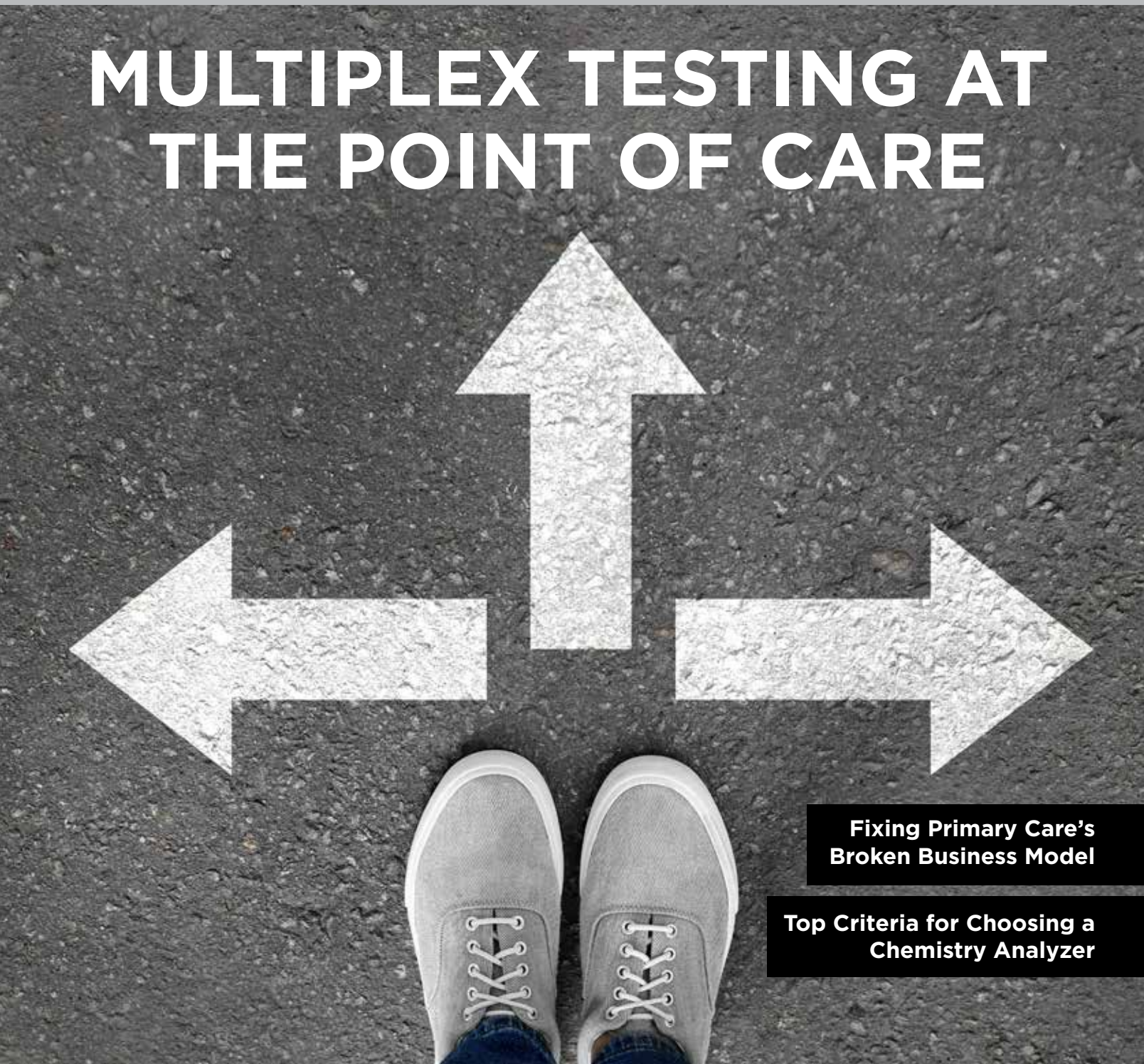
2023 | Issue 7

Physicians office Resource

Resources for You, Your Patients, & Your Practice



MULTIPLEX TESTING AT THE POINT OF CARE

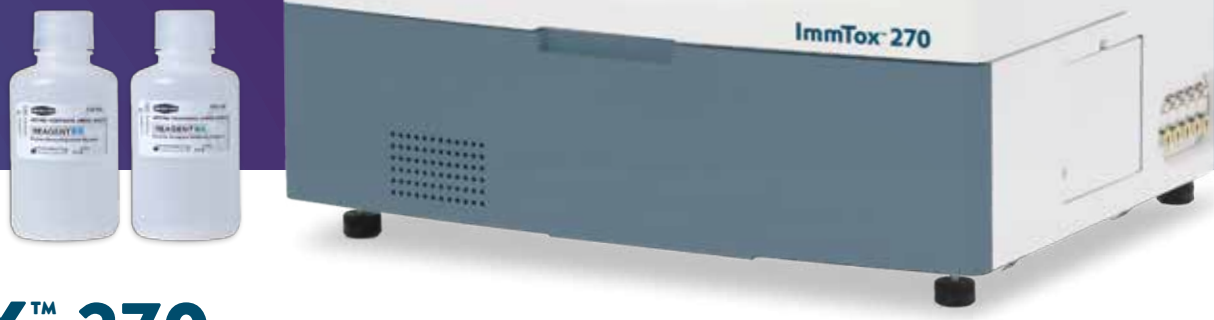
Fixing Primary Care's Broken Business Model

Top Criteria for Choosing a Chemistry Analyzer

TOXICOLOGY SCREENING

SIMPLIFIED.

Comprehensive toxicology menu now with **14 CLIA[1] categorized moderate complexity assays.**



IMMTOX™ 270

BENCHTOP ANALYZER

Toxicology screening solutions for physician offices, pain management, treatment centers and laboratories testing 200+ patient samples/mo.

Scan this QR code to view the ImmTox™ 270 product video

MODERATE COMPLEXITY ASSAYS – FDA 510(K) CLEARED	
6-acetylmorphine (6-AM Heroin metabolite)	EDDP (Methadone metabolite)
Amphetamine	Fentanyl*
Barbiturates	Methamphetamine
Benzodiazepines	Opiates
Benzoylecgonine (Cocaine metabolite)	Oxycodone
Buprenorphine	Phencyclidine (PCP)
Cannabinoids (THC)	Tramadol

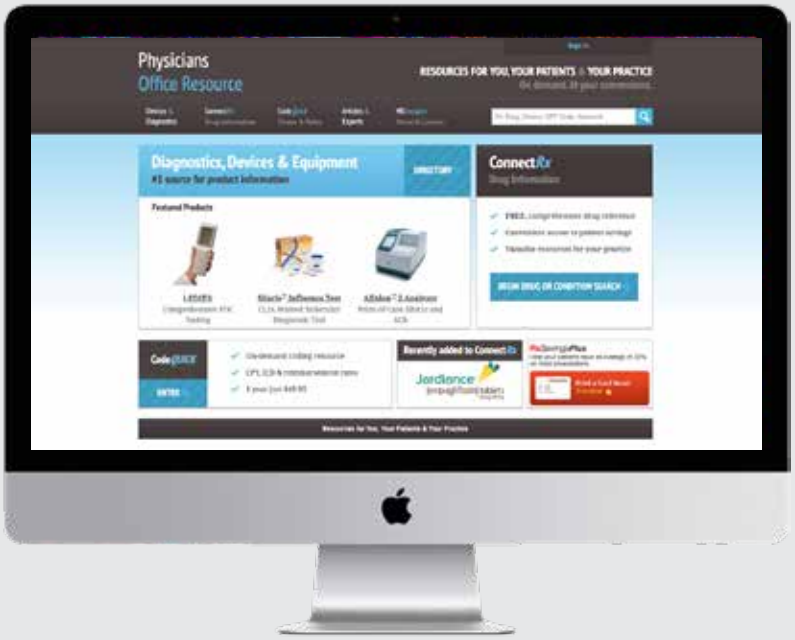
CONTACT ABBOTT CLINICAL LAB SOLUTIONS

855-425-9428 | CLS_SALES@ABBOTT.COM

1. Clinical Laboratory Improvement Amendments (CLIA) / * SEFRIA Fentanyl

© 2022 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners. Any photos displayed are for illustrative purposes only. COL-09575 v3 12/22

Abbott



Getting the most from this guide

There are two simple ways to request information about the products and services found in Physicians Office Resource.

1. Go to www.PhysiciansOfficeResource.com and enter the four-digit reference number found next to the product or service into the search field, then request additional information, schedule a demo, or speak with a sales agent all with just a simple click of a button.

2. Find the Business Reply Card in this issue, circle the desired reference numbers, complete the form, and drop into any USPS mailbox. A representative will contact you as quickly as possible to answer your questions.

www.PhysiciansOfficeResource.com

Physicians office Resource

PUBLISHED BY
Medical Education Resources, LLC

PUBLISHER
Aaron R. Medaris
amedaris@physiciansofficeresource.com

CEO
Andrew C. Nimmo
acnimmo@physiciansofficeresource.com

PRESIDENT
John D. Pasquale
jpasquale@pharmaconnect.com

BUSINESS MANAGER
Marci J. Hills
mhills@physiciansofficeresource.com

TRAVEL EDITOR
Brandi L. Brower

EDITORIAL BOARD
Michael Paquin, FHIMSS
Barry Craig, MLT (NCA), CLC

STAFF WRITER
Dylan J. Chadwick

CREATIVE DIRECTOR
PRODUCTION MANAGER
Jessica Elmer

Copyright ©2023

To continue your free subscription of Physicians Office Resource magazine, please fill out the Business Reply Card (BRC) located within this magazine and drop in any United States Post Office mailbox.

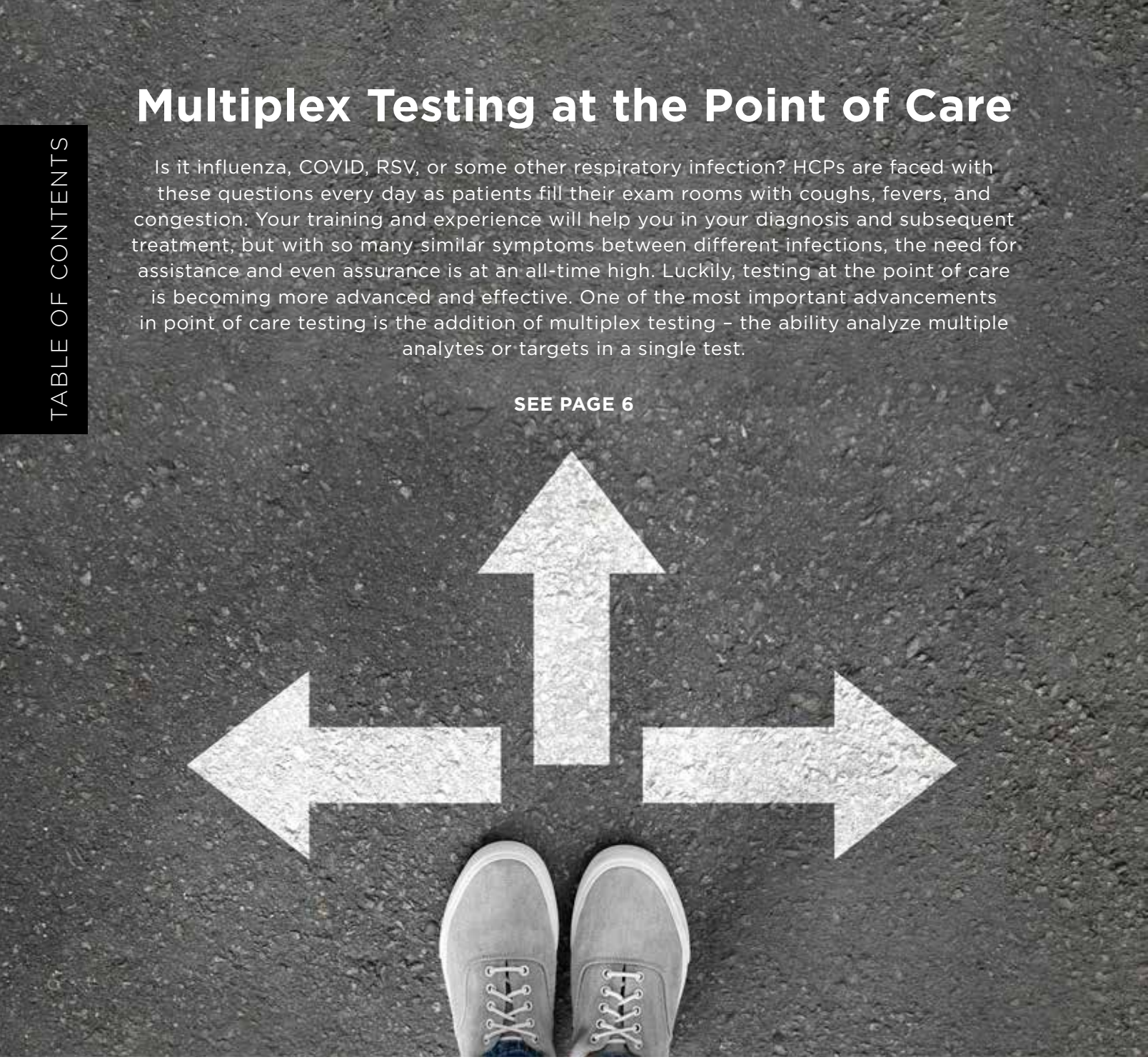
If you are a manufacturer of medical products or provide services to medical professionals and would like to advertise your products or services to the nation's top physicians doing in-office testing, call 801-380-6094 or visit: POR.io for more information.

