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DISEASE › INFECTIOUS DISEASE

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

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

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

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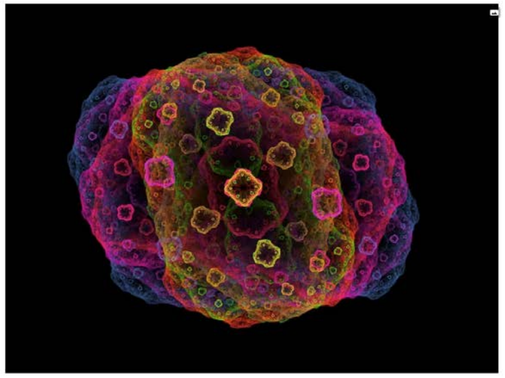
DIAGNOSTICS › ASSAYS

Molecular syndromic testing: Will panels improve care?

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



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

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

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DISEASE › INFECTIOUS DISEASE

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

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

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

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

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CME / CE

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

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

CME / CE Released: 3/13/2023 **Valid for credit through:** 3/13/2024

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3

Alzheimers Disease (AD): Impact on Global Health

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

Figure 1. Older Age Conditions

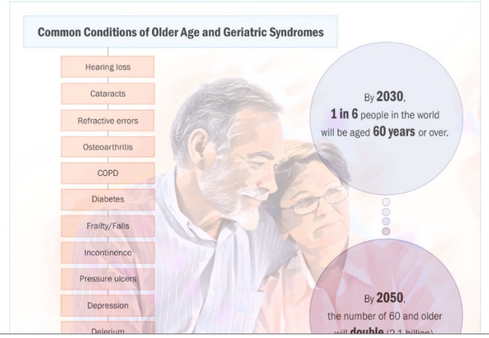

exhibit strong correlation with amyloid PET, they are widely accepted in the AD community as supporting a diagnosis of early stage AD.[32,33]

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

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

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

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Activity Review

Prevalence and clinical manifestations of herpes virus

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

Activity Progress

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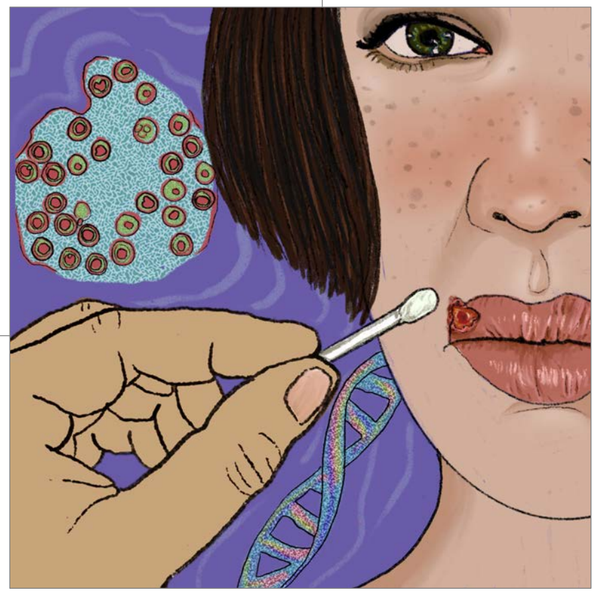
Lesion-causing herpes simplex

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



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

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

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

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

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

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

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

The only way to definitively determine a diagnosis is through

in over 11% of suspected HSV cases.

50% of these cases are in genital regions.

suspected to be VZV due to presentation.

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

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

Clinical diagnosis of VZV may need to rule out HSV

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

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

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

VZV Differential Diagnosis

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

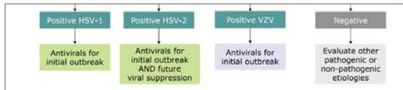


Figure 10. Utilizing multiplex testing for any patient with suspected HSV or VZV can eliminate unnecessary testing, reduce time to diagnosis, and improve treatment timelines.

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

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

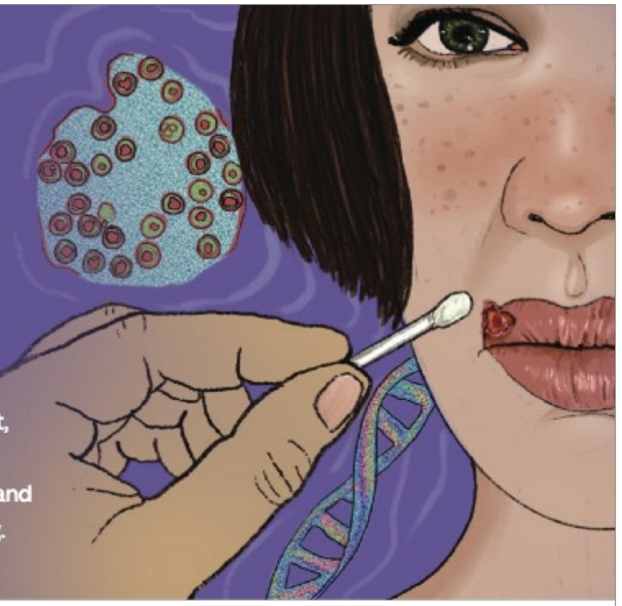
Neonatal HSV

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

Neonatal VZV

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

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 diagnositc 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

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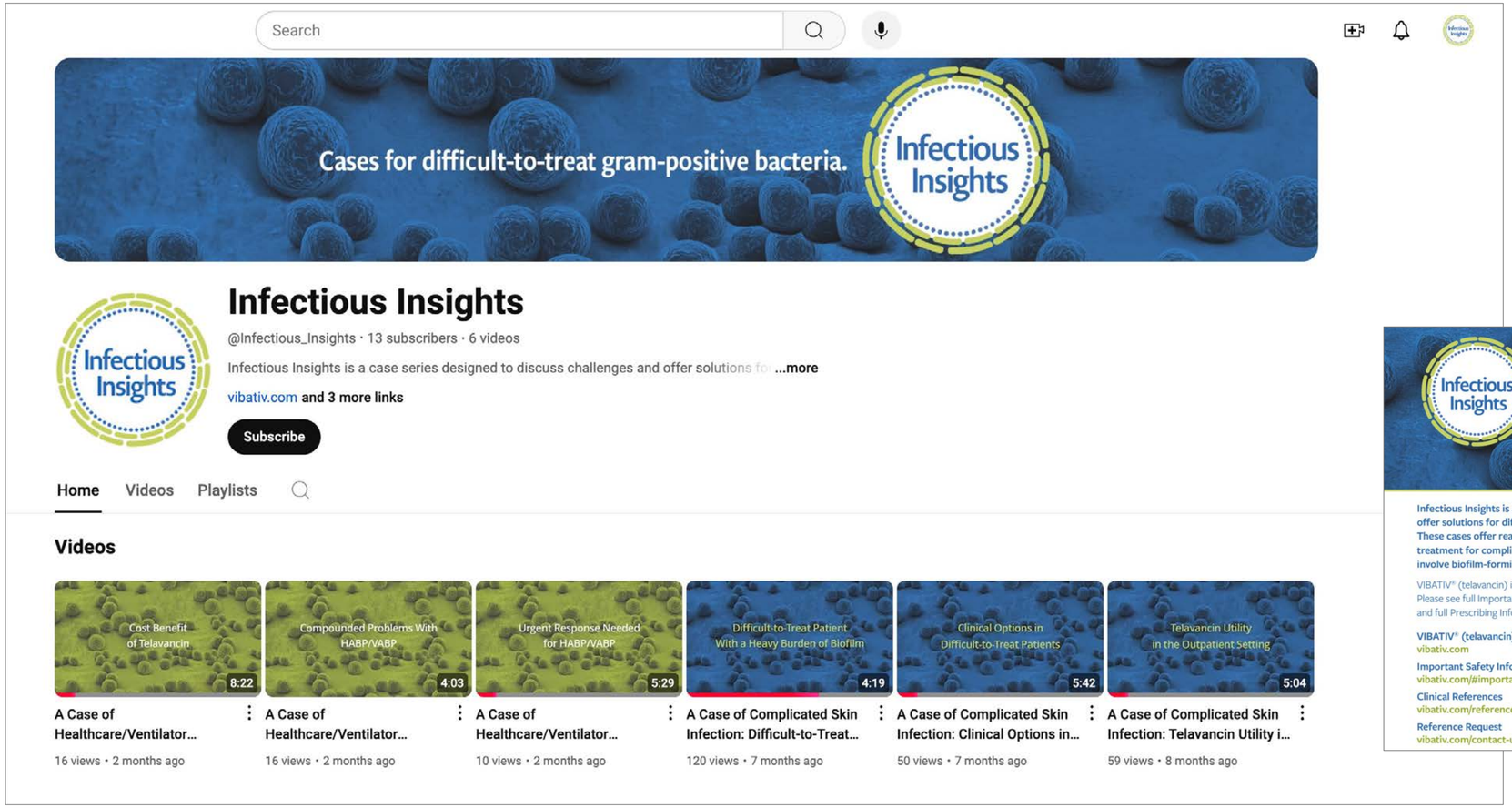
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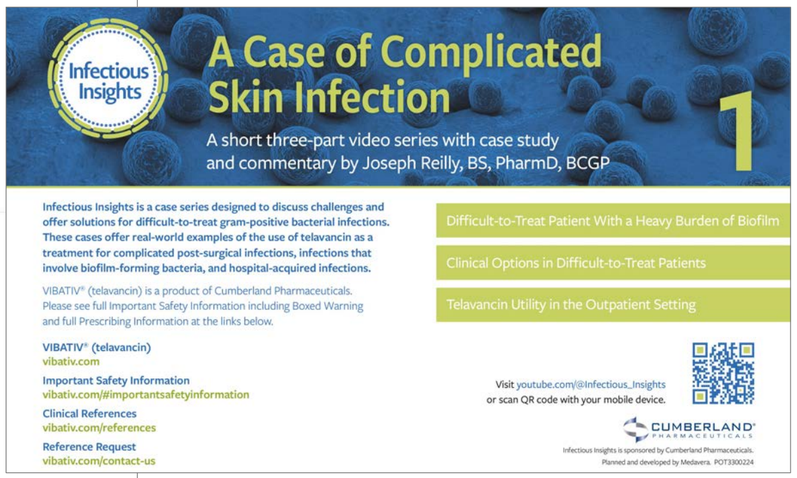
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1
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Infectious Insights
A Case of Complicated Skin Infection


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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.

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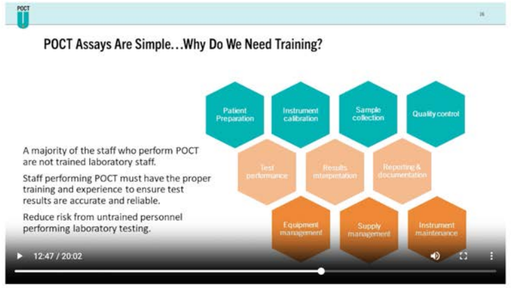

Part 2

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

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75% Agree improves performance

100% Say useful in daily work

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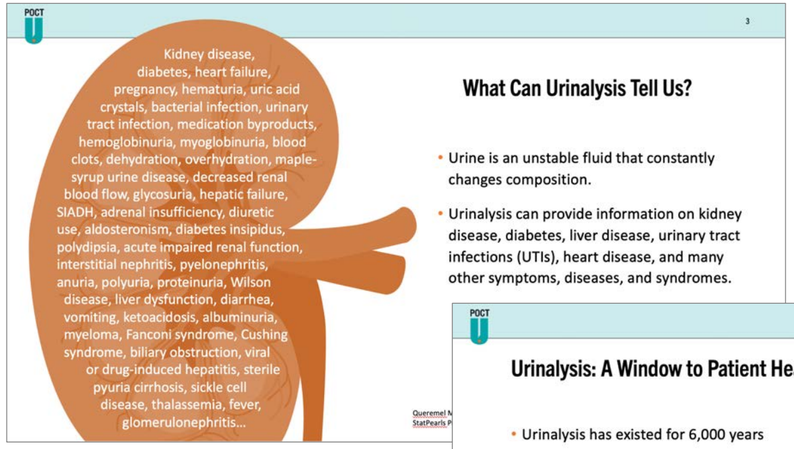
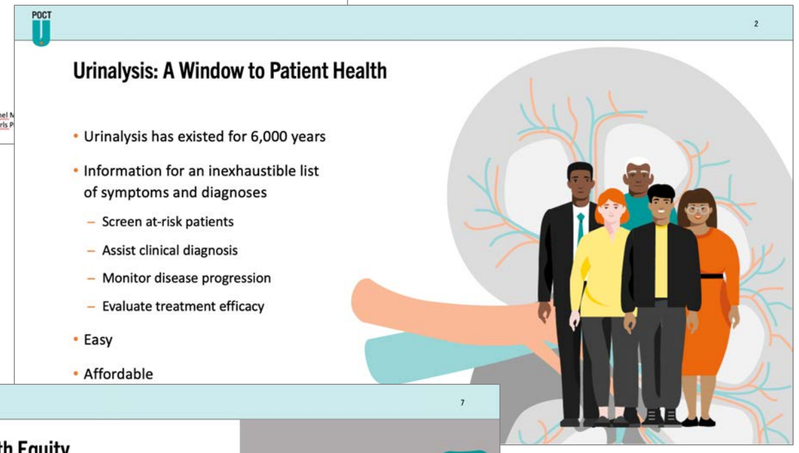
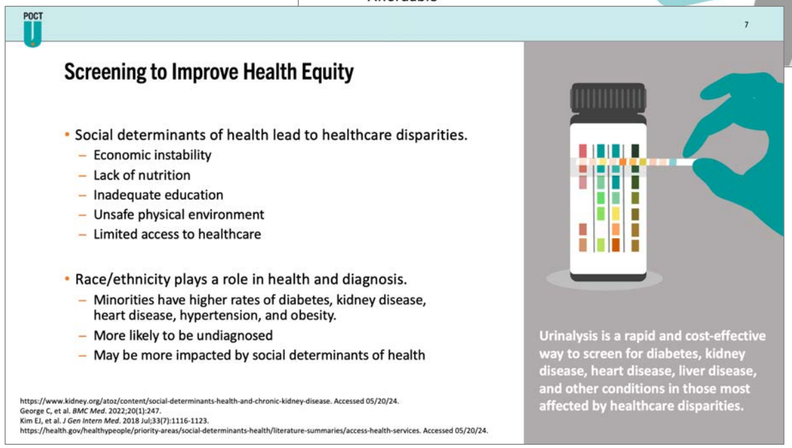






Reasons patients are not getting uACR tests:

Ordering rates may be low because

uACR isn't part of a standard blood lab panel

like eGFR and serum creatinine.[2]

Outpatient facilities

may not have a standard protocol for urine collection.[2]

Physicians are not ordering guideline-recommended uACR screening tests.[2]

Patients **don't understand** the reason for the test.[2]

Morning collections are difficult for patients with **afternoon** appointments.[2]

Urine collection is inconvenient for patients at home, particularly **24-hour samples.**[2]

Caring for those with diabetes

Diabetes is a multifaceted disease.[1] 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.[1]

You are central to their success which requires utilizing creative and collaborative strategies to help them manage their disease.[1]

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).[2]

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.[2] Estimated glomerular filtration rate (eGFR) uses serum creatinine to measure kidney function.[3] 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.[4,5] 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.[4,5]

Diagnostic criteria for CKD[4–5]

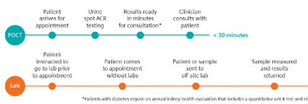
Impaired Kidney Function

eGFR: < 60 mL/min/1.73 m²
uACR: ≥ 30 mg/g for > 3 months

Annual Assessment

- type 1 diabetics with a 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.[4,6] A uACR ≥ 30 mg/g indicates kidney damage, even without an elevated eGFR.[4,6]



*Patients with diabetes require an annual kidney health evaluation that includes a quantitative uACR test and eGFR.[4] These tests are not CLIA waived. Patients with all other risk factors for kidney disease can be screened with a CLIA waived, semi-quantitative kidney function test.

Compliance may be improved by using POCT uACR[7]

Although the 24-hour collection has been the "gold standard" for uACR, spot POCT uACR correlates well with 24-hour collection results in adults.[4] 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.[4,6]

With moderate complexity or CLIA-waived POCT uACR, patients can be tested during the same appointment. They don't need a separate lab 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.[7,8]

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.[7,9]

POCT benefits baby and clinicians

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

Patient-side testing in the NICU offers many benefits—the most important of which is responding quickly to your tiniest and most vulnerable patient.

Results can be obtained within 1 minute of sample loading.[9]

Single or multiple analytes can be tested.[9]

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.[11]

A tiny amount of blood is needed.[9]

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.[1]

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.[1]

Neonates have immature organ systems, different airway and lung mechanics, and a higher basal metabolic requirement for oxygen.[1]

Early signs of clinical deterioration are often nonspecific, making a diagnosis challenging.[4] Blood analysis is integral to monitoring Neonatal Intensive Care Unit (NICU) patients.[1]

Point-of-care bedside blood analyzers have been shown to reduce red blood cell transfusions in low birth weight infants.[5,6]

Blood drawn for laboratory testing should not exceed 5% of the total blood volume per draw.[1] A 10 ml blood sample drawn with standard tubes may represent as much as 10% of the total blood volume in a preterm neonate.[1]

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.

Too much blood sampling can cause endogenous blood loss and has been associated with the development of bronchopulmonary dysplasia.[8]

Modern handheld point-of-care analyzers need **as little as 92 µl or 0.092 ml to run 13 different tests** as compared to a standard laboratory tube which holds ~3 ml of blood.[8]

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.[10] They also recommend that blood should be analyzed within 15 minutes of sampling.[10]

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 to access central lines and blood lactate measurements can indicate infection.[10]

Underdeveloped digestive tract and liver should be monitored for hyperbilirubinemia, metabolic acidosis, and hypoglycemia.[10]

Underdeveloped lungs may need ventilator support and frequent blood gas measurements for inconsistent breathing and respiratory distress syndrome.[10]

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 95% is type 1. Type A1 has subtypes A1a, A1b, A1c, and others with A1c being the most common.[11]

Almost all outcome studies on diabetes complications are now based on HbA1c.[3,4,12]

Compared with glucose, A1c levels have lower biological variability and are not affected by stress and exercise.[13]

Every 1% decrease in the A1c level in a diabetes patient can remarkably lower the risk of complications.[14–18]

The average person without diabetes has an A1c level of **<5.7%**.[12]

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.[14]

The use of the A1c test for monitoring the **degree of control of glucose metabolism** in patients with diabetes was proposed in **1976**.[3]

Caring for those with diabetes

Diabetes is a multifaceted disease.[1] 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.[1]

You are central to their success which requires utilizing creative and collaborative strategies to help them manage their disease.[1]

Caring about A1c

Checking patients' A1c levels regularly helps lower risks of complications from diabetes.[7,8] **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.[7] Testing A1c at the point of care has also been shown to reduce costs associated with post-visit testing.[8]

"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
Smithsonian Institution

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.[5]

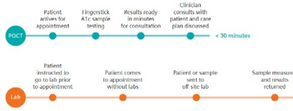
Incorporating A1c POCT into a patient visit customizes the appointment to the patient's glycemic status. Providing A1c levels with immediate feedback helps providers influence patients to improve their glycemic control.[19]

POCT A1c

- Streamlined and efficient with no patients lost in the process
- Better patient understanding
- Better clinician/patient relationship
- Better outcomes

