



**Quality Corner**




By Rhonda Burgard, Client Services Supervisor

**Workflow Analysis**

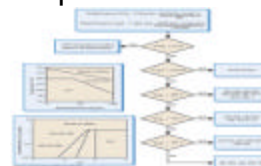
The path of workflow is the sequence of events from the initiation of a laboratory request through the provision of a test result including any necessary follow-up that contributes to patient outcomes.

Understanding the path of workflow provides the laboratory with the opportunity for identification of decision points that may be error prone or may provide an opportunity for efficiencies.

Lean, the Toyota Production System, tools of "flow" and "value stream mapping" may be useful in the analysis of workflow processes.

**Flow Analysis:** Track the movement of an individual sample or patient through an entire process. Observe the movements and document the decisions of the person performing the task at each step in the process. Flowcharting software can be used for documentation. List the steps in the process. Use the  symbol to indicate the start and end of a process. Use the  symbol to indicate an action step. Use the  symbol to indicate a

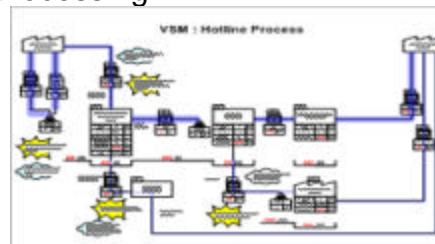
decision point. Directional arrows indicate the flow of the process.



Spaghetti diagrams can be used to document the physical distances between steps in a process. This allows the laboratory to identify opportunities for improvement by redesign of the workspace or reducing the number of locations a sample or patient is moved to.



**Value Stream Mapping:** Analysis of each step in the process to include processing time, batch size, cycle time, reliability, and the location of errors allows the laboratory to identify efficiencies and to reduce total testing time, material usage, errors and over-processing.



Additional resources are available on the Joint Commission website [www.jointcommission.org](http://www.jointcommission.org).

## Cyclosporine and FK506 Testing

By Rhonda Burgard, Client Services Supervisor

Cyclosporine (Test code QCYC) and Tacrolimus (Test code FK506) is now being performed by enzyme multiplied immunoassay technology (EMIT) on a Siemens instrument platform.

The new Cyclosporine method provides results that run approximately 15% lower than the previously used Abbott method but more closely reflect the HPLC/MS test method that is considered the gold standard for these tests.

The therapeutic ranges for Tacrolimus and Cyclosporine are:

- Cyclosporine (QCYC) 85-225 ng/ml (new range)
- Tacrolimus (FK506) 5-20 ng/ml (No change in range)

(Cyclosporine tests sent to ARUP laboratories (Test code CYCA) are unaffected by this change.)

## Infection Prevention

By Rhonda Burgard, Client Services Supervisor

The Center for Medicare and Medicaid Services (CMS) has clarified the infection control guideline for moving devices between patients. If a device such as a glucose meter is used in one patient room and then transported to a second patient room for use there is a potential for the device to carry blood borne pathogens.

CMS requires that portable test devices or any other item that is placed on a surface in a patient room must be decontaminated with 1:10 bleach solution or other CDC level IV disinfectant before being moved to another patient's room.

Items such as tourniquets should be left in the patient room for single patient use only and discarded at discharge.

For outpatients, the recommendation is to use disposable tourniquets and to disinfect the arm of the drawing chair between patients.

Always remember to disinfect hands between each patient draw.

## Ice Packs

By Rhonda Burgard, Client Services Supervisor

Please use only Northern Plains Laboratory supplied gel -shipping packs when sending specimens. These packs have been validated to keep specimens at the appropriate transportation temperatures. It is important to only use blue packs to send frozen specimens and only white packs for refrigerated specimens. Use of non-approved packs or the incorrect pack type may contribute to inappropriate shipping temperatures. Approved ice packs are:

	Temp	Item number	Description	Dimension
Blue Gel Pack	Frozen	80096	XC-12-R	6"x6"
White Gel Pack	Refrig	801084	ProPack Polar Pack Koolit Therma Frost	6" x 6"

To avoid damage to the Styrofoam coolers, please do not use gel packs larger than the approved dimensions.