TABLE OF CONTENTS

Multiplex Testing at the Point of Care

Is it influenza, COVID, RSV, or some other respiratory infection? HCPs are faced with these questions every day as patients fill their exam rooms with coughs, fevers, and congestion. Your training and experience will help you in your diagnosis and subsequent treatment, but with so many similar symptoms between different infections, the need for assistance and even assurance is at an all-time high. Luckily, testing at the point of care is becoming more advanced and effective. One of the most important advancements in point of care testing is the addition of multiplex testing – the ability analyze multiple analytes or targets in a single test.

SEE PAGE 6



24

FIXING PRIMARY CARE'S BROKEN BUSINESS MODEL

Primary care visits are never quick; we don't give much advice over the phone or online; and we prioritize the government's and insurance companies' public health agenda over our own patients' concerns.

32

TOP CRITERIA FOR CHOOSING A CHEMISTRY ANALYZER FOR A POL

When working with limited resources, such as time, money, and space there are some essential characteristics you should look for when choosing your first or replacement chemistry analyzer.



EASY ORDERING

QUICK DELIVERY

A wide range of equipment for physicians and healthcare professionals.

Medical Device Depot ©Inc.

Top brands always at the best price.

sdi DIAGNOSTICS

2901





2902

defibtech



2903



MAICO

2904



Nasiff Associates, Inc.

2905

CLINTON INDUSTRIES INC.



2906

WelchAllyn



2907



ADC

2908

SITEWIDE SALE

COUPON CODE **MDDSAVE**

for additional savings at checkout!

SPIRE INTEGRATED SOLUTIONS Medical Device Depot®, Inc. is part of the Spire Integrated Solutions family.

© 2022 . Medical Device Depot . ALL RIGHTS RESERVED

Medical Device Depot ©Inc.

Toll Free 877-646-3300

medicaldevicedepot.com



Multiplex Testing at the Point of Care

BY AARON MEDARIS, PHYSICIANS OFFICE RESOURCE

Is it influenza, COVID, RSV, or some other respiratory infection? HCPs are faced with these questions every day as patients fill their exam rooms with coughs, fevers, and congestion. Your training and experience will help you in your diagnosis and subsequent treatment, but with so many similar symptoms between different infections, the need for assistance and even assurance is at an all-time high. Luckily, testing at the point of care is becoming more advanced and effective. One of the most important advancements in point of care testing is the addition of multiplex testing – the ability analyze multiple analytes or targets in a single test. Multiplex testing is nothing new but has been steadily evolving over the last several decades and is gaining a larger presence in physician offices and urgent care centers around the nation. In this article, take a closer look at multiplex testing, its development over the years, and how it's making a difference in point of care testing.

Understanding Multiplex Testing

Multiplex testing, also known as multiplexing or multiplex assay, is a technique used in laboratory diagnostics to simultaneously analyze multiple analytes or targets in a single test. It allows for the efficient and cost-effective detection of multiple biomarkers or genetic variants in a single sample.

Traditionally, diagnostic tests would focus on a single target, requiring separate tests for each analyte of interest. Multiplex testing revolutionizes this process by enabling the detection of multiple targets in a parallel and high-throughput manner.

There are different methods of multiplex testing, depending on the specific application and technology used. Here are a few examples:

- Multiplex Polymerase Chain Reaction (PCR): PCR is a widely used technique to amplify and detect specific DNA sequences. Multiplex PCR involves designing primers that can amplify multiple target DNA sequences simultaneously. By incorporating different fluorescent dyes or molecular tags, the amplified products can be differentiated and detected in a single reaction.

- Multiplex Immunoassays: These assays are used to detect and quantify proteins or antibodies in a biological sample. Multiplex immunoassays employ different types of capture beads or microarrays, each coated with specific antibodies or antigens. By labeling the analytes with fluorescent or enzymatic tags, multiple targets can be detected and quantified simultaneously.

- Mass Spectrometry-based Multiplexing: Mass spectrometry can be used for multiplex analysis by labeling analytes with unique mass tags. By introducing stable isotopes or mass labels, multiple samples can be combined and analyzed together, allowing for the simultaneous detection of multiple targets.

Multiplex testing offers several advantages over single-target assays, including reduced sample volume requirements, lower costs, and faster turnaround time. It has found applications in various fields, including clinical diagnostics, infectious disease

testing, genetic testing, and drug discovery.

The Evolution of Multiplex Testing

The concept of multiplex testing has been evolving over several decades, and the specific techniques used in multiplex testing have been developed and refined over time. Here are some key milestones in the history of multiplex testing:

- **1980s:** The development of enzyme-linked immunosor bent assays (ELISAs) laid the foundation for multiplex immunoassays. ELISAs allowed for the quantification of a single analyte, but researchers began exploring ways to expand the assay to measure multiple targets simultane ously.

- **1990s:** Multiplex PCR techniques started to emerge during this period. Researchers began developing methods to amplify and detect multiple DNA targets using PCR, such as multiplex allele-specific PCR (AS-PCR) and multiplex ligation-dependent probe amplifica tion (MLPA).

- **Late 1990s to early 2000s**: The advent of microarray technology revolutionized multiplex testing. DNA microarrays allowed for the simultaneous analysis of thousands of genetic targets. This technology enabled gene expression profiling, SNP genotyping, and other multiplex applications.

- **2000s:** The field of multiplex immunoassays expanded with the introduction of microsphere-based technologies. Luminex Corporation introduced the xMAP® (Multiplexed Assays with Beads) technology, which uses color-coded beads to enable the detection of multiple analytes simultaneously.

- **2010s:** Advances in next-generation sequencing (NGS) technologies facilitated high-throughput multiplex sequencing. Techniques such as targeted sequencing panels and amplicon sequencing allowed researchers to simultaneously analyze multiple genetic variants or mutations.

These milestones illustrate the progressive development and application of multiplex testing techniques. The field continues to evolve, with ongoing advancements in technology, assay design, and data analysis methods, enabling even more comprehensive and efficient multiplex testing capabilities.

Multiplex Testing at the Point of Care

Multiplex testing at the point of care refers to the use of multiplex assays or devices in settings outside of a central laboratory, such as clinics, doctor's offices, or even at home. Point-of-care multiplex testing offers several advantages, including rapid results, immediate clinical decision-making, and improved patient management. Here are some examples of how multiplex testing is used at the point of care:

- **Infectious Disease Diagnosis:** Multiplex assays are commonly used for the simultaneous detection of multiple pathogens in infectious disease diagnostics. Point-of-care multiplex tests can rapidly identify the presence of multiple viral, bacterial, or parasitic pathogens in a single sample, enabling timely diagnosis and appropriate treatment decisions. For example, a single test may detect respiratory viruses like influenza A and B, respiratory syncytial virus (RSV), and SARS-CoV-2 (the virus that causes COVID-19).

- **Syndromic Panels:** Syndromic panels combine multiplex testing with a broad range of targets related to specific clinical syndromes, such as respiratory infections, gastrointestinal infections, or sexually transmitted infections. These panels can simultaneously detect multiple pathogens associated with a particular syndrome, providing a comprehensive diagnostic approach and aiding in targeted treatment.

- **Pharmacogenetics:** Point-of-care multiplex testing can be utilized to analyze multiple genetic variants associated with drug metabolism or treatment response. These tests can provide insights into an individual's genetic profile and help guide personalized medication selection or dosing adjustments.

- **Cancer Biomarkers:** Multiplex assays can be used at the point of care to detect multiple cancer biomarkers, such as specific mutations or protein mark ers. These tests aid in cancer diagnosis, prognosis, and treatment decision-making, allowing for a more targeted and personalized approach.

- **Rapid Screening:** Multiplex tests can be employed for rapid screening of various conditions or diseases. For instance, multiplex lateral flow assays are commonly used for point-of-care testing of pregnancy, infectious diseas es, cardiac markers, or drug testing. These tests provide quick results and are often simple to use, making them suitable for non-laboratory settings.

Recent advancements even include CLIA Waived multiplex testing, allowing healthcare professionals to make immediate and informed decisions, leading to improved patient care and outcomes.

As we ramp up for cold and flu season and patient begin to fill your exam room with coughs, congestion, and fevers, remember there are sound diagnostic multiplex tests available to assist in your diagnosis.

Physicians Office Resource Invites You to

GO ELECTRONIC!

Sign up for our monthly eNewsLetter and get
Physicians Office Resource delivered to your Inbox!



Sign up at PhysiciansOfficeResource.com/home/contact/



2909

EASY, INTEGRATED WITH-PATIENT TESTING I-STAT SYSTEM

From Abbott Point of Care

The handheld i-STAT System offers a broad menu of diagnostic tests at the patient's side in just minutes. With just a few drops of blood, the i-STAT System delivers real time, lab-accurate results for a wide range of tests, including chemistries, blood gas, coagulation, cardiac markers, and more. Minimize delays and wasted time with on-side tests. Easy, intuitive operation.

For intended use and complete product information, visit pointof-care.abbott.

For in vitro diagnostic use only. This material is intended for a U.S. audience only. i-STAT is a trademark of Abbott. Physician Office Resource i-STAT Product Description — US 3064.REV1 08/20

View Brochures, Videos & More at POR.io
Enter Number **2909** in the Search Area

FULL COMPLEMENT OF CLIA-WAIVED BLOOD CHEMISTRY TESTS PICCOLO XPRESS® CHEMISTRY ANALYZER

From Abbott Point of Care

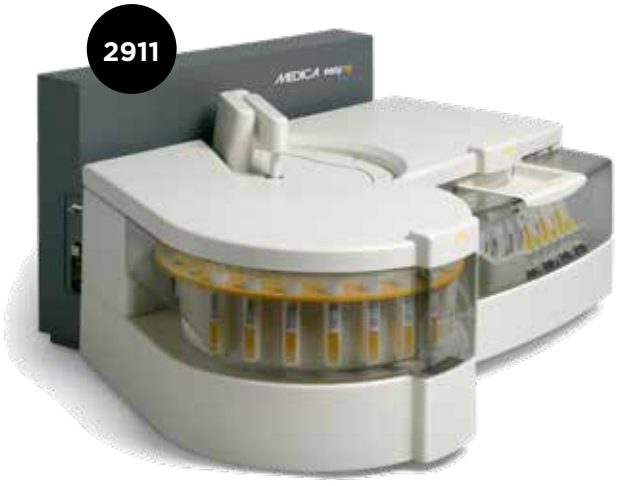
The Piccolo Xpress Chemistry Analyzer provides physician offices with lab-accurate results for a broad range of CLIA-waived general chemistry tests, including metabolic panels, lipids, live, and kidney function, and more with just 100 microliters of blood. Easy to use, the Piccolo Xpress provides results during a patient's visit, accelerating treatment decisions, increasing efficiency, and supporting patient satisfaction. Automated quality control on every test helps ensure accuracy.

View Brochures, Videos & More at POR.io
Enter Number **2910** in the Search Area



2910

2911



EASYRA® BENCHTOP CHEMISTRY ANALYZER FOR PHYSICIAN OFFICES WITH LABORATORIES

From Carolina Liquid Chemistries

When upgrading or starting a lab, look no further. With a moderately complex menu of 35 general chemistry and 14 urine drug screens, the EasyRA is well-suited for oncology, rheumatology, and multi-specialty practices needing a high-speed benchtop clinical chemistry analyzer. The EasyRA® offers photometric throughput of 240+ tests/hr (up to 480 tests/hr with ISE) and STAT samples in under 8 minutes. This all-in-one system is easy to learn and easy to operate.

View Brochures, Videos & More at POR.io
Enter Number **2911** in the Search Area

LumiraDx™

Not all Antigen Tests are Created Equal



The LumiraDx SARS-CoV-2 Ag test utilizes next-generation microfluidic technology, bringing lab-comparable performance to the point of care.

- 97.6% positive agreement to RT-PCR in patients up to 12 days following symptom onset • Microfluidic immunofluorescence assay
- Easy to use • Results in minutes • Small, low-waste consumable
- CLIA Waived*



2912

Scan to learn more.
LumiraDx.com

*The LumiraDx SARS-CoV-2 Ag test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product 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 declaration is terminated, or authorization is revoked sooner. S-COM-ART-02381 R3 2022/11



RX IMOLA

From HORIBA Medical

The RX imola is a cost-effective system that delivers consistent high-quality results. Capable of handling the workload of a medium to high throughout laboratory and a combined throughput of 560 tests per hour, the RX imola provides rapid, comprehensive testing on a small footprint analyzer when it matters most, with direct HbA1c testing capabilities.

