2020 | Issue 11

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The New BioFire® Respiratory 2.1-EZ (RP2.1-EZ)[1] Panel (EUA)[1] Covers COVID-19 Detection in Your Clinic

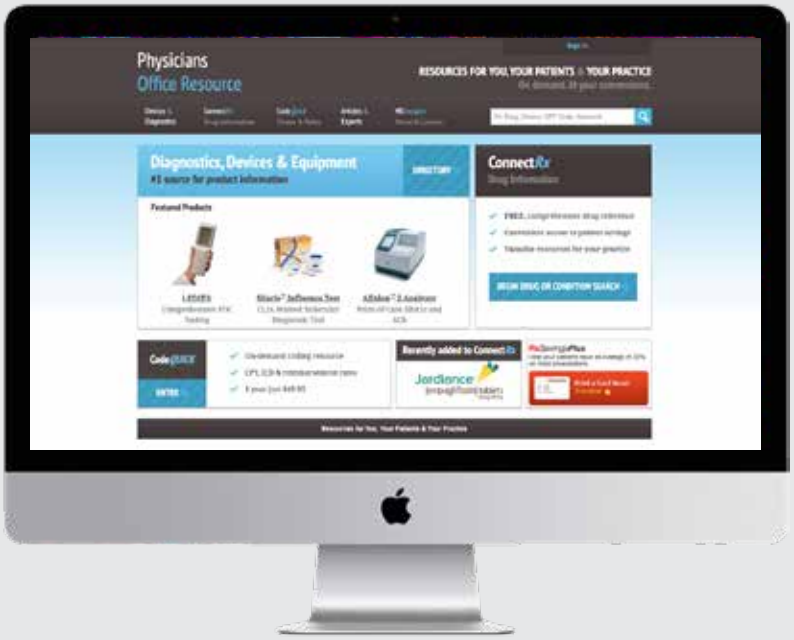
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The New BioFire® Respiratory 2.1-EZ (RP2.1-EZ)[1] Panel (EUA)[1] Covers COVID-19 Detection in Your Clinic

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 (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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THE EVOLUTION OF WHITE BLOOD CELL DIFFERENTIAL TECHNOLOGIES

—

Hematology analyzers count and characterize blood cells for the screening and monitoring of disease. Analyzers vary in capabilities, sophistication and detection technologies.

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3 TIPS FROM AN ATTORNEY TO AVOID A MEDICAL MALPRACTICE LAWSUIT

—

Twenty years of defending doctors and hospitals in medical malpractice cases has made me into a nervous patient. When you see the worst, you look for it. At least I do. That's why when I was scheduled for a minor elective procedure, I was nervous.

32

THE SECRET TO MAKING AI WORK FOR PHYSICIANS

—

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FEATURE

The Evolution of White Blood Cell Differential Technologies

BY DONALD WRIGHT, GABRIELLA LAKOS

INTRODUCTION

Hematology analyzers count and characterize blood cells for the screening and monitoring of disease. Analyzers vary in capabilities, sophistication and detection technologies. The most common technologies are electrical impedance, radio frequency conductivity, optical light scatter (optical flow cytometry), cytochemistry and fluorescence. Optimal combinations of these detection methods provide an accurate automated complete blood count (CBC) including white blood cell (WBC) differential in a short turnaround time.

Although many other detection methods are still in use, optical technology has represented a key innovation in automated hematology analysis since its introduction.[1,2,3,4] Light, scattered and detected at specific angles, captures an array of information about cell size, structure, inner complexity, nuclear segmentation and cytoplasmic granulation. As an innovative expansion of optical flow cytometry, Multi-Angle Polarized Scatter Separation (MAPSS™) technology (Abbott Diagnostics, Hematology, Santa

KEY ACRONYMS

CBC	Complete Blood Count, also known as Full Blood Count (FBC)
WBC	White Blood Cell
MAPSS™	Multi-Angle Polarized Scatter Separation
IG	Immature Granulocyte
RBC	Red Blood Cell
PLT	Platelet
NRBC	Nucleated Red Blood Cell

