Northern Plains Laboratory

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New Urine Preservative Tube

By Rhonda Burgard, Client Services Supervisor

NPL will now be providing BD Vacutainer Urinalysis Preservative Plus Urine Tubes to our out-of-town clients (supply #: 801671) that submit urine samples to NPL for dipstick and/or microscopic testing. This supply item will replace Stabilur tablets that were previously ordered (supply # 800893) for urine preservation.

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BD Vacutainer® Urinalysis Preservative Plus Urine Tubes are designed for automated and manual chemistry dipstick urinalysis and to also obtain sediment for microscopic examination. The preservative allows for transport, testing and storage of the specimen up to 72 hours at room temperature or refrigerator temperature. The urinalysis preservative is intended to inhibit the metabolism of or render non-viable the bacteria normally present in urine while maintaining cellular integrity.

BD Vacutainer® Urinalysis Preservative Plus Urine Tubes are 8.0 mL draw volume, 16 x 100 mm, with a urinalysis preservative and BD Hemogard™ Closure with yellow shield color. A minimum fill line of 7.0 mL and a maximum fill line of 9.0 mL is indicated on the label. The tubes have sterile interiors.

Note: These tubes are not suitable for culture. For urine culture, use BD C&S Preservative Urine Tubes (Boric Acid tubes).

Preservative

The mean concentration of the preservative in the urine sample in BD Vacutainer® Urinalysis Preservative Plus Urine Tube is:
Sodium Propionate 94%
Ethyl Paraben 5.6%
Chlorhexidine 0.4%

Quality Corner- Standard Operating Procedure

By Rhonda Burgard, Client Services Supervisor

The procedure manual is a key component of laboratory quality. CLIA requires that the laboratory have written procedures for all testing it performs. Laboratory policies may be included in the procedure manual, or kept as a separate policy manual.

Manufacturer's procedures may be used but they must be customized to reflect your laboratory practice and include all of the required elements. Each procedure must include the following elements:

- Test name
- Directions for specimen collection including requirements for patient preparation, specimen collection containers, the amount and type of specimen required, labeling, storage, preservation, transportation, processing, and acceptability or rejection of the specimen.

- Preparation and storage of solutions, controls, reagents, calibrators and stains
- Directions for calibration and calibration verification
- Control procedures including the type of control and the number and frequency of controls runs. Control limits must be established, criteria for acceptability defined and actions taken for control failures described.
- Step by step directions for the performance of the test including calculations and microscopic examinations, including slide preparation must be included.
- Directions for reporting results including the reportable range and panic or alert values and actions to be taken must be described
- Description of actions to be taken if the test system becomes inoperable.
- Limitations including interfering substances must be described.
- References

The laboratory director must approve and sign and date each new and revised procedure before it is put into use. Review of procedure manuals may be required annually or biannually and delegation by the laboratory director may or may not be allowed depending on your accrediting organization.

Manuals may be stored on a hard copy or electronically and should be available to staff at all times. Discontinued procedures must be maintained for two years (Five years for blood bank).

Reference: COLA Lab Guide -The Procedure Manual

Helicobacter Pylori UBT Kits

By Rhonda Burgard, Client Services Supervisor

The BreathTeck UBT kit used for Helicobacter Pylori breath tests contains a 3 gram pouch of a diagnostic drug, Pranactin-Citric (citric acid, anhydrous, Mannitol, Aspartame and C Urea) that patients inject prior to specimen collection. Therefore, it is considered a diagnostic/pharmaceutical drug and must be ordered by a licensed health care practitioner and administered by a health care professional. These kits should never be given to a patient to take home and collect.

Reflex Testing Policy

By Rhonda Burgard, Client Services Supervisor

The Northern Plains Laboratory Reflex Testing policy has been updated. A copy of the updated policy is enclosed in this mailing and also available in the NPL Test Catalog at www.northernplainslab.com.