View Brochures, Videos & More at POR.io
Enter Number **2913** in the Search Area

TOXICOLOGY SCREENING SIMPLIFIED ABBOTT'S IMMTOX 270 BENCHTOP ANALYZER NOW WITH 14 ASSAYS CLIA CATEGORIZED AS MODERATE COMPLEXITY

From Abbott

The ImmTox270 benchtop analyzer offers comprehensive toxicology screening solutions for physician offices, treatment centers and independent laboratories.

Broad test menu with over 20 assays to choose from including 14 that are now available as moderately complex.

With complete laboratory solutions from consultation to licensure, and compliance the Abbott Clinical Laboratory Solutions team has you covered.

View Brochures, Videos & More at POR.io
Enter Number **2914** in the Search Area





DC-LINEATE CALIBRATION/ LINEARITY MATERIAL

From SEKISUI Diagnostics

The DC-Lineate is a unique, trilevel calibration/linearity material that is used in conjunction with assays for the quantitative determination of UIBC levels in clinical samples. The material is conveniently packaged in a 2 x 5 mL configuration for each of the three levels and is traceable back to the National Institute of Standards and Technology (NIST). It can be used on a broad range of clinical chemistry analyzers and has a shelf life up to 14-days after reconstitution.

View Brochures, Videos & More at POR.io
Enter Number **2915** in the Search Area

RIGHT SIZE. RIGHT PERFORMANCE.
THE RIGHT FIT FOR YOUR LABORATORY.



LOW VOLUME

LOW TO MID VOLUME

CELL-DYN **EMERALD 22**



CELL-DYN **EMERALD**

A suite of harmonized hematology solutions to meet the needs of your laboratory

- Support diverse test volumes
- Technological sophistication for routine and specialized testing
- Commutable results



CELL-DYN **EMERALD 22 AL**

MID VOLUME



CELL-DYN **RUBY**

CORELABORATORY.ABBOTT/HEMATOLOGY

© 2022 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners. Any photos displayed are for illustrative purposes only.
CELL-DYN Ruby and CELL-DYN Emerald 22 AL are Class I laser products. For in vitro diagnostic use only. ADD-142016-GBL-EN 10/22

Abbott



2920

WHY COMPROMISE? FAST AND RELIABLE RESULTS ARE NOW DELIVERED AT THE POINT OF CARE.

From LumiraDx

Introducing the next generation in point-of-care diagnostics. With a growing menu of tests, LumiraDx uses a simple process that allows for more time with your patients by using microfluidic technology that delivers results in minutes. Learn more about rapid COVID-19 diagnostic solutions for your physician office at LumiraDx.com.

View Brochures, Videos & More at POR.io
Enter Number **2920** in the Search Area

SOFIA® 2 FLUORESCENT IMMUNOASSAY ANALYZER AND RAPID DIAGNOSTIC TEST KITS

From Quidel

Sofia® 2 Fluorescent Immunoassay Analyzer and Rapid Diagnostic Test Kits Sofia 2 takes rapid testing to a new level. Proven lateral-flow technology and advanced fluorescent chemistry are all integrated into this small benchtop analyzer which can be used in any point-of-care setting. Sofia 2 kits are easy to use and adaptable to any healthcare setting. Excellent performance, objectivity, quality control, LIS capabilities, and an expanding test menu make Sofia 2 the perfect solution for the physician's office laboratory.

View Brochures, Videos & More at POR.io
Enter Number **2921** in the Search Area



2921



2922

THIS CHANGES EVERYTHING. FASTER. SMALLER. SMARTER.

From bioMérieux

bioMérieux knows that an evolving world deserves evolved diagnostics. Our latest innovation, the BIOFIRE® SPOTFIRE® Respiratory Solution, is the first FDA-cleared and CLIA-waived COVID-19 testing solution. The BIOFIRE® SPOTFIRE® System is an easy-to-use system that runs the BIOFIRE® SPOTFIRE® Respiratory (R) Panel. Benefits of the SPOTFIRE Respiratory Solution include: 15 respiratory targets on 1 PCR test with results in about 15 minutes; minimal benchtop space with vertical scalability up to four modules; easy to use with an intuitive user interface.

View Brochures, Videos & More at POR.io
Enter Number **2922** in the Search Area

POC-22-NAM-3308

Meet the Quadruple Aim in Diabetes Care with In-office HbA1c and uACR

Better outcomes. Lower costs. Better patient experience. Better clinician experience.

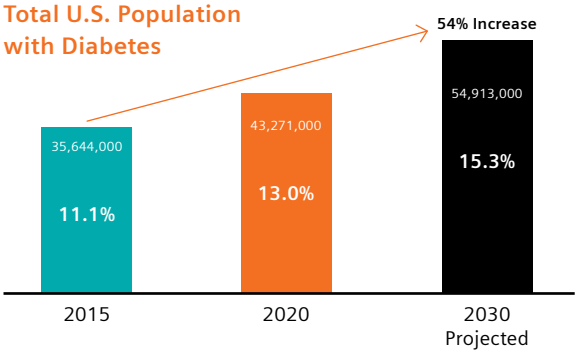


Comprehensive diabetes-management solutions at the point-of-care

Gain key insights into your patient's current status and drive guideline recommended test adherence:

DCA Vantage® Analyzer
CLIA-waived HbA1c
- Rapid assessment for glycemic control

CLINITEK Status® Connect System
CLIA-waived analyzer for routine urinalysis
- Rapid kidney health assessment:
  CLINITEK® Microalbumin 2 Strip
  Albumin-to-creatinine ratio (ACR)





The Prevalence of Diabetes Among U.S. Adults is on the Rise[1]

Help your patients reverse the trend

Customize your patient consultations to enhance physician-patient partnership toward improved outcomes.

siemens-healthineers.us/chronicdisease

1. *Rowley, William R et al. "Diabetes 2030: Insights from Yesterday, Today, and Future Trends." Population health management vol. 20,1 (2017): 6-12. doi:10.1089/pop.2015.0181.*

SIEMENS Healthineers

ADVANCED OVARIAN CANCER

In women with sBRCAm or gBRCAm* **advanced ovarian cancer** following response to first-line platinum-based chemotherapy*[1]

Long-term follow-up data: PFS and NEW interim Overall Survival analyses[2,3]

SOLO-1

sBRCAm or gBRCAm[1,4]

Primary analysis: Sustained PFS in first-line maintenance[1,4]

LYNPARZA (n=260)	Placebo (n=131)
Not Reached	13.8 months (~1.2 years)

HR=0.30 (95% CI: 0.23–0.41); *P*<0.0001

Median duration of follow-up (primary analysis): 41 months for LYNPARZA and 41 months for placebo (DCO: May 17, 2018).[4]

Post hoc 5-year follow-up analysis[2]

LYNPARZA (n=260)	Placebo (n=131)
56 months (~4.7 years)	13.8 months (~1.2 years)

HR=0.33 (95% CI: 0.25–0.43)

Median PFS follow-up time (post hoc follow-up analysis): efficacy and safety were assessed with long-term follow-up; 5 years after the last patient was randomized (4.8 years for LYNPARZA and 5 years for placebo; DCO: March 5, 2020).[2]

*Select patients for this indication based on an FDA-approved companion diagnostic.[1]

STUDY DESIGN[1,4]

SOLO-1 was a phase 3 trial of women with s*BRCA*m or g*BRCA*m advanced ovarian cancer in complete or partial response to first-line platinum-based chemotherapy. Patients were randomized 2:1 (N=391) to receive LYNPARZA tablets 300 mg BID (n=260) or placebo (n=131). The primary endpoint was investigator-assessed PFS.

Secondary endpoints were second progression-free survival (the time from randomization to second disease progression or death), overall survival, the time from randomization to the first subsequent therapy or death, the time from randomization to the second subsequent therapy or death, and health-related quality of life.

Treatment with LYNPARZA was continued for up to 2 years or until disease progression or unacceptable toxicity. Patients who remained in complete response received a maximum treatment duration of 2 years; patients whose disease remained stable could continue to receive LYNPARZA beyond 2 years.

INDICATION

LYNPARZA is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

First-Line Maintenance *BRCA*m Advanced Ovarian Cancer

For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated (g*BRCA*m or s*BRCA*m) advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

There are no contraindications for LYNPARZA.

WARNINGS AND PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): Occurred in approximately 1.5% of patients exposed to LYNPARZA monotherapy, and the majority of events had a fatal outcome. The median duration of therapy in patients who developed MDS/AML was 2 years (range: <6 months to >10 years).
All of these patients had previous chemotherapy with platinum agents and/or other DNA-damaging agents, including radiotherapy.

Do not start LYNPARZA until patients have recovered from hematological toxicity caused by previous chemotherapy (≤Grade 1). Monitor complete blood count for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities, interrupt LYNPARZA and monitor blood count weekly until recovery.

If the levels have not recovered to Grade 1 or less after 4 weeks, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. Discontinue LYNPARZA if MDS/AML is confirmed.

Pneumonitis: Occurred in 0.8% of patients exposed to LYNPARZA monotherapy, and some cases were fatal. If patients present with new or worsening respiratory symptoms such as dyspnea, cough, and fever, or a radiological abnormality occurs, interrupt LYNPARZA treatment and initiate prompt investigation. Discontinue LYNPARZA if pneumonitis is confirmed and treat patient appropriately.

Venous Thromboembolic Events (VTE): Including severe or fatal pulmonary embolism (PE) occurred in patients treated with LYNPARZA. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism, and treat as medically appropriate, which may include long-term anticoagulation as clinically indicated.

Embryo-Fetal Toxicity: Based on its mechanism of action and findings in animals, LYNPARZA can cause fetal harm. A pregnancy test is recommended for females of reproductive potential prior to initiating treatment.

Females
Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 6 months following the last dose.

ADVERSE REACTIONS—First-Line Maintenance *BRCA*m Advanced Ovarian Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received LYNPARZA in the **first-line maintenance setting** for **SOLO-1** were: nausea (77%), fatigue (67%), abdominal pain (45%), vomiting (40%), anemia (38%), diarrhea (37%), constipation (28%), upper respiratory tract infection/influenza/nasopharyngitis/bronchitis (28%), dysgeusia (26%), decreased appetite (20%), dizziness (20%), neutropenia (17%), dyspepsia (17%), dyspnea (15%), leukopenia (13%), urinary tract infection (13%), thrombocytopenia (11%), and stomatitis (11%).

Lynparza® olaparib tablets 150 mg

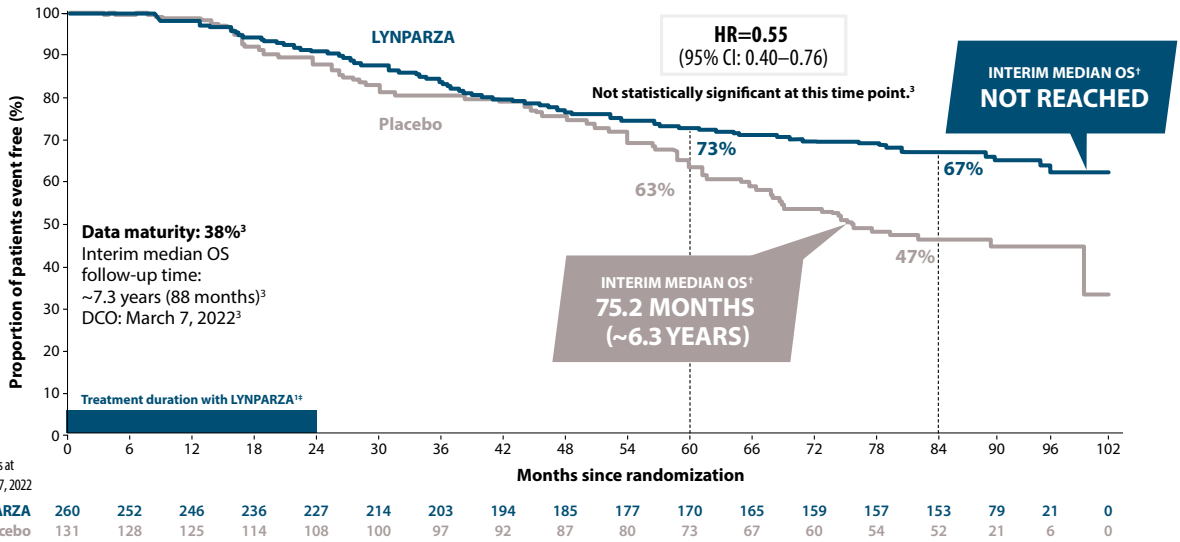
NEW INTERIM OVERALL SURVIVAL DATA

Prespecified descriptive interim analysis in patients with a **BRCAm**[3]

Interim Overall Survival: At 7 years, approximately two-thirds (67%) of patients were alive with LYNPARZA and 47% were alive with placebo[3]

LYNPARZA reduced risk of death by 45%[3]

84 (32%) events in the LYNPARZA arm and 65 (50%) events in the placebo arm[3]



Number of patients at risk at DCO: March 7, 2022

LYNPARZA	260	252	246	236	227	214	203	194	185	177	170	165	159	157	153	79	21	0
Placebo	131	128	125	114	108	100	97	92	87	80	73	67	60	54	52	21	6	0

†44.3% of patients in the placebo group received subsequent PARP inhibitor therapy, compared with 14.6% of patients in the LYNPARZA group.[3]

‡Treatment was continued for up to 2 years or until disease progression or unacceptable toxicity; however, patients with evidence of disease at 2 years, who in the opinion of the treating healthcare provider could derive further benefit from continuous treatment, could be treated beyond 2 years.[1]

Discover additional information and resources at ***LYNPARZAhcp.com***

IMPORTANT SAFETY INFORMATION (Cont'd)

ADVERSE REACTIONS—First-Line Maintenance *BRCA*m Advanced Ovarian Cancer (Cont'd)

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients who received LYNPARZA in the **first-line maintenance setting** for **SOLO-1** were: decrease in hemoglobin (87%), increase in mean corpuscular volume (87%), decrease in leukocytes (70%), decrease in lymphocytes (67%), decrease in absolute neutrophil count (51%), decrease in platelets (35%), and increase in serum creatinine (34%).

