2022 | Issue 4

Physicians office Resource

Resources for You, Your Patients, & Your Practice

POINT-OF-CARE TESTING:

Facilitating Positive Outcomes in Chronic Disease Management

PAGE 6



MDescapes

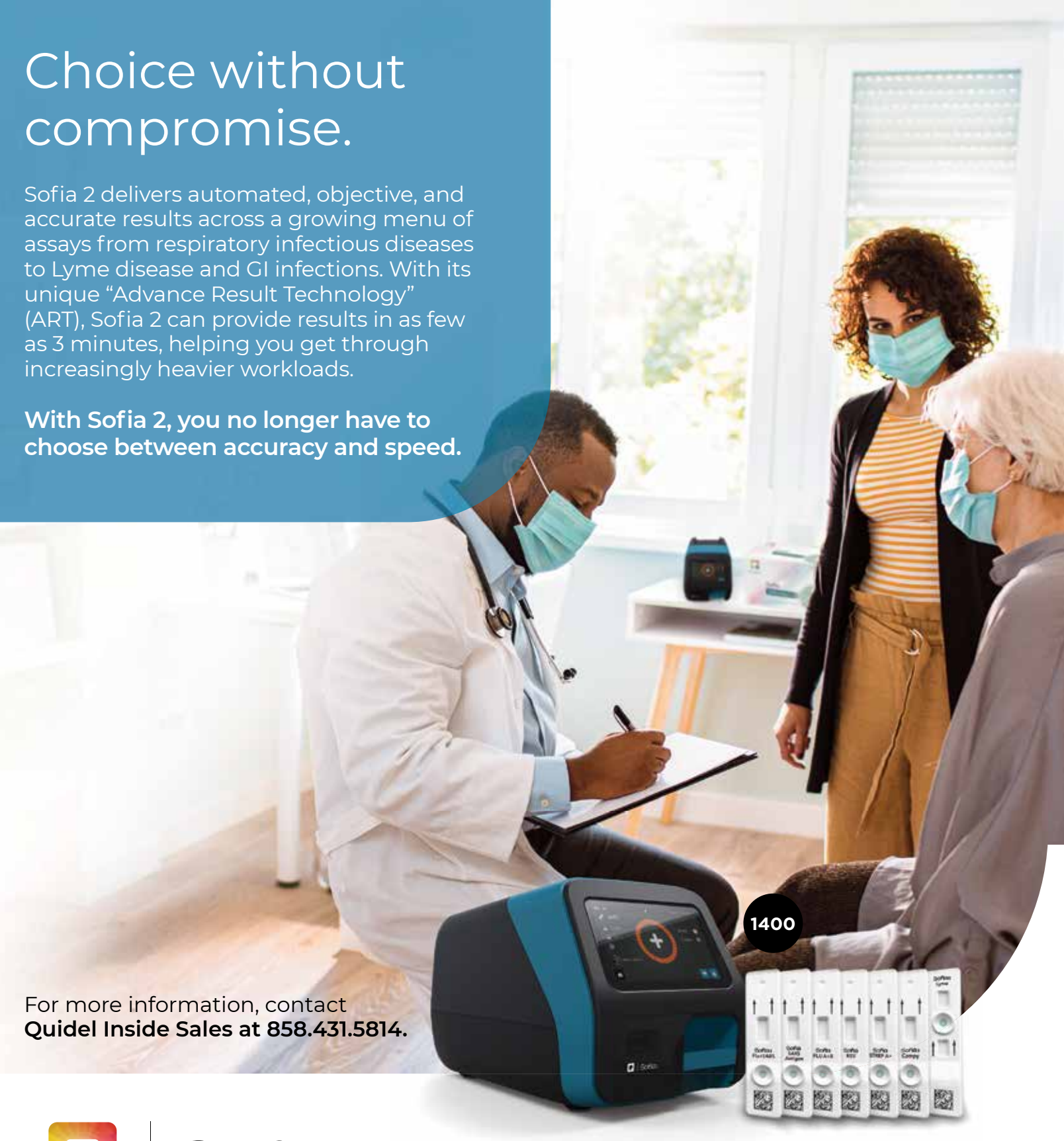
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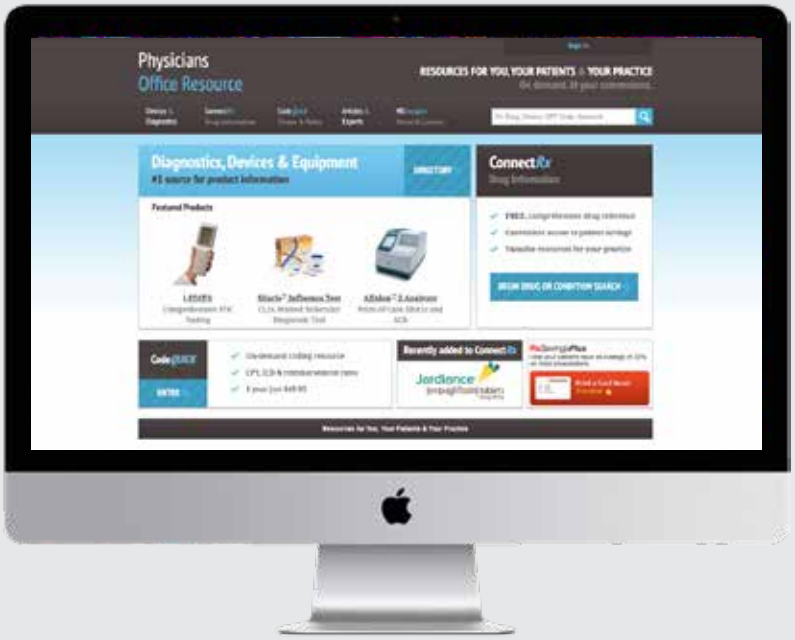
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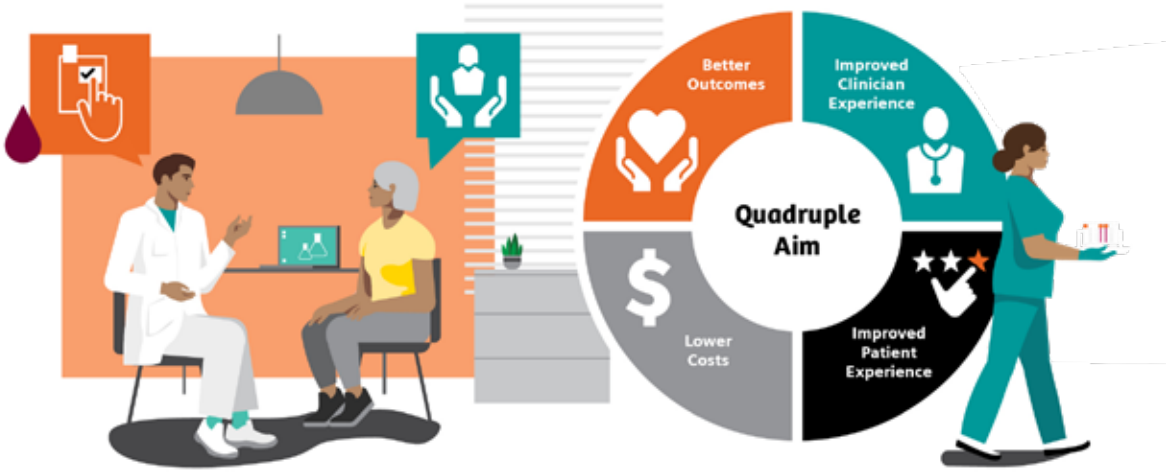
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RANCH OF THE DREAMERS - FOUR SEASONS SANTA FE

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FEATURE

Point-of-care Testing:

FACILITATING POSITIVE OUTCOMES IN CHRONIC DISEASE MANAGEMENT

BY SUSAN GARRAMONE
SENIOR CLINICAL MARKETING MANAGER
SIEMENS HEALTHINEERS

Introduction

Chronic diseases are the leading causes of death and disability in the U.S. and are leading drivers of the nation's rising healthcare costs.1 Chronic diseases are defined as conditions that last 1 year or more and require ongoing medical attention, limit activities of daily living, or both. Heart disease, cancer, chronic lung disease, stroke, Alzheimer's disease, diabetes, and chronic kidney disease are among the most common. A staggering 40% of adults in the U.S. have two or more chronic diseases.1 Unfortunately, chronic diseases are common, serious, and costly.

Common Comorbidities: Diabetes and Chronic Kidney Disease

Diabetes is the seventh-leading cause of death in the United States, affecting more than 37 million Americans.2,3 It is attributed to an estimated $327 billion in annual medical and lost productivity costs.2,3 Generally, care for patients with diabetes accounts for 1 in 4 healthcare dollars spent in the U.S., and a large portion of these costs results from diabetes-associated comorbidities that include potential neurological, cardiovascular, renal, and other chronic complications.3 In fact, diabetes is a risk factor for the development of chronic kidney disease (CKD); 1 in 3 adults with diabetes also have chronic kidney disease!4 In the U.S., where kidney disease is the tenth-leading cause of death, annual Medicare costs related to CKD are greater than $81 billion.[5,6]

Graphic 1



Graphic 2A



In addition to major healthcare cost implications, complications from diabetes and CKD may have significant impact on patient well-being and quality of life. Early recognition and management of diabetes and CKD enable timely intervention and greater opportunity to protect patient health. Tragically, 40% of patients with diabetes and 90% of patients with CKD are unaware that they have these conditions.[5,7]

With primary care being the first point of contact and foundation of a person's healthcare team, the ability to test, diagnose, consult, and manage diabetes and CKD in the primary care setting may provide the opportunity to prevent clinically worsening disease and improve patient outcomes and overall population health.[8,9]

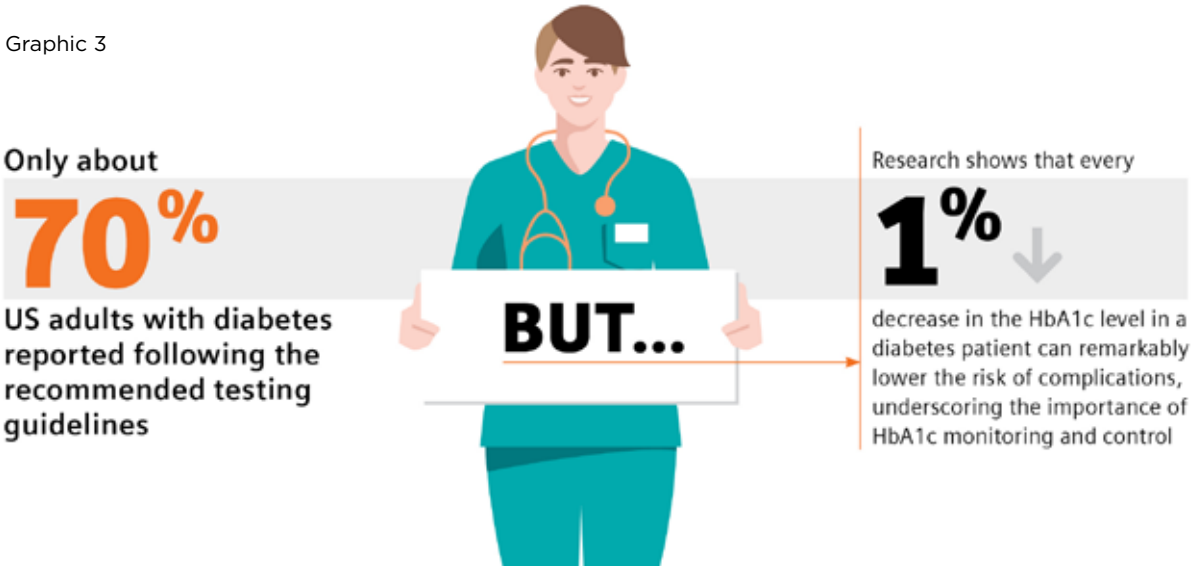
Diabetes and Hemoglobin A1c Testing

Glycated hemoglobin (A1c, hemoglobin A1c, HbA1c), which reflects average levels of blood glucose over the previous 2–3 months, is the most widely used test to monitor chronic glycemic control and the efficacy of treatment.10 In contrast to blood glucose levels, which fluctuate throughout the day based on diet and activity, the HbA1c level reflects a patient's glycemic control for the past 3 months.[10]