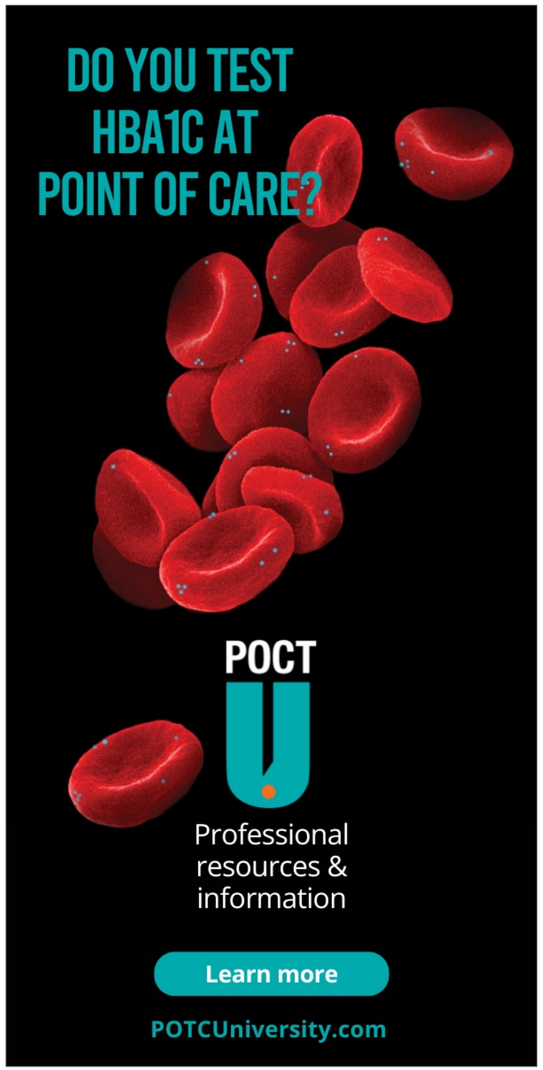
Central lab

- 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
- Extra work for the practice



Guide your patients

American Diabetes Association A1c Guidelines[5]	
A1c goals	< 7.0% (53 mmol/mol)
	Lower may be acceptable and beneficial if it can be achieved safely without significant hypoglycemia or other adverse effects
	Less stringent goals (< 8.0% [64 mmol/mol]) may be appropriate for patients with limited life expectancy or where harms outweigh benefits of treatment.
	Beaseless 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.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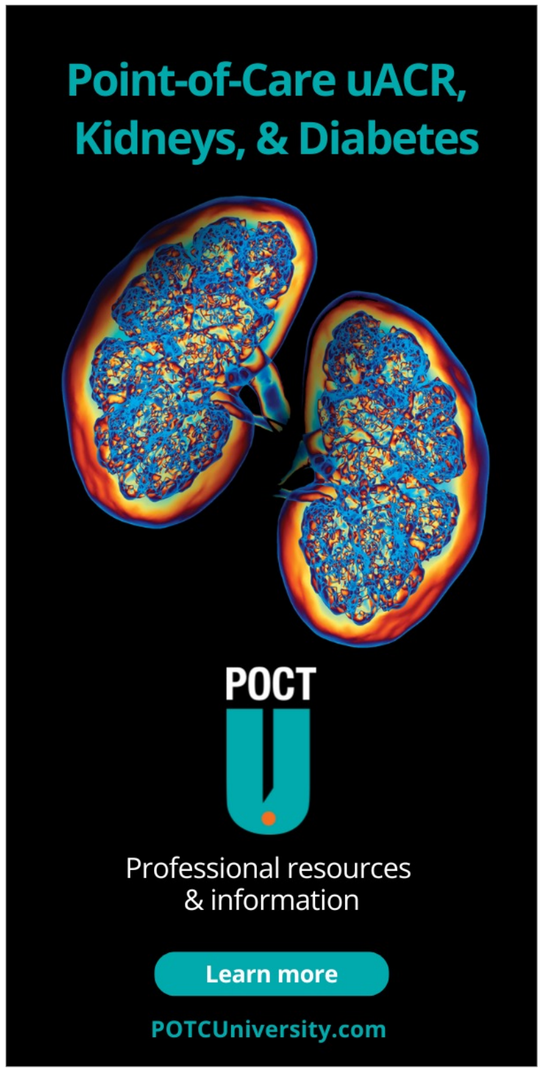
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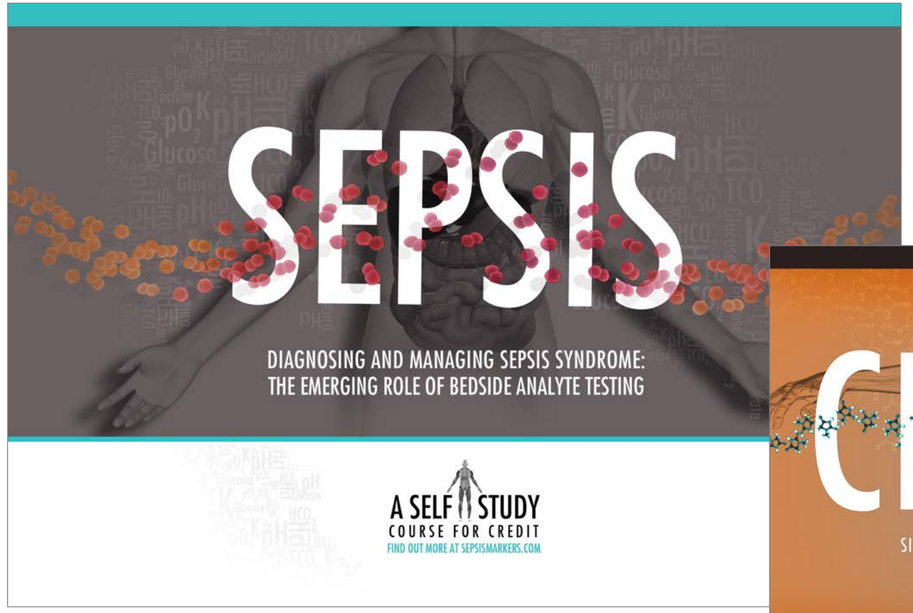
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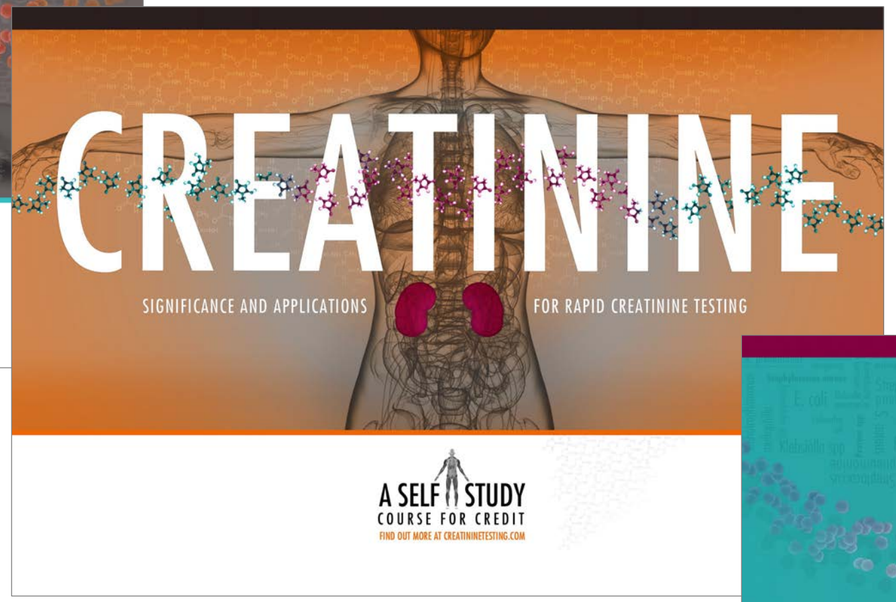
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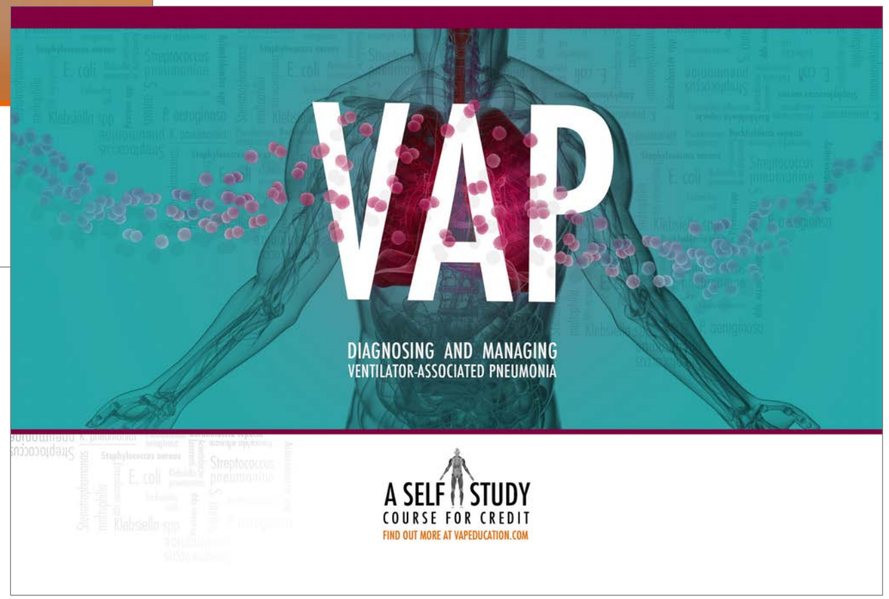
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UPDATED CONTENT

SEPSIS

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

View Learning Activity | CME Self-Assessment | Download Slide Set

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

Sepsis is an overwhelming immune response to an infection. It kills more than 250,000 Americans each year and is becoming more common, especially in the hospital. Sepsis is a medical emergency that can be difficult to define, diagnose, and treat, but every minute counts in the effort to save lives.

This is an accredited self-study learning activity.

Click on View Learning Activity to study the slides and notes. When you are finished studying, you many click on CME Self-Assessment and complete the post-test and evaluation. Follow the instructions for achieving CME credit. You may also download the slide set to have for your files.

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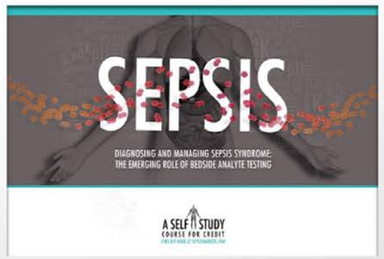

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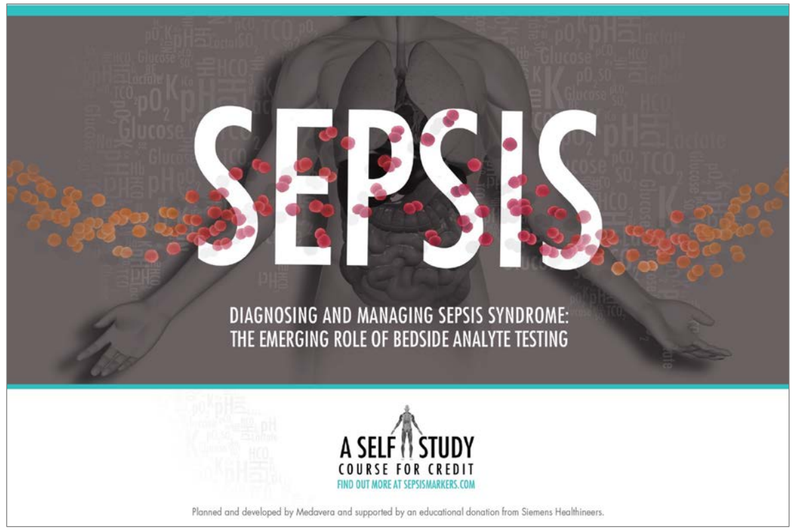
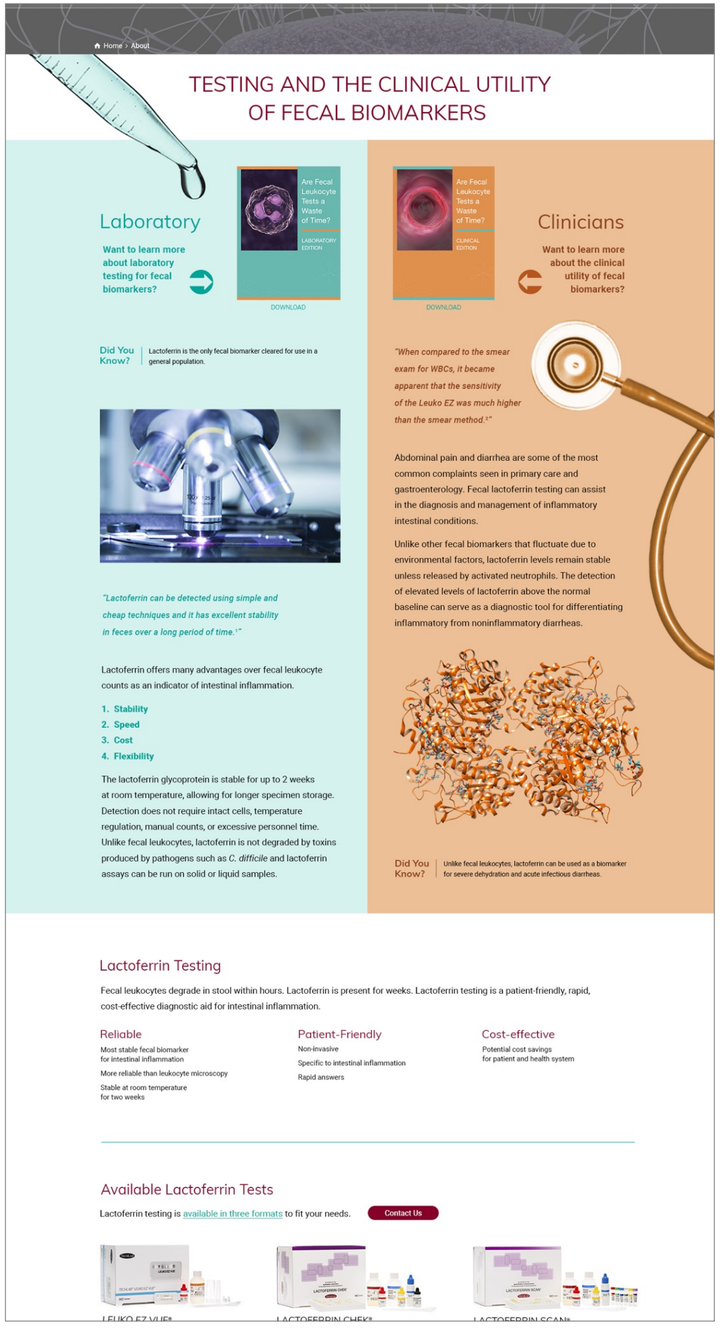
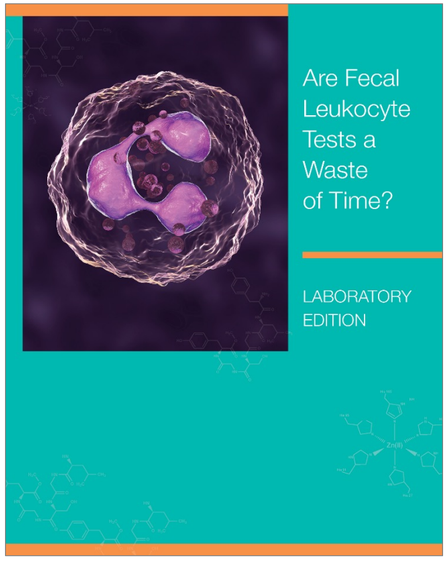







Doubts about the utility of fecal leukocyte tests have been publicly voiced.

Doubts about the utility of fecal leukocyte tests using microscopy have been publicly voiced, but detection of leukocyte-release lactoferrin overcomes the challenges. For over a century, fecal leukocytes have been used to diagnose and differentiate between acute inflammatory and non-inflammatory diarrheas. A quantitative cell count from a fecal smear, the fecal leukocyte test (FLT), was originally performed at the patient's bedside as a point-of-care test (POCT) by a trained microscopist.

As clinics, where samples are taken, and laboratories, where fecal specimens are tested, have grown further apart, doubts about the current utility of the FLT have been voiced. Are FLTs now a waste of time?

False-Negatives With FLTs

When assaying with FLTs, technicians can only detect and count intact leukocytic 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 FLTs due to the degradation of the leukocytes.

Also, toxins released by some enteric pathogens such as Clostridioides difficile can lyse neutrophils. A study published in 2006 concluded that the fecal leukocyte test had poor sensitivity and was not a good predictor of C. difficile-associated diarrhea, which accounts for more than 25% of all antibiotic-associated diarrheas.[2]

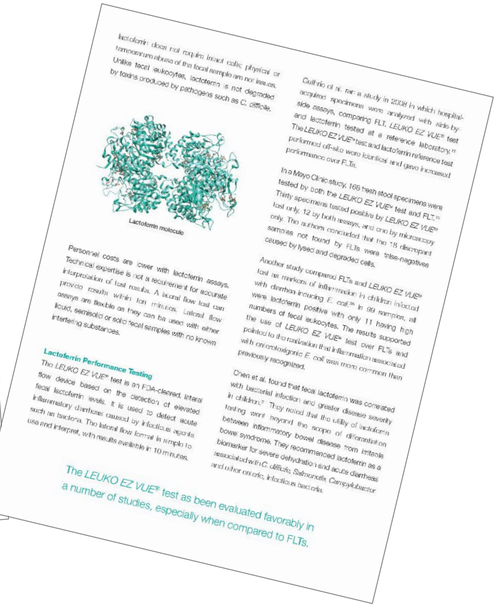
As far back as 1977, Pickering et al. reported a lack of correlation between fecal leukocytes and the recovery of enteric pathogens in feces.[2,3] The American College of Gastroenterology recommended the use of FLTs in 1997 despite their acknowledgments that the assay exhibited low sensitivity (40%) which was reported in a large systematic review with meta-analysis published the previous year.[3,4] In a 2004 performance assessment involving 205 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 FLTs.[5] 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."[5]

FLT Costs

Gupta et al. published a 100-year history of the stool cellular exudate test—also known as the FLT.[3] 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 $329,000 per year on approximately 58,000 fecal leukocyte assays. This translated to a cost of roughly $5.69 per assay. In 2018, the Medicare midpoint reimbursement for a fecal leukocyte test was $5.27.

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


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.

Lactoferrin molecule

Personnel costs are lower with lactoferrin assays. Technical expertise is not a requirement for accurate interpretation of test results. A leuko EZ vue fecal test process results within ten minutes. Lateral flow assays are flexible as they can be used with either liquid, semisolid or solid fecal samples with no known interfering substances.

Lactoferrin Performance Testing

The LEUKO EZ VUE® test is an FDA-cleared, lateral flow device based on the detection of elevated fecal lactoferrin levels. It is used to detect acute inflammatory diarrheas caused by infectious agents such as bacteria. The lateral flow format is simple to use and interpret, with results available in 10 minutes.

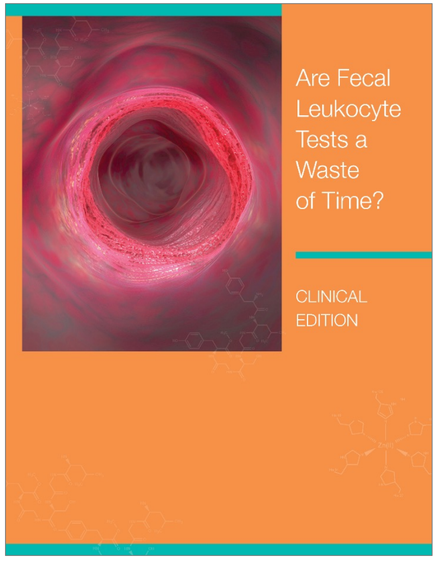
Guilfoile et al. ran a study in 2008 in which hospital-acquired specimens were analyzed with side-by-side assays, comparing FLT, LEUKO EZ VUE® test and lactoferrin tested at a reference laboratory.[1,6] The LEUKO EZ VUE® test and lactoferrin reference test performed similarly and had a higher performance than FLTs.

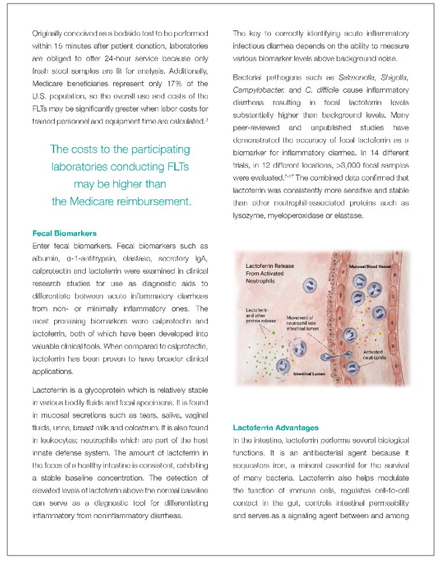
In a Mayo Clinic study, 186 fresh stool specimens were tested by both the LEUKO EZ VUE® test and FLT.[1,6] Thirty specimens tested positive by LEUKO EZ VUE® test only. The authors considered that the 18 discrepant samples not found by FLTs were false-negatives caused by dyslexic and degraded cells.

