Physicians office Resource™

Resources for You, Your Patients, & Your Practice



2025 BUYERS GUIDE

POC-24-NAM-5696

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

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



Diabetes management solutions at the point-of-care

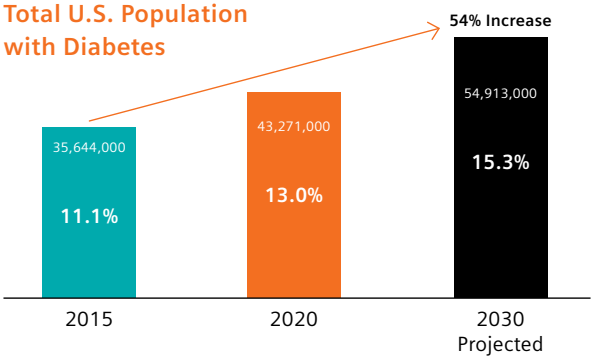
Gain insights into your patient's current status with real-time actionable results.

DCA Vantage® Analyzer
Rapid assessment of glycemic control and kidney health

HbA1c
- CLIA-waived

Albumin-to-creatinine ratio (ACR)
- CLIA Moderate Complexity

CLINITEK Status® Connect System
CLIA-waived analyzer for routine urinalysis, including kidney health
- CLINITEK® Microalbumin 2 Strip (ACR)



4600



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

Help your patients reverse the trend

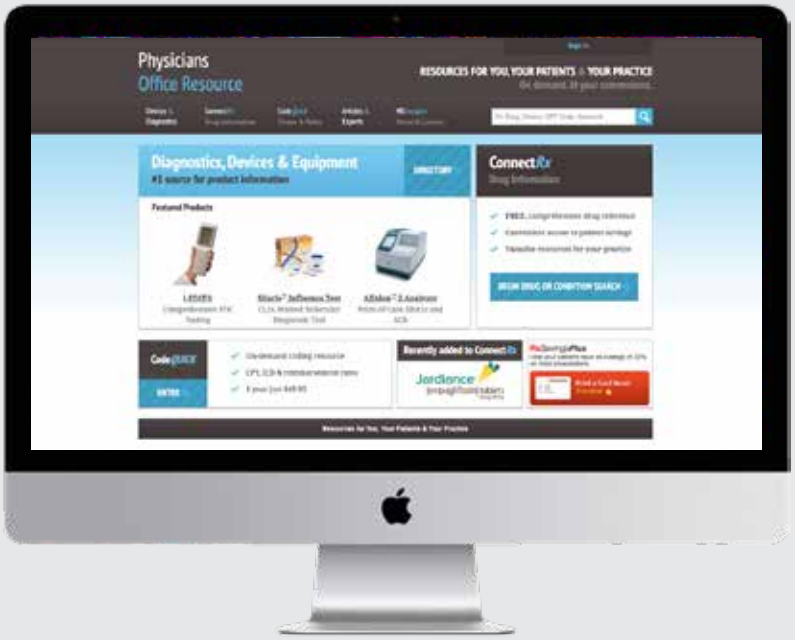
Customize your patient consultations to enhance physician-patient partnership toward improved outcomes.

SIEMENS Healthineers
Learn more

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



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

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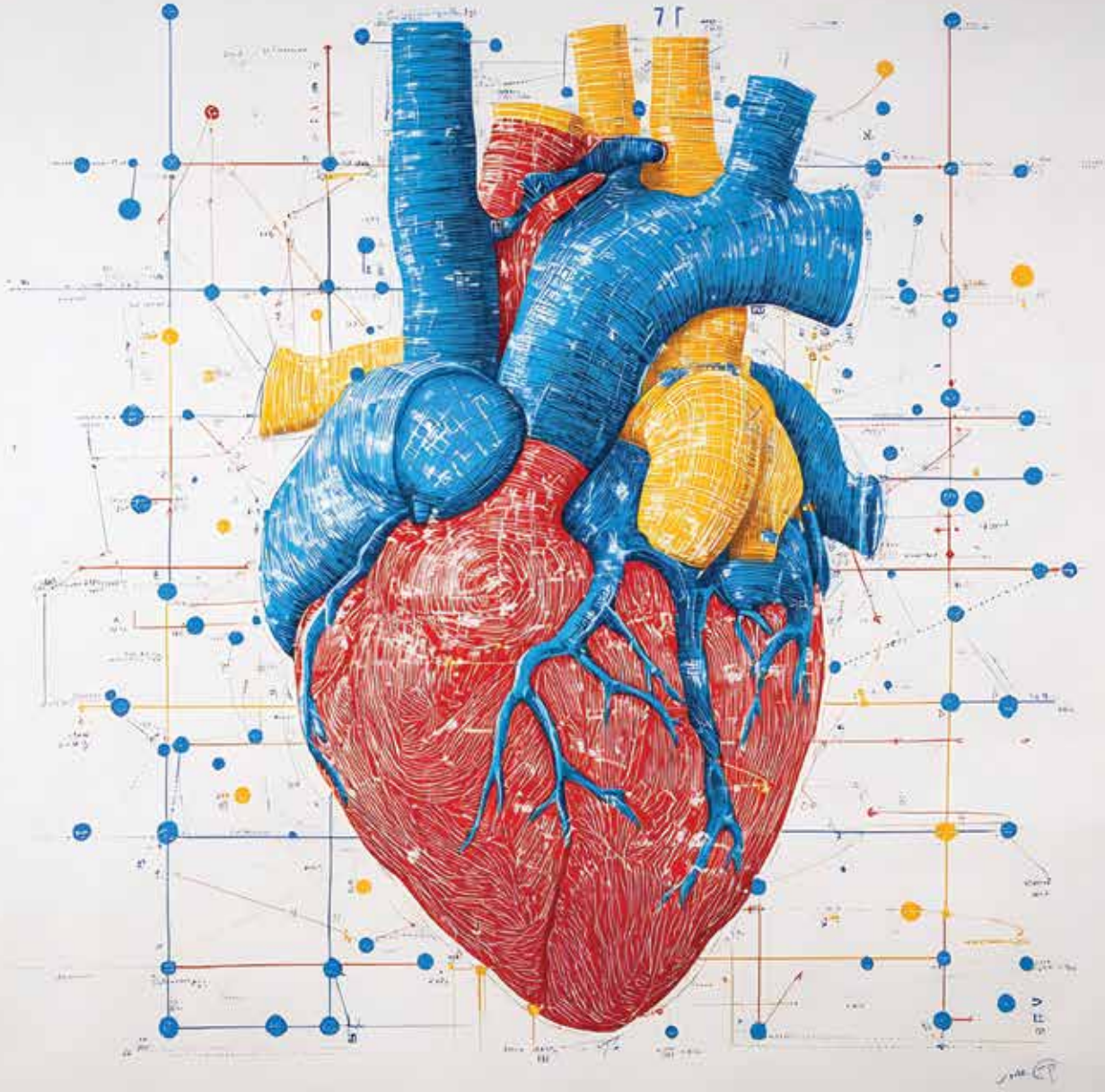
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MDescapes Year of Destinations

Early Detection,

Rapid Diagnosis,

Better Outcomes

4601



4602



4603



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privigen®
Immune Globulin Intravenous (Human), 10% Liquid

PROVEN EFFECTIVE IN PATH, the largest Ig study in CIDP*

Improves functional **ability**
Featuring proline for Ig **stability**



Important Safety Information

Privigen is indicated for the treatment of:

- Primary humoral immunodeficiency (PI)
- Chronic immune thrombocytopenic purpura (ITP) in patients age 15 years and older
- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults
  - Limitation of use: maintenance therapy in CIDP has not been studied for periods longer than 6 months. Individualize duration of treatment beyond 6 months based on patient response.

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin products, including Privigen. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products that contain sucrose. Privigen does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction or renal failure, administer Privigen at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.**

See full prescribing information for complete boxed warning.

Privigen is contraindicated in patients with history of anaphylactic or severe systemic reaction to human immune globulin, in patients with hyperprolinemia, and in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

In patients at risk of developing acute renal failure, monitor urine output and renal function, including blood urea nitrogen and serum creatinine.

Hyperproteinemia, increased serum viscosity, or hyponatremia can occur with Privigen. Infrequently, aseptic meningitis syndrome (AMS) may occur—especially with high doses or rapid infusion.

Hemolysis, either intravascular or due to enhanced red blood cell sequestration, may occur. Risk factors include non-O blood group and high doses. Closely monitor patients for hemolysis and hemolytic anemia.

During and shortly following Privigen infusion, elevations of systolic and diastolic blood pressure (including cases of hypertensive urgency) have been observed. These elevations resolved or significantly improved within hours with oral

PI & ITP SINCE **2007**

>1 MILLION PATIENT-YEARS OF THERAPY[1]

CIDP SINCE **2017**

Proven efficacy:

Overall response rates to Privigen were 61% and 73% in PRIMA and PATH,* respectively†

Rapid response:

Almost all who responded† to Privigen did so after 1–2 maintenance treatments at Weeks 4 and 7*

Demonstrated tolerability:

In both studies*, 97% of adverse reactions were mild or moderate in intensity with 2 and 8 subjects experiencing serious adverse reactions in PRIMA and PATH, respectively‡

Information for you and your patients:

Clinical information, patient resources, and videos at ConnectRx.com

Reference: 1. Data on file. Available from CSL Behring as PVG-006.

*In a prospective, open-label, single-arm, multicenter clinical study (Privigen Impact on Mobility and Autonomy [PRIMA]), 28 subjects with CIDP received a Privigen loading dose of 2 g/kg followed by Privigen maintenance doses of 1 g/kg every 3 weeks for up to 21 weeks with 3-week follow-up. In a second prospective, open-label Privigen prerandomization phase of a multicenter clinical study (Polyneuropathy and Treatment with Hizentra [PATH]), 207 IVIg-pretreated subjects with CIDP received a Privigen loading dose of 2 g/kg followed by up to 4 Privigen maintenance doses of 1 g/kg every 3 weeks for up to 13 weeks.

†Overall response rate was defined as percentage of subjects who experienced at least a 1-point decrease in adjusted INCAT score.

‡Serious adverse reactions included hemolysis (2), exacerbation of CIDP (2), acute rash, diastolic increased blood pressure, hypersensitivity, pulmonary embolism, respiratory failure, and migraine. A total of 4 patients discontinued treatment due to serious adverse reactions.

Visit the Privigen page at ConnectRx.com for more information and to access support resources

anti-hypertensive therapy or observation alone. Check patients for a history of hypertension and monitor blood pressure during this period.

Consider relative risks and benefits before prescribing high-dose regimen for chronic ITP and CIDP in patients at increased risk of thrombosis, hemolysis, acute kidney injury or volume overload. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

Privigen is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

In clinical studies of patients with PI, the most common adverse reactions to Privigen, observed in >5% of subjects, were headache, fatigue, nausea, chills, vomiting, back pain, pain, elevated body temperature, abdominal pain, diarrhea, cough, stomach discomfort, chest pain, joint swelling/effusion, influenza-like illness, pharyngolaryngeal pain, urticaria, and dizziness. Serious adverse reactions were hypersensitivity, chills, fatigue, dizziness, and increased body temperature.

In clinical studies of patients being treated for chronic ITP, the most common adverse reactions, seen in >5% of subjects, were laboratory findings consistent with hemolysis, headache, elevated body temperature, anemia, nausea, and vomiting. A serious adverse reaction was aseptic meningitis syndrome.

In clinical studies of patients being treated for CIDP, the most common adverse reactions observed in >5% of subjects, were headache, asthenia, hypertension, nausea, pain in extremity, hemolysis, influenza-like illness, leukopenia, and rash. Serious adverse reactions were hemolysis, exacerbation of CIDP, acute rash, increased diastolic blood pressure, hypersensitivity, pulmonary embolism, respiratory failure, and migraine.

Treatment with Privigen might interfere with a patient's response to live virus vaccines and could lead to misinterpretation of serologic testing. In patients over 65, do not exceed recommended dose and infuse at the minimum rate practicable.

Please see the following brief summary of prescribing information for Privigen, including boxed warning.

CSL Behring

BRIEF SUMMARY OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PRIVIGEN safely and effectively. See full prescribing information for PRIVIGEN.

PRIVIGEN® Immune Globulin Intravenous (Human), 10% Liquid

Initial U.S. Approval: 2007

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

See full prescribing information for complete boxed warning.

- **Thrombosis may occur with immune globulin products, including PRIVIGEN. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. PRIVIGEN does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction or failure, administer PRIVIGEN at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.**

----------INDICATIONS AND USAGE----------

PRIVIGEN is an Immune Globulin Intravenous (Human), 10% Liquid indicated for the treatment of:

- Primary humoral immunodeficiency (PI)
- Chronic immune thrombocytopenic purpura (ITP) in patients age 15 years and older
- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults

Limitations of Use:

PRIVIGEN maintenance therapy in CIDP has not been studied beyond 6 months.

----------CONTRAINDICATIONS----------

- History of anaphylactic or severe systemic reaction to human immune globulin
- Hyperprolinemia (PRIVIGEN contains the stabilizer L-proline)
- IgA-deficient patients with antibodies to IgA and a history of hypersensitivity

----------WARNINGS AND PRECAUTIONS----------

- IgA-deficient patients with antibodies to IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions.
- Monitor renal function, including blood urea nitrogen and serum creatinine, and urine output in patients at risk of developing acute renal failure.
- Hyperproteinemia, increased serum viscosity, and hyponatremia may occur.
- Aseptic meningitis syndrome (AMS) may occur, especially with high doses or rapid infusion.
- Hemolysis that is either intravascular or due to enhanced red blood cell sequestration may occur. Risk factors include high doses and non-O blood group. Closely monitor patients for hemolysis and hemolytic anemia.
- Elevations of systolic and diastolic blood pressure (including cases of hypertensive urgency) have been observed during/shortly following PRIVIGEN infusion. These blood pressure elevations were resolved or significantly improved within hours with either observation alone or changes in oral anti-hypertensive therapy. Check patients for a history of hypertension and monitor blood pressure during and following PRIVIGEN infusion.
- Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).
- Carefully consider the relative risks and benefits before prescribing the high dose regimen (for chronic ITP and CIDP) in patients at increased risk of thrombosis, hemolysis, acute kidney injury, or volume overload.
- PRIVIGEN is made from human blood and may contain infectious agents, e.g., viruses, the variant Creutzfeldt Jakob disease [vCJD] agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

----------ADVERSE REACTIONS----------

- **PI** – The most common adverse reactions, observed in >5% of study subjects, were headache, fatigue, nausea, chills, vomiting, back pain, pain, elevated body temperature, abdominal pain, diarrhea, cough, stomach discomfort, chest pain, joint swelling/effusion, influenza-like illness, pharyngolaryngeal pain, urticaria, and dizziness. Serious adverse reactions were hypersensitivity, chills, fatigue, dizziness, and increased body temperature.
- **Chronic ITP** – The most common adverse reactions, observed in >5% of study subjects, were laboratory findings consistent with hemolysis (hemoglobin and hematocrit decrease without blood loss in conjunction with positive direct antiglobulin test (DAT) and elevated blood lactate dehydrogenase (LDH) and/or indirect bilirubin), headache, elevated body temperature, anemia, nausea, and vomiting. A serious adverse reaction was aseptic meningitis.
- **CIDP –** The most common adverse reactions observed in >5% of study subjects were headache, asthenia, hypertension, nausea, pain in extremity, hemolysis, influenza like illness, leukopenia, and rash. Serious adverse reactions were hemolysis, exacerbation of CIDP, acute rash, blood pressure diastolic increased, hypersensitivity, pulmonary embolism, respiratory failure, and migraine.

To report SUSPECTED ADVERSE REACTIONS, contact CSL Behring Pharmacovigilance at 1-866-915-6958 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

----------DRUG INTERACTIONS----------

The passive transfer of antibodies may:

- Lead to misinterpretation of the results of serological testing.
- Interfere with the response to live virus vaccines.

----------USE IN SPECIFIC POPULATIONS----------

- Geriatric: In patients over age 65 or in any patient at risk of developing renal insufficiency, do not exceed the recommended dose, and infuse PRIVIGEN at the minimum rate practicable.

See 17 for PATIENT COUNSELING INFORMATION.

Based on March 2022 revision

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CSL Behring

THEY ARE IN YOUR WAITING ROOM RIGHT NOW.

Patients with Peripheral Artery Disease (PAD) who may be facing a heart attack, stroke, amputation, or even death within the next 5 years.

1 OUT OF 3 HAS PAD

Diabetics | Smokers | Over age 65

AND THEY PROBABLY DON'T KNOW IT. ARE *YOU* TESTING THEM?



PERIPHERAL ARTERY DISEASE (PAD) is an often silent condition where narrowed arteries reduce blood flow to the legs, causing symptoms like leg pain, numbness, and slow-healing wounds.

DON'T LET PAD SNEAK UP ON YOU OR THESE PATIENTS.
50% report no symptoms, while those that do attribute their pain to arthritis or "old age".

THESE PATIENTS *TRUST YOU* TO FIND THEIR PAD
before they have a heart attack, stroke, or even die. PAD also leads to significant disability and reduced quality of life.

INTRODUCING ABI-Q: A USER-FRIENDLY SOLUTION FOR EARLY PAD TESTING.

EASY
- No Doppler or vascular anatomy knowledge necessary.
- Can be done in five minutes or less by any staff member.
- Non-invasive, patient-friendly test.

