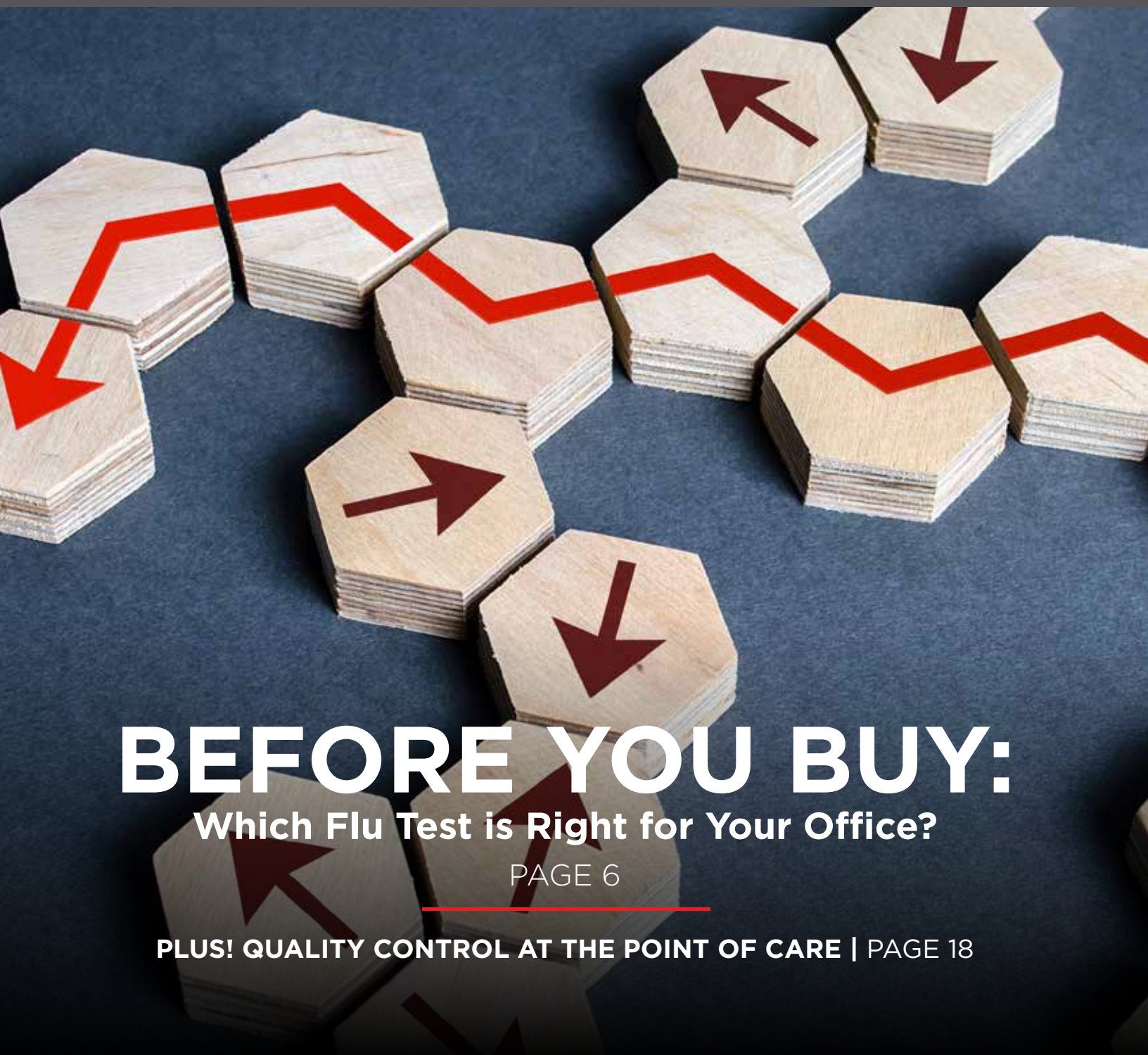
2020 | Issue 1

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Resources for You, Your Patients, & Your Practice

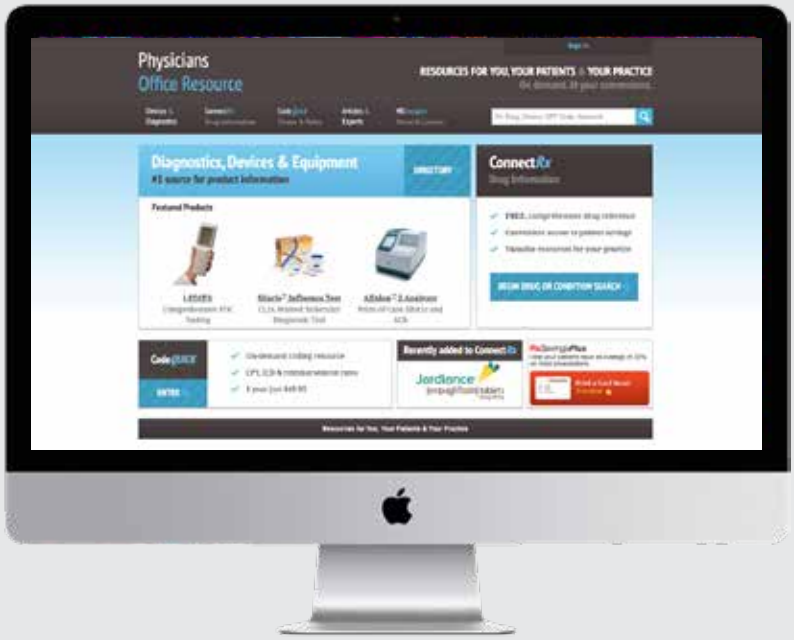


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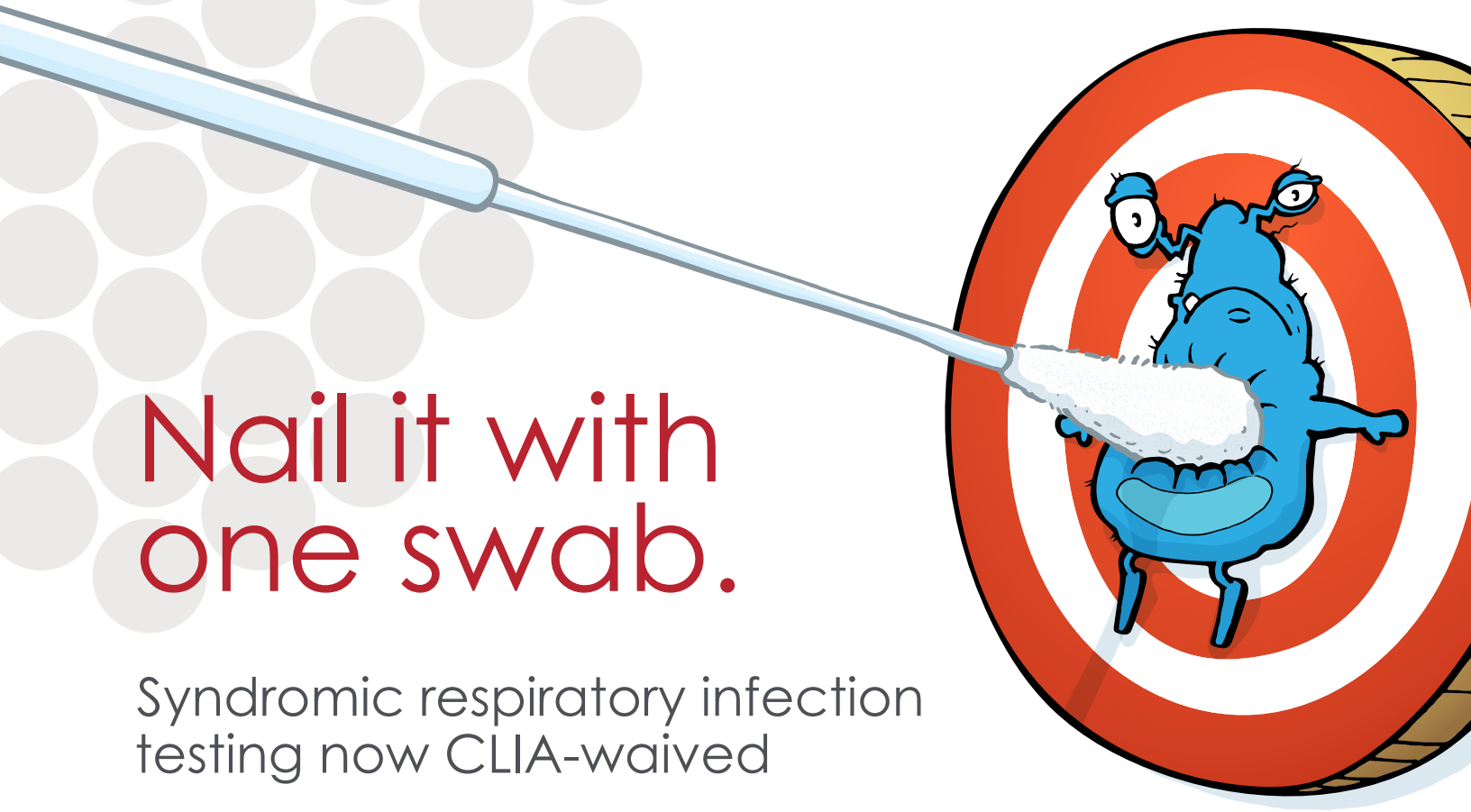
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BioFire RP EZ Pathogens

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Coronavirus
Human Metapneumovirus
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Influenza A
Influenza A/H1
Influenza A/H1-2009
Influenza A/H3
Influenza B
Parainfluenza Virus
Respiratory Syncytial Virus

Bacteria
Bordetella pertussis
Chlamydophila pneumoniae
Mycoplasma pneumoniae

[1] CLIA Certificate of Waiver required to perform testing.

