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Happy Holidays from All of Us at Northern Plains Laboratory

ASCP Recommendations for Commonly Used Tests

By Rhonda Burgard, Client Services Supervisor

ASCP as part of their Choosing Wisely campaign has added five tests to their list of inappropriate and over utilized tests. The recommendations are:

- Don't request just a serum creatinine to test adult patients with diabetes and/or hypertension for chronic kidney disease. Use the Kidney profile (serum creatinine with eGFR and urinary albumin-creatinine ratio)
- Don't transfuse plasma to correct a laboratory value; treat the clinical status of the patient.
- Don't order IgM antibody serologic studies to assess for acute infections with infectious agents no longer endemic in the US and avoid using IgM antibody studies to test for acute infection in the absence of sufficient pre-test probability.
- Do not perform peripheral blood flow cytometry to screen for hematological malignancy in the setting of mature neutrophilia.
- Don't perform Procalcitonin testing without an established, evidence-based protocol.

Reference: ASCP.org/choosingwisely

Quality Corner- Resolving Quality Control Outliers

By Rhonda Burgard, Client Services Supervisor

When a QC value falls outside two standard deviations (SD) from the mean consider using the 1:2s QC Rule to begin the problem solving process. Repeat the QC run and if the repeat values are within 2 SD limits the error was a random occurrence and QC and patient results can be reported. However, if any repeated QC result is outside the 2 SD limits the run is rejected and patient results are held for retesting. If any QC result is outside the three SD limit the run must be rejected.

When troubleshooting QC errors evaluate the following

- Operator error
- QC material integrity
- Reagent integrity
- Instrument malfunction

Confirm all procedures for preparation of QC material and/or reagents and test performance were followed properly. If pipettes are used in the preparation have they been calibrated to confirm proper dispensing?

Verify control materials are in-date, have been properly stored, and have been properly prepared. Consider the stability

of open vials. If repeating the QC run with a fresh vial of QC material resolves the problem, patient results may be reported. If repeating the run does not resolve the problem, look at interlab reports and/or assayed control values to confirm your mean and SD are set correctly when compared to the expected mean and SD values.

Verify reagents are in-date, have been properly stored and prepared and on-board stability has not been exceeded. Look at the date of the last calibration for the analyte. Is there a possibility of reagent or QC material contamination? Consider a change of reagents, starting a new lot of reagents or calibration. If the problem is determined to be reagent based, patient results since the last acceptable QC run should be repeated.

Verify instrument maintenance is current. Have there been any temperature, humidity or power fluctuations? Has there been deterioration of the light source? Has there been a recent software update? If the problem is determined to be instrument based, patient results since the last acceptable QC run should be repeated.

Taking a logical step by step approach to evaluation of QC outliers will save operator time and ensure reliable and accurate test results.

Test Complexity

By Rhonda Burgard, Client Services Supervisor

As you review in-house test menu at the end of the year, please ensure your test kits and/or collection procedures match the CLIA test complexity you have assigned to the test.

Rapid Strep, Influenza A+B HcG, Mono and RSV kits and/or specimen requirements may make the test either waived or moderately complex. The test complexity should be listed on your kit box.

Also, review your package insert for specimen requirements as they relate to test complexity. Any transport media that requires an additional elution step, or specimens that require centrifugation (serum/plasma) typically will change the complexity of the test from waived to moderately complex.

Compared to waived testing, moderately complex testing has additional requirements for proficiency testing, competency, quality control and quality monitoring. If quality control is not performed each day of testing an IQCP may be required. If you have any questions please contact the NPL Client Services at 701-530-5700.

ARUP Specimen Requirement Change

By Rhonda Burgard, Client Services Supervisor

To better support specimen integrity and to ensure high-quality patient care, ARUP will discontinue the referral of tests that require -70C as the only acceptable temperature for specimen submission. ARUP recommends these tests be shipped directly to the performing laboratory. ARUP test codes affected are: 2003180, 2003304, 2009380, 99078, 99131, 99121, 99133, 99120, 99072, 2009416 and 2009382. Effective Nov 5th, 2018 ARUP will cancel any of the above tests that are submitted.

New Antibody Titer Method

By Dr. Jared Schmidt, MD Medical Director

Northern Plains Laboratory is changing the methodology for running prenatal antibody titers. The new methodology may result in titers several dilutions higher than what is currently being reported. The highest antibody titer level reported out will be 1024. These higher results do not imply there is an increased chance of hemolytic disease of the newborn (HDN), but are merely a consequence of the new methodology.