ACCURATE
- Accuracy equal or better than Doppler ABI.
- Useful for diabetics with calcified arteries.

REIMBURSABLE
- **Great ROI:** the typical internist has 800 Medicare patients, per ACP.
- Testing five patients per week can pay for the system in less than two months.
- CPT 93923 (ABI w/exercise), with a national average of $142/exam.





4608

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Newman Medical newman-medical.com | 800-267-5549 | info@newman-medical.com

| 2025 |

MEDICAL CONFERENCES

JANUARY

American Association for Hand Surgery
2025 Annual Meeting
January 14 – 18, 2025
Big Island, Hawaii
978-927-8330
www.handsurgery.org

American Society for Reconstructive Microsurgery Annual Meeting 2025
January 17 – 21, 2025
Big Island, Hawaii
312-456-9579
www.microsurg.org

CANS Annual Meeting 2025
California Association of Neurological Surgeons
January 17 - 19, 2025
Aptos, CA
916-457-2267
www.cans1.org

STS Annual Meeting
Society of Thoracic Surgeons
January 24 – 26, 2025
Los Angeles, CA
312-202-5800
www.sts.org

FEBRUARY

Pri-Med South
February 6 – 8, 2025
Ft. Lauderdale, FL
877-477-4633
www.pri-med.com

ORS 2025 Annual Meeting
Orthopaedic Research Society
February 7 – 11, 2025
Phoenix, AZ
847-823-5770
www.ors.org

Biophysical Society Annual Meeting 2025
Biophysical Society
February 15 – 19, 2025
Los Angeles, CA
240-290-5600
www.biophysics.org/2025meeting#/

SCCM Critical Care Congress
Society of Critical Care Medicine
February 23 – 25, 2025
Orlando, FL
847-827-6888
www.sccm.org

2025 AAAAI Annual Meeting
American Academy of Allergy Asthma & Immunology
February 28 – March 3, 2025
San Diego, CA
414-272-6071
www.annualmeeting.aaaai.org

MARCH

2025 Annual HIMSS Conference & Exhibition
Healthcare Information and Management Systems
March 3 – 6, 2025
Las, Vegas
855-326-8342
www.himssconference.org

AAD Annual Meeting 2025
American Academy of Dermatology
March 7 – 11, 2025
Orlando, FL
866-503-7546
www.aad.org/meetings/annual-meeting

AAOS Annual Meeting 2025
American Academy of Orthopaedic Surgeons
March 10 – 14, 2025
San Diego, CA
847-823-7186
www.aaos.org

SAGES 2025 Annual Meeting
Society of American Gastrointestinal Endoscopic Surgeons
March 12 – 15, 2025
Long Beach, CA
310-437-0544
www.sages2025.org

SGO 2025 Annual Meeting on Women's Cancer
Society of Gynecologic Oncologists
March 14 – 17, 2025
Seattle, WA
312-235-4060
www.sgo.org

The Aesthetic Meeting 2025
The American Society for Aesthetic Plastic Surgery
March 20 – 23, 2025
Austin, TX
800-364-2147
www.surgery.org

AMGA Annual Conference 2025
American Medical Group Association
March 26, – 29, 2025
Grapvine, TX
703-838-0033
www.amga.org

SSO 2025 Annual Cancer Symposium
Society of Surgical Oncology
March 27 – 29, 2025
Tampa, FL
847-427-1400
www.surgonc.org

AAC 2025 Annual Scientific Session and Expo
American College of Cardiology
March 29 – 31, 2025
Chicago, IL
800-253-4636
https://accscientificsession.acc.org

SIR 2025 Annual Scientific Meeting
Society of Interventional Radiology
March 29 – April 2, 2025
Nashville, TN
800-488-7284
www.SIRmeeting.org

APRIL

AAPM Annual Meeting
American Academy of Pain Medicine
April 3 – 6, 2025
Austin, TX
847-375-4731
https://painconnect.org

ACP Internal Medicine Meeting 2025
American College of Physicians
April 3 – 5, 2025
New Orleans, LA
800-523-1546
https://annualmeeting.acponline.org/

AORN Global Surgical Conference & Expo 2025
Association of Perioperative Registered Nurses
April 5 – 8, 2025
Boston, MA
800-755-2676
www.aorn.org

AAN Annual Meeting 2025
American Academy of Neurology
April 5 – 9, 2025
San Deigo, CA
800-879-1960
www.aan.com

Pri-Med Southwest 2025
April 10 – 12, 2025
Houston, TX
877-774-6338
www.pri-med.com

ASLMS 2025 Annual Conference
American Society for Laser Medicine & Surgery
April 24 – 26, 2025
Orlando, FL
877-258-6028
www.aslms.org

AACR Annual Meeting 2025
American Association of Cancer Research
April 25 – 30, 2025
Chicago, IL
866-423-3965
www.aacr.org

AANS Annual Scientific Meeting 2025
American Association of Neurological Surgeons
April 25 – 28, 2025
Boston, MA
847-378-0500
www.aans.org

ARRS Annual Meeting 2025
American Roentgen Ray Society
April 27 – May 1, 2025
San Diego, CA
866-940-2777
www.arrs.org

ASBS Annual Meeting 2025
American Society of Breast Surgeons
April 30 – May 4, 2025
Las Vegas, NV
877-992-5470
www.breastsurgeons.org

MAY

AATS Annual Meeting 2025
American Association for Thoracic Surgery
May 2 – 5, 2025
Seattle, WA
978-927-8330
www.aats.org

ACR Annual Meeting 2025
American College of Radiology
May 3 – 7, 2025
Washington, DC
800-243-7419
www.acr.org/annual-meeting

Pri-Med West 2025
May 8 – 10, 2025
Anaheim, CA
877-774-6338
www.pri-med.com

AACE 2025 Annual Scientific & Clinical Congress
American Association of Clinical Endocrinologists
May 15 – 17, 2025
Orlando, FL
904-353-7878
https://am.aace.com

AANA Annual Congress 2025
Arthroscopy Association of North America
May 8 – 10 2025
Washinton, DC
847-292-2262
www.aana.org

ACOG 2025 Annual Clinical and Scientific Meeting
American College of Obstetricians and Gynecologists
May 16 – 18, 2025
Minneapolis, MN
800- 673-8444
www.acog.org

ATS 2025 International Conference
American Thoracic Society
May 16 – 21, 2025
San Francisco, CA
212-315-8600
conference.thoracic.org

ASNR Annual Meeting & The Foundation of the ASNR Symposium 2025
American Society of Neuroradiology
May 17 – 21, 2025
Philadephia, PA
630-574-0220
www.asnr.org

2025 MEDICAL CONFERENCES

ACSM Annual Meeting
American College of Sports Medicine
May 27 – 30, 2025
Atlanta, GA
317-637-9200
www.acsm.org/annual-meeting/annual-home

JUNE

AMA Annual Meeting of House of Delegates 2025
American Medical Association
June 6 – 10, 2025
Chicago, Illinois
800-621-8335
www.ama-assn.org

APIC Annual Conference 2025
Association for Professional in Infection Control and Epidemiology
June 16 – 18, 2025
Phoenix, AZ
202-789-1890
annual.apic.org

BIO International Convention 2025
Biotechnology Industry Organization
June 16 – 19, 2025
Boston, MA
202-962-6655
bio.org

SNMMI 2025 Annual Meeting
Society of Nuclear Medicine & Molecular Imaging
June 21 – 24, 2025
New Orleans, LA
703-708-9000
www.snmmi.org

JULY

ENDO Annual Meeting 2025
The Endocrine Society
July 12 – 15, 2025
San Francisco, CA
888-363-6274
www.endocrine.org

AAPM Annual Meeting 2025
American Association of Physicists in Medicine
July 27 – 30, 2025
Washington, DC
571-298-1300
www.aapm.org

ADLM 2025 Annual Meeting & Clinical Lab Expo
(Formerly AACC)
Association for Diagnostics & Laboratory Medicine
July 27 – 31, 2025
Chicago, IL
800-892-1400
www.aacc.org

AUGUST

PDA Annual Meeting
Pacific Dermatologic Association
August 22 – 24, 2025
San Diego, CA
888-388-8815
www.pacificderm.org

SEPTEMBER

ACEP Annual Scientific Assembly 2025
American College of Emergency Physicians
September 7 – 10, 2025
Salt Lake City, UT
800-798-1822
www.acep.org

ASTRO Annual Meeting 2025
American Society for Therapeutic Radiology & Oncology
September 28 – October 1, 2025
San Francisco, CA
703-502-1550
www.astro.org

OCTOBER

FMX 2025
American Academy of Family Physicians
October 5 – 9, 2025
Anaheim, CA
800-274-2237
www.aafp.org

The ANESTHESIOLOGY 2025 Annual Meeting
American Society of Anesthesiologists
October 10 – 14, 2025
San Antonio, TX
847-825-5586
www.asahq.org

CNS Annual Meeting 2025
Congress of Neurological Surgeons
October 11 – 15, 2025
Houston, TX
847-240-2500
www.cns.org/annual-meeting

ASHG 2025
American Society of Human Genetics
October 14 – 18, 2025
Boston, MA
301-634-7300
www.ashg.org

AAO Annual Meeting 2025
American Academy of Ophthalmology
October 17 – 20, 2025
Orlando, FL
415-561-8500
www.aao.org

CHEST 2025 ACCP Annual Meeting
American College of Chest Physicians
October 19 – 22, 2025
Chicago, IL
800-343-2227
www.chestnet.org

ISPE Annual Meeting 2025
International Society for Pharmaceutical Engineering
October 26 – 29, 2025
Carlotte, NC
301-364-9201
www.ispe.org

ASRM Scientific Congress and Expo 2025
American Society for Reproductive Medicine
October 25 – 29, 2025
San Antonio, TX
205-978-5000
www.asrm.org

NOVEMBER

ACAAI 2025 Annual Meeting
American College of Allergy Asthma & Immunology
November 6 – 10, 2025
Orlando, FL
847-427-1200
www.acaai.org

NASS 2025 Annual Meeting
North American Spine Society
November 14 – 17, 2025
Denver, CO
630-230-3600
www.spine.org

RSNA 2025
Scientific Assembly and Annual Meeting
Radiological Society of North America
November 30 – December 4, 2025
Chicago, IL
800-381-6660
www.rsna.org



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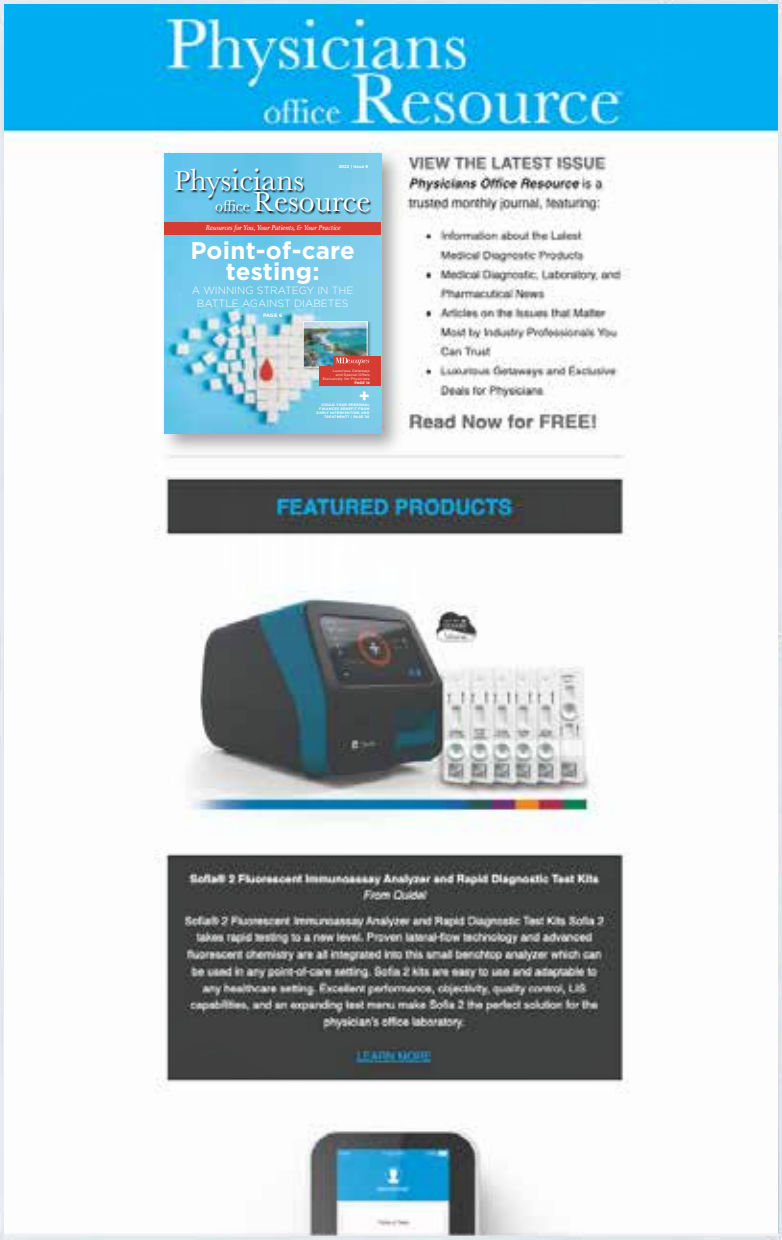
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Bone Disease
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National Breast & Cervical Cancer Early Detection Program
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Celiac Disease Foundation
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www.nationaleatingdisorders.org
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BRUKINSA: MAKE A POWERFUL IMPACT

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hemorrhage

Fatal and serious hemorrhage has occurred in patients with hematological malignancies treated with BRUKINSA. Grade 3 or higher hemorrhage including intracranial and gastrointestinal hemorrhage, hematuria, and hemothorax was reported in 3.8% of patients treated with BRUKINSA in clinical trials, with fatalities occurring in 0.2% of patients. Bleeding of any grade, excluding purpura and petechiae, occurred in 32% of patients.

Bleeding has occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Coadministration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage.

Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days before and after surgery depending upon the type of surgery and the risk of bleeding.

Infections

Fatal and serious infections (including bacterial, viral, or fungal infections) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA. Grade 3 or higher infections occurred in 26% of patients, most commonly pneumonia (7.9%), with fatal infections occurring in 3.2% of patients. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, *pneumocystis jirovecii* pneumonia, and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (21%), thrombocytopenia (8%) and anemia (8%) based on laboratory measurements, developed in patients treated with BRUKINSA. Grade 4 neutropenia occurred in 10% of patients, and Grade 4 thrombocytopenia occurred in 2.5% of patients.

Monitor complete blood counts regularly during treatment and interrupt treatment, reduce the dose, or discontinue treatment as warranted. Treat using growth factor or transfusions, as needed.

Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 14% of patients treated with BRUKINSA. The most frequent second primary malignancy was non-melanoma skin cancers (8%), followed by other solid tumors in 7% of the patients (including melanoma in 1% of patients) and hematologic malignancies (0.7%). Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

Cardiac Arrhythmias

Serious cardiac arrhythmias have occurred in patients treated with BRUKINSA. Atrial fibrillation and atrial flutter were reported in 4.4% of patients treated with BRUKINSA, including Grade 3 or higher cases in 1.9% of patients. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher ventricular arrhythmias were reported in 0.3% of patients.

Monitor for signs and symptoms of cardiac arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea, chest discomfort), manage appropriately, and consider the risks and benefits of continued BRUKINSA treatment.

Hepatotoxicity, Including Drug-Induced Liver Injury

Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of drug-induced liver injury (DILI), has occurred in patients treated with Bruton tyrosine kinase inhibitors, including BRUKINSA.

Evaluate bilirubin and transaminases at baseline and throughout treatment with BRUKINSA. For patients who develop abnormal liver tests after BRUKINSA, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity. If DILI is suspected, withhold BRUKINSA. Upon confirmation of DILI, discontinue BRUKINSA.

Embryo-Fetal Toxicity

Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity, including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for 1 week after the last dose. Advise men to avoid fathering a child during treatment and for 1 week after the last dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

ADVERSE REACTIONS

The most common adverse reactions (≥30%), including laboratory abnormalities, in patients who received BRUKINSA (N=1729) are decreased neutrophil count (51%), decreased platelet count (41%), upper respiratory tract infection (38%), hemorrhage (32%), and musculoskeletal pain (31%).

THE ONLY BTKi APPROVED ACROSS 5 B-CELL MALIGNANCIES[1-3]

CLL

Superiority vs BR in 1L[1]
The only BTKi with superiority vs ibrutinib in 2L[1-3]
Efficacy sustained long term with ~4-year data in 1L and ~3-year data in 2L[4,5]

WM

#1 prescribed BTKi in previously untreated patients[6]

MCL

Powerful responses over ~3 years[1,7]

MZL

The only BTKi approved in marginal zone lymphoma[1-3]

FL*

The first and only BTKi approved in follicular lymphoma[1-3]

*In combination with obinutuzumab.

1L=first line; 2L=second line; BR=bendamustine+rituximab; BTKi=Bruton's tyrosine kinase inhibitor; CLL=chronic lymphocytic leukemia; FL=follicular lymphoma; MCL=mantle cell lymphoma; MZL=marginal zone lymphoma; WM=Waldenström's macroglobulinemia.

