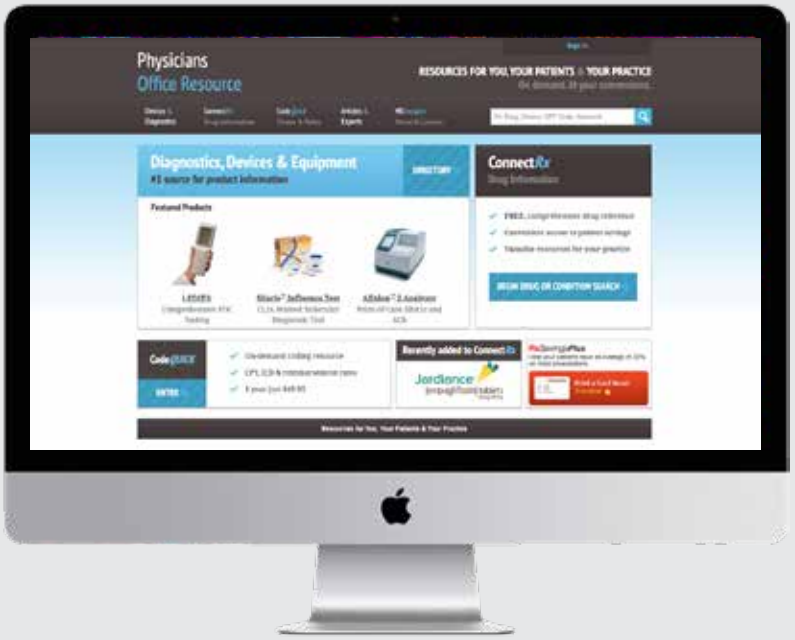
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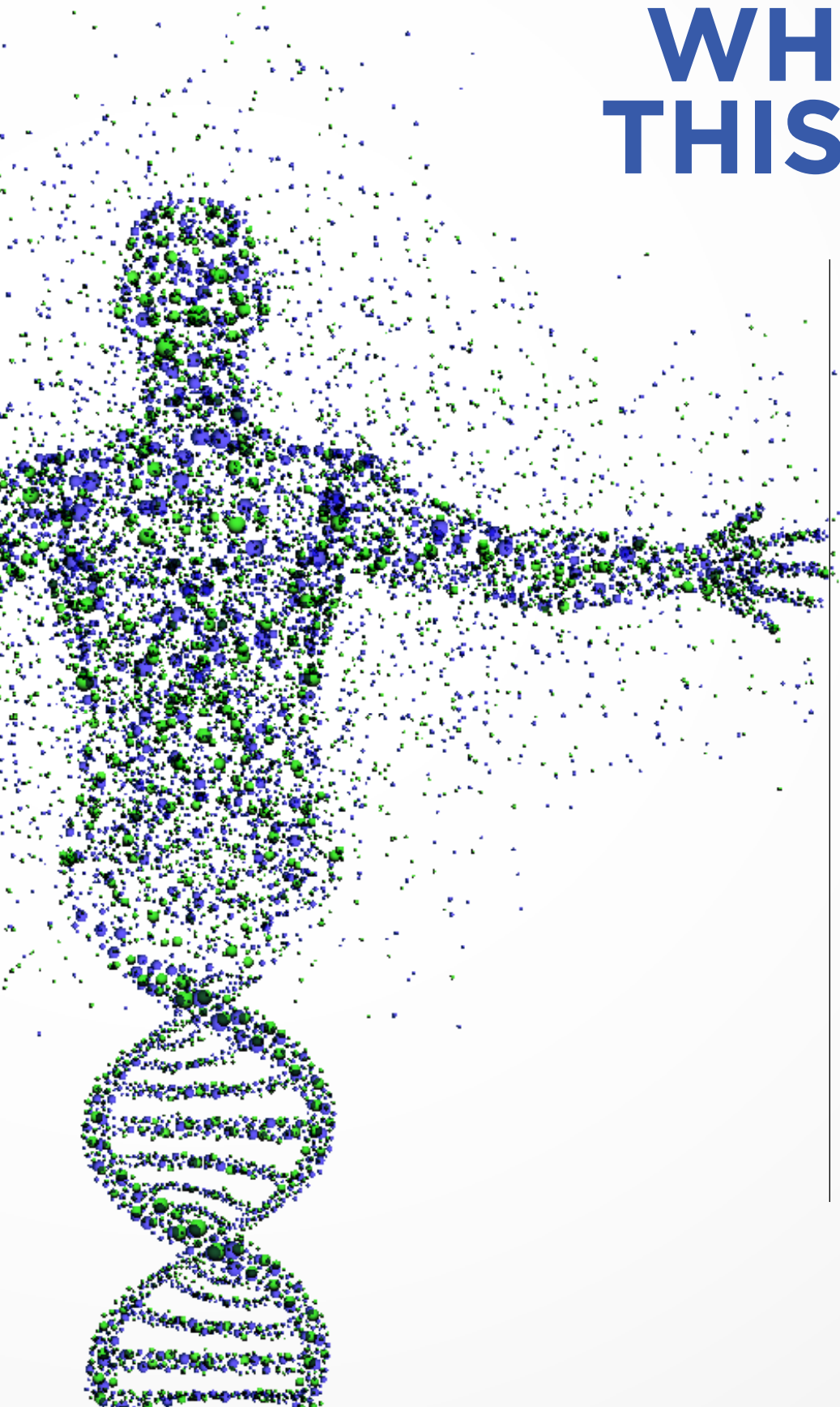


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ADD-00073919 12/20.

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2021

MEDICAL conferences

JANUARY

American Association for Hand Surgery
2021 Annual Meeting
January 10 – 21, 2021
Virtual Meeting
978-927-8330
www.handsurgery.org

Pri-Med – PrimaryCare-Now
January 14, 2021
Virtual Meeting
877-477-4633
www.pri-med.com

CANS Annual Meeting 2021
California Association of Neurological Surgeons
January 15 - 17, 2021
Venue to be Determined
916-457-2267
www.cans1.org

American Society for Reconstructive Microsurgery Annual Meeting 2021
January 16 – 17, 2021
Virtual Meeting
312-456-9579
www.microsurg.org

STS Annual Meeting
Society of Thoracic Surgeons
January 29 – 31, 2021
Virtual Meeting
312-202-5800
www.sts.org

SCCM Critical Care Congress
Society of Critical Care Medicine
January 31 – February 12, 2021
Virtual Meting
847-827-6888
www.sccm.org

FEBRUARY

ORS 2021 Annual Meeting
Orthopaedic Research Society
February 12 – 16, 2021
Virtual Meeting
847-823-5770
www.ors.org/2021annual-meeting/

Biophysical Society Annual Meeting 2021
Biophysical Society
February 22 – 26, 2021
Virtual Meeting
240-290-5600
www.biophysics.org/2021meeting

2021 AAAAI Annual Meeting
American Academy of Allergy Asthma & Immunology
February 26 – March 1, 2021
Virtual Meeting
414-272-6071
www.annualmeeting.aaaai.org

MARCH

SSO 2021 Annual Cancer Symposium
Society of Surgical Oncology
March 18 – 19, 2021
Virtual Meeting
847-427-1400
www.surgonc.org

AAD Annual Meeting 2021
American Academy of Dermatology
March 19 – 23, 2021 – CANCELLED
San Francisco, CA
866-503-7546
www.aad.org/meetings/annual-meeting

SGO 2021 Annual Meeting on Women's Cancer
Society of Gynecologic Oncologists
March 19 – 25, 2021
Virtual Meeting
312-235-4060
www.sgo.org

ENDO Annual Meeting 2021
The Endocrine Society
March 20 – 23, 2021
Virtual Meeting
888-363-6274
www.endocrine.org

SIR 2021 Annual Scientific Meeting
Society of Interventional Radiology
March 20 – 26, 2021
Virtual Meeting
800-488-7284
www.SIRmeeting.org

CLMA – KnowledgeLab 2021
Clinical Lab Manager Association
March 21 – 23, 2021
Nashville, TN
312-321-5111
www.clma.org

APRIL

AACR Annual Meeting 2021
American Association of Cancer Research
April 10 – 15, 2021
Virtual Meeting
866-423-3965
www.aacr.org

AANS Annual Scientific Meeting 2021
American Association of Neurological Surgeons
April 17 – 21, 2021
Vancouver, BC
847-378-0500
www.aans.org

AAN Annual Meeting 2021
American Academy of Neurology
April 17 – 22, 2021
San Francisco, CA
800-879-1960
www.aan.com

ARRS Annual Meeting 2021
American Roentgen Ray Society
April 18 – 22, 2021
Virtual Meeting
866-940-2777

www.arrs.org

AMGA Annual Conference 2021
American Medical Group Association
April 20 – 21, 2021
Virtual Meeting
703-838-0033
www.amga.org

ASLMS 2021 Annual Conference
American Society for Laser Medicine & Surgery
April 24 – 25, 2021
Virtual Meeting
877-258-6028
www.aslms.org

ASBS Annual Meeting 2021
American Society of Breast Surgeons
April 28 – May 2, 2021
Orlando, FL
877-992-5470
www.breastsurgeons.org

ACP Internal Medicine Meeting 2021
American College of Physicians
April 29 – May 1, 2021
Virtual Meeting
800-523-1546
annualmeeting.acponline.org

ASAPS Aesthetic Meeting 2021
The American Society for Aesthetic Plastic Surgery
April 29 – May 3, 2021
Miami Beach, FL
800-364-2147
www.surgery.org

AATS Annual Meeting 2021
American Association for Thoracic Surgery
April 30 – May 2, 2021
Virtual Meeting
978-927-8330
www.aats.org

ACOG 2021 Annual Clinical and Scientific Meeting
American College of Obstetricians and Gynecologists
April 30 – May 3, 2021
Washington, DC
800- 673-8444
www.acog.org

MAY

ATS 2021 International Conference
American Thoracic Society
May 14 – 19, 2021
San Diego, CA
212-315-8600
conference.thoracic.org

AAC 2021 Annual Scientific Session and Expo
American College of Cardiology
May 15 – 17, 2021
Atlanta, GA
800-253-4636
accscientificsession.acc.org

ACR Annual Meeting 2021
American College of Radiology
May 15 – 19, 2021
Virtual Meeting
800-243-7419
www.acr.org/annual-meeting

ASNR Annual Meeting & The Foundation of the ASNR Symposium 2021
American Society of Neuroradiology
May 22 – 27, 2021
San Francisco, CA
630-574-0220
www.asnr.org

AACE 2021 Annual Scientific & Clinical Congress
American Association of Clinical Endocrinologists
May 26 – 29, 2021
Las Vegas, NV
904-353-7878
www.aace.com

JUNE

ACSM Annual Meeting
American College of Sports Medicine
June 1 – 5, 2021
Washington, DC
317-637-9200
www.acsmannualmeeting.org

SNMMI 2021 Annual Meeting
Society of Nuclear Medicine & Molecular Imaging
June 12 – 15, 2021
Washington, DC
703-708-9000
www.snmmi.org

AMA Annual Meeting of House of Delegates 2021
American Medical Association
June 12 – 16, 2021
Chicago, Illinois
800-621-8335
www.ama-assn.org