Remember during cold weather conditions to prevent samples from freezing, add extra packing material (paper) to fill any empty spaces in the shipping container.

## Clostridium difficile by PCR

By Ron Piatz, Research and Development

Northern Plains Laboratory (NPL) is pleased to announce the addition of the Cepheid Xpert *Clostridium difficile* assay to our in house test menu. The Cepheid Xpert *C. difficile* Assay is a qualitative *in vitro* diagnostic test for rapid detection of Toxigenic *C. difficile* from unformed (liquid or soft) stool specimens collected from patients suspected of having *C. difficile* infection.

Prior to the addition of PCR testing, enzyme immunoassay (EIA) methodology was utilized to detect *C. difficile* toxins. EIA methodology lacks the sensitivity of newer PCR tests. The sensitivity of the Xpert *C. difficile* assay is listed at 94% plus the assay provides a rapid result with total testing time less than one hour. The more sensitive PCR methodology will eliminate the need for repeat testing on patients with negative test results.

*Clostridium difficile*, a gram-positive spore-forming anaerobic bacillus that was first linked to disease in 1978, is the major cause of antibiotic-associated diarrhea (AAD) and pseudomembranous colitis. Mature colonic bacterial flora in a healthy adult is generally resistant to *C. difficile* colonization. However, if the normal colonic flora is altered, resistance to colonization is lost. The most common risk factor is exposure to antibiotics. *C. difficile*'s primary virulence factor is cytotoxin B. The genes coding for toxin A (*tcdA*; the enterotoxin) and toxin B (*tcdB*) are parts of the pathogenicity locus (PaLoc). Most pathogenic strains are toxin A-positive, toxin B-positive (A+B+) strains although toxin A-negative, toxin B-positive (A-B+) have been recognized as pathogenic. The Xpert *C. difficile* assay utilizes automated

real-time polymerase chain reaction (PCR) to detect toxin B gene sequences (*tcdB*) associated with toxin producing *C. difficile*.

### Specimen:

- Collect 1 mL or 1 gm of liquid or unformed stool specimen in a clean container. Stool is stable for 24 hours at room temperature or 5 days at 2-8°C.

Test Code	CPT Code	Test Name	Specimen Requirements	Reference Range
CDP	87798	<i>Clostridium difficile</i> by PCR	Stool sample	Negative

## New Drug Testing Options

By Ron Piatz, Research and Development

Northern Plains Laboratory (NPL) has recently evaluated improved options for serum and urine drug testing. Factors evaluated included drugs detected, detection limits, confirmation testing and improved report format.

Below is a list of new MEDTOX drug screens, which will be offered by NPL.

These tests from MEDTOX laboratories offer comprehensive pain management and drugs of abuse tests that provide screening and automatic confirmatory, quantitative results for detected drugs. The urine results are corrected for creatinine with appropriate units (ng/mg creatinine) and reported by drug category. The reports also include interpretive comments that correlate the patient's test results to the patient's medication (drug) regimen if the patient's list of medications is provided with the order for the test.

### **Pain management drug screen, comprehensive, urine with reported medications (Test code: PCUMX)**

This is a comprehensive urine drug screen that is specifically intended for pain

management testing. This test provides screening and confirmatory, quantitative results for detected drugs including fentanyl. The results are corrected for creatinine and reported by drug category.

The PCUMX report also includes interpretive comments that correlate the patient's test results to the patient's medication (drug) regimen. The patient's list of medications is provided with the order for the test. The "Patient Prescription Regimen" form can be found in the NPL Test Catalog at [www.northernplainslab.com](http://www.northernplainslab.com). Select the PCUMX test code and follow the link. Test results are flagged as UNEXPECTED if they do not match the patient's medication regimen. Trending of patient test results is available for providers with the appropriate security access.

