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Quality Corner

Quality Stories

By Rhonda Burgard, Client Services Supervisor

Northern Plains Laboratory clients are continually working to improve the quality and efficiency of laboratory operations. Here are a couple of quality stories.

Urine culture contamination: The baseline urine culture audit indicated a 30% contamination rate (mixed flora detected). Contaminated urine cultures both delay appropriate patient care and have wasted supply and labor costs. The laboratory in conjunction with nursing staff worked to provide better patient and nursing education for the collection of clean catch urine samples. Contamination rates were reduced from 30% to 10%.

Critical call documentation: Baseline data collection indicated that only 86% of critical values were called within the acceptable threshold of 20 minutes. In addition there was inconsistent compliance with documentation of read back verification, test name and name of the person the result was called to. Staff reviewed the critical call policy and completed a competency quiz. Critical calling information is audited monthly and shared with staff. Compliance has improved for documentation of calling critical results and currently 98% of critical results are called within 20 minutes of verification.

If you have a quality story you would like to share please email Rhonda Burgard at rburgard@primecare.org.

Maternal Serum Screen Test Changes

By Rhonda Burgard, Client Services Supervisor

On February 20th, 2018 ARUP Laboratories inactivated their current maternal serum screen tests (AFPM4) and replaced them with new test codes (MAFP4). The new test codes will allow clients to transmit required information electronically via interface prompts, update risk calculations and provide clarified laboratory results. Please see the attached test change information for additional information on these new test codes.

North Dakota Board of Clinical Laboratory Practice Continuing Education Requirement Changes

By Rhonda Burgard, Client Services Supervisor

Effective until June 30, 2018, an individual licensed by the board must complete twenty continuing education contact hours for the two year licensing period to maintain licensure in ND. Effective July 1, 2018 the requirement will change to twenty four continuing education hours for the two year licensing period.

COLA and CAP Accreditation Requirement Changes

By Rhonda Burgard, Client Services Supervisor

The following changes have been made by COLA and CAP to the 2018 checklists:

- COLA M 5: The standard has been changed to allow IQCP for media QC. The CLSI alternative does not apply to chocolate agar, Campylobacter media or selective media for the isolation of Neisseria species. Nor is it applicable to those systems with multiple sections of selective or indicator producing media when they are used for identification of organisms.
- COLA M 9: This standard has been revised to allow IQCP for biochemical identification systems.
- COLA BA 6: This standard has been revised to allow IQCP for weekly QC of antimicrobial susceptibility testing.
- COLA BA 7: This standard has been revised to require a 15 replicate study, or a 20-30 consecutive testing day study prior to implementing IQCP and weekly QC for susceptibility testing.
- COLA MDT1 thru MDT 13 COLA has added new requirements pertaining to Molecular Diagnostics Testing
- CAP COM.50300 The QC study conducted for an IQCP must be conducted over the same timeframe as the proposed QC frequency. For example if QC will be performed monthly the study must be conducted over 31 days.

The 2018 COLA inspection checklist is available for download from the COLA Central website under the Education tab. www.cola.org

GC/Chlamydia Orders

By Rhonda Burgard, Client Services Supervisor

When ordering the GC/Chlamydia (CNGAM) on a thin prep vial please indicate the correct specimen source: TPREP-Thin prep vial. Do not use the genital source code.

Supply Item

By Rhonda Burgard, Client Services Supervisor

Because of low usage, Northern Plains Laboratory will no longer be stocking ARUP ACD solution A (Supply item 800237). We will continue to stock Mayo ACD solution B (Supply item 800238)

Ice Packs

By Rhonda Burgard, Client Services Supervisor

The blue and white ice packs provided by Northern Plains Laboratory have been certified to withstand shipping conditions and to maintain specimens at the appropriate temperatures. Please do not substitute vendor supplied ice packs when shipping your specimens.

Ice packs sent in blue shipping containers should be returned to you unless they have broken or leaked in transit. Please unpack these ice packs upon receipt and store them at the appropriate temperatures. Additional ice packs can be ordered as a supply item.

If your ice packs sent in blue shipping containers are not being returned, please notify Northern Plains Laboratory client services department at 701-530-5700.

Change in Mandatory Reportable Conditions

By Rhonda Burgard, Client Services Supervisor

The North Dakota Department of Health Division of Disease Control continually monitors the reportable conditions list in an effort to stay current with changing/emerging disease and to remove diseases which have provided minimal value to public health improvement. In January 2018, the following changes were made to the NDPHL Mandatory Reportable Conditions.

- Campylobacteriosis continues to be reportable but isolates do not have to be sent to NDPHL
- Coccidioidomycosis continues to be reportable but isolates do not have to be sent to NDPHL
- Enterococcus, vancomycin resistant (VRE) is no longer a mandatory reportable condition
- Hepatitis A, B, C, D, E are reportable. Hepatitis C, NAT (detectable or non-detectable) and Hepatitis C genotype results are reportable.
- Any positive HIV test, including gene sequencing and drug resistant patters and HIV NAT (including non-detectable) are reportable
- All lead blood levels are reportable
- Novel severe acute respiratory illnesses are reportable
- Organisms resistant to a carbapenem or with emerging antimicrobial resistance are reportable
- Pertussis continues to be reportable but isolates do not have to be sent to NDPHL
- Psittacosis is no longer a mandatory reportable condition
- *Staph aureus*, MRSA is no longer a mandatory reportable condition
- *Strep pneumoniae* (invasive) continues to be a mandatory reportable condition but streptococcus group A and B are no longer reportable
- Toxic shock syndrome is no longer a mandatory reportable condition
- Tuberculosis infection continues to be reportable including both tuberculosis disease and infection
- Unexplained and emerging critical illness and death are mandatory reportable conditions.

