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DISEASE › INFECTIOUS DISEASE

Molecular testing ushers in a new era of rapid diagnostics for pharyngitis

Jane M. Caldwell, PhD
Bobby L. Boyanton Jr., MD
June 15, 2023

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Acute pharyngitis "sore throat" is an inflammatory condition of the pharynx and/or tonsils commonly observed in both adults and children. Viruses are primarily responsible, but bacteria are also implicated. Infection with beta-hemolytic *Streptococcus pyogenes*, or Group A streptococcus (GAS), accounts for 5%–15% and 20%–30% of infections in adults and children worldwide, respectively. Acute pharyngitis is one of the most common reasons for primary care visits[1] and is the most common diagnosis linked to antibiotic use in school-aged children.[2] Antibiotics are ineffective against viral pharyngitis and do not shorten illness duration or improve patient outcomes. Because throat culture takes up to 48 hours to produce actionable results, clinicians may preemptively prescribe antibiotics "just in case" the infection is due to GAS. This practice leads to unnecessary antibiotic use and the promotion of bacterial resistance. According to a recent study, it is estimated that nearly half of antibiotic prescriptions for pharyngitis are unnecessary because most infections are of viral origin.[3] This practice also wastes healthcare resources and unnecessarily subjects patients to antibiotic-associated side effects. Moreover, other pathogenic bacteria may be responsible for the infection and these may not be responsive to conventional GAS therapy. Rapid, accurate, and reliable testing solutions are needed to provide timely patient information during the clinician office visit. State-of-the-art nucleic acid amplification tests (NAAT) can fulfill this need and have the potential to improve antimicrobial stewardship.[3] This article will address the

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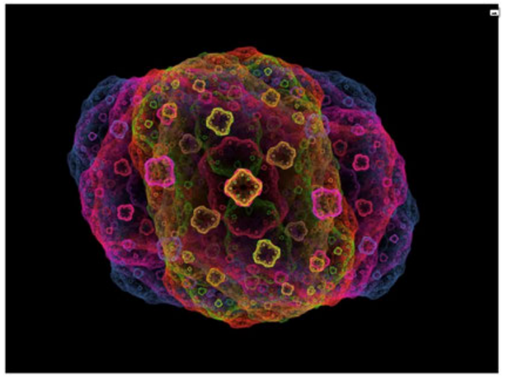
Molecular syndromic testing: Will panels improve care?

Jane M. Caldwell, PhD
Tamara Ranalli, PhD, Carrie V. Vause, MS
July 13, 2023



The number of infectious disease syndromes commonly seen in primary care, urgent care, and emergency departments in the United States is staggering. Acute respiratory illnesses (ARI), ranging from mild upper respiratory tract infections to serious illnesses such as pneumonia, are the most common reasons to seek ambulatory care[1] with total deaths attributed to COVID-19 on death certificates as 1,132,414.[2] Gastrointestinal tract (GIT) infections such as acute gastroenteritis have been estimated to account for over 175 million cases each year.[3] Sepsis, a serious bloodstream infection, causes up to 381,000 deaths annually.[4] Central nervous system (CNS) infections such as meningitis and encephalitis are associated with high mortality and morbidity[5] with viral forms responsible for nearly 20,000 U.S. hospitalizations per year.[6] The U.S. Centers for Disease Control and Prevention (CDC) reported that 1 in 5 U.S. residents had a sexually transmitted infection (STI) in 2018 which translated to an estimated 26 million new cases that year.[7]

All these infections may be caused by bacteria, fungi, viruses, parasites, or combinations of two or more of the above and present challenges for accurate diagnosis. Furthermore, many

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DISEASE › INFECTIOUS DISEASE

Benefits of molecular test-and-treat for Group A Streptococcus pharyngitis

Jane M. Caldwell, PhD, Rachael M. Liesman, PhD, D(ABMM)
June 24, 2024

Group A streptococcal (GAS) infections have been on the rise since late 2022 and 2023 after an overall low incidence during the years of the COVID-19 pandemic.[1] GAS infections are common among children and may be asymptomatic or produce mild infections such as pharyngitis, impetigo, and scarlet fever.[1] Symptoms of GAS pharyngitis, also known as strep throat, include fever, pain when swallowing, sudden onset sore throat, red and swollen tonsils, white patches or pus on tonsils, tiny red spots on the roof of mouth, and swollen lymph nodes in the front of the neck.[2] GAS pharyngitis typically occurs in winter and early spring in temperate climates.

Invasive GAS (iGAS) infections are potentially life threatening and clinical presentation of iGAS infections include sepsis, necrotizing fasciitis, streptococcal toxic shock syndrome, and other severe infections. Presently, iGAS infections affect 1.8 million persons worldwide, both young and old, with a mortality rate approaching 20%.[1] iGAS infections may have non-specific symptoms such as fever, which makes clinical diagnosis problematic. Preliminary 2023 data from the U.S. Centers for Disease Control and Prevention (CDC) indicate that the number of severe infections caused by GAS reached a 20-year high.[2] Similarly, non-invasive GAS, including GAS

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CME / CE

Pathologies and the Use of Cerebrospinal-Fluid-Based Biomarkers in Alzheimers Disease

Authors: Marwan N. Sabbagh, MD, FAAN; Carrie V. Vause, MS; Jane M. Caldwell, PhD Faculty and Disclosures

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Alzheimers Disease (AD): Impact on Global Health

People all around the world are living longer. Most can expect to live beyond their 60th birthday. According to the World Health Organization,[1] 1 in 6 people worldwide will be 60 years of age or older by 2030. Unfortunately, longer life span doesn't always translate into longer health. Recent statistics show that the duration of life in good health has remained constant, which implies that the additional years are mired in poor health or reduced capacity for many.[1] Common health conditions associated with advanced age include hearing loss, cataracts, osteoarthritis, diabetes, depression and dementia (Figure 1).[1] Dementia, a loss of cognitive function, poses a significant economic burden to healthcare systems and society as a whole because of reduced productivity for both the patients and their caregivers. Because the disease progression can take many years and no cure is available, dementia is becoming a global health crises with 50 million people currently affected.[2] A common cause of dementia, Alzheimers disease (AD) is believed to account for 60% to 80% of cases.[3] The yearly cost of AD and other dementias in the United States alone is predicted to increase to more than $1 trillion by 2050.[3] The emergence of COVID-19 resulted in more than 1.3 million hospitalizations among US adults age 65 and older between January 2020 and July 2021.[3] Because critical illness and hospitalization is believed to increase the risk of long-term cognitive impairment in older people, the pandemic may increase the number of AD cases and their resulting costs beyond earlier estimates.[3]

Figure 1. Older Age Conditions

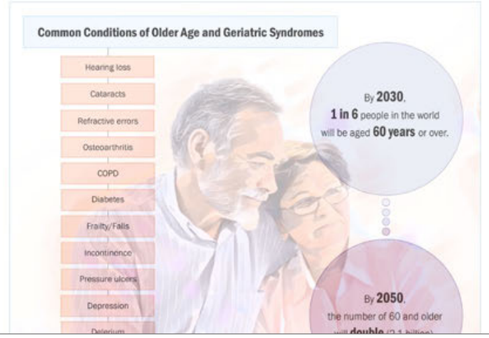

exhibit strong correlation with amyloid PET, they are widely accepted in the AD community as supporting a diagnosis of early stage AD.[32,33]

Figure 2. CSF Biomarkers and AD Diagnosis Functionality [34-46]

CSF Biomarker	Function in AD Diagnosis
t-tau	• Predicts neurodegeneration via correlation to NFTs • Not specific to AD
p-tau	• Correlates to NFTs, particularly p-tau181 • Specific to AD, sensitivity > 90% • May be low in non-White individuals
Aβ40	• Represents total Aβ levels in cortical tissue • Not specific to AD • May be low in non-White individuals
Aβ42	• Levels in CSF are decreased due to increaed Aβ aggregation • High concordance with amyloid PET • Associated with AD
Aβ42/Aβ40	• Adjusts for individual differences in Aβ • Low ratio indicative of AD, high ratio may be other subcortical damage • High concordance with amyloid PET • Classifies more patients correctly than Aβ42 alone
p-tau/Aβ42	• Ratio indicative of AD and MCI • High concordance with amyloid PET • May be low in non-White individuals
Neurofilament light	• Increased in AD patients, particularly those with rapid progression • Not specific to AD • May be low in non-White individuals

Abbreviations: Aβ, amyloid beta; AD, Alzheimers disease; CSF, cerebrospinal fluid; MCI, mild cognitive impairment; NFT, neurofibrillary tangle; PET, positron emission tomography.

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Activity Review

Prevalence and clinical manifestations of herpes virus

Known to affect more than 400 million people worldwide, genital herpes is a commonly seen, sexually-transmitted infection (STI) whose causative agents are the large, double-stranded DNA viruses known as herpes simplex virus type 1 (HSV-1) and type 2 (HSV-2) (1). These viral conditions are transmitted by intimate person-to-person contact such as kissing, oral sex, vaginal sex and anal sex (2). These viruses cause a variety of human diseases and have the ability to establish a lifelong, latent infection and carriage. In the United States (U.S.), 50% to 80% of adults have oral herpes (HSV-1) characterized by cold sores or blisters in or near the mouth (2). Genital herpes may by caused by either HSV-1 or HSV-2 and affects one out of six Americans aged 14 to 49 years (2). Genital herpes infections can also manifest as blisters or sores but may remain hidden or asymptomatic (2). Historically, HSV-1 is associated with oral cold sores, while HSV-2 is associated with genital herpes infection. However, as a result of oral-to-genital contact, there is an increasing prevalence of HSV-1 in genital lesions and HSV-2 in oral lesions(3, 4). Up to 90% of HSV-2 infections are unrecognized and undiagnosed. Early diagnosis and treatment can reduce transmission (3, 4). (Figure 1)

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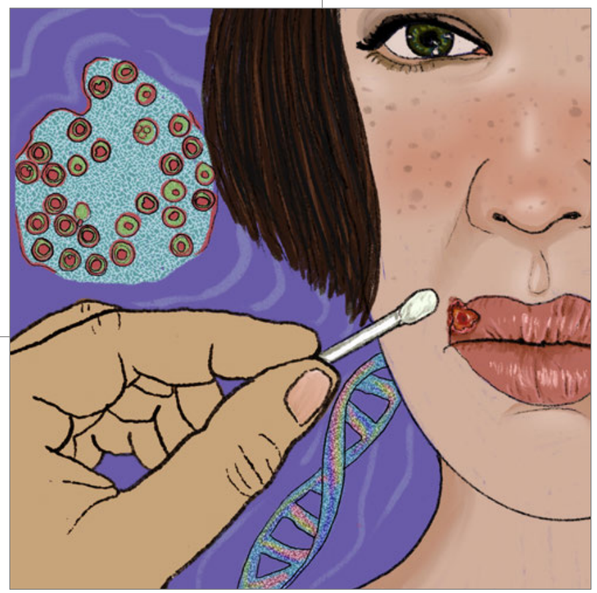
Lesion-causing herpes simplex

- There are two subtypes of HSV.
- HSV-1 most commonly affects skin and oral mucous membranes, while HSV-2 lesions are seen in genital mucous membranes.
- As a result of oral-to-genital contact, there is an increasing prevalence of HSV-1 in genital lesions and HSV-2 in oral lesions.
- Over 66% of individuals under 50 have HSV-1.
- HSV-2 is one of the most common sexually transmitted infections with up to 90% of infections unrecognized and undiagnosed.
- Early diagnosis and treatment can reduce transmission.

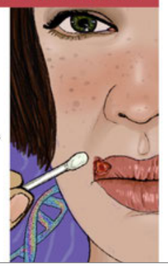


Lymphogranuloma venereum (LGV)	Dermatitis
Granuloma inguinale (donovanosis)	Folliculitis
Fungal/yeast infections	Ecthyma
Crohn's disease	Cnidaria envenomation
Behçet's syndrome	Contact stomatitis
Fixed drug eruptions	Lichen striatus

Figure 3. Aside from HSV and VZV, many other infectious and non-infectious etiologies may lead to cutaneous, oral, or genital lesions (5, 14).

While HSV are most commonly associated with mucocutaneous locations and VZV typically present as clusters in dermatomal distributions (15-17) early eruptions in the sacral area may be mistaken for HSV. Likewise, early vesicular lesions in immunocompromised patients or steroid abusers could be caused by either HSV or VZV (9, 18). Immunocompromised patients often present with atypical lesions that are difficult to define visually. The only way to definitively determine a diagnosis is through laboratory testing. (Figure 4)

Similar clinical presentations of HSV, VZV, and other lesion-causing pathogens impact diagnosis



Visual differentiation is not possible for most lesion-causing pathogens.

Atypical presentations are difficult to distinguish.
- VZV in genital dermatomes
- Immunocompromised patients

HSV-1 & HSV-2 may not be distinguishable by oral vs. genital lesion patterns.

The only way to definitively determine a diagnosis is through

in over 11% of suspected HSV cases.

50% of these cases are in genital regions.

suspected to be VZV due to presentation.

Figure 7. VZV is detected in over 11% of suspected HSV cases, primarily in genital regions. Over 75% of t suspected to be VZV during initial presentation (12, 13).

Over 8% of the specimens submitted for HSV testing were found to contain VZV and half of these (4.2%) (13). HSV was found in over 19% of suspected VZV cases (Figure 8) (13). Because HSV has a different ris recurrence, distinguishing HSV and VZV is important for patient education and outcomes. Those findings combining HSV/VZV in a molecular detection platform (1, 13).

Clinical diagnosis of VZV may need to rule out HSV

Dermatome distribution of herpes zoster may be distinctive enough to make an accurate clinical diagnosis.

HSV is the primary differential diagnosis for VZV, particularly when the face and genital region are affected.

HSV is found in over 19% of suspected typical VZV cases.

VZV Differential Diagnosis

HSV	Insect bites
Impetigo	Papular urticaria
Contact dermatitis	Candida
Folliculitis	Dermatitis herpetiformis
Scabies	Drug eruptions

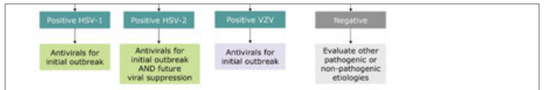


Figure 10. Utilizing multiplex testing for any patient with suspected HSV or VZV can eliminate unnecessary testing, reduce time to diagnosis, and improve treatment timelines.

Early differentiation between herpes virus types is important because compared to HSV-1, HSV-2 causes more severe episodes and recurs more frequently (up to 12 times a year). HSV-2 has higher rates of viral shedding - most often while the patient is asymptomatic. Additionally, HSV-2 recurrent infections require suppressive therapy to prevent transmission with a tendency for these infections to develop antiviral resistance. NAATs can assist in patient management for OB-GYN cases in addition to physical examinations, history of HSV-1 or HSV-2 infection, and serology tests to prevent neonatal infection (25, 28). Infants that contract neonatal VZV are at the highest risk when the infection occurs 5 days before and up to 2 days after birth. During this period, maternal infection leads to a 50% risk of transmission and a 20% risk of fatality to the infant. Earlier maternal VZV infections lead to milder symptoms. Infected newborns can develop herpes zoster in their first year of life. Early diagnosis and treatment have been proven to prevent infant fatalities related to neonatal VZV (Figure 11).

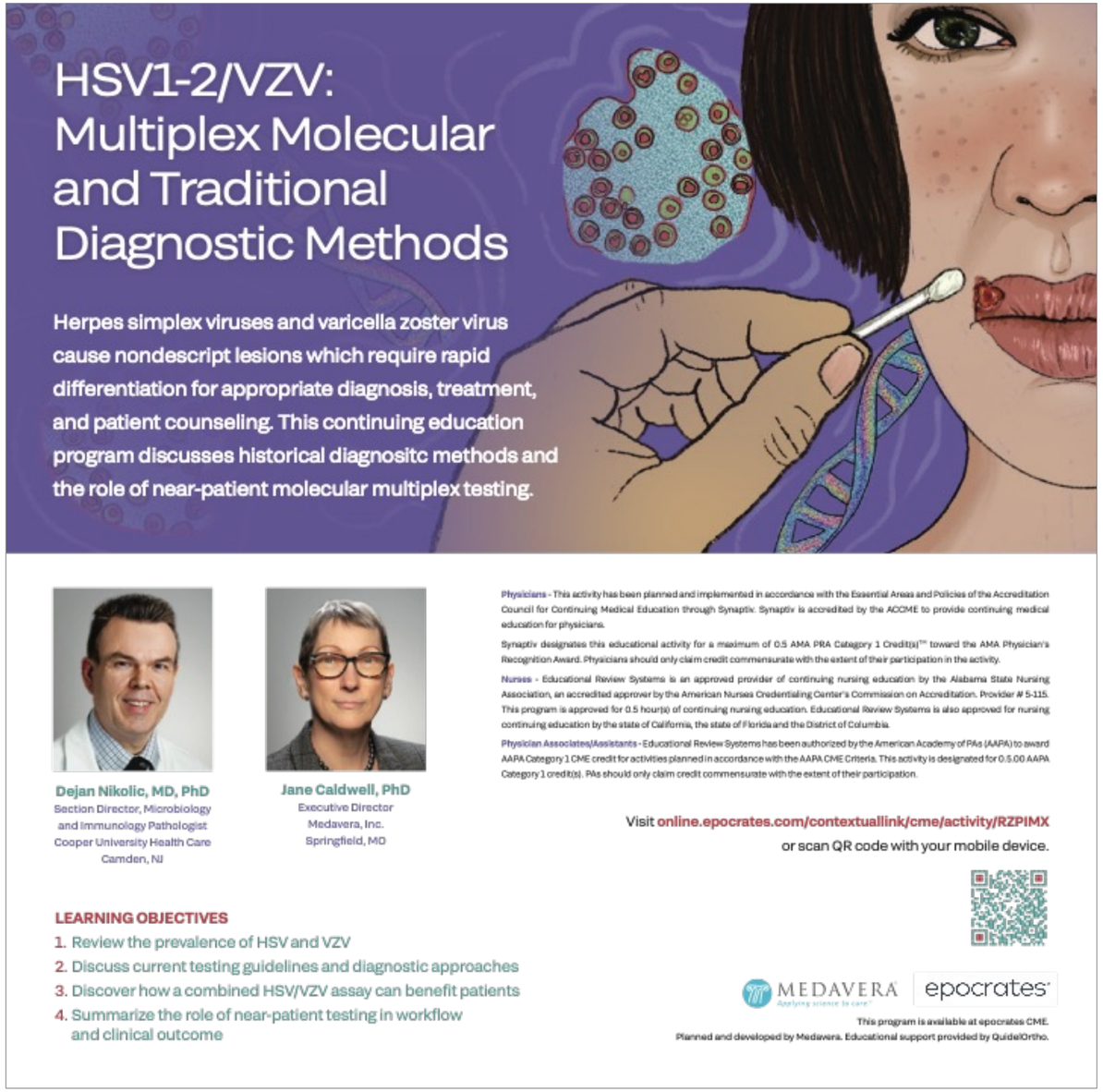
Early diagnosis and treatment of neonatal HSV and VZV can prevent infant fatalities

Neonatal HSV

- Neonatal HSV transmission can occur in the uterus (5%), during the perinatal period (85%), or during the postnatal period (10%).
- HSV-1 infection may be asymptomatic in two-thirds of women.
- 80% of neonates who become infected are born to mothers with no history of genital herpes.
- Disseminated neonatal HSV leads to CNS effects, organ dysfunction, sepsis, and death.
- **Late diagnosis and treatment are associated with high morbidity and mortality.**

Neonatal VZV

- Highest risk period corresponds to a VZV maternal infection contracted just around delivery (−5 days to +2 days).
- During this period, infection without treatment is associated with a 20%–50% risk of transmission and a fatality rate of 20%.
- Infection is mild to moderate in infants exposed to VZV 20 to 5 days before delivery.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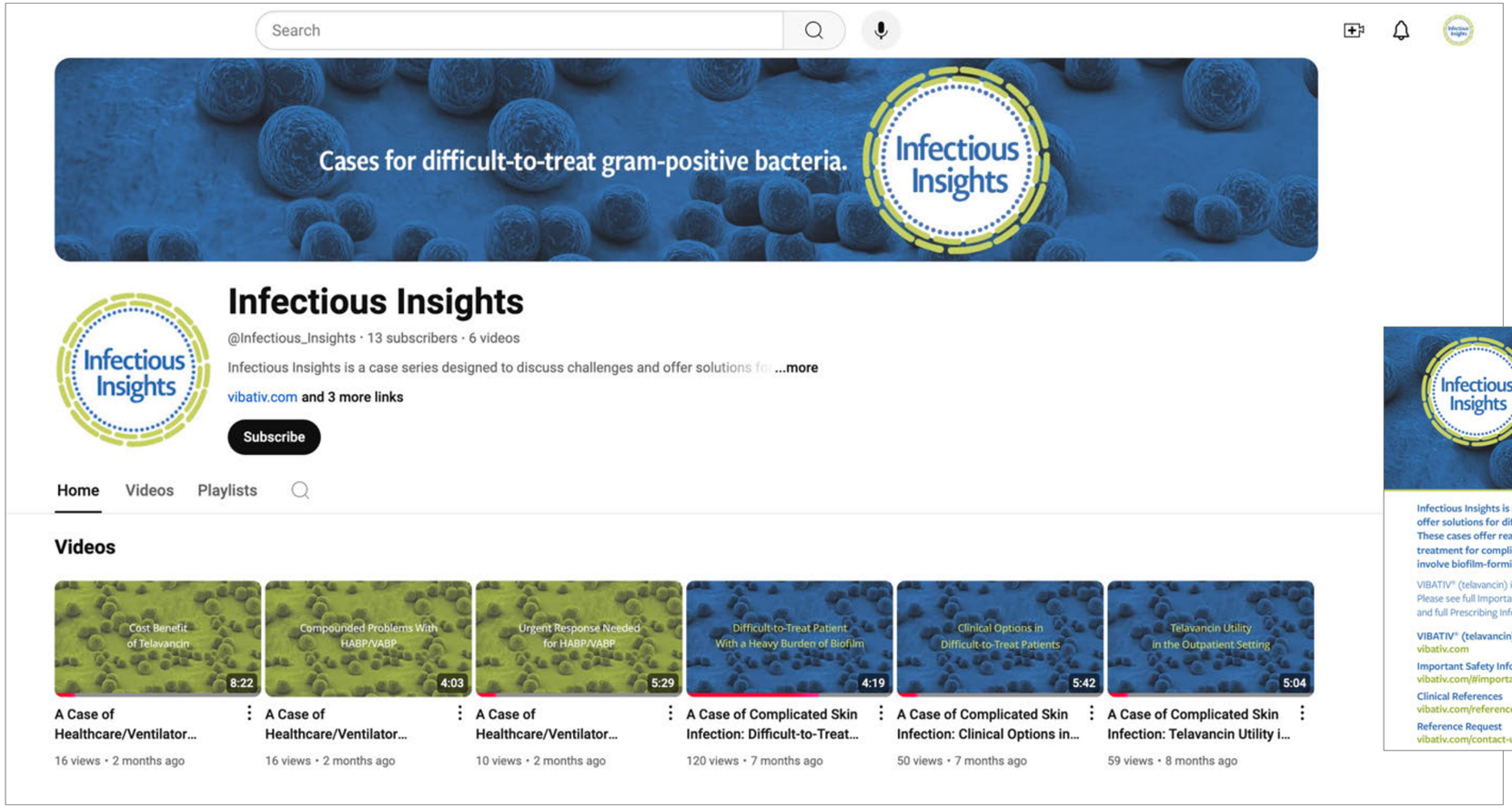
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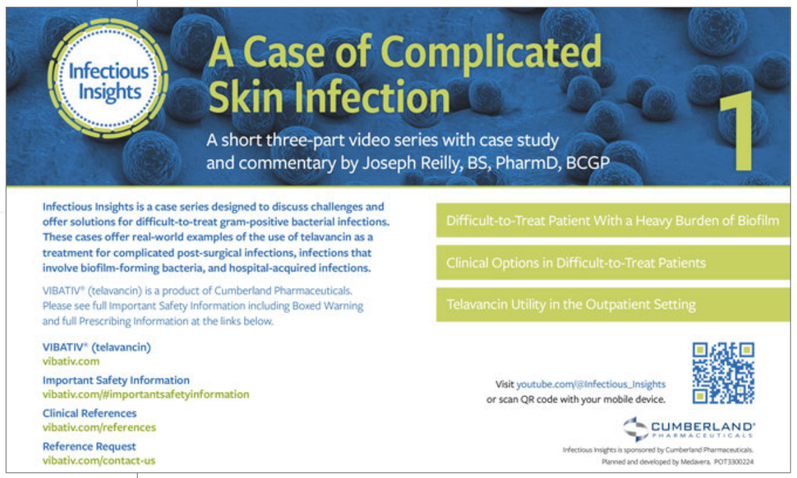
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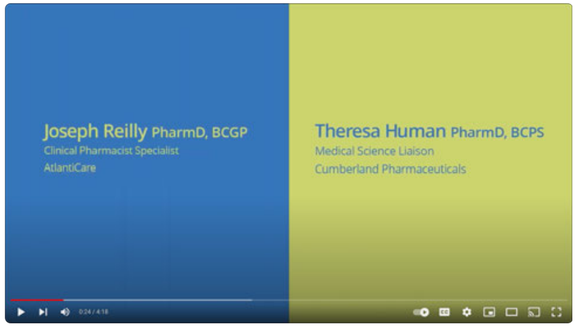
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Validation of the Clinical Performance and Reproducibility of the Savanna HSV 1+2/VZV Assay

Matthew L Faron [1], Jane M Caldwell [2], Lavannya Sabharwal [1], Amorina Purpora [1], Jennifer Meece [3], Puspa Bhattarai [4], Julie O'Neill [4], Melody Christian [4], Neelam X Dhiman [5], Jennifer Halliday [6], Jessica S Hoff [1], Carrie V Vause [7], Paul A Granato [4]

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Abstract

Herpes simplex virus 1 (HSV-1), HSV 2 (HSV-2), and varicella-zoster virus (VZV) cause nondescript cutaneous and mucocutaneous lesions requiring rapid, differential identification for appropriate diagnosis and patient counseling. Decentralized multiplex molecular assays may provide more rapid results than existing methodologies but require clinical validation. This multicenter study evaluated the clinical performance of the Savanna HSV 1+2/VZV Assay against the high-complexity Lyra Direct HSV 1+2/VZV real-time PCR nucleic acid test for the detection of HSV-1, HSV-2, and VZV from clinical specimens. The Savanna HSV 1+2/VZV Assay is an automated, moderate-complexity, real-time PCR assay recently cleared by the US Food and Drug Administration for the simultaneous detection and differentiation of HSV-1, HSV-2, and VZV DNA isolated from lesion swabs. In this study, 744 clinical specimens (531 female, 213 male) were evaluated by Savanna and compared with Lyra. Discrepant result analysis was conducted with the moderate-complexity Solana HSV 1+2/VZV isothermal nucleic acid test. For 744 clinical samples, Savanna exhibited overall, positive, and negative percent agreement of 99.5%, 100%, and 99.3% for HSV-1; 99.9%, 100%, and 99.8% for HSV-2; and 100%, 100%, and 100% for VZV. The Savanna HSV 1+2/VZV Assay exhibited excellent performance in a multicenter, clinical study. Savanna can provide laboratory-equivalent results outside of the central laboratory with the potential to deliver accurate results during the patient visit.

