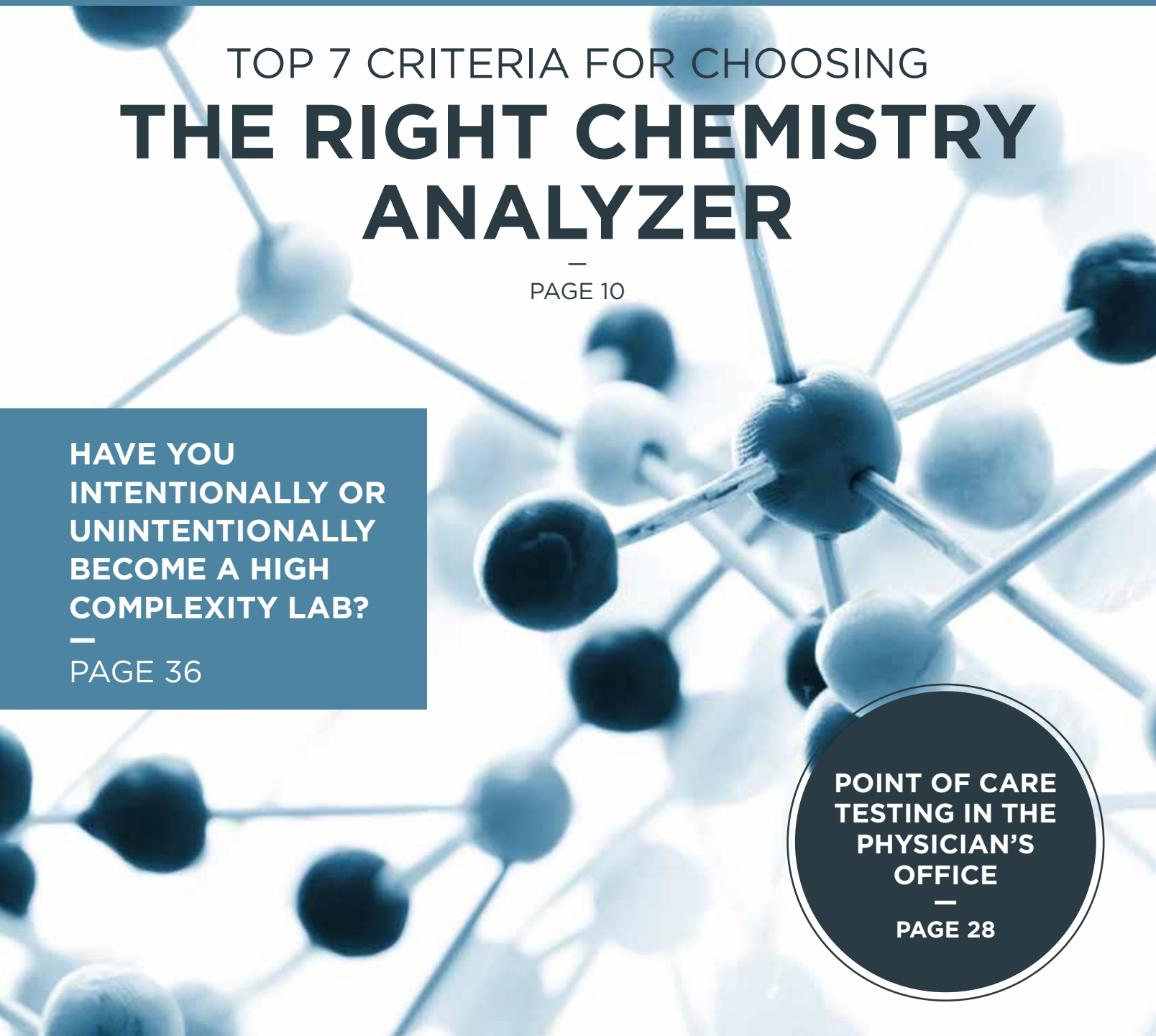
2021 | Issue 5

Physicians office Resource™

Resources for You, Your Patients, & Your Practice



TOP 7 CRITERIA FOR CHOOSING THE RIGHT CHEMISTRY ANALYZER

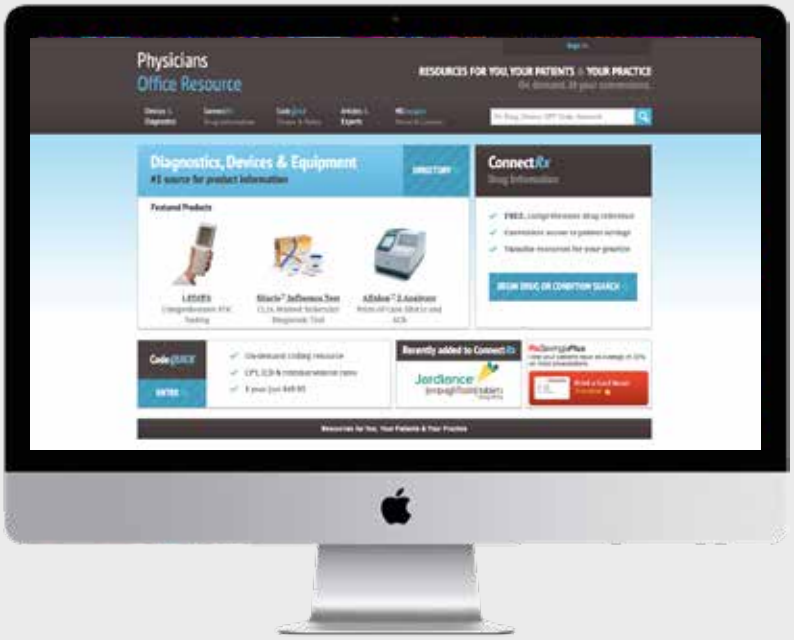
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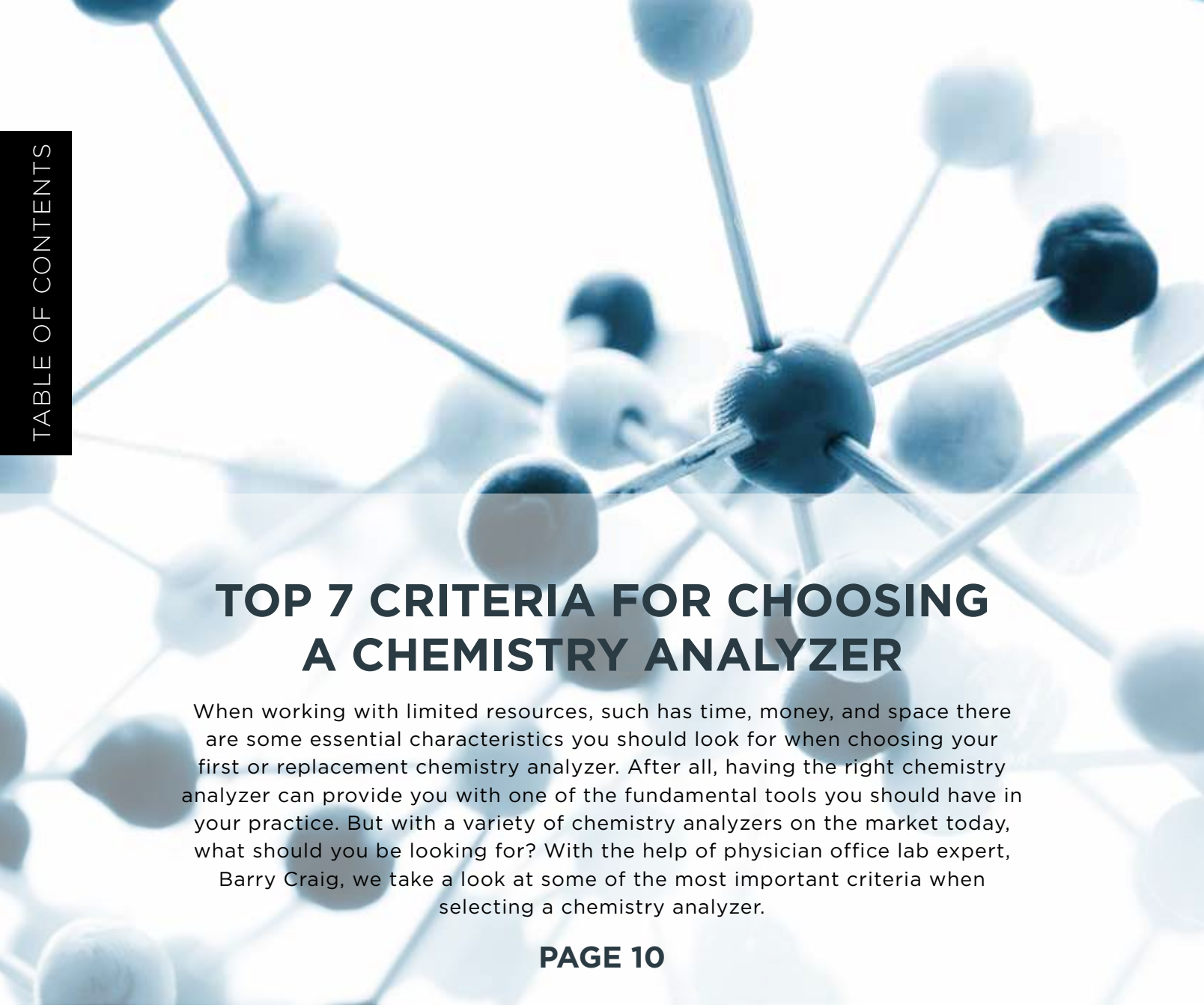
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*2016 Proficiency Testing Results, American Proficiency Institute, www.api-pt.com [*Piccolo Xpress*]. See cartridge information at www.pointofcare.abbott [*i-STAT*].

