

AVALON HEALTHCARE SOLUTIONS WHY LAB TESTS AND THEIR VALUES MATTER TO HEALTH PLANS IN 2022

January 18, 2022



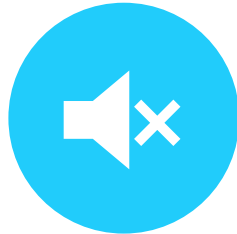
OVERVIEW & INTRODUCTIONS

Kerri Fritsch, Chief Client Officer, Avalon

Before we start



This meeting is being recorded.



We will be **MUTING** everyone except the presenter to make sure the AUDIO is clean and clear.



Q&A will be done by using the “**Questions**” feature.

Agenda

OVERVIEW AND INTRODUCTIONS

Kerri Fritsch, Chief Client Officer, Avalon

HEALTHCARE POLICY UPDATE FROM WASHINGTON, D.C.

Julie Barnes, Principal, Maverick Health Policy

COVID-19 LAB NETWORK UPDATE

Mike Snyder, EVP Network Operations, Avalon

IMPORTANCE OF LAB TESTING AND THEIR VALUES IN 2022

Rahul Singal, M.D., Chief Medical Officer, Avalon

CLOSING REMARKS

Bill Kerr, M.D., Chief Executive Officer, Avalon



HEALTHCARE POLICY UPDATE FROM WASHINGTON, D.C.

Julie Barnes, Principal, Maverick Health Policy



Overview

- Breaking News (OTC Lab Tests and Vaccine Mandates)
- No Surprises Act Update
- Lab Test Scrutiny in Medicare
- What's Next for Health Policy (Legislative & Regulatory)

Poll Question

What topic is of most interest to you today?

- A. Breaking News (OTC Lab Tests and Vaccine Mandates)
- B. No Surprises Act Update
- C. Lab Test Scrutiny in Medicare
- D. What's Next for Health Policy (Legislative & Regulatory)



Jan. 10, 2022: Tri-agency guidance on over-the-counter COVID-19 lab test reimbursement

Jan. 12, 2022: U.S. Senate HELP Committee Confirmation Hearing of FDA Commissioner Candidate Dr. Robert Califf

Jan 13, 2022: U.S. Supreme Court ruling on COVID-19 vaccine-or-test requirement for private employers

Jan 16, 2022: COVID-19 PHE 90-day extension



Tri-agency Guidance on OTC COVID-19 Lab Tests

Released on January 10, 2022

- Requires private health insurers to cover at-home COVID-19 lab tests during Public Health Emergency effective 1/15/22 (not retroactive)
- No doctor order necessary
- Max 8 tests per month per covered life
- People either submit a claim for reimbursement or plans provide “direct coverage” by reimbursing sellers directly.



Private employer vax-or-test mandate

- OSHA workplace hazard statute doesn't include forcing 80M workers to be vaccinated or be tested weekly.
- Rule is a “blunt instrument” — “most lifeguards and linemen face the same regulations as do medics and meatpackers.”



Healthcare workers vaccination mandate

- HHS has authority to protect patient health.
- Court cited to amicus briefs — healthcare workers and public health organizations “overwhelmingly support” vax mandate.
- **Enforcement of healthcare workers mandate starts March 15 for the 25 states that were under court injunction.**



No Surprises Act Update



Effective January 1, 2022:

- Balance billing prohibition and public notice of same
- Arbitrate payment disputes
- Providers must explain costs to uninsured



12/30/21: Tri-agency guidance on IDR process published



Expected soon: AEOB proposed rule

<https://www.cms.gov/nosurprises>





U.S. Department of
Health and Human Services
Office of Inspector General

COVID-19 Tests and Genetic Lab Tests Increasing Costs in Medicare Part B, Dec. 2021

HHS OIG released two reports:

- COVID-19 tests represented 20% of Part B lab test spending.
- Orders for genetic tests are multiplying exponentially – fraud & abuse issue.

What to watch:

- MedPAC - PAMA
- FDA LDT oversight (VALID Act)

U.S. Department of Health and Human Services
Office of Inspector General
Data Brief
December 2021, OEI-09-21-00240

COVID-19 Tests Drove an Increase in Total Medicare Part B Spending on Lab Tests in 2020, While Use of Non-COVID-19 Tests Decreased Significantly

Key Takeaway
Medicare Part B spent \$1.5 billion on COVID-19 tests in 2020, while at the same time, spending on non-COVID-19 tests declined by \$1.2 billion. The result was a net spending increase of 4 percent, but the decrease in utilization of non-COVID-19 tests raises questions about the potential impacts on beneficiary health.