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Syndromic Testing: The Right Test, The First Time.

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2020 is shaping up to be another bad flu season. Is your office prepared? With a wide variety of flu tests on the market, which one is best for your practice? Physicians Office Resource has teamed up with the best manufactures in the world to bring you the information you need to make the best purchasing decisions for your practice. Turn to pages 10-11 of this issue to learn more about what flu tests are available and which one would be best for your practice.

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WHICH FLU TEST IS RIGHT FOR YOUR OFFICE?

By now, physicians may have an idea of what's to come this flu season, based on how the flu season has already played out in other parts of the world. In previous years, however, despite forewarnings, the United States and European countries are sometimes caught off guard with a "Perfect Storm" of challenges.

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QUALITY CONTROL AT POC TESTING

Point of care testing (POCT) refers to testing that is performed near or at the site of a patient with the result leading to a possible change in the care of the patient. The popularity and demand of POCT has been growing rapidly, however, this should come as no surprise as there are many advantages to POCT.

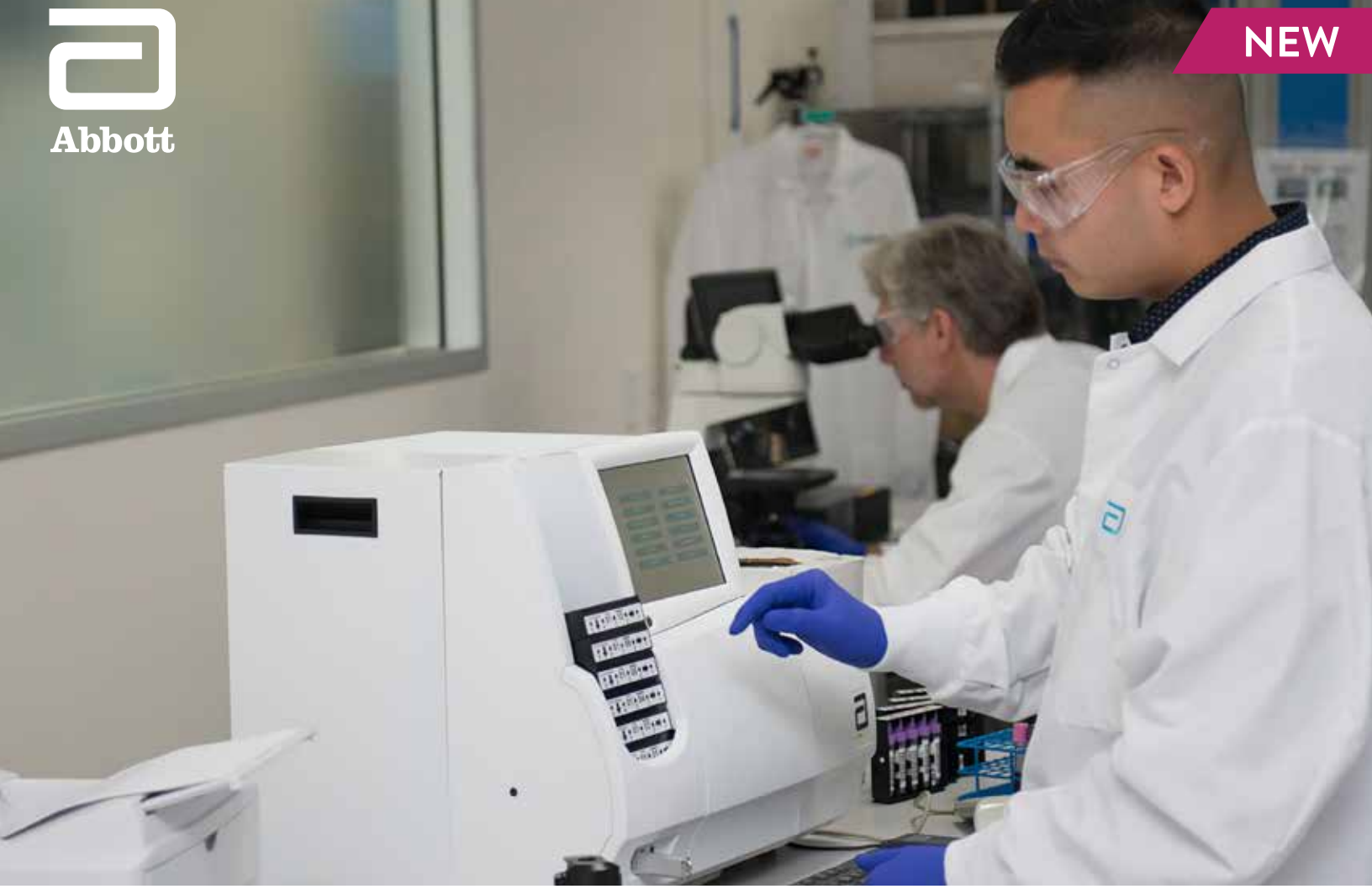
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DIABETES PATIENT MANAGEMENT: TIME IN RANGE

Diabetes management has changed dramatically with each new technological innovation. It wasn't that long ago when knowing a patient's glucose level was basically guess work. Yes there were tools to measure glucose, however these tools were difficult to use and highly inaccurate.

Abbott

NEW



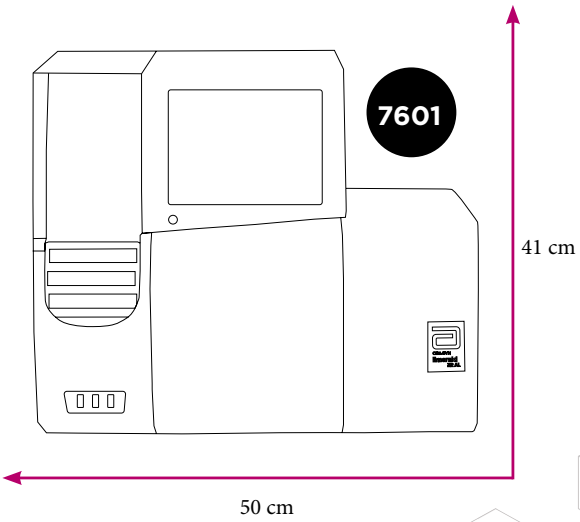
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BEFORE YOU BUY:
Which Flu Test Is Right for Your Office?

BY SEKISUI DIAGNOSTICS

BEFORE YOU BUY:
By now, physicians may have an idea of what's to come this flu season, based on how the flu season has already played out in other parts of the world. In previous years, however, despite forewarnings, the United States and European countries are sometimes caught off guard with a "Perfect Storm" of challenges for the influenza season. Physician offices should be stocking up on flu tests and other supplies in preparation for this year's flu season. What do they need to know before they choose a flu test?

PLANNING AHEAD
So much of flu season is a guessing game, especially when trying to plan for it. The World Health Organization (WHO), the Center for Disease Control (CDC), and the Food and Drug Administration (FDA) weigh in with their recommendation to which strains should be included in the upcoming flu vaccine well before the season gets started. Their prediction on what strains should be included will dictate how effective the vaccine will be. How severe the flu season is difficult to predict ahead of time, and the key indicators used by the WHO, CDC, and others can only be obtained after flu season begins!

So, what can clinicians and distributors do to prepare?

First, conducting a business assessment of what the clinicians experienced last year and looking at historical data can help dictate a plan to ensure they procure enough product.

Second, weigh the pros and cons of the tests they are currently using and tests they might be considering. Clinicians should consider the following:

Performance—Is test sensitivity and specificity the most critical?

Volume—How many tests does your facility perform during an average flu season?

Ease of Use – how simple is the test to perform?

CLIA Complexity – Does the facility require Waived Complexity (These simple and accurate tests are exempt from CLIA health and safety standards) or Moderate Complexity (These tests are more complex and have requirements for quality control, quality assurance, and more) Tests.

Results reporting—Is it important for your facility to have an instrument-based result or visual read result, or is either one acceptable?

Sample type—Does the test need to allow for multiple sample types (nasal, nasopharyngeal, aspirate/wash, and/or viral transport media (VTM))?

Connectivity—Is it important for the testing device to be able to transmit the results electronically?

Cost of the test

The time to result

Does the test require confirmation testing for negative results?

Depending on what characteristics (from right) are important to the clinician will help determine what type of test is a good fit for the facility. The manufacturer and distribution representative would be able to help guide the clinician to a product that is just right for them.

It should be noted that no flu test provides 100% accuracy. Results depend on the type of test used, the strain of virus and the integrity of the sample. It is very important when bringing on any test to review any limitations of the test, such as strain detection, any patient age limitations and performance data, along with sample collection and handling best practices and make sure that all staff is trained to provide the best in class testing.

THE IMPORTANCE OF TESTING

Due to the known performance issues surrounding the RIDTs, some physicians may argue that it's not necessary to administer a flu test in order to diagnose and treat.

Testing does not usually change how a patient will be treated for a flu diagnosis, so why bother? It turns out there are several reasons.

