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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 visits¹ 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 complexity of acute pharyngitis diagnosis and treatment and summarize emerging clinical

LATEST IN INFECTIOUS DISEASE

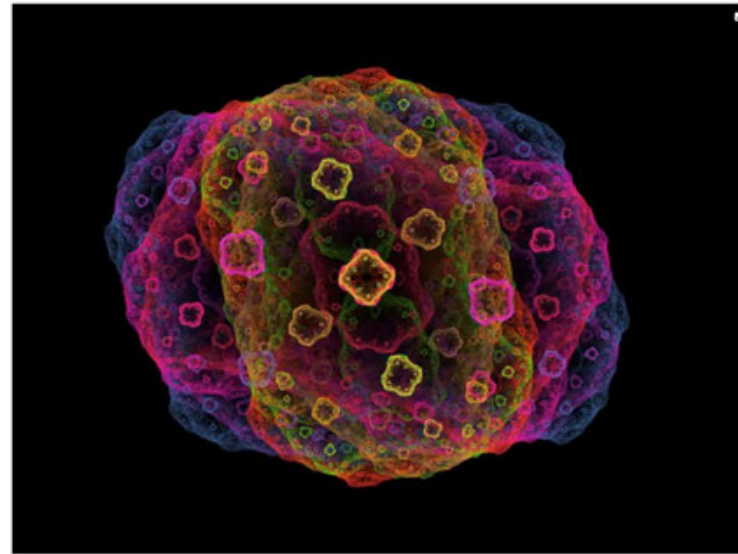
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The number of infectious disease syndromes commonly seen in primary care, urgent care, and emergency departments in the United States is staggering. Acute respiratory illnesses (ARI), ranging from mild upper respiratory tract infections to serious illnesses such as pneumonia, are the most common reasons to seek ambulatory care¹ 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 morbidity⁵ 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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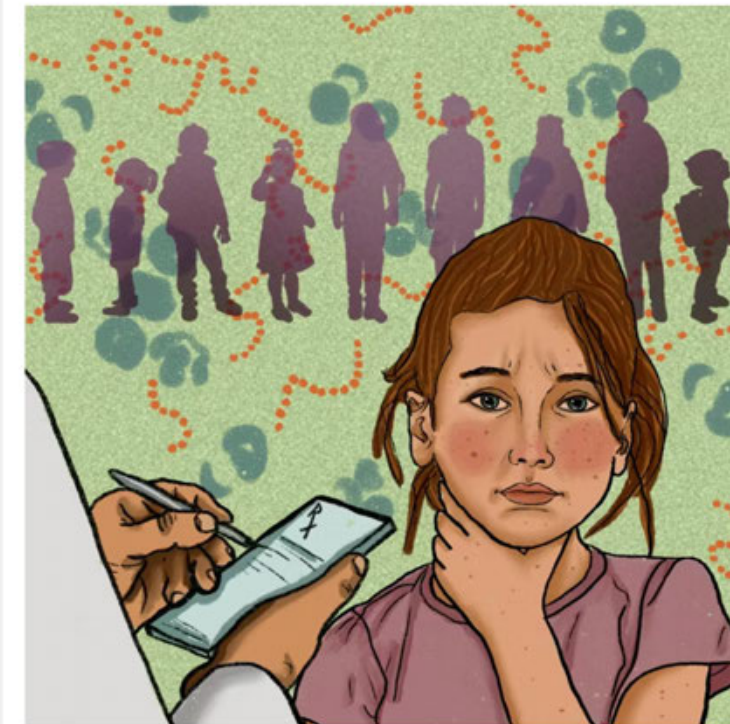
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Group A streptococcal (GAS) infections have been on the rise since late 2022 and 2023 after an overall low incidence during the years of the COVID-19 pandemic.¹ GAS infections are common among children and may be asymptomatic or produce mild infections 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 pharyngitis, has returned to similar or higher levels than those in the pre-COVID-19 pandemic.³ The

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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 crisis 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	<ul style="list-style-type: none"> Predicts neurodegeneration via correlation to NFTs Not specific to AD
p-tau	<ul style="list-style-type: none"> Correlates to NFTs, particularly p-tau181 Specific to AD, sensitivity > 90% May be low in non-White individuals
Aβ40	<ul style="list-style-type: none"> Represents total Aβ levels in cortical tissue Not specific to AD May be low in non-White individuals
Aβ42	<ul style="list-style-type: none"> Levels in CSF are decreased due to increased Aβ aggregation High concordance with amyloid PET Associated with AD
Aβ42/Aβ40	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Ratio indicative of AD and MCI High concordance with amyloid PET May be low in non-White individuals
Neurofilament light	<ul style="list-style-type: none"> 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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HSV1-2/VZV: Multiplex Molecular and Traditional Diagnostic Methods

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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 be 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)



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 laboratory testing.**

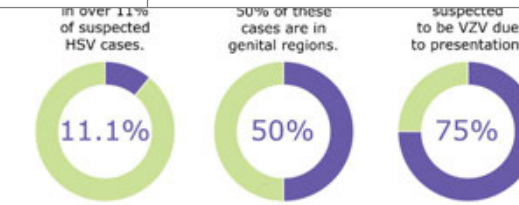


Figure 7. VZV is detected in over 11% of suspected HSV cases, primarily in genital regions. Over 75% of suspected to be VZV during initial presentation (12, 13). Over 8% of the specimens submitted for HSV testing were found to contain VZV and half of these (4.2%) (13). HSV was found in over 19% of suspected VZV cases (Figure 8) (13). Because HSV has a different 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 found in over 19% of suspected typical VZV cases.

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

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

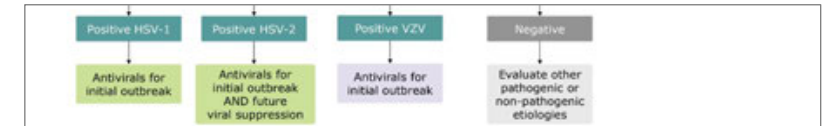


Figure 10. Utilizing multiplex testing for any patient with suspected HSV or VZV can eliminate unnecessary testing, reduce time to diagnosis, and improve treatment timelines. Early differentiation between herpes virus types is important because compared to HSV-1, HSV-2 causes more severe episodes and 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.

HSV1-2/VZV: Multiplex Molecular and Traditional Diagnostic Methods

Herpes simplex viruses and varicella zoster virus cause nondescript lesions which require rapid differentiation for appropriate diagnosis, treatment, and patient counseling. This continuing education program discusses historical diagnostic methods and the role of near-patient molecular multiplex testing.



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LEARNING OBJECTIVES

1. Review the prevalence of HSV and VZV
2. Discuss current testing guidelines and diagnostic approaches
3. Discover how a combined HSV/VZV assay can benefit patients
4. Summarize the role of near-patient testing in workflow and clinical outcome

HSV1-2/VZV: Multiplex Molecular and Traditional Diagnostic Methods



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HSV1-2/VZV: Multiplex Molecular and Traditional Diagnostic Methods



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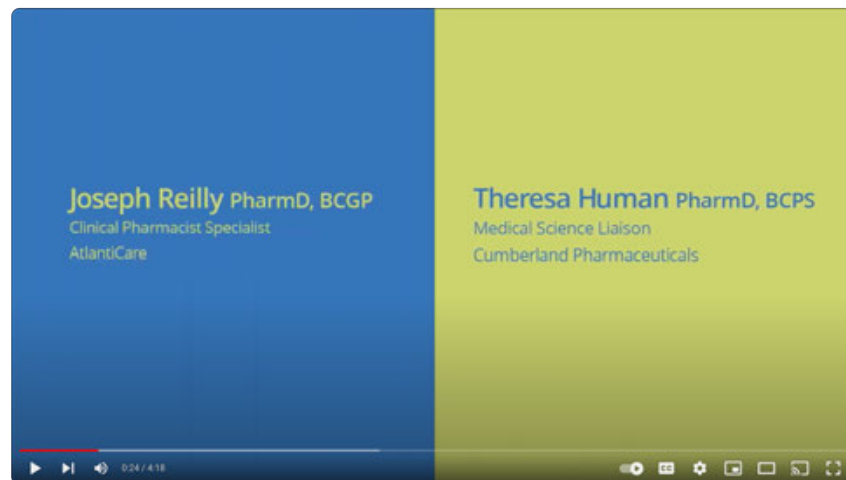
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Multicenter Study > J Mol Diagn. 2025 Jul;27(7):605-614. doi: 10.1016/j.jmoldx.2025.03.009.

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Validation of the Clinical Performance and Reproducibility of the Savanna HSV 1+2/VZV Assay

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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 Caldwell¹, Claudia Mily Espinosa², Ritu Banerjee³, Joseph B Domachowske⁴

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PMID: 40418273 PMID: 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.

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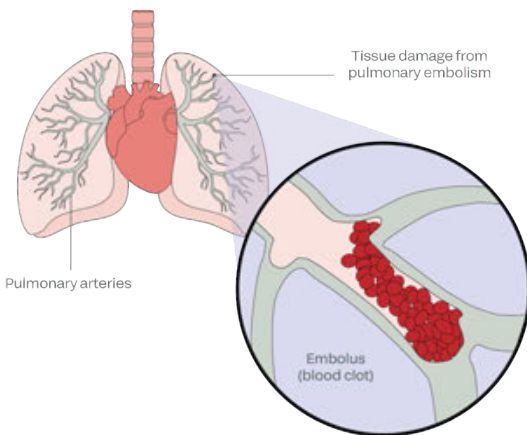
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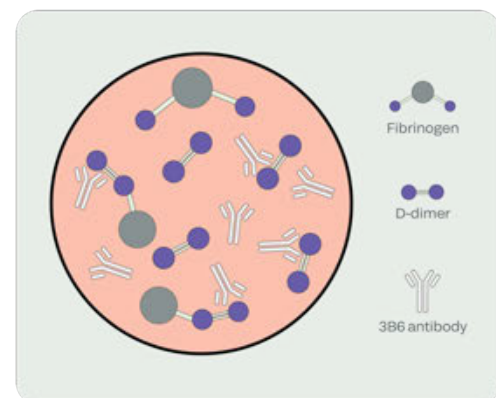
25%
Sudden death is the first symptom in about one-quarter of people who have a PE.¹

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



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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: $\geq 93\%$
- Analytic correlation: $R^2 = 0.93$

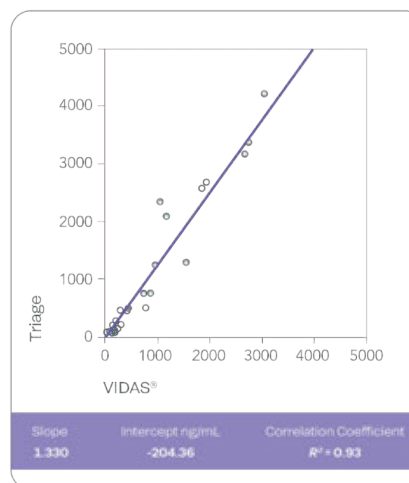
The rapid whole blood Triage D-Dimer Test compares favorably with the Vidas and is especially well suited for applications at the point of care.¹⁰

Intended Use

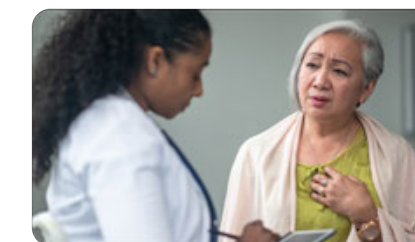
The Triage D-Dimer Test is a fluorescence immunoassay to be used with the QuidelOrtho Triage Meters for the quantitative determination of cross-linked fibrin degradation products containing D-dimer in EDTA whole blood and plasma specimens.⁵

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

The Quidel Triage D-Dimer Test vs. VIDAS¹⁰



quidelortho.com | 800.874.1517 | MM10004400EN00 (04/24)



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.

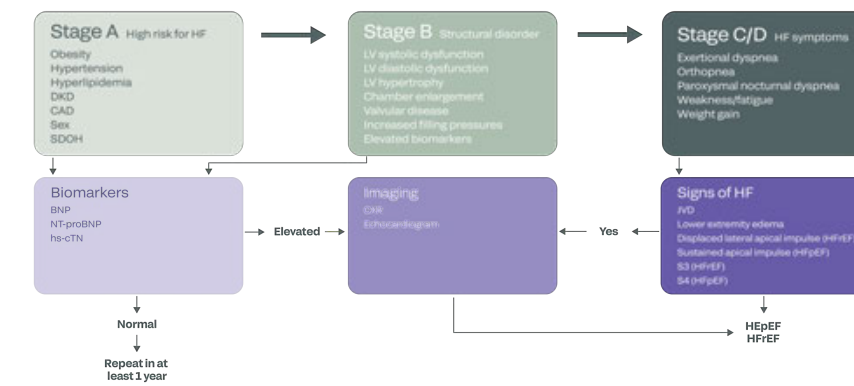
Diabetes is an epidemic. Lifetime risk for HF can be as high as 10.8% in patients with prediabetes and 32.4% with diabetes.⁴ BNP has a clear role in assessing cardiovascular complications in these patients.

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



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 been in the pharmacy field since 1977. Duane has worked for small community pharmacies, been a Pharmacy Resident at 151 supermarkets, and worked for a large pharmacy chain. To fill the healthcare gap in rural areas, Duane is providing selected test-and-treat services in his pharmacy as a clinical pharmacist. Duane's test-and-treat program not only provides access to care but also the sustainability of working with other organizations. Duane and his team of pharmacists to be

The challenge: in

Duane describes the challenge of professional lines of work in that over 270,000 people live in rural areas. That is in our state. That is in our country. The second challenge is not just rural, but an aging population. Duane is also program-based training pharmacists can be trained. Duane indicates that once pharmacists are trained, they can show that we (pharmacists) only see them through the pharmacist's eyes and test-and-treat

Case Study

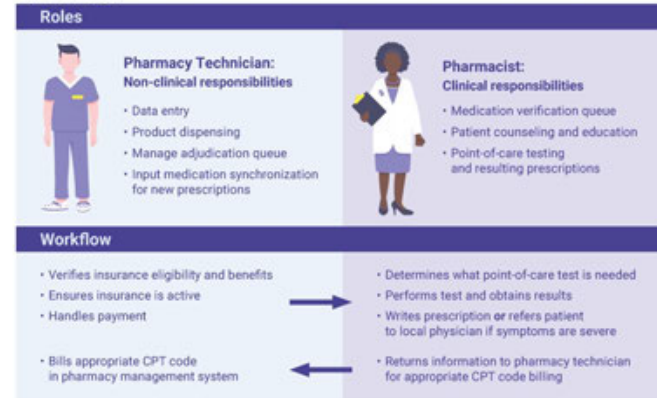
Sponsored by an educational grant from QuidelOrtho

“...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.

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2. New Analysis Suggests Adverse Drug Events Are the 3rd Leading Cause of Death in the USA. *PracticalNeurology*. Published March 26, 2025. Accessed June 9, 2025. <https://practicalneurology.com/news/new-analysis-suggests-adverse-drug-events-are-the-3rd-leading-cause-of-death-in-the-usa/3473820/>

Duane Jones, BS Pharm, PD
Regional Pharmacy Supervisor
Community Pharmacy Residency Director
Clinical Programs Director

What is test and treat and could you describe how test and treat works outside the primary care clinic?

Test-and-Treat
Reduction in hospitalizations ~30%
And reduction in emergency department visits
Not all states allow pharmacy testing

Tell me about your workflow processes.

<p>Technician Staff Non-clinical tasks</p> <ul style="list-style-type: none"> Data entry Product dispensing Adjudication queue 	<p>Pharmacist Test-and-treat Enhanced clinical services</p>
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How Pharmacists Implemented a Test-to-Treat Program and Transformed Access to Care



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

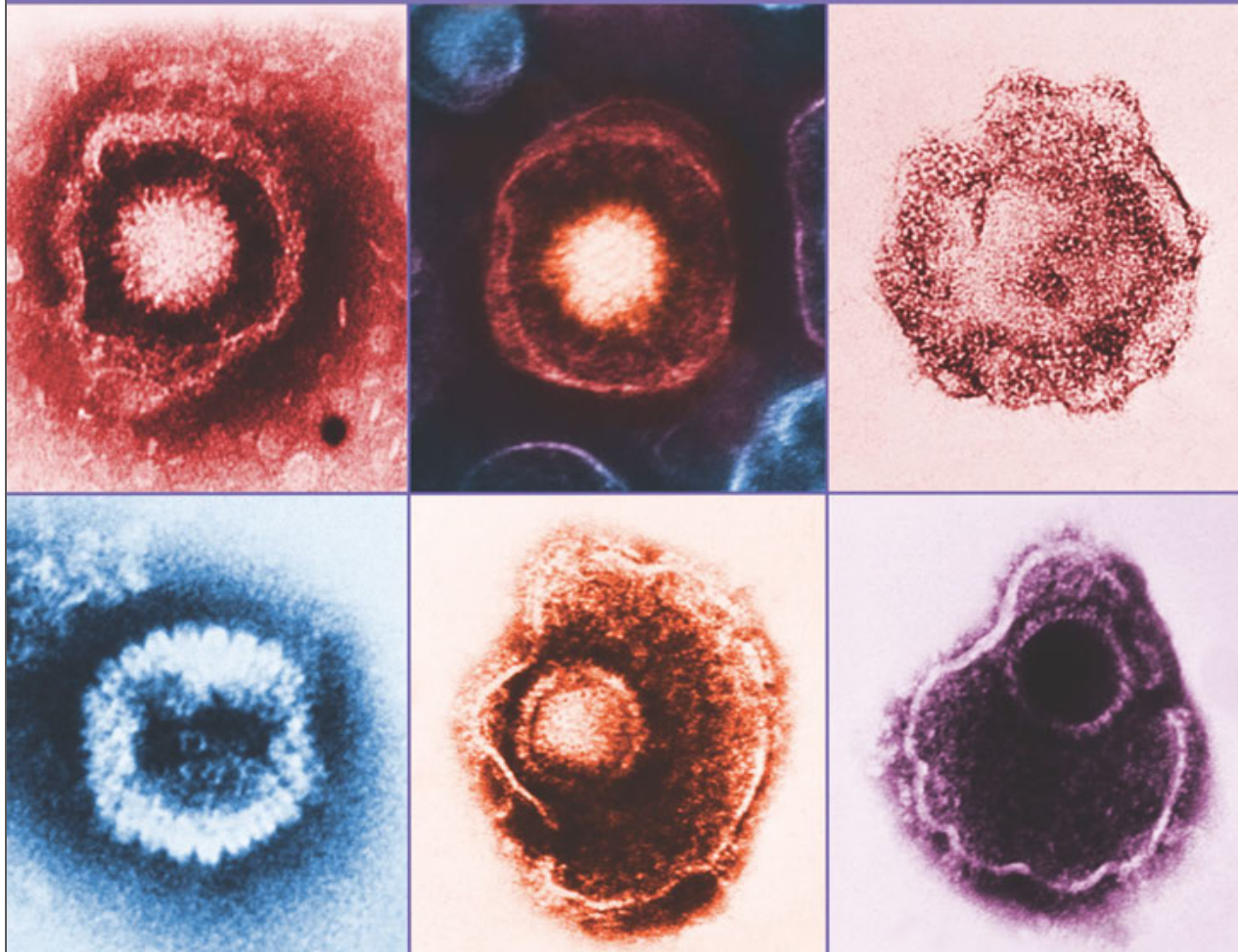
having me. It's a pleasure to be here.

Jennifer Griffin. Dr. Griffin is a clinical pharmacist for Harps food stores where she provides point-of-care testing, treatment workflow, and marketing clinical services. Dr. Griffin has a Doctor of Pharmacy degree from Harding University College of Pharmacy, Bachelor of Science in Pharmacy Administration and a Master of Science in Health Promotion from the University of Arkansas. She is also a past president of the Arkansas Pharmacists Association and has been written for NCPA's *America's Pharmacists Magazine* and participates in the CPESN USA Network Development Committee as a member.

