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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<sup>1</sup> and is the most common diagnosis linked to antibiotic use in school-aged children.<sup>2</sup> 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.<sup>3</sup> 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.<sup>3</sup> This article will address the complexities of acute pharyngitis diagnosis and treatment and summarize emerging clinical

**LATEST IN INFECTIOUS DISEASE**

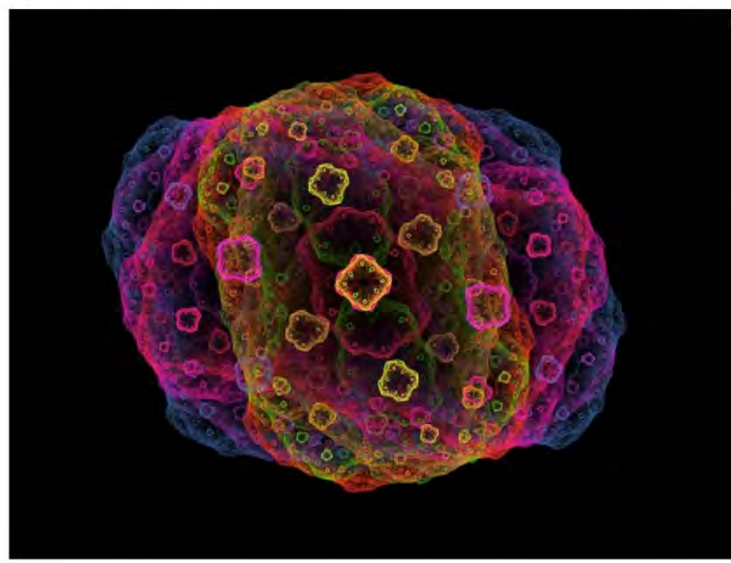
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The number of infectious disease syndromes commonly seen in primary care, urgent care, and emergency departments in the United States is staggering. Acute respiratory illnesses (ARI), ranging from mild upper respiratory tract infections to serious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

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 pathogens that cause widely different treatment plans produce similar symptoms making

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Group A streptococcal (GAS) infections have been on the rise since late 2022 and 2023 after an overall low incidence during the years of the COVID-19 pandemic.<sup>1</sup> GAS infections are common among children and may be asymptomatic or produce mild infections such as pharyngitis, impetigo, and scarlet fever.<sup>1</sup> 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.<sup>2</sup> 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%.<sup>1</sup> 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.<sup>2</sup> Similarly, non-invasive GAS, including GAS pharyngitis, has returned to similar or higher levels than those seen in the pre-COVID-19 pandemic years.<sup>2</sup> The

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## CME / CE

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

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

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### Alzheimers Disease (AD): Impact on Global Health

People all around the world are living longer. Most can expect to live beyond their 60th birthday. According to the World Health Organization,<sup>[1]</sup> 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.<sup>[1]</sup> Common health conditions associated with advanced age include hearing loss, cataracts, osteoarthritis, diabetes, depression and dementia (Figure 1).<sup>[1]</sup> 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.<sup>[2]</sup> A common cause of dementia, Alzheimers disease (AD) is believed to account for 60% to 80% of cases.<sup>[3]</sup> The yearly cost of AD and other dementias in the United States alone is predicted to increase to more than \$1 trillion by 2050.<sup>[3]</sup> 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.<sup>[3]</sup> 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.<sup>[3]</sup>

**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.<sup>[32,33]</sup>

**Figure 2. CSF Biomarkers and AD Diagnosis Functionality** <sup>[34-46]</sup>

CSF Biomarker	Function in AD Diagnosis
t-tau	<ul style="list-style-type: none"> <li>Predicts neurodegeneration via correlation to NFTs</li> <li>Not specific to AD</li> </ul>
p-tau	<ul style="list-style-type: none"> <li>Correlates to NFTs, particularly p-tau181</li> <li>Specific to AD, sensitivity &gt; 90%</li> <li>May be low in non-White individuals</li> </ul>
Aβ40	<ul style="list-style-type: none"> <li>Represents total Aβ levels in cortical tissue</li> <li>Not specific to AD</li> <li>May be low in non-White individuals</li> </ul>
Aβ42	<ul style="list-style-type: none"> <li>Levels in CSF are decreased due to increased Aβ aggregation</li> <li>High concordance with amyloid PET</li> <li>Associated with AD</li> </ul>
Aβ42/Aβ40	<ul style="list-style-type: none"> <li>Adjusts for individual differences in Aβ</li> <li>Low ratio indicative of AD, high ratio may be other subcortical damage</li> <li>High concordance with amyloid PET</li> <li>Classifies more patients correctly than Aβ42 alone</li> </ul>
p-tau/Aβ42	<ul style="list-style-type: none"> <li>Ratio indicative of AD and MCI</li> <li>High concordance with amyloid PET</li> <li>May be low in non-White individuals</li> </ul>
Neurofilament light	<ul style="list-style-type: none"> <li>Increased in AD patients, particularly those with rapid progression</li> <li>Not specific to AD</li> <li>May be low in non-White individuals</li> </ul>

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

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

Released: 6/4/2024 Expires: 6/3/2025 Earn up to .5 Credit

### Activity Review

#### Prevalence and clinical manifestations of herpes virus

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



### Lesion-causing herpes simplex

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



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

Figure 3. Aside from HSV and VZV, many other infectious and non-infectious etiologies may lead to cutaneous, oral, or genital lesions (5, 14). While HSV are most commonly associated with mucocutaneous locations and VZV typically present as clusters in dermatomal distributions (15-17) early eruptions in the sacral area may be mistaken for HSV. Likewise, early vesicular lesions in immunocompromised patients or steroid abusers could be caused by either HSV or VZV (9, 18). Immunocompromised patients often present with atypical lesions that are difficult to define visually. The only way to definitively determine a diagnosis is through laboratory testing. (Figure 4)

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

- Visual differentiation is not possible for most lesion-causing pathogens.
- Atypical presentations are difficult to distinguish.
  - VZV in genital dermatomes
  - Immunocompromised patients
- HSV-1 & HSV-2 may not be distinguishable by oral vs. genital lesion patterns.
- **The only way to definitively determine a diagnosis is through laboratory testing.**

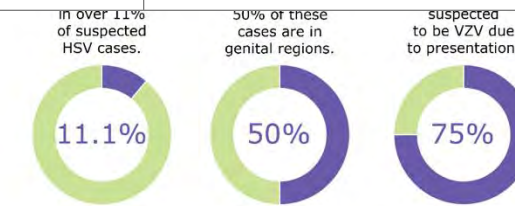


Figure 7. VZV is detected in over 11% of suspected HSV cases, primarily in genital regions. Over 75% of suspected HSV cases are found to be VZV during initial presentation (12, 13). Over 8% of the specimens submitted for HSV testing were found to contain VZV and half of these (4.2%) (13). HSV was found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



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

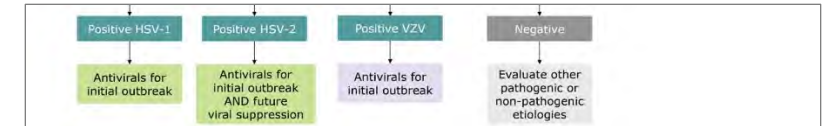


Figure 10. Utilizing multiplex testing for any patient with suspected HSV or VZV can eliminate unnecessary testing, reduce time to diagnosis, and improve treatment timelines. Early differentiation between herpes virus types is important because compared to HSV-1, HSV-2 causes more severe episodes and recurs more frequently (up to 12 times a year). HSV-2 has higher rates of viral shedding - most often while the patient is asymptomatic. Additionally, HSV-2 recurrent infections require suppressive therapy to prevent transmission with a tendency for these infections to develop antiviral resistance. NAATs can assist in patient management for OB-GYN cases in addition to physical examinations, history of HSV-1 or HSV-2 infection, and serology tests to prevent neonatal infection (25, 28). Infants that contract neonatal VZV are at the highest risk when the infection occurs 5 days before and up to 2 days after birth. During this period, maternal infection leads to a 50% risk of transmission and a 20% risk of fatality to the infant. Earlier maternal VZV infections lead to milder symptoms. Infected newborns can develop herpes zoster in their first year of life. Early diagnosis and treatment have been proven to prevent infant fatalities related to neonatal VZV (Figure 11).

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

#### Neonatal HSV

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

#### Neonatal VZV

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

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

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



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## LEARNING OBJECTIVES

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

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



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



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

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


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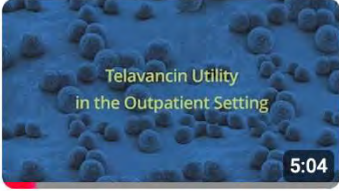



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**POCT** POINT OF CARE TESTING UNIVERSITY

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

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

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### Part 2

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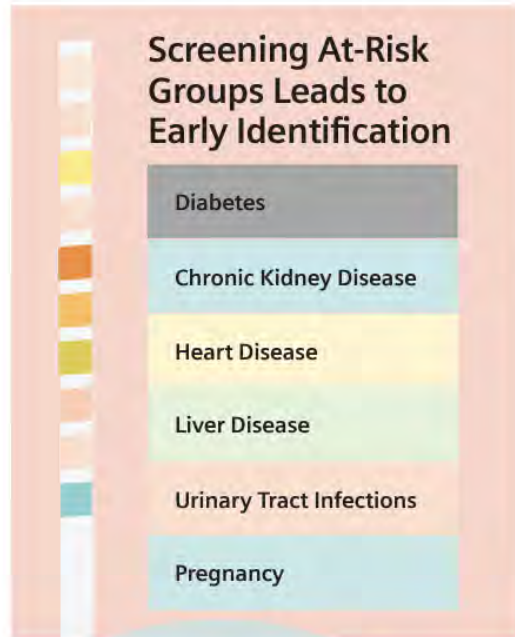
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- Aids diagnosis
- Monitor & evaluate treatment
- No loss to follow-up

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



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Reduce test time



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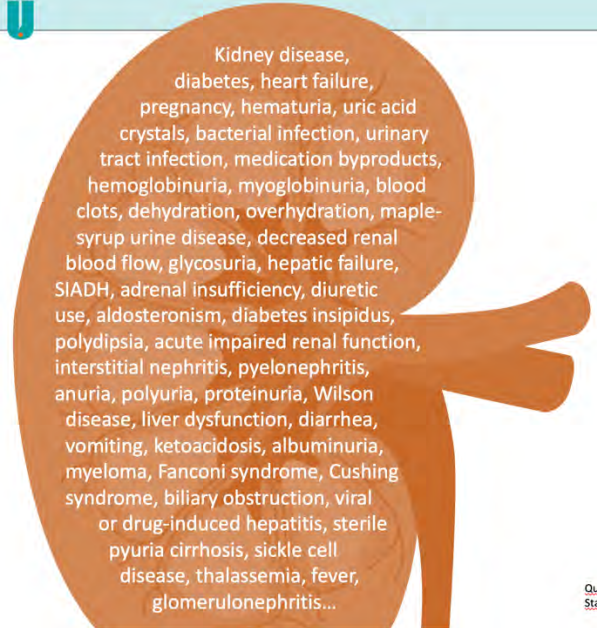


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## What Can Urinalysis Tell Us?

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

## Urinalysis: A Window to Patient Health

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



## Screening to Improve Health Equity

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

<https://www.kidney.org/atoz/content/social-determinants-health-and-chronic-kidney-disease>. Accessed 05/20/24.  
 George C, et al. *BMC Med.* 2022;20(1):247.  
 Kim EJ, et al. *J Gen Intern Med.* 2018 Jul;33(7):1116-1123.  
<https://health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/access-health-services>. Accessed 05/20/24.



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





### 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.<sup>1</sup>

**Outpatient facilities** may not have a standard protocol for urine collection.<sup>2</sup>

Physicians are not ordering guideline-recommended uACR screening tests.<sup>3</sup>

Patients **don't understand** the reason for the test.<sup>4</sup>

**Morning collections** are difficult for patients with **afternoon appointments.**<sup>5</sup>

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

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

### Caring for those with diabetes

Diabetes is a multifaceted disease.<sup>1</sup> 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.<sup>2</sup>

**You are central to their success** which requires utilizing creative and collaborative strategies to help them manage their disease.<sup>3</sup>

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).<sup>4</sup>

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.<sup>5</sup> Estimated glomerular filtration rate (eGFR) uses serum creatinine to measure kidney function.<sup>6</sup> 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.<sup>7,8</sup> 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 or at least once a year.<sup>9,10</sup>

### Diagnostic criteria for CKD<sup>4-6</sup>

**Impaired Kidney Function**  
 eGFR < 60 mL/min/1.73 m<sup>2</sup>  
 uACR ≥ 30 mg/g or ≥ 3 mg/mmol

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

eGFR may be normal in stage 1 or 2 kidney disease so both tests should be used to assess kidney function in anyone at risk.<sup>11</sup> A uACR ≥ 30 mg/g indicates kidney damage, even without an elevated eGFR.<sup>12</sup>

### Compliance may be improved by using POCT uACR<sup>7</sup>

Although the 24-hour collection has been the "gold standard" for uACR, spot POCT uACR correlates well with 24-hour collection results in adults.<sup>13</sup> 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.<sup>14</sup>

With moderate complexity or CLIA-waived POCT uACR, patients can be tested during the same appointment. They don't need to collect urine at home, and results are available immediately. uACR is a key indicator of microalbuminuria, the first stage of kidney failure in patients with diabetes.<sup>15</sup>

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.<sup>16</sup>

### POCT benefits baby and clinicians

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

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

Results can be obtained **within 1 minute** of sample loading.<sup>1</sup>

**Single or multiple analytes can be tested.**<sup>2</sup>

**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 sedation. Consequences of a prolonged response time are worse in preterm infants.<sup>3</sup>

**A tiny amount of blood is needed!**

### Neonatal care is critical

According to the World Health Organization, a newborn infant, or neonate, is a child under 28 days of age. During the first 28 days of life, a child is at highest risk of dying.<sup>1</sup>

**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.<sup>2</sup>

Neonates have immature organ systems, different airway and lung mechanics, and a higher basal metabolic requirement for oxygen.<sup>3</sup>

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

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

Blood drawn for laboratory testing should not exceed 5% of the total blood volume per draw.<sup>7</sup> A 10 mL blood sample drawn with standard tubes may represent as much as 10% of the total blood volume in a preterm neonate.<sup>8</sup>

### Babies have precious little blood

In term and preterm neonates, the total blood volume ranges from 80 to 115 mL/kg.<sup>1</sup> Studies have shown that reduced fetal hemoglobin levels are related to increased neonatal morbidity rates.<sup>2</sup>

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

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.<sup>4</sup>

### 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.<sup>1</sup> They also recommend that blood should be analyzed within 15 minutes of sampling.<sup>2</sup>

### 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 culture measurements can indicate infection.<sup>1</sup>

Underdeveloped lungs may need ventilator support and frequent blood gas measurements for inconsistent breathing and respiratory disease syndromes.<sup>2</sup>

Underdeveloped digestive tract and liver should be monitored for hypoglycemia, metabolic acidosis, and hypoglycemia.<sup>3</sup>

Underdeveloped kidneys need careful monitoring for potassium, other electrolytes, and possible acidosis.<sup>4</sup>

### 7 things to know about A1c

The "A" in A1c stands for "Adult."<sup>1</sup>

After a person reaches 6 months of age nearly all their hemoglobin is type A and approximately 90% is type 1. Type A1 has subtypes A1a, A1b, A1c, and others with A1c being the most common.<sup>2</sup>

Almost all outcome studies on diabetes complications are now based on HbA1c.<sup>3</sup>

Every 1% decrease in the A1c level in a diabetes patient can remarkably lower the risk of complications.<sup>4,5</sup>

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.<sup>6</sup>

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

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

### Caring for those with diabetes

Diabetes is a multifaceted disease.<sup>1</sup> 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.<sup>2</sup>

**You are central to their success** which requires utilizing creative and collaborative strategies to help them manage their disease.<sup>3</sup>

Caring about A1c: Checking patients' A1c levels regularly helps lower risks of complications from diabetes.<sup>4</sup> 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.<sup>5</sup> Testing A1c at the point of care has also been shown to reduce costs associated with post-visit testing.<sup>6</sup>

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

**Don't lose patients to follow-up.**

### Patient-side A1c testing

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

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.<sup>2</sup>

**POCT A1c:**

- Unattended and efficient with no patient involvement
- Better patient understanding
- Better risk/management relationship
- Better outcomes

**Central lab:**

- Many strips 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<sup>1</sup>**

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 (e.g., 8.0% [64 mmol/mol]) may be appropriate for patients with limited life expectancy or when harms outweigh benefits of treatment.

Between glycemic targets based on individualized criteria

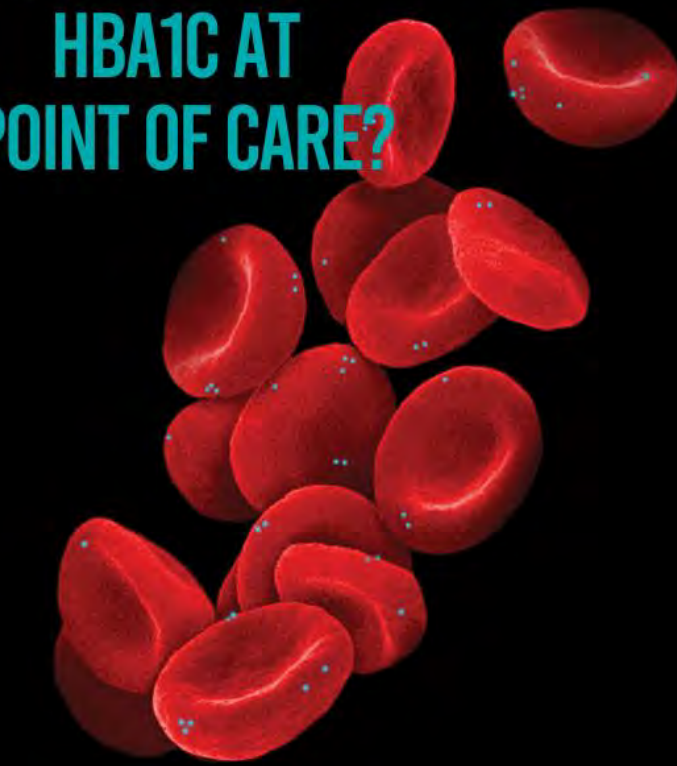
Setting a glycemic goal during consultations is likely to improve patient outcomes

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

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



DO YOU TEST  
HBA1C AT  
POINT OF CARE?