• Empirical treatment has a disadvantage in that many more patients are receiving treatment than actually have the flu giving rise to a possible antiviral shortage and possibly delaying the right treatment for another health issue.

• Testing patients provides valuable information to the clinician that can enable them to rule out other illnesses, helps determine a more direct therapy plan, and reduces the risk of unnecessary antiviral or antibiotics therapy, while increasing the chances that the patient will receive anti-viral therapy early when it is most effective.

• Testing will also help determine whether an outbreak of flu is occurring. Since the implementation of rapid molecular tests and the drive by the FDA reclassification to have better RIDTs into the market clinicians can have the opportunity to utilize a highly accurate test to be more confident in the results to drive direct therapy.

THE 5 "PS"

In the end, it comes down to the 5 "Ps" – Proper Preparation Prevents Poor Performance! Don't be afraid to keep stock of flu tests all year round. Understand new options—with the fear of changing strains, new technologies are more important than ever. Just remember, you have choices!

HOW SEKISUI DIAGNOSTICS CAN HELP

Sekisui Diagnostics offers three flu tests to help clinicians master the art of influenza testing.



The **CLIA-Waived Silaris®** Influenza A&B Test is a molecular diagnostic test utilizing polymerase chain reaction (PCR) technology providing accurate results for early diagnosis and proper management of influenza.



The **CLIA-Waived OSOMâ Ultra Flu A & B Test** is a FDA Class II compliant in-vitro rapid qualitative test that detects influenza type A and type B nucleoprotein antigens directly from nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens obtained from patients with signs and symptoms of respiratory infection.



The **Acucy™ Influenza A&B Test** on the Acucy™ System provides clinicians flexibility in workflow and accurate, standardized results for improved patient care

Flu Diagnostic Testing Comparison

DIAGNOSTIC CHALLENGES

There are a number of diagnostic options available. However, choices may have to be made in terms of:

ACCURACY
Patient receives correct diagnosis

TIME
Patient receives correct diagnosis in a timely manner

COST
Diagnosis is obtained cost-effectively and affordably

WHAT'S OUT THERE?
There are several types of flu tests available on the market. Rapid molecular tests detect the genetic material of the virus and typically produce results in 30 minutes or less. These are considered to be more accurate than rapid influenza diagnostic tests (RIDTs). RIDTs are lateral flow immunochemical membrane tests that can be either read visually or by an instrument and are intended to detect the presence (or absence) of a target antigen in 15 minutes or less.

METHOD	FEATURES			
CLIA WAIVED VISUAL MOLECULAR	• Rapid PCR molecular platforms can be smaller and faster, and can be brought closer to the patient, for improved clinical impact • Molecular performance • Next generation molecular assays have focused on ease of use providing the familiar workflow of traditional lateral flow assays • Cost is less than traditional molecular with same reimbursement • Considered a Gold Standard of testing along with viral culture[1]	🟢	🟢	🟢
TRADITIONAL MOLECULAR	• Highly accurate and definitive results • Labor-intensive workflow • Cost of rapid molecular tests is higher than lateral flow, but that may be offset by reducing unnecessary use of antibiotics • Considered a Gold Standard of testing along with viral culture[1]	🟢	🟡	🔴
READER IMMUNOCHEMICAL	• Easy to perform • Affordable, making them suitable for use in a variety of settings from laboratories to near-patient • Typically provide results in minutes, allowing clinicians to test and treat quickly • Improves objectivity by removing visual read	🟡	🟢	🟡
VISUAL IMMUNOCHEMICAL	• Easy to perform • Affordable, making them suitable for use in a variety of settings from laboratories to near-patient • Typically provide results in minutes, allowing clinicians to test and treat quickly • Better accuracy with the FDA Flu Reclassification[2]	🔴	🟢	🟢

1 https://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm
2 Federal Register / Vol. 82, No. 8 / Thursday, January 12, 2017 / Rules and Regulations

FLU TESTING PRODUCT FOCUS



7602

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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OSOM® ULTRA FLU A&B

From Sekisui Diagnostics

The OSOM® Ultra Flu A&B test is a rapid qualitative assay for the detection of Influenza A and Influenza B from multiple sample types. The OSOM® Ultra Flu A&B provided physicians with the ability to rapidly and accurately diagnosis influenza which enables a choice of antiviral therapy, helps avoid the overuse of antibiotics, and prevents healthcare costs related to unnecessary testing and treatment.

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7603



7604

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.

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FLU TESTING PRODUCT FOCUS



CLIA-WAIVED FOR RAPID DETECTION OF FLU A+B

From BD Veritor

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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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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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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- You have many high risk patients, including anyone over 65 or diabetics or smokers
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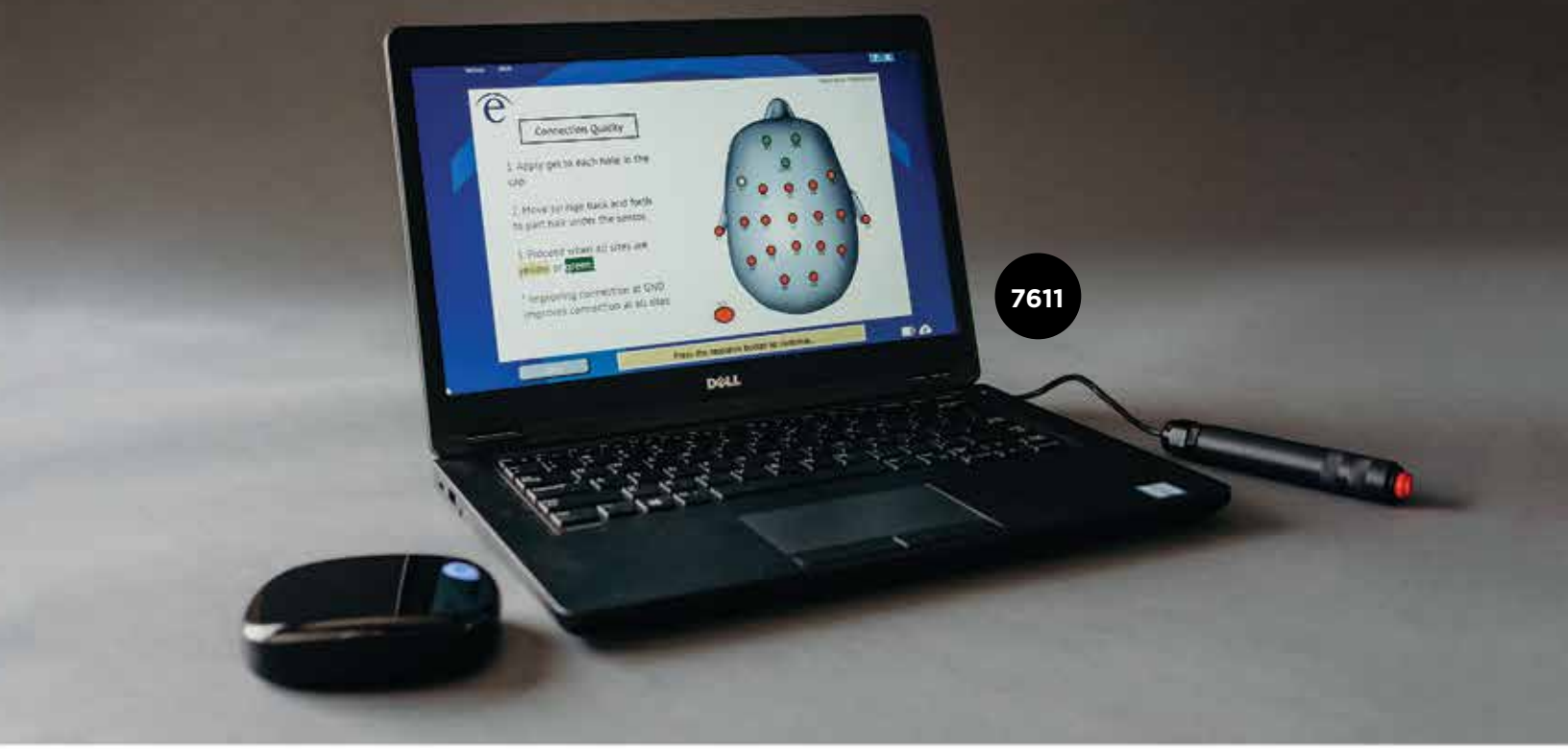
simpleABI Cuff-Link systems are easy to learn and use
- Push button remote, automatic calculations/waveforms
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Reimbursable.
$725 Medicare national average 2019[1]