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Rapid diagnosis of acute pediatric respiratory infections with Point-of-Care and multiplex molecular testing

Jane M Caldwell [1], Claudia Mily Espinosa [2], Ritu Banerjee [3], Joseph B Domachowske [4]

Affiliations + expand

PMID: 40418273 PMCID: PMC12234638 DOI: 10.1007/s15010-025-02553-5

Erratum in

Correction: Rapid diagnosis of acute pediatric respiratory infections with Point-of-Care and multiplex molecular testing.

Caldwell JM, Espinosa CM, Banerjee R, Domachowske JB.

Infection. 2025 Jun;53(Suppl 1):15. doi: 10.1007/s15010-025-02593-x.

PMID: 40587050 Free PMC article. No abstract available.

Abstract

Acute infections of the respiratory tract are very common in pediatric patients, with an estimated global incidence of 17.2 billion cases in 2019. Accurate and timely diagnosis and treatment of acute respiratory infections can prevent progression to more serious pathologies, especially in the young, elderly, immunocompromised, and other high-risk groups. Due to the significant increase in the number of multiplex molecular tests available, there are now many diagnostic options which generate results within minutes or hours, many of which can be performed at point-of-care or near-patient rather than being sent out to a centralized laboratory. Rapid molecular single- or multiplex testing conducted at point-of-care or near-patient offers the potential to improve timely and accurate diagnosis, decrease inappropriate antibiotic use, decrease reliance on chest radiographs, improve timely antiviral administration, reduce the length of hospital stay, reduce the number of clinical visits, and, ultimately, improve patient outcomes. Optimal use of user-friendly multiplex

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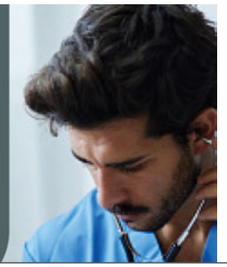
QuidelOrtho

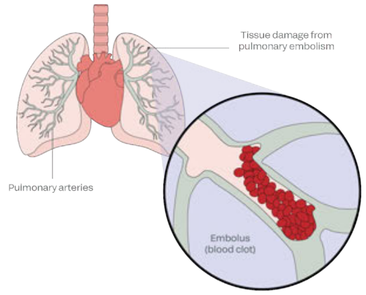
The Right D-Dimer



Suspected DVT or PE?

Symptoms of deep vein thrombosis (DVT) and pulmonary embolism (PE) can be confounding but the right test is available.

The Quidel Triage D-Dimer Test offers trusted results at the point of care assisting with a time-efficient and potentially life-saving diagnosis.



A whole blood rapid D-dimer test is associated with a shorter emergency department (ED) length of stay (LOS) and improved clinical decision making.[2] DVT and PE diagnostic strategies that include D-dimer testing are more cost-effective for hospitals and patients.[3-4]

Common and deadly

25%
Sudden death is the first symptom in about one-quarter of people who have a PE.[1]

1/3
One third of people with DVT or PE will have a recurrence within 10 years.[1]

900,000
Almost a million people could be affected by DVT or PE each year in the United States.[1]

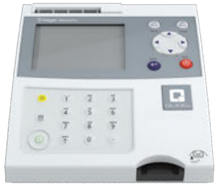
60,000 - 100,000
Up to 100,000 Americans die of DVT/PE each year.[1]

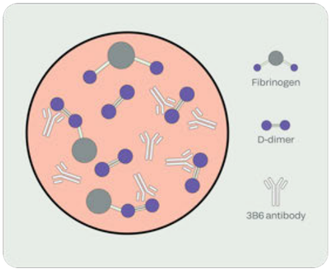
33% - 50%
One third to one half of people who have had a DVT, will have long-term complications in the affected limb.[1]

Quidel Triage D-Dimer Test

A rapid, quantitative immunoassay.

- Performed on the Quidel Triage MeterPro[®S]
- Results in approximately 20 minutes[5]
- Uses highly sensitive fluorescence immunoassay (FIA) technology[5]
- Utilizes the preferred and specific 3B6 D-dimer antibody[5-6]





The right antibody. The right test.

- Antibody specificity plays a significant role in distinguishing D-dimer from other fibrin degradation products (FDPs).[5-6]
- The Quidel Triage D-Dimer Test utilizes the highly specific 3B6 monoclonal antibody for cross-linked D-dimer.[5-6]
- The 3B6 antibody detects only cross-linked FDPs for accurate measurement of the sample.[5-6]

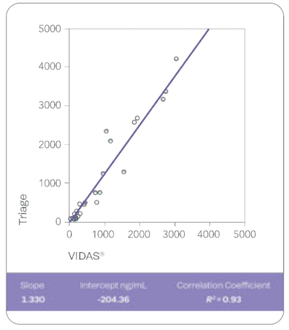
Available D-dimer assays have varying sensitivities.[7-9] Assays like Quidel Triage D-Dimer Test use capture and detection antibodies for higher sensitivity than latex agglutination.[8]

Triage fluorescence immunoassay technology with 3B6 D-dimer antibodies create a point-of-care test that compares favorably to the "gold standard" VIDAS® assay.[10]

- Diagnostic agreement: ≥ 93%
- Analytic correlation: $R^2 = 0.93$

The rapid whole blood Triage D-Dimer Test compares favorably with the Vidas and is especially well suited for applications at the point of care.[10]

The Quidel Triage D-Dimer Test vs. VIDAS[10]

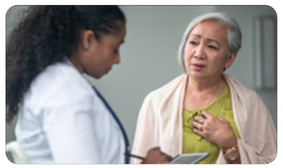


Slope	Intercept ng/mL	Correlation Coefficient
1.330	-204.36	$R^2 = 0.93$

Intended Use

The Triage D-Dimer Test is a fluorescence immunoassay to be used with the QuidelOrtho Triage Meters for the quantitative determination of cross-linked fibrin degradation products containing D-dimer in EDTA whole blood and plasma specimens.[5]

The Triage D-Dimer Test is used as an aide in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation or thromboembolic events including pulmonary embolism and deep vein thrombosis.[5]



Detect HF early in patients at risk

You offer the first line of defense in the battle against HF. With early detection, leading to early treatment, you have the opportunity to have a profound impact on your patients' health. And with the accurate, easy-to-use Quidel Triage BNP Test, that detection can take place within minutes—right in your office.

CLIA-Waived Quidel Triage BNP Test

Evaluation at the point of care

The Quidel Triage BNP Test is the only CLIA-waived assay that meets ADA guidelines for BNP testing.[5-7]

Quidel Triage®
BNP Test

The right test for heart failure

The Quidel Triage® BNP Test can determine the status of their heart at the point of care.

Since 1988, B-type natriuretic peptide (BNP) has been used to evaluate patients who present with shortness of breath or suspected heart failure (HF).[1-2]

Obtaining a BNP for suspected cardiac causes of dyspnea provides diagnostic value especially when the cause is unclear and the physical examination is equivocal.[3]

Heart failure is a complication of diabetes.

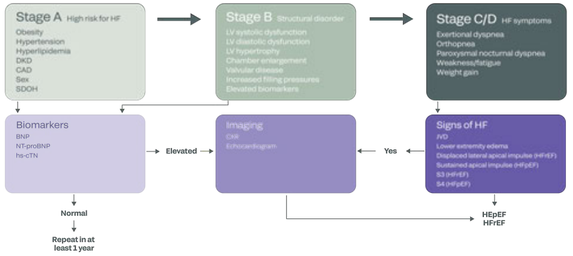
Diabetes is an epidemic. Lifetime risk for HF can be as high as 10.8% in patients with prediabetes and 32.4% with diabetes.[4] BNP has a clear role in assessing cardiovascular complications in these patients.

In patients with diabetes...

- HF can develop without hypertension, coronary or valvular disease.[5]
- HF may be the first presentation of cardiovascular disease.[5]
- HF represents a major cardiovascular complication with lifetime risk.[4]

In 2024, the American Diabetes Association (ADA) updated their Standards of Care to recommend annual HF screening:

"The committee recommends considering screening asymptomatic adults with diabetes for the development of cardiac structural or functional abnormalities (stage B heart failure) by measurement of natriuretic peptides, including BNP or NT-proBNP levels."[6]



QuidelOrtho

Case Study

Sponsored by an educational grant from QuidelOrtho

Transforming Access to Care:

Starting a Test-and-Treat Program in Your Pharmacy

Duane Jones, BS Pharm, PD
Regional Pharmacy Supervisor
Clinical Program Director
~ *Harps Food Stores, Inc.*
Residency Site Coordinator
~ *UAMS College of Pharmacy*

Jennifer Griffin, PharmD, MS
Clinical Pharmacist
~ *Pharmacy Division of Harps Food Stores, Inc.*

- **On average, patients see pharmacists in their pharmacy 33 times a year, but visit their primary care physicians only three times a year.**[1]
- **Pharmacy test-and-treat programs provide access to care and follow protocols to ensure antibiotic stewardship which helps reduce the risk of antibiotic resistance.**
- **Establishing the right workflow allows pharmacists to test and treat and improve outcomes.**

The journey toward pharmacy test-and-treat

Duane Jones has
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and test-and-treat

1. How Community Pharmacies Enable Health Plans to Measurably Improve Adherence and Quality Measures. EnliveHealth. Published October 29, 2020. Accessed May 27, 2025. https://enlivehealth.co/blog/power-of-community-pharmacies-to-improve-adherence-and-quality-measures/
2. New Analysis Suggests Adverse Drug Events Are the 3rd Leading Cause of Death in the USA. Practicalneurology.com. Published March 26, 2025. Accessed June 9, 2025. https://practicalneurology.com/news/new-analysis-suggest-adverse-drug-events-are-the-3rd-leading-cause-of-death-in-the-usa/2473820/

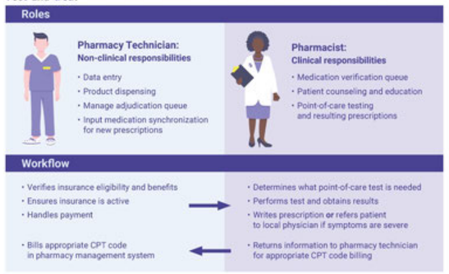
Case Study

Sponsored by an educational grant from QuidelOrtho

> *"...it can be time consuming on the front end when you're developing your process. But once your system is in place and your team is trained, it becomes a smooth and sustainable workflow."*
>
> Jennifer Griffin, PharmD, MS

data entry, product dispensing, and managing the adjudication queue. Another key part of the workflow is medication synchronization that allowed Harps to transition a majority of their prescription workload from acute to scheduled, so pharmacists have more flexibility to step away from the verification queue when they need to see a patient.

Test-and-treat

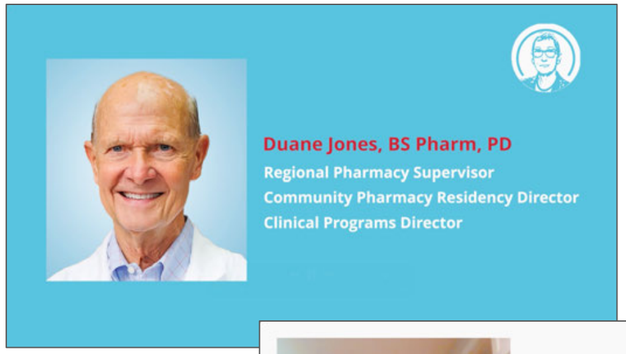


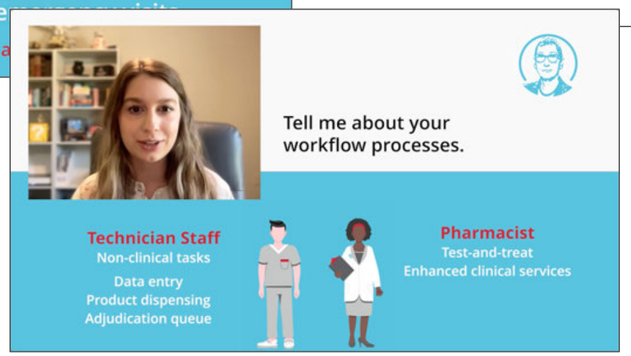
Promoting pharmacy sustainability through reimbursement

For many pharmacies, billing and obtaining insurance reimbursement for patient testing, treatment and counseling can be very time consuming and frankly onerous. To address the reimbursement barrier at Harps, Jennifer has streamlined reimbursement and explained their process: "To be honest, it can be time consuming on the front end when you're developing your process. But once your system is in place and your team is trained, it becomes a smooth and sustainable workflow." At Harps pharmacies, they discovered a way to bill medical claims through their pharmacy management system to help streamline the claim creation and submission process. In a nutshell: When a patient enters the pharmacy for a test-and-treat service, a technician takes their insurance card and verifies eligibility and benefits. They make sure the patient's insurance is active on the date of service and they verify what kind of copay deductible or co-insurance the patient may have. Then they collect that amount, the patient receives the service, and the patient is on their way to feeling better. The technician completes the interaction when they bill the appropriate CPT code in the pharmacy management system.

Duane and Jennifer want to share this workflow with other pharmacies to help them build their process, empower their staff, and make reimbursements totally manageable. But will this make community and independent pharmacies more sustainable? "Yes!" according to Jennifer. "It really comes down to getting more payers on board. The more payers that we have that recognize and reimburse us for the value of these services offered in the pharmacy setting, the more successful and sustainable we will be." This workflow is described as win-win. The patients receive fast, convenient access to care, and pharmacy viability and sustainability are supported. Duane recommends the National Community Pharmacists Association (NCPA)[6] and the Community Pharmacy Enhanced Services Network (CPESN)[7] for resources on implementing test-and-treat programs and to find out about individual state laws governing pharmacists and reimbursement. Pharmacies will have to contact their Department of Health to inquire about reporting requirements and CLIA waiver, and then will have to ensure both the pharmacist and pharmacy are credentialed by the various payers.

6. NCPA - National Community Pharmacists Association. Accessed May 27, 2025. https://ncpa.org
7. Community Pharmacy Enhanced Services Network CPESN. Cpesn.com. Accessed May 27, 2025. https://cpesn.com





How Pharmacists Implemented a Test-to-Treat Program and Transformed Access to Care

OMG OnMedicalGrounds

PODCAST 48

00:00
Dr. Jane Caldwell
Hi, I'm your host, Jane Caldwell. Welcome to the *On Medical Grounds* podcast, your source for engaging, relevant, evidence-based medical information. Today, we'll discuss how pharmacy point-of-care test-and-treat programs can improve access to care, and how one pharmacy group instituted a testing and billing workflow that simplified reimbursements.

Let me introduce our first guest, Dr. Duane Jones. Dr. Jones serves multiple functions for the Pharmacy Division of Harps Food Stores. He is the regional pharmacy supervisor, community pharmacy residency director, and clinical programs director for this, the largest employee-owned company in Arkansas with 151 supermarkets in Arkansas and the surrounding states of Oklahoma, Missouri, Kansas, Mississippi, and Louisiana. Dr. Jones was a 2022 Luminary of the Year and past chairman of the Community Pharmacy Enhanced Services Network in Arkansas. He is an adjunct assistant professor at the University of Arkansas for Medical Sciences College of Pharmacy, and program director for the MTM The Future Today, which provides team-based training programs for pharmacists and pharmacy technicians. Dr. Jones was Arkansas Pharmacists Association's 2019 Pharmacist of the Year. Dr. Jones's professional experience includes community pharmacy, home infusion and compounding, hospice, nursing home consulting, and community clinical pharmacy.

Hello, Dr. Jones. Thank you for joining us today.

Duane Jones

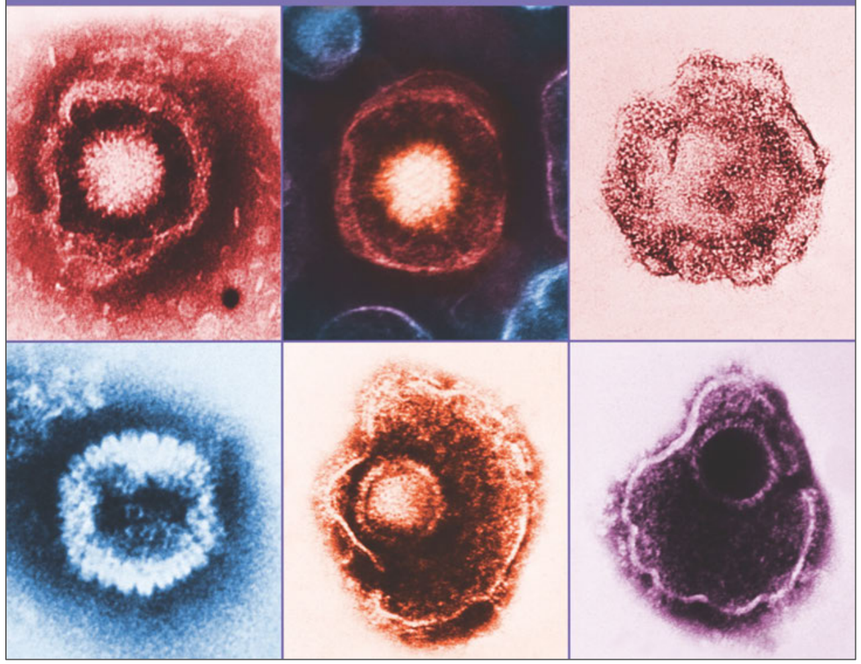
having me. It's a pleasure to be here.

nnifer Griffin. Dr. Griffin is a clinical pharmacist for Harps food stores where she
ling, point-of-care testing, treatment workflow, and marketing clinical services.
f Pharmacy degree from Harding University College of Pharmacy, Bachelor of
inistration and a Master of Science in Health Promotion from the University of
s written for NCPA's *America's Pharmacists Magazine* and participates in the CPESN
am. She also serves on the CPESN USA Network Development Committee as a

n Medical Grounds.

HSV & VZV Lesions: Diagnostic Challenges and Multiplex Solutions

A case-based educational monograph
Educational support provided by QuidelOrtho



Case Report: Suspected HSV in a Woman of Color

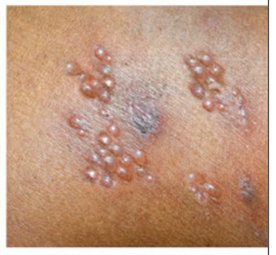
Jessica Dalby, MD

Patient Presentation

A 55-year-old Black woman presented to her primary care physician with a rash on her right buttock that began the day before accompanied by itching and burning. She had not had similar symptoms previously. She was diagnosed with Stage 1 hypertension at a wellness check 6 months prior and was incorporating lifestyle changes in lieu of starting medications at her request. She had been divorced for 10 years and had 2 new sexual partners in the past 12 months. She had undergone routine STI screening at her appointment 6 months ago without evidence of infection. At the time of the current visit, the patient stated that the rash had become increasingly itchy and painful over the last 24 hours and that she had noted some itching in the area before noticing the rash but couldn't confirm an exact timespan.

The patient's blood pressure was mildly elevated at 132/84, she was afebrile and other vital signs were normal. A pelvic exam revealed a rash on the right buttock near

midline with a collection of violaceous papules and a few vesicles. No genital or rectal lesions were present. The patient reported discomfort to touch of the lesion on her buttock.



Further discussion with the patient revealed that she had unprotected sex with one partner two weeks prior and had noticed abnormal fatigue over the last 48 hours. The physician informed the patient that this could be HSV and she was shocked to hear this possibility. She requested laboratory confirmation. A vesicle was unroofed with a sterile scalpel and a swab was used to sample the base of the lesion and sent to the physician office lab for analysis with a multiplex molecular panel containing HSV-1, HSV-2, and VZV. The patient decided to wait the required 30 minutes for her results so she did not have to wait for a call or make an additional appointment. At this time, blood was drawn for a basic metabolic panel to rule out other causes for her fatigue as well as a complete blood count.

Lab Results

Basic Metabolic Panel

Test Name	Result	Reference Range
Sodium	141	136 - 144 mmol/L
Potassium	4.2	3.7 - 5.1 mmol/L
Chloride	101	98 - 107 mmol/L
Calcium	9.3	8.5 - 10.2 mg/dL
Bicarbonate	28	22 - 30 mmol/L
Glucose	91	74 - 99 mg/dL
Blood Urea Nitrogen	14	7 - 21 mg/dL
Creatinine	0.83	0.58 - 0.96 mg/dL

Complete Blood Count

Test Name	Result	Reference Range
WBC	9.8	4 - 10 k/mcL
RBC	5.2	4 - 5.4 mill/mcL
Hgb	15.2	11.5 - 15.5 g/dL
Hct	42	36-68%
MCV	91	20 - 100 fL
MCH	29	27 - 31 pg
MCHC	34	32 - 36 g/dL
Platelet	320	150 - 400 k/mcL

HSV1+2/VZV

Test Name	Result
HSV-1	Negative
HSV-2	Negative
VZV	**Positive**

Diagnosis

The patient was notified that her rash lesions were positive for the presence of VZV. When asked, the patient reported that she had varicella infection as a child, but it had been very mild, so she had not felt the need to get a shingles vaccination. Because the patient was within the 72-hour effective treatment window, she was prescribed a course of acyclovir and educated about shingles.

Key Learning Points

- The patient is a woman of color. The lesions were violaceous papules with a few vesicles, an atypical presentation compared to standard descriptions of HSV that are based on lighter skin tones.
- Women of color have the highest rates of HSV-2 in the U.S., frequently leading providers to empirically diagnose HSV in this patient population.
- Empiric treatment and presumption of HSV is likely to lead to patient emotional distress, affecting current and future sexual relationships. Empiric treatment without verification may influence a patient to use fewer precautions if she has a partner with known HSV.
- Multiplex molecular testing allowed for a rapid turnaround time, inclusion of other lesion-causing pathogens, and assurance to the patient that she did not need long-term antiviral medication to prevent recurrence.

POCT

POINT OF CARE TESTING UNIVERSITY

Home

Educational Resources for Innovative Technologies

POINT OF CARE TESTING UNIVERSITY or POCT "U" provides educational resources related to the use and implementation of point-of-care medical technologies. Programs with continuing education credits are available as well as teaching materials and other resources for you—all to support providers in their efforts to deliver quality health care.

FREE access below:

- CME/CE credits
- Self-study programs
- Webinars
- Podcasts
- Downloadable educational materials
- External guidelines and resources

Critical Care +

Primary Care +

Personal Health
COMING SOON

Resources +

Webinar

The Path to Painless Point-of-Care Implementation: Training, Competency, & Quality Control
Self-study online course - Physicians, Nurses, Respiratory therapists, and Laboratory professionals
View — CME/CE

The Path to Painless Point-of-Care Implementation
Self-study online course - Physicians, Nurses, Respiratory therapists, and Laboratory professionals
View — CME/CE

Blood Gas

Self-Study

SEPSIS: Diagnosing and Managing Sepsis Syndrome - The Emerging Role of Bedside Analyte Testing
Self-study online course - Physicians, Nurses, Respiratory therapists, and Laboratory professionals
View — CME/CE

CREATININE: Significance and Applications for Rapid Creatinine Testing
Self-study online course - Physicians, Nurses, Respiratory therapists, and Laboratory professionals
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VAP: Diagnosing and Managing Ventilator-Associated Pneumonia
Self-study online course - Physicians, Nurses, Respiratory therapists, and Laboratory professionals
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Podcasts

Medical Mystery Cases - A Bird's Eye View
October 31, 2023
Listen — CME/CE

Medical Mystery Cases - A Rocky Start
October 12, 2023
Listen — CME/CE

Medical Mystery Cases - An Urgent Discovery
October 20, 2022
Listen

Latest Webinar: Diabetes Dilemmas: CGM, A1c Measurements, & New Management Strategie

POCT

POINT OF CARE TESTING UNIVERSITY

Home

The Path to Painless Point-of-Care Implementation: Training, Competency, & Quality Control

In a follow-up to our previous webinar with Dr. Marcia Zucker, she joins POCTU again in this three-part short webinar series to share her in-depth knowledge of CLIA regulations and provide detailed information on training requirements, competency assessment, and quality control required for instituting point-of-care tests. Each part of this webinar series can provide 0.5 hours of continuing educational credits for physicians, nurses, respiratory therapists, and laboratory professionals for a total of 1.5 credit hours.

Part 1

Part 2

Latest Webinar: The Path to Painless Point-of-Care Implementation: Training, Competency, & Quality Control | Latest Webinar: The Path to Pa

POCT

POINT OF CARE TESTING UNIVERSITY

POCT Urinalysis: Rapid Window to Patient Health

In-office clinical benefits:

→ Convenient, reliable screening
→ Aids diagnosis
→ Monitor & evaluate treatment
→ No loss to follow-up

In-office testing allows physicians to consult with patients and determine next steps all in one visit.

Screening At-Risk Groups Leads to Early Identification

- Diabetes
- Chronic Kidney Disease
- Heart Disease
- Liver Disease
- Urinary Tract Infections
- Pregnancy

Screening to Improve Health Equity

Social determinants of health lead to healthcare disparities.

Race/ethnicity plays a role in health and diagnosis.

Urinalysis is a rapid and cost-effective way to screen for diabetes, kidney disease, heart disease, liver disease, and other conditions in those most affected by healthcare disparities.