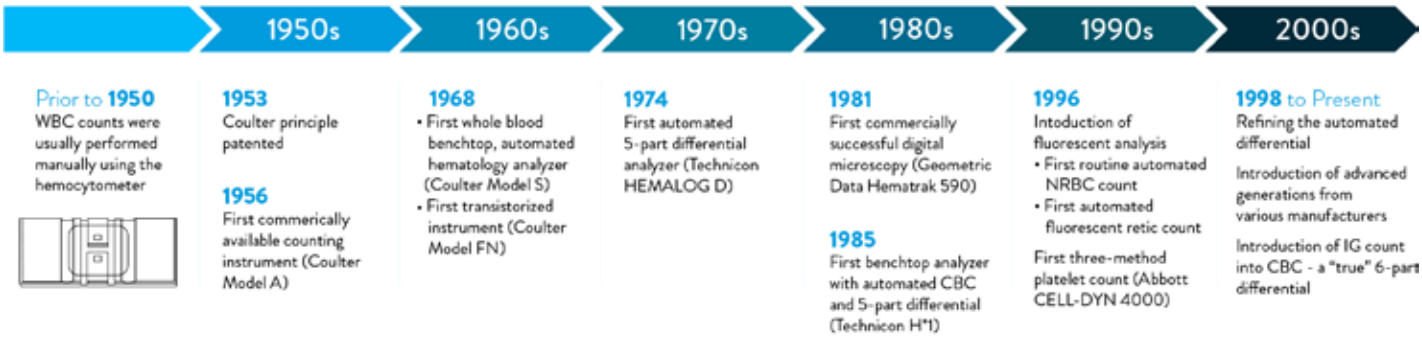


Figure 1. Automated WBC and differential count technology development timeline

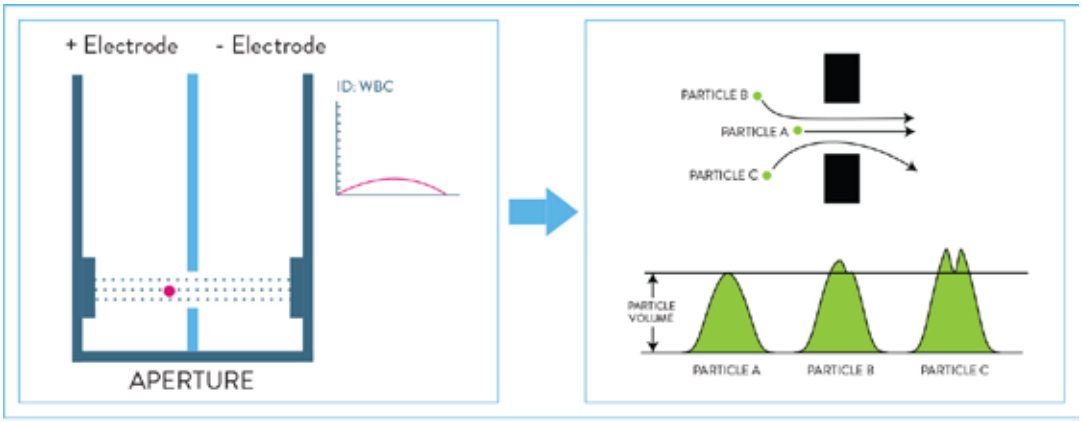


Figure 2a. Representation of Coulter Principle.

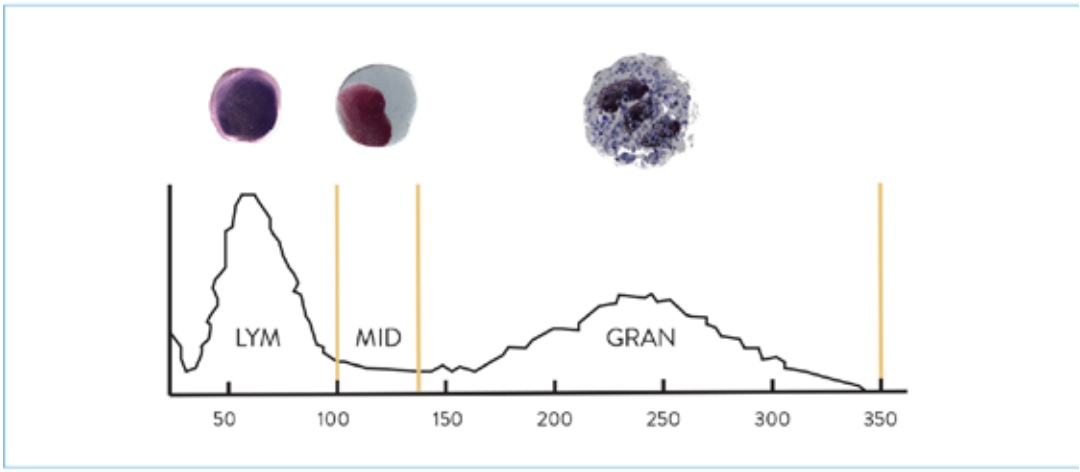


Figure 2b. Three-part WBC differential by impedance.

Clara, CA, USA) uses four different light scatter signals to characterize distinct cellular features for the identification of various blood cells. MAPSS™ technology reliably automates WBC differentials, and continues to be improved and expanded upon. The MAPSS™ and advanced MAPSS™ technology that are integrated in Abbott hematology analyzers enable clinical laboratories to obtain high quality results.

THE EVOLUTION OF WBC DIFFERENTIAL TECHNOLOGY

The automated WBC differential provides the absolute and relative (%) concentrations of the five different types of WBCs (neutrophil, eosinophil and basophil granulocytes, lymphocytes and monocytes) present in normal blood. This provides information for diagnosis and assessment of infections, immune system or bone marrow disorders, and hemato-oncological diseases. Traditionally, the WBC differential has been determined by manual counting and classification of 100 or 200 WBCs on a stained blood smear.[5] This method, although it is highly imprecise,[6] is still considered the reference method for the WBC differential,[7] and may be performed as a reflex test after an automated CBC analysis. Today WBC differentials are usually performed on automated hematology analyzers. Although the automated WBC differential is very reliable and accurate, a manual differential is often required to confirm the presence of immature or reactive cells, blasts and other pathological cell types.