Another study comparing FLTs and LEUKO EZ VUE® test on matters of inflammation in children initiated with diarrhea including C. coli in 80 samples, all were lactoferrin positive with only 11 having high numbers of fecal leukocytes. The results supported the use of LEUKO EZ VUE® test over FLTs and pointed to the correlation that inflammation associated with enteropathogenic E. coli was more common than previously recognized.

Chen et al. found that fecal lactoferrin was correlated with bacterial infection and greater disease severity in children.[7] They noted that this utility of lactoferrin testing went beyond the scope of differentiation between inflammatory bowel disease from irritable bowel syndrome. They recommended lactoferrin as a biomarker for severe dehydration and acute diarrheas associated with C. difficile, Salmonella, Campylobacter and other enteric infections in bacteria.

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




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 FLTs may be significantly greater when labor costs for trained personnel and equipment time are calculated.[3]

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

Fecal Biomarkers

Enter fecal biomarkers. Fecal biomarkers such as albumin, α-1-antitrypsin, elastase, secretory IgA, calprotectin and lactoferrin were examined in clinical research studies for use as diagnostic aids to differentiate between acute inflammatory diarrheas 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 bodily 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 diarrheas.

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 diarrheas resulting in fecal lactoferrin levels substantially higher than background levels. Many peer-reviewed and unpublished studies have demonstrated the accuracy of fecal lactoferrin as a biomarker for inflammatory diarrheas. In 14 different trials, in 12 different locations, >3,000 fecal samples were evaluated.[5,6,7] The combined data confirmed that lactoferrin was consistently more sensitive and stable than other neutrophil-associated proteins such as lysozyme, myeloperoxidase or elastase.

Lactoferrin Advantages

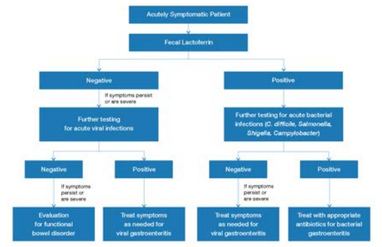
In the intestine, lactoferrin performs several biological functions. It is an antibacterial agent because it sequesters iron, a mineral essential for the survival of many bacteria. Lactoferrin also helps modulate the function of immune cells, regulates cell-to-cell contact in the gut, controls intestinal permeability and serves as a signaling agent between and among epithelial and immune cells.[7] 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.[7] Lactoferrin also corresponds to moderate or severe Vesikari and Clark scores of gastroenteritis disease severity, suggesting the role of the biomarker in staging infectious diarrheas.[7]

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



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.**

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

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OpioidReduction.com

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

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

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

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

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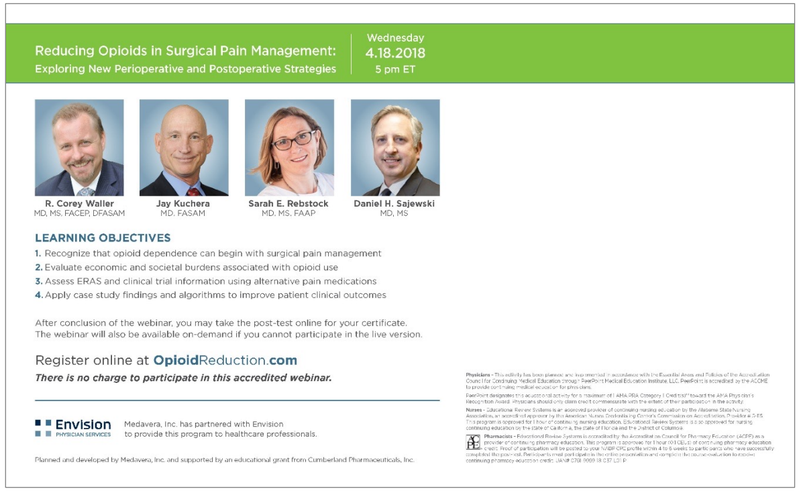

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ADA 2016 Abstract

Rio Grande Valley's ACO Quantitative Achievements with Type 2 Diabetes Mellitus Program

Jose F. Pena, Pedro J. Penalo

The state of Texas has a population of almost 27 million with Hispanics and the elderly accounting for an ever-increasing proportion of that number. The Rio Grande Valley (RGV), located in the southern tip of the state, contains Hidalgo County, one of the poorest in the nation. The Medicare per capita cost in this county is above $12,300 annually. This is significantly higher than the national average of $8,874. The large numbers of Medicare-Medicaid beneficiaries, who make up an estimated 45% of the population, contribute to this high annual cost.

The prevalence of type 2 diabetes mellitus (T2DM) within the RGV is 29% with Medicare beneficiaries at 45%. RGV Accountable Care Organization (ACO) has developed innovative strategies for targeting, assessing, treating and caring for T2DM patients with an HbA1c greater than 8. These strategies include the use of care coordinators, a nutritionist (who rotates through the physicians' offices, frequent alerts of care gaps in the electronic health record, point-of-care HbA1c measurement to name a few. RGV ACO has achieved reduction of healthcare costs significantly below the regional averages while improving quality of life, resulting in additional payments from Medicare to sustain reforms in care that are not normally reimbursed under fee-for-service.

In 2014, RGV ACO used 33 performance measures required as part of their Medicare Shared Savings Program (MSSP). Shared savings achieved is linked to success on quality measures (including HbA1c < 8%, LDL < 100mg/dL, blood pressure < 140/90 mmHg, tobacco non-use). In the composite score of T2DM metrics, they achieved the top 1 % of all ACOs in the nation. RGV ACO has reduced the per capita costs for Medicare beneficiaries by 14% through reducing hospital admission, readmissions, and implementing a home visit program. RGV ACO has achieved tremendous success in improving patient's quality of life and reducing cost of care. The potential of this ACO model with financial incentives aligned with great outcomes is immeasurable.

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Case Study

Rio Grande Valley Accountable Care Organization Point-Of-Care Case Study

"If I could sum up why we use point-of-care testing into one word it would be efficiency," says Dr. Pedro Penalo who is the VP of Quality at RGV and has used point-of-care testing for HbA1c and lipids in his clinic for 5 years.

Introduction

Diabetes Mellitus is a life-threatening disease with 415 million patients across the globe.[1] The economic burden of diagnosed diabetes in the US is currently at an estimated $245 billion annually ($176 billion in direct medical costs and $69 billion in reduced productivity).[2] With its increasing incidence and high cost of treatment due to complications and non-compliance, diabetes places an enormous burden on the economic resources of the U.S. healthcare system.[3,4]

In order to manage this condition, the American Diabetes Association (ADA) recommends testing HbA1c as a measure of glycemic control. Less than 7% of type 2 diabetes patients, the most common type of diabetes, are tested for HbA1c at the frequency that the guidelines recommend.[5] Patient's fear of needles, time constraints and lack of understanding the importance of laboratory testing are some of the reasons for missed appointments that result in diminished therapeutic outcomes. Point-of-care finger stick testing has been shown to help to increase guideline compliant HbA1c testing frequency and glycemic control while reducing operational inefficiencies and spending.[6-7]

The Rio Grande Valley (RGV) Accountable Care Organization (ACO) has developed and implemented solid strategies to improve their type 2 diabetes patients' glycemic control and quality of life and is having some great success. RGV ACO utilizes 33 quality measures established by the Centers for Medicare and Medicaid Services (CMS).[8] Their primary focus is on those type 2 diabetes patients with an HbA1c value greater than 8% — they are currently reaching 80% of this patient-type with 70% of those patients participating in at least one of the RGV ACO diabetes strategies. They have achieved significant cost savings (e.g., $20.2 million in reduced healthcare expenditures in the Medicare Shared Savings Program Performance Year 1) for type 2 diabetes prevention and intervention through utilization of point-of-care testing for HbA1c and lipids, comprehensive education and consistent follow-up and care plan implementation with these patients.

the HISTORY of

INFLUENZA

from DEVASTATION to DISCOVERY

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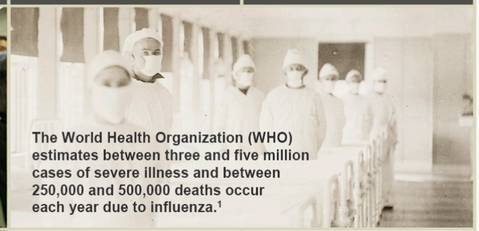
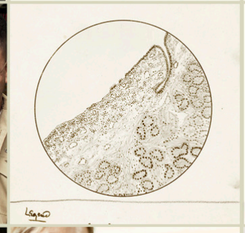


The World Health Organization (WHO) estimates between three and five million cases of severe illness and between 250,000 and 500,000 deaths occur each year due to influenza.[1]

Perhaps one of the greatest lessons in public health was the "Spanish" influenza pandemic of 1918–1919.[2] All influenza A pandemics have since resulted from the 1918 virus, including "drifted" H1N1 viruses and reassorted H2N2 and H3N2 viruses.[3] The devastation caused by this pandemic then lead to the discovery of human influenza type A virus in 1933 and the development of the first vaccine in 1937.[4,5] Influenza type B was then identified in 1940.[6]

The following decades resulted in significant discoveries: introduction of antiviral treatments, rapid diagnostics, and improvements in surveillance and treatment.[7-11] It is important for healthcare professionals to understand this chronology of events and to look foward to continued improvements in surveillance, identification, and the treatment of influenza. This accredited, self-study program is designed for these purposes.



A SELF STUDY
COURSE FOR CREDIT

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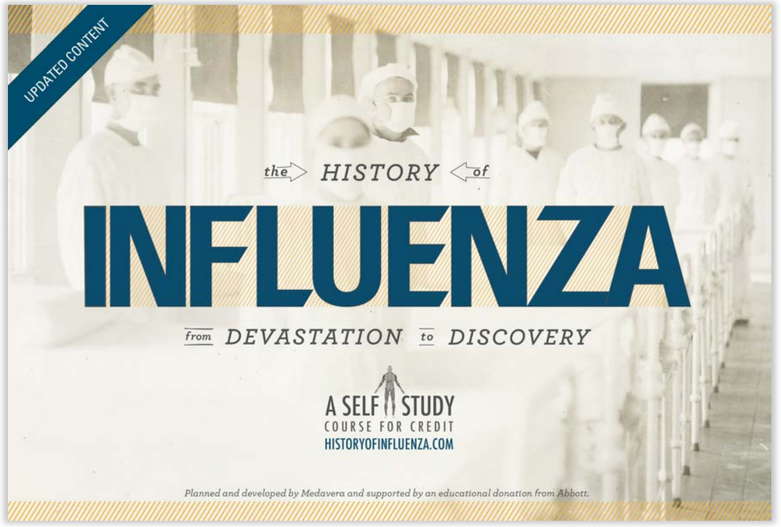

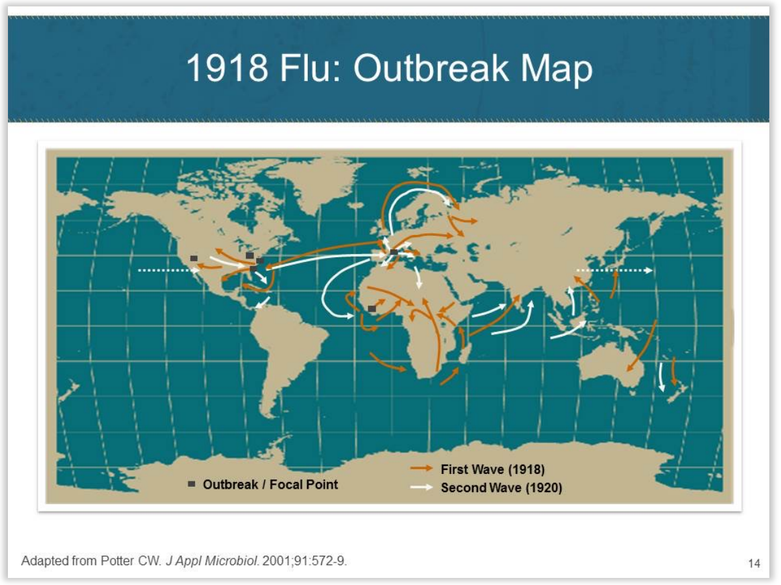

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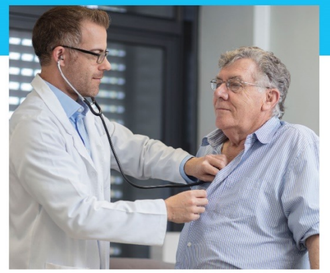

Clinical & Operational Benefits

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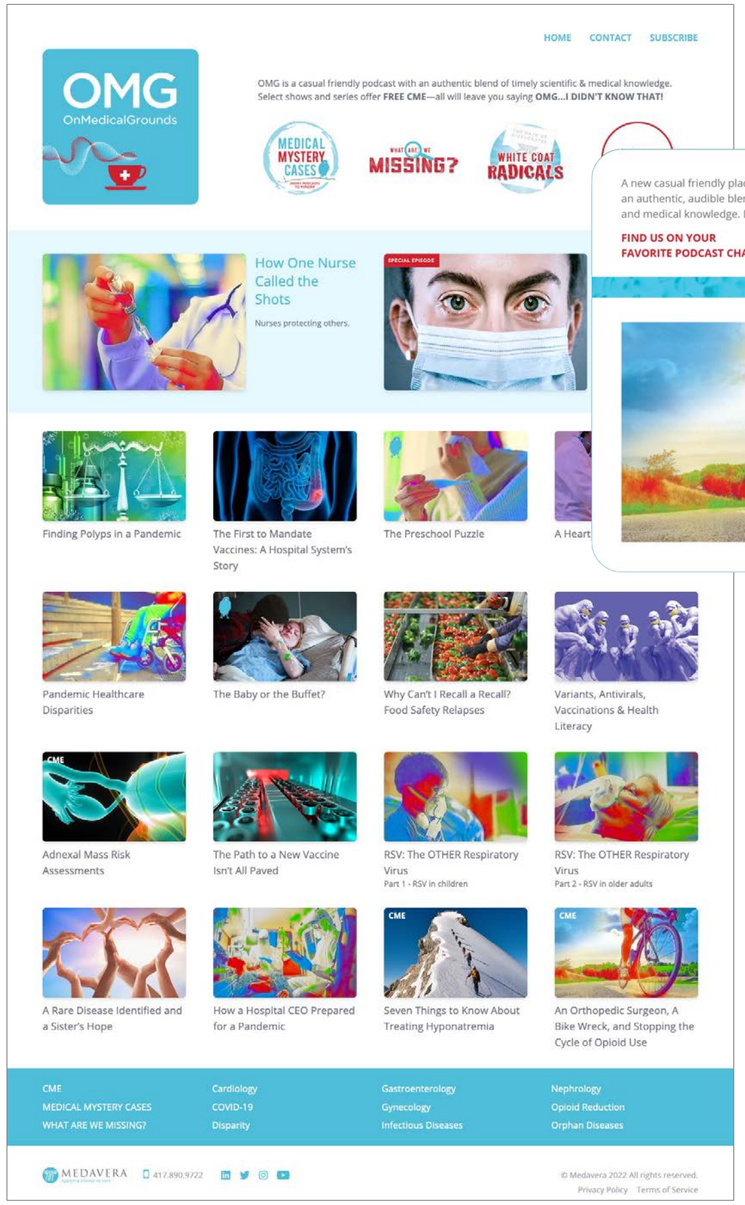
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The Path to a New Vaccine Isn't All Paved
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Part 1 - RSV in children
RSV: The OTHER Respiratory Virus
Part 2 - RSV in older adults
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How a Hospital CEO Prepared for a Pandemic
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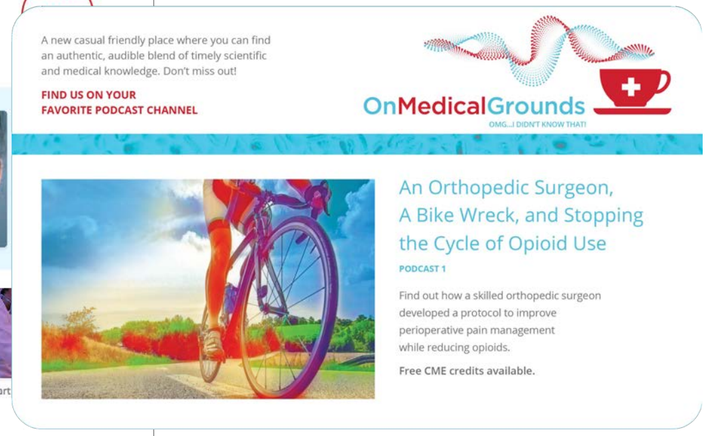
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SHORT TALES TO PONDER


IT WAS A DARK AND STORMY MORNING...
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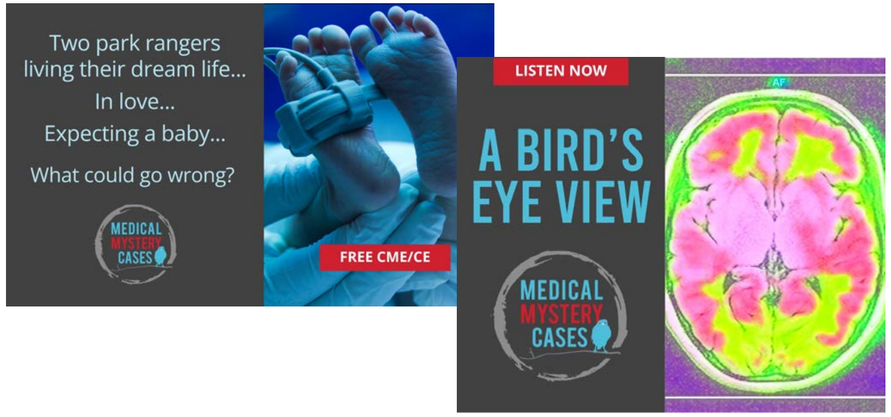
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In love...
Expecting a baby...
What could go wrong?
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A BIRD'S EYE VIEW
MEDICAL MYSTERY CASES