DRUG INTERACTIONS

Anticancer Agents: Clinical studies of LYNPARZA with other myelosuppressive anticancer agents, including DNA-damaging agents, indicate a potentiation and prolongation of myelosuppressive toxicity.

CYP3A Inhibitors: Avoid coadministration of strong or moderate CYP3A inhibitors when using LYNPARZA. If a strong or moderate CYP3A inhibitor must be coadministered, reduce the dose of LYNPARZA. Advise patients to avoid grapefruit, grapefruit juice, Seville oranges, and Seville orange juice during LYNPARZA treatment.

CYP3A Inducers: Avoid coadministration of strong or moderate CYP3A inducers when using LYNPARZA.

USE IN SPECIFIC POPULATIONS

Lactation: No data are available regarding the presence of olaparib in human milk, its effects on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in the breastfed infant, advise a lactating woman not to breastfeed during treatment with LYNPARZA and for 1 month after receiving the final dose.

Pediatric Use: The safety and efficacy of LYNPARZA have not been established in pediatric patients.

Hepatic Impairment: No adjustment to the starting dose is required in patients with mild or moderate hepatic impairment (Child-Pugh classification A and B). There are no data in patients with severe hepatic impairment (Child-Pugh classification C).

Renal Impairment: No dosage modification is recommended in patients with mild renal impairment (CLcr 51-80 mL/min estimated by Cockcroft-Gault). In patients with moderate renal impairment (CLcr 31-50 mL/min), reduce the dose of LYNPARZA to 200 mg twice daily. There are no data in patients with severe renal impairment or end-stage renal disease (CLcr ≤30 mL/min).

You are encouraged to report the negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

Please see Brief Summary of Prescribing Information on the following pages.

BID=twice daily; *BRCA*m=*BRCA* mutation; CI=confidence interval; DCO=data cutoff; g*BRCA*m=germline *BRCA*-mutated; HR=hazard ratio; OS=overall survival; PARP=poly (ADP-ribose) polymerase; PFS=progression-free survival; s*BRCA*m=somatic *BRCA*-mutated.

References: 1. LYNPARZA® (olaparib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2022. **2.** Banerjee S, Moore K, Colombo N, et al. Maintenance olaparib for patients with newly diagnosed advanced ovarian cancer and a *BRCA* mutation (SOLO1/GOG 3004): 5-year follow-up of a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2021;22(12):1721-1731. **3.** DiSilvestro P, Banerjee S, Colombo N, et al. Overall survival with maintenance olaparib at a 7-year follow-up in patients with newly diagnosed advanced ovarian cancer and a *BRCA* mutation: the SOLO1/GOG 3004 trial. *J Clin Oncol.* Published online September 9, 2022. doi:10.1200/JCO.22.01549 **4.** Moore K, Colombo N, Scambia G, et al. Maintenance olaparib in patients with newly diagnosed advanced ovarian cancer. *N Engl J Med.* 2018;379(26):2495-2505.

AstraZeneca LYNPARZA is a registered trademark of the AstraZeneca group of companies. ©2022 AstraZeneca. All rights reserved. US-70189 11/22

LYNPARZA® (olaparib) tablets, for oral use

Initial U.S. Approval: 2014

Brief Summary of Prescribing Information. For complete prescribing information consult official package insert.

INDICATIONS AND USAGE

First-Line Maintenance Treatment of *BRCA*-mutated Advanced Ovarian Cancer

Lynparza is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza *[see Dosage and Administration (2.1) in the full Prescribing Information]*.

First-line Maintenance Treatment of HRD-positive Advanced Ovarian Cancer in Combination with Bevacizumab

Lynparza is indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:

- a deleterious or suspected deleterious *BRCA* mutation, and/or
- genomic instability

Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza *[see Dosage and Administration (2.1) in the full Prescribing Information]*.

Maintenance Treatment of Recurrent Ovarian Cancer

Lynparza is indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.

DOSAGE AND ADMINISTRATION

Patient Selection

Information on FDA-approved tests for the detection of genetic mutations is available at http://www.fda.gov/companiondiagnostics.

Select patients for treatment with Lynparza based on the presence of deleterious or suspected deleterious HRR gene mutations, including *BRCA* mutations, or genomic instability based on the indication, biomarker, and sample type (Table 1).

Table 1 Biomarker Testing for Patient Selection*

Indication	Biomarker	Sample type		
		Tumor	Blood	Plasma (ctDNA)
First-line maintenance treatment of germline or somatic *BRCA*m advanced ovarian cancer	*BRCA1*m, *BRCA2*m	X	X	
First-line maintenance treatment of HRD-positive advanced ovarian cancer in combination with bevacizumab	*BRCA1*m, *BRCA2*m and/or genomic instability	X		
Maintenance treatment of recurrent ovarian cancer	No requirement for biomarker testing			

* Where testing fails or tissue sample is unavailable/insufficient, or when germline testing is negative, consider using an alternative test, if available.

Recommended Dosage

The recommended dosage of Lynparza is 300 mg taken orally twice daily, with or without food.

If a patient misses a dose of Lynparza, instruct patient to take their next dose at its scheduled time. Instruct patients to swallow tablets whole. Do not chew, crush, dissolve, or divide tablet.

First-Line Maintenance Treatment of *BRCA*-mutated Advanced Ovarian Cancer

Continue treatment until disease progression, unacceptable toxicity, or completion of 2 years of treatment. Patients with a complete response (no radiological evidence of disease) at 2 years should stop treatment. Patients with evidence of disease at 2 years, who in the opinion of the treating healthcare provider can derive further benefit from continuous treatment, can be treated beyond 2 years.

First-Line Maintenance Treatment of HRD-positive Advanced Ovarian Cancer in Combination with Bevacizumab

Continue Lynparza treatment until disease progression, unacceptable toxicity, or completion of 2 years of treatment. Patients with a complete response (no radiological evidence of disease) at 2 years should stop treatment. Patients with evidence of disease at 2 years, who in the opinion of the treating healthcare provider can derive further benefit from continuous Lynparza treatment, can be treated beyond 2 years.

When used with Lynparza, the recommended dose of bevacizumab is 15 mg/kg every three weeks. Bevacizumab should be given for a total of 15 months including the period given with chemotherapy and given as maintenance. Refer to the Prescribing Information for bevacizumab when used in combination with Lynparza for more information.

Recurrent Ovarian Cancer

Continue treatment until disease progression or unacceptable toxicity for:

- Maintenance treatment of recurrent ovarian cancer

Dosage Modifications for Adverse Reactions

To manage adverse reactions, consider interruption of treatment or dose reduction. The recommended dose reduction is 250 mg taken twice daily.

If a further dose reduction is required, then reduce to 200 mg taken twice daily.

Dosage Modifications for Concomitant Use with Strong or Moderate CYP3A Inhibitors

Avoid concomitant use of strong or moderate CYP3A inhibitors with Lynparza.

If concomitant use cannot be avoided, reduce Lynparza dosage to:

- 100 mg twice daily when used concomitantly with a strong CYP3A inhibitor.
- 150 mg twice daily when used concomitantly with a moderate CYP3A inhibitor.

After the inhibitor has been discontinued for 3 to 5 elimination half-lives, resume the Lynparza dose taken prior to initiating the CYP3A inhibitor *[see Drug Interactions (7.2) and Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Dosage Modifications for Renal Impairment

Moderate Renal Impairment

In patients with moderate renal impairment (CLcr 31-50 mL/min), reduce the Lynparza dosage to 200 mg orally twice daily *[see Use in Specific Populations (8.6) and Clinical Pharmacology (12.3) in the full Prescribing Information]*.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid Leukemia

Myelodysplastic syndrome (MDS)/Acute Myeloid Leukemia (AML) has occurred in patients treated with Lynparza and some cases were fatal.

In clinical studies enrolling 2901 patients with various cancers who received Lynparza as a single agent *[see Adverse Reactions (6.1) in the full Prescribing Information]*, the cumulative incidence of MDS/AML was approximately 1.5% (43/2901). Of these, 51% (22/43) had a fatal outcome. The median duration of therapy with Lynparza in patients who developed MDS/AML was 2 years (range: < 6 months to > 10 years). All of these patients had received previous chemotherapy with platinum agents and/or other DNA damaging agents including radiotherapy.

Do not start Lynparza until patients have recovered from hematological toxicity caused by previous chemotherapy (≤ Grade 1). Monitor complete blood count for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities, interrupt Lynparza and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. If MDS/AML is confirmed, discontinue Lynparza.

Pneumonitis

In clinical studies enrolling 2901 patients with various cancers who received Lynparza as a single agent *[see Adverse Reactions (6.1) in the full Prescribing Information]*, the incidence of pneumonitis, including fatal cases, was 0.8% (24/2901). If patients present with new or worsening respiratory symptoms such as dyspnea, cough and fever, or a radiological abnormality occurs, interrupt Lynparza treatment and promptly assess the source of the symptoms. If pneumonitis is confirmed, discontinue Lynparza treatment and treat the patient appropriately.

Venous Thromboembolic Events

Venous thromboembolic events (VTE), including severe or fatal pulmonary embolism (PE), occurred in patients treated with Lynparza *[see Adverse Reactions (6.1) in the full Prescribing Information]*. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism and treat as medically appropriate, which may include long-term anticoagulation as clinically indicated.

Embryo-Fetal Toxicity

Lynparza can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals. In an animal reproduction study, administration of olaparib to pregnant rats during the period of organogenesis caused teratogenicity and embryo-fetal toxicity at exposures below those in patients receiving the recommended human dose of 300 mg twice daily. Apprise pregnant women of the potential hazard to a fetus and the potential risk for loss of the pregnancy. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Lynparza. Based on findings from genetic toxicity and animal reproduction studies, advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of Lynparza *[see Use in Specific Populations (8.1, 8.3) in the full Prescribing Information]*.

ADVERSE REACTIONS

The following adverse reactions are discussed elsewhere in the labeling:

- Myelodysplastic Syndrome/Acute Myeloid Leukemia *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- Pneumonitis *[see Warnings and Precautions (5.2) in the full Prescribing Information]*
- Venous Thromboembolic Events *[see Warnings and Precautions (5.3) in the full Prescribing Information]*

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described in the WARNINGS AND PRECAUTIONS reflect exposure to Lynparza as a single agent in 2901 patients; 2135 patients with exposure to 300 mg twice daily tablet dose including five controlled, randomized, trials (SOLO-1, SOLO-2, OlympiAD, POLO, and PROfound) and to 400 mg twice daily capsule dose in 766 patients in other trials that were pooled to conduct safety analyses. In these trials, 56% of patients were exposed for 6 months or longer and 28% were exposed for greater than one year in the Lynparza group.

In this pooled safety population, the most common adverse reactions in ≥10% of patients were nausea (60%), fatigue (55%), anemia (36%), vomiting (32%), diarrhea (24%), decreased appetite (22%), headache (16%), dysgeusia (15%), cough (15%), neutropenia (14%), dyspnea (14%), dizziness (12%), dyspepsia (12%), leukopenia (11%), and thrombocytopenia (10%).

First-Line Maintenance Treatment of *BRCA*-mutated Advanced Ovarian Cancer

SOLO-1

The safety of Lynparza for the maintenance treatment of patients with *BRCA*-mutated advanced ovarian cancer following first-line treatment with platinum-based chemotherapy was investigated in SOLO-1 *[see Clinical Studies (14.1) in the full Prescribing Information]*. Patients received Lynparza tablets 300 mg orally twice daily (n=260) or placebo (n=130) until disease progression or unacceptable toxicity. The median duration of study treatment was 25 months for patients who received Lynparza and 14 months for patients who received placebo.

Among patients who received Lynparza, dose interruptions due to an adverse reaction of any grade occurred in 52% and dose reductions due to an adverse reaction occurred in 28%. The most frequent adverse reactions leading to dose interruption or reduction of Lynparza were anemia (23%), nausea (14%), and vomiting (10%). Discontinuation due to adverse reactions occurred in 12% of patients receiving Lynparza. The most frequent adverse reactions that led to discontinuation of Lynparza were fatigue (3.1%), anemia (2.3%), and nausea (2.3%).