On 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 lesions 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 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 for her results as she did not have to wait for a call or another appointment. At this time, she was drawn for a basic metabolic panel and other causes for her fatigue as well as a complete blood count.



6

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

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

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

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.

7





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



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

Blood Gas

Self-Study

<p>SEPSIS: Diagnosing and Managing Sepsis Syndrome - The Emerging Role of Bedside Analyte Testing Self-study online course - Physicians, Nurses, Respiratory therapists, and Laboratory professionals</p>	View	 CME/CE
<p>CREATININE: Significance and Applications for Rapid Creatinine Testing Self-study online course - Physicians, Nurses, Respiratory therapists, and Laboratory professionals</p>	View	 CME/CE
<p>VAP: Diagnosing and Managing Ventilator-Associated Pneumonia Self-study online course - Physicians, Nurses, Respiratory therapists, and Laboratory professionals</p>	View	 CME/CE

Podcasts

<p>Medical Mystery Cases - A Bird's Eye View October 31, 2023</p>	Listen	 CME/CE
<p>Medical Mystery Cases - A Rocky Start October 12, 2023</p>	Listen	 CME/CE
<p>Medical Mystery Cases - An Urgent Discovery October 20, 2022</p>	Listen	

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

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POINT OF CARE TESTING UNIVERSITY

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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



POCT Assays Are Simple...Why Do We Need Training?

A majority of the staff who perform POCT are not trained laboratory staff. Staff performing POCT must have the proper training and experience to ensure test results are accurate and reliable. Reduce risk from untrained personnel performing laboratory testing.



Part 2

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

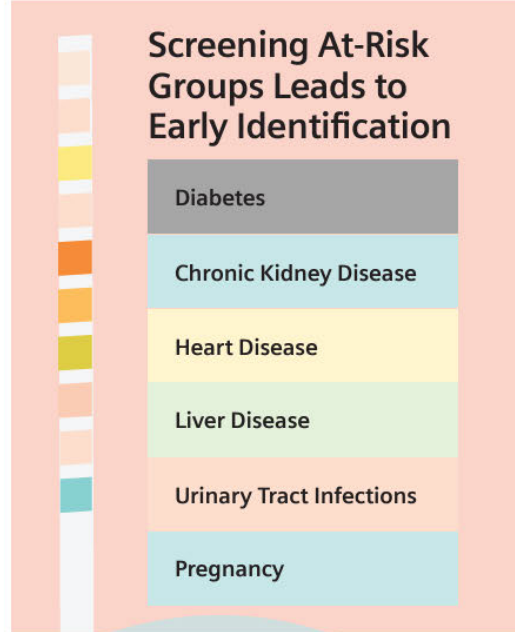
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POCT Urinalysis: Rapid Window to Patient Health

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 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



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2. Yeo SC, et al. *Clin Kid J.* 2023;17(1):sfad137.
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12. van Delft S, et al. *BMJ Open.* 2016 Aug 8;6(8):e011230.
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3

Kidney disease, diabetes, heart failure, pregnancy, hematuria, uric acid crystals, bacterial infection, urinary tract infection, medication byproducts, hemoglobinuria, myoglobinuria, blood clots, dehydration, overhydration, maple-syrup urine disease, decreased renal blood flow, glycosuria, hepatic failure, SIADH, adrenal insufficiency, diuretic use, aldosteronism, diabetes insipidus, polydipsia, acute impaired renal function, interstitial nephritis, pyelonephritis, anuria, polyuria, proteinuria, Wilson disease, liver dysfunction, diarrhea, vomiting, ketoacidosis, albuminuria, myeloma, Fanconi syndrome, Cushing syndrome, biliary obstruction, viral or drug-induced hepatitis, sterile pyuria cirrhosis, sickle cell disease, thalassemia, fever, glomerulonephritis...

What Can Urinalysis Tell Us?

- Urine is an unstable fluid that constantly changes composition.
- Urinalysis can provide information on kidney disease, diabetes, liver disease, urinary tract infections (UTIs), heart disease, and many other symptoms, diseases, and syndromes.

2

Urinalysis: A Window to Patient Health

- Urinalysis has existed for 6,000 years
- Information for an inexhaustible list of symptoms and diagnoses
 - Screen at-risk patients
 - Assist clinical diagnosis
 - Monitor disease progression
 - Evaluate treatment efficacy
- Easy
- Affordable

7

Screening to Improve Health Equity

- Social determinants of health lead to healthcare disparities.
 - Economic instability
 - Lack of nutrition
 - Inadequate education
 - Unsafe physical environment
 - Limited access to healthcare
- Race/ethnicity plays a role in health and diagnosis.
 - Minorities have higher rates of diabetes, kidney disease, heart disease, hypertension, and obesity.
 - More likely to be undiagnosed
 - May be more impacted by social determinants of health

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.

<https://www.kidney.org/atoz/content/social-determinants-health-and-chronic-kidney-disease>. Accessed 05/20/24.
George C, et al. *BMC Med.* 2022;20(1):247.
Kim EJ, et al. *J Gen Intern Med.* 2018 Jul;33(7):1116-1123.
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Reasons patients are not getting uACR tests:

Ordering rates may be low because **uACR isn't part of a standard blood lab panel** like eGFR and serum creatinine.¹

Outpatient facilities may not have a standard protocol for urine collection.²

Physicians are not ordering guideline-recommended uACR screening tests.³

Patients **don't understand** the reason for the test.⁴

Morning collections are difficult for patients with **afternoon** appointments.⁵

Urine collection is inconvenient for patients at home, particularly **24-hour samples.**⁶

Caring for those with diabetes

Diabetes is a multifaceted disease.⁷ Successful management requires patients to create new habits around medication adherence, changing their diets, exercise, and other lifestyle changes. Only 1 in 4 adults with diagnosed diabetes have been shown to achieve combined diabetes goals.⁸

You are central to their success which requires utilizing creative and collaborative strategies to help them manage their disease.

Point-of-care testing (POCT) can help overcome some obstacles.

Caring for their kidneys

Approximately 1 in 3 adults with diabetes has chronic kidney disease (CKD).⁹

You already know diabetes is a kidney-buster for patients with diabetes. Did you know that—

There are two markers for CKD that should be assessed every year in at-risk patients but only 21% get both recommended tests.¹⁰ Estimated glomerular filtration rate (eGFR) uses serum creatinine to measure kidney function.¹¹ Urine albumin-to-creatinine ratio (uACR) tests for albuminuria, indicating kidney damage.

Don't lose patients to follow-up.

ADA/KDIGO guidelines

Guidelines recommend yearly testing for both markers in anyone at risk.¹² The American Diabetes Association (ADA) and the Kidney Disease Improving Global Outcomes (KDIGO) organization recommend assessment of uACR and eGFR in patients with type 1 diabetes (T1D) with a duration of 5 years, in all patients with type 2 diabetes (T2D), and in all patients with comorbid hypertension at least once a year.¹³

Diagnostic criteria for CKD^{14,5}

Impaired Kidney Function
 eGFR < 60 mL/min/1.73 m²
 uACR ≥ 30 mg/g or ≥ 3 mg/mmol

Annual Assessment
 • Type 1 diabetes with duration of > 5 years
 • All patients with type 2 diabetes
 • All patients with comorbid hypertension

eGFR may be normal in stage 1 or 2 kidney disease so both tests should be used to assess kidney function in anyone at risk.¹⁴ A uACR ≥ 30 mg/g indicates kidney damage, even without an elevated eGFR.¹⁵

Compliance may be improved by using POCT uACR⁷

Although the 24-hour collection has been the "gold standard" for uACR, spot POCT uACR correlates well with 24-hour collection results in adults.¹⁶ uACR tests measure albumin and creatinine in a one-time "spot" urine sample. Because daily creatinine production is consistent, this ratio test is an alternative method to a 24-hour urine sample for the measurement of albuminuria.¹⁷

With moderate complexity or CLIA-waived POCT uACR, patients can be tested during the same appointment. They don't need to collect urine at home, and results are available immediately. uACR is a key indicator of microalbuminuria, the first stage of kidney failure in patients with diabetes.¹⁸

Assessing your patients yearly can catch the early signs of kidney disease before eGFR is elevated, providing a key window for patient education, counseling, and treatment to slow or stop progression of chronic kidney disease.¹⁹

POCT: Patient arrives for appointment → Urine spot uACR testing → Results ready in minutes for consultation* → Clinician consults with patient → < 30 minutes

Lab: Patient instructed to go to lab prior to appointment → Patient comes to appointment without labs → Patient or sample sent to off-site lab → Sample measured and results returned → Case pulled, results reviewed, and treatment decision made → Patient called multiple times until reached → Letter sent to patient on lab results → Patient advised to adjust meds but has questions → Patient returns for consultation appointment → Day 15

*Patients with diabetes require an annual kidney health evaluation that includes a quantitative uACR test and eGFR. These tests are not CLIA-waived. Patients with all other test factors for kidney disease can be screened with a CLIA-waived, semi-quantitative testing kit from Siemens.



POCT benefits baby and clinicians

There are clear advantages to routine point-of-care testing (POCT) in the NICU.

Point-of-care testing in the NICU offers many benefits—the most important of which is responding quickly to your most and most vulnerable patients.

Results can be obtained **within 1 minute** of sample loading.¹

Single or multiple analytes can be tested.²

You do not have to leave your patient.

Response time is a critical factor that affects the overall time of intermittent hypoxia treatments and the depth of desaturation. Consequences of a prolonged response time are worse in preterm infants.³

A tiny amount of blood is needed!

Neonatal care is critical

According to the World Health Organization, a newborn infant, or neonate, is a child under 28 days of age. During the first 28 days of life, a child is at highest risk of dying.⁴

Transitioning from a fetus to a newborn is the most complex physiologic adaptation that occurs in humans. Every organ system is involved and often there is a need for medical assistance.⁵

Neonates have immature organ systems, different airway and lung mechanics, and a higher basal metabolic requirement for oxygen.⁶

Early signs of clinical deterioration are often nonspecific, making a diagnosis challenging. Blood analysis is integral to monitoring Neonatal Intensive Care Unit (NICU) patients.⁷

Point-of-care bedside blood analyzers have been shown to reduce red blood cell transfusions in low birth weight infants.⁸

Blood drawn for laboratory testing should not exceed 5% of the total blood volume per draw.⁹ A 10 ml blood sample drawn with standard tubes may represent as much as 10% of the total blood volume in a preterm neonate.¹⁰

Babies have precious little blood

In term and preterm neonates, the total blood volume ranges from 80 to 115 mL/kg.¹

Studies have shown that reduced fetal hemoglobin levels are related to increased neonatal morbidity rates.²

Too much blood sampling can cause endogenous blood loss and has been associated with the development of bronchopulmonary dysplasia.³

Modern handheld point-of-care analyzers need as little as **90 µl or 0.092 ml** to run 13 different tests as compared to a standard laboratory tube which holds **3 ml** of blood.⁴

NICU respiratory care guidelines

The American Association for Respiratory Care Clinical Practice Guidelines state that capillary blood gas analysis should be used with arterial samples to monitor temperature, blood pressure, and perfusion.⁵ They also recommend that blood should be analyzed within 15 minutes of sampling.⁶

Premature infants need rapid capillary point-of-care blood gas testing

Underdeveloped immune system leads to higher risk of infections. Capillary testing reduces the need for axillary, central line and blood for culture measurements, can indicate infection.⁷

Underdeveloped digestive tract and liver should be monitored for hypoglycemia, metabolic acidosis, and hyperglycemia.⁸

Underdeveloped lungs may need ventilator support and frequent blood gas measurements to maintain breathing and respiratory distress syndrome.⁹

Underdeveloped kidneys need careful monitoring for potassium, other electrolytes, and possible acidosis.¹⁰

7 things to know about A1c

The "A" in **A1c** stands for "Adult."

After a person reaches 6 months of age nearly all their hemoglobin is type A and approximately 90% is type 1. Type 1A has subtypes 1A1, 1A2, 1A3, and others with A1c being the most common.¹

At least all outcome studies on diabetes complications are now based on HbA1c.^{2,3}

Compared with glucose, A1c levels have lower biological variability and are not affected by stress and exercise.⁴

Every **1%** decrease in the A1c level in a diabetes patient can remarkably lower the risk of complications.^{5,6}

Though A1c results represent a long-term average, a person's blood glucose levels within the past **30 days** have a greater effect on the A1c reading than those in previous months.⁷

The average person without diabetes has an A1c level of **<5.7%**.

The use of the A1c test for monitoring the degree of control of glucose metabolism in patients with diabetes was proposed in **1976**.

Caring for those with diabetes

Diabetes is a multifaceted disease.⁸ Successful management requires patients to create new habits around medication adherence, changing their diets, exercise, and other lifestyle changes. Only 1 in 4 adults with diagnosed diabetes have been shown to achieve combined diabetes goals.⁹

You are central to their success which requires utilizing creative and collaborative strategies to help them manage their disease.

Caring about A1c: Checking patients' A1c levels regularly helps lower risks of complications from diabetes.¹⁰ Using A1c point-of-care testing (POCT) can help them comply. Practices with A1c POCT are 3.7 times less likely to miss A1c testing compared with practices without POCT.¹¹ Testing A1c at the point of care has also been shown to reduce costs associated with post-visit testing.¹²

"Never doubt that a small group of thoughtful, committed citizens can change the world; indeed, it's the only thing that ever has."
 —Margaret Mead
 Sociologist, Anthropologist

Don't lose patients to follow-up.

Patient-side A1c testing

A1c testing can be performed at point-of-care patient-side settings such as a physician office or clinic. The ADA states that POCT for A1c provides opportunity for more timely treatment changes.¹

Incorporating A1c POCT into a patient visit customizes the appointment to the patient's glycemic status. Providing A1c levels with immediate feedback helps providers influence patients to improve their glycemic control.²

POCT A1c:

- Streamlined and efficient with no patient prep
- Isle bedside
- Better patient understanding
- Better clinician/patient relationship
- Better outcomes

Central lab:

- Many steps can take several days with multiple visits, calls, follow-ups
- Patients can get "lost" along the way
- Inconvenient for the patient and provider
- Patients wait for the practice

POCT: Patient arrives for appointment → Fingerstick A1c sample testing → Results ready in minutes for consultation* → Clinician consults with patient and care plan discussed → < 30 minutes

Lab: Patient instructed to go to lab prior to appointment → Patient comes to appointment without labs → Patient or sample sent to off-site lab → Sample measured and results returned → Case pulled, results reviewed, and treatment decision made → Patient called multiple times until reached → Letter sent to patient on lab results → Patient advised to adjust meds but has questions → Patient returns for consultation appointment → Day 15

*Patients with diabetes require an annual kidney health evaluation that includes a quantitative uACR test and eGFR. These tests are not CLIA-waived. Patients with all other test factors for kidney disease can be screened with a CLIA-waived, semi-quantitative testing kit from Siemens.

Guide your patients

American Diabetes Association A1c Guidelines³

A1c goals: **< 7.0%** (5% recommended)

Lower may be acceptable and beneficial if it can be achieved safely without significant hypoglycemia or other adverse effects.

Less stringent goals (e.g., 8.0% [6.5% recommended]) may be appropriate for patients with limited life expectancy or when harms outweigh benefits of treatment.


Reverse glycemic targets based on individualized criteria.

Setting a glycemic goal during consultations is likely to improve patient outcomes.

A1c assessment frequency: **At least two times a year** in patients who are meeting treatment goals and have stable glycemic control.

At least quarterly and as needed in patients whose therapy has recently changed and/or who are not meeting glycemic goals.

DO YOU TEST HBA1C AT POINT OF CARE?

