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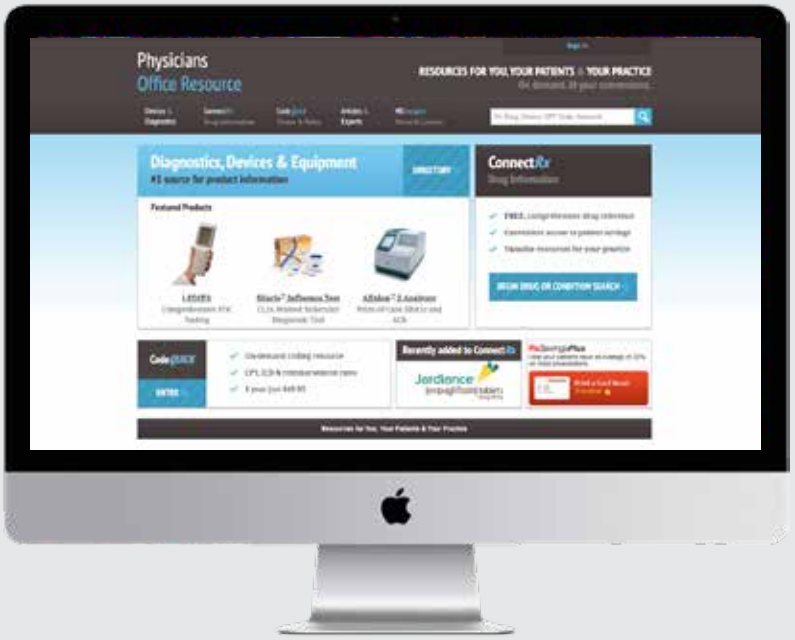
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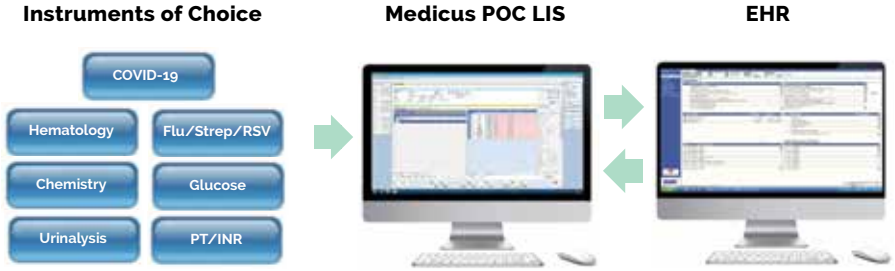
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6

CORONAVIRUS LABORATORY TESTING

After successful genetic sequencing and characterization of the SARS-CoV-2 virus, instrument manufacturers raced to develop laboratory tests for the detection of SARS-CoV-2. Widespread testing of the population is essential to mitigate the spread of the virus through quarantining and contact tracing.

18

THE ROLE OF VITAMIN D IN THE COVID-19 PANDEMIC

Potential treatments were being investigated daily, including research of common vitamin sufficiency. Vitamin C and Zinc have long been known to boost immune system health, which could help against this respiratory illness.

28

PLANNING FOR NEW INSTRUMENTS/NEW TESTS

Whether planning a new, start-up laboratory operation, or performing an analysis of current testing, (providing input for decisions on whether or not to purchase new or replacement instruments, or add or delete tests), it is important to do a realistic assessment not only of what you want to offer your ordering physicians, but what you can realistically offer.

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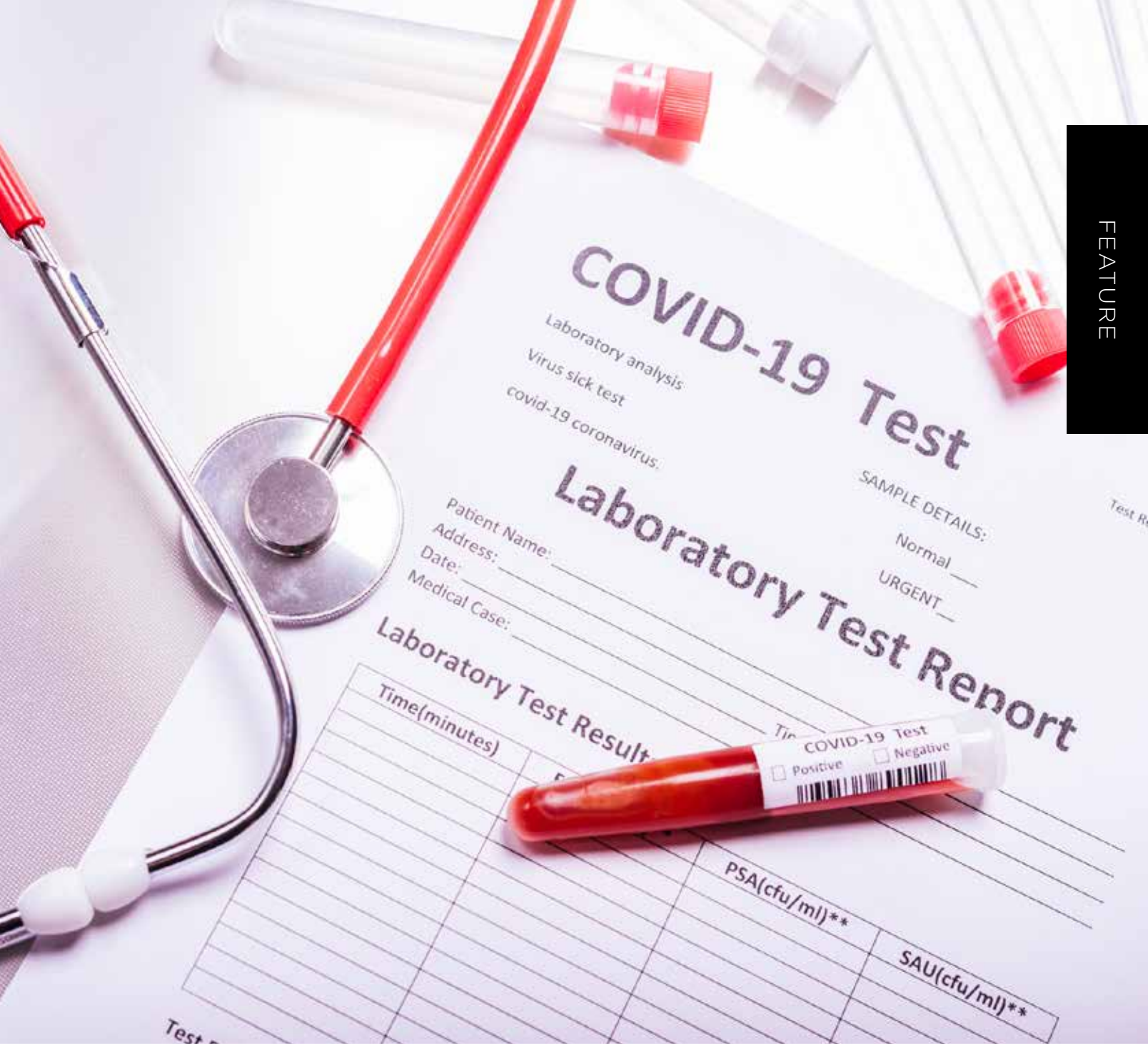
CORONAVIRUS LABORATORY TESTING:

Which Methodology is Right for Your Practice and Your Patients?

BY MARC SEAMAN, PH.D

It's been a year since reports of SARS-CoV-2, the coronavirus that causes COVID-19, emerged in the United States. After successful genetic sequencing and characterization of the SARS-CoV-2 virus, instrument manufacturers raced to develop laboratory tests for the detection of SARS-CoV-2. Widespread testing of the population is essential to mitigate the spread of the virus through quarantining and contact tracing. As of December 2020, the Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) to over 250 tests in the three main test classes – Molecular/Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), rapid antigen and antibody testing. The first two tests detect active disease and the third detects evidence of past infection. Additionally, there are significant differences between each class of test in terms of suggested timing from onset of symptoms, specimen collection route, time to results, cost, specificity, and sensitivity. In this article, we will give a brief overview of the science and technology behind each class of tests and how the technology and science inform the selection of the proper test to administer to identify SARS-CoV-2 infection in the patient population.

Nearly all molecular laboratory instrument manufacturers have developed and received EUA for RT-PCR SARS-CoV-2 tests. Coronavirus RT-PCR test specimens are typically collected via swab in the nasopharynx, nasal cavity or throat; saliva is a less common specimen collected for Coronavirus RT-PCR testing. PCR uses DNA, double-stranded genetic code, as a template to amplify and generate detectable levels



of DNA from miniscule, non-detectable levels on a specimen swab. Using extremely specific reagents called primers, PCR replicates template DNA to make exact copies of the template DNA. This process is repeated 20-30 times and because each new copy serves as the template for another copy in the next cycle, the amount of DNA doubles and increases exponentially with every cycle. After 20-30 cycles, previously undetectable genetic material is now detectable. DNA is detected via fluorescent signal produced by fluorescent dyes that bind DNA. Coronaviruses do not use double stranded DNA for their genetic code, instead they use single stranded RNA. In order to convert single stranded RNA to double-stranded so that PCR amplification can occur, reverse transcription is needed. Once RNA is converted to a double-stranded DNA-like template, PCR can proceed to generate detectable levels of Coronavirus genetic material to diagnose infection. Due to the amplification of specific genetic material, PCR has exquisite sensitivity and specificity, meaning false-negatives and false-positives are rare; these are good traits of a diagnostic screening test. Specimen processing and preparation and PCR analysis can typically be completed in 4 to 6 hours, so results can be available to the patient on the same day; however, laboratories are sometimes not able to turn around results same day due to instrument and operator availability, laboratory backlog and inefficiencies in reporting systems. As a result, turnaround times of up to one week are possible, if not common.

Another test for active infection is antigen testing. Al-

"...there are significant differences between each class of test in terms of suggested timing from onset of symptoms, specimen collection route, time to results, cost, specificity, and sensitivity."

though not as common as RT-PCR for Coronavirus testing, many instrument manufacturers have received EUA for diagnostic SARS-CoV-2 antigen tests. The coronavirus is composed of lipid, RNA and protein molecules. Whereas RT-PCR detects viral RNA, antigen testing detects viral proteins. The nucleocapsid protein and spike protein on the outer coating are the main targeted proteins/antigens in antigen testing. Antigen test specimens are collected via swab from the nasopharynx and nasal cavity. Once collected the specimen is processed to disassociate the coronavirus into its lipid, RNA and protein components. The processed specimen is added to a lateral flow device and viral components are pulled through the device via capillary effect. The first section of the antigen testing device contains labeled (e.g. fluorescent) coronavirus specific antibodies and when the viral protein components contact these antibodies, a coronavirus protein-labeled antibody complex is created. Next, the coronavirus protein-labeled antibody complexes pass over a line of immobilized coronavirus specific antibodies that bind and immobilize the protein-labeled antibody complexes. Over time, the number of complexes accumulate on the immobilization line and the presence of coronavirus proteins can be detected. Viral components travel quickly through the lateral flow antigen testing device, usually in 5 to 30 minutes, therefore "rapid" is usually associated with antigen tests and results are available to the patient within the hour or at least on the same day. However, unlike in RT-PCR, viral antigens are not amplified, so antigen testing has comparatively less sensitivity. Because antibodies are very specific for coronavirus antigens, specificity of antigen testing is excellent. This means that the chance for false-negatives is increased in antigen testing compared to RT-PCR, but like RT-PCR, false-positive results are rare.