Patients should be considered at a high risk for HDN when the patient has a history of a previous pregnancy affected by HDN and/or a two fold increase in patient's titer (e.g. original titer = 8; subsequent titer = 32). At higher titer levels, the degree of fetal cell hemolysis (HDN) is dependent on the antibodies IgG sub-class, efficiency of placental transfer, the density of fetal red cell antigens, efficiency of clearance of antibody-coated red cells by the fetal spleen etc. Therefore the titer is only an indication that a more direct assessment of the fetus is required. Anti-Kell, in addition to causing hemolysis, may bind to the red cell precursors in the fetal bone marrow, suppressing fetal red cell production therefore causing fetal anemia. Therefore, fetal anemia (HDN) may occur at lower Kell titer levels.

When the paternity of the baby can be established, the father's phenotype for the corresponding antigen should be determined.

The new methodology will only be used for titration of newly identified antibodies. Any antibody titers being used to monitor HDN which were started with the old methodology will continue to be tested with the old method to ensure consistency throughout the pregnancy.

If you have any questions or concerns please contact the Northern Plains Blood Bank at 701-530-5700.

CPT Coding Changes For 2019

By Ann Oie, Compliance

The 2019 CPT codes for clinical laboratory tests will be effective January 1, 2019. CPT 2019 changes must be incorporated on January 1, 2019. Below is a list of new, deleted and modified CPT codes excluding any changes to the molecular pathology section (CPT codes 81105 thru 81479), Multianalyte Assays with Algorithmic Analyses (MMAA) (CPT codes 81490 thru 81599) and Proprietary Laboratory Analyses (CPT codes 0001U thru 0061U).

New 2019 CPT Codes excluding Molecular Pathology & MMAA codes

Code	Description
82642	Dihydrotestosterone (DHT)
83722	Lipoprotein, Direct Measurement; small dense LDL cholesterol

Deleted CPT Codes excluding Molecular Pathology &MMAA codes

Code	Description
	None

Revised 2019 CPT Codes excluding Molecular Pathology & MMAA codes

Code	2017 Description	2018 Revised Description
	None	

Reference: Current Procedural Terminology (CPT) 2019, American Medical Association

Reference Laboratory Name Change

By Rhonda Burgard, Client Services Supervisor

Mayo Medical Laboratories has changed their name to Mayo Clinic Laboratories. There is no change in ownership. Accreditation, licensure, permit, NPI and registration numbers remain unchanged.
This change will affect the name of the performing laboratory on your test reports. The test catalog link located at www.mayomedicallaboratories.com. will change but will automatically forward to the new domain name for a period of one year.

BD Coagulation Tube Notification

By Rhonda Burgard, Client Services Supervisor

BD has issued a product notification indicating that a small percentage of sodium citrate tubes over fill by 11-14%. Overfilling may lead to an incorrect blood-to-additive ration and may lead to incorrect coagulation analytic results or poor product performance. Please watch your fill volumes carefully when collecting coagulation testing.

Patients Drawn at the CHI St. Alexius Phlebotomy Department

By Rhonda Burgard, Client Services Supervisor

If sending non-hospital patients to the CHI St. Alexius phlebotomy department for to have their blood drawn, please fax your orders to 701-530-6777 at least one day prior to the scheduled draw. Patients should park in the Rosser parking lot and use the east entrance. Phlebotomy hours of operation are 0530-1700 M-F.

HIV and Hepatitis B Virus Testing Change

By Rhonda Burgard, Client Services Supervisor

Effective 11-12-18, ARUP Laboratories discontinued the Human Immunodeficiency Virus Types 1 and 2 (HIV-1, HIV-2) Antibodies by CIA with Reflex to HIV-1 Antibody Confirmation by Western Blot test. (NPL test code HIVAI, ARUP test code 2005377) NPL recommends Human Immunodeficiency Virus (HIV) Combo Antigen/Antibody (HIV-1/O/2) by CIA with Reflex to HIV-1 Antibody Confirmation by Western Blot test as the replacement test for (NPL test code remains **HIVAI**, ARUP test code 2006526)
The HIVAI test is a fourth-generation screening test the simultaneous qualitative detection of Human Immunodeficiency Virus Type 1 (HIV-1) p24 antigen and antibodies to HIV Type 1 (HIV-1) and HIV Type 2 (HIV-2). Results of the screen cannot be used to distinguish between the presence of HIV-1 p24 antigen, HIV-1 antibody, or HIV-2 antibody. Repeatedly reactive HIV-1, 2 antigen/antibody screening results will reflex to Western Blot HIV-1 confirmation. Additional charges apply. This test does not complete the 2014 CDC Recommended Algorithm for Laboratory Diagnosis of HIV Infection. The recommendation is to order further testing on a separate specimen for HIV-1 Nucleic Acid will be made for certain results. Preferred test is Human Immunodeficiency Virus (HIV) Combo Antigen/Antibody (HIV-1/O/2) by ELISA, Reflexive Panel (NPL test code **HIVCA.** ARUP test code 2012674) performed on EDTA plasma. This multi-test algorithm is recommended by the Centers for Disease Control and Prevention (CDC) and was adopted by the Clinical