***i-STAT* Part No:** 04J60-20 Waived Kit, 04J48-50 Moderately Complex Kit, 06F20-20 Waived Analyzer, 04P75-03 Moderately Complex Analyzer
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TOP 7 CRITERIA FOR CHOOSING A CHEMISTRY ANALYZER

When working with limited resources, such has time, money, and space there are some essential characteristics you should look for when choosing your first or replacement chemistry analyzer. After all, having the right chemistry analyzer can provide you with one of the fundamental tools you should have in your practice. But with a variety of chemistry analyzers on the market today, what should you be looking for? With the help of physician office lab expert, Barry Craig, we take a look at some of the most important criteria when selecting a chemistry analyzer.

PAGE 10

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POINT-OF-CARE TESTING IN THE PHYSICIAN'S OFFICE: IMPROVING OUTCOMES AND REDUCING COSTS

—

Whether it's diagnosing vitamin D deficiencies, managing thyroid disorders or monitoring prostate cancer, one clear motivation for performing diagnostic testing in-house is the ability to minimize return patient visits for medical decision-making, thereby enhancing patient care.

36

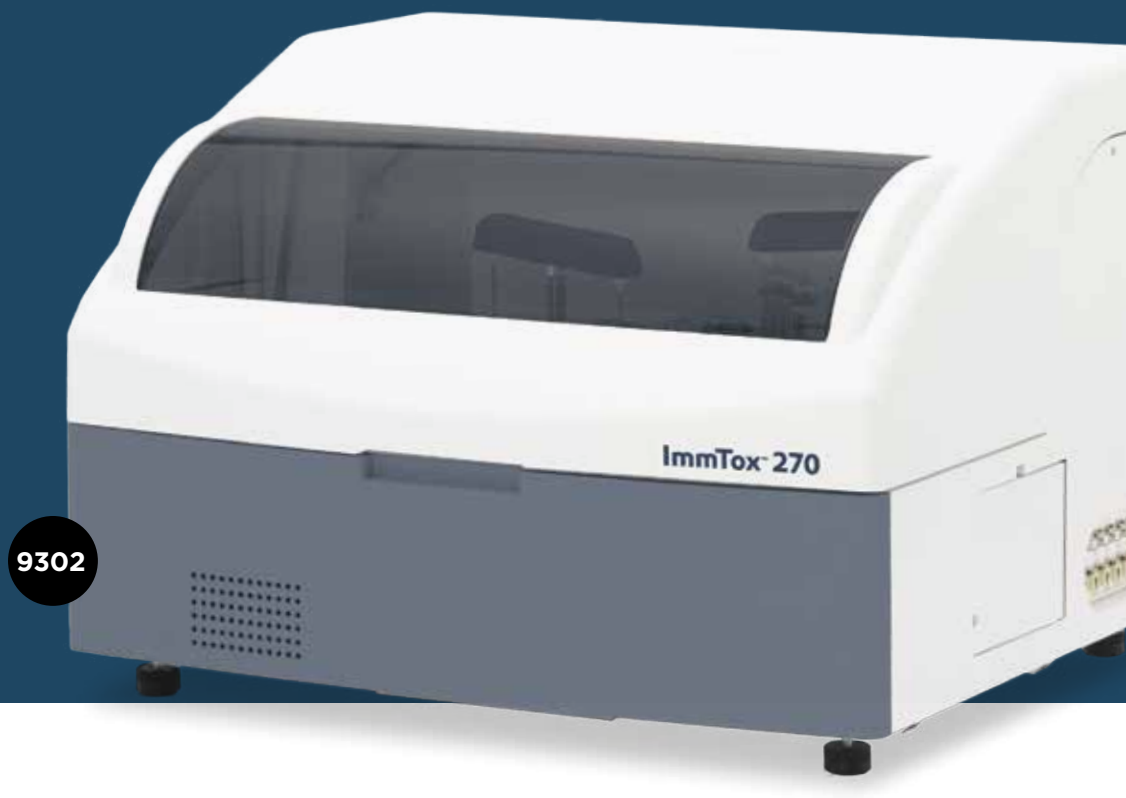
HAVE YOU INTENTIONALLY OR UNINTENTIONALLY BECOME A HIGH COMPLEXITY LAB?

—

There may be circumstances when laboratories consider the option to modify an FDA-cleared or approved test system. These may be due to the specific needs of the population served; or based on cost/benefit analyses of instrumentation and reagent use...