Connectivity With Analyzers Improves Performance

- Remove subjectivity
- Reduce test time
- Eliminate transcription errors
- Improve documentation

POCT Urinalysis Analyzers Are Beneficial to Current Users

75% Agree improves performance

100% Say useful in daily work

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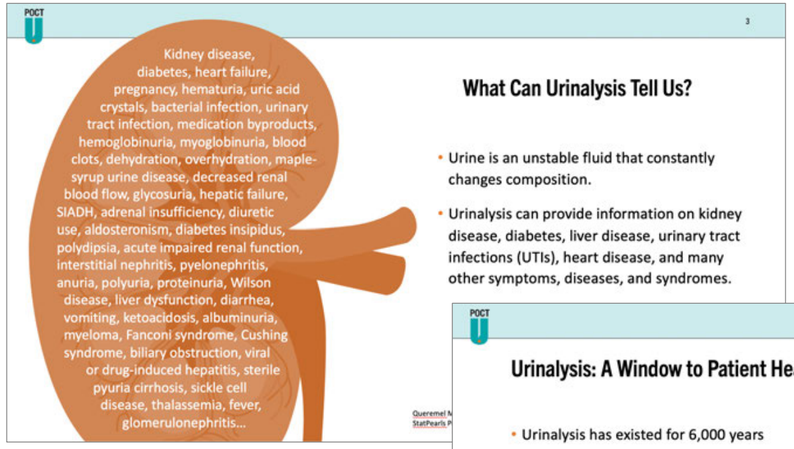
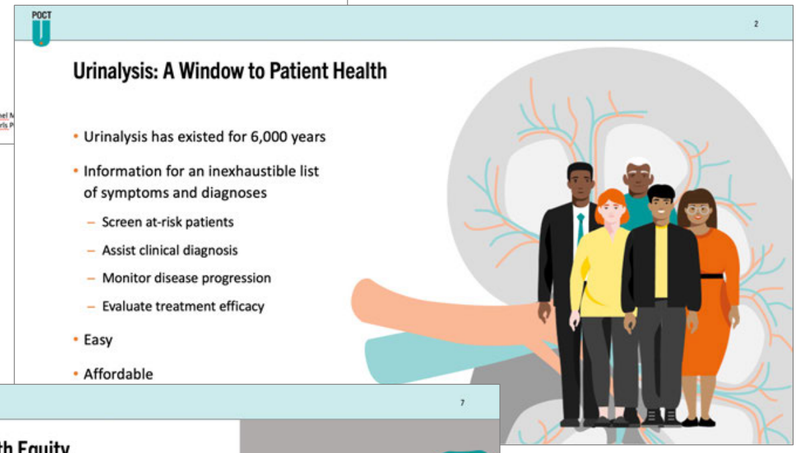
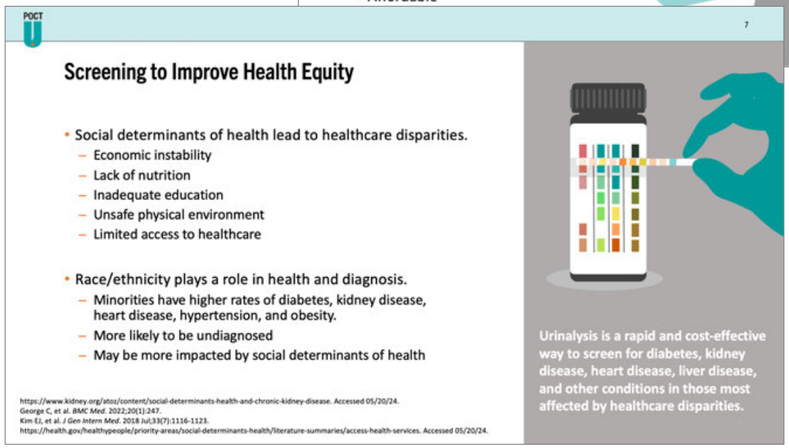
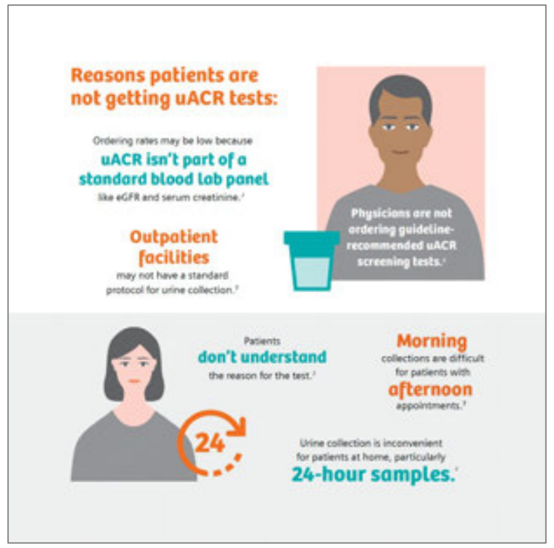
Planned and developed by Medavera. Educational support provided by Siemens Healthineers.

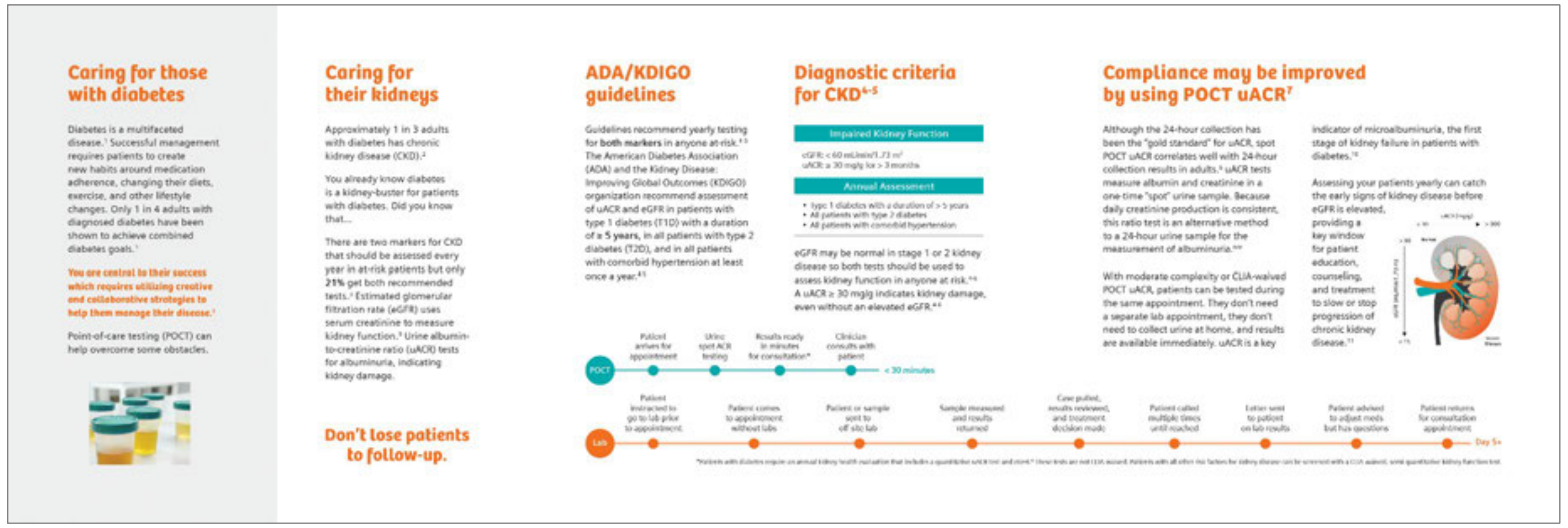


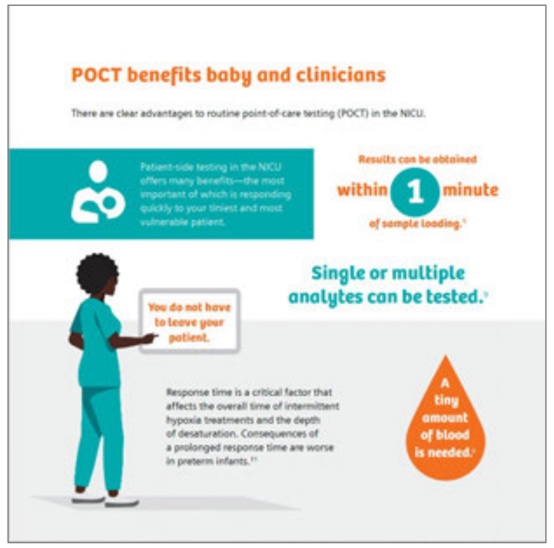


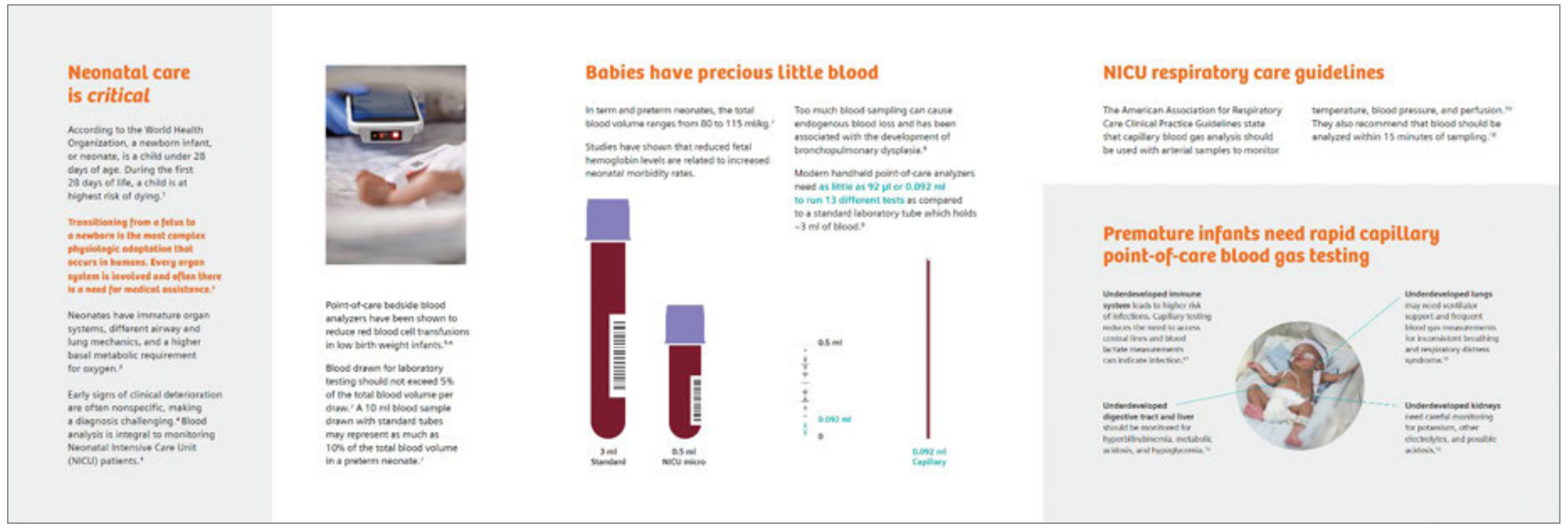


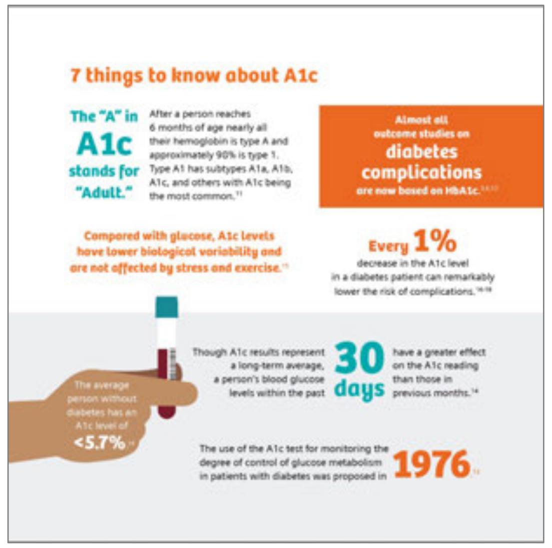

Point of Care
Patient-Side
Kidney Testing
SIEMENS
Healthineers
Point of Care
Patient-Side
NICU Testing
Point of Care
Patient-Side
Hemoglobin
A1c Testing

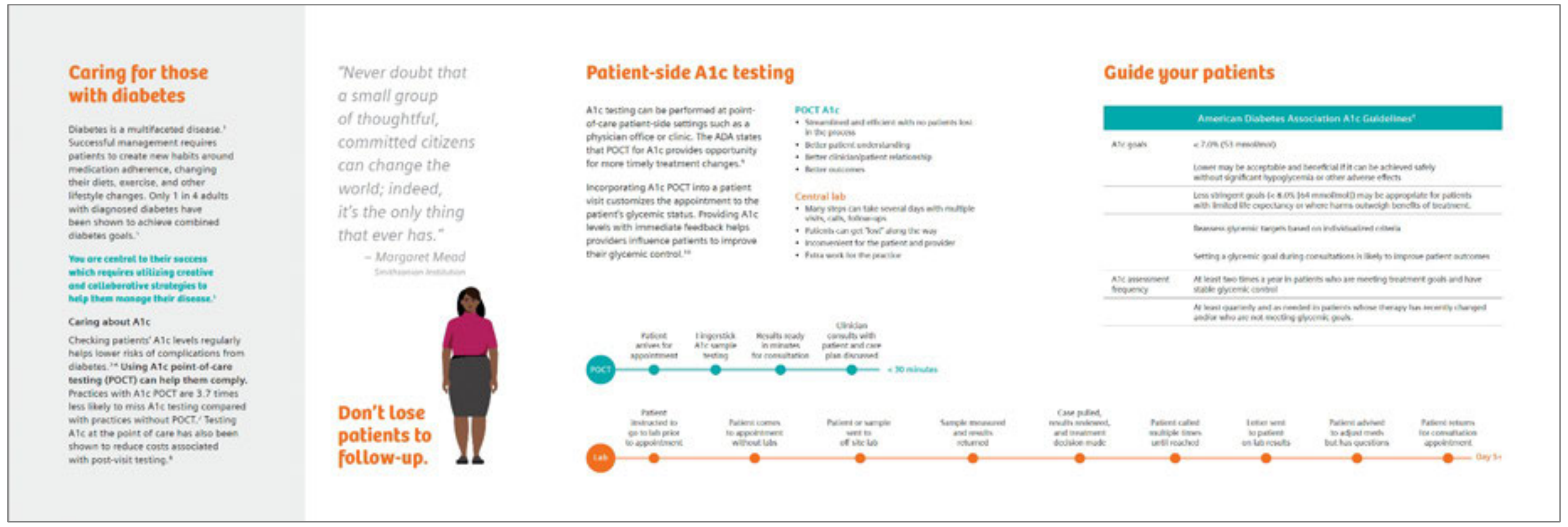

Reasons patients are not getting uACR tests:
uACR isn't part of a standard blood lab panel
Outpatient facilities
Physicians are not ordering guideline-recommended uACR screening tests.
don't understand
Morning
afternoon
24-hour samples.

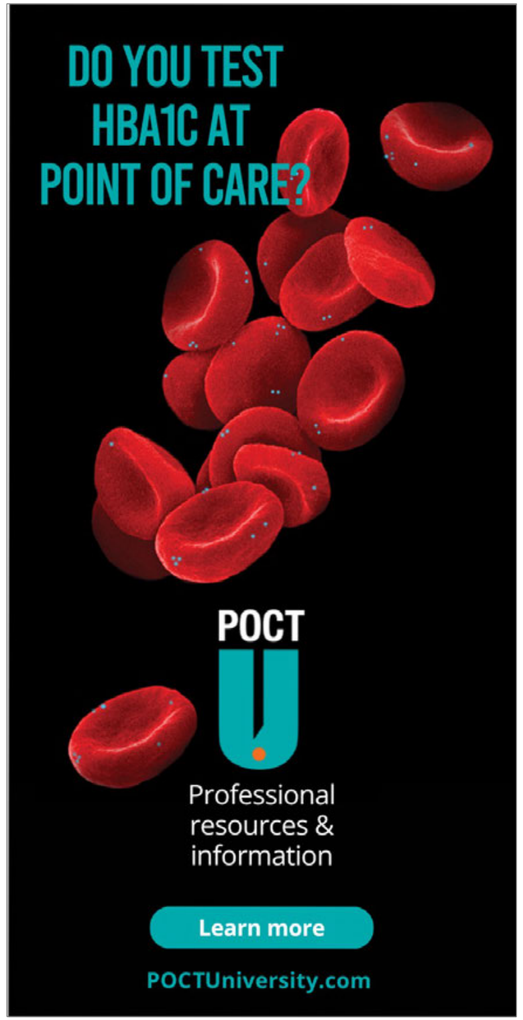

Caring for those with diabetes
Caring for their kidneys
ADA/KDIGO guidelines
Diagnostic criteria for CKD
Compliance may be improved by using POCT uACR
Don't lose patients to follow-up.


POCT benefits baby and clinicians
within 1 minute
Single or multiple analytes can be tested.


Neonatal care is critical
Babies have precious little blood
NICU respiratory care guidelines
Premature infants need rapid capillary point-of-care blood gas testing


7 things to know about A1c
A1c
diabetes complications
Every 1%
30 days
1976


Caring for those with diabetes
Patient-side A1c testing
Guide your patients
Don't lose patients to follow-up.


DO YOU TEST HBA1C AT POINT OF CARE?
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Professional resources & information
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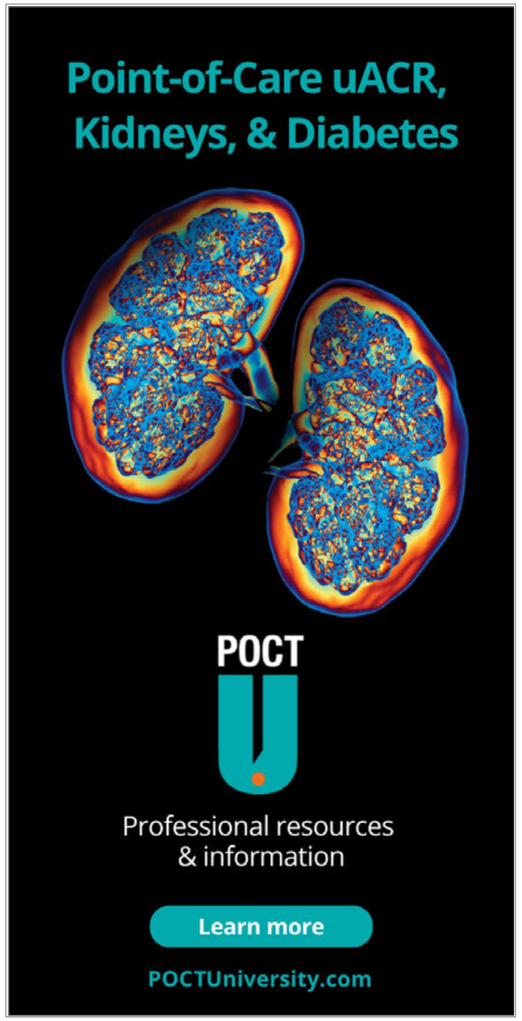
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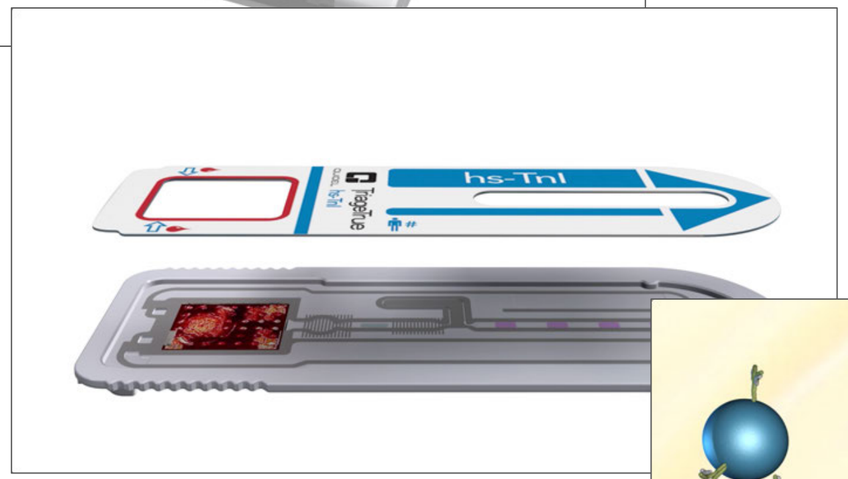
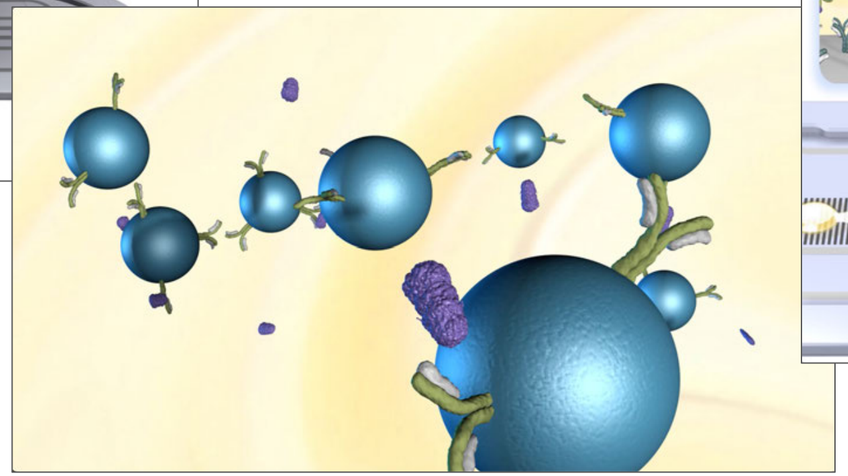
Advanced microfluidics



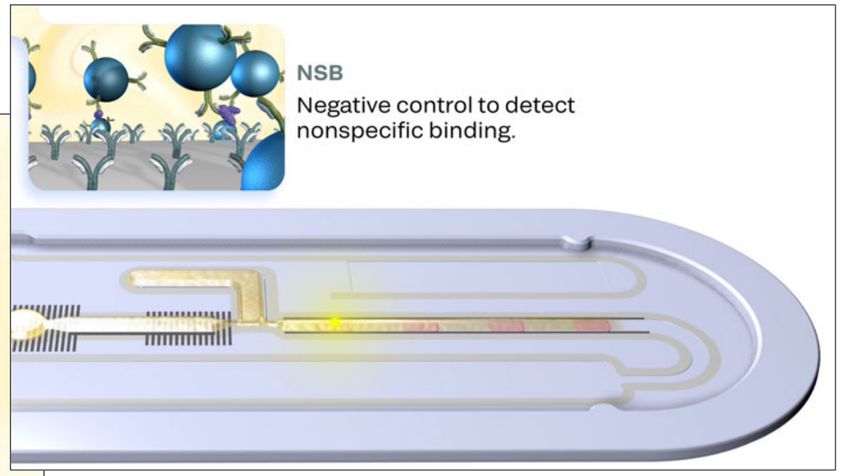


2019

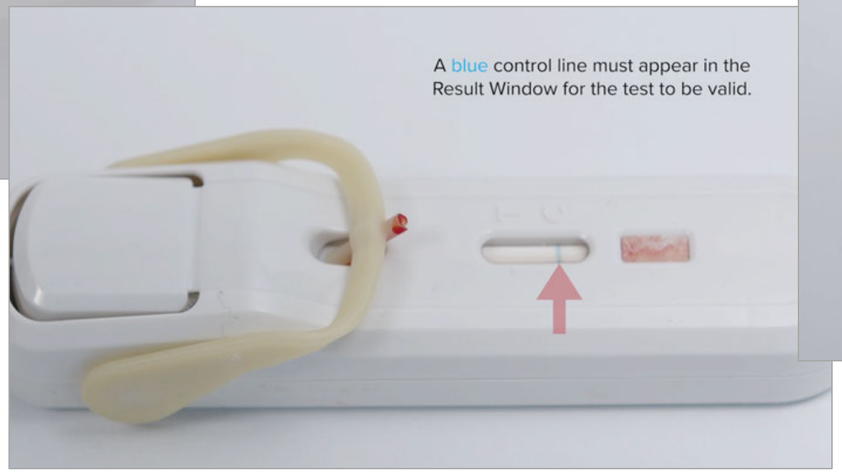
Quidel Triage™

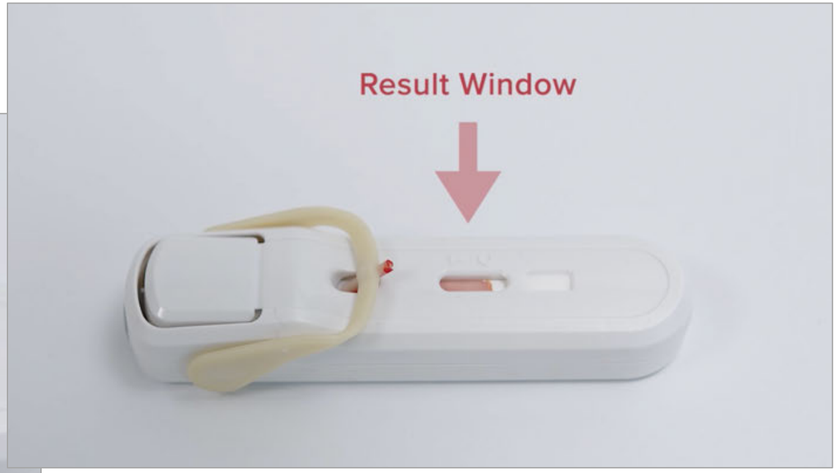
MeterPro™

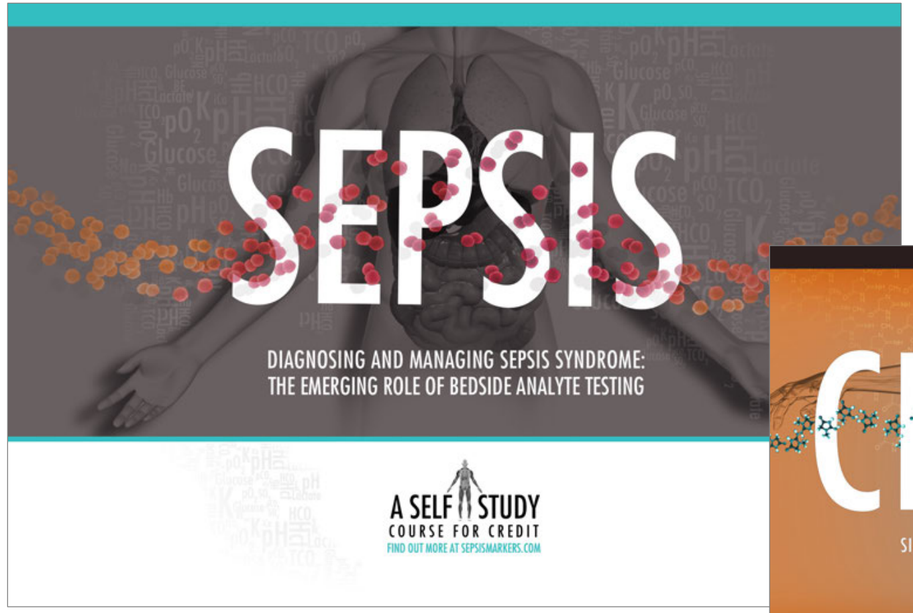
FDA cleared
updated system

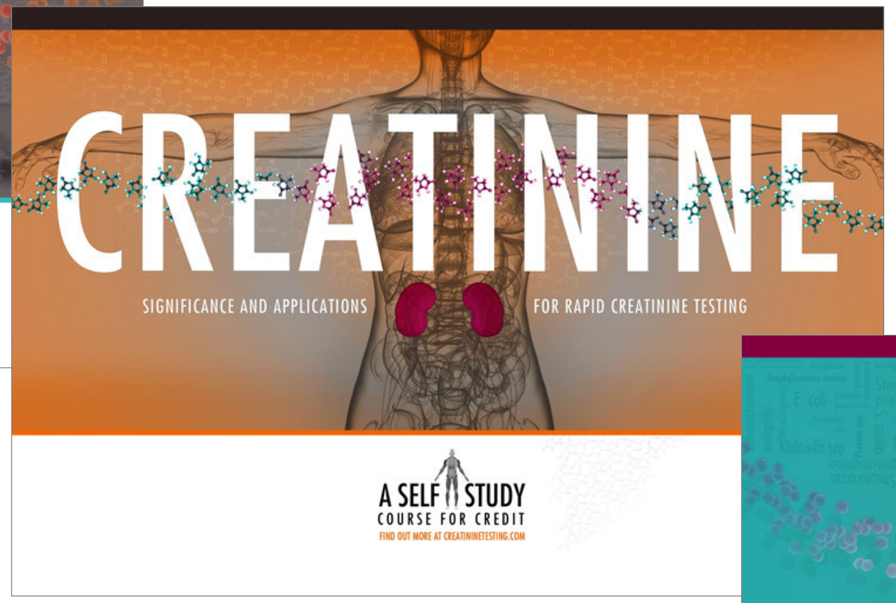


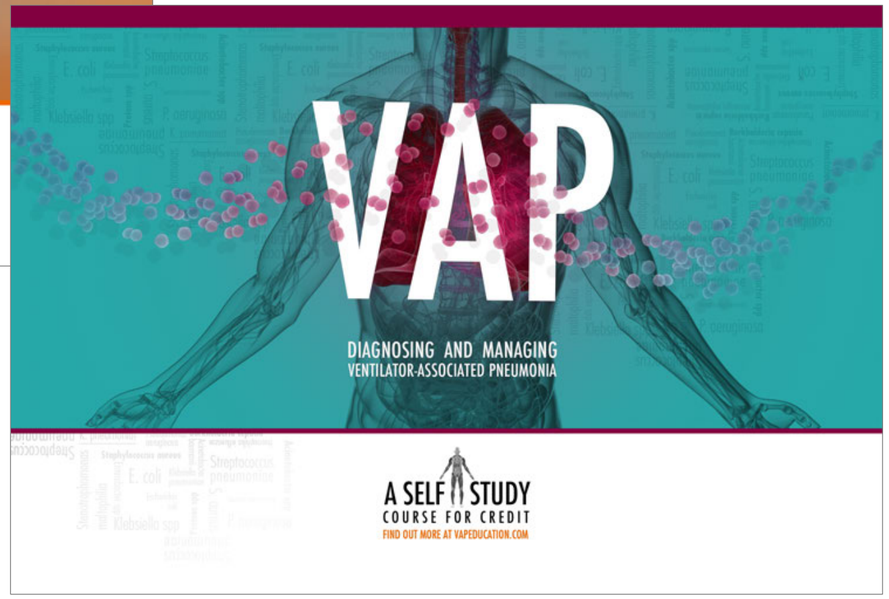

FebriDx
FebriDx
FebriDx
Materials Provided:
25 Single Use FebriDx® Tests
1 Package Insert
1 Quick Reference Instructions
You Will Also Need:
Timer
Gloves
Alcohol Pad
Gauze
Band-Aid®


A blue control line must appear in the
Result Window for the test to be valid.