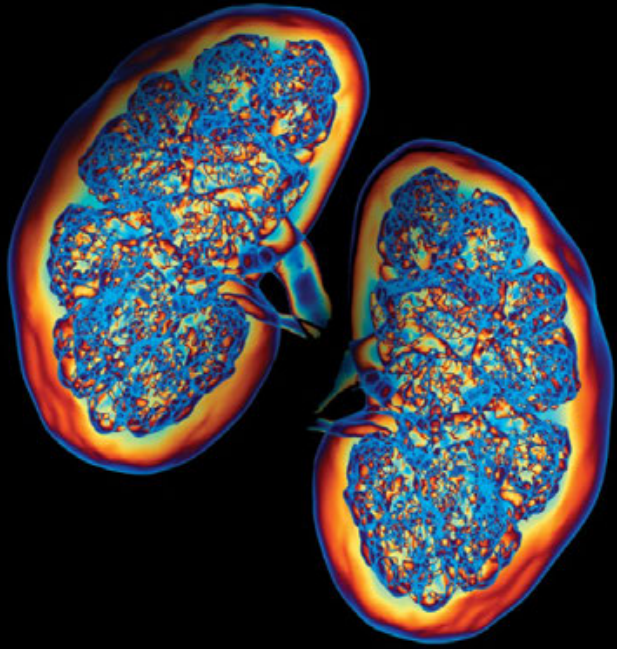


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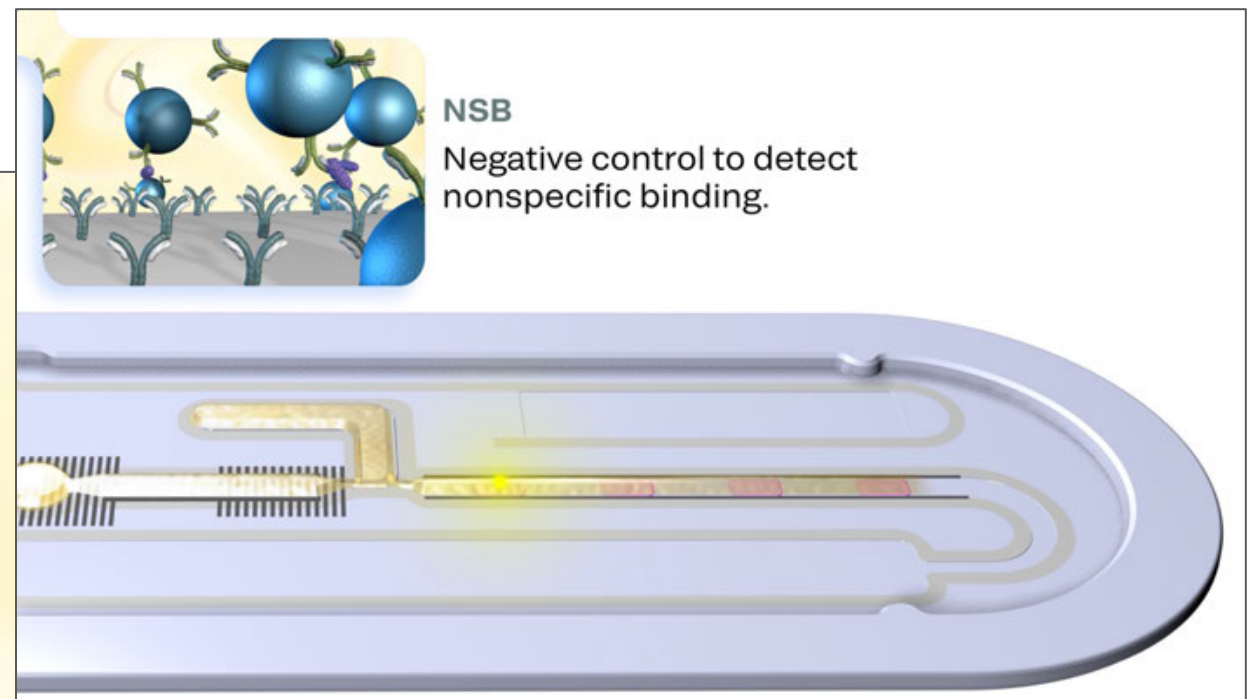
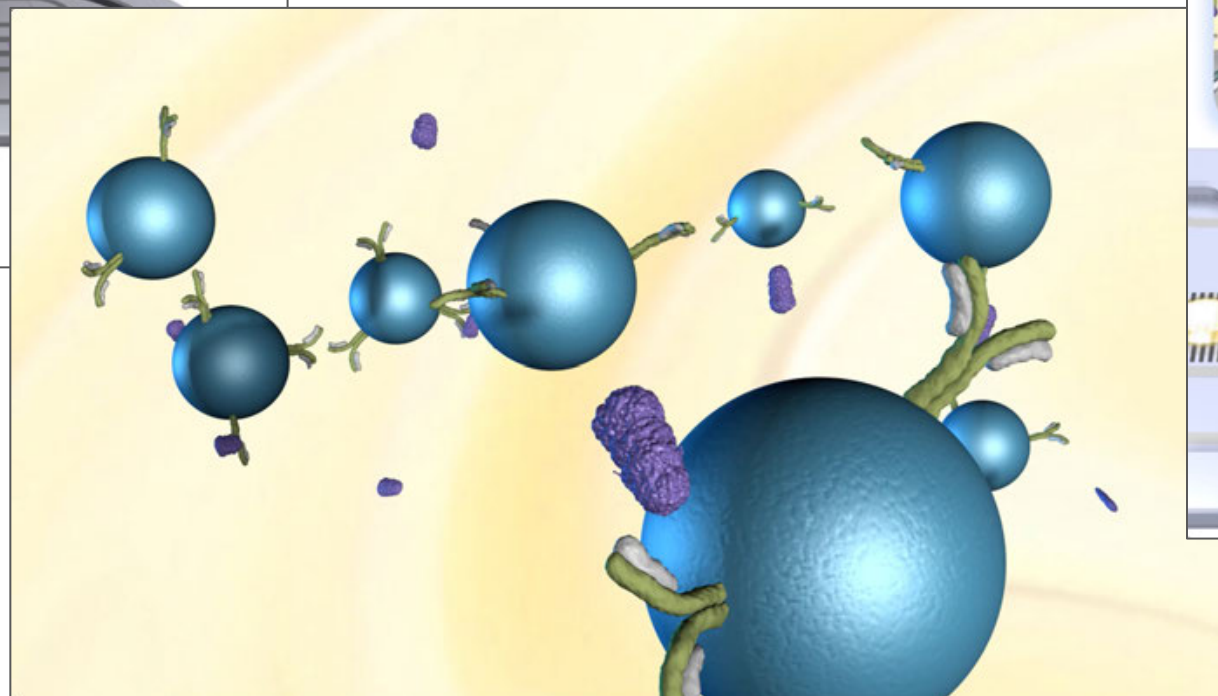
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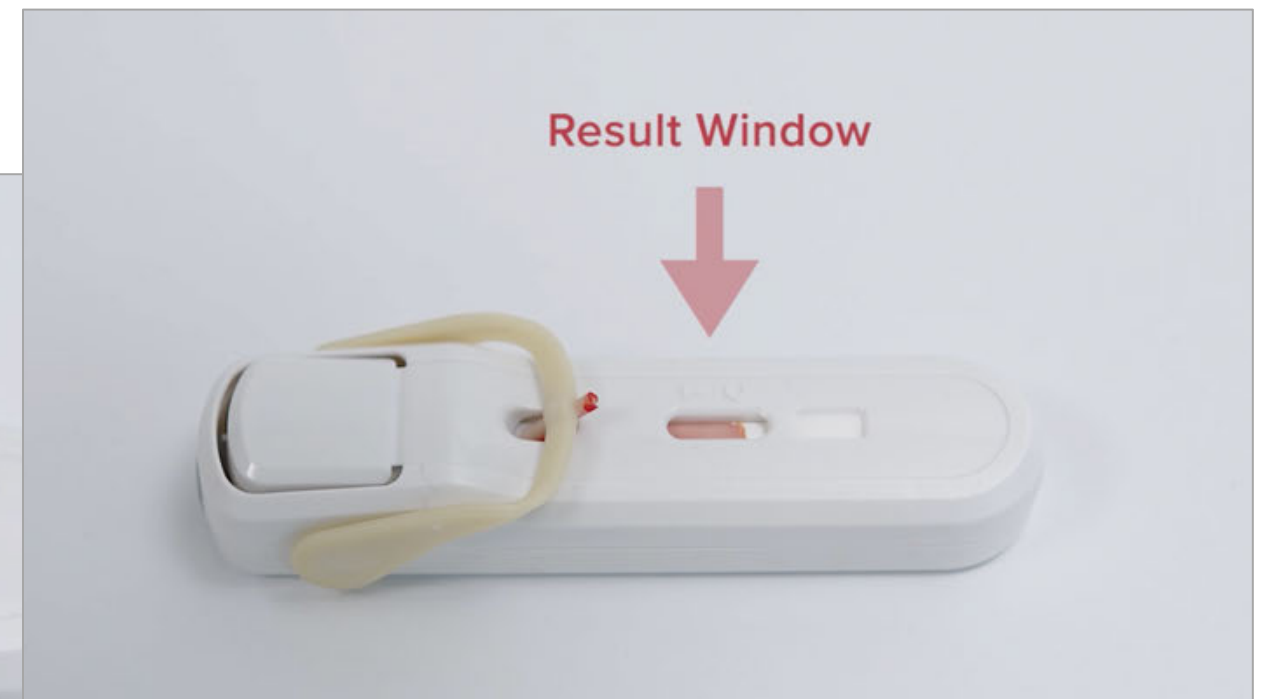
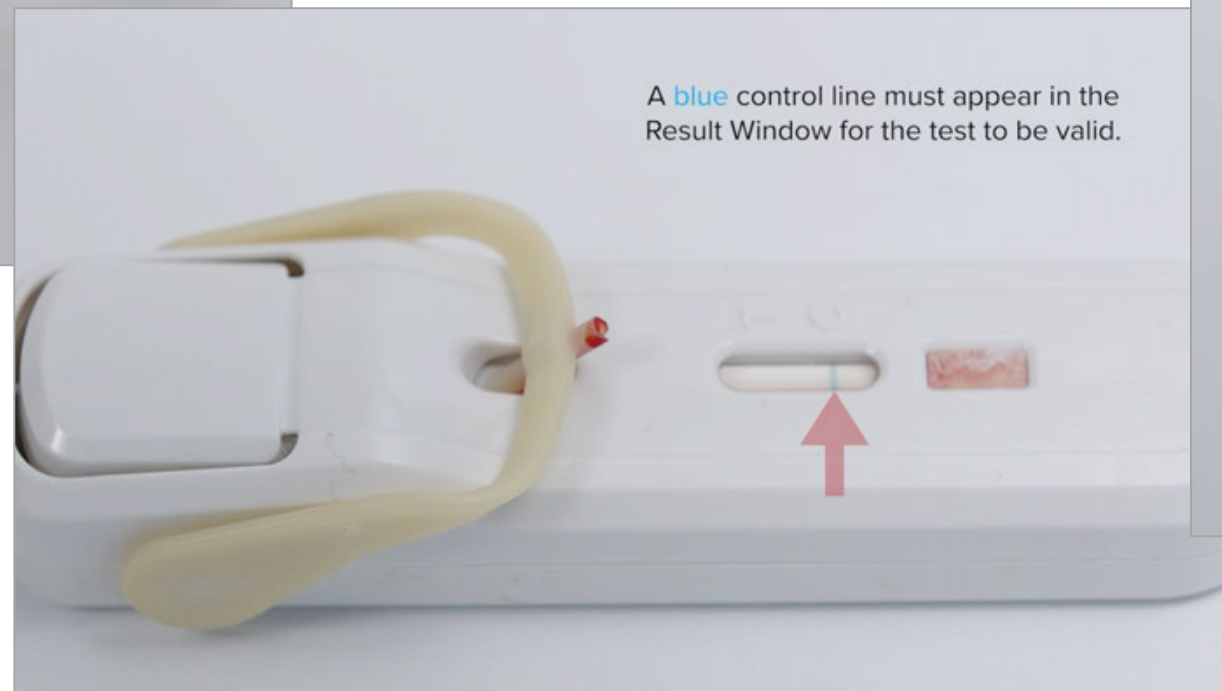
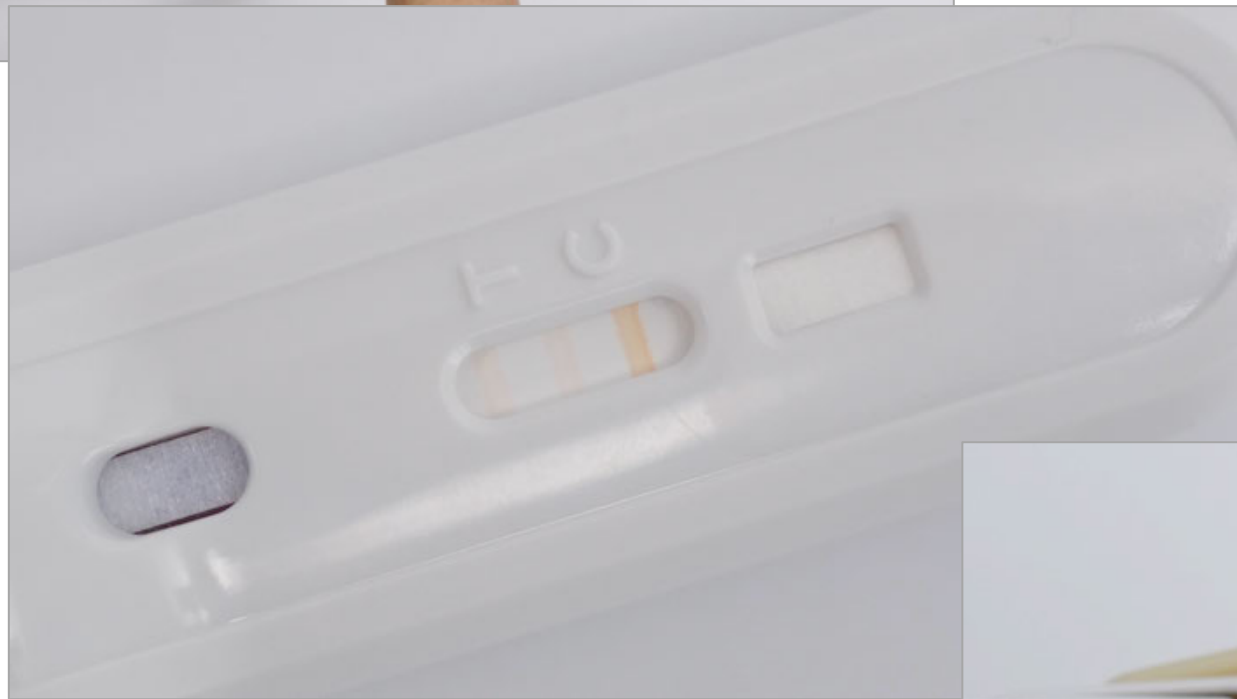
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MeterPro™
FDA cleared
updated system





Materials Provided:
25 Single Use FebriDx® Tests
1 Package Insert
1 Quick Reference Instructions

You Will Also Need:
Timer
Gloves
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Gauze
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SEPSIS

DIAGNOSING AND MANAGING SEPSIS SYNDROME:
THE EMERGING ROLE OF BEDSIDE ANALYTE TESTING

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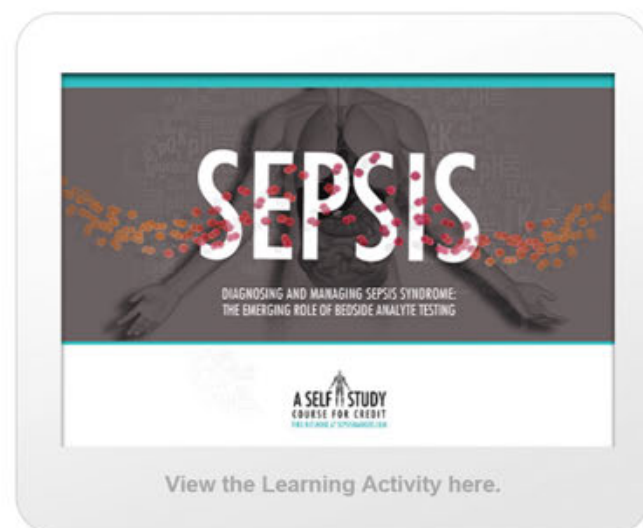
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This self-study course will provide current information on the role of sepsis biomarkers and bedside analyte testing in improving the prognosis for patients with sepsis.

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 may 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.



[View the Learning Activity here.](#)

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SEPSIS

DIAGNOSING AND MANAGING SEPSIS SYNDROME:
THE EMERGING ROLE OF BEDSIDE ANALYTE TESTING

A SELF STUDY COURSE FOR CREDIT
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THE EMERGING ROLE OF BEDSIDE ANALYTE TESTING

Physicians – This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through Synativ. Synativ is accredited by the ACCME to provide continuing medical education for physicians. Synativ designates this educational activity for a maximum of 1 AMA PRA Category 1 Credit(s)[™] toward the AMA Physician's Recognition Award. Physicians should only claim credit commensurate with the extent of their participation in the activity.

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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.

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To learn more visit [SepsisMarkers.com](https://sepsismarkers.com)

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TESTING AND THE CLINICAL UTILITY OF FECAL BIOMARKERS

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Are Fecal Leukocyte Tests a Waste of Time?

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Want to learn more about the clinical utility of fecal biomarkers?



Are Fecal Leukocyte Tests a Waste of Time?

DOWNLOAD

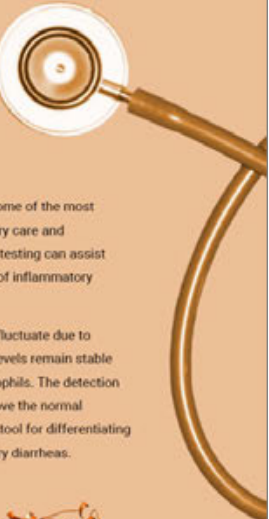
Did You Know?

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."

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 diarrhea.

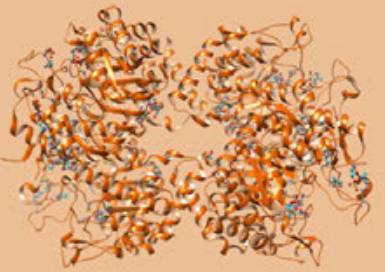


"Lactoferrin can be detected using simple and cheap techniques and it has excellent stability in feces over a long period of time."

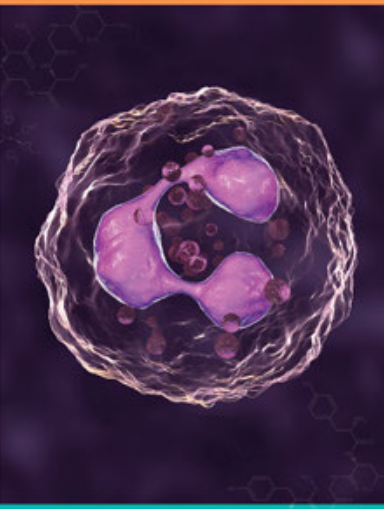
Lactoferrin offers many advantages over fecal leukocyte counts as an indicator of intestinal inflammation.

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 diarrhea.



Are Fecal Leukocyte Tests a Waste of Time?

LABORATORY EDITION

Doubts about the utility of fecal leukocyte tests have been publicly voiced.

Of enteric pathogens in feces.¹² The American College of Gastroenterology recommended the use of FLT[®] in 1987 despite their acknowledgment that the assay exhibited low sensitivity (80%) which was reported in a large systematic review with meta-analysis published the previous year.¹³ In a 2004 performance assessment involving 206 patients, results did not distinguish between infectious and noninfectious diarrhea, detection of an invasive or noninvasive pathogen by stool culture, or response to antimicrobial therapy when evaluated by FLT.¹⁴ They concluded that the FLT does not change patient management and summarized with the following statement:

"The fecal leukocyte test was only 20% better than a coin toss."¹⁵

False-Negatives With FLT
When assaying with FLT, technicians can only detect and count intact leukocyte cells which have been stained with methylene blue. These fragile cells can rupture and degrade during transportation to off-site laboratories due to physical and temperature abuse. If not promptly counted, there is the potential for false-negatives in FLT's due to the degradation of the leukocytes.

FLT Costs
The Gupta et al. published a 100-year history of the stool cellular exudate test—also known as the FLT.¹⁶ The authors highlighted the limitations and excessive costs of the assay. From 2012 through 2016, the Centers for Medicare and Medicaid Services spent an average of \$293,000 per year on approximately 58,000 fecal leukocyte assays. This translated to a cost of roughly \$5.69 per assay in 2016, the Medicare midpoint reimbursement for a fecal leukocyte test was \$5.27.

As far back as 1977, Pickering et al. reported a lack of correlation between fecal leukocytes and the recovery of enteric pathogens in feces.¹⁷

Another study compared FLT[®] and LEUKO EZ VUE[®] with stool specimens were tested by both the LEUKO EZ VUE[®] test and FLT.¹⁸ They reported that only 12 of 12 by both assays, and only by microscopy some were not found by FLT's were false-negatives caused by lysed and degraded cells.

Technical expertise is not a requirement for accurate fecal leukocyte results. A fecal flow test one assay can be run on feces with other interfering substances.

Lactoferrin Performance Testing
The LEUKO EZ VUE[®] test is an FDA-cleared lateral flow device based on the detection of enteric inflammatory diarrhea caused by *E. coli* as a biomarker. The lateral flow device is simple to use and interpret, with results available in 10 minutes.

Chen et al. found that fecal lactoferrin was correlated with bacterial infection and similar disease severity testing were beyond the scope of differentiation between inflammatory bowel disease from intestinal disease syndromes. They recommended lactoferrin as a biomarker for severe ulcerative colitis and acute diarrhea and other colitis, as well as a marker.

The LEUKO EZ VUE[®] test as been evaluated favorably in a number of studies, especially when compared to FLT's.



Are Fecal Leukocyte Tests a Waste of Time?

CLINICAL EDITION

Originally conceived as a bedside test to be performed within 15 minutes after patient donation, laboratories are obliged to offer 24-hour service because only fresh stool samples are fit for analysis. Additionally, Medicare beneficiaries represent only 17% of the U.S. population, so the overall use and costs of the FLT may be significantly greater when labor costs for trained personnel and equipment time are calculated.¹⁹

The key to correctly identifying acute inflammatory infectious diarrhea depends on the ability to measure various biomarker levels above background noise.

Bacterial pathogens such as *Salmonella*, *Shigella*, *Campylobacter* and *C. difficile* cause inflammatory diarrhea resulting in fecal leukocytosis levels substantially higher than background levels. Many peer-reviewed and unpublished studies have demonstrated the accuracy of fecal lactoferrin as a biomarker for inflammatory diarrhea. In 14 different trials, in 12 different locations, >3,000 fecal samples were evaluated.^{20,21} The combined data confirmed that lactoferrin was consistently more sensitive and stable than other neutrophil-associated proteins such as lysozyme, myeloperoxidase or elastase.

The costs to the participating laboratories conducting FLT's may be higher than the Medicare reimbursement.

Fecal Biomarkers
Enteric fecal biomarkers. Fecal biomarkers such as albumin, α -1-antitrypsin, ribiase, secretory IgA, calprotectin and lactoferrin were examined in clinical research studies for use as diagnostic aids to differentiate between acute inflammatory diarrhea from non- or minimally inflammatory ones. The most promising biomarkers were calprotectin and lactoferrin, both of which have been developed into valuable clinical tools. When compared to calprotectin, lactoferrin has been proven to have broader clinical applications.

Lactoferrin is a glycoprotein which is relatively stable in various body fluids and fecal specimens. It is found in mucosal secretions such as tears, saliva, vaginal fluids, urine, breast milk and colostrum. It is also found in leukocytes; neutrophils which are part of the host innate defense system. The amount of lactoferrin in the feces of a healthy intestine is consistent, exhibiting a stable baseline concentration. The detection of elevated levels of lactoferrin above the normal baseline can serve as a diagnostic tool for differentiating inflammatory from noninflammatory diarrhea.