INDICATIONS

BRUKINSA is a kinase inhibitor indicated for the treatment of adult patients with:

- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
- Waldenström's macroglobulinemia (WM)
- Mantle cell lymphoma (MCL) who have received at least one prior therapy
- Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen
- Relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy

The MCL, MZL and FL indications are approved under accelerated approval based on overall response rate and durability of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Find out how BRUKINSA leads the way in BTKis at **BRUKINSA.com**

Enroll patients in the BRUKINSA patient support program at **myBeiGene.com**

DRUG INTERACTIONS

CYP3A Inhibitors: When BRUKINSA is coadministered with a strong CYP3A inhibitor, reduce BRUKINSA dose to 80 mg once daily. For coadministration with a moderate CYP3A inhibitor, reduce BRUKINSA dose to 80 mg twice daily.

CYP3A Inducers: Avoid coadministration with strong or moderate CYP3A inducers. Dose adjustment may be recommended with moderate CYP3A inducers.

SPECIFIC POPULATIONS

Hepatic Impairment: The recommended dose of BRUKINSA for patients with severe hepatic impairment is 80 mg orally twice daily.

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

References: 1. BRUKINSA. Package insert. BeiGene USA, Inc.; 2024. **2.** CALQUENCE. Package insert. AstraZeneca Pharmaceuticals LP; 2022. **3.** IMBRUVICA. Package insert. Pharmacyclics LLC, Janssen Biotech, Inc; 2023. **4.** Munir T, Shadman M, Robak T, et al. Zanubrutinib (zanu) vs bendamustine + rituximab (BR) in patients (pts) with treatment-naive chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL): extended follow-up of the SEQUOIA study. Presented at: European Hematology Association (EHA) 2023 Hybrid Congress; June 8-15, 2023. Abstract P639. **5.** Brown JR, Eichhorst B, Lamanna N, et al. Extended follow-up of ALPINE randomized phase 3 study confirms sustained superior progression-free survival of zanubrutinib versus ibrutinib for treatment of relapsed/refractory chronic lymphocytic leukemia and small lymphocytic lymphoma (R/R CLL/SLL). Presented at: American Society of Hematology (ASH) Annual Meeting and Exposition; December 9-12, 2023. **6.** Data on file. BeiGene USA, Inc. **7.** Song Y, Zhou K, Zou D, et al. Zanubrutinib in relapsed/refractory mantle cell lymphoma: long-term efficacy and safety results from a phase 2 study. *Blood*. 2022;139(21):3148-3158.

Brukinsa® zanubrutinib 80 mg capsules

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0923-BRU-PRC-213-r2 7/2024

BRIEF SUMMARY OF PRESCRIBING INFORMATION
FOR BRUKINSA® (zanubrutinib)
SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Mantle Cell Lymphoma

BRUKINSA is indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

This indication is approved under accelerated approval based on overall response rate *[see Clinical Studies (14.1)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

1.2 Waldenström's Macroglobulinemia

BRUKINSA is indicated for the treatment of adult patients with Waldenström's macroglobulinemia (WM) *[see Clinical Studies (14.2)]*.

1.3 Marginal Zone Lymphoma

BRUKINSA is indicated for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti–CD20-based regimen.

This indication is approved under accelerated approval based on overall response rate *[see Clinical Studies (14.3)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

1.4 Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

BRUKINSA is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) *[see Clinical Studies (14.4)]*.

1.5 Follicular Lymphoma

BRUKINSA is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate and durability of response *[see Clinical Studies (14.5)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Hemorrhage

Fatal and serious hemorrhage has occurred in patients with hematological malignancies treated with BRUKINSA. Grade 3 or higher hemorrhage including intracranial and gastrointestinal hemorrhage, hematuria, and hemothorax was reported in 3.8% of patients treated with BRUKINSA in clinical trials, with fatalities occurring in 0.2% of patients. Bleeding of any grade, excluding purpura and petechiae, occurred in 32% of patients.

Bleeding has occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Coadministration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage.

Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days before and after surgery depending upon the type of surgery and the risk of bleeding.

5.2 Infections

Fatal and serious infections (including bacterial, viral, or fungal infections) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA. Grade 3 or higher infections occurred in 26% of patients, most commonly pneumonia (7.9%), with fatal infections occurring in 3.2% of patients. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, *pneumocystis jirovecii* pneumonia, and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

5.3 Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (21%), thrombocytopenia (8%), and anemia (8%) based on laboratory measurements, developed in patients treated with BRUKINSA *[see Adverse Reactions (6.1)]*. Grade 4 neutropenia occurred in 10% of patients, and Grade 4 thrombocytopenia occurred in 2.5% of patients.

Monitor complete blood counts regularly during treatment and interrupt treatment, reduce the dose, or discontinue treatment as warranted *[see Dosage and Administration (2.4)]*. Treat using growth factor or transfusions, as needed.

5.4 Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 14% of patients treated with BRUKINSA. The most frequent second primary malignancy was non-melanoma skin cancers (8%), followed by other solid tumors in 7% of the patients (including melanoma in 1% of patients) and hematologic malignancies (0.7%). Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

5.5 Cardiac Arrhythmias

Serious cardiac arrhythmias have occurred in patients treated with BRUKINSA. Atrial fibrillation and atrial flutter were reported in 4.4% of patients treated with BRUKINSA, including Grade 3 or higher cases in 1.9% of patients. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher ventricular arrhythmias were reported in 0.3% of patients.

Monitor for signs and symptoms of cardiac arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea, chest discomfort), manage appropriately *[see Dosage and Administration (2.4)]*, and consider the risks and benefits of continued BRUKINSA treatment.

5.6 Hepatotoxicity, Including Drug-Induced Liver Injury

Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of drug-induced liver injury (DILI), has occurred in patients treated with Bruton tyrosine kinase inhibitors, including BRUKINSA.

Evaluate bilirubin and transaminases at baseline and throughout treatment with BRUKINSA. For patients who develop abnormal liver tests after BRUKINSA, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity. If DILI is suspected, withhold BRUKINSA. Upon confirmation of DILI, discontinue BRUKINSA.

5.7 Embryo-Fetal Toxicity

Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity, including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for 1 week after the last dose. Advise men to avoid fathering a child during treatment and for 1 week after the last dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus *[see Use in Specific Populations (8.1)]*.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are discussed in more detail in other sections of the labeling:

- Hemorrhage *[see Warnings and Precautions (5.1)]*
- Infections *[see Warnings and Precautions (5.2)]*
- Cytopenias *[see Warnings and Precautions (5.3)]*
- Second Primary Malignancies *[see Warnings and Precautions (5.4)]*
- Cardiac Arrhythmias *[see Warnings and Precautions (5.5)]*
- Hepatotoxicity, including DILI *[see Warnings and Precautions (5.6)]*

6.1 Clinical Trials 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 in the WARNINGS AND PRECAUTIONS reflect exposure to BRUKINSA in nine monotherapy and 2 combination clinical trials, administered at 160 mg twice daily in 1608 patients and at 320 mg once daily in 121 patients. Among these 1729 patients, the median duration of exposure was 27.6 months, 78% of patients were exposed for at least 12 months, and 60% of patients were exposed for at least 24 months.

In this pooled safety population, the most common adverse reactions (≥30%), including laboratory abnormalities, were neutrophil count decreased (51%), platelet count decreased (41%), upper respiratory tract infection (38%), hemorrhage (32%), and musculoskeletal pain (31%).

Mantle Cell Lymphoma (MCL)

The safety of BRUKINSA was evaluated in 118 patients with MCL who received at least one prior therapy in two single-arm clinical trials, BGB-3111-206 [NCT03206970] and BGB-3111-AU-003 [NCT02343120] *[see Clinical Studies (14.1)]*. The median age of patients who received BRUKINSA in studies BGB-3111-206 and BGB-3111-AU-003 was 62 years (range: 34 to 86), 75% were male, 75% were Asian, 21% were White, and 94% had an ECOG performance status of 0 to 1. Patients had a median of 2 prior lines of therapy (range: 1 to 4). The BGB-3111-206 trial required a platelet count ≥75 × 10^9/L and an absolute neutrophil count ≥1 × 10^9/L independent of growth factor support, hepatic enzymes ≤2.5 × upper limit of normal, total bilirubin ≤1.5 × ULN. The BGB-3111-AU-003 trial required a platelet count ≥50 × 10^9/L and an absolute neutrophil count ≥1 × 10^9/L independent of growth factor support, hepatic enzymes ≤3 × upper limit of normal, total bilirubin ≤1.5 × ULN. Both trials required a creatinine clearance (CLcr) ≥30 mL/min. Both trials excluded patients with prior allogeneic hematopoietic stem cell transplant, exposure to a BTK inhibitor, known infection with HIV, and serologic evidence of active hepatitis B or hepatitis C infection, and patients requiring strong CYP3A inhibitors or strong CYP3A inducers. Patients received BRUKINSA 160 mg twice daily or 320 mg once daily. Among patients receiving BRUKINSA, 79% were exposed for 6 months or longer, and 68% were exposed for greater than one year.

Fatal adverse reactions within 30 days of the last dose of BRUKINSA occurred in 8 (7%) of 118 patients with MCL. Fatal cases included pneumonia in 2 patients and cerebral hemorrhage in one patient.

Serious adverse reactions were reported in 36 patients (31%). The most frequent serious adverse reactions that occurred were pneumonia (11%) and hemorrhage (5%).

Of the 118 patients with MCL treated with BRUKINSA, 8 (7%) patients discontinued treatment due to adverse reactions in the trials. The most frequent adverse reaction leading to treatment discontinuation was pneumonia (3.4%). One (0.8%) patient experienced an adverse reaction leading to dose reduction (hepatitis B).

Table 3 summarizes the adverse reactions in BGB-3111-206 and BGB-3111-AU-003.

Table 3: Adverse Reactions (≥10%) in Patients Receiving BRUKINSA in BGB-3111-206 and BGB-3111-AU-003 Trials

Body System	Adverse Reaction	Percent of Patients (N=118)	
		All Grades %	Grade 3 or Higher %
Infections and infestations	Upper respiratory tract infection[a]	39	0
	Pneumonia[b]	15	10[c]
	Urinary tract infection	11	0.8
Skin and subcutaneous tissue disorders	Rash[d]	36	0
	Bruising[e]	14	0
Gastrointestinal disorders	Diarrhea	23	0.8
	Constipation	13	0
Vascular disorders	Hypertension	12	3.4
	Hemorrhage[f]	11	3.4[c]
Musculoskeletal and connective tissue disorders	Musculoskeletal pain[g]	14	3.4
Respiratory, thoracic, and mediastinal disorders	Cough	12	0

[a] Upper respiratory tract infection includes upper respiratory tract infection, upper respiratory tract infection viral.
[b] Pneumonia includes pneumonia, pneumonia fungal, pneumonia cryptococcal, pneumonia streptococcal, atypical pneumonia, lung infection, lower respiratory tract infection, lower respiratory tract infection bacterial, lower respiratory tract infection viral.
[c] Includes fatal adverse reaction.
[d] Rash includes all related terms containing rash.
[e] Bruising includes all related terms containing bruise, bruising, contusion, ecchymosis.
[f] Hemorrhage includes all related terms containing hemorrhage, hematoma.
[g] Musculoskeletal pain includes musculoskeletal pain, musculoskeletal discomfort, myalgia, back pain, arthralgia, arthritis.

Other clinically significant adverse reactions that occurred in <10% of patients with mantle cell lymphoma include major hemorrhage (defined as ≥ Grade 3 hemorrhage or CNS hemorrhage of any grade) (5%) and headache (4.2%).

Table 4: Selected Laboratory Abnormalities[a] (>20%) in Patients with MCL in Studies BGB-3111-206 and BGB-3111-AU-003

Laboratory Parameter	Percent of Patients (N=118)	
	All Grades (%)	Grade 3 or 4 (%)
Hematologic abnormalities		
Neutrophils decreased	45	20
Lymphocytosis[b]	41	16
Platelets decreased	40	7
Hemoglobin decreased	27	6
Chemistry abnormalities		
Blood uric acid increased	29	2.6
ALT increased	28	0.9
Bilirubin increased	24	0.9

[a] Based on laboratory measurements.
[b] Asymptomatic lymphocytosis is a known effect of BTK inhibition.

Waldenström's Macroglobulinemia (WM)

The safety of BRUKINSA was investigated in two cohorts of Study BGB-3111-302 (ASPEN). Cohort 1 included 199 patients with MYD88 mutation (*MYD88^{MUT}*) WM, randomized to and treated with either BRUKINSA (101 patients) or ibrutinib (98 patients). The trial also included a non-randomized arm, Cohort 2, with 26 wild type MYD88 (*MYD88^{WT}*) WM patients and 2 patients with unknown MYD88 status *[see Clinical Studies (14.2)]*.

Among patients who received BRUKINSA, 93% were exposed for 6 months or longer, and 89% were exposed for greater than 1 year.

In Cohort 1 of the ASPEN study safety population (N=101), the median age of patients who received BRUKINSA was 70 years (45-87 years old); 67% were male, 86% were White, 4% were Asian, and 10% were not reported (unknown race). In Cohort 2 of the ASPEN study safety population (N=28), the median age of patients who received BRUKINSA was 72 (39-87 years old); 50% were male, 96% were White, and 4% were not reported (unknown race).

In Cohort 1, serious adverse reactions occurred in 44% of patients who received BRUKINSA. Serious adverse reactions in >2% of patients included influenza (3%), pneumonia (4%), neutropenia and neutrophil count decreased (3%), hemorrhage (4%), pyrexia (3%), and febrile neutropenia (3%). In Cohort 2, serious adverse reactions occurred in 39% of patients. Serious adverse reactions in >2 patients included pneumonia (14%).

Permanent discontinuation of BRUKINSA due to an adverse reaction occurred in 2% of patients in Cohort 1 and included hemorrhage (1 patient), neutropenia and neutrophil count decreased (1 patient); in Cohort 2, permanent discontinuation of BRUKINSA due to an adverse reaction occurred in 7% of patients and included subdural hemorrhage (1 patient) and diarrhea (1 patient).

Dosage interruptions of BRUKINSA due to an adverse reaction occurred in 32% of patients in Cohort 1 and in 29% in Cohort 2. Adverse reactions which required dosage interruption in >2% of patients included neutropenia, vomiting, hemorrhage, thrombocytopenia, and pneumonia in Cohort 1. Adverse reactions leading to dosage interruption in >2 patients in Cohort 2 included pneumonia and pyrexia.

Dose reductions of BRUKINSA due to an adverse reaction occurred in 11% of patients in Cohort 1 and in 7% in Cohort 2. Adverse reactions which required dose reductions in >2% of patients included neutropenia in Cohort 1. Adverse reaction leading to dose reduction occurred in 2 patients in Cohort 2 (each with one event: diarrhea and pneumonia).

Table 5 summarizes the adverse reactions in Cohort 1 in ASPEN.

Table 5: Adverse Reactions (≥10%) Occurring in Patients with WM Who Received BRUKINSA in Cohort 1

Body System	Adverse Reaction	BRUKINSA (N=101)		Ibrutinib (N=98)	
		All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Infections and infestations	Upper respiratory tract infection[a]	44	0	40	2
	Pneumonia[b]	12	4	26	10
	Urinary tract infection	11	0	13	2
Gastrointestinal disorders	Diarrhea	22	3	34	2
	Nausea	18	0	13	1
	Constipation	16	0	7	0
	Vomiting	12	0	14	1
General disorders	Fatigue[c]	31	1	25	1
	Pyrexia	16	4	13	2
	Edema peripheral	12	0	20	0
Skin and subcutaneous tissue disorders	Bruising[d]	20	0	34	0
	Rash[e]	29	0	32	0
	Pruritus	11	1	6	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain[f]	45	9	39	1
	Muscle spasms	10	0	28	1
Nervous system disorders	Headache	18	1	14	1
	Dizziness	13	1	12	0
Respiratory, thoracic, and mediastinal disorders	Cough	16	0	18	0
	Dyspnea	14	0	7	0
Vascular disorders	Hemorrhage[g]	42	4	43	9
	Hypertension	14	9	19	14

[a] Upper respiratory tract infection includes upper respiratory tract infection, laryngitis, nasopharyngitis, sinusitis, rhinitis, viral upper respiratory tract infection, pharyngitis, rhinovirus infection, upper respiratory tract congestion.
[b] Pneumonia includes lower respiratory tract infection, lung infiltration, pneumonia, pneumonia aspiration, pneumonia viral.
[c] Fatigue includes asthenia, fatigue, lethargy.
[d] Bruising includes all related terms containing bruise, contusion, or ecchymosis.
[e] Rash includes all related terms rash, maculo-papular rash, erythema, rash erythematous, drug eruption, dermatitis allergic, dermatitis atopic, rash pruritic, dermatitis, photodermatoses, dermatitis acneiform, stasis dermatitis, vasculitic rash, eyelid rash, urticaria, skin toxicity.
[f] Musculoskeletal pain includes back pain, arthralgia, pain in extremity, musculoskeletal pain, myalgia, bone pain, spinal pain, musculoskeletal chest pain, neck pain, arthritis, musculoskeletal discomfort.
[g] Hemorrhage includes epistaxis, hematuria, conjunctival hemorrhage, hematoma, rectal hemorrhage, periorbital hemorrhage, mouth hemorrhage, post procedural hemorrhage, hemoptysis, skin hemorrhage, hemorrhoidal hemorrhage, ear hemorrhage, eye hemorrhage, hemorrhagic diathesis, periorbital hematoma, subdural hemorrhage, wound hemorrhage, gastric hemorrhage, lower gastrointestinal hemorrhage, spontaneous hematoma, traumatic hematoma, traumatic intracranial hemorrhage, tumor hemorrhage, retinal hemorrhage, hematochezia, diarrhea hemorrhagic, hemorrhage, melena, post-procedural hematoma, subdural hematoma, anal hemorrhage, hemorrhagic disorder, pericardial hemorrhage, postmenopausal hemorrhage, stoma site hemorrhage, subarachnoid hemorrhage.