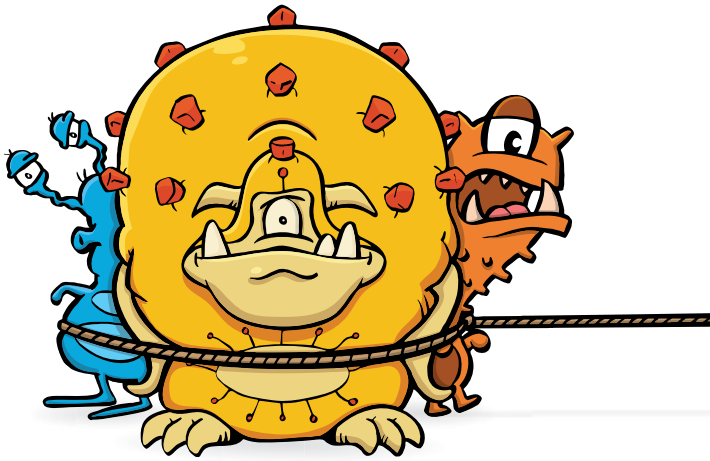
The third class of testing, antibody testing, detects prior coronavirus infection. During infection, the body generates antibodies to the pathogen as part of the immune response. Antibodies are also called immunoglobulins and the two most common antibody isotypes found in blood are Immunoglobulin G (IgG) and Immunoglobulin M (IgM). IgG and IgM antibodies are detectable typically 1 to 3 weeks after symptom onset. IgM levels peak approximately a week after infection, whereas IgG production begins 1 week after symptom onset and peaks 3-4 weeks after symptom onset. Most antibody tests detect IgG and IgM simultaneously. Antibody tests utilize a number of technologies including: Enzyme-Linked Immunosorbent Assay (ELISA), Chemiluminescence Enzyme Immunoassays (CLIA), Chemiluminescent Microparticle Immunoassay (CMIA), Fluorescence Immunoassays (FIA), and the Lateral Flow Immunoassays (LFIA). Although there are many antibody detection technologies, each detects the presence of patient generated antibodies against coronavirus in the same basic manner. For illustrative purposes, lateral flow antibody test technology will be described. First, the anti- coronavirus antibodies in a patient's blood sample incubate with labeled manufactured coronavirus protein mimetics to form labeled protein-antibody complexes. Next, protein-antibody complexes pass over a line of immobilized antibodies that recognize either IgG or IgM (IgG and IgM specific to the Coronavirus? Or just any IgG/IgM floating in the serum?). If recognized, movement is halted and protein-antibody complexes accumulate on the line, generating a signal that can be detected. Like antigen testing, antibody testing can be completed quickly and results can be available to the patient on the same day of testing. In terms of sensitivity and specificity, antibody tests perform similar to antigen tests; they are less sensitive compared to RT-PCR, but all three testing methods have excellent specificity.

In determining which platform is right for your testing needs, the factors presented in this article should be considered. If ease of testing and rapid time to results is desired, antigen testing would likely be a fit; however, the lack of sensitivity of antigen testing leads to the potential for more false-negatives. RT-PCR tests have the highest sensitivity, but results often take days or up to a week to become available to physicians and patients. If you're interested in determining the extent of recent past coronavirus infection within your patient population, antibody testing is the best fit.

—

Marc Seaman, Ph.D, received a bachelor's degree in Biomedical Engineering at the Georgia Institute of Technology and a doctoral degree in Biomedical Engineering from the University of Virginia. As an accomplished scientist with over a decade of experience in academic research and pharmaceutical contract research, Marc is now working within the medical device industry. As Director of Business Development for Medicus Laboratory Information Systems, Marc will continue his work in science, along with offering new ways to implement, document, manage and monitor patient data more efficiently. Helping labs help patients is a passion and strong career focus of Marc's. With proven expertise in PCR technologies, Marc will now share innovative ways to offer the clinical and research laboratory environment excellent solutions for all testing disciplines including infectious disease testing and reporting.

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1. This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
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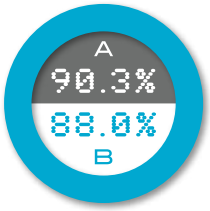


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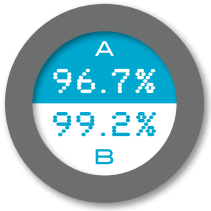
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Urgent care facilities, primary care practices, and other outpatient settings at the front lines of the COVID-19 pandemic need on-site testing solutions to support patient assessment and monitoring. With-patient testing can lead to better healthcare performance by facilitating decisions that can optimize patient outcomes in real time, improving the quality of patient care.

For facilities treating COVID-19 patients, having rapid, accurate diagnostic test results may be useful when assessing or monitoring patients for:

- **C-Reactive Protein (CRP)**
  Levels may be elevated in COVID-19 cases, especially severe cases.[2-15]
- **Liver, Kidney and Cardiac function**
  Elevated levels of the following biomarkers may be indicators of COVID-19 severity:[16-27]
  - Alanine Aminotransferase (ALT)[16,17,20-27]
  - Albumin (ALB)[16,19-22,25-27]
  - Aspartate Aminotransferase (AST)[16,17,19-21,23-26]
  - Creatine Kinase (CK)[16,18,20,22-24]
  - Creatinine (CREAT)[16,22,23,25,27]
  - Total Bilirubin (TBILI)[16,20,25,27]



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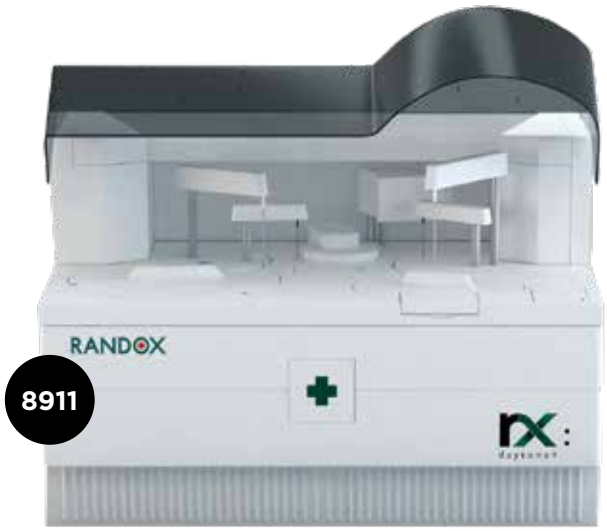
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2

