma donations, or along with other clinical information as part of a well-defined testing plan for groups or individuals."

CURRENT AVALON CLINICAL ADVISORY BOARD RECOMMENDATIONS

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.*

TRENDS IN LABORATORY TESTING

With the entire country engaging in stay at home or lockdown orders starting in March and of various durations, no shortage of articles portend the looming disaster to the healthcare community and patients as office visits are skipped and treatments deferred.[i] Hospitals, physicians, and laboratories are collectively dealing with fewer patients, and therefore fewer tests being performed to manage patients, surveille health conditions or conduct annual checkups. Financial viability of businesses and the long-term impact on patient health are top of mind for many.

Avalon has reviewed outpatient laboratory claims data to assess the impact to the healthcare community using laboratory testing as a surrogate for patient office visits and informative itself. While the data represents the last 8 to 10 weeks of claims information, the analyses describe which COVID tests are most often ordered, which type of laboratories are suffering the most, which patients are forgoing doctor visits, and how steep laboratory testing declined.

COVID TESTING IS DOMINATED BY PCR-BASED ASSAYS

While PCR and Antibody (Ab) tests are available, PCR testing dominates claims volume **(Figure 1)** submitted through Avalon's network of providers. In early March, the procedures codes submitted reflected the early CMS codes (**U0001** and **U0002**) and the single AMA code (**87635**) for PCR based assays. In mid-April, CMS authorized two higher priced codes specific for high throughput technologies (**U0003** and **U0004**) and immediately, **U0003** begins to be billed replacing the prior CMS and AMA codes.

Concurrently, AMA released specific codes for antibody testing, and a surge of antibody testing is found in claims data. The subsequent reduction in Ab testing could be attributable to physicians realizing Ab results currently lack clinical utility or are holding claims until clarity around pricing has been established by CMS. Since CMS finalized pricing on May 19th

PROCEDURE CODE	SHORT DESCRIPTION & USAGE
U0001	PCR based testing - utilizing test kits from the CDC to perform the testing
U0002	SPCR based testing – utilizing laboratory developed kits (non-CDC), non-amplified probe
87635	Amplified probe PCR testing
U0003	Amplified probe using high throughput technology
U0004	High throughput technology using any technique
86328	Antibody test - Single step method (e.g. reagent strip) for the detection of COVID-19
86769	Antibody test – Multistep method (e.g. analyzer) for the detection of COVID-19

for **86328** and **86769**, an increase in Ab claims may be seen in the coming weeks.

Interestingly, the additional, same claim laboratory services most frequently found with a definitive COVID19 diagnosis code (**U07.1**) cover a range of tests, from routine testing for CBC or metabolic panels to more suspect tests such as troponin and assay of lactic acid (**Table 1**). It is beyond the scope of this article to evaluate the clinical appropriateness of the tests; however, a plan would be prudent to specify appropriate and allowable laboratory tests subject to the CARES Act[ii] mandates for waiver of cost sharing requirements.