BIO International Convention 2021
Biotechnology Industry Organization
June 14 – 17, 2021
TBD
202-962-6655
bio.org/

SAGES 2021 Annual Meeting
Society of American Gastrointestinal Endoscopic Surgeons
June 15 – 18, 2021
Las Vegas, NV
310-437-0544
www.sages2021.surgery

Pri-Med Southwest 2021
June 17 – 19, 2021
Houston, TX
877-774-6338
www.pri-med.com

APIC Annual Conference 2021
Association for Professional in Infection Control and Epidemiology
June 28 – 30, 2021
Austin, TX
202-789-1890
ac2021.site.apic.org

JULY

AANA Annual Congress 2021
Arthroscopy Association of North America
July 7 – 11, 2021
Nashville, TN
847-292-2262
www.aana.org

AAPM Annual Meeting 2021
American Association of Physicists in Medicine
July 25 – 29, 2021
Columbus, OH
571-298-1300
www.aapm.org

AACC 2021 Annual Meeting & Clinical Lab Expo
American Association for Clinical Chemistry
July 25 – 29, 2021
Anaheim, CA
800-892-1400
www.aacc.org

AUGUST

Pri-Med West 2021
August 4 – 7, 2021
Anaheim, California
877-774-6338
www.pri-med.com

AORN Global Surgical Conference & Expo 2021
Association of Perioperative Registered Nurses
August 7 – 11, 2021
Orlando, FL
800-755-2676
www.aorn.org

2021 Annual HIMSS Conference & Exhibition
Healthcare Information and Management Systems
August 9 – 13, 2021
Las Vegas, NV
855-326-8342
www.himssconference.org

PDA Annual Meeting
Pacific Dermatologic Association
August 19 – 22, 2021
Lake Tahoe, CA
888-388-8815
www.pacificderm.org

AAOS Annual Meeting 2021
American Academy of Orthopaedic Surgeons
August 31 – September 3, 2021
San Diego, CA
847-823-7186
www.aaos.org

SEPTEMBER

FMX 2021
American Academy of Family Physicians
September 28 – October 2, 2021
Anaheim, CA
800-274-2237
www.aafp.org

OCTOBER

NASS 2021 Annual Meeting
North American Spine Society
October 7 – 10, 2021
San Diego, CA
630-230-3600
www.spine.org

The ANESTHESIOLOGY 2021 Annual Meeting
American Society of Anesthesiologists
October 9 – 13, 2021
San Diego, CA
847-825-5586
www.asahq.org

ASRM Scientific Congress and Expo 2021
American Society for Reproductive Medicine
October 16 – 20, 2021
Baltimore, MD
205-978-5000
www.asrm.org

CNS Annual Meeting 2021
Congress of Neurological Surgeons
October 16– 20, 2021
Austin, TX
847-240-2500
www.cns.org

ASTRO Annual Meeting 2021
American Society for Therapeutic
Radiology & Oncology
October 24 – 27, 2021
TBD
703-502-1550
www.astro.org

CHEST 2021 ACCP Annual Meeting
American College of Chest Physicians
October 24 –27, 2021
Vancouver, BC
800-343-2227
www.chestnet.org

ACEP Annual Scientific Assembly 2021
American College of Emergency Physicians
October 25 – 28, 2021
Boston, MA
800-798-1822
www.acep.org

ASHG 2021
American Society of Human Genetics
October TBD
TBD
301-634-7300
www.ashg.org

NOVEMBER

ISPE Annual Meeting 2021
International Society for Pharmaceutical Engineering
November 1 – 3, 2021
Boston, MA
301-364-9201
www.ispe.org

ACAAI 2021 Annual Meeting
American College of Allergy Asthma & Immunology
November 4 – 8, 2021
New Orleans, LA
847-427-1200
www.acaai.org

AAO Annual Meeting 2021
American Academy of Ophthalmology
November 13 – 15, 2021
New Orleans, LA
415-561-8500
www.aao.org

RSNA 2021
Scientific Assembly and Annual Meeting
Radiological Society of North America
November 28 – December 2, 2021
Chicago, Illinois
800-381-6660
www.rsna.org

DECEMBER

No Conferences

CONFERENCES WITH DATES TO BE DETERMINED

AAPM Annual Meeting
American Academy of Pain Medicine
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Virtual Meeting
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www.annualmeeting.painmed.org

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***Piccolo Xpress* Part No:** 07P05-50 *Piccolo Xpress* with 3YR Serv, 07P05-51 *Piccolo Xpress* with 5YR Serv

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AJOVY®
(fremanezumab-vfrm)
injection 225 mg/1.5 mL

AJOVY IS AVAILABLE IN AN AUTOINJECTOR

AJOVY is indicated for the preventive treatment of migraine in adults

FEATURES OF THE EASY-TO-USE AUTOINJECTOR[1]



97% **of HCP and patient evaluators found the AJOVY Autoinjector easy to use in two human factor studies (N=77)[1]***

Please provide proper training to patients and/or caregivers on the preparation and administration of the AJOVY Autoinjector, as well as the prefilled syringe. Available resources include Instructions for Use in the full Prescribing Information, and an IFU video can be accessed at AJOVYhcp.com.

4 X PER YEAR | Only 4 injection days per year with quarterly dosing

✓ AJOVY can also be administered monthly

IMPORTANT SAFETY INFORMATION

Contraindications: AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients.

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria were reported with AJOVY in clinical trials. Most reactions were mild to moderate, but some led to discontinuation or required corticosteroid treatment. Most reactions were reported from within hours to one month after administration. If a hypersensitivity reaction occurs, consider discontinuing AJOVY and institute appropriate therapy.

Adverse Reactions: The most common adverse reactions (≥5% and greater than placebo) were injection site reactions.

Please see the Brief Summary of the full Prescribing Information on the adjacent page.

*Two human factor studies assessed evaluators' ability to complete critical tasks in order to demonstrate use of the AJOVY Autoinjector in simulated-use sessions. When asked "Was the autoinjector easy to use?", 97% in study 1 (N=30) and 98% in study 2 (N=47) answered "Yes."[1]

Reference: 1. Data on file. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.

To learn more, visit AJOVYhcp.com

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teva

BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR AJOVY® (fremanezumab-vfrm) injection, for subcutaneous use

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

AJOVY is indicated for the preventive treatment of migraine in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

Two subcutaneous dosing options of AJOVY are available to administer the recommended dosage:

- 225 mg monthly, or
- 675 mg every 3 months (quarterly), which is administered as three consecutive subcutaneous injections of 225 mg each.

When switching dosage options, administer the first dose of the new regimen on the next scheduled date of administration. If a dose of AJOVY is missed, administer as soon as possible. Thereafter, AJOVY can be scheduled from the date of the last dose.

2.2 Important Administration Instructions

AJOVY is for subcutaneous use only.

AJOVY may be administered by healthcare professionals, patients, and/or caregivers. Prior to use, provide proper training to patients and/or caregivers on the preparation and administration of AJOVY prefilled syringe, including aseptic technique *[see Instructions for Use in full Prescribing Information]*:

- Remove AJOVY from the refrigerator. Prior to use, allow AJOVY to sit at room temperature for 30 minutes protected from direct sunlight. Do not warm by using a heat source such as hot water or a microwave. Do not use AJOVY if it has been at room temperature for 24 hours or longer.
- Follow aseptic injection technique every time AJOVY is administered.
- Inspect AJOVY for particles or discoloration prior to administration. Do not use if the solution is cloudy, discolored, or contains particles.
- Administer AJOVY by subcutaneous injection into areas of the abdomen, thigh, or upper arm that are not tender, bruised, red, or indurated. For multiple injections, you may use the same body site, but not the exact location of the previous injection.
- Do not co-administer AJOVY with other injectable drugs at the same injection site.

4 CONTRAINDICATIONS

AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients *[see Warnings and Precautions (5.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria, were reported with AJOVY in clinical trials. Most reactions were mild to moderate, but some led to discontinuation or required corticosteroid treatment. Most reactions were reported from within hours to one month after administration.

If a hypersensitivity reaction occurs, consider discontinuing AJOVY, and institute appropriate therapy.

6 ADVERSE REACTIONS

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

- Hypersensitivity Reactions *[see Warnings and Precautions (5.1)]*

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 clinical practice.

The safety of AJOVY was evaluated in 2512 patients with migraine who received at least 1 dose of AJOVY, representing 1279 patient-years of exposure. Of these, 1730 patients were exposed to AJOVY 225 mg monthly or AJOVY 675 mg quarterly for at least 6 months, 775 patients for at least 12 months, and 138 patients for at least 15 months. In placebo-controlled clinical trials (Studies 1 and 2), 662 patients received AJOVY 225 mg monthly for 12 weeks (with or without a loading dose of 675 mg), and 663 patients received AJOVY 675 mg quarterly for 12 weeks. In the controlled trials, 87% of patients were female, 80% were White, and the mean age was 41 years.

The most common adverse reactions in the clinical trials for the preventive treatment of migraine (incidence at least 5% and greater than placebo) were injection site reactions. The adverse reactions that most commonly led to discontinuations were injection site reactions (1%). Table 1 summarizes adverse reactions reported in the 3-month placebo-controlled studies (Study 1 and Study 2), and the 1-month follow-up period after those studies.

Table 1: Adverse Reactions Occurring with an Incidence of At Least 2% for Either Dosing Regimen of AJOVY and At Least 2% Greater Than Placebo in Studies 1 and 2

Adverse Reaction	AJOVY 225 mg Monthly (n=290) %	AJOVY 675 mg Quarterly (n=667) %	Placebo Monthly (n=668) %
Injection site reactions[a]	43	45	38

[a] Injection site reactions include multiple related adverse event terms, such as injection site pain, induration, and erythema.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to fremanezumab-vfrm in the studies described below with the incidence of antibodies in other studies to other products may be misleading. Clinical immunogenicity of AJOVY was monitored by analyzing anti-drug antibodies (ADA) and neutralizing antibodies in drug-treated patients. The data reflect the percentage of patients whose test results were positive for antibodies to AJOVY in specific assays.

In 3-month placebo-controlled studies, treatment-emergent ADA responses were observed in 6 out of 1701 (0.4%) AJOVY-treated patients. One of the 6 patients developed anti-AJOVY neutralizing antibodies at Day 84. In the ongoing long-term open-label study, ADA were detected in 1.6% of patients (30 out of 1888). Out of 30 ADA-positive patients, 17 had a neutralizing activity in their post-dose samples. Although these data do not demonstrate an impact of anti-fremanezumab-vfrm antibody development on the efficacy or safety of AJOVY in these patients, the available data are too limited to make definitive conclusions.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with the use of AJOVY in pregnant women. AJOVY has a long half-life. This should be taken into consideration for women who are pregnant or plan to become pregnant while using AJOVY. Administration of fremanezumab-vfrm to rats and rabbits during the period of organogenesis or to rats throughout pregnancy and lactation at doses resulting in plasma levels greater than those expected clinically did not result in adverse effects on development *[see Animal Data]*. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The estimated rate of major birth defects (2.2-2.9%) and miscarriage (17%) among deliveries to women with migraine are similar to rates reported in women without migraine.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Published data have suggested that women with migraine may be at increased risk of preeclampsia and gestational hypertension during pregnancy.