Laboratory Standards Institute (CLSI) for the diagnosis of HIV.
Interfaced clients will need to modify the result code for test code HIVAI.

Component Test Code*	Component Chart Name	Specimen Requirement	CPT Code	LOINC
HIVAI	HIV 1,2 Combo Antigen/Antibody	1.5 mL serum 0.75 mL min. Refrigerated stability 1 wk.	87389 if reflexed add 86689	56888-1

In addition, ARUP Laboratories has added several new HIV tests by quantitative NAAT. These tests can be used to confirm HIV-1 infections in patients who test positive for HIV-1 antibody and resolve inconclusive HIV-1 antibody test results. The quantitative range of this assay is 1.47-7.00 log copies/mL and it detects HIV-1 group M subtypes (A, C, D, F, G, CRF01-AE, and CRF02-AG) and groups N and O. See the ARUP test catalog at www.aruplab.com for tests Human Immunodeficiency Virus HIV by Quantitative NAAT, Plasma (3000867), CSF (300872) with reflex to HIV Genotype by Sequencing (3000870), and reflex to HIV Phenosense GT (3000871)

Also effective on November 12th ARUP inactivated the Hepatitis B Virus by Quantitative PCR test (NPL Test code HBVQA, ARUP test code 0056025) and replaced it with the Hepatitis B Virus (HBV) by Quantitative NAAT test (ARUP test code 3000863). The new test aids in assessing viral response to treatment as measured by changes in HBV DNA concentration and quantifies genotypes A-H. Quantitative range of this assay is 1.00-9.00 log IU/mL.

If you have any questions or concerns or would like billing information please contact the Northern Plains Client Services at 701-530-5700.

CoaguChek Recall

By Rhonda Burgard, Client Services Supervisor

The FDA has issued a Class 1 recall of some lot numbers of the Roche CoaguChek XS Pt test strips. A Class 1 recall is the most serious type of recall. According to the FDA, use of these devices may cause serious injuries or death.

The recall of the CoaguChek XS test strips is due to inaccurate INR test results at INR values of > 4.5 INR, when compared to laboratory results. The company will supply new test strips. Until the new strips are received, stop using the affected test strips. Protime/INR monitoring should be done via a venous blood draw and tested by on laboratory based instrument. Patients are encouraged to contact their health care providers before making any changes to their warfarin dose. The link to the FDA website listing the affected lot numbers of test strips is located at https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm624822.htm.

Please make sure your providers have been notified of the possible positive bias with the affected test strips.

Quantiferon TB Gold Plus Test

By Rhonda Burgard, Client Services Supervisor

The Quantiferon TB Gold Plus test is a fourth generation Interferon Gamma Release Assay for TB detection, latent or active. The test is 97% specific and > 84% sensitive and is an alternate to the TST test in identification of tuberculosis infection.

This fourth generation test has added a fourth tube to the collection kit. The new tube adds an additional antigen that targets CD8+ T cells which play a critical role in immunological control in the production of the cytokine INF-y and host defense against *M tuberculosis.* The new test code for the 4th generation test is “QFT4J”. Test code “QFTBJ” has been discontinued.

The new tubes draw blood relatively slowly, keep the tube on the needle for 2-3 seconds once the tube appears to have completed filling. The new tubes require slightly more specimen volume. Please fill to the line marked on the tube. Do not under fill or over fill the collection tubes. Immediately after filling the tubes, shake the tubes firmly ten times. If a “butterfly needle” is being used to collect blood, a “purge” tube should be used to ensure that the tubing is filled with blood prior to the QFT-Plus tubes being used.

If the tubes will arrive at Northern Plains within 14 hours of collection send un-incubated and un-centrifuged. NPL will receive the specimens as “not spun”, incubate and centrifuge the tubes. Alternately, the tubes may be incubated at 37C for 16-24 hours at the client location, centrifuged and sent refrigerated to NPL. Any tubes received “unspun” will be assumed to require incubation.