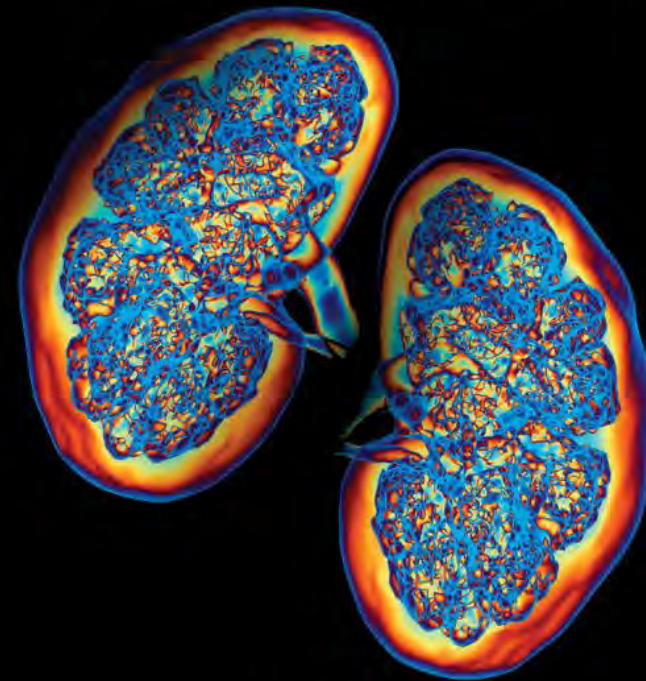


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**This self-study course will provide current information on the role of sepsis biomarkers and bedside analyte testing in improving the prognosis for patients with sepsis.**

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.

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## TESTING AND THE CLINICAL UTILITY OF FECAL BIOMARKERS

### Laboratory

Want to learn more about laboratory testing for fecal biomarkers?




Are Fecal Leukocyte Tests a Waste of Time?

LABORATORY EDITION

DOWNLOAD

### Clinicians

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




Are Fecal Leukocyte Tests a Waste of Time?

CLINICAL EDITION

DOWNLOAD

#### Did You Know?

Lactoferrin is the only fecal biomarker cleared for use in a general population.



"Lactoferrin can be detected using simple and cheap techniques and it has excellent stability in feces over a long period of time."<sup>1</sup>

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

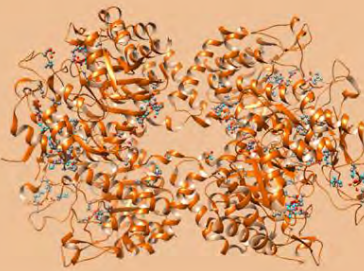
1. Stability
2. Speed
3. Cost
4. Flexibility

The lactoferrin glycoprotein is stable for up to 2 weeks at room temperature, allowing for longer specimen storage. Detection does not require intact cells, temperature regulation, manual counts, or excessive personnel time. Unlike fecal leukocytes, lactoferrin is not degraded by toxins produced by pathogens such as *C. difficile* and lactoferrin assays can be run on solid or liquid samples.

"When compared to the smear exam for WBCs, it became apparent that the sensitivity of the Leuko EZ was much higher than the smear method."<sup>2</sup>

Abdominal pain and diarrhea are some of the most common complaints seen in primary care and gastroenterology. Fecal lactoferrin testing can assist in the diagnosis and management of inflammatory intestinal conditions.

Unlike other fecal biomarkers that fluctuate due to environmental factors, lactoferrin levels remain stable unless released by activated neutrophils. The detection of elevated levels of lactoferrin above the normal baseline can serve as a diagnostic tool for differentiating inflammatory from noninflammatory diarrhea.

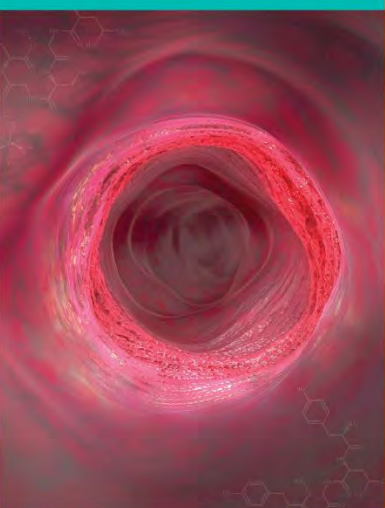


Did You Know? Unlike fecal leukocytes, lactoferrin can be used as a biomarker for severe dehydration and acute infectious diarrhea.



## Are Fecal Leukocyte Tests a Waste of Time?

LABORATORY EDITION



## Are Fecal Leukocyte Tests a Waste of Time?

CLINICAL EDITION

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

**D**oubts about the utility of fecal leukocyte tests using microscopy have been publicly voiced, but detection of leukocyte-released lactoferrin overcomes the challenges. For over a century, fecal leukocytes have been used to diagnose and differentiate between acute inflammatory and non-inflammatory diarrhea. A quantitative test (FLT) 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 FLT's now a waste of time?

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

**FLT Costs**  
Guzta et al. published a 100-year history of the stool cellular exudate test—also known as the FLT.<sup>1</sup> 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 inpatient reimbursement for a fecal leukocyte test was \$5.27.

**The fecal leukocyte test was only 20% better than a coin toss.<sup>2</sup>**

**Personal costs are over with lactoferrin assays.** Technical expertise is not a requirement for accurate lactoferrin results which test results are flexible as they can be used with either intestinal or extra-intestinal samples with no known interfering substances.

**Lactoferrin Performance Testing**  
The LEUKO EZ VUE<sup>®</sup> test is an FDA-cleared, lateral flow device based on the detection of elevated lactoferrin levels. It is used to detect acute inflammatory diarrhea caused by a fecal flora species such as bacteria. The lateral flow device is simple to use and interpret, with results available in 10 minutes.

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### Lactoferrin does not require intact cells (physical or functional) for detection of the fecal leukocyte test results.

Unlike fecal leukocytes, lactoferrin is not degraded by toxins produced by pathogens such as *C. difficile*.

Costs of a test in a study in 2018 in which lactoferrin assays, compared to FLT, LEUKO EZ VUE<sup>®</sup> test and lactoferrin tested at a reference laboratory.<sup>3</sup> The LEUKO EZ VUE<sup>®</sup> test and lactoferrin reference test performed equally well in terms of sensitivity and specificity.

In a Mayo Clinic study, 108 fresh stool specimens were tested by both the LEUKO EZ VUE<sup>®</sup> test and FLT.<sup>4</sup> Thirty specimens tested positive by LEUKO EZ VUE<sup>®</sup> test only. The authors concluded that the 18 specimens not found by FLT's were false-negative caused by lysed and degraded cells.

Another study compared FLT's and LEUKO EZ VUE<sup>®</sup> test with respect to inflammation in children. In total, 1000 stool specimens were tested. In 100 specimens, all were lactoferrin positive with only 11 having high numbers of fecal leukocytes. The results supported the use of LEUKO EZ VUE<sup>®</sup> test over FLT's and pointed to a conclusion that inflammation associated with enterogenic *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.<sup>5</sup> They noted that the utility of lactoferrin testing went beyond the scope of differential diagnosis between inflammatory bowel disease, non-infectious bowel syndrome. They recommended lactoferrin as a biomarker for severe dehydration and acute diarrhea associated with *C. difficile*, *Salmonella*, *Campylobacter* and other enteric infections.

**The LEUKO EZ VUE<sup>®</sup> test has been evaluated favorably in a number of studies, especially when compared to FLT's.**

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

Originally conceived as a bedside test to be performed within 15 minutes after patient collection, laboratories are obliged to offer 24-hour service because only fresh stool samples are fit for analysis. Additionally, Medicare beneficiaries represent only 17% of the U.S. population, so the overall use and costs of the FLT's may be significantly greater when labor costs for trained personnel and equipment time are calculated.<sup>1</sup>

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 *Shigella*, *Shigella*, *Campylobacter* and *C. difficile* cause inflammatory diarrhea 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 diarrhea. In 14 different trials, in 12 different locations, >5,000 fecal samples were evaluated.<sup>1-12</sup> The combined data confirmed that lactoferrin was consistently more sensitive and stable than other neutrophil-associated proteins such as lysozyme, myeloperoxidase or elastase.

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

Lactoferrin is a glycoprotein which is relatively stable in various body fluids and fecal specimens. It is found in mucosal secretions such as tears, saliva, vaginal fluids, urine, breast milk and colostrum. It is also found in leukocytes; neutrophils which are part of the host innate defense system. The amount of lactoferrin in the lumen of a healthy intestine is constant, 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 non-inflammatory diarrhea.

**Lactoferrin Advantages**  
In the intestines, 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.<sup>1</sup> 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.<sup>13</sup> Lactoferrin also corresponds to moderate or severe Vesikari and Clark scores of gastroenteritis disease severity, suggesting the role of the biomarker in staging infectious diarrhea.<sup>14</sup>

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.



**Lactoferrin Release From Activated Neutrophils**  
Lactoferrin and other proteins are released from activated neutrophils into the intestinal lumen.

