



# Laboratory Dimensions

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Volume 23, Issue 1  
March 2016

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## Laboratory Test Utilization Management

### The Need

The world of healthcare is changing in many ways. Reimbursement for medical services is decreasing in many areas, while the cost to provide the services is increasing. Fee-for-service reimbursement is transitioning to a more value-based model, where increased volume does not mean increased revenue. High quality care is rewarded by payers, and poor performers are penalized. High deductible insurance plans mean higher out-of-pocket costs for patients. Now there is an emphasis on having integrated Information Technology (IT) systems including electronic patient records. All of these factors lead healthcare systems to create a system that allows the right test to be ordered at the right time for patients. *Starting a utilization management program for laboratory tests has become essential for quality patient care, as well as cost containment.*

### Goals of a Utilization Management (UM) Program

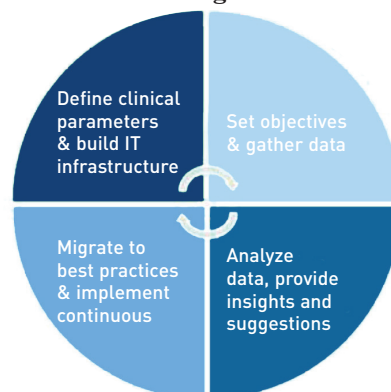
There is cost savings associated with UM efforts, but the main driver of a successful UM program is **patient-centered care**.

Important Components of the Overall UM Plan:

1. Standardizing processes and equipment
2. Reducing unnecessary testing
3. Promoting underutilized tests
4. Using algorithms for decision making
5. Optimizing ordering processes through IT

Each of these goals takes time to develop and requires a commitment to sustain and enhance them.

### Utilization Management Model



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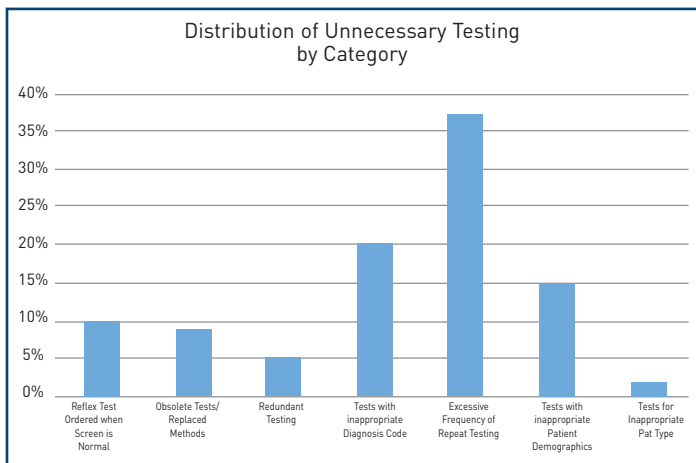
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Here are some examples of testing that may not be clinically appropriate:

- TSH normal, FT4 follow up
- Troponin, CKMB ordered together
- HgbA1c more than once every 21 days
- PSA, patient >75 years old
- 1,25-DiHydroxy Vitamin D to routinely measure Vitamin D unless hypercalcemia and decreased kidney function.

The following information is based on the evaluation of 100+ laboratories, “Can Real-time Dashboards Improve Lab Test Utilization,” presented by Thomas P. Joseph, MBA, (MT(ASCP) and Denis Burke, MBA of Visiun, on May 15, 2015.



## Sanford's Approach

Sanford Health has started a UM program for laboratory testing. At its core is a “Laboratory Test Utilization Management (LTUM) committee”. This group includes a co-chairperson, pathologists, local physician champions, Information Technology, quality— as well as technical experts within the laboratories. Proposals for changes that reflect best practice are brought forward to the committee. These “targets” include removal of obsolete tests, elimination of standing

orders, creating Best Practice Alerts (BPA) for clinicians as they order tests, and reduction of the “shotgun” approach to test ordering. Algorithms may be created so appropriate tests will be reflexively ordered based on a single order placed by the clinician. *The algorithmic approach eliminates unnecessary testing and standardizes the process across the system.*

One area that has been a focus of UM nationally is genetic testing. There is a large menu of genetic tests available because of new technology and the ability to mainstream these specialty tests. They are also very costly compared to routine laboratory tests. Taking a “shotgun” approach to genetic testing is very expensive to the patient and may not yield any more useful information than a single, specific test. Sanford Health has genetic counselors that are an integral part of aiding clinicians and patients in getting the appropriate tests ordered, as well as a resource for interpretation of the tests.