Impedance and Cytochemistry

Electrical impedance is a cell counting and sizing technique based on the measurement of changes in electrical impedance (resistance) produced by a particle (i.e. a blood cell). It was the first automated technology to count cells and measure the size of WBCs, Red Blood Cells (RBCs) and Platelets (PLTs). Blood cells are suspended in a conductive fluid and pass through an aperture of known size with electrodes on either side. As cells pass through the orifice, they cause a change in electrical conductance which is proportional to the size of the particle (Coulter Principle,[8] **Figure 2a**). Early challenges to this meth-

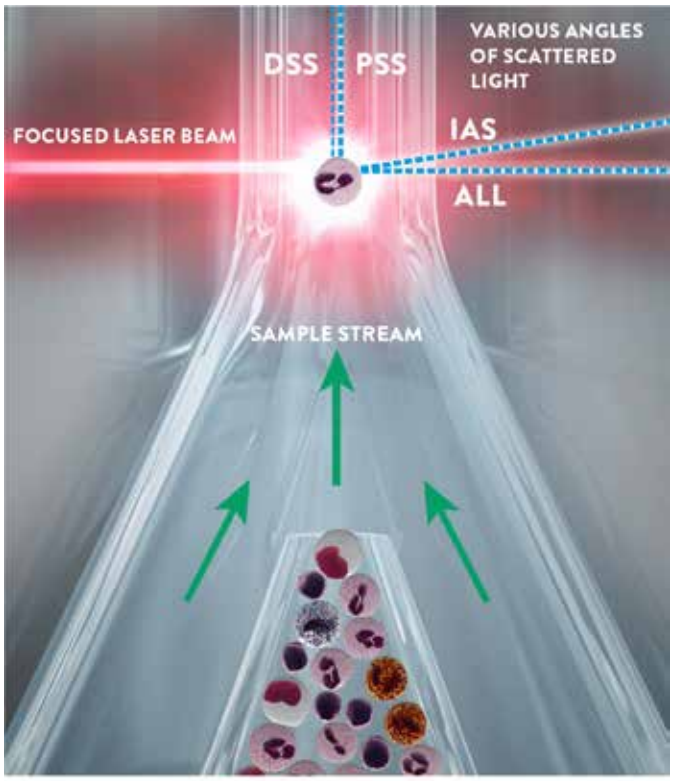


Figure 3. Optical flow cytometry Multi-Angle Polarized Scatter Separation (MAPSS™).

od were managing coincidence events, where two cells pass through the aperture too close together and cells being recounted due to the recirculation of cells around the detection area of the aperture. Impedance technology can deliver a three-part WBC differential, where cells are grouped into three sizes: lymphocytes, mid-range cells and granulocytes (**Figure 2b**). It does not allow for the differentiation of the granulocyte subtypes. The limitation of this technology is that it is based purely on measuring cell size. Therefore, abnormal cells, such as nucleated red blood cells (NRBCs), PLT clumps, giant PLTs or unlysed red cells cannot be separated and may interfere with normal cell populations.

Some current hematology analyzers still rely on impedance technology, though with additional technologies to improve the white cell differential. The utilization of a high frequency signal, defined as radio frequency (RF) conductivity, allows the discrimination between different WBC subpopulations.[8] RF signals pass through the cell, producing a response that is related to nuclear composition, cytoplasmic density and other differences in internal structures. This technology aims at mitigating the inherent limitations of impedance technology. Cytochemical staining is another technology that is used to distinguish between cells containing myeloperoxidase (a lysosomal enzyme located in the azurophilic granules of the neutrophils and its precursors, eosinophils and monocytes) and peroxidase-negative cells, which include lymphocytes and basophils.[9]

To reduce the occurrence of coincidence and re-circulation, a technique called hydrodynamic focusing was developed. Hydrodynamic focusing enables cells to follow a path of least resistance, surrounded by sheath fluid, and to proceed in single file based on the principal of laminar flow. This technique can be used in both electrical impedance as well as with optical cell counting methods.

Optical Technologies

Optical flow cytometry provides several advantages over traditional impedance methods. During optical light scatter measurement, a beam of laser light is passed through a diluted blood specimen stream that is projected into the flow cell by hydrodynamic focusing. As each cell passes through, the focused light is scattered in various directions and detected by photodetectors which convert the signal into an electric pulse. The electronic signals are transmitted to a computer for storage and analysis. The signals provide information about cellular characteristics such as size, internal complexity, nuclear lobularity/segmentation and cytoplasmic granularity, which are used to identify the cells. Cells with similar light scatter properties form a cluster in the scattergram, and can be separated from other cell clusters using advanced software algorithms. Some analyzers only use two angles of light, whereas others use multi-angle optical scatter analysis (**Figure 3**).

The more detectors (positioned at various angles) that are used to collect signals from each cell, the more information generated on cellular characteristics, thereby increasing the accuracy of cell identification. The use of optical technology led to the ability to provide five-part WBC differentials and depending on the sophistication of the instrument, some current analyzers provide six-part WBC differentials, including immature granulocyte (IG) counts.[10]

Adding the detection capability of a fluorescent signal further enhances the potential of optical technology. Fluorescent flow cytometry captures the light emitted from internal cellular components that are stained

with a fluorescent dye as cells pass through the flow cell in front of the laser beam. Fluorescence is frequently integrated with multiple-angle optical light scatter methods to further improve the WBC differential subtype classification.