The American Diabetes Association (ADA) recommends the assessment of glycemic status (A1c or other glycemic measurement) at least two times per year in patients who are meeting treatment goals (and who have stable glycemic control) and at least quarterly, and as needed, in patients whose therapy has recently changed and/or who are not meeting glycemic goals.11 HbA1c testing can be performed in point-of-care (POC) settings such as a physician's office or laboratory, though the ADA states that POC testing for A1c provides opportunity for more timely treatment changes.[11]

According to the CDC, between 2011 and 2016, only 67.3–71.4% of U.S. adults with diabetes reported following the recommended testing guidelines.12 This statistic is very concerning from a population health perspective, as low adherence to HbA1c testing has been shown to lead to higher HbA1c levels, which in turn may lead to complications and comorbidities.13 Research shows that every 1% decrease in the HbA1c level in a diabetes patient can remarkably lower the risk of complications, underscoring the importance of HbA1c monitoring and control.[14]

Graphic 3

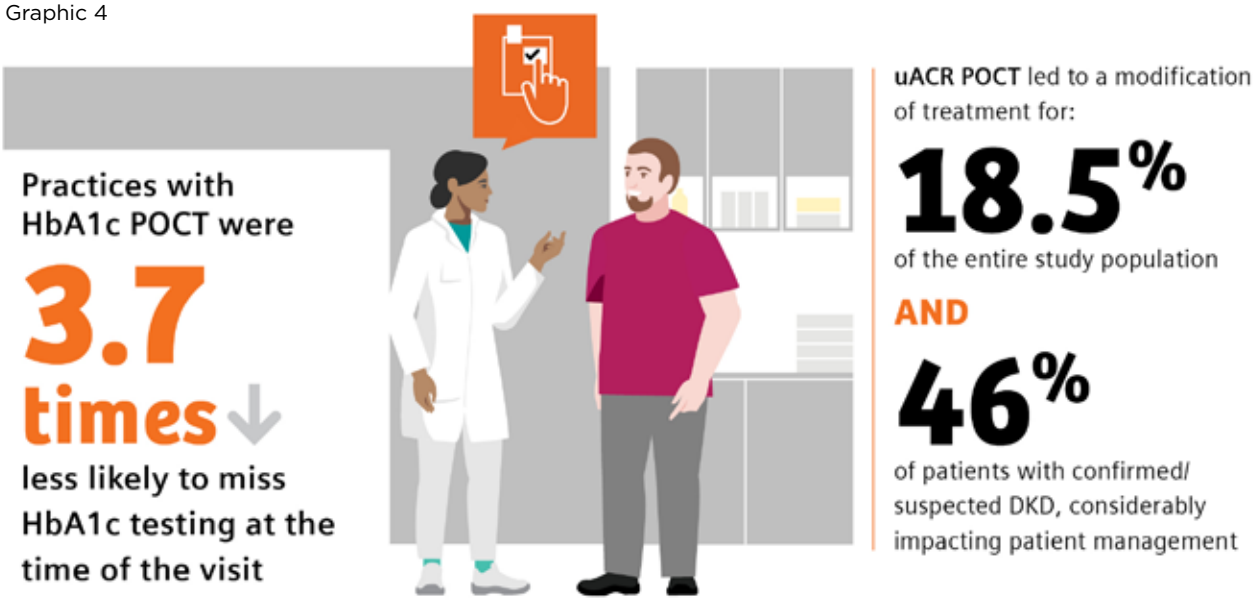


A review of the literature suggests that incorporating A1c testing into the patient visit and customizing the consultation to the patient's status appear to help physicians influence their patients to improve their glycemic control.[15]

The benefit of POC HbA1c testing has been widely reported in the literature.9,15-19 Of note is a study by Crocker et al. that demonstrated that POC HbA1c testing led to 3.7 times decreased likelihood of missing HbA1c testing.9 Nearly 1 in 4 of the individuals tested were found to have clinically worsening diabetes. Their diagnosis using POC testing enabled more timely intervention in diabetes management. A recent review by Rhyu et al. also highlighted the benefits of POC HbA1c testing in the physician's office, where the authors concluded that "POC A1c testing in primary care, if widely available and integrated into workflow, has the potential to positively impact diabetes care. Real-time feedback may change patient and physician behaviors, allowing earlier therapeutic intensification." [15]

In addition to addressing the clinical benefit, numerous studies have shown the cost-effectiveness of implementing POC HbA1c testing.16-20 Rosa et al. found that "compared to a centralized laboratory test, the use of the POC-A1c device in a healthcare unit increased the chance of the early control of type 2 diabetes and reduced costs in relation to DM-related outcomes."19 Crocker et al. reported that point-of-care HbA1c testing "can significantly improve clinical operations with cost reductions through improved practice efficiency," realizing a potential savings from improved efficiency of $24.64 per patient. This savings resulted from 89% and 85% decreases in follow-up phone calls and letters, respectively, and a 61% decrease in patient revisits.[17]

Graphic 4



CKD and Urinary Albumin-to-Creatinine Ratio (uACR)

The benefits of uACR testing at the point of care have similarly been studied, with findings of accuracy, convenience, improved patient access, and improvements in test adherence.21-25 The ADA recommends performing a spot uACR and estimated glomerular filtration rate (eGFR) test at least annually in patients with type 1 diabetes with duration of >5 years and in all patients with type 2 diabetes regardless of treatment. Patients with diabetes and urinary albumin >300 mg/g creatinine and/or an estimated glomerular filtration rate of 30–60 mL/min/1.73 m2 should be monitored twice annually to guide therapy.[26]

A recent study by Christofides and Desai discussed the importance of monitoring albuminuria in patients with type 2 diabetes as an essential tool in the detection of onset of CKD and monitoring disease progression. They stated, "Access to UACR testing may be improved by using Clinical Laboratory Improvements Amendments (CLIA)-waived point of care UACR testing options, that is, those approved for use closer to the patient and not necessarily in a central laboratory," and noted that using a CLIA-waived POC uACR option was a means to optimize test ordering. [21]

CLIA stands for Clinical Laboratory Improvement Amendments of 1988, a set of U.S. regulatory standards that apply to all clinical laboratory testing performed on humans (except for clinical trials and basic research), regardless of where the test is performed. A test system or product that is granted waived status is defined, in part, as a methodology that is simple and accurate to render negligible the likelihood of erroneous results.27 Many POC tests meet this classification, as they require no formal training, and operators must only follow the manufacturer's instructions for use. Waived POC tests are portable, easy to use, and offer accurate, quick near-patient results, making them particularly useful for testing in a physician's office. In this environment a physician can test a patient at the time of visit and obtain the result in real time, providing the opportunity to counsel the patient and make treatment adjustments at the time of the office visit. [28]

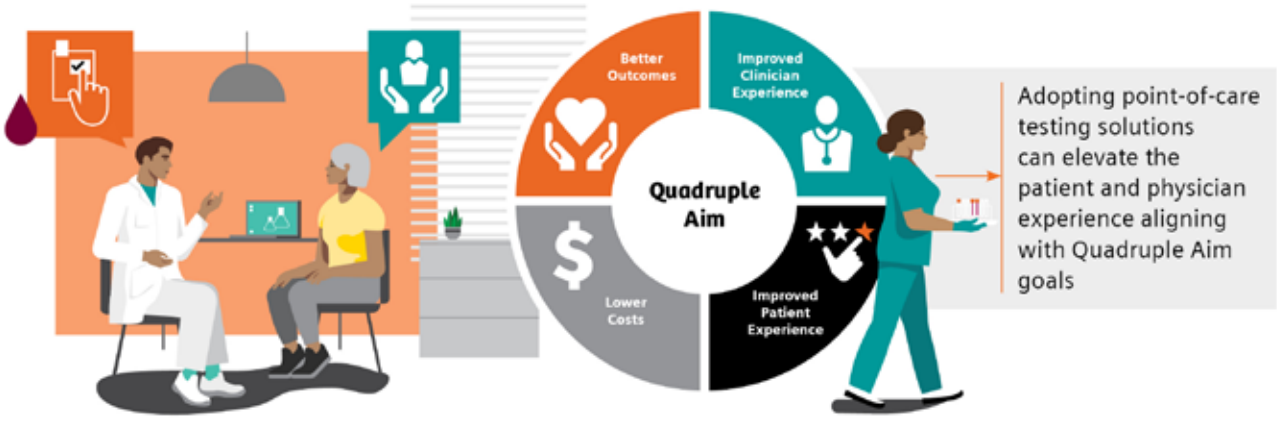
There is a documented need for strategies to improve routine CKD assessment nationwide and overcome testing barriers to increase test adherence.

A study by Folkherts et al. reported that physicians treating patients with diabetes are selectively adhering to chronic kidney disease screening guidelines where, despite recommendations to monitor both eGFR and urinary ACR, less than half of patients were screened for albuminuria during the 1-year follow-up.29 Additionally, a large retrospective study of patients at-risk for CKD by Alfego et al. found only 21% of adults at risk for CKD and 32.2% of patients with diabetes specifically had guideline-recommended uACR testing.30 Schultes et al. found that the implementation of ACR POCT in daily general practice can improve the diagnosis of diabetic kidney disease (DKD) in diabetes, which may support improved management of CKD.22 DKD was newly diagnosed in 8.6% of the entire study population and DKD was suspected in 9.9% based on their ACR POCT values. In 18.5% of the entire study population ACR POCT led to a change in medication, demonstrating a benefit in patient management. When surveyed regarding the relevance of the ACR POCT, 75% of physicians considered the test very important for people with diabetes; 25% rated it important.