Medicare Part B spending on clinical diagnostic laboratory (lab) tests in 2020 was affected by significant new spending on COVID-19 tests, a type of test that did not exist before the pandemic. Overall spending increased from \$7.7 billion in 2019 to \$8.0 billion in 2020. This increase in spending was driven by \$1.5 billion in new spending on COVID-19 tests, including \$1.0 billion on a rapid COVID-19 test procedure code, which was the number 1 test by spending.

Aside from COVID-19 tests, spending for all other tests, as a group, decreased by about \$1.2 billion in 2020. The decline in spending was driven by a sharp decline in non-COVID-19 tests during the early months of the pandemic, as well as further reductions in payment rates for some of these tests, as required by the Protecting Access to Medicare Act of 2014 (PAMA).

Why OIG Did This Review
PAMA changed the way the Medicare program sets payment rates for lab tests by aligning Medicare payment rates with private payment rates. The Centers for Medicare & Medicaid Services (CMS) calculated new rates that took effect in 2018. As part of PAMA, Congress also mandated that the Office of Inspector General (OIG) publicly release an annual analysis of the top 25 tests based on Medicare spending and conduct analyses that OIG determines appropriate. This data brief provides an analysis of Medicare payments for lab tests in 2020.

How OIG Did This Review
We analyzed claims data for lab tests performed in 2020 that CMS paid for under the Clinical Laboratory Fee Schedule (CLFS). These tests are covered under Medicare Part B and do not include COVID-19 tests provided by community testing programs or tests that Medicare paid for under other payment systems, such as the payment system for critical access hospitals or the Hospital Outpatient Prospective Payment System. We identified the top 25 lab tests based on Medicare spending for tests performed in 2020. We also identified key statistics and emerging trends, including Medicare spending by procedure code and test category.

Use of non-COVID-19 tests decreased significantly in 2020.

Year	Spending on Lab Tests (\$ billion)
2019	\$7.7B
2020	\$8.0B

Source: OIG analysis of 2019-2020 spending on lab tests in Medicare Part B, 2021.

U.S. Department of Health & Human Services
Office of Inspector General
HHS OIG Data Brief • December 2021 • A-09-20-03027

Trends in Genetic Tests Provided Under Medicare Part B Indicate Areas of Possible Concern

Key Takeaways:
For calendar years 2016 through 2019, our data analysis showed the following:

- ✓ Medicare payments for genetic tests quadrupled.
- ✓ The number of genetic testing procedure codes Medicare covered increased by 161 percent. The number of genetic tests Medicare paid for increased by 230 percent.
- ✓ The average amount Medicare paid per beneficiary who received at least one genetic test increased by 75 percent. The average number of genetic tests paid per beneficiary increased by 43 percent.
- ✓ The number of laboratories that received more than \$1 million in Medicare payments per year for genetic tests almost tripled, and the number of providers ordering genetic tests for beneficiaries more than doubled.

Although there are legitimate reasons for these increases, the increases indicate areas of possible concern, such as excessive and fraudulent genetic testing, which may negatively affect beneficiaries cost of genetic tests if Medicare denies claims. In addition, Medicare requirements and guidance related to coverage of genetic testing have been limited and have varied among Medicare contractor jurisdictions.

Purpose of This Data Brief
Genetic testing plays a vital role in determining the risk of developing certain diseases and assisting providers in determining medical treatment. Genetic test results can provide awareness of potential future health problems and help people make informed decisions about their health care.

Because use of and spending on genetic tests have grown rapidly, we analyzed Medicare Part B genetic-testing data for calendar years 2016 through 2019 (audit period). This data brief offers the Centers for Medicare & Medicaid Services (CMS) and other stakeholders insights into trends and areas of possible concern related to genetic testing.

Our objective was to analyze nationwide trends in genetic tests provided and payments made under Medicare Part B.

Background
Genetic Testing
Genetic testing is the use of laboratory procedures to analyze genes, chromosomes, or gene products (i.e.,

Data Brief: Trends in Genetic Tests Provided Under Medicare Part B (A-09-20-03027)

1



What's Next for Congress?

- **Feb 18:** CR Expires, new funding of federal gov't may mean public health data infrastructure, FTC/DOJ funding
- **Sept 30:** PDUFA Reauth – Cures 2.0

And....

- Build Back Better?
- VALID Act of 2021?



