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Quality Corner- Process Control

By Rhonda Burgard, Client Services Supervisor

Process control encompasses the activities involved in ensuring a laboratory process is stable, predictable and operating at an acceptable level of performance with only normal variation.

Aspects of process control include

- Standard Operating Procedures- This include instructions for how to perform a task and list the requirements of quality control of the test method.
- Process validation- The collection of data specific to the test method like test validation information, risk assessments, reagent receipt and storage, internal and external quality control and training and competency records can identify gaps within a new or problem prone process.
- Computer system validation- Validation of the computer system is required at installation and also when there are changes to software and/or hardware.
- New test validation- All new analytical tests must be validated for accuracy, precision, reportable range, reference intervals, and linearity.
- Quality control- Two levels of quality control are required daily unless the test method is eligible for an Individual Quality Control Plan (IQCP). Quality control outliers must be investigated and corrective action implemented before reporting patient values. In addition the laboratory must participate in external quality control thru enrollment in proficiency testing programs.
- Training- All staff performing a test must document proof of training and annual competency. All six elements of competency, direct observations, unknown sample analysis, result review, problem solving, direct observation of instrument maintenance and review of intermediate test results, must be documented.
- Tracking and Trending-The laboratory should conduct periodic audits of its processes looking for gaps in performance.

Reference: AABB Technical Manual 19th Edition

ASO Reportable Range Change

By Michelle Steiner, Core Lab Supervisor

The upper reportable range for ASO titer (test code ASO) has changed from 1000 IU/mL to > 750 IU/mL.

If you have any questions or concerns please contact NPL at 701-530-5700 or 1-800-645-1003

Vitamin D Testing

By Patti Schmidt, CPC, Billing Supervisor

Please share with providers as this was previously published in the NPL newsletter in March of 2019: Effective January 1, 2019, BCBS established a policy for payment of the Vitamin D assay. Per their rationale, Vitamin D testing is only appropriate in higher risk patients (ex. Osteoporosis, chronic kidney disease, long term high risk medications known to lower Vitamin D, known vitamin D deficiency). Routine screening or complaints of fatigue are not considered appropriate reasons for testing but we continue to see those diagnoses and others being used. Also, we are continuing to see that BCBS has not changed their policy since putting it into effect on January 1, 2019. They are not reimbursing for the testing and NPL is not able to bill the patient. The 2019 medical policy is located at: http://wwww.bcbsndmedicalpolicy.com/documents/vitamin-d-assay/

ARUP Change to Monoclonal Protein Test

By Rhonda Burgard, Client Services Supervisor

ARUP Laboratories has replaced the Bence Jones Protein, Quantitation and Characterization with reflex to Kappa/Lambda Free Light Chains with Ratio (Urine) (NPL test code BJPUR, ARUP test # 2002464) and the Kappa and Lambda Free Light Chains (Bence Jones Protein), Quantitative, Urine (NPL test code IFEU, ARUP test # 0050618) with the Monoclonal Protein Study, 24 hour, Urine (ARUP test # 3002105. NPL test code stays BJPUR) and Light Chains Test (ARUP test # 3002104. New NPL test code IFFLU). These tests do not include any reflex testing.

Quantitative Fecal Fat

By Rhonda Burgard, Client Services Supervisor

Northern Plains Laboratory has inactivated the Quantitative Fecal Fat (FFAT) test code. Substitute tests are:

- Fat, Fecal Qualitative (ARUP test # 0020385) NPL test code (FAT)
- Fat, Fecal Quantitative 24-Hour Collection (Includes Homogenization) (ARUP test # 2002354) NPL test code (NPL test code: Ref, comment in ARUP test name/number)
- Fat, Fecal Quantitative 48-Hour Collection (Includes Homogenization) (ARUP test # 2002355) NPL test code (NPL test code: Ref, comment in ARUP test name/number)
- Fat, Fecal Quantitative 72-Hour Collection (Includes Homogenization) (ARUP test # 2002356) NPL test code (NPL test code: Ref, comment in ARUP test name/number)

If you have any further questions, please contact NPL at 1-800-645-1003.