Conclusion

Primary care physicians treat at least 90% of patients with diabetes in the United States.31 Patients with diabetes are at risk of developing CKD and monitoring for both conditions is important for disease management. Guidelines call for routine testing of HbA1c and uARC for disease monitoring and management.12,27 Adoption of in-office POC HbA1c and uACR testing may provide physicians an important tool toward the goal of closing the diabetes care gap, enabling convenient, efficient, cost-effective testing, and facilitating improved patient adherence to testing. Increased patient test adherence will enable faster intervention and treatment, leading to improved patient outcomes and decreased overall diabetes-related healthcare costs—a win for all in the fight against chronic disease.

Graphic 5



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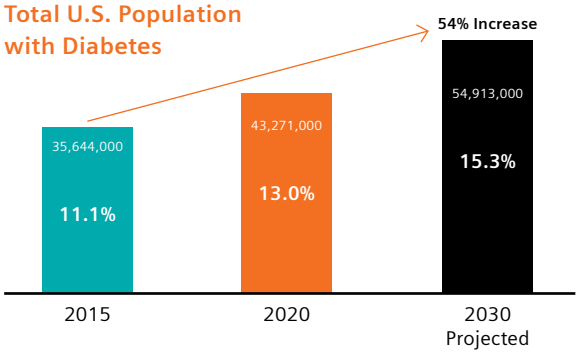


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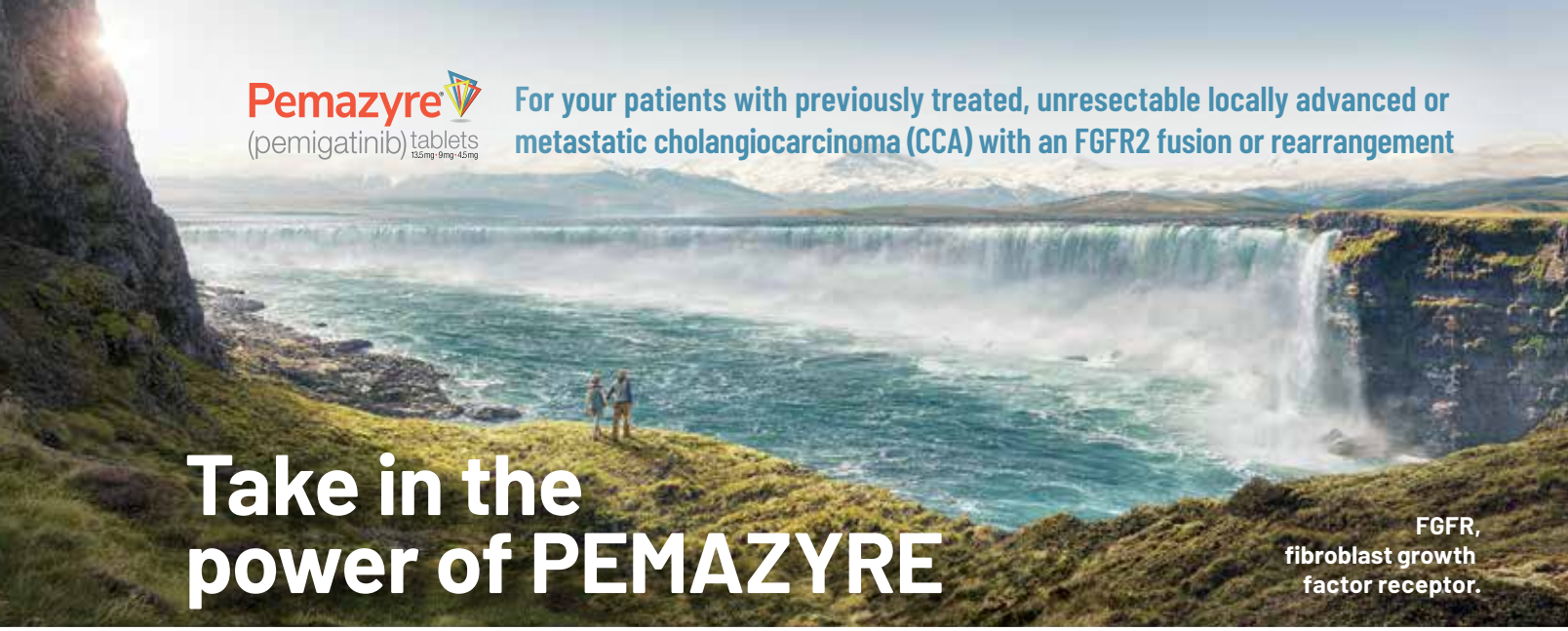
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The major efficacy outcomes were evaluated in 107 patients with an FGFR2 fusion or non-fusion rearrangement* in a multicenter, open-label, single-arm study of 146 total patients with locally advanced unresectable or metastatic cholangiocarcinoma who had received ≥1 previous line of systemic therapy.[1,†]

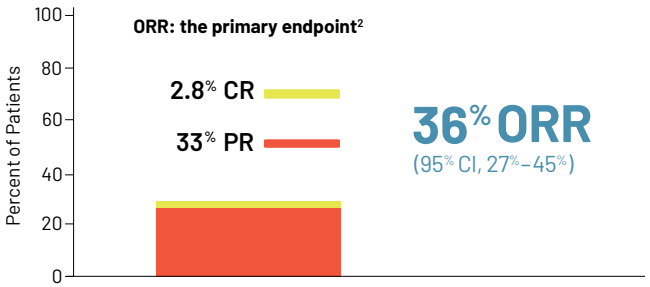
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Clinical response rates of PEMAZYRE[1]



Efficacy evaluable population (N=107)

Note: Data are from IRC per RECIST v1.1, and CR and PR are confirmed.

*Determined by a clinical trial assay performed at a central laboratory.

†Patients received PEMAZYRE in 21-day cycles at a dosage of 13.5 mg orally once daily for 14 consecutive days, followed by 7 days off therapy, until disease progression or unacceptable toxicity occurred. The major efficacy outcome measures were ORR and DoR, as determined by IRC according to RECIST v1.1.

‡95% CI, 6.0-14.5 months and was calculated using the Brookmeyer and Crowley's method.[1]

CI, confidence interval; DoR, duration of response; IRC, independent review committee; ORR, overall response rate; RECIST, Response Evaluation Criteria in Solid Tumors.

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Among 466 patients who received PEMAZYRE across clinical trials, RPED occurred in 6% of patients, including Grade 3-4 RPED in 0.6%. The median time to first onset of RPED was 62 days. RPED led to dose interruption of PEMAZYRE in 1.7% of patients, and dose reduction and permanent discontinuation in 0.4% and in 0.4% of patients, respectively. RPED resolved

continued

Please see Important Safety Information for PEMAZYRE continued on the adjacent page.

IMPORTANT SAFETY INFORMATION (CONTINUED)

or improved to Grade 1 levels in 87.5% of patients who required dosage modification of PEMAZYRE for RPED.

Perform a comprehensive ophthalmological examination including OCT prior to initiation of PEMAZYRE and every 2 months for the first 6 months and every 3 months thereafter during treatment. For onset of visual symptoms, refer patients for ophthalmologic evaluation urgently, with follow-up every 3 weeks until resolution or discontinuation of PEMAZYRE. Modify the dose or permanently discontinue PEMAZYRE as recommended in the prescribing information for PEMAZYRE.

Dry Eye: Among 466 patients who received PEMAZYRE across clinical trials, dry eye occurred in 27% of patients, including Grade 3-4 in 0.6% of patients. Treat patients with ocular demulcents as needed.

Hyperphosphatemia and Soft Tissue Mineralization

PEMAZYRE can cause hyperphosphatemia leading to soft tissue mineralization, cutaneous calcification, calcinosis, and non-uremic calciphylaxis. Increases in phosphate levels are a pharmacodynamic effect of PEMAZYRE. Among 466 patients who received PEMAZYRE across clinical trials, hyperphosphatemia was reported in 92% of patients based on laboratory values above the upper limit of normal. The median time to onset of hyperphosphatemia was 8 days (range 1-169). Phosphate lowering therapy was required in 29% of patients receiving PEMAZYRE.

Monitor for hyperphosphatemia and initiate a low phosphate diet when serum phosphate level is >5.5 mg/dL. For serum phosphate levels >7 mg/dL, initiate phosphate lowering therapy and withhold, reduce the dose, or permanently discontinue PEMAZYRE based on duration and severity of hyperphosphatemia as recommended in the prescribing information.

Embryo-Fetal Toxicity

Based on findings in an animal study and its mechanism of action, PEMAZYRE can cause fetal harm when administered to a pregnant woman. Oral administration of pemigatinib to pregnant rats during the period of organogenesis caused fetal malformations, fetal growth retardation, and embryo-fetal death at maternal exposures lower than the human exposure based on area under the curve (AUC) at the clinical dose of 13.5 mg.

Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose.

Adverse Reactions

Serious adverse reactions occurred in 45% of patients receiving PEMAZYRE. Serious adverse reactions in ≥2% of patients who received PEMAZYRE included abdominal pain, pyrexia, cholangitis, pleural effusion, acute kidney injury, cholangitis infective, failure to thrive, hypercalcemia, hyponatremia, small intestinal obstruction, and urinary tract infection. Fatal adverse reactions occurred in 4.1% of patients, including failure to thrive, bile duct obstruction, cholangitis, sepsis, and pleural effusion.

Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received PEMAZYRE. Adverse reactions requiring permanent discontinuation in ≥1% of patients included intestinal obstruction and acute kidney injury.

Dosage interruptions due to an adverse reaction occurred in 43% of patients who received PEMAZYRE. Adverse reactions requiring dosage interruption in ≥1% of patients included stomatitis, palmar-plantar erythrodysesthesia syndrome, arthralgia, fatigue, abdominal pain, AST increased, asthenia, pyrexia, ALT increased, cholangitis, small intestinal obstruction, alkaline phosphatase increased, diarrhea, hyperbilirubinemia, electrocardiogram QT prolonged, decreased appetite, dehydration, hypercalcemia, hyperphosphatemia, hypophosphatemia, back pain, pain in extremity, syncope, acute kidney injury, onychomadesis, and hypotension.

Dose reductions due to an adverse reaction occurred in 14% of patients who received PEMAZYRE. Adverse reactions requiring dosage reductions in ≥1% of patients who received PEMAZYRE included stomatitis, arthralgia, palmar-plantar erythrodysesthesia syndrome, asthenia, and onychomadesis.

Clinically relevant adverse reactions occurring in ≤10% of patients included fractures (2.1%). In all patients treated with pemigatinib, 1.3% experienced pathologic fractures (which included patients with and without cholangiocarcinoma [N=466]). Soft tissue mineralization, including cutaneous calcification, calcinosis, and non-uremic calciphylaxis associated with hyperphosphatemia were observed with PEMAZYRE treatment.

Within the first 21-day cycle of PEMAZYRE dosing, serum creatinine increased (mean increase of 0.2 mg/dL) and reached steady state by Day 8, and then decreased during the 7 days off therapy. Consider alternative markers of renal function if persistent elevations in serum creatinine are observed.