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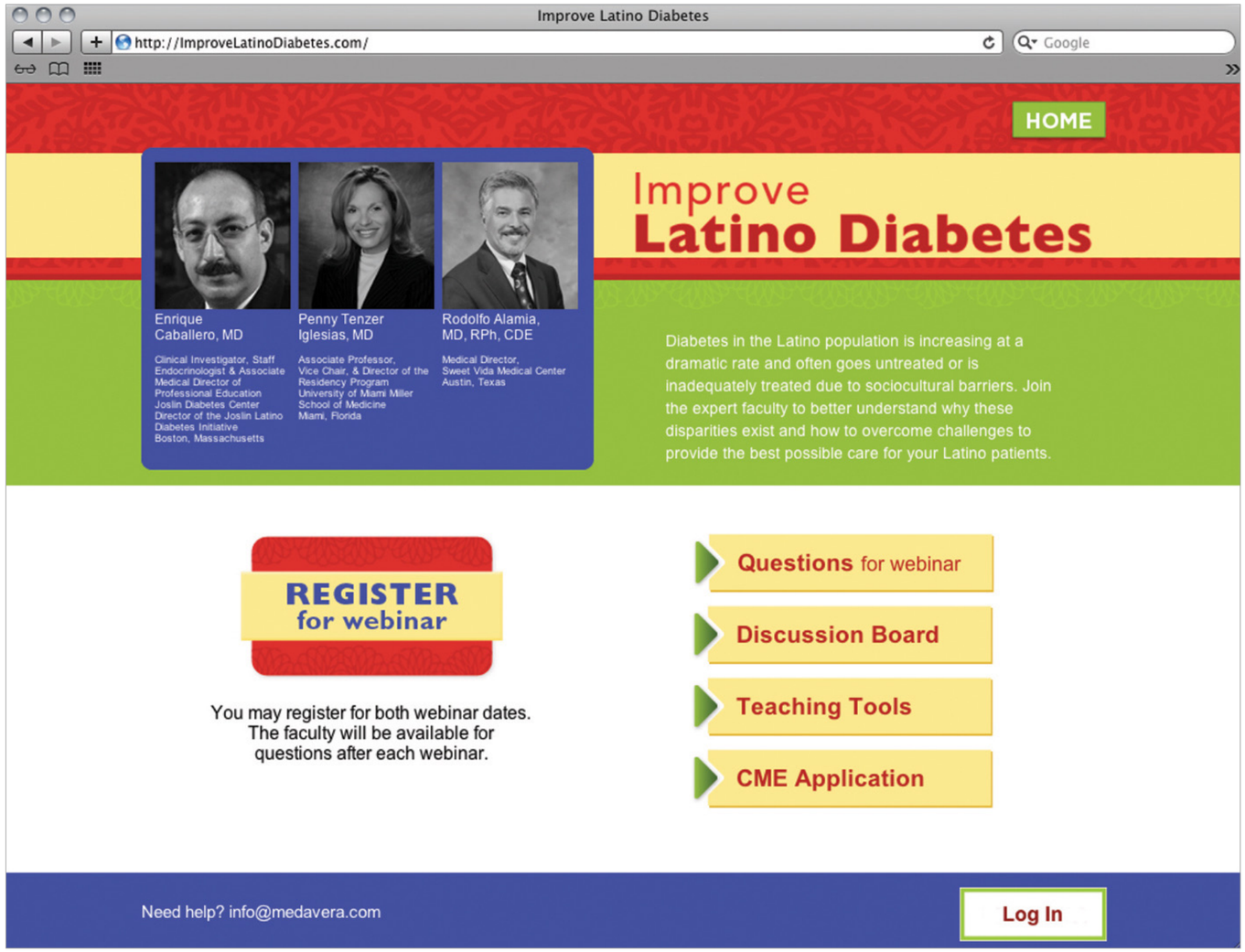
Improve Latino Diabetes
http://ImproveLatinoDiabetes.com/
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Improve
Latino Diabetes
Enrique Caballero, MD
Clinical Investigator, Staff Endocrinologist & Associate Medical Director of Professional Education Joslin Diabetes Center Director of the Joslin Latino Diabetes Initiative Boston, Massachusetts
Penny Tenzer Iglesias, MD
Associate Professor, Vice Chair, & Director of the Residency Program University of Miami Miller School of Medicine Miami, Florida
Rodolfo Alamia, MD, RPh, CDE
Medical Director, Sweet Vida Medical Center Austin, Texas
Diabetes in the Latino population is increasing at a dramatic rate and often goes untreated or is inadequately treated due to sociocultural barriers. Join the expert faculty to better understand why these disparities exist and how to overcome challenges to provide the best possible care for your Latino patients.
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Improving Cultural Competency Among Healthcare Practitioners:
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WEBINAR DATES AND TIME:
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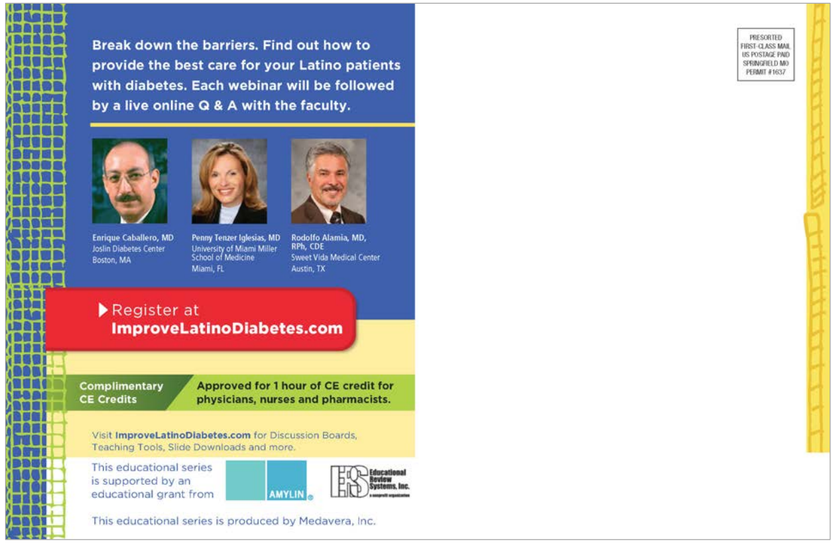
Break down the barriers. Find out how to provide the best care for your Latino patients with diabetes. Each webinar will be followed by a live online Q & A with the faculty.
Enrique Caballero, MD
Joslin Diabetes Center
Boston, MA
Penny Tenzer Iglesias, MD
University of Miami Miller School of Medicine
Miami, FL
Rodolfo Alamia, MD, RPh, CDE
Sweet Vida Medical Center
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AA PHARMACEUTICALS

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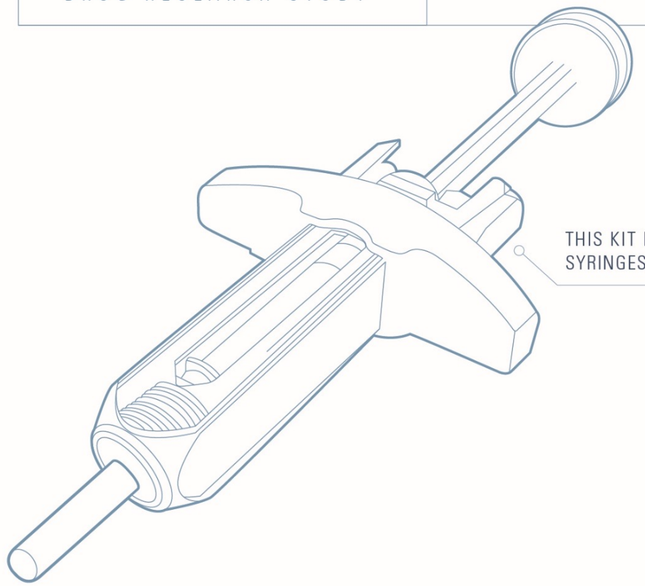
DRUG RESEARCH STUDY

Patient Guide

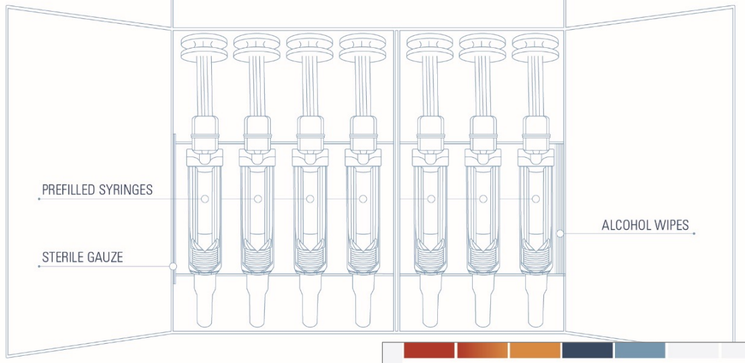


THIS KIT INCLUDES 7 PREFILLED DISPOSABLE SYRINGES & SUPPLIES FOR DAILY PATIENT USE

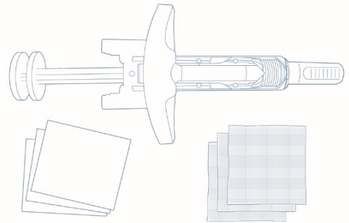
This kit contains supplies and the study drug.

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.



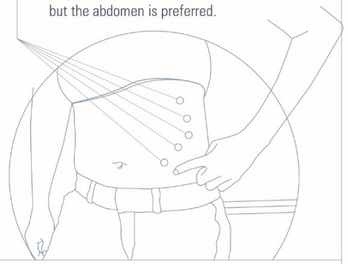
1 **Remove the items you will need from the kit, including an alcohol wipe, sterile gauze and a prefilled syringe.**



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.



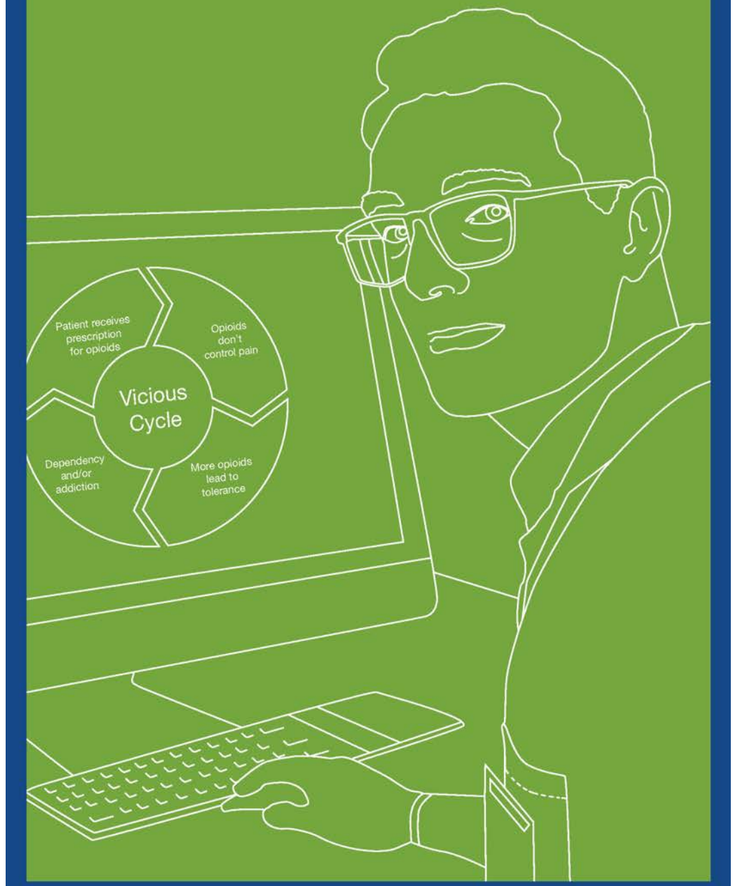
Do not administer your dose in an area that is bruised or swollen, or where the skin is irritated, red, infected, scarred or tattooed.

IT’S A CHALLENGE:

IMPROVING PAIN MANAGEMENT
WHILE REDUCING OPIOIDS

TWO MAJOR CHALLENGES:

YOUR BUDGET AND PAIN MANAGEMENT



PAIN MANAGEMENT

INDICATION

CALDOLOR is a nonsteroidal anti-inflammatory drug indicated in adults and pediatric patients six months and older for the:

- Management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics
- Reduction of fever

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

CALDOLOR is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to ibuprofen or any components of the drug product, and in patients who have a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients. CALDOLOR is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

WARNINGS AND PRECAUTIONS

CALDOLOR should be used with caution in patients with known cardiovascular (CV) disease or risk factors for CV disease, a history of peptic ulcer disease and/or GI bleeding, renal or liver disease or symptoms of, hypertension, and heart failure. When used in such patients, attention to using the lowest effective dose for the shortest time period is important to reduce the risk of serious adverse events. Avoid use in pregnant women starting at 30 weeks gestation.

ADVERSE REACTIONS

The most common adverse reactions are nausea, flatulence, vomiting, headache, hemorrhage and dizziness (>5%). The most common adverse reactions in pediatric patients are infusion site pain, vomiting, nausea, anemia and headache (≥2%).

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, 5.1)
- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events. (5.2)

See full prescribing information for complete box warning on the Package Insert attached to the center of this visual aid.

4

Improve Pain Management

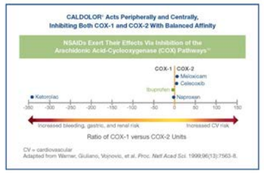
Pain management has become increasingly challenging. There are pressures to offer more effective pain control and reduce opioid use at the same time.[9]

Pain happens both centrally and peripherally.[1,2] **CALDOLOR® is a non-opioid IV NSAID that helps manage pain[1]:**

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

CALDOLOR® Acts Peripherally and Centrally, Inhibiting Both COX-1 and COX-2 With Balanced Affinity

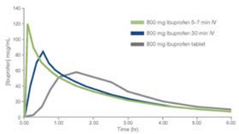
NSAIDs Exert Their Effects Via Inhibition of the Arachidonic Acid-Cyclooxygenase (COX) Pathways[10]



CV = cardiovascular

Adapted from Warner, Giuliano, Mojovic, et al. *Proc. Natl Acad Sci.* 1999;96(13):7563-8.

CALDOLOR® Blood Levels Reach a Higher Maximum[11]



5

OPIOID REDUCTION

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- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events. (5.2)

See full prescribing information for complete box warning on the Package Insert attached to the center of this visual aid.

8

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.[1] In a safety and efficacy trial of CALDOLOR® as a post-operative analgesic following abdominal hysterectomy, the median morphine requirement was reduced by 19% ($P < 0.001$).[3,4] A third trial evaluated the use of CALDOLOR® in pediatric tonsillectomy and found a 50% reduction in the amount of post-operative fentanyl ($P = 0.021$).[5]

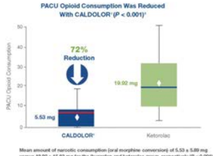
Patients Treated With CALDOLOR® Used Up to 50% Fewer Morphine Equivalents[1,3,5,6]

Procedure	Number	*P* Value	Amount of Opioid Reduction
Elective orthopedic surgery	N = 185	$P < 0.001$	30.9% ↓
Abdominal hysterectomy	N = 319	$P < 0.001$	19.0% ↓
Pediatric tonsillectomy	N = 138	$P = 0.021$	50.0% ↓

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.[4]

PACU Opioid Consumption Was Reduced With CALDOLOR® ($P < 0.001$)[4]

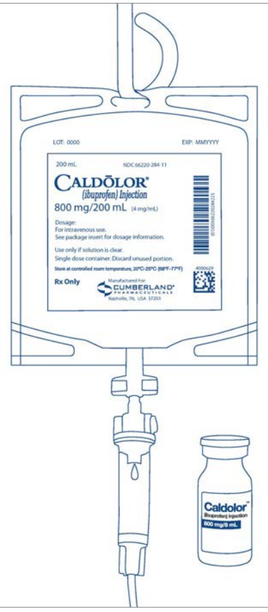


Mean amount of narcotic consumption (oral morphine conversion) of 5.53 v. 5.89 mg versus 19.92 v. 15.65 mg for the ibuprofen and ketorolac group, respectively ($P < 0.001$), represented by open diamonds. Horizontal lines in bars represent median values.

PACU = post-anesthesia care unit

9

EASE OF USE



CALDŌLOR®
(ibuprofen) Injection

Hang With Us

CALDOLOR® is now available in a premixed bag and at similar cost.[1]

Ready-to-use drug forms are shown to reduce provider time by 32% and material cost by 60%.[6,7]

- **Proven pain control**[1,3,4,5]
- **Reduces opioid use**[1,3,4,5]
- **Cost-effective**[1,6]

CALDOLOR® is also indicated for pediatric use for both fever and analgesia.[1,7]

1. CALDOLOR® Prescribing Information. Nashville, TN: Cumberland Pharmaceuticals Inc.; 2019.
2. van der Linden P, Douchamps J, Schmitt C, et al. Ready-to-use injection preparations versus conventional reconstituted admixtures: economic evaluation in a real-life setting. *Pharmacoeconomics.* 2002;20(8):529-36.
3. Single N, Rock A, Pavliv L, A multi-center, randomized, double-blind placebo-controlled trial of intravenous ibuprofen (IV-Ibuprofen) for treatment of pain in post-operative orthopedic adult patients. *Pain Med.* 2010;11(8):1284-95.
4. Southworth SR, Woodward EJ, Peng A, et al. An integrated safety analysis of intravenous ibuprofen (CALDOLOR®) in adults. *J Pain Res.* 2019;8:753-65.
5. Le V, Kumudula L, Schiavoni-Cola J, et al. Premedication with intravenous ibuprofen improves recovery characteristics and stress response in adults undergoing laparoscopic cholecystectomy: A randomized controlled trial. *Pain Med.* 2016;17(9):1163-73.
6. Rubio J. Impact safety, efficiency, and the bottom line with premixed IV products. *Pharm Purchas Product.* 2008. https://www.pppmag.com/documents/VINJ/vol_05_06.pdf. Accessed November 5, 2018.
7. Moss JR, Wilcox MF, Bendel LP, et al. A multicenter, randomized, double-blind placebo-controlled, single dose trial of the safety and efficacy of intravenous ibuprofen for treatment of pain in pediatric patients undergoing tonsillectomy. *Pediatr Anesth.* 2014;24(5):483-9.

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

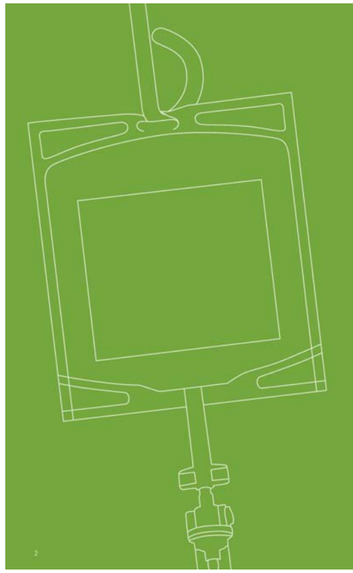
- Non-steroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.
- CALDOLOR is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Bleeding, Ulceration and Perforation

- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

CUMBERLAND PHARMACEUTICALS **PSA3471218**

EFFICACY



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

INDICATION

CALDOLOR is a nonsteroidal anti-inflammatory drug indicated in adults and pediatric patients six months and older for the:

- Management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics
- Reduction of fever

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

CALDOLOR is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to ibuprofen or any components of the drug product, and in patients who have a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients. CALDOLOR is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

WARNINGS AND PRECAUTIONS

CALDOLOR should be used with caution in patients with known cardiovascular (CV) disease or risk factors for CV disease, a history of peptic ulcer disease and/or GI bleeding, renal or liver disease or symptoms of, hypertension, and heart failure. When used in such patients, attention to using the lowest effective dose for the shortest time period is important to reduce the risk of serious adverse events. Avoid use in pregnant women starting at 30 weeks gestation.

ADVERSE REACTIONS

The most common adverse reactions are nausea, flatulence, vomiting, headache, hemorrhage and dizziness (>5%). The most common adverse reactions in pediatric patients are infusion site pain, vomiting, nausea, anemia and headache (≥2%).

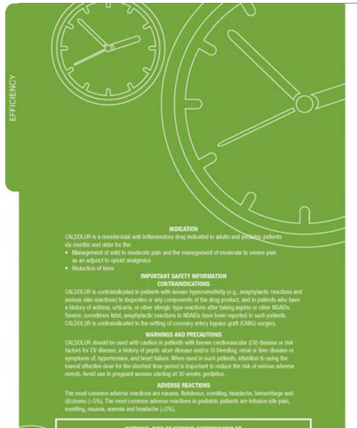
WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

- 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, 5.1)
- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events. (5.2)

See full prescribing information for complete box warning on the Package Insert attached to the center of this visual aid.

2 3

EFFICACY



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See full prescribing information for complete box warning on the Package Insert attached to the center of this visual aid.

4

Your Time Is Valuable

CALDOLOR® is now available in a single-use premixed bag, requiring no dilution and at similar cost.[6,7]

Traditional 797 Compounding Preparation

CALDOLOR® in a Premixed Bag

The Proven Benefits of Premixed

Ready-to-use drug forms are shown to reduce provider time by 32% and material cost by 60%.[6] Staff welcomes such ease of preparation and reduction of errors and handling risks.[8]

The CALDOLOR® premixed bag is ready when you need it and shelf-stable for up to 2 years.[7] The premixed bag is convenient to use; store it in the operating room, store it in the anesthesia cart, store it in post-op recovery. Wherever you want, whenever you need it, CALDOLOR® will be there.