**Lactoferrin Advantages**  
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### Diagnostic Algorithm With Fecal Lactoferrin

```

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

### Lactoferrin Testing




Fecal leukocytes degrade in stool within hours. Lactoferrin is present for weeks. Lactoferrin testing is a patient-friendly, rapid, cost-effective diagnostic aid for intestinal inflammation.

<b>Reliable</b> Most stable fecal biomarker for intestinal inflammation More reliable than leukocyte microscopy Stable at room temperature for two weeks	<b>Patient-Friendly</b> Non-invasive Specific to intestinal inflammation Rapid answers	<b>Cost-effective</b> Potential cost savings for patient and health system
---	---	---

Lactoferrin is a glycoprotein which is relatively stable in various body fluids and fecal specimens. It is found in mucosal secretions such as tears, saliva, vaginal fluids, urine, breast milk and colostrum. It is also found in leukocytes; neutrophils which are part of the host innate defense system. The amount of lactoferrin in the lumen of a healthy intestine is constant, 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 non-inflammatory diarrhea.

### Available Lactoferrin Tests

Lactoferrin testing is available in three formats to fit your needs. [Contact Us](#)

HOME REGISTER LOGIN



# PAIN MANAGEMENT CASE STUDIES:

## A Surgeon's Perspective

06.24.20  
2 PM Eastern Time



**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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Program

CME Assessment

Downloads

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.



Medavera is a leader in medical education. Our team of experienced medical and scientific professionals identifies gaps in knowledge and care, methodically researches the subject matter, identifies the top experts to guide the content and utilize formats that will provide the best learning opportunity. Great content, respected leaders, and user-friendly platforms create successful interactions and learning.


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### PAIN MANAGEMENT CASE STUDIES:

## A Surgeon's Perspective



Stephen R. Southworth  
MD, MS, MBA, FACS

Surgical patients are at increased risk for opioid-use disorders due to pre- and post-operative prescribing. **Dr. Stephen Southworth** discusses how intravenous ibuprofen may provide an alternative solution to reduce pain and opioid use before and after surgery.

This activity is accredited for physicians and nurses. After the live webinar, the program will be available on-demand with a full transcript and educational slides for download.

#### Learning Objectives

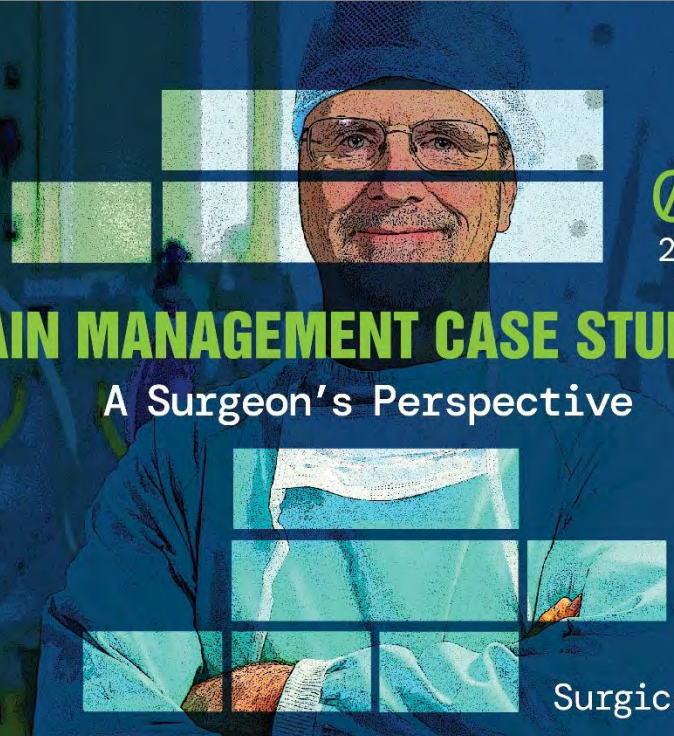
1. Discuss the problem of opioid use in pre- and post-surgical patients.
2. Explain the pain management alternatives to opioids available.
3. Describe the use of intravenous ibuprofen as part of the multimodal pain pathway.

Register online  
[SurgicalPainCases.com](http://SurgicalPainCases.com)

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

**There is no charge to participate.**

Planned and developed by Medavera, Inc.



# PAIN MANAGEMENT CASE STUDIES:

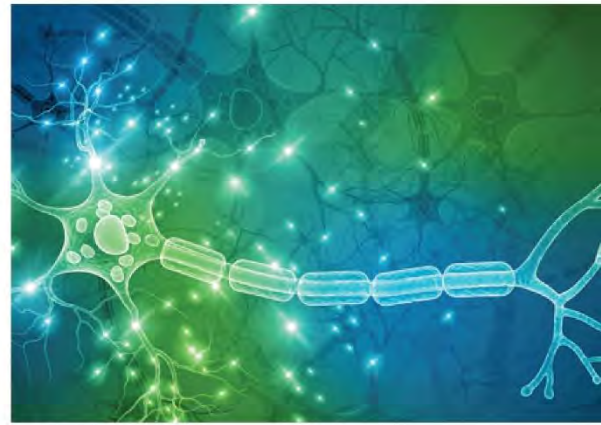
## A Surgeon's Perspective

06.24.20  
2 PM Eastern Time

Accredited  
**FREE WEBINAR**  
Complimentary CME & CEUs

[SurgicalPainCases.com](http://SurgicalPainCases.com)

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



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

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

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

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

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

- Register | Login
Program
CME Assessment
Downloads



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Registration form with fields for First name, Last name, Email, and Message.

Reducing Opioids in Surgical Pain Management: Exploring New Perioperative and Postoperative Strategies Wednesday 4.18.2018 5 pm ET



Reducing Opioids in Surgical Pain Management: Exploring New Perioperative and Postoperative Strategies Wednesday 4.18.2018 5 pm ET



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

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

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

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

Physicians' Thursday has been previously approved by the American Board of Medical Specialties and the American Board of Family Medicine. This program is approved for 1 hour of CME credit. There is no charge to participate in this accredited webinar.

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



#### ADA 2016 Abstract

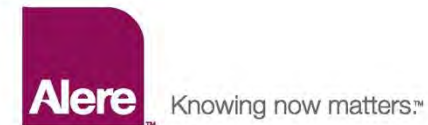
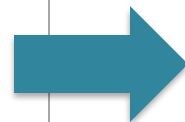
Rio Grande Valley's ACO Quantitative Achievements with Type 2 Diabetes Mellitus Program

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.



## 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.<sup>1</sup> 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).<sup>2</sup> 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.<sup>3,4</sup>

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.<sup>5</sup> 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.<sup>5-7</sup>

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).<sup>8</sup> 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

VIEW LEARNING ACTIVITY	DOWNLOAD CME APPLICATION	DOWNLOAD SLIDE SET
	 <p>The World Health Organization (WHO) estimates between three and five million cases of severe illness and between 250,000 and 500,000 deaths occur each year due to influenza.<sup>1</sup></p>	
	<p>Perhaps one of the greatest lessons in public health was the "Spanish" influenza pandemic of 1918–1919.<sup>2</sup> All influenza A pandemics have since resulted from the 1918 virus, including "drifted" H1N1 viruses and reassorted H2N2 and H3N2 viruses.<sup>3</sup> The devastation caused by this pandemic then led to the discovery of human influenza type A virus in 1933 and the development of the first vaccine in 1937.<sup>4,5</sup> Influenza type B was then identified in 1940.<sup>6</sup></p>	<p>The following decades resulted in significant discoveries: introduction of antiviral treatments, rapid diagnostics, and improvements in surveillance and treatment.<sup>7,8</sup> It is important for healthcare professionals to understand this chronology of events and to look forward to continued improvements in surveillance, identification, and the treatment of influenza. This accredited, self-study program is designed for these purposes.</p>
		
		
<p>©2019 Medavera. All rights reserved.</p>	<p>Planned and developed by Medavera. Supported by an educational donation from Abbott.</p>	<p>Inquires: Carrie Vause info@medavera.com</p>

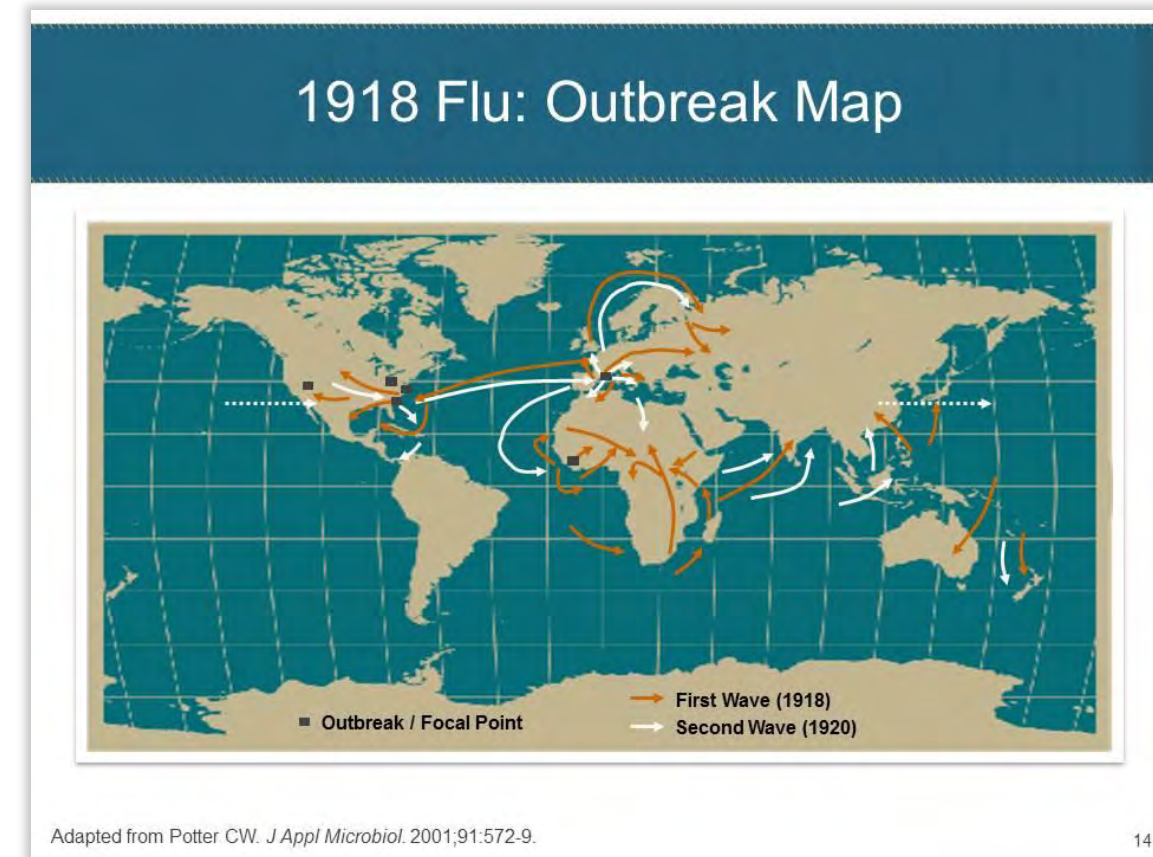
UPDATED CONTENT

the HISTORY of  
**INFLUENZA**

From DEVASTATION to DISCOVERY

A SELF STUDY  
COURSE FOR CREDIT  
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Adapted from Potter CW. *J Appl Microbiol.* 2001;91:572-9.

14

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- The Sysmex XW-100 can help:
- Expedite diagnosis and treatment
  - Improve patient satisfaction
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Common Questions

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Find out how a skilled orthopedic surgeon developed a protocol to improve perioperative pain management while reducing opioids. Free CME credits available.

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PODCAST 1  
Find out how a skilled orthopedic surgeon developed a protocol to improve perioperative pain management while reducing opioids. Free CME credits available.

**THE NEED FOR DIABETES SCREENING**



**OMG!** LISTEN - FREE CME/CE

**Osteomyelitis: Achieving Antibiotic Penetration**




**LISTEN NOW**

**MEDICAL MYSTERY CASES**



SHORT TALES TO PONDER