The most common adverse reactions (incidence ≥20%) were hyperphosphatemia (60%), alopecia (49%), diarrhea (47%), nail toxicity (43%), fatigue (42%), dysgeusia (40%), nausea (40%), constipation (35%), stomatitis (35%), dry eye (35%), dry mouth (34%), decreased appetite (33%), vomiting (27%), arthralgia (25%), abdominal pain (23%), hypophosphatemia (23%), back pain (20%), and dry skin (20%).

Drug Interactions

Avoid concomitant use of strong and moderate CYP3A inhibitors with PEMAZYRE. Reduce the dose of PEMAZYRE if concomitant use with a strong or moderate CYP3A inhibitor cannot be avoided. Avoid concomitant use of strong and moderate CYP3A inducers with PEMAZYRE.

Special Populations

Advise lactating women not to breastfeed during treatment with PEMAZYRE and for 1 week after the final dose.

Reduce the recommended dose of PEMAZYRE for patients with severe renal impairment as described in the prescribing information.

Reduce the recommended dose of PEMAZYRE for patients with severe hepatic impairment as described in the prescribing information.

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

References: 1. PEMAZYRE (pemigatinib) Prescribing Information. Incyte Corporation. **2.** Abou-Alfa GK, Sahai V, Hollebecque A, et al. *Lancet Oncol.* 2020;21(5):671-684. **3.** Lowery MA, Ptashkin R, Jordan E, et al. *Clin Cancer Res.* 2018;24(17):4154-4161. **4.** Javle MM, Murugesan K, Shroff RT, et al. *J Clin Oncol.* 2019;37(15 suppl):4087. **5.** Hollebecque A, de Bono JS, Plummer R, et al. *Ann Oncol.* 2019;30(suppl 1):mdz029. **6.** Frampton GM, Fichtenholtz A, Otto GA, et al. *Nat Biotechnol.* 2013;31(11):1023-1031.

Pemazyre® (pemigatinib) tablets 13.5mg·9mg·4.5mg | Incyte

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Pemazyre®
(pemigatinib) tablets
13.5mg • 9mg • 4.5mg

BRIEF SUMMARY: For Full Prescribing Information, see package insert.
INDICATIONS AND USAGE PEMAZYRE is indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test *[see Dosage and Administration (2.1) in Full Prescribing Information]*. This indication is approved under accelerated approval based on overall response rate and duration of response *[see Clinical Studies (14.1) in Full Prescribing Information]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
CONTRAINDICATIONS None.
WARNINGS AND PRECAUTIONS Ocular Toxicity Retinal Pigment Epithelial Detachment (RPED) PEMAZYRE can cause RPED, which may cause symptoms such as blurred vision, visual floaters, or photopsia. Clinical trials of PEMAZYRE did not conduct routine monitoring including optical coherence tomography (OCT) to detect asymptomatic RPED; therefore, the incidence of asymptomatic RPED with PEMAZYRE is unknown. Among 466 patients who received PEMAZYRE across clinical trials, RPED occurred in 6% of patients, including Grade 3-4 RPED in 0.6%. The median time to first onset of RPED was 62 days. RPED led to dose interruption of PEMAZYRE in 1.7% of patients, and dose reduction and permanent discontinuation in 0.4% and in 0.4% of patients, respectively. RPED resolved or improved to Grade 1 levels in 87.5% of patients who required dosage modification of PEMAZYRE for RPED. Perform a comprehensive ophthalmological examination including OCT prior to initiation of PEMAZYRE and every 2 months for the first 6 months and every 3 months thereafter during treatment. For onset of visual symptoms, refer patients for ophthalmologic evaluation urgently, with follow-up every 3 weeks until resolution or discontinuation of PEMAZYRE. Modify the dose or permanently discontinue PEMAZYRE as recommended *[see Dosage and Administration (2.3) in Full Prescribing Information]*. Dry Eye Among 466 patients who received PEMAZYRE across clinical trials, dry eye occurred in 27% of patients, including Grade 3-4 in 0.6% of patients. Treat patients with ocular demulcents as needed.
Hyperphosphatemia and Soft Tissue Mineralization PEMAZYRE can cause hyperphosphatemia leading to soft tissue mineralization, cutaneous calcification, calcinosis, and non-uremic calciphylaxis. Increases in phosphate levels are a pharmacodynamic effect of PEMAZYRE *[see Clinical Pharmacology (12.2) in Full Prescribing Information]*. Among 466 patients who received PEMAZYRE across clinical trials, hyperphosphatemia was reported in 92% of patients based on laboratory values above the upper limit of normal. The median time to onset of hyperphosphatemia was 8 days (range 1-169). Phosphate lowering therapy was required in 29% of patients receiving PEMAZYRE. Monitor for hyperphosphatemia and initiate a low phosphate diet when serum phosphate level is > 5.5 mg/dL. For serum phosphate levels > 7 mg/dL, initiate phosphate lowering therapy and withhold, reduce the dose, or permanently discontinue PEMAZYRE based on duration and severity of hyperphosphatemia *[see Dosage and Administration (2.3) in Full Prescribing Information]*. **Embryo-Fetal Toxicity** Based on findings in an animal study and its mechanism of action, PEMAZYRE can cause fetal harm when administered to a pregnant woman. Oral administration of pemigatinib to pregnant rats during the period of organogenesis caused fetal malformations, fetal growth retardation, and embryo-fetal death at maternal exposures lower than the human exposure based on area under the curve (AUC) at the clinical dose of 13.5 mg. Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose *[see Use in Specific Populations (8.1, 8.3) in Full Prescribing Information]*. **ADVERSE REACTIONS** The following adverse reactions are discussed elsewhere in the labeling: • Ocular Toxicity *[see Warnings and Precautions (5.1) in Full Prescribing Information]* • Hyperphosphatemia and Soft Tissue Mineralization *[see Warnings and Precautions (5.2) in Full Prescribing Information]*. **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 PEMAZYRE was evaluated in FIGHT-202, which included 146 patients with previously treated, locally advanced or metastatic cholangiocarcinoma *[see Clinical Studies (14.1) in Full Prescribing Information]*. Patients were treated orally with PEMAZYRE 13.5 mg once daily for 14 days on followed by 7 days off therapy until disease progression or unacceptable toxicity. The median duration of treatment was 181 days (range: 7 to 730 days). The median age of PEMAZYRE-treated patients was 59 years (range 26-78), 58% were females, and 71% were White. Serious adverse reactions occurred in 45% of patients receiving PEMAZYRE. Serious adverse reactions in ≥ 2% of patients who received PEMAZYRE included abdominal pain, pyrexia, cholangitis, pleural effusion, acute kidney injury, cholangitis infective, failure to thrive, hypercalcemia, hyponatremia, small intestinal obstruction, and urinary tract infection. Fatal adverse reactions occurred in 4.1% of patients, including failure to thrive, bile duct obstruction, cholangitis, sepsis, and pleural effusion. Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received PEMAZYRE. Adverse reactions requiring permanent discontinuation in ≥ 1% of patients included intestinal obstruction and acute kidney injury. Dosage interruptions due to an adverse reaction occurred in 43% of patients who received PEMAZYRE. Adverse reactions requiring dosage interruption in ≥ 1% of patients included stomatitis, palmar-plantar erythrodysesthesia syndrome, arthralgia, fatigue, abdominal pain, AST increased, asthenia, pyrexia, ALT increased, cholangitis, small intestinal obstruction, alkaline phosphatase increased, diarrhea, hyperbilirubinemia, electrocardiogram QT prolonged, decreased appetite, dehydration, hypercalcemia, hyperphosphatemia, hypophosphatemia, back pain, pain in extremity, syncope, acute kidney injury, onychomadesis, and hypotension. Dose reductions due to an adverse reaction occurred in 14% of patients who received PEMAZYRE. Adverse reactions requiring dosage reductions in ≥ 1% of patients who received PEMAZYRE included stomatitis, arthralgia, palmar-plantar erythrodysesthesia syndrome, asthenia, and onychomadesis. Table 1 summarizes the adverse reactions in FIGHT-202. Table 2 summarizes laboratory abnormalities in FIGHT-202.

Table 1: Adverse Reactions (≥ 15%) in Patients Receiving PEMAZYRE in FIGHT-202

	PEMAZYRE N=146	
Adverse Reaction	**All Grades[a] (%)**	**Grades ≥ 3* (%)**
Metabolism and nutrition disorders		
Hyperphosphatemia[b]	60	0
Decreased appetite	33	1.4
Hypophosphatemia[c]	23	12
Dehydration	15	3.4
Skin and subcutaneous tissue disorders		
Alopecia	49	0
Nail toxicity[d]	43	2.1
Dry skin	20	0.7
Palmar-plantar erythrodysesthesia syndrome	15	4.1
Gastrointestinal disorders		
Diarrhea	47	2.7
Nausea	40	2.1
Constipation	35	0.7
Stomatitis	35	5
Dry mouth	34	0
Vomiting	27	1.4
Abdominal pain	23	4.8
General disorders		
Fatigue	42	4.8
Edema peripheral	18	0.7
Nervous system disorders		
Dysgeusia	40	0
Headache	16	0
Eye disorders		
Dry eye[e]	35	0.7
Musculoskeletal and connective tissue disorders		
Arthralgia	25	6
Back pain	20	2.7
Pain in extremity	19	2.1

Table 1 continued above.

Table 1 continued.

	PEMAZYRE N=146	
Adverse Reaction	**All Grades[a] (%)**	**Grades ≥ 3* (%)**
Infections and infestations		
Urinary tract infection	16	2.7
Investigations		
Weight loss	16	2.1

*Only Grades 3 – 4 were identified.
[a] Graded per NCI CTCAE 4.03.
[b] Includes hyperphosphatemia and blood phosphorous increased; graded based on clinical severity and medical interventions taken according to the "investigations-other, specify" category in NCI CTCAE v4.03.
[c] Includes hypophosphatemia and blood phosphorous decreased.
[d] Includes nail toxicity, nail disorder, nail discoloration, nail dystrophy, nail hypertrophy, nail ridging, nail infection, onychalgia, onychoclasis, onycholysis, onychomadesis, onychomycosis, and paronychia.
[e] Includes dry eye, keratitis, lacrimation increased, pinguecula, and punctate keratitis.

Clinically relevant adverse reactions occurring in ≤ 10% of patients included fractures (2.1%). In all patients treated with pemigatinib, 1.3% experienced pathologic fractures (which included patients with and without cholangiocarcinoma [N=466]). Soft tissue mineralization, including cutaneous calcification, calcinosis, and non-uremic calciphylaxis associated with hyperphosphatemia were observed with PEMAZYRE treatment.