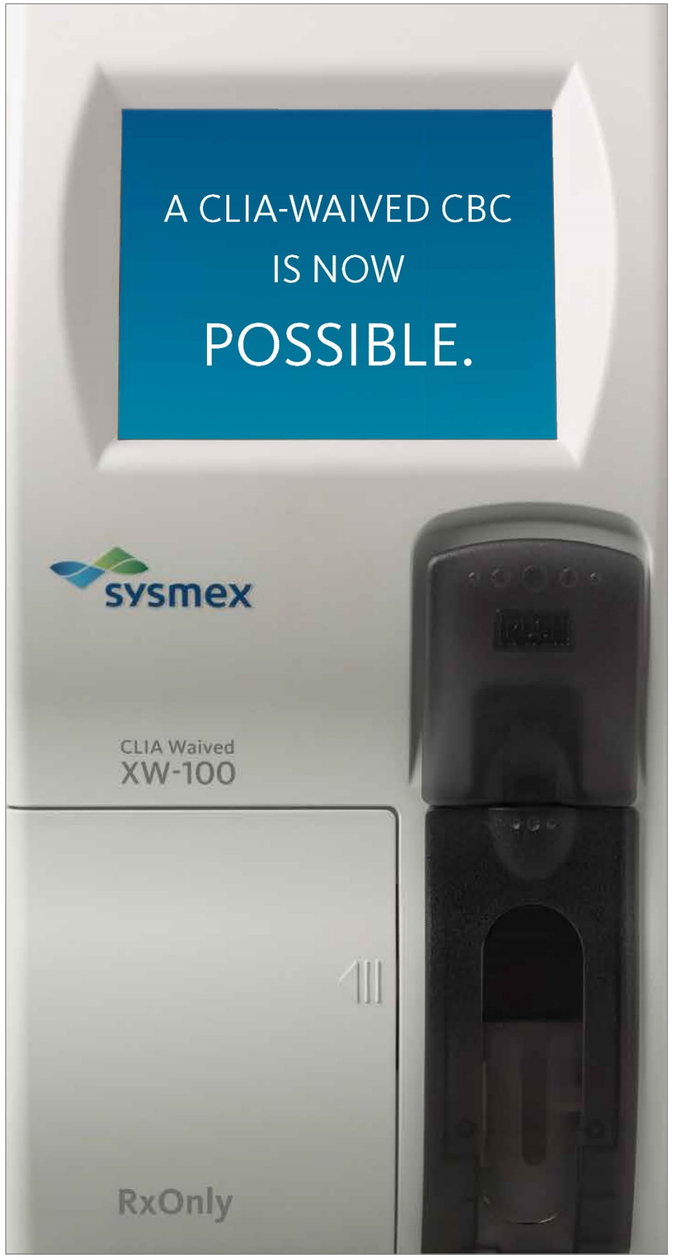
CALDOLOR® is also indicated for pediatric use for both fever and analgesia.[1,7]

Summary of Branded Pain Products

Brand Name	Generic Name	Pediatric Indication[12,13]	Premixed Bag[12,13]	Opioid Sparing[4,5]	Approx. Cost (ASP/Dose)
CALDOLOR® Vial	IV ibuprofen	Yes	–	Yes	$16.08[12]
CALDOLOR® Premixed Bag	IV ibuprofen	Yes	Yes	Yes	$19.65[12]
Ofirmev®	IV acetaminophen	Yes	Yes	Yes	$41.06[12]
Exparel®	Bupivacaine	No	No	Yes	$295.43[12]