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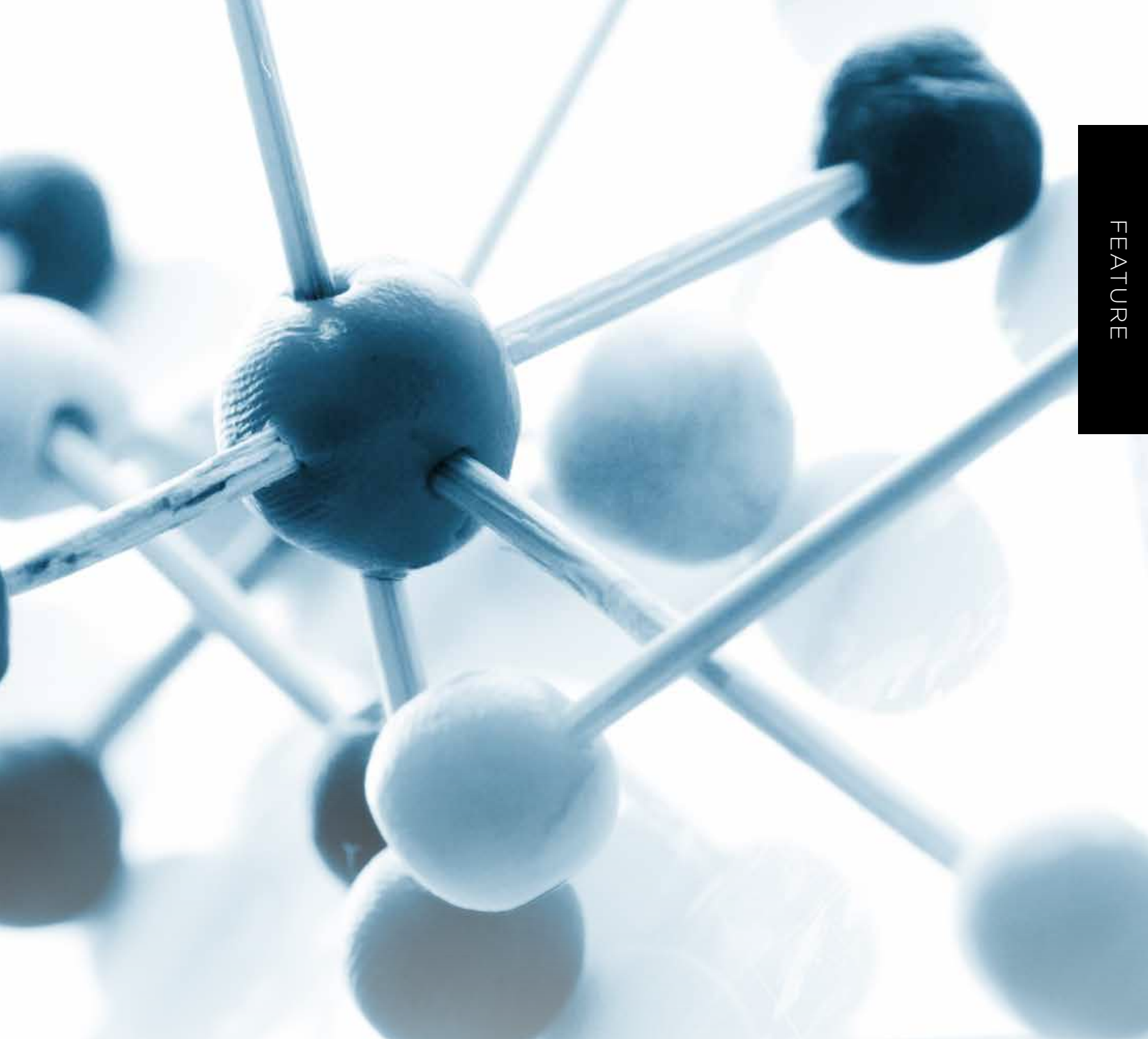
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TOP 7 CRITERIA FOR CHOOSING A

Chemistry Analyzer for a POL

A PHYSICIANS OFFICE RESOURCE DISCUSSION WITH BARRY CRAIG OF LABORATORY CONSULTING, LLC



Last fall, we experienced a deep and early freeze where I live, and unfortunately, I wasn't paying attention to the weather and failed to remove my garden hose from the outside of my house. The water froze within the hose and into the hose bib (the outside faucet that you connect your hose to. Yeah, I didn't know it was called that either). The expanding ice in the line caused the hose bib to burst within our house. Luckily, our basement isn't finished so there wasn't any real damage except to the hose bib which had split. The fix didn't look too difficult, I figured it would be a quick and inexpensive job, so I called a plumber to come out and give me an estimate. Boy, was I shocked to see those numbers come back! I couldn't believe it would cost so much to have such a small repair fixed. Being the frugal, or as my wife calls me, cheap, man that I am, I set out to try and fix it myself. I did some research on the internet and bought a top-of-the-line hose bib, then called my father-in-law who is quite handy and explained my situation. Just hoping to get some coaching through the repair process, I was surprised when my father-in-law said he had a specific tool that could help get the job done and would bring it the next time he was in town. The next time he was in town, we cut the pipe, inserted the new hose bib and utilized my father in law's tool called a throw press to connect the ends of the new hose bib and the old pipe. The whole process took less than 10 minutes. Because of my father-in-law's tools and knowledge I saved hundreds of dollars on that small repair. I know many of you are thinking, what does all this have to do with choosing the right chemistry analyzer for my lab? Well, luckily for us, we have someone like my father-in-law that is extremely knowledgeable about the physician office lab space. Barry Craig has over 25 years of experience and worked with hundreds of POLs. For this article, we've tapped into his knowledge and experience to help you as you select a new chemistry analyzer.

When thinking about adding or replacing a chemistry analyzer to your lab, I'm sure many of you have asked questions such as:

I'm I outsourcing tests that I could easily do in my office with the right chemistry analyzer?

Would having the right chemistry analyzer provide a better patient experience?

Can having the right chemistry analyzer help generate additional revenue?

When working with limited resources, such has time, money, and space there are some essential characteristics you should look for when choosing your first or replacement chemistry analyzer. After all, having the right chemistry analyzer can provide you with one of the fundamental tools you should have in your practice. But with a variety of chemistry analyzers on the market today, what should you be looking for? After talking with a Barry, here are his top criteria and questions to ask yourself and sales rep when selecting a chemistry analyzer:

1. Service

This was the top criteria on every industry expert that I spoke with. How good is said company's service? Do they answer promptly? Do they guarantee a service or repair call within 24 hours of notification? Are the repair people employees and factory trained or are they "contracted" repair people with no affiliation to the company that makes the instrument? Are parts readily available or do you sit for weeks waiting on a part from overseas? The answers to these questions can make your break your experience. Ask for referrals of other labs that they have worked with. If they are confident in their service abilities, they should have no problem connecting you to another pleased customer.

2. Cost

The cost of the instrument is just the beginning. How does the instrument, reagents, calibrators, and controls cost compare to others in the market? The cheapest may be cheap for a reason. How much will the service contract cost once the warranty runs out?

3. Performance

As the question suggests, look at the performance of your proposed instrument by examining its performance on PT testing. How well does it score to comparable instruments? Does it have only a few units in use or hundreds? The more units in use, the better it should score on the PT events. Even if only a few units are listed, look at the performance first. Fewer units doesn't mean it is not a well-made instrument, it may just be newer to the market. Ask for references for sites already using the instrument. Try to find units in use independently and not who the sales guy suggests you call.

4. Ease of use

Does it have a multitude of maintenance steps daily? Does it require constant replacement of tubing, filters, etc.? Does the instrument program easily or do the operational steps take a lot of time? How thorough is the training for the instrument?

5. Reliability

Check with as many sources as possible to determine the "downtime" factor. It does not matter how pretty it is, or how cheap it is if the machine is not working. Not running means not billing. Check with the sales guy, the company that makes the machine, anyone who can help you find units that have been in operation for a while.

6. Test Menu

What type of tests are you planning on running? Make sure to review the test menu with your rep to verify that your most common tests are included. Certain CLIA Waived units are great for POLs because they have a smaller footprint and run many common tests. However, if you're looking for a greater variety of tests make sure to look at other benchtop units that require a Compliance Certificate from CLIA.

7. Volume

You should always look at your current test volume. Remember, you cannot suddenly increase your number of tests. If you currently don't have a chemistry analyzer, the send out history will tell the tale of whether you need to move up, stay pat, or fold. If you're looking to replace an existing chemistry unit, realize, if you are only running a small volume now or sending out a small volume to a reference lab, you may not have enough testing to warrant purchasing a larger unit. Figure out your break-even point on cost and then look at how many tests you actually send out or perform.

These are just a handful of criteria when choosing a chemistry analyzer, there will be more that you will want to consider, but these will provide a good foundation as you make your decision.