Table 2: Select Laboratory Abnormalities (≥ 10%) Worsening from Baseline in Patients Receiving PEMAZYRE in FIGHT-202

	PEMAZYRE[a] N=146	
Laboratory Abnormality	**All Grades[b] (%)**	**Grades ≥ 3 (%)**
Hematology		
Decreased hemoglobin	43	6
Decreased lymphocytes	36	8
Decreased platelets	28	3.4
Increased leukocytes	27	0.7
Decreased leukocytes	18	1.4
Chemistry		
Increased phosphate[c]	94	0
Decreased phosphate	68	38
Increased alanine aminotransferase	43	4.1
Increased aspartate aminotransferase	43	6
Increased calcium	43	4.1
Increased alkaline phosphatase	41	11
Increased creatinine[d]	41	1.4
Decreased sodium	39	12
Increased glucose	36	0.7
Decreased albumin	34	0
Increased urate	30	10
Increased bilirubin	26	6
Decreased potassium	26	5
Decreased calcium	17	2.7
Increased potassium	12	2.1
Decreased glucose	11	1.4

[a]The denominator used to calculate the rate varied from 142-146 based on the number of patients with a baseline value and at least one post-treatment value.
[b]Graded per NCI CTCAE 4.03.
[c]Based on CTCAE 5.0 grading.
[d]Graded based on comparison to upper limit of normal.

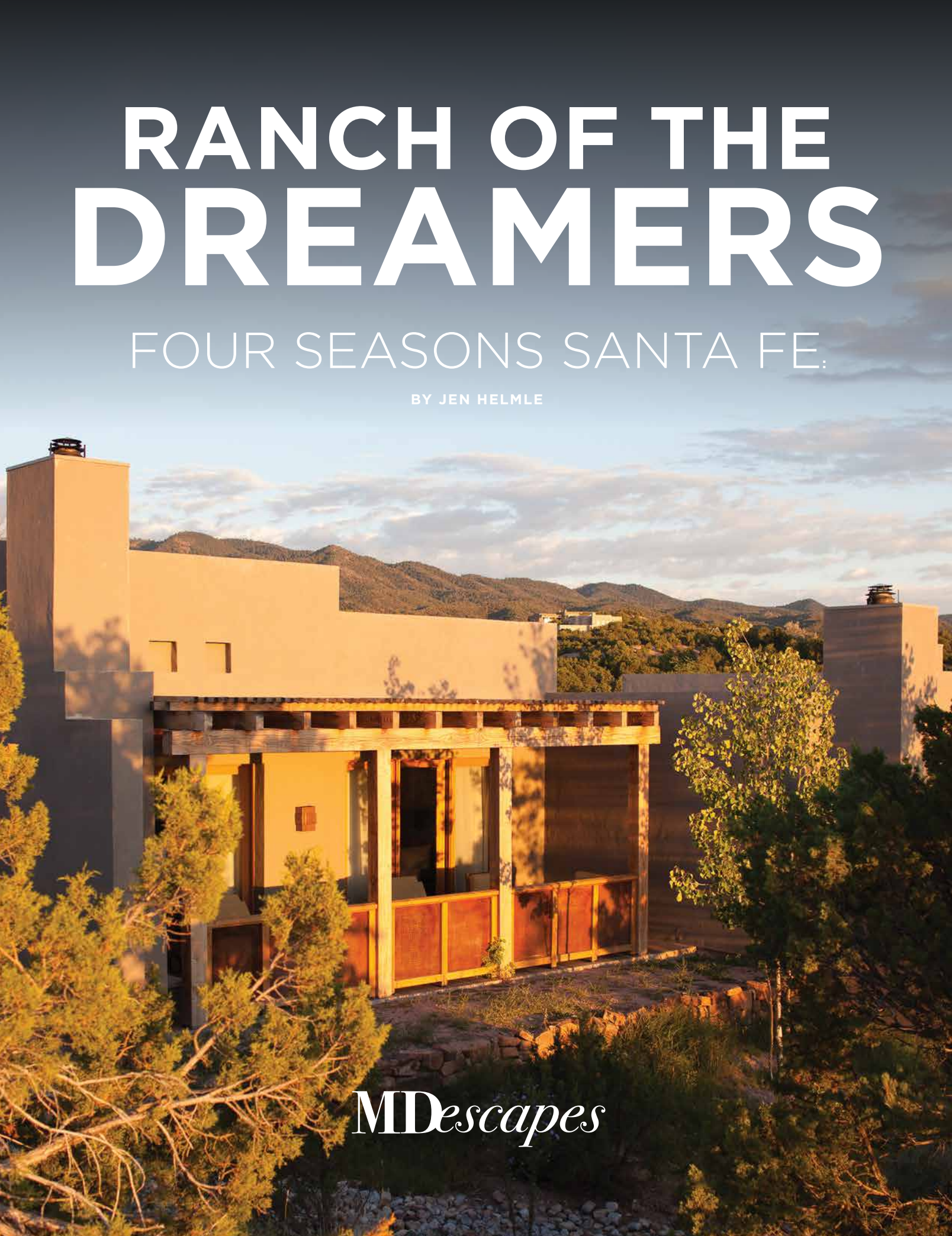
Increased Creatinine Within the first 21-day cycle of PEMAZYRE dosing, serum creatinine increased (mean increase of 0.2 mg/dL) and reached steady state by Day 8, and then decreased during the 7 days off therapy. Consider alternative markers of renal function if persistent elevations in serum creatinine are observed *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*. **DRUG INTERACTIONS Effect of Other Drugs on PEMAZYRE** Strong and Moderate CYP3A Inducers Concomitant use of PEMAZYRE with a strong or moderate CYP3A inducer decreases pemigatinib plasma concentrations, *[see Clinical Pharmacology (12.3) in Full Prescribing Information]* which may reduce the efficacy of PEMAZYRE. Avoid concomitant use of strong and moderate CYP3A inducers with PEMAZYRE. Strong and Moderate CYP3A Inhibitors Concomitant use of a strong or moderate CYP3A inhibitor with PEMAZYRE increases pemigatinib plasma concentrations, *[see Clinical Pharmacology (12.3) in Full Prescribing Information]* which may increase the incidence and severity of adverse reactions. Avoid concomitant use of strong and moderate CYP3A inhibitors with PEMAZYRE. Reduce PEMAZYRE dosage if concomitant use of strong and moderate CYP3A inhibitors cannot be avoided *[see Dosage and Administration (2.4) in Full Prescribing Information]*. **USE IN SPECIFIC POPULATIONS Pregnancy** Risk Summary Based on findings in an animal study and its mechanism of action, PEMAZYRE can cause fetal harm or loss of pregnancy when administered to a pregnant woman *[see Clinical Pharmacology (12.1) in Full Prescribing Information]*. There are no available data on the use of PEMAZYRE in pregnant women. Oral administration of pemigatinib to pregnant rats during the period of organogenesis at maternal plasma exposures below the human exposure at the clinical dose of 13.5 mg resulted in fetal malformations, fetal growth retardation, and embryo-fetal death (*see Data*). Advise pregnant 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* Once daily oral administration of pemigatinib to pregnant rats during the period of organogenesis resulted in 100% embryofetal mortality due to post-implantation loss at doses ≥ 0.3 mg/kg (approximately 0.6 times the human exposure based on AUC at the clinical dose of 13.5 mg). Fetal survival was unaffected at 0.1 mg/kg per day; however, once daily oral administration of pemigatinib at the 0.1 mg/kg dose level (approximately 0.2 times the human exposure based on AUC at the clinical dose of 13.5 mg) resulted in reduced mean fetal body weight and an increase in fetal skeletal and visceral malformations, major blood vessel variations, and reduced ossification. **Lactation** Risk Summary There are no data on the presence of pemigatinib or its metabolites in human milk or their effects on either the breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed children from PEMAZYRE, advise women not to breastfeed during treatment and for 1 week after the final dose. **Females and Males of Reproductive Potential** Pregnancy Testing Verify pregnancy status of females of reproductive potential prior to initiating PEMAZYRE *[see Use in Specific Populations (8.1) in Full Prescribing Information]*. Contraception PEMAZYRE can cause fetal harm when administered to pregnant women *[see Use in Specific Populations (8.1) in Full Prescribing Information]*. **Females** Advise females of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose. **Males** Advise males with female partners of reproductive potential to use effective contraception during treatment with PEMAZYRE and for 1 week after the final dose. **Pediatric Use** The safety and effectiveness of PEMAZYRE have not been established in pediatric patients. Animal Toxicity Data In 4- or 13-week repeat-dose toxicology studies in rats and non-human primates, animals displayed toxicities in bone and teeth at pemigatinib exposures lower than the human exposure at the clinical dose of 13.5 mg. Physeal and cartilage dysplasia were present in multiple bones in both species, and tooth (incisor) abnormalities (complete loss of ameloblasts with associated secondary changes) occurred in rats. Six weeks after cessation of dosing, these findings did not show complete evidence of recovery, and additional tooth-related findings (mal-aligned, whitened, broken, and trimmed/thinned incisors) developed in the 13-week study. **Geriatric Use** In FIGHT-202, 32% of patients were 65 years and older, and 8% of patients were 75 years and older. No overall differences in safety or effectiveness were observed between these patients and younger patients. **Renal Impairment** Reduce the recommended dosage of PEMAZYRE for patients with severe renal impairment (eGFR 15 to 29 mL/min/1.73 m^2, estimated by Modification of Diet in Renal Disease [MDRD] equation) *[see Dosage and Administration (2.5) and Clinical Pharmacology (12.3) in Full Prescribing Information]*. No dosage adjustment is recommended for patients with mild or moderate renal impairment (eGFR 30 to 89 mL/min/1.73 m^2). No dosage adjustment is recommended for patients with end-stage renal disease (eGFR < 15 mL/min/1.73 m^2) who are receiving intermittent hemodialysis. *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*. **Hepatic Impairment** Reduce the recommended dosage of PEMAZYRE for patients with severe hepatic impairment (total bilirubin > 3 × ULN with any AST) *[see Dosage and Administration (2.6) and Clinical Pharmacology (12.3) in Full Prescribing Information]*. No dosage adjustment is recommended for patients with mild (total bilirubin > upper limit of normal [ULN] to 1.5 × ULN or AST > ULN) or moderate (total bilirubin >1.5–3 × ULN with any AST) hepatic impairment *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*.

PEMAZYRE is a registered trademark of Incyte Corporation.
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RANCH OF THE DREAMERS

FOUR SEASONS SANTA FE:

BY JEN HELMLE



MDescapes



IF YOU EQUATE LUXURY WITH OPULENCE, YOU MAY DRIVE RIGHT PAST THE ENTRANCE OF THE FOUR SEASONS RESORT RANCHO ENCANTADO SANTA FE.

There is nothing more than a small sign indicating you are about to turn into a resort that blends maybe too well into the beautiful desert landscape of the Sangre de Cristo foothills with the Rio Grande River Valley and Jemez Mountains not far in the distance. You may forget (big mistake) you were pulling into a Four Seasons but do not be fooled because this resort has every bit as much refined luxury as any of the other properties lucky enough to wear this brand's name. Now I hear the saying "never judge a book by its cover" going through my head and it is as true now as it ever was. I had never been to New Mexico, never even had it on my radar. To be honest when trying to choose a resort to explore I tend to be all water, sand and flip flops. I wanted to look deeper into this amazing country we call home and find an area perhaps unexplored to others as it was to me that may appeal to many of the diverse personalities we communicate with. It's hard for me to imagine not everyone wants to sit on a beach under an umbrella or cabana and "do nothing" as a way of relaxing. Well, I have found the perfect place for those who want to do "nothing" (like yours truly) and "everything" when it comes to being indoors or outdoors in the breathtaking, historical west and still get away from it all. Four Seasons Rancho Encantado and the area around it are enchanted and enchanting as its name indicates.