What's Next for Federal Agencies?

- CMS Hospital Price Transparency Enforcement
- CMS Health Plan Transparency in Coverage begins July 1, 2022
- CMS e-Prior Authorization and Payer-to-Payer Proposed Rules (February?)
- HHS OIG Rule on Information Blocking Enforcement
- ONC Guidance on Standardization of Lab Results?
- FTC / DOJ increases scrutiny of provider consolidation
- FTC exerts greater control over non-HIPAA consumer health data privacy



www.maverickhealthpolicy.com



COVID-19 LAB NETWORK UPDATE

Mike Snyder, EVP Network Operations, Avalon

Avalon Managed Network COVID-19 PCR Capacity and Turnaround Times

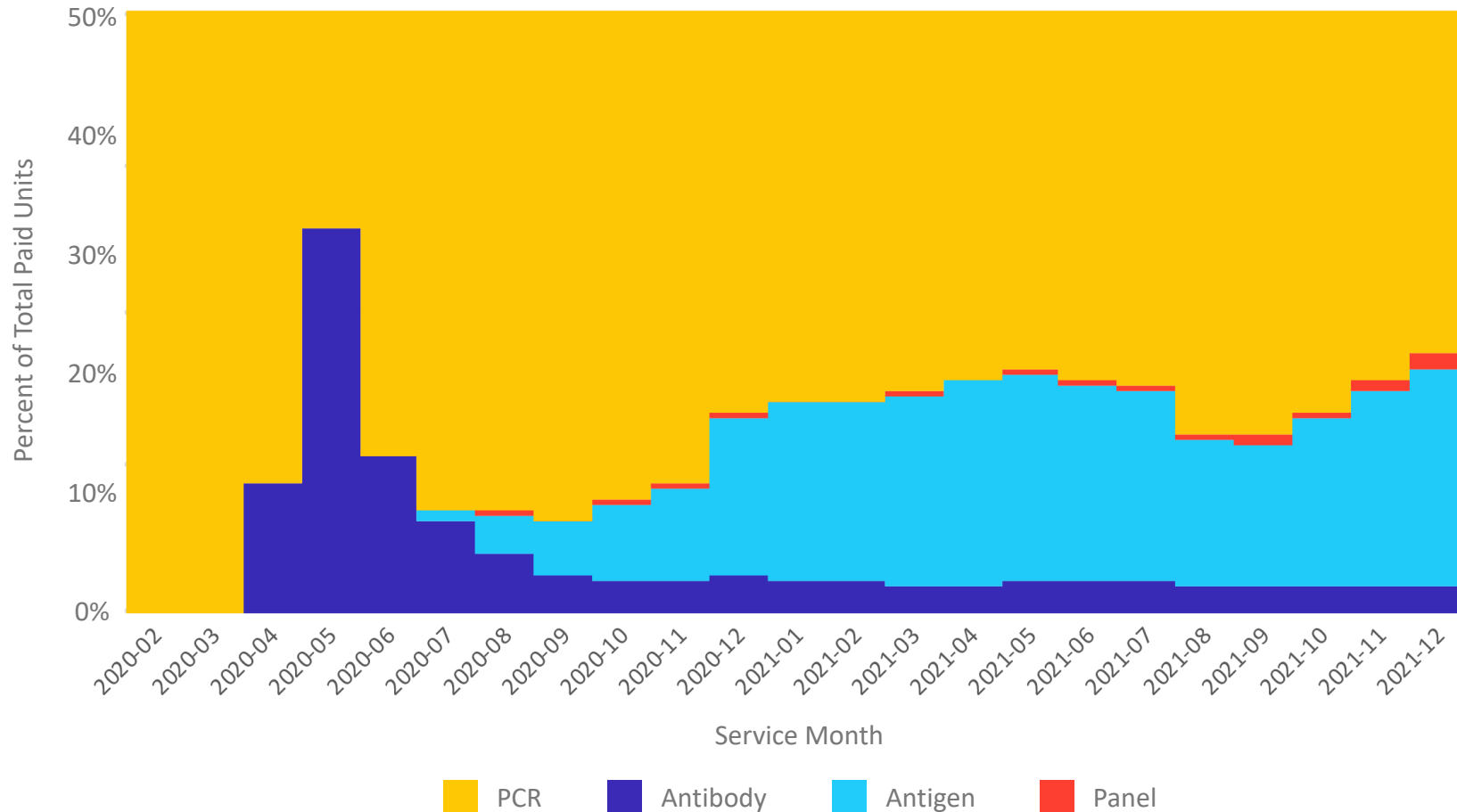
NEWS FROM THE LAB INDUSTRY

- BioReference, LabCorp and Quest all report that the sensitivity of their PCR and antigen testing is not impacted by the current variants, including Omicron.
- Through its subsidiary, Scarlet Health (scarlethealth.com), BioReference is offering at home or work COVID-19 testing.
- Both Quest and LabCorp are offering “observed collection” for COVID-19 at some designated patient service centers and retail locations. See the Quest and LabCorp websites for details.
- Walgreens is offering the Pixel by LabCorp COVID-19 home collection kits as an OTC testing option.