Lactoferrin Advantages
In the intestine, lactoferrin performs several biological functions. It is an antibacterial agent because it sequesters iron, a mineral essential for the survival of many bacteria. Lactoferrin also helps modulate the function of immune cells, regulates cell-to-cell contact in the gut, controls intestinal permeability and serves as a signaling agent between and among epithelial and immune cells.²² Due to its various functions in the intestinal lumen, bacterial pathogens causing inflammatory diarrhea trigger a significant increase in fecal lactoferrin, making lactoferrin a highly accurate biomarker for intestinal inflammation.

Abdominal pain, diarrhea, and inflammation are some of the most common complaints seen in primary care and gastroenterology. Determining infectious from non-infectious etiologies directly impacts treatment decisions and patient outcomes. Due to its role in bacterial pathology, lactoferrin can provide valuable information for differential diagnosis. The stability of lactoferrin allows for longer specimen storage prior to testing; up to 2 weeks at room temperature. Detection of lactoferrin does not require intact cells; physical or temperature abuse of the fecal sample are not issues. Unlike fecal leukocytes, lactoferrin is not degraded by toxins produced by pathogens such as *C. difficile*.

It is significantly elevated in bacterial infections such as *Salmonella* or *Campylobacter* when compared to norovirus, rotavirus, or healthy patients.²³ Lactoferrin also corresponds to moderate or severe Vesikari and Clark scores of gastroenteritis disease severity, suggesting the role of the biomarker in staging infectious diarrhea.²⁴

Lactoferrin offers many practical advantages over fecal leukocyte counts as an indicator of intestinal inflammation. It can be used as part of a diagnostic algorithm to determine the cause of intestinal inflammation in patients with consistent symptoms of diarrhea and abdominal pain. A negative fecal lactoferrin test can quickly rule out non-inflammatory causes and a positive test is suggestive of inflammatory causes that include certain types of bacterial infections as well as other inflammatory disorders.

Diagnostic Algorithm With Fecal Lactoferrin

```

    graph TD
      A[Acutely Symptomatic Patient] --> B[Fecal Lactoferrin]
      B --> C[Negative]
      B --> D[Positive]
      C --> E["If symptoms persist at six weeks"]
      E --> F[Further testing for acute viral infections]
      F --> G[Negative]
      F --> H[Positive]
      G --> I["If symptoms persist or are severe"]
      I --> J[Evaluation for functional bowel disorder]
      H --> K[Treat symptoms as needed for viral gastroenteritis]
      D --> L[Further testing for acute bacterial infections (C. difficile, Salmonella, Shigella, Campylobacter)]
      L --> M[Negative]
      L --> N[Positive]
      M --> O["If symptoms persist or are severe"]
      O --> P[Treat symptoms as needed for viral gastroenteritis]
      N --> Q[Treat with appropriate antibiotics for bacterial gastroenteritis]
  
```

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.

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PAIN MANAGEMENT CASE STUDIES:

A Surgeon's Perspective

06.24.20
2 PM Eastern Time



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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PAIN MANAGEMENT CASE STUDIES:

A Surgeon's Perspective

Stephen R. Southworth
MD, MS, MBA, FACS

Surgical patients are at increased risk for opioid-use disorders due to pre- and post-operative prescribing. **Dr. Stephen Southworth** discusses how 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. After the live webinar, the program will be available on-demand with a full transcript and educational slides for download.

Learning Objectives

1. Discuss the problem of opioid use in pre- and post-surgical patients.
2. Explain the pain management alternatives to opioids available.
3. Describe the use of intravenous ibuprofen as part of the multimodal pain pathway.

Register online
SurgicalPainCases.com

After conclusion of the webinar, the program will also be available on-demand.

There is no charge for this activity.

Planned and developed by Medavera, Inc.

06.24.20
2 PM Eastern Time

PAIN MANAGEMENT CASE STUDIES:

A Surgeon's Perspective

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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.

Planned and developed by Medavera, Inc. and supported by an educational grant from Cumberland Pharmaceuticals, Inc.

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

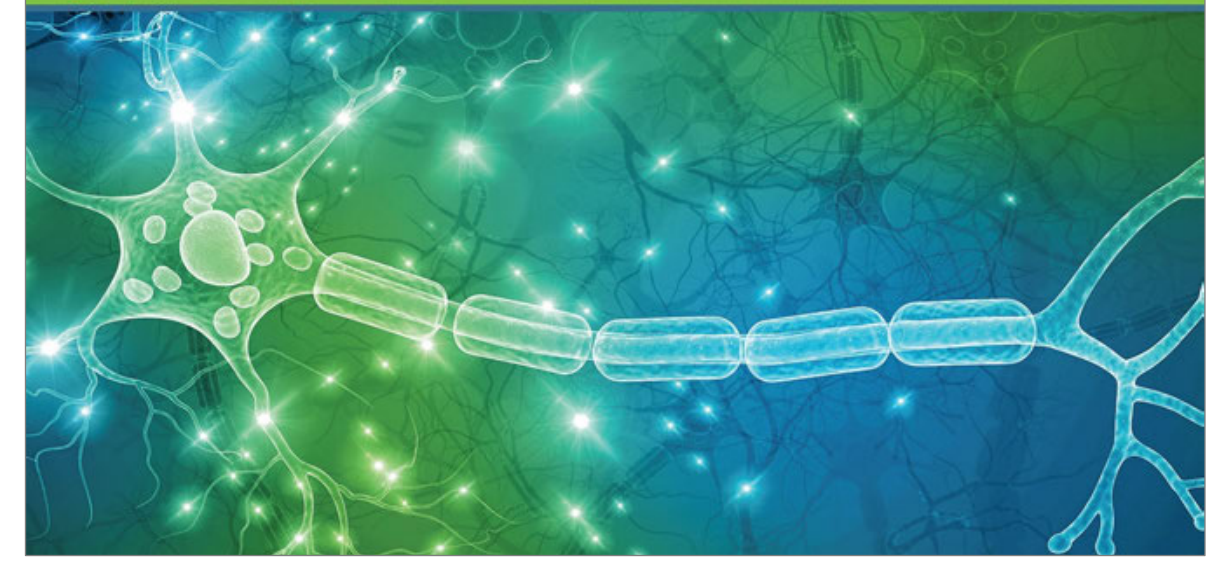
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Reducing Opioids in Surgical Pain Management: Exploring New Perioperative and Postoperative Strategies

Wednesday
4.18.2018
5 pm ET



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

Wednesday
4.18.2018
5 pm ET



R. Corey Waller MD, MS, FACP, DFASAM
Jay Kuchera MD, FASAM
Sarah E. Rebstock MD, MS, FAAP
Daniel H. Sajewski MD, MS

- LEARNING OBJECTIVES**
1. Recognize that opioid dependence can begin with surgical pain management
 2. Evaluate economic and societal burdens associated with opioid use
 3. Assess ERAS and clinical trial information using alternative pain medications
 4. Apply case study findings and algorithms to improve patient clinical outcomes

After conclusion of the webinar, you may take the post-test online for your certificate. The webinar will also be available on-demand if you cannot participate in the live version.

Register online at OpioidReduction.com
There is no charge to participate in this accredited webinar.

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

Planned and developed by Medavera, Inc. and supported by an educational grant from Cumberland Pharmaceuticals, Inc.

Disclaimer: This activity has been planned and implemented in accordance with the Essential Areas and Follow-up of the Accreditation Council for Continuing Medical Education (ACCME) and the Accreditation Council for Pharmacy Education (ACPE) to provide continuing medical education for physicians. This activity is intended for physicians. The program is approved for a maximum of 1.00 CME credit for physicians. **Pharmacists:** Cumberland Pharmaceuticals is an approved provider of continuing medical education for the American College of Clinical Pharmacy (ACCP) as a provider of continuing pharmacy education. This program is approved for a maximum of 1.00 CPE credit for pharmacists. **Nurses:** Cumberland Pharmaceuticals is an approved provider of continuing medical education for the American Nurses Credentialing Center (ANCC) as a provider of continuing nursing education. This program is approved for a maximum of 1.00 CNE credit for nurses. **Physicians:** This program is approved for 1 hour of continuing medical education. Cumberland Pharmaceuticals is an approved provider of continuing medical education for the American Board of Family Medicine (ABFM) as a provider of continuing medical education. This program is approved for a maximum of 1.00 CME credit for family physicians. **Physicians:** This program is approved for 1 hour of continuing medical education. Cumberland Pharmaceuticals is an approved provider of continuing medical education for the American Board of Internal Medicine (ABIM) as a provider of continuing medical education. This program is approved for a maximum of 1.00 CME credit for internal medicine physicians. **Physicians:** This program is approved for 1 hour of continuing medical education. Cumberland Pharmaceuticals is an approved provider of continuing medical education for the American Board of Pediatrics (ABP) as a provider of continuing medical education. This program is approved for a maximum of 1.00 CME credit for pediatricians. **Physicians:** This program is approved for 1 hour of continuing medical education. Cumberland Pharmaceuticals is an approved provider of continuing medical education for the American Board of Geriatrics (ABG) as a provider of continuing medical education. This program is approved for a maximum of 1.00 CME credit for geriatricians. **Physicians:** This program is approved for 1 hour of continuing medical education. Cumberland Pharmaceuticals is an approved provider of continuing medical education for the American Board of Geriatric Psychiatry (ABGP) as a provider of continuing medical education. This program is approved for a maximum of 1.00 CME credit for geriatric psychiatrists. **Physicians:** This program is approved for 1 hour of continuing medical education. Cumberland Pharmaceuticals is an approved provider of continuing medical education for the American Board of Geriatric Medicine (ABGM) as a provider of continuing medical education. This program is approved for a maximum of 1.00 CME credit for geriatric medicine physicians. **Physicians:** This program is approved for 1 hour of continuing medical education. Cumberland Pharmaceuticals is an approved provider of continuing medical education for the American Board of Geriatric Neurology (ABGN) as a provider of continuing medical education. This program is approved for a maximum of 1.00 CME credit for geriatric neurology physicians. **Physicians:** This program is approved for 1 hour of continuing medical education. Cumberland Pharmaceuticals is an approved provider of continuing medical education for the American Board of Geriatric Psychiatry (ABGP) as a provider of continuing medical education. This program is approved for a maximum of 1.00 CME credit for geriatric psychiatrists. **Physicians:** This program is approved for 1 hour of continuing medical education. Cumberland Pharmaceuticals is an approved provider of continuing medical education for the American Board of Geriatric Medicine (ABGM) as a provider of continuing medical education. This program is approved for a maximum of 1.00 CME credit for geriatric medicine physicians. **Physicians:** This program is approved for 1 hour of continuing medical education. Cumberland Pharmaceuticals is an approved provider of continuing medical education for the American Board of Geriatric Neurology (ABGN) as a provider of continuing medical education. This program is approved for a maximum of 1.00 CME credit for geriatric neurology physicians.

the HISTORY of
INFLUENZA
 From DEVASTATION to DISCOVERY

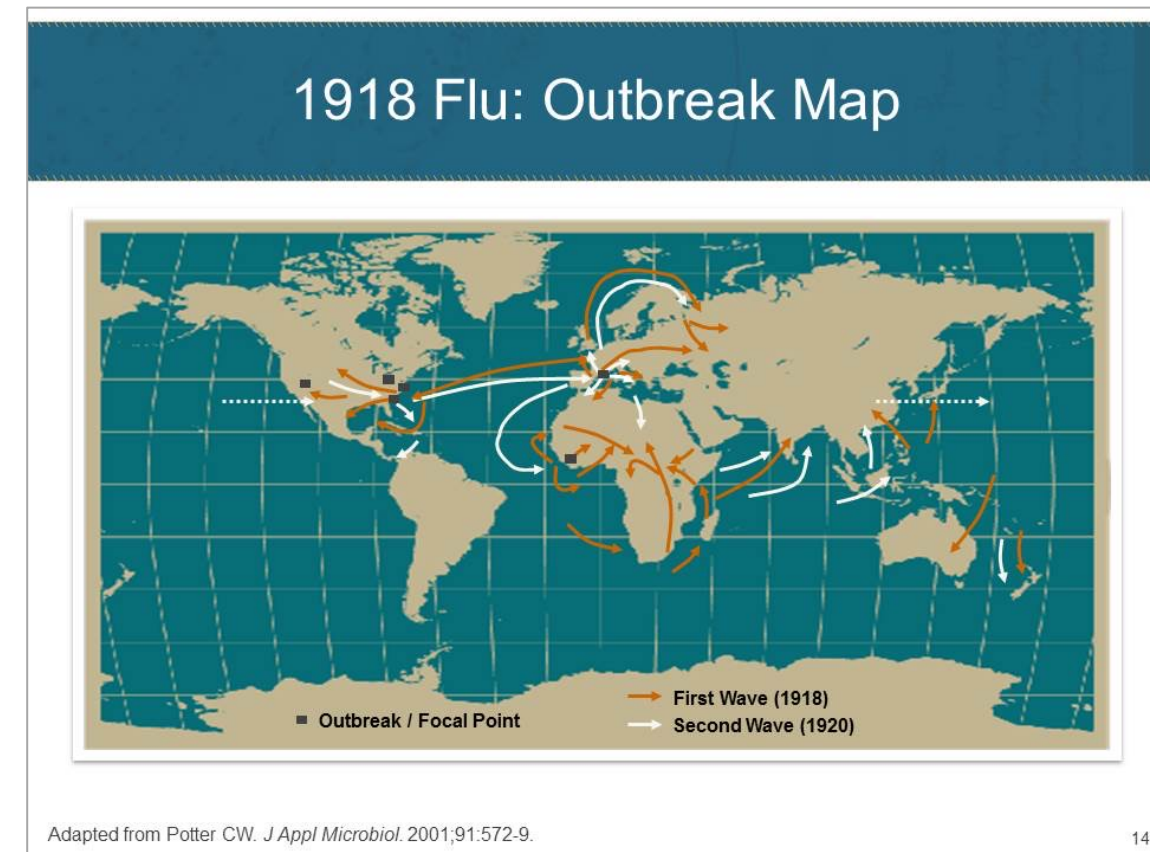
VIEW LEARNING ACTIVITY	DOWNLOAD CME APPLICATION	DOWNLOAD SLIDE SET
	<p>The World Health Organization (WHO) estimates between three and five million cases of severe illness and between 250,000 and 500,000 deaths occur each year due to influenza.¹</p>	
	<p>Perhaps one of the greatest lessons in public 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 led 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</p>	<p>The following decades resulted in significant discoveries: introduction of antiviral treatments, rapid diagnostics, and improvements in surveillance and treatment.^{7,8} It is important for healthcare professionals to understand this chronology of events and to look forward to continued improvements in surveillance, identification, and the treatment of influenza. This accredited, self-study program is designed for these purposes.</p>
		
		
©2019 Medavera. All rights reserved.	Planned and developed by Medavera. Supported by an educational donation from Abbott.	
		Inquires: Carrie Vause info@medavera.com

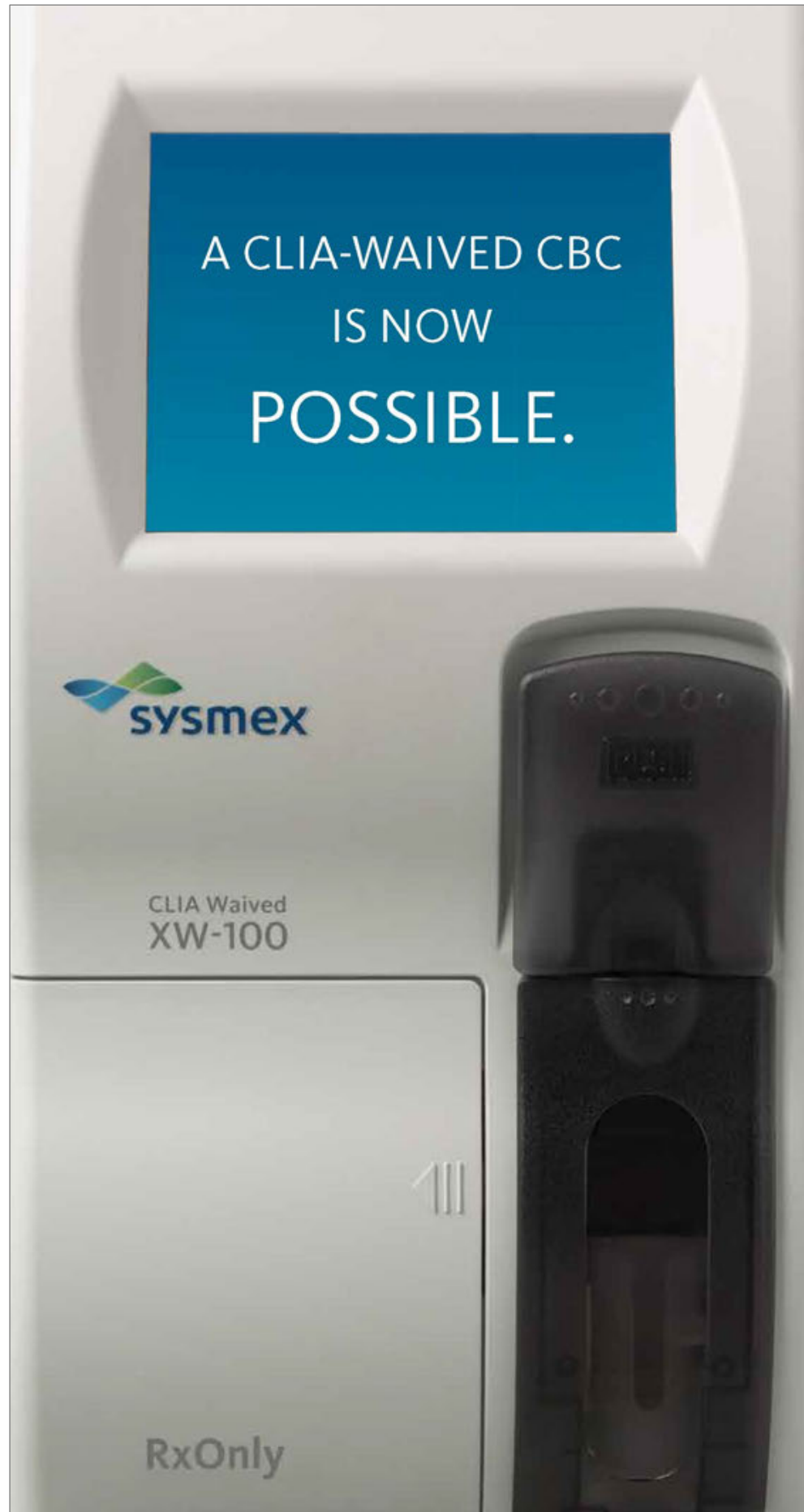
UPDATED CONTENT

the HISTORY of
INFLUENZA
 From DEVASTATION to DISCOVERY

A SELF STUDY COURSE FOR CREDIT
 HISTORYOFINFLUENZA.COM

Planned and developed by Medavera and supported by an educational donation from Abbott.