The Four Seasons Rancho Encantado sits on 57 rolling acres just 10 minutes from downtown Santa Fe and 20 miles from Santa Fe Regional Airport, but you feel like you have arrived into the tranquility of a place in the middle of nowhere. When you pull up to the resort it screams peaceful. No big towers or large buildings, just this intimate boutique resort integrated into the rugged natural surroundings. The lobby is unassuming, and you don't know what to expect behind its doors. There is a doorman there immediately to attend to you, your bags and escort you into the small but elegant lobby so smoothly you barely have time to notice the huge woodburning fireplace with Adirondack chairs made out of skis ready to have you sit down if making it inside is just too much. If you have the energy to make it through you will be rewarded with a warm greeting from the front desk ready to help you get settled and explore all the resort has to offer. Adjacent to the reception desk is the lobby and bar area with a beautiful fireplace, tables and a long leather banquette sofa. Every wall is dressed in beautiful artwork. Terra, the resort's main restaurant, sits to the right side of the bar and is stunning with glass walls of wine, an attention-grabbing fireplace and many places to relax and await a spectacular meal. Through both the lobby/bar area and Terra there are glass doors that lead to one of the amazing patios that hosts a huge outdoor firepit and small conversation areas where you can enjoy the beautiful cloudless sky having morning



coffee or watching one of the best sunsets you will ever see with a signature cocktail. More on that to come!

The resort has 65 Casitas that are spread out to ensure privacy, peace and views for days. Fifty-six are the singular guest casitas and 9 are suites. The most popular and private are the Encantado Suites. Measuring over 1000 square feet with two fireplaces, a living room, powder room and fenced in secluded courtyard. Perfect for your furry friend because the resort is pet friendly which I personally think is awesome. These suites sit on the property's highest elevation and have unrestricted beautiful views. I stayed in the mountain view casita which was located on the second floor and I could see the lobby and the lobby views of the mountains and landscape from my elevated level. All casita rooms are at least 600 square feet of tastefully elegant Soutwest styled comfort. There was a mini bar upon entering with a welcome granola, homemade cornbread and jam gift. The bathroom was spa style with a huge stone tiled shower, a double vanity with a large mirror and a huge soaking tub I wanted to spend days in. Did I mention the floors could be heated? Well, they could, and I did. It was awesome. The room itself had a wood burning fireplace stocked with fresh wood, fire starters and matches. If you don't feel confident in your fire-starting skills there is a fire butler, yes that is a real person, and they come assemble and create your fire for you. The blow torch they carry makes them much more official than trying with your matches. The casita I was in had a king bed which was like a cloud to sleep in with nightstands on each side and two comfy sitting chairs and a table at the foot of the bed. There was also a desk and chair. Two sliding doors opened to a partially covered balcony with two chairs, a table and lounge chair. Since it was March and not quite warm at night yet, I found my favorite thing to do was open the doors and sit in the chairs at the foot of the bed with the breeze blowing in while looking at the amazing scenery with my fire, started by my butler, burning away. I will probably never say those words again.

> "You could happily spend the day reading, snoozing, and enjoying the beautiful desert air. "

For a small resort the Four Seasons Rancho Encantado has so much to offer when it comes to activities it may need another article! As I am a self-proclaimed lounger, I found myself to be busy for the 72 hours I was lucky enough to stay here. But if you want to come and do nothing, no one here is going to make you do anything except what you want to. Just to the right of the lobby is a line of buildings that sit slightly elevated and house most of the



amenities the resort has to offer. The year-round outdoor heated pool and whirlpool have amazing views. You could happily spend the day reading, snoozing, and enjoying the beautiful desert air. There is also a pool snack bar open seasonally. Next to the pool is a full-service fitness center with plenty of free weights, strength machines, bikes, ellipticals and treadmills also with those same amazing views. The cardio machines have screens so you could even plug in your favorite workout video or watch a show. There are towels, waters and earphones available for your workout. I needed the towels and water desperately since I haven't worked out in high elevation in a while! There is a dedicated movement studio located next door to the gym which offers a daily morning yoga class. Pilates is also available. If you want a private session with a certified trainer for the gym, yoga or Pilates that can be arranged for you.

Now we are going to get serious about adventure and activities. The resort has its own adventure center. Don't know what that means? I had no idea either until I tentatively stuck my head inside and realized I am not even close to knowing what outdoor adventure is. It is not sitting by the firepit when it's cold out and having to walk to the inside fireplace! Basically, anything you want, like, or have considered trying to do outside feels like it is offered here. You can be an individual, couple, group or family and they can help create adventure based on your specific wants and needs. And it is all coordinated by a gentleman named Hans Loehr who is the Adventure Architect at the resort. I love that title. I am considering changing my titles of wife, mother and newly employed travel writer to something way cooler. I'll let you know if I can think of anything. But Adventure Architect is so appropriate here. Hans and his expert team of guides customize and curate a plan it feels like for literally anything there is to do in these stunning surroundings. Some tours are 3 hours others can be customized to half or full days. There are mountain biking tours ranging from riding around downtown Santa Fe and its historic buildings, churches, monuments and especially the bustling plaza to serious mountain biking in the many valleys, mountain ranges, canyons and basins surrounding the resort and downtown. Like to be on foot? There are several different types of hiking tours available. A guided complimentary one offered at the resort each morning, which I did and liked because it was doable and informative about the history of the resort (it used to be a luxury dude ranch a little over 50 years ago run by a widow from Cleveland named Betty Eagen) the history of the area and the people who were native to it. The resort also gives you a map to do the hike yourself, which is also a great way to explore. If you are a serious hiker, several guided hiking options are available through the adventure center. Also offered are customized and guided jeep tours, horseback riding, hot-air ballooning, skiing, golf, fly fishing, whitewater rafting and star gazing if you can squeeze it all in. That's just the physical activity tours! I love that this resort has tours that are specifically for guests who are interested in the area of Santa Fe and its deep, diverse history.



There are guided tours of downtown Santa Fe, the Georgia O'Keeffe/Abiquiu art tour, Native American Cultural Tour, Bonanza Movie Set Tour, New Mexican Wine and culture tour, Ghost Ranch and Pilgrimages to the old Spanish Territory to name a few. It feels like they can customize a tour to any interest you may have so stop in and see what Adventure Architects can help you dream up.

If you are more into exploring on your own the resort offers complimentary shuttles to downtown every hour and pick up on the half hour from two different locations in the city so you can spend the day roaming around the beautiful architecture, stop by The Basilica of St. Francis of Assisi, the innumerous shops, jewelry stores, hundreds of amazing art galleries, restaurants and soak in all that culture in your own timing.
Now if you are totally wiped by all that activity as I am typing about it then you need to head straight to The Spa at Rancho Encantado and just let it all melt away. This spa makes me HAPPY! At 10,000 square feet and the largest in the Four Seasons portfolio. It boasts 15 treatment rooms as well as a warming room with fireplace, drinks and snacks to wait for or mellow out after a treatment. There are full-service private locker rooms for both women and men. You can feel it all melt away the minute you walk in and are greeted by one of the amazing spa staff. They have the softest robes, curated beauty, candles and wellness products available to purchase. I was lucky enough to have Danielle who was amazing and gave me a full tour and booked me a massage catered to my middle-aged needs. Thank you to my masseuse Katherine from Boston who was the shoulder whisperer. They offer massage both individual and couples, therapeutic and relaxing, hydrating facials to help your parched altitude skin, nails, bridal beauty and body work such as hand and foot treatments, seasonal body therapies and stone work. They use many oils and products made from plants native to this area such as prickly pear, jojoba and turquoise sage. There is a romance package for two if you are a honeymooner or just without kids. Need your Chakara balanced? Who doesn't these days! They can help with that too. One of the best and welcome findings at the spa was for no additional fee, if you are a guest of the resort, you can reserve one of their private outdoor enclosed courtyards which have a heated whirlpool, steam or dry sauna room, outdoor private shower and lounge chairs with heat lamps. There is water or tea available or maybe if you were me and really feeling the need to relax, a glass of rose while soaking up the late afternoon sun and just feeling grateful for being where I was.

Did I even eat while I was there? I haven't even mentioned my second favorite thing besides lounging which is eating. I'm now back in the lobby and in the bar and there are many places to sit inside and outside and enjoy a small plate, a big meal, a cocktail, a mocktail or a chlorophyll water. Don't know what that is? Ask one of the awesome men at the valet station and they will fix that altitude dehydration right away. They are



the unsung mixologists. The large outdoor firepit does smores nightly for those with the young or young at heart. One of my favorite places I found to hang out was the inner open-air courtyard in the middle of the hotel main area. It has a huge fireplace, pergolas strung with lights, high tops, low dining tables and umbrella covered conversation areas with sofas. The main restaurant Terra offers breakfast, lunch and dinner with a regionally sourced modern take on Southwest cuisine. For those of you who may be travelling with kids they have a children's menu and those under 5 eat free. Some menu items I sampled that stood out to me were the maple butternut squash soup, vegan Spanish rice bowl, the octopus a la plancha, grilled sea bass, broccolini with romesco and chile roasted chicken with the best ever brussel sprouts. As someone who has to be gluten free, I found the menu to be very inclusive of food preferences or needs. I also found the kitchen to be accommodating of a request. If they could make it for you the way you needed it to be, they did it and with a smile. If you are there for dinner, ask to be served by Larry. He has been a fixture at the resort in dining and the bar and he is not only a lovely gentleman to speak with he is very knowledgeable about the dinner and wine menu, which is spectacular.

In the bar area by the fireplace sits a portrait of Betty Eagen and pictures of the history of Encantado Ranch. I love that the resort pays tribute to those who have helped create this magical place. The bar offers daily specials such as food and drink priced happy hour, an all-day dining menu and live music on weekends. If you don't drink don't worry, the bartenders have an entire menu of craft mocktails that look and taste just as good. You don't have to drink alcohol to have an elevated curated experience in the bar here. They do, however, if you partake, have daily events you can register for such as the tequila tasting I signed up for my last afternoon. I am a tequila lady. Love it. I can wholeheartedly recommend the jalapeno margarita and tequila old fashioned here for sure. Do I know anything about it? Apparently not. At the time of the tasting the bar was set up for the 6 guests that registered. Each person signed up, in this case 3 couples (shout out to my bestie Christine for being my plus one on this trip, we should all have a Christine in our lives) had a place setting with homemade chips, guacamole and salsa as well as a tiny little tasting glass. We sipped, swirled and were educated on the three distinct styles of tequila which I already knew about but quickly discovered each had qualities, taste profiles and characteristics unique to each tequila even within those three categories. It was fun to try, be educated about something and meet new people such as my new friends from San Fran by way of Mumbai and Japur who were sitting next to me. I guess tequila is like people, unique with its own special qualities and should be honored for them. You just have to take the time to learn about them.

