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From all of us at
Northern Plains Laboratory

Minimum Specimen Volumes

By Rhonda Burgard, Client Services Supervisor

One of the most common reasons for a canceled test is receipt of an insufficient quantity of specimen. When submitting specimens, please send the preferred volume rather than the minimum volumes, especially for testing that could require reflex testing. If you are sending minimum volumes for more than one test, add additional volume for aliquotting of the test specimen. For example: HCRNQ: 3.0mL preferred volume, 1.5mL minimum volume. Send 3.0mL if at all possible.

If sending liquid specimens for several tests, it is preferable to put all the sample into one tube instead of dividing it into multiple tubes. However, if sending frozen specimens, put the specimen for each test into a separate transport tube. Because some testing is not performed daily, is often not possible for the testing lab to thaw and share frozen samples.

Quality Corner

ASCP's *Choosing Wisely*

By Rhonda Burgard, Client Services Supervisor

The American Society for Clinical Pathology has released a list of 20 test recommendations for tests that are commonly ordered but not always appropriate. The list is designed to support conversations between patients, laboratory professionals and providers about what care is really necessary.

ASCP recommendations are:

1. Don't perform population based screening for 20-OH-Vitamin D deficiency. Vit. D deficiency is common in many populations, especially those at higher latitudes. Laboratory testing is only appropriate in high risk patients when results will be used to institute more aggressive therapy (i.e. Obesity, osteoporosis, chronic kidney disease, some infections, malabsorption)
2. Don't perform low risk HPV testing. HPV that causes genital warts or minor changes of the cervix is not associated with disease progression and no treatment or therapy is indicated.
3. Avoid routine preoperative testing for low risk surgeries without a clinical indication. Findings influence management in under 3% of patients tested.

4. Only order SEPT9 to screen for colon cancer on patients for whom conventional diagnosis is not possible. The sensitivity of the SEPT9 test is similar to commonly ordered stool guaiac or fecal immune tests.
5. Don't use bleeding time test to guide patient care. The bleeding time is an older assay that has been replace by alternate coagulation tests.
6. Don't order an erythrocyte sedimentation rate (ESR) to look for inflammation in patients with undiagnosed conditions. Order a C-reactive protein (CRP) which will return to normal with a day or two of the inflammation being resolved while ESR remains elevated for several days.
7. Don't test Vitamin K levels unless the patient has an abnormal INR and does not respond to Vitamin K therapy.
8. Don't test for myoglobin or CK-MB in the diagnosis of acute myocardial infarction. Instead, order a troponin I or troponin T.
9. Don't order multiple tests in the initial evaluation of a patient with suspected non-neoplastic thyroid disease. Order a TSH and, if abnormal, follow up with additional testing.
10. Don't proscribe testosterone therapy unless there is laboratory evidence of testosterone deficiency.
11. Don't routinely order expanded lipid panels (particle sizing, nuclear magnetic resonance) as screening tests for cardiovascular disease.
12. Don't order amylase in cases of suspected acute pancreatitis. Instead, order a lipase test which is more sensitive, particularly in alcohol-induced pancreatitis
13. Don't order serology for *H. pylori*. Use the stool antigen or urea breath test instead.
14. Don't order hemoglobin electrophoresis in patient who have a prior result and do not require therapeutic intervention or monitoring.
15. Do not test for Protein C, Protein S or ATIII levels during an active clotting event.
16. Do not order red cell folate levels. In adults consider folate supplementation instead of testing.
17. Don't perform sentinel lymph node biopsy or other diagnostic tests for evaluation of early, thin melanoma
18. Don't perform FISH for myelodysplastic syndrome (MDS) related abnormalities on bone marrow samples when an adequate conventional karyotype is obtained.
19. Don't order a frozen section if the result will not affect immediate patient management.
20. Don't use sputum cytology to evaluate patients with peripheral lung lesions.

Use of the ASCP recommendations will improve quality, lower costs and provide more effective use of medical laboratory resources and personnel.

Reference: Choosing Wisely, ASCP Twenty Things Physician and Patients Should Question, Oct 2017

New Transport Tubes

By Rhonda Burgard, Client Services Supervisor

To prevent specimens from leaking, please remember to push the cap down firmly on the new transport tubes to make sure they are securely sealed.

Specimen Tube Type Change for QuantiFERON-TB Gold Testing

By Rhonda Burgard, Client Services Supervisor

Quigen, the manufacturer of the QuantiFERON-TB Gold Plus test has announced approval by the Food and Drug Administration (FDA) of their fourth-generation test. This test adds CD8+ technology and increases the specificity and sensitivity of the test to tuberculosis (TB) and adds additional information concerning latent TB infections. The new test kit will require four collection tubes instead of three, but will allow for the collection of a single lithium heparin sample which may be processed up to 48-53 hours after venipuncture without affecting the accuracy of the test.

New test kits were released by Quigen in October 2017 and will require validation by testing laboratories. Northern Plains Laboratory will notify clients as the new kits become available.

Reference Range Change

By Rhonda Burgard, Client Services Supervisor

The reference range for antinuclear antibodies (ANA) by indirect fluorescence assay (ARUP test codes ANAGA and ANAA) has changed from 1:40 to 1:80. This means that all patient samples will start with an initial screening dilution of 1:80.