**IT WAS A DARK AND STORMY MORNING...**



**MEDICAL MYSTERY CASES**

**LISTEN NOW**

Two park rangers living their dream life...  
In love...  
Expecting a baby...  
What could go wrong?

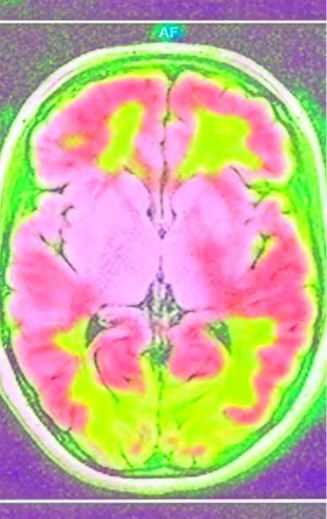


**MEDICAL MYSTERY CASES**

**FREE CME/CE**

**LISTEN NOW**

**A BIRD'S EYE VIEW**



**MEDICAL MYSTERY CASES**

**MEDICAL MYSTERY CASES**


**NEW EPISODE DROPPED!**



Improve Latino Diabetes

http://ImproveLatinoDiabetes.com/ Google

HOME



**Enrique Caballero, MD**  
Clinical Investigator, Staff Endocrinologist & Associate Medical Director of Professional Education Joslin Diabetes Center Director of the Joslin Latino Diabetes Initiative Boston, Massachusetts

**Penny Tenzer Iglesias, MD**  
Associate Professor, Vice Chair, & Director of the Residency Program University of Miami Miller School of Medicine Miami, Florida

**Rodolfo Alamia, MD, RPh, CDE**  
Medical Director, Sweet Vida Medical Center Austin, Texas

## Improve Latino Diabetes

Diabetes in the Latino population is increasing at a dramatic rate and often goes untreated or is inadequately treated due to sociocultural barriers. Join the expert faculty to better understand why these disparities exist and how to overcome challenges to provide the best possible care for your Latino patients.

**REGISTER**  
for webinar

You may register for both webinar dates. The faculty will be available for questions after each webinar.

- ▶ Questions for webinar
- ▶ Discussion Board
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WEBINAR

## Improve Latino Diabetes

**Improving Cultural Competency Among Healthcare Practitioners: Understanding and Overcoming Sociocultural Barriers for the Adoption of Injectable Therapies in the Type 2 DM Latino Population**

There is no charge to participate in this program. Pre-register at [ImproveLatinoDiabetes.com](http://ImproveLatinoDiabetes.com)

**WEBINAR DATES AND TIME:**

February 21, 2012 2 pm ET  
April 10, 2012 2 pm ET

Break down the barriers. Find out how to provide the best care for your Latino patients with diabetes. Each webinar will be followed by a live online Q & A with the faculty.



**Enrique Caballero, MD**  
Joslin Diabetes Center Boston, MA

**Penny Tenzer Iglesias, MD**  
University of Miami Miller School of Medicine Miami, FL

**Rodolfo Alamia, MD, RPh, CDE**  
Sweet Vida Medical Center Austin, TX

▶ Register at [ImproveLatinoDiabetes.com](http://ImproveLatinoDiabetes.com)

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Visit [ImproveLatinoDiabetes.com](http://ImproveLatinoDiabetes.com) for Discussion Boards, Teaching Tools, Slide Downloads and more.

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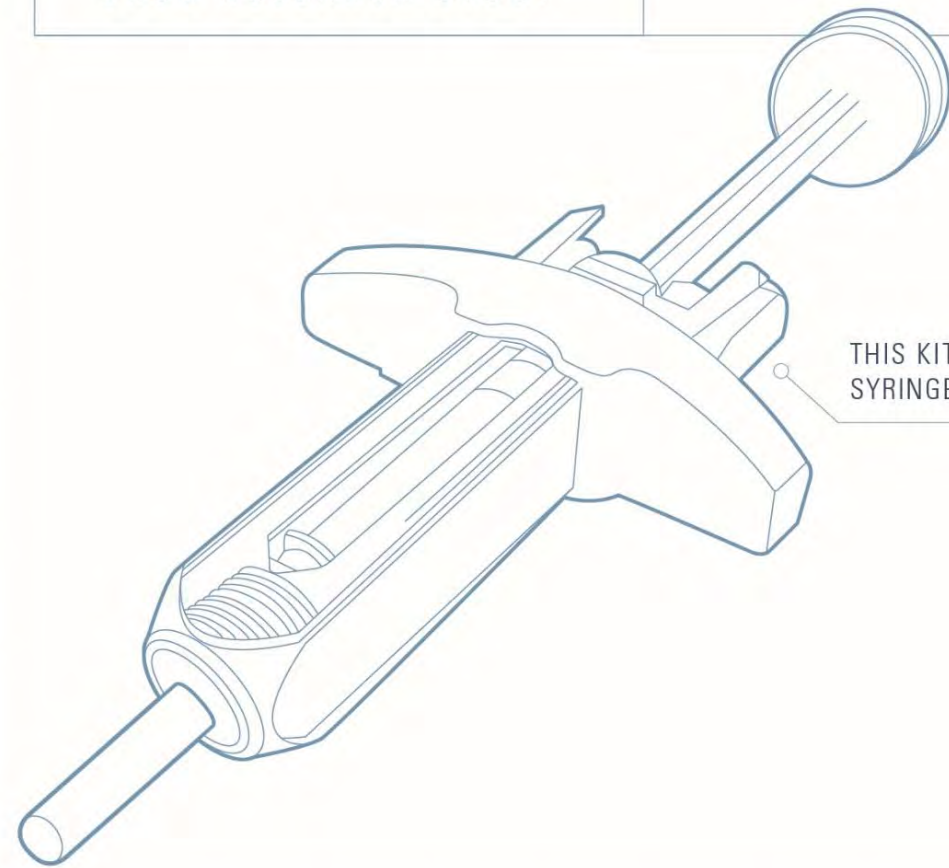
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AA PHARMACEUTICALS

AA101488

DRUG RESEARCH STUDY

# Patient Guide

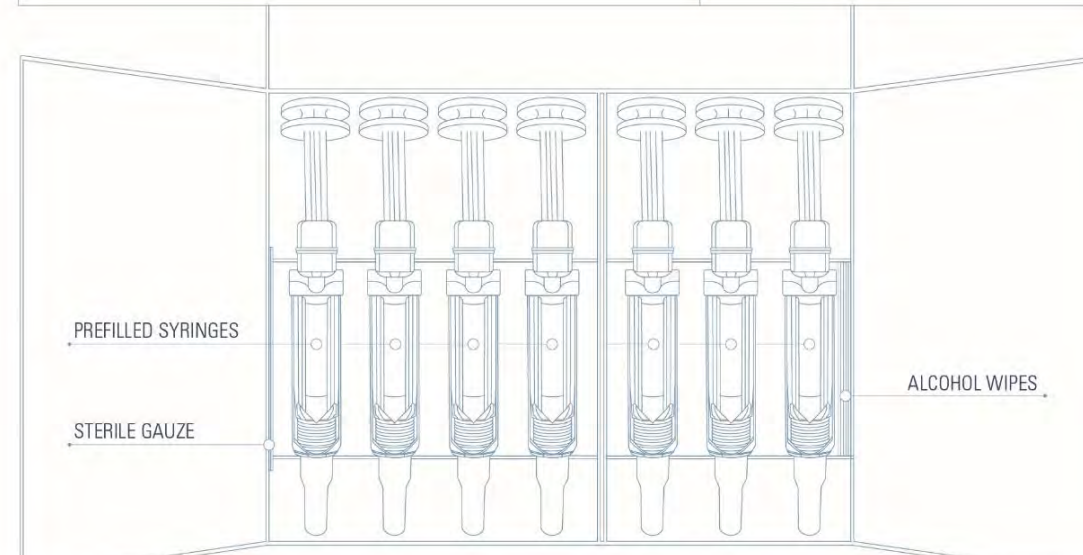


THIS KIT INCLUDES 7 PREFILLED DISPOSABLE SYRINGES & SUPPLIES FOR DAILY PATIENT USE

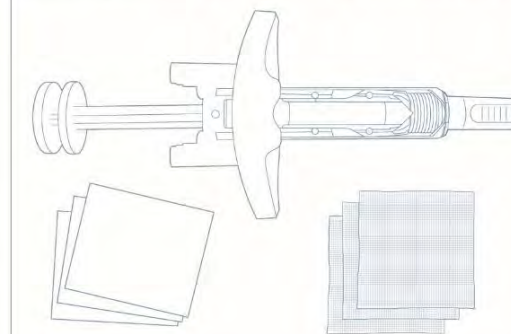
## This kit contains supplies and the study drug.

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

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



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

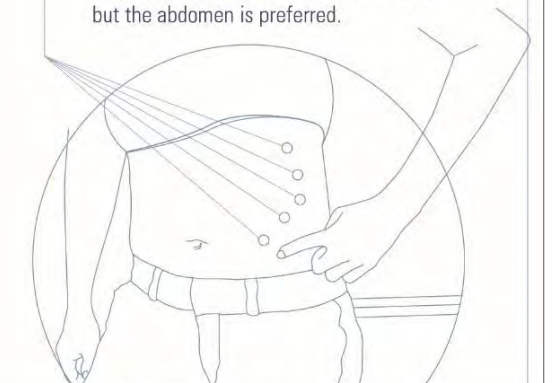


**2** Wash your hands thoroughly with soap and water.



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

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



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

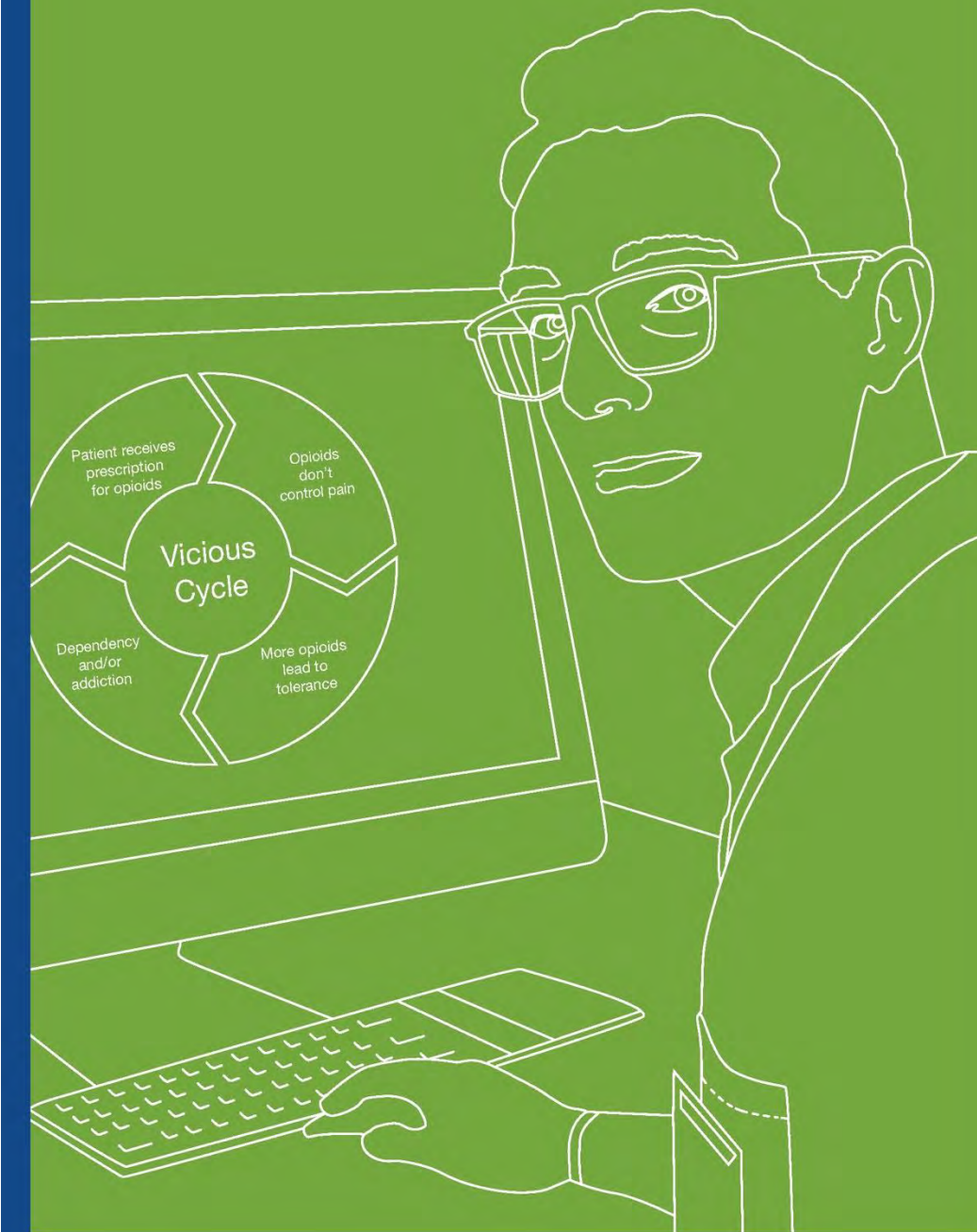
## IT'S A CHALLENGE:

IMPROVING PAIN MANAGEMENT  
WHILE REDUCING OPIOIDS



## TWO MAJOR CHALLENGES:

YOUR BUDGET AND 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 hypotension, 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.

The most common adverse reactions in pediatric patients are infusion site pain, vomiting, nausea, diarrhea 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 intestine, 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)

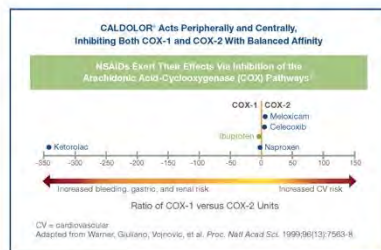
See full prescribing information for complete box warning on the Package Insert attached to the center of this visual aid.

**Improve Pain Management**

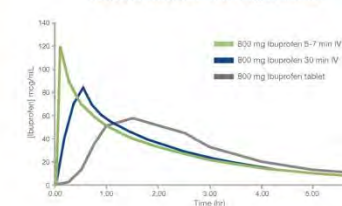
Pain management has become increasingly challenging. There are pressures to offer more effective pain control and reduce opioid use at the same time.<sup>1</sup>

Pain happens both centrally and peripherally.<sup>2,3</sup> CALDOLOR<sup>®</sup> is a non-opioid IV NSAID that helps manage pain<sup>4</sup>:

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



**CALDOLOR<sup>®</sup> Blood Levels Reach a Higher Maximum<sup>6</sup>**



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

**Reduce Opioids**

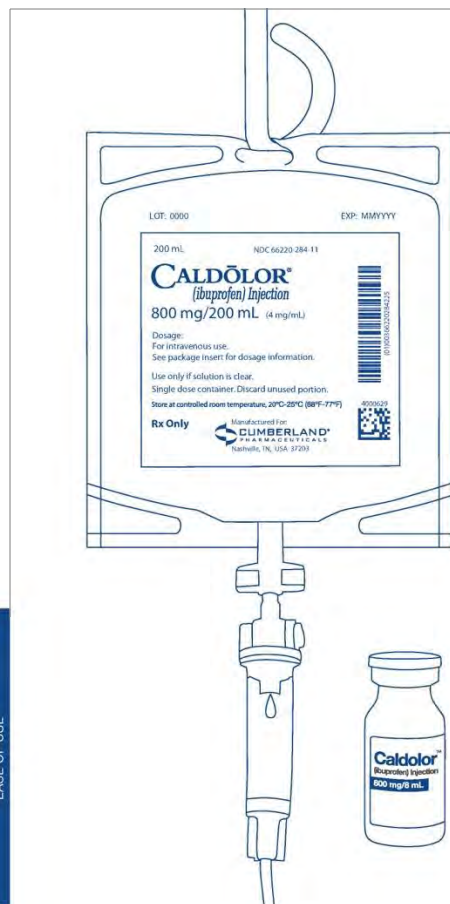
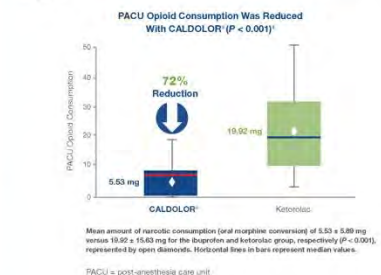
In three multicenter, randomized, double-blind placebo-controlled trials, CALDOLOR<sup>®</sup> was found to reduce opioids when compared to placebo. In elective orthopedic surgery, patients who received CALDOLOR<sup>®</sup> used 30.9% less morphine (P < 0.001) than those receiving placebo.<sup>7</sup> In a safety and efficacy trial of CALDOLOR<sup>®</sup> as a post-operative analgesic following abdominal hysterectomy, the median morphine requirement was reduced by 19% (P < 0.001).<sup>14</sup> A third trial evaluated the use of CALDOLOR<sup>®</sup> in pediatric tonsillectomy and found a 50% reduction in the amount of post-operative fentanyl (P = 0.021).<sup>8</sup>

**Patients Treated With CALDOLOR<sup>®</sup> Used Up to 50% Fewer Morphine Equivalents<sup>14,15</sup>**

Procedure	Number	P Value	Amount of Opioid Reduction
Elective orthopedic surgery	N = 135	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<sup>®</sup> and IV ketorolac for the treatment of post-operative pain in patients undergoing arthroscopic knee surgery.<sup>4</sup>



**CALDOLOR<sup>®</sup> (ibuprofen) Injection**

**Hang With Us**  
CALDOLOR<sup>®</sup> is now available in a pre-mixed bag and at similar cost.<sup>1</sup>

Ready-to-use drug forms are shown to reduce provider time by 32% and material cost by 60%.<sup>2</sup>

- Proven pain control!<sup>3,4,5</sup>
- Reduces opioid use!<sup>3,4,6</sup>
- Cost-effective!<sup>1,6</sup>

CALDOLOR<sup>®</sup> is also indicated for pediatric use for both fever and analgesia.<sup>1,7</sup>

1. CALDOLOR<sup>®</sup> Prescribing Information. Newville, TN: Cumberland Pharmaceuticals Inc.; 2016.
2. van den Linden W, Grootenboer J, Grootenboer C, et al. Ready-to-use injection preparations versus conventional recombinated ampoules: economic evaluation in a realistic setting. PharmacoEconomics 2002;20(4):209-20.
3. Singh N, Rhee A, Patel L. A multicenter, randomized, double-blind placebo-controlled trial of intravenous ibuprofen (IV-ibuprofen) for treatment of pain in post-operative orthopedic adult patients. Pain Med 2013;15(1):54-60.
4. Southworth SR, Woodward EJ, Peng A, et al. An integrated safety analysis of intravenous ibuprofen (CALDOLOR<sup>®</sup>) in adults. J Pain Res 2015;8:753-64.
5. Lu Y, Kumada L, Sidorov-Gale J, et al. Pharmacokinetics with intravenous ibuprofen (premix ready) characteristics and their response in adults undergoing laparoscopic cholecystectomy. A randomized controlled trial. Pain Med 2016;17(10):1762-72.
6. Rubin J. Impact safety, efficacy, and the bottom line with premixed IV products. Pharm Purchasing Product 2008. [https://www.pharmapurchasing.com/documents/V020104\\_36\\_38.pdf](https://www.pharmapurchasing.com/documents/V020104_36_38.pdf). Accessed November 5, 2016.
7. Mose JF, Wlazna M, Borek 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):485-9.

**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 intestine, 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.

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**CALDOLOR<sup>®</sup> (ibuprofen) Injection CAN HELP WITH BOTH<sup>1-5</sup>**