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

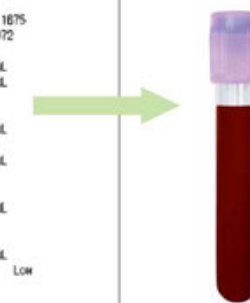
Blood parameters can be complicated to measure. The complexity of the sample and underlying patient conditions may result in suppression of results. This will appear as 4 asterisks (****) where in most cases a result would be generated. The Sysmex XW-100 is designed to protect your patients and your 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 # G2883
 Date Jun 14, 2019
 Time 12:18 PM
 Operator MWZ
 Patient ID 1875
 Patient DOB May 28, 1972

WBC	6.2 × 10 ⁹ /L
RBC	4.38 × 10 ¹² /L
HGB	xxxx
HCT	xxxx
PLT	344 × 10 ⁹ /L
#Neut	4.4 × 10 ⁹ /L
%Neut	71.3 %
#Lymph	1.6 × 10 ⁹ /L
%Lymph	25.6 %
#OtherWBC	0.2 × 10 ⁹ /L
%OtherWBC	3.1 % Low
MCV	xxxx



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

NOTES
 RECOMMEND FURTHER TESTING.
 Adult Reference Ranges

WBC	3.9 - 10.4 × 10 ⁹ /L
RBC	3.71 - 5.52 × 10 ¹² /L
HGB	10.9 - 16.7 g/dL
HCT	32.5 - 49.4 %
PLT	148 - 382 × 10 ⁹ /L
#Neut	2.2 - 7.1 × 10 ⁹ /L
%Neut	48.4 - 76.9 %
#Lymph	0.9 - 3.4 × 10 ⁹ /L
%Lymph	14.7 - 45.9 %
#OtherWBC	0.2 - 1.2 × 10 ⁹ /L
%OtherWBC	3.2 - 16.9 %
MCV	82.5 - 98.0 fL

---End-Report---

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

SUPPORT

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Clinical & Operational Benefits



Comparison & Results Including Suppression



Common Questions



IMAGINE LIVING LIKE THIS



POLIO WARD 1953



IMAGINE THIS TO LIVE



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 of vaccine-preventable diseases and vaccine development. Dr. Offit is a member of the National Advisory Committee. In 2011, his book *How to Succeed in Medicine Without Really Trying* was selected by Kirkus Reviews as one of the best books of the year. He recently, he has written *Our Post-Pandemic World.*"



AUDIO ONLY

Part 3

...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...
...accomplishment. It's like trying to imagine a fourth or fifth dimension. He 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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How One Nurse Called the Shots
Nurses protecting others.

SPECIAL EPISODE
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.

Finding Polyps in a Pandemic

The First to Mandate Vaccines: A Hospital System's Story

The Preschool Puzzle

A Heart Has

Pandemic Healthcare Disparities

The Baby or the Buffet?

Why Can't I Recall a Recall? Food Safety Relapses

Variants, Antivirals, Vaccinations & Health Literacy

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

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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



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

Improve Latino Diabetes

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.

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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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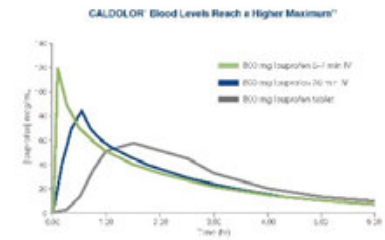
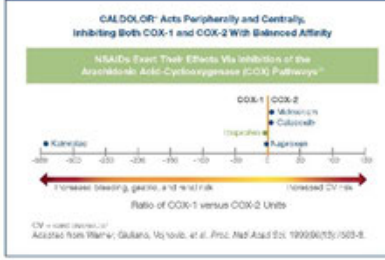


Improve Pain Management

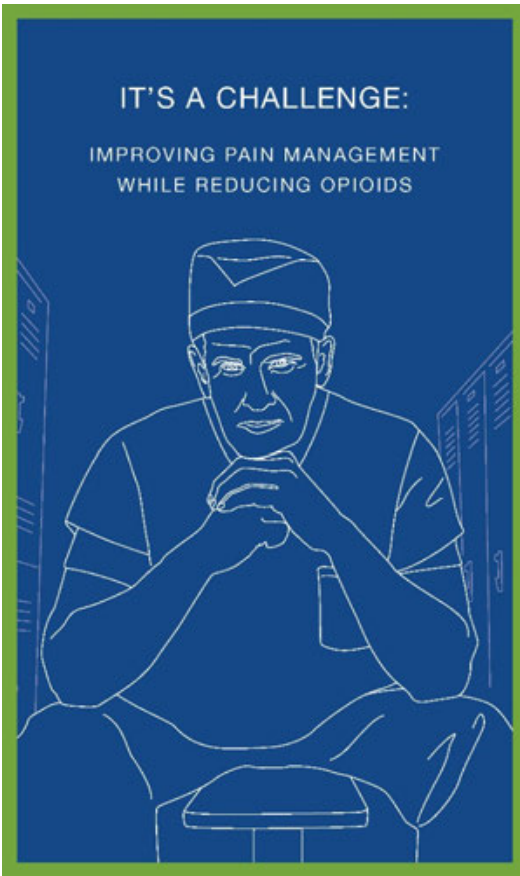
Pain management has become increasingly challenging. There are pressures to offer more effective pain control and reduce opioid use at the same time.*

Pain happens both centrally and peripherally.† CALDOLOR® is a non-opioid IV NSAID that helps manage pain†:

- at the nociceptors
• at the dorsal horn
• by crossing the blood brain barrier



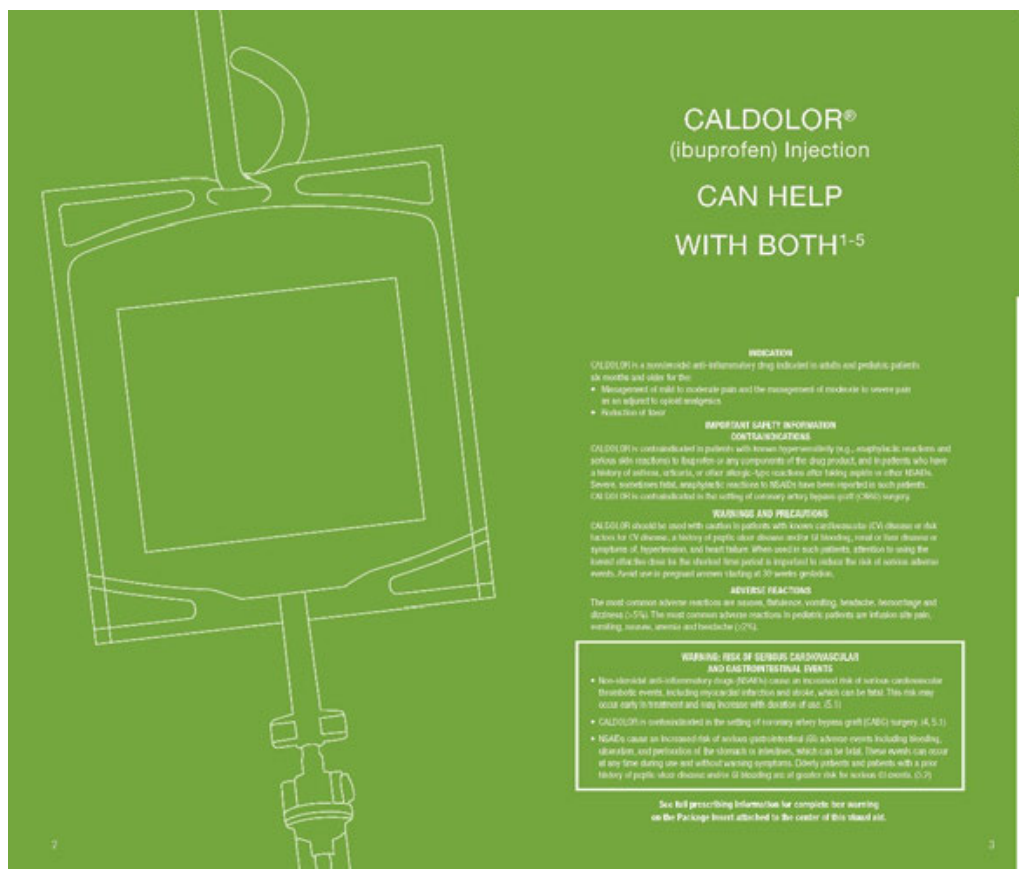
See full prescribing information for complete list warning on the Package Insert attached to the center of this visual and



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



TWO MAJOR CHALLENGES: YOUR BUDGET AND PAIN MANAGEMENT



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



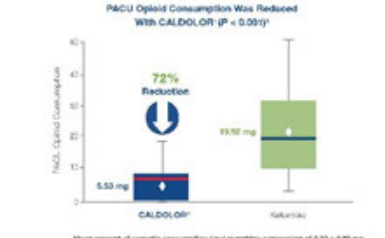
Reduce Opioids

In three multicenter, randomized, double-blind placebo-controlled trials, CALDOLOR® was found to reduce opioids when compared to placebo. In elective orthopedic surgery patients who received CALDOLOR® used 30.9% less morphine (P < 0.001) than those receiving placebo.† In a safety and efficacy trial of CALDOLOR® as a post-operative analgesic following abdominal hysterectomy, the median morphine requirement was reduced by 19% (P < 0.001).† A third trial evaluated the use of CALDOLOR® in pediatric tonsillectomy and found a 50% reduction in the amount of post-operative fentanyl (P = 0.021).†

Table with 4 columns: Procedure, Number, P Value, Amount of Opioid Reduction. Rows include Elective orthopedic surgery, Abdominal hysterectomy, and Pediatric tonsillectomy.

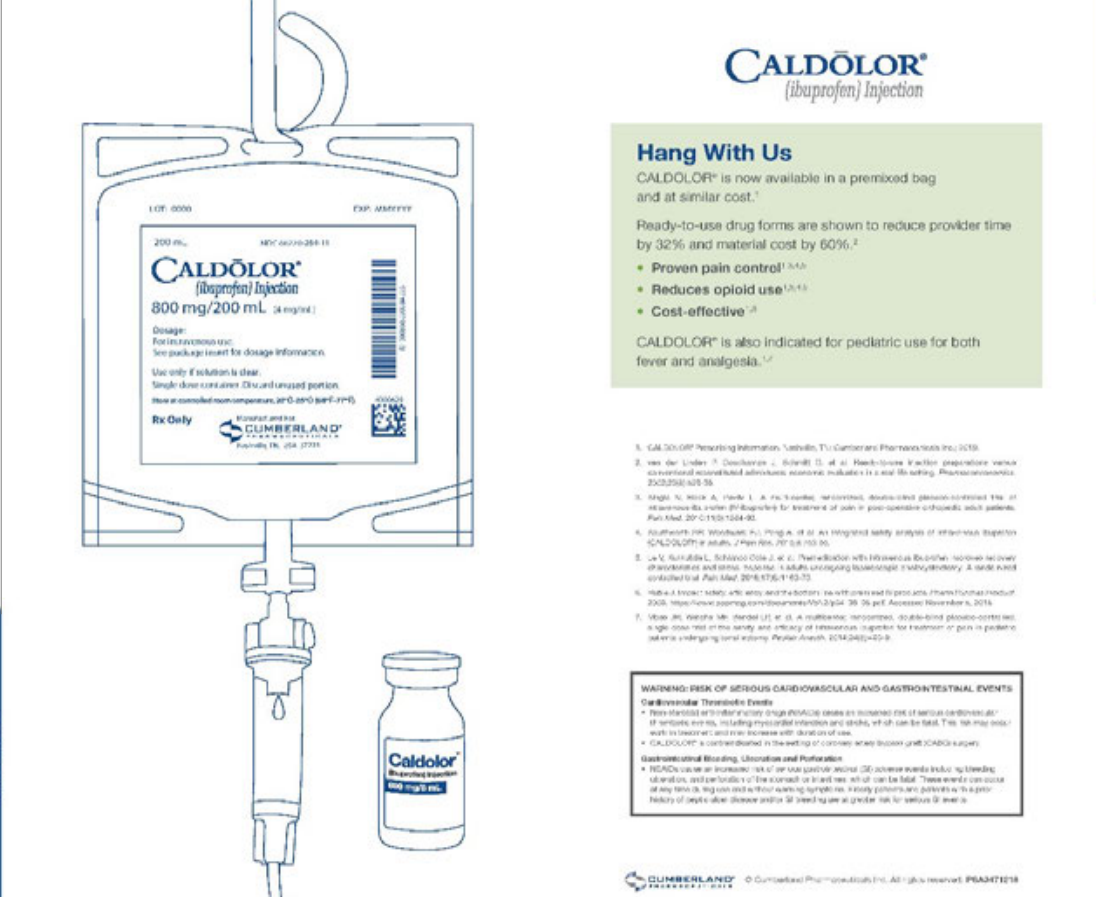
Arthroscopic Knee Surgery

This study assessed the efficacy of CALDOLOR® and IV ketorolac for the treatment of post-operative pain in patients undergoing arthroscopic knee surgery.†



See amount of opioid consumption (total morphine consumption at 0.5h, 1.5h and 3h) in PACU for the CALDOLOR and ketorolac group, respectively (P = 0.001), represented by open diamonds. Reduced bars represent median values. PACU = post-anesthesia care unit.

See full prescribing information for complete list warning on the Package Insert attached to the center of this visual and



CALDOLOR® (ibuprofen) Injection

Hang With Us CALDOLOR® is now available in a pre-mixed bag and at similar cost.†

Ready-to-use drug forms are shown to reduce provider time by 32% and material cost by 60%.†

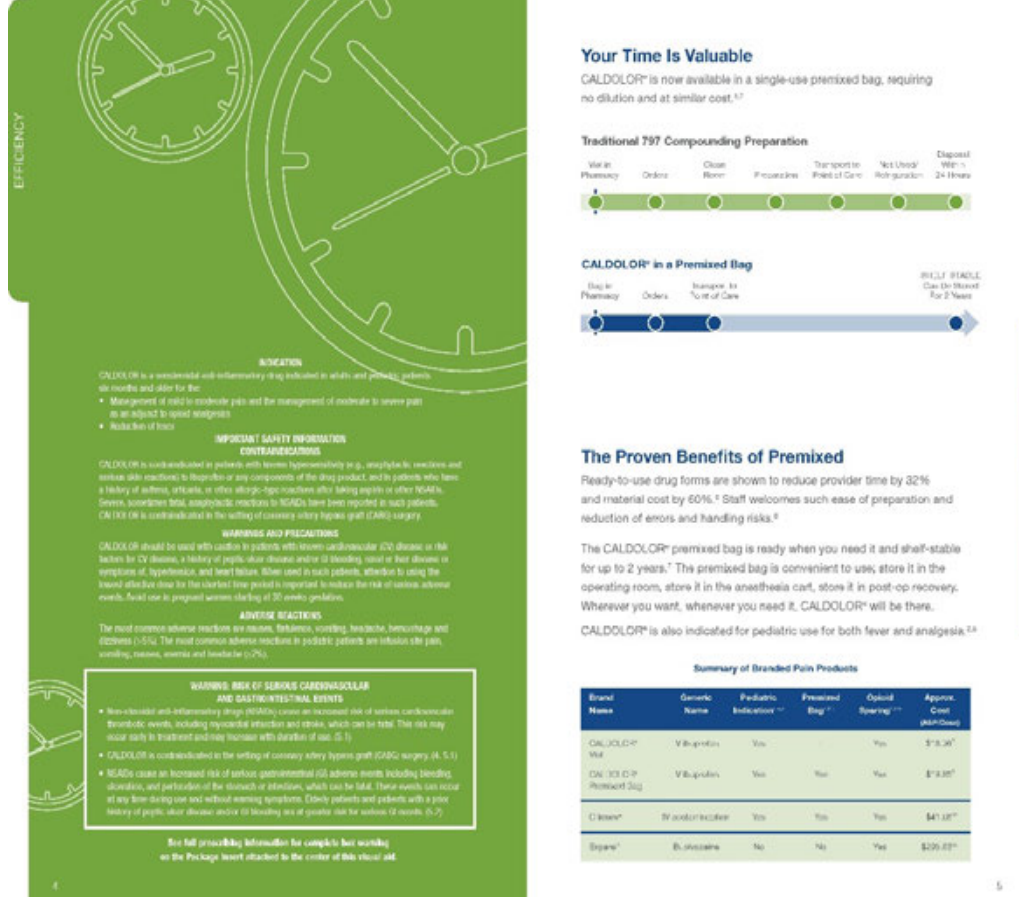
- Proven pain control†1-3,5
• Reduces opioid use†1,3,5
• Cost-effective†8

CALDOLOR® is also indicated for pediatric use for both fever and analgesia.†

- 1. CALDOLOR® Prescribing Information, Version 11.0, Clumberland Pharmaceuticals Inc., 2018.
2. See also Under 'Contraindications' (4.1) and 'Warnings and Precautions' (5.1) regarding severe cardiovascular events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. (5.1)
3. Singh, N, Mehta, A, et al. Pain practice, randomized, double-blind placebo-controlled trial of intravenous ketorolac IV drip for treatment of pain in post-operative orthopedic patients. Pain Med. 2017;19(10):1846-55.
4. Nourmandi, M, et al. Pain practice, randomized, double-blind placebo-controlled trial of intravenous ibuprofen (CALDOLOR®) in adults. J Pain Res. 2017;10:155-60.
5. Li, L, Sun, J, et al. Pain practice, randomized, double-blind placebo-controlled trial of intravenous ketorolac IV drip for treatment of pain in post-operative orthopedic patients. Pain Med. 2017;19(10):1846-55.
6. Nourmandi, M, et al. Pain practice, randomized, double-blind placebo-controlled trial of intravenous ibuprofen (CALDOLOR®) in adults. J Pain Res. 2017;10:155-60.
7. Singh, N, Mehta, A, et al. Pain practice, randomized, double-blind placebo-controlled trial of intravenous ketorolac IV drip for treatment of pain in post-operative orthopedic patients. Pain Med. 2017;19(10):1846-55.
8. See amount of opioid consumption (total morphine consumption at 0.5h, 1.5h and 3h) in PACU for the CALDOLOR and ketorolac group, respectively (P = 0.001), represented by open diamonds. Reduced bars represent median values. PACU = post-anesthesia care unit.

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS
• Non-steroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. (5.1)
• CALDOLOR® is contraindicated in the setting of coronary artery bypass graft (CABG) surgery. (4.3)
• NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestine, which can be fatal. These events can occur at any time during use and without warning symptoms. (5.2)
• CALDOLOR® is contraindicated in the setting of coronary artery bypass graft (CABG) surgery. (4.3)
• NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestine, which can be fatal. These events can occur at any time during use and without warning symptoms. (5.2)
• CALDOLOR® is contraindicated in the setting of coronary artery bypass graft (CABG) surgery. (4.3)

See full prescribing information for complete list warning on the Package Insert attached to the center of this visual and



Your Time Is Valuable

CALDOLOR® is now available in a single-use pre-mixed bag, requiring no dilution and at similar cost.†



Ready-to-use drug forms are shown to reduce provider time by 32% and material cost by 60%.† Staff welcomes such ease of preparation and reduction of errors and handling risks.†

The CALDOLOR® pre-mixed bag is ready when you need it and shelf-stable for up to 2 years.† The pre-mixed bag is convenient to use, store it in the operating room, store it in the anesthesia cart, store it in post-op recovery. Whenever you want, whenever you need it, CALDOLOR® will be there.

CALDOLOR® is also indicated for pediatric use for both fever and analgesia.†

The Proven Benefits of Premixed

Ready-to-use drug forms are shown to reduce provider time by 32% and material cost by 60%.† Staff welcomes such ease of preparation and reduction of errors and handling risks.†

The CALDOLOR® pre-mixed bag is ready when you need it and shelf-stable for up to 2 years.† The pre-mixed bag is convenient to use, store it in the operating room, store it in the anesthesia cart, store it in post-op recovery. Whenever you want, whenever you need it, CALDOLOR® will be there.

CALDOLOR® is also indicated for pediatric use for both fever and analgesia.†

Summary of Pediatric Pain Products table with columns: Brand Name, Generic Name, Pediatric Indication, Premixed Bag, Opioid Sparing, Approx. Cost per Hour.