Clinically relevant adverse reactions in <10% of patients who received BRUKINSA included localized infection, atrial fibrillation or atrial flutter, and hematuria.

Table 6 summarizes the laboratory abnormalities in ASPEN.

Table 6: Select Laboratory Abnormalities[a] (≥20%) that Worsened from Baseline in Patients with WM Who Received BRUKINSA in Cohort 1

Laboratory Abnormality	BRUKINSA[b]		Ibrutinib[b]	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Hematologic abnormalities				
Neutrophils decreased	50	24	34	9
Platelets decreased	35	8	39	5
Hemoglobin decreased	20	7	20	7
Chemistry abnormalities				
Glucose increased	45	2.3	33	2.3
Creatinine increased	31	1	21	1
Calcium decreased	27	2	26	0
Potassium increased	24	2	12	0
Phosphate decreased	20	3.1	18	0
Urate increased	16	3.2	34	6
Bilirubin increased	12	1	33	1

[a] Based on laboratory measurements.
[b] The denominator used to calculate the rate varied from 86 to 101 based on the number of patients with a baseline value and at least one post-treatment value.

Marginal Zone Lymphoma

The safety of BRUKINSA was evaluated in 88 patients with previously treated MZL in two single-arm clinical studies, BGB-3111-214 and BGB-3111-AU-003 *[see Clinical Studies (14.3)]*. The trials required an absolute neutrophil count ≥1 × 10^9/L, platelet count ≥50 or ≥75 × 10^9/L and adequate hepatic function and excluded patients requiring a strong CYP3A inhibitor or inducer. Patients received BRUKINSA 160 mg twice daily (97%) or 320 mg once daily (3%). The median age in both studies combined was 70 years (range: 37 to 95), 52% were male, 64% were White, and 19% were Asian. Most patients (92%) had an ECOG performance status of 0 to 1. Eighty percent received BRUKINSA for 6 months or longer, and 67% received treatment for more than one year.

Two fatal adverse reactions (2.3%) occurred within 30 days of the last dose of BRUKINSA, including myocardial infarction and a Covid-19–related death.

Serious adverse reactions occurred in 40% of patients. The most frequent serious adverse reactions were pyrexia (8%) and pneumonia (7%).

Adverse reactions lead to treatment discontinuation in 6% of patients, dose reduction in 2.3%, and dose interruption in 34%. The leading cause of dose modification was respiratory tract infections (13%).

Table 7 summarizes selected adverse reactions in BGB-3111-214 and BGB-3111-AU-003.

Table 7: Adverse Reactions Occurring in ≥10% Patients with MZL Who Received BRUKINSA

Body System	Adverse Reaction	BRUKINSA (N=88)	
		All Grades (%)	Grade 3 or 4 (%)
Infections and infestations	Upper respiratory tract infection[a]	26	3.4
	Urinary tract infection[b]	11	2.3
	Pneumonia[c,d]	10	6
Gastrointestinal disorders	Diarrhea[e]	25	3.4
	Abdominal pain[f]	14	2.3
	Nausea	13	0
Skin and subcutaneous tissue disorders	Bruising[g]	24	0
	Rash[h]	21	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain[i]	27	1.1
Vascular disorders	Hemorrhage[j]	23	1.1
General disorders	Fatigue[k]	21	2.3
Respiratory, thoracic, and mediastinal disorders	Cough[l]	10	0

[a] Upper respiratory tract infection includes upper respiratory tract infection, nasopharyngitis, sinusitis, tonsillitis, rhinitis, viral upper respiratory tract infection.
[b] Urinary tract infection includes urinary tract infection, cystitis, Escherichia urinary tract infection, pyelonephritis, cystitis.
[c] Pneumonia includes COVID-19 pneumonia, pneumonia, bronchopulmonary aspergillosis, lower respiratory tract infection, organizing pneumonia.
[d] Includes 2 fatalities from COVID-19 pneumonia.
[e] Diarrhea includes diarrhea and diarrhea hemorrhagic.
[f] Abdominal pain includes abdominal pain, abdominal pain upper, abdominal discomfort.
[g] Bruising includes contusion, ecchymosis, increased tendency to bruise, post procedural contusion.
[h] Rash includes rash, rash maculo-papular, rash pruritic, dermatitis, dermatitis allergic, dermatitis atopic, dermatitis contact, drug reaction with eosinophilia and systemic symptoms, erythema, photosensitivity reaction, rash erythematous, rash papular, seborrheic dermatitis.
[i] Musculoskeletal pain includes back pain, arthralgia, musculoskeletal pain, myalgia, pain in extremity, musculoskeletal chest pain, bone pain, musculoskeletal discomfort, neck pain.
[j] Hemorrhage includes epistaxis, hematuria, hemorrhoidal hemorrhage, hematoma, hemoptysis, conjunctival hemorrhage, diarrhea hemorrhagic, hemorrhage urinary tract, mouth hemorrhage, pulmonary hematoma, subcutaneous hematoma, gingival bleeding, melena, upper gastrointestinal hemorrhage.
[k] Fatigue includes fatigue, lethargy, asthenia.
[l] Cough includes cough and productive cough.

Clinically relevant adverse reactions in <10% of patients who received BRUKINSA included peripheral neuropathy, second primary malignancies, dizziness, edema, headache, petechiae, purpura, and atrial fibrillation or flutter.

Table 8 summarizes select laboratory abnormalities.

Table 8: Select Laboratory Abnormalities (≥20%) that Worsened from Baseline in Patients with MZL

Laboratory Abnormality[a]	BRUKINSA	
	All Grades (%)	Grade 3 or 4 (%)
Hematologic abnormalities		
Neutrophils decreased	43	15
Platelets decreased	33	10
Lymphocytes decreased	32	8
Hemoglobin decreased	26	6
Chemistry abnormalities		
Glucose increased	54	4.6
Creatinine increased	34	1.1
Phosphate decreased	27	2.3
Calcium decreased	23	0
ALT increased	22	1.1

[a] The denominator used to calculate the rate varied from 87 to 88 based on the number of patients with a baseline value and at least one post-treatment value.

Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

The safety data described below reflect exposure to BRUKINSA (160 mg twice daily) in 675 patients with CLL from two randomized controlled clinical trials *[see Clinical Studies (14.4)]*. The trials required patients to be unsuitable for fludarabine, cyclophosphamide, and rituximab (FCR) therapy defined as age ≥65 years, or age 18 to <65 years with either a total Cumulative Illness Rating Scale (CIRS) >6, CLcr 30 to 69 mL/min, or history of serious or frequent infections. The trial excluded patients with AST or ALT ≥2 times the upper limit of normal (ULN) or bilirubin ≥3 times (ULN) and patients requiring a strong CYP3A inhibitor or inducer.

SEQUOIA

The safety of BRUKINSA monotherapy in patients with previously untreated CLL/SLL was evaluated in a randomized, multicenter, open-label, actively controlled trial *[see Clinical Studies (14.4)]*. Patients without deletion of chromosome 17p13.1 (17p deletion) (Cohort 1) received either BRUKINSA 160 mg twice daily until disease progression or unacceptable toxicity (n=240) or bendamustine plus rituximab (BR) for 6 cycles (n=227). Bendamustine was dosed at 90 mg/m^2/day intravenously on the first 2 days of each cycle, and rituximab was dosed at 375 mg/m^2 on day 1 of Cycle 1 and 500 mg/m^2 on day 1 of Cycles 2 to 6.

Additionally, the same BRUKINSA regimen was evaluated in 111 patients with previously untreated CLL/SLL with 17p deletion in a non-randomized single arm (Cohort 2).

Randomized Cohort: Previously Untreated CLL/SLL without 17p Deletion

In patients with previously untreated CLL/SLL without 17p deletion, the median age was 70, 62% were male, 89% were White, 2% were Asian, and 2% were Black. Most patients (93%) had an ECOG performance status of 0 to 1.

The median duration of exposure to BRUKINSA was 26 months, with 71% exposed for more than 2 years.

Serious adverse reactions occurred in 36% of patients who received BRUKINSA. Serious adverse reactions that occurred in ≥5% of patients were COVID-19, pneumonia, and second primary malignancy (5% each). Fatal adverse reactions occurred in 11 (4.6%) patients with the leading cause of death being COVID-19 (2.1%).

Adverse reactions led to permanent discontinuation of BRUKINSA in 8% of patients, dose reduction in 8%, and dose interruption in 46%. The most common adverse reactions leading to permanent discontinuation were second primary malignancy and COVID-19. The leading causes of dose modification (≥5% of all patients) were respiratory infections (COVID-19, pneumonia) and hemorrhage.

Table 9 summarizes select adverse reactions in this randomized cohort.

Table 9: Adverse Reactions in ≥10% Patients with Previously Untreated CLL/SLL without 17p Deletion in SEQUOIA

System Organ Class Preferred Term	CLL/SLL without 17p deletion			
	BRUKINSA (N=240)		BR (N=227)	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain[a]	33	1.7	17	0.4
Infections and infestations				
Upper respiratory tract infection[b]	28	1.3	15	0.9
Pneumonia[c]	13*	5	8†	4
Vascular disorders				
Hemorrhage[d]	27*	4	4	0.4
Hypertension[e]	14	7	5	2.6
Skin and subcutaneous tissue disorders				
Rash[f]	24	1.3	30	5
Bruising[g]	24	0	2.6	0
Respiratory, thoracic, and mediastinal disorders				
Cough[e]	15	0	10	0
Gastrointestinal disorders				
Diarrhea	14	0.8	12†	0.9
Constipation	10	0.4	18	0
Nausea	10	0	33	1.3
General disorders				
Fatigue[h]	14	1.3	21	1.8
Neoplasms				
Second primary malignancy[i]	13*	6	1.3	0.4
Nervous system disorders				
Headache[e]	12	0	8	0
Dizziness[j]	11	0.8	5	0

* Includes 3 fatal outcomes.

† Includes 2 fatal outcomes.

[a] Musculoskeletal pain: musculoskeletal pain, arthralgia, back pain, pain in extremity, myalgia, neck pain, spinal pain, musculoskeletal discomfort, bone pain.

[b] Upper respiratory tract infection: upper respiratory tract infection, nasopharyngitis, sinusitis, rhinitis, pharyngitis, upper respiratory tract congestion, laryngitis, tonsillitis and upper respiratory tract inflammation, and related terms.

[c] Pneumonia: pneumonia, COVID-19 pneumonia, lower respiratory tract infection, lung infiltration, and related terms including specific types of infection.

[d] Hemorrhage: all terms containing hematoma, hemorrhage, hemorrhagic, and related terms indicative of bleeding.

[e] Includes multiple similar adverse reaction terms.

[f] Rash: Rash, dermatitis, drug eruption, and related terms.

[g] Bruising: all terms containing bruise, bruising, contusion, or ecchymosis.

[h] Fatigue: fatigue, asthenia, and lethargy.

[i] Second primary malignancy: includes non-melanoma skin cancer, malignant solid tumors (including lung, renal, genitourinary, breast, ovarian, and rectal), and chronic myeloid leukemia.

[j] Dizziness: dizziness and vertigo.

Other clinically significant adverse reactions occurring in <10% of BRUKINSA recipients in this cohort included COVID-19 (9%), edema (8%), abdominal pain (8%), urinary tract infection (7%), and atrial fibrillation or flutter (3.3%).

Table 10 summarizes select laboratory abnormalities in this cohort.

Table 10: Select Laboratory Abnormalities (≥20%) that Worsened from Baseline in Patients with Previously Untreated CLL/SLL without 17p Deletion in SEQUOIA

Laboratory Abnormality[a]	BRUKINSA		BR	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Hematologic abnormalities				
Neutrophils decreased	37	15	80	53
Hemoglobin decreased	29	2.5	66	8
Platelets decreased	27	1.7	61	11
Leukocytes increased	21[b]	21	0.4	0.4
Chemistry abnormalities				
Glucose increased[c]	55	7	67	10
Creatinine increased	22	0.8	18	0.4
Magnesium increased	22	0	14	0.4
Alanine aminotransferase increased	21	2.1	23	2.2

[a] The denominator used to calculate the rate was 239 in the BRUKINSA arm and 227 in the BR arm, based on the number of patients with a baseline value and at least one post-treatment value. Grading is based on NCI CTCAE criteria.

[b] Lymphocytes increased in 15%.

[c] Nonfasting conditions.

Single-Arm Cohort: Previously Untreated CLL/SLL and 17p Deletion

In 111 patients with previously untreated, 17p del CLL/SLL, the median age was 70, 71% were male, 95% were White, and 1% were Asian. Most patients (87%) had an ECOG performance status of 0 to 1. The median duration of exposure to BRUKINSA was 30 months.

Fatal adverse reactions occurred in 3 (2.7%) patients, including pneumonia, renal insufficiency, and aortic dissection (1 patient each).

Serious adverse reactions occurred in 41% of patients treated with BRUKINSA. Serious adverse reactions reported in ≥5% of patients were pneumonia (8%) and second primary malignancy (7%).

Adverse reactions led to treatment discontinuation in 5% of patients, dose reduction in 5%, and dose interruption in 51%. The leading causes of dose modification (≥5% of all patients) were pneumonia, neutropenia, second primary malignancy, and diarrhea.

Table 11 summarizes select adverse reactions in this cohort.

Table 11: Adverse Reactions in ≥10% of Patients with Previously Untreated CLL/SLL and 17p Deletion in SEQUOIA

System Organ Class Preferred Term	CLL/SLL with 17p Deletion	
	BRUKINSA (N=111)	
	All Grades (%)	Grade 3 or 4 (%)
Infections and infestations		
Upper respiratory tract infection[a]	38	0
Pneumonia[b]	20*	8
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[c]	38	2.7
Skin and subcutaneous tissue disorders		
Rash[d]	28	0
Bruising[e]	26	0.9
Vascular disorders		
Hemorrhage[f]	28	4.5
Hypertension[g]	11	5.4

Table 11: Adverse Reactions in ≥10% of Patients with Previously Untreated CLL/SLL and 17p Deletion in SEQUOIA (Continued)

System Organ Class Preferred Term	CLL/SLL with 17p Deletion BRUKINSA (N=111)	
	All Grades (%)	Grade 3 or 4 (%)
Neoplasms		
Second primary malignancy[h]	22†	6
Gastrointestinal disorders		
Diarrhea	18	0.9
Nausea	16	0
Constipation	15	0
Abdominal pain[g]	12	1.8
Respiratory, thoracic, and mediastinal disorders		
Cough[g]	18	0
Dyspnea[g]	13	0
General disorders and administration site conditions		
Fatigue[i]	14	0.9
Nervous system disorders		
Headache	11	1.8

* Includes 1 fatal outcome.
† Includes non-melanoma skin cancer in 13%.
[a] Upper respiratory tract infection: upper respiratory tract infection, nasopharyngitis, sinusitis, rhinitis, pharyngitis, upper respiratory tract congestion, upper respiratory tract inflammation, viral upper respiratory tract infection, and related terms.
[b] Pneumonia: pneumonia, COVID-19 pneumonia, lower respiratory tract infection, and related terms including specific types of infection.
[c] Musculoskeletal pain: musculoskeletal pain, arthralgia, back pain, pain in extremity, myalgia, neck pain, bone pain.
[d] Rash: Rash, dermatitis, toxic skin eruption, and related terms.
[e] Bruising: all terms containing bruise, bruising, contusion, or ecchymosis.
[f] Hemorrhage: all terms containing hematoma, hemorrhage, hemorrhagic, and related terms indicative of bleeding.
[g] Includes multiple similar adverse reaction terms.
[h] Second primary malignancy: includes non-melanoma skin cancer, malignant solid tumors (including bladder, lung, renal, breast, prostate, ovarian, pelvis, and ureter), and malignant melanoma.
[i] Fatigue: fatigue, asthenia, and lethargy.

Clinically significant adverse reactions occurring in <10% of BRUKINSA recipients in this cohort included urinary tract infection (8%), edema (7%), atrial fibrillation or flutter (4.5%), and COVID-19 (3.6%).

Table 12 summarizes select laboratory abnormalities in this cohort.

Table 12: Select Laboratory Abnormalities (≥20%) that Worsened from Baseline in Patients with Previously Untreated CLL/SLL and 17p Deletion in SEQUOIA

Laboratory Abnormality[a]	BRUKINSA	
	All Grades (%)	Grade 3 or 4 (%)
Hematologic abnormalities		
Neutrophils decreased	42	19[b]
Hemoglobin decreased	26	3.6
Platelets decreased	23	0.9
Chemistry abnormalities		
Glucose increased[c]	52	6
Magnesium increased	31	0
Creatinine increased	27	0.9

[a] The denominator used to calculate the rate varied from 110 to 111 based on the number of patients with a baseline value and at least one post-treatment value. Grading is based on NCI CTCAE criteria.
[b] Grade 4, 9%.
[c] Non-fasting conditions.

ALPINE

The safety of BRUKINSA monotherapy was evaluated in patients with previously treated CLL/SLL in a randomized, multicenter, open-label, actively controlled trial *[see Clinical Studies (14.4)]*. In ALPINE, 324 patients received BRUKINSA monotherapy, 160 mg orally twice daily and 324 patients received ibrutinib monotherapy, 420 mg orally daily until disease progression or unacceptable toxicity.