Tables 2 and 3 summarize adverse reactions and laboratory abnormalities in SOLO-1.

Table 2 Adverse Reactions* in SOLO-1 (≥10% of Patients Who Received Lynparza)

Adverse Reaction	Lynparza tablets n=260		Placebo n=130	
	All Grades (%)	Grades 3 – 4 (%)	All Grades (%)	Grades 3 – 4 (%)
Gastrointestinal Disorders				
Nausea	77	1	38	0
Abdominal pain†	45	2	35	1
Vomiting	40	0	15	1
Diarrhea‡	37	3	26	0
Constipation	28	0	19	0
Dyspepsia	17	0	12	0
Stomatitis§	11	0	2	0
General Disorders and Administration Site Conditions				
Fatigue¶	67	4	42	2
Blood and Lymphatic System Disorders				
Anemia	38	21	9	2
Neutropenia#	17	6	7	3
Leukopenia Þ	13	3	8	0
Thrombocytopenia ß	11	1	4	2
Infections and Infestations				
Upper respiratory tract infection/ influenza/nasopharyngitis/bronchitis	28	0	23	0
UTI à	13	1	7	0
Nervous System Disorders				
Dysgeusia	26	0	4	0
Dizziness	20	0	15	1
Metabolism and Nutrition Disorders				
Decreased appetite	20	0	10	0
Respiratory, Thoracic and Mediastinal Disorders				
Dyspnea è	15	0	6	0

* Graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.0.
† Includes abdominal pain, abdominal pain lower, abdominal pain upper, abdominal distension, abdominal discomfort, and abdominal tenderness.
‡ Includes colitis, diarrhea, and gastroenteritis.
§ Includes stomatitis, aphthous ulcer; and mouth ulceration.
¶ Includes asthenia, fatigue, lethargy, and malaise.
# Includes neutropenia, and febrile neutropenia.
Þ Includes leukopenia, and white blood cell count decreased.
ß Includes platelet count decreased, and thrombocytopenia.
à Includes urosepsis, urinary tract infection, urinary tract pain, and pyuria.
è Includes dyspnea, and dyspnea exertional.

In addition, the adverse reactions observed in SOLO-1 that occurred in <10% of patients receiving Lynparza were increased blood creatinine (8%), lymphopenia (6%), VTE (3%), hypersensitivity (2%), MDS/AML (1%), dermatitis (1%), and increased mean cell volume (0.4%).

Table 3 Laboratory Abnormalities Reported in ≥25% of Patients in SOLO-1

Laboratory Parameter*	Lynparza tablets n†=260		Placebo n†=130	
	Grades 1-4 (%)	Grades 3-4 (%)	Grades 1-4 (%)	Grades 3-4 (%)
Decrease in hemoglobin	87	19	63	2
Increase in mean corpuscular volume	87	–	43	–
Decrease in leukocytes	70	7	52	1
Decrease in lymphocytes	67	14	29	5
Decrease in absolute neutrophil count	51	9	38	6
Decrease in platelets	35	1	20	2
Increase in serum creatinine	34	0	18	0

* Patients were allowed to enter clinical studies with laboratory values of CTCAE Grade 1.
† This number represents the safety population. The derived values in the table are based on the total number of evaluable patients for each laboratory parameter.

First-line Maintenance Treatment of HRD-positive Advanced Ovarian Cancer in Combination with Bevacizumab

PAOLA-1

The safety of Lynparza in combination with bevacizumab for the maintenance treatment of patients with advanced ovarian cancer following first-line treatment containing platinum-based chemotherapy and bevacizumab was investigated in PAOLA-1 *[see Clinical Studies (14.2) in the full Prescribing Information]*. This study was a placebo-controlled, double-blind study in which 802 patients received either Lynparza 300 mg BID in combination with bevacizumab (n=535) or placebo in combination with bevacizumab (n=267) until disease progression or unacceptable toxicity. The median duration of treatment with Lynparza was 17.3 months and 11 months for bevacizumab post-randomization on the Lynparza/bevacizumab arm.

Fatal adverse reactions occurred in 1 patient due to concurrent pneumonia and aplastic anemia. Serious adverse reactions occurred in 31% of patients who received Lynparza/bevacizumab. Serious adverse reactions in >5% of patients included hypertension (19%) and anemia (17%).

Dose interruptions due to an adverse reaction of any grade occurred in 54% of patients receiving Lynparza/bevacizumab and dose reductions due to an adverse reaction occurred in 41% of patients who received Lynparza/bevacizumab.

The most frequent adverse reactions leading to dose interruption in the Lynparza/bevacizumab arm were anemia (21%), nausea (7%), vomiting (3%), and fatigue (3%), and the most frequent adverse reactions leading to reduction in the Lynparza/bevacizumab arm were anemia (19%), nausea (7%), and fatigue (4%).

Discontinuation due to adverse reactions occurred in 20% of patients receiving Lynparza/bevacizumab. Specific adverse reactions that most frequently led to discontinuation in patients treated with Lynparza/bevacizumab were anemia (4%) and nausea (3%).

Tables 4 and 5 summarize adverse reactions and laboratory abnormalities in PAOLA-1, respectively.

Table 4 Adverse Reactions* Occurring in ≥10% of Patients Treated with Lynparza/ bevacizumab in PAOLA-1 and at ≥5% Frequency Compared to the Placebo/bevacizumab Arm

Adverse Reactions	Lynparza/bevacizumab n=535		Placebo/bevacizumab n=267	
	Grades 1-4 (%)	Grades 3-4 (%)	Grades 1-4 (%)	Grades 3-4 (%)
General Disorders and Administration Site Conditions				
Fatigue (including asthenia)†	53	5	32	1.5
Gastrointestinal Disorders				
Nausea	53	2.4	22	0.7
Vomiting	22	1.7	11	1.9
Blood and Lymphatic Disorders				
Anemia‡	41	17	10	0.4
Lymphopenia§	24	7	9	1.1
Leukopenia¶	18	1.9	10	1.5

* Graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.0.
† Includes asthenia, and fatigue.
‡ Includes anemia, anemia macrocytic, erythropenia, haematocrit decreased, haemoglobin decreased, normochromic anemia, normochromic normocytic anemia, normocytic anemia, and red blood cell count decreased.
§ Includes B-lymphocyte count decreased, lymphocyte count decreased, lymphopenia, and T-lymphocyte count decreased.
¶ Includes leukopenia, and white blood cell count decreased.

The most common adverse reactions (≥ 10%) for patients receiving Lynparza/bevacizumab irrespective of the frequency compared with the placebo/bevacizumab arm were nausea (53%), fatigue (including asthenia) (53%), anemia (41%), lymphopenia (24%), vomiting (22%), diarrhea (18%), neutropenia (18%), leukopenia (18%), urinary tract infection (15%), and headache (14%).

The adverse reactions that occurred in <10% of patients receiving Lynparza/bevacizumab were dysgeusia (8%), dyspnea (8%), stomatitis (5%), dyspepsia (4.3%), erythema (3%), dizziness (2.6%), hypersensitivity (1.7%) and MDS/AML (0.7%).

In addition, venous thromboembolic events occurred more commonly in patients receiving Lynparza/bevacizumab (5%) than in those receiving placebo/bevacizumab (1.9%).

Table 5 Laboratory Abnormalities Reported in ≥25% of Patients in PAOLA-1*

Laboratory Parameter†	Lynparza/bevacizumab n†=535		Placebo/bevacizumab n†=267	
	Grades 1-4 (%)	Grades 3-4 (%)	Grades 1-4 (%)	Grades 3-4 (%)
Decrease in hemoglobin	79	13	55	0.4
Decrease in lymphocytes	63	10	42	3.0
Increase in serum creatinine	61	0.4	36	0.4
Decrease in leukocytes	59	3.4	45	2.2
Decrease in absolute neutrophil count	35	7	30	3.7
Decrease in platelets	35	2.4	28	0.4

* Reported within 30 days of the last dose.
† Patients were allowed to enter clinical studies with laboratory values of CTCAE Grade 1.
‡ This number represents the safety population. The derived values in the table are based on the total number of evaluable patients for each laboratory parameter.

Maintenance Treatment of Recurrent Ovarian Cancer

SOLO-2

The safety of Lynparza for the maintenance treatment of patients with platinum sensitive g*BRCA*m ovarian cancer was investigated in SOLO-2 *[see Clinical Studies (14.3) in the full Prescribing Information]*. Patients received Lynparza tablets 300 mg orally twice daily (n=195) or placebo (n=99) until disease progression or unacceptable toxicity. The median duration of study treatment was 19.4 months for patients who received Lynparza and 5.6 months for patients who received placebo.

Among patients who received Lynparza, dose interruptions due to an adverse reaction of any grade occurred in 45% and dose reductions due to an adverse reaction occurred in 27%. The most frequent adverse reactions leading to dose interruption or reduction of Lynparza were anemia (22%), neutropenia (9%), and fatigue/asthenia (8%). Discontinuation due to an adverse reaction occurred in 11% of patients receiving Lynparza.

Tables 6 and 7 summarize adverse reactions and laboratory abnormalities in SOLO-2.

Table 6 Adverse Reactions* in SOLO-2 (≥20% of Patients Who Received Lynparza)

Adverse Reaction	Lynparza tablets n=195		Placebo n=99	
	Grades 1-4 (%)	Grades 3-4 (%)	Grades 1-4 (%)	Grades 3-4 (%)
Gastrointestinal Disorders				
Nausea	76	3	33	0
Vomiting	37	3	19	1
Diarrhea	33	2	22	0
Stomatitis†	20	1	16	0
General Disorders and Administration Site Conditions				
Fatigue including asthenia	66	4	39	2
Blood and Lymphatic Disorders				
Anemia‡	44	20	9	2
Infections and Infestations				
Nasopharyngitis/URI/sinusitis/ rhinitis/influenza	36	0	29	0
Musculoskeletal and Connective Tissue Disorders				
Arthralgia/myalgia	30	0	28	0
Nervous System Disorders				
Dysgeusia	27	0	7	0
Headache	26	1	14	0
Metabolism and Nutrition Disorders				
Decreased appetite	22	0	11	0

* Graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.0.
† Represents grouped term consisting of abscess oral, aphthous ulcer, gingival abscess, gingival disorder, gingival pain, gingivitis, mouth ulceration, mucosal infection, mucosal inflammation, oral candidiasis, oral discomfort, oral herpes, oral infection, oral mucosal erythema, oral pain, oropharyngeal discomfort, and oropharyngeal pain.
‡ Represents grouped term consisting of anemia, hematocrit decreased, hemoglobin decreased, iron deficiency, mean cell volume increased and red blood cell count decreased.

In addition, the adverse reactions observed in SOLO-2 that occurred in <20% of patients receiving Lynparza were neutropenia (19%), cough (18%), leukopenia (16%), hypomagnesemia (14%), thrombocytopenia (14%), dizziness (13%), dyspepsia (11%), increased creatinine (11%), MDS/AML (8%), edema (8%), rash (6%), VTE (5%), and lymphopenia (1%).

Table 7 Laboratory Abnormalities Reported in ≥25% of Patients in SOLO-2

Laboratory Parameter*	Lynparza tablets n†=195		Placebo n†=99	
	Grades 1-4 (%)	Grades 3-4 (%)	Grades 1-4 (%)	Grades 3-4 (%)
Increase in mean corpuscular volume‡	89	-	52	-
Decrease in hemoglobin	83	17	69	0
Decrease in leukocytes	69	5	48	1
Decrease in lymphocytes	67	11	37	1
Decrease in absolute neutrophil count	51	7	34	3
Increase in serum creatinine	44	0	29	0
Decrease in platelets	42	2	22	1

* Patients were allowed to enter clinical studies with laboratory values of CTCAE Grade 1.
† This number represents the safety population. The derived values in the table are based on the total number of evaluable patients for each laboratory parameter.
‡ Represents the proportion of subjects whose mean corpuscular volume was > upper limit of normal (ULN).

Study 19

The safety of Lynparza as maintenance monotherapy was evaluated in patients with platinum sensitive ovarian cancer who had received 2 or more previous platinum containing regimens in Study 19 *[see Clinical Studies (14.3) in the full Prescribing Information]*. Patients received Lynparza capsules 400 mg orally twice daily (n=136) or placebo (n=128). At the time of final analysis, the median duration of exposure was 8.7 months in patients who received Lynparza and 4.6 months in patients who received placebo.

Adverse reactions led to dose interruptions in 35% of patients receiving Lynparza; dose reductions in 26% and discontinuation in 6% of patients receiving Lynparza.

Tables 8 and 9 summarize adverse reactions and laboratory abnormalities in Study 19.