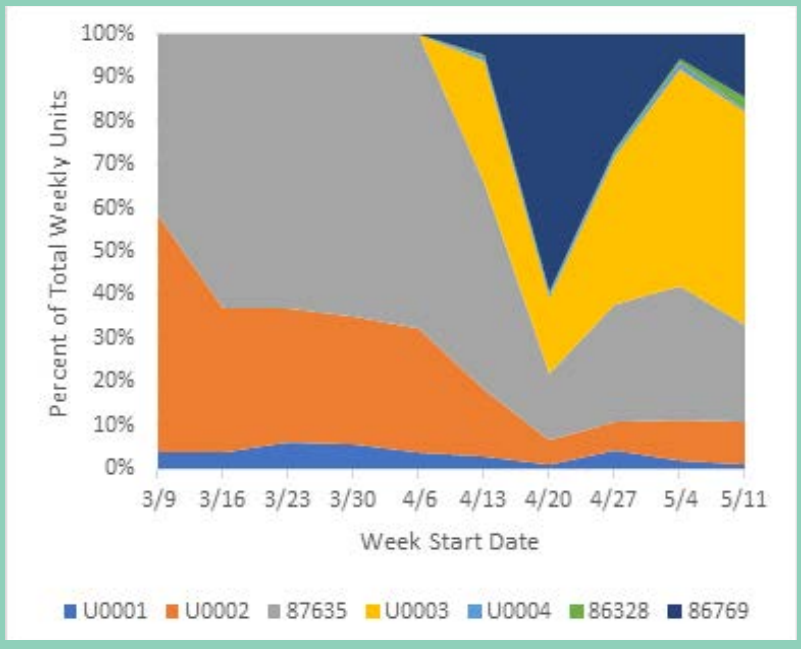


Figure 1: *Weekly Claim Volume*

OVERALL LABORATORY TESTING DROPPED PRECIPITOUSLY IN APRIL

As stay at home and lockdown orders spread across the country in late March and through April, laboratory testing consequentially dropped. **Figure 2** shows overall testing trends relative to January claim volumes indicating that April was down nearly 50%.

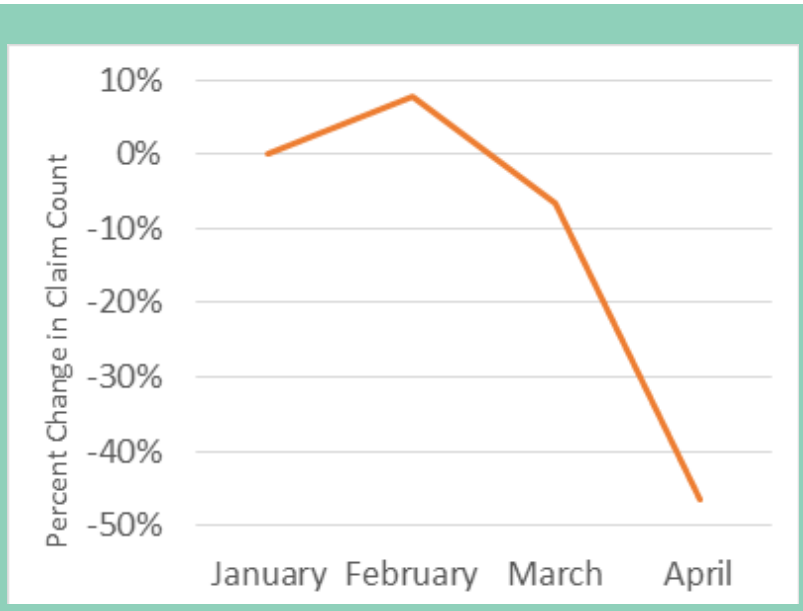


Figure 2: *2020 monthly laboratory test claim volume relative to January*

A lengthening of the time between the date of service and the claim submission date is occurring, potentially due to provider staffing shortages or providers holding claims due to coding and pricing uncertainty (data not shown).

The average time delay in April 2020 almost doubled to 37 days relative to April 2019. The monthly change in laboratory test volume by place of service (**Figure 3**) shows a dire picture for physician office laboratories, and hence for the physician offices. Lab tests are often a consequence of a patient visit to a physician, and therefore

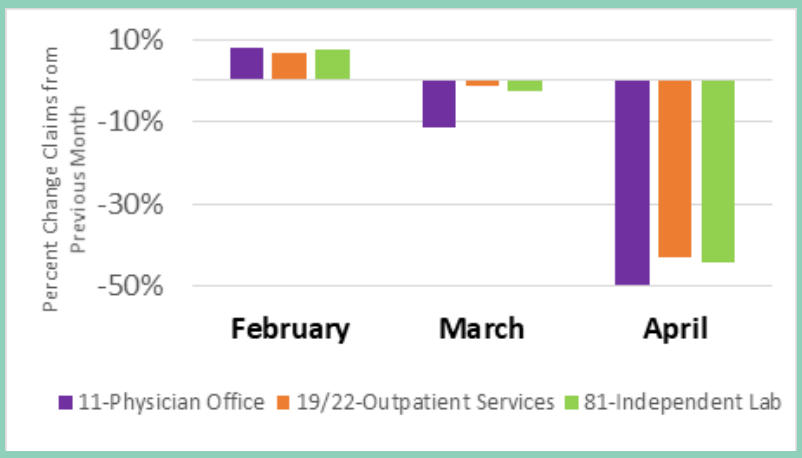


Figure 3: *2020 month over month laboratory claim volume changes by place of service*

claim volume is a surrogate for patient traffic. Physician offices experienced the largest month over month drop in both March and April. Independent and hospital labs in March maintained close to February levels with a subsequent drop in volume in April, again as the stay a home orders were implemented.