In ALPINE, the median duration of exposure was 24 months for BRUKINSA. Adverse reactions leading to death in the BRUKINSA arm occurred in 24 (7%) patients. Adverse reactions leading to death that occurred in >1% of patients were pneumonia (2.8%) and COVID-19 infection (1.9%).

One hundred and four patients in the BRUKINSA arm (32%) reported ≥1 serious adverse reaction. Serious adverse reactions occurring in ≥5% of patients were pneumonia (10%), COVID-19 (7%), and second primary malignancies (5%).

Adverse reactions led to treatment discontinuation in 13% of patients, dose reduction in 11%, and dose interruption in 42%. The leading cause of treatment discontinuation was pneumonia. The leading causes of dose modification (≥5% of all patients) were respiratory infections (COVID-19, pneumonia) and neutropenia.

Table 13 summarizes select adverse reactions in ALPINE.

Table 13: Adverse Reactions in ≥10% of Patients with Relapsed or Refractory CLL/SLL Who Received BRUKINSA in ALPINE

System Organ Class Preferred Term	BRUKINSA (N=324)		Ibrutinib (N=324)	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Infections and infestations				
Upper respiratory tract infection[a]	27	1.2	22	1.2
Pneumonia[b]	18*	9	19†	11
COVID-19[c]	14*	7	10†	4.6
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain[d]	26	0.6	28	0.6
Vascular disorders				
Hemorrhage[e]	24*	2.5	26†	3.7
Hypertension[f]	19	13	20	13
Skin and subcutaneous tissue disorders				
Rash[g]	20	1.2	21	0.9
Bruising[h]	16	0	14	0
Gastrointestinal disorders				
Diarrhea	14	1.5	22	0.9
General disorders				
Fatigue[i]	13	0.9	14	0.9
Respiratory, thoracic, and mediastinal disorders				
Cough[f]	11	0.3	11	0
Nervous system disorders				
Dizziness[f]	10	0	7	0

* Includes fatal outcomes: pneumonia (9 patients), COVID-19 (8 patients), and hemorrhage (1 patient).
† Includes fatal outcomes: pneumonia (10 patients), COVID-19 (9 patients), and hemorrhage (2 patients).
[a] Upper respiratory tract infection: upper respiratory tract infection, sinusitis, pharyngitis, rhinitis, nasopharyngitis, laryngitis, tonsillitis, and related terms.
[b] Pneumonia: Pneumonia, COVID-19 pneumonia, lower respiratory tract infection, lung infiltration, and related terms including specific types of infection.
[c] COVID-19: COVID-19, COVID-19 pneumonia, postacute COVID-19 syndrome, SARS-CoV-2 test positive.
[d] Musculoskeletal pain: musculoskeletal pain, arthralgia, back pain, pain in extremity, myalgia, neck pain, spinal pain, bone pain, and musculoskeletal discomfort.
[e] Hemorrhage: all terms containing hematoma, hemorrhage, hemorrhagic, and related terms indicative of bleeding.
[f] Includes multiple similar adverse reaction terms.
[g] Rash: Rash, Dermatitis, and related terms.
[h] Bruising: all terms containing bruise, bruising, contusion, or ecchymosis.
[i] Fatigue: asthenia, fatigue, lethargy.

Clinically relevant adverse reactions in <10% of patients who received BRUKINSA included urinary tract infection (9%), supraventricular arrhythmias (9%) including atrial fibrillation or flutter (4.6%), abdominal pain (8%), headache (8%), pruritus (6.2%), constipation (5.9%), and edema (4.6%).

Table 14 summarizes select laboratory abnormalities in ALPINE.

Table 14: Select Laboratory Abnormalities (≥20%) that Worsened from Baseline in Patients Who Received BRUKINSA in ALPINE

Laboratory Abnormality[a]	BRUKINSA		Ibrutinib	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Hematologic abnormalities				
Neutrophils decreased	43	15	33	16
Hemoglobin decreased	28	4	32	3.7
Lymphocytes increased	24	19	26	19
Platelets decreased	22	4	24	3.4
Chemistry abnormalities				
Glucose increased	52	5	29	2.8
Creatinine increased	26	0	23	0
Phosphate decreased	21	2.5	13	2.2
Calcium decreased	21	0.6	29	0

[a] The denominator used to calculate the rate was 321 in the BRUKINSA arm, and varied from 320 to 321 in the ibrutinib arm, based on the number of patients with a baseline value and at least one post-treatment value. Grading is based on NCI CTCAE criteria.

Follicular Lymphoma

The safety of BRUKINSA in combination with obinutuzumab was evaluated in 143 adult patients with relapsed or refractory follicular lymphoma (FL) in study BGB-3111-212 (ROSEWOOD), a randomized, multicenter, open-label trial *[see Clinical Studies (14.5)]*. The trial required an absolute neutrophil count ≥1 × 10^9/L, platelet count ≥50 × 10^9/L, and CLcr ≥30 mL/min and excluded patients requiring a strong CYP3A inhibitor or inducer.

Patients were randomized to receive either BRUKINSA 160 mg twice daily until disease progression or unacceptable toxicity plus obinutuzumab (n=143) or obinutuzumab monotherapy (n=71). Obinutuzumab was dosed at 1,000 mg intravenously on Days 1, 8, and 15 of Cycle 1; on Day 1 of Cycles 2 to 6; and then every 8 weeks for up to 20 doses. At the discretion of the investigator, obinutuzumab was administered intravenously on Day 1 (100 mg) and on Day 2 (900 mg) of Cycle 1 instead of 1,000 mg on Day 1 of Cycle 1.

In patients who received BRUKINSA in combination with obinutuzumab, the median age was 63, 49% were female, 63% were White, and 21% were Asian. Most patients (97%) had an ECOG performance status of 0 to 1. The median duration of BRUKINSA treatment was 12 months, with 24% of patients treated for at least 2 years.

Serious adverse reactions occurred in 35% of patients who received BRUKINSA in combination with obinutuzumab. Serious adverse reactions in ≥5% of patients included pneumonia (11%) and COVID-19 (10%). Fatal adverse reactions occurred in 4.2% of patients, with the leading cause of death being COVID-19 (2.1%).

Adverse reactions led to permanent discontinuation of BRUKINSA in 17% of patients, dose reduction in 9%, and dose interruption in 40%. Adverse reactions leading to permanent discontinuation in ≥2% of patients were pneumonia, COVID-19, and second primary malignancy. The leading causes of BRUKINSA dosage modification (42% of all patients) were pneumonia, COVID-19, thrombocytopenia, and neutropenia.

Table 15 summarizes adverse reactions in BGB-3111-212.

Table 15: Adverse Reactions in ≥10% of Patients with Relapsed or Refractory FL Who Received BRUKINSA in Study BGB-3111-212

System Organ Class Preferred Term	BGB-3111-212			
	BRUKINSA + Obinutuzumab (N=143)		Obinutuzumab (N=71)	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
General disorders and administration site conditions				
Fatigue[a,b]	27	1.4	25	1.4
Pyrexia	13	0	20	0
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain[a,c]	22	3.5	23	1.4
Vascular disorders				
Hemorrhage[a,d]	20	1.4	10	1.4
Gastrointestinal disorders				
Diarrhea	18	2.8	17	1.4
Constipation	13	0	9	0
Abdominal pain[a]	11	2.1	11	0
Infections and infestations				
Upper respiratory tract infection[a,e]	17	2.8	10	0
Pneumonia[a,f,*]	15	13	11	7
COVID-19[a,*]	13	9	11	4.2
Herpes virus infection[g]	11	2.1	1.4	0
Urinary tract infection[h]	10	1.4	7	0
Respiratory, thoracic, and mediastinal disorders				
Cough[a]	14	0	14	0
Dyspnea[a,*]	11	2.1	13	0
Skin and subcutaneous tissue disorders				
Rash[a,i]	11	0	14	0

* Includes fatal outcomes: COVID-19 (3 patients), pneumonia (2 patients), dyspnea (1 patient).
[a] Includes multiple related terms.
[b] Fatigue: Fatigue, asthenia, and lethargy.
[c] Musculoskeletal pain: Back pain, musculoskeletal pain, musculoskeletal discomfort, noncardiac chest pain, neck pain, pain in extremity, myalgia, spinal pain, bone pain, arthralgia, and related terms.
[d] Hemorrhage: All terms containing hematoma, hemorrhage, hemorrhagic, and related terms indicative of bleeding.
[e] Upper respiratory tract infection: Upper respiratory tract infection, sinusitis, pharyngitis, laryngitis, rhinitis, nasopharyngitis, laryngopharyngitis, tonsillitis bacterial, and related terms.
[f] Pneumonia: Pneumonia, COVID-19 pneumonia, lung infiltration, lung consolidation, and related terms including specific types of infection.
[g] Herpes virus infection: Herpes viral infection, herpes zoster, herpes simplex, herpes simplex reactivation, varicella, and Epstein-Barr viremia.
[h] Urinary tract infection: Urinary tract infection, cystitis, pyelonephritis, and related terms.
[i] Rash: Rash, erythema, dermatitis, drug eruption, skin reaction, and related terms.

Clinically relevant adverse reactions in <10% of patients who received BRUKINSA in combination with obinutuzumab included bruising, edema, pruritus, petechiae, vomiting, headache, arthralgia, hypertension, sepsis, cardiac arrhythmias, renal insufficiency, febrile neutropenia, transaminase elevation, and pneumonitis.

Table 16: Select Laboratory Abnormalities (≥20%) that Worsened from Baseline in Patients Who Received BRUKINSA in Study BGB-3111-212

Laboratory Abnormality[a]	BGB-3111-212			
	BRUKINSA + Obinutuzumab		Obinutuzumab	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Hematologic abnormalities				
Platelets decreased	65	11	43	11
Neutrophils decreased	47	17	42	14
Hemoglobin decreased	31	0.8	23	0
Lymphocytes decreased	30	11	51	25
Chemistry				
Glucose increased[b]	53	8	41	9
Alanine aminotransferase increased	23	0	28	0
Phosphate decreased	21	0.8	14	0

[a] The denominator used to calculate the rate was 122 in the BRUKINSA + obinutuzumab arm, and varied from 56 to 58 in the obinutuzumab arm, based on the number of patients with a baseline value and at least one post-treatment value. Grading is based on NCI CTCAE criteria.
[b] Nonfasting conditions.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of BRUKINSA. 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.

- Hepatobiliary disorder: drug-induced liver injury

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7 DRUG INTERACTIONS

7.1 Effect of Other Drugs on BRUKINSA

Table 17: Drug Interactions that Affect Zanubrutinib

Moderate and Strong CYP3A Inhibitors	
Clinical Impact	• Coadministration with a moderate or strong CYP3A inhibitor increases zanubrutinib C_{max} and AUC *[see Clinical Pharmacology (12.3)]* which may increase the risk of BRUKINSA toxicities.
Prevention or management	• Reduce BRUKINSA dosage when coadministered with moderate or strong CYP3A inhibitors *[see Dosage and Administration (2.3)]*.
Moderate and Strong CYP3A Inducers	
Clinical Impact	• Coadministration with a moderate or strong CYP3A inducer decreases zanubrutinib C_{max} and AUC *[see Clinical Pharmacology (12.3)]* which may reduce BRUKINSA efficacy.
Prevention or management	• Avoid coadministration of BRUKINSA with strong CYP3A inducers *[see Dosage and Administration (2.3)]*. • Avoid coadministration of BRUKINSA with moderate CYP3A inducers *[see Dosage and Administration (2.3)]*. If these inducers cannot be avoided, increase BRUKINSA dosage to 320 mg twice daily *[see Dosage and Administration (2.3)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on findings in animals, BRUKINSA can cause fetal harm when administered to pregnant women. There are no available data on BRUKINSA use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of zanubrutinib to pregnant rats during the period of organogenesis was associated with fetal heart malformation at approximately 5-fold human exposures *(see Data)*. Women should be advised to avoid pregnancy while taking BRUKINSA. If BRUKINSA is used during pregnancy, or if the patient becomes pregnant while taking BRUKINSA, the patient should be apprised of the potential hazard to the fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

Embryo-fetal development toxicity studies were conducted in both rats and rabbits. Zanubrutinib was administered orally to pregnant rats during the period of organogenesis at doses of 30, 75, and 150 mg/kg/day. Malformations in the heart (2 or 3-chambered hearts) were noted at all dose levels in the absence of maternal toxicity. The dose of 30 mg/kg/day is approximately 5 times the exposure (AUC) in patients receiving the recommended dose of 160 mg twice daily.

Administration of zanubrutinib to pregnant rabbits during the period of organogenesis at 30, 70, and 150 mg/kg/day resulted in postimplantation loss at the highest dose. The dose of 150 mg/kg is approximately 32 times the exposure (AUC) in patients at the recommended dose and was associated with maternal toxicity.

In a pre and postnatal developmental toxicity study, zanubrutinib was administered orally to rats at doses of 30, 75, and 150 mg/kg/day from implantation through weaning. The offspring from the middle and high dose groups had decreased body weights preweaning, and all dose groups had adverse ocular findings (e.g., cataract, protruding eye). The dose of 30 mg/kg/day is approximately 5 times the AUC in patients receiving the recommended dose.

8.2 Lactation

Risk Summary

There are no data on the presence of zanubrutinib or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions from BRUKINSA in a breastfed child, advise lactating women not to breastfeed during treatment with BRUKINSA and for two weeks following the last dose.

8.3 Females and Males of Reproductive Potential

BRUKINSA can cause embryo-fetal harm when administered to pregnant women *[see Use in Specific Populations (8.1)]*.

Pregnancy Testing

Pregnancy testing is recommended for females of reproductive potential prior to initiating BRUKINSA therapy.

Contraception

Females

Advise female patients of reproductive potential to use effective contraception during treatment with BRUKINSA and for 1 week following the last dose of BRUKINSA. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

Males

Advise men to avoid fathering a child while receiving BRUKINSA and for 1 week following the last dose of BRUKINSA.

8.4 Pediatric Use

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

8.5 Geriatric Use

Of the 1729 patients with MCL, MZL, WM, CLL/SLL, and FL in clinical studies with BRUKINSA, 59% were ≥65 years of age, and 21% were ≥75 years of age. Patients ≥65 years of age had numerically higher rates of Grade 3 or higher adverse reactions and serious adverse reactions (57% and 38%, respectively) than patients <65 years of age (51% and 29%, respectively). No overall differences in effectiveness were observed between younger and older patients.

8.6 Renal Impairment

No dosage modification is recommended in patients with mild, moderate, or severe renal impairment (CLcr ≥15 mL/min, estimated by Cockcroft-Gault). Monitor for BRUKINSA adverse reactions in patients on dialysis *[see Clinical Pharmacology (12.3)]*.

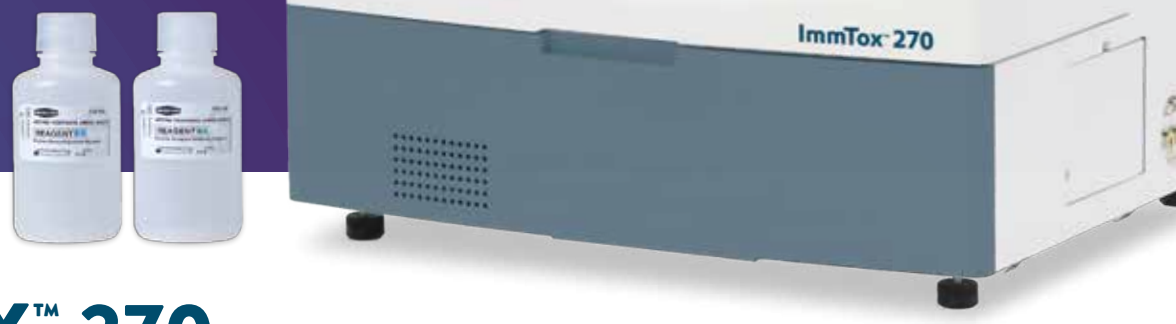
8.7 Hepatic Impairment

Dosage modification of BRUKINSA is recommended in patients with severe hepatic impairment *[see Dosage and Administration (2.2)]*. The safety of BRUKINSA has not been evaluated in patients with severe hepatic impairment. No dosage modification is recommended in patients with mild to moderate hepatic impairment. Monitor for BRUKINSA adverse reactions in patients with hepatic impairment *[see Clinical Pharmacology (12.3)]*.