NPL encourages the use of test code PCUMX for pain management testing. The options for urine drugs of abuse testing are either the DSCR qualitative test or the PCUMX test if confirmatory, quantitative results are desired. These tests replace the current urine drug screen test, which was previously sent to MEDTOX. (Test code: DSMTX)

#### **Drug screen 10, serum, MEDTOX (Test code: PCSMX)**

This is a serum drug of abuse screen which tests for 10 different drug categories. Categories tested are: amphetamines, barbiturates, benzodiazepines, cocaine and metabolites, opiates, oxycodone, phencyclidine, THC, methadone, and propoxyphene. This test provides screening by immunoassay and reflex to confirmatory, quantitative results for detected drugs. This test replaces the Drugs of Abuse 9 Panel, Serum or Plasma, which was previously sent to ARUP (Test code: DS9A)

#### **Pain management drug screen, comprehensive, blood with reported medications (Test code: PCFMX)**

This is a comprehensive drug screen on whole blood (serum is also acceptable) that is specifically intended for pain management testing. This test provides screening and confirmatory, quantitative results for detected drugs including fentanyl. The results are reported by drug category.

The PCFMX report also includes interpretive comments that correlate the patient's test results to the patient's medication (drug) regimen. The patient's list of medications is provided with the order for the test. The "Patient Prescription Regimen" form can be found in the NPL Test Catalog at [www.northernplainslab.com](http://www.northernplainslab.com). Select the PCFMX test code and follow the link. Test results are flagged as UNEXPECTED if they do not match the patient's medication regimen. Trending of patient test results is available for providers with the appropriate security access.

#### **Fentanyl, urine (Test code: FNTLU)**

Order this assay if only a urine fentanyl level is desired. Note: Do not request this assay in addition to test code PCUMX. The PCUMX test already includes a fentanyl screen with reflex to a confirmatory, quantitative result.

#### **Fentanyl, serum (Test code: FNTLS)**

Order this assay if only a serum fentanyl level is desired. Note: Do not request this assay in addition to test code PCFMX. The PCFMX test already includes a fentanyl screen with reflex to a confirmatory, quantitative result.

Test Code	CPT Code	Test Name	Specimen Requirement	Ref Range
PCUMX	80100 80101(x9) 82570	Pain Management Drug Screen, Comprehensive, Urine	30 ml (3 ml min) of random urine - Send at 2-8°C	By report
PCSMX	80101(x10)	Drug Screen 10, Serum, Medtox	5-10 ml of serum from a plain red top or plasma from a grey top, EDTA or heparin tube. - Send at 2-8°C	By report
PCFMX	80100 80101(x12)	Pain Management Drug Screen, Comprehensive, Blood	10 ml whole blood (grey top tube) or serum from a plain red top tube. - Send at 2-8°C	By report
FNTLU	80101 82542 (if pos)	Fentanyl, Urine	10 ml of random urine - Send at 2-8°C	By report
FNTLS	80101 82542 (if pos)	Fentanyl, Serum	3 ml serum from plain red top tube - Send at 2-8°C	By report

### Specimen processing

By Todd Pace, Core Lab Supervisor

During a recent study, primary gel serum tubes were inspected for visible red cell contamination. 41% of 376 primary tubes studied had visual red cell contamination and had to be aliquoted and re-spun. Red cell contamination of serum samples can affect some test results. We recommend prior to sending samples in primary tubes, you carefully inspect the tube to make sure the gel barrier is completely intact and that there are no visible red cells in the serum portion of the sample. To assure even better test results we recommend you aliquot the serum sample into a "pour off" tube prior to sending to NPL.

### ARUP Test Changes

By Rhonda Burgard, Client Services Supervisor

The reference interval has changed for the Inhibin B (ARUP 0070413) test. The Generation II assay currently in use at ARUP laboratories has an increased affinity

for Inhibin B, resulting in higher values (approximately 50%) than the Generation I assay. Undetectable results remain the same.