A form with a listing of reportable conditions is enclosed in this mailing. Additional forms can be printed at www.ndhealth.gov/Disease/Disease%20Reporting/.

Occult Blood, Fecal by Immunoassay – Hemosure® iFOB

By Ron Piatz, Research and Development

Northern Plains Laboratory (NPL) is pleased to announce the addition of the Hemosure iFOB Test. The Hemosure® Immunological Fecal Occult Blood Test is a qualitative, sandwich dye conjugate immunoassay.

In comparison with Guaiac-based testing, Hemosure® has a higher specificity due to its unique combination of monoclonal and polyclonal antibodies that are specific to human hemoglobin, unlike Guaiac-based tests, that also detect peroxidase activity from animal blood and other food. Therefore, traditional abstinence of food and medications by patients is no longer

necessary. This may enhance patient compliance with specimen collection.

By reducing the number of false positive results over the conventional guaiac method, Hemosure® may be a more valuable and cost-effective aid in the diagnosis of gastrointestinal bleeding disorders and colorectal cancer screening.

Benefits of using an iFOB (FIT):

- No dietary or medication restrictions.
- May greatly enhance patient compliance.
- Specific to human hemoglobin - reduces false positives.
- Ability to detect as low as 50 ng human Hgb/mL (Traditional Guaiac 90,000 ng or higher of Hgb/mL)
- One sample required for iFOB (Traditional Guaiac three samples required)

Specimen:
Collect random stool sample in Hemosure Sample Collection Tube.

1. Unscrew the purple cap from the sample collection tube. (Do not pour out the liquid.)
2. Poke spiral applicator into stool at 6 different sites. Use only enough fecal material to cover the tip of the applicator. (Do not clump, scoop, or fill the tube with feces.)
3. Screw the applicator back into the tube and secure tightly. – send to the lab for testing.

For additional testing information, please contact NPL at 701-530-5700 or 1-800-645-1003.

Test Code	CPT Code(s)	Test Name	Specimen	Reference Range
IFOB	82274	Occult Blood, Fecal by Immunoassay	Stool	Negative

Biotin Interference

By Rhonda Burgard, Client Services Supervisor

The FDA has issued a Safety Communication warning “Biotin May Interfere with Lab Tests”.

Biotin (Vitamin B7) is a water-soluble B vitamin that helps turn carbs, fats and proteins into energy. The recommended daily intake varies based on age (adults: 30 microgram/day). Biotin can be found in various foods as well as multivitamins, prenatal vitamins and dietary supplements. Some dietary supplements marketed for hair, skin and nail growth may contain biotin concentrations up to 650 times the recommended daily intake (5-10 mg). High dose supplementation of biotin (> 10 mg/day) may be recommended for patients with certain inherited metabolic deficiencies or conditions such as multiple sclerosis (MS).

While standard intake levels of biotin do not typically cause interference with laboratory testing, higher levels may interfere with certain immunoassays, causing both significant false high and false low test results depending on the test.

Patients and providers may be unaware of biotin interference in laboratory tests. In fact, patients may be unaware they are taking higher than recommended levels of biotin. It is important that providers are aware of this potential interference, especially if test results are

suspicious or inconsistent with the patient's clinical history.[2] Please share this information with your medical staff.

FDA recommendations for health care providers:

- Talk to your patients about any supplements they may be taking and for potential sources of biotin.
- Be aware that many lab tests that use biotin technology are potentially affected.
- Communicate to the lab conducting the testing if your patient is taking biotin.
- If the lab result doesn't match the clinical presentation of the patient, consider biotin interference as a possible source of error.
- Report to the lab and FDA of any adverse events following incorrect laboratory test results due to biotin interference. www.fda.gov/MedWatch/report.

FDA recommendations for laboratories:

- Identify assays that use biotin technology.
- Ask patients if they are taking biotin.
- Educate health care providers and laboratory staff about biotin interference with laboratory test results.
- Contact the instrument manufacturer if you have questions about biotin interferences.

FDA recommendations for patients:

- Talk to your provider if you are taking or considering taking biotin and know if your supplements contain biotin
- Talk to your provider if you are concerned about your laboratory test results.

Reference:
1) FDA: Biotin (vitamin B7) safety communication www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts.htm.
2) ARUP Laboratories: Biotin Interference www.aruplab.com/biotin.
3) Siemens Healthcare Customer Bulletin, Dec 2017

2018 Microbiology Nomenclature Changes

By Ron Piatz, Research and Development

The following organisms have had nomenclature changes:

- Old: Enterobacter aerogenes
  New: Klebsiella aerogenes
- Old: Clostridium difficile
  New: Clostridioides difficile
- Old: Propionibacterium acnes
  New: Cutibacterium acnes

The Clinical and Laboratory Standards Institute (CLSI) monitors changes in nomenclature and susceptibility requirements and annually updates CLSI M100 – Performance Standards for Antimicrobial Susceptibility Testing Guidelines. It is very important for all laboratories performing and reporting Microbiology susceptibility testing to be aware of any changes and to review and incorporate these changes to current susceptibility testing or reporting if appropriate. Currently the 28th edition of the CLSI M100 is available for purchase at www.clsi.org. Instrument manufacturers typically also release updated software at the start of the year. Please make sure your instrument has the most recent software version installed.