Table 8 Adverse Reactions* in Study 19 (≥20% of Patients Who Received Lynparza)

Adverse Reaction	Lynparza capsules n=136		Placebo n=128	
	Grades 1-4 (%)	Grades 3-4 (%)	Grades 1-4 (%)	Grades 3-4 (%)
Gastrointestinal Disorders				
Nausea	71	2	36	0
Vomiting	35	2	14	1
Diarrhea	28	2	25	2
Constipation	22	1	12	0
Dyspepsia	20	0	9	0
General Disorders and Administration Site Conditions				
Fatigue (including asthenia)	63	9	46	3
Blood and Lymphatic Disorders				
Anemia†	23	7	7	1
Infections and Infestations				
Respiratory tract infection	22	2	11	0
Metabolism and Nutrition Disorders				
Decreased appetite	21	0	13	0
Nervous System Disorders				
Headache	21	0	13	1

* Graded according to NCI CTCAE v4.0.
† Represents grouped terms of related terms that reflect the medical concept of the adverse reaction.

In addition, the adverse reactions in Study 19 that occurred in <20% of patients receiving Lynparza were dysgeusia (16%), dizziness (15%), dyspnea (13%), pyrexia (10%), stomatitis (9%), edema (9%), increase in creatinine (7%), neutropenia (5%), thrombocytopenia (4%), leukopenia (2%), MDS/AML (1%), VTE (1%), and lymphopenia (1%).

Table 9 Laboratory Abnormalities Reported in ≥25% of Patients in Study 19

Laboratory Parameter*	Lynparza capsules n†=136		Placebo n†=129	
	Grades 1-4 (%)	Grades 3-4 (%)	Grades 1-4 (%)	Grades 3-4 (%)
Decrease in hemoglobin	82	8	58	1
Increase in mean corpuscular volume‡	82	-	51	-
Decrease in leukocytes	58	4	37	2
Decrease in lymphocytes	52	10	32	3
Decrease in absolute neutrophil count	47	7	40	2
Increase in serum creatinine	45	0	14	0
Decrease in platelets	36	4	18	0

* Patients were allowed to enter clinical studies with laboratory values of CTCAE Grade 1.
† This number represents the safety population. The derived values in the table are based on the total number of evaluable patients for each laboratory parameter.
‡ Represents the proportion of subjects whose mean corpuscular volume was > ULN.

Postmarketing Experience

The following adverse reactions have been identified during post approval use of Lynparza. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune System Disorders: Hypersensitivity including angioedema.

Skin and subcutaneous tissue disorders: Erythema nodosum, rash, dermatitis.

DRUG INTERACTIONS

Use with Anticancer Agents

Clinical studies of Lynparza with other myelosuppressive anticancer agents, including DNA damaging agents, indicate a potentiation and prolongation of myelosuppressive toxicity.

Effect of Other Drugs on Lynparza

Strong and Moderate CYP3A Inhibitors

Coadministration of CYP3A inhibitors can increase olaparib concentrations, which may increase the risk for adverse reactions *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*. Avoid coadministration of strong or moderate CYP3A inhibitors. If the strong or moderate inhibitor must be coadministered, reduce the dose of Lynparza *[see Dosage and Administration (2.4) in the full Prescribing Information]*.

Strong and Moderate CYP3A Inducers

Concomitant use with a strong or moderate CYP3A inducer decreased olaparib exposure, which may reduce Lynparza efficacy *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*. Avoid coadministration of strong or moderate CYP3A inducers.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on findings in animals and its mechanism of action *[see Clinical Pharmacology (12.1) in the full Prescribing Information]*, Lynparza can cause fetal harm when administered to a pregnant woman. There are no available data on Lynparza use in pregnant women to inform the drug-associated risk. In an animal reproduction study, the administration of olaparib to pregnant rats during the period of organogenesis caused teratogenicity and embryo-fetal toxicity at exposures below those in patients receiving the recommended human dose of 300 mg twice daily *(see Data)*. Apprise pregnant women of the potential hazard to the fetus and the potential risk for loss of the pregnancy.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. The estimated background risk in the U.S. general population of major birth defects is 2-4%; and the risk for spontaneous abortion is approximately 15-20% in clinically recognized pregnancies.

Data

Animal Data

In a fertility and early embryonic development study in female rats, olaparib was administered orally for 14 days before mating through to Day 6 of pregnancy, which resulted in increased post-implantation loss at a dose level of 15 mg/kg/day (with maternal systemic exposures approximately 7% of the human exposure ($AUC_{0\text{-}24h}$) at the recommended dose).

In an embryo-fetal development study, pregnant rats received oral doses of 0.05 and 0.5 mg/kg/day olaparib during the period of organogenesis. A dose of 0.5 mg/kg/day (with maternal systemic exposures approximately 0.18% of human exposure ($AUC_{0\text{-}24h}$) at the recommended dose) caused embryo-fetal toxicities including increased post-implantation loss and major malformations of the eyes (anophthalmia, microphthalmia), vertebrae/ribs (extra rib or ossification center; fused or absent neural arches, ribs, and sternebrae), skull (fused exoccipital), and diaphragm (hernia). Additional abnormalities or variants included incomplete or absent ossification (vertebrae/sternebrae, ribs, limbs) and other findings in the vertebrae/sternebrae, pelvic girdle, lung, thymus, liver, ureter, and umbilical artery. Some findings noted above in the eyes, ribs, and ureter were observed at a dose of 0.05 mg/kg/day olaparib at lower incidence.

Lactation

Risk Summary

No data are available regarding the presence of olaparib in human milk, or on its effects on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in the breastfed infants from Lynparza, advise a lactating woman not to breastfeed during treatment with Lynparza and for one month after receiving the last dose.

Females and Males of Reproductive Potential

Pregnancy Testing

Recommend pregnancy testing for females of reproductive potential prior to initiating treatment with Lynparza.

Contraception

Females

Lynparza can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1) in the full Prescribing Information]*. Advise females of reproductive potential to use effective contraception during treatment with Lynparza and for at least 6 months following the last dose.

Pediatric Use

Safety and effectiveness of Lynparza have not been established in pediatric patients.

Geriatric Use

Of the 2901 patients with advanced solid tumors who received Lynparza as a single agent, 680 (23%) patients were aged ≥65 years, and this included 206 (7%) patients who were aged ≥75 years. Thirteen (0.4%) patients were aged ≥85 years.

Of the 535 patients with advanced solid tumors who received Lynparza tablets 300 mg orally twice daily in combination with bevacizumab, 204 (38%) patients were aged ≥65 years, and this included 31 (6%) patients who were aged ≥75 years.

No overall differences in the safety or effectiveness of Lynparza were observed between these patients and younger patients.

Renal Impairment

No dosage modification is recommended in patients with mild renal impairment (CLcr 51 to 80 mL/min estimated by Cockcroft-Gault). Reduce Lynparza dosage to 200 mg twice daily in patients with moderate renal impairment (CLcr 31 to 50 mL/min) *[see Dosage and Administration (2.5) in the full Prescribing Information]*. There are no data in patients with severe renal impairment or end-stage disease (CLcr ≤30 mL/min) *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Hepatic Impairment

No adjustment to the starting dose is required in patients with mild or moderate hepatic impairment (Child-Pugh classification A and B). There are no data in patients with severe hepatic impairment (Child-Pugh classification C) *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Distributed by:
AstraZeneca Pharmaceuticals LP
Wilmington, DE 19850
©AstraZeneca 2022

10/2022 US-70178 11/22



INSULIN INSIGHTS

From Semler Scientific

Using algorithms that codify the ADA standards of care Insulin Insights' game-changing technology empowers clinicians with actionable data to help inform insulin dosing decisions. This FDA-cleared software as a medical device aims to improve diabetic patient outcomes, lower glycated hemoglobin, and reduce the risk of long-term complications. It is the only comprehensive dosing solution for all patients and insulin regimens.

View Brochures, Videos & More at POR.io
Enter Number **2925** in the Search Area

NOVA PRIMARY BLOOD GLUCOSE REFERENCE ANALYZER

From Nova Biomedical

The U.S. FDA has cleared Nova Primary as a blood glucose reference analyzer that fills the need for a new reference analyzer to replace the YSI STAT PLUS 2300 (YSI, Inc., Yellow Springs, OH). Manufacturers of blood glucose measuring devices and clinical diabetes researchers have relied on the YSI 2300 as a reference and correlation analyzer. However, YSI, Inc. no longer supports the analyzer, and its discontinuation has left a critical industry void. With today's FDA clearance, Nova Primary from Nova Biomedical is now available in the U.S. and worldwide.

View Brochures, Videos & More at POR.io
Enter Number **2926** in the Search Area





COMPREHENSIVE IN-OFFICE DIABETES TESTING WITH THE DCA VANTAGE® AND CLINITEK STATUS®+ ANALYZERS

From Siemens Healthineers

Siemens Healthineers DCA Vantage® and CLINITEK Status® family of analyzers provide hemoglobin A1c (HbA1c) and albumin-to-creatinine ratio (ACR) testing at the point of care. Meet quality measures for A1c control and kidney disease check in minutes with CLIA-waived HbA1c testing and ACR[1] ratio. Improve patient experience and overall outcome by providing actionable results in minutes.

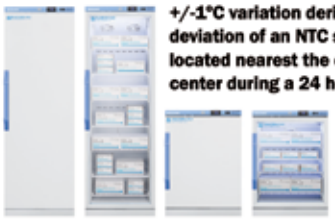
1. Moderately complex on the DCA Vantage Analyzer. CLIA-waived on the CLINITEK Status+ Analyzer.

View Brochures, Videos & More at POR.io
Enter Number **2927** in the Search Area

VACCINE FREEZERS & REFRIGERATORS

Visit us at medicaldevicedepot.com for more information and options

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 chamber geometric center during a 24 hour test period

2928

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

Advanced Temperature Control & Durable Performance

- **Intelligent microprocessor digital temperature controller**
- **Adjustable operating control range from +2 to +8°C**
- **Digital display of the min/max temperature in Celsius or Fahrenheit**
- **Password protected control parameters beyond setpoitn**
- **Optimized forced air cooling for excellent stability & uniformity with rapid recovery**
- **Open door and high/low temperature alarms**
- **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	$936.00
ARG1PV	1 cu.ft.	21.5"	17.5"	20"	Glass	$949.00
ARS3PV	3 cu.ft.	33.75"	18.5"	19"	White	$1,089.00
ARG3PV	3 cu.ft.	33.75"	18.5"	19.5"	Glass	$1,102.00
ARS6PV	6 cu.ft.	32.5"	23.5"	24.5"	White	$1,235.00
ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	$1,266.00
ARS8PV	8 cu.ft.	50"	23.38"	24.5"	White	$1,654.00
ARG8PV	8 cu.ft.	50"	23.38"	25"	Glass	$1,667.00
ARS12PV	12 cu.ft.	61.75"	23.38"	24.5"	White	$2,139.00
ARG12PV	12 cu.ft.	61.75"	23.38"	25"	Glass	$2,152.00
ARS15PV	15 cu.ft.	72"	23.5"	24.5"	White	$2,321.00
ARG15PV	15 cu.ft.	72"	23.5"	25"	Glass	$2,334.00

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	$2,789.00
ARG23ML	23 cu.ft.	83.75	27.5	31	(1) Glass	$3,114.00
ARS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	$4,674.00
ARG49ML	49 cu.ft.	83.75	55.25	31	(2) Glass	$5,031.00

Pharma-Lab Freezers

Accucold	Capacity	Height	Width	Depth	Door	PRICE
AFS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	$3,205.00
AFS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	$5,194.00

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

Medical Device Depot ©Inc.

Toll Free 877-646-3300

medicaldevicedepot.com

SITEWIDE SALE

COUPON CODE MDDSAVE

for additional savings at checkout!

SPIRE INTEGRATED SOLUTIONS Medical Device Depot® is part of the Spire Integrated Solutions family.

© 2022 . Medical Device Depot . ALL RIGHTS RESERVED



FIXING PRIMARY CARE'S BROKEN BUSINESS MODEL

BY HANS DUVEFELT, MD

Primary care visits are never quick; we don't give much advice over the phone or online; and we prioritize the government's and insurance companies' public health agenda over our own patients' concerns.

Imagine health care as a retail customer experience for a few minutes:

Imagine you're going to Walmart to buy a bag of dog food, a new coffee maker or to equip a small kitchen in your newly built mother-in-law apartment.

1. You've bought dog food there before, so you know exactly where it is. You just want to quickly grab a bag and get out of there.

2. You have a rough idea of where the coffee makers are; you know some brands you trust, but you might have one or two questions before you select one, and if they don't have one you like, you might get it somewhere else. Or, you might even check their website to see which models they carry.

3. For the new kitchen, you have a list, but know you probably haven't thought of everything, so you plan to walk down the aisles in the kitchen and home departments. You plan to spend a fair amount of money, so you might be on the lookout for special sales or promotions. But, you definitely don't want someone else to choose all the items for you.

Can Walmart meet your needs in all these situations? Probably yes.

Now, think about how your doctor's office works

1. Can you quickly get in and out if you have a simple problem like conjunctivitis?

2. Are they able to give you information on what your options are for a recurring shoulder dislocation; could they refer you to a shoulder specialist without first waiting weeks to see your primary care doctor?

3. You have lots of issues and try to get an appointment to deal with them all at once; you think of it as a physical, but last time you had a physical, your doctor brought up all kinds of things you don't particularly see as priorities for yourself.