5

DOSING AND ADMINISTRATION



IT MAY FIT WELL IN YOUR PRACTICE

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

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

VALUABLE INFORMATION

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

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

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

PROTECTING YOU AND YOUR PATIENTS

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

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

SYSMEX XW-100 RESULTS
(SUPPRESSED)

```
Instrument type XW100
Serial # G2683

Date Jan 14, 2019
Time 12:18 PM
Operator              MKZ

Patient ID            1675
Patient DOB May 26, 1972

WBC        6.2 × 10³/µL
RBC       4.36 × 10⁶/µL
HGB       ****
HCT       ****
PLT        344 × 10³/µL

#Neut      4.4 × 10³/µL
%Neut     71.3 %

#Lymph     1.8 × 10³/µL
%Lymph    25.6 %

#OtherWBC  0.2 × 10³/µL
%OtherWBC  3.1 %      Low

MCV        ****

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

Adult Reference Ranges
--------------------------
WBC        3.9 -  10.4 × 10³/µL
RBC       3.71 -  5.52 × 10⁶/µL
HGB       10.9 -  16.7 g/dL
HCT       32.5 -  49.4 %
PLT        148 -   392 × 10³/µL
#Neut      2.2 -   7.1 × 10³/µL
%Neut     46.4 -  76.3 %
#Lymph     0.9 -   3.4 × 10³/µL
%Lymph    14.7 -  45.9 %
#OtherWBC  0.2 -   1.2 × 10³/µL
%OtherWBC  3.2 -  16.9 %
MCV       82.5 -  98.0 fL

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

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

HIV TESTING CAN CHANGE EVERYTHING

Determine™ HIV-1/2 Ag/Ab Combo

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

—Jonathan Mermin, MD, MPH

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

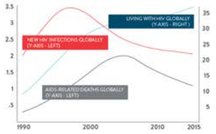
HIV INCIDENCE AND DISTRIBUTION

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

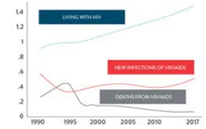
In 2018 there were **37,832** new HIV diagnoses.[1] Approximately **80%** of new HIV transmissions are from individuals who do not know they have HIV infection or are not receiving regular care.[1]

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

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



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



A NEW CHALLENGE — OPIOID USE AND HIV INCIDENCE

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

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

TYPES OF HIV TESTING AND TIME TO RESULTS

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

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

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

HIV ANTIGEN AND ANTIBODY TESTING

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

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

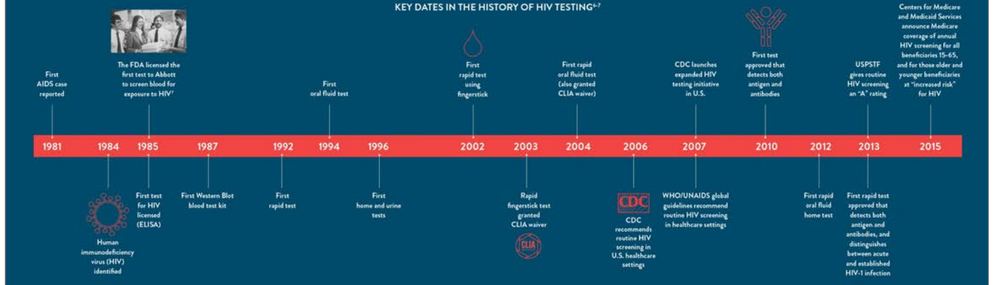
Detection of HIV after becoming infected has been difficult to ascertain, especially if tests are performed during the window period (the period of time between becoming infected with HIV and the ability of a test to detect HIV) which increases the likelihood of a false negative.

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

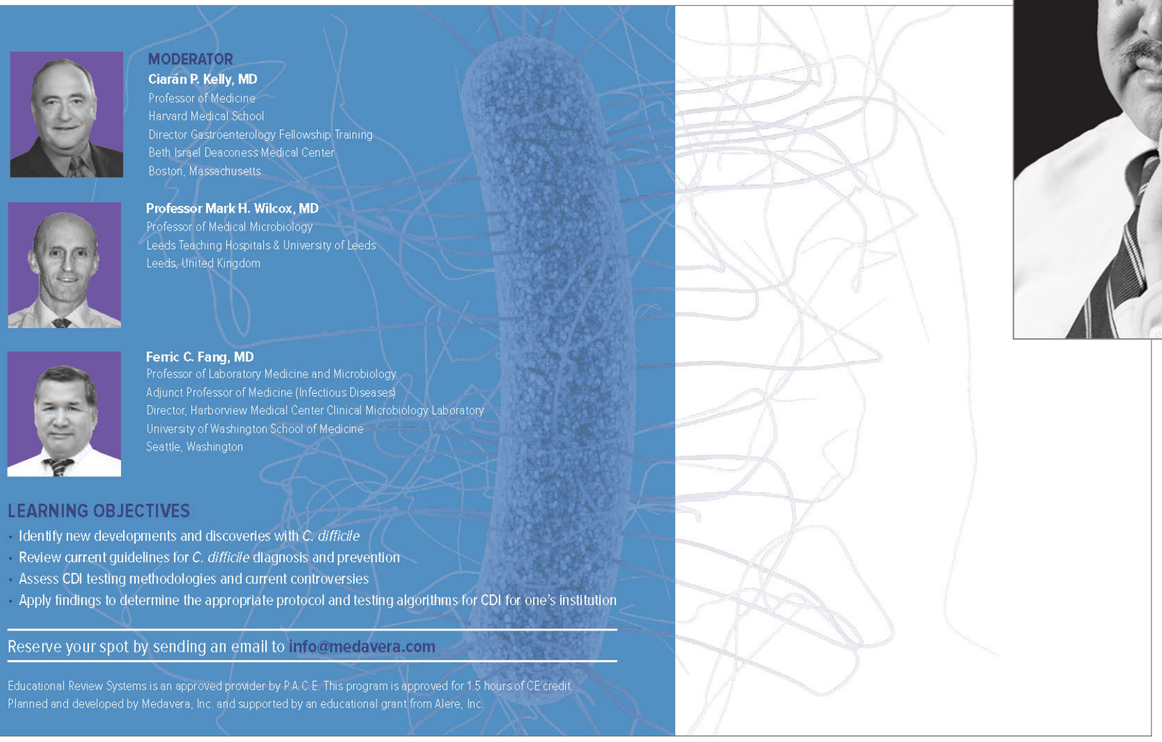
FALSE NEGATIVES IN ANTIBODY-ONLY AND ANTIBODY/ANTIGEN HIV TESTS[9]

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	13-66%	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]




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
by the American Society for Microbiology.
Professor
Mark H. Wilcox, MD


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
Leeds Teaching Hospitals & University of Leeds
Leeds, United Kingdom
Ferric C. Fang, MD
Professor of Laboratory Medicine and Microbiology
Adjunct Professor of Medicine (Infectious Diseases)
Director, Harborview Medical Center Clinical Microbiology Laboratory
University of Washington School of Medicine
Seattle, Washington
LEARNING OBJECTIVES
· Identify new developments and discoveries with C. difficile
· Review current guidelines for C. difficile diagnosis and prevention
· Assess CDI testing methodologies and current controversies
· Apply findings to determine the appropriate protocol and testing algorithms for CDI for one's institution
Reserve your spot by sending an email to info@medavera.com
Educational Review Systems is an approved provider by P.A.C.E. This program is approved for 1.5 hours of CE credit
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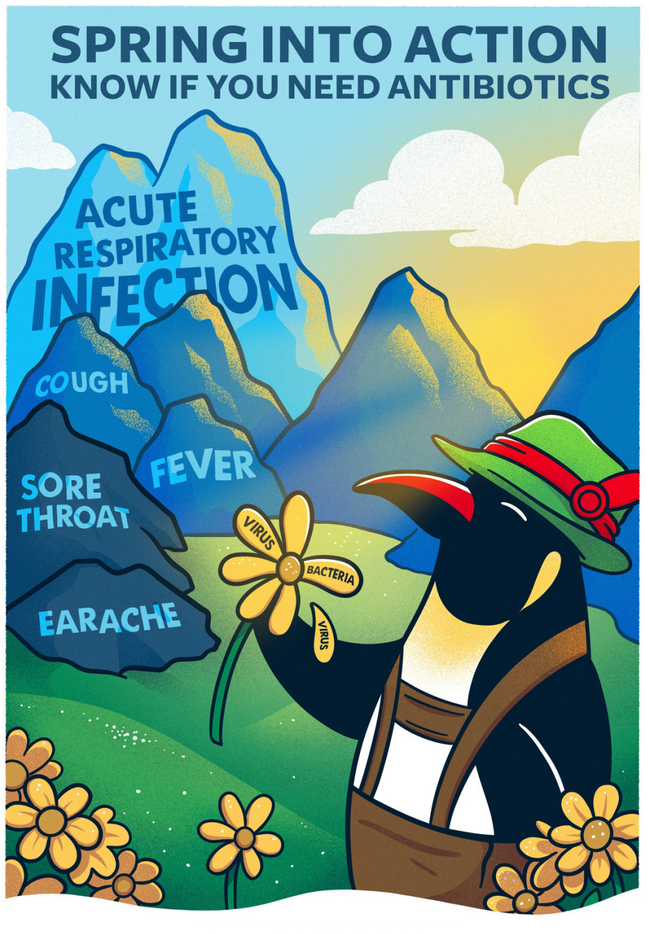
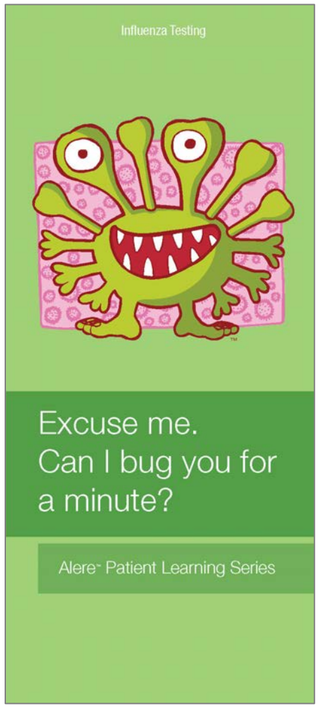
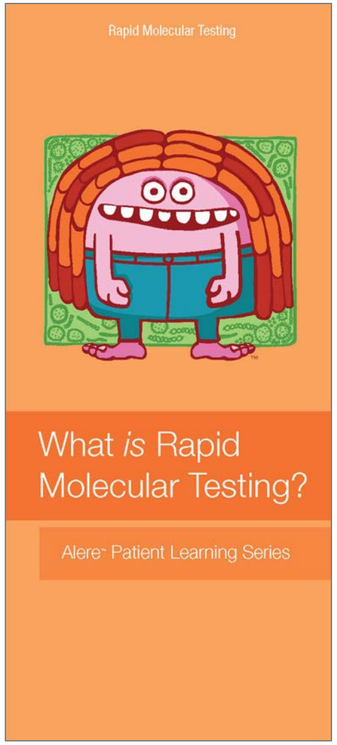
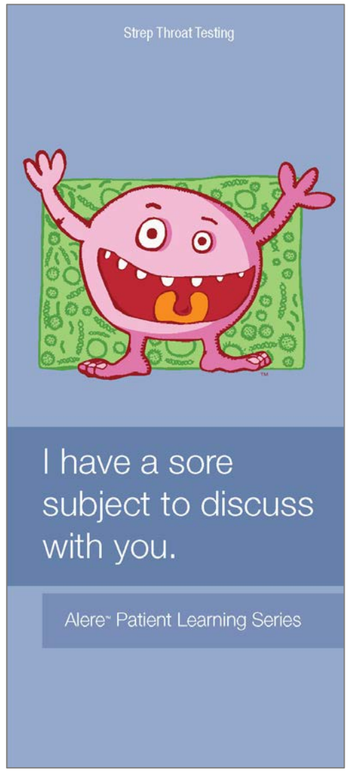
IN UNCHARTERED WATERS,
KNOW IF YOU NEED ANTIBIOTICS.
COUGH
FEVER
SORE THROAT
EAR ACHE
#STEWARTSHIPP
ANTIBIOTIC RESISTANCE
ASK YOUR DOCTOR IF YOU NEED ANTIBIOTICS

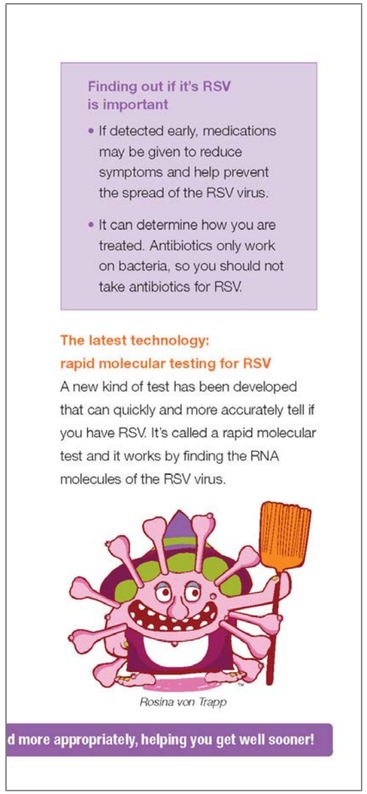

IT CAN BE A SLIPPERY SLOPE.
KNOW IF YOU NEED ANTIBIOTICS
ACUTE RESPIRATORY INFECTION
ANTIBIOTIC RESISTANCE
COUGH
FEVER
SORE THROAT
EARACHE
#STEWARTSHIPP
FINISH
ASK YOUR DOCTOR IF YOU NEED ANTIBIOTICS

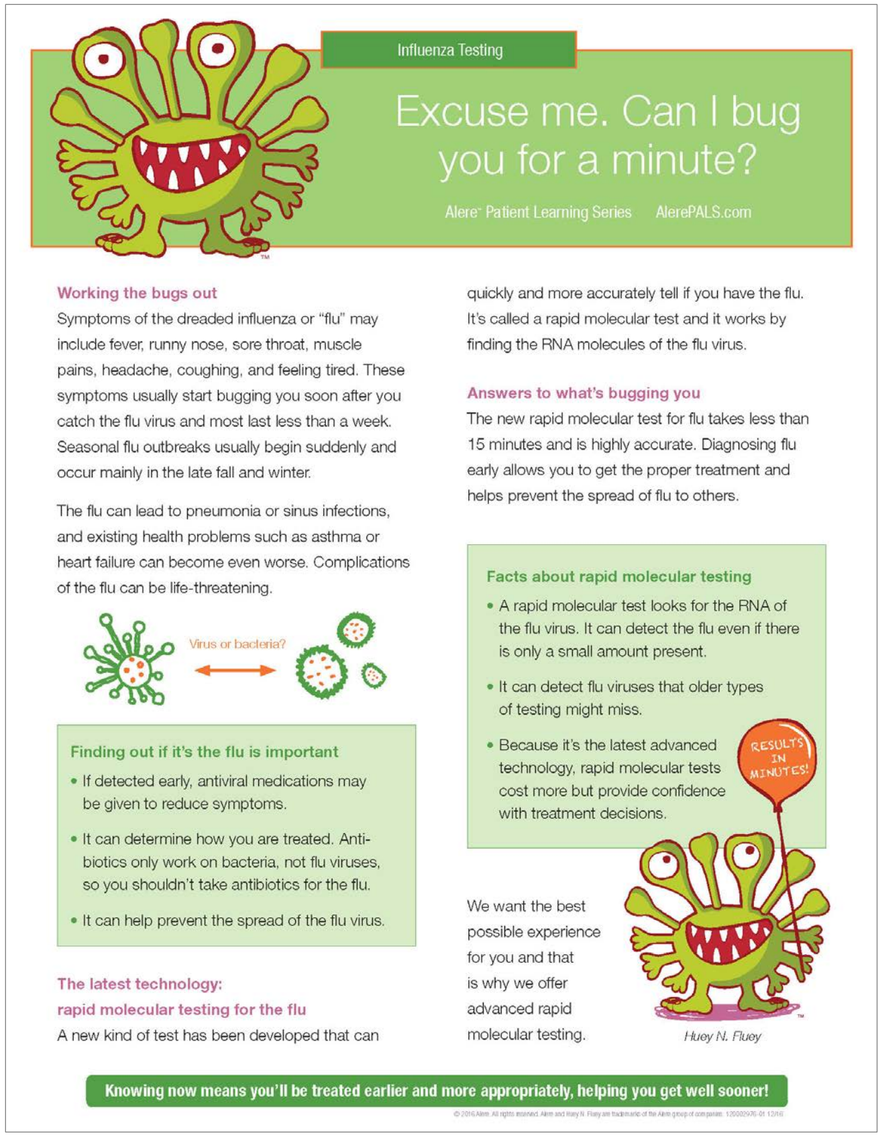

SPRING INTO ACTION
KNOW IF YOU NEED ANTIBIOTICS
ACUTE RESPIRATORY INFECTION
COUGH
FEVER
SORE THROAT
EARACHE
VIRUS
BACTERIA
VIRUS
ASK YOUR DOCTOR IF YOU NEED ANTIBIOTICS

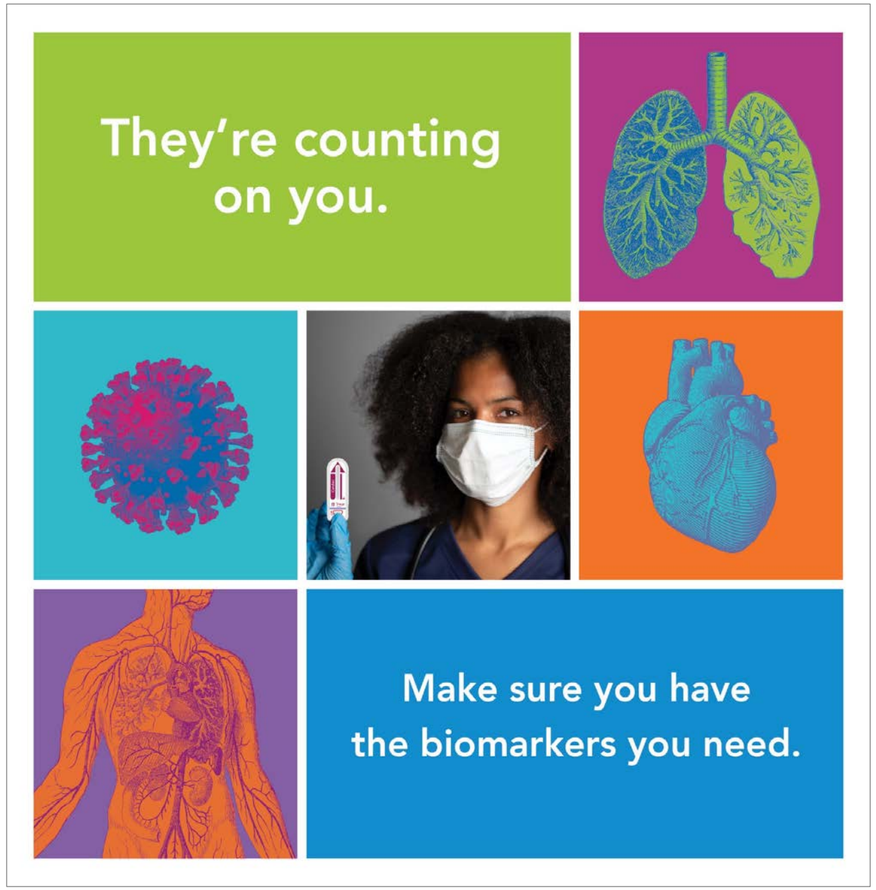

Influenza Testing
Excuse me.
Can I bug you for a minute?
Alere™ Patient Learning Series

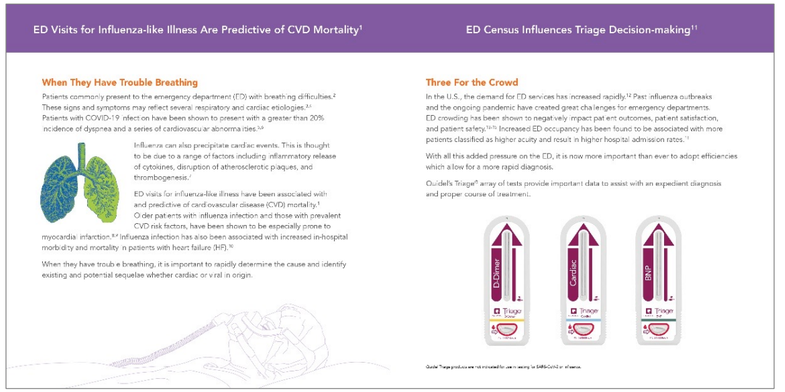

Rapid Molecular Testing
What *is* Rapid Molecular Testing?
Alere™ Patient Learning Series

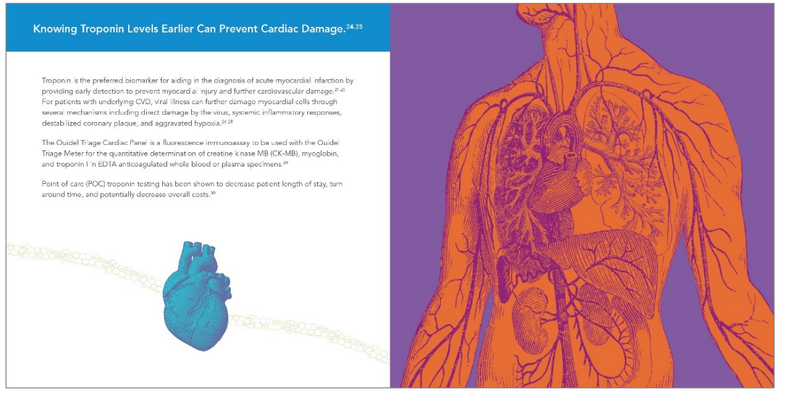

Strep Throat Testing
I have a sore subject to discuss with you.
Alere™ Patient Learning Series

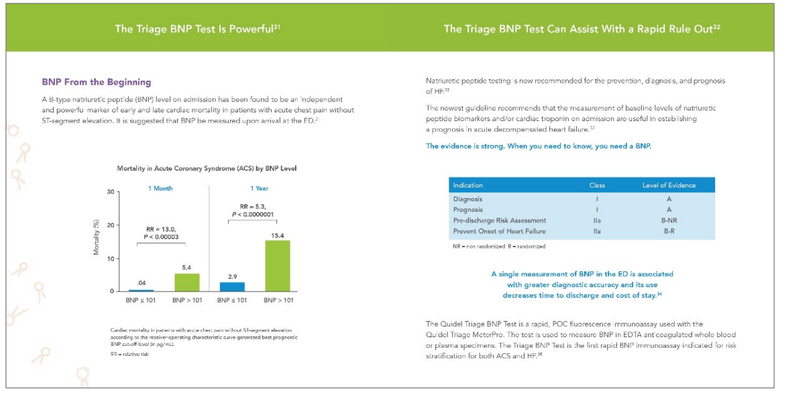

Finding out if it's RSV is important
• If detected early, medications may be given to reduce symptoms and help prevent the spread of the RSV virus.
• It can determine how you are treated. Antibiotics only work on bacteria, so you should not take antibiotics for RSV.
The latest technology: rapid molecular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


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


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

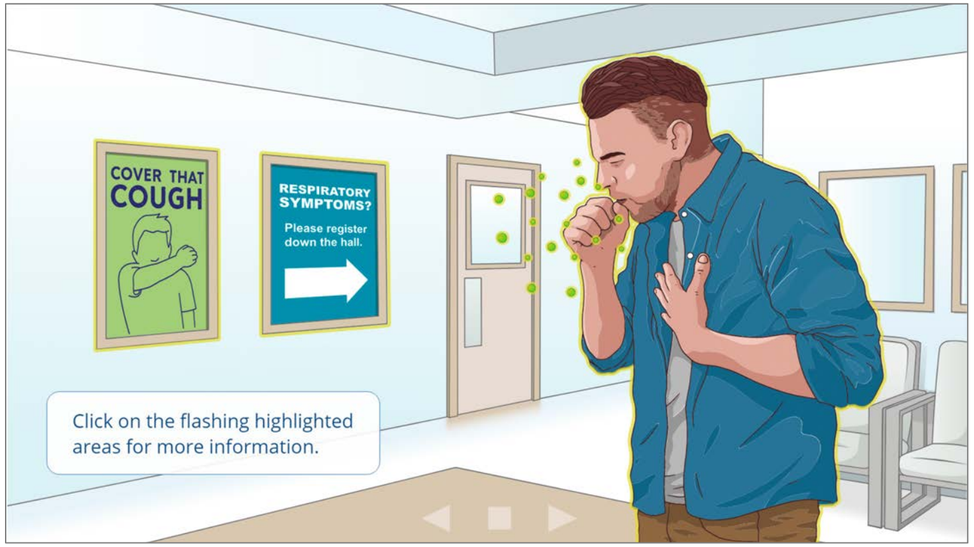

ED Visits for Influenza-like Illness Are Predictive of CVD Mortality[1]
When They Have Trouble Breathing
Patients commonly present to the emergency department (ED) with breathing difficulties.[4] These signs and symptoms may reflect several respiratory and cardiac etiologies.[5] Patients with COVID-19 infection have been shown to present with a greater than 20% incidence of dyspnea and a series of cardiovascular abnormalities.[6,8]
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 disease (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-making[11]
Three For the Crowd
In the U.S., the demand for ED services has increased rapidly.[12] Past 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.[1]
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:
D-Dimer
Triage
Cardiac
Triage
BNP
Triage

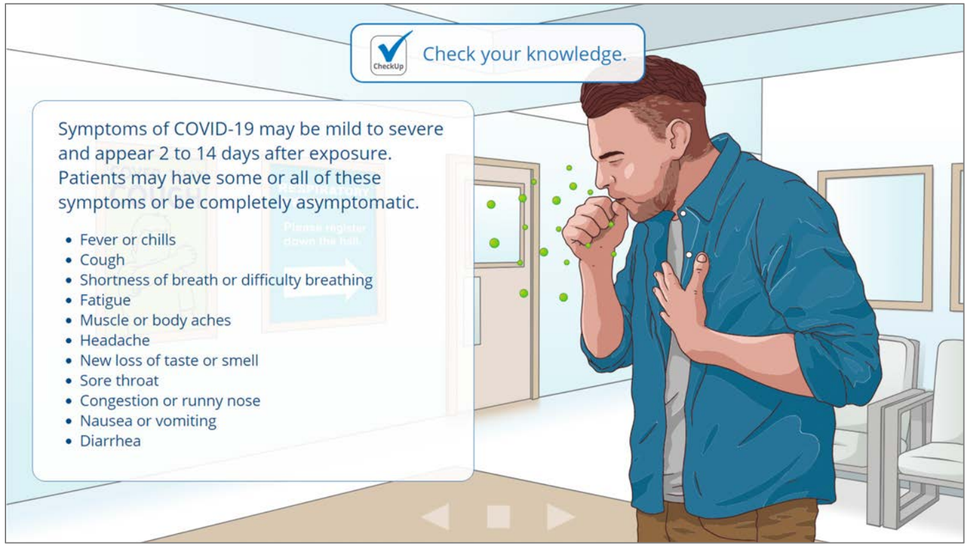

Knowing Troponin Levels Earlier Can Prevent Cardiac Damage.[24,25]
Troponin is the preferred biomarker for aiding in the diagnosis of acute myocardial infarction by providing early detection to prevent myocardial injury and further cardiovascular damage.[21,22] For patients with underlying CVD, viral illness can further damage myocardial cells through several mechanisms including direct damage by the virus, systemic inflammatory responses, destabilized coronary plaque, and aggravated hypoxia.[21,23]
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.[26]
Point of care (POC) troponin testing has been shown to decrease patient length of stay, turn around time, and potentially decrease overall costs.[30]

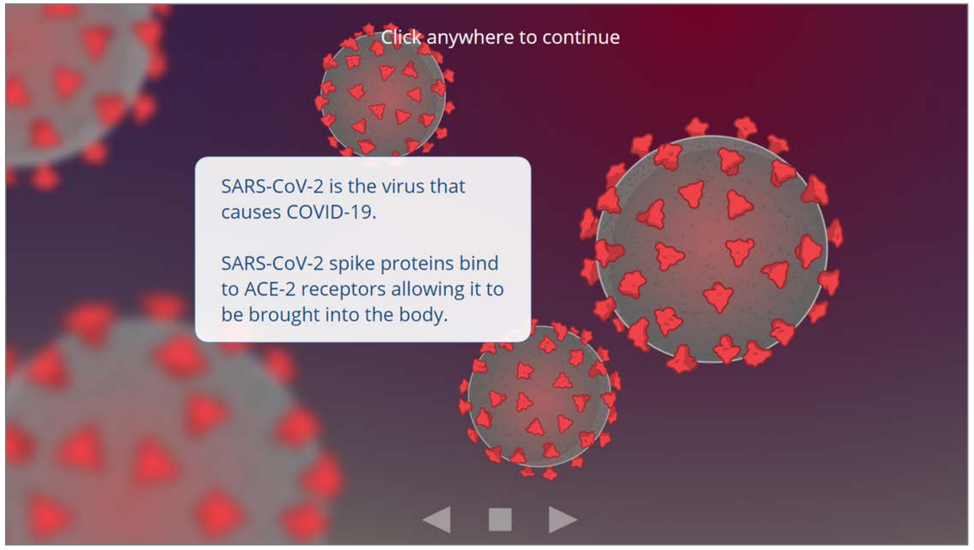

The Triage BNP Test Is Powerful[31]
BNP From the Beginning
A B-type natriuretic peptide (BNP) level on admission has been found to be an independent and powerful marker of early and late cardiac mortality in patients with acute chest pain without ST-segment elevation. It is suggested that BNP be measured upon arrival at the ED.[1]
Mortality in Acute Coronary Syndrome (ACS) by BNP Level
1 Month
1 Year
RR = 13.0, P < 0.00003
RR = 5.3, P < 0.0000001
Mortality (%)
30
20
10
0
.04
5.4
2.9
15.4
BNP ≤ 101
BNP > 101
BNP ≤ 101
BNP > 101
Cardiac mortality in patients with acute chest pain without ST-segment elevation according to the receiver-operating characteristic curve-generated best prognostic BNP cutoff level (< pg/mL).
RR = relative risk
The Triage BNP Test Can Assist With a Rapid Rule Out[32]
Natriuretic peptide testing is now recommended for the prevention, diagnosis, and prognosis of HF.[33]
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.[33]
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 = non 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.[34]
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.[35]

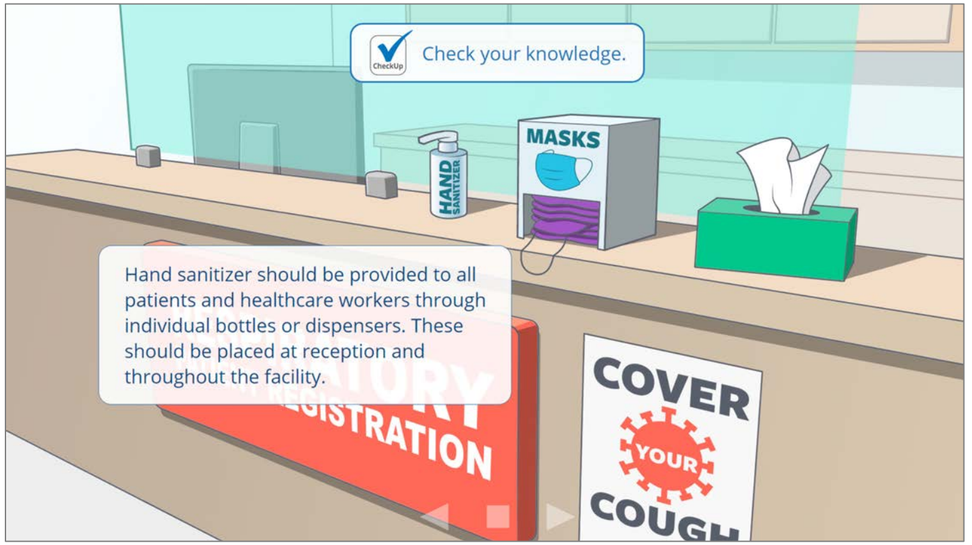

Their hearts are in your hands.
Triage
10 Facts to Know About Chest Pain
QUIDEL

Training


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


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


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


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

sysmex | Lighting the way with diagnostics

Hematology Analyzer

XW™-100 Sales Guide

CLIA-waived.
Automated Hematology Analyzer.

CBCin3.com

Internal Use Only

TAP HERE FOR NEXT PAGE

CBC Overview

Cellular Components of Whole Blood

RED BLOOD CELLS (RBCs)

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

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

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

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

PLATELETS

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

04 | XW-100

PREV

CBC Overview

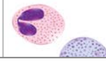
WHITE BLOOD CELLS (WBCs)

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

Neutrophils
The most abundant type of white cell in an adult is the neutrophil, which normally accounts for roughly 50-75% of the WBCs in venous blood. Their main function is to ingest
neutrophil count rises, it's
is being stimulated. If the
in patients on chemother
infections.

Lymphocytes
Lymphocytes account for
venous blood. The main j
help identify and "remem
lymphocytes usually indic

Monocytes
Monocytes are about 2-8
microbes. Monocytes can
of the immune system. Th
as Other WBCs.



Eosinophils & Basophils
Eosinophils and basophils
activated in patients with
along with basophils, dur

CBCs Simplified

CBCs Made Simple

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

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

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

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

The XW-100 Has a Small Footprint

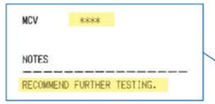
The XW-100 fits on a standard bench or countertop. The full weight of the XW-100 is only 38 lbs. It is 13.8" high, 7.3" wide, and 18.1" deep.

Repeat Testing

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

Normal Result

Suppressed Result



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

12 | XW-100

Internal Use Only

Internal Use Only

XW-100 | 11

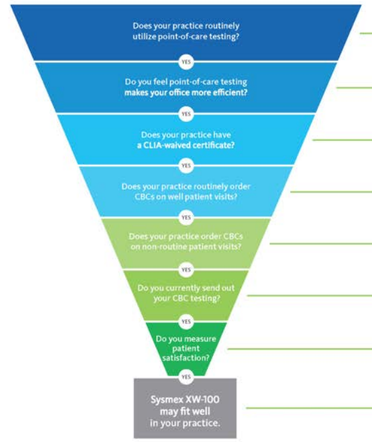
PREV

NEXT

Good Fit Chart

Sales Walkthrough

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



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

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

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

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

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

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

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

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

16 | XW-100

Internal Use Only

Internal Use Only

XW-100 | 17

PREV

NEXT

QUIDEL | Triage®

Case Study 2
Chest Pain Diagnosis

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

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