Result Window


SEPSIS
DIAGNOSING AND MANAGING SEPSIS SYNDROME:
THE EMERGING ROLE OF BEDSIDE ANALYTE TESTING
A SELF STUDY
COURSE FOR CREDIT
FIND OUT MORE AT SEPSISMARKERS.COM


CREATININE
SIGNIFICANCE AND APPLICATIONS
FOR RAPID CREATININE TESTING
A SELF STUDY
COURSE FOR CREDIT
FIND OUT MORE AT CREATININETESTING.COM


VAP
DIAGNOSING AND MANAGING
VENTILATOR-ASSOCIATED PNEUMONIA
A SELF STUDY
COURSE FOR CREDIT
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UPDATED CONTENT
SEPSIS
DIAGNOSING AND MANAGING SEPSIS SYNDROME:
THE EMERGING ROLE OF BEDSIDE ANALYTE TESTING
View Learning Activity
CME Self-Assessment
Download Slide Set
This self-study course will provide current information on the role of sepsis biomarkers and bedside analyte testing in improving the prognosis for patients with sepsis.
Sepsis is an overwhelming immune response to an infection. It kills more than 250,000 Americans each year and is becoming more common, especially in the hospital. Sepsis is a medical emergency that can be difficult to define, diagnose, and treat, but every minute counts in the effort to save lives.
This is an accredited self-study learning activity.
Click on View Learning Activity to study the slides and notes. When you are finished studying, you many click on CME Self-Assessment and complete the post-test and evaluation. Follow the instructions for achieving CME credit. You may also download the slide set to have for your files.
A SELF STUDY
COURSE FOR CREDIT
SEPSIS
DIAGNOSING AND MANAGING SEPSIS SYNDROME:
THE EMERGING ROLE OF BEDSIDE ANALYTE TESTING
A SELF STUDY
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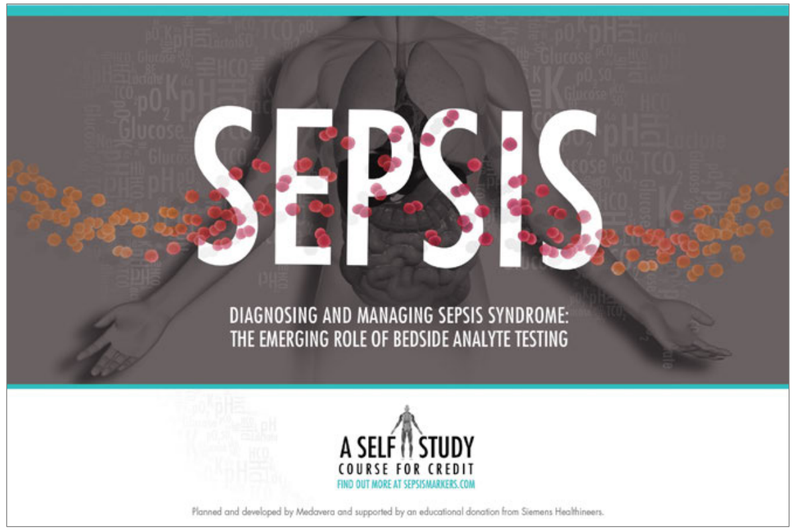
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SEPSIS
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THE EMERGING ROLE OF BEDSIDE ANALYTE TESTING
Complimentary CME & CEUs
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Respiratory Therapy – This program has been approved for 1.5 contact hours Continuing Respiratory Care Education (CRCE) credit by the American Association for Respiratory Care, 9425 N. MacArthur Blvd., Suite 100, Irving, TX 75063 Course #213078000.
Laboratory Technicians – One PACE credit will be provided for this self-study program. This session is approved for 1.5 Florida CE credits. Florida Board of Clinical Laboratory Personnel approved number: 50-12563.
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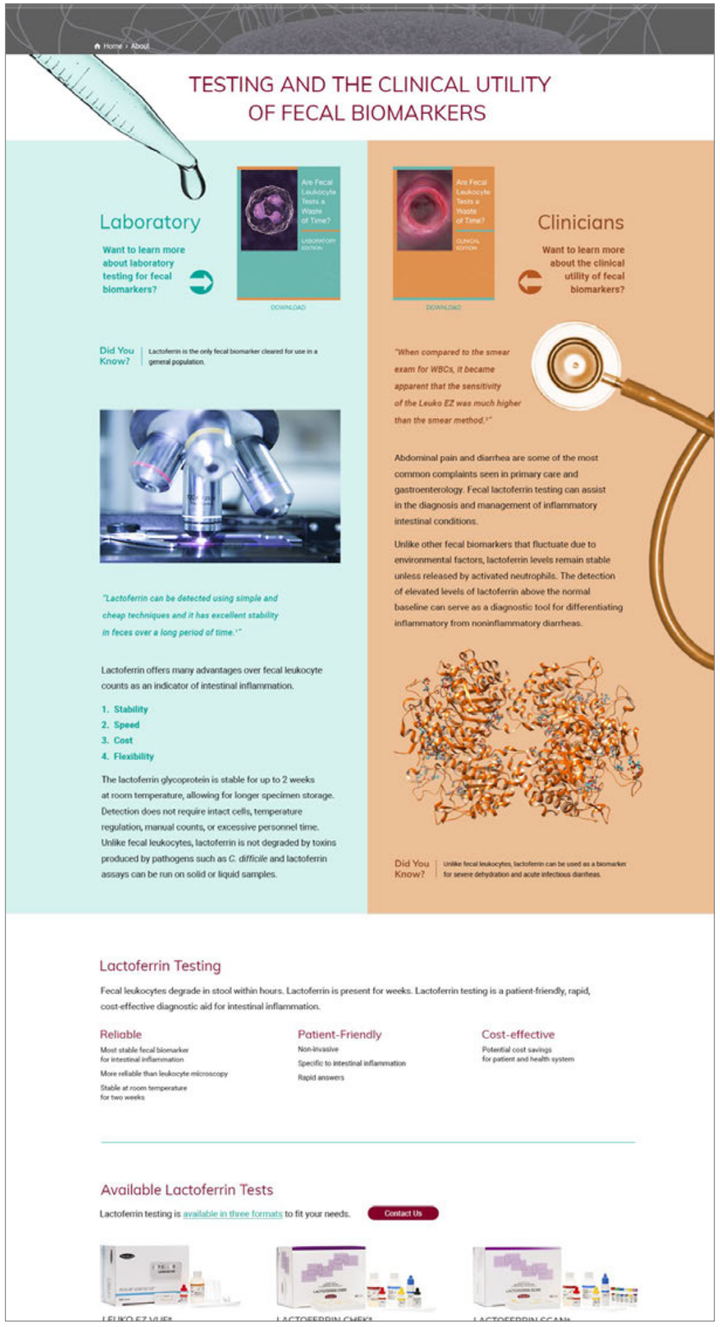
6.2021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TESTING AND THE CLINICAL UTILITY OF FECAL BIOMARKERS
Laboratory
Want to learn more about laboratory testing for fecal biomarkers?
Are Fecal Leukocyte Tests a Waste of Time?
LABORATORY EDITION
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Clinicians
Want to learn more about the clinical utility of fecal biomarkers?
Are Fecal Leukocyte Tests a Waste of Time?
CLINICAL EDITION
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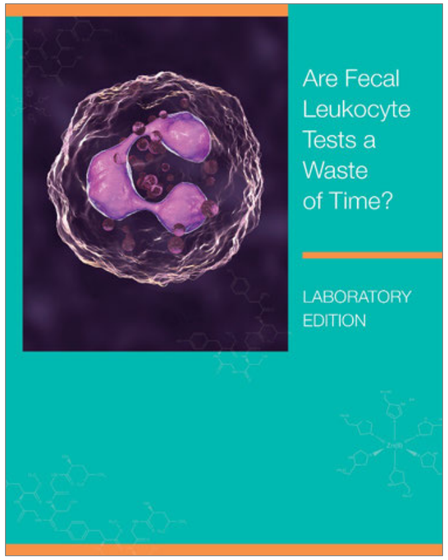
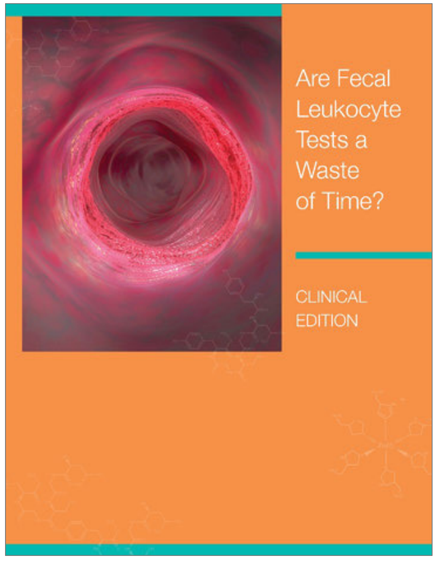
Did You Know? Lactoferrin is the only fecal biomarker cleared for use in a general population.
"When compared to the smear exam for WBCs, it became apparent that the sensitivity of the Leuko EZ was much higher than the smear method."
"Lactoferrin can be detected using simple and cheap techniques and it has excellent stability in feces over a long period of time."
Abdominal pain and diarrhea are some of the most common complaints seen in primary care and gastroenterology. Fecal lactoferrin testing can assist in the diagnosis and management of inflammatory intestinal conditions.
Unlike other fecal biomarkers that fluctuate due to environmental factors, lactoferrin levels remain stable unless released by activated neutrophils. The detection of elevated levels of lactoferrin above the normal baseline can serve as a diagnostic tool for differentiating inflammatory from noninflammatory diarrheas.
Lactoferrin offers many advantages over fecal leukocyte counts as an indicator of intestinal inflammation.
1. Stability
2. Speed
3. Cost
4. Flexibility
The lactoferrin glycoprotein is stable for up to 2 weeks at room temperature, allowing for longer specimen storage. Detection does not require intact cells, temperature regulation, manual counts, or excessive personnel time. Unlike fecal leukocytes, lactoferrin is not degraded by toxins produced by pathogens such as C. difficile and lactoferrin assays can be run on solid or liquid samples.
Did You Know? Unlike fecal leukocytes, lactoferrin can be used as a biomarker for severe dehydration and acute infectious diarrheas.
Lactoferrin Testing
Fecal leukocytes degrade in stool within hours. Lactoferrin is present for weeks. Lactoferrin testing is a patient-friendly, rapid, cost-effective diagnostic aid for intestinal inflammation.
Reliable
Most stable fecal biomarker for intestinal inflammation
More reliable than leukocyte microscopy
Stable at room temperature for two weeks
Patient-Friendly
Non-invasive
Specific to intestinal inflammation
Rapid answers
Cost-effective
Potential cost savings for patient and health system
Available Lactoferrin Tests
Lactoferrin testing is available in three formats to fit your needs.
Contact Us

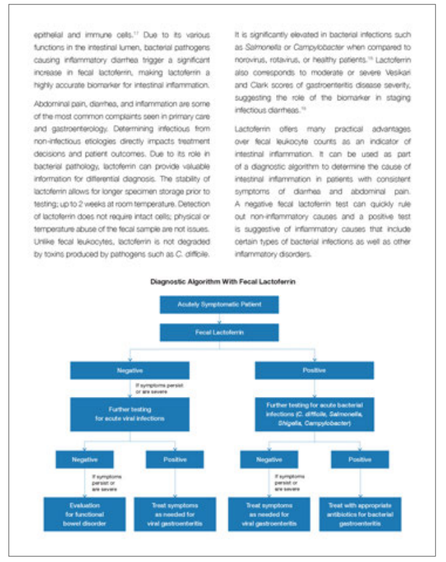

Are Fecal Leukocyte Tests a Waste of Time?
LABORATORY EDITION


Doubts about the utility of fecal leukocyte tests have been publicly voiced.
"The fecal leukocyte test was only 20% better than a coin toss."


The LEUKO EZ VUE® test is been evaluated favorably in a number of studies, especially when compared to FLTs.


Are Fecal Leukocyte Tests a Waste of Time?
CLINICAL EDITION


The costs to the participating laboratories conducting FLTs may be higher than the Medicare reimbursement.


Diagnostic Algorithm With Fecal Lactoferrin
Acutely Symptomatic Patient
Fecal Lactoferrin
Negative
Positive
Further testing for acute viral infections
Further testing for acute bacterial infections (C. difficile, Salmonella, Shigella, Campylobacter)
Evaluation for functional bowel disorder
Treat symptoms as needed for viral gastroenteritis
Treat with appropriate antibiotics for bacterial gastroenteritis

Registration is required in order to view the live webinar. An email with a link for the live webinar will immediately be sent to you via email upon registration.

Wednesday, June 24, 2020
2:00 - 3:00 pm ET

Surgical patients are at increased risk for opioid-use disorders due to pre- and post-operative prescribing. Intravenous ibuprofen may provide an alternative solution to reduce pain and opioid use before and after surgery.

This activity is accredited for physicians and nurses. The webinar will be available on-demand after the live portion with downloads of the transcript and educational slides posted. **There is no charge for this activity.**

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Reducing Opioids in Surgical Pain Management: Exploring New Perioperative and Postoperative Strategies

Wednesday, April 18, 2018
5:00 - 6:00 pm ET

The U.S. opioid epidemic continues and drug overdose deaths have nearly tripled during the past few years. Many patients who present for surgery and anesthesia may already be opioid-dependent. Strategies are needed to reduce the use of opioids before, after, and for long-term pain management.

This activity is accredited for physicians, nurses, and pharmacists. The webinar will be available on-demand after the live portion with downloads of the transcript and educational slides posted (see Downloads). There is no charge for this activity.

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Medavera, Inc. has partnered with Envision to provide this program to healthcare professionals.

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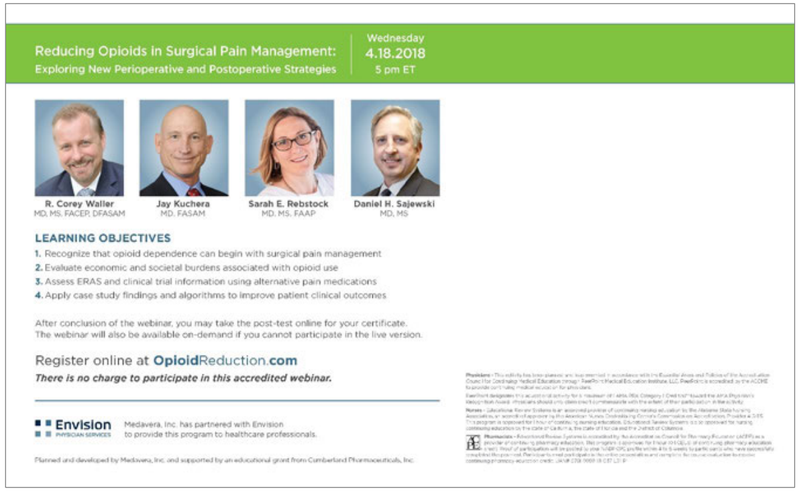


the HISTORY of
INFLUENZA
from DEVASTATION to DISCOVERY
VIEW LEARNING ACTIVITY
DOWNLOAD CME APPLICATION
DOWNLOAD SLIDE SET
The World Health Organization (WHO) estimates between three and five million cases of severe illness and between 250,000 and 500,000 deaths occur each year due to influenza.[1]
Perhaps one of the greatest lessons in public health was the "Spanish" influenza pandemic of 1918–1919.[2] All influenza A pandemics have since resulted from the 1918 virus, including "drifted" H1N1 viruses and reassorted H2N2 and H3N2 viruses.[3] The devastation caused by this pandemic then lead to the discovery of human influenza type A virus in 1933 and the development of the first vaccine in 1937.[4,5] Influenza type B was then identified in 1940.[6]
The following decades resulted in significant discoveries: introduction of antiviral treatments, rapid diagnostics, and improvements in surveillance and treatment.[7-11] It is important for healthcare professionals to understand this chronology of events and to look foward to continued improvements in surveillance, identification, and the treatment of influenza. This accredited, self-study program is designed for these purposes.
A SELF STUDY
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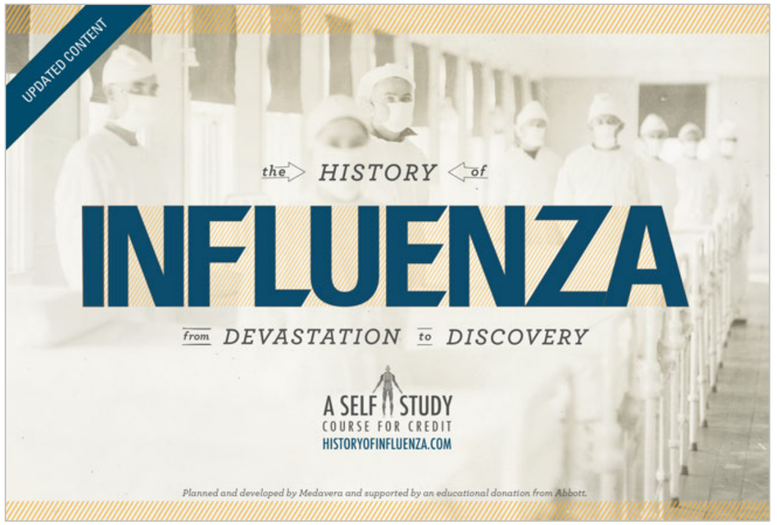
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the HISTORY of
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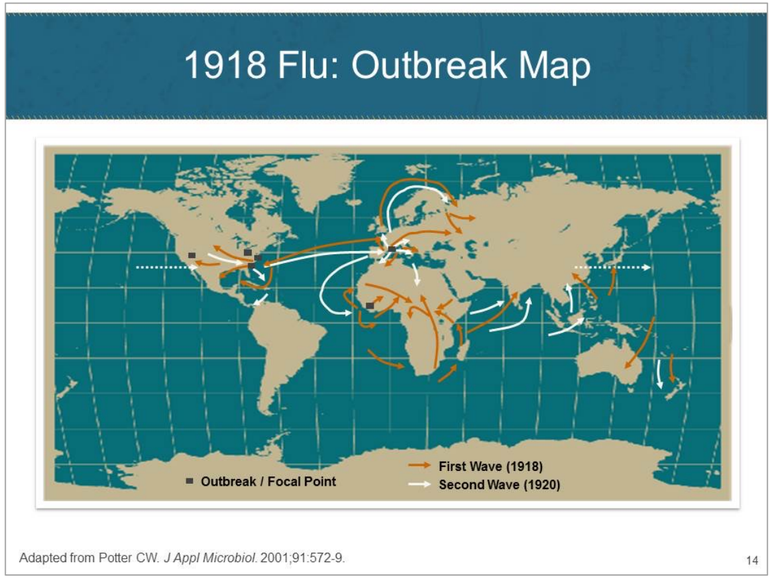
1918 Flu: Outbreak Map
Outbreak / Focal Point
First Wave (1918)
Second Wave (1920)
Adapted from Potter CW. J Appl Microbiol. 2001;91:572-9.
14

IT MAY FIT WELL IN YOUR PRACTICE

Previously, CBC testing required sending samples to a lab for results. The Sysmex XW-100 has changed that. The CLIA-waived designation ensures that it's simple to use, has a low risk of providing erroneous results, and can be operated without additional training beyond simply reading the manufacturer's instructions and following the on-screen prompts.

The Sysmex XW-100 can be an especially good fit for your well patient visits. It is very compact with a height of 13.8 inches and a width of 7.3 inches. The Sysmex XW-100 and its reagents can fit on a countertop. Daily QC takes less than 30 minutes.

VALUABLE INFORMATION

The Sysmex XW-100 offers a 3-part differential with 12 different parameters:

- Total #WBCs
- Total #RBCs
- Hemoglobin
- Hematocrit
- Total #platelets
- Total #neutrophils
- % of neutrophils
- Total #lymphocytes
- % of lymphocytes
- Total #other WBCs
- % of other WBCs
- MCV

The Sysmex XW-100 is not for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases/disorders, oncology patients, critically ill patients, or children under the age of two.

PROTECTING YOU AND YOUR PATIENTS

Blood parameters can be complicated to measure. The complexity of the sample and underlying patient conditions may result in suppression of results. This will appear as 4 asterisks (****) where in most cases a result would be generated. The Sysmex XW-100 is designed to protect your patients and your practice from inaccurate results.

For more information, review the Sysmex XW-100 Quick Guide or visit **CBCin3.com**.

SYSMEX XW-100 RESULTS
(SUPPRESSED)

```
Instrument type XW100
Serial # G2683

Date Jan 14, 2019
Time 12:16 PM
Operator              MKZ

Patient ID            1675
Patient DOB May 26, 1972

WBC        6.2 x 10^3/uL
RBC        4.36 x 10^6/uL
HGB        ****
HCT        ****
PLT         344 x 10^3/uL

#Neut      4.4 x 10^3/uL
%Neut      71.3 %

#Lymph     1.8 x 10^3/uL
%Lymph    25.6 %

#OtherWBC  0.2 x 10^3/uL
%OtherWBC  3.1 %       Low

MCV        ****

NOTES
-----------------------
RECOMMEND FURTHER TESTING.

Adult Reference Ranges
-----------------------
WBC        3.9 -  10.4 x 10^3/uL
RBC        3.71 -  5.52 x 10^6/uL
HGB        10.9 -  16.7 g/dL
HCT        32.5 -  49.4 %
PLT         148 -  302 x 10^3/uL
#Neut       2.2 -  7.1 x 10^3/uL
%Neut      46.4 -  76.9 %
#Lymph      0.9 -  3.4 x 10^3/uL
%Lymph     14.7 -  45.9 %
#OtherWBC   0.2 -  1.2 x 10^3/uL
%OtherWBC   3.2 -  16.9 %
MCV        82.5 -  98.0 fL

---End-Report---
```

Rerun sample if device alerts to do so. If results are still suppressed, send sample out as per your standard protocol.

sysmex | Lighting the way with diagnostics

HOW IT HELPS SUPPORT CONTACT

INTRODUCING THE SYSMEX® XW™-100

A CLIA-WAIVED CBC IS NOW POSSIBLE

The Sysmex XW-100 is the first FDA-cleared, CLIA-waived CBC analyzer to provide reliable, convenient, and often, same-visit CBC results.
A 15 µL venous blood sample is required.
The sample-to-result time is just 3 minutes.