Data

Animal Data

When fremanezumab-vfrm (0, 50, 100, or 200 mg/kg) was administered to male and female rats by weekly subcutaneous injection prior to and during mating and continuing in females throughout organogenesis, no adverse embryofetal effects were observed. The highest dose tested was associated with plasma exposures (AUC) approximately 2 times that in humans at a dose of 675 mg.

Administration of fremanezumab-vfrm (0, 10, 50, or 100 mg/kg) weekly by subcutaneous injection to pregnant rabbits throughout the period of organogenesis produced no adverse effects on embryofetal development. The highest dose tested was associated with plasma AUC approximately 3 times that in humans (675 mg).

Administration of fremanezumab-vfrm (0, 50, 100, or 200 mg/kg) weekly by subcutaneous injection to female rats throughout pregnancy and lactation resulted in no adverse effects on pre- and postnatal development. The highest dose tested was associated with plasma AUC approximately 2 times that in humans (675 mg).

8.2 Lactation

Risk Summary

There are no data on the presence of fremanezumab-vfrm in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for AJOVY and any potential adverse effects on the breastfed infant from AJOVY or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of AJOVY did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Manufactured by:
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This Brief Summary is based on the full Prescribing Information for AJOVY AJO-004.

teva

FRE-42210 February 2020

DIAGNOSTIC AND DEVICE companies

A

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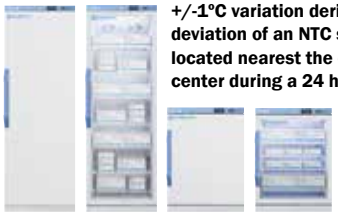
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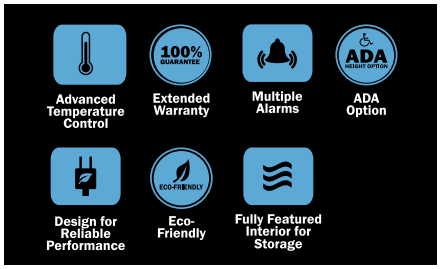
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ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	943.00
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1 Estimate the maximum number of doses of publicly-provided vaccine and privately purchased vaccine that will be in your refrigerator.

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

Public Vaccine _____

Private Vaccine + _____

Total doses = _____

Multiply (max inventory) x 1.25

Maximum doses = _____

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

Max. Doses	Minimum Cubic Ft.
2,000+ doses	may need more than one refrigerator
1000-2000	40 cu.ft
900-1000	36 cu.ft
801-900	21-23 cu.ft
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For facilities treating COVID-19 patients, having rapid, accurate diagnostic test results may be useful when assessing or monitoring patients for:

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

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HEALTH AGENCY hotlines

Adoption
National Adoption Center
www.adopt.org
(800) 862-3678

Aging
National Aging Info and Referral Support Center
www.nasuad.org
(202) 898-2578

Alcohol Abuse
Al-Anon Family Groups
www.al-anon.alateen.org
(757) 563-1600

Allergy/Asthma
American Academy of Allergy, Asthma & Immunology
www.aaaai.org
(414) 272-6071

FARE/ Food Allergy
Research & Education
www.foodallergy.org
(800) 929-4040

Alzheimer's Disease
Alzheimer's Association
www.alz.org
(800) 272-3900

Anemia
Aplastic Anemia & MDS International Foundation
www.aamds.org
(800) 747-2820

Sickle Cell Disease
Association of America, Inc.
www.sicklecelldisease.org
(800) 421-8453

Arthritis
Arthritis Foundation Info Hotline
www.arthritis.org
(844) 571-4357

Bladder Diseases
Interstitial Cystitis Association
www.ichelp.org
(703) 442-2070

Blood Disorders
National Hemophilia Foundation
www.hemophilia.org
(212) 328-3700

Bone Marrow
National Bone Marrow Transplant Link
www.nbmtlink.org
(800) 546-5268

Bone Disease
National Institute of Arthritis & Musculoskeletal & Skin Diseases
www.niams.nih.gov
(877) 226-4267

Breast Disease
National Breast & Cervical Cancer Early Detection Program
www.cdc.gov/cancer/nbccedp
(800) 232-4636

Digestive Disorders/ Diseases
Crohn's & Colitis Foundation of America
www.ccfa.org
(800) 932-2423

Celiac Disease Foundation
www.celiac.org
(818) 716-1513

Eating Disorders
National Eating Disorders Association
www.nationaleating-disorders.org
(800) 931-2237

Eye Disease
American Macular Degeneration Foundation
www.macular.org
(888) 622-8527

The Vision Council
www.thevisioncouncil.org
(866) 826-0290

Glaucoma Research Foundation
www.glaucoma.org
(415) 986-3162

Fibromyalgia
National Fibromyalgia Association
www.fmaware.org

Gastrointestinal Diseases
International Foundation for Functional Gastrointestinal Disorders
www.iffgd.org
(414) 964-1799

Growth Disorders
Human Growth Foundation
www.hgfound.org
(800) 451-6434

Hearing Disorders
International Hearing Society
www.ihsinfo.org
(734) 522-7200

Heart Disease
American Heart Association
www.heart.org
(800) 242-8721

Hepatitis C
Hepatitis C Association
www.hepcassoc.org
(908) 769-8479

Hospital/Hospice Care
Caring Connections
www.caringinfo.org
(703) 837-1500

Immunization
National Immunization Hotline
www.cdc.gov/vaccines
(800) 232-4636

Impotence
American Urological Association
www.auanet.org
(866) 746-4282

Insurance/Medicare/Medicaid
Medicare Issues Hotline
www.medicare.gov
(800) 633-4227

Kidney Disease
National Kidney Foundation
www.kidney.org
(800) 622-9010

Lead
EPA Lead Information Center
www.epa.gov/lead
(800) 424-5323

Liver Diseases
American Liver Foundation
www.liverfoundation.org
(212) 668-1000

Lung Disease/Asthma/Allergy
American Lung Association
www.lungusa.org
(800) 586-4872

Mental Health
Mental Health America
www.mental-healthamerica.net
(800) 969-6642

Minority Health
US Department of Health and Human Services
Office of Minority Health
www.minorityhealth.hhs.gov
(800) 444-6472

Nervous System Disease
American Parkinson Disease Association
www.apdaparkinson.org
(800) 223-2732

Multiple Sclerosis Foundation
www.msfocus.org
(888) 673-6287

National Stroke Association
www.stroke.org
(800) 242-8721

Organ Donation
Living Bank
www.livingbank.org
(800) 528-2971

Pancreatic Disease
Pancreatic Cancer Action Network
www.pancan.org
(877) 573-9971

Paralysis and Spinal Injury
Christopher & Dana Reeve Foundation
www.christopherreeve.org
(800) 539-7309

Parkinson's Disease
Parkinson's Disease Foundation
www.parkinson.org
(800) 473-4636

Pediatrics
American Academy of Pediatrics
www.aap.org
(800) 433-9016

Poison Control
American Association of Poison Control Centers
www.aapcc.org
(800) 222-1222

Professionals
American Medical Association
www.ama-assn.org
(800) 622-3211

Rehabilitation
National Rehabilitation Info. Ctr.
www.naric.com
(800) 346-2742

Rheumatic Diseases
Scleroderma Foundation
www.scleroderma.org
(800) 722-4673

Sexually Transmitted Diseases
CDC Sexually Transmitted Diseases Info.
www.cdc.gov/std/
(800) 232-4636

Skin Disease
National Psoriasis Foundation
www.psoriasis.org
(800) 723-9166

Spinal Diseases
National Scoliosis Foundation, Inc.
www.scoliosis.org
(800)673-6922

Stroke
National Stroke Association
www.stroke.org
(800) 242-8721

Sudden Infant Death Syndrome
American SIDS Institute
www.sids.org
(239) 431-5425

Surgery/Facial Plastic Surgery
American Society of Plastic Surgeons
www.plasticsurgery.org
(847) 228-9900

Thyroid Disease
American Thyroid Association
www.thyroid.org
(703) 998-8890

Veterans
Veterans Special Issue Helpline
Department ofVeterans Affairs
www.va.gov
(844) 698-2311

VA Suicide Prevention
www.mentalhealth.va.gov
(844) 698-2311

Vision Disorders
American Council of the Blind
www.acb.org
(800) 424-8666



LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

A breakthrough for patients with advanced CSCC[1]

LIBTAYO® is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.[1]

For patients with mCSCC or laCSCC receiving 3 mg/kg every 2 weeks in Study 1540:



31% PR
(partial response)†

15% CR
(complete response)‡

ORR: 63 out of 137 patients (95% CI, 37%-55%)[1,2]

79% of responders (50 out of 63 patients) reached a DOR of ≥6 months[1,2]*

54% of responders (34 out of 63 patients) reached a **DOR of ≥12 months**[1,2]*

Median DOR was not reached (range: 1.9–24.2+ months)[1-3]*

*Median duration of follow-up was 11.1 months for combined CSCC in Study 1540.[1] See additional study design details below.

In an additional cohort in Study 1540, 56 mCSCC patients received LIBTAYO at a dose of 350 mg intravenously every 3 weeks for up to 54 weeks. With a median duration of follow-up of 8.0 months, the confirmed ORR was 41% (95% CI: 28, 55), and 65% of responders had a DOR ≥6 months.[1]

Median DOR was not reached (range: 2.1–11.1+ months)[2]

Plus sign (+) denotes ongoing at last assessment.

- **Study 1540**—EMPOWER-CSCC 1—was a global, pivotal, open-label, nonrandomized, multicohort study that included a total of 193 patients with mCSCC or laCSCC who were not candidates for curative surgery or curative radiation.[1,2,4] Patients received LIBTAYO 3 mg/kg intravenously every 2 weeks for up to 96 weeks or 350 mg LIBTAYO every 3 weeks for up to 54 weeks.[1,3] Treatment continued until progression of disease, unacceptable toxicity, or completion of planned treatment.[1] The cutoff for Study 1540 data in the USPI is September/October 2018[2]
- The major efficacy outcome measures were confirmed ORR, defined as CR plus PR as assessed by independent central review (ICR), and ICR-assessed DOR[1]
- Study 1540 excluded patients with autoimmune disease who required systemic therapy with immunosuppressant agents within 5 years; history of solid organ transplant; prior treatment with anti–PD-1/programmed death ligand 1 (PD-L1) blocking antibodies or other immune checkpoint inhibitor therapy; infection with HIV, hepatitis B, or hepatitis C; or ECOG PS ≥2[1]

The recommended dosage of LIBTAYO is 350 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.[1]

†Partial response is defined as a decrease of 30% or greater in the sum of the diameters of target lesions, taking as reference the baseline sum of diameters, per RECIST 1.1. Partial response of externally visible disease is defined as a decrease of 50% or greater in the sum of products of perpendicular longest diameters of target lesions, per WHO Criteria. Nontarget lesions could not have progressive disease, and there could be no new lesions. Responses had to be maintained for at least 4 weeks.[2]

‡Complete response is defined as disappearance of all target lesions for at least 4 weeks. Nontarget lesions also had to be a complete response, and there could be no new lesions. Any pathological lymph nodes (whether target or nontarget) must have reduction in short axis to <10 mm (<1 cm). Only includes patients with complete healing of prior cutaneous involvement; patients with laCSCC in Study 1540 required biopsy to confirm CR.[1,2]

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue and usually occur during treatment; however, they can also occur after discontinuation. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously. Early identification and management are essential to ensuring safe use of PD-1–blocking antibodies. Monitor for symptoms and signs of immune-mediated adverse reactions. Evaluate clinical chemistries, including liver tests and thyroid function tests, at baseline and periodically during treatment. Institute medical management promptly to include specialty consultation as appropriate.