Lab	RT-PCR Y/N	Multiple Platforms	Capacity (per day)	TAT
Quest	Y	Y	300,000	1-2 days
LabCorp	Y	Y	300,000	2-3 days
Quest	Y	Y	300,000	1-2 days
Mako Medical Lab	Y	Y	150,000	1 day
Aegis	Y	Y	110,000	2 days
BioReference	Y	Y	100,000	1-2 days
Premier Medical Lab	Y	Y	100,000	1-2 days
Eurofins-Diatherix	Y	N	60,000	1-3 days
GenetWorx	Y	Y	40,000	2 days
AccuReference	Y	N	30,000	1-2 days
PathGroup	Y	Y	20,000	1-2 days
Sonic-CPL	Y	Y	20,000	1-3 days
AIT (American Institute of Tox)	Y	Y	18,000	1-2 days
MDL (Medical Diagnostic Lab)	Y	N	12,000	1 day
LabTech	Y	Y	10,000	2 days
Precision Genetics	Y	N	8,000	1-2 days
Genesis DX	Y	Y	5,000	1 day
Inform Diagnostics	Y	N	5,000	2 days
Luxor	Y	Y	5,000	1 day
Neogenomics	Y	Y	5,000	1-4 days
Transplant Genomics	Y	N	5,000	1-2 days
BAKO	Y	N	2,500	1-2 days
Radeas	Y	Y	2,400	1-2 days
NephronPharm	Y	Y	2,000	2-3 days
Wake Medical Lab Consultants	Y	Y	1,600	1 day

Avalon Observation of COVID-19 Testing Trends

PERCENT OF MONTHLY PAID UNITS BY COVID-19 TEST TYPE



- Among claims data received by Avalon, PCR remains the dominant paid testing for COVID-19.
- Antigen testing increased at the end of 2020 but has since remained at a relatively consistent average, flexing slightly with the reported surge events.
- The volume of combination panels (e.g., COVID-19 and Flu) remain low despite the fear of the return of the flu.



IMPORTANCE OF LAB TESTING AND THEIR VALUES IN 2022

Rahul Singal, M.D., Chief Medical Officer, Avalon

Genetic Testing – Projections and Medicare FFS Data

- **Total Size** – U.S. Market is \$5.2B to \$14.8B depending upon reference.¹⁻³
- **CAGR projection** range from 10.6% 11.6% to 13%¹⁻³
- Variability dependent upon definitions
- Are CAGR estimates too low based upon Medicare experience?

1 Global Market Insights, March 2021

2 Allied Market Research, Sept 2020

3 Fortune Business Insights,
<https://www.fortunebusinessinsights.com/u-s-genetic-testing-market-105034>

MEDICARE FEE FOR SERVICE DATA

Year	Total Lab Spending	Genetic Test Spending	% Genetic Test Spend	CAGR Genetic
2015	\$6.96 B	\$ 289 MM	4.2%	
2016	\$6.77 B	\$ 393 MM	5.8%	36.0%
2017	\$7.13 B	\$ 473 MM	6.6%	27.9%
2018	\$7.59 B	\$ 969 MM	12.8%	49.7%
2019	\$7.68 B	\$1,360 MM	17.7%	47.3%

Reference – Office of the Inspector General (OIG) Data Brief: Despite Savings on Many Lab Tests in 2019, Total Medicare Spending Increased Slightly Because of Increased Utilization for Certain High-Priced Tests, December 2020 OEI-09-20-00450

2019 PMPM (per member per month) with Medicare FFS population of approximately 35M would be \$21.70 for total lab PMPM and \$3.89 PMPM for genetic testing