The Sysmex XW-100 can help:

- Expedite diagnosis and treatment
- Improve patient satisfaction
- Streamline workflow

Clinical & Operational Benefits

Comparison & Results Including Suppression

Common Questions

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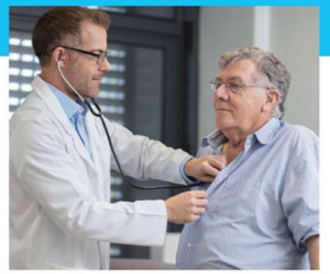
HOW IT HELPS SUPPORT CONTACT

SUPPORT

Quick Guides & Instructions for Use Manual
Download Instructions for Use Manual
Intended Use
Suppressed Results
Training & Validation
Quality Control • General Care • Reagents
Printer • Connectivity
Regulatory Documents



Clinical & Operational Benefits

Comparison & Results Including Suppression

Common Questions

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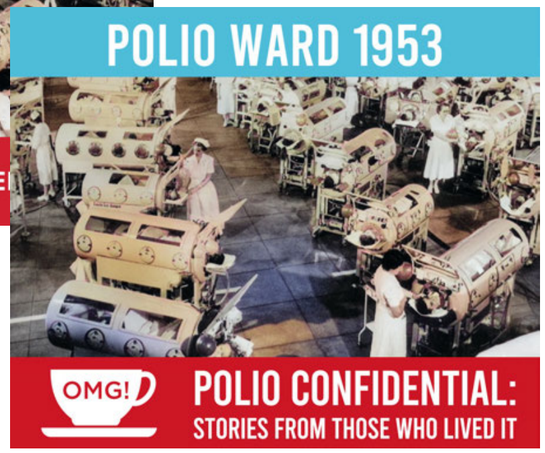
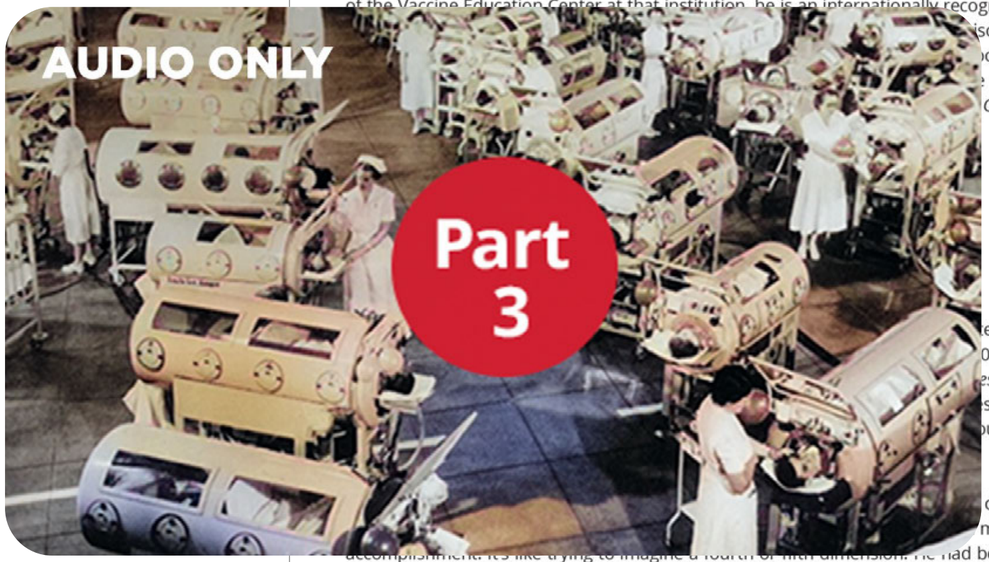




Polio Confidential: Stories From Those Who Lived It

Part 1 - The Continued Path Toward Prevention

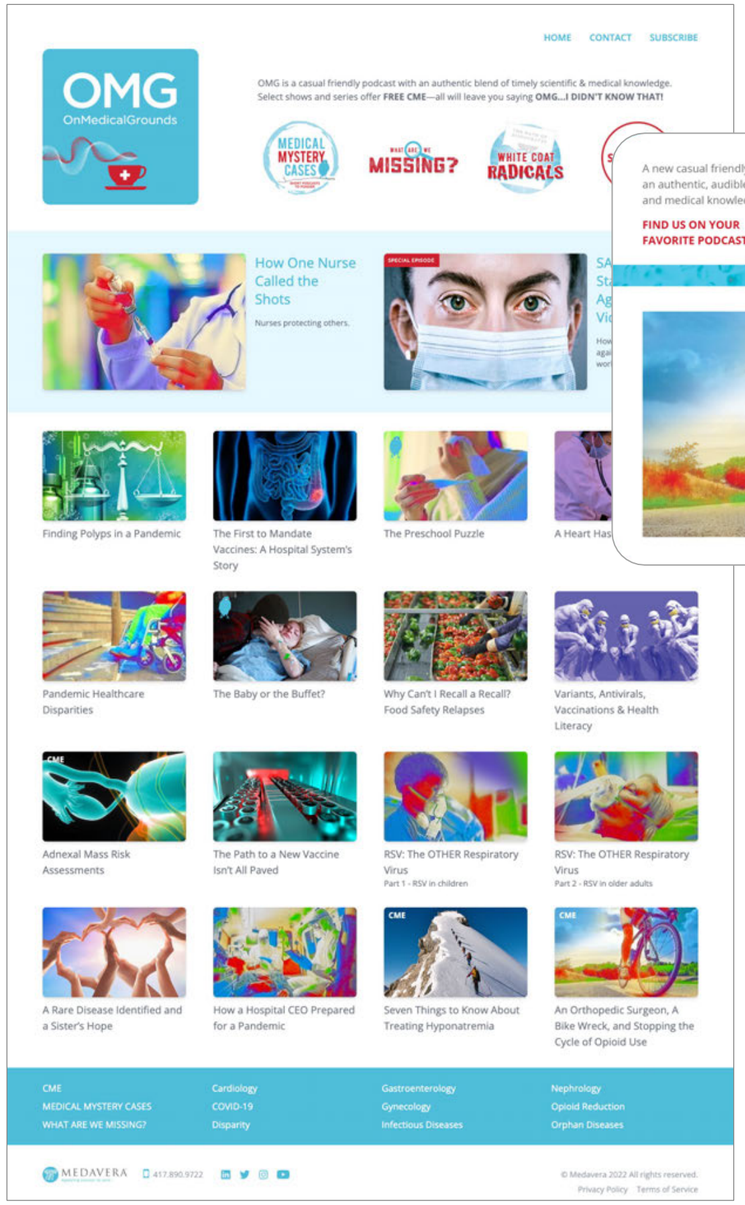
PODCAST 44

00:12
Dr. Jane Caldwell
Hi, this is Jane Caldwell. Welcome to the *On Medical Grounds* podcast, your source for engaging, relevant, evidence-based medical information. We're hosting a three-part series on polio, a serious disease that was almost totally eradicated in my lifetime due to polio vaccination programs worldwide. We'll be talking to polio survivors, healthcare providers who cared for polio victims, and a noted expert on polio vaccines.

Today is part one of Polio Confidential: Stories from Those Who Lived It, The Continued Path Toward Prevention. Today I'm speaking with Dr. Paul Offit. Dr. Offit is a professor of pediatrics and an attending physician at the Division of Infectious Diseases at the Children's Hospital of Philadelphia. As director of the Vaccine Education Center at that institution, he is an internationally recognized expert in the fields
isory Committee. In 2011,
ok was selected by Kirkus
recently, he has written
Our Post-Pandemic World."

eners so they know who
008 when you published
es." You were friends with
s have been credited with
us disease?

developer, of nine of the
many ways unimaginable,
had been a friend for 20 years
and in October of 2004, he was diagnosed with disseminated cancer and given roughly six months to live, which is exactly how long he did live. He lived till April of 2005. And, you know, I asked if it would be okay with him if I would interview him periodically during that time. And I did about maybe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OnMedicalGrounds
OMG is a casual friendly podcast with an authentic blend of timely scientific & medical knowledge.
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MEDICAL MYSTERY CASES
WHAT ARE WE MISSING?
WHITE COAT RADICALS
How One Nurse Called the Shots
Nurses protecting others.
SPECIAL EPISODE
Finding Polyps in a Pandemic
The First to Mandate Vaccines: A Hospital System's Story
The Preschool Puzzle
Pandemic Healthcare Disparities
The Baby or the Buffet?
Why Can't I Recall a Recall? Food Safety Relapses
Variants, Antivirals, Vaccinations & Health Literacy
CME
Adnexal Mass Risk Assessments
The Path to a New Vaccine Isn't All Paved
RSV: The OTHER Respiratory Virus
Part 1 - RSV in children
RSV: The OTHER Respiratory Virus
Part 2 - RSV in older adults
A Rare Disease Identified and a Sister's Hope
How a Hospital CEO Prepared for a Pandemic
Seven Things to Know About Treating Hyponatremia
An Orthopedic Surgeon, A Bike Wreck, and Stopping the Cycle of Opioid Use
CME
MEDICAL MYSTERY CASES
WHAT ARE WE MISSING?
Cardiology
COVID-19
Disparity
Gastroenterology
Gynecology
Infectious Diseases
Nephrology
Opioid Reduction
Orphan Diseases
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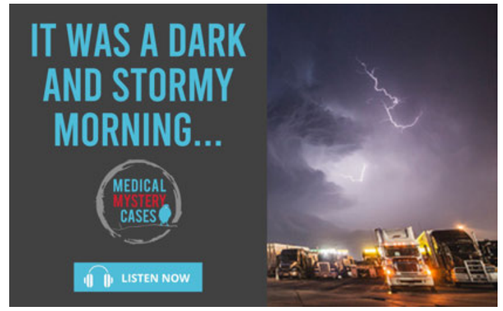
OMG...I DIDN'T KNOW THAT!
An Orthopedic Surgeon, A Bike Wreck, and Stopping the Cycle of Opioid Use
PODCAST 1
Find out how a skilled orthopedic surgeon developed a protocol to improve perioperative pain management while reducing opioids.
Free CME credits available.

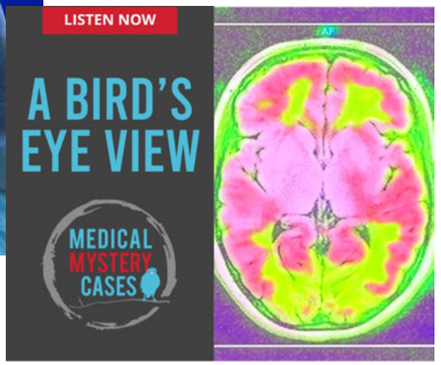

THE NEED FOR DIABETES SCREENING
OMG!
LISTEN - FREE CME/CE


Osteomyelitis: Achieving Antibiotic Penetration
LISTEN NOW

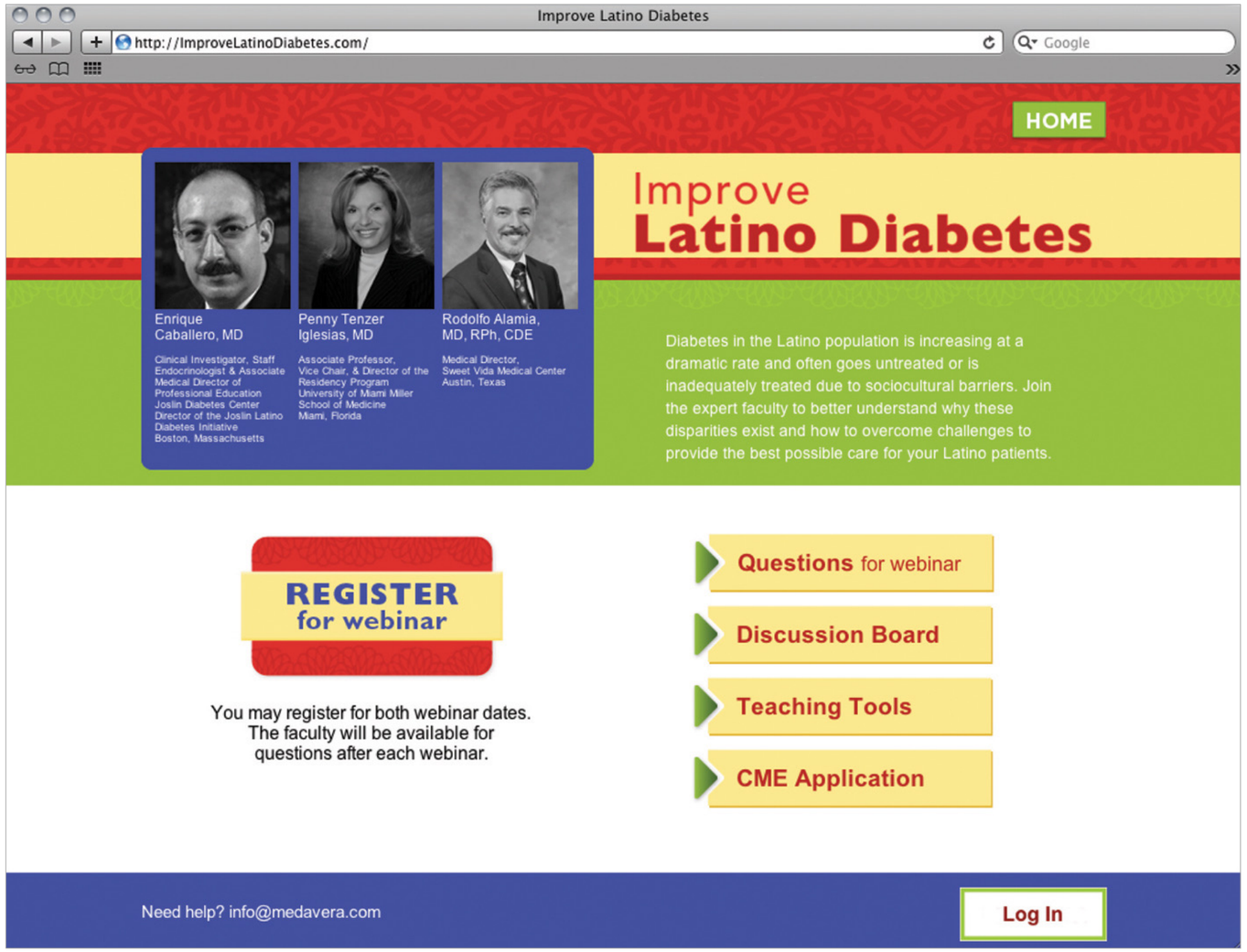

MEDICAL MYSTERY CASES
SHORT TALES TO PONDER


IT WAS A DARK AND STORMY MORNING...
MEDICAL MYSTERY CASES
LISTEN NOW


Two park rangers living their dream life...
In love...
Expecting a baby...
What could go wrong?
MEDICAL MYSTERY CASES
FREE CME/CE


LISTEN NOW
A BIRD'S EYE VIEW
MEDICAL MYSTERY CASES


MEDICAL MYSTERY CASES
NEW EPISODE DROPPED!


Improve Latino Diabetes
http://ImproveLatinoDiabetes.com/
Google
HOME
Improve
Latino Diabetes
Enrique Caballero, MD
Clinical Investigator, Staff Endocrinologist & Associate Medical Director of Professional Education Joslin Diabetes Center Director of the Joslin Latino Diabetes Initiative Boston, Massachusetts
Penny Tenzer Iglesias, MD
Associate Professor, Vice Chair, & Director of the Residency Program University of Miami Miller School of Medicine Miami, Florida
Rodolfo Alamia, MD, RPh, CDE
Medical Director, Sweet Vida Medical Center Austin, Texas
Diabetes in the Latino population is increasing at a dramatic rate and often goes untreated or is inadequately treated due to sociocultural barriers. Join the expert faculty to better understand why these disparities exist and how to overcome challenges to provide the best possible care for your Latino patients.
REGISTER for webinar
You may register for both webinar dates. The faculty will be available for questions after each webinar.
Questions for webinar
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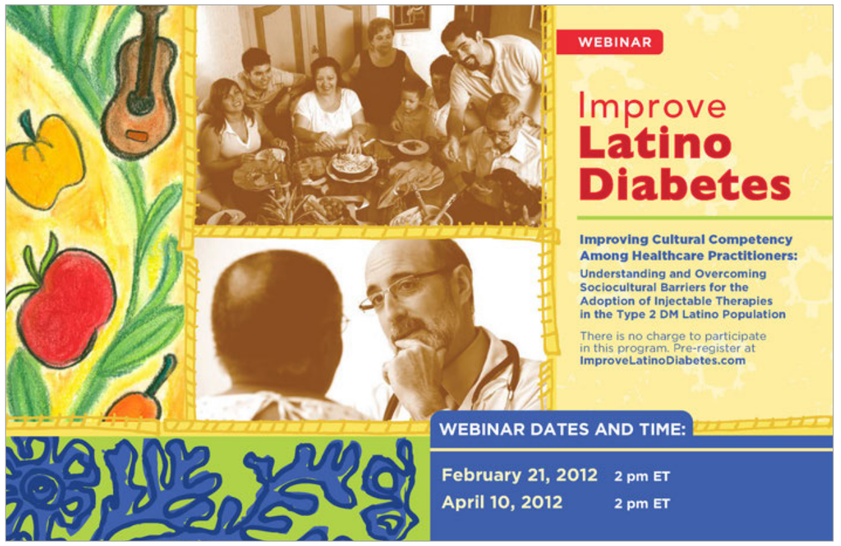
WEBINAR
Improve
Latino Diabetes
Improving Cultural Competency Among Healthcare Practitioners:
Understanding and Overcoming Sociocultural Barriers for the Adoption of Injectable Therapies in the Type 2 DM Latino Population
There is no charge to participate in this program. Pre-register at ImproveLatinoDiabetes.com
WEBINAR DATES AND TIME:
February 21, 2012 2 pm ET
April 10, 2012 2 pm ET


Break down the barriers. Find out how to provide the best care for your Latino patients with diabetes. Each webinar will be followed by a live online Q & A with the faculty.
Enrique Caballero, MD Joslin Diabetes Center Boston, MA
Penny Tenzer Iglesias, MD University of Miami Miller School of Medicine Miami, FL
Rodolfo Alamia, MD, RPh, CDE Sweet Vida Medical Center Austin, TX
Register at ImproveLatinoDiabetes.com
Complimentary CE Credits
Approved for 1 hour of CE credit for physicians, nurses and pharmacists.
Visit ImproveLatinoDiabetes.com for Discussion Boards, Teaching Tools, Slide Downloads and more.
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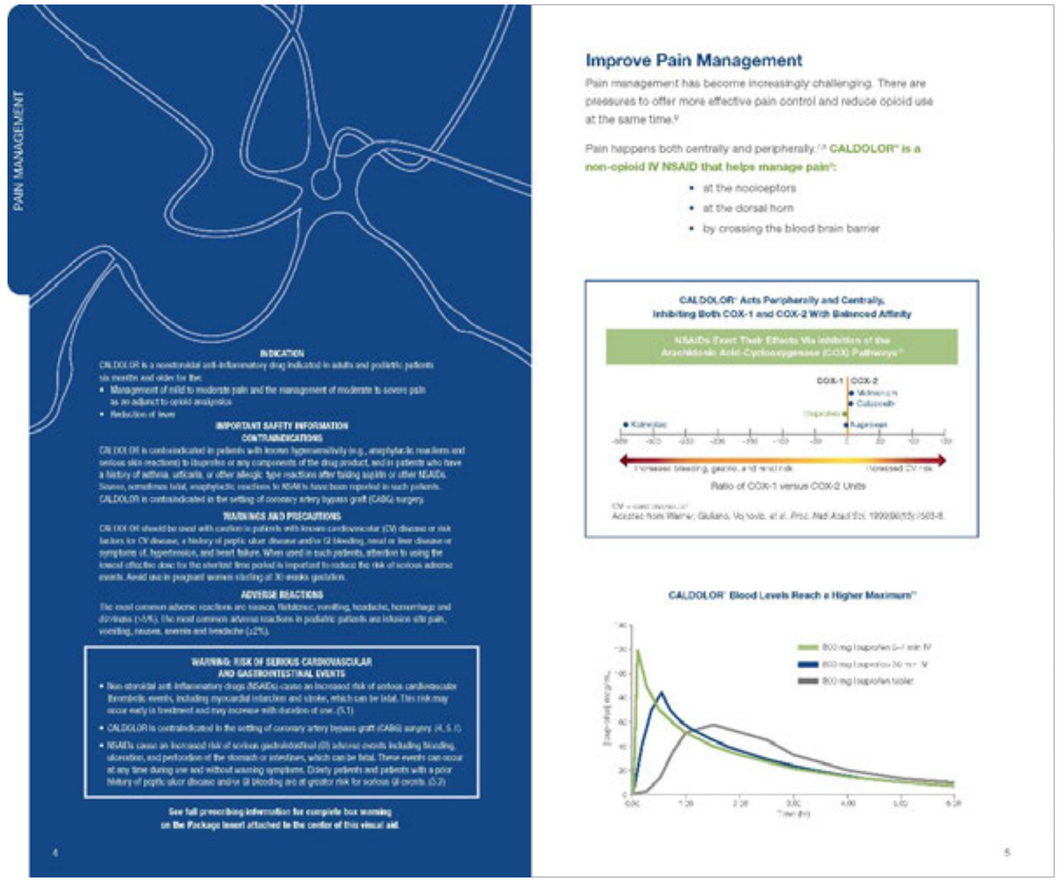
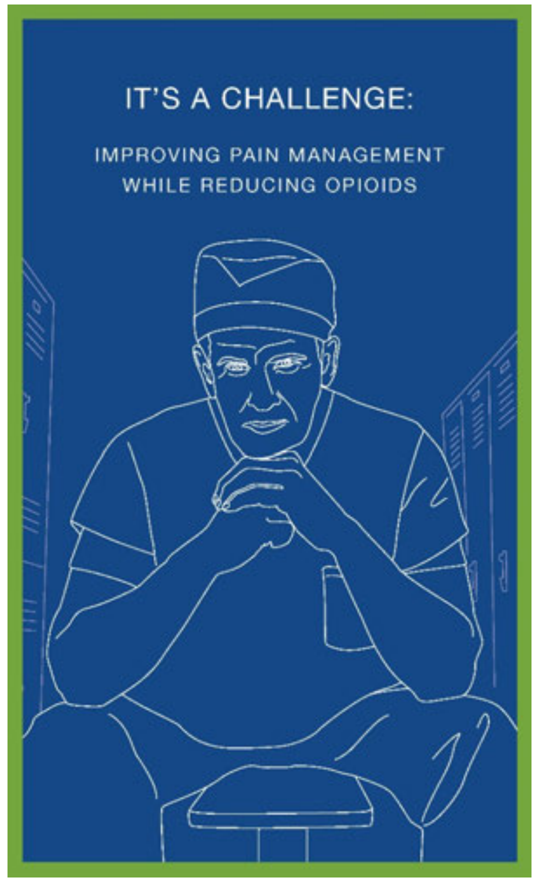
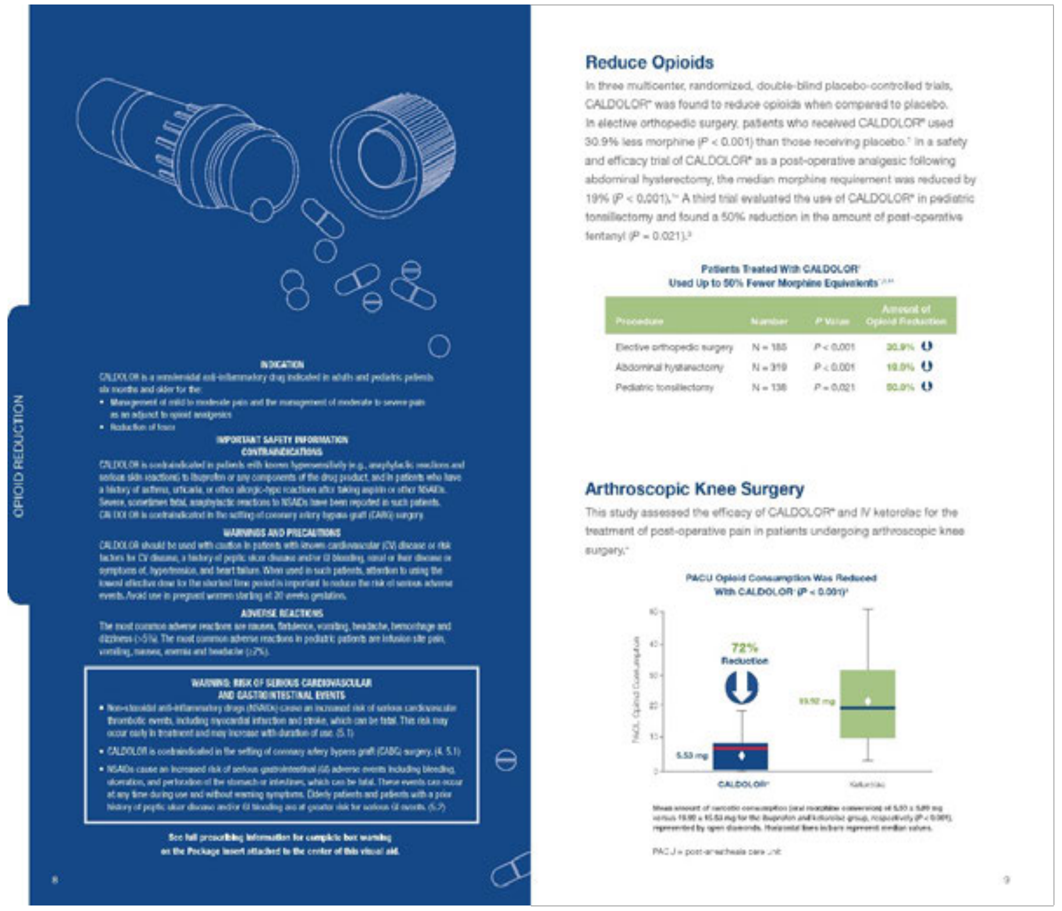
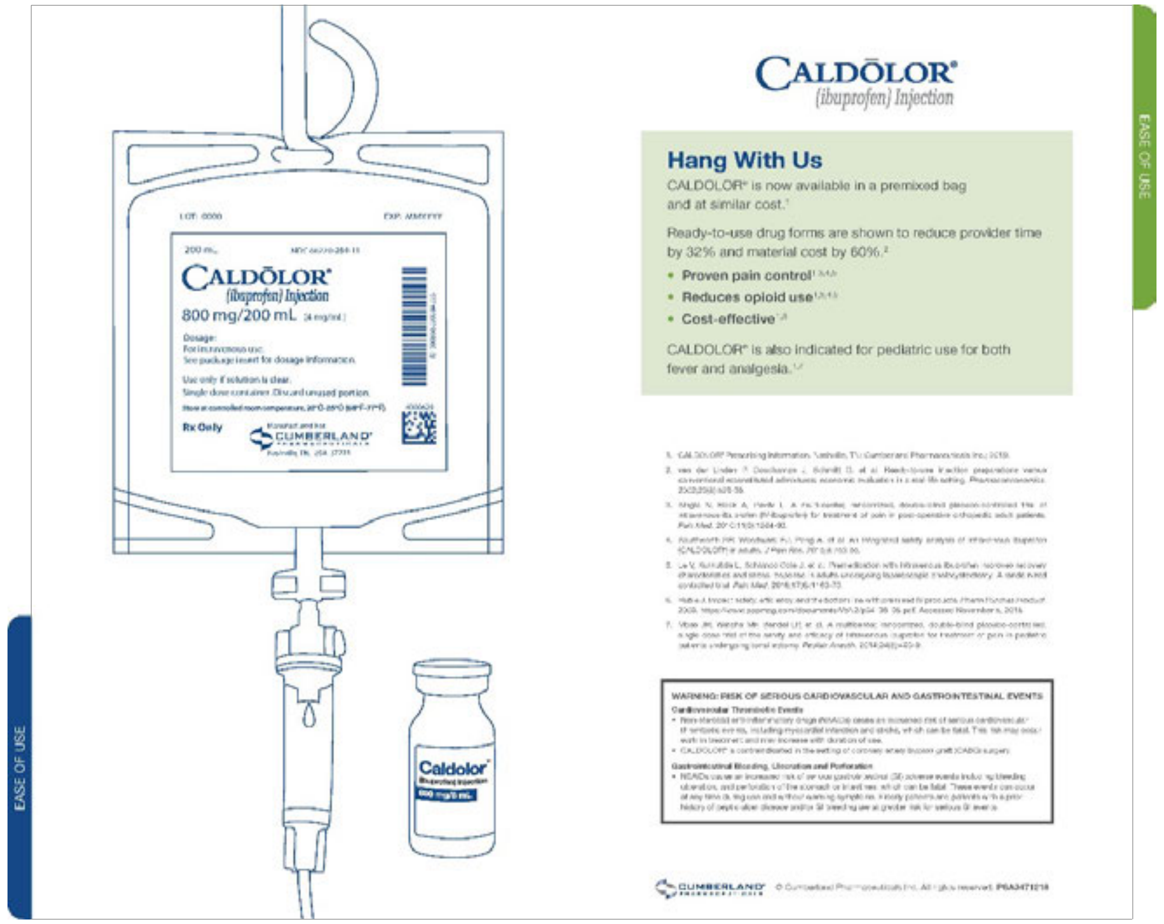