We would like to offer a big thanks to Barry Craig and his insights for helping us with this article. Barry is a trusted voice within the lab industry with over 25 years experience and hundreds of labs helped.

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*EUA authorized by FDA

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

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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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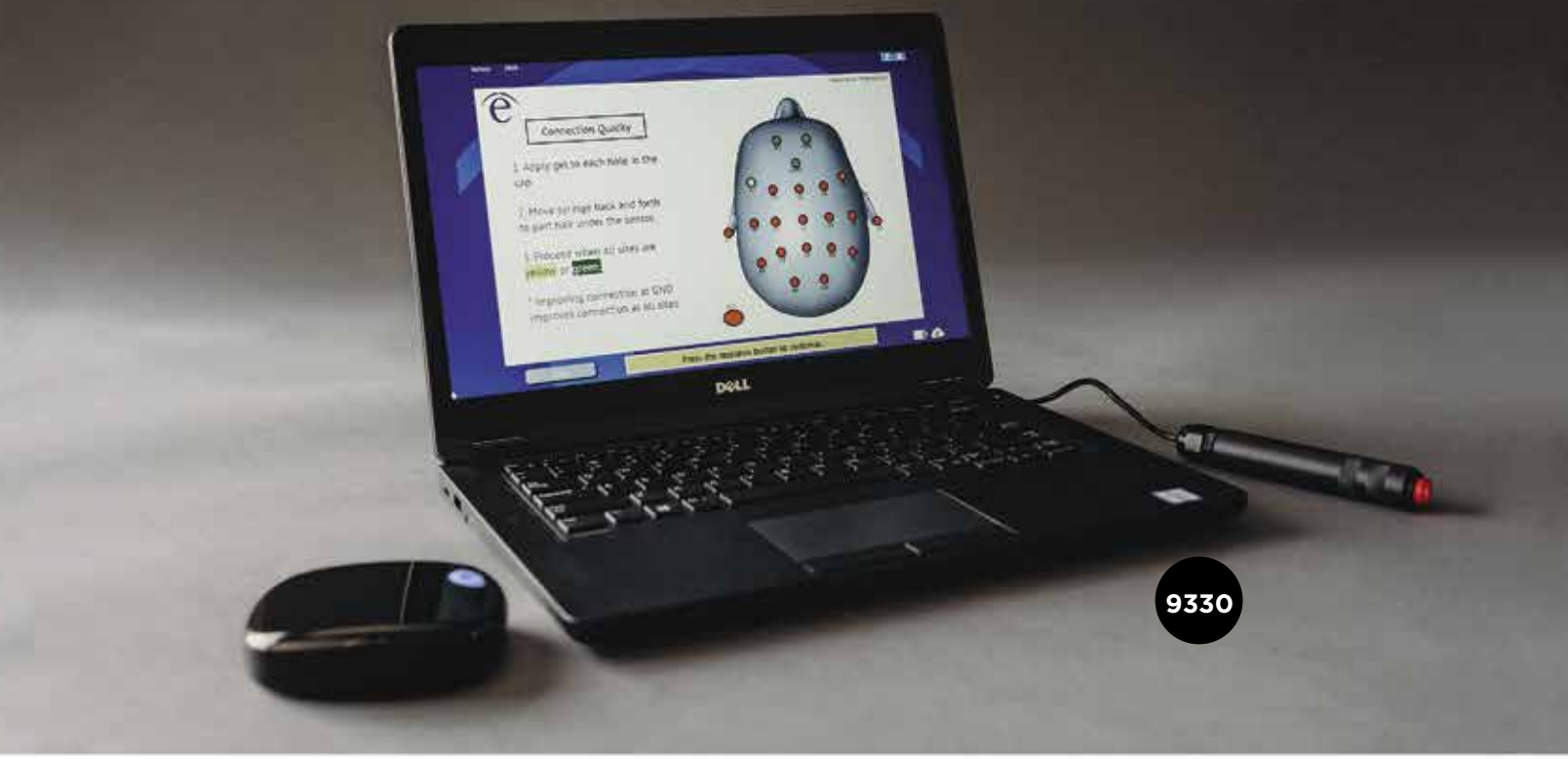
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Memory loss biomarkers to aid in diagnosis



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

Easy-to-use.
In-office assessment via computational EEG/ERP

Reimbursable.
$725 Medicare national average 2019[1]

eVox® Aids in Diagnosis

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

The eVox® System may help you detect, diagnose, and intervene early.

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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.



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HISTOFREEZER® FLEX

From CryoConcepts

This canister-based devices is the latest advance in portable cryosurgery for the physician office. Its advanced design give doctors the option of using cones or buds to deliver the cryogen to the treatment site. There is no risk of cryogen splattering during treatment and our cryogen stays colder versus other products on the market which lead to better first time outcomes.

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CRYOMEGA®

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CryoLab is a desk-top sized unit that delivers cryogen and employs pre-set spray times to ensure safe and effective treatment. Our lighted wand can spray the cryogen from any direction making it easier to treat all locations on the patient. CryoLab® can dispense nitrous oxide or carbon dioxide allowing physicians to treat cosmetically sensitive areas on the face, hands, and chest with less trauma and downtime.

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CareStart SARS-CoV-2 Rapid Antigen Test (20 Tests)
As an intended point-of-care (POC) designated test with a 10 min processing time, CareStart COVID-19 Antigen Test allows effective screening of COVID-19 infection on a large scale. Rapid results within 10 minutes. Identify acute infection with 88.4% sensitivity and 100% specificty. FDA & EUA approved!



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Analyzes (EEG) brain processing speed (Evoke Potentials), heart health (EKG) mental health (Neuropyschology); Each test is processed into a fully-finished, clinically actionable report that uncovers symptoms associated with dementia, anxiety, depression, PTSD, TBI and more.

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CLIA-WAIVED BIOFIRE® FILMARRAY® RESPIRATORY PANEL (RP) EZ

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Cepheid's GeneXpert Xpress® brings standardized molecular testing to any healthcare setting. Employing the highly accurate and easy to use lab in a cartridge technology in every GeneXpert system, the GeneXpert Xpress® is a true on-demand walkaway testing system that provides accurate and reliable detection of Strep A, Flu A, Flu B and RSV. Two or four-module configurations save valuable bench space and reduce the need for multiple testing platforms.

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From Sekisui Diagnostics

The Acucy™ Influenza A&B Test is for the rapid, qualitative detection of influenza A and B viral nucleoprotein antigens from both nasal and nasopharyngeal swabs. Utilizing the Acucy™ Reader in either the point-of-care or laboratory setting, workflow flexibility is achieved with both Read Now and Walk Away features. The combination provides clinicians with standardized and definitive result interpretation.

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A molecular test utilizing polymerase chain reaction (PCR) technology providing accurate results for early diagnosis and proper management of influenza.

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From Sekisui

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Is it viral or bacterial? A CBC with 3-part differential can provide the clues to help distinguish between viral and bacterial infections before you decide to treat. The Micros 60 Hematology analyzer provides a CBC with 3-part Diff result in less than 60 seconds using only 10 µL of sample. Connect to the Lite[DM] Patient Data Management System for an affordable way to consolidate patient results to one report.

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TURN SMALL PLACES INTO SMART SPACES

From Abbott

With reduced budgets, shrinking laboratory space and staffing challenges, many laboratories need a solution that lets them work smarter with less. The CELL-DYN Emerald 22 AL is a full performance, automated optical 5-part differential analyzer that delivers smarter results for small to midsize clinical laboratories.