A1c Reference Range Change

By Michelle Steiner, Core Lab Supervisor

The hemoglobin A1C Reference Range has been changed to reflect the most current ADA recommended ranges (see below).

NGSP%	Suggested Diagnosis	Sample Type
≥6.5	Diabetic[4-6]	EDTA whole blood
5.7–6.4	Pre-Diabetic[4]	
<5.7	Non-Diabetic	
Recommended by the American Diabetes Association (ADA): American Diabetes Association. Diagnosis and Classification of Diabetes Mellitus. *Diabetes* Care **2010**, *33* (Suppl. 1), S62–S69.		

Manual Requisitions

By Rhonda Burgard, Client Services Supervisor

Manual requisitions no longer require that the numbered sticker be attached to the upper right hand corner of the requisition. Requisitions will be provided that have your location code pre-printed on them. If you have a stock of manual requisitions on hand, please continue to use them but handwrite your location on the requisition in the upper right hand corner.

The small numbered stickers are no longer required on each individual specimens submitted. Please make sure all specimens are labeled with two unique identifiers, patient first and last name and either a date or birth or medical record number. It is recommended that the date & time of collection also be noted on the specimen. If different specimen types are sent to NPL such as serum, plasma and/or urine please note the specimen type on each appropriate vial.

Northern Plains Laboratory may refuse to accept specimens that are not appropriately labeled with two unique identifiers. In addition, we reserve the right to discard any unlabeled specimens. There are specific mandatory blood bank labeling requirements for those sites that NPL performs type and crossmatch testing. These requirements are available in the NPL Test Catalog.

If you have any questions or concerns please contact NPL at 701-530-5700 or 1-800-645-1003

High Sensitivity Troponin Testing

By Rhonda Burgard, Client Services Supervisor

High sensitivity troponin assays have been available in countries outside of the United States for many years. In the United States, the FDA approved the Roche high sensitivity troponin assay in January 2017, the Beckman and Siemens assays in the summer of 2018, and the Abbot assay in October 2019. There are differences between the different assays and patient results may not correlate from one assay to another. Clinical laboratories implementing these assays will need to determine the following:

- Reference ranges: The cutoff concentration for high sensitivity assays is set at the 99th percentile of a health population with males having higher results than females. The FDA requires the manufacturers of high sensitivity troponin assays to list different cutoff points for males and females as well as a combined cutoff that encompasses both. However each institution must decide if separate gender specific reference intervals should be adopted at their institutions.

- Units of measure: The accepted reporting units for current troponin testing is ng/mL. High sensitivity assays are reported in ng/L so the reportable values remain as whole numbers not decimals.

- QC material: QC material will have to cover low, cut point and high values. Current QC material may have

values that are too high for the high sensitivity troponin assay lower range.

- Frequency of blood collections for patients with chest pain: Current assay protocols require serial testing at zero, six and twelve hours or zero, three and six hours. High sensitivity troponin assays reduce the frequency to zero and either one or two hours based on institutional policy with a 6 hour confirmatory test.

- Because the new assay is so sensitive, results may be more affected by pre-analytical variables like fibrin, hemolysis and biotin. Recognizing when values may be impacted by interfering substances should be considered when implementing these assays.

It is important the providers be educated on the differences between current and high sensitivity troponin assays and be involved in the implementation of this new assay.

Reference: Implementing hs-cTn assays into the clinical practice, MLO Feb 2020
No dawdle in switch to high-sensitivity troponin, CAP Today, Dec 2019

I Stat Recall

By Rhonda Burgard, Client Services Supervisor

According to the notification from Abbott, clients using the I Stat blue chem8+ cartridge and CG4+ blood gas cartridge should transition to an alternate method. Until that time they should not use the Chem 8+ cartridge for capillary samples. If they do use the blue Chem 8+ and CG4+ cartridges for arterial and venous specimens they need to notify the providers that "performance of these cartridges has not yet been fully characterized" and "if results do not match the patient's clinical presentation, the patient sample should be tested by an alternate test method or a reference laboratory". Since these test cartridges are no longer waived, QC must be run each day of testing or an IQCP written or existing IQCP modified.