PAIN MANAGEMENT
Improve Pain Management
Pain management has become increasingly challenging. There are pressures to offer more effective pain control and reduce opioid use at the same time.
CALDOLOR® is a non-opioid IV NSAID that helps manage pain:
at the nociceptors
at the dorsal horn
by crossing the blood brain barrier
CALDOLOR® Blood Levels Reach a Higher Maximum

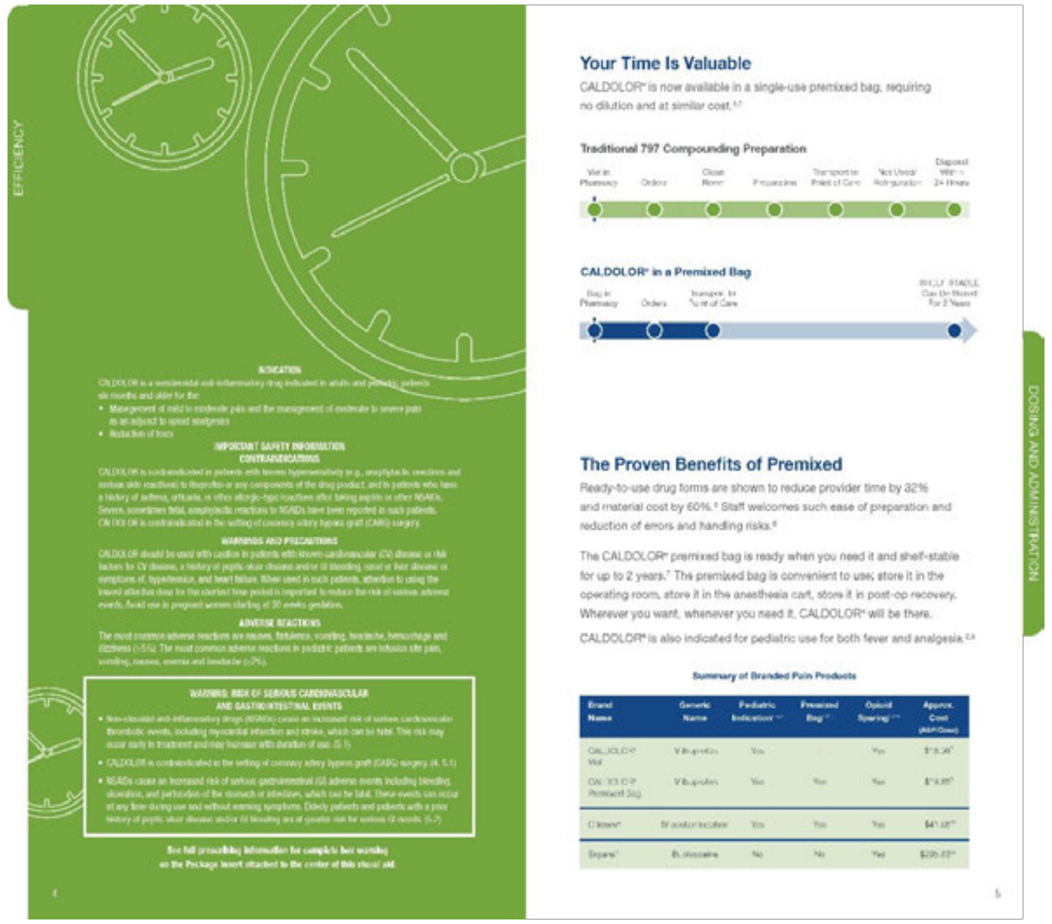

IT'S A CHALLENGE:
IMPROVING PAIN MANAGEMENT
WHILE REDUCING OPIOIDS

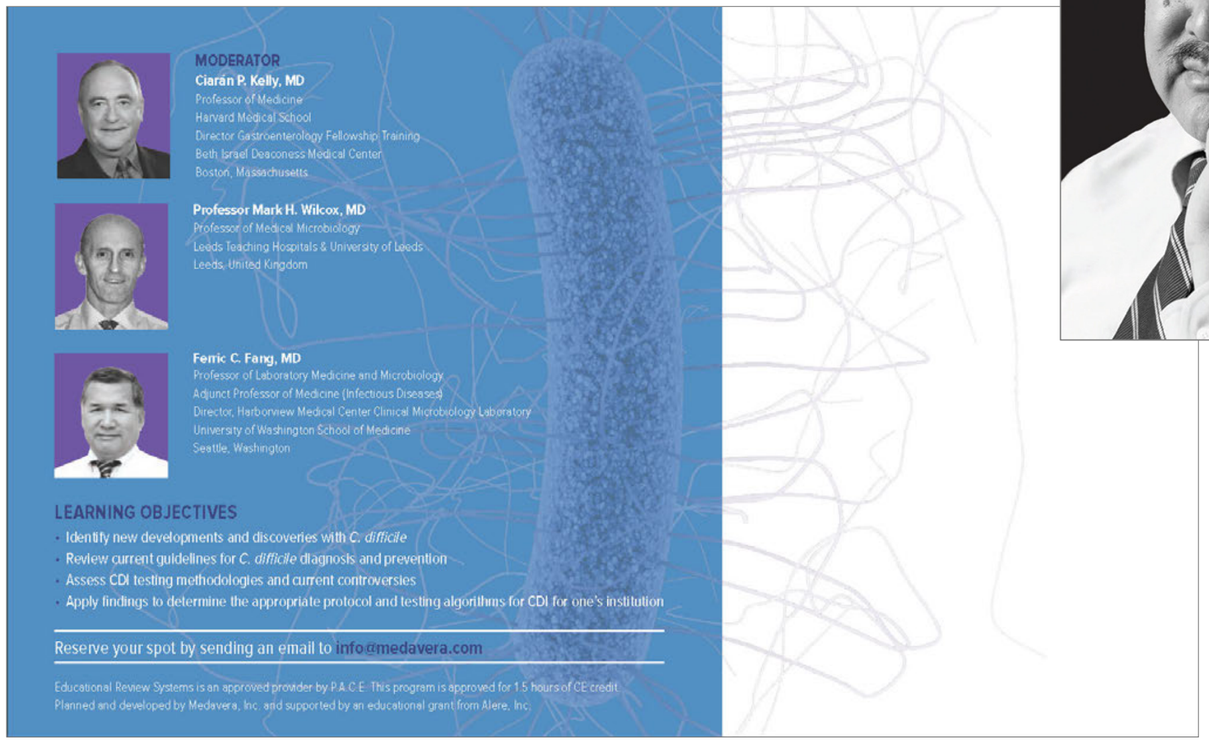

TWO MAJOR CHALLENGES:
YOUR BUDGET AND PAIN MANAGEMENT
Vicious Cycle


CALDOLOR®
(ibuprofen) Injection
CAN HELP
WITH BOTH[1-5]


OPIOID REDUCTION
Reduce Opioids
Arthroscopic Knee Surgery
72% Reduction


EASE OF USE
CALDOLOR®
(ibuprofen) Injection
Hang With Us
CALDOLOR® is now available in a premixed bag and at similar cost.
Proven pain control
Reduces opioid use
Cost-effective
800 mg/200 mL
Caldolor


EFFICIENCY
Your Time Is Valuable
Traditional 797 Compounding Preparation
CALDOLOR® in a Premixed Bag
The Proven Benefits of Premixed
Summary of Branded Pain Products
DOSING AND ADMINISTRATION



MODERATOR

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Professor of Medicine
Harvard Medical School
Director Gastroenterology Fellowship Training
Beth Israel Deaconess Medical Center
Boston, Massachusetts

Professor Mark H. Wilcox, MD
Professor of Medical Microbiology
Leeds Teaching Hospitals & University of Leeds
Leeds, United Kingdom

Ferric C. Fang, MD
Professor of Laboratory Medicine and Microbiology
Adjunct Professor of Medicine (Infectious Diseases)
Director, Harborview Medical Center Clinical Microbiology Laboratory
University of Washington School of Medicine
Seattle, Washington

LEARNING OBJECTIVES

- Identify new developments and discoveries with *C. difficile*
- Review current guidelines for *C. difficile* diagnosis and prevention
- Assess CDI testing methodologies and current controversies
- Apply findings to determine the appropriate protocol and testing algorithms for CDI for one's institution

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HIV TESTING CAN CHANGE EVERYTHING

Determine™ HIV-1/2 Ag/Ab Combo

"Every time someone gets tested for HIV, we are one step closer to ending the AIDS epidemic. Learning your HIV status opens the door to powerful HIV prevention and treatment options that could save your life or the life of someone you love."

—Jonathan Mermin, MD, MPH

Dr. Mermin is the Director of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), and a Rear Admiral in the U.S. Public Health Service.

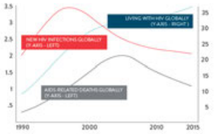
HIV INCIDENCE AND DISTRIBUTION

According to HIV.gov, there are approximately **1.1 million** people living with HIV in the U.S. and **1 in 7** are unaware they are infected with it.[1]

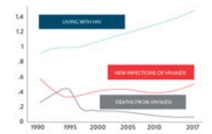
In 2018 there were **37,832** new HIV diagnoses.[1] Approximately **80%** of new HIV transmissions are from individuals who do not know they have HIV infection or are not receiving regular care.[1]

The prevention and treatment of people with HIV should be of utmost concern as this will decrease the number contracting the virus and proceeding to AIDS.

GLOBAL NUMBER OF AIDS-RELATED DEATHS, NEW HIV INFECTIONS, AND PEOPLE LIVING WITH HIV, 1990–2015[4] (IN MILLIONS)



PREVALENCE, NEW CASES AND DEATHS FROM HIV IN THE UNITED STATES[4] (IN MILLIONS)



A NEW CHALLENGE — OPIOID USE AND HIV INCIDENCE

People who inject drugs accounted for **9%** (3,405) of the 37,832 diagnoses of HIV in the United States in 2018. Up to

of HIV due to injection drug use, however the opioid epidemic has disproportionately affected nonurban areas,

TYPES OF HIV TESTING AND TIME TO RESULTS

HIV tests can be conventional or rapid.[6,7]

CONVENTIONAL	
CONVENTIONAL BLOOD TEST	< HOUR TO SEVERAL DAYS[5]
CONVENTIONAL ORAL FLUID TEST	A FEW DAYS TO TWO WEEKS[5]
RAPID	
RAPID TEST POINT OF CARE	≤ 20 MINUTES[6,7]
NEGATIVE	NO FURTHER TESTING NEEDED
POSITIVE	LABORATORY CONFIRMATION NEEDED
HOME	
HOME TEST	20 MINUTES TO THREE DAYS[5]

Picture from 1985 of Abbott scientists with the first HIV test kit, the Abbott HTLV-III.

HIV ANTIGEN AND ANTIBODY TESTING

Antibody-only tests were developed in the 1980s and improved the specificity and positive predictive value of the screening procedures by adding recombinant antigens, specifically HIV-1 p24, HIV-2, and HIV-1 group O. Antibody-only assays reduced the antibody-negative window to 4–6 weeks after exposure. With the addition of HIV-2, confirmatory testing of that protein was added to the developing CDC algorithm for HIV testing.[8]

IgM detection was added to assays to produce a new type of HIV test. The IgM/IgG combination reduced the antibody-negative window to approximately 3 weeks. The development of a **p24 antigen** detection ELISA could detect the virus as early as two weeks.[8]

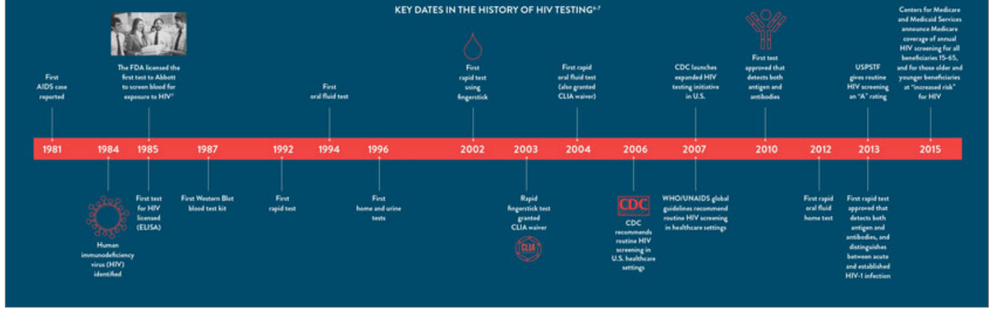
Detection of HIV after becoming infected has been difficult to ascertain, especially if tests are performed during the window period (the period of time between becoming infected with HIV and the ability of a test to detect HIV) which increases the likelihood of a false negative.

The probability of a false negative decreases with the use of an antibody-antigen test.

FALSE NEGATIVES IN ANTIBODY-ONLY AND ANTIBODY/ANTIGEN HIV TESTS[5]

TIME SINCE EXPOSURE	ANTIBODY TEST (CHANCE OF A FALSE NEGATIVE TEST RESULT)	ANTIBODY/ ANTIGEN TEST (CHANCE OF A FALSE NEGATIVE TEST RESULT)
0–9 DAYS	100% CHANCE	100% CHANCE
10–15 DAYS	95–99%	79–99%
16–20 DAYS	56–80%	35–51%
21–28 DAYS	13–46%	8–31%
29–50 DAYS	5–9%	0–8%
51–80 DAYS	3–4%	0%
MORE THAN 80 DAYS	0–1%	0%

KEY DATES IN THE HISTORY OF HIV TESTING[6,7]

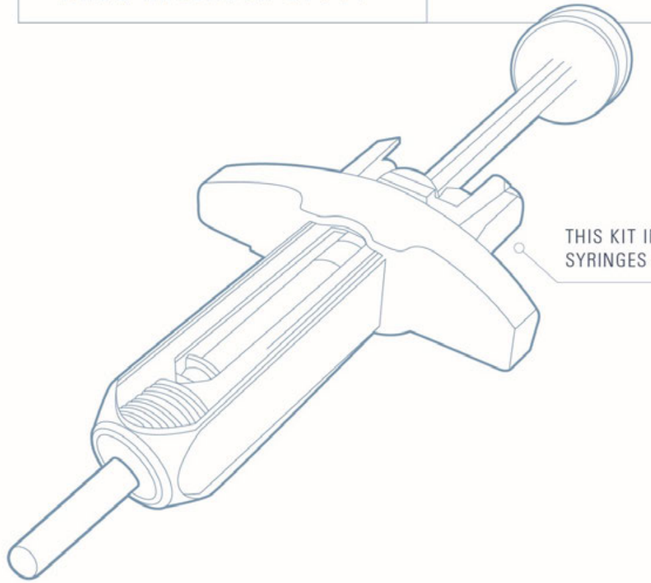


AA PHARMACEUTICALS

AA101488

DRUG RESEARCH STUDY

Patient Guide

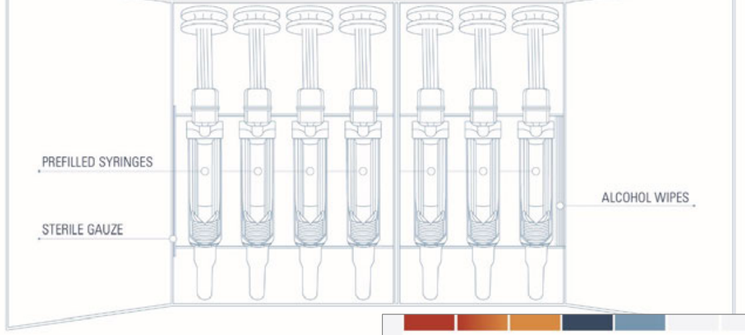


THIS KIT INCLUDES 7 PREFILLED DISPOSABLE SYRINGES & SUPPLIES FOR DAILY PATIENT USE

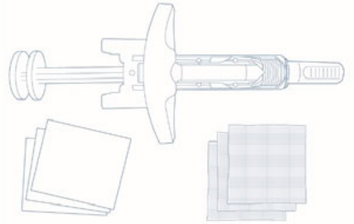
This kit contains supplies and the study drug.

This includes alcohol wipes and sterile gauze along with the study drug—already contained in prefilled syringes.

The syringes must be kept at room temperature, between 68 and 77 degrees Fahrenheit or 20 – 25 degrees Celsius.



1 **Remove the items you will need from the kit, including an alcohol wipe, sterile gauze and a prefilled syringe.**



2 **Wash your hands thoroughly with soap and water.**

3 **Choose an administration site along your abdomen.**

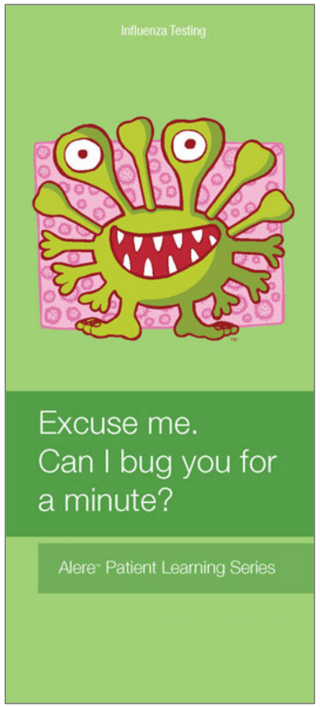
The preferred site is the abdomen. It is important that you do not administer the dose in the same spot every time. Alternate your injection to a different spot along the abdomen each day. The thigh or upper arm may also be used as administration sites, but the abdomen is preferred.

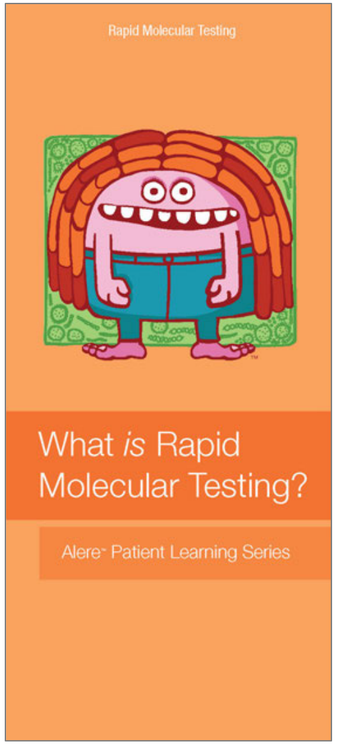
Do not administer your dose in an area that is bruised or swollen, or where the skin is irritated, red, infected, scarred or tattooed.

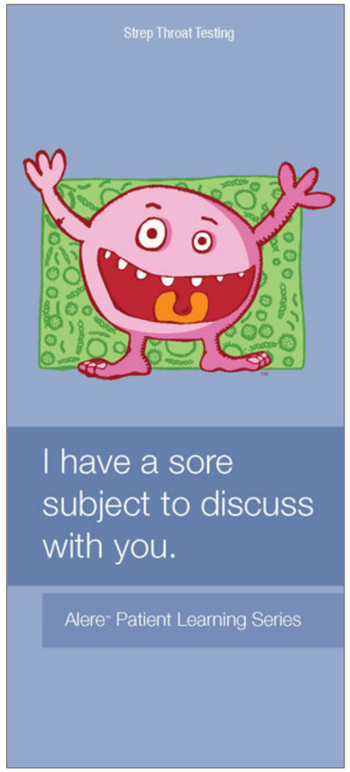

IN UNCHARTERED WATERS,
KNOW IF YOU NEED ANTIBIOTICS.
COUGH
FEVER
SORE THROAT
EAR ACHE
#STEWARTSHIPP
ANTIBIOTIC
RESISTANCE
ASK YOUR DOCTOR IF YOU NEED ANTIBIOTICS

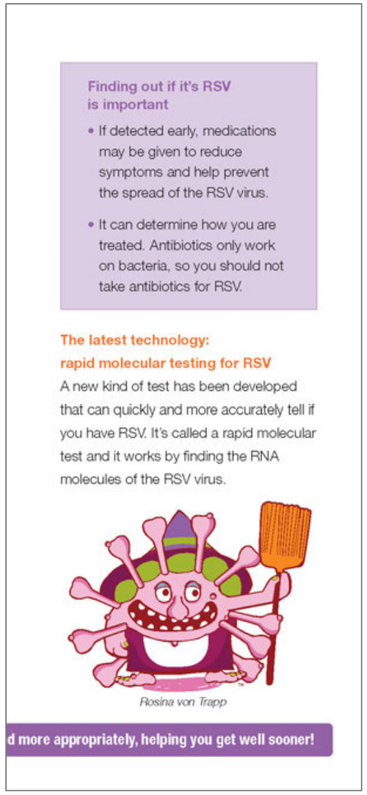

IT CAN BE A SLIPPERY SLOPE.
KNOW IF YOU NEED ANTIBIOTICS
ACUTE RESPIRATORY
INFECTION
ANTIBIOTIC
RESISTANCE
COUGH
FEVER
SORE THROAT
EARACHE
#STEWARTSHIPP
FINISH
ASK YOUR DOCTOR IF YOU NEED ANTIBIOTICS

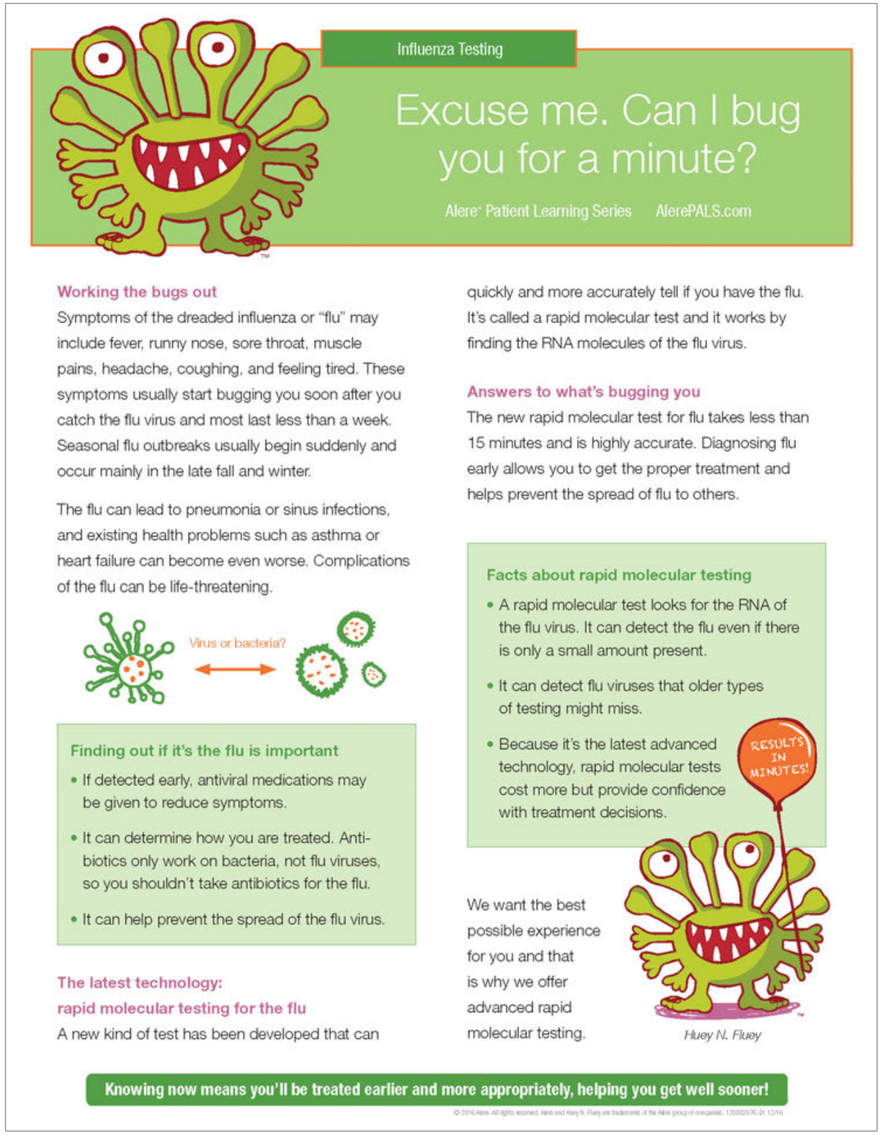

SPRING INTO ACTION
KNOW IF YOU NEED ANTIBIOTICS
ACUTE
RESPIRATORY
INFECTION
COUGH
FEVER
SORE
THROAT
EARACHE
VIRUS
BACTERIA
VIRUS
ASK YOUR DOCTOR IF YOU NEED ANTIBIOTICS


Influenza Testing
Excuse me.
Can I bug you for a minute?
Alere™ Patient Learning Series

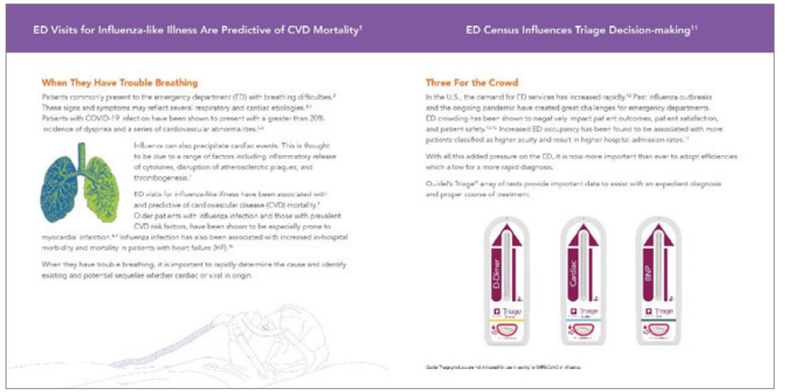

Rapid Molecular Testing
What *is* Rapid Molecular Testing?
Alere™ Patient Learning Series

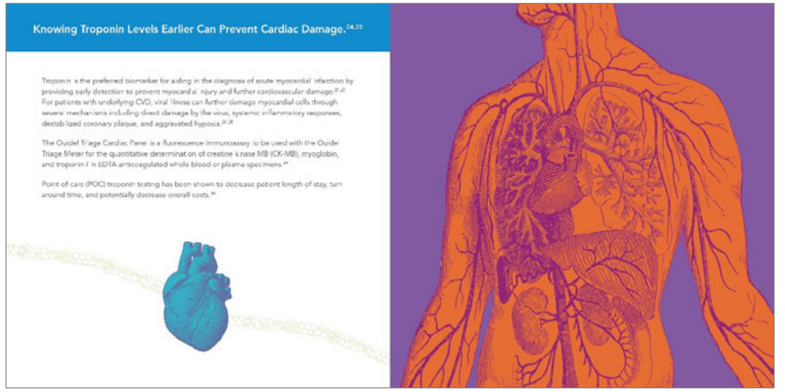

Strep Throat Testing
I have a sore subject to discuss with you.
Alere™ Patient Learning Series

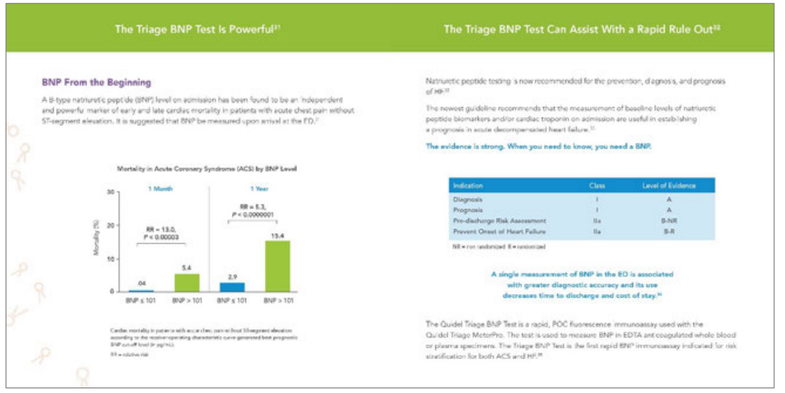

Finding out if it's RSV is important
• If detected early, medications may be given to reduce symptoms and help prevent the spread of the RSV virus.
• It can determine how you are treated. Antibiotics only work on bacteria, so you should not take antibiotics for RSV.
The latest technology: rapid molecular testing for RSV
A new kind of test has been developed that can quickly and more accurately tell if you have RSV. It's called a rapid molecular test and it works by finding the RNA molecules of the RSV virus.
Rosina von Trapp
d more appropriately, helping you get well sooner!