- Compact Design
- Walkaway Functionality
- Ease Of Use
- Smart Safety Features

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CELL-DYN EMERALD HEMATOLOGY ANALYZER

From Abbott

CELL-DYN Emerald is a 3-part differential hematology analyzer that offers high performance in an affordable, compact design that provides reliable and accurate patient results every time. As a smaller operating laboratory, you need a solution that offers reliable results. CELL-DYN Emerald provides results in under 65 seconds. CELL-DYN Emereald's small size, simple touch screen software and reliability offer an easy-to-use, truly compact table/bench top instrument for easy performance in your laboratory.

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ACCURATE RESULTS EVERY TIME.

CELL-DYN EMERALD

Compact, easy-to-use 3-part differential hematology analyzer provides you with proven methods and technology, including electronic impedance, absorption spectrophotometry, electronic valves, cyanide-free lyse reagent, LCD color touch screen and USB ports.

COMPACT DESIGN

Conserving valuable laboratory workspace with a small footprint and only 2 reagents plus on-board cleaner.

EASE OF USE

- Decreasing manual entry errors and increasing compliance by use of barcoded reagents
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FLEXIBLE USER INTERFACE

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Helping you keep your commitments

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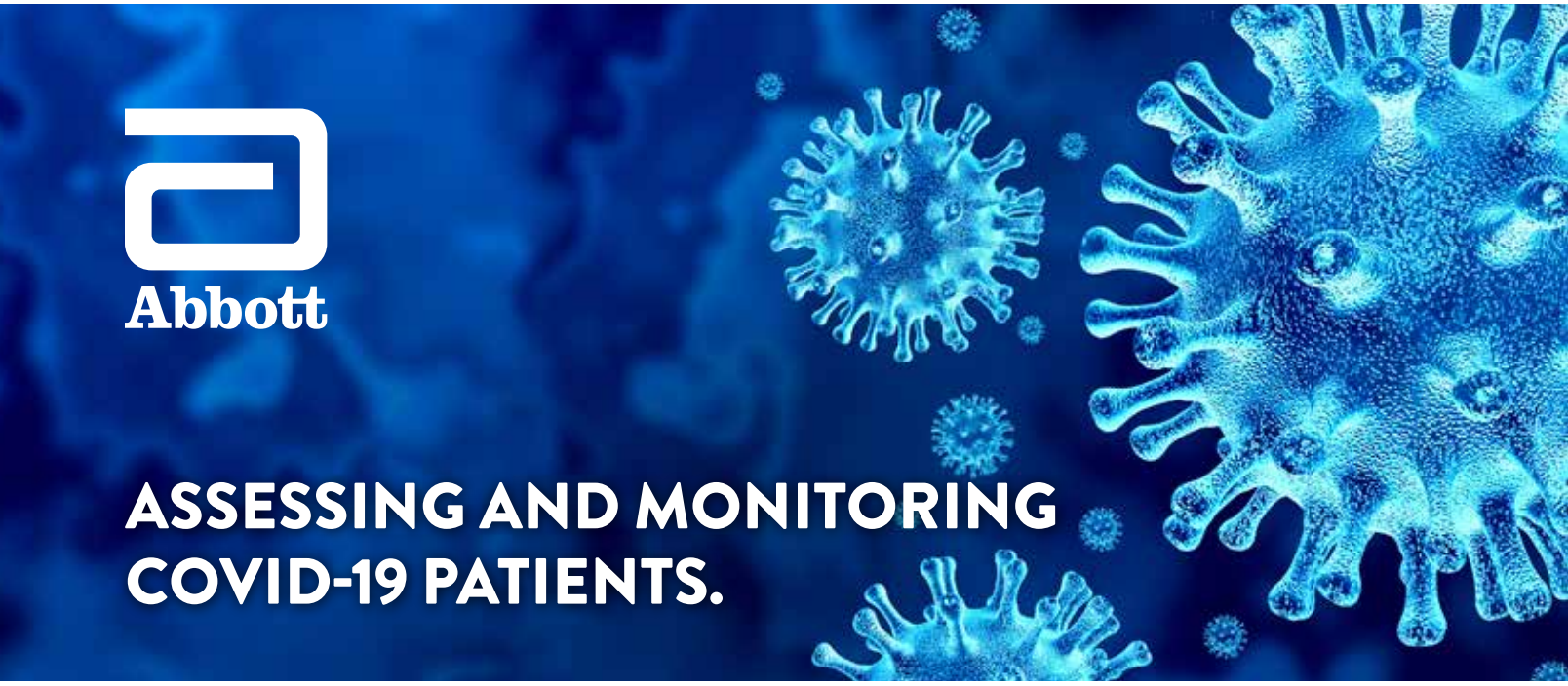
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ASSESSING AND MONITORING COVID-19 PATIENTS.

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]



piccolo xpress chemistry analyzer

For *in vitro* diagnostic use only.

The Piccolo Xpress does not directly diagnose COVID-19.

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The Piccolo Xpress portable diagnostic analyzer offers a full complement of blood chemistry tests, including CLIA-waived tests.

Get accurate results in minutes, at the point-of-care.

SEE A LIST OF KEY PICCOLO XPRESS PANELS ON BACK.



KEY PICCOLO XPRESS PANELS.

CLIA-WAIVED PANELS



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Na+, K+, CI-, tCO_2, Ca, BUN, Crea, Glu, ALB, ALP, ALT, AST, TP, tBIL, eGFR*



MetLyte 8
Na+, K+, Cl-, tCO_2, BUN, Crea, Glu, CK, eGFR*



Liver Panel Plus
ALB, ALP, ALT, AMY, AST, GGT, tBIL, TP

*Calculated

MODERATELY COMPLEX PANELS



BioChemistry Panel Plus
ALB, ALP, ALT, AMY, AST, BUN, Ca, Crea, Glu, GGT, TP, UA, CRP, eGFR*



MetLyte Plus CRP
Na+, K+, Cl-, tCO_2, BUN, Crea, Glu, CK, CRP, eGFR*



Hepatic Function Panel
ALB, ALP, ALT, AST, tBIL, dBIL, TP

To learn how the Piccolo Xpress portable diagnostic analyzer can help transform your patient care, contact your Abbott Point of Care Representative or visit www.pointofcare.abbott