eVox® Aids in Diagnosis

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

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

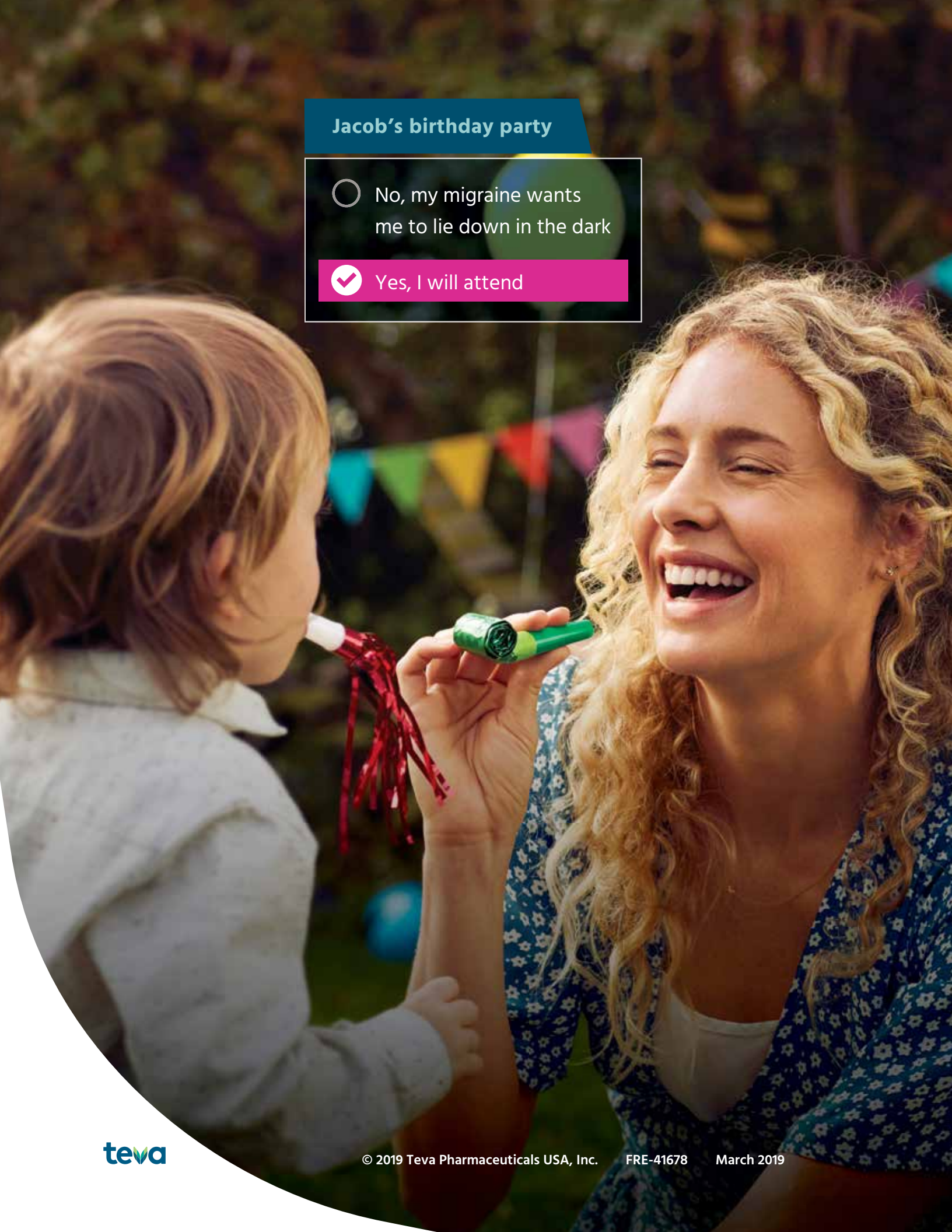
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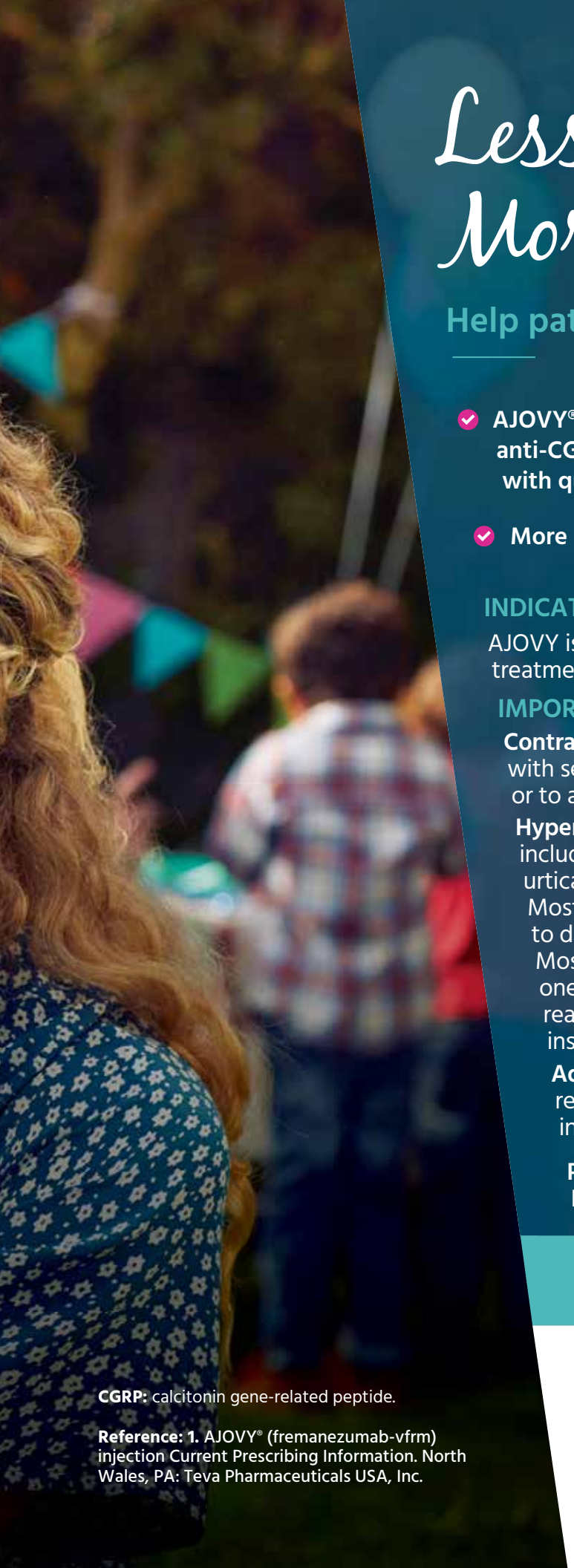
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[1]2019 NATIONAL AVERAGE MEDICARE PHYSICIAN FEE SCHEDULE, NON FACILITY SETTING https://www.cms.gov/apps/physician-fee-schedule/overview.aspx
Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019 Final Rule.

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



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Less migraine. More moments.™

Help patients say yes to more moments

- **AJOVY® (fremanezumab-vfrm) injection is the only anti-CGRP treatment for the prevention of migraine with quarterly and monthly dosing options[1]**
- **More migraine-free days with AJOVY in clinical trials[1]**

INDICATION

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

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 Brief Summary of full Prescribing Information on the following page.

To learn more, visit AJOVYhcp.com

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

CGRP: calcitonin gene-related peptide.

Reference: 1. AJOVY® (fremanezumab-vfrm) injection Current Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.

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 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.

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This Brief Summary is based on the full Prescribing Information for AJOVY AJO-002.

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FRE-41620 March 2019



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QUALITY CONTROL
at Point of Care Testing

BY JAMES CRILLY - QC MARKETING MANAGER – RANDOX LABORATORIES LTD.

Point of care testing (POCT) refers to testing that is performed near or at the site of a patient with the result leading to a possible change in the care of the patient. The popularity and demand of POCT has been growing rapidly, however, this should come as no surprise as there are many advantages to POCT, for example, the convenience of being able to obtain a rapid result at the patient's bedside, thus allowing immediate action, saving time and improving the potential outcome for the patient.

Although there are many benefits of using POCT devices in terms of their convenience, these benefits are only true if the results produced are both accurate and reliable. Ensuring accuracy and reliability is the primary responsibility of Quality Control.

IMPORTANCE OF QUALITY CONTROL FOR POCT DEVICES

ISO 15189 states that "Quality Control materials shall be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result" (1).

Therefore, when implementing a QC strategy for POCT devices the risk of harm to the patient should be the foundation of the plan: where and why do errors occur and what are the consequences of an erroneous result to the patient? It is important to balance the risk of harm to the patient with the stringency of the QC procedure applied. Inaccurate results can have serious implications for the patient including misdiagnosis and/or inappropriate or incorrect medical procedures being carried out unnecessarily, resulting in monetary implications for the hospital.

POCT procedures have been previously shown to be less stable than those run within the laboratory. A recent study found that the most common phase for errors in POCT was analytical, with 65.3% of errors occurring during this phase. (2) Conversely, in laboratory based testing the analytical phase is the least common source for errors (3) thus, highlighting the importance of QC procedures for POCT devices while also outlining how the potential risk of harm to a patient may be greater for POC tests compared to those performed on laboratory based analyzers. This study also revealed that the potential impact of quality control error on a POCT device having a moderate adverse impact on patient outcome was 14.7% (2), demonstrating that for POCT devices there is larger room for error and a greater need for quality control.

In 2006 a new ISO standard; ISO 22870 was released specifically for POCT titled: "POCT – Requirements for quality and competence" (4). ISO 22870 advises that where available, Internal Quality Control and participation in an External Quality Assessment scheme is required in the point of care setting. ISO 22870 is designed to be used in conjunction with IS0 15189.

CHOOSING IQC MATERIAL THAT'S APPROPRIATE FOR USE WITH POCT DEVICES

All POCT devices should run third party IQC samples. It is important to choose IQC material that fully meets the needs of the laboratory.

When implementing an IQC strategy it is important to take into consideration the differing designs of the device and potential risk of harm of the patient. When choosing an appropriate QC material look for the following features:

· Ease of use – many samples are available in a 'liquid-ready-to-use' format which require no preparation. This format can be conveniently stored at +2 to +8o C meaning it can be stored safely on the ward rather than in a laboratory freezer.