In general, withhold LIBTAYO for Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions. Permanently discontinue LIBTAYO for Grade 4 and certain Grade 3 immune-mediated adverse reactions. For Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions, administer corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) or other appropriate therapy until improvement to Grade 1 or less followed by a corticosteroid taper over 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids. Institute hormone replacement therapy for endocrinopathies as warranted.

Immune-mediated pneumonitis: Immune-mediated pneumonitis occurred in 2.4% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 3 (0.7%), and Grade 2 (1.3%). Pneumonitis led to permanent discontinuation of LIBTAYO in 1.3% of patients. Systemic corticosteroids were required in all patients with pneumonitis, including 85% who received prednisone ≥40 mg/day or equivalent. Pneumonitis resolved in 62% of patients. Withhold LIBTAYO for Grade 2, and permanently discontinue for Grade 3 or 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated colitis: Immune-mediated colitis occurred in 0.9% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.6%). Colitis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with colitis, including 60% who received prednisone ≥40 mg/day or equivalent. Colitis resolved in 80% of patients. Withhold LIBTAYO for Grade 2 or 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated hepatitis: Immune-mediated hepatitis occurred in 2.1% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 4 (0.2%), and Grade 3 (1.7%). Hepatitis led to permanent discontinuation of LIBTAYO in 0.9% of patients. Systemic corticosteroids were required in all patients with hepatitis, including 91% who received prednisone ≥40 mg/day or equivalent. Hepatitis resolved in 64% of patients. Withhold LIBTAYO if AST or ALT increases to more than 3 and up to 10 times the upper limit of normal (ULN) or if total bilirubin increases up to 3 times the ULN. Permanently discontinue LIBTAYO if AST or ALT increases to more than 10 times the ULN or total bilirubin increases to more than 3 times the ULN. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated endocrinopathies: Withhold LIBTAYO if clinically necessary for Grade 2, 3, or 4.

- **Adrenal insufficiency:** Adrenal insufficiency occurred in 0.4% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.2%)
- **Hypophysitis:** Hypophysitis, which can result in hypopituitarism, occurred in 0.2% of 534 patients receiving LIBTAYO, which consisted of 1 patient with Grade 3 hypophysitis
- **Hypothyroidism:** Hypothyroidism occurred in 6% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (5.6%); no patients discontinued hormone replacement therapy

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.

LIBTAYO® (cemiplimab-rwlc) demonstrated meaningful tumor reduction in clinical trial patients[1,2]

Partial responses

These are examples from the 31% of patients who had a partial response in clinical trials. Individual patient responses may vary.

Locally advanced CSCC Not a candidate for curative surgery or curative radiation

History

- 70-year-old male
- Auricular lesions†

Outcomes*

- Best overall response: PR per composite (RECIST 1.1 + WHO Criteria) evaluation by ICR
- Best percent change in target lesion(s): 91.9% per WHO Criteria

Screening | **After 16 weeks** | **After 32 weeks**



Metastatic CSCC

History

- 66-year-old male
- Periclavicular lesions

Outcomes*

- Best response: PR per composite (RECIST 1.1 + WHO Criteria) evaluation by ICR
- Best percent change in target lesion(s): 71.1% per RECIST 1.1

Screening | **After 24 weeks** | **After 48 weeks**



*Results as of data cutoff October 27, 2017.[2]

†This patient also had cranial lesions that were included in the calculation of best percent change in target lesion(s). Those images are not included here.[2]

DOR=duration of response; ECOG=Eastern Cooperative Oncology Group; ICR=independent central review; PS=performance status; Q2W=every 2 weeks; Q3W=every 3 weeks; RECIST=Response Evaluation Criteria in Solid Tumors; WHO=World Health Organization.

See more patient profiles at LIBTAYOhcp.com.

Important Safety Information (continued)

Warnings and Precautions (continued)

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated endocrinopathies (continued):

- **Hyperthyroidism:** Hyperthyroidism occurred in 1.5% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.4%); hyperthyroidism resolved in 38% of patients
- **Type 1 diabetes mellitus:** Type 1 diabetes mellitus, which can present with diabetic ketoacidosis, occurred in 0.7% of 534 patients, including Grade 4 (0.4%) and Grade 3 (0.4%); type 1 diabetes mellitus led to permanent discontinuation of LIBTAYO in 0.2% of patients

Immune-mediated nephritis with renal dysfunction: Immune-mediated nephritis occurred in 0.6% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.2%). Nephritis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with nephritis, including 67% who received prednisone ≥40 mg/day or equivalent. Nephritis resolved in all patients. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Immune-mediated dermatologic adverse reactions: Immune-mediated dermatologic reactions, including erythema multiforme and pemphigoid, occurred in 1.7% of 534 patients receiving LIBTAYO, including Grade 3 (1.1%) and Grade 2 (0.6%). In addition, Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) have been observed with LIBTAYO and with other products in this class. Systemic corticosteroids were required in all patients with dermatologic reactions, including 89% who received prednisone ≥40 mg/day or equivalent. Dermatologic reactions resolved in 33% of patients. Approximately 22% of patients had recurrence of dermatologic reactions after re-initiation of LIBTAYO. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Other immune-mediated adverse reactions: The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 534 patients who received LIBTAYO or were reported with the use of other PD-1–blocking and PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

- **Neurological:** Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, nerve paresis, and autoimmune neuropathy
- **Cardiovascular:** Myocarditis, pericarditis, and vasculitides
- **Ocular:** Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various Grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss
- **Gastrointestinal:** Pancreatitis to include increases in serum amylase and lipase levels, gastritis, and duodenitis
- **Musculoskeletal and connective tissue:** Myositis, rhabdomyolysis, and associated sequelae, including renal failure, arthritis, and polymyalgia rheumatica
- **Hematological and immunological:** Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, and solid organ transplant rejection

Infusion-related reactions

Severe infusion-related reactions (Grade 3) occurred in 0.2% of patients receiving LIBTAYO. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion for Grade 1 or 2, and permanently discontinue for Grade 3 or 4.

Embryo-fetal toxicity

LIBTAYO can cause fetal harm when administered to a pregnant woman due to an increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose.

Adverse reactions

- Serious adverse reactions occurred in 35% of patients. Serious adverse reactions that occurred in ≥2% of patients were pneumonitis, cellulitis, sepsis, and pneumonia. The most common Grade 3-4 adverse reactions (≥2%) were cellulitis, anemia, hypertension, pneumonia, musculoskeletal pain, fatigue, pneumonitis, sepsis, skin infection, and hypercalcemia
- LIBTAYO was permanently discontinued due to adverse reactions in 8% of patients; adverse reactions resulting in permanent discontinuation were pneumonitis, cough, pneumonia, encephalitis, aseptic meningitis, hepatitis, arthralgia, muscular weakness, neck pain, soft tissue necrosis, complex regional pain syndrome, lethargy, psoriasis, rash maculopapular, proctitis, and confusional state
- The most common adverse reactions (incidence ≥20%) were fatigue, rash, and diarrhea musculoskeletal pain, and nausea

Use in specific populations

- **Lactation:** Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO
- **Females and males of reproductive potential:** Verify pregnancy status in females of reproductive potential prior to initiating LIBTAYO

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

References: 1. LIBTAYO (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc., and sanofi-aventis U.S. LLC. **2.** Data on file. Regeneron Pharmaceuticals Inc. **3.** Migden MR et al. *N Engl J Med.* 2018;379(4):341-351. **4.** Study of REGN2810 in patients with advanced cutaneous squamous cell carcinoma. ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/study/NCT02760498. Updated July 16, 2020. Accessed July 25, 2020.

To learn more about LIBTAYO, speak with your sales representative or visit LIBTAYOhcp.com.

REGENERON | SANOFI GENZYME

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LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

LIBTAYO® (cemiplimab-rwlc) injection, for intravenous use

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

LIBTAYO is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Severe and Fatal Immune-Mediated Adverse Reactions

LIBTAYO is a monoclonal antibody that belongs to a class of drugs that binds to the programmed death receptor-1 (PD-1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response with the potential for breaking of peripheral tolerance and induction of immune-mediated adverse reactions. Important immune-mediated adverse reactions listed under Warnings and Precautions may not be inclusive of all possible immune-mediated reactions.

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. While immune-mediated adverse reactions usually manifest during treatment with PD-1/PD-L1 blocking antibodies, immune-mediated adverse reactions can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously.

Early identification and management are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. Monitor for symptoms and signs of immune-mediated adverse reactions. Evaluate clinical chemistries, including liver tests and thyroid function tests, at baseline and periodically during treatment. Institute medical management promptly to include specialty consultation as appropriate.

In general, withhold LIBTAYO for Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions. Permanently discontinue LIBTAYO for Grade 4 and certain Grade 3 immune-mediated adverse reactions *[see Dosage and Administration (2.2)]*. For Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions, administer corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) or other appropriate therapy until improvement to Grade 1 or less followed by a corticosteroid taper over one month *[see Dosage and Administration (2.2)]*. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids. Institute hormone replacement therapy for endocrinopathies as warranted.

Immune-Mediated Pneumonitis

Immune-mediated pneumonitis occurred in 2.4% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 3 (0.7%) and Grade 2 (1.3%) *[see Adverse Reactions (6.1)]*. Pneumonitis led to permanent discontinuation of LIBTAYO in 1.3% of patients. Systemic corticosteroids were required in all patients with pneumonitis, including 85% who received prednisone ≥ 40 mg per day or equivalent. Pneumonitis resolved in 62% of patients.

Immune-Mediated Colitis

Immune-mediated colitis occurred in 0.9% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.6%) *[see Adverse Reactions (6.1)]*. Colitis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with colitis, including 60% who received prednisone ≥ 40 mg per day or equivalent. Colitis resolved in 80% of patients.

Immune-Mediated Hepatitis

Immune-mediated hepatitis occurred in 2.1% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 4 (0.2%), and Grade 3 (1.7%) *[see Adverse Reactions (6.1)]*. Hepatitis led to permanent discontinuation of LIBTAYO in 0.9% of patients. Systemic corticosteroids were required in all patients with hepatitis, including 91% who received prednisone ≥ 40 mg per day or equivalent. Hepatitis resolved in 64% of patients.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

Adrenal insufficiency occurred in 0.4% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%), and Grade 2 (0.2%) *[see Adverse Reactions (6.1)]*.

Hypophysitis

Hypophysitis, which can result in hypopituitarism, occurred in 0.2% of 534 patients receiving LIBTAYO, which consisted of one patient with Grade 3 hypophysitis.

Hypothyroidism

Hypothyroidism occurred in 6% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (5.6%). No patients discontinued hormone replacement therapy.

Hyperthyroidism

Hyperthyroidism occurred in 1.5% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.4%). Hyperthyroidism resolved in 38% of patients.