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3

8929

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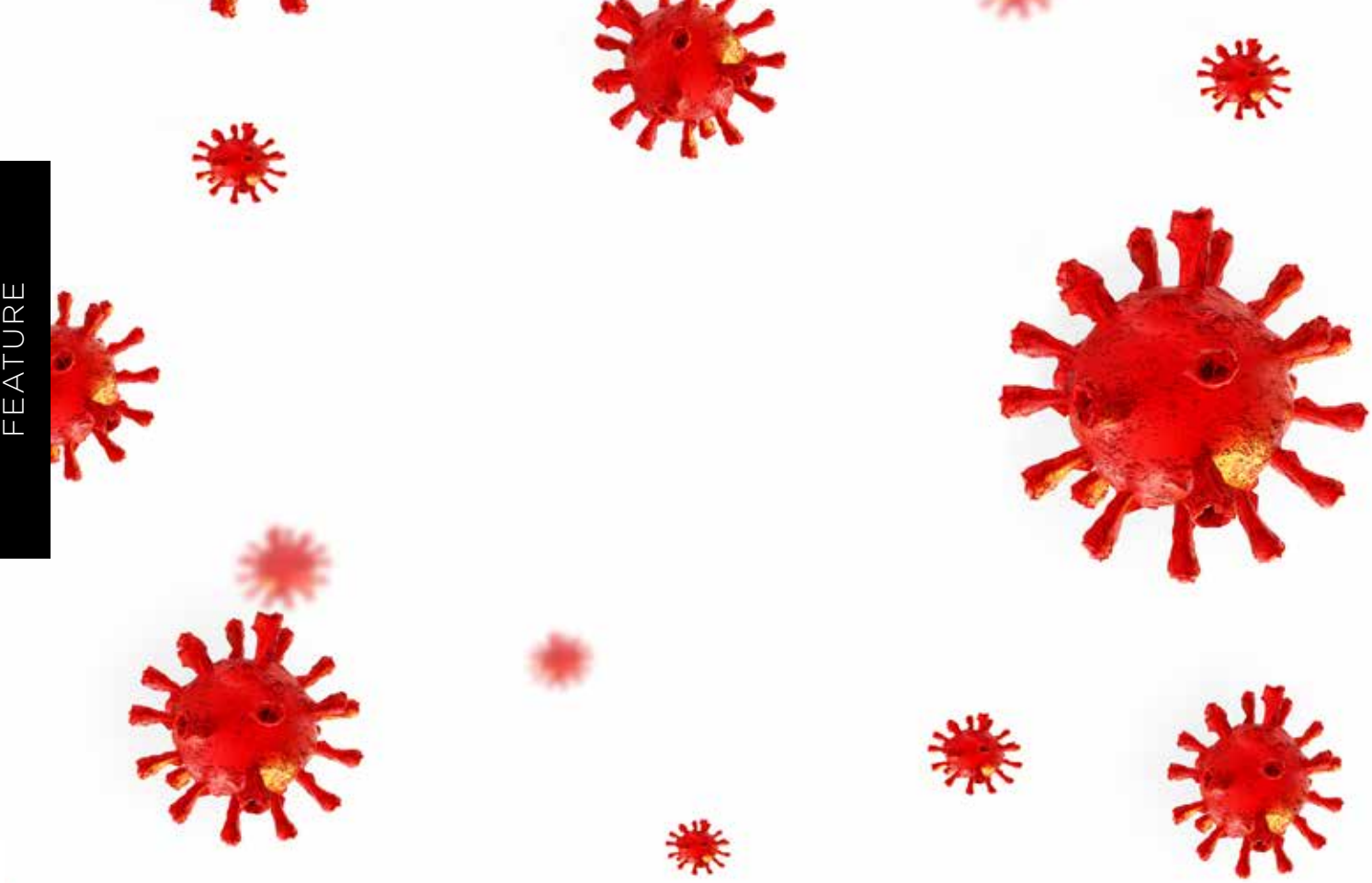
- Medicare mandates yearly cognitive assessment
- Takes 10-15 minutes to prep patient, 20 minutes to test
- Analyzes: brain health (EEG), brain processing speed (Evoke Potentials), heart health (EKG), mental health (neuropsychology)
- Reimburses using 6 CPT codes, National Average = $750 - $1000 per test
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THE ROLE OF VITAMIN D IN THE COVID-19 PANDEMIC

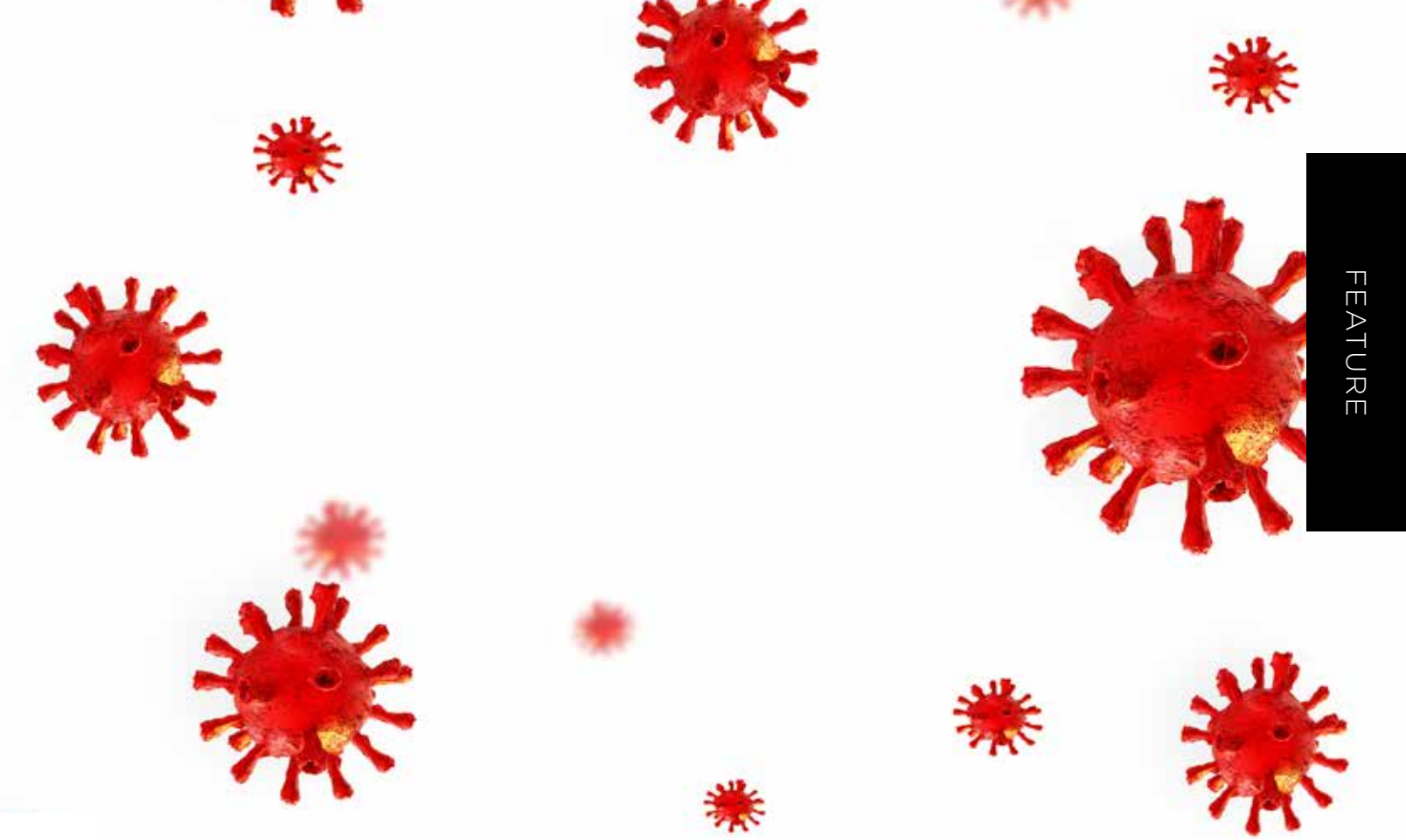
Growing evidence shows proper vitamin D levels help fight severity of illness, mortality rates.