Medical Device Product Correction

By Rhonda Burgard, Client Services Supervisor

BD has confirmed that approximately 3.4% of BD Vacutainer Plus Plastic Citrate Blood Collection Tubes (2.7 mL) will exhibit over fill draw volumes from 11-14%. (All lots within expiration) Overfilling of tubes will result in an incorrect blood-to-additive ratio and can lead to incorrect analytic results. BD has indicated the over fill draw volume will not impact critical patient care and there is no need to return the product to BD. Please observe the fill volumes on your tubes carefully and recollect the sample if the draw volume exceeds 10% over the nominal volume.

Test Changes at ARUP

By Rhonda Burgard, Client Services Supervisor

Due to continued reagent issues with the Mycophenolic Acid and Metabolites (ARUP test # 2010359) ARUP is unable to report the mycophenolic acid acyl-glucuronide component. A therapeutic range for the mycophenolic acid acyl-glucuronide is not well-established and not routinely reported by other reference laboratories. This component will be removed and inactivated from test 2010359.

ARUP will no longer accept whole blood specimens for Magnesium, RBC (0092079) and if they are not drawn in a metals free tube Vacutainer Royal blue tube and received in an element trace free transport tube the test will be rejected.

ARUP is now offering QuantiFERON-TB Gold Plus, 4-Tube test. The three tube collection kits will only be accepted until August, 20, 2018.

ARUP is now offering Ethyl Glucuronide in Umbilical Cord Testing (Test # 3000443) for detection and management of fetal alcohol exposure, withdrawal symptoms and for social and medical long-term needs.

PAML and LabCorp Conversion

By Rhonda Burgard, Client Services Supervisor

In 2017, PAML Laboratories was sold to LabCorp. Testing that Northern Plains Laboratory previously sent to PAML in Spokane, Washington is now being processed at the LabCorp Denver, Colorado facility. It is expected that this move should reduce turn-around times for many of the tests previously processed by PAML.

As a result of this change, PAML test codes had to be converted to LabCorp test codes. New, deleted or changed test information is sent to client locations via email and on an HVR printout. It is also included in each quarterly newsletter. **In order for your orders to cross the interface from your EMR/LIS to the Northern Plains Laboratory LIS these new test codes must be built in your EMR/LIS. Orders placed using obsolete test codes will not cross the interface and may end up not be performed as ordered by the provider.**

This conversion required a large test build for Northern Plains Laboratory IT staff, the Meditech conversion team and also many of our clients. I would like to thank everyone for the time and effort spent on this conversion. Please be aware that there are some changes in specimen, transport and/or stability requirements. Access the Northern Plains Laboratory test catalog at www.northernplainslab.com to find the most recent information.

Quantiferon tests are now being collected in a LabCorp test kit. Each tube in the test kit should be appropriately labeled with the patient name and identification number. The kit box should be sealed and labeled with the patient name and identification number. Check the blue box on the top of the kit to indicate if the specimen has been incubated or not. Specimens submitted that are not in the sealed kit box will be rejected by LabCorp. LabCorp expects to have the new 4 tube Quantiferon collection kits available in

July, 2018. **Please note the shorter stability (84 hours of collection) with LabCorp Quantiferon testing when collecting and shipping Quantiferon tests.**

Specimen Preparation- Platelet Poor Plasma

By Rhonda Burgard, Client Services Supervisor

CLSI recommends that the capped specimen tube for coagulation testing be centrifuged for 10 minutes at 1500g at room temperature. Centrifuges such as a “Stat-spin”, which spin at higher rates and shorter duration, are also acceptable. Fresh plasma samples tested within 24 hours for PT or 4 hours for APTT, are not affected by platelet counts as high as 200,000 /µL.