A foundational element to a UM program is *an integrated medical record across the healthcare system.* Sanford Health shares a common electronic medical record, as well as ancillary systems that create a uniform means to implement systematic changes. Tests that are deemed obsolete may be removed across the system by IT. Best Practice Alerts may be created to “pop up” when a clinician is ordering a test to give some guidance on alternative or more appropriate tests. These “pop-ups” can indicate that a patient had a particular test recently, saving the patient an additional blood draw, as well as eliminating duplicate charges. In the future, there may be the ability to give the clinicians one-click access to a library of algorithms, so they may be able to easily and consistently select the best test or tests for the patient.

## Summary

The delivery of healthcare is an ever-changing model. *There needs to be a change of focus from treating the sick, to caring for the population before they require the most expensive types of care.* Appropriate treatments and utilization of ancillary services will continue to be considered and refined. All of this work ultimately provides high quality, cost effective care for our patients.

## Meet Our New Regulatory Manager

Raema Neugebauer is a results driven healthcare professional with over 25 years of clinical laboratory and management experience in both the hospital and clinic settings. Raema has a Bachelor's degree in Medical Technology, is ASCP certified, and has a Master's degree in Healthcare Administration. She has served as the Clinical Supervisor, COLA Director, and Technical Consultant for multiple Sanford Laboratories

clinic laboratories, facilitating successful inspections and accreditations through COLA, CAP, and CLIA.

Raema's experience provides the ability to constructively engage and collaborate with all operational and clinical healthcare stakeholders to focus on delivering patient centric healthcare. As Sanford Laboratories Regulatory Manager, Raema can assist

with consulting and identifying operational and process improvement opportunities, root cause analysis, and strategic implementation planning. Raema comes to this position well prepared to meet your needs. “Since the laboratory plays such a crucial role in healthcare delivery, I am committed to strengthening value-added services in the ongoing efforts of providing quality patient care.”



**Raema Neugebauer,**  
MHA, BA, MT(ASCP)

# Clostridium difficile—Understanding the Need for the 2-Step Algorithm

The diagnosis of *Clostridium difficile* infection (CDI) is based on clinical history and the presence of diarrhea in combination with a laboratory test. The optimal test to be used for laboratory diagnosis of CDI has been a topic of controversy dating back to before the advent of enzyme immunoassays and the promise of a rapid diagnosis. Much of the debate includes disagreement between diagnostic tests and how they should be utilized therefore resulting in a lack of confidence in clinical decisions and public health reporting.

## What are the challenges of diagnosing CDI?

1. **Asymptomatic carriers of *C. difficile*:** It is estimated that 3-15% of healthy adults are colonized with *C. difficile*. In newborns and healthy infants carriage seems to vary depending upon age of the child, but by their third birthday rates drop to that seen in adults. Colonization of residents in long term care facilities may be as high as 57%. *How do we then distinguish carriers who present with diarrhea from individuals with true infection?*
2. **Diagnostic assays either detect the bacterium, toxins or toxin genes:** Enzyme immunoassays (EIAs) and lateral flow tests detect the presence of toxin and in some assays the presence of glutamate dehydrogenase (GDH). Nucleic acid amplification tests detect the presence of a toxin gene.
3. **There are two reference or gold-standard methods each detecting a different target, the cell cytotoxicity assay and the cytotoxigenic culture:** the cell cytotoxicity assay detects the toxin present in the fecal sample. This assay is the best indicator of active disease. It does not detect carriers (or potential excretors). This assay will match more closely with CDI based on clinical indicators and patient outcomes. The cytotoxigenic culture answers the question of whether or not *C. difficile* bacteria are present, and if they are, they have the ability

to produce toxin. It is the best at detecting the bacteria but not in terms of detecting disease. The problem with both of these reference or gold-standard assays is the difference in targets tested and the lengthy time to obtain a result rendering them impractical as diagnostic laboratory tests. Several commercial diagnostic assays have been compared to one of the reference methods therefore hindering the laboratories in their ability to determine which assay most accurately aids in detection of true CDI.

4. **There is no test of cure:** Test of cure has not been recommended by any guidelines and therefore **NO** laboratory test can determine the absence of the organism. The organism can persist for up to 30 days in 20% of patients that have resolved their symptoms of diarrhea.

Inaccurate diagnosis has implications for infection control practice, patient management and performance management for institutions, therefore both the healthcare provider and the laboratory must have a clear understanding of what the laboratory assay targets.