Package the tubes in a biohazard bag as you would any blood specimen. Kit boxes may be discarded.

Please order replacement 4 tube Quantiferon kits and discard any 3 tube Quantiferon kits you may have in inventory.

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

Supply Requests

By Rhonda Burgard, Client Services Supervisor

To remain in compliance with HIPPA laws, Northern Plains Laboratory (NPL) may only provide supplies used to collect and transport specimens tested and billed for by NPL. Stock no more than a month’s supply of any one supply item on your shelf and monitor your supply outdates. You may return any short dated supply items to NPL.

Please consolidate your supply orders into one weekly order. We encourage you to electronically place or fax your supply orders to the NPL rather than placing phone orders, which are sometimes ambiguous and difficult to interpret by mailroom staff. Orders sent to the mailroom prior to noon Monday-Friday will be filled the same day.

NPL has transitioned to only one size of white cardboard mailing box (large) (supply item 800991) and Styrofoam cooler (large) (supply item 801004). The electronic and manual supply request forms have been updated. The newest

version of the supply order form is enclosed in this newsletter. Please discard any old versions of this form.

ARUP laboratories has preset reorder points for supply items provided for testing performed at ARUP. For specimen tubes that have low volume usage, VIP/Glucagon/PTHRP Protease inhibitor tubes for example, please do not stock excess tubes in your inventory. Also, try to avoid sending testing performed at NPL in ARUP or LabCorp provided transport tubes. These tubes are not line compatible with the NPL automation system.

If you have any questions or concerns please contact the Northern Plains Mailroom supervisor at 701-530-5700.

Aerobic/Anaerobic Cultures

By Pat Gerhardt, Microbiology

The primary agents of skin and tissue infections are *Staphylococcus aureus*, *Pseudomonas aeruginosa*, members of the *Enterobacteriaceae*, beta hemolytic strep and **anaerobes.** Often when submitting samples for culture looking for anaerobes is forgotten/omitted. Consider ordering an anaerobic culture on samples using the following guidelines for common types of superficial and deep wounds and abscesses.

Specimen types	Site or source	Comments	Test Code to use
Superficial	Boils, furuncles, infected cysts, skin abscesses, superficial surgical wounds	Defined as an infected space that may drain through the skin but does not extend deeper than the dermis	MC aerobes only identified
Deep	Any site, including deep tissues; usually related to secondary infection of a deep wound, contusion or hematoma	Defined as a closed infected space that extends deeper than the dermis into deep tissues whose cavity may be encapsulated	AC both aerobes and anaerobes identified
Wound Superficial	Abrasion, cut laceration, or ulcer (any site), plus associated skin disease (impetigo, folliculitis, cellulites) or burns	Defined as a wound in the skin that does not extend deeper than the dermis	MC aerobes only identified
Deep	Typically applies to deep surgical wounds that go across a mucosal surface (e.g. abdominal, pelvic, or chest), bite wounds (human or animal) deep traumatic wounds (e.g. gunshots, stabs, punctures) third degree burns due to electrocution.	Defined as a wound that penetrated deeper than the dermis of the skin or is located in deep tissues	AC aerobes and anaerobes identified

This chart (incorporated from *Clinical Microbiology Procedures Handbook* 3rd Edition, Lynne Garcia, and *A Guide to Management in Clinical Microbiology,* 3rd Edition, J. Michael Miller and Shelly A. Miller) will aid the provider in determining the correct test to order based on source/site of the specimen.

Test Code MC (Culture Miscellaneous) - only aerobic organisms with be identified as appropriate.

Test Code AC (Culture, Aerobe & Anaerobe) - both aerobic and anaerobic isolates will be identified as appropriate.

Collecting specimens.

Anaerobic cultures of surface wound samples are discouraged since anaerobes are abundant on skin surfaces and are common surface wound contaminants. If anaerobes suspected suggest using the following guidelines:

- Aerobic and anaerobic culture is indicated for all types of deep wounds and bites (both human and animal) that are clinically infected.
- However, limit swab sampling to wounds that are clinically infected or those than are chronic and not healing.
- Superficial or deep wounds, including bites, should be cultured only if there is purulence, chronic drainage, or not healing.
- After cleaning with saline and sterile gauze, gently roll swab over the surface of the wound approximately five times, focusing on the area where there is evidence of pus or inflamed tissue.

Remember:

Obtaining a good specimen is the clinician's responsibility. Generating good test results is the laboratory's responsibility. When these are combined, a negative test can be as helpful as a positive one. Eileen M. Burd, Ph. D., D (ABMM)