MAPSS™ Technology

The Multi-Angle Polarized Scatter Separation (MAPSS™) technology from Abbott uses four light scatter detectors to determine various cellular features. The application of a depolarized light detector is a unique characteristic of this method and allows for specific identification of eosinophil granulocytes. The four detectors generate the following signals:

- 0° or Axial Light Loss (ALL): related to size
- 0° to 10° Intermediate Angle Scatter (IAS): related to cellular complexity
- 90° Polarized Side Scatter (PSS): related to nuclear lobularity/segmentation
- 90° Depolarized Side Scatter (DSS): related to eosinophil granules

These signals correlate with morphological characteristics that can be determined visually under the microscope from a stained slide. Various combinations of these four measurements are used to classify the WBC subpopulations and provide morphological flagging. Fluorescent flow cytometry is used to detect NRBCs based on DNA staining when additional reagent and a detector for fluorescence signal is added.

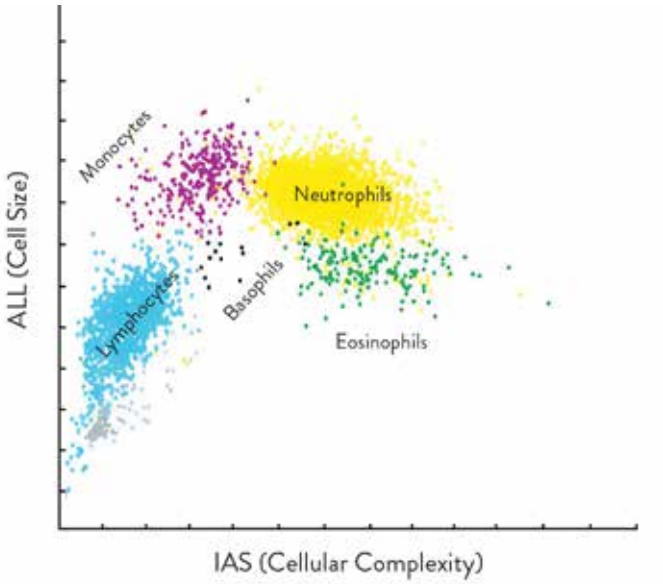


Figure 5: Example of a single channel approach: All five basic WBC types (neutrophil, eosinophil and basophil granulocytes, lymphocytes and monocytes) can be identified by using one reagent and one measurement principle: optical light scatter.

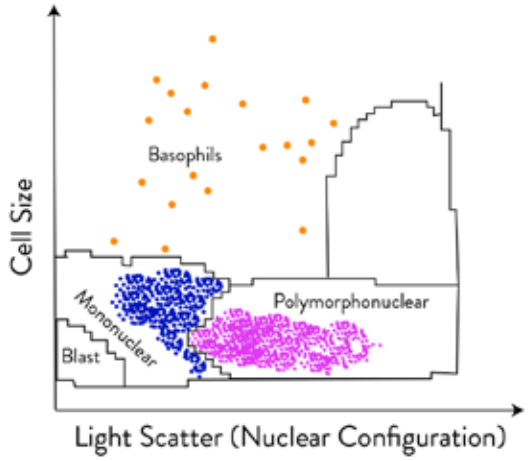


Figure 4a.

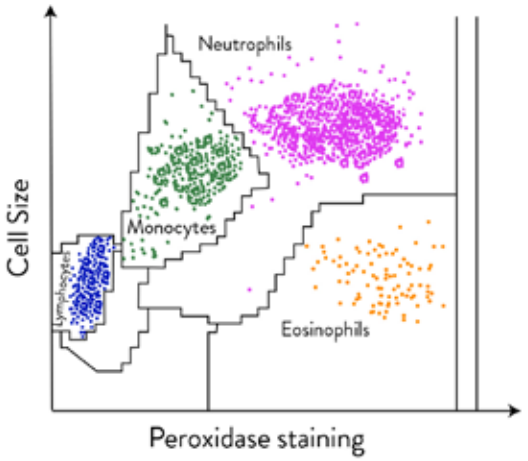


Figure 4b.

Figure 4: a) Two angles of light scatter are used to identify basophils; b) Cell size (based on light scatter) and cytochemical staining are used to identify neutrophils, eosinophils, monocytes and lymphocytes.

Multi- vs. Single-Channel Analysis

Contemporary hematology analyzers utilize various technologies for the differentiation of WBC subpopulations through two main approaches. One approach is a multi-channel system, when two or more discrete detection systems are used to identify and enumerate WBCs. Two or more dilutions are made from the blood and each is analyzed in a separate area (reaction chamber) of the hematology system, using different technological principles and different reagents. For example, neutrophils, eosinophils, monocytes and lymphocytes may be determined and reported with one method and basophils with another method (**Figure 4**), or samples with WBC flags are re-analyzed with a different method for the detection of immature/malignant cells.[11,12] The multi-channel approach uses the detection strength of one technology to overcome the

limitation of another, with the overall aim to improve detection accuracy. The drawback of multi-channel systems is the need for multiple reagents and the increased complexity of the system and the workflow.