The closest alternate cartridge for CG4+ is EG6+. This cartridge provides blood gasses plus H+H, Na and K+. There are also three other options: EG7+ adds ionized calcium to the EG6+. CG8+ adds glucose to the EG6+. EC8+ includes Na, K+, Cl, Anion Gap, Glu, BUN, H+H and blood gasses but does not include a pO2 or O2 sat. All cartridges are moderately complex. QC should be run each day of testing or an IQCP written.

If a creatinine is desired there is a creatinine only cartridge. Waived.

Long term, laboratories may consider replacing the I Stat with another point of care blood gas analyzer or waived chemistry instrument.

If you have questions or concerns please contact NPL client services at 701-530-5700.

Human Coronavirus

By Robert Arndt, Microbiology Supervisor

Human Coronaviruses (CoV) were established as respiratory pathogens in the 1960s and six serological variants associated with human disease had been characterized prior to the emergence of a new novel coronavirus COVID-19 (SARS-CoV-2) that is of current global concern. These viruses are most commonly associated with upper respiratory tract infections; however, they have also been detected in individuals with lower respiratory tract infections.[7–9] Coronaviruses have been associated with croup and exacerbation of asthma.[7,10] Coronavirus infection occurs more often in the winter and there appears to be a periodicity of epidemics for some strains.[8] Coronavirus infections (with the exception of SARS, MERS-CoV, and possibly COVID-19) are generally self-limiting.

The **Respiratory Panel by PCR (RPPCR)** and **Pneumonia Panel by PCR plus Bacterial Culture (PNARC)** performed at NPL can detect the four common coronaviruses: **229E**, **OC43**, **HKU1**, and **NL63**. These are reported as a "Detected" result for Coronavirus. Our panels **cannot** detect Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV), Middle East Respiratory Syndrome Coronavirus (MERS-CoV, and the novel 2019-nCoV. Currently, in the United States, only the CDC and state or local Public Health Laboratories have systems that are able to detect this new novel strain of coronavirus. Please refer to Health Alerts provided by your Public Health Lab and the CDC for any questions pertaining to this novel coronavirus.

If you have any questions or concerns please contact Northern Plains Laboratory Client Services at 701-530-5700.

Northern Plains Laboratory (NPL) Antibiotic reporting changes for gram negative bacilli

By Robert Arndt, Microbiology Supervisor

Due to the manufacturer discontinuing the production of our current gram negative susceptibility panel, NPL has switched to a new panel, the AST-gn99 card for MIC susceptibility testing of non-fastidious gram negative organisms, including Enterobacteriaceae, Pseudomonas and other non-Enterobacteriaceae gram negative bacilli. Some of the changes that you will notice on reports:

Enterobacteriaceae

- No ampicillin/sulbactam result
- Amoxacillin/clavulanic acid added- will report in place of ampicillin/sulbactam
- Cefuroxime-axetil- will report for **urine** isolates when cefazolin is resistant
- ESBL- comment changed from "ESBL producing organism" to:
  - ****Susceptibility pattern consistent with*** *****Extended Spectrum Beta-Lactamase(ESBL)producing organism**
- No Ceftriaxone result for- Enterobacter cloacae, Enterobacter cloacae complex, Morganella species, Proteus vulgaris. Cefepime will be reported on these isolates.