**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 hypotension, 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.

The most common adverse reactions in pediatric patients are infusion site pain, vomiting, nausea, diarrhea and headache (2%).

**ADVERSE REACTIONS**  
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 intestine, 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.

**Your Time Is Valuable**  
CALDOLOR<sup>®</sup> is now available in a single-use pre-mixed bag, requiring no dilution and at similar cost.<sup>1,2</sup>

**Traditional 797 Compounding Preparation**

Wait in Pharmacy	Orders	Clean Room	Preparation	Transport to Point of Care	No Need Refrigeration	Dispose Within 24 Hours
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**CALDOLOR<sup>®</sup> in a Premixed Bag**

Bag in Pharmacy	Orders	Transport to Point of Care	SHIELD-STABLE Can Be Stored For 2 Years
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**The Proven Benefits of Premixed**  
Ready-to-use drug forms are shown to reduce provider time by 32% and material cost by 60%.<sup>2</sup> Staff warnings such as ease of preparation and reduction of errors and handling risks.<sup>6</sup>

The CALDOLOR<sup>®</sup> premixed bag is ready when you need it and shelf-stable for up to 2 years.<sup>3</sup> 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 work, whenever you need it, CALDOLOR<sup>®</sup> will be there. CALDOLOR<sup>®</sup> is also indicated for pediatric use for both fever and analgesia.<sup>1,4,5</sup>

**Summary of Branded Pain Products**

Brand Name	Generic Name	Pediatric Indication <sup>1</sup>	Premixed Bag <sup>1</sup>	Opioid Sparing <sup>1</sup>	Approx. Cost (ASP/Day) <sup>1</sup>
CALDOLOR <sup>®</sup> (Val)	IV ibuprofen	Yes	—	Yes	\$16.00 <sup>1</sup>
CALDOLOR <sup>®</sup> (Premix Bag)	IV ibuprofen	Yes	Yes	Yes	\$19.00 <sup>1</sup>
Ontrium <sup>®</sup>	IV acetaminophen	Yes	Yes	Yes	\$41.00 <sup>1</sup>
Exparel <sup>®</sup>	Ropivacaine	No	No	Yes	\$205.00 <sup>1</sup>

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



### 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

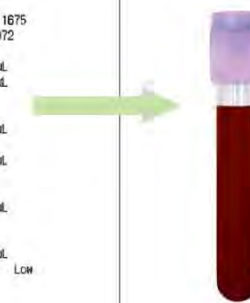
The Sysmex XW-100 is not for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases/disorders, oncology patients, critically ill patients, or children under the age of two.

### 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](http://CBCin3.com).

SYSMEX XW-100 RESULTS (SUPPRESSED)	
Instrument type	XW100
Serial #	G2883
Date	Jan 14, 2019
Time	12:18 PM
Operator	MKZ
Patient ID	1875
Patient DOB	May 28, 1972
WBC	6.2 × 10 <sup>9</sup> /L
RBC	4.38 × 10 <sup>12</sup> /L
HGB	****
HCT	****
PLT	344 × 10 <sup>9</sup> /L
#Neut	4.4 × 10 <sup>9</sup> /L
%Neut	71.3 %
#Lymph	1.6 × 10 <sup>9</sup> /L
%Lymph	25.6 %
#OtherWBC	0.2 × 10 <sup>9</sup> /L
%OtherWBC	3.1 % Low
MCV	****
NOTES	
RECOMMEND FURTHER TESTING.	
Adult Reference Ranges	
WBC	3.9 - 10.4 × 10 <sup>9</sup> /L
RBC	3.71 - 5.52 × 10 <sup>12</sup> /L
HGB	10.9 - 16.7 g/dL
HCT	32.5 - 45.4 %
PLT	148 - 382 × 10 <sup>9</sup> /L
#Neut	2.2 - 7.1 × 10 <sup>9</sup> /L
%Neut	46.4 - 76.9 %
#Lymph	0.9 - 3.4 × 10 <sup>9</sup> /L
%Lymph	14.7 - 45.9 %
#OtherWBC	0.2 - 1.2 × 10 <sup>9</sup> /L
%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<sup>®</sup> HIV-1/2 Ag/Ab Combo

## HIV INCIDENCE AND DISTRIBUTION

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

In 2018 there were **37,832** new HIV diagnoses.<sup>2</sup> Approximately **80%** of new HIV transmissions are from individuals who do not know they have HIV infection or are not receiving regular care.<sup>3</sup>

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<sup>4</sup> (IN MILLIONS)

### PREVALENCE, NEW CASES AND DEATHS FROM HIV IN THE UNITED STATES<sup>4</sup> (IN MILLIONS)

People who inject drugs accounted for **9%** (3,405) of the 37,832 diagnoses of HIV in the United States in 2018. Up to **40%** of new users share needles. The prescription opioid epidemic has disproportionately affected nonurban areas, where HIV prevalence rates are normally low. These

“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.

## A NEW CHALLENGE — OPIOID USE AND HIV INCIDENCE

### TYPES OF HIV TESTING AND TIME TO RESULTS

HIV tests can be conventional or rapid.<sup>1,2</sup>

TEST TYPE	POINT OF CARE	TIME TO RESULTS
<b>CONVENTIONAL</b>		
CONVENTIONAL BLOOD TEST	→	1 HOUR TO SEVERAL DAYS <sup>3</sup>
CONVENTIONAL ORAL FLUID TEST	→	A FEW DAYS TO TWO WEEKS <sup>3</sup>
<b>RAPID</b>		
RAPID TEST POINT OF CARE	→	±20 MINUTES <sup>3,4</sup>
NEGATIVE	→	NO FURTHER TESTING NEEDED
POSITIVE	→	LABORATORY CONFIRMATION NEEDED
<b>HOME</b>		
HOME TEST	→	20 MINUTES TO THREE DAYS <sup>5</sup>



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.<sup>6</sup>

**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.<sup>6</sup>

**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<sup>7</sup>

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

### KEY DATES IN THE HISTORY OF HIV TESTING<sup>8,9</sup>

- 1981:** First AIDS case reported.
- 1984:** Human immunodeficiency virus (HIV) identified.
- 1985:** The FDA licensed the first test to Abbott to screen blood for exposure to HIV.<sup>10</sup>
- 1987:** First Western Blot blood test kit.
- 1992:** First rapid test.
- 1994:** First home and urine tests.
- 2002:** First rapid test using fingerstick.
- 2003:** Rapid fingerstick test granted CLIA waiver.
- 2004:** First rapid oral fluid test (also granted CLIA waiver).
- 2006:** CDC recommends routine HIV screening in U.S. healthcare settings.
- 2007:** WHO/UNAIDS global guidelines recommend routine HIV screening in healthcare settings.
- 2010:** First test approved that detects both antigen and antibodies.
- 2012:** First rapid oral fluid home test.
- 2013:** First rapid test approved that detects both antigen and antibodies, and distinguishes between acute and established HIV-1 infection.
- 2015:** USPSTF gives routine HIV screening an "A" rating, and for those older and younger beneficiaries at "increased risk" for HIV.
- 2015:** Centers for Medicare and Medicaid Services announce Medicare coverage of annual HIV screening for all beneficiaries 15-65, and for those older and younger beneficiaries at "increased risk" for HIV.



**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](mailto: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. Planned and developed by Medavera, Inc. and supported by an educational grant from Alere, Inc.



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

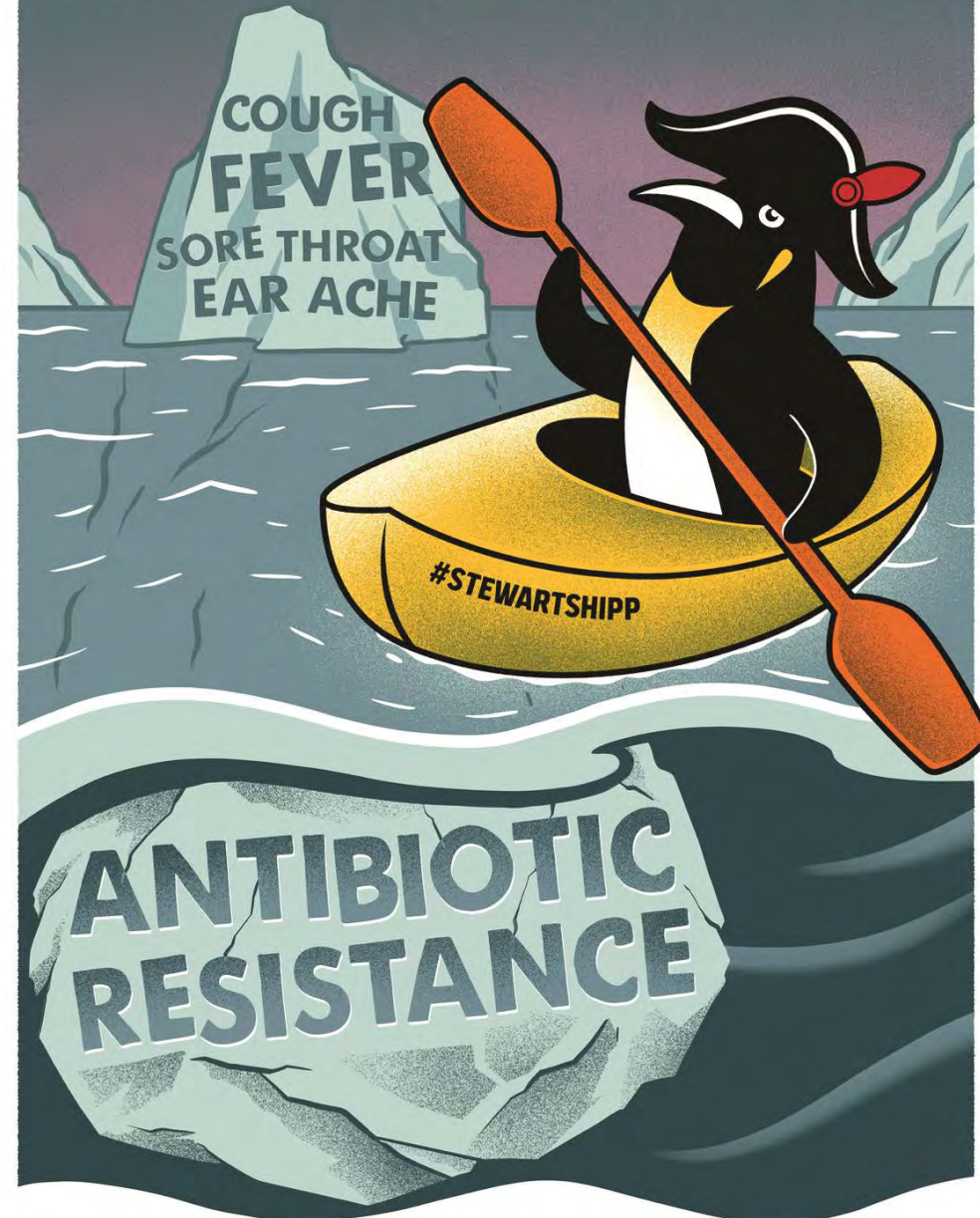
Bissonet Meeting Room  
New Orleans Marriott

This event is neither sponsored nor endorsed  
by the American Society for Microbiology.



Professor  
Mark H. Wilcox, MD

**IN UNCHARTERED WATERS,  
KNOW IF YOU NEED ANTIBIOTICS.**



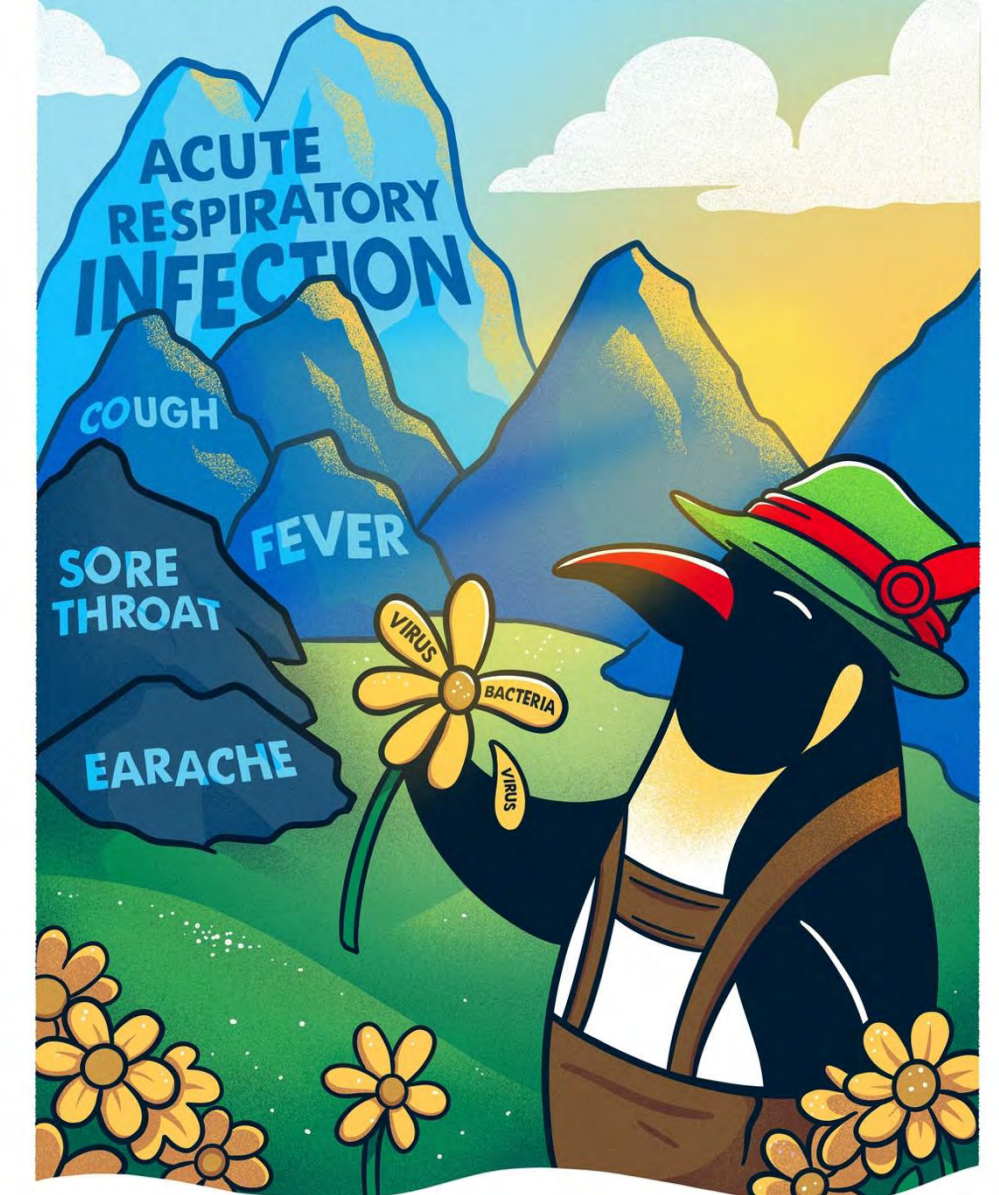
**ASK YOUR DOCTOR IF YOU NEED ANTIBIOTICS**

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



**ASK YOUR DOCTOR IF YOU NEED ANTIBIOTICS**

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



**ASK YOUR DOCTOR IF YOU NEED ANTIBIOTICS**

Influenza Testing



Excuse me.  
Can I bug you for a minute?

Alere® Patient Learning Series

Rapid Molecular Testing



What is Rapid  
Molecular Testing?

Alere® Patient Learning Series

Strep Throat Testing



I have a sore  
subject to discuss  
with you.

Alere® Patient Learning Series

Finding out if it's RSV  
is important

- If detected early, medications may be given to reduce symptoms and help prevent the spread of the RSV virus.
- It can determine how you are treated. Antibiotics only work on bacteria, so you should not take antibiotics for RSV.

**The latest technology:  
rapid molecular testing for RSV**

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



Rosina von Trapp

...d more appropriately, helping you get well sooner!

Influenza Testing



Excuse me. Can I bug  
you for a minute?