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

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

Diagnostic Testing:

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

Cardiac biomarkers

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

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

Repeat cardiac biomarkers 3 hours later

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

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

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

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

Play Chest Pain Trivia!

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

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

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

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

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

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

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

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

the same | twice
three times | four times

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

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

Heartburn | Headache
Gastroenteritis | Pneumonia

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

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

1960s | 1970s
2000 | 2010

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

CS1026300EN00 (02/18)

Alere™

Case Study: Influenza A and B

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

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

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

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

Diagnostic Testing:

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

Dx:
Influenza A.

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

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

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

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

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

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

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

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

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

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

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Tradeshow Booths


NephroCheck®
AKI deserves better biomarkers.
Find them here.
TIMP-2 + IGFBP-7 = NephroCheck®.


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


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


PROTECT THE KIDNEYS
WITH BETTER BIOMARKERS.
TIMP-2 + IGFBP-7 = THE NEPHROCHECK TEST
FIND THEM HERE!
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Innovative biomarkers. Smarter healthcare.
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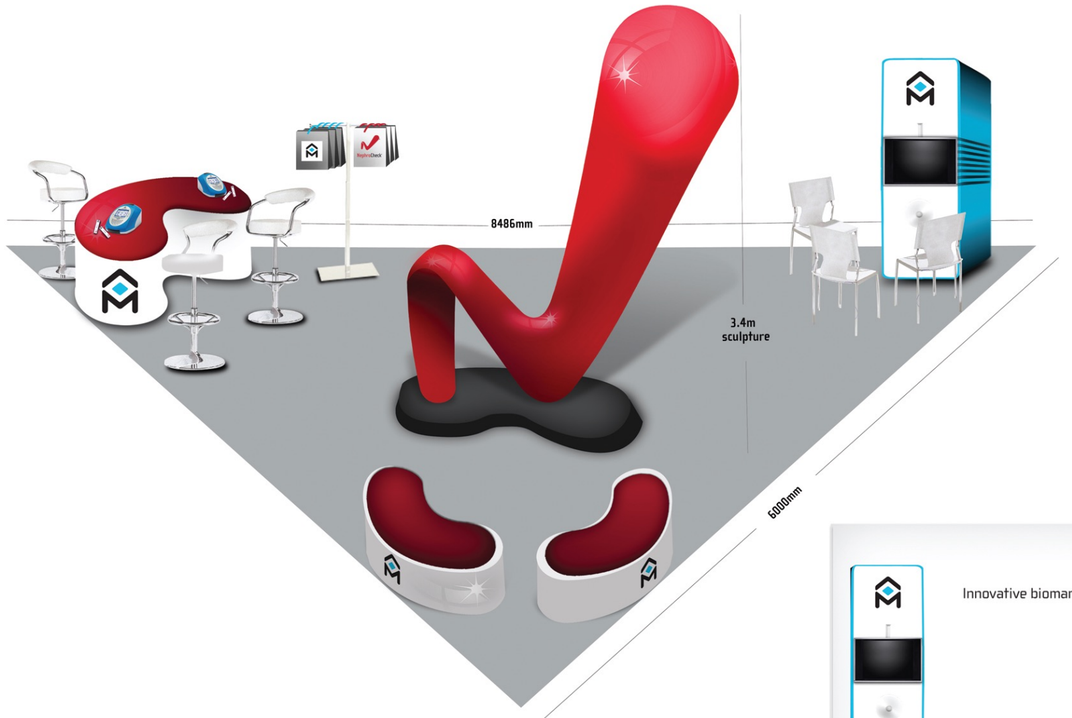
THE FIRST REAL IMPROVEMENT IN
RENAL TESTING IN OVER 60 YEARS
[TIMP-2]•[IGFBP-7]=THE NEPHROCHECK® TEST
NephroCheck
Assess AKI Risk. Now.
ASTUTE MEDICAL
Innovative biomarkers. Smarter healthcare.


8486mm
3.4m
sculpture
6000mm


Innovative biomarkers.
Smarter healthcare.
ASTUTE MEDICAL
ASTUTE MEDICAL


Singulex
COUNT ON CLARITY
ONE MOLECULE AT A TIME
HIGHEST PRECISION + SUPERIOR SENSITIVITY = A MORE INFORMED DIAGNOSIS
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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 immunochemistry diagnostics, delivering the unparalleled sensitivity and precision of Single Molecule Counting (SMC™) technology to hospital and reference laboratories worldwide.
Singulex
Boldly go where no immunoassays have gone before.
Break sensitivity barriers to understand disease in a new way.
Come and explore this new frontier. Join us in booth #1826 at AACC 2014.
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Singulex
Singulex


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
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SEE HEART FAILURE CLEARLY
Superior Prognostic Biomarker
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Reduce Recurrent Stroke

The Genomadix Cube™

Now a Ready-to-Use Non-Opioid For Proven Pain Management

Caldolor is now available in a pre-mixed, ready-to-use, bag that requires no dilution

- Effective pain management
- Safety similar to placebo in clinical studies
- Anti-inflammatory effect that can start prior to surgery
- Safe in children as young as 6 months of age
- 2.3 million doses administered since launch

INDICATION

CALDOLOR is a nonsteroidal anti-inflammatory drug indicated in adults and pediatric patients six months and older for the:

- Management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics
- Reduction of fever

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS

CALDOLOR is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to ibuprofen or any components of the drug product, and in patients who have a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients. CALDOLOR is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

WARNINGS AND PRECAUTIONS

CALDOLOR should be used with caution in patients with known cardiovascular (CV) disease or risk factors for CV disease, a history of peptic ulcer disease and/or GI bleeding, renal or liver disease, and those taking medications that interfere with coagulation. Use the lowest effective dose for the shortest time period is important to reduce the risk of serious adverse events. Avoid use in pregnant women starting at 30 weeks gestation.

ADVERSE REACTIONS

The most common adverse reactions are nausea, flatulence, vomiting, headache, hemorrhage and dizziness (>2%). The most common adverse reactions in pediatric patients are infusion site pain, vomiting, nausea, anemia and headache (≥2%).

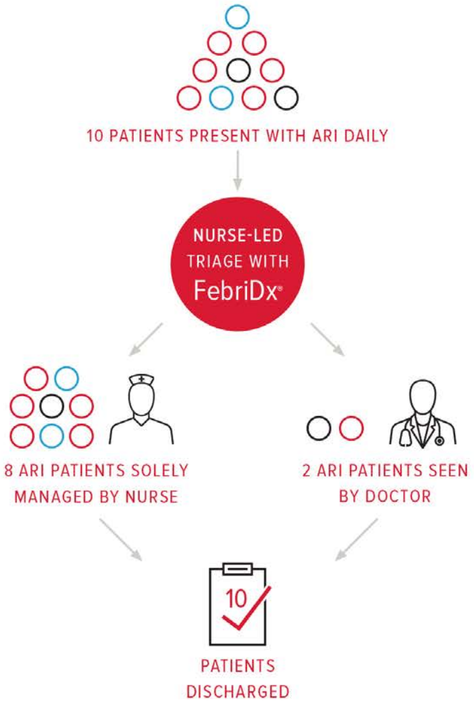
WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

See full prescribing information for complete boxed warning

- 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. (4.1, 5)
- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events. (5.2)

FebriDx®

Can Help Your Practice and Your Patients



IN A 10,000 PATIENT PRACTICE, USING FEBRIDX® SAVES DOCTORS ~ 43 DAYS ANNUALLY.[1]

1. Lumos Diagnostics internal data, 2019.

1-hour CYP2C19 Genotyping

Rapidly Identify Loss of Function Patients

- FDA 510(k) cleared
- 1-hour PCR results
- Accurate for relevant alleles *2, *3, *17
- Easy buccal swab
- CPT Code 81225

Genomadix Cube™

Genomadix
Molecular testing.
Where and when you need it.

For In Vitro Diagnostic Use MAR-00002v2.0

DAPT Optimized?

Reduce Recurrent Stroke

Genomadix Cube™

- FDA 510(k) cleared
- 1-hour PCR results
- Accurate for relevant alleles *2, *3, *17
- Easy buccal swab
- CPT Code 81225

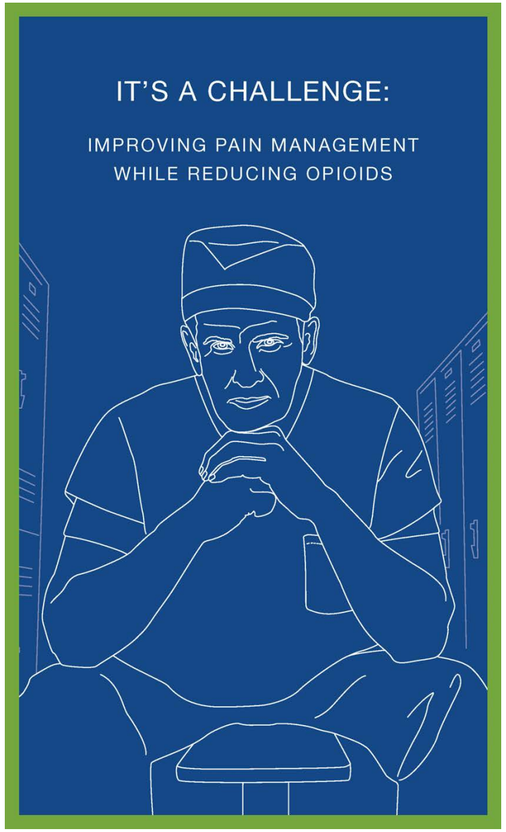
Genomadix
Molecular testing.
Where and when you need it.

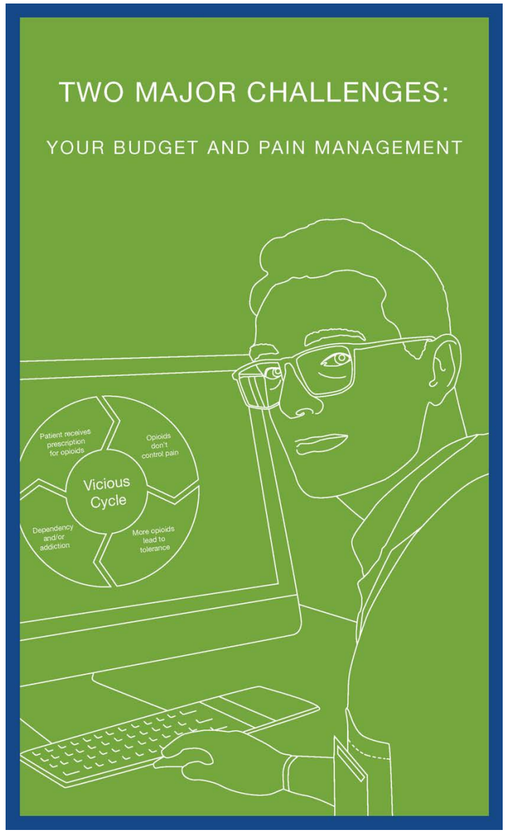
For In Vitro Diagnostic Use MAR-00002v2.0

Now a Ready-to-Use Non-Opioid For Proven Pain Management

Caldolor is now available in a pre-mixed, ready-to-use, bag that requires no dilution

- Effective pain management
- Safety similar to placebo in clinical studies
- Anti-inflammatory effect that can start prior to surgery
- Safe in children as young as 6 months of age
- 2.3 million doses administered since launch





Slide Decks

POCT 26

Implementation and Validation

1 Installation

2 System Configuration

3 Device calibration and QC

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

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

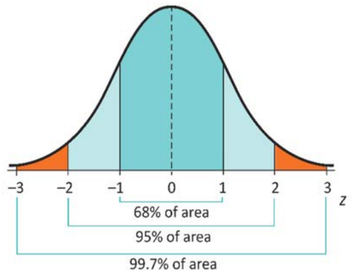
POCT 32

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/CLIA/Downloads/6064bk.pdf
Hazra A, Gogtay N. IJD. 2017;62(1):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/CLIA/Downloads/6064bk.pdf
Hazra A, Gogtay N. IJD. 2017;62(1):18-24.

POCT 44

IQCP Is a Continuous Process

Maintenance

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

Revision

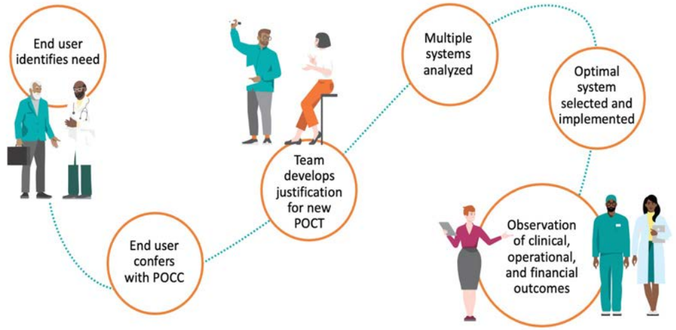
- Quality Assessment
- Risk Assessment

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

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

POCT 20

Correct Implementation Starts With the End User



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 39

QC & POCT

Reagent issues
- Traditional QC may not be relevant

Process issues
- Value of POCT QC varies by test system

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

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

POCT 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 Rev.* 2014;35:155.
Abel G, et al. Point-of-care testing: A "how-to" guide for The non-laboratorian. AACC. 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

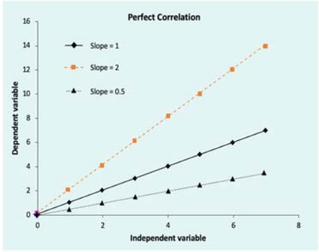
Chemical analyzers
- Biochemical reactions
- Enzymes, carbohydrates, lipids, protein and non-protein nitrogen, inorganic elements, liver function and other indicators

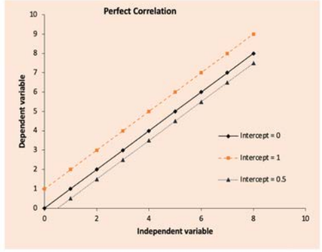
Abel G, et al. Point-of-care testing: A "how-to" guide for The non-laboratorian. AACC. 2022.

POCT 29

Accuracy and Correlation

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





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. AACC. 2022.

Treponema pallidum

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

TP is primarily transmitted through sexual contact.

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

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

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)

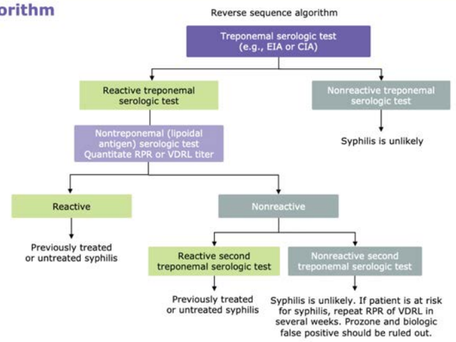
Reverse antibody algorithm

Benefits

- Treponemal tests are specific for TP infection

Limitations

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



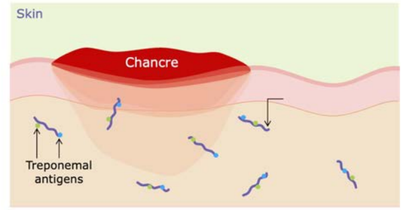
Papp JR, et al. *MMWR Recomm Rep*. 2024;73(RR-1):1–32.

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

Syphilis testing and antibodies: Treponemal tests

Treponemal Test

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

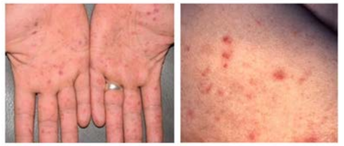


Papp JR, et al. *MMWR Recomm Rep*. 2024;73(RR-1):1–32.

Syphilis lesions can differ according to skin color

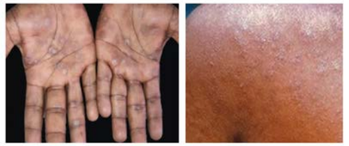
Standard description (seen in light skin)

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



Skin of color

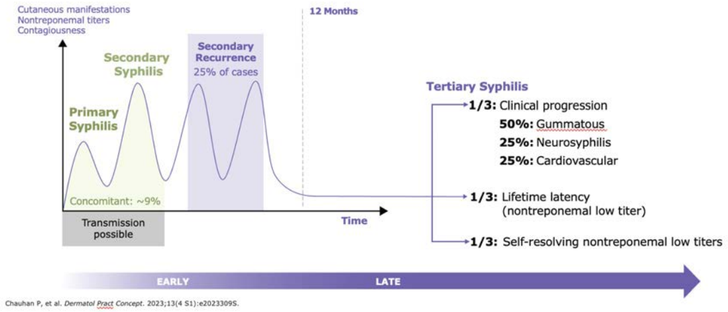
- May appear orange or hyperpigmented
- White and peripheral scales
- Vascular pattern almost always absent
- Bilateral annular facial plaques more frequent



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

Early syphilis (secondary stage). https://wellcomecollection.org/works/z9pjcf23

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



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

Molecular testing for syphilis has benefits

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

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

Sensitivity depends on multiple factors:

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

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

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

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

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

Clinical Manifestations Cannot Differentiate Etiologies

Bacterial

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

Viral

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

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

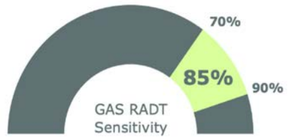
Nearly 40% of pediatric patients tested for GAS are not in compliance with IDSA guidelines.

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

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

RADT May Miss Positive Cases of Acute Pharyngitis

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



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

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

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

RADTs Have Several Limitations