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POINT OF CARE

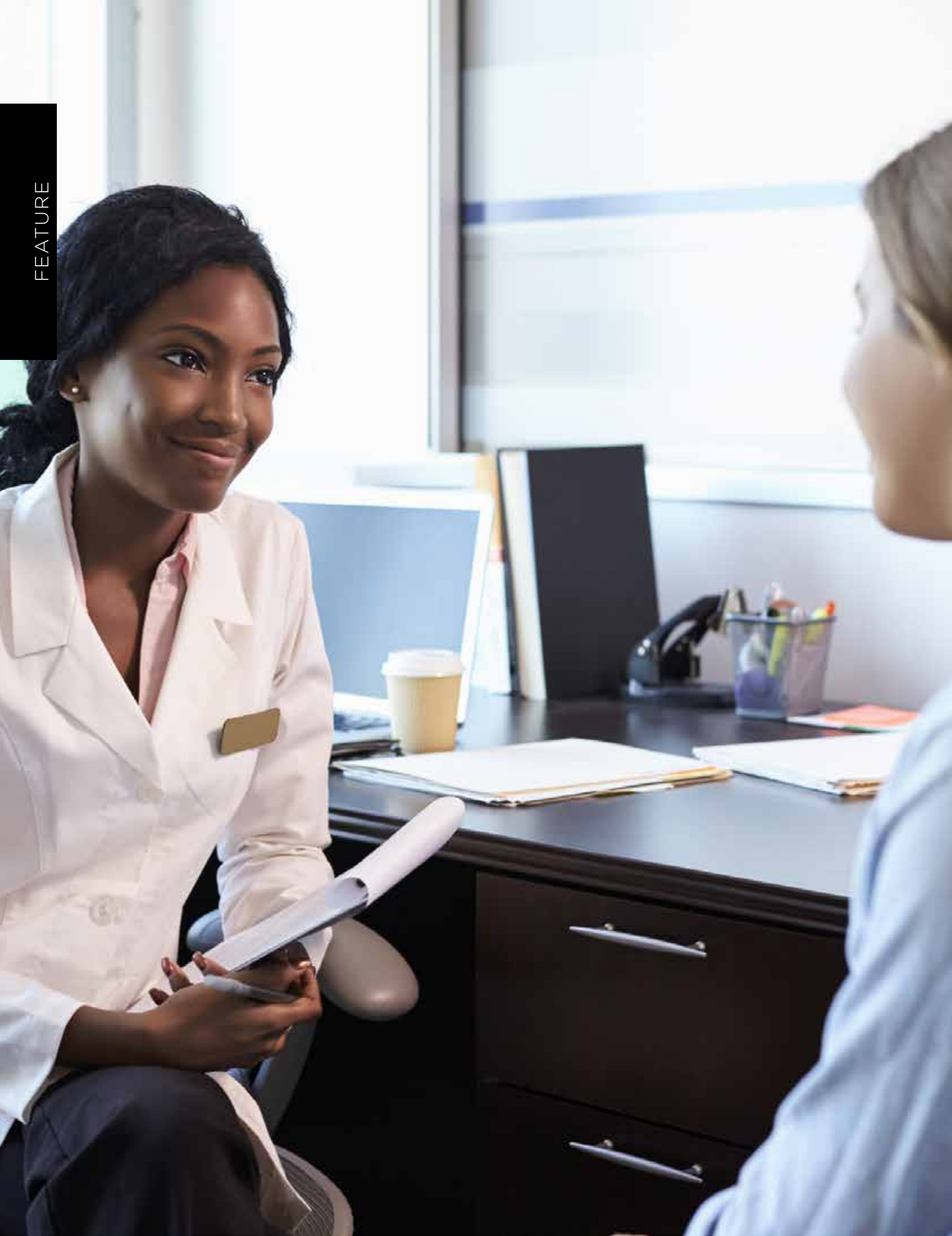
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POINT-OF-CARE TESTING IN THE PHYSICIAN'S OFFICE

Improving Outcomes and Reducing Costs

BY SEKISUI DIAGNOSTICS

Whether it's diagnosing vitamin D deficiencies, managing thyroid disorders or monitoring prostate cancer, one clear motivation for performing diagnostic testing in-house is the ability to minimize return patient visits for medical decision-making, thereby enhancing patient care.

The average physician's office sends out a range of samples for testing by hospital, central or reference labs. However, the expanding presence of on-site POLs demonstrates that diagnostic testing at the point-of-care (POC) can improve patient outcomes while reducing practice costs and creating additional revenue opportunities. These are several key reasons for starting up a POL. Some other reasons include:

- Healthcare reform and patient-centered care
- [a] Technological advancements (faster, easier-to-use devices)
- Laboratory staff shortages
- Increasing older population and more chronic disease
- Rising incidence of lifestyle diseases (e.g., cardiac, diabetes)
- Increasing trend toward healthcare decentralization
- Long-term savings
- Rural locations with limited lab services

In many cases, bringing some of these outsourced tests in-house can offer other benefits to doctor's offices, including:

- Increased Efficiencies: allows the practice to function more efficiently, with improved staff efficiency & lower labor costs
- Convenience: allows the physician to deliver results in person, face-to-face, which can foster better patient understanding, retention, and compliance
- Marketplace Differentiation: can provide a competitive advantage for the practice to differentiate it from other practices
- Improved Quality of Care: eliminates the risk that the patient does not return in a timely fashion
- Improved Practice Sustainability: requires less patient record review from previous visits

MACRA: What this means to the POL

The Medicare Access and CHIP Reauthorization Act (MACRA) will change how Medicare pays for physician services. Most physicians will be paid under the default track of the new program known as the Merit-based Incentive Payment System (MIPS).MIPS Provides incentives and penalties of Medicare professional service payments based on quality and cost performance vs. volume of procedures/tests performed.

Because MACRA rewards clinicians for value over volume same day point-of-care testing can improve two key MACRA objectives: outcomes and quality of care. Diagnostic tests such as Flu, Strep, PSA, Fecal Occult Blood (for colorectal cancer screening) and others are all tests which address MACRA quality measures and move patients along the road to recovery faster while reducing health risks. *(SOURCE: https://qpp.cms.gov/mips/quality-measures*

To Learn more about the full Quality Payment Program visit: https://qpp.cms.gov/

Physicians' Office Point-of-Care Testing: Getting Started

When considering what tests to bring in-house, you'll need to have a thorough understanding of what would be required – from upfront costs, space & staffing, to time or training if upgrading to moderately complex testing.

Once a comparative value of advantages and disadvantages has been explored, your office can make a determination of which tests would be good candidates for your in-house Physician Office Lab.

A Review From a Healthcare Provider

Miramont Family Medicine is a mid-size physician's office in Colorado that was seeking a way to provide the highest-quality care while maintaining the lowest-cost services to their patients. When Miramont Family Medicine adopted their Patient-Centered Medical Home (PCMH) model - implementing a Physician Office Laboratory (POL) was key part of the model. Their goals were to:

- *Improve patient outcomes*
- *Improve their patients experience, by ensuring patients receive the necessary care when and where they need it*
- *Provide greater patient convenience,*
- *Improve practice efficiency and productivity*

Miramont found that using their POL resulted in patients receiving their test results during their office visit, which ensured they immediately received their diagnosis and care regimen. Also, Miramont found that utilizing their on-site POL significantly reduced staff labor costs from the 20 minutes it used to take to prepare and send out tests to only 10 minutes per test.

Want to Learn More About Physician Office Labs?

The Sekisui Diagnostics team understands what medical practices need to effectively create and run a POL and can provide them with a comprehensive product line for point-of-care testing.

Learn more at
Visit sekisuidiagnostics.com/about-us/contact-us/

How a Point-of-Care POL Works

While there are key differences in each medical practice, there are some commonalities among the requirements for a POL: startup funds, appropriate space, staff to train and allocate to testing, and a sufficient testing load to make it feasible and profitable. Among these requirements the top three considerations are:

SPACE

While a physician's office may not require a large space for a lab, it will require a dedicated space. In some cases, a large closet may suffice. The lab space must have electrical outlets and running water - and be located away from food prep or eating areas. You'll need to ensure there is enough room for a person to maneuver with tabletop instruments, a sink, and a refrigerator in easy reach to optimize efficiency.

STAFF

Your practice will need to have staff that can learn to operate the equipment and perform the test protocols. This may or may not require additional staff, since bringing technology in-house to perform diagnostic testing will likely lead to an overall increase in labor efficiency.

TESTS

Determining which tests to offer in-house will be driven by the particulars of your practice. Standard test menus which are ordered routinely in a general medical practice may include:

General chemistry (CMP, BMP, lipid profile, CPK, lipase, iron panel, uric acid, HbA1C, urine microalbumin and others)

Hematology (CBS, PT/INR, D-dimer, ESR)
Rapid tests (Flu, Strep, IFOB, Trichomonas, BV, hCG)

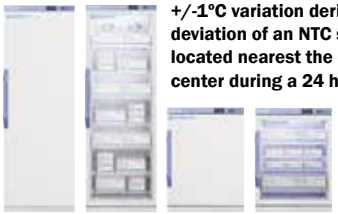
Immunochemistry (TSH, free T4, PSA, testosterone, vitamin D, troponin, myoglobin, BNP, RPR, HIV, Hep-C and others)

Whether your practice is looking to perform CLIA-waived assays or moderately complex assays, it's important to find a diagnostic test supplier that can address a broad assortment of testing solutions, including instrumentation, assays & supplies.