Alere® Patient Learning Series AlerePALS.com

**Working the bugs out**

Symptoms of the dreaded influenza or "flu" may include fever, runny nose, sore throat, muscle pains, headache, coughing, and feeling tired. These symptoms usually start bugging you soon after you catch the flu virus and most last less than a week. Seasonal flu outbreaks usually begin suddenly and occur mainly in the late fall and winter.

The flu can lead to pneumonia or sinus infections, and existing health problems such as asthma or heart failure can become even worse. Complications of the flu can be life-threatening.



**Finding out if it's the flu is important**

- If detected early, antiviral medications may be given to reduce symptoms.
- It can determine how you are treated. Antibiotics only work on bacteria, not flu viruses, so you shouldn't take antibiotics for the flu.
- It can help prevent the spread of the flu virus.

**The latest technology:  
rapid molecular testing for the flu**

A new kind of test has been developed that can

quickly and more accurately tell if you have the flu. It's called a rapid molecular test and it works by finding the RNA molecules of the flu virus.

**Answers to what's bugging you**

The new rapid molecular test for flu takes less than 15 minutes and is highly accurate. Diagnosing flu early allows you to get the proper treatment and helps prevent the spread of flu to others.

**Facts about rapid molecular testing**

- A rapid molecular test looks for the RNA of the flu virus. It can detect the flu even if there is only a small amount present.
- It can detect flu viruses that older types of testing might miss.
- Because it's the latest advanced technology, rapid molecular tests cost more but provide confidence with treatment decisions.

RESULTS  
IN  
MINUTES!



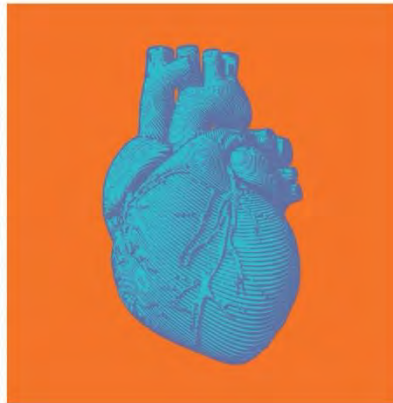
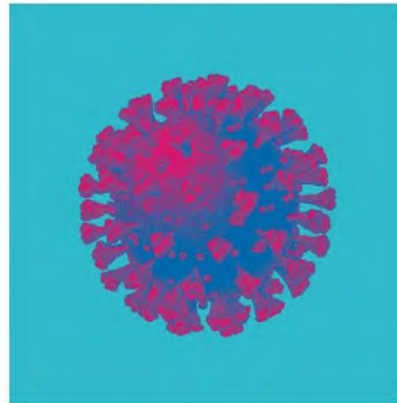
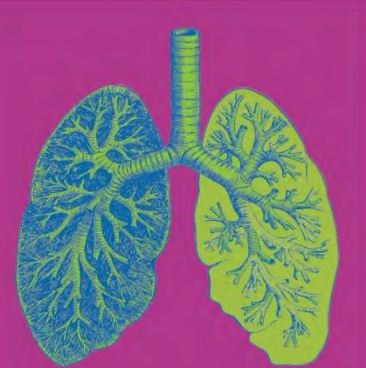
Huey N. Fluey

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

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

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They're counting on you.



Make sure you have the biomarkers you need.

ED Visits for Influenza-like Illness Are Predictive of CVD Mortality<sup>1</sup>

When They Have Trouble Breathing

Patients commonly present to the emergency department (ED) with breathing difficulties.<sup>2</sup> These signs and symptoms may reflect several respiratory and cardiac etiologies.<sup>2,3</sup> Patients with COVID-19 infection have been shown to present with a greater than 20% incidence of dyspnea and a series of cardiovascular abnormalities.<sup>2,3</sup>



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.<sup>4</sup>

ED visits for influenza-like illness have been associated with and predictive of cardiovascular disease (CVD) mortality.<sup>1</sup> Older patients with influenza infection and those with prevalent CVD risk factors, have been shown to be especially prone to myocardial infarction.<sup>5,6</sup> Influenza infection has also been associated with increased in-hospital morbidity and mortality in patients with heart failure (HF).<sup>6</sup>

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<sup>11</sup>

Three For the Crowd

In the U.S., the demand for ED services has increased rapidly.<sup>12</sup> Post-influenza outbreaks and the ongoing pandemic have created great challenges for emergency departments. ED crowding has been shown to negatively impact patient outcomes, patient satisfaction, and patient safety.<sup>13,14</sup> Increased ED occupancy has been found to be associated with more patients classified as higher acuity and result in higher hospital admission rates.<sup>11</sup>

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<sup>®</sup> array of tests provide important data to assist with an expedient diagnosis and proper course of treatment.



Quidel Triage products are not intended for use during SARS-CoV-2 infection.

Knowing Troponin Levels Earlier Can Prevent Cardiac Damage.<sup>24,25</sup>

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.<sup>24,25</sup> 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.<sup>24,25</sup>

The Quidel Triage Cardiac Panel is a fluorescence immunoassay to be used with the Quidel Triage Meter for the quantitative determination of creatine kinase (CK-MB), myoglobin, and troponin I in EDTA anticoagulated whole blood or plasma specimens.<sup>26</sup>

Point of care (POC) troponin testing has been shown to decrease patient length of stay, turn around time, and potentially decrease overall costs.<sup>26</sup>



The Triage BNP Test Is Powerful<sup>11</sup>

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.<sup>11</sup>

Mortality in Acute Coronary Syndrome (ACS) by BNP Level



<sup>11</sup> Cardiac mortality in patients with acute chest pain without ST-segment elevation according to the receiver operating characteristic curve generated best prognostic BNP cut-off level is 99 ng/mL.  
<sup>12</sup> ED = emergency department.

The Triage BNP Test Can Assist With a Rapid Rule Out<sup>12</sup>

Natriuretic peptide testing is now recommended for the prevention, diagnosis, and prognosis of HF.<sup>12</sup>

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.<sup>12</sup>

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

Indication	Class	Level of Evidence
Diagnosis	I	A
Prognosis	I	A
Friedreich's Risk Assessment	IIa	B-AR
Prevent Onset of Heart Failure	IIa	B-R

NR = non-randomized; R = randomized

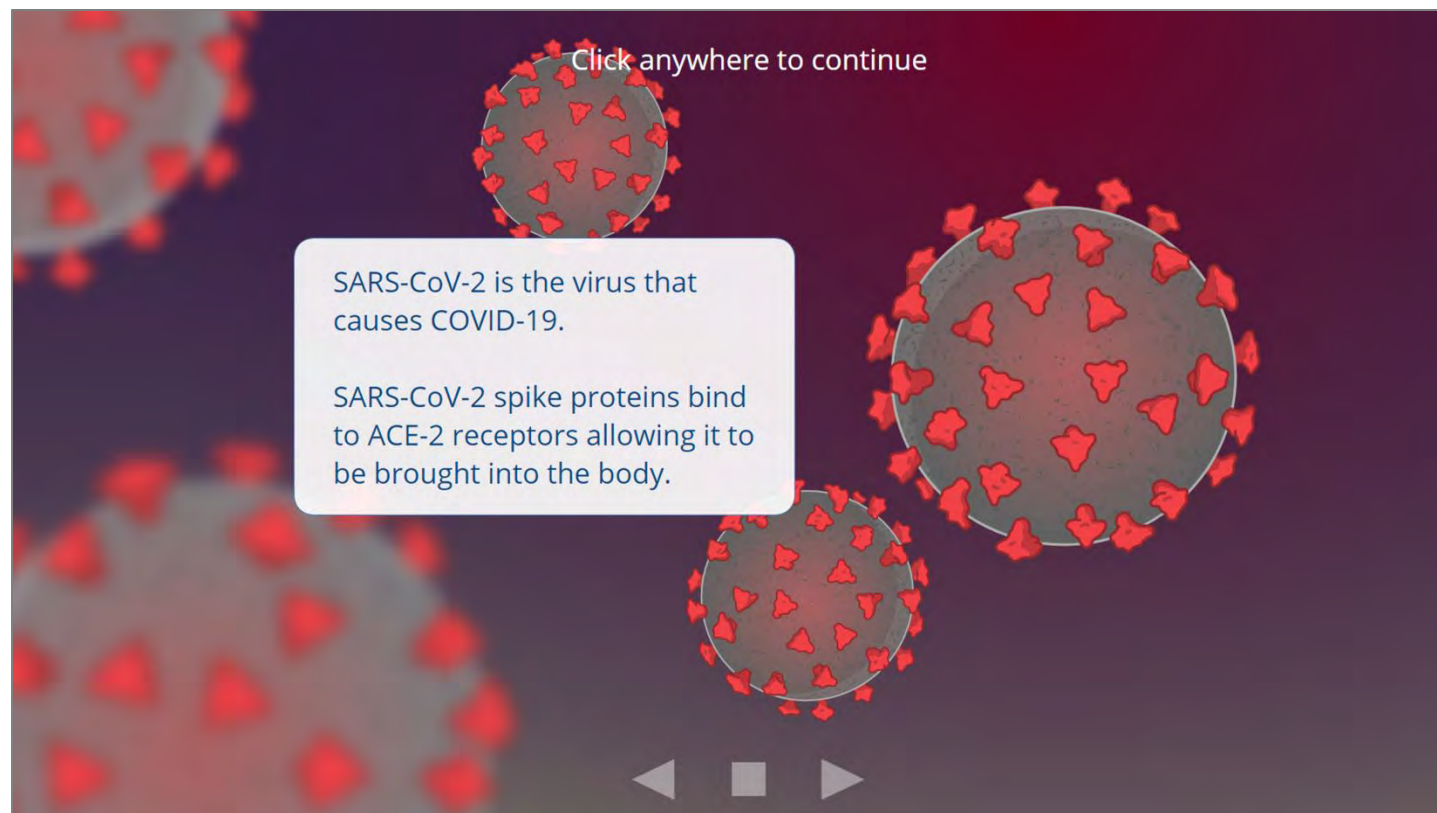
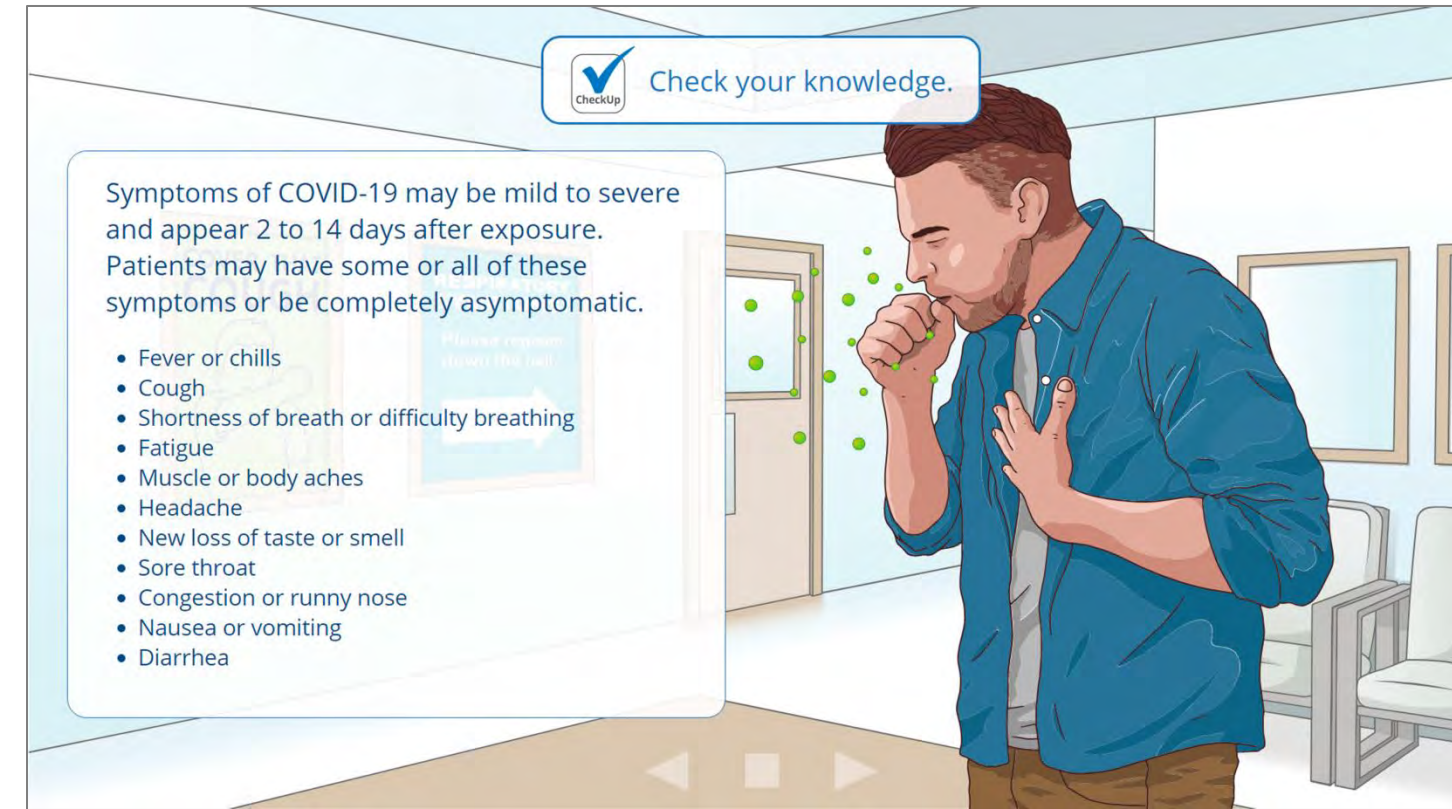
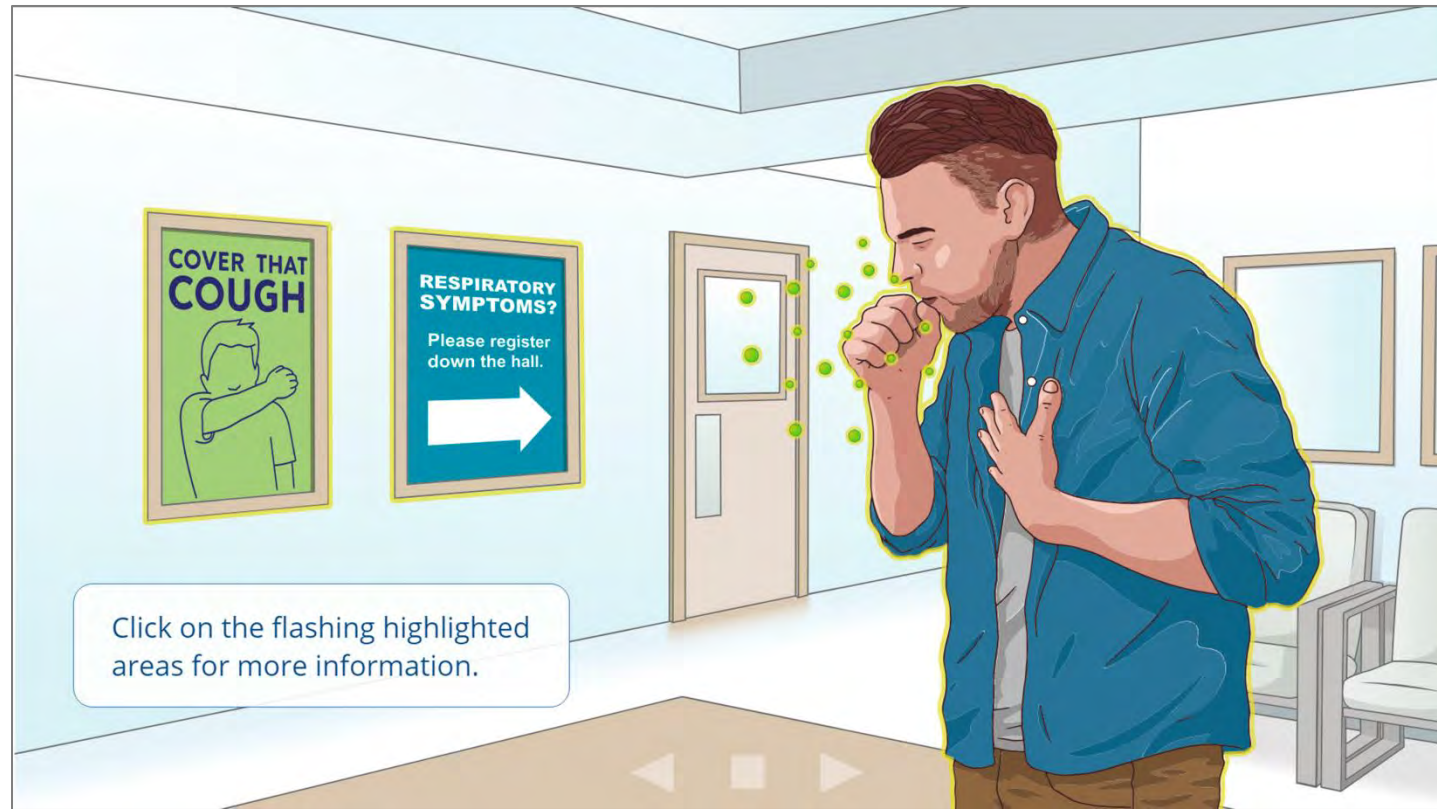
A single measurement of BNP in the ED is associated with greater diagnostic accuracy and its use decreases time to discharge and cost of stay.<sup>12</sup>

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.<sup>12</sup>





# Training



# Hematology Analyzer XW™-100 Sales Guide



**CLIA-waived.  
Automated Hematology  
Analyzer.**

CBCin3.com

Internal Use Only

TAP HERE FOR NEXT PAGE



### CBC Overview

Cellular Components of Whole Blood

#### RED BLOOD CELLS (RBCs)

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

#### HGB

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

#### HCT

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

#### MCV

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

#### WHITE BLOOD CELLS (WBCs)

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

#### Neutrophils

The most abundant type of white cell in an adult is the neutrophil, which normally accounts for roughly 50-70% of the WBCs in venous blood. Their main function is to ingest and destroy bacteria. If the neutrophil count rises, it's being stimulated. If the count is low, it may indicate infection in patients on chemotherapy.

#### Lymphocytes

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

#### Monocytes

Monocytes are about 2-8% of the WBCs. Monocytes can ingest and destroy bacteria. They are also involved in the immune system, along with other WBCs.

#### Eosinophils & Basophils

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

#### PLATELETS

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

### CBCs Simplified

#### CBCs Made Simple

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

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

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

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

#### The XW-100 Has a Small Footprint

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

13.8"

18.1"

7.3"

### Good Fit Chart

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

Does your practice routinely utilize point-of-care testing?

Does your practice routinely order CBCs on well patient visits?

Does your practice order CBCs on non-routine patient visits?

Do you currently send out your CBC testing?

Do you measure patient satisfaction?

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