Type 1 Diabetes Mellitus

Type 1 diabetes mellitus, which can present with diabetic ketoacidosis, occurred in 0.7% of 534 patients, including Grade 4 (0.4%) and Grade 3 (0.4%). Type 1 diabetes mellitus led to permanent discontinuation of LIBTAYO in 0.2% of patients.

Immune-Mediated Nephritis with Renal Dysfunction

Immune-mediated nephritis occurred in 0.6% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.2%) *[see Adverse Reactions (6.1)]*. Nephritis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with nephritis, including 67% who received prednisone ≥ 40 mg per day or equivalent. Nephritis resolved in all patients.

Immune-Mediated Dermatologic Adverse Reactions

Immune-mediated dermatologic reactions, including erythema multiforme and pemphigoid, occurred in 1.7% of 534 patients receiving LIBTAYO, including Grade 3 (1.1%) and Grade 2 (0.6%) *[see Adverse Reactions (6.1)]*. In addition, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been observed with LIBTAYO and with other products in this class. Systemic corticosteroids were required in all patients with dermatologic reactions, including 89% who received prednisone ≥ 40 mg per day or equivalent. Dermatologic reactions resolved in 33% of patients. Approximately 22% of patients had recurrence of dermatologic reactions after re-initiation of LIBTAYO.

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 534 patients who received LIBTAYO *[see Adverse Reactions (6.1)]* or were reported with the use of other PD-1/PD-L1 blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.

Neurological: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome / myasthenia gravis, Guillain-Barre syndrome, nerve paresis, autoimmune neuropathy

Cardiovascular: Myocarditis, pericarditis, vasculitides

Ocular: Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada like syndrome, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss.

Gastrointestinal: Pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis

Musculoskeletal and Connective Tissue: Myositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica

Hematological and Immunological: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection

5.2 Infusion-Related Reactions

Severe infusion-related reactions (Grade 3) occurred in 0.2% of patients receiving LIBTAYO *[see Adverse Reactions (6.1)]*. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue LIBTAYO based on severity of reaction *[see Dosage and Administration (2.2)]*.

5.3 Embryo-Fetal Toxicity

Based on its mechanism of action, LIBTAYO can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

6 ADVERSE REACTIONS

The following serious adverse reactions are described elsewhere in the labeling.

- Severe and Fatal Immune-Mediated Adverse Reactions *[see Warnings and Precautions (5.1)]*
- Infusion-Related Reactions *[see Warnings and Precautions (5.2)]*

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 described in Warnings and Precautions reflect exposure to LIBTAYO in 534 patients in two open-label, single-arm, multicohort studies (Study 1423 and Study 1540), including 98 patients with mCSCC (nodal or distant), 65 patients with laCSCC, and 371 patients with other advanced solid tumors. LIBTAYO as a single agent or in combination with chemotherapy or radiation was administered intravenously at doses of 1 mg/kg every 2 weeks (n=27), 3 mg/kg every 2 weeks (n=446), 3 mg/kg every 3 weeks (n=12), 10 mg/kg every 2 weeks (n=6), 200 mg every 2 weeks (n=20) or 350 mg every 3 weeks (n=23). Among the 534 patients, 38% were exposed for ≥ 6 months and 16% were exposed for ≥ 12 months.

The data described below reflect exposure to LIBTAYO in 219 patients with advanced CSCC (metastatic or locally advanced disease) in Study 1423 and Study 1540 *[see Clinical Studies (14)]*. Of these 219 patients, 131 had mCSCC (nodal or distant) and 88 had laCSCC. Patients received LIBTAYO 1 mg/kg every 2 weeks (n=1), 3 mg/kg every 2 weeks (n=162) or 350 mg every 3 weeks (n=56) as an intravenous infusion until disease progression, unacceptable toxicity, or completion of planned treatment. The median duration of exposure was 38 weeks (2 weeks to 110 weeks).

The safety population characteristics were: median age of 72 years (38 to 96 years), 83% male, 96% white, and European Cooperative Oncology Group (ECOG) performance score (PS) of 0 (44%) and 1 (56%).

The most common adverse reactions reported in at least 20% of patients were fatigue, rash, diarrhea, musculoskeletal pain, and nausea. The most common Grade 3-4 adverse reactions (≥ 2%) were cellulitis, anemia, hypertension, pneumonia, musculoskeletal pain, fatigue, pneumonitis, sepsis, skin infection, and hypercalcemia. LIBTAYO was permanently discontinued due to adverse reactions in 8% of patients; adverse reactions resulting in permanent discontinuation were pneumonitis, cough, pneumonia, encephalitis, aseptic meningitis, hepatitis, arthralgia, muscular weakness, neck pain, soft tissue necrosis, complex regional pain syndrome, lethargy, psoriasis, rash maculopapular, proctitis, and confusional state. Serious adverse reactions occurred in 35% of patients. Serious adverse reactions that occurred in at least 2% of patients were pneumonitis, cellulitis, sepsis, and pneumonia.

Table 1 summarizes the adverse reactions that occurred in ≥ 10% of patients and Table 2 summarizes Grade 3 or 4 laboratory abnormalities worsening from baseline in ≥ 1% of patients receiving LIBTAYO.

Table 1: Adverse Reactions in ≥ 10% of Patients with Advanced CSCC Receiving LIBTAYO in Study 1423 and Study 1540

Adverse Reactions	LIBTAYO N=219	
	All Grades %	Grades 3-4 %
General and Administration Site		
Fatigue[a]	34	3
Skin and Subcutaneous Tissue		
Rash[b]	31	1
Pruritus[c]	18	0
Gastrointestinal		
Diarrhea[d]	25	0.5
Nausea	21	0
Constipation	13	0.5
Vomiting	10	0.5
Musculoskeletal and Connective Tissue		
Musculoskeletal pain[e]	24	3
Arthralgia	11	1
Respiratory		
Cough[f]	14	0

(continued)

Table 1: Adverse Reactions in ≥ 10% of Patients with Advanced CSCC Receiving LIBTAYO in Study 1423 and Study 1540 (continued)

Adverse Reactions	LIBTAYO N=219	
	All Grades %	Grades 3-4 %
Hematology		
Anemia	11	4
Endocrine		
Hypothyroidism	10	0
Metabolism and Nutrition		
Decreased appetite	10	0

Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v.4.03

a. Fatigue is a composite term that includes fatigue and asthenia
b. Rash is a composite term that includes rash, rash maculopapular, erythema, dermatitis, dermatitis bullous, rash generalized, pemphigoid, rash erythematous, rash macular, rash pruritic, drug eruption, psoriasis, and skin reaction
c. Pruritus is a composite term that includes pruritus and pruritus allergic
d. Diarrhea is a composite term that includes diarrhea and colitis
e. Musculoskeletal pain is a composite term that includes back pain, pain in extremity, myalgia, musculoskeletal pain, and neck pain
f. Cough is a composite term that includes cough and upper airway cough syndrome

Table 2: Grade 3 or 4 Laboratory Abnormalities Worsening from Baseline in ≥ 1% of Patients with Advanced CSCC Receiving LIBTAYO in Study 1423 and Study 1540

Laboratory Abnormality	Grade 3-4 (%)[a]
Chemistry	
Increased aspartate aminotransferase	2
Increased INR	2
Hematology	
Lymphopenia	9
Anemia	5
Electrolytes	
Hyponatremia	5
Hypophosphatemia	4
Hypercalcemia	2

Toxicity graded per NCI CTCAE v. 4.03

[a.] Percentages are based on the number of patients with at least 1 post-baseline value available for that parameter.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to cemiplimab-rwlc in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

Anti-drug antibodies (ADA) were tested in 467 patients who received LIBTAYO. The incidence of cemiplimab-rwlc treatment-emergent ADAs was 1.1% using an electrochemiluminescent (ECL) bridging immunoassay; 0.2% were persistent ADA responses. In the patients who developed anti-cemiplimab-rwlc antibodies, there was no evidence of an altered pharmacokinetic profile of cemiplimab-rwlc.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on its mechanism of action, LIBTAYO can cause fetal harm when administered to a pregnant woman *[see Clinical Pharmacology (12.1)]*. There are no available data on the use of LIBTAYO in pregnant women. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death *(see Data)*. Human IgG4 immunoglobulins (IgG4) are known to cross the placenta; therefore, LIBTAYO has the potential to be transmitted from the mother to the developing fetus. Advise women of the potential risk to a fetus.

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

Animal reproduction studies have not been conducted with LIBTAYO to evaluate its effect on reproduction and fetal development. A central function of the PD-1/PD-L1 pathway is to preserve pregnancy by maintaining maternal immune tolerance to the fetus. In murine models of pregnancy, blockade of PD-L1 signaling has been shown to disrupt tolerance to the fetus and to result in an increase in fetal loss; therefore, potential risks of administering LIBTAYO during pregnancy include increased rates of abortion or stillbirth. As reported in the literature, there were no malformations related to the blockade of PD-1/PD-L1 signaling in the offspring of these animals; however, immune-mediated disorders occurred in PD-1 and PD-L1 knockout mice.

Based on its mechanism of action, fetal exposure to cemiplimab-rwlc may increase the risk of developing immune-mediated disorders or altering the normal immune response.

8.2 Lactation

Risk Summary

There is no information regarding the presence of cemiplimab-rwlc in human milk, or its effects on the breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO.

8.3 Females and Males of Reproductive Potential

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating LIBTAYO *[see Use in Specific Populations (8.1)]*.

Contraception

LIBTAYO can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*.

Females

Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose.

8.4 Pediatric Use

The safety and effectiveness of LIBTAYO have not been established in pediatric patients.

8.5 Geriatric Use

Of the 219 mCSCC or laCSCC patients who received LIBTAYO in clinical studies, 34% were 65 years up to 75 years and 41% were 75 years or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

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www.futuremedamerica.com

Medical Device Depot
www.medicaldevicedepot.com

Micro Direct, Inc.
www.mdspiro.com

Midmark Diagnostics, Inc.
www.midmark.com

MIR – Medical International Research
www.spirometry.com

ndd Medical Technologies
www.nddmed.com

Vitalograph
www.vitalograph.com

Welch Allyn
www.welchallyn.com

STREP TESTING
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BD
www.BD.com/veritorsystem

Cepheid
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Beckman Coulter, Inc.
www.beckmancoulter.com

LifeSign, LLC
www.lifesignmed.com

Roche
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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Few cases (0.36%) of adverse reactions of cystitis, pyelonephritis and other upper urinary tract infection (UTI) have been reported in Phexxi™ clinical studies. Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of Phexxi™ in females of reproductive potential with history of recurrent urinary tract infection or urinary tract abnormalities.

ADVERSE REACTIONS

Most common adverse reactions were vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal mycotic infection, urinary tract infection, vulvovaginal discomfort, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria, and vulvovaginal pain.

Patients should be counseled on the following:

- **To contact and consult with their healthcare provider for severe or prolonged genital irritation or experiencing urinary tract symptoms.**
- **To discontinue Phexxi™ if they develop a local hypersensitivity reaction.**
- **That Phexxi™ does not protect against HIV infection or other sexually transmitted infections.**

To report SUSPECTED ADVERSE REACTIONS, contact Evofem at toll-free phone 1-833-EVFMBIO or you may contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.