However, CLSI recommends platelet poor plasma samples be prepared for all other coagulation samples especially those with extended storage times that will be stored refrigerated or frozen. CLSI defines platelet poor plasma as plasma with a platelet count of less than 10,000/µL. This is critical because the presence of activated platelets in the sample will neutralize heparin activity. This can result in lower Ptt or Anti-Xa results and may mask the presence of Lupus Anticoagulant (false negative). Double centrifugation is recommended for these plasma aliquots.

In order to determine if the centrifuge time and speed can attain platelet poor plasma, centrifuge two specimens (one with a normal platelet count and the other with a high platelet count) for the determined amount of time and then run the plasma portion of the sample through the hematology analyzer to determine the platelet count. If the platelet count is higher than 10,000/µL, the sample should be centrifuged for a longer period of time. Once the laboratory establishes the optimum time and speed to process the specimen, a periodic check should be performed every six months or after centrifuge repair to ensure that the platelet count is still acceptable.

Reference: CLSI H21 A5 Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays, 5th Edition

Test Changes at Mayo Medical Laboratories

By Rhonda Burgard, Client Services Supervisor

A new screening test for bile acid malabsorption in patients with irritable bowel syndrome-diarrhea (IBS-D) is available at Mayo. Patients with increased bile acids in their stool often suffer from chronic diarrhea, a condition called bile acid malabsorption (BAM). Approximately 25-30% of patients with IBS-D have BAM. The 7AC4, Bile Acid Synthesis, Serum test (7AC4) replaces the 24 hour fecal fat test in detection of bile acid malabsorption.

Mayo Medical Laboratories is also offering a new Prostate Health Index (phi) test (PHI11) that combines a PSA, free PSA and p2 PSA test into a single score used to predict the probability of prostate cancer. Studies have shown that using this risk stratification may reduce the number of unnecessary biopsies by 30% and reduce costs for the patient.

The specimen requirement for the Liver Fibrosure test performed at Mayo

Medical Laboratories has changed to require that the specimen be protected from light. Please refer to the Mayo Test Catalog at www.mayomedicallaboratories.com if you have any questions.

New Test: Group B Strep by PCR – Prenatal Screen

By Ron Piatz, Research and Development

Northern Plains Laboratory (NPL) is pleased to announce the addition of the Cepheid Xpert Group B Strep Lim Broth PCR assay on April 30, 2018. This assay is a qualitative in vitro diagnostic test designed to detect Group B *Streptococcus* (GBS) DNA from enriched vaginal/rectal swab specimens, using fully automated real time polymerase chain reaction (PCR). Xpert GBS LB Assay testing is indicated as an aid in determining GBS colonization status in antepartum women.

GBS bacterial infection is associated with serious illness in newborns born to women who are colonized with the bacteria. Transmission of GBS occurs from GBS-colonized women to their newborn before birth (antepartum) or during birth (intrapartum). In the United States, GBS infection is the major cause of death in newborns who develop sepsis, pneumonia, or meningitis. The standard of care for preventing neonatal GBS disease is screening pregnant women at 35–37 weeks of gestation to determine their GBS colonization status. Utilizing a molecular PCR screening method, which studies have proven to have increased sensitivity over traditional bacterial culture methods, should result in increased GBS detection that may have a positive direct impact on patient care.

Note: All PCR positive GBS samples will be cultured so that antibiotic susceptibility testing can be performed.

Specimen: Collect swab specimen using an Aimes or Liquid Stuarts swab/transport media.

- Collect at 35 – 37 weeks of Pregnancy.
- Swab vagina, sampling secretions from the lower one third of the vagina. Using the same swab, next insert into rectum about ≥ 0.5 cm beyond the anal sphincter.
- Place the culture swab into Aimes or Stuarts transport media.
- Be sure to appropriately label the specimen with sample identification.

Transport swab specimen to the laboratory. Swab sample is stable for 24 hours at room temperature or for up to 6 days if stored refrigerated at 2-8 °C

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
GBS P	87653	Group B Strep by PCR	Vag/Rectal Swab	Negative