Poorly collected samples can contain suboptimal quantities of GAS.
False Negative

Liquid transport media may dilute GAS Concentration.
False Negative

Operator must observe and interpret color and/or lines in test strips.
False Negative / False Positive

RADTs only detect GAS and cannot distinguish colonization or infection.
False Negative / False Positive

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

Acute Pharyngitis Symptoms

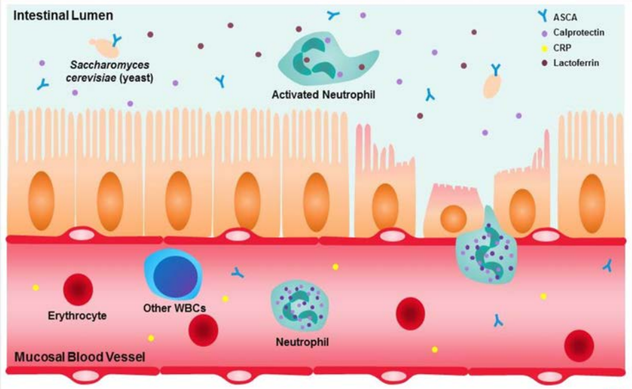
- Headache
- Tender anterior cervical lymph nodes
- Tonsillar exudates
- Sore throat
- Chills
- Fever
- Vomiting
- Nausea
- Abdominal pain
- Rash
- Myalgia
- Fatigue

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

Role of Biomarkers in IBD

Why wouldn't we at least ADD a fecal biomarker?

IBD Inflammatory Biomarkers



ASCA: anti-*Saccharomyces cerevisiae* antibodies; CRP: C-reactive protein; WBC: white blood cell

2

Could Fecal Biomarkers Improve Current Procedures?

Ideal Fecal Biomarker for IBD

- Concentration should reflect severity of intestinal inflammation
- Should not be elevated in non-intestinal inflammation

→ Sensitive and Specific

- Changes in concentration reflect response to therapy and disease recurrence
- Robust cut-offs should indicate inflammation and mucosal healing

→ Responsive

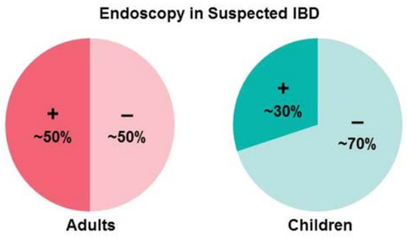
- Stable at room temperature
- Easily transported with no freeze/thaw effects
- Assay with low sample and test variability

→ Stable

Lopez RN, Leach ST, Lemberg DA, et al. *J Gastroenterol Hepatol.* 2017;32:577–82.

3

Fecal Biomarkers Can Distinguish Between Patients With IBS and IBD Prior to Endoscopy

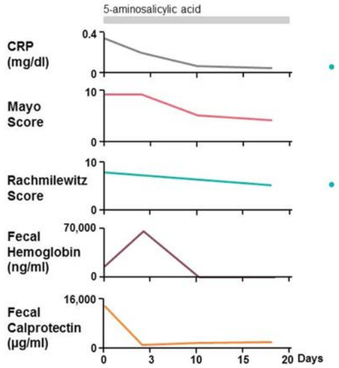


- IBD is verified in about 50% of adults and 30% of children.
- Fecal biomarkers are only elevated in patients with active IBD and are not elevated in patients with functional disorders such as IBS.

Lehmann FS, Burri E, Beglinger C. *Ther Adv Gastroenterol.* 2015;8(1):23–36.

4

Serial Objective Measurements for IBD

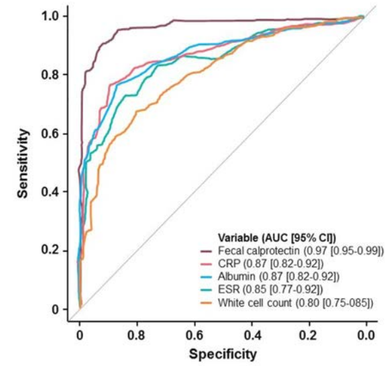


- Fecal biomarkers can be measured serially to assess response to therapy or to detect disease recurrence.[1]
- Serial measurements of fecal lactoferrin reliably assess disease recurrence in post-operative patients.[2]
  - Lactoferrin levels drop significantly after surgery and remain low in the absence of recurrence.

1. Fukunaga S, Kuwaki K, Mitsuyama K, et al. *Int J Mol Med.* 2018;41:107-18.
2. Lamb CA, Mohiuddin MK, Gicquel J, et al. *Brit J Surg.* 2009;96:663–74.

5

Calprotectin Is More Sensitive and Specific Than Serum Markers for Differentiating IBD from IBS



Kennedy NA, Clark A, Walkden A, et al. *J Crohns Colitis.* 2015;9(1):41–49.11

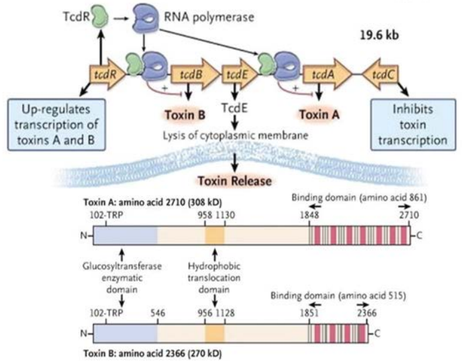
6

NAATs Are the Best Diagnostic Approach for *Clostridium difficile* Infections

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

C. difficile Infection (CDI) Is Caused by Toxins

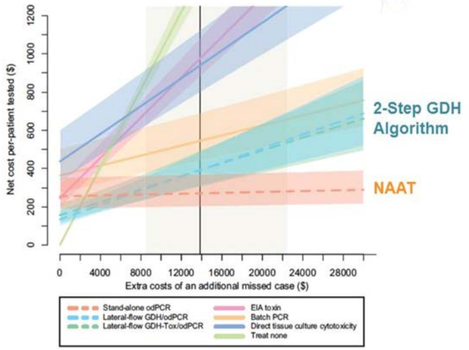


NAAT Is More Sensitive Than EIA/Cytotoxin Assays

Site No.	Site Assay	N	Sensitivity (%)	
			NAAT	Site
1	Toxin A/B EIA	1023	94.1	67.5
2	GDH-EIA	268	91.4	74.3
3	Toxin A/B EIA	293	92.3	53.8
4	Toxin A/B EIA	312	91.4	54.3
5	GDH-EIA-PCR	114	92.3	61.5
6	Toxin A/B EIA	173	97.0	33.3
7	Cytotoxin	110	90.9	54.5

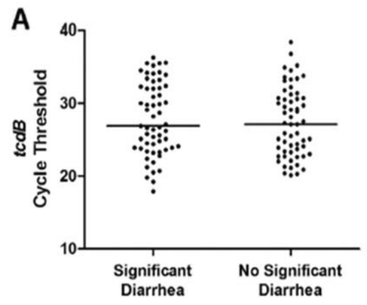
Tenover FC, Novak-Weekley S, Woods CW, et al. *J Clin Microbiol.* 2010;48(10):3719–24.

NAAT Is the Most Cost-Effective Diagnostic Strategy for *C. difficile*



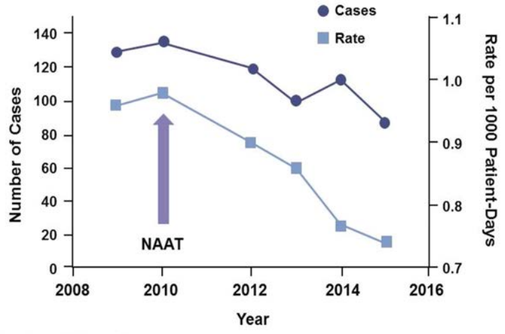
Schroeder LF, Robilotti E, Peterson LR, et al. *J Clin Microbiol.* 2014;52(2):489-96.

Organism Load Cannot Distinguish Asymptomatic Carriage and CDI



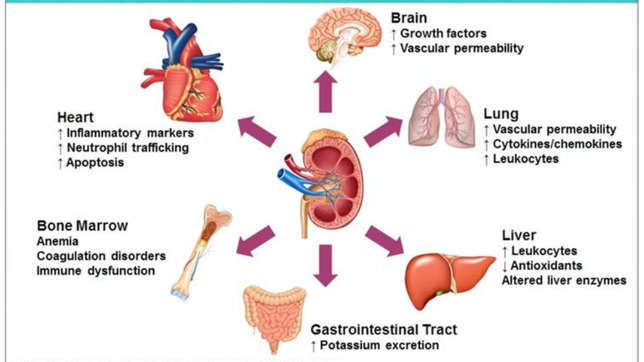
Anikst VE, Gaur RL, Schroeder LF, et al. *Diagn Microbiol Infect Dis.* 2016;84(4):343-6.

C. difficile NAAT Can Facilitate Infection Control



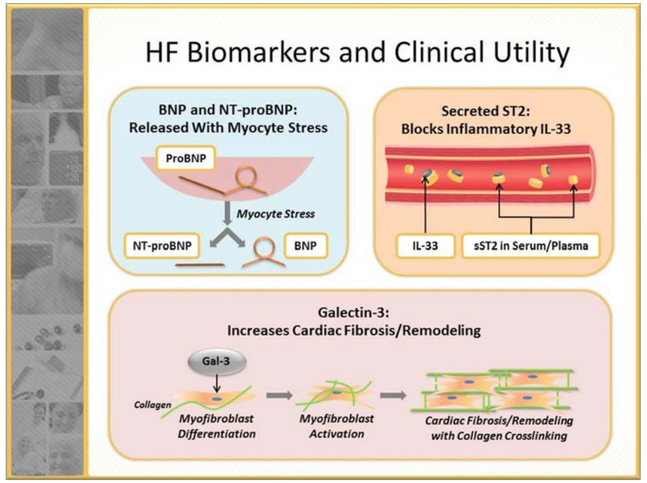
Unpublished internal institutional data.

Extra-Renal Effects of Kidney Injury

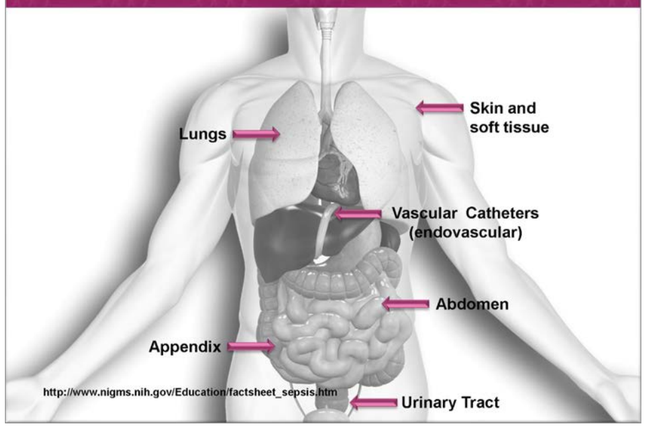


Adapted from Winterberg PD, Lu CY. *Am J Med Soc.* 2012;344:318-25.

HF Biomarkers and Clinical Utility



Locations for Common Infection



Optimum Pain Management

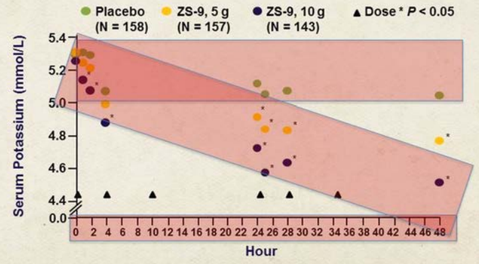
10

New and Familiar Strategies With Medications

Russell D. Weisz, MD

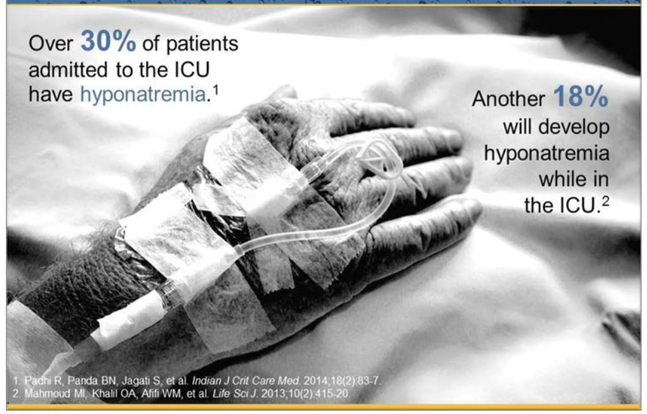
25 TEAMHealth

Mean Serum Potassium Levels Over Time During the Open-label Phase



Packham DK, Rasmussen HS, Lavin PT, et al. *N Engl J Med.* 2015;372:222-31.

Hyponatremia in Critically Ill Patients



Over **30%** of patients admitted to the ICU have hyponatremia.[1]

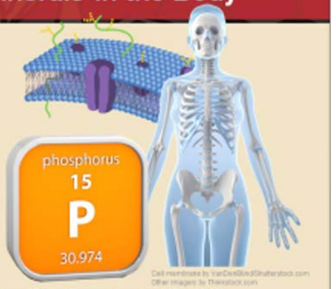
Another **18%** will develop hyponatremia while in the ICU.[2]

1. Padhi R, Panda BN, Jagati S, et al. *Indian J Crit Care Med.* 2014;18(2):83-7.
2. Mahmoud MI, Khalil OA, Afifi WM, et al. *Life Sci J.* 2013;10(2):415-20.

Phosphorus is One of the Seven Major Essential Minerals in the Body[1]

Phosphorus plays a role in:

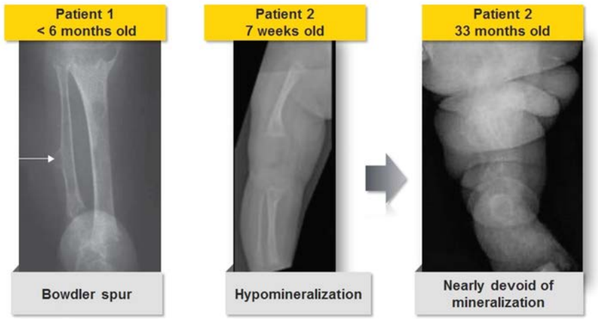
- Skeletal development[2]
- Mineral metabolism[3]
- Cell membrane phospholipid content and function[4]
- Cell signaling[5]
- Platelet aggregation[6]
- Energy production in cells[2]



P, phosphorus

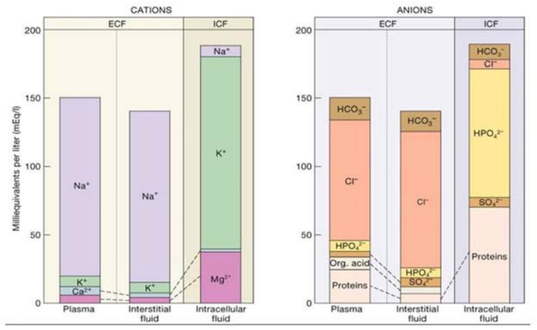
1. Garrett RH, Grisham CH. *Principles of Biochemistry With a Human Focus.* Cengage Learning. 2001:438-69.
2. Bringhust FR, Demay MB, Krane SM, et al. In: Longo DL, Fauci AS, Kasper DL, Hauser SL, Jameson JL, Loscalzo J, editors. *Harrison's Principles of Internal Medicine.* 18th ed. 2012. pp. 3082–95.
3. Quarles LD. *J Clin Invest.* 2008;118(12):3820-28.
4. Alberts B, Johnson A, Lewis J, et al. *Molecular Biology of the Cell.* New York, NY: Garland Science, Taylor & Francis. 5th ed. 2008. pp. 617-50.
5. Evenepoel P, Wolf M. *Kidney Int.* 2013;83(5):789-91.
6. Yi W, Li Q, Shen J, et al. *PLoS One.* 2014;9(8):e102394.

Radiographic Findings of HPP: Bowdler Spurs and Progressive Skeletal Demineralization[1,2]



Images used with permission from Massachusetts Medical Society.
1. Whyte, MP. (2012); 2. Whyte, MP. (2008); references listed at end of presentation.

Cations and Anions Distribution



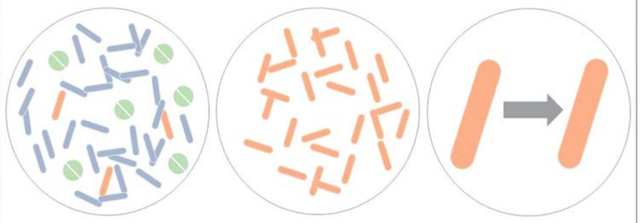
http://www.austincc.edu

Diabetes Incidence in 2015 Estimated Projections for 2040

International Diabetes Federation. *IDF Diabetes Atlas, 7th edn.* Brussels, Belgium: International Diabetes Federation, 2015. http://www.diabetesatlas.org.

Antibiotic Resistance

How does antibiotic resistance develop?



There are lots of bacteria. A few are antibiotic-resistant. Antibiotics kill susceptible bacteria.

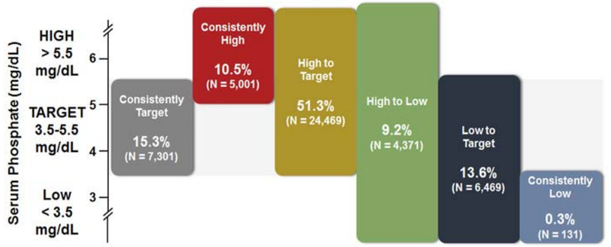
Antibiotic-resistant bacteria that are not killed by antibiotics are able to grow and multiply.

Antibiotic-resistant bacteria can also directly pass that resistance to other bacteria.

https://www.cdc.gov/drugresistance/about.html. Accessed 1/31/17.

Phosphate Binder Use in CKD Patients New to Hemodialysis May Be Inadequate

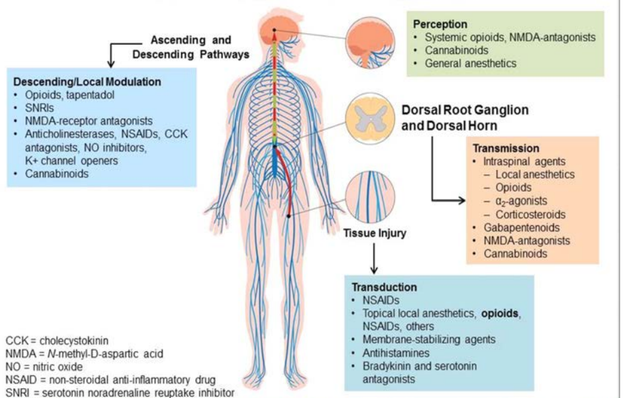
- National data from large U.S. dialysis provider
  - Serum phosphorus levels for 47,742 patients for months 4-9 following initiation of hemodialysis (retrospective analysis)



Consistently Target, Consistently High, Consistently Low: patients whose monthly mean phosphate levels were all I the target, high, or low range, respectively; High to Target: patients with at least one high reading ad one target reading with no readings in the low range; High to Low: at least one phosphate reading in high and low ranges; Target to Low: at least one target reading and one low reading, with no readings in the high range

Farrand KF, Copley JB, Heise J, et al. *Int J Nephrol Renovasc Dis*. 2014;7:261-69.

Broad-Spectrum Analgesics



CCK = cholecystokinin
NMDA = *N*-methyl-D-aspartic acid
NO = nitric oxide
NSAID = non-steroidal anti-inflammatory drug
SNRI = serotonin noradrenaline reuptake inhibitor

Adapted from Polomano RC, Fillman M, Giordano NA, et al. *Am J Nurs*. 2017;117(3 Suppl 1):S12-S26. TEAMHealth

Microbe Types

Bacteria
Gram negative bacteria are the most common type seen in VAP
May be gram positive during MRSA outbreak

Viruses
Not as common as bacterial causes, may be seen in immunodeficient patients

Fungi
Occasionally seen in immunodeficient patients, rarely causative

Monomicrobial
Only one pathogen type

Polymicrobial
Most common VAP infection type
Multiple pathogens

Centers for Disease Control. VAP FAQs. http://www.cdc.gov/HAI/vap/vap_faqs.html. Accessed April 6, 2014.
Krein SL, Kowalski CP, Damschroder L, et al. *Infect Control Hosp Epidemiol*. 2008;29:933-40.
Tedja R, Gordon S. http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/infectious-disease/health-care-associated-pneumonia. Accessed April 6, 2014.
Combes A, Figliolini C, Trouillet J, et al. *Chest*. 2002;121(5):1618-23.

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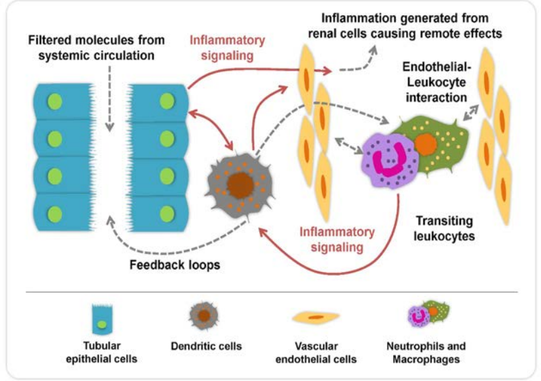
Pathogenesis of AKI

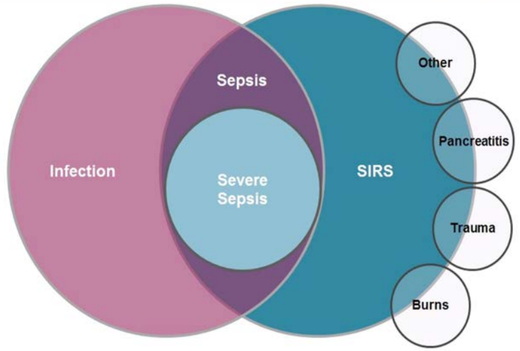


Adapted from Wen X, Murugan R, Peng Z, Kellum JA. *Contrib Nephrol*. 2010;165:39-45.

Iron in the Body: Both Good & Bad

- Iron is the most abundant metal in the human body.
- Most of this iron is bound to protein and in enzymes and is safe and beneficial for the body.
- Labile iron is free iron.
  - It is less than 3% (70-90 mg) of total cellular iron (3-5 g) under *normal* conditions.
  - It is highly reactive and can cause damage to tissues and organs.

The Relationship Between SIRS, Sepsis, and Severe Sepsis



Bone RC, Balk RA, Cerra FB et al. *Chest*. 1992;101:1644-55.

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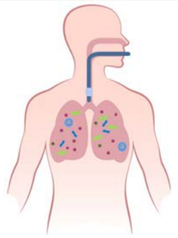
Ventilator-Associated Pneumonia: Characterization

Intubation or mechanical ventilation

24 Hrs | 48 Hrs | 72 Hrs



Onset of VAP

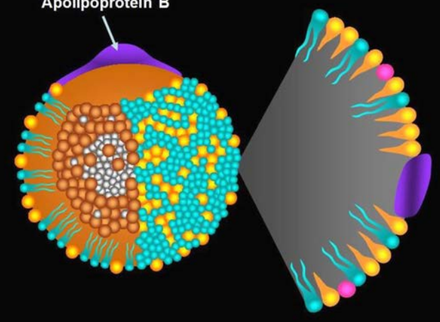
- Presence of a new or progressive infiltrate
- Signs of systemic infection (fever, altered white blood cell count)
- Changes in sputum characteristics
- Detection of a causative agent

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 Francis[1]

1946-47 Discovery of annual influenza viral mutations[2]

1945 First inactivated human influenza vaccine licensed[1]

1967 First adamantane, "amantadine" was first approved for treatment and prophylaxis[3]

1991 First reverse transcription-PCR (RT-PCR) assay for detection of influenza virus was described[4]

1993 Second adamantane, rimantadine, was approved[3]

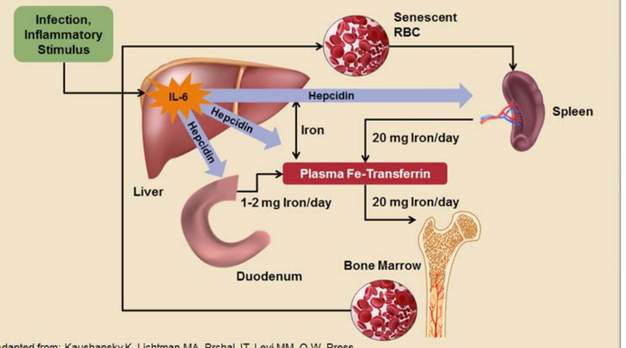
1999 Two neuraminidase inhibitors, zanamivir and oseltamivir, were approved for prophylaxis and treatment of influenza[3]

2005 Cell culture based vaccines[5]

1930 1940 1950 1960 1970 1980 1990 2000 2010

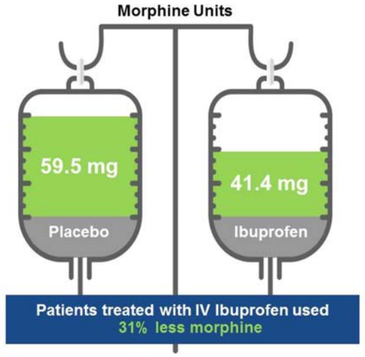
HISTORY OF INFLUENZA 25

Effect of Inflammation on Iron Concentrations



Adapted from: Kaushansky K, Lichtman MA, Prchal JT, Levi MM. O.W. Press, Burns LJ, Callgiuri M: Williams Hematology, 9th Edition. 2016. 13

Better Pain Control With Less Morphine



Patients treated with IV Ibuprofen used 31% less morphine

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

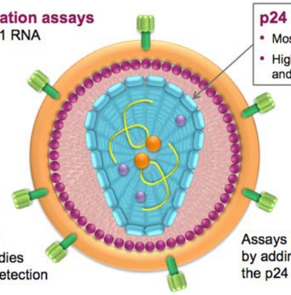
TEAMHealth

HIV-1 p24 Capsid Protein

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

p24 Capsid Protein

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



Transient detection
Later in infection antibodies can interfere with p24 detection

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

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

Competencies

Accredited Programs

Branding

Case Studies

Custom Photography

Digital / Social Media Advertising

Enduring Materials

Graphic Design

KOL Portals

Live & On-Demand Webinars

Live Symposia

Medical Illustration

Newsletters

Packaging & Product Design

Patient Education Materials

Peer-Reviewed Manuscripts

Print Media

Responsive Websites

Sales Collateral

Slide Deck Development

Speakers Bureau

Tradeshow Booth Design & Strategy

Video Production

Thank you for your time.

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