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

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

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

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

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

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

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

#### Repeat Testing

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

#### Normal Result

MCV 83.6

NOTES

#### Suppressed Result

MCV XXXX

NOTES

RECOMMEND FURTHER TESTING.

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



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

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

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

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

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

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

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

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

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

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



## Play Chest Pain Trivia!

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

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

Less than 100,000	200,000	<b>More than 600,000</b>
400,000	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	<b>African American</b>
Hispanic American	White/Caucasian American

(Benjamin EJ, Balsa JM, Chuvo-Strisun L, et al. Circulation. 2017;135:e1-458.)

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

the same	<b>twice</b>
three times	four times

(<https://my.clevelandclinic.org/health/articles/17493-smoking>, Accessed 07 February 2018.)

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

<b>Heartburn</b>	Headache
Gastroenteritis	Pneumonia

(<https://health.clevelandclinic.org/2016/10/7-alarmpath-in-youngest-patients-with-heart-attacks/>, 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	<b>2000</b>
2000	2010	

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



## Case Study: Influenza A and B

**Patient Name:** Jim L.  
**Temp:** 100.1 **BP:** 120/83  
**HR:** 89 **RR:** 19 **O<sub>2</sub>:** 95%  
**Hx:** None to date.

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

Yesterday morning, his symptoms worsened and he asked to be

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

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

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

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

To learn more contact your local Account Executive **1.877.441.7440** | [alere.com](http://alere.com)

**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.

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

Influenza "originated in 15th century Italy, attributed to "influence of the \_\_\_\_\_."

Stars	<b>Stars</b>
Humors	

(<https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html>)

Influenza viruses infect up to \_\_\_\_\_ of each year.

50%	<b>20%</b>
100%	

(<https://facts.randomhistory.com/2018/07/19/flu.html>)

\_\_\_\_\_ die in the U.S. each year from flu.

20,000	<b>56,000</b>
56,000	

(<https://www.cdc.gov/vaccines/adults/uptd/flu.html>)

\_\_\_\_\_ of the flu and lost work productivity \_\_\_\_\_ in the U.S. alone.

Millions	<b>Billions</b>
Trillions	

(<https://facts.randomhistory.com/2018/07/19/flu.html>)

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

Three	<b>Five</b>
Seven	Nine

(<https://www.cdc.gov/flukeyfacts.html>)



# Slide Decks

### Implementation and Validation

**1 Installation**

**2 System Configuration**

**3 Device calibration and QC**

- CMS Brochure # 3 – Calibration and Calibration Verification<sup>1</sup>
- Implement / Validate IQCP – CMS Brochures 11-13<sup>2</sup>

1. <http://www.cms.gov/Regaffairs/ExternalAffairs/CD/Downloads/2015a.pdf>  
2. <http://www.cms.gov/Regaffairs/ExternalAffairs/CD/Downloads/2015a.pdf>

### 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

z

<http://www.cms.gov/Regaffairs/ExternalAffairs/CD/Downloads/2015a.pdf>  
Page 4, Appendix A, 2/10/2015 9:16

### 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/Regaffairs/ExternalAffairs/CD/Downloads/2015a.pdf>  
Page 4, Appendix A, 2/10/2015 9:16

### 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<sup>1</sup>

<http://www.cms.gov/Regaffairs/ExternalAffairs/CD/Downloads/2015a.pdf>  
Appendix B, 2/15

### Correct Implementation Starts With the End User

**End user identifies need**

**Multiple systems analyzed**

**Optimal system selected and implemented**

**Observation of clinical, operational, and financial outcomes**

**End user confers with POCC**

**Team develops justification for new POCT**

### Initial Training and Competency Timeline

**Initial Training**


**Competency Assessment**

**Personnel Approval to Perform POCT**

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


Source: S. J. APTC, 2017, S202(2) 347-378

**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://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014

**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?



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**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:<sup>1</sup>

- 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




https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014

**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

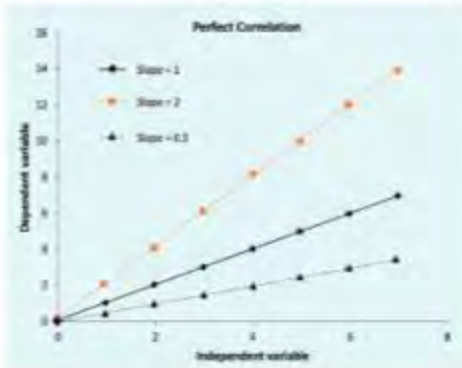


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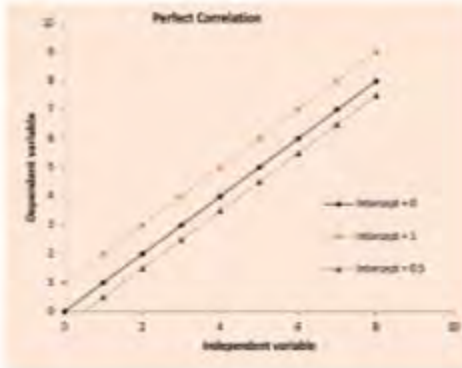
**Accuracy and Correlation**

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

**Perfect Correlation**



**Perfect Correlation**



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**POCT Methodologies Exist for Several Conditions and Specialties**

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



https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014; https://doi.org/10.1093/ptp/ptz014


### 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.ncbi.nlm.nih.gov/pmc/articles/PMC4164875/pdf/201404111224.pdf  
 Page credit: National Institutes of Health and Infectious Diseases (NIH)

### Reverse antibody algorithm

**Reverse sequence algorithm**

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

- Reactive treponemal serologic test
  - Non-treponemal (VDRL, RPR, VDRL, RPR, etc.)
  - Reactive
    - Previously treated or untreated syphilis
  - Non-reactive
    - Reactive second treponemal serologic test
      - Previously treated or untreated syphilis
    - Non-reactive second treponemal serologic test
      - Syphilis is unlikely. If patient is at risk for syphilis, repeat RPR or VDRL in several weeks. Positive and biologic false positive should be ruled out.
- Non-reactive treponemal serologic test
  - Syphilis is unlikely

**Benefits**

- Treponemal tests are specific for TP infection

**Limitations**

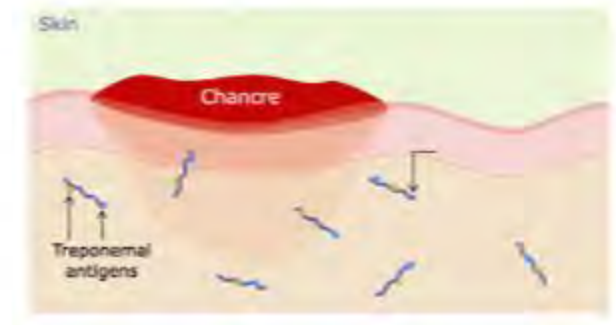
- Could take 3-5 days
- Positive treponemal tests do not indicate active infection
- Treponemal tests can be more expensive and are higher in complexity

Page 16, et al. JAMA Network Plus. 2024;1(10):1-10  
 CIA = Chemiluminescent immunoassay; EIA = enzyme immunoassay; RPR = rapid plasma reagin; 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.



Page 16, et al. JAMA Network Plus. 2024;1(10):1-10

### 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**

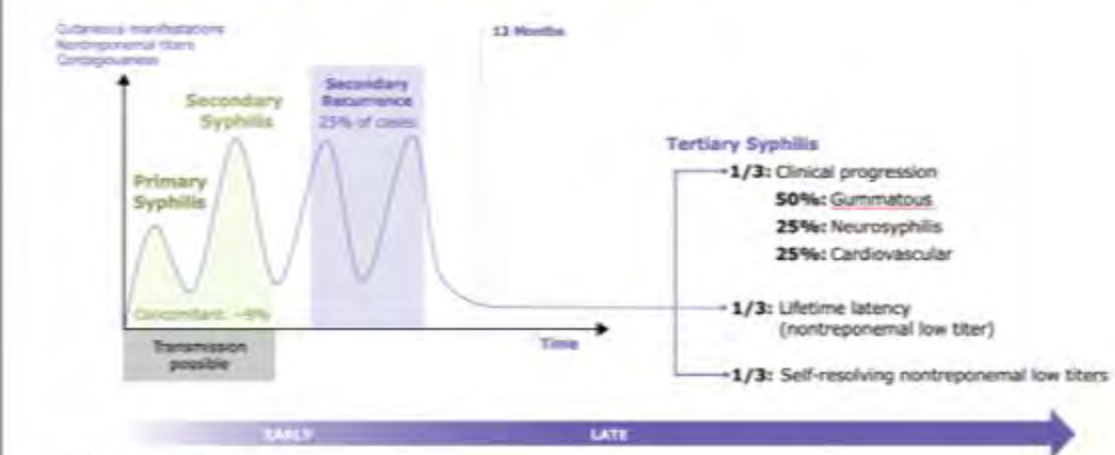
- May appear orange or hyperpigmented
- White and peripheral scales
- Vascular pattern almost always absent
- Bilateral annular facial plaques more frequent



Shah C, Schwartzman K, Bhattacharya A. J Clin Invest. 2023 May;133(5):201-207.  
 Okunski J, Behroozi S, Ding J, et al. JAMA Dermatol. 2022 Oct 1;158(10):1452-1458.  
 Hershkovitz T, Serebrin N, Serebrin L. Syphilis for dermatologists. Curr Dermatol. 2024 Mar Apr;43(3):139-154.  