See full prescribing information for complete list warning on the Package Insert attached to the center of this visual and



MODERATOR

Ciarán P. Kelly, MD

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
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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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Professor
Ferric C. Fang, MD



The *C. diff*
DEBATE:

The Role of Diagnostics in Disease Determination

Saturday Evening

6.3.2017

Program & Dinner • 7:30 PM

ASM Microbe 2017

Bissonet Meeting Room
New Orleans Marriott

This event is neither sponsored nor endorsed
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Professor
Mark H. Wilcox, MD



HIV TESTING CAN CHANGE EVERYTHING

Determine[®] HIV-1/2 Ag/Ab Combo

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.² Approximately **80%** of new HIV transmissions are from individuals who do not know they have HIV infection or are not receiving regular care.³

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* (IN MILLIONS)

PREVALENCE, NEW CASES AND DEATHS FROM HIV IN THE UNITED STATES* (IN MILLIONS)

—Jonathan Mermin, MD, MPH

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

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 **40%** of these people share needles. The prevalence of HIV due to injection drug use, however the opioid epidemic has disproportionately affected nonurban areas, where HIV prevalence rates are normally low. These

TYPES OF HIV TESTING AND TIME TO RESULTS

HIV tests can be conventional or rapid.^{1,2}

TEST TYPE	TIME TO RESULTS
CONVENTIONAL BLOOD TEST	1 HOUR TO SEVERAL DAYS ¹
CONVENTIONAL ORAL FLUID TEST	A FEW DAYS TO TWO WEEKS ¹
RAPID TEST POINT OF CARE	15 TO 20 MINUTES ¹
NEGATIVE	NO FURTHER TESTING NEEDED
POSITIVE	LABORATORY CONFIRMATION NEEDED
HOME TEST	20 MINUTES TO THREE DAYS ¹

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.³

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.⁴

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.

FALSE NEGATIVES IN ANTIBODY-ONLY AND ANTIBODY/ANTIGEN HIV TESTS⁵

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}

- 1981: First AIDS case reported
- 1984: Human immunodeficiency virus (HIV) identified
- 1985: The FDA licensed the first test to Abbott to screen blood for exposure to HIV⁸
- 1987: First Western Blot blood test kit
- 1992: First rapid test
- 1994: First oral fluid test
- 1996: First home and urine tests
- 2002: First rapid test using fingerstick
- 2003: Rapid fingerstick test granted CLIA waiver
- 2004: First rapid oral fluid test (also granted CLIA waiver)
- 2006: CDC recommends routine HIV screening in U.S. healthcare settings
- 2007: WHO/UNAIDS global guidelines recommend routine HIV screening in healthcare settings
- 2010: First test approved that detects both antigen and antibodies
- 2012: First rapid oral fluid home test
- 2013: USPSTF gives routine HIV screening an "A" rating
- 2015: First rapid test approved that detects both antigen and antibodies, and distinguishes between acute and established HIV-1 infection

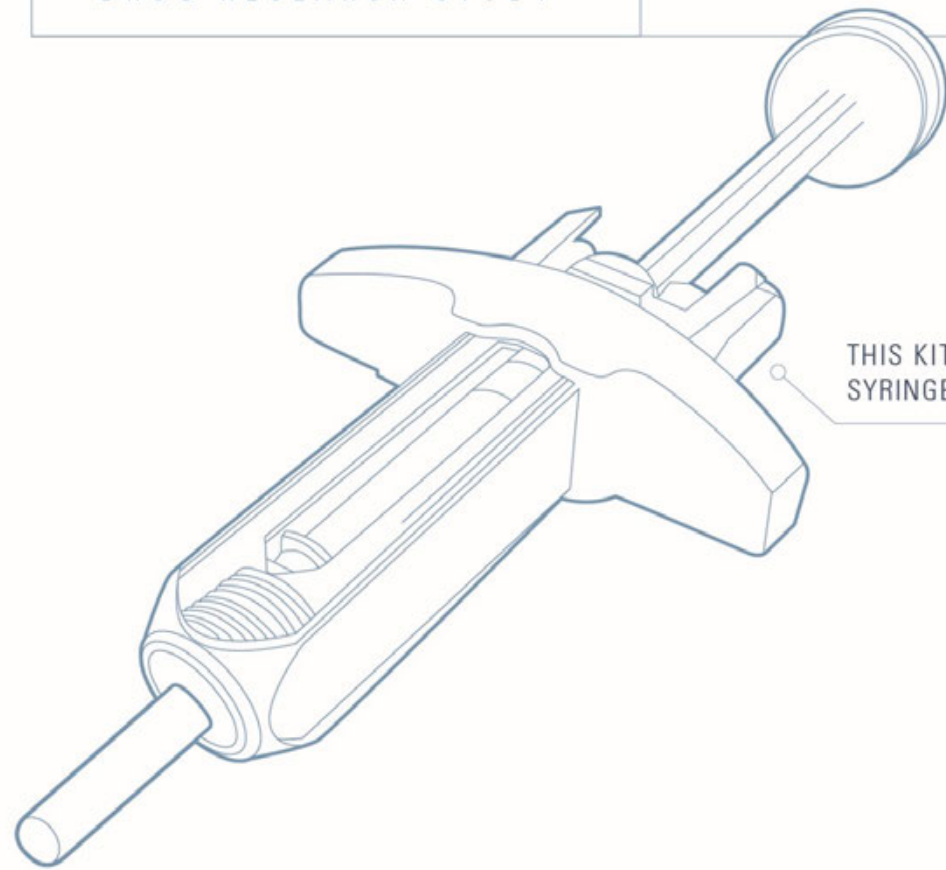
Centers for Medicare and Medicaid Services announce Medicare coverage of annual HIV screening for all beneficiaries 15-65, and for those older and younger beneficiaries at "increased risk" for HIV

AA PHARMACEUTICALS

AA101488

DRUG RESEARCH STUDY

Patient Guide

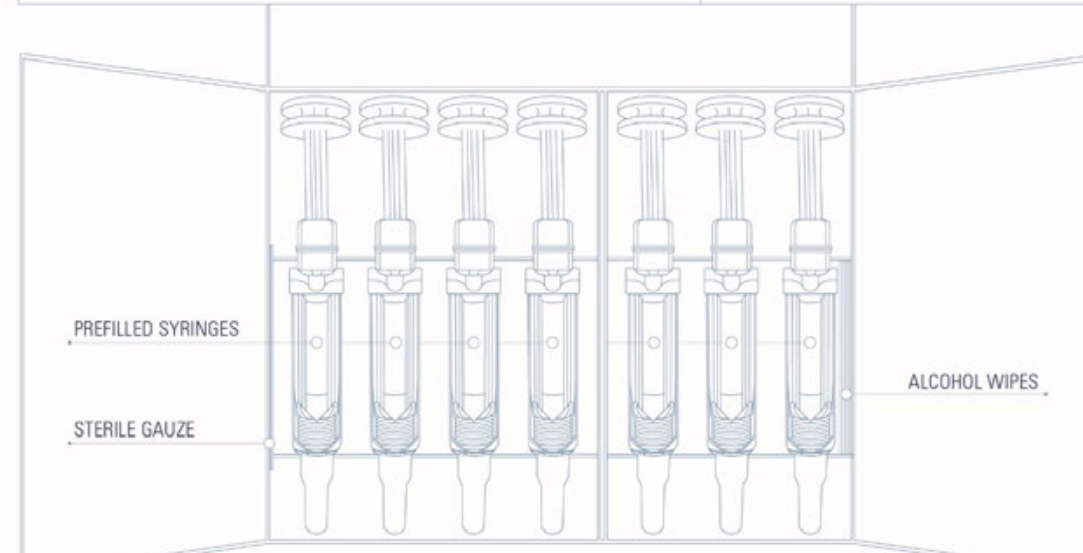


THIS KIT INCLUDES 7 PREFILLED DISPOSABLE SYRINGES & SUPPLIES FOR DAILY PATIENT USE

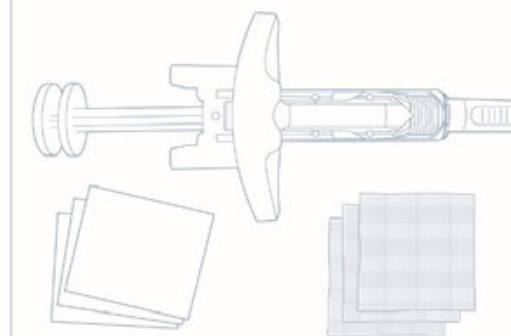
This kit contains supplies and the study drug.

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.**



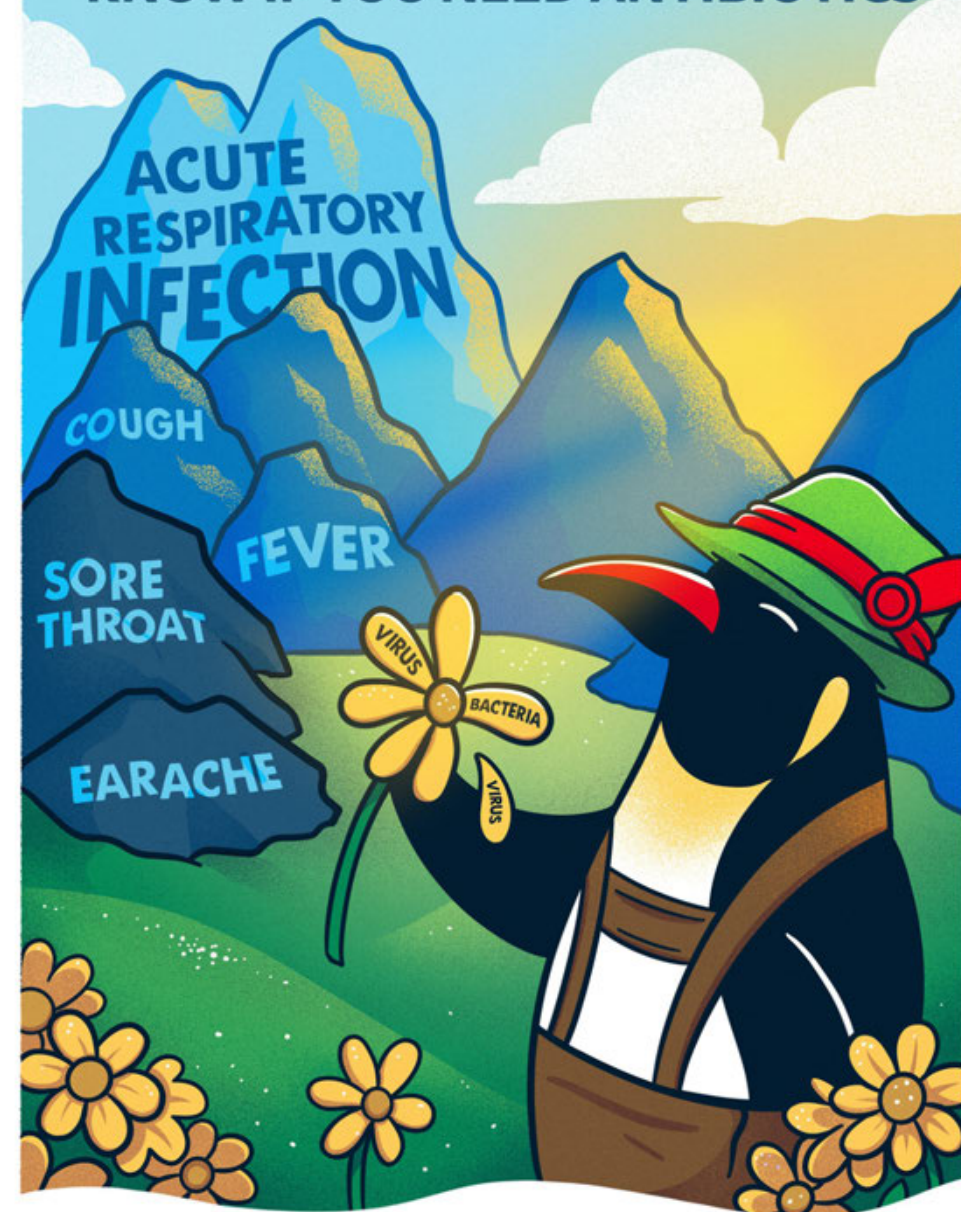
ASK YOUR DOCTOR IF YOU NEED ANTIBIOTICS

**IT CAN BE A SLIPPERY SLOPE.
KNOW IF YOU NEED ANTIBIOTICS**




ASK YOUR DOCTOR IF YOU NEED ANTIBIOTICS

**SPRING INTO ACTION
KNOW IF YOU NEED ANTIBIOTICS**



ASK YOUR DOCTOR IF YOU NEED ANTIBIOTICS


Influenza Testing



Excuse me. Can I bug you for a minute?

Alere® Patient Learning Series

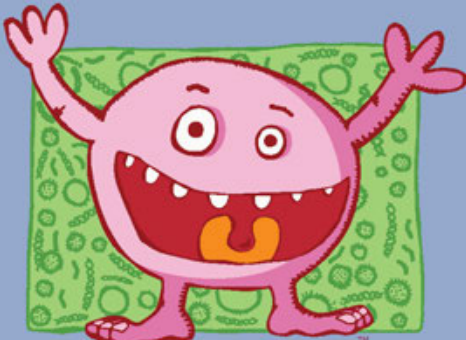
Rapid Molecular Testing



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

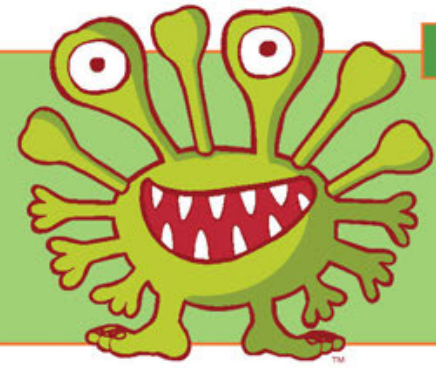
A new kind of test has been developed that can quickly and more accurately tell if you have RSV. It's called a rapid molecular test and it works by finding the RNA molecules of the RSV virus.



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.



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.

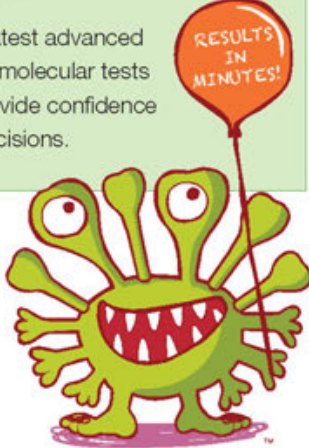
Answers to what's bugging you

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.

We want the best possible experience for you and that is why we offer advanced rapid molecular testing.

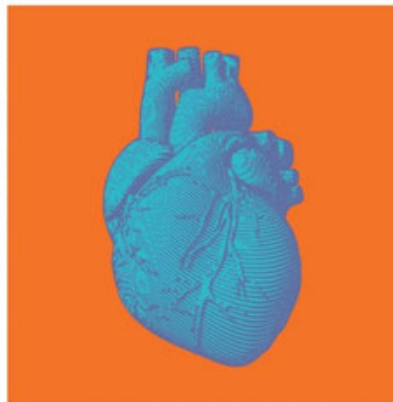
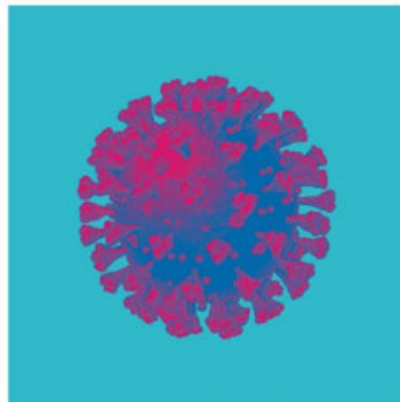


Huey N. Fluey

Knowing now means you'll be treated earlier and more appropriately, helping you get well sooner!

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They're counting on you.



Make sure you have the biomarkers you need.

ED Visits for Influenza-like Illness Are Predictive of CVD Mortality¹

When They Have Trouble Breathing

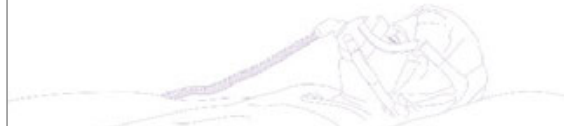
Patients commonly present to the emergency department (ED) with breathing difficulties.² These signs and symptoms may reflect severe respiratory and cardiac etiologies.^{3,4} Patients with COVID-19 infection have been shown to present with a greater than 20% incidence of dyspnea and a series of cardiovascular abnormalities.^{5,6}



Influenza can also precipitate cardiac events. This is thought to be due to a range of factors including inflammatory release of cytokines, disruption of atherosclerotic plaques, and thrombogenesis.⁷

ED visits for influenza-like illness have been associated with and predictive of cardiovascular (CVD) mortality.¹ Older patients with influenza infection and those with prevalent CVD risk factors, have been shown to be especially prone to myocardial infarction.^{8,9} Influenza infection has also been associated with increased in-hospital morbidity and mortality in patients with heart failure (HF).¹⁰

When they have trouble breathing, it is important to rapidly determine the cause and identify existing and potential sequelae whether cardiac or viral in origin.



ED Census Influences Triage Decision-making¹¹

Three For the Crowd

In the U.S., the demand for ED services has increased rapidly.¹² Post-influenza outbreaks and the ongoing pandemic have created great challenges for emergency departments. ED crowding has been shown to negatively impact patient outcomes, patient satisfaction, and patient safety.^{13,14} Increased ED occupancy has been found to be associated with more patients classified as higher acuity and result in higher hospital admission rates.¹⁵

With all this added pressure on the ED, it is now more important than ever to adopt efficiencies which allow for a more rapid diagnosis.

Quidel's Triage[®] array of tests provide important data to assist with an expedient diagnosis and proper course of treatment.



Quidel Triage products are not intended for use in pregnancy or lactation.

Knowing Troponin Levels Earlier Can Prevent Cardiac Damage.^{16,17}

Troponin is the preferred biomarker for aiding in the diagnosis of acute myocardial infarction by providing early detection to prevent myocardial injury and further cardiovascular damage.^{18,19} For patients with underlying CVD, viral illness can further damage myocardial cells through several mechanisms including direct damage by the virus, systemic inflammatory responses, destabilized coronary plaque, and aggravated hypoxia.^{20,21}

The Quidel Triage Cardiac Panel is a fluorescence immunoassay to be used with the Quidel Triage Meter for the quantitative determination of creatine kinase-MB (CK-MB), myoglobin, and troponin I in EDTA anticoagulated whole blood or plasma specimens.²²

Point of care (POC) troponin testing has been shown to decrease patient length of stay, turn around time, and potentially decrease overall costs.²³

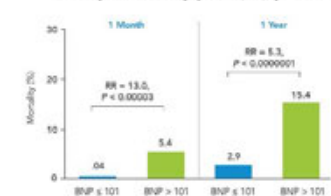


The Triage BNP Test Is Powerful²⁴

BNP From the Beginning

A B-type natriuretic peptide (BNP) level on admission has been found to be an independent and powerful marker of early and late cardiac mortality in patients with acute chest pain without ST-segment elevation. It is suggested that BNP be measured upon arrival at the ED.²⁵

Mortality in Acute Coronary Syndrome (ACS) by BNP Level



Cardiac mortality in patients with ACS is shown as total 30-day mortality according to the most appropriate pharmacologic care generated base groups. BNP cut-off level in ng/mL. RR = relative risk.

The Triage BNP Test Can Assist With a Rapid Rule Out²⁶

Natriuretic peptide testing is now recommended for the prevention, diagnosis, and prognosis of HF.²⁷

The newest guideline recommends that the measurement of baseline levels of natriuretic peptide biomarkers and/or cardiac troponin on admission are useful in establishing a prognosis in acute decompensated heart failure.²⁸

The evidence is strong. When you need to know, you need a BNP.