INDICATIONS AND USAGE
Phexxi™ is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

LIMITATIONS OF USE
Phexxi™ is not effective for the prevention of pregnancy when administered after intercourse.

Please see full Prescribing Information for Phexxi™.
Please see Brief Summary on the following page.

REFERENCES: 1. Phexxi™ [Prescribing Information]. Evofem Biosciences, Inc: San Diego, CA; May 2020. **2.** Phexxi™ Vaginal Gel. Medi-Span®; June 8, 2020. **3.** Bayer LL, Jensen JT. ACIDFORM: a review of evidence. *Contraception*. 2014;90:11-18. **4.** Nayak S, Avery A, McLeod Griffiss J, Charles CD, Culwell KR. A randomized placebo-controlled pilot study of the effect and duration of Amphora, a multipurpose vaginal pH regulator, on vaginal pH. *Clin Exp Obstet Gynecol*. 2019;46(5):736-742.

EVOFEM BIOSCIENCES

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EVFM-US-000071 • August 2020 • Produced in USA.

phexxi™

(lactic acid, citric acid, and potassium bitartrate) Vaginal Gel 1.8%, 1%, 0.4%

BRIEF SUMMARY: Consult the Package Insert for complete Prescribing Information

INDICATIONS AND USAGE

PHEXXI™ is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

LIMITATIONS OF USE

PHEXXI is not effective for the prevention of pregnancy when administered after intercourse.

WARNINGS AND PRECAUTIONS

Cystitis and Pyelonephritis

Among 2804 subjects who received PHEXXI in Studies 1 and 2, 0.36% (n=10) reported adverse reactions of cystitis, pyelonephritis, or other upper urinary tract infection (UTI). Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of PHEXXI in females of reproductive potential with a history of recurrent urinary tract infection or urinary tract abnormalities.

ADVERSE REACTIONS

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 safety of PHEXXI (pre-filled applicator with 5-gram dose) has been evaluated in two clinical trials (Study 1 and Study 2) in 2804 subjects (over 19,000 cycles of exposure). The racial/ethnic distribution was 66% White, 27% Black or African American, 2% Asian, 1% American Indian or Alaska Native, 0.3% Native Hawaiian or Pacific Islander, and 5% other; 32% of the study population was Hispanic. Study 1 included a one-year extension phase where 342 U.S. subjects were exposed to PHEXXI for 13 cycles.

Hypersensitivity Reaction:

Of the 2804 PHEXXI-treated subjects in Studies 1 and 2, one subject reported a suspected drug hypersensitivity. Avoid PHEXXI use in females of reproductive potential with suspected hypersensitivity to the ingredients in PHEXXI.

The most common adverse reactions (≥10%) in the U.S. population in Studies 1 and 2 (n = 2480) were: vulvovaginal burning sensation (18.0%) and vulvovaginal pruritus (14.5%). The majority of these adverse reactions were mild and few led to discontinuation. Table 1 summarizes the most common adverse reactions (≥ 2%) reported by subjects using PHEXXI in the U.S.

Table 1. Adverse Reactions that Occurred in ≥ 2% of Subjects Who Used PHEXXI to Prevent Pregnancy (Studies 1 and 2 – U.S. population only)

Adverse Reaction	PHEXXI (N=2480) (%)
Vulvovaginal Burning Sensation	18.0
Vulvovaginal Pruritus	14.5
Vulvovaginal Mycotic Infection*	9.1
Urinary Tract Infection†,‡	9.0
Vulvovaginal Discomfort	9.0
Bacterial Vaginosis	8.4
Vaginal Discharge	5.5
Genital Discomfort	4.1
Dysuria	3.1
Vulvovaginal pain	2.1

*Includes preferred terms (PT) vulvovaginal mycotic infection and vulvovaginal candidiasis.
†Includes PTs urinary tract infection, streptococcal urinary tract infection, Escherichia urinary tract infection, and urinary tract infection bacterial.
‡Does not include PTs cystitis, kidney infection, and pyelonephritis [see *Warnings and Precautions (5.1) of PHEXXI Full Prescribing Information*].

Among subjects who used PHEXXI in Studies 1 and 2, 1.6% discontinued from the clinical trials due to an adverse reaction. The most common adverse reactions leading to study discontinuation were vulvovaginal burning sensation (0.7%); and vulvovaginal pruritus and vulvovaginal discomfort (0.1% each).

Adverse Reactions in Male Partners:

Among male partners of subjects who used PHEXXI for contraception in Study 2, 9.8% (131 of 1330) reported symptoms of local discomfort (burning, itching, pain, and "other"). Of these local discomfort symptoms, 74.7% were mild, 21.4% were moderate, and 3.9% were severe. Two subjects discontinued participation in the study due to male partner symptoms.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There is no use for PHEXXI in pregnancy; therefore, discontinue PHEXXI during pregnancy. There are no data with the use of PHEXXI in pregnant women or animals. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4 percent and 15 to 20 percent, respectively.

Lactation

Risk Summary

There are no data on the presence of lactic acid, citric acid, and potassium bitartrate or their metabolites in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric Use

The safety and effectiveness of PHEXXI have been established in females of reproductive potential.

Efficacy is expected to be the same for post-menarchal females under the age of 17 as for users 17 years and older. The use of PHEXXI before menarche is not indicated.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling.

Advise the patient to read the Patient Information and FDA-approved patient labeling (Instructions for Use).

Advise the patient:

- To intravaginally administer the contents of one pre-filled single-dose applicator of PHEXXI before **each** episode of vaginal intercourse and to administer an additional dose if intercourse does not occur within one hour of administration [*see Dosage and Administration (2.1) of PHEXXI Full Prescribing Information*].
- To consult their healthcare provider for severe or prolonged genital irritation [*see Adverse Reactions (6.1) of PHEXXI Full Prescribing Information*].
- To discontinue PHEXXI if they develop a local hypersensitivity reaction [*see Adverse Reactions (6.1) of PHEXXI Full Prescribing Information*].
- To contact their health care provider if experiencing urinary tract symptoms [*see Warnings and Precautions (5.1) of PHEXXI Full Prescribing Information*].
- That PHEXXI does not protect against HIV infection and other sexually transmitted infections.

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U.S. Patent 6,706,276

REFDOC-000554

To report SUSPECTED ADVERSE REACTIONS, contact Evofem at toll-free phone 1-833-EVFMBIO or you may contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

EVOFEM BIOSCIENCES®

2021

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BRAIN FUNCTION ASSESSMENT



MEMORY LOSS BIOMARKERS TO AID IN DIAGNOSIS IN PRIMARY CARE PRACTICES

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The eVox® System is an FDA 510(k) cleared medical device to aid primary and specialty care physicians in diagnosis of memory loss and other cognitive disorders. eVox® measures memory loss biomarkers that may aid in detecting memory loss sooner, identifying the root cause of memory loss, and performing a differential diagnosis. eVox® procedures are performed in-office and are reimbursable by Medicare and commercial payers.

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EASY, INTEGRATED WITH-PATIENT TESTING I-STAT SYSTEM

From Point of Care at Abbott

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

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

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

From Abbott

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.

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CHEMISTRY ANALYZERS

EASY, INTEGRATED WITH-PATIENT TESTING I-STAT SYSTEM

From Point of Care at Abbott

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

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

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From Abbott

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1. Clinical Laboratory Improvement Amendments (CLIA)

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CHEMISTRY ANALYZERS



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From Abbott

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CHEMISTRY ANALYZERS



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CHOLESTEROL



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

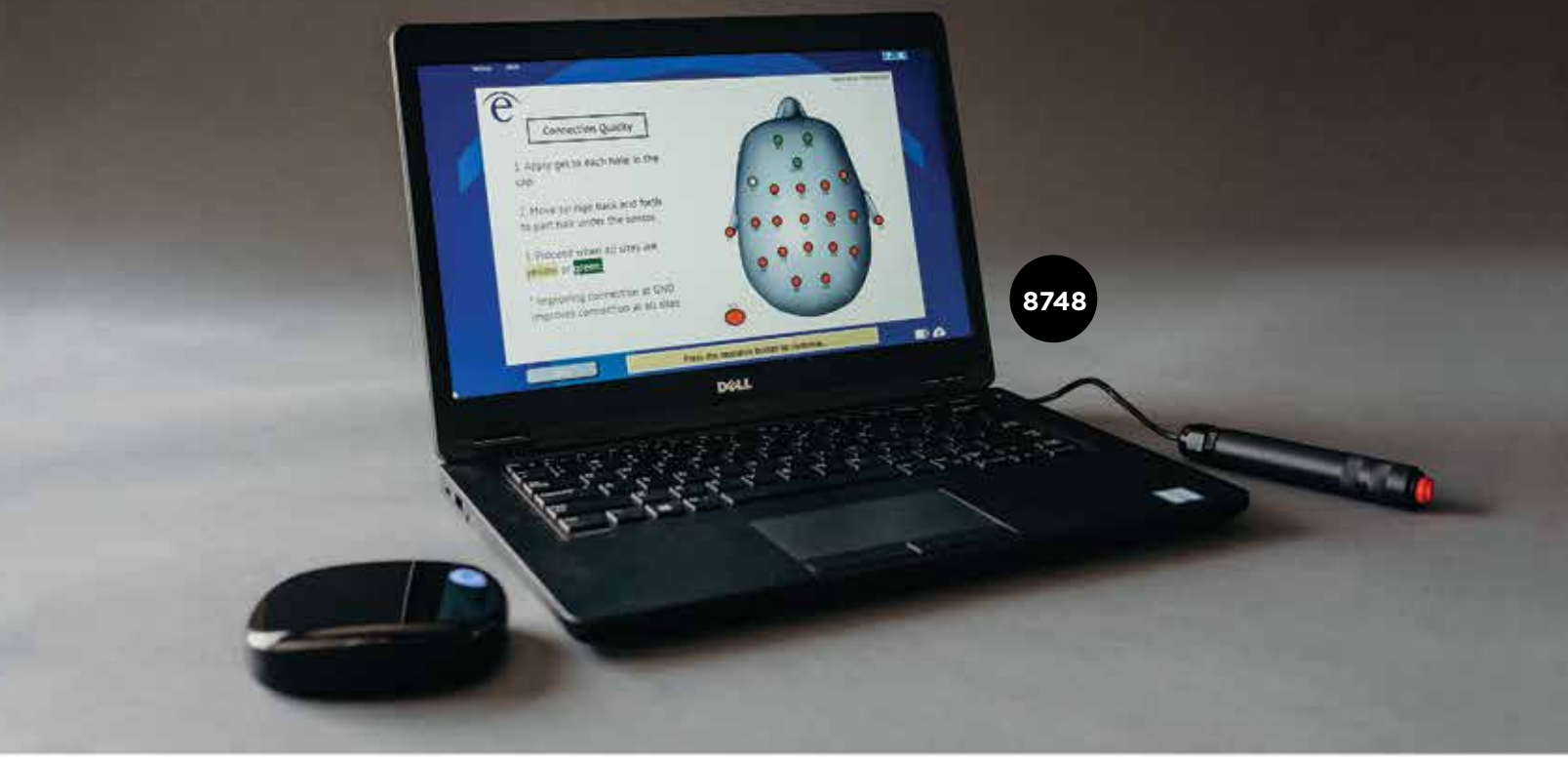
From Abbott

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.