VACCINE FREEZERS and REFRIGERATORS

- Built-in readout for current & high/low temperature
- Audible & visual high/low temperature alarms
- Optimized efficient performance for stable temperature
- Eco-friendly natural refrigerants for a greener footprint

Solid & Glass Door Refrigerators From 1 to 15 Cu.ft.



+/-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.

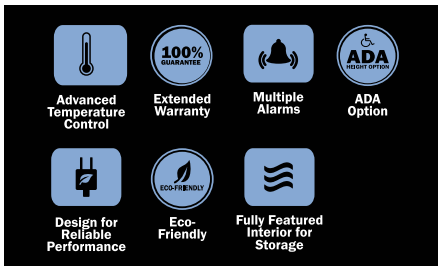


Refrigeration designed and purpose-built for pharmacy, medication, and vaccination applications to support meeting CDC/VFC vaccine storage guidelines

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Advanced Temperature Control & Durable Performance

- Intelligent microprocessor digital temperature controller
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- Digital display of the min/max temperature in Celsius or Fahrenheit
- Password protected control parameters beyond setpoitn
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- Factory installed lock conveniently located towards the top of each unit
- Adjustable shelving can be spaced in ½" intervals for flexible storage



Pharma-Vac Refrigerators

Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS1PV	1 cu.ft.	21.5"	17.5"	19.5"	White	**865.00**
ARG1PV	1 cu.ft.	21.5"	17.5"	20"	Glass	**878.00**
ARS3PV	3 cu.ft.	33.75"	18.5"	19"	White	**965.00**
ARG3PV	3 cu.ft.	33.75"	18.5"	19.5"	Glass	**969.00**
ARS6PV	6 cu.ft.	32.5"	23.5"	24.5"	White	**1,060.00**
ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	**1,072.00**
ARS8PV	8 cu.ft.	50"	23.38"	24.5"	White	**1,284.00**
ARG8PV	8 cu.ft.	50"	23.38"	25"	Glass	**1,349.00**
ARS12PV	12 cu.ft.	61.75"	23.38"	24.5"	White	**1,788.00**
ARG12PV	12 cu.ft.	61.75"	23.38"	25"	Glass	**1,801.00**
ARS15PV	15 cu.ft.	72"	23.5"	24.5"	White	**1,970.00**
ARG15PV	15 cu.ft.	72"	23.5"	25"	Glass	**1,983.00**

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	**2,466.00**
ARG23ML	23 cu.ft.	83.75	27.5	31	(1) Glass	**2,811.00**
ARS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**3,634.00**
ARG49ML	49 cu.ft.	83.75	55.25	31	(2) Glass	**4,186.00**

Pharma-Lab Freezers

Accucold	Capacity	Height	Width	Depth	Door	PRICE
AFS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	**2,804.00**
AFS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**4,299.00**

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:

877-646-3300

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MICROS ES 60 HEMATOLOGY ANALYZER WITH 3-PART DIFFERENTIAL

From HORIBA Medical

Simple to use and easy to maintain with a zero maintenance concept, the Micros ES 60 is a small tabletop hematology analyzer with an integrated data management system. The analyzer provides a CBC with 3-part differential result in less than 60 seconds using only 10 µL of sample. Connect to the Lite^{DM} Patient Data Management System for an affordable way to consolidate patient results to one report.

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PENTRA XLR HEMATOLOGY ANALYZER WITH 5-PART DIFFERENTIAL

From HORIBA Medical

The Pentra XLR hematology analyzer with autoloader provides a CBC with 5-part Diff result using proprietary technology that ensures an accurate count and differential on the first run. The Pentra XLR also provides a complete menu of Retic parameters for treating oncology and anemia patients. The autoloader processes 80 samples an hour and provides random continuous access for medium- to high-volume clinics and rural or community hospitals.

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PENTRA 60 C+ HEMATOLOGY ANALYZER WITH 5-PART DIFFERENTIAL

From HORIBA Medical

Now you can have the same results hospitals and reference labs provide in a small, benchtop analyzer. The Pentra 60 C+ hematology analyzer provides a CBC with 5-part differential result using proprietary technology that ensures an accurate count and differential on the first run. Reduce repeats and reflex to the microscope with Pentra hematology technology.

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IMMUNOASSAY ANALYZERS



FULLY AUTOMATED QUANTITIVE IMMUNOASSAY ANALYZER

From Sekisui Diagnostics

The FastPack® IP System is a fully automated quantitative immunoassay analyzer designed for use in the Physician Office laboratory. Utilizing sophisticated chemiluminescence technology, the FastPack® IP System provides the capability to produce complex immunoassay results in 12 minutes or less with a push of a button. Menu includes Vitamin D, Testosterone, TSH, Free T4 PSA and hCG.

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THE NANOENTEK FREND IMMUNOASSAY SYSTEM

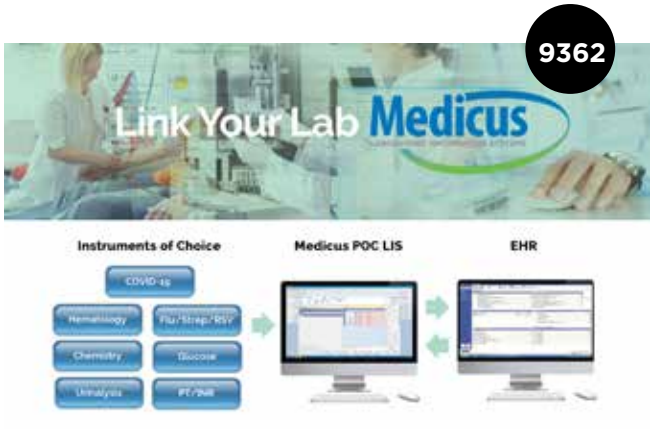
From NanoEnTek

The NanoEnTek FREND Immunoassay System provides Vitamin D, TSH, fT4, PSA, and Testosterone results in minutes with a no cost placement program. Complete all 5 tests in less than 20 minutes for same visit patient consultation. PSA and TSH results are available in 3 minutes or less. Imagine having a new source of revenue with improved practice efficiency and patient satisfaction. Thoughtfully designed, with your practice in mind.

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LABORATORY SERVICES



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From Medicus LIS

If you are considering in-house lab testing, including Covid-19 testing and required reporting to state agencies, connecting Lab to LIS and EHR makes the process of test orders to completed results much easier. Providers receive test results posted to patient charts in real-time, expediting patient care, saving time, money and even preparing for lab test reimbursement goals. Link Your Lab with Medicus LIS today! Contact us: 888-643-8081 sales@medicuslis.com

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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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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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SPIROMETRY IS EASY

From MicroDirect

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MD SPIRO

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It's Good Medicine - Your patients are correctly diagnosed and treated more accurately and conveniently in your office. The earlier you detect the disease; the easier you can treat it.

It's Easy - A spirometry test takes less than five minutes to perform.

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HAVE YOU INTENTIONALLY OR UNINTENTIONALLY BECOME A HIGH COMPLEXITY LAB?

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

There may be circumstances when laboratories consider the option to modify an FDA-cleared or approved test system. These may be due to the specific needs of the population served; or based on cost/benefit analyses of instrumentation and reagent use; or based on the logistics of in-house testing capabilities. CLIA allows clinical laboratories to modify their FDA-approved tests, and even to develop their own tests, known as laboratory-developed tests (LDTs), as long as they follow the requirements to validate the performance characteristics of their modified or in-house developed tests.