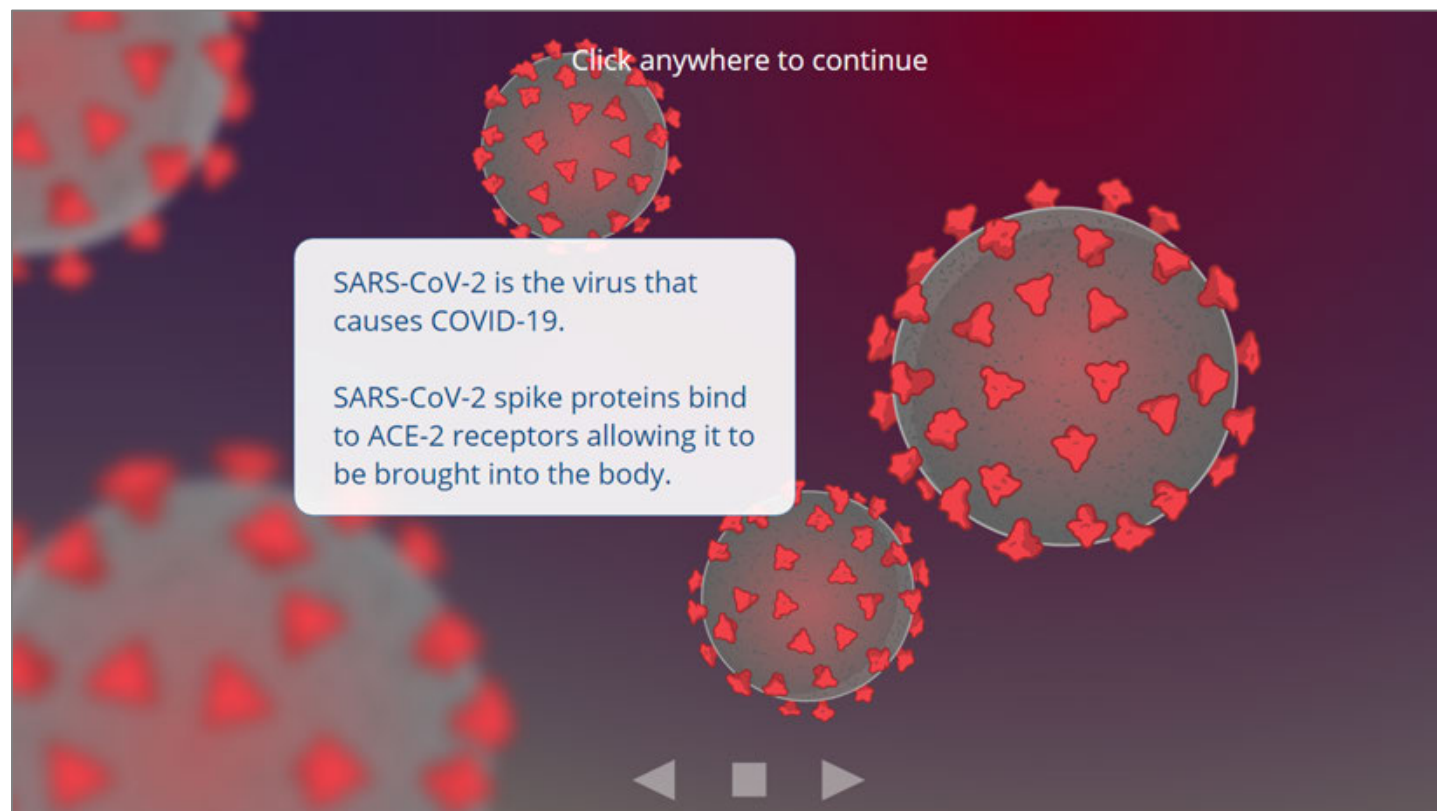
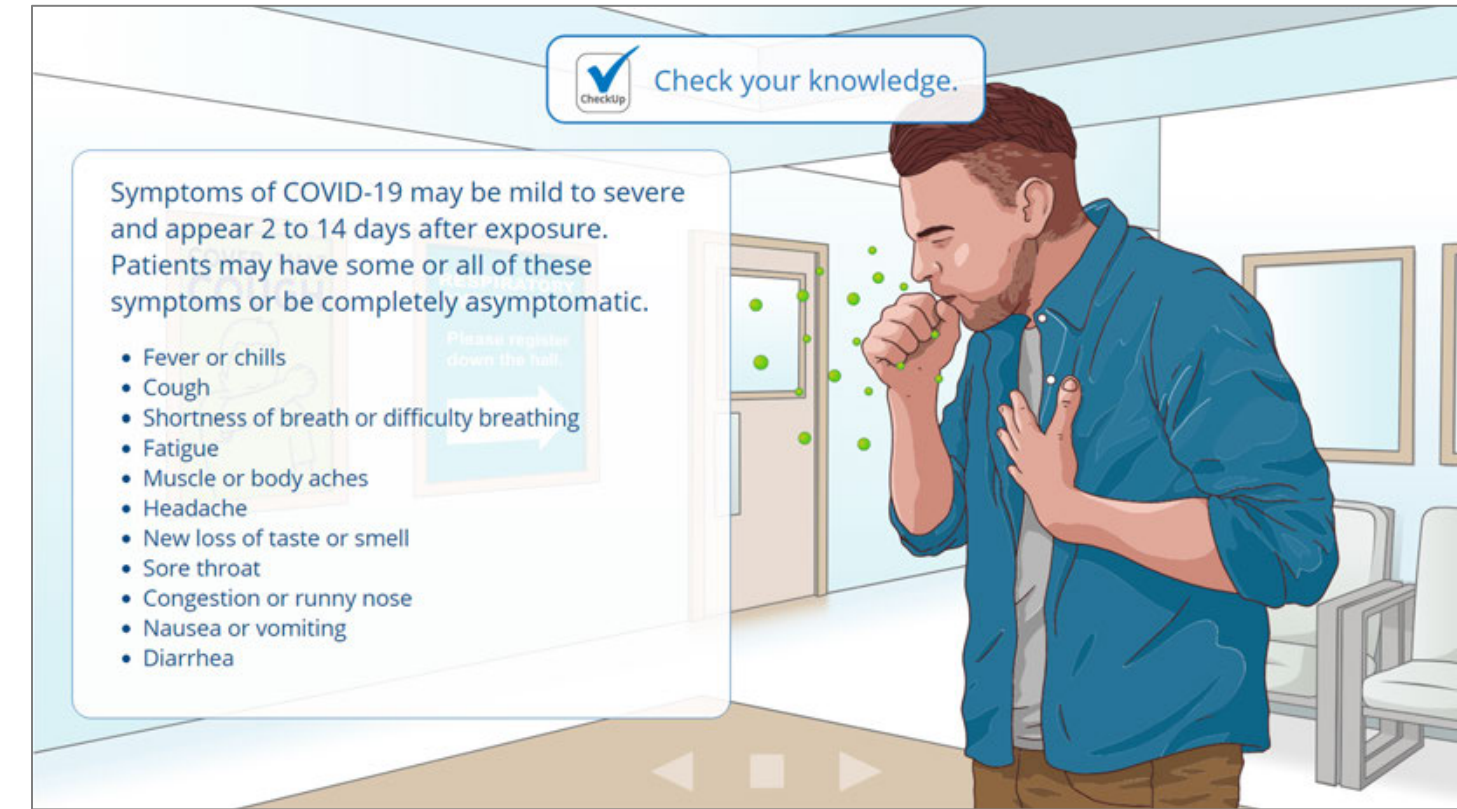
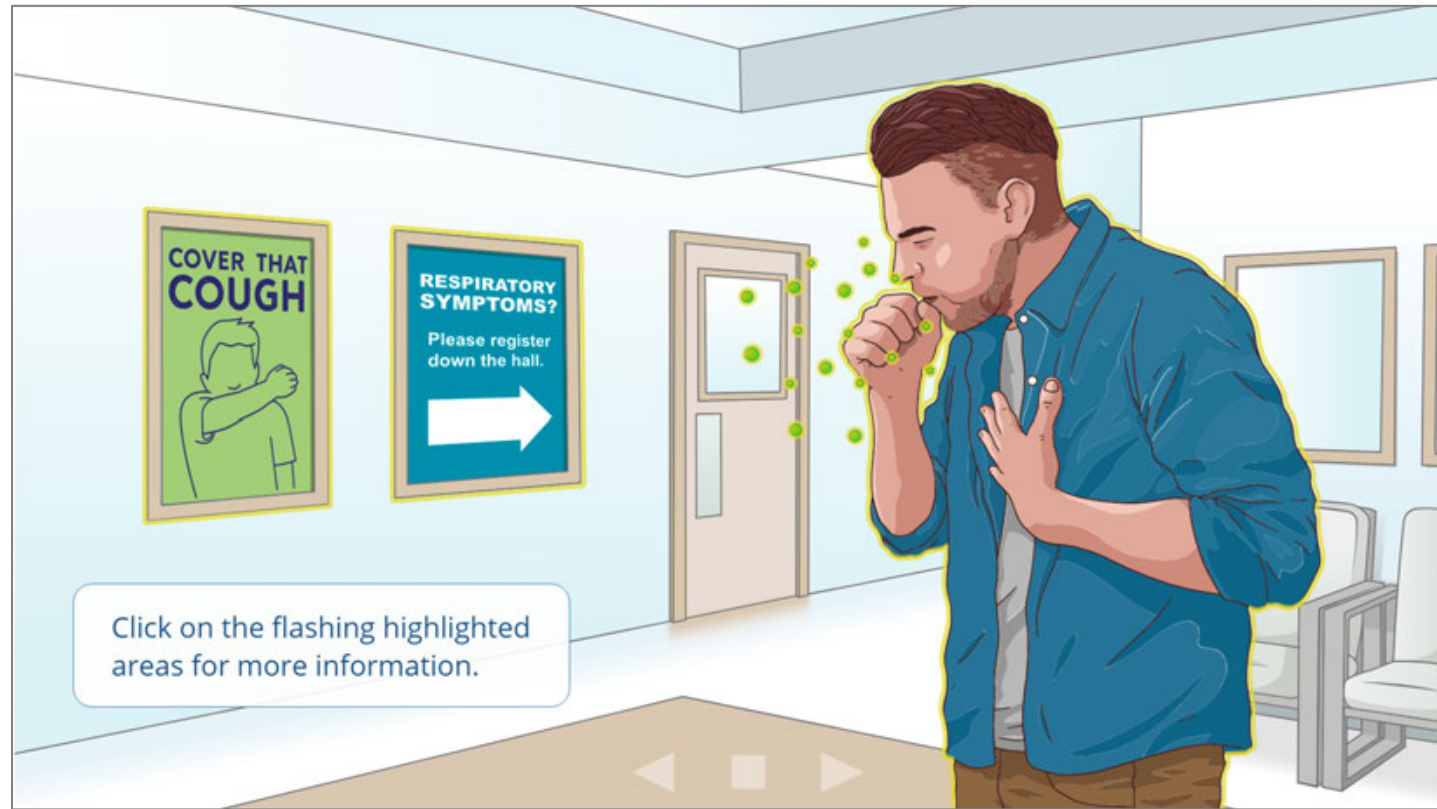
Indication	Class	Level of Evidence
Diagnosis	I	A
Prognosis	I	A
Pre-discharge Risk Assessment	IIa	B-NR
Prevent Onset of Heart Failure	IIa	B-R

NR = not randomized, R = randomized

A single measurement of BNP in the ED is associated with greater diagnostic accuracy and its use decreases time to discharge and cost of stay.²⁹

The Quidel Triage BNP Test is a rapid, POC fluorescence immunoassay used with the Quidel Triage MeterPro. The test is used to measure BNP in EDTA anticoagulated whole blood or plasma specimens. The Triage BNP Test is the first rapid BNP immunoassay indicated for risk stratification for both ACS and HF.³⁰





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.

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 50-75% of the WBC's in venous blood. Their main function is to ingest and destroy bacteria. If the neutrophil count rises, it's being stimulated. If the count is low, it may indicate infection.

Lymphocytes
Lymphocytes account for roughly 20-40% of the WBC's in venous blood. The main job is to help identify and "remember" antigens. Lymphocytes usually indicate infection.

Monocytes
Monocytes are about 2-8% of the WBC's. Monocytes can become macrophages or dendritic cells. They are involved in the immune system, as are other WBCs.

Eosinophils & Basophils
Eosinophils and basophils are involved in allergic reactions and are activated in patients with asthma, allergies, and other conditions.

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 clotting.

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, 18.1" wide, and 18.1" deep.

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 than 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.

Repeat Testing

This technology will not completely eliminate healthcare providers may need to re-test some of samples that are currently being sent out, at same-visit results for patients.

Normal Result

MCV 83.6

NOTES

Suppressed Result

MCV **XXXX**

NOTES

RECOMMEND FURTHER TESTING.

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

Patient Name: John M.
Date: January 2, 2018
Temp: 98.6 **BP:** 206/89
HR: 101 **RR:** 14 **O₂:** 96%
Hx: Hypertension, hyperlipidemia

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

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.

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.

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

Repeat cardiac biomarkers 3 hours later
CK-MB 3.9 ng/mL
Myoglobin 79 ng/mL
Troponin I < 0.05 ng/mL

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.

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.



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	More than 600,000
400,000	More than 600,000	<small>(https://www.cdc.gov/heartdisease/heart_attack.htm. Accessed 30 January 2018.)</small>

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

Asian American	African American
Hispanic American	White/Caucasian American
	<small>(Benjamin EJ, Blaha MJ, Chiuve SE, et al. Circulation. 2017;135:e1-e458.)</small>

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
	<small>(https://my.clevelandclinic.org/health/articles/17488-smoking. Accessed 07 February 2018.)</small>

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

Heartburn	Headache
Gastroenteritis	Pneumonia
	<small>(https://health.clevelandclinic.org/2016/10/75-things-that-pain-in-your-chest-heartburn-or-a-heart-attack/. Accessed 07 February 2018.)</small>

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
2000	2010	<small>(Thygesen K, Alpert JS, Jaffe AS, et al. Circulation. 2012;126(16):2020-35.)</small>



Case Study: Influenza A and B

Patient Name: Jim L.
Temp: 100.1 **BP:** 120/83
HR: 89 **RR:** 19 **O₂:** 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.

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?

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.

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

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

_____ "originated in 15th century Italy, attributed to "influence of the _____."

Stars	Stars
Humors	<small>(https://www.cdc.gov/vaccines/pubs/p4800a/Bu.htm)</small>

Flu viruses infect up to _____ of each year.

50%	20%
100%	<small>(https://www.cdc.gov/vaccines/pubs/p4800a/Bu.htm)</small>

_____ die in the U.S. each year from flu.

20,000	56,000
56,000	<small>(https://www.cdc.gov/vaccines/pubs/p4800a/Bu.htm)</small>

_____ the flu and lost work productivity _____ in the U.S. alone.

Millions	Billions
Trillions	<small>(https://www.cdc.gov/vaccines/pubs/p4800a/Bu.htm)</small>

5 Healthy adults are contagious one day before and up to _____ days after showing influenza symptoms.

Three	Five
Seven	Nine
	<small>(https://www.cdc.gov/flukeyfacts.htm)</small>







CLICK IMAGE TO PLAY



The Sgx Clarity™ System
 Breaking the sensitivity barrier. One molecule at a time.



Previously unattainable clinical clarity will soon be within reach.

Currently under development, the Sgx Clarity™ System will break through current sensitivity barriers in immunoassay diagnostics, delivering the unparalleled sensitivity and precision of Single Molecule Counting (SMC) technology to hospital and reference laboratory workflows.

"After decades of my little innovation with protein assays, single molecule detection has finally arrived. Singulex's elegant Single Molecule Counting Technology has the potential to detect ultra-rare protein levels at previously undetectable precise increments. SMC offers enhanced precision and ultra-sensitive measurement capabilities allowing for improvement in patient risk assessment and health management at the clinical level."

— **Rae E.S. Yu, PhD, MDC, IACB**
 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 informing 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 ultra-sensitive cardiac troponin-I assay. Having this type of information may lead to more informed treatment decisions, which may slow disease progression for these future patients."

— **James L. Januzzi 3, MD, IACB**
 Cardiologist, Massachusetts General Hospital
 Peter D. 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 #1825 at AACC 2014.

Singulex.com




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




Stewart Shipp
@StewartShipp

POCT 26

Implementation and Validation

- 1 Installation**
- 2 System Configuration**
- 3 Device calibration and QC**
 - CMS Brochure # 3 – Calibration and Calibration Verification¹
 - Implement / Validate IQCP
 - CMS Brochures 11-13²



1. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CIA/Downloads/10088a.pdf>
2. https://www.cms.gov/Regulations-and-Guidance/Legislation/CIA/CIA_Brochures.html

POCT 32

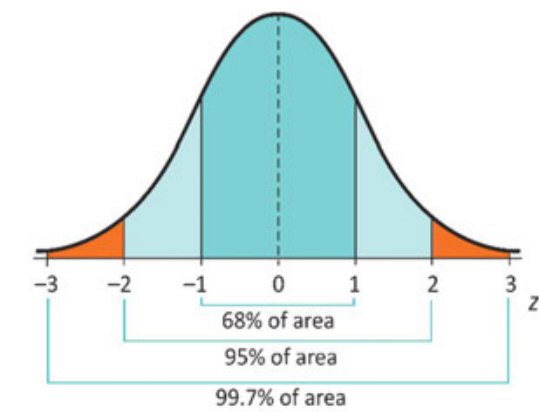
Validation - Reference Interval and Reportable Range

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/CIA/Downloads/10048a.pdf>
Harris A. *Quality*, N. ID. 2017-02011 18-24.

POCT 28

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/CIA/Downloads/10048a.pdf>
Harris A. *Quality*, N. ID. 2017-02011 18-24.

POCT 44

IQCP Is a Continuous Process



Maintenance

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

Revision

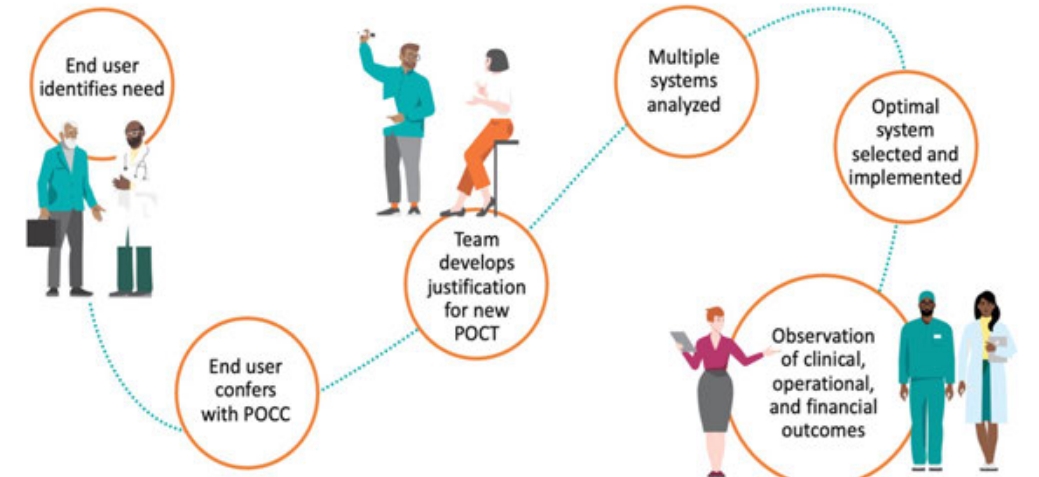
- Quality Assessment
- Risk Assessment

Each change is documented and signed as per original IQCP¹

https://www.cms.gov/Regulations-and-Guidance/Legislation/CIA/Downloads/IQCP_Workbook.pdf. Accessed January 16, 2024.

POCT 20

Correct Implementation Starts With the End User



End user identifies need

Multiple systems analyzed

Optimal system selected and implemented


Team develops justification for new POCT

End user confers with POCC

Observation of clinical, operational, and financial outcomes

POCT 20

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 29

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-I/subchapter-G/part-493/subpart-4/subject-group-ECFR493.4000/section-493.1256. Accessed January 16, 2024.
https://www.cms.gov/regulations-and-guidance/regulation/2014/01/14rtrp-workbook.pdf. Accessed January 16, 2024.