Here are the existing realities of primary care

We can't afford to just see you for something quick. Our quality indicators, which more and more will determine how we get paid, will go down if we don't screen you at every visit and offer interventions for depression, smoking, alcohol misuse, hypertension, weight management, immunization needs and much more.

We won't refer you without seeing you, and we often hesitate giving you medical advice over the phone. Our providers are not scheduled for anything else besides seeing patients, because the rules of how we are paid still emphasize face-to-face visits over "population management." So our providers are busy all day long seeing patients for visits that could have been simple but are loaded up with mandatory screenings and interventions and our medical assistants, besides being busy with all our screening questionnaires, are discouraged from giving medical advice they aren't formally trained to provide.

Is there a doctor shortage?

We are said to have a doctor shortage. We have an aging population with more and more chronic diseases, like diabetes and heart disease. The need for skilled and experienced medical providers is continually increasing.

We have no public health system to speak of in this country, so the government, through Medicare and Medicaid, has mandated that health care providers do the things the public health system does in other countries.

This is, plain and simple, what is clogging up the works in health care today: Too much non-doctor work is crammed into each patient visit, and we can't charge for giving advice or directing care except in a face-to-face visit.

You don't need to go to medical school to give immunizations, tell people smoking is bad for you, explain that "low fat" foods cause obesity, or promote regular exercise. You don't even need to be a doctor, PA or NP to screen for high blood pressure – only to treat it. (Some pundits, in utter desperation, have suggested we send pharmacists to school to learn how to treat hypertension, but there are of course plenty of licensed medical providers who are able and willing to do that if we get freed up from the less-skilled tasks I just listed above.)

Patients and doctors have no control

Now, why are we doing all those things we do if they are so inefficient? Quite simply, whoever pays us has the power to define our work. We call that "health insurance," but that is not exactly what we are dealing with. Insurance, for home, auto or employer liability, has nothing to do with predictable events or minor issues. Your car insurance doesn't pay for oil changes or tire wear, not even for a minor paint scratch. But somehow that is what we expect health insurance to cover for our bodies. In terms of auto insurance, most people probably figure an insurance job carries an inflated price tag and lots of paperwork. The same is true for health care, which should not be a surprise to anyone. For example, years ago the overhead cost of insurance billing for each primary care doctor was reported to be $80,000. That, put very plainly, is money that patients and employers are ultimately paying through premiums and deductibles.

And all the mandated screenings are there because Medicare, in particular, has the right to micromanage doctors' work because they are paying for health care visits, which could be quicker and less costly if patients had control over their health care spending.

How could we do better?

We do three things in primary care, each with its own workflow and, really, each with its own economics.

1. We could do our part of public health more effectively. Allow us to promote immunizations and other primary preventions outside our already crammed fifteen-minute visits. Pay us a per patient per year stipend to reach out to target populations through mail, phone, web or, when appropriate, in person about general health issues. Stop imagining we can do all of it and still treat diseases, acute and chronic, in our measly fifteen minutes. Right now, that is just clicking boxes with little actual substance. Use some of the government money that should have been spent on a working public health system if you want us to step in and do the government's work.

2. Make it economically feasible for medical providers to oversee patient care by acknowledging that reading incoming reports, answering phone or web inquiries and coordinating care with specialists and hospitals are essential parts of being a medical home for patients. Such activities should not be unpaid services eked out at the expense of lunch, bathroom breaks or dinner with our families.

3. Allow us to define each office visit together with our patients. It is insulting to everyone involved to have to interrogate someone with a splitting headache, twisted ankle or bleeding laceration about their diet and alcohol habits. I could see many more patients if I could delegate those things to outreach staff or simply not do it every visit. Right now we are made to act as if we will never see that patient again. I was trained to provide care over time, in a relationship based practice. That is proven to be an effective and fiscally sound way to deliver health care. The third task is the only one that makes sense to pay us for on a per-visit basis, whereas the first two deserve their own payment method. Personally, I wonder if the first few hundred dollars worth of primary care visits are worth churning through the expensive bureaucratic insurance machinery, or if it wouldn't make more sense to just allow each patient a set amount of spending at their discretion. I am not writing about privately financed, direct primary care or concierge medicine. Those obviously exist, and may work well for many people, but the health care payment options for most Americans are what desperately need fixing.

Only if we acknowledge that public health, population health, and face-to-face visits are three separate aspects of health care can we move forward in reforming primary care. And only if we recognize and reimburse physicians' non-face-to-face work fairly will we see the improved customer service and doctor-patient communications we are now only paying lip service to.

Where would Google be if we had to make an appointment to sit down with a search consultant and pose our questions, fifteen minutes at a time? It may be an outlandish analogy, but health care needs some shaking up.

—

Hans Duvefelt, MD is a Family Physician, Writer, Teacher and Mentor. You can read more of his articles at acountrydoctorwrites.wordpress.com

medicaldevicedepot.com

3 WAYS TO START IMMEDIATELY INCREASING REVENUE

1 Neuro-Cognitive Testing

2929

- 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**
- Each test is processed into a fully-finished, clinically actionable report
- Easy to understand biomarkers facilitate more informed medical interventions, such as biofeedback

2 ANS Testing

(can be combined with SUDOMOTOR into 1 full system)

2930

- Takes less than 10 minutes to perform, software provides verbal cues
- Tests for autonomic balance, vascular health, physical/mental stress, peripheral nerve health and other critical hidden risk factors
- **Reimburses $170/test using 3 CPT codes**
- Provides a 1 page summary up to a full 24 page comprehensive report



3 SudoMotor Testing

2931

(can be combined with ANS into 1 full system)

- Takes 3 minutes to analyze a patients' hands and feet
- Provides a 1 page summary report
- Assesses peripheral nerve health (c-fiber function) and asymmetry between each hand and foot
- **Reimburses $130/test (national average)**

Medical Device Depot ©Inc.

Toll Free 877-646-3300

SITEWIDE SALE

COUPON CODE **MDDSAVE**

for additional savings at checkout!

SPIRE INTEGRATED SOLUTIONS

Medical Device Depot® is part of the Spire Integrated Solutions family.

© 2021 Medical Device Depot ALL RIGHTS RESERVED



THIS CHANGES EVERYTHING. FASTER. SMALLER. SMARTER.

From bioMérieux

bioMérieux knows that an evolving world deserves evolved diagnostics. Our latest innovation, the BIOFIRE® SPOTFIRE® Respiratory Solution, is the first FDA-cleared and CLIA-waived COVID-19 testing solution. The BIOFIRE® SPOTFIRE® System is an easy-to-use system that runs the BIOFIRE® SPOTFIRE® Respiratory (R) Panel. Benefits of the SPOTFIRE Respiratory Solution include: 15 respiratory targets on 1 PCR test with results in about 15 minutes; minimal benchtop space with vertical scalability up to four modules; easy to use with an intuitive user interface.

View Brochures, Videos & More at POR.io
Enter Number **2932** in the Search Area

ACUCY INFLUENZA A&B TEST

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.

View Brochures, Videos & More at POR.io
Enter Number **2933** in the Search Area





OSOM ULTRA PLUS FLU A&B TEST

From Sekisui Diagnostics

Stronger Clinical Performance Takes Lateral Flow Testing To The Next Level. Providing superior rapid results at the point-of-care. Fast, easy, cost effective so you can test and treat in one visit.

- High Performance- Equivalent or exceeding the performance of reader devices, without the need for an instrument
- Results in 10 minutes
- OSOM® Custom Care- Exceptional Support/Training by licensed medical technologists and experienced healthcare professionals
- Made in the USA

View Brochures, Videos & More at POR.io
Enter Number **2934** in the Search Area

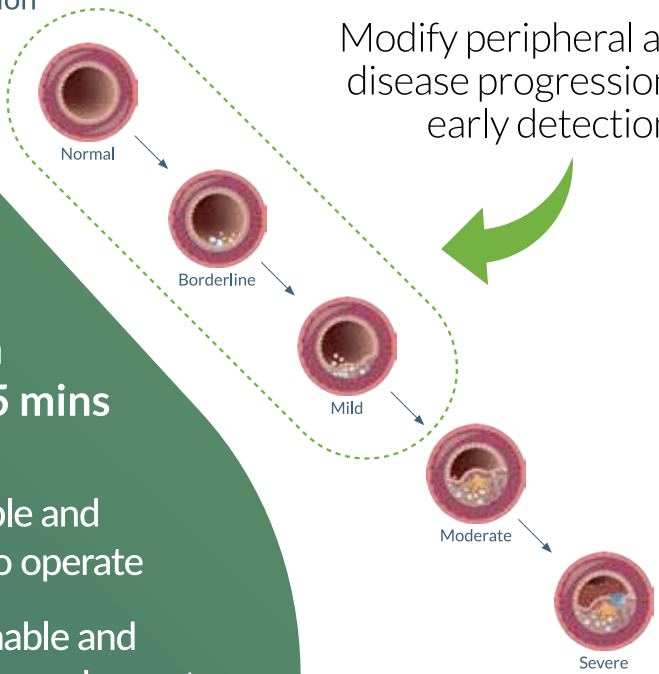
If you have patients *40+* with diabetes mellitus (DM)* you should consider this FDA cleared test[1]

QuantaFlo® PAD

The prevalence of peripheral arterial disease (PAD) in people with DM over the age of 40 is estimated at 20%. For those over 50 with DM it increases to 29%[2].



PAD Disease Progression



Early Detection = *Early* Prevention

Modify peripheral arterial disease progression with early detection



QuantaFlo® PAD

An accurate test that aids in *early* detection of PAD in < 5 mins

- ☑ FDA cleared
- ☑ Portable and easy to operate
- ☑ Non-invasive and painless
- ☑ Actionable and easy to read report

QuantaFlo® is successfully used by primary care offices, specialty practices and home assessments.

Learn more about QuantaFlo

ML00163.Rev A

*2016 AHA/ACC Lower Extremity PAD Guidelines: Age ≥ 65y; Age 50-64y, with risk factors for atherosclerosis; Age <50 y, with diabetes mellitus; and one additional risk factor or atherosclerosis[1]

1. Gerhard-Herman, M. D., Gornik, H. L., Barrett, C., Barshes, N. R., Corriere, M. A., Drachman, D. E., Fleisher, L. A., Fowkes, F. G., Hamburg, N. M., Kinlay, S., Lookstein, R., Misra, S., Mureebe, L., Olin, J. W., Patel, R. A. G., Regensteiner, J. G., Schanzer, A., Shishehbor, M. H., Stewart, K. J., ... Walsh, M. E. (2017). 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease: Executive summary: A report of the american college of cardiology/american heart association task force on clinical practice guidelines. Circulation, 135(12). https://doi.org/10.1161/cir.0000000000000470

2. Thiruvoipati, T., Kielhorn, C. E., & Armstrong, E. J. (2015). Peripheral artery disease in patients with diabetes: Epidemiology, mechanisms, and outcomes. World journal of diabetes, 6(7), 961–969. https://doi.org/10.4239/wjd.v6.i7.961



CELL-DYN EMERALD 22 HEMATOLOGY ANALYZER

From Abbott

The CELL-DYN Emerald 22 is a full performance 5-part hematology analyzer for smaller clinical laboratories seeking productivity in smaller spaces.

Benefits:
- Compact Design - To conserve valuable workspace.
- Small and Powerful - Includes a numeric keypad entry, reagent tray, and integrated color touchscreen monitor.
- Easy and Automated - Barcoded reagents and touch-free scheduled daily maintenance, startup and shutdown.
- Online product training - Self-pace training available 24x7 on the Abbott's Hematology Academy.

View Brochures, Videos & More at POR.io
Enter Number **2936** in the Search Area

MICROS HEMATOLOGY ANALYZER WITH 3-PART DIFFERENTIAL PLUS THE LITEDM

From HORIBA Medical

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.

View Brochures, Videos & More at POR.io
Enter Number **2937** in the Search Area





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

View Brochures, Videos & More at POR.io
Enter Number **2938** in the Search Area



2939

MD6300 MICRO SPIROMETER
FULL FUNCTION LOW COST SPIROMETER

From Mirco Direct

The Micro Spirometer is the newest offering in the Micro Direct spirometer line. Specifically designed for situations where low cost, precision spirometry measurements are required, the Micro Spirometer is lightweight and portable making it suitable for the physician office. The Micro Spirometer features a large color touch screen that is icon driven. The Micro Spirometer is supplied with Device Studio. A PC software for producing printouts of tests results or for creating PDF reports for attachment to the patients' EMR file.

View Brochures, Videos & More at POR.io
Enter Number **2939** in the Search Area

MD6800 PNEUMOTRAC SPIROMETER
A POWERFUL SOLUTION FOR PC-BASED SPIROMETRY

From Micro Direct

The Pneumotrac connects to your PC by USB and captures reliable tests results immediately using the Spirotrac 6 software. These results can be printed or shared easily with compatible EMR systems. The Pneumotrac features a highly accurate, extremely stable Fleisch pneumotrach and meets the latest 2019 ATS/ERS standardization of spirometry ensuring testing meets the most up-to-date guidelines. Real-time curves and new animated incentives encourage maximal patient performance and obtain prompt quality feedback using the latest test session/session acceptability, usability and repeatability criteria.