However, it is important to realize when considering modification of a test procedure that the modified use of a test system defaults the test to the high complexity testing category under CLIA regulations, and as a result, the testing site must meet all applicable CLIA requirements for high complexity testing. These requirements include establishing performance specifications that validate that the LDTs, and the modified standard methods are fit for the intended use, and that the lab has personnel qualified to perform high complexity testing. Thus, decisions to modify test procedures or use must be made with full awareness of the consequences for the laboratory operation.

What does test system "modification" mean?

Modification means producing results via test systems not yet approved by the FDA; as well as applying these test results in a way other than that described in the intended use, precautions, limitations, or other sections of the manufacturer's instructions.

MODIFICATIONS TO EXISTING FDA-APPROVED TEST SYSTEMS INCLUDE:

1. Using instruments / kits for testing that have not received approval from the FDA for use in the United States, even if widely used in other countries.

2. Using reagent / instrument combinations that do not have FDA approval. This might mean using reagents from manu facturers different from those of the instrument, and which are not listed by either the instrument or reagent manufacturer as approved for use by either.
3. Deviating from manufacturers' directions for performing the tests.

4. "Off-label use": utilizing the test in a manner not yet approved by the FDA.

A special note about "Off-label Use" of waived blood glucose monitoring systems:

Using a waived blood glucose monitoring system (BGMS) to test a patient whose hematocrit or oxygenation level is above or below the range indicated in the manufacturer's instructions would be an example of an "off- label use" of this system. Results of blood glucose testing in this situation may lead to clinical interventions that could cause patient harm. If the patient's hematocrit and oxygenation level are within the manufacturer's stated limits, then performing a glucose test using the waived glucose monitoring system would not be considered off-label testing and the test system would still be considered waived.

(New) Laboratory Developed Tests (LDTs)

In the past, these have also been referred to as "in-house" tests. These are tests that have been developed, evaluated and validated by the laboratory itself. Often, a laboratory will choose to develop and use an LDT because a commercial test is not available to meet their needs. LDTs generally have not been subjected to FDA oversight because these diagnostic tests are never sold to other laboratories or hospitals. Historically, LDTs comprised a relatively small volume of testing intended for use in diagnosing rare diseases or to meet the specific needs of a local patient population.

There can be several reasons why a commercial test has not been developed for a particular analyte or disease of interest. For example, many LDTs are genetic tests developed for rare diseases. These are also diseases affecting only a small subset of the population, thus reducing the incentive for a manufacturer to develop a commercial version because the market for such a product would be small, without a potential decent return on investment.

Even one modified test system will change your laboratory to a testing facility that must meet all applicable CLIA requirements for high-complexity testing

If your laboratory is CLIA waived, and you modify a waived test system, the modified test system must now meet all applicable CLIA requirements for high complexity testing. These include added requirements for Proficiency Testing, the establishment of Performance Specifications, Quality Control, Quality Assessment, and adherence to high complexity personnel qualifications. Laboratories with a CLIA Certificate of Waiver (COW) that are using modified test systems will need to upgrade to a CLIA Certificate of Compliance (COC) or a CLIA Certificate of Accreditation (COA), if they continue to use modified test systems; this includes required biennial on-site inspections.

If your laboratory is a moderate complexity CLIA facility, and you modify a moderate complexity test system, this test system also defaults to the high complexity testing category and will require the modified test system to meet all applicable CLIA requirements for high complexity testing, including the establishment of performance specifications, and adherence to high complexity personnel qualifications. No change in compliance or accreditation certificates would be needed.

High Complexity Testing requirements include:

1. The Establishment of Performance Specifications

A key requirement of the CLIA regulations for all laboratories that modify an FDA-cleared or approved test system is to establish (validate) performance specifications for that test system (i.e., accuracy, precision, analytical sensitivity, analytical specificity including interfering substances, reportable range of test results, reference intervals and any other performance characteristic required for test performance).

The FDA requires that modified or lab developed tests provide target values for test results and provide evidence for the expected ranges as well as information on test limitations and other factors that could generate false results.
The validation results include a statement as to whether the method is fit for the intended use. The needs of the customer define the intended use of the method. If all the data quality objectives are met as indicated by the data collected, the method is considered as validated.
Note: State and local jurisdictions vary in how they regulate laboratory testing. Some have requirements governing testing, personnel licensure, or phlebotomy. The person overseeing testing should ensure that all state and local requirements are met. When state, local, and federal requirements are not the same, follow the strictest requirement that applies to your site.
Validation standards set by accreditation organizations may also meet or exceed those set by CLIA, including standards regarding evaluation of lab-developed tests. Participating laboratories must meet these standards and criteria as well.
2. More Stringent Personnel Requirements

The personnel standards for high-complexity laboratories are appropriately more stringent than the requirements for moderate-complexity facilities. There are five positions that must be filled in high-complexity labs:
A. Director;
B. Technical supervisor;
C. General supervisor;
D. Clinical consultant, and
E. Testing personnel.

A significant commitment in resources may be needed to fulfill these requirements if the laboratory is not a high complex facility already.

Detailed CLIA personnel requirements for high complexity testing can be found at http://www.mass.gov/eohhs/docs/dph/clinical-lab/clia-lab-qualifications.pdf
The decision: whether to continue using your modified or laboratory developed test procedure or not?

This requires you to perform a cost / benefit analysis, taking into consideration the following:

Does the modification of your test procedure change the complexity of your laboratory from waived or moderate complexity to high complexity? Is it worth all the attendant CLIA requirements for high complexity testing, including additional types of personnel, higher levels of personnel qualifications, more stringent performance specifications, additional quality control procedures, and even a new a CLIA classification for the laboratory?

If you are already a high complexity laboratory, consider the cost of establishing additional performance specifications, and the need for added personnel who are qualified to perform high complexity tests.

Irwin Z. Rothenberg is a Technical Writer/Quality Advisor for COLA's Educational subsidiary, COLA Resources, Inc. (CRI), a leader in online continuing education for physicians, laboratory personnel, and allied health professionals. CRI offers continuing education through online courses, informational products in both electronic and hard copy form, webinars on cutting-edge technology and regulatory issues, and CRI on-site Symposia for Clinical Laboratories, providing live educational sessions and interactive workshops with leading industry organizations. For more information, visit their website at www.criedu.org or call 1-800-981-9883.

Endnotes

1 Munley, E, Leading Age. CMS Clarifies Off-Label Use of Waived Blood Glucose Monitoring Systems in Healthcare Facilities. December 11, 2014. https://www.leadingage.org/CMS_Clarifies_Off_Label_WaivedBlood_Glucose_Monitoring_Systems_in_Facilities.aspx

2 MLO. Laboratory Developed Tests: what may be coming. October 19, 2012. http://www.mlo-online.com/laboratory-developed-tests-what-may-be-coming.php

3 Lab Tests Online. AACC. Laboratory Developed Tests(LDTs) April 14, 2011 https://labtestsonline.org/understanding/features/ldt

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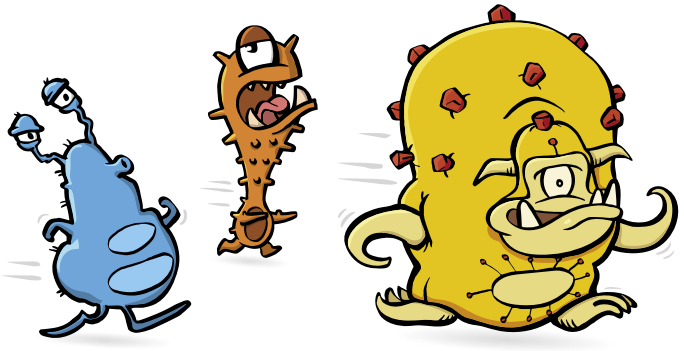


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1. This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple 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.
2. For use with the CLIA-waived BioFire® FilmArray® 2.0 EZ configuration.

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