POCT 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?

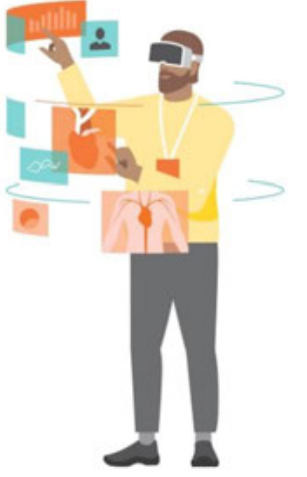


POCT 46

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 Adv. 2014;35:155.
Abel G, et al. Point-of-care testing: A "how to" guide for the non-laboratorian. AACCC. 2022.

POCT 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



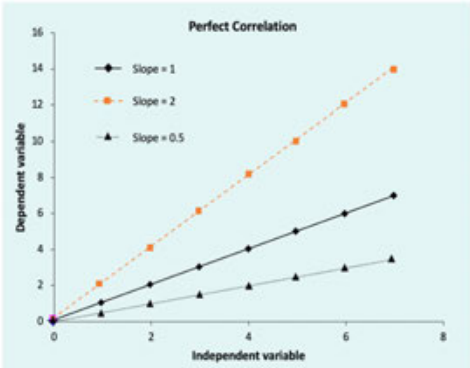
Abel G, et al. Point-of-care testing: A "how to" guide for the non-laboratorian. AACCC. 2022.

POCT 29

Accuracy and Correlation

Determined by correlation to local standard - Correlate does not mean match

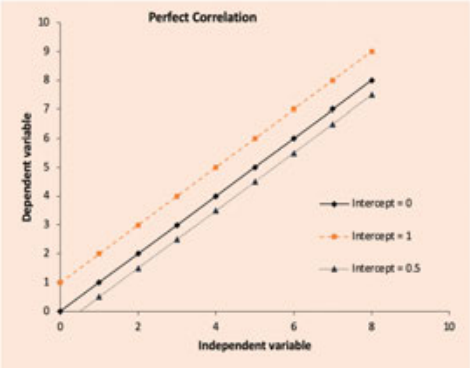
Perfect Correlation



Dependent variable vs Independent variable

- Slope = 1
- Slope = 2
- Slope = 0.5

Perfect Correlation




Dependent variable vs Independent variable

- Intercept = 0
- Intercept = 1
- Intercept = 0.5

POCT 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. AACCC. 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)



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

Reverse antibody algorithm

Reverse sequence algorithm

Treponemal serologic test (e.g., EIA or CIA)

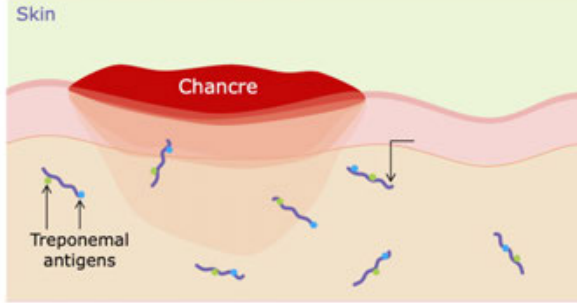
- Reactive treponemal serologic test
 - Nontreponemal (lipoidal antigen) serologic test
Quantitate RPR or VDRL titer
 - Reactive
 - Previously treated or untreated syphilis
 - Nonreactive
 - Reactive second treponemal serologic test
 - Previously treated or untreated syphilis
 - Nonreactive second treponemal serologic test
 - Syphilis is unlikely. If patient is at risk for syphilis, repeat RPR or VDRL in several weeks. Prozone and biologic false positive should be ruled out.
- Nonreactive treponemal serologic test
 - Syphilis is unlikely

Papp JR, et al. MMWR Recomm Rep. 2024;73(RR-1):1-32.
CIA = chemiluminescence immunoassay; EIA = enzyme immunoassay; RPR = rapid plasma reagin; 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

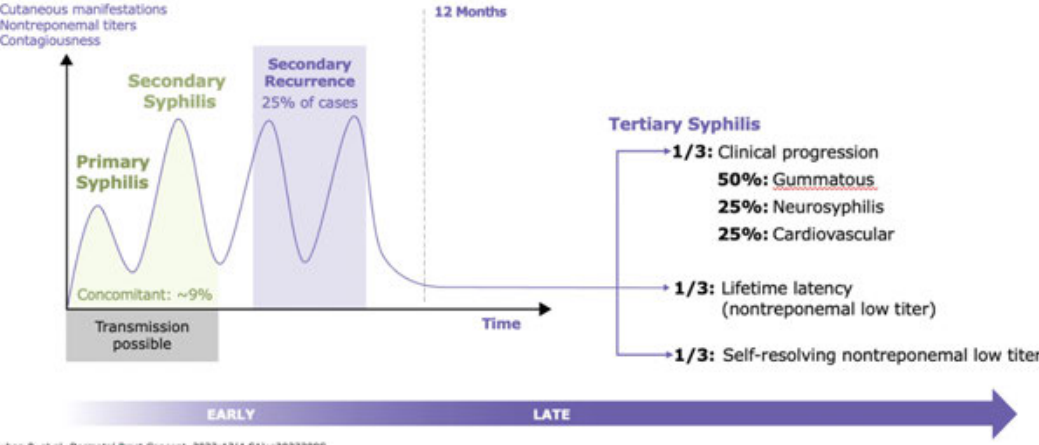
- May appear orange or hyperpigmented
- White and peripheral scales
- Vascular pattern almost always absent
- Bilateral annular facial plaques more frequent



Whiting C, Schwartzman G, Khachemoune A. J Clin Derm. 2023 Mar;24(2):287-297.
Chauhan P, Behara B, Ding DD, et al. Dermatol Pract Concept. 2023 Oct 1;13(4 51):e20233095.
Navarete J, Saavedra-Portales S. Syphilis for dermatologists: Current concepts. Clin Dermatol. 2024 Mar-Apr;42(2):134-154.
Korasmikan N, Lajon M, Ramachandran S, Fernandes SD. J Family Med Prim Care. 2022 Mar;11(3):1218-1226.
Early syphilis (secondary stage).
https://wellcomecollection.org/works/rh9p733

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

Cutaneous manifestations
Nontreponemal titers
Contagiousness



Primary Syphilis
Concomitant: ~9%
Transmission possible

Secondary Syphilis

Secondary Recurrence
25% of cases

Tertiary Syphilis

- 1/3: Clinical progression
 - 50%: Gummatous
 - 25%: Neurosyphilis
 - 25%: Cardiovascular
- 1/3: Lifetime latency (nontreponemal low titer)
- 1/3: Self-resolving nontreponemal low titers

Chauhan P, et al. Dermatol Pract Concept. 2023;13(4 51):e20233095.

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

Skelink 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.

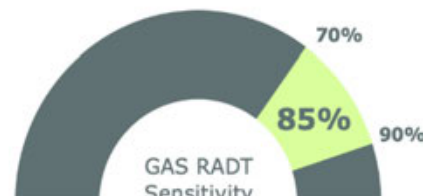
- Greater return rates
- Misdiagnosis
- Inappropriate antibiotics
- Allergic reactions
- Loss of school days



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, Ghaffar 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

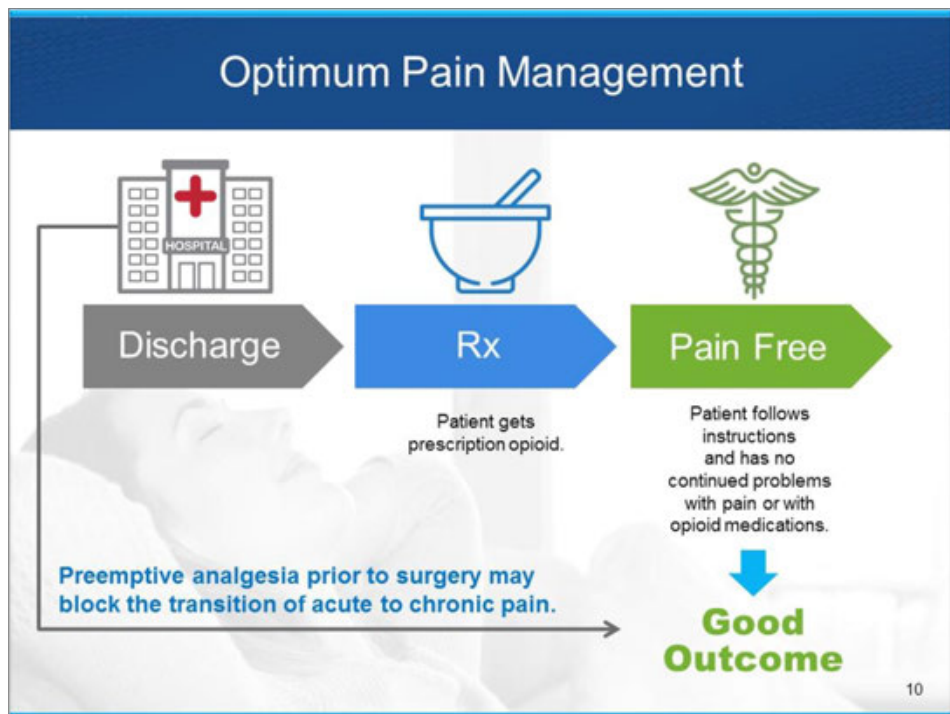
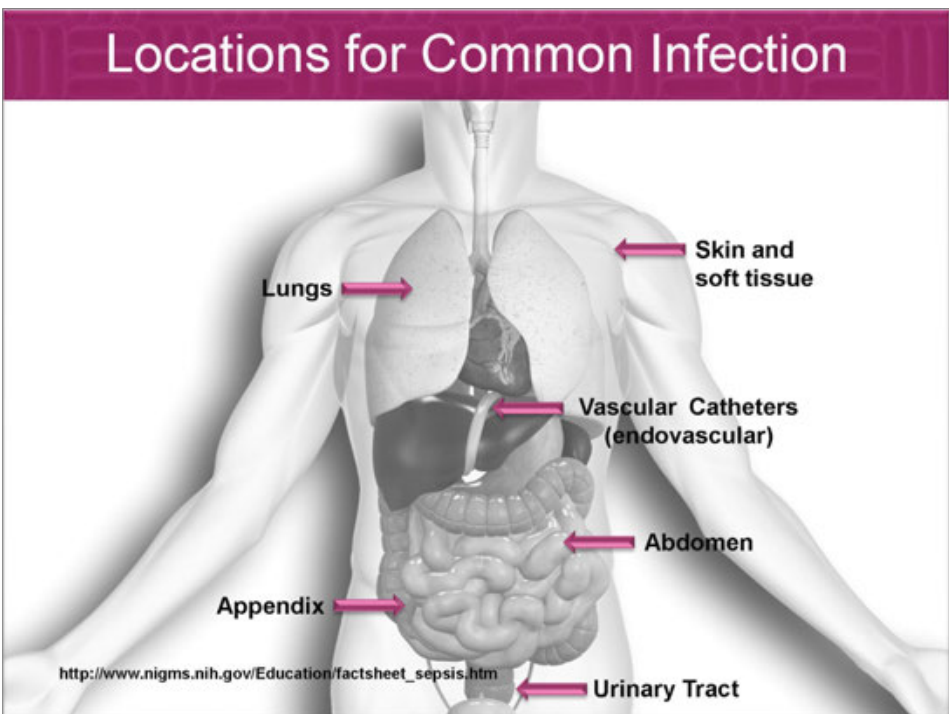
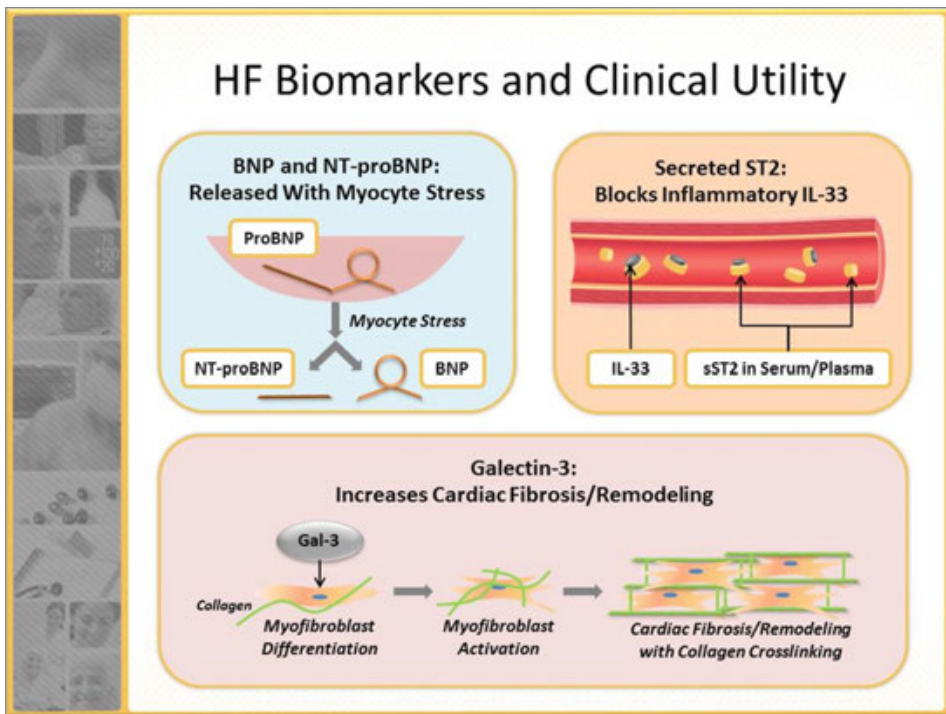
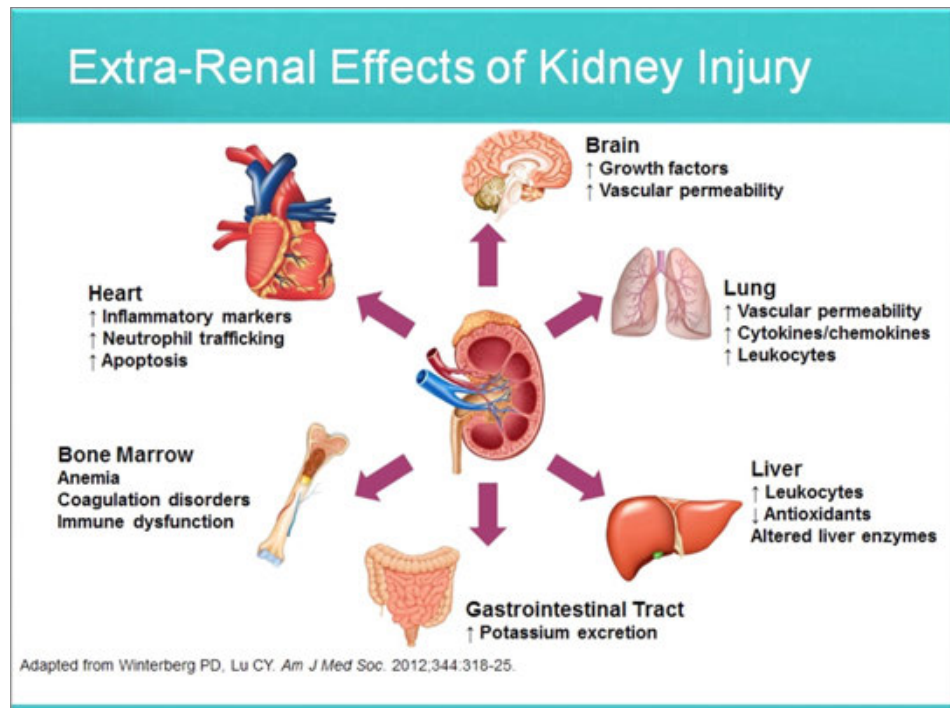
Thompson TZ, McMullen AR. J Clin Microbiol. 2020;58(5):e01494-19.

Acute Pharyngitis Symptoms

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



Skelink NS, Albert RH. Essen Infect Dis Topics Primary Care. 2008:15-24.

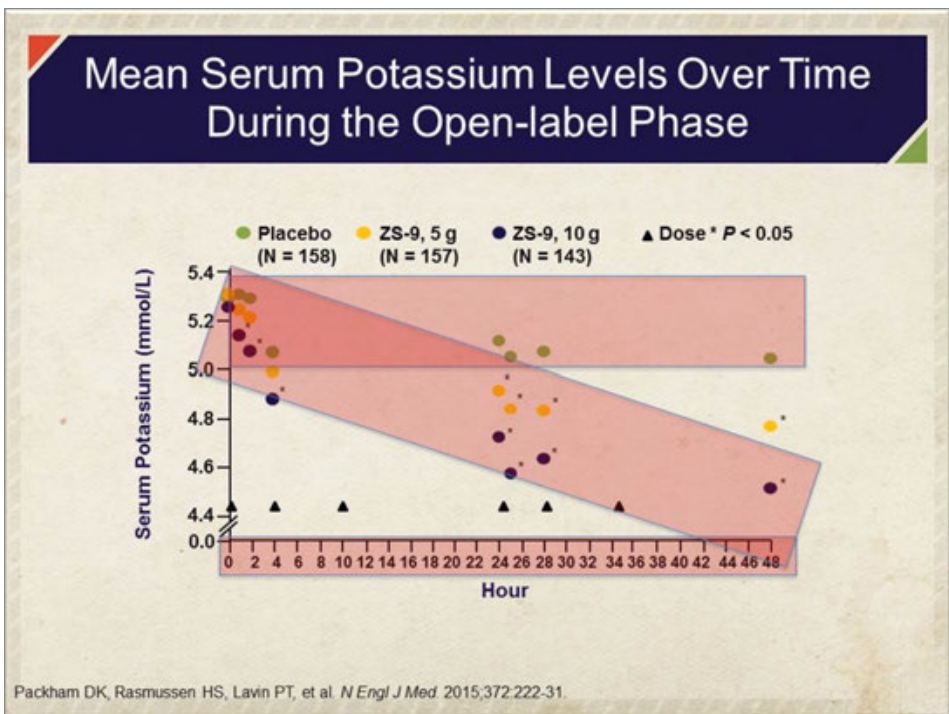


New and Familiar Strategies With Medications

Russell D. Weisz, MD

25

TEAMHealth



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

1935-41 First live human influenza vaccine tested by Salk and Francis¹

1946-47 Discovery of annual influenza viral mutations²

1945 First inactivated human influenza vaccine licensed¹

1967 First adamantane, "amantadine" was first approved for treatment and prophylaxis³

1991 First reverse transcription-PCR (RT-PCR) assay for detection of influenza virus was described⁴

1993 Second adamantane, rimantadine, was approved³

1999 Two neuraminidase inhibitors, zanamivir and oseltamivir, were approved for prophylaxis and treatment of influenza³

2005 Cell culture based vaccines⁵

1930 1940 1950 1960 1970 1980 1990 2000 2010

INFLUENZA 25

Effect of Inflammation on Iron Concentrations

Infection, Inflammatory Stimulus

IL-6

Hepcidin

Liver

Spleen

Duodenum

Bone Marrow

Senescent RBC

Iron

20 mg Iron/day

1-2 mg Iron/day

20 mg Iron/day

Plasma Fe-Transferrin

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

Morphine Units

59.5 mg

Placebo

41.4 mg

Ibuprofen

Patients treated with IV Ibuprofen used 31% less morphine

Singla N, Rock A, Paviv 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

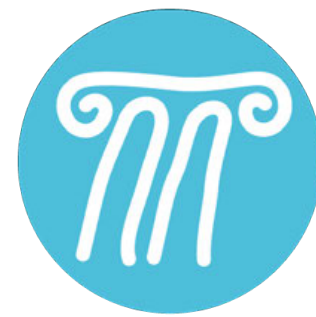
Slide Deck Development

Speakers Bureau

Tradeshow Booth Design & Strategy

Video Production

Thank you for your time.



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