The second approach is a single-channel system, when one WBC dilution is made (using one reagent), and all reportable WBC results are generated based on one technological principle. MAPSS™ technology uses single channel analysis; optical and fluorescent flow cytometry signatures for each cellular event are used for cell classification (**Figure 5**).

FUTURE TRENDS

There have been numerous promising directions that could positively impact the future of the automated WBC differential. The International Council for Standardization in Hematology (ICSH) has proposed a new reference method for the leukocyte differential based on the use of monoclonal antibodies (mAbs) and multicolor flow cytometry.[13] This would provide manufacturers with reproducible and accurate WBC classification for the development and improvement of automated technologies.

Another opportunity for improvement is the incorporation of additional light scatter measurements in the characterization of blood cells, with the aim of more accurate classification of WBC subpopulations and potential identification of immature or pathological cell types. An example of this trend is Abbott's Advanced MAPSS™ technology. Advanced MAPSS™ enables the differentiation of seven subpopulations of nucleated cells including neutrophils, lymphocytes, monocytes, eosinophils, basophils, immature granulocytes (including metamyelocytes, myelomyelocytes and promyelocytes), and NRBCs (if present) by utilizing seven light scatter detectors and fluorescent flow cytometry.

SUMMARY

Since their invention in the 1950s, automated hematology analyzers have become increasingly sophisticated, allowing more precise and accurate CBC and WBC differential results.

Manufacturers and hematology laboratories are increasingly taking advantage of optical technology for the analysis of blood cells. Optical and fluorescent flow cytometric methods can provide a 6-part WBC differential and NRBC count, thereby surpassing traditional impedance technologies.

Abbott hematology analyzers utilize MAPSS™ technology for optical CBC and WBC differential analysis. For more information on Abbott's hematology analyzers, please visit: **www.corelaboratory.abbott**

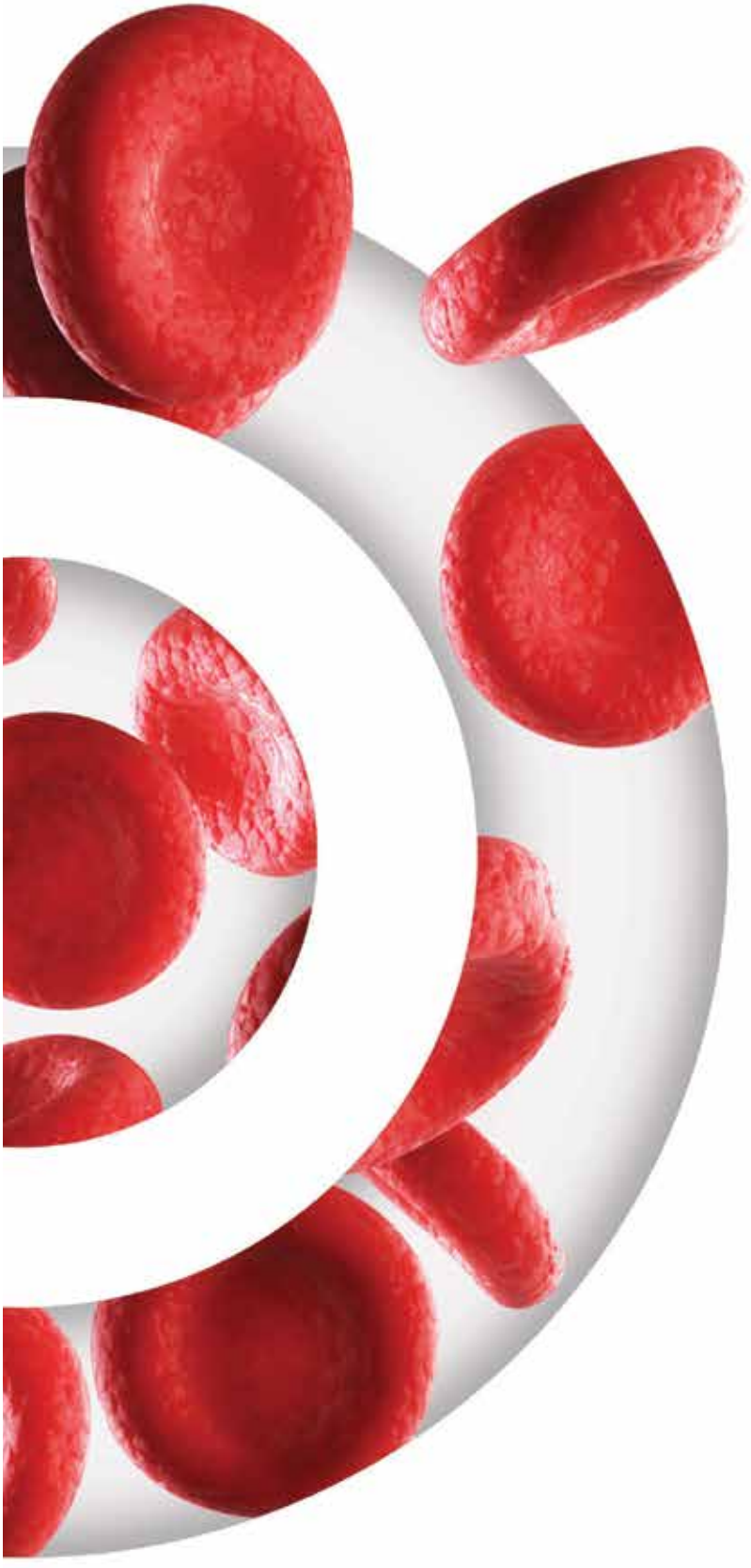
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ORR: 63 out of 137 patients (95% CI, 37%-55%)[1,2]