· A matrix similar to the patient sample – choose samples that are as close to a human sample as possible, in-line with ISO15189 regulations.

· Clinically relevant concentrations – analytes should be available at clinically significant concentrations to accurately validate patient sample results.

· Accurately assigned - method/ instrument specific target values and ranges should be accurately assigned.

· Third party – ISO 15189 recommends quality control material is from a third-party source.

ADDITIONAL SOFTWARE AVAILABLE

Perhaps a reason for the higher rate of error associated with a POCT device is due to a lack of responsibility on behalf of the staff performing the POCT. Ultimately, responsibility should lie within the laboratory but how can the quality of results released by POCT devices be managed when the people performing the tests are spread out in a hospital setting, and out of direct view of the laboratory QC Technician?

The review process can be facilitated by QC management software, which helps the laboratory monitor the reliability and accuracy of results released in the POC setting.

There are a number of QC management programs available, however the following requirements should be sought after:

· Up to date peer group – Ideally a QC management program should have a peer group functionality to enable the comparison of results to other laboratories worldwide using the same lot of control, method and instrument. Peer group monitoring should be in real time, and therefore, should be updated daily.

· Multiple instrument registrations – the ability to register multiple instruments is vital in POCT as there will be a number of POCT devices through the POC setting that will need monitored.

· Online access – within a POC setting it's important that results can be entered online, anywhere at any time. This also means that the lab manager can remotely log onto the software to view the QC results entered for specific POC devices throughout the hospital or beyond.

· Multiple user levels - Different user level accounts should be avail able so that lab managers can track results. This also ensures that each POC operator is performing appropriate maintenance, instrument calibration and is adequately trained to use the device.

· User defined acceptable limits - to be applied to QC results, so that results can automatically be rejected or accepted.

Indeed, major sources of error have been previously categorized to be commonly due to operator incompetence and a disregard for test procedures, and the use of uncontrolled reagents and testing equipment (5). Therefore, through using appropriate QC management software in the POC setting, the laboratory can reduce the level of risk and ensure accurate results are obtained.

CONCLUSION

It is important to remember that the benefits of POCT are only true if the results obtained are accurate and reliable, however, given the large number of POCT devices available on the market choosing an appropriate quality control plan for your instrument can be challenging. By following the guidelines outlined in this paper in addition to ISO 15189 and ISO 22870:2006 you can be assured that the management and overall results of your POCT devices will be of a higher and more reliable quality.

Randox Laboratories are able to help laboratories with their POCT requirements due to our ever-expanding portfolio of liquid ready-to-use controls suitable for use at the POC. Our range of controls suitable for use include Urinalysis, Blood Gas, Liquid HbA1c and more. Additionally, Randox can also supply Acusera 24.7 – our interlaboratory data management software – with real-time peer group updates, comprehensive yet easy to read reports as well as interactive and user-friendly charts. Our software is also capable of automatically calculating measurement of uncertainty and sigma scores automatically.

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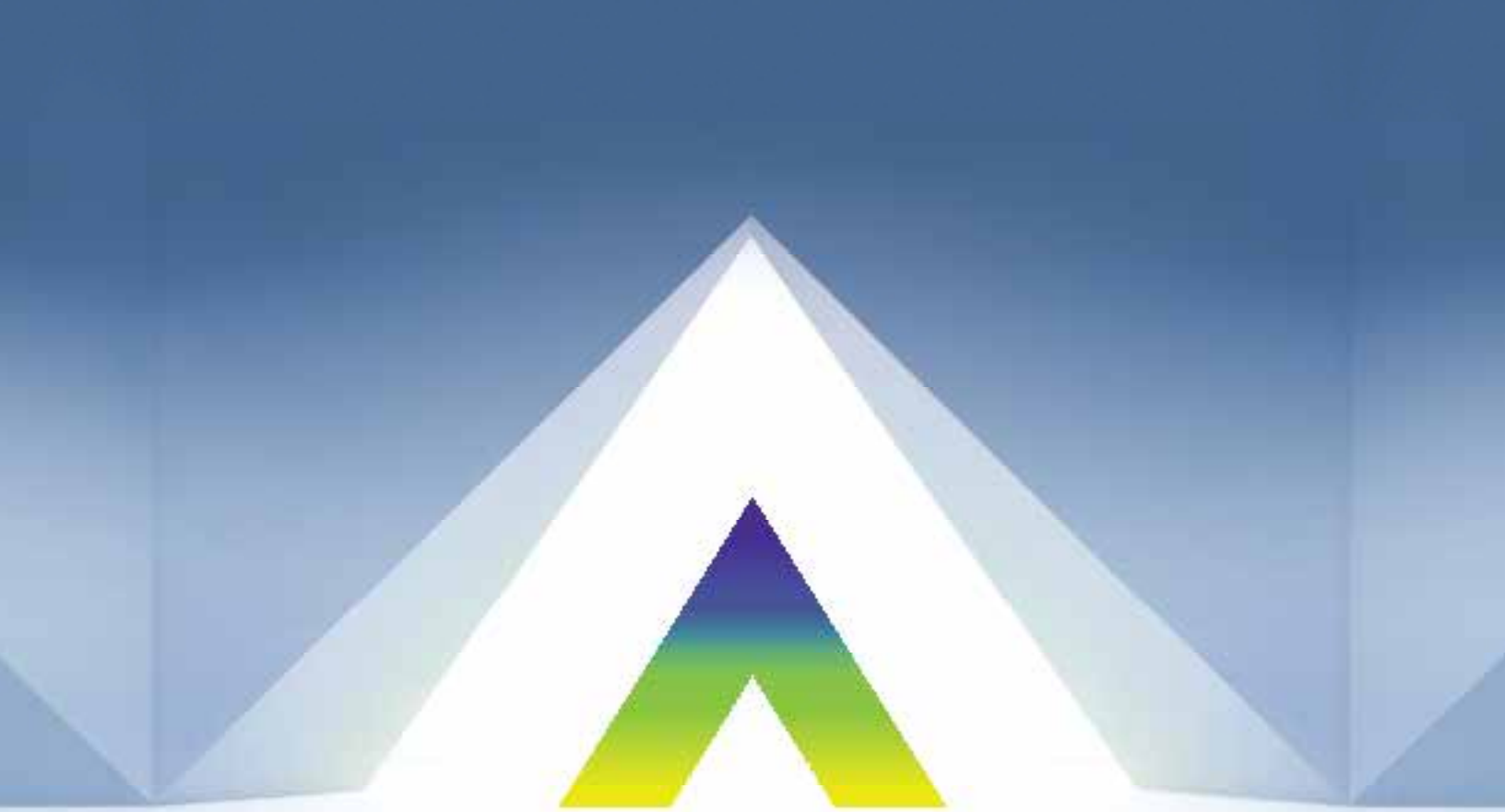


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DIABETES PATIENT MANAGEMENT:

Time in Range the Newest Metric

BY DAVID KLIFF, THE DIABETIC INVESTOR

Diabetes management has changed dramatically with each new technological innovation. It wasn't that long ago when knowing a patient's glucose level was basically guess work. Yes there were tools to measure glucose, however these tools were difficult to use and highly inaccurate. This all changed with the invention of blood glucose monitors which measured glucose using a drop of blood. Although the process wasn't perfect; for the first-time patients were able to accurately measure their glucose levels on a regular.

The biggest jump in glucose measurement came with the invention and now widespread adoption of continuous glucose monitoring systems (CGMS). For the first time not only could a patient see their glucose levels, they could also see a series of continuous readings. This explosion of data created a whole new world of diabetes management. Patients not only knew where their levels are but thanks to advancements in CGMS they knew were their glucose levels were trending.

This is turn created a new metric for measuring glucose control. HbA1c, always considered the gold standard for measuring glycemic control, was augmented with a new metric, time in range (TIR). Several studies noted that two patients could have exactly the same HbA1c but vastly different TIR profiles. Further studies noted that TIR was as critical if not more so than HbA1c in determining whether or not the patient was at risk for many of the complications experienced with poor glycemic control.

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Thanks to CGMS it was now possible to more effectively manage a patient who previously was thought to be under good control because their HbA1c was 7 or below. TIR management allowed patients and their physicians to design therapy regimens which kept the patient in a tighter glycemic range therefore further reducing the likelihood of complications.

Even better the more advanced CGMS systems were supplemented with smartphone apps and/or web sites which provided advanced reporting capabilities. Using these cloud-based capabilities patients could now easily share not just their readings but also the many reports produced by the sites/apps.

In its simplest form TIR isn't just about detecting and avoiding hypoglycemic events. TIR management is equally about avoiding the higher highs.

As you are aware, in a real world setting its virtually impossible to keep any patient, no matter how engaged they are with diabetes management, in a tight range 100% of the time. However many physicians and patients have adopted a goal of not just keeping their HbA1c below 7 but staying in range 70% or more of the time. Something that wasn't even considered only a short time ago.

TIR has become so critical a metric that efforts are underway by many of the diabetes governing bodies to expand the definition of what constitutes good glycemic from just HbA1c to include TIR. It's critical to note that as revealing as TIR is becoming this metric is more meaningful to intensively managed insulin using patients then it is to non-intensively managed patients. There is good reason for this as non-intensively managed patients due to their regimen have less control over their swings in their glucose levels.