BY SEKISUI DIAGNOSTICS

When global scientists and researchers began sequencing the complete genome of SARS-CoV-2, the virus that causes COVID-19, they were racing to find treatment solutions for the novel coronavirus. Potential treatments were being investigated daily, including research of common vitamin sufficiency. Vitamin C and Zinc have long been known to boost immune system health, which could help against this respiratory illness. But how big could vitamin D's role be in combating the effects of COVID-19?

Somewhat surprisingly, researchers have discovered a strong correlation between severe vitamin D deficiency and mortality rates in COVID-19. Hospitals and clinics in China, France, Germany, Italy, Iran, South Korea, Spain, Switzerland, the United Kingdom and the United States have noted patients with lower levels of vitamin D had higher mortality rates than patients who were not deficient in vitamin D.

Unexplained differences in COVID-19 mortality rates from country to country originally led researchers to examine vitamin D levels and cytokine storm – a hyperinflammatory condition caused by an overactive immune system – and a correlation between vitamin D deficiency and mortality. For example, patients from Italy, Spain and the United Kingdom



had lower levels of vitamin D compared to patients in other countries, and they also had higher mortality rates. Patients in Norway, Finland and Sweden had higher vitamin D levels despite less sunlight exposure than Italy and Spain because supplementation and fortification of foods is more common in these Nordic countries.

The correlation between low vitamin D levels, cytokine storm and death from COVID-19 is statistically significant. Cytokine storm can severely damage lungs and lead to acute respiratory distress syndrome, and this is what seems to be the cause of most COVID-19 related deaths. However, vitamin D enhances the immune system and helps prevent the immune system from becoming dangerously overactive. It won't prevent a patient from contracting COVID-19, but according to some recent studies, it might cut the mortality rate of COVID-19 in half and reduce complications.

Researchers note that vitamin D deficiency is more prevalent in African American patients and elderly patients – two populations that have been most affected by COVID-19.

How many people are vitamin D deficient?

Vitamin D deficiency is very common as an estimated 1 billion people worldwide have low levels of vitamin D in their blood. About 42% of adults in the United States are deficient, and this percentage jumps to 69% in Hispanics and 82% in African Americans. Exposure to sunlight each day helps the human body to manufacture the required amount of vitamin D, but most people avoid sun exposure due to the fear of developing skin cancer. To prevent vitamin D deficiency, one should spend 15 to 20 minutes daily in the sunlight with 40% of the skin surface exposed.

High concentration of melanin in the skin slows the production of vitamin D and aging greatly reduces skin production of vitamin D. The amount of vitamin D your skin makes also depends on the time of day, season and latitude. It may decrease or be completely absent during winter months, depending upon lifestyle.

Vitamin D supplementation

To make it even more challenging, vitamin D isn't found in many foods. However, it can be found in fortified milk, fortified cereal and fatty fish like salmon, mackerel and sardines. The recommended daily amount of vitamin D is 400 international units (IU) for children up to 12 months, 600 IU for ages 1 to 70, and 800 IU for ages over 70 years. Taking a multivitamin with vitamin D will likely help older adults who don't get regular exposure to sunlight, have trouble absorbing vitamin D and are at higher risk for developing osteoporosis. Vitamin D is generally considered safe when taken in appropriate doses.



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The OSOM® Ultra hCG Combo test is a simple immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine for the early confirmation of pregnancy. Internal studies have confirmed that the OSOM® Ultra hCG Combo test does not have a false negative result from hCG variants providing physicians with a higher level of confidence.

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1. Clinical Laboratory Improvement Amendments (CLIA)

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PRODUCT FOCUS



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*EUA authorized by FDA

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BIOFIRE® RESPIRATORY 2.1-EZ (RP2.1-EZ)[1] PANEL (EUA)[1]

From BioFire

SARS-CoV-2 is everyone's top suspect, but many other respiratory bugs can cause similar, overlapping symptoms. In your clinic, you can test for 19 common respiratory pathogens, including SARS- CoV-2, with the BioFire RP2.1-EZ Panel (EUA)[1]—now available under an FDA Emergency Use Authorization. Syndromic testing means all it takes is one test and just 45 minutes to round up SARS-CoV-2—and all the other usual respiratory suspects.