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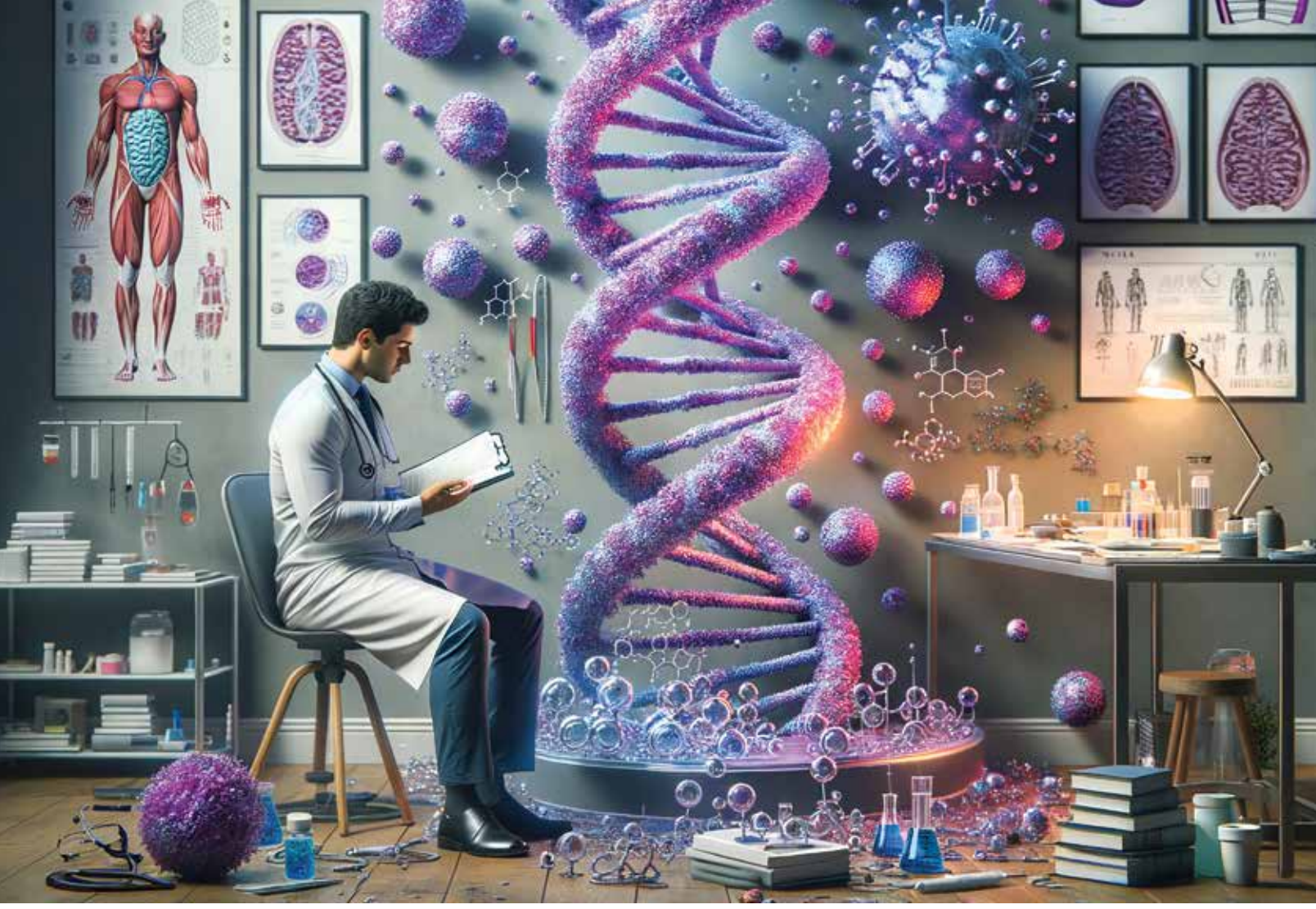
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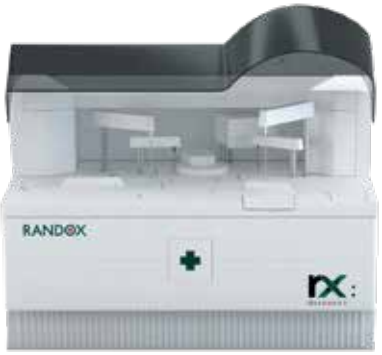
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4629

SCAN TO LEARN MORE

The RX daytona+ is a fully automated, benchtop, clinical chemistry analyzer capable of performing high quality testing, with a combined throughput of 450 tests per hour, for accurate results you can trust. The most versatile analyzer in its class, the RX daytona+ combines robust hardware and intuitive software with the world leading RX series test menu for unrivaled performance, with direct HbA1c testing capabilities.



RX IMOLA

From Randox Laboratories

4630

SCAN TO LEARN MORE

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.



medicaldevicedepot.com

3 WAYS TO START IMMEDIATELY INCREASING REVENUE

1 Neuro-Cognitive Testing

4631

- 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)

4632

- 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

4633

(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!

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CLIA WAIVED

DRIVE IMPROVED PATIENT OUTCOMES WITH REAL-TIME, ACTIONABLE RESULTS!

From Siemens Healthineers

4634

SCAN TO LEARN MORE

The DCA Vantage® Analyzer is a multi-parameter, point-of-care analyzer for monitoring glycemic control in patients with diabetes and detecting early kidney disease.

Benefits of the DCA Vantage System:
- CLIA-waived HbA1c test that is IFCC and NGSP-certified
- 1 µl finger stick without fasting – HbA1c results in 6 minutes
- Random urine sample provides A:C ratio in 7 minutes*
- Requires no sample or reagent preparation prior to testing
- Sample integrity safeguards

*CLIA moderately complex.



NEED MORE CONTROL OVER YOUR POINT-OF-CARE URINALYSIS TESTING PROCESS?

From Siemens Healthineers

4635

SCAN TO LEARN MORE

CLINITEK Status ® Connect System simplifies wireless or wired connectivity and testing oversight in point-of-care urinalysis for improved risk management.
- Offers flexible connectivity solutions by integrating data directly to the LIS, EMR or via point-of-care data management software solutions
- Provides improved POC testing workflow efficiencies when interfaced to leading data management solutions
- Minimize transcription errors with the 2-D bar-code scanner
- Improves risk management through advanced operator control functions, prevents unauthorized use
- Drives compliance across testing sites with programmable QC protocols and QC lockout
- Auto-Checks* help to ensure the quality and accuracy of data while facilitating an enhanced interpretation of results.

*Only available when using Siemens test strips with IR or color bands



BIOFIRE SPOTFIRE

From bioMerieux

4636

SCAN TO LEARN MORE

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.



CLIA WAIVED

ACUCY INFLUENZA A&B TEST

From Sekisui Diagnostics

4637

SCAN TO LEARN MORE

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.



OSOM® BVBLUE®

From Sekisui Diagnostics

4638

SCAN TO LEARN MORE

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.



OSOM® TRICHOMONAS RAPID TEST

From Sekisui Diagnostics

4639

SCAN TO LEARN MORE

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.



CLIA WAIVED

OSOM ULTRA PLUS FLU A&B TEST

From Sekisui Diagnostics

4640

SCAN TO LEARN MORE

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



OSOM® ULTRA STREP A TEST

From Sekisui Diagnostics

4641

SCAN TO LEARN MORE

The OSOM® Ultra Strep A test is a color immunochromatographic assay intended for the qualitative detection of Group A Streptococcus antigen directly from throat swab specimens. Shown to be not statistically different than single swab culture. Sensitivity 95.7% and 100% Specificity. Includes two additional test sticks for External QC. CLIA Waived.



ULTRA HCG COMBO TEST

From Sekisui Diagnostics

4642

SCAN TO LEARN MORE

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.



CLIA WAIVED

FIRST EVER CLIA WAIVED HEMATOLOGY ANALYZER

From Sysmex

4643

SCAN TO LEARN MORE

Faster test results, clinical decisions and greater practice efficiency are coming to physicians' offices with the first CLIA-waived CBC analyzer. Hematology diagnostics leader Sysmex is bringing more lab testing to the point of care. One of the most common blood tests can be conducted reliably and accurately on-site, in as few as three minutes. The device's ease of use and innovative technology means in-house staff can operate it in just a few easy steps, without lengthy certification and training. The new Sysmex XW-100 will improve health care efficiency and patient care.



COVID-19 TESTING

BIOFIRE SPOTFIRE

From bioMerieux

4644

SCAN TO LEARN MORE

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.



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

From LumiraDx

4645

SCAN TO LEARN MORE

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.



COVID-19 TESTING

SOFIA® 2 FLUORESCENT IMMUNOASSAY ANALYZER AND RAPID DIAGNOSTIC TEST KITS

From QuidelOrtho

4646

SCAN TO LEARN MORE

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.



COVID-19 OR FLU? STOP GUESSING. ONE SWAB, ONE TEST, RESULTS IN JUST 10 MINUTES

From Sekisui Diagnostics

4647

SCAN TO LEARN MORE

From only one sample, the OSOM® Flu SARS-CoV-2 Combo Test simultaneously detects and differentiates between COVID-19, Flu A, and Flu B in just 10 minutes, allowing healthcare providers to make more informed decisions when treating patients who are symptomatic with viral infections that have similar symptoms, but different treatment protocols. Designed for point-of-care testing, the OSOM® Flu SARS-CoV-2 Combo Test empowers healthcare providers with the confidence necessary to initiate immediate treatment and isolation protocols at the very first patient visit.

This test has not been FDA cleared or approved. It is authorized by FDA under an EUA for use by authorized laboratories. It has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens and 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 S360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



METRIX® COVID-19 TEST – A MOLECULAR LAB ANYWHERE AND EVERYWHERE

From Sekisui Diagnostics

4648

SCAN TO LEARN MORE

The Metrix® COVID-19 is a novel technology includes clinical claims for symptomatic and asymptomatic individuals, along with dual-sample types for nasal or saliva, allowing for an enhanced point-of-care testing experience. The reader is compact and robust, it's ideal for professional use in diverse locations, including clinics and mobile health units. It's a maintenance free device with no calibration step required.



COVID-19 TESTING

BE PREPARED FOR RESPIRATORY SEASONS WITH THE OSOM® COVID-19 ANTIGEN RAPID TEST

From Sekisui Diagnostics

4649

SCAN TO LEARN MORE

The OSOM® COVID-19 Antigen Rapid Test is a lateral flow immunoassay that detects the SARS-CoV-2 nucleocapsid protein with a nasal swab in only 15 minutes at the point-of-care. The test is intended to be used by healthcare professionals or operators on patients suspected of COVID-19 within the first 7 days of symptom onset. The clinical performance compares favorably against polymerase chain reaction methodology, with a positive percent agreement of 95.1% and a negative percent agreement of 97%.

OSOM® COVID-19 Antigen Rapid Test has not been FDA cleared or approved. It is authorized by FDA under an EUA for prescription use only. It has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens and 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 S360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



DIABETES/BLOOD GLUCOSE

ACCURATE, ACTIONABLE RESULTS FROM THE LEADER IN POINT-OF-CARE LIPID TESTING

From Abbott

4650

SCAN TO LEARN MORE

The CLIA-waived Alere Cholestech LDX™ Analyzer is engineered for confidence, providing accurate, actionable, and readily accessible results that have set the standard in point-of-care lipid profile, cholesterol, and glucose testing. Results are easy to obtain. Fingerstick sampling and a small sample size (40µL) makes results less painful and time consuming.



NOVA PRIMARY BLOOD GLUCOSE REFERENCE ANALYZER

From Nova Biomedical

4651

SCAN TO LEARN MORE

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.



DIABETES/BLOOD GLUCOSE

QUANTAFLO® PAD

From Semler Scientific

4652

SCAN TO LEARN MORE

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



EARLY DETECTION AND MANAGEMENT OF CHRONIC CONDITIONS WITH DCA VANTAGE® AND CLINITEK STATUS®+ ANALYZERS

From Siemens Healthineers

4653

SCAN TO LEARN MORE

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. Monitor glycemic control in patients with diabetes and screening for kidney disease in patients at-risk, in-office. Enable real-time consultation, eliminating loss to follow-up. Improve the patient experience and overall outcome by providing actionable results in minutes.

CLIA-waived: DCA HbA1c; CLINITEK Microalbumin 2 (ACR)
CLIA Moderate Complexity: DCA® Microalbumin/Creatinine (ACR)



FLU AND RESPIRATORY

STATUS FLU A&B

From LifeSign

4654

SCAN TO LEARN MORE

Status Flu A & B is an in vitro rapid qualitative test that detects influenza type A and type B directly from nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens obtained from patients with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of Influenza A and B viral infections.

- CLIA waived *Innovative flip design with onboard sample extraction
- Premeasured developer solution capsule for increased accuracy and ease of use
- Flocked nasal swabs for improved patient comfort and superior specimen collection



FLU AND RESPIRATORY

STATUS COVID-19/FLU A&B PANEL TEST

From LifeSign

4655

SCAN TO LEARN MORE

A Rapid Immunoassay for the Simultaneous Direct Detection and Differential Diagnosis of SARS-CoV-2, Influenza Type A and Type B Antigen from Anterior Nasal and Nasopharyngeal swab specimens. Infections with these viruses may present similar symptoms. Can you tell them apart? WE CAN!



BIOFIRE SPOTFIRE

From bioMerieux

4656

SCAN TO LEARN MORE

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.



SOFIA® 2 FLUORESCENT IMMUNOASSAY ANALYZER AND RAPID DIAGNOSTIC TEST KITS

From QuidelOrtho

4657

SCAN TO LEARN MORE

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.



FLU AND RESPIRATORY

ACUCY INFLUENZA A&B TEST

From Sekisui Diagnostics

4658

SCAN TO LEARN MORE

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.



COVID-19 OR FLU? STOP GUESSING. ONE SWAB, ONE TEST, RESULTS IN JUST 10 MINUTES

From Sekisui Diagnostics

4659

SCAN TO LEARN MORE

From only one sample, the OSOM® Flu SARS-CoV-2 Combo Test simultaneously detects and differentiates between COVID-19, Flu A, and Flu B in just 10 minutes, allowing healthcare providers to make more informed decisions when treating patients who are symptomatic with viral infections that have similar symptoms, but different treatment protocols. Designed for point-of-care testing, the OSOM® Flu SARS-CoV-2 Combo Test empowers healthcare providers with the confidence necessary to initiate immediate treatment and isolation protocols at the very first patient visit.

This test has not been FDA cleared or approved. It is authorized by FDA under an EUA for use by authorized laboratories. It has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens and 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 S360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



METRIX® COVID-19 TEST – A MOLECULAR LAB ANYWHERE AND EVERYWHERE

From Sekisui Diagnostics

4660

SCAN TO LEARN MORE

The Metrix® COVID-19 is a novel technology includes clinical claims for symptomatic and asymptomatic individuals, along with dual-sample types for nasal or saliva, allowing for an enhanced point-of-care testing experience. The reader is compact and robust, it's ideal for professional use in diverse locations, including clinics and mobile health units. It's a maintenance free device with no calibration step required.



FLU AND RESPIRATORY

BE PREPARED FOR RESPIRATORY SEASONS WITH THE OSOM® COVID-19 ANTIGEN RAPID TEST

From Sekisui Diagnostics

4661

SCAN TO LEARN MORE

The OSOM® COVID-19 Antigen Rapid Test is a lateral flow immunoassay that detects the SARS-CoV-2 nucleocapsid protein with a nasal swab in only 15 minutes at the point-of-care. The test is intended to be used by healthcare professionals or operators on patients suspected of COVID-19 within the first 7 days of symptom onset. The clinical performance compares favorably against polymerase chain reaction methodology, with a positive percent agreement of 95.1% and a negative percent agreement of 97%.

OSOM® COVID-19 Antigen Rapid Test has not been FDA cleared or approved. It is authorized by FDA under an EUA for prescription use only. It has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens and 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 S360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



OSOM ULTRA PLUS FLU A&B TEST

From Sekisui Diagnostics

4662

SCAN TO LEARN MORE

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



OSOM® ULTRA STREP A TEST

From Sekisui Diagnostics

4663

SCAN TO LEARN MORE

The OSOM® Ultra Strep A test is a color immunochromatographic assay intended for the qualitative detection of Group A Streptococcus antigen directly from throat swab specimens. Shown to be not statistically different than single swab culture. Sensitivity 95.7% and 100% Specificity. Includes two additional test sticks for External QC. CLIA Waived.



HEMATOLOGY

CELL-DYN EMERALD 22 HEMATOLOGY ANALYZER

From Abbott

4664

SCAN TO LEARN MORE

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.



TURN SMALL PLACES INTO SMART SPACES

From Abbott

4665

SCAN TO LEARN MORE

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



MICROS HEMATOLOGY ANALYZER WITH 3-PART DIFFERENTIAL PLUS THE LITEDM

From HORIBA Medical

4666

SCAN TO LEARN MORE

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.



HEMATOLOGY

STATE-OF-THE-ART BENCHTOP CBC ANALYZER

From OLO

4667

SCAN TO LEARN MORE

OLO® by Sight Diagnostics® is a state-of-the-art benchtop CBC analyzer that leverages AI, spectroscopy, and digital fluorescent microscopy to provide lab-grade results through full blood sample digitization. OLO offers 19 CBC parameters, including a 5-part white blood cell differential and 14 distinct flags. It handles venous and capillary blood samples with a minimum of 27 µL, and is suitable for children as young as three months. OLO's unique cartridge-based technology, free from liquid reagents, and its internal controls offer easy maintenance, room-temperature storage, reduced operational overhead, and IQCP- eligibility.

OLO is FDA 510(k) cleared for use in moderately complex laboratories. For full indications for use and safety information, please refer to the Quality and Compliance page at www.sighdx.com.



HEMATOLOGY TESTING MADE EASY

From Sysmex

4668

SCAN TO LEARN MORE

Designed for labs testing up to 25 samples per day, the Sysmex pocH-100i™ has the smallest footprint of any analyzer on the market. The instrument requires only 15uL of whole blood for reporting of 17 clinical parameters, including a 3-part WBC Differential. It is ideal for urgent care, physician office lab, small clinic, or any outpatient setting where a point of care CBC is needed.



NOW IT'S MORE THANK JUST A BLOOD TEST

From Sysmex

4669

SCAN TO LEARN MORE

With its simplified operation, the Sysmex XP-300™ is ideal for clinics and physician office labs. It provides a CBC with 17 different parameters, including a 3-part WBC Differential. The XP-300+M combines the accuracy and reliability of a Sysmex CBC with the agility of Medicus Middleware. Features include EMR connectivity, instrument interfaces and a QC module.