For the less intensively managed patient TIR remains a valuable metric it's just differently than it is for an intensively managed patient. For example with a non-intensively managed patient TIR discovers whether their current therapy regimen is effective. Even better thanks to CGMS the physician and patient do not have to wait for the results of an HbA1c. Additionally this means the patient avoids a blood draw. The data from the CGMS can be used to calculate Average Mean Glucose which is easily converted to the equivalent HbA1c.

It goes without saying that TIR is invaluable for the intensively managed patient. These patients can now see many of the factors which go into determining their insulin dosing calculations. For example two critical factors with in determining insulin dosing are time to insulin action and duration of insulin action. CGMS takes all the guess work out of determining these factors the physician and patient can see them. Many physicians and patients have begun to readjust their insulin dosing for the better thanks to this data therefore enabling optimum glucose control.

Thankfully CGMS have become more sophisticated, cheaper and more patient friendly making it easier than to keep a patient in a tighter glucose range. Welcome to the new frontier of diabetes management.

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

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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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SELF-CONTAINED DIAGNOSTIC WORKSTATION

From Vitalograph

Vitalograph introduces the Compact Expert diagnostic workstation. The device is a full touch-screen based medical workstation, which comes equipped with Vitalograph's flagship Pneumotrac spirometer. This accurate, robust and linear Fleisch pneumotach produces over 50 spirometry parameters, automatically stores all test data, calibration data and clinical audit trail data in a secure network capable SQL Server database. An intuitive user interface enhances the routine workflow in most practices, allowing quick patient throughput. Beyond spirometry, it is a desktop testing station for ECG, Pulse Oximetry, Weight , COPD assessment, and Blood Pressure measurements.

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FULLY AUTOMATED QUANTITIVE IMMUNOASSAY ANALYZER

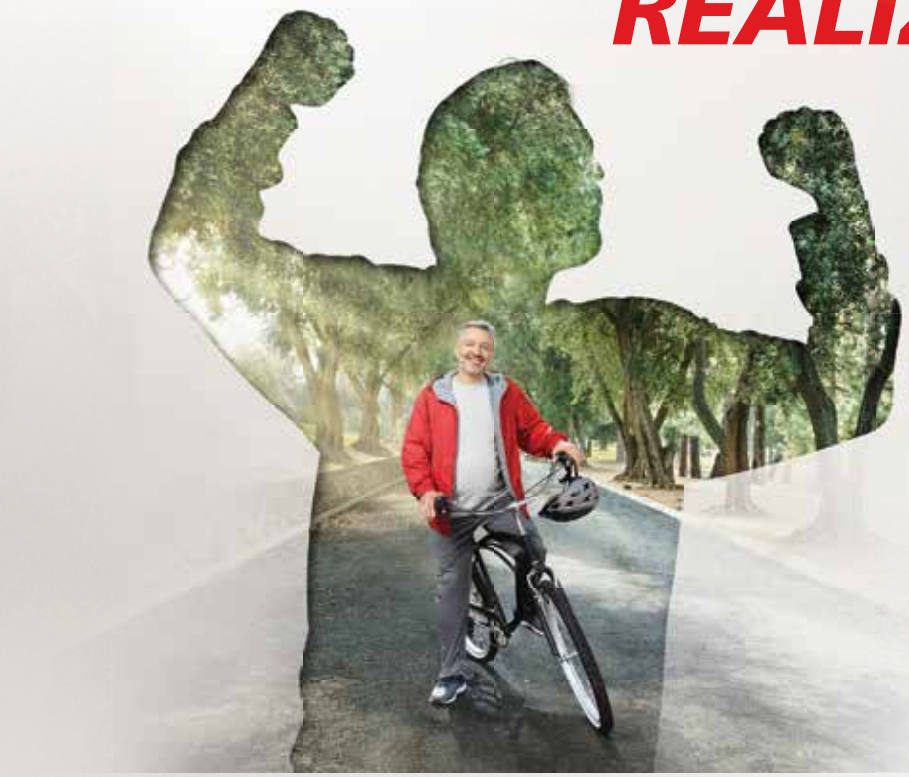
From Sekisui Diagnostics

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

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For adult patients with type 2 diabetes,
treated with diet and exercise

REALIZE THE POTENTIAL



Choose Ozempic® as your first injectable—
the only once-weekly GLP-1 RA with
superior results vs Trulicity®[1,2]

SUPERIOR GLYCEMIC CONTROL

SUPERIOR WEIGHT REDUCTION

Ozempic® is not indicated for weight loss.

CV SAFETY

as evaluated in a 2-year CVOT.[2]

Ozempic® is not indicated for reduction
in major adverse CV events (MACE).

SUSTAIN 6: A 2-year, randomized, multinational, double-blind, placebo-controlled, parallel-group CV safety trial that was designed to assess noninferiority of Ozempic® vs standard of care by excluding the preapproval noninferiority margin of 1.8. A total of 3297 adult patients with type 2 diabetes and high risk of CV events were randomized based on evidence of CV disease, insulin treatment, and renal impairment to once-weekly Ozempic® 0.5 mg (n=826), Ozempic® 1 mg (n=822), or placebo (n=1649) in addition to standard of care treatments such as oral antidiabetic treatments, insulin, antihypertensives, diuretics, lipid-lowering therapies, and antithrombotic medication at investigator discretion. The primary composite endpoint was the time from randomization to first occurrence of a MACE, defined as CV death, nonfatal myocardial infarction, or nonfatal stroke.[3]

Indication and Limitations of Use

Ozempic® (semaglutide) injection 0.5 mg or 1 mg is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

- Ozempic® is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans.
- Ozempic® has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Ozempic® is not a substitute for insulin. Ozempic® is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis.

Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

- **In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Ozempic® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined.**
- **Ozempic® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Ozempic® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Ozempic®.**

Contraindications

- Ozempic® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with known hypersensitivity to semaglutide or to any of the product components.

Warnings and Precautions

- **Risk of Thyroid C-Cell Tumors:** Patients should be referred to an endocrinologist for further evaluation if serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging.
- **Pancreatitis:** Acute and chronic pancreatitis have been reported in clinical studies. Observe patients carefully for signs and symptoms of pancreatitis (persistent severe abdominal pain, sometimes radiating to the back with or without vomiting). If pancreatitis is suspected, discontinue Ozempic® promptly, and if pancreatitis is confirmed, do not restart.
- **Diabetic Retinopathy Complications:** In a 2-year trial involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with Ozempic® (3.0%) compared to placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline than among patients without a known history of diabetic retinopathy.

  Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. The effect of long-term glycemic control with semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

novo nordisk®

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In a 40-week trial, in patients on metformin, for each dose comparison

Ozempic® was superior to Trulicity® in A1C and weight reduction[1]

ONCE-WEEKLY OZEMPIC® semaglutide injection 0.5 mg | 1 mg



Ozempic® outperformed Trulicity® in reducing A1C[1]

–1.4% with **Ozempic® 0.5 mg** (Baseline: 8.3%) vs
–1.1% with **Trulicity® 0.75 mg** (Baseline: 8.2%); *P*=0.002

–1.6% with **Ozempic® 1 mg** (Baseline: 8.2%) vs
–1.3% with **Trulicity® 1.5 mg** (Baseline: 8.2%); *P*=0.0004



Secondary endpoint

Ozempic® demonstrated superior body weight reduction vs Trulicity®[1]

Ozempic® is not indicated for weight loss.

–9.3 lb with **Ozempic® 0.5 mg** (Baseline: 213 lb) vs
–4.6 lb with **Trulicity® 0.75 mg** (Baseline: 211 lb); ETD=–4.7 lb (95% CI; –6.5, –2.9)

–12.8 lb with **Ozempic® 1 mg** (Baseline: 211 lb) vs
–6.2 lb with **Trulicity® 1.5 mg** (Baseline: 206 lb); ETD=–6.7 lb (95% CI; –8.5, –5.0)

SUSTAIN 7: A 40-week, multinational, multicenter, randomized, open-label, four-armed, pair-wise, active-controlled, parallel-group trial to compare the efficacy and safety of Ozempic® vs dulaglutide. A total of 1201 adult patients with type 2 diabetes inadequately controlled on metformin were randomized to receive Ozempic® 0.5 mg (n=301), Ozempic® 1 mg (n=300), dulaglutide 0.75 mg (n=299), or dulaglutide 1.5 mg (n=299) once weekly. The primary endpoint was mean change in A1C from baseline at Week 40. Secondary endpoints included mean change in body weight at Week 40 and proportion of patients achieving A1C <7% at Week 40. Results based on a sensitivity analysis of retrieved dropout population.[1]

Learn more about Ozempic® and the CVOT at ***OzempicPro.com***.

- **Never Share an Ozempic® Pen Between Patients:** Ozempic® pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens.
- **Hypoglycemia:** The risk of hypoglycemia is increased when Ozempic® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin.
- **Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of Ozempic® in patients reporting severe adverse gastrointestinal reactions.
- **Hypersensitivity:** Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with GLP-1 receptor agonists. If hypersensitivity reactions occur, discontinue use of Ozempic®; treat promptly per standard of care, and monitor until signs and symptoms resolve. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist.
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Ozempic®.

Adverse Reactions

- The most common adverse reactions, reported in ≥5% of patients treated with Ozempic® are nausea, vomiting, diarrhea, abdominal pain, and constipation.

Drug Interactions

- The risk of hypoglycemia may be lowered by a reduction in the dose of the secretagogue or insulin.
- Ozempic® causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications, so caution should be exercised.