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.

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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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3 TIPS FROM AN ATTORNEY TO AVOID A MEDICAL MALPRACTICE LAWSUIT

BY HEATHER HANSEN, JD

Twenty years of defending doctors and hospitals in medical malpractice cases has made me into a nervous patient. When you see the worst, you look for it. At least I do. That's why when I was scheduled for a minor elective procedure, I was nervous. I set aside the day, canceling all of my depositions and planning to spend the day on emails and phone calls. My specialist's office texted me to confirm the procedure date, which was a week away. Then I received an email from her office with the same date, but a different location. This made my med mal antenna go up, but I told myself to chill.

In the days leading up to the procedure I was traveling from NYC to San Francisco to teach, so when I hadn't received any instructions I planned to call the specialist's office the day before the procedure. When I did, the assistant informed me that my procedure was scheduled for that day, and to begin in an hour. Since I was in the green room at Dr. Oz at the time, this wouldn't do. I told her that they had confirmed, by text and email, that the procedure was tomorrow. She didn't apologize, but did reschedule me for one week later, on a Wednesday. I asked her to send instructions for the prep. When I didn't receive them by Friday morning, I emailed the office and asked for them. In response, I got an email with a messily scanned page of instructions. They said I couldn't take Advil for a week before the procedure — I had taken Advil that morning. They said I needed an escort to and from the procedure — I hadn't planned for that. I called the office, and the assistant said that I didn't really need to avoid Advil and I didn't really need the escort. I canceled the procedure. It was all too disorganized, impersonal and messy.

Minutes later, the doctor called me. She was very upset that I'd canceled my procedure because it messed with her schedule. I tried my best to remain professional in response to her unprofessional behavior. I wanted her to understand something. "Doctor, if I had any sort of complication as a result of this procedure, you've provided any good attorney with a way to pursue a case."

I once heard a medical malpractice attorney who represents patients give a talk. He said "I look for damages. If there's damages, I will take the case. I'm a good lawyer. I can create liability." Doctors make it easy for lawyers to create liability when they lack perspective, when they don't have systems in place, and when they are just plain messy. Studies show that there is very little correlation between true negligence and lawsuits. I believe that the best way to avoid lawsuits is with better perspective and better systems. After 20 years of defending doctors, I know how to avoid lawsuits. If I were this doctor's attorney, this is what I'd tell her.

1. GET A SYSTEM

My specialist clearly did not have a system in place. Systems save lives, as anyone who has read Atul Gawande's "The Check-



list Manifesto" could tell you. But systems also save doctors from lawsuits. If, after all of the issues I described above, I'd had a complication during my procedure with my specialist, the jury wouldn't like to see the lack of a system to ensure the patient didn't take Advil and did get home safe. More importantly, the fact that I didn't get the instructions until five days before the procedure could have caused a complication. If I bled as a result of the NSAID, or fell on my way home, the doctor would arguably be responsible. The assistant's instruction that I didn't need to follow those instructions also could have caused a complication. I kept notes on our phone calls — I bet she didn't. When you don't have a system, and you don't have documentation, you do have a problem when it comes time for trial.

2. GET PERSPECTIVE

Had my doctor seen things from my perspective, she never would have called me to berate me for canceling. I was frustrated, nervous and confused. Now I was mad. And mad patients sue doctors. Wendy Levinson has been on the forefront of the work that shows us that patients sue doctors who don't communicate well. Frustrated, nervous, confused patients are just looking for some empathy. If a doctor can't put herself into a patient's shoes, she is going to have trouble at trial when she has to put herself in a juror's shoes. And she is far more likely to find herself having to do so.

3. GET CLEAN

I don't mean wash your hands, though this goes without saying. I mean don't be messy. When I have to defend a doctor with missing notes, inconsistent practices, and undocumented phone calls, I know I'm facing an uphill battle. Messiness gives the patient reason to be upset, and it gives the patient's attorney so much to play with in establishing a case. When you're messy, you are making the patient's attorney's job fun.

Defensive medicine adds $45 billion to the cost of health care. Doctors are ordering more tests, and doing more procedures in an effort to avoid lawsuits. I've defended doctors for over 20 years. I love and respect health care providers, but I know better than almost anyone how human they can be. And I know that small fixes can make a huge difference. Get a system, put it in place, and stick to it. Get perspective, be empathetic and communicate with your patients. Get clean, and don't allow your practice to be messy and disorganized no matter how busy you may be. This is the best type of defensive medicine, and it is free.