## What is the target for each of the diagnostic laboratory assays?

1. **Glutamate dehydrogenase (GDH):** will find all *C. difficile* organisms, toxin producers and nontoxin producers, in addition it will find other Clostridium. It has good sensitivity and the ability to predict a negative result; however the specificity for the toxin is low.
2. **Toxin enzyme immunoassays:** detect the presence of the toxin. This test method is highly specific for toxin detection but fails in sensitivity.
3. **Nucleic acid amplification tests (NAATs):** detect toxin gene, which means the detection of toxigenic organisms rather than the toxin in the stool. NAATs

are highly sensitive and specific for toxin gene detection but will not discern if there is free toxin present in the stool.

Polage et al demonstrated in an observational study that patients who were *C. difficile* toxin negative by EIA but positive by PCR had significantly less diarrhea at the time of testing, more rapidly resolved their diarrhea and had fewer complications or deaths than those who were positive by both the EIA and the PCR tests. His study also noted that patients who were negative for toxin by EIA but positive by PCR had presentations and outcomes no different than patients who were negative by EIA and PCR. The strength of Polage's study is the large number of samples tested, the inclusion of clinical data and the follow up of patients after discharge. Another large study by Planche et al found that when death from CDI occurred, it was more likely in a patient positive for toxin than those who were colonized but did not have toxin detected. His observation also included that death among patients who were colonized but did not have detectable toxin was not different from patients who were not colonized with *C. difficile*.

These studies and others have prompted discussions of algorithmic testing in the literature. In March, 2016 the Clinical Practice Committee for Sanford Enterprise approved changes to the CDI clinical guideline for adults. One major change was the implementation of a 2 test laboratory algorithm using PCR to identify the gene for toxin-B production and then reflexing all positive PCRs to an EIA to determine the actual presence of toxin. The studies performed by Polage, Planche and their colleagues appear to contribute to the growing evidence that NAAT assays found to be positive with no toxin detected may represent colonization and not true CDI. Whichever test or combination of tests is used to aid in the diagnosing of CDI, it is important to realize that careful selection of the patient to test is as vital as the understanding of the principle of the laboratory test utilized.

Sanford Laboratories offers the two-step algorithm, *C. difficile*

Address Service Requested

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toxin B by NAD, reflex to A/B Toxin Detection; test code NBLD0538.

- In addition, for those facilities which wish to optimize your own testing with the second step process we offer the individual test assays:
  - *C. difficile* Toxin B by Nucleic Acid Detection (NAD); test code NBLD0386
  - *C. difficile* Toxin A/B; test code NBLD0224

References:

Optimizing the Laboratory Diagnosis of *Clostridium difficile* Infection. Peter H. Gilligan. Clin Lab Med 35 (2015) 299-312.

Overdiagnosis of *Clostridium difficile* Infection in the Molecular Era. Polage CR et al. JAMA Intern Med. 2015 Sep 8:1-10.

Differences in outcome according to *Clostridium difficile* testing method: a prospective multicenter diagnostic validation study of *C. difficile* infection. Timothy Planche et al. Lancet Infect Dis 2013;13: 936-945

## New Order Code for Occult Blood Testing

We are standardizing our methods for Fecal Occult Blood testing throughout the Sanford Enterprise Region and are changing the order codes to make them simpler and more descriptive.

Sanford Laboratories replaced test ordering code **NBLD0298 Occult Blood Fecal (iFOB)** with **NBLD0510 Occult Blood, CRC Screen (FIT, IMMUNOCHEMICAL)**.

### **NBLD0510 OCCULT BLOOD, CRC SCREEN (FIT, IMMUNOCHEMICAL)**

This test is ordered when screening for Colorectal Cancer (CRC). This is a fecal immunochemical test (FIT, iFOB) method that is performed in the laboratory. **FIT** is the recommended method for colorectal cancer screening. This method only requires one sample, thus increasing patient satisfaction and compliance over the previous three screening cards.

As noted in our *16th Edition Catalog of Services – Update #11* sent to our Sanford Laboratories' clients on January 12th, 2016: "*There were no changes to the Methodology, CPT code, or pricing. Test name is being updated to more accurately reflect current methodology.*" In addition, no changes were made to the specimen requirements.

Note: The guaiac method, which is typically performed at the primary care setting, is the preferred method when an active bleed is suspected.

If you have questions about this updated information on **Occult Blood Testing**, please call the Sanford Laboratories' Client Support in your region.