If the quote by John C. Maxwell says "You're only as good as the people you have around you" then GM Bixente Pery must be Superman. I noticed him every morning greeting his employees and guests with a smile and a word and that enthusiasm and kindness flowed from every employee I had the pleasure of interacting with. Whether it was housekeeping, shuttle drivers who were kind enough to take the back way to educate me on the local history, front desk, valets, groundkeepers, bartenders, waiters, waitresses and my beloved fire butler there was not one person who didn't seem dedicated to this resort, the guests, their experience here and the area they themselves call their home. I hope everyone I met and didn't meet knows they are important in a guest's experience and I am here to say they are and thank you! I was truly grateful to have come to such an exceptional resort, with amazing people, history, experiences, remarkable beauty and charm. At the turn of the last century, it was known as the "Rancho de las Sonadores" or Ranch of the Dreamers. It most certainly was a dream to visit here and I hope you get the chance to experience this special place. I hope to return to this slice of paradise again myself.

ALL-IN-ONE DIAGNOSTICS SOLUTIONS



1404

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

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

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1405



BONE HEALTH



1406

WHY BINDEX® IS A GAME-CHANGER IN OSTEOPOROSIS DIAGNOSTICS.

From Bindex Medical

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

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

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

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Scalable Chemistry Solutions for the physicians office laboratories

Reliability and consistency

The performance and quality are designed into the complete system across all key components:

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- calibrators & controls
- ISE (Ion-Selective Electrode)
- remote diagnostics

1407



ENVOY500+

Larger volume

- 20-80 patients per day



1408



Selectra Pro M

Mid-volume

- 10-40 patients per day

1409



Selectra Pro S

Compact

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ENVOY500+ is available in the USA only.



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EASY, INTEGRATED WITH-PATIENT TESTING I-STAT SYSTEM

From Abbott Point of Care

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

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

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

From Abbott Point of Care

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

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1411

1412



ENVOY500+ DELIVERING PROVEN RESULTS IN CLINICAL CHEMISTRY

From EliTech

The fully automated Envoy500+ is designed to deliver the performance of a large floor model analyzer but provides the cost efficiency of a benchtop analyzer (TPH approx. 490). It enables accurate treatment decisions sooner. Envoy500+ delivers savings the laboratory requires with the following features positive sample and reagent identification, clot detection, liquid level sensing, dry ISE module, reusable glass cuvettes, and many more.

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TOXICOLOGY SCREENING
SIMPLIFIED

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



IMMTOX™ 270 BENCHTOP ANALYZER

Toxicology screening solutions for physician offices, treatment centers and laboratories.

- 25 assay menu
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- Compact footprint
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1. Clinical Laboratory Improvement Amendments (CLIA)

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Abbott



DRUGS OF ABUSE TESTING AND ROUTINE CHEMISTRY PANELS ON A SINGLE ANALYZER

From Carolina Liquid Chemistries

Carolina Liquid Chemistries Corp. announces the successful launch of Medica Corporation's high-speed benchtop analyzer, the EasyRA®. The updated analyzer now operates at a photometric rate of up to 240 tests per hour or up to 480 tests per hour with ISE. The EasyRA urine drug screening and general chemistry reagents are CLIA categorized as moderately complex. This all-in-one system allows clinical laboratories to screen for drugs of abuse in urine while also allowing healthcare providers to assess routine chemistry panels on a single analyzer.

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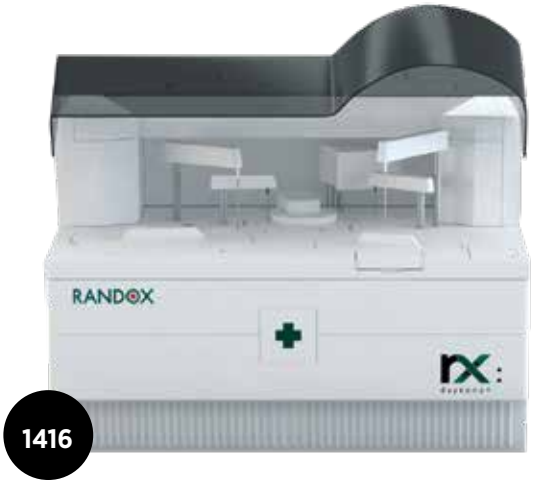
PENTRA C400 CHEMISTRY ANALYZER

From HORIBA Medical

One benchtop, not a whole lab! No water system, drain or special electrical connected required to operate the Pentra C400 chemistry analyzer. Now you can have the power of a floor model analyzer on the benchtop! The Pentra C400 chemistry system processes up to 420 tests/hr including ISEs and offers routine metabolic assays, TDMs, DAUs and Adulterants, HbA1c and Vitamin D tests. With 40 open channels, you can add much more for a complete menu to meet your practice needs.

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RX DAYTONA+

From Randox Laboratories

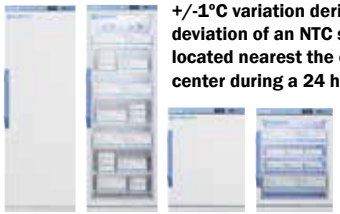
The RX daytona+ is a fully automated, benchtop, clinical chemistry analyzer capable of performing high quality testing, with a combined throughput of 450 tests per hour, for accurate results you can trust. The most versatile analyzer in its class, the RX daytona+ combines robust hardware and intuitive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

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- Built-in readout for current & high/low temperature
- Audible & visual high/low temperature alarms
- Optimized efficient performance for stable temperature
- Eco-friendly natural refrigerants for a greener footprint

Solid & Glass Door Refrigerators From 1 to 15 Cu.ft.



+/-1°C variation derived from the maximum deviation of an NTC sensor in a 1 oz. vial located nearest the champer geometric center during a 24 hour test period

1417

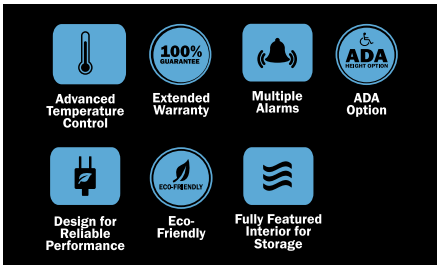
Refrigerators & Freezers From 23 to 49 Cu.ft.



Refrigeration designed and purpose-built for pharmacy, medication, and vaccination applications to support meeting CDC/VFC vaccine storage guidelines

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- Factory installed lock conveniently located towards the top of each unit
- Adjustable shelving can be spaced in ½" intervals for flexible storage



Pharma-Vac Refrigerators

Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS1PV	1 cu.ft.	21.5"	17.5"	19.5"	White	**936.00**
ARG1PV	1 cu.ft.	21.5"	17.5"	20"	Glass	**949.00**
ARS3PV	3 cu.ft.	33.75"	18.5"	19"	White	**1,059.50**
ARG3PV	3 cu.ft.	33.75"	18.5"	19.5"	Glass	**1,072.50**
ARS6PV	6 cu.ft.	32.5"	23.5"	24.5"	White	**1,180.40**
ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	**1,193.40**
ARS8PV	8 cu.ft.	50"	23.38"	24.5"	White	**1,497.60**
ARG8PV	8 cu.ft.	50"	23.38"	25"	Glass	**1,510.60**
ARS12PV	12 cu.ft.	61.75"	23.38"	24.5"	White	**2,002.00**
ARG12PV	12 cu.ft.	61.75"	23.38"	25"	Glass	**2,015.00**
ARS15PV	15 cu.ft.	72"	23.5"	24.5"	White	**2,294.50**
ARG15PV	15 cu.ft.	72"	23.5"	25"	Glass	**2,307.50**

models with data loggers are available

Pharma-Lab Refrigerators

Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	**2,762.50**
ARG23ML	23 cu.ft.	83.75	27.5	31	(1) Glass	**3,113.50**
ARS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**4,413.50**
ARG49ML	49 cu.ft.	83.75	55.25	31	(2) Glass	**4,771.00**

Pharma-Lab Freezers

Accucold	Capacity	Height	Width	Depth	Door	PRICE
AFS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	**3,178.50**
AFS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	**5,063.50**

visit www.medicaldevicedepot.com for all product information and options

Choosing the Right Sized Unit

Below are a few handy steps for determining the ideal Accucold refrigerator size for your clinic:

1 Estimate the maximum number of doses of publicly-provided vaccine and privately purchased vaccine that will be in your refrigerator.

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

Public Vaccine _____

Private Vaccine + _____

Total doses = _____

Multiply (max inventory) x 1.25

Maximum doses = _____

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

Max. Doses	Minimum Cubic Ft.
2,000+ doses	may need more than one refrigerator
1000-2000	40 cu.ft
900-1000	36 cu.ft
801-900	21-23 cu.ft
701-800	17-19.5 cu.ft
400-700	11-16.7 cu.ft
100-399	4.9-6.1 cu.ft

For product application suggestions or recommendations please feel free to contact our product specialists to discuss your options at:

877-646-3300

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1418



BD VERITOR™ PLUS SYSTEM

From BD Veritor™

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

*EUA authorized by FDA

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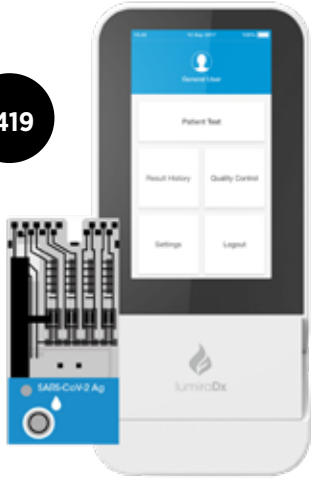
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From LumiraDx

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

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1420

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

From BioFire

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

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

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3 WAYS TO START IMMEDIATELY INCREASING REVENUE

1 Neuro-Cognitive Testing 1421

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

2 ANS Testing 1422

(can be combined with SUDOMOTOR into 1 full system)

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



3 SudoMotor Testing 1423

(can be combined with ANS into 1 full system)

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

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1424

CARESTART™ COVID-19 ANTIGEN TEST

From Mercedes Scientific®

This point-of-care (POC) designated test is one of the top-used amongst our customers.

Features/Benefits:
- CLIA WAIVED
- Results within 15 minutes
- Anterior nasal swab specimen collection
- Detects SARS-CoV-2 nucleocapsid protein antigen
- 87.2% sensitivity and 100% specificity

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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SOFIA® 2 FLUORESCENT IMMUNOASSAY ANALYZER AND RAPID DIAGNOSTIC TEST KITS

From Quidel

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

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1425





1426

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

From Carolina Liquid Chemistries

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

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1427

HISTOFREEZER® FLEX

From CryoConcepts

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

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CRYOLAB® MEDICAL

From CryoConcepts

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

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1428



1429

CRYOCLEAR®

From CryoConcepts

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

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THE BREWER BASIC EXAM TABLE

From Brewer

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

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BREWER'S ACCESS™ HIGH-LOW EXAM TABLE

From Brewer

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

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BREWER'S FLEX™ ACCESS EXAM TABLE

From Brewer

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

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Now there's an easy and effective way to screen for osteoporosis.