Influenza Testing
Excuse me. Can I bug you for a minute?
Alere™ Patient Learning Series AlerePALS.com
Working the bugs out
Symptoms of the dreaded influenza or "flu" may include fever, runny nose, sore throat, muscle pains, headache, coughing, and feeling tired. These symptoms usually start bugging you soon after you catch the flu virus and most last less than a week. Seasonal flu outbreaks usually begin suddenly and occur mainly in the late fall and winter.
The flu can lead to pneumonia or sinus infections, and existing health problems such as asthma or heart failure can become even worse. Complications of the flu can be life-threatening.
Virus or bacteria?
Finding out if it's the flu is important
• If detected early, antiviral medications may be given to reduce symptoms.
• It can determine how you are treated. Antibiotics only work on bacteria, not flu viruses, so you shouldn't take antibiotics for the flu.
• It can help prevent the spread of the flu virus.
The latest technology: rapid molecular testing for the flu
A new kind of test has been developed that can quickly and more accurately tell if you have the flu. It's called a rapid molecular test and it works by finding the RNA molecules of the flu virus.
Answers to what's bugging you
The new rapid molecular test for flu takes less than 15 minutes and is highly accurate. Diagnosing flu early allows you to get the proper treatment and helps prevent the spread of flu to others.
Facts about rapid molecular testing
• A rapid molecular test looks for the RNA of the flu virus. It can detect the flu even if there is only a small amount present.
• It can detect flu viruses that older types of testing might miss.
• Because it's the latest advanced technology, rapid molecular tests cost more but provide confidence with treatment decisions.
RESULTS IN MINUTES!
We want the best possible experience for you and that is why we offer advanced rapid molecular testing.
Huey N. Fluey
Knowing now means you'll be treated earlier and more appropriately, helping you get well sooner!

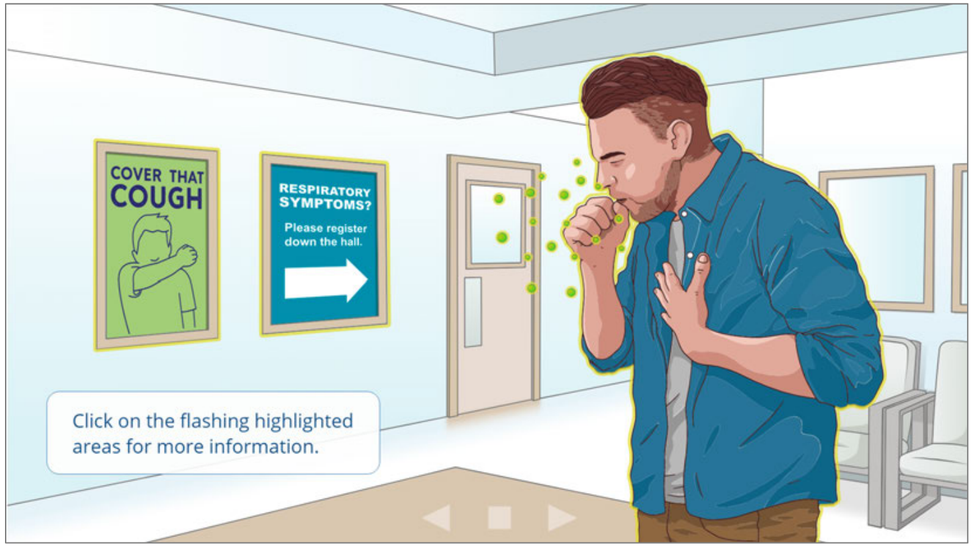

They're counting on you.
Make sure you have the biomarkers you need.

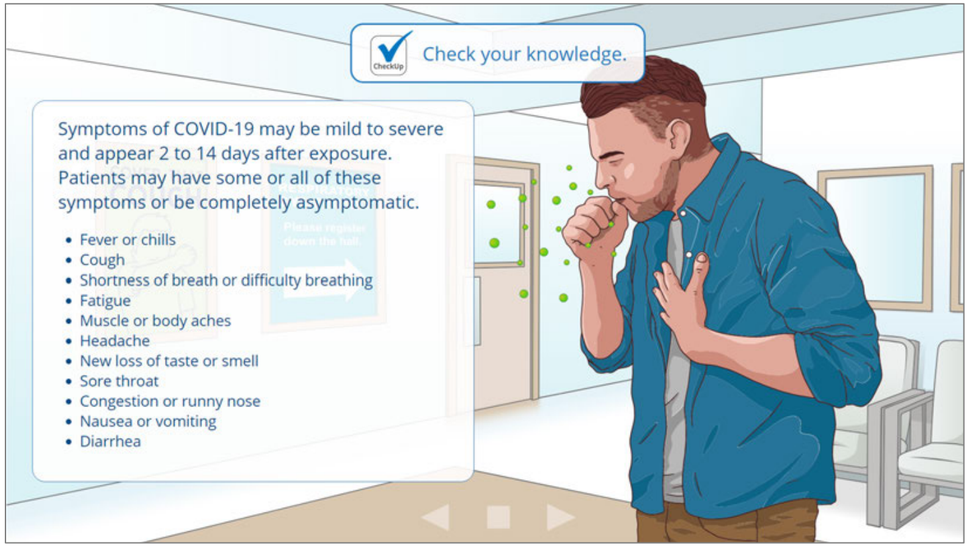

ED Visits for Influenza-like Illness Are Predictive of CVD Mortality[3]
When They Have Trouble Breathing
ED Census Influences Triage Decision-making[11]
Three For the Crowd

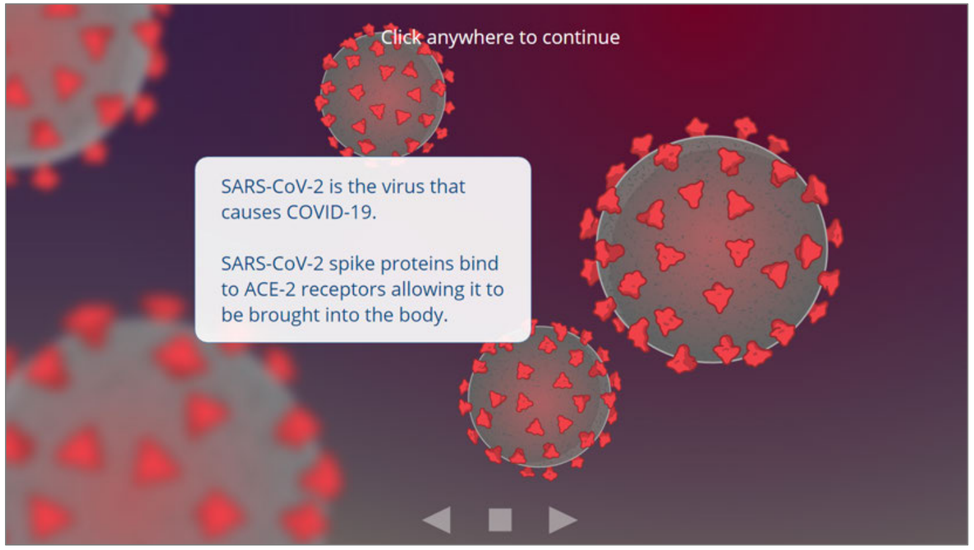

Knowing Troponin Levels Earlier Can Prevent Cardiac Damage.[14,15]


The Triage BNP Test Is Powerful[11]
BNP From the Beginning
The Triage BNP Test Can Assist With a Rapid Rule Out[12]


Their hearts are in your hands.
Triage
QUIDEL


COVER THAT COUGH
RESPIRATORY SYMPTOMS?
Please register down the hall.
Click on the flashing highlighted areas for more information.


Check your knowledge.
Symptoms of COVID-19 may be mild to severe and appear 2 to 14 days after exposure. Patients may have some or all of these symptoms or be completely asymptomatic.
• Fever or chills
• Cough
• Shortness of breath or difficulty breathing
• Fatigue
• Muscle or body aches
• Headache
• New loss of taste or smell
• Sore throat
• Congestion or runny nose
• Nausea or vomiting
• Diarrhea


Click anywhere to continue
SARS-CoV-2 is the virus that causes COVID-19.
SARS-CoV-2 spike proteins bind to ACE-2 receptors allowing it to be brought into the body.


Check your knowledge.
MASKS
HAND SANITIZER
Hand sanitizer should be provided to all patients and healthcare workers through individual bottles or dispensers. These should be placed at reception and throughout the facility.
COVER
YOUR
COUGH

sysmex | Lighting the way with diagnostics

Hematology Analyzer

XW™-100 Sales Guide

CLIA-waived.
Automated Hematology Analyzer.

CBCin3.com

Internal Use Only

TAP HERE FOR NEXT PAGE

CBC Overview

Cellular Components of Whole Blood

RED BLOOD CELLS (RBCs)

Red blood cells, or RBCs, are also sometimes called erythrocytes. They are, by far, the most abundant blood cells, making up about 45% of the volume of human blood. A microliter of blood can contain more than 5 million red cells. RBCs have one main function in the body—to transport oxygen. If a patient has a decreased red count, they have a condition called anemia. Nutritional deficiency, genetic abnormalities, malignancy, and blood loss are just a few of the reasons a person can become anemic.

HGB

Hemoglobin is the oxygen-carrying portion of the blood and is what gives RBCs their red color. One of the main components of the hemoglobin molecule is iron. Patients who are iron deficient can become anemic if there is not enough iron stored to make new red cells.

HCT

Red cells account for nearly 50% of the total volume of whole blood. The hematocrit is a measurement of the red cell portion of the blood. A normal adult hematocrit is 35-50%; women typically have lower hematocrits than men.

MCV

The MCV, or mean corpuscular volume, tells us about the average size of each red cell. Small red cells can indicate that a patient is iron deficient, while abnormally large red cells may indicate a vitamin deficiency.

PLATELETS

Platelets are the smallest of all cells found in the blood and are involved in blood clotting. High or low platelet counts can be caused by infection, bleeding, or certain drugs. If abnormal platelet counts are sustained, it is important to determine the cause. Low platelet counts can lead to bleeding or hemorrhage; high platelet counts can lead to spontaneous

PREV

CBC Overview

WHITE BLOOD CELLS (WBCs)

White blood cells, or WBCs, are a major component of the immune system and may be elevated or decreased normal white cell counts range from 4,000 to 10,000 per microliter of blood.

Neutrophils

The most abundant type of white cell in an adult is the neutrophil, which normally accounts for roughly 50-70% of the WBCs in venous blood. Their main function is to ingest

neutrophil count rises, it

is being stimulated. If the

In patients on chemother

infections.

Lymphocytes

Lymphocytes account for

venous blood. The main p

help identify and "reawa

lymphocytes usually indi

Monocytes

Monocytes are about 2-8

microbes. Monocytes can

of the immune system. I

as Other WBCs.

Eosinophils & Basophils

Eosinophils and basophil

activated in patients with

along with basophils, dur

CBCs Simplified

CBCs Made Simple

The Sysmex XW-100 provides same-visit CBC results with 12 parameters including a 3-part differential.

As a CLIA-waived device, using the XW-100 requires no training beyond following the manufacturer's instructions and on-screen prompts. It's simple to use which expands the ability of staff to perform CBC testing.

Once the analyzer is ready to process samples, the sample-to-result time for the XW-100 can be as little as three minutes. And the potential for same-visit CBC results opens up opportunities for patients and healthcare providers to interact at the time of testing, allowing physicians to provide immediate feedback to patients.

When results can be provided at the same visit, nurses don't have to spend time ordering and recording lab results, calling patients, leaving messages, waiting for callbacks or sending letters. The XW-100 can help improve efficiency, which may ultimately improve bottom line.

The XW-100 Has a Small Footprint

The XW-100 fits on a standard bench or countertop. The full weight of the XW-100 is only 38 lbs. It is 13.8" high, 7.3" wide, and 18.1" deep.

Repeat Testing

This technology will not completely eliminate

healthcare providers may need to re-test some

of samples that are currently being sent-out, a

same-visit results for patients.

Normal Result

MCV 83.6

NOTES

Suppressed Result

MCV <<<

NOTES

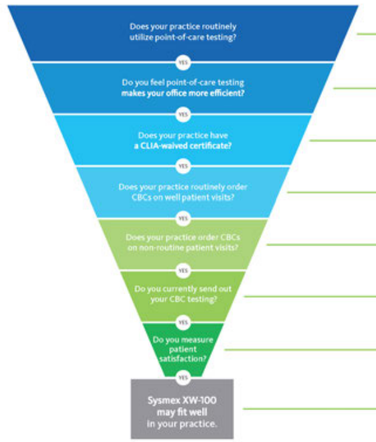
RECOMMEND FURTHER TESTING.

CLIA waivers are for tests that are simple to operate, have a low risk of erroneous results, and provide results do not require interpretation. Suppressions cut off values are enabled in order to mitigate risks associated with potentially erroneous or critical medical interventions.

PREV NEXT

Good Fit Chart

When you are meeting a customer, there are questions you can ask to help them decide if the XW-100 is right for them. An easy way to evaluate this is through the Good Fit chart.



If they aren't sure, ask about other POC tests like glucose and strep.

If they aren't sure, ask about time and follow-up required for nurses to track and file lab test results and then call patients to report results, leave messages for callbacks, make callbacks, mail letters to patients with results, etc.

If physician isn't sure, you may need to follow-up with lab manager. However, if there are already POC tests at the practice, it is likely they have a waiver.

Some practices use CBCs in up to 50% of visits. Some rarely use them. Most physicians will have an idea of how often they order a CBC for screening.

This number will likely be higher than for well-patient visits. This is important for getting information that can be used in the same visit to treat the patient.

If CBCs are sent out, ask about turnaround time. Do they come back the same day or only after 24 hours? The XW-100 provides results faster and more efficiently that any non-waived test.

Point out that many patients will report higher patient satisfaction scores when they can get same visit test results and don't have to receive messages and call the office back.

The XW-100 isn't suitable for every practice. But if a customer answers yes to all or most of these questions, then they would be a good fit.

Sales Walkthrough

PREV NEXT

QUIDEL | Triage®

Case Study 2
Chest Pain Diagnosis

Patient Name: John M.
Date: January 2, 2018
Temp: 98.6 **BP:** 206/89
HR: 101 **RR:** 14 **O_2:** 96%
Hx: Hypertension, hyperlipidemia

Observations:
A 65-year-old African American male presents to the Emergency Department complaining of two days of intermittent chest discomfort. He describes his pain as a non-radiating pressure with nausea, but not vomiting. He has mild shortness of breath when he is standing up or walking. John says he has no other symptoms.

He admits to smoking 1½ packs of cigarettes a day for 10 years, but states he does not use alcohol or drugs.

The patient is alert and oriented with no apparent distress and his physical examination is normal. His heart has a regular rhythm, without murmurs, and he has no cyanosis or edema in the limbs.

Diagnostic Testing:

ECG	Normal sinus rhythm, non-specific ST-T wave changes
Chest X-ray	Normal
CBC	Normal

Cardiac biomarkers

CK-MB	3.0 ng/mL
Myoglobin	63 ng/mL
Troponin I	< 0.05 ng/mL
BNP	88 pg/mL

Tx:
Aspirin, nitroglycerin, and ibuprofen. John's pain is relieved with ibuprofen.

Repeat cardiac biomarkers 3 hours later

CK-MB	3.9 ng/mL
Myoglobin	79 ng/mL
Troponin I	< 0.05 ng/mL

Dx:
Cardiac biomarkers along with other clinical information are not indicative of an MI diagnosis.

Patient is referred for a follow-up with his primary care provider and a cardiologist. On visiting the cardiologist, he has a normal stress test. He is advised on proper diet and exercise for heart health and is given a prescription for nitroglycerin tablets as needed.

Quidel | Rapid Diagnostics | quidel.com | 800.874.1517 | 858.552.1100

Play Chest Pain Trivia!

Circle the correct answer, then scratch off to see if it matches.

1 How many Americans are estimated to have a heart attack this year?

Less than 100,000 | 200,000
400,000 | More than 600,000

More than 600,000
(https://www.cdc.gov/heartdisease/heart_attack.htm. Accessed 30 January 2018.)

2 Which group has the highest incidence of fatal and non-fatal heart attack?

Asian American | African American
Hispanic American | White/Caucasian American

African American
(Benjamin EJ, Blaha MJ, Chiuve SE, et al. Circulation. 2017;135:e1–e458.)

3 People who smoke a pack of cigarettes a day have _____ the risk of heart attack as non-smokers.

the same | twice
three times | four times

twice
(http://my.clevelandclinic.org/healthy/articles/17488-smoking. Accessed 07 February 2018.)

4 This common condition can produce symptoms similar to a heart attack.

Heartburn | Headache
Gastroenteritis | Pneumonia

Heartburn
(https://health.clevelandclinic.org/2016/10/7is-that-pain-in-your-chest-heartburn-or-a-heart-attack/. Accessed 07 February 2018.)

5 When did cardiac troponin (cTn) become the recommended biomarker for the evaluation of patients with a possible diagnosis of acute myocardial infarction (AMI)?

1960s | 1970s
2000 | 2010

2000
(Thygesen K, Alpert JS, Jaffe AS, et al. Circulation. 2012;126(16):2020-35.)

CS1026300EN00 (02/18)

Alere™

Case Study: Influenza A and B

Patient Name: Jim L.
Temp: 100.1 **BP:** 120/83
HR: 89 **RR:** 19 **O_2:** 95%
Hx: None to date.

Observations:
A 47-year-old male presents to his primary care provider with mild fever, fatigue, headache, cough, and congestion which he has had for two days. Jim says he has been traveling extensively the past few weeks. Between meetings, hotels, and jet lag, he has gotten little time to sleep or recuperate.

Yesterday morning, his symptoms worsened and he asked to be worked in to an appointment this afternoon so he could get started on antibiotics. Due to his airline travel, Jim is certain that he has a sinus infection requiring an antibiotic. Aside from his current illness, he says he is quite healthy, works out daily, maintains a healthy lifestyle, and has yearly physicals.

When asked, Jim states that his last flu shot was two years ago. He doesn't recall being exposed to anyone with influenza, although he does admit that he has been interacting with many people at recent tradeshows.

Diagnostic Testing:

Rapid molecular tests	
Influenza A	**Positive.**
Influenza B	Negative.

Dx:
Influenza A.

Jim is prescribed an antiviral medication and given instructions not to go back to work until he meets the CDC criteria of no fever for at least 24 hours without the use of fever reducers. He is given an education sheet on the influenza virus with information on how to limit its spread to others and the importance of vaccination.

Discussion:
Jim was certain he needed antibiotics. What are some of the consequences of giving antibiotics to someone with influenza?

What kind of advice would you give to Jim in terms of influenza prevention?

To learn more contact your local Account Executive **1.877.441.7440 | alere.com**

ivia! Circle the correct answer, then scratch off to see if it matches.

za" originated in 15th century Italy, ttributed to "influence of the _____."
Stars | Humors
Stars
(https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html)

lu viruses infect up to _____ of each year.
50% | 100%
20%
(http://facts.randomhistory.com/2009/07/19_flu.html)

e die in the U.S. each year from flu.
20,000 | 56,000
56,000
(https://www.cdc.gov/vaccines/adults/vpd.html)

g the flu and lost work productivity _____ in the U.S. alone.
Millions | Billions | Trillions
Billions
(http://facts.randomhistory.com/2009/07/19_flu.html)

5 Healthy adults are contagious one day before and up to _____ days after showing influenza symptoms.
Three | Five
Seven | Nine
Seven
(https://www.cdc.gov/flu/keyfacts.htm)

Alere™


NephroCheck
Protect the kidneys with better biomarkers.
Find them here!
TIMP-2 + IGFBP-7 = The NephroCheck Test


PROTECT THE KIDNEYS
WITH BETTER BIOMARKERS.
TIMP-2 × IGFBP-7 = THE NEPHROCHECK TEST
FIND THEM HERE!
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ASTUTE MEDICAL
Innovative biomarkers. Smarter healthcare.
PROTECT THE KIDNEYS
WITH BETTER BIOMARKERS.
TIMP-2 × IGFBP-7 = THE NEPHROCHECK TEST
FIND THEM HERE!
ASTUTE MEDICAL
Innovative biomarkers. Smarter healthcare.


THE FIRST REAL IMPROVEMENT IN
RENAL TESTING IN OVER 60 YEARS
[TIMP-2]×[IGFBP-7]=THE NEPHROCHECK TEST
NephroCheck
ASTUTE MEDICAL
Innovative biomarkers. Smarter healthcare.
THE FIRST REAL IMPROVEMENT IN
RENAL TESTING IN OVER 60 YEARS
[TIMP-2]×[IGFBP-7]=THE NEPHROCHECK TEST
NephroCheck

CLICK IMAGE TO PLAY


The Sgx Clarity™ System
Breaking the sensitivity barrier. One molecule at a time.
Previously unobtainable clinical clarity will soon be within reach.
Currently under development, the Sgx Clarity™ System will break through current sensitivity barriers in immunochemistry diagnostics, delivering the unparalleled sensitivity and precision of Single Molecule Counting (SMC™) technology to hospital and reference laboratories worldwide.
"After decades of very little innovation with protein assays, single-molecule detection has finally arrived. Singulex's elegant Single Molecule Counting Technology has the potential to detect above-normal protein levels at previously undiscoverable, precise increments. SMC offers enhanced precision and ultrasensitive measurement capabilities allowing for improvement in patient risk assessment and health management at the clinical level."
– Alan H.B. Wu, PhD, DABCC, FACB
Professor, Laboratory Medicine Chief,
Clinical Chemistry Laboratory
San Francisco General Hospital
"Predicting future cardiac performance and risk in heart failure patients can be incredibly valuable in formulating patient treatment plans. In a study we conducted here at Mass General, we concluded that identification of those heart failure patients whose disease will worsen over time may be possible utilizing Singulex's ultrasensitive cardiac troponin-I assay. Having this type of information may lead to more informed treatment decisions, which may slow disease progression for heart failure patients."
– James L. Januzzi Jr., MD, FACC
Cardiologist, Massachusetts General Hospital
Hutter Family Professor of Medicine,
Harvard Medical School
Singulex
Boldly go where no immunoassays have gone before.
Break sensitivity barriers to understand disease in a new way.
Come and explore this new frontier. Join us in booth #1826 at AACC 2014.
Singulex.com


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Viral or Bacterial?
10 MINUTE TEST
FebriDx® is the first and only rapid POC test to differentiate a viral from a bacterial acute respiratory infection.
REDUCE ANTIBIOTIC USE
ACCURATE (99% NPV)
LOWER HEALTHCARE COSTS
LUMOS DIAGNOSTICS
FebriDx.com
FebriDx®
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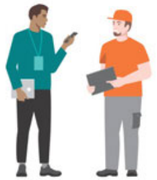
@StewartShipp

Implementation and Validation

1 Installation



2 System Configuration

3 Device calibration and QC

- CMS Brochure # 3 – Calibration and Calibration Verification[1]
- Implement / Validate IQCP
  - CMS Brochures 11-13[2]

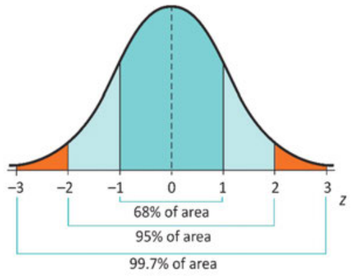
1. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6065bk.pdf
2. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

Validation - Reference Interval and Reportable Range

Reference Range

- Usually, 99th percentile
  - If determined using a 100-patient study, values listed in increasing order, 99th value is 99th percentile
  - Approximated as the mean value of the normal reference group plus three standard deviations.