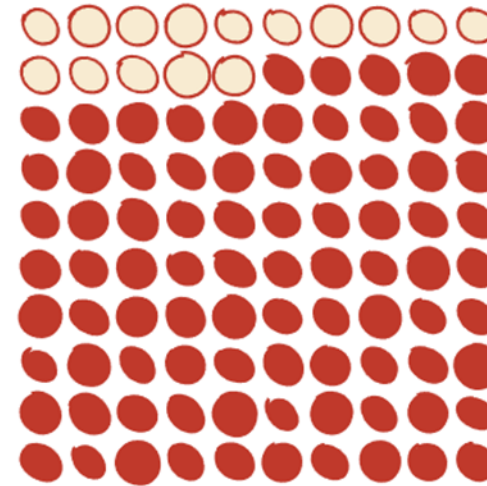
Media Attention Around Prenatal Testing

NEW YORK TIMES: JANUARY 1, 2022

- Review of prenatal testing experience
- Article pointed out aggressive promotion materials in some genetic lab brochures
- Certain prenatal screening tests screen for very rare disorders. They have over 80% **false** positive predictive value and require an invasive more expensive test for follow up. Patients experience anxiety, additional costs, and the authors suggest unnecessary abortions

The New York Times *When They Warn of Rare Disorders, These Prenatal Tests Are Usually Wrong*

Some of the tests look for missing snippets of chromosomes. For every 15 times they correctly find a problem ...



... they are wrong 85 times

Statistics – Application to Populations

		Test Result		Actual
		No	Yes	
Actual	No	True Negative	False Positive	$TN+FP$
	Yes	False Negative	True Positive	$FN+TP$
Total Test		$TN+FN$	$FP+TP$	100

Positive Predictive Value ($TP/(TP+FP)$)

Negative Predictive Value ($TN/(TN+FN)$)

Sensitivity ($TP/(TP+FN)$)

Specificity ($TN/(TN+FP)$)

Population: Prevalence of condition dramatically drives outcomes (see next slide)

- High probability: >20%. Examples include COVID+ if symptoms and surge, Coronary Artery Disease (CAD) with symptoms
- Low probability/“screening”: 1% to 3%. Examples include asymptomatic COVID or CAD
- Rare: <1 in 1000. Specific genetic cancer tests

Sensitivity vs Specificity: Opposing forces

- Sensitivity: Limit false negatives at expense of false positives
- Specificity: Limit false positives (additional testing dangerous)

Medical Tests – Range of Sensitivity and Specificity

- History and Physical: 50% to 75%
- Imaging: 80% to 90%
- Lab Testing: 90% to 95%
- Genetic Testing: 95%+

Gold Standard Test (95% Sensitivity and 95% Specificity) Applied to 3 Different Populations

1000 people in each population	Symptomatic (30% positive)	Asymptomatic (2% positive)	Rare (0.2% positive) 1 in 500
# With actual condition	300	20	2
# Tested positive	320	69	52
% True positives (Positive Predictive Value)	89%	27.5%	3.6% (96% wrong!)
# People missed (False Negative)	15	1	0.1
Negative Predictive Value	97.8%	99.9%	99.9%

Dramatic differences in test performance based upon population

“Facts are stubborn things, but statistics are pliable.” Mark Twain

Avalon Experience and Continued Genetic Tests Investment

- Preliminary Analysis of Avalon's annual growth rate for past 5 years in genetic spend is < 10%.
- New tests are closely evaluated by Avalon's Policy Research (Science) Team and Clinical Advisory Board. For example, Pre-natal testing has 2 levels of tests:
 - CPT 81420: Traditional screening that's covered by Avalon. Must have trisomy for chromosomes 15, 18, 21.
 - CPT 81422: Microdeletions for rare conditions is not covered by Avalon (and >50% more expensive than 81420).

Use of Laboratory Specific "Z-Codes" Drive Test Specificity

- ICD10 Z codes are used for a variety of health factors including SDOH, screening, exposures, immunizations, counseling, observations, etc. AvPreliminary Analysis of Avalon's annual growth rate for the past 5 years in genetic spend is < 10%.
- Palmetto GBA, a Medicare Fee for Service (FFS) claims processing contractor created "Z Codes for Genetic Tests" 10 years ago and requires usage for claims payment for Genetic tests. The system is now used in 22 states. Z codes for genetic tests were created to increase test specificity and enable claims editing post service as Medicare FFS does not allow PA.
- Optum Health has acquired the exclusive license from Palmetto for the non-Medicare FFS market. Avalon is collaborating with Optum Health to bring Z coding to its customer base.