1. This test is not FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories.

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FIRST EUA POINT-OF-CARE (POC/WAIVED/ FINGERSTICK) COVID-19 ANTIBODY TEST NOW AVAILABLE

From Carolina Liquid Chemistries

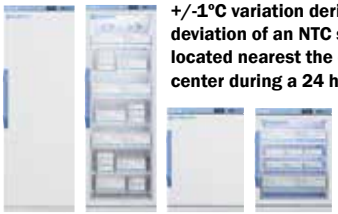
The Fastep® COVID-19 IgG/IgM Rapid Test Device by Assure Tech., distributed in the USA by Carolina Liquid Chemistries, has received FDA Emergency Use Authorization for use with fingerstick whole blood specimens at the point-of-care, i.e. in patient care settings operating under CLIA Certificate of Waiver such as doctor's offices, hospitals, urgent care centers and emergency rooms rather than having to be sent to a central lab.Refer to carolinachemistries.com for instructions for use, fact sheets, FDA EUA letters, clinical performance studies, and material safety data sheets. Not FDA cleared; only for emergency use under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless authorization is terminated or revoked.

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+/-1°C variation derived from the maximum deviation of an NTC sensor in a 1 oz. vial located nearest the champer geometric center during a 24 hour test period

Refrigerators & Freezers From 23 to 49 Cu.ft.

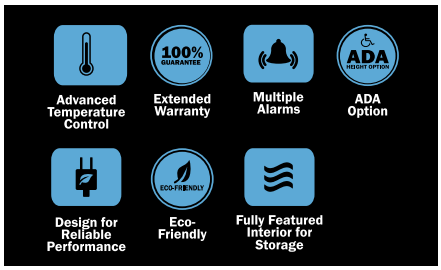


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Pharma-Vac Refrigerators

Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS1PV	1 cu.ft.	21.5"	17.5"	19.5"	White	**815.00**
ARG1PV	1 cu.ft.	21.5"	17.5"	20"	Glass	**820.00**
ARS3PV	3 cu.ft.	33.75"	18.5"	19"	White	**884.00**
ARG3PV	3 cu.ft.	33.75"	18.5"	19.5"	Glass	**897.00**
ARS6PV	6 cu.ft.	32.5"	23.5"	24.5"	White	**996.00**
ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	**1,010.00**
ARS8PV	8 cu.ft.	50"	23.38"	24.5"	White	**1,218.00**
ARG8PV	8 cu.ft.	50"	23.38"	25"	Glass	**1,287.00**
ARS12PV	12 cu.ft.	61.75"	23.38"	24.5"	White	**1,690.00**
ARG12PV	12 cu.ft.	61.75"	23.38"	25"	Glass	**1,704.00**
ARS15PV	15 cu.ft.	72"	23.5"	24.5"	White	**1,866.00**
ARG15PV	15 cu.ft.	72"	23.5"	25"	Glass	**1,879.00**

models with data loggers are available

Pharma-Lab Refrigerators

Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	**2,311.00**
ARG23ML	23 cu.ft.	83.75	27.5	31	(1) Glass	**2,633.00**
ARS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**3,503.00**
ARG49ML	49 cu.ft.	83.75	55.25	31	(2) Glass	**4,037.00**

Pharma-Lab Freezers

Accucold	Capacity	Height	Width	Depth	Door	PRICE
AFS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	**2,633.00**
AFS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**4,037.00**

visit www.medicaldevicedepot.com for all product information and options

Choosing the Right Sized Unit

Below are a few handy steps for determining the ideal Accucold refrigerator size for your clinic:

1 Estimate the maximum number of doses of publicly-provided vaccine and privately purchased vaccine that will be in your refrigerator.

Refrigerator: Add the number of doses on hand (current inventory) from your last order form.

Public Vaccine _____

Private Vaccine + _____

Total doses = _____

Multiply (max inventory) x 1.25

Maximum doses = _____

2 Match your maximum doses with the minimum cubic feet needed to safely store your vaccine

Max. Doses	Minimum Cubic Ft.
2,000+ doses	may need more than one refrigerator
1000-2000	40 cu.ft
900-1000	36 cu.ft
801-900	21-23 cu.ft
701-800	17-19.5 cu.ft
400-700	11-16.7 cu.ft
100-399	4.9-6.1 cu.ft

For product application suggestions or recommendations please feel free to contact our product specialists to discuss your options at:

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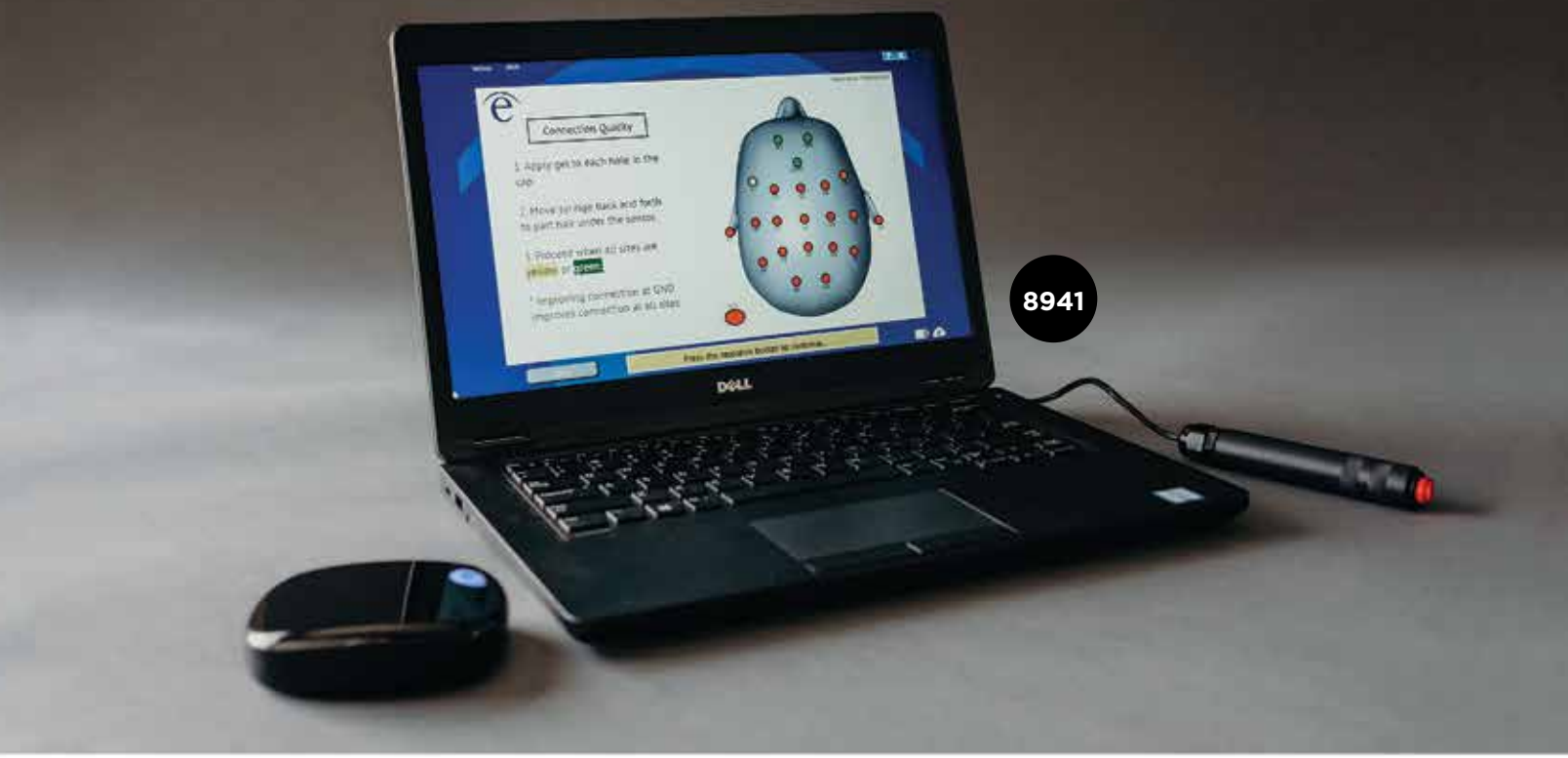
This is a new pen-like cryo devices that dispenses carbon dioxide which is perfect for superficial lesions such as sun spots, age spots, and shin tags. CryoClear® has enough gas to treat between 20 and 30 lesions depending on the size and type.