 Hershkovitz T, Serebrin N, Serebrin L, Serebrin L. J Am Acad Dermatol. 2022 Mar;1(3):1254-1255.  
 Page credit: National Institutes of Health and Infectious Diseases (NIH)

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

Clinical manifestations: Nontreponemal titers, Conspicuous



**Primary Syphilis**

- Concomitant -40%
- Transmission possible

**Secondary Syphilis**

- Secondary Recurrence 25% of cases

**Tertiary Syphilis**

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

Okunski J, et al. JAMA Dermatol. 2023;159(10):1452-1458

### 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.



Page 16, et al. JAMA Network Plus. 2024;1(10):1-10



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

Thompson WW, et al. Pediatrics. 2010;125(5):e1279-1285.

**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**

Thompson WW, et al. Pediatrics. 2010;125(5):e1279-1285.

**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.

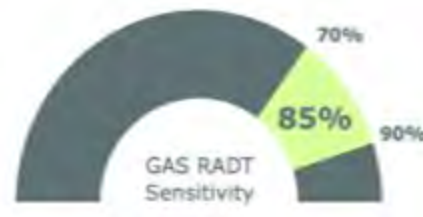
- Greater return rates
- Misdiagnosis
- Inappropriate antibiotics
- Allergic reactions
- Loss of school days



Thompson WW, et al. Pediatrics. 2010;125(5):e1279-1285.

**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.<sup>1</sup>







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

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

1. Archer G, et al. Pediatrics. 2001;107(5):e100-104.  
2. Thompson WW, et al. Pediatrics. 2010;125(5):e1279-1285.  
3. Archer G, et al. Pediatrics. 2001;107(5):e100-104.  
4. Lee H, et al. Pediatrics. 2001;107(5):e100-104.  
5. Archer G, et al. Pediatrics. 2001;107(5):e100-104.


**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 WW, et al. Pediatrics. 2010;125(5):e1279-1285.

**Acute Pharyngitis Symptoms**

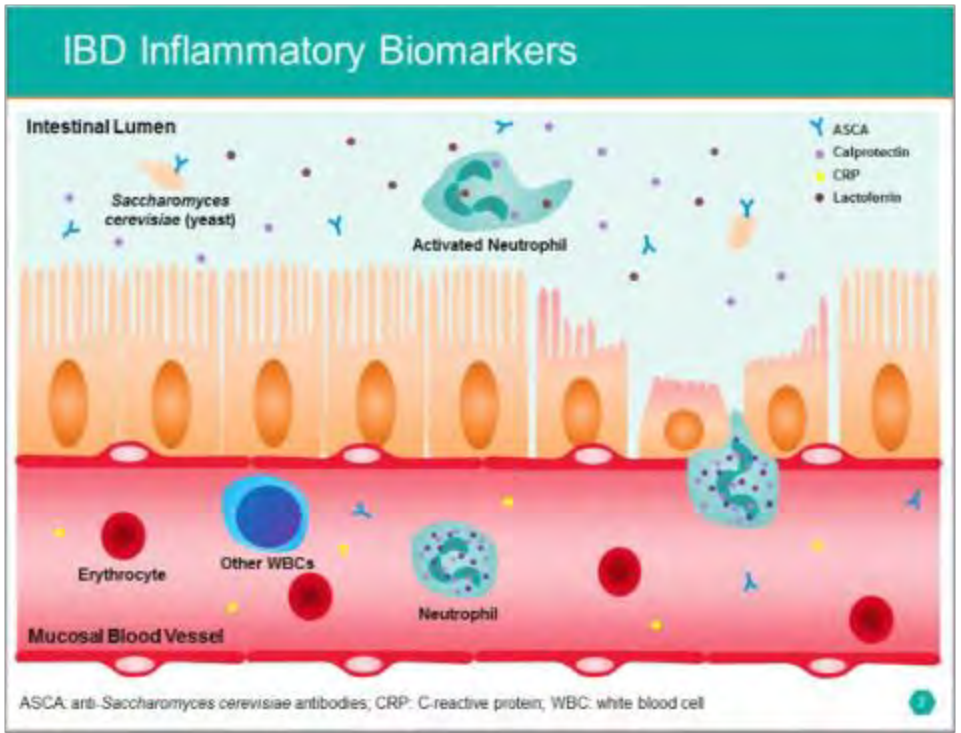
		Headache
Tender anterior cervical lymph nodes	Tonsillar exudates	Sore throat
	Chills	Fever
Vomiting	Nausea	Abdominal pain
		Rash
	Myalgia	Fatigue



Thompson WW, et al. Pediatrics. 2010;125(5):e1279-1285.

## Role of Biomarkers in IBD

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



### 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
- Changes in concentration reflect response to therapy and disease recurrence
- Robust cut-offs should indicate inflammation and mucosal healing
- Stable at room temperature
- Easily transported with no freeze/thaw effects
- Assay with low sample and test variability

**Sensitive and Specific**

**Responsive**

**Stable**

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

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

#### Endoscopy in Suspected IBD

- 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, Buzi E, Beglinger C. *Ther Adv Gastroenterol*. 2015;8(1):23-38.

### Serial Objective Measurements for IBD

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

1 Fukunaga S, Kusaki K, Mitsuyama K, et al. *Int J Mol Med*. 2016;41:107-16.  
2 Lamb CA, Mohiuddin MK, Giorgio J, et al. *Br J Surg*. 2009;96:663-74.

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

**Variable [AUC [95% CI]]**

- Fecal calprotectin (0.97 [0.95-0.99])
- CRP (0.87 [0.82-0.92])
- Albumin (0.87 [0.82-0.92])
- ESR (0.85 [0.77-0.92])
- White cell count (0.80 [0.75-0.85])

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

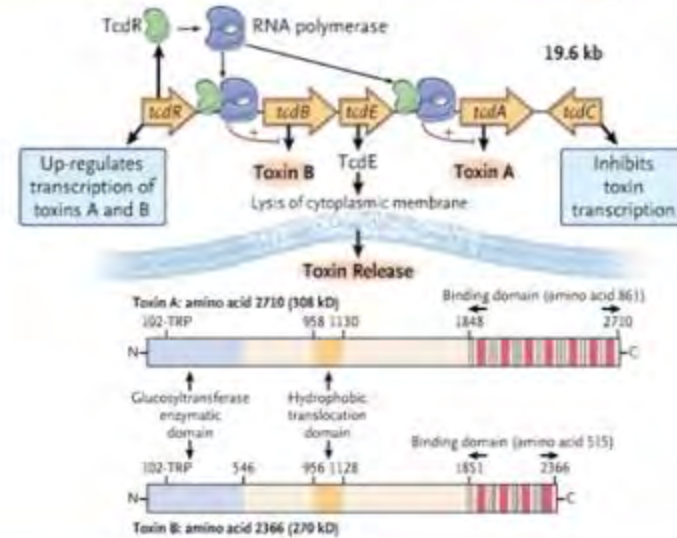
## NAATs Are the Best Diagnostic Approach for *Clostridium difficile* Infections



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

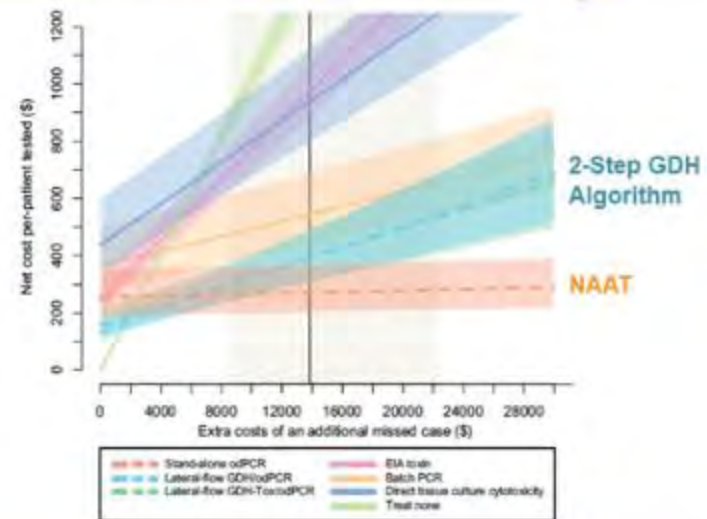


## NAAT Is More Sensitive Than EIA/Cytotoxin Assays

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

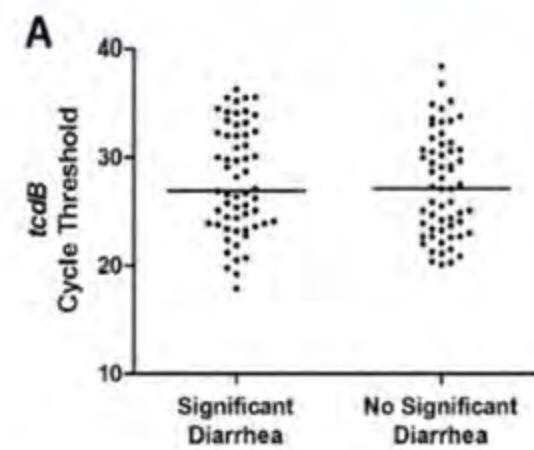
Tenover FC, Novak-Weekley S, Woods CW, et al. *J Clin Microbiol* 2010;48(10):3719-24

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



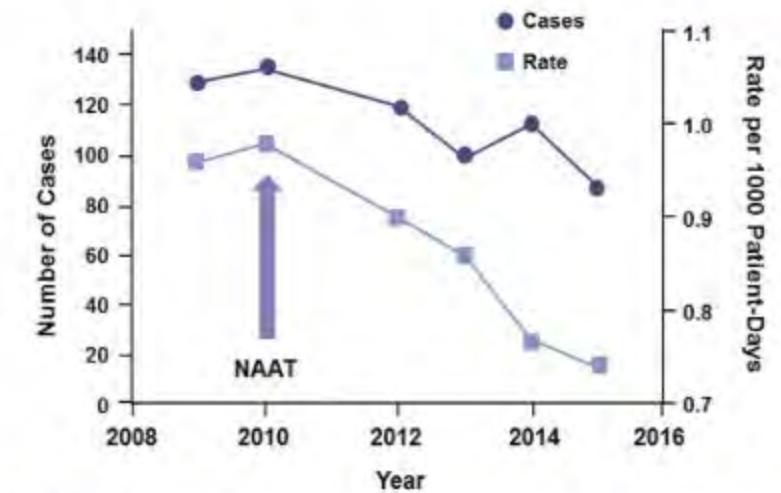
Schroeder LF, Robilotti E, Peterson LR, et al. *J Clin Microbiol* 2014;52(2):489-96

## Organism Load Cannot Distinguish Asymptomatic Carriage and CDI



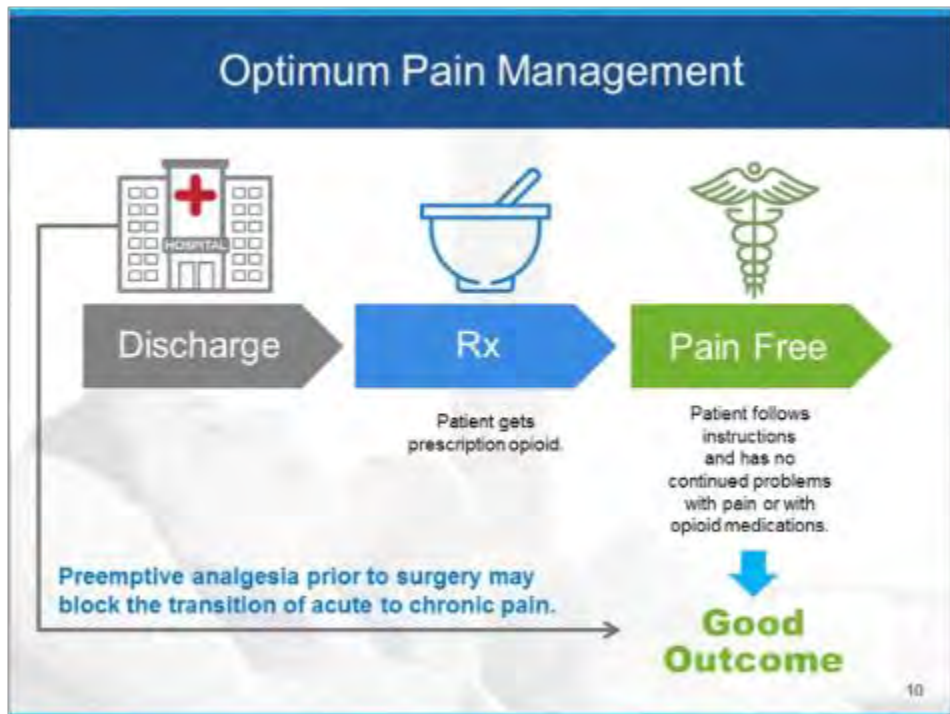
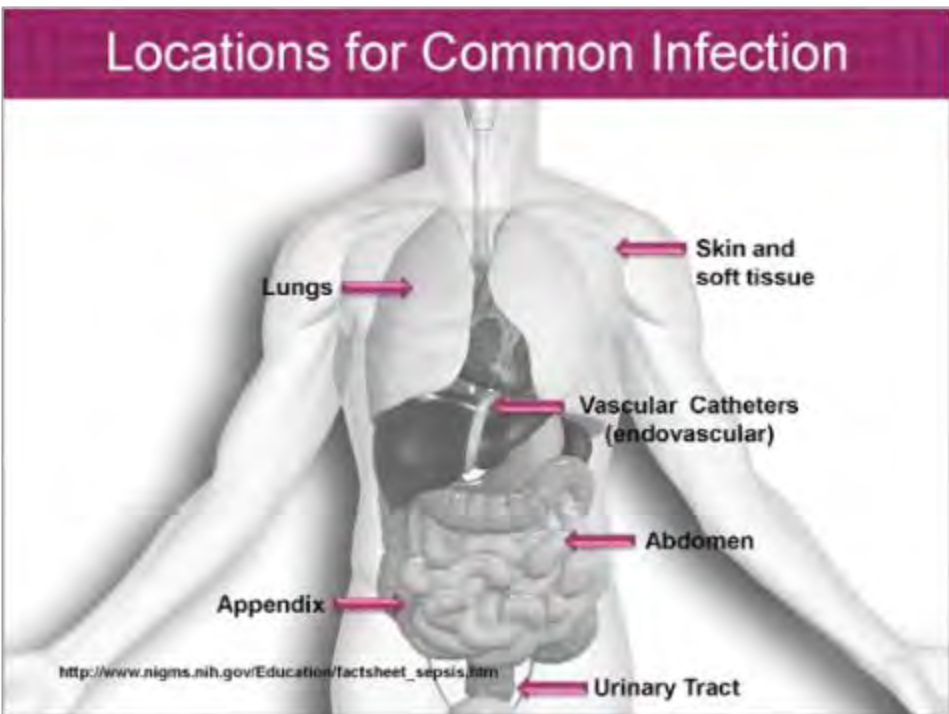
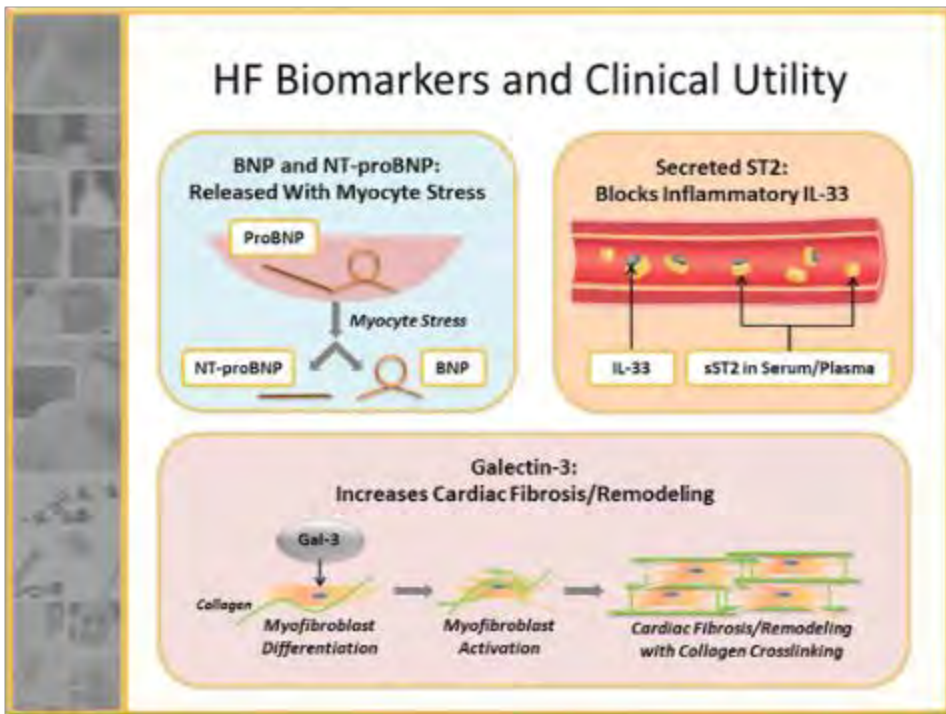
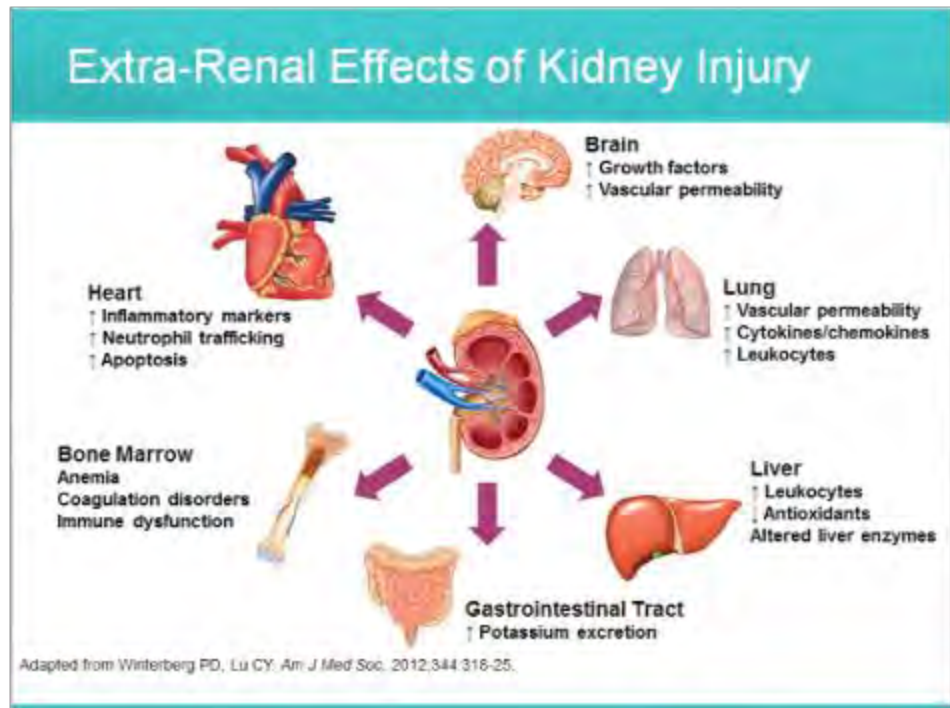
Ankist VE, Gaur RL, Schroeder LF, et al. *Diagn Microbiol Infect Dis* 2016;84(4):343-6

## *C. difficile* NAAT Can Facilitate Infection Control



Unpublished internal institutional data

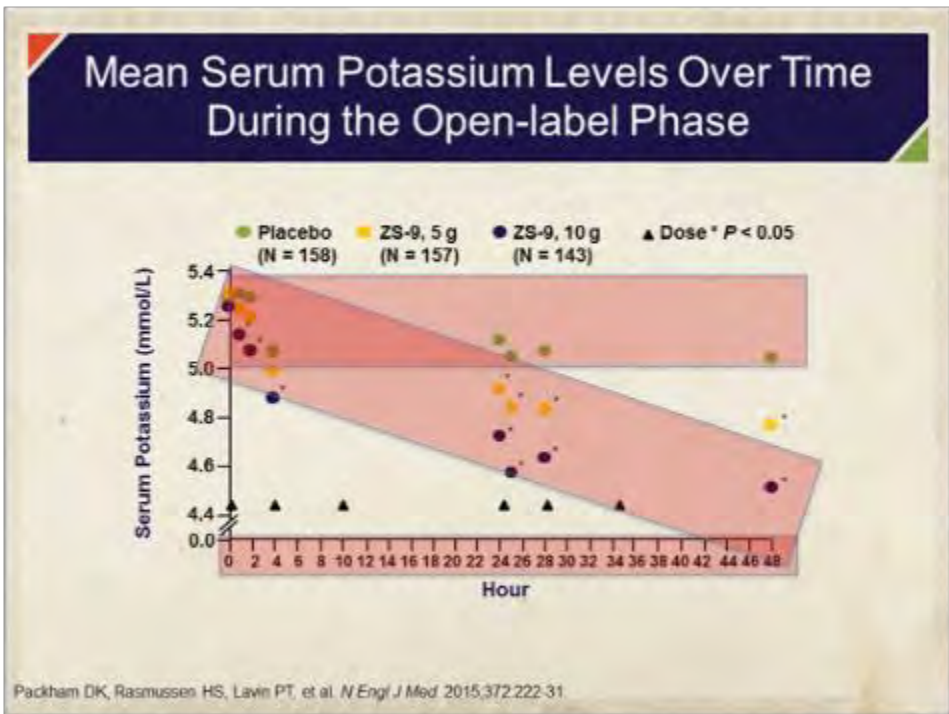




### New and Familiar Strategies With Medications

Russell D. Weisz, MD


TEAMHealth



## Hyponatremia in Critically Ill Patients

Over **30%** of patients admitted to the ICU have hyponatremia.<sup>1</sup>

Another **18%** will develop hyponatremia while in the ICU.<sup>2</sup>




1. Fakhri R, Penda BN, Jagali S, et al. Indian J Crit Care Med. 2014;18(1):1-7  
2. Mahmoud M, Khalil OA, Alili WM, et al. Life Sci J. 2013;10(2):115-20

## Phosphorus is One of the Seven Major Essential Minerals in the Body<sup>1</sup>


Phosphorus plays a role in:

- Skeletal development<sup>2</sup>
- Mineral metabolism<sup>3</sup>
- Cell membrane phospholipid content and function<sup>4</sup>
- Cell signaling<sup>5</sup>
- Platelet aggregation<sup>6</sup>
- Energy production in cells<sup>2</sup>

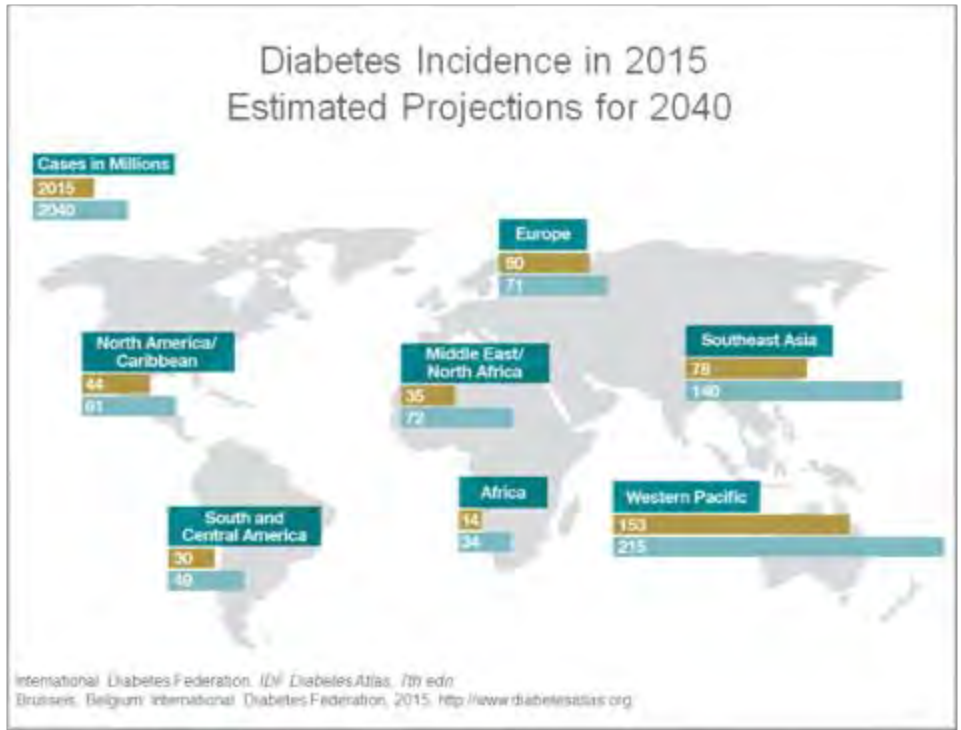
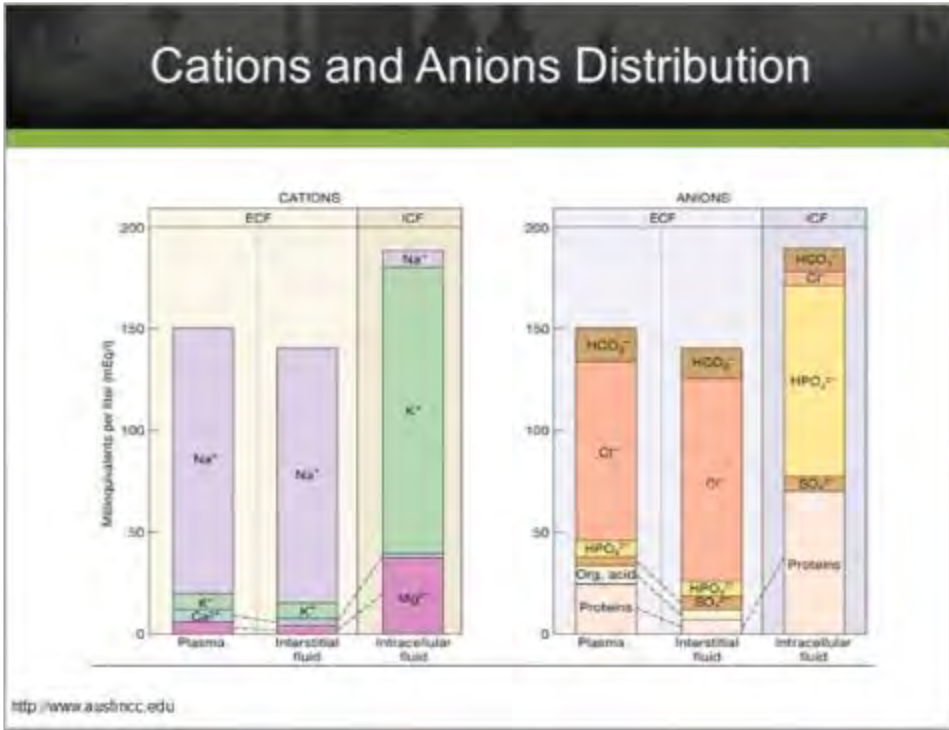


P, phosphorus  
1. Garrett RH, Grisham CH. Principles of Biochemistry With a Human Focus. Cengage Learning; 2001:438-69.  
2. Bringhurst FR, Demay MB, Krane SM, et al. In: Longo DL, Fauci AS, Kasper DL, Hauser SL, Jameson JL, Loscalzo J, editors. Harrison's Principles of Internal Medicine. 18th ed. 2012. pp. 3082-95.  
3. Quarles LD. J Clin Invest. 2008;118(12):3820-25.  
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. 817-50.  
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: Bowler Spurs and Progressive Skeletal Demineralization<sup>1,2</sup>

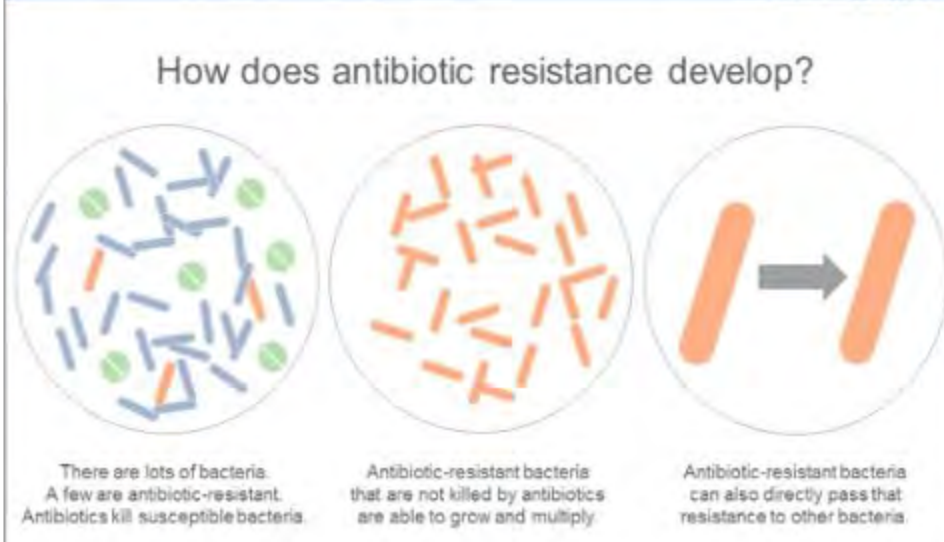


Images used with permission from Massachusetts Medical Society  
1. Whyte MP (2012); 2. Whyte MP (2008), references listed at end of presentation



## Antibiotic Resistance

### How does antibiotic resistance develop?

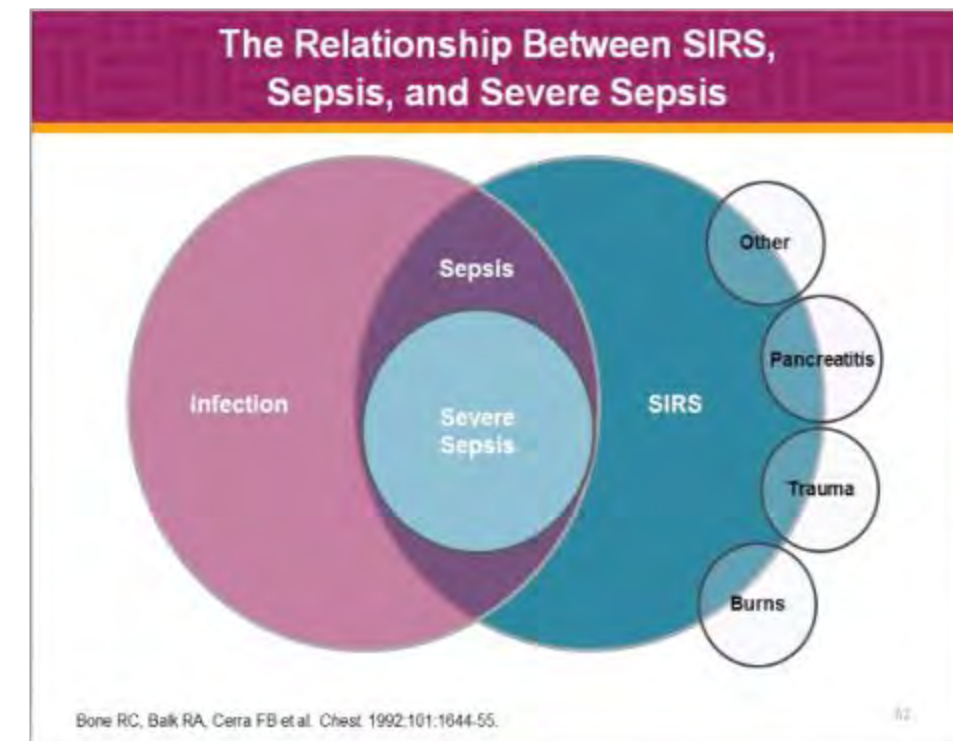
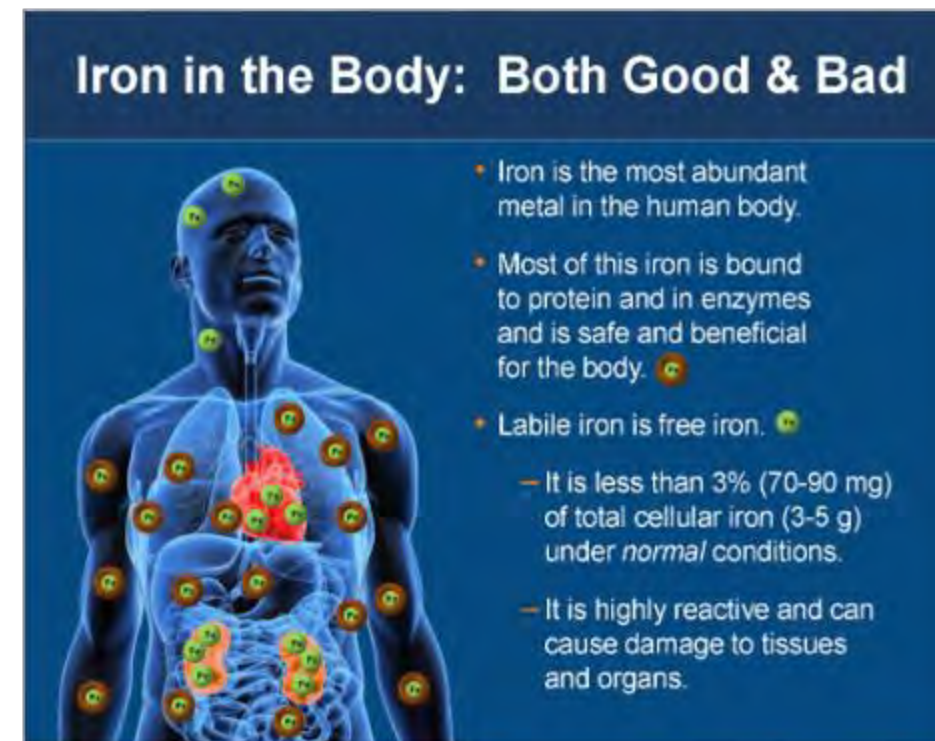
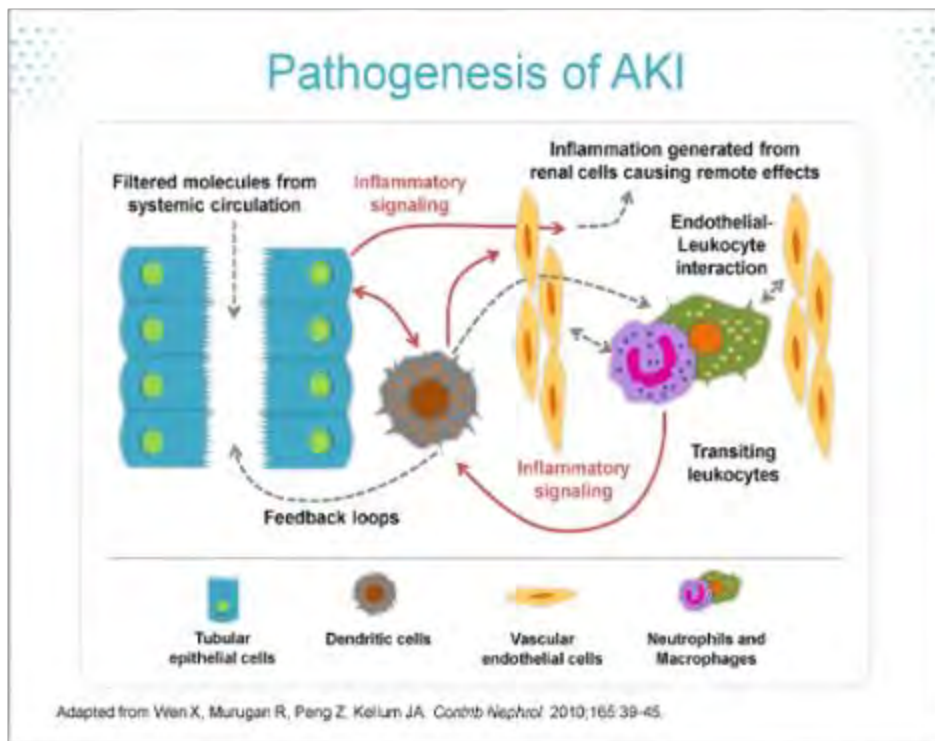
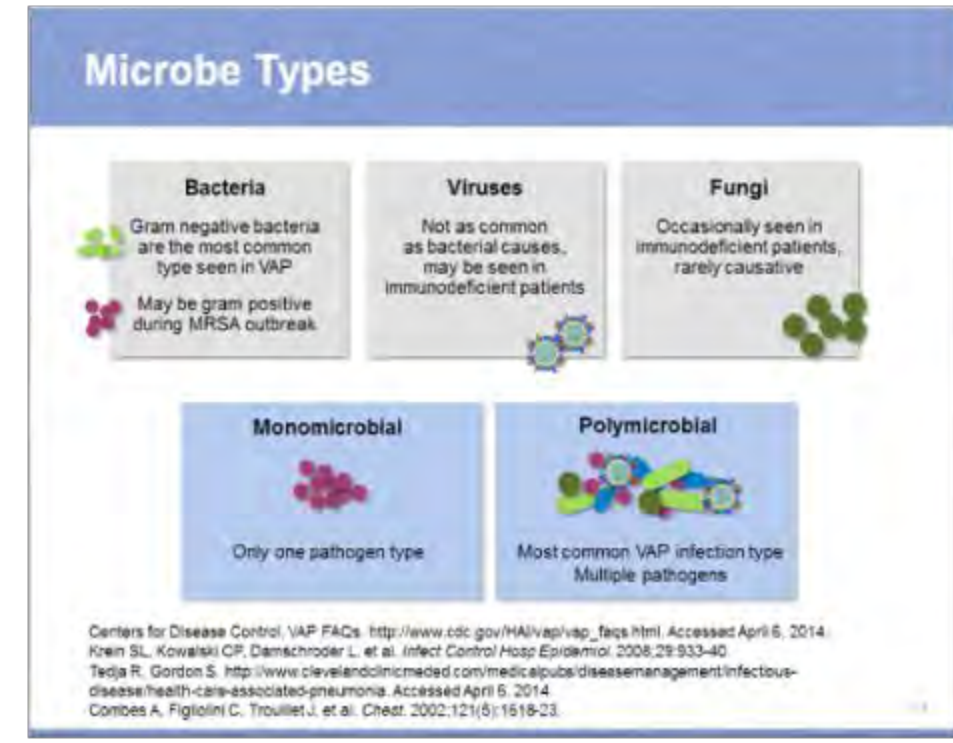
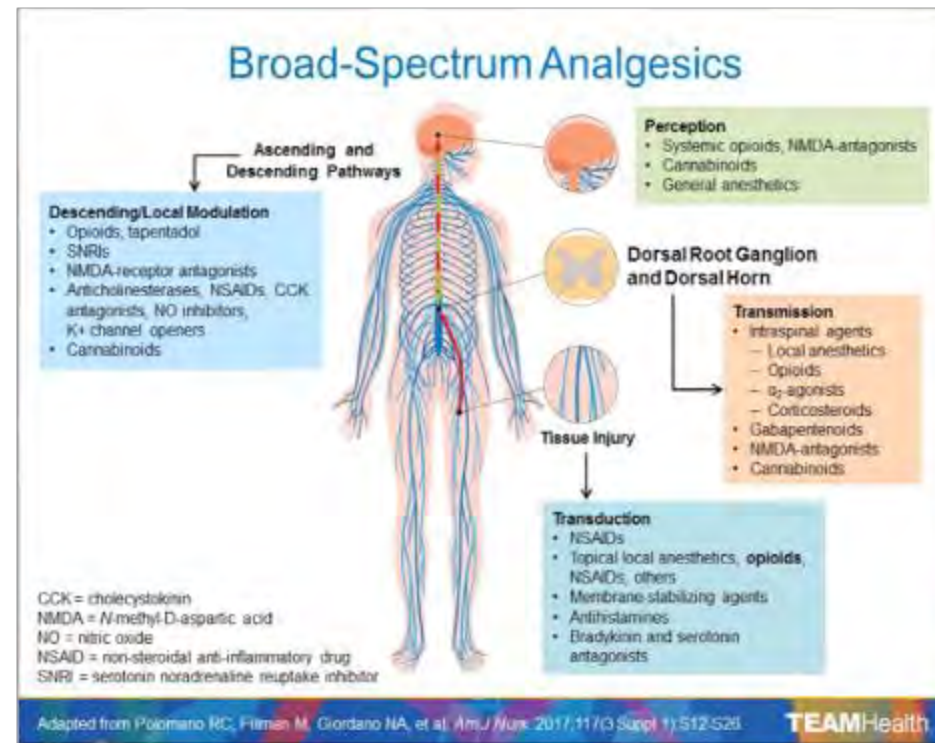
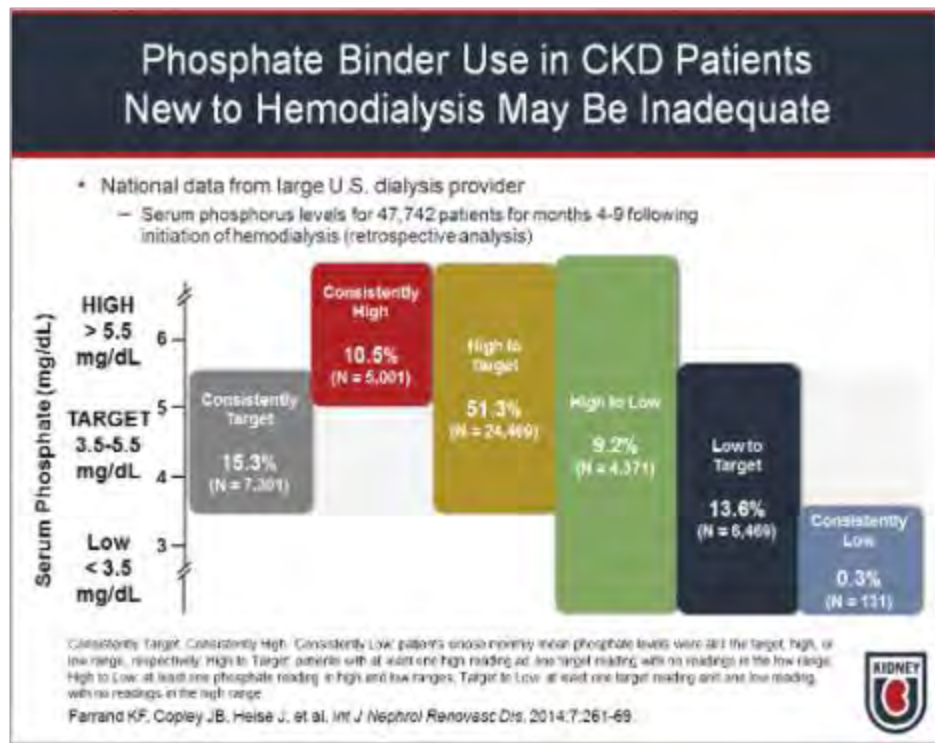


There are lots of bacteria. A few are antibiotic-resistant. Antibiotics kill susceptible bacteria.

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.ncbi.nlm.nih.gov/pmc/articles/PMC3401101/ Accessed 1/31/17



### 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

### 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<sup>1</sup>

1945 First inactivated human influenza vaccine licensed<sup>2</sup>

1946-47 Discovery of annual influenza viral mutations<sup>3</sup>

1967 First adamantane "amantadine" was first approved for treatment and prophylaxis<sup>4</sup>

1991 First reverse transcription-PCR (RT-PCR) assay for detection of influenza virus was described<sup>5</sup>

1993 Second adamantane, rimantadine, was approved<sup>6</sup>

1999 Two neuraminidase inhibitors, zanamivir and oseltamivir, were approved for prophylaxis and treatment of influenza<sup>7</sup>

2005 Cell culture-based vaccines<sup>8</sup>

1930 1940 1950 1960 1970 1980 1990 2000 2010

INFLUENZA 25

### Effect of Inflammation on Iron Concentrations

Infection, Inflammatory Stimulus

Liver

Hepcidin

Spleen

Iron

20 mg Iron/day

Plasma Fe-Transferrin

1-2 mg Iron/day

Duodenum

Bone Marrow

Senescent RBC

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

### Better Pain Control With Less Morphine

Morphine Units

59.5 mg Placebo

41.4 mg Ibuprofen

Patients treated with IV Ibuprofen used 31% less morphine

Single N, Rock A, Palfi 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

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