Heather Hansen is a communications consultant and attorney. She can be reached at Heather Hansen Presents.

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ASSESSING AND MONITORING COVID-19 PATIENTS.

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

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

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



piccolo xpress chemistry analyzer

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KEY PICCOLO XPRESS PANELS.

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

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

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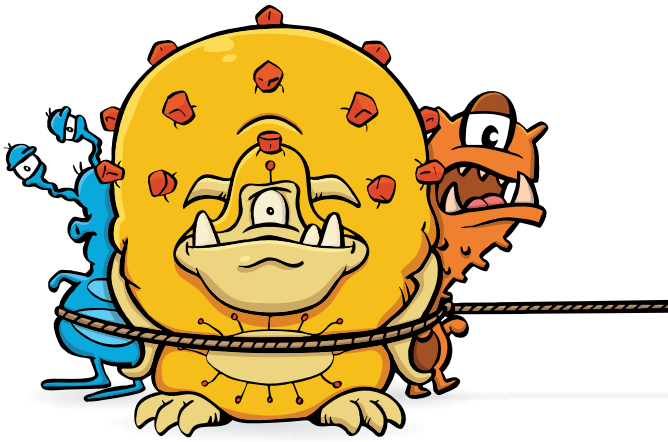
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Round up SARS-CoV-2 and 18 other pathogens.



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 just 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?

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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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INTRODUCING

A non-hormonal contraceptive—the first and only vaginal pH modulator (VPM) that works immediately to maintain the vagina's acidic pH in the presence of semen to prevent pregnancy.[1-4]

phexxi™

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Now Available!

AN FDA-APPROVED, NON-HORMONAL, IN-THE-MOMENT CONTRACEPTIVE

MANY WOMEN HAVE UNMET NEEDS WHEN IT COMES TO BIRTH CONTROL[5]

They are looking for an option that:

- Is non-hormonal
- Is used in the moment
- Is woman controlled
- Begins working immediately

IN FACT...

There are

21 MILLION WOMEN

at risk for pregnancy who are NOT using hormonal contraception[6]

Discover why Phexxi™ may be an option for your patients by visiting **HCP-Phexxi.com/contraceptive**

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.

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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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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.

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Designed by primary care doctors, BPCorrect is a complete home blood pressure monitoring platform consisting of a patient app and clinician portal. While many apps help patients track and display their BP, BPCorrect is the only app that guides patients through a scientific approach to accurately measure BP in the safety and privacy of their homes. BPCorrect works with affordable, validated BP monitors from well-known manufacturers. The web-based clinician portal, available in fall 2020, securely receives patients' readings, summarizes these for providers and clinical staff members, and facilitates billing for remote monitoring. Please visit www.bpcorrect.com for more info.

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

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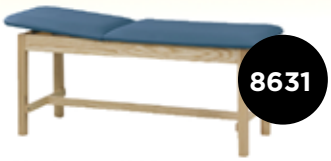
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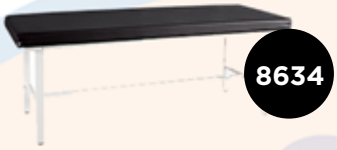
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FEATURE

THE SECRET TO MAKING AI WORK FOR PHYSICIANS

BY BRANDON MCCUTCHEON, MD

If you are a physician or know a physician or have ever visited one, chances are you have probably heard them complain about technology in health care. More to the point, they are likely to be complaining about the one piece of technology that affects their lives minute-to-minute: the electronic health record (EHR). To get a sense of how central EHRs are to our daily routines, consider that physicians now spend more time in the EHR than they do seeing patients (6 hours of an average 11-hour work day). And while it is easy to write them off as luddites unable to adapt to new technology, an important study by the RAND organization noted that physicians approve of EHRs in principle and see the potential for the technology to improve the delivery of clinical care.

So where is the disconnect between the vision that physicians see for the EHR and its implementation in clinical practice? Instead of being a tool to facilitate communication and coordination, the EHR has become an additional burden. Common critiques include that fact that EHR technology interferes with face-to-face patient-physician communication (this has become the aptly named "screen between"), has significantly increased the amount of time physicians spend performing data entry and clerical duties (and in some cases, has created brand new administrative tasks), and is associated with poor user experience. It all feels as if the physician is working for the EHR rather than the other way around.

The changes physicians have had to make to clinical practice because of the EHR have had profound impacts. For example, EHRs have been identified as the #1 reason for physician burnout. This is particularly problematic given that one study demonstrated over half of all physicians are suffering from professional burnout. What's more, physicians who were dissatisfied with their EHR and clerical burden were also more likely to have plans of leaving clinical practice. This adds to ongoing concerns of an impending physician workforce shortage.
How have physicians responded? Medical scribes have emerged as one solution. Medical scribes follow the physician into the exam room where they observe the interaction and subsequently draft up the physician's documentation. While scribes are a great way to alleviate some of the EHR burden, they are not without limitations: scribes can be unaffordable for some providers (approximately $35,000 per year), require initial generalized training, need additional ramp-up time to learn the preferences of a specific physician, and are subject to turnover. Another approach has included retraining existing medical personnel such as clinic nurses or medical assistants to assist the physician with clerical duties. The challenge is both of these approaches involve mobilizing additional human resources to make up for the shortcoming of technology. Instead of creating more efficiencies and reducing human clerical burden, we continue to come up with creative workflow "hacks" for working around the EHR rather than improving it.