- **Reportable Range**
  - Use controls, calibrators, patient samples
  - Only samples within the validated range should be used for patient assessment / treatment



http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6064bk.pdf
Hazra A, Gogtay N. IJD. 2017;62(1):18-24.

Accuracy and Precision

Accuracy = Measure of how close a measurement is to the "true" result

- How often a measurement is close to the bulls-eye

Precision = Measure of the percent coefficient of variation (CV)

- How close repeated measurements of the same sample are to each other

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6064bk.pdf
Hazra A, Gogtay N. IJD. 2017;62(1):18-24.

IQCP Is a Continuous Process

Maintenance

- Define routine review frequency
- Identify problems with existing equipment
- Change locations using IQCP

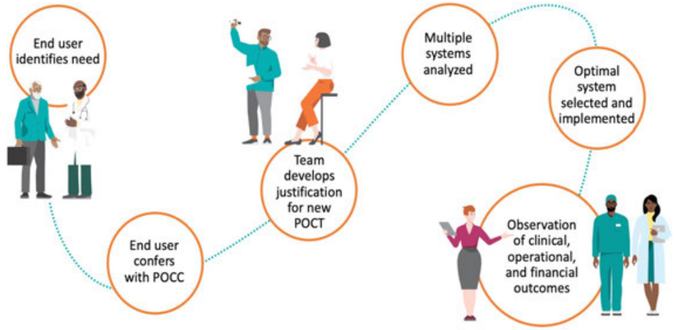
Revision

- Quality Assessment
- Risk Assessment

Each change is documented and signed as per original IQCP[1]

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf. Accessed January 16, 2024.

Correct Implementation Starts With the End User



Initial Training and Competency Timeline

- **Must be completed before any patient testing**
- **Include training needs identified in IQCP development**
- **Documentation retained**

Personnel Approved to Perform POCT

Yenice S. *EJIFCC*. 2021;32(2):167–178.

POCT U 39

QC & POCT

Reagent issues
- Traditional QC may not be relevant

Process issues
- Value of POCT QC varies by test system

Organization
- Risk assessment process can define QC frequency
- Risk defined QC procedures

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-K/subject-group-ECFRc96daead380f6ed/section-493.1256. Accessed January 16, 2024.
https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/qcp-workbook.pdf. Accessed January 16, 2024.

POCT U 24

Personnel and Training Requirements

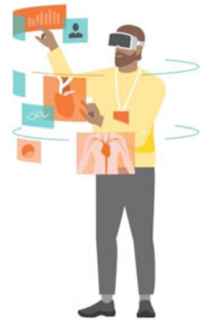
- Operators
- Supervisors
- Compliance oversight (Lab?)
- Providers/ Clinicians

- Support Personnel
  - IT, purchasing, materials management, etc.
  - Who will provide training?
  - Who will perform the ongoing inventory management?

POCT U 46

Future of POCT Involves New Disease States and New Technologies

The future of POCT will likely bring new testing for a wide variety of uses, such as the following:[1]
- Mobile wearable devices
- Transcutaneous monitors
- Breath alcohol testing, breath hydrogen/H. pylori testing
- Continuous glucose monitoring
- Lab-on-a-chip (LOC)
- DNA testing
- Molecular PCR
- Sepsis
- Stroke markers
- Epidemic and pandemic testing



John AS, Price CP. *Clin Biochem Rev.* 2014;35:155.
Abel G, et al. Point-of-care testing: A "how-to" guide for The non-laboratorian. AACC. 2022.

POCT U 17

Multiple Laboratory Areas

Immunoassays
- Antibody/antigen
- Small molecular proteins, hormones, fatty acids, drugs and other substances

Molecular assays
- DNA or RNA
- Pathogens, biomarkers, genes

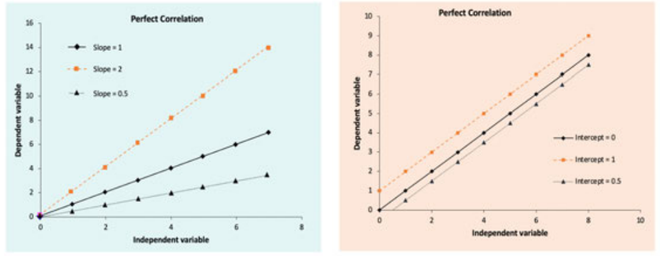
Chemical analyzers
- Biochemical reactions
- Enzymes, carbohydrates, lipids, protein and non-protein nitrogen, inorganic elements, liver function and other indicators

Abel G, et al. Point-of-care testing: A "how-to" guide for The non-laboratorian. AACC. 2022.

POCT U 29

Accuracy and Correlation

Determined by correlation to local standard - <u>Correlate does not mean match</u>



POCT U 16

POCT Methodologies Exist for Several Conditions and Specialties

- Hematology
- Coagulation
- Infectious disease
- Cardiovascular disease
- Diabetes
- Kidney disease
- Pregnancy
- Critical care
- Blood gas
- Chemistry

Abel G, et al. Point-of-care testing: A "how-to" guide for The non-laboratorian. AACC. 2022.

Treponema pallidum

Treponema pallidum (TP) is the pathogenic spirochete bacterium that causes syphilis.

TP is primarily transmitted through sexual contact.

TP causes a multi-stage systemic infection that can lead to serious sequelae in multiple organ systems if left untreated:

- Neurosyphilis (central nervous system)
- Ocular syphilis
- Otosyphilis
- Cardiovascular syphilis
- Congenital syphilis (maternal-to-fetal infection)

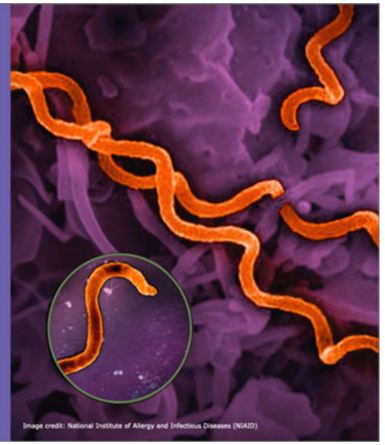


Image credit: National Institute of Allergy and Infectious Diseases (NIAID)

https://www.cdc.gov/std/treatment-guidelines/syphilis.htm. Accessed April 15, 2024.
Papp JR, et al. *MMWR Recomm Rep.* 2024;73(RR-1):1–32.

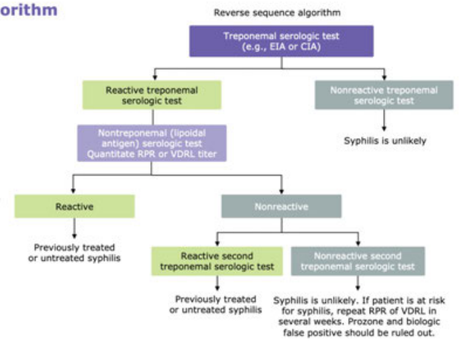
Reverse antibody algorithm

Benefits

- Treponemal tests are specific for TP infection

Limitations

- Could take 3-5 days
- Positive treponemal tests do not indicate active infection
- Treponemal tests can be more expensive and are higher in complexity



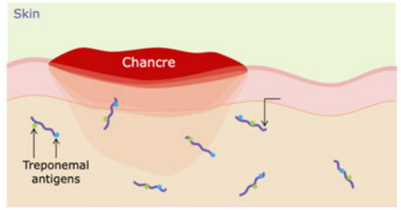
Papp JR, et al. *MMWR Recomm Rep.* 2024;73(RR-1):1–32.

CIA = chemiluminescence immunoassay; EIA = enzyme immunoassay; RPR = rapid plasma regain; TPPA = *Treponema pallidum* particle agglutination; VDRL = Venereal Disease Research Laboratory.

Syphilis testing and antibodies: Treponemal tests

Treponemal Test

- Detects an antibody response to antigens **specific** to TP that enter blood or CSF.
- Can be used to confirm positive nontreponemal screening tests.
- Can evaluate early when nontreponemal tests may not be reactive.
- Treponemal antibodies can persist after treatment and cannot differentiate between a current and previously treated infection.

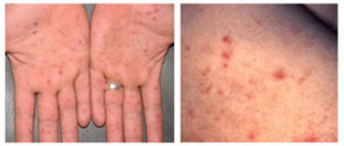


Papp JR, et al. *MMWR Recomm Rep.* 2024;73(RR-1):1–32.

Syphilis lesions can differ according to skin color

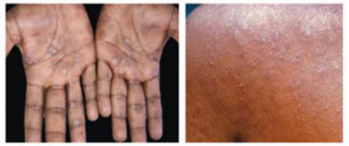
Standard description (seen in light skin)

- Reddish-brown
- Scale prominent in skin furrows, points inward
- Vascular pattern may be absent



Skin of color

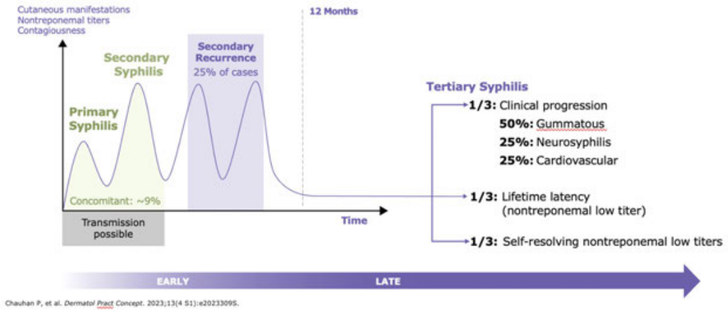
- May appear orange or hyperpigmented
- White and peripheral scales
- Vascular pattern almost always absent
- Bilateral annular facial plaques more frequent



Whiting C, Schwartzman G, Khachemoune A. *J Clin Derm.* 2023 Mar;24(2):287-297.
Chauhan P, Behera B, Ding DD, et al. *Dermatol Pract Concept.* 2023 Oct 1;13(4 S1):e2023309S.
Navarrete J, Saavedra-Portales S. Syphilis for dermatologists: Current concepts. *Clin Dermatol.* 2024 Mar-Apr;42(2):134-154.
Narasimhan M, Legoo M, Ramachandran R, Fernandes SD. *J Family Med Prim Care.* 2022 Mar;11(3):1216-1220.

Early syphilis (secondary stage). https://wellcomecollection.org/works/z9pjqf23

Syphilis stages differ by manifestations, recurrence rates, antibody titers, and tertiary or latent symptoms



Chauhan P, et al. *Dermatol Pract Concept.* 2023;13(4 S1):e2023309S.

Molecular testing for syphilis has benefits

No FDA-approved nucleic acid amplification tests (NAATs) are available for syphilis.

Laboratory-based NAATs have been used for primary and secondary syphilis lesions.

Sensitivity depends on multiple factors:

- Genes (rRNA, tpp47, or polA are most common)
- Stage
- Specimen type (direct lesion exudate, serum, CSF)

NAATs might offer more timely diagnosis of primary syphilis compared with serologic testing.

Papp JR, et al. *MMWR Recomm Rep.* 2024;73(RR-1):1–32.

IDSA recommends that antibiotics only be prescribed with a positive GAS RADT due to antimicrobial resistance.

Shulman ST, et al. *Clin Infect Dis*. 2012;55(10):1279-1282.

Clinical Manifestations Cannot Differentiate Etiologies

Bacterial

- Erythematous and swollen pharynx
- Tonsillar hypertrophy
- Tonsillar inflammation (with or without exudates)
- Fever
- Edematous uvula
- Petechial rash along the palate
- Tender anterior cervical lymphadenopathy

Viral

Skolnik NS, Albert RH. *Essen Infect Dis Topics Primary Care*. 2008:15–24.

Non-Compliance With IDSA Guidelines Is a Problem in Pediatric Patients

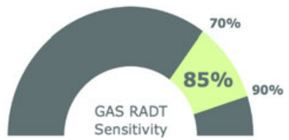
Nearly 40% of pediatric patients tested for GAS are not in compliance with IDSA guidelines.

- Greater return rates
- Misdiagnosis
- Inappropriate antibiotics
- Allergic reactions
- Loss of school days

Thompson JM, et al. *Pediatr Emerg Care*. 2022;38(2):e519-e523.

RADT May Miss Positive Cases of Acute Pharyngitis

GAS RADTs were developed over 40 years ago for use at the point-of-care or within clinical laboratories.[1]



Systematic reviews and meta-analyses estimate the sensitivity for GAS RADT at 85% with a range of 70-90%.[2-5]

IDSA recommends throat culture for children and adolescents with a negative RADT due to low sensitivity for GAS in some studies.

1. Mustafa Z, Ghaffari M. *Front Cell Infect Microbiol*. 2020;10:563627
2. Shulman ST, et al. *Clin Infect Dis*. 2012;55(10):1279-1282.
3. Ruiz-Aragón J, et al. *Ann Pediatr (Barc)*. 2010;72(6):391-402.
4. Lean WL, et al. *Pediatrics*. 2014;134(4):771-81.
5. Cohen JF, et al. *Cochrane Database Syst Rev*. 2016;7(7):CD010502.

RADTs Have Several Limitations

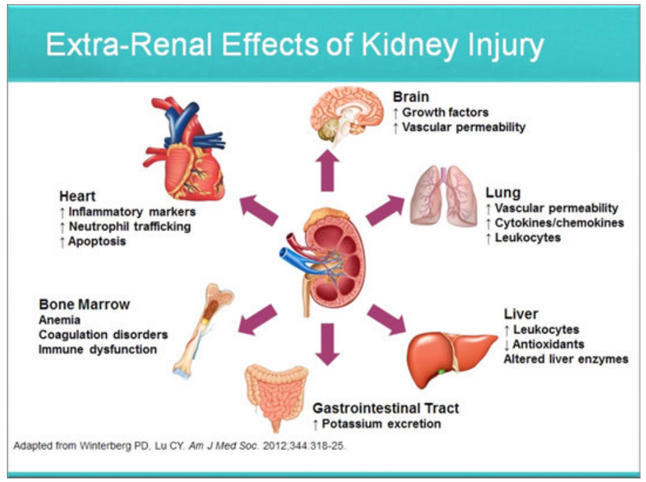
- Poorly collected samples can contain suboptimal quantities of GAS. **False Negative**
- Liquid transport media may dilute GAS Concentration. **False Negative**
- Operator must observe and interpret color and/or lines in test strips. **False Negative / False Positive**
- RADTs only detect GAS and cannot distinguish colonization or infection. **False Negative / False Positive**

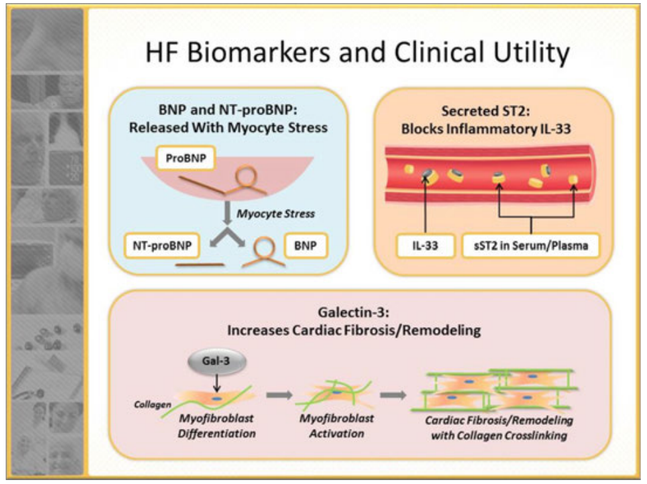
Thompson TZ, McMullen AR. *J Clin Microbiol*. 2020;58(6):e01494-19.

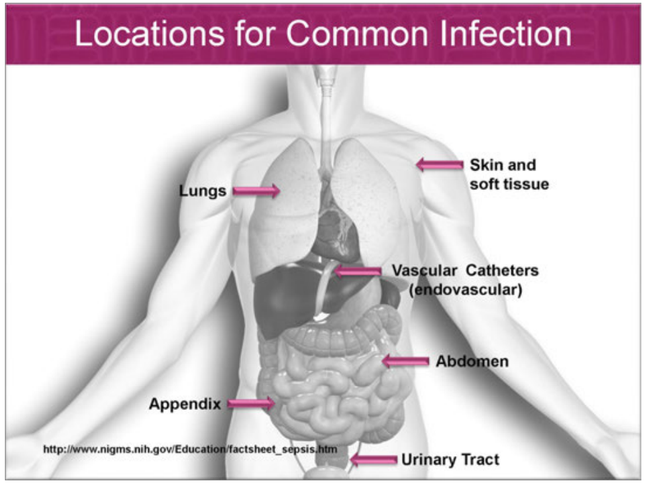
Acute Pharyngitis Symptoms

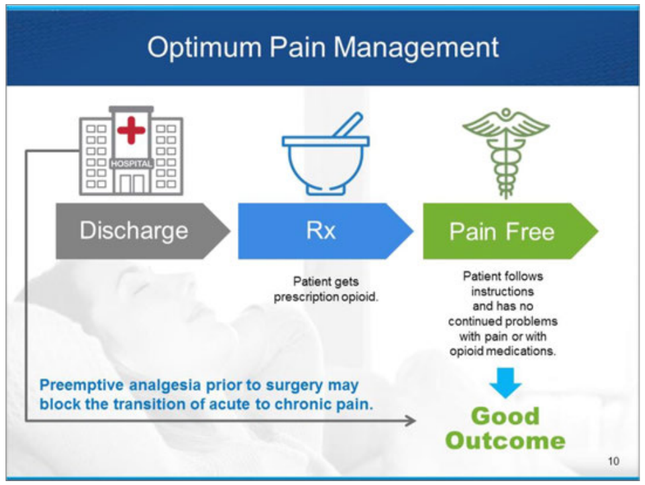
- Headache
- Tender anterior cervical lymph nodes
- Tonsillar exudates
- Sore throat
- Chills
- Fever
- Vomiting
- Nausea
- Abdominal pain
- Rash
- Myalgia
- Fatigue

Skolnik NS, Albert RH. *Essen Infect Dis Topics Primary Care*. 2008:15–24.

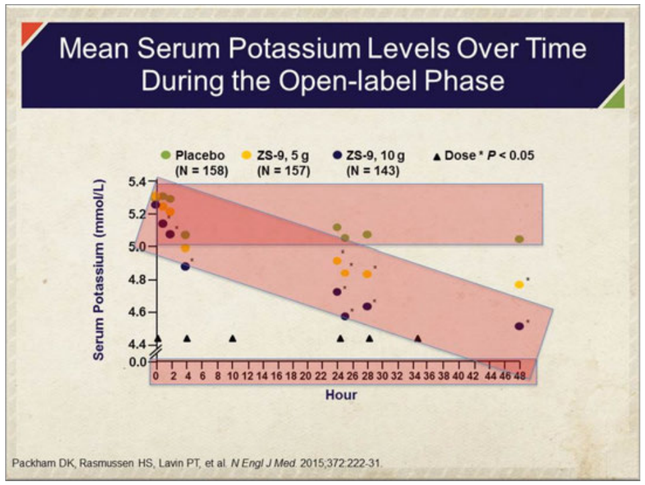

Extra-Renal Effects of Kidney Injury
Brain
↑ Growth factors
↑ Vascular permeability
Heart
↑ Inflammatory markers
↑ Neutrophil trafficking
↑ Apoptosis
Lung
↑ Vascular permeability
↑ Cytokines/chemokines
↑ Leukocytes
Bone Marrow
Anemia
Coagulation disorders
Immune dysfunction
Liver
↑ Leukocytes
↓ Antioxidants
Altered liver enzymes
Gastrointestinal Tract
↑ Potassium excretion
Adapted from Winterberg PD, Lu CY. Am J Med Soc. 2012;344:318-25.


HF Biomarkers and Clinical Utility
BNP and NT-proBNP:
Released With Myocyte Stress
ProBNP
Myocyte Stress
NT-proBNP
BNP
Secreted ST2:
Blocks Inflammatory IL-33
IL-33
sST2 in Serum/Plasma
Galectin-3:
Increases Cardiac Fibrosis/Remodeling
Gal-3
Collagen
Myofibroblast Differentiation
Myofibroblast Activation
Cardiac Fibrosis/Remodeling with Collagen Crosslinking


Locations for Common Infection
Lungs
Skin and soft tissue
Vascular Catheters (endovascular)
Abdomen
Appendix
Urinary Tract
http://www.nigms.nih.gov/Education/factsheet_sepsis.htm


Optimum Pain Management
HOSPITAL
Discharge
Rx
Pain Free
Patient gets prescription opioid.
Patient follows instructions and has no continued problems with pain or with opioid medications.
Preemptive analgesia prior to surgery may block the transition of acute to chronic pain.
Good Outcome
10

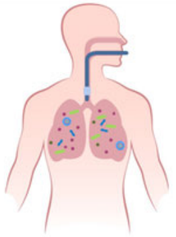

New and Familiar Strategies With Medications
Russell D. Weisz, MD
25
TEAMHealth


Mean Serum Potassium Levels Over Time During the Open-label Phase
Placebo (N = 158)
ZS-9, 5 g (N = 157)
ZS-9, 10 g (N = 143)
Dose * P < 0.05
Serum Potassium (mmol/L)
5.4
5.2
5.0
4.8
4.6
4.4
0.0
0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30 32 34 36 38 40 42 44 46 48
Hour
Packham DK, Rasmussen HS, Lavin PT, et al. N Engl J Med. 2015;372:222-31.

Ventilator-Associated Pneumonia: Characterization

Intubation or mechanical ventilation

24 Hrs | 48 Hrs | 72 Hrs



Onset of VAP

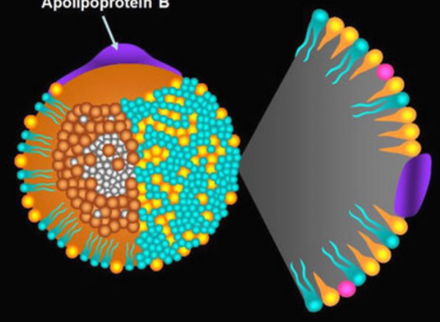
- Presence of a new or progressive infiltrate
- Signs of systemic infection (fever, altered white blood cell count)
- Changes in sputum characteristics
- Detection of a causative agent

American Thoracic Society, Infectious Diseases Society of America. *Am J Respir Crit Care Med.* 2005;171:388-416. 10

Lipids

LDL-C

Apolipoprotein B

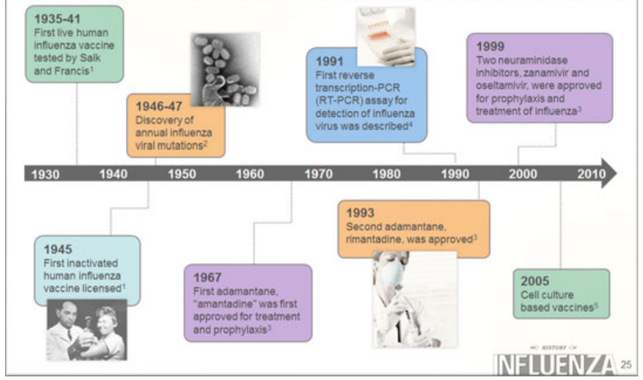


HDL

LDL

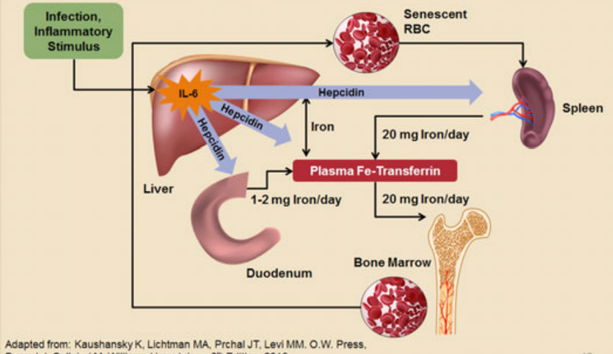
VLDL

Vaccine, Treatment, and Testing Development Timeline



25

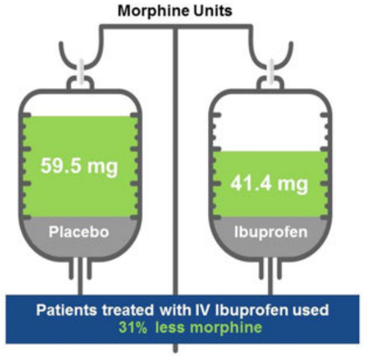
Effect of Inflammation on Iron Concentrations



Adapted from: Kaushansky K, Lichtman MA, Prchal JT, Levi MM, O.W. Press, Burns LJ, Caligiuri M: Williams Hematology, 9th Edition. 2016.

13

Better Pain Control With Less Morphine



Patients treated with IV Ibuprofen used 31% less morphine

Singla N, Rock A, Pavliv L. *Pain Med.* 2010;11:1284-93.

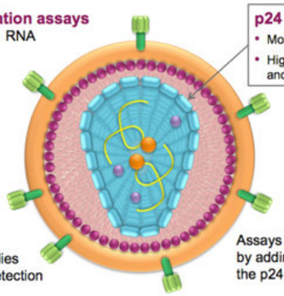
TEAMHealth

HIV-1 p24 Capsid Protein

Detected by **4th generation assays** **4 to 10 DAYS** after HIV-1 RNA

p24 Capsid Protein

- Most abundant viral protein
- High serum levels in early and late stages of HIV infection



Transient detection
Later in infection antibodies can interfere with p24 detection

Assays have **improved** by adding methods to **disrupt** the p24 antibody complex

http://www.cdc.gov/hiv/pdf/hivtestingalgorithmrecommendation-final.pdf
Tang S, Zhao J, Wang A, et al. *Clin Vaccine Immunol.* 2010;17(8)1244-51.

Competencies

Accredited Programs

Branding

Case Studies

Custom Photography

Digital / Social Media Advertising

Enduring Materials

Graphic Design

KOL Portals

Live & On-Demand Webinars

Live Symposia

Medical Illustration

Newsletters

Packaging & Product Design

Patient Education Materials

Peer-Reviewed Manuscripts

Print Media

Responsive Websites

Sales Collateral

Slide Deck Development

Speakers Bureau

Tradeshow Booth Design & Strategy

Video Production

Thank you for your time.

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