The economic consequences will be acutely felt for physician offices which perform testing as the patient and testing revenues vanished. Testing is down in all areas, and a review of ordering physicians specialties revealed family medicine, nurse practitioners, and physician assistants face the steepest decline in test volume. Internal medicine and specialists have had a relatively lower reduction in ordered tests.

THE REDUCTION IN LAB TESTS IS ASSOCIATED WITH HEALTHY PEOPLE

An outstanding question is the impact to the long-term health of patients if they are forgoing testing during the stay at home period. If chronically ill patients are not receiving appropriate care or underlying conditions are not detected early, then treatment interventions may be delayed resulting in more complex issues for the health care system to absorb. Essentially, answering the question requires knowing which patients are receiving fewer tests and how long tests are being deferred.

Avalon utilized the Charlson Comorbidity Index (CCI)[iii], a measurement of a patient's mortality based on comorbidities extracted from diagnosis codes. In short, the higher the CCI, the higher the risk of mortality and therefore the greater importance of routine visits to their physicians.

Based on laboratory claims information, member's CCI were allocated to risk classifications and compared between March and April (**Figure 4**). Fortunately, the highest risk patients are seeing the lowest rate of reduction in testing, meaning that for many patients with chronic, severe conditions they are receiving the necessary medical oversight. Also, the no risk group has the largest reduction

TABLE 1: TOP 20 PROCEDURES ORDERED WITH DIAGNOSIS CODE U07.1 (COVID-19+) AND A COVID TEST
Complete cbc w/auto diff wbc (85025)
Comprehensive metabolic panel (80053)
Routine venipuncture (36415)
Influenza assay w/optic (87804)
IADNA SARS-COV-2 COVID-19 AMPLIFIED PROBE TQ (87635)
Metabolic panel total ca (80048)
(COVID-19) amplified probe, high throughput technologies(U0003)
Assay of troponin quant (84484)
Blood culture for bacteria (87040)
C-reactive protein (86140)
Non-CDC COVID19 (U0002)
Assay of magnesium (83735)
Thromboplastin time partial (85730)
Assay of ferritin (82728)
Assay of lactic acid (83605)
Fibrin degradation quant (85379)
Detect agent nos dna amp (87798)
Lactate (ld) (ldh) enzyme (83615)
Prothrombin time (85610)
Strep a assay w/optic (87880)