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FDA 510(k) cleared to aid in diagnosis of cognitive disorders

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Reimbursable.
$725 Medicare national average 2019[1]

eVox® Aids in Diagnosis

1 in 3 cases of dementia could be prevented with early interventions[2].

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[1]2019 NATIONAL AVERAGE MEDICARE PHYSICIAN FEE SCHEDULE, NON FACILITY SETTING https://www.cms.gov/apps/physician-fee-schedule/overview.aspx
Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019 Final Rule.

[2]Boise L, et al. Am J Alzheimers Dis 1999;14:20-26.



SPIROMETRY IS EASY

From MicroDirect

Unless the equipment is easy to use, it will not be fully utilized by your staff. The MicroLab and MicroLoop are menu driven via a large graphic display and the test takes less than five minutes to perform. The easy-to-read reports, quality checks and built-in interpretation assist with your diagnosis. Your office sees patients with indications for spirometry on a daily basis. Accurately and quickly diagnosis them so you can properly treat them.

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MICRO 1 SPIROMETER

From MicroDirect

Specifically designed for situations where low cost precision spirometry measurements are required, the Micro I Spirometer measures the following parameters FEV1, FVC, PEF, FEF25-75, EEV6, FEV1/FVC, FEV1/FEV6, FEF25 and FEF25 that cn be displayed along with percent predicted and post bronchodilator comparisons and provide an optional printout if needed. Extremely lightweight and portable making it suitable for hospital outreach clinics, bedside screenings, health fair screenings and other situations where remote testing is required.

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PORTABLE, SINGLE CLICK OPERATION SPIROMETER

From MicroDirect

The MicroDirect SpiroUSB many features include single click operation of all main functions, full ATS/ERS test quality checks, real time Flow/Volume and Volume/Time traces, a choice of child incentive displays, choice of predicted values, estimated lung age, pre/post bronchodilator comparisons and can be used on multiple PC's with dongle software protection key. The child incentive display and ATS quality checks ensure maximal results every time. Use with a laptop for true portability.

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THE BREWER BASIC EXAM TABLE

From Brewer

Full featured, entry-level exam table design. The Brewer Basic Exam Table features a pneumatic cylinder, seamless upholstery, and the largest storage capacity available. We invite you to compare features, price, warranty and you will find the Brewer Basic Exam Table is clearly the best entry level exam table available.

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FEATURE

PLANNING FOR NEW INSTRUMENTS AND TESTS

BY IRWIN Z. ROTHENBERG, MBA, MS, CLS(ASCP),
TECHNICAL WRITER /QUALITY ADVISOR, COLA RESOURCES, INC.

Introduction

Whether planning a new, start-up laboratory operation, or performing an analysis of current testing, (providing input for decisions on whether or not to purchase new or replacement instruments, or add or delete tests), it is important to do a realistic assessment not only of what you want to offer your ordering physicians, but what you can realistically offer. The laboratory's test menu should be aligned as closely as possible with physician expectations and needs, as well as the laboratory's operational capabilities.

By strengthening relationships with ordering physicians, laboratories can more accurately forecast future service needs and make the best decisions as to test menu, instrumentation, and staffing, including which tests to outsource or maintain in-house.

Begin this process by:

Reviewing Basic Information about the Current / Proposed Laboratory Operation

The first step in the planning process for adding new tests and new instrumentation begins with asking the following baseline questions regarding the present or proposed laboratory operation:

- What is your present test menu? Present instrumentation? Present staffing levels?
- What medical specialties are represented by your ordering physicians? (an important determinant of what tests will be requested, as well as patient demographics)
- Do you anticipate changes in the number of client physicians served? New specialties added? New populations served?
- What are your current or anticipated test volumes / demand for specific tests?
- What is the complexity of testing already performed or planned? (waived vs. non-waived, with attendant regulatory requirements, including personnel)



- What are your present hours of operation with attendant staffing levels / type and volume of testing performed per shift / commitment for turn-around times?

- What are your anticipated operating and capital budgets? (important determinant for changes to instrumentation and level of automation; as well as staffing expertise)

- Is adequate work space available to accommodate all phases of new patient testing from specimen collection to test result reporting?