Estradiol, Thyroglobulin, TPO and Thyroid antibody assay test methodology will change on April 12th, 2010. Please note new specimen requirements, performance schedule and reference intervals for these tests. (See the ARUP test catalog at HYPERLINK "<http://www.aruplab.com>" [www.aruplab.c](http://www.aruplab.com))

OKT3, Circulating Drug Level (ARUP 0095895) test has been discontinued.

### NPL Test Code Changes

By Rhonda Burgard, Client Services Supervisor

Enclosed with this newsletter is a list of test code changes. Please note there are two new test codes that may be of particular interest.

Order the test code "ANC" when only an anaerobic culture and identification are required (aerobic organism identification reported by submitting laboratory).

Order the test code "RFLXA" when an "ANA" was ordered and reported and the physician wants to add reflex testing for SSA, SSB, SMITH, RNP, CENT, HISTN, and JO1.

### Mayo Test Information

By Rhonda Burgard, Client Services Supervisor

Mayo Medical Laboratories will not be printing a hard copy of their test catalog in 2010. Updated test information is available on-line at [www.mayomedicallaboratories.com](http://www.mayomedicallaboratories.com).

The patient information sheet specific to several genetic testing assays is now mandatory. For specimens received without the completed information sheet Mayo will

hold the specimen for 96 hours past the draw time and then will perform testing. There is a link to the form on the Mayo website for each of the specific tests.

### **Sweat Chloride Screening**

By Todd Pace, Core Lab Supervisor

Based on a recommendation from the Cystic Fibrosis Foundation, the Sweat Chloride Screening test will no longer be offered by NPL. The Sweat Chloride Screen is a semi-quantitative test for sweat chloride. Results were reported as Negative (<40 meq/L), Borderline (>40 but <60 meq/L), or Positive (>60 meq/L). The Cystic Fibrosis Foundation recommended in a recent inspection of the CF Center at St. Alexius Medical Center that the semi-quantitative test be discontinued and replaced with the quantitative test for sweat chloride.

The Sweat Chloride, Quantitative test will continue to be performed at NPL. All orders for Sweat Chloride Screening will be performed using the quantitative sweat chloride method. Sweat Chloride testing is done by appointment only. Arrangements for sweat chloride testing can be made by calling NPL at 530-5700

### **Internet-based Provider Enrollment, Chain and Ownership System (PECOS)**

By Denise Semerad, Billing Specialist

The Centers for Medicare & Medicaid Services (CMS) has implemented an Internet-based Medicare provider enrollment process known as Internet-based Provider Enrollment, Chain and Ownership System (PECOS).

All physicians are **required** to enroll in this program as soon as possible so their information will be in the system effective January 1, 2011.

CMS indicated that it would not pay claims where the referring or ordering physician or health care practitioner is not in the PECOS database.

If your physician(s) are not in the PECOS database, and you are sending referral work for a Medicare beneficiary to Northern Plains Laboratory or Pathology Consultants, PC, Medicare will DENY our claims.

The following information is available to help you determine if you are set up correctly as a Medicare participating physician in PECOS.

1. Have an NPPES User ID and password to use Internet-based PECOS.
2. Go to Internet-based PECOS by clicking on this link. <https://pecos.cms.hhs.gov/>

### **Northern Plains Laboratory Fall Seminar**

By Rhonda Burgard, Client Services Supervisor

The NPL Fall Seminar will be held Thursday, September 16<sup>th</sup> at the Ramkota Hotel in Bismarck, ND. A social and golf outing is planned for the evening of Wednesday, September 15<sup>th</sup>. If you have suggestions for topics or speakers please email Rhonda Burgard at [rburgard@primecare.org](mailto:rburgard@primecare.org). A full agenda and registration form will be enclosed with the June NPL newsletter.