Use in Specific Populations

- There are limited data with semaglutide use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. Discontinue Ozempic® in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide.

Please see Brief Summary of Prescribing Information on following pages.

GLP-1 RA=glucagon-like peptide-1 receptor agonist; CV=cardiovascular; CVOT=cardiovascular outcomes trial; ETD=estimated treatment difference; CI=confidence interval.

References: 1. Pratley RE, Aroda VR, Lingvay I, et al. Semaglutide versus dulaglutide once weekly in patients with type 2 diabetes (SUSTAIN 7): a randomised, open-label, phase 3b trial. *Lancet Diabetes Endocrinol.* 2018;6(4):275-286. **2.** Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc; 2017. **3.** Marso SP, Bain SC, Consoli A, et al. Semaglutide and cardiovascular outcomes in patients with type 2 diabetes. *N Engl J Med.* 2016;375(19):1834-1844.

ONCE-WEEKLY OZEMPIC® semaglutide injection 0.5 mg | 1 mg

OZEMPIC® (semaglutide) injection

Rx Only

BRIEF SUMMARY: Please consult package insert for full prescribing information.

WARNING: RISK OF THYROID C-CELL TUMORS: In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether OZEMPIC® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined *[see Warnings and Precautions]*. OZEMPIC® is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) *[see Contraindications]*. Counsel patients regarding the potential risk for MTC with the use of OZEMPIC® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with OZEMPIC® *[see Contraindications and Warnings and Precautions]*.

INDICATIONS AND USAGE: OZEMPIC® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: OZEMPIC® is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans *[see Warnings and Precautions]*. OZEMPIC® has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis *[see Warnings and Precautions]*. OZEMPIC® is not a substitute for insulin. OZEMPIC® is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis, as it would not be effective in these settings.

CONTRAINDICATIONS: OZEMPIC® is contraindicated in patients with: A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) *[see Warnings and Precautions]*; Known hypersensitivity to semaglutide or to any of the product components *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS: Risk of Thyroid C-Cell Tumors: In mice and rats, semaglutide caused a dose-dependent and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure at clinically relevant plasma exposures. It is unknown whether OZEMPIC® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined. Cases of MTC in patients treated with liraglutide, another GLP-1 receptor agonist, have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans. OZEMPIC® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of OZEMPIC® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with OZEMPIC®. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin value may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated. **Pancreatitis:** In glycemic control trials, acute pancreatitis was confirmed by adjudication in 7 OZEMPIC®-treated patients (0.3 cases per 100 patient years) versus 3 in comparator-treated patients (0.2 cases per 100 patient years). One case of chronic pancreatitis was confirmed in an OZEMPIC®-treated patient. In a 2-year trial, acute pancreatitis was confirmed by adjudication in 8 OZEMPIC®-treated patients (0.27 cases per 100 patient years) and 10 placebo-treated patients (0.33 cases per 100 patient years), both on a background of standard of care. After initiation of OZEMPIC®, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, OZEMPIC® should be discontinued and appropriate management initiated; if confirmed, OZEMPIC® should not be restarted. **Diabetic Retinopathy Complications:** In a 2-year trial involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with OZEMPIC® (3.0%) compared to placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline (OZEMPIC® 8.2%, placebo 5.2%) than among patients without a known history of diabetic retinopathy (OZEMPIC® 0.7%, placebo 0.4%). Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. The effect of long-term glycemic control with semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy. **Never Share an OZEMPIC® Pen Between Patients:** OZEMPIC® pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens. **Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin:** The risk of hypoglycemia is increased when OZEMPIC® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. Patients may require a lower dose of the secretagogue or insulin to reduce the risk of hypoglycemia in this setting *[see Adverse Reactions, Drug Interactions]*. **Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of OZEMPIC® in patients reporting severe adverse gastrointestinal reactions. **Hypersensitivity:** Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with GLP-1 receptor agonists. If hypersensitivity reactions occur, discontinue use of OZEMPIC®; treat promptly per standard of care, and monitor until signs and symptoms resolve. Do not use in patients with a previous hypersensitivity to OZEMPIC® *[see Contraindications]*. Anaphylaxis and angioedema have been reported with other GLP-1 receptor agonists. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to anaphylaxis with OZEMPIC®. **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with OZEMPIC®.

ADVERSE REACTIONS: The following serious adverse reactions are described below or elsewhere in the prescribing information: Risk of Thyroid C-cell Tumors *[see Warnings and Precautions]*; Pancreatitis *[see Warnings and Precautions]*; Diabetic Retinopathy Complications *[see Warnings and Precautions]*; Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin *[see Warnings and Precautions]*; Acute Kidney Injury *[see Warnings and Precautions]*; Hypersensitivity *[see Warnings and Precautions]*. **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. Pool of Placebo-Controlled Trials: The data in Table 1 are derived from 2 placebo-controlled trials (1 monotherapy trial and 1 trial in combination with basal insulin) in patients with type 2 diabetes. These data reflect exposure of 521 patients to OZEMPIC® and a mean duration of exposure to OZEMPIC® of 32.9 weeks. Across the treatment arms, the mean age of patients was 56 years, 3.4% were 75 years or older and 55% were male. In these trials 71% were White, 7% were Black or African American, and 19% were Asian; 21% identified as Hispanic or Latino ethnicity. At baseline, patients had type 2 diabetes for an average of 8.8 years and had a mean HbA_{1c} of 8.2%. At baseline, 8.9% of the population reported retinopathy. Baseline estimated renal function was normal (eGFR ≥90 mL/min/1.73m^2) in 57.2%, mildly impaired (eGFR 60 to 90 mL/min/1.73m^2) in 35.9% and moderately impaired (eGFR 30 to 60 mL/min/1.73m^2) in 6.9% of patients. Pool of Placebo- and Active-Controlled Trials: The occurrence of adverse reactions was also evaluated in a larger pool of patients with type 2 diabetes participating in 7 placebo- and active-controlled glycemic control trials including two trials in Japanese patients evaluating the use of OZEMPIC® as monotherapy and add-on therapy to oral medications or insulin. In this pool, a total of 3150 patients with type 2 diabetes were treated with OZEMPIC® for a mean duration of 44.9 weeks. Across the treatment arms, the mean age of patients was 57 years, 3.2% were 75 years or older and 57% were male. In these trials, 60% were White, 6% were Black or African American, and 31% were Asian; 16% identified as Hispanic or Latino ethnicity. At baseline, patients had type 2 diabetes for an average of 8.2 years and had a mean HbA_{1c} of 8.2%. At baseline, 7.8% of the population reported retinopathy. Baseline estimated renal function was normal (eGFR ≥90 mL/min/1.73m^2) in 63.1%, mildly impaired (eGFR 60 to 90 mL/min/1.73m^2) in 34.3%, and moderately impaired (eGFR 30 to 60 mL/min/1.73m^2) in 2.5% of the patients. Common Adverse Reactions: Table 1 shows common adverse reactions, excluding hypoglycemia, associated with the use of OZEMPIC® in the pool of placebo-controlled trials. These adverse reactions occurred more commonly on OZEMPIC® than on placebo, and occurred in at least 5% of patients treated with OZEMPIC®.

Table 1. Adverse Reactions in Placebo-Controlled Trials Reported in ≥5% of OZEMPIC®-Treated Patients with Type 2 Diabetes Mellitus

Adverse Reaction	Placebo (N=262) %	OZEMPIC® 0.5 mg (N=260) %	OZEMPIC® 1 mg (N=261) %
Nausea	6.1	15.8	20.3
Vomiting	2.3	5.0	9.2
Diarrhea	1.9	8.5	8.8
Abdominal pain	4.6	7.3	5.7
Constipation	1.5	5.0	3.1

In the pool of placebo- and active-controlled trials and in the 2-year cardiovascular outcomes trial, the types and frequency of common adverse reactions, excluding hypoglycemia, were similar to those listed in Table 1. *Gastrointestinal Adverse Reactions:* In the pool of placebo-controlled trials, gastrointestinal adverse reactions occurred more frequently among patients receiving OZEMPIC® than placebo (placebo 15.3%, OZEMPIC® 0.5 mg 32.7%, OZEMPIC® 1 mg 36.4%). The majority of reports of nausea, vomiting, and/or diarrhea occurred during dose escalation. More patients receiving OZEMPIC® 0.5 mg (3.1%) and OZEMPIC® 1 mg (3.8%) discontinued treatment due to gastrointestinal adverse reactions than patients receiving placebo (0.4%). In addition to the reactions in Table 1, the following gastrointestinal adverse reactions with a frequency of <5% were associated with OZEMPIC® (frequencies listed, respectively, as: placebo; 0.5 mg; 1 mg): dyspepsia (1.9%, 3.5%, 2.7%), eructation (0%, 2.7%, 1.1%), flatulence (0.8%, 0.4%, 1.5%), gastroesophageal reflux disease (0%, 1.9%, 1.5%), and gastritis (0.8%, 0.8%, 0.4%). Other Adverse Reactions: *Hypoglycemia:* Table 2 summarizes the incidence of events related to

hypoglycemia by various definitions in the placebo-controlled trials.