View Brochures, Videos & More at POR.io
Enter Number **2940** in the Search Area



2940



2941

MD6000 ALPHA SPIROMETER
THE FUTURE OF DESKTOP SPIROMETRY

From Micro Direct

The Alpha features a highly accurate, extremely stable Fleisch pneumotrach and meets the latest 2019 ATS/ERS standardization of spirometry ensuring testing meets the most up-to-date guidelines. Performing a test is very easy using the large icon driven touch screen. A test quality grading system and live testing prompts give you confidence and peace of mind when performing the test. Reports are printed instantly using the fast, integrated printer or obtain an 8.5" x 11" printout via Device Studio software that is included with the Alpha.

View Brochures, Videos & More at POR.io
Enter Number **2941** in the Search Area



TOP CRITERIA FOR CHOOSING A CHEMISTRY ANALYZER FOR A POL

BY BARRY CRAIG, 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 as 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.

SYNDROMIC TESTING



2942

BIOFIRE® FILMARRAY® TORCH

From bioMérieux

The BIOFIRE® FILMARRAY® TORCH is a fully integrated, random, and continuous-access system designed to meet your laboratory's syndromic infectious disease testing needs. The benchtop footprint of the BIOFIRE TORCH saves precious lab space, and its scalability meets high throughput demands. BIOFIRE® FILMARRAY® Link Software automatically uploads patient results. Fully compatible with all BIOFIRE® FILMARRAY® Panels intended for use in CLIA-moderate settings, the BIOFIRE TORCH helps you maximize efficiency and productivity.

View Brochures, Videos & More at POR.io
Enter Number **2942** in the Search Area

PERIPHERAL ARTERIAL DISEASE

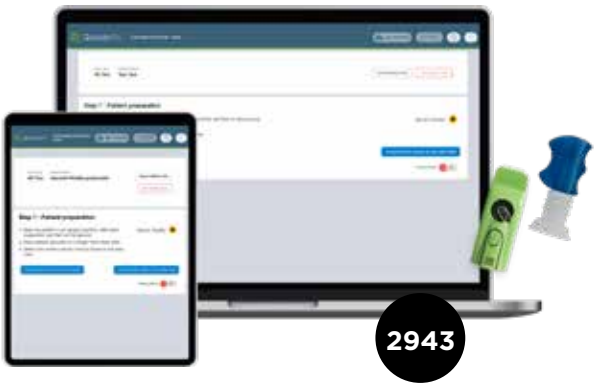
QUANTAFLO® HD

From Semler Scientific

The QuantaFlo® HD application assists in the early detection of Heart Dysfunction (HD). As published in the Journal of Preventive Medicine, QuantaFlo HD showed a statistically significant correlation with cardiac echocardiography, which is a gold standard for diagnosing heart failure.1 The test is highly sensitive, able to detect even asymptomatic HD, and can be performed in the outpatient clinic or the home setting in approximately 5 mins. Results are available immediately and graded as either positive or negative for HD allowing for improved patient selection for echocardiography.

1. Howell, S. C., & Master, R. C. (2023). Clinical Evaluation of Volume Plethysmography as an Aid for Diagnosis of Heart Failure in the Primary Care Setting. Journal of Preventive Medicine, 8(2). https://doi.org/https://preventive-medicine.imedpub.com/clinical-evaluation-of-volume-plethysmography-as-an-aid-for-diagnosis-of-heart-failure-in-the-primary-care-setting.pdf

View Brochures, Videos & More at POR.io
Enter Number **2943** in the Search Area



2943



2944

QUANTAFLO® PAD

From Semler Scientific

QuantaFlo® PAD is an easy to use, accurate, point of care, non-invasive solution that aids in the early detection of peripheral arterial disease (PAD). This FDA cleared device can be administered by a medical aide in less than 5 minutes. As published in the Journal of Vascular Surgery and the American Journal of Preventive Medicine, QuantaFlo detected undiagnosed PAD in 31.6% of patients +65.1 QuantaFlo is portable and integrates with other technologies and platforms. It is ideal for both home and clinic environments.

1. Smolderen KG, Ameli O, Chaisson CE, Heath K, Mena-Hurtado C. Peripheral Artery Disease Screening in the Community and 1-Year Mortality, Cardiovascular Events, and Adverse Limb Events, AJPM Focus (2022), https://doi.org/10.1016/j.focus.2022.100016

View Brochures, Videos & More at POR.io
Enter Number **2944** in the Search Area

Personal finance education, tailored to you.



Get our mobile app for free.

@scrubmoneyorg
scrubmoney.org

2945



OSOM® BVBLUE®

From Sekisui Diagnostics

The OSOM® BVBLUE® detects elevated vaginal fluid sialidase activity, an enzyme produced by bacterial pathogens associated with bacterial vaginosis including Gardnerella, Bacteroides, Prevotella and Mobiluncus. OSOM® BVBLUE® is more sensitive than Amsel criteria providing physicians with a more accurate diagnosis to treat and minimize serious health consequences such as early spontaneous preterm births and miscarriage.

View Brochures, Videos & More at POR.io
Enter Number **2946** in the Search Area

OSOM® TRICHOMONAS RAPID TEST

From Sekisui Diagnostics

The OSOM® Trichomonas Rapid Test is intended for the qualitative detection of Trichomonas vaginalis antigens from vaginal swabs or from the saline solution. The OSOM® Trichomonas Rapid Test is a CLIA-waived rapid test available today. OSOM® Trichomonas is more sensitive than wet mount due to the assay being able to detect viable and non-viable organisms which offers significant benefits to the patient and clinician alike.

View Brochures, Videos & More at POR.io
Enter Number **2947** in the Search Area





ULTRA HCG COMBO TEST

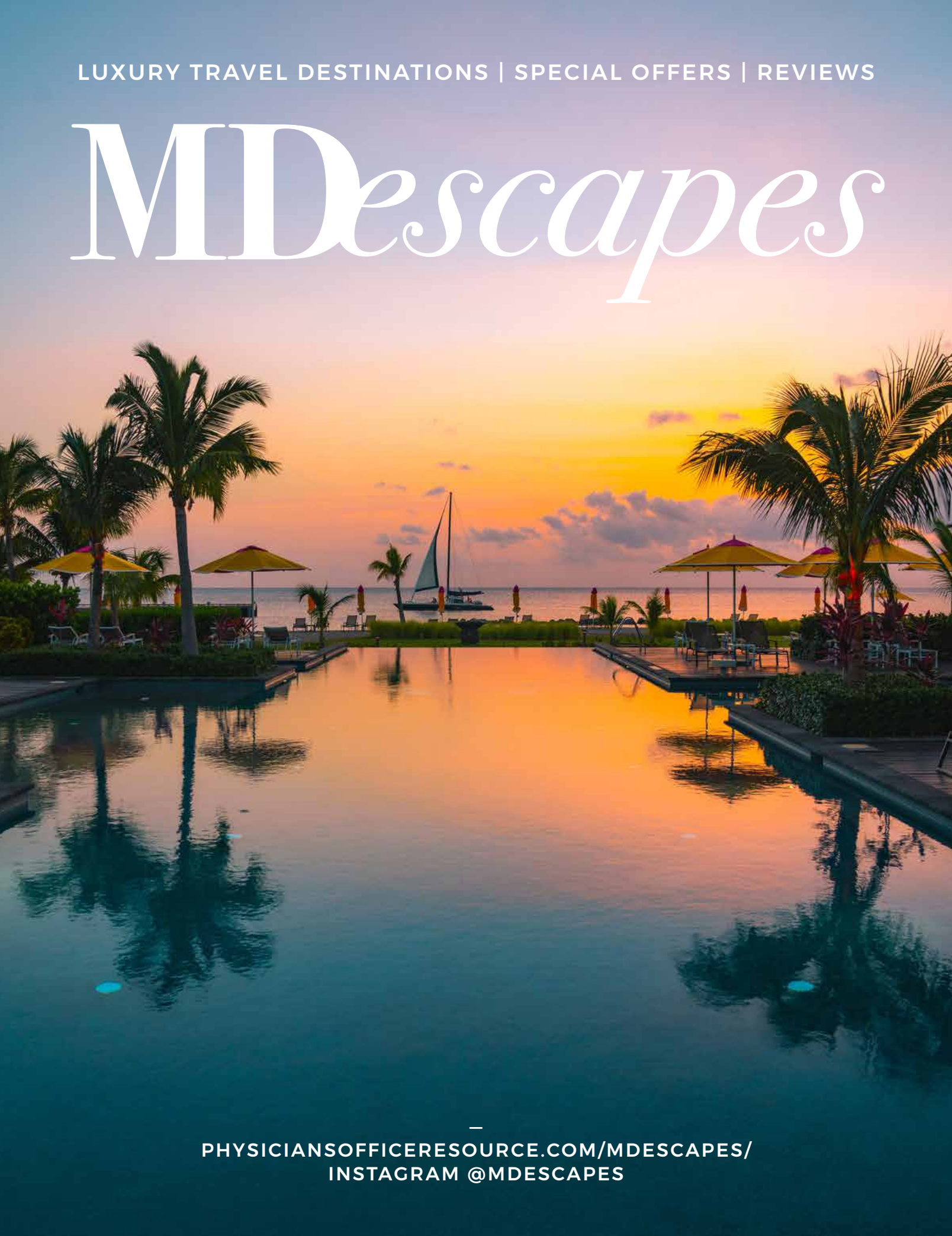
From Sekisui Diagnostics

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.

View Brochures, Videos & More at POR.io
Enter Number **2948** in the Search Area

LUXURY TRAVEL DESTINATIONS | SPECIAL OFFERS | REVIEWS

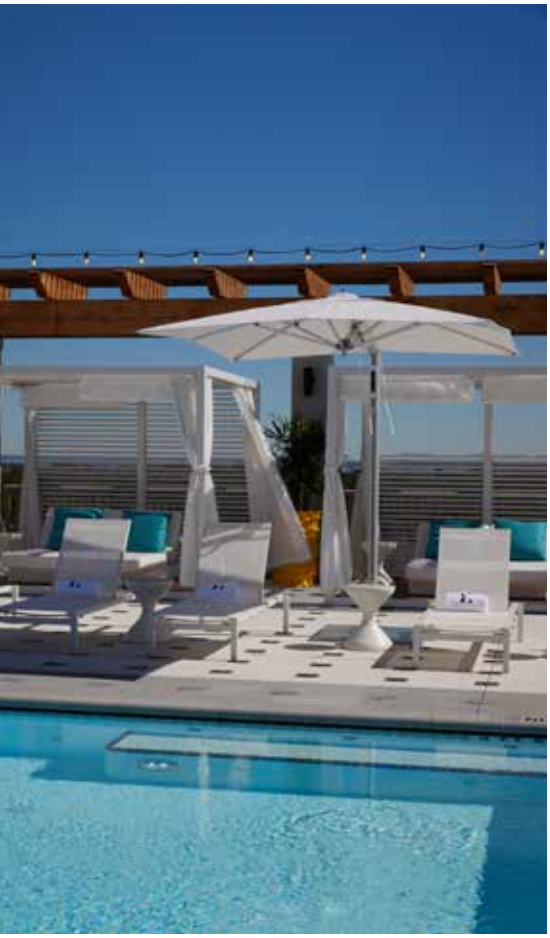
MDescapes



PHYSICIANSOFFICERESOURCE.COM/MDESCAPES/
INSTAGRAM @MDESCAPES









Our goal is to REWARD YOU

MDescapes features exclusive luxury travel discounts and offers! Our goal is to reward you, the healthcare professional, and help provide the rest, adventure, and memoires that accompany a luxury vacation.

FOUR SEASONS NEVIS

FOUR SEASONS PUNTA MITA

FOUR SEASONS NEW ORLEANS

FOUR SEASONS SANTA FE

CARTON HOUSE

SANDESTIN GOLF AND BEACH RESORT

AND MORE

—

FIND YOUR ESCAPE AT

PhysiciansOfficeResource.com/MDescapes



We recognize your passion for providing accurate results which help diagnose and drive treatment decisions. We also know you are resilient and must navigate through some difficult and chaotic days while providing the best possible service to physicians, patients, and your organization.

At SEKISUI Diagnostics, we are committed to providing high-quality, U.S.-made respiratory health rapid tests that are accurate and easy to use, allowing you to get the answers fast.

Like you, we understand there is a patient behind every answer—and that's what matters most.

To learn more about our Flu Test promotions, visit osomtests.com or call 800-332-1042



OSOM® MONO TEST **2949**

OSOM® ULTRAPLUS FLU A&B TEST **2950**

OSOM® ULTRA STREP A TEST **2951**

© 2022 SEKISUI Diagnostics, LLC. All rights reserved. OSOM® is a registered trademark of SEKISUI Diagnostics, LLC.
Because every result matters™ is a trademark of SEKISUI Diagnostics, LLC.

SEKISUI DIAGNOSTICS
Because every result matters™