Ciprofloxacin and Levofloxacin have revised breakpoints for interpretive criteria. A comment will be added when MIC values fall in a range that is now considered reduced sensitivity:

- Ciprofloxacin – A comment will append when MICs are 0.5, 1 or 2
    - *Clinical failure may occur with a ciprofloxacin MIC of >=0.5 ug/ml. Contact Pharmacy or ID for alternative dosing*
- Levofloxacin- A comment will append when MICs are 1, 2 or 4
        - *Clinical failure may occur with a levofloxacin MIC of >=1.0 ug/ml. Contact Pharmacy or ID for alternative dosing*

Pseudomonas aeruginosa-No ceftazidime result - Disk diffusion (Kirby-Bauer only) for ceftazidime – available upon request

Ciprofloxacin and Levofloxacin have revised breakpoints for interpretive criteria. A comment will be added when MIC values fall in a range that is now considered reduced sensitivity:

- Ciprofloxacin - A comment will append when MICs are 1 or 2
    - *Clinical failure may occur with a ciprofloxacin MIC of >=1.0 ug/ml. Contact Pharmacy or ID for alternative dosing*
- Levofloxacin - A comment will append when MICs are 2 or 4
    - *Clinical failure may occur with a levofloxacin MIC of >=2.0 ug/ml. Contact Pharmacy or ID for alternative dosing*

For questions, contact Northern Plains Microbiology lab 701-530-5734.

Mycoplasma genitalium

By Ron Piatz, Research and Development

Northern Plains Laboratory (NPL) is pleased to announce the addition of the APTIMA Mycoplasma genitalium assay to our in house test menu. The Aptima Mycoplasma genitalium assay is an *in vitro* nucleic acid amplification test (NAAT) for the qualitative detection of ribosomal RNA (rRNA) from *Mycoplasma genitalium* on the fully automated Panther® system. It is intended for use as an aid in the diagnosis of *M. genitalium* urogenital infections in male and female patients suspected of *M. genitalium* infection.

M. genitalium is a sexually-transmitted bacterium belonging to the class *Mollicutes*. *M. genitalium* has a cell membrane but no cell wall and lives on and in the epithelial cells of the urinary and genital tracts of men and women. In higher risk populations, prevalence of 9% to 24% in men and 11% to 16% in women has been reported. The prevalence of *M. genitalium* in higher risk populations often exceeds that of *Neisseria gonorrhoeae* and is similar to the prevalence of *Chlamydia trachomatis*.

Published studies indicate that infection with *M. genitalium* was shown to be strongly associated with non-gonococcal urethritis (NGU) in men. In evaluated subjects, *M. genitalium* was detected in 15% to 25% of men with symptomatic NGU and >30% of men with non-chlamydial NGU. In women, several studies have reported *M. genitalium* to be associated with cervicitis. A recent meta-analysis also shows that infection with *M. genitalium* was associated with an approximately

two-fold increase in risk for cervicitis, pelvic inflammatory disease, preterm birth, spontaneous abortion, and infertility.

Specimen:
The assay may be used to test the following specimens: clinician-collected and self-collected vaginal swabs (in a clinical setting), clinician-collected endocervical swabs, female and male urine, clinician-collected male urethral swabs, and self-collected penile meatal swabs (in a clinical setting).
• Aptima Unisex Swab Specimen Collection Kit for endocervical and male urethral swab specimens
• Aptima Urine Collection Kit for male and female urine specimens
• Aptima Multitest Swab Specimen Collection Kit – vaginal & male penile meatal swabs specimens.

NPL Reference Range:
Mycoplasma genitalium by Transcription-Mediated Amplification (TMA) **- NEGATIVE**

Test Code	CPT Code	Test Name	Specimen Requirements
MGEN	87563	Mycoplasma genitalium by TMA	Genital swab or urine collection

New Collection Swab

By Ron Piatz, Research and Development

Northern Plains Laboratory is pleased to announce we now have the ability to perform GC/chlamydia on additional specimen types.

The Aptima® Multitest Swab Specimen Collection Kit (supply item #801777) is intended to be used for collection of the following swab specimen types:

- Mycoplasma genitalium testing – clinician or patient collected vaginal swab and patient collected penile meatal swab.
- Chlamydia/GC - clinician or patient collected vaginal swab, clinician collected throat swab and clinician collected rectal swab.

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