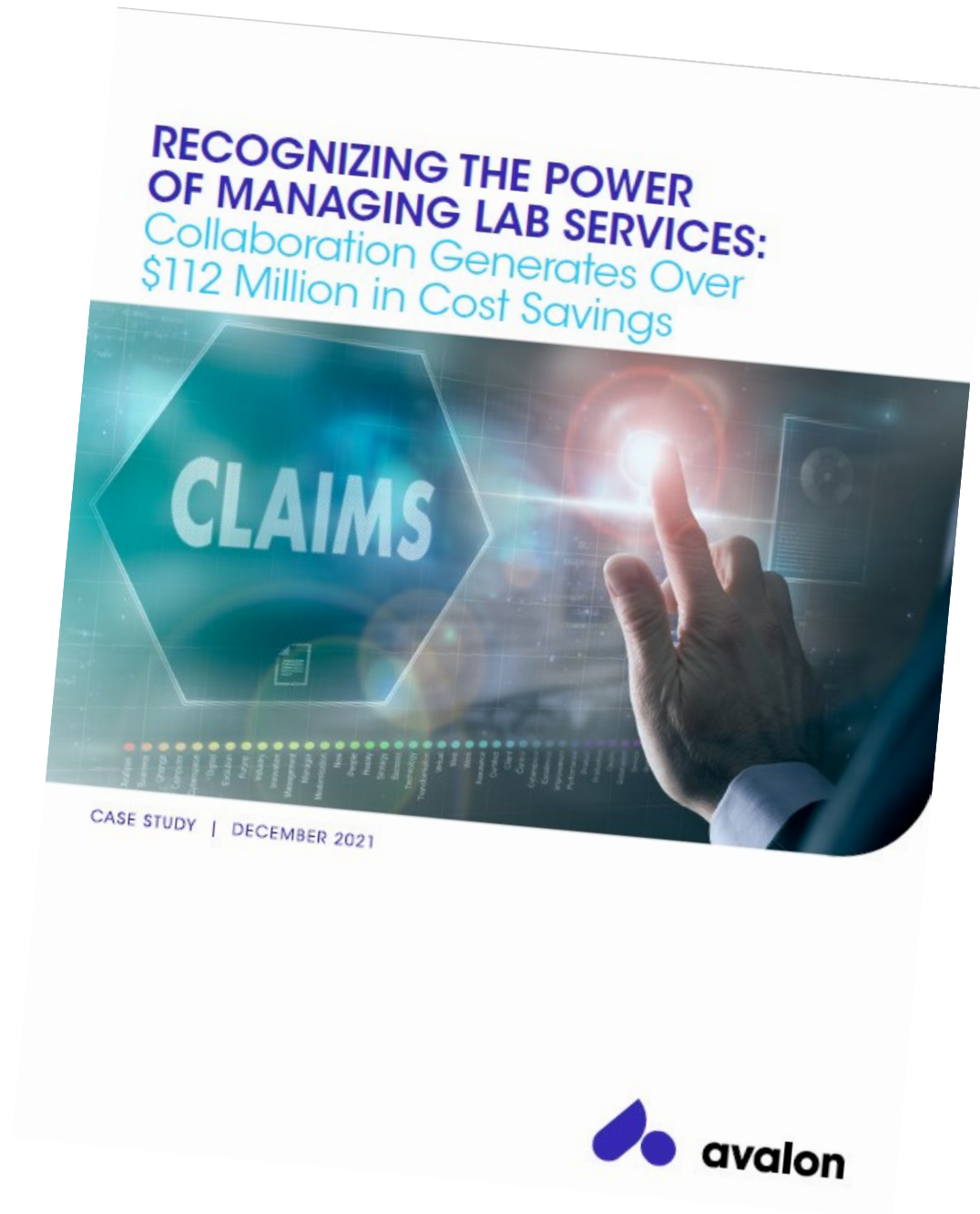
CLOSING REMARKS

Bill Kerr, M.D., Chief Executive Officer, Avalon

Avalon Highlights of 2021

- Launched our new category – Lab Insights.
- 15 successful client implementations.
- Reported \$112 million in cost savings for client Blue Cross NC through collaboration.
- Released the industry's first Lab Trend Report.
- Members realized \$39 million savings in out-of-pocket costs.
- Led 10 informational webinars.
- Covered lives continues to grow at more than 25 million by the end of the year.
- Avalon team is now 175 associates strong.

Case Study



Download on our website
www.avalonhcs.com

Thank you



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SAVE THE DATE
MARCH 15 | 2:00 - 3:00 PM EST