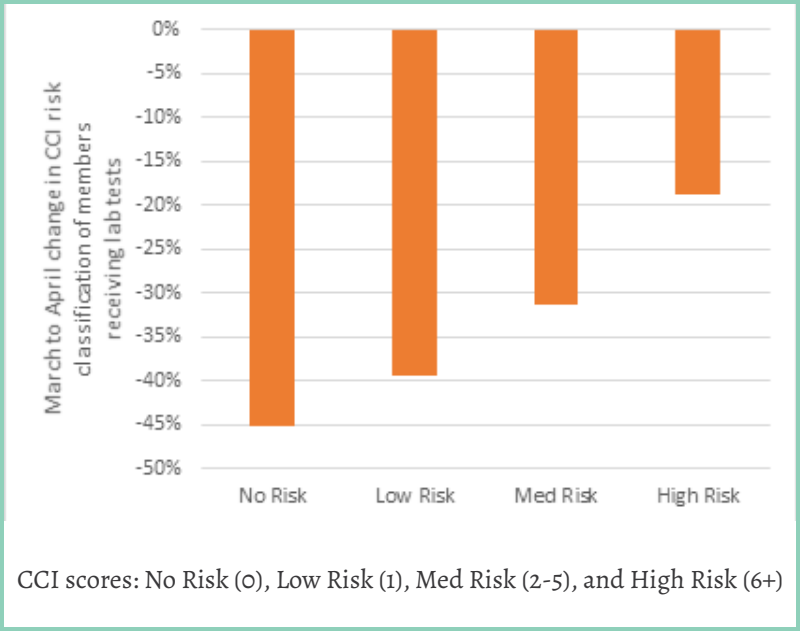


Figure 4: *Charlson Comorbidity Index classification and test volume reduction*

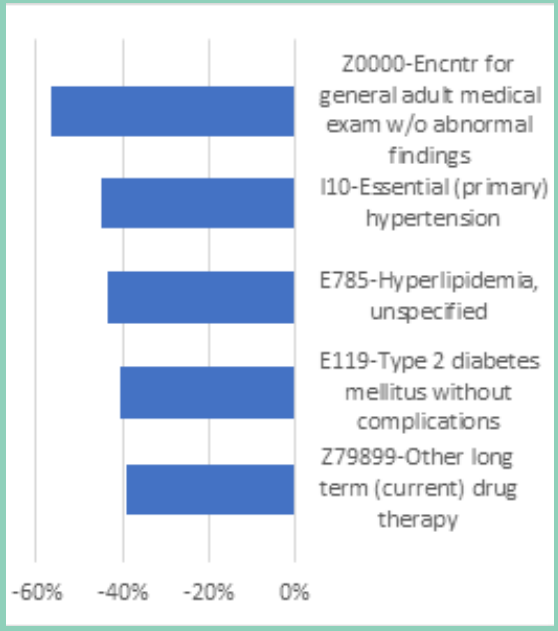


Figure 5: *Decrease in primary diagnosis codes from March to April 2020*

in tests which are associated predominantly with annual check-ups. As patients begin to feel more comfortable returning to the doctors after stay at home orders are lifted, the no risk group may return for their annual check-ups, resulting in a bolus of associated testing.

The top five procedure code reductions and diagnosis code reductions further support that healthy individuals are skipping their testing. Three of the top five procedure codes are commonly associated with annual check-up testing: lipid panels, CBCs, and metabolic panels (**Table 2**). The reduction in primary diagnosis codes further corroborates a reduction in annual checkups as evidenced by the more than 50% reduction in Z00.00 (Encounter for general adult medical exam without abnormal findings).

The presence of hypertension, lipidemia, and diabetes in the top five diagnosis codes raises a concern as these are chronic conditions which left unmanaged may result in more complicated conditions or situations involving hospitalization.

TABLE 2: TOP FIVE PROCEDURE CODES UNIT VOLUME REDUCTION FROM MARCH TO APRIL 2020

Procedure Code	*Decrease*
Tissue exam by pathologist (88305)	-52.1%
Lipid panel (80061)	-47.7%
Comprehensive metabolic panel (80053)	-44.5%
Glycosylated hemoglobin test (83036)	-42.8%
Complete cbc w/auto diff wbc (85025)	-40.0%

Similarly, to the CCI, Avalon employed the Clinical Classification Software methodology to cluster patients' diagnosis codes into a reasonable set of clinical categories. The changes in categories between March and April were reviewed, and consistent with the primary diagnosis code analysis, significant reductions in testing for chronic conditions were found (**Table 3**). Interestingly, while the country experiences a pandemic, testing for infectious diseases recorded significant reductions in claim volume. Social distancing, better hygiene practices as well as stay at home orders have generally reduced infectious disease transmission.

GOOD NEWS...TESTING APPEARS TO BE RETURNING

Forgoing testing and the associated medical oversight for chronic conditions can be tolerated over short time periods. Longer periods without oversight and necessary interventions may result in worsening clinical conditions, hospitalizations, and poorer quality of life for the affected patient. Testing volumes have been increasing since the middle of April when the lowest weekly claim volume occurred (**Figure 6**).

TABLE 3: REDUCTIONS IN LAB CLAIMS BY CLINICAL CLASSIFICATION SOFTWARE CATEGORY

	Clinical Classification Software Category	*% Claim Decrease*
Potentially Infectious Disease Oriented	Influenza	-85.1%
	Other upper respiratory infections	-72.7%
	Fever of unknown origin	-68.3%
	Other lower respiratory disease	-55.8%
	Immunizations & screening for infectious disease	-46.4%
	Malaise and fatigue	-45.8%
	Abdominal pain	-41.1%
Monitoring Chronic Conditions	Other nutritional, endocrine, and metabolic disorders	-48.5%
	Essential hypertension	-44.8%
	Thyroid disorders	-43.0%
	Disorders of lipid metabolism	-42.8%
	Diabetes mellitus without complication	-42.0%
	Diabetes mellitus with complications	-41.3%

Continuation of the trend forecasts a return to pre-pandemic testing volumes by June. Clearly many factors will influence the volume return, such as patient comfort level with office visits, health insurance membership, and a second wave of COVID19 infections. If the period of deferral of office visits and lab testing is limited to 30 to 45 days as estimated in Figure 6, then combined with the modest reduction in high risk patients, one could argue the dire predictions of long term impact to patient's health may not be realized. Additionally, the surveillance associated with annual checkups will return. However, the pandemic still remains, social distancing becomes the norm which drives continued uncertainty. Still, on the present course, early indicators are pointing to better outcomes.