HEMATOLOGY

FIRST EVER CLIA WAIVED HEMATOLOGY ANALYZER

From Sysmex

4670

SCAN TO LEARN MORE

Faster test results, clinical decisions and greater practice efficiency are coming to physicians' offices with the first CLIA-waived CBC analyzer. Hematology diagnostics leader Sysmex is bringing more lab testing to the point of care. One of the most common blood tests can be conducted reliably and accurately on-site, in as few as three minutes. The device's ease of use and innovative technology means in-house staff can operate it in just a few easy steps, without lengthy certification and training. The new Sysmex XW-100 will improve health care efficiency and patient care.



LABORATORY SERVICES

MEDICUS LIS

From Medicus LIS

4671

SCAN TO LEARN MORE

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



CLIA COMPLIANT, USER-FRIENDLY, COST-EFFECTIVE, ELECTRONIC DOCUMENTATION SYSTEM

From MyInspection

4672

SCAN TO LEARN MORE

- Meets all CLIA compliance requirements
- No interpretation of CLIA regulations required – includes all policies, procedures, electronic fillable forms stored systematically for easy retrieval
- Remote access – manage individual or multiple labs remotely from your PC, tablet or phone
- Easy to audit and document changes with electronic signatures and dating
- Expert guidance from licensure to your customized documentation system
- Be, stay compliant and inspection ready – reduce time, cost, and stress



LIPID TESTING

ACCURATE, ACTIONABLE RESULTS FROM THE LEADER IN POINT-OF-CARE LIPID TESTING

From Abbott

4673

SCAN TO LEARN MORE

The CLIA-waived Alere Cholestech LDX™ Analyzer is engineered for confidence, providing accurate, actionable, and readily accessible results that have set the standard in point-of-care lipid profile, cholesterol, and glucose testing. Results are easy to obtain. Fingerstick sampling and a small sample size (40µL) makes results less painful and time consuming.



MULTIPLEX TESTING

BIOFIRE SPOTFIRE

From bioMerieux

4674

SCAN TO LEARN MORE

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.



BE PREPARED FOR RESPIRATORY SEASONS WITH THE OSOM® COVID-19 ANTIGEN RAPID TEST

From Sekisui Diagnostics

4675

SCAN TO LEARN MORE

The OSOM® COVID-19 Antigen Rapid Test is a lateral flow immunoassay that detects the SARS-CoV-2 nucleocapsid protein with a nasal swab in only 15 minutes at the point-of-care. The test is intended to be used by healthcare professionals or operators on patients suspected of COVID-19 within the first 7 days of symptom onset. The clinical performance compares favorably against polymerase chain reaction methodology, with a positive percent agreement of 95.1% and a negative percent agreement of 97%.

OSOM® COVID-19 Antigen Rapid Test has not been FDA cleared or approved. It is authorized by FDA under an EUA for prescription use only. It has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens and 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 S360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



PERIPHERAL ARTERIAL DISEASE

PAD TESTING SYSTEMS IDEAL FOR PRIMARY CARE TO VASCULAR SPECIALISTS

from Newman Medical

4676

SCAN TO LEARN MORE

Your Patients Trust YOU To Find Their Peripheral Artery Disease
- High-risk patients include those over 65, diabetics, and smokers.
- If left untreated, 25% of patients with PAD will experience a heart attack or stroke within 5 years.
- PAD symptoms are often mistaken for arthritis or old age.

The simpleABI Cuff-Link System is Easy to Learn and Use.
- With a push-button remote, automatic calculations, and waveforms, it's incredibly user-friendly.
- Reports are straightforward to save and share since the system is PC-based.

Outstanding Value and Reimbursements
- The system pays for itself in less than a year with just one test per week.
- Medicare reimbursements vary by exam and location, averaging from $91 to $174.



QUANTAFLO® PAD

From Semler Scientific

4677

SCAN TO LEARN MORE

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



SPIROMETRY

MD6300 MICRO SPIROMETER FULL FUNCTION LOW COST SPIROMETER

From Mirco Direct

4678

SCAN TO LEARN MORE

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.



SPIROMETRY

MD6800 PNEUMOTRAC SPIROMETER A POWERFUL SOLUTION FOR PC-BASED SPIROMETRY

From Micro Direct

4679

SCAN TO LEARN MORE

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.



STREP TESTS

SOFIA® 2 FLUORESCENT IMMUNOASSAY ANALYZER AND RAPID DIAGNOSTIC TEST KITS

From QuidelOrtho

4680

SCAN TO LEARN MORE

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.



OSOM® ULTRA STREP A TEST

From Sekisui Diagnostics

4681

SCAN TO LEARN MORE

The OSOM® Ultra Strep A test is a color immunochromatographic assay intended for the qualitative detection of Group A Streptococcus antigen directly from throat swab specimens. Shown to be not statistically different than single swab culture. Sensitivity 95.7% and 100% Specificity. Includes two additional test sticks for External QC. CLIA Waived.



SYNDROMIC TESTING

BIOFIRE® FILMARRAY® TORCH

From bioMérieux

4682

SCAN TO LEARN MORE

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.



TOXICOLOGY

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

From Abbott

4683

SCAN TO LEARN MORE

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.



TOXICOLOGY URINE DRUG SCREENING REAGENTS

From Abbott

4684

SCAN TO LEARN MORE

Prescription drug misuse and illicit drug abuse is a growing public health challenge in this country. Building a test profile that covers highly misused drugs has never been so vital. With over 20 relevant assays to choose from Abbott's suite of Immunalysis reagents allows you to easily screen for relevant substances. Our complete line of assays, calibrators, and controls enables you to implement an efficient drug screening program in office.



TOXICOLOGY

FIRST EVER FDA-CLEARED AND CATEGORIZED, POINT-OF-CARE FENTANYL TEST (<6 MINUTES)

From Carolina Liquid Chemistries

4685

SCAN TO LEARN MORE

Carolina Liquid Chemistries Corp. introduces the Fentanyl Urine Detection Test on CLC's next-generation RYAN™ immunofluorescent analyzer. This FDA cleared and CLIA categorized, moderately complex, compact, point-of-care system detects fentanyl qualitatively in human urine at a cutoff concentration of 1.0 ng/mL. The test can be run in < 6 minutes, produces a chartable result, and is interfaceable. For detailed information, visit carolinachemistries.com/products/fentanyl-urine-detect-on-clc-ryan-analyzer/.



URINALYSIS

EARLY DETECTION AND MANAGEMENT OF CHRONIC CONDITIONS WITH DCA VANTAGE® AND CLINITEK STATUS®+ ANALYZERS

From Siemens Healthineers

4686

SCAN TO LEARN MORE

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. Monitor glycemic control in patients with diabetes and screening for kidney disease in patients at-risk, in-office. Enable real-time consultation, eliminating loss to follow-up. Improve the patient experience and overall outcome by providing actionable results in minutes.

CLIA-waived: DCA HbA1c; CLINITEK Microalbumin 2 (ACR)
CLIA Moderate Complexity: DCA® Microalbumin/Creatinine (ACR)



WOMEN'S HEALTH

WHY BINDEX® IS A GAME-CHANGER INOSTEOPOROSIS DIAGNOSTICS.

From Bindex Medical

4687

SCAN TO LEARN MORE

Comparable to DXA
Extensive clinical research has proven Bindex to be 90% accurate in detecting osteoporosis. It can replace nearly 70% of DXA scans for patients with suspected osteoporosis.

Fast and effective
Using safe pulse-echo ultrasound to measure cortical bone thickness, Bindex analyzes bone density in just seconds.

Easy to use anywhere
Lightweight and pocket-sized, Bindex allows patients to receive on-the-spot bone density scans in doctors' offices, hospitals and clinics and at home.



WOMEN'S HEALTH

OSOM® BVBLUE®

From Sekisui Diagnostics

4688

SCAN TO LEARN MORE

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.



OSOM® TRICHOMONAS RAPID TEST

From Sekisui Diagnostics

4689

SCAN TO LEARN MORE

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.



ULTRA HCG COMBO TEST

From Sekisui Diagnostics

4690

SCAN TO LEARN MORE

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.





9 TRAVEL DESTINATIONS YOU CAN'T MISS IN 2025

Whether you're craving pristine beaches or vibrant cities, these nine must-visit destinations around the world promise stunning scenery, rich culture, and unforgettable adventures for every type of traveler.

HARBOUR VILLAGE BEACH CLUB · TURTLE BAY RESORT · FOUR SEASON ORLANDO AT WALT DISNEY WORLD · SECRETS CAP CANA · BALBOA BAY RESORT · DESOLATION HOTEL THE TAMPA EDITION HOTEL · FOUR SEASONS NASHVILLE · FOUR SEASONS LAS VEGAS

MDescapes

MD-ESCAPES.COM

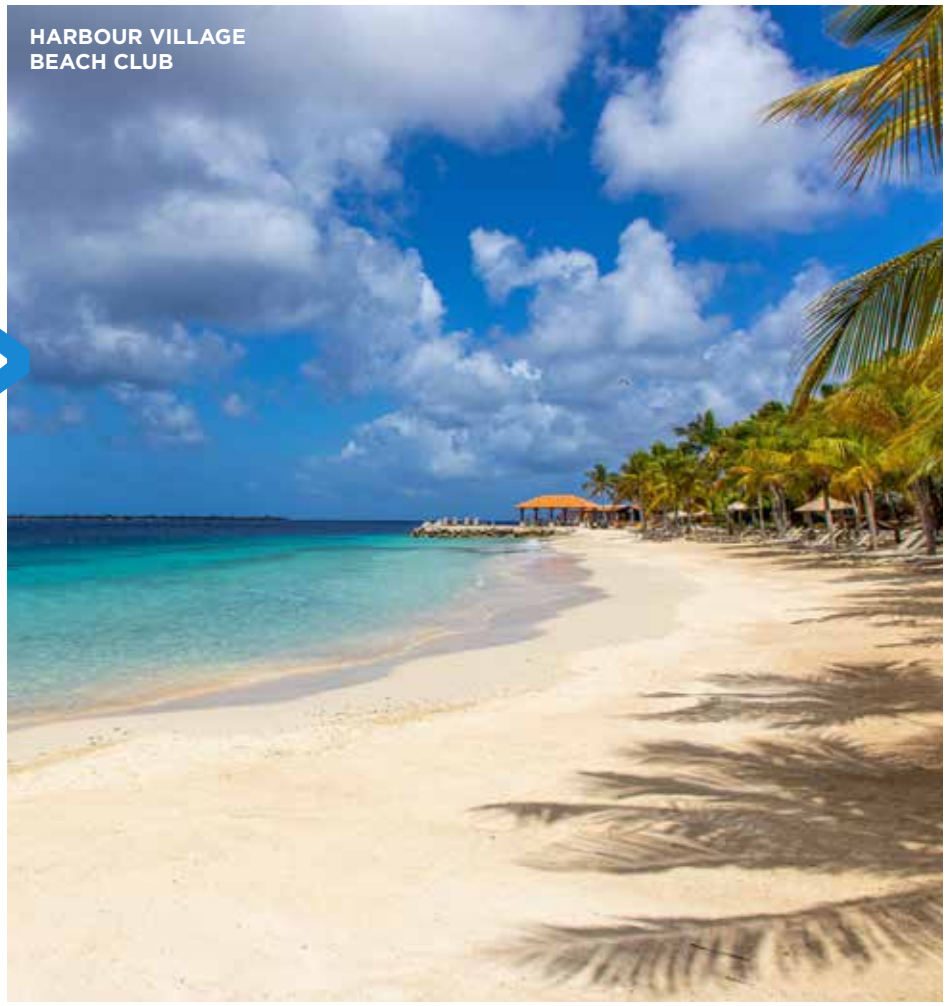
MDescapes

HARBOUR VILLAGE BEACH CLUB

BONAIRE, CARIBBEAN

Tucked away on a private stretch of white sand and palm trees, you will find the iconic Harbour Village Beach Club. An oasis beloved by sun lovers, scuba divers, and seafarers alike. Our boutique Bonaire retreat captures the breezy, barefoot elegance of the Dutch Caribbean, consistently earning the title of "Bonaire's leading hotel" in the World Travel Awards.

SCAN TO LEARN MORE



HARBOUR VILLAGE BEACH CLUB



TURTLE BAY RESORT

TURTLE BAY RESORT

OAHU, HAWAII

Deeply rooted in the land, the history, and the layered richness of Oahu, at Turtle Bay you'll find an authentic connection to a place of uncommon natural splendor and the warm, welcoming community within it. Where your days are filled with constant discovery and moments that touch your soul, allowing you to explore the uncommon depths of this remarkable coast.

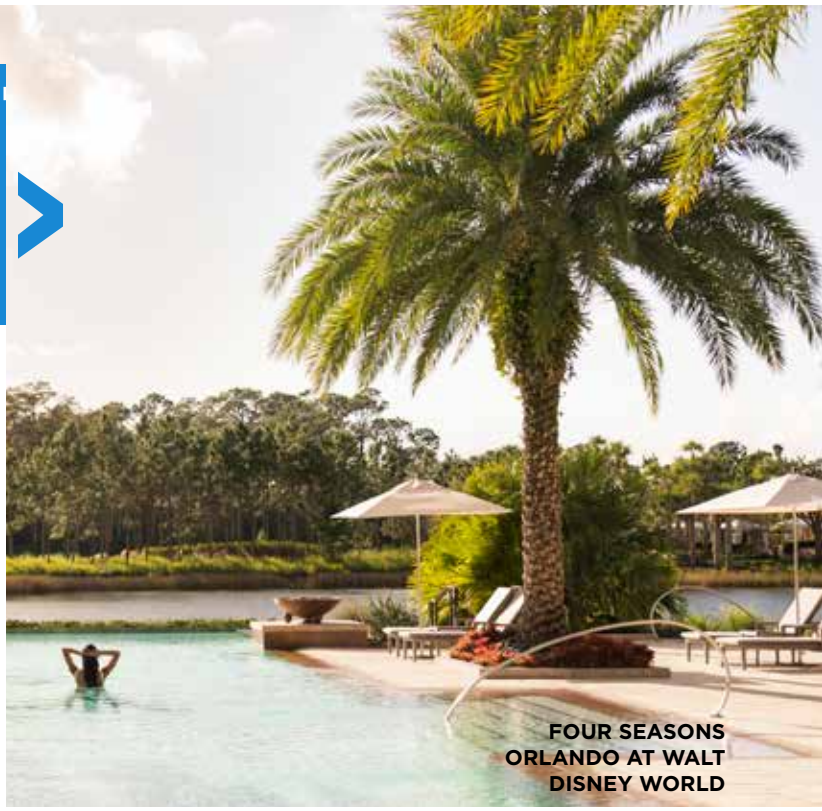
SCAN TO LEARN MORE

FOUR SEASON ORLANDO AT WALT DISNEY WORLD

ORLANDO, FLORIDA

Discover an elevated escape with the perfect balance of fun and relaxation at our AAA Five Diamond, luxury Orlando Resort. Splash around with the family at Explorer Island water park, or unwind beneath swaying palms at Oasis adult-only pool while we entertain your young ones at our complimentary kids camp. Treat yourself to a soothing, post-park massage at The Spa, then toast to the nightly Walt Disney World® fireworks views over dinner at our Michelin-starred rooftop steakhouse Capa.

SCAN TO LEARN MORE



FOUR SEASONS ORLANDO AT WALT DISNEY WORLD



SECRETS CAP CANA

SECRETS CAP CANA

PUNTA CANA DOMINICAN REPUBLIC

Secrets Cap Cana Resort & Spa is a sophisticated, adults-only hideaway located in the exclusive gated community of Cap Cana Facing the clear Caribbean Sea along the white sand of the exclusive Juanillo Beach. Secrets Cap Cana Resort & Spa is proud to support the Punta Cana Promise as part of the ongoing commitment to ensure that guests will continue to receive the highest levels of service and security they have come to know and expect from Secrets Cap Cana. The Punta Cana Promise reaffirms the commitment to a set of security standards and safety guidelines in one of the top travel destinations in the Dominican Republic.

SCAN TO LEARN MORE

MDescapes

BALBOA BAY RESORT

NEWPORT BEACH , CALIFORNIA

Balboa Bay Resort is Newport Beach's premier waterfront retreat offering stunning bay views and sunsets over Balboa Bay's harbor. It is the #1 Resort in Newport Beach per U.S. News & World Report, and it is rated as a Forbes Four-Star and AAA Four-Diamond resort.