The answers to these questions provide guidance for any changes to the test menu, which will be a driver for decisions on whether to acquire new or replacement instruments.

The next step forward is to perform a Cost/Benefit analysis of your present operation, and of the proposed changes to the test systems to determine economic and logistical feasibility.

Determine the Feasibility of Adding New Tests:
Perform a Cost / Benefit Analysis
It is by taking into account the internal as well as external factors in the laboratory environment, that the decisions made will have the best chance of success.

Below are items to consider for your cost/benefit analysis:

- Instrument capacity for current or proposed test menu (is it "right-sized" for test volume and level of staffing)

- Instrument cost (purchase or lease)

- Reagent cost (are you obligated to purchase reagents from a particular manufacturer?)

- Reagent life (expiration dates: days, weeks, months before/ after opening packages)

- Storage requirements for reagents (do you need to buy a new refrigerator or freezer?)
- Frequency and expense of Quality Controls, Calibration, and Maintenance
- Tests run singly or in batch-mode
- Comparison of in-house testing with reference laboratory charges and turn-around time
- Complexity of present and proposed testing.
- Staffing requirements: number, training expenses; qualifications and experience beyond present staffing; continuing education
- Proficiency Testing requirements
- Facility space, ventilation, electrical needs; hazardous disposal requirements
- Time and involvement of the Lab Director, and the Technical Consultant
- Document storage requirements / LIS capability
- Adjusting the front office staffing to handle additional pre and post analytical paperwork and communications

Additional strategies to determine the appropriateness of testing offered, and the instrumentation needed.

• Analyze test mix and outsource demanded but low-volume tests. Only outsource these tests if you can provide the test results a lower cost and with a better turnaround time.

• Project test demand and costs to determine which tests to perform in house. Conversely, analysis of send-out volumes may indicate opportunities to bring certain tests in-house.

• Partner with reference laboratories. Reference laboratories can provide valuable support in the form of financial analysis, methodology assessment, and provision of clinical samples to help make in-source-versus-outsource decisions and to establish and increase on-site test volumes.

Consider external factors as well

Consider what is going on in the laboratory industry today, noting trends both locally and across the country and seeing if these factors may affect your laboratory:

• What will be the impact of changes in reimbursement / payment mechanisms?

• What is the current market for your laboratory services? Estimating market size and location is a critical component to determine market opportunity. These estimates will drive financial outcomes.

• If you are part of an organization that has adopted the concept of value-based medical care, and it now part of an Accountable Care Organization (ACO), or accepts "bundled payments", your expenses will come under increased pressure to be held down and minimized. You may be encouraged to outsource more than originally planned.

• The well-documented staffing shortage may be a factor in your area; consider your local situation if planning to increase testing, add shifts, and new pre-analytic services.

Of course, providing the highest level of service for your patients may justify costs associated with the above considerations, but it is vital to ensure that your instrumentation can handle the changes in projected demand in terms of test volume capacity, variety of tests offered, operating times and staffing. This may require considering more automation. Automation has long been regarded as an important means for clinical laboratories to achieve greater operational efficiency, test accuracy, method standardization, total data handling and reduced turnaround time; in short, an improved quality of patient care.

The development of new generations of automated standalone and bench top equipment has made automation a more viable option for labs of all sizes—and in many cases, a necessary option for labs seeking to remain competitive in today's marketplace.

Steps in Determining the Right Automation for Your Laboratory

A. Questions to ask when deciding how much automation is needed

The amount of automation needed depends on the type and size of your laboratory. If all you are looking for is increased throughput and you don't really have to deal with diverse assays and readouts, then you might want to think about modular components. So with a few nonintegrated pieces of equipment, you can get the throughput you need without a huge investment, or additional space required.

B. Set priorities for automation based on realistic budget limitations

Once you have taken care of the above, and determined your needs, start getting quotes on systems needed. Budget negotiations will begin, with sets of reality checks on what is doable and what is not. Decisions should be based on priorities set in advance.

C. A few more points to remember

Always choose a vendor who can provide prompt, affordable service to minimize any downtime. Remember the data management involved. There are different sets of tools for data processing, data mining and data visualization, and you need to think about how you are going to track and analyze this data. Finally, create an infrastructure that can

be easily modified or expanded for other applications.

D. Plan for downtime for routine maintenance and equipment breakdown

E. Consider purchasing a service contract
A service contract can include many services beyond a general warranty, such as software updates, calibration, certification, preventative maintenance, priority service, and/or additional discounts on upgrades. Service contracts can be costly, and you can either discuss options with colleagues or make your own informed decision. Several reasons why you may chose to purchase a service contract could include reduced hassles if your equipment breaks, faster/priority repairs and a predictable expense in your budget. If a piece of equipment is critical to your work, you use it frequently, and major repairs are very expensive, a service contract may be worthwhile. In terms of budget, you will know exactly what you are going to pay in advance and will not be blindsided with a major "surprise" expense.

Recognize the strategic importance of physician / laboratory relationships

One of the ways that laboratories can use their resources more effectively is to strengthen their relationships with physicians. These relationships are vital as strategic assets, and, as the demands on physicians continue to multiply, they will increasingly rely on their laboratory partners for diagnostic support. Physicians increasingly seek a diagnostic resource that can meet all of their testing needs.
Laboratories are discovering that they are well positioned to provide medical guidance and direction for clinicians who are trying to maneuver their way through the increasingly complex world of laboratory testing.
To efficiently manage laboratory test utilization requires both ensuring adequate utilization of needed tests in some patients and discouraging superfluous tests in other patients.
An important step in this process is to work with client physicians on a program of proper test utilization to encourage the most efficient and relevant use of the testing offered.

The key role of competent management in accomplishing these goals

Effective laboratory planning requires competent management It is through the application of management skills that you can implement change with minimal disruption. Competent laboratory management includes effective communication with the staff; providing key information and direction for the continuing future development of the laboratory; and encouraging involvement in the development of strategic plans.

Successful management can motivate staff to provide feedback about their workload; instruments and kits used; make suggestions for improvement of, and changes to, their test menu; and provide information about interactions with other offices, departments, physicians, and patients. These types of information play an important role when developing strategies for cost containment, automation, growth, re-alignment, and even repositioning of the lab in the community.

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