Table 2. Hypoglycemia Adverse Reactions in Placebo-Controlled Trials In Patients with Type 2 Diabetes Mellitus

	Placebo	OZEMPIC® 0.5 mg	OZEMPIC® 1 mg
Monotherapy			
(30 weeks)	**N=129**	**N=127**	**N=130**
Severe†	0%	0%	0%
Documented symptomatic (≤70 mg/dL glucose threshold)	0%	1.6%	3.8%
Severe† or Blood Glucose Confirmed Symptomatic (≤56 mg/dL glucose threshold)	1.6%	0%	0%
Add-on to Basal Insulin with or without Metformin			
(30 weeks)	**N=132**	**N=132**	**N=131**
Severe†	0%	0%	1.5%
Documented symptomatic (≤70 mg/dL glucose threshold)	15.2%	16.7%	29.8%
Severe† or Blood Glucose Confirmed Symptomatic (≤56 mg/dL glucose threshold)	5.3%	8.3%	10.7%

†"Severe" hypoglycemia adverse reactions are episodes requiring the assistance of another person.

Hypoglycemia was more frequent when OZEMPIC® was used in combination with a sulfonylurea *[see Warnings and Precautions]*. Severe hypoglycemia occurred in 0.8% and 1.2% of patients when OZEMPIC® 0.5 mg and 1 mg, respectively, was co-administered with a sulfonylurea. Documented symptomatic hypoglycemia occurred in 17.3% and 24.4% of patients when OZEMPIC® 0.5 mg and 1 mg, respectively, was co-administered with a sulfonylurea. Severe or blood glucose confirmed symptomatic hypoglycemia occurred in 6.5% and 10.4% of patients when OZEMPIC® 0.5 mg and 1 mg, respectively, was co-administered with a sulfonylurea. Injection Site Reactions: In placebo-controlled trials, injection site reactions (e.g., injection-site discomfort, erythema) were reported in 0.2% of OZEMPIC®-treated patients. Increases in Amylase and Lipase: In placebo-controlled trials, patients exposed to OZEMPIC® had a mean increase from baseline in amylase of 13% and lipase of 22%. These changes were not observed in placebo-treated patients. Cholelithiasis: In placebo-controlled trials, cholelithiasis was reported in 1.5% and 0.4% of patients-treated with OZEMPIC® 0.5 mg and 1 mg, respectively. Cholelithiasis was not reported in placebo-treated patients. Increases in Heart Rate: In placebo-controlled trials, OZEMPIC® 0.5 mg and 1 mg resulted in a mean increase in heart rate of 2 to 3 beats per minute. There was a mean decrease in heart rate of 0.3 beats per minute in placebo-treated patients. Fatigue, Dysgeusia and Dizziness: Other adverse reactions with a frequency of >0.4% were associated with OZEMPIC® include fatigue, dysgeusia and dizziness. **Immunogenicity:** Consistent with the potentially immunogenic properties of protein and peptide pharmaceuticals, patients treated with OZEMPIC® may develop anti-semaglutide antibodies. 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, the incidence of antibodies to semaglutide in the studies described below cannot be directly compared with the incidence of antibodies in other studies or to other products. Across the placebo- and active-controlled glycemic control trials, 32 (1.0%) OZEMPIC®-treated patients developed anti-drug antibodies (ADAs) to the active ingredient in OZEMPIC® (i.e., semaglutide). Of the 32 semaglutide-treated patients that developed semaglutide ADAs, 19 patients (0.6% of the overall population) developed antibodies cross-reacting with native GLP-1. The in vitro neutralizing activity of the antibodies is uncertain at this time.

DRUG INTERACTIONS: Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin: The risk of hypoglycemia is increased when OZEMPIC® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogues) or insulin *[see Warnings and Precautions]*. **Oral Medications:** OZEMPIC® causes a delay of gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. In clinical pharmacology trials, semaglutide did not affect the absorption of orally administered medications to any clinically relevant degree. Nonetheless, caution should be exercised when oral medications are concomitantly administered with OZEMPIC®.

USE IN SPECIFIC POPULATIONS: Pregnancy: Risk Summary: There are limited data with semaglutide use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. There are clinical considerations regarding the risks of poorly controlled diabetes in pregnancy *(see Clinical Considerations)*. Based on animal reproduction studies, there may be potential risks to the fetus from exposure to semaglutide during pregnancy. OZEMPIC® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In pregnant rats administered semaglutide during organogenesis, embryofetal mortality, structural abnormalities and alterations to growth occurred at maternal exposures below the maximum recommended human dose (MRHD) based on AUC. In rabbits and cynomolgus monkeys administered semaglutide during organogenesis, early pregnancy losses and structural abnormalities were observed at below the MRHD (rabbit) and ≥5-fold the MRHD (monkey). These findings coincided with a marked maternal body weight loss in both animal species *(see Data)*. The estimated background risk of major birth defects is 6–10% in women with pre-gestational diabetes with an HbA_{1c} >7 and has been reported to be as high as 20–25% in women with a HbA_{1c} >10. 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. Clinical Considerations: *Disease associated maternal and fetal risk:* Poorly controlled diabetes during pregnancy increases the maternal risk for diabetic ketoacidosis, pre-eclampsia, spontaneous abortions, preterm delivery, stillbirth and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia related morbidity. Data: *Animal Data:* In a combined fertility and embryofetal development study in rats, subcutaneous doses of 0.01, 0.03 and 0.09 mg/kg/day (0.1-, 0.4-, and 1.1-fold the MRHD) were administered to males for 4 weeks prior to and throughout mating and to females for 2 weeks prior to mating, and throughout organogenesis to Gestation Day 17. In parental animals, pharmacologically mediated reductions in body weight gain and food consumption were observed at all dose levels. In the offspring, reduced growth and fetuses with visceral (heart blood vessels) and skeletal (cranial bones, vertebra, ribs) abnormalities were observed at the human exposure. In an embryofetal development study in pregnant rabbits, subcutaneous doses of 0.0010, 0.0025 or 0.0075 mg/kg/day (0.03-, 0.3-, and 2.3-fold the MRHD) were administered throughout organogenesis from Gestation Day 6 to 19. Pharmacologically mediated reductions in maternal body weight gain and food consumption were observed at all dose levels. Early pregnancy losses and increased incidences of minor visceral (kidney, liver) and skeletal (sternebra) fetal abnormalities were observed at ≥0.0025 mg/kg/day, at clinically relevant exposures. In an embryofetal development study in pregnant cynomolgus monkeys, subcutaneous doses of 0.015, 0.075, and 0.15 mg/kg twice weekly (1.0-, 5.2-, and 14.9-fold the MRHD) were administered throughout organogenesis, from Gestation Day 16 to 50. Pharmacologically mediated, marked initial maternal body weight loss and reductions in body weight gain and food consumption coincided with the occurrence of sporadic abnormalities (vertebra, sternebra, ribs) at ≥0.075 mg/kg twice weekly (≥5X human exposure). In a pre- and postnatal development study in pregnant cynomolgus monkeys, subcutaneous doses of 0.015, 0.075, and 0.15 mg/kg twice weekly (0.7-, 3.3-, and 7.2-fold the MRHD) were administered from Gestation Day 16 to 140. Pharmacologically mediated marked initial maternal body weight loss and reductions in body weight gain and food consumption coincided with an increase in early pregnancy losses and led to delivery of slightly smaller offspring at ≥0.075 mg/kg twice weekly (≥3X human exposure). **Lactation:** Risk Summary: There are no data on the presence of semaglutide in human milk, the effects on the breastfed infant, or the effects on milk production. Semaglutide was present in the milk of lactating rats, however, due to species-specific differences in lactation physiology, the clinical relevance of these data are not clear *(see Data)*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for OZEMPIC® and any potential adverse effects on the breastfed infant from OZEMPIC® or from the underlying maternal condition. Data: In lactating rats, semaglutide was detected in milk at levels 3-12 fold lower than in maternal plasma. **Females and Males of Reproductive Potential:** Discontinue OZEMPIC® in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide *[see Use in Specific Populations]*. **Pediatric Use:** Safety and efficacy of OZEMPIC® have not been established in pediatric patients (younger than 18 years). **Geriatric Use:** In the pool of placebo- and active-controlled glycemic control trials, 744 (23.6%) OZEMPIC®-treated patients were 65 years of age and over and 102 OZEMPIC®-treated patients (3.2%) patients were 75 years of age and over. In SUSTAIN 6, the cardiovascular outcome trial, 788 (48.0%) OZEMPIC®-treated patients were 65 years of age and over and 157 OZEMPIC®-treated patients (9.6%) patients were 75 years of age and over. No overall differences in safety or efficacy were detected between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out. **Renal Impairment:** No dose adjustment of OZEMPIC® is recommended for patients with renal impairment. In subjects with renal impairment including end-stage renal disease (ESRD), no clinically relevant change in semaglutide pharmacokinetics (PK) was observed. **Hepatic Impairment:** No dose adjustment of OZEMPIC® is recommended for patients with hepatic impairment. In a study in subjects with different degrees of hepatic impairment, no clinically relevant change in semaglutide pharmacokinetics (PK) was observed.

OVERDOSAGE: In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. A prolonged period of observation and treatment for these symptoms may be necessary, taking into account the long half-life of OZEMPIC® of approximately 1 week.

More detailed information is available upon request.

For information about OZEMPIC® contact: Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, NJ 08536, 1-888-693-6742

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Manufactured by: Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark

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PATENT INFORMATION:

http://novonordisk-us.com/patients/products/product-patents.html

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OZEMPIC®
semaglutide injection 0.5mg|1mg



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4

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