Technology is supposed to be an efficiency gainer. It is supposed to increase the productivity of the existing human workforce. Most sectors worry that technology will put humans out of work. With that said, skeptics may rightfully question the notion of improving technology with … more technology. However, the problem is not technology itself but rather the way it is envisioned, designed, and implemented into clinical practice.

Tools such as artificial intelligence (AI) and natural language processing (NLP) offer exciting opportunities to improve upon the existing healthcare IT environment. And If three easy steps



are followed in implementing these tools, we can make an important leap from our current status quo to a future where technology integrates seamlessly into the clinical workflow.

First, the creators of technology must take a problem-oriented approach. Notice that above I mention "tools such as artificial intelligence (AI) and natural language processing (NLP)." That is because these should be seen as solutions to a specific problem rather than just another technology we should squeeze into the clinical workflow. Therefore, by viewing AI and NLP as one of perhaps many tools we can mobilize to solve the problem of excessive data entry and clerical duties for physicians, we are more likely to succeed in creating value for physicians and building a product that they actually love (rather than the ones they currently lament).

Second, we must include physicians in the solution creation process. Good entrepreneurs refer to this as customer discovery and would not dream of launching an initial product without getting extensive feedback from the end user. We must see the problem we are solving through the eyes of the physician. How do they understand it? How does it impact their workflow? Where are the greatest opportunities for improvement? By attempting to see the problem through their lens, we are able to build solutions with the right combination of features that physicians will actually want.

Third, we must see the problems as more than just equations to be solved. With AI and NLP, there is the tendency to think that all that is needed is more data and a better performing algorithm. While adequate performance is undoubtedly necessary, it is not sufficient. The challenge with making AI work for clinicians is as much one of packaging it into an intuitive design and an enjoyable user interface (UI)/user experience (UX) as it is about enhancing performance. The best performing model is not much good if the physician hates the way it looks and feels; or worse, if it adds additional time to their workflow.

The EHR we have today does not have to be the one we have tomorrow. Efficient and enjoyable clinical practice is possible. A future where doctors spend more time with their patients than they do with the EHR is achievable. It just requires a problem-oriented approach, end-user engagement, attention to the clinical workflow, and beautiful design.

—

Brandon A. McCutcheon, MD; Chief Executive Officer: Brandon is a neurosurgeon in residency at the Mayo Clinic with a passion for data science and novel analytic methods. He is enthusiastic about tackling large-scale, high-impact problems. Brandon has founded and led a prior healthcare IT startup in addition to publishing over 40 peer-reviewed scientific manuscripts in clinical data science and machine learning.



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The CLIA-Waved BD Veritor™ Plus System for rapid detection of Flu A+B, combines speed and accuracy. It provides clear digital results in under 11 minutes and has demonstrated performance compared to molecular tests.[1] It is easy to use and has a low cost of ownership. The BD Veritor ™ Plus System is CLIA-Waved for Flu, RSV and Group A Strep.

[1] (BD Veritor System for Rapid Detection of Flu A+B, CLIA-waved kit package insert, 8087667 (14) 2018-06. BD Veritor System for Rapid Detection of Flu A+B, laboratory kit package insert, 8087666 (11) 2017-10., 2018-06.)

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simpleABI Cuff-Link systems are easy to learn and use
- Push button remote, automatic calculations/waveforms
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- Takes less than 10 minutes to perform, software provides verbal cues
- Tests for autonomic balance, vascular health, physical/mental stress, peripheral nerve health and other critical hidden risk factors
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- Provides a 1 page summary up to a full 24 page comprehensive report

8660



2 SUDOMOTOR TESTING (can be combined with ANS into 1 full system)

- Takes 3 minutes to analyze a patients' hands and feet
- Provides a 1 page summary report
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8661



3 ALLERGY TESTING

- Turn Key, comprehensive system
- 80-panel test, NO HIGH RISK (shellfish/peanuts/berries)
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- Reimburses average $270 - $350/test, costs ~ $100/test (antigens/applicators)
- Options for Immunotherapy Treatment

8662



4 NEURO-COGNITIVE TESTING

- Medicare mandates yearly cognitive assessment
- Takes 10-15 minutes to prep patient, 20 minutes to test
- Analyzes: brain health (EEG), brain processing speed (Evoke Potentials), heart health (EKG), mental health (neuropsychology)
- Reimburses using 6 CPT codes, National Average = $750 - $1000 per test
- Each test is processed into a fully-finished, clinically actionable report
- Easy to understand biomarkers facilitate more informed medical interventions, such as biofeedback

8663

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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

TOXICOLOGY SCREENING
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Comprehensive toxicology menu now with 14 CLIA[1] categorized moderately complex assays.



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1. Clinical Laboratory Improvement Amendments (CLIA)

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