SCAN TO LEARN MORE



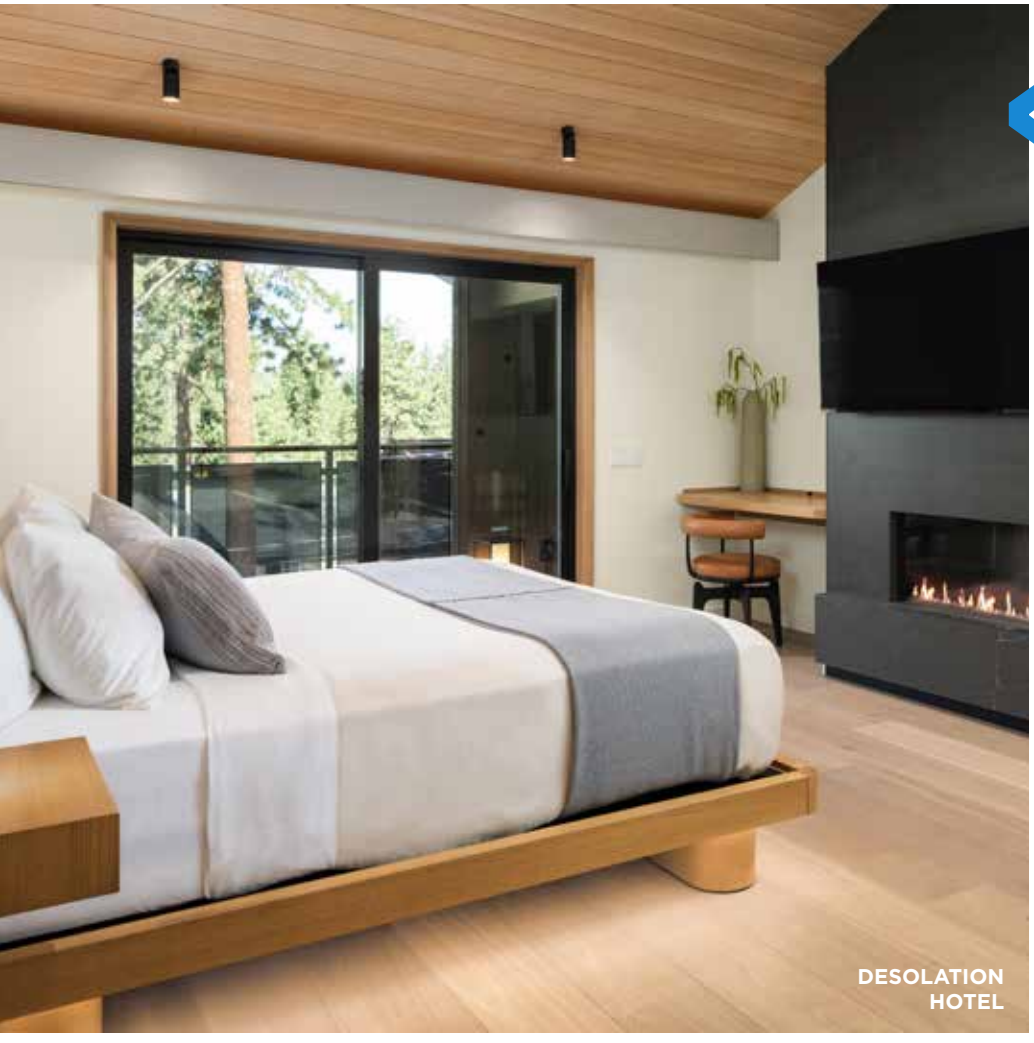
TURTLE BAY RESORT

DESOLATION HOTEL

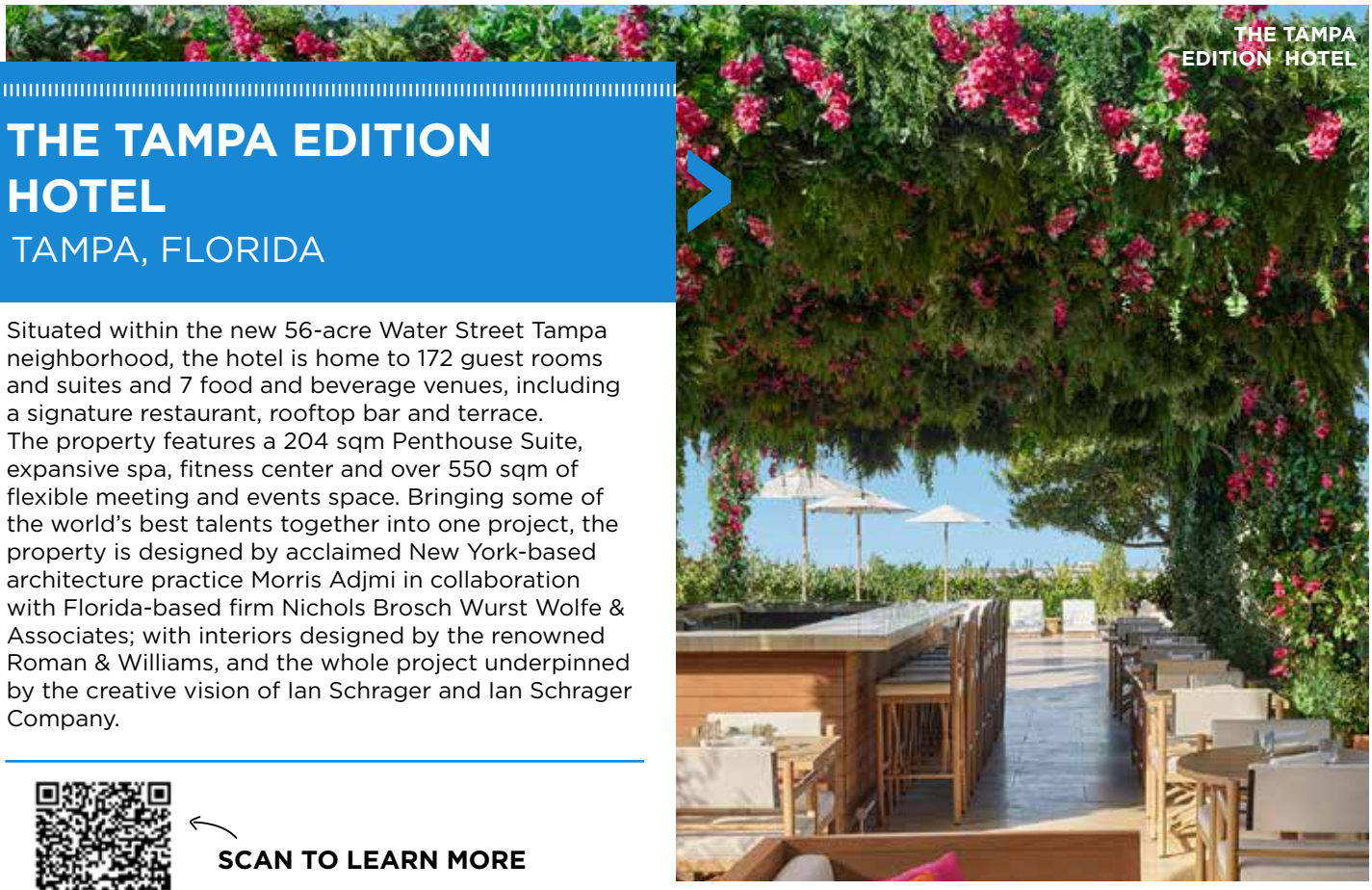
LAKE TAHOE, CALIFONIA

At Desolation Hotel, modern conveniences and eco-luxury commingle with Japanese tranquility and Scandinavian design. Our one-of-a-kind South Lake Tahoe experience inspires adventure and invites tranquility, providing the right space to recharge your battery. Balancing reverence for the past with appreciation for the present, Desolation Hotel nods to the simple days of yesteryear, while modern technology serves as a quiet backbone to the entire resort experience.

SCAN TO LEARN MORE



DESOLATION HOTEL



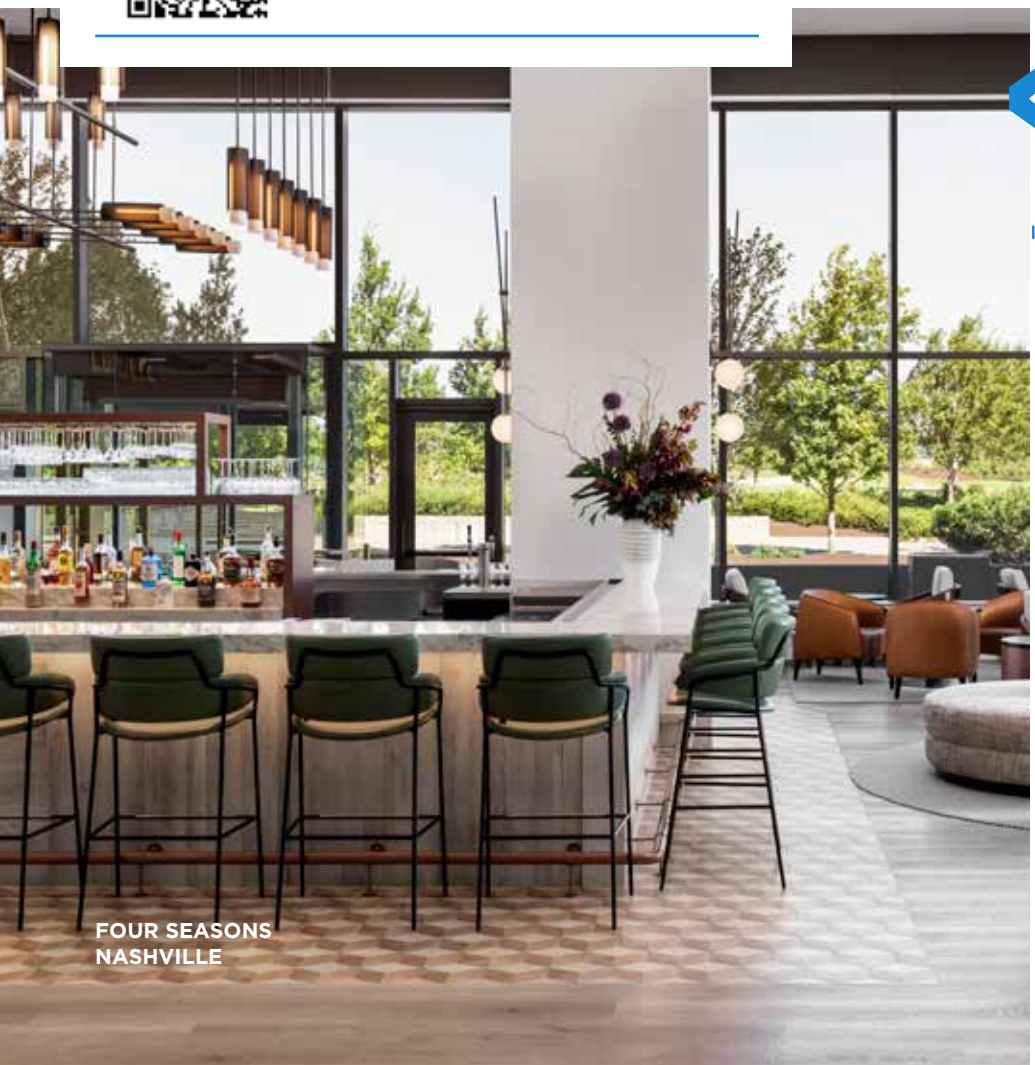
THE TAMPA EDITION HOTEL

THE TAMPA EDITION HOTEL

TAMPA, FLORIDA

Situated within the new 56-acre Water Street Tampa neighborhood, the hotel is home to 172 guest rooms and suites and 7 food and beverage venues, including a signature restaurant, rooftop bar and terrace. The property features a 204 sqm Penthouse Suite, expansive spa, fitness center and over 550 sqm of flexible meeting and events space. Bringing some of the world's best talents together into one project, the property is designed by acclaimed New York-based architecture practice Morris Adjmi in collaboration with Florida-based firm Nichols Brosch Wurst Wolfe & Associates; with interiors designed by the renowned Roman & Williams, and the whole project underpinned by the creative vision of Ian Schrager and Ian Schrager Company.

SCAN TO LEARN MORE



FOUR SEASONS NASHVILLE

FOUR SEASONS

NASHVILLE, TENNESSEE

Welcome to Four Seasons Hotel Nashville, a luxury hotel located in the heart of downtown's vibrant SoBro neighborhood. This new social hub is just steps away from the city's iconic music, sports, and entertainment venues. Experience the rhythm of our lively restaurants and event spaces, the tranquility of our Spa, and the stunning views from our rooftop pool overlooking the Cumberland River and Riverfront Park. With the unmatched service of Four Seasons and warm Southern hospitality, we'll inspire an authentic experience of Music City.

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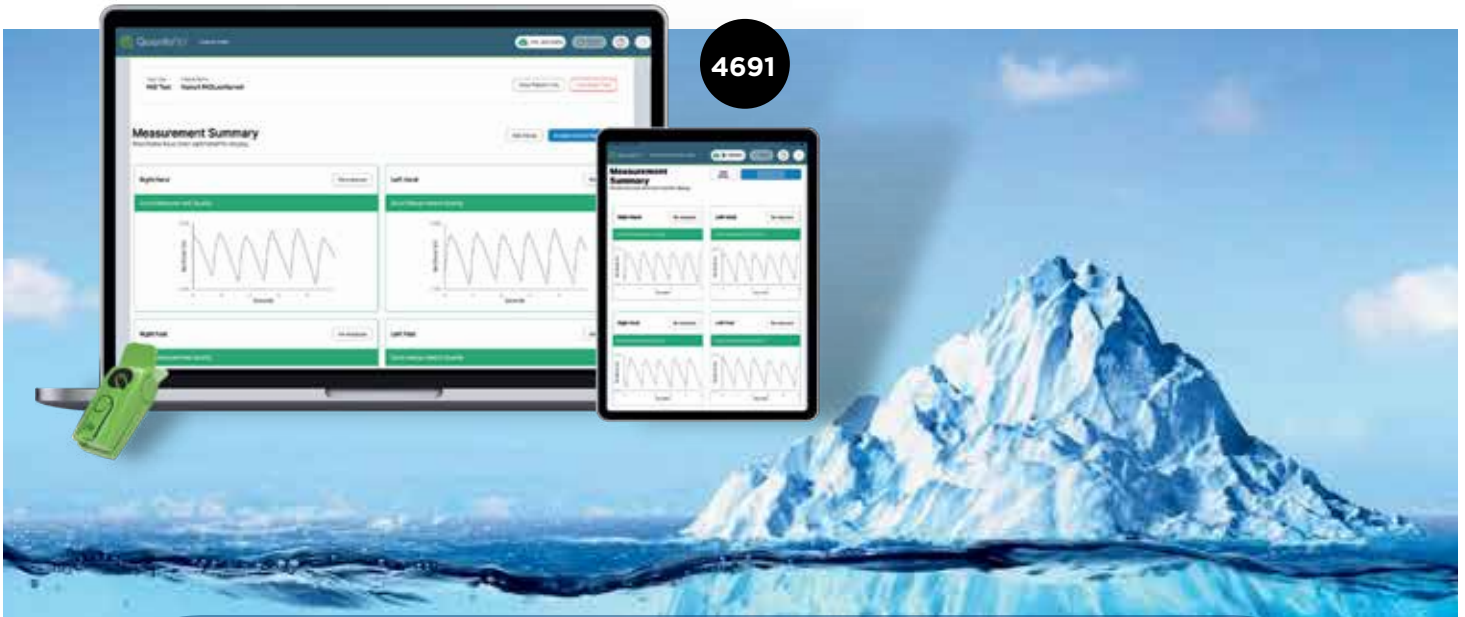


FOUR SEASONS
LAS VEGAS, NEVADA

As one of the only non-gaming and non-smoking hotels on The Strip, Four Seasons Hotel Las Vegas is a unique oasis in the heart of the action-packed sports and entertainment capital of the world. Offering Five Diamond luxury accommodations, acclaimed dining and a Forbes Five-Star spa, Four Seasons offers the best of both worlds: a resort retreat amid the famous energy of Las Vegas.

SCAN TO LEARN MORE

THE POWER TO DETECT THE HIDDEN THREAT OF PERIPHERAL ARTERIAL DISEASE (PAD)



"PAD IS ASYMPTOMATIC IN 75% OF ELDERLY PATIENTS." [1]

IN PRIMARY CARE: "THE RISK OF MORTALITY WAS SIMILAR IN SYMPTOMATIC AND ASYMPTOMATIC PATIENTS WITH PAD" [2]

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1. Sillesen, H., & Falk, E. (2011). Peripheral artery disease (PAD) screening in the asymptomatic population: why, how, and who?. Current atherosclerosis reports, 13(5), 390–395. https://doi.org/10.1007/s11883-011-0196-x
2. Diehm, C., Allenberg, J. R., Pittrow, D., Mahn, M., Tepohl, G., Haberl, R. L., Darius, H., Burghaus, I., Trampisch, H. J., & German Epidemiological Trial on Ankle Brachial Index Study Group (2009). Mortality and vascular morbidity in older adults with asymptomatic versus symptomatic peripheral artery disease. Circulation, 120(21), 2053–2061. https://doi.org/10.1161/CIRCULATIONAHA.109.865600

ML00190 Rev A



A Broad Range of Respiratory Point-of-Care Tests

We recognize your **passion** for providing high quality care to patients displaying symptoms associated with respiratory infections, and we appreciate your efforts and **resiliency** working to reduce the rapid spread of these infections.

We are committed to providing **high quality, molecular and antigen point-of-care tests for detecting the most common respiratory infections**, so you can get the answers fast and your patients back to doing what they love.

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

Learn more about our tests for Flu A&B, COVID-19, Strep A, and more.

For more information, call 800-332-1042 or visit sekisuidiagnostics.com/respiratory-health



The Aptitude Metrix® COVID-19 Test is provided by SEKISUI Diagnostics

The Metrix COVID-19, OSOM COVID-19 Antigen Rapid Test, and OSOM Flu SARS-CoV-2 Combo Test have not been FDA cleared or approved. They are authorized by FDA under an EUA for use by authorized laboratories. The Metrix COVID-19 has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The OSOM COVID-19 Antigen Rapid Test has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens. OSOM Flu SARS-CoV-2 Combo Test has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens. The use of these products are 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 S360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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