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

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



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

From Abbott

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

View Brochures, Videos & More at POR.io
Enter Number **8749** in the Search Area

LAB-ACCURATE RESULTS FOR ACR AND HBA1C

From Abbott

With its compact size and panel of tests, the Afinion 2 system is ideal for point-of-care testing in physician offices, clinics, community health centers and hospital out-patient clinics. From just a small urine or fingerstick whole blood sample, lab-accurate results for ACR and HbA1c are made available during the consultation.

View Brochures, Videos & More at POR.io
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BD VERITOR™ PLUS SYSTEM

From BD Veritor™

The BD Veritor™ Plus System is a portable, easy-to-use, testing solution for SARS-COV-2*, Flu A+ B and other respiratory tract infections that delivers results in 15 minutes or less. It features two analysis modes that adapt to your workflow, online education tools, and optional reporting capabilities including the BD Synapsys™ Informatics Solution—making it the point-of-care diagnostic tool you won't want to be without.

*EUA authorized by FDA

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

From BioFire

The BioFire RP EZ accurately detects and identifies 14 viral and bacterial pathogens—not just Flu A and Flu B—so you can provide your patients with the right treatment, the first time. The test is easy and can be performed right in your office or clinic, with results in about an hour. The BioFire RP EZ is designed to run on a single computer/instrument configuration (EZ Configuration) of the BioFire® FilmArray® 2.0 System.

—

View Brochures, Videos & More at POR.io
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RELIABLE DETECTION OF STREP A, FLU A, FLU B AND RSV

From Cepheid

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

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ORAQUICK® HCV RAPID ANTIBODY TEST

From OraSure

The OraQuick® HCV Rapid Antibody Test is the FIRST and ONLY FDA-approved, point of care test for the detection of HCV antibodies. This CLIA-waived platform delivers an accurate diagnosis in 20 minutes. The test can be completed in 3 simple steps from fingerstick or venous whole blood with less than 2 minutes of hands on time. It is ideal for testing programs in both clinical and non-clinical settings, as well as outreach events.

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ORAQUICK ADVANCE® RAPID HIV-1/2 ANTIBODY TEST

From OraSure

The OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test is an FDA-approved point of care screening test for use with oral fluid, fingerstick or venous whole blood and plasma. The test delivers lab accurate results within 20 minutes with less than 2 minutes of hands on time. This simple test is ideal for testing programs in both clinical and non-clinical settings, as well as outreach events.

View Brochures, Videos & More at POR.io
Enter Number **8755** in the Search Area

ACUCY INFLUENZA A&B TEST

From Sekisui Diagnostics

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

View Brochures, Videos & More at POR.io
Enter Number **8756** in the Search Area





SILARIS™ INFLUENZA A&B TEST

From Sekisui Diagnostics

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

Accurate
- √ Molecular Results
- √ State-of-the art microfluidic cassette technology
- √ PCR test using proprietary OscAR™ Technology

Affordable
- √ Single Test Diagnosis
- √ Controls in every kit
- √ Molecular reimbursement (CPT Code 87502)

Simple
- √ Easy to Use
- √ Compact portable dock with no calibration required
- √ Room temperature storage

View Brochures, Videos & Mores at POR.io
Enter Number **8757** in the Search Area



OSOM ULTRA PLUS FLU A&B TEST

From Sekisui

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

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View Brochures, Videos & More at POR.io
Enter Number **8758** in the Search Area

OSOM® BVBLUE®

From Sekisui Diagnostics

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

View Brochures, Videos & More at POR.io
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ULTRA HCG COMBO TEST

From Sekisui Diagnostics

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

View Brochures, Videos & More at POR.io
Enter Number **8760** in the Search Area



OSOM® TRICHOMONAS RAPID TEST

From Sekisui Diagnostics

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

View Brochures, Videos & More at POR.io
Enter Number **8761** in the Search Area

OSOM® ULTRA STREP A TEST

From Sekisui Diagnostics

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..

View Brochures, Videos & More at POR.io
Enter Number **8762** in the Search Area





FIRST EVER CLIA WAIVED HEMATOLOGY ANALYZER

From Sysmex

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.

View Brochures, Videos & Mores at POR.io
Enter Number **8763** in the Search Area



BD VERITOR™ PLUS SYSTEM

From BD Veritor™

The BD Veritor™ Plus System is a portable, easy-to-use, testing solution for SARS-COV-2*, Flu A+ B and other respiratory tract infections that delivers results in 15 minutes or less. It features two analysis modes that adapt to your workflow, online education tools, and optional reporting capabilities including the BD Synapsys™ Informatics Solution—making it the point-of-care diagnostic tool you won't want to be without.

*EUA authorized by FDA

View Brochures, Videos & More at POR.io
Enter Number **8764** in the Search Area

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

From BioFire

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

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

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

From Carolina Liquid Chemistries

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

View Brochures, Videos & More at POR.io
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COVID-19 TESTING



MEDICUS LIS

From Medicus LIS

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

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CRYOSURGERY

HISTOFREEZER® FLEX

From CryoConcepts

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

—

View Brochures, Videos & More at POR.io
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CRYOLAB® MEDICAL

From CryoConcepts

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

—

View Brochures, Videos & More at POR.io
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CRYOSURGERY



8770

CRYOMEGA®

From CryoConcepts

This pen-like device is the perfect choice when low entry costs, portability, and precise delivery are critical to the practice. CryOmega® dispenses nitrous oxide – the coldest portable cryogen and the pinpoint tip allow physicians to effective treat the lesion site without harming healthy tissue.

—

View Brochures, Videos & More at POR.io
Enter Number **8770** in the Search Area

CRYOCLEAR®

From CryoConcepts

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

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8771

DRUG TESTING



8772

TOXICOLOGY URINE DRUG SCREENING REAGENTS

From Abbott

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.

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DRUG TESTING



Toxicology Screening Simplified Abbott's ImmTox 270 Benchtop Analyzer Now with 14 assays CLIA Categorized as Moderate Complexity

From Abbott

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

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

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

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EXAM ROOM EQUIPMENT

THE BREWER BASIC EXAM TABLE

From Brewer

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

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BREWER'S ACCESS™ HIGH-LOW EXAM TABLE

From Brewer

Design provides an 18" profile in the seated position to allow level transfer from standard wheelchair heights, complete with upright seat back and safety grab bars to simplify reliable patient transfers. The system also offers abundant storage capacity with Brewer's signature pass-through drawer system and it is backed by Brewer's standard 3-year warranty.

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EXAM ROOM EQUIPMENT



BREWER'S FLEX™ ACCESS EXAM TABLE

From Brewer

Step up to power table performance for less with Brewer's Flex™ Access Exam Table. Industry-leading 700-lb. patient weight capacity, unique safety features and unmatched ergonomic patient access maximize your clinical efficiency and ROI. A streamlined footprint and optional upgrades like safety grab bars, stirrups, and pass-through work surface provide ultimate flexibility for your practice.

View Brochures, Videos & More at POR.io
Enter Number **8776** in the Search Area

FLU TESTING

BD VERITOR™ PLUS SYSTEM

From BD Veritor™

The BD Veritor™ Plus System is a portable, easy-to-use, testing solution for SARS-COV-2*, Flu A+ B and other respiratory tract infections that delivers results in 15 minutes or less. It features two analysis modes that adapt to your workflow, online education tools, and optional reporting capabilities including the BD Synapsys™ Informatics Solution—making it the point-of-care diagnostic tool you won't want to be without.

*EUA authorized by FDA

View Brochures, Videos & More at POR.io
Enter Number **8777** in the Search Area





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

From BioFire

The BioFire RP EZ accurately detects and identifies 14 viral and bacterial pathogens—not just Flu A and Flu B—so you can provide your patients with the right treatment, the first time. The test is easy and can be performed right in your office or clinic, with results in about an hour. The BioFire RP EZ is designed to run on a single computer/instrument configuration (EZ Configuration) of the BioFire® FilmArray® 2.0 System.

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View Brochures, Videos & More at POR.io
Enter Number **8778** in the Search Area

FLU TESTING



ACUCY INFLUENZA A&B TEST

From Sekisui Diagnostics

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

View Brochures, Videos & More at POR.io
Enter Number **8779** in the Search Area

SILARIS™ INFLUENZA A&B TEST

From Sekisui Diagnostics

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

Accurate
√ Molecular Results
√ State-of-the art microfluidic cassette technology
√ PCR test using proprietary OscAR™ Technology

Affordable
√ Single Test Diagnosis
√ Controls in every kit
√ Molecular reimbursement (CPT Code 87502)

Simple
√ Easy to Use
√ Compact portable dock with no calibration required
√ Room temperature storage

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Enter Number **8780** in the Search Area





OSOM ULTRA PLUS FLU A&B TEST

From Sekisui

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

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View Brochures, Videos & More at POR.io
Enter Number **8781** in the Search Area

FOBT



CLIA-WAIVED OSOM® IFOB

From Sekisui Diagnostics

The CLIA-waived OSOM® iFOB test gives the physician and the patient a simpler, more compliant colon cancer screening option that is highly accurate and specific to human hemoglobin. With the ability of a convenient take home kit, patients can collect in the privacy of their own home with no dietary or drug restrictions in just one sample increasing the physician compliance for yearly screening.

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GLUCOSE TESTING

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

From Abbott

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.

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Enter Number **8783** in the Search Area



HbA1c



LAB-ACCURATE RESULTS FOR ACR AND HBA1C

From Abbott

With its compact size and panel of tests, the Afinion 2 system is ideal for point-of-care testing in physician offices, clinics, community health centers and hospital out-patient clinics. From just a small urine or fingerstick whole blood sample, lab-accurate results for ACR and HbA1c are made available during the consultation.

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EASY, INTEGRATED WITH-PATIENT TESTING I-STAT SYSTEM

From Point of Care at Abbott

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

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

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

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TURN SMALL PLACES INTO SMART SPACES

From Abbott

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

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

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CELL-DYN EMERALD HEMATOLOGY ANALYZER

From Abbott

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

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MINÍÍMIZE THE HASSLE OF ESR TESTING IN YOUR LAB

From ALCOR Scientific

miniiSED™ is the newest of the iSED® family of ESR analyzers from ALCOR Scientific. The miniiSED™ measurement of ESR is accurate and unaffected by variables associated with traditional methodologies, such as hematocrit. This single position, fully automated ESR analyzer works directly from primary EDTA tubes, requires 100 µL of sample, has an internal barcode reader, and produces results in 15 seconds! miniiSED™ is the ideal solution to ESR testing for small laboratories, POL's, and emergency clinics. Proudly manufactured in the USA.

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MICROS HEMATOLOGY ANALYZER WITH 3-PART DIFFERENTIAL PLUS THE LITE^{DM}

From HORIBA Medical

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

View Brochures, Videos & More at POR.io
Enter Number **8789** in the Search Area





PENTRA 60 C+ HEMATOLOGY ANALYZER WITH 5-PART DIFFERENTIAL

From HORIBA Medical

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

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MICROS ES 60 HEMATOLOGY ANALYZER WITH 3-PART DIFFERENTIAL

From HORIBA Medical

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

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PENTRA XLR HEMATOLOGY ANALYZER WITH 5-PART DIFFERENTIAL

From HORIBA Medical

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

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FIRST EVER CLIA WAIVED HEMATOLOGY ANALYZER

From Sysmex

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.