Bindex®

Fast, accurate and comparable to DXA.

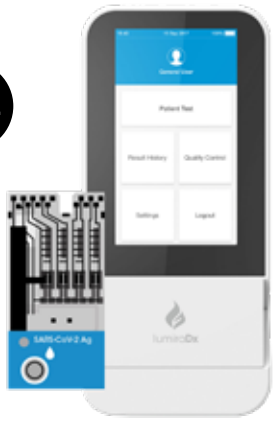
Bindex is the world's first evidence-based, point-of-care osteoporosis diagnostics device that provides results comparable with DXA. Portable, hand-held and lightweight, Bindex scans in seconds and at a fraction of the cost allowing you to quickly provide much-needed osteoporosis diagnostics for your at-risk patients.

NOW YOU CAN TRIAL BINDEX AT NO COST.

To trial Bindex in your office, visit **bindex.us/launch** or call **(970)-306-7452.**

BINDEX

1434



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

From LumiraDx

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

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From BioFire

The BioFire® FilmArray® Torch is a fully integrated, random, and continuous access system designed to meet your laboratory's syndromic infectious disease testing needs. The BioFire Torch offers a radically reduced benchtop footprint, saving precious space in the lab, and its scalability meets high throughput demands. BioFire® FilmArray® Link Software automatically uploads patient results. Fully compatible with all CLIA Moderate BioFire® FilmArray® Panels, the BioFire Torch helps you maximize efficiency and productivity.

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FLU AND RESPIRATORY



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

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From Abbott

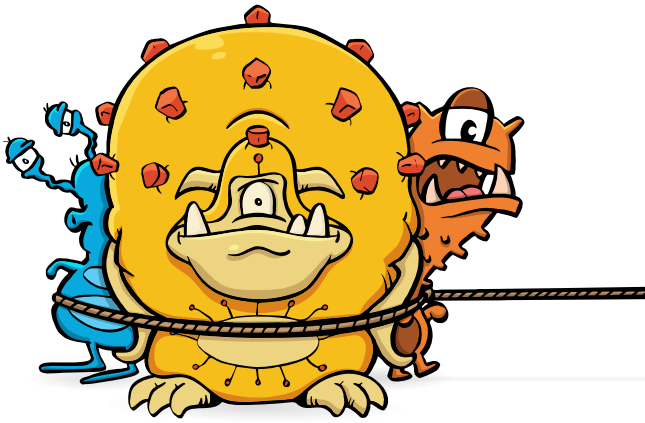
Prescription drug misuse and illicit drug abuse is a growing public health challenge in this country. Building a test profile that covers highly misused drugs has never been so vital. With over 20 relevant assays to choose from Abbott's suite of Immunalysis reagents allows you to easily screen for relevant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

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The new BioFire® Respiratory 2.1-EZ (RP2.1-EZ) Panel (EUA)[1] covers SARS-CoV-2 detection and so much more.

Right now, SARS-CoV-2 is everyone's top suspect, but many other respiratory bugs can cause similar, overlapping symptoms. Testing for just SARS-CoV-2 or influenza could mean running the risk of missing the real culprit, leading to missed infections, or even coinfections. Additionally, many rapid diagnostic tests sacrifice accuracy for speed, with sensitivities oftentimes ranging from 50–70%.[2]

Now you can test for 18 common respiratory pathogens in your clinic, including SARS-CoV-2 in patients suspected of a COVID-19 infection with syndromic testing from the BioFire RP2.1-EZ Panel—now available under an FDA Emergency Use Authorization (EUA).[1,3] Syndromic testing means all it takes is one test and about 45 minutes to round up SARS-CoV-2—and all the other usual respiratory suspects. What's your frontline solution for respiratory season and beyond?

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



BioFire RP2.1-EZ Panel (EUA)

Overall 97.1% sensitivity and 99.3% specificity (prospective specimens)[4]

SARS-CoV-2 98.0% sensitivity and 100% specificity (archived specimens)[5]

SARS-CoV-2 100% PPA and 100% NPA (contrived specimens)[6]

BIOFIRE®

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 invitro 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. http://www.cdc.gov/flu/professionals/diagnosis/rapidlab.htm 3. For use with the CLIA-waived BioFire® FilmArray® 2.0 EZ configuration. 4. Based on the prospective portion of the clinical study for the BioFire® FilmArray® Respiratory 2 (RP2) Panel. 5. Based on the archived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel EUA submission 6. Based on the contrived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel EUA submission.

BFR0001-0517-02


SUB TOTAL
1256.00
1256.00
1173.83
82.17
1260.00
-4.00
CASH(THB)
BALANCE (THB)
2013
107,812
109,928
39,912

KEEPING YOUR PERSONAL FINANCES AFLOAT DURING ECONOMIC UPS AND DOWNS

BY ANDREW HARMS AND MIRIAM SWEENEY

You've seen the headlines.

"Consumer costs are on the rise.'"

"Price of energy is increasing."

"Transportation is becoming more expensive."

"Today's 20-somethings will be able to afford the homes that the 1990s 20-somethings could in two decades."

And by now, some part of it has probably hit close to home.

Economic shifts like this affect everything eventually. We want to hash out how it can and should affect budgeting.

Budgeting can feel like a four-letter word, but it doesn't have to. In the end, budgeting is giving your money a job. A good budget considers first whatever needs and wants you have, and then earmarks different groups of your money to meet those needs.

In this article, we'll talk about what physicians—particularly those early in our careers—can do to navigate these unique and challenging times, particularly with respect to the impact of rising costs on our personal budgets.

Here's why the call to review your personal budget is timely and maybe a little painful: it's unlikely that income increases for most in this group will keep pace with the increasing household monthly expenditures. According to a 2021 Medscape survey conducted between 2017 and 2020, resident salaries rise at an average of 3% per year. 1 The bad news: inflation is outpacing your salary increases. That means now is a good time to revisit your expense categories in order to stay within your monthly budget and continue to meet your goals for savings and retirement.

Budgeting in the current environment

Budgeting is giving your money a job, where every dollar has a home. Like many experts, we favor zero-based budgeting at ScrubMoney. Whether the dollar goes toward rent, food, savings, or Amazon Prime, every dollar has a known and established purpose.

But earmarking EVERYTHING can feel overwhelming. That's why we use a simplified version of budgeting, where you only really keep track of four categories. This method, created by Miriam Bay Sweeney, was inspired by Clayton Christensen's Jobs to be Done framework and included in Rufus Sweeney's first courses on personal finance for med students in ScrubMoney, a personalized financial education software geared to serve physicians. The framework suggestscreating your own expense categories along the lines of Fixed vs. Variable and Negotiable vs. Non-negotiable:

Examples of **Fixed/non-negotiable** expenses include: Housing, Transportation,

Insurance, and Loan repayment

Examples of **Fixed/negotiable expenses** include: Subscription services

Examples of **Variable/non-negotiable expenses** include: Groceries, gasoline

Examples of **Variable/negotiable expenses** include: Hobbies, spending on entertainment

Let's take a closer look at each category in the context of rising consumer costs and the relative outpacing of income increases for physicians.

When looking at the Fixed/non-negotiable category, it's unlikely that many adjustments to lower monthly expenses can be realized immediately. Nevertheless, it's important to see if your bills have gone up for items in this category. We've seen many people miss cost adjustments in this category, so here are two tips for consideration:

1) **Review your statements**. Are you paying more for insurance this year versus the last time you reviewed your budget? Have additional costs been added to your utility bills?

2) **Explore improved options for loan consolidation and repayment if available**. Perhaps it's been a while since you re-examined your repayment options. Search out trusted advice and speak with your lenders. While we know the life of physicians-in-training and attendings is demanding, book some time to consider your debt strategy. You will thank yourself later.

The **Fixed/negotiable expense category** is certainly one that commands your attention. Are each of your monthly subscription services necessary and utilized regularly? What could you save each month by eliminating an unutilized or unnecessary subscription service?

We're all guilty of paying out hard-earned dollars to underutilized subscriptions at one time or another. When cost of living is not surging, we often may splurge or not treat this category as anything more than harmless, superfluous spending. But just maybe, in this environment, you'd rather have that $9.99/mo newsletter ($120 annually) set aside and saved in order to buy your next airfare, given your flight may be more expensive than the last time you traveled. As mentioned before, pull out your statements and review your outgoing dollars.

The expense category that most likely has experienced the most upward pressure on your monthly budget is the Variable/non-negotiable category. According to Moody's Analytics and government data, in February alone, food prices were up 1% while energy prices were up 3.5%. On a year-over-year basis, the consumer price index was up 7.9% in February. Having inflation at 7.9% on a year-ago basis, compared with the 2.1% average growth in 2018 and 2019, is costing the average household $296.45 per month. 2 Moody's adds: 'It is going to get worse before it gets better.' Keep this in mind, review this expense category, and don't be caught off guard.

For many, we've made it to and perhaps through training with the help of revolving credit lines. Credit card payments, linked to interest rates, have been relatively low for many years—though high relative to other forms of debt, of course. Now that trend has inflected upward. Similar to food and transportation costs, make sure you're well aware of your line-item budget expenses for principal and interest payments on any revolving credit lines with existing balances. In a December Bankrate study, 41% of cardholders carrying a balance didn't know their interest rate. Currently, the average interest rate of cards is 16%, but rates can go as high as 25% or more. 3 The bottom line: paying off debt will become increasingly costly.

The final category makes space for fun: the variable/negotiable monthly expenses for such things like dining out and entertainment. You don't need to feel like this budget should be reduced to zero in order to survive economic fluctuations. Just ensure that you've considered the rising cost landscape and have planned accordingly. Remember: a budget feels great when it helps your actions align with your intentions.

Recommit to your financial goals

Depending on your circumstances, you may have priorities geared toward paying off debt, building an emergency savings fund, buying a home, or saving for retirement. Regardless of your situation, a review of your spending habits and attention to detail to amend a workable zero-based budget will prepare you to stay on track while working toward your financial goals.

Zero-based budgeting is a great tool for physicians to use, especially in this challenging environment for consumers. Any effort you make to avoid surprises from a tightening budget will be rewarded by peace of mind and financial confidence. With this perspective backed by effort and action, your monthly budget can be your weapon of freedom in this era of persistently higher cost of living.

REFERENCES

—

1 Medscape Residents Salary & Debt Report 2021

2 Maybe U.S. Consumers Won't Turn Fuelish (Capital Market Research) (Weekly Market Outlook) (moodysanalytics.com)

3 Credit Card Interest Rates to Rise, Too | Kiplinger

Doctors make a lot of money, right?

So we're not worried about that $1M or so most of us surrender to things like interest payments on student debt.

Right?

1444

Brush up on the basics of physician personal finance. Visualize your financial future. And do it without anyone selling your personal information or trying to convince you to make a stupid investment.

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From Sekisui Diagnostics

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ULTRA HCG COMBO TEST

From Sekisui Diagnostics

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15 cu ft Refrigerator w/ Solid Door (ARS15PV): $2,294.50

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