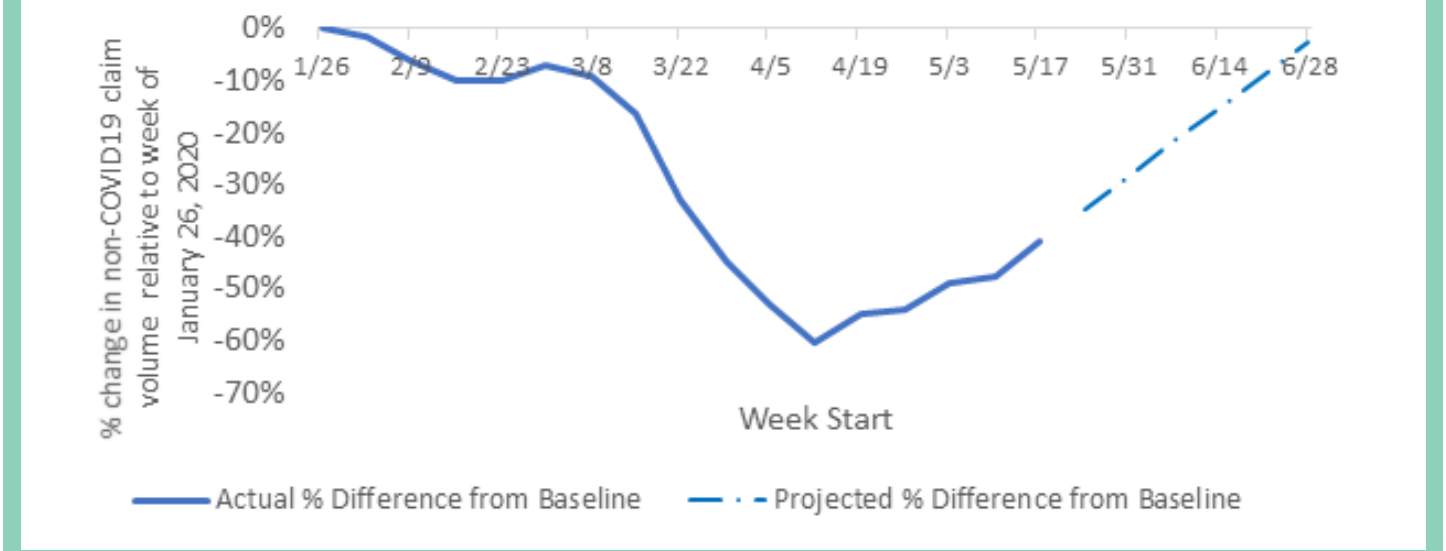


Figure 6: *Outpatient laboratory claim volume rebounds in May*

REFERENCES

All links accessed on 5/20/20:

[i] Coronavirus update: 600 doctors warn Trump of 'Mass Causalty Incident" if lockdown continues. https://www.ibtimes.com/coronavirus-update-600-doctors-warn-trump-mass-casualty-incident-if-lockdown-2979938

A second, hidden pandemic will follow covid-19. We need to plan for it. https://www.washingtonpost.com/opinions/2020/04/08/covid-19-pandemic-will-end-americas-next-health-crisis-is-already-starting/?arc404=true

Resuming California's Deferred and Preventative Health Care https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/ResumingCalifornia%E2%80%99sDeferredandPreventiveHealthCare.aspx

[ii] For ease of reference, the CARES Act will represent both CARES Act and FFCRA. FAMILIES FIRST CORONAVIRUS RESPONSE ACT, Public Law 116–127 (Mar. 18, 2020). CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT, Public Law 116–136 (Mar. 27, 2020).

[iii] For a quick explanation of the Charlson Comorbidity Index see http://mchp-appserv.cpe.umanitoba.ca/viewConcept.php?printer=Y&conceptID=1098

[iv] For an explanation of Clinical Classifications Software for Services and Products https://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcproc.jsp