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8794

HEMATOLOGY TESTING MADE EASY

From Sysmex

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.

View Brochures, Videos & More at POR.io
Enter Number **8794** in the Search Area

SYSMEX XN-L™ SERIES AUTOMATED HEMATOLOGY ANALYZERS

From Sysmex

Now lower volume customers can enjoy the same capabilities in CBC testing as larger hospitals and reference labs. Enhanced clinical value is standard and optional licenses for reticulocyte or body fluid testing are available. The XN-L analyzers are the first to feature BeyondCare℠ Quality Monitor, an innovative, web-based QC and calibration management program.

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8795



8796

NOW IT'S MORE THANK JUST A BLOOD TEST

From Sysmex

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.

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IMMUNOASSAY ANALYZERS



FULLY AUTOMATED QUANTITIVE IMMUNOASSAY ANALYZER

From Sekisui Diagnostics

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

View Brochures, Videos & More at POR.io
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THE NANOENTEK FREND IMMUNOASSAY SYSTEM

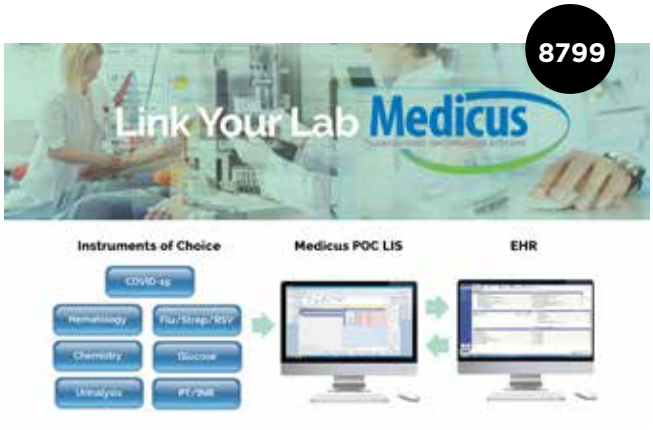
From NanoEnTek

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

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LABORATORY SERVICES



MEDICUS LIS

From Medicus LIS

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

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LABORATORY SERVICES



MAKE LABORATORY COMPLIANCE AND INSPECTION EASIER

From My Inspection

Make laboratory compliance and inspections easier by changing how you document, save and retrieve all information necessary to meet CLIA and accreditation regulations. With two unique electronic tools My Compliance Manual and MyInspection™ Software, the guesswork and tedious task of interpreting and documenting policy, procedure, forms, charts and logs is over. Your lab will be compliant, have less paper, and be inspection ready.

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Enter Number **8800** in the Search Area

LIPID TESTING

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

From Abbott

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.

View Brochures, Videos & More at POR.io
Enter Number **8801** in the Search Area



PULSE OXIMETRY



PRONTO® PULSE CO-OXIMETER®

From Masimo

Pronto® Pulse Co-Oximemter® with rainbow® Technology for Noninvasive Spot-Checking of Total Hemoglobin (SpHb®) and Sp02 in a Handheld device. Featuring Masimo SET® Measure-through Motion and Low Perfusion™ Pulse Oximetry Technology:
> Helps clinicians monitor more than 100 million patients a year[1]
>Used by the top 10 U.S. hopitals listed in the 2017-18 U.S. News and World Report Best Hospitals Honor Roll[2]

1 Estimate: Masimo data on file.
2 http://health.usnews.com/health-care/best-hospitals/articles/best-hospitals-honor-roll-and-overview

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PULSE OXIMETRY



RAD-97™ PULSE CO-OXIMETER®

From Masimo

Rad-97™ Pulse CO-Oximeter® with Integrated Noninvasive Blood Pressure (NIBP) in a Standalone Bedside device
>Upgradable rainbow SET™ Measurements allow for continuous monitoring of multiple additional parameters
> Customizable display allows for quick assessment of patient status
> Configurable patient profile settings for a variety of patient populations
> Connectivity Solutions for electronic charting of patient data

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REAGENTS

TOXICOLOGY URINE DRUG SCREENING REAGENTS

From Abbott

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.

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RSV TESTING



BD VERITOR™ PLUS SYSTEM

From BD Veritor™

The BD Veritor™ Plus System is a portable, easy-to-use, testing solution for SARS-COV-2*, Flu A+ B and other respiratory tract infections that delivers results in 15 minutes or less. It features two analysis modes that adapt to your workflow, online education tools, and optional reporting capabilities including the BD Synapsys™ Informatics Solution—making it the point-of-care diagnostic tool you won't want to be without.

*EUA authorized by FDA

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8806

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

From BioFire

The BioFire RP EZ accurately detects and identifies 14 viral and bacterial pathogens—not just Flu A and Flu B—so you can provide your patients with the right treatment, the first time. The test is easy and can be performed right in your office or clinic, with results in about an hour. The BioFire RP EZ is designed to run on a single computer/instrument configuration (EZ Configuration) of the BioFire® FilmArray® 2.0 System.

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BIOFIRE® FILMARRAY® TORCH

From BioFire

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 BioFire Torch offers a radically reduced benchtop footprint, saving precious space in the lab, and its scalability meets high throughput demands. BioFire® FilmArray® Link Software automatically uploads patient results. Fully compatible with all CLIA Moderate BioFire® FilmArray® Panels, the BioFire Torch helps you maximize efficiency and productivity.

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8807



8808

THE SILARIS® RSV TEST

From Sekisui Diagnostics

The Silaris® RSV Test is a molecular diagnostic test utilizing polymerase chain reaction (PCR) technology providing accurate results to aid in early diagnosis and proper management of RSV. The system is easy to use, compact, portable and CLIA Waived so you can test and treat in one visit.

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RSV TESTS



RELIABLE DETECTION OF STREP A, FLU A, FLU B AND RSV

From Cepheid

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

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SPIROMETRY

MICRO 1 SPIROMETER

From MicroDirect

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

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SPIROMETRY IS EASY

From MicroDirect

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

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SPIROMETRY



8812

PORTABLE, SINGLE CLICK OPERATION SPIROMETER

From MicroDirect

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

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STI

ORAQUICK® HCV RAPID ANTIBODY TEST

From OraSure

The OraQuick® HCV Rapid Antibody Test is the FIRST and ONLY FDA-approved, point of care test for the detection of HCV antibodies. This CLIA-waived platform delivers an accurate diagnosis in 20 minutes. The test can be completed in 3 simple steps from fingerstick or venous whole blood with less than 2 minutes of hands on time. It is ideal for testing programs in both clinical and non-clinical settings, as well as outreach events.

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8813



8814

ORAQUICK ADVANCE® RAPID HIV-1/2 ANTIBODY TEST

From OraSure

The OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test is an FDA-approved point of care screening test for use with oral fluid, fingerstick or venous whole blood and plasma. The test delivers lab accurate results within 20 minutes with less than 2 minutes of hands on time. This simple test is ideal for testing programs in both clinical and non-clinical settings, as well as outreach events.

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BD VERITOR™ PLUS SYSTEM

From BD Veritor™

The BD Veritor™ Plus System is a portable, easy-to-use, testing solution for SARS-COV-2*, Flu A+ B and other respiratory tract infections that delivers results in 15 minutes or less. It features two analysis modes that adapt to your workflow, online education tools, and optional reporting capabilities including the BD Synapsys™ Informatics Solution—making it the point-of-care diagnostic tool you won't want to be without.

*EUA authorized by FDA

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RELIABLE DETECTION OF STREP A, FLU A, FLU B AND RSV

From Cepheid

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

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OSOM® ULTRA STREP A TEST

From Sekisui Diagnostics

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..

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TELEMEDICINE



OPTIMIZE PRODUCTIVITY AND EXPAND YOUR PRACTICE

From MedPod

The Medpod Medical Cart optimizes productivity and load balancing by enabling access to remote physicians during high volume periods or to reach low-density populations. Medpod's proprietary software integrates with a wide range of professional medical devices and gives the remote provider control of the devices to conduct an examination that is on par with a face-to-face visit. Patient images, audio and data can be captured, annotated, tagged and uploaded in real-time or stored and forwarded into the EHR by either remote or local provider.

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DEFINING MOBILE TELEDIAGNOSTICS

From MedPod

With the ability to deploy into a medical office in less than 2 minutes, MobileDoc is the ultimate portable practice. Revolutionary in its compact and mobile design, MobileDoc integrates best-in-class professional medical-grade devices with state-of-the-art HD video and EHR connectivity. Physicians can provide care remotely that is on par or better than a face-to-face visit, including conducting basic exams, checking vitals, and performing specialty testing—shattering the boundaries of traditional care.

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URINALYSIS



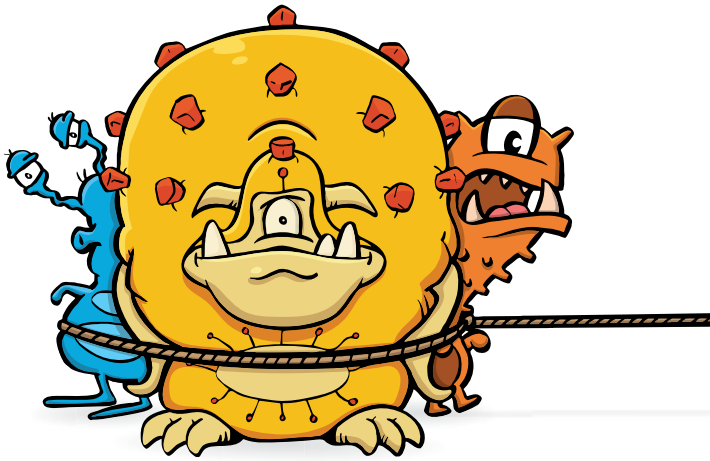
LAB-ACCURATE RESULTS FOR ACR AND HBA1C

From Abbott

With its compact size and panel of tests, the Afinion 2 system is ideal for point-of-care testing in physician offices, clinics, community health centers and hospital out-patient clinics. From just a small urine or fingerstick whole blood sample, lab-accurate results for ACR and HbA1c are made available during the consultation.

View Brochures, Videos & More at POR.io
Enter Number **8820** in the Search Area

Round up SARS-CoV-2 and 18 other pathogens.



The new BioFire® Respiratory 2.1-EZ (RP2.1-EZ) Panel[1] covers COVID-19 detection in your clinic.

SARS-CoV-2 is everyone's top suspect, but many other respiratory bugs can cause similar, overlapping symptoms. In your clinic, you can test for 19 common respiratory pathogens, including SARS-CoV-2, with the BioFire RP2.1-EZ Panel—now available under an FDA Emergency Use Authorization.[1,2]



Syndromic testing means all it takes is one test and about 45 minutes to round up SARS-CoV-2—and all the other usual respiratory suspects. Rapid answers on a broad range of pathogens can inform patient management and alleviate patients and staff alike. What's your frontline solution into respiratory season and beyond?

To learn more, visit **biofiredx.com**

BIOFIRE®

BY BIOMÉRIEUX

Syndromic Testing: The Right Test, The First Time.

1. This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
2. For use with the CLIA-waived BioFire® FilmArray® 2.0 EZ configuration.

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