This change improves the reliability of the test in distinguishing between negative and positive results and reduces the rate of false-positive results.

New Test for Patients with Suspected Coronary Artery Disease (CAD)

By Rhonda Burgard, Client Services Supervisor

Plasma ceramides are predictors of adverse cardiovascular events resulting from unstable atherosclerotic plaque. Elevated concentrations of circulating ceramides are associated with ischemia heart disease, myocardial infarction, hypertension, stroke and type 2 diabetes mellitus, insulin resistance and obesity.

Three ceramides have been highly linked to cardiovascular disease and insulin resistance: Cer16:0, Cer 18:0 and Cer 24:1.

Individuals with high ceramides are at higher risk of cardiovascular events even after adjusting for age, gender, smoking status and serum biomarkers (LDL, HDL, cholesterol, CRP, LP-PLA2). Plasma ceramides can predict adverse cardiovascular events within one year among patients with CAD or within three to five years for patients with CAD and/or chronic heart failure.

FDA Reclassifies Influenza Virus Detection Devices

By Rhonda Burgard, Client Services Supervisor

The Food and Drug Administration has reclassified Influenza Virus Detection Devices from Class I to Class II medical devices. Effective January 1, 2018 Rapid Influenza test devices must meet the FDA requirements for sensitivity and specificity and the manufacturer must test their device with Influenza strains provided by the FDA.

Many of the influenza test kits currently on the market do not meet the minimum requirements set forth by the FDA. Customers can continue to purchase their existing kits until January 12, 2018 and use them until their final expiration date. Please check with your vendor for their compliance status with this new ruling.

Reference: Federal Register, Microbiology Devices, Reclassification of Influenza Virus Antigen, 1-12-17

Revised GYN Cytology Forms

By Ron Piatz, Research and Development

Pathology Consultants, PC has new GYN Cytology Request forms. These forms are lime green in color. When you receive the new forms, please discard any unused orange GYN Cytology Request forms.

The new form contains some new testing options:

- If the appropriate box is checked, *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing may now be performed directly from the Thin Prep Pap vial which eliminate the need to collect the separate Aptima swab or urine specimen. Interfaced clients should order the test code “CNGAM”
- In addition to the High-Risk HPV screen, HPV Genotyping for HPV 16, 18/45 has been added to the request form. This test detects E6/E7 viral messenger RNA of the high-risk HPV types 16, 18, and 45 only. HPV types 16, 18, and 45 are associated with approximately 80% of all invasive cervical cancers. HPV Genotyping identifies those patients at most risk for progression to cervical carcinoma and may aid in determining the appropriate triaging for the patient. It is intended for use in women 21 years and older with ASC-US cervical cytology results and a positive High-Risk HPV screen and in women 30 years and older with positive High-Risk HPV

Please share this information with your medical staff.

Go Green Initiative

By Rhonda Burgard, Client Services Supervisor

Reduction of the use of paper is part of Northern Plains Laboratories commitment to reducing waste and protecting the environment.

Northern Plains Laboratory has streamlined the electronic disposition of test reports so that all verified tests within a specific timeframe will print on the same piece of paper. Tests that are verified after that timeframe will continue to print on a separate piece of paper.

All interfaced clients have the option of turning off paper reports. Please contact Northern Plains Laboratory IT department at 1-800-659-0395 if you would like to consider this option.

Shipping Laboratory Specimens

By Rhonda Burgard, Client Services Supervisor

Please remember, with the approach of colder weather, to package specimens to avoid freezing. Place specimens in the center of the shipping container and avoid direct contact with refrigerator packs. Fill empty spaces in the shipping container with paper towels, bubble wrap or other packing material.

If sending EDTA specimens for CBC's, you may request that NPL provide you with Styrofoam tube holders which provide extra insulation and may help reduce platelet clumping. Avoid sending slides for hematology on the same side of the shipping container as specimens preserved in formalin.

To reduce shipping costs please fill both sides of the double shipping containers. It is acceptable to send frozen samples separated by the foam wedge in the same container as refrigerated samples. Or, to send refrigerated samples separated by the foam wedge in the same container as ambient samples.

Northern Plains Laboratory tracks the expected receipt of specimens daily on our "Did not receive" logs and contacts clients when specimens have not arrived in the expected timeframe. Federal Express, UPS and SpeeDee Delivery offer specimen tracking. To assist in specimen tracking, NPL recommends documenting your tracking number on your send log when shipping your specimens.

If, for some reason, you are unable to ship your specimens, please contact Northern Plains Laboratory Client Services at 701-530-5700 and let us know that the receipt of your specimens will be delayed. If winter weather makes it impossible for the courier companies to travel, Northern Plains Laboratory will send a HVR memo and/or call the impacted clients.

Competency Assessment

By Rhonda Burgard, Client Services Supervisor

As the end of the year approaches, please remember to have completed competency checklists available for all staff including your laboratory director, technical and general supervisors, technical and clinical consultants and testing personnel.

Test personnel, including supervisory personnel that perform testing, must have their competency evaluated during initial orientation, semi-annually the first year of hire and annually thereafter.

Competency forms must include documentation of the use of **all** of the following criteria for each employee performing a test:

- Direct observation of test performance, including patient preparation, specimen handling, processing and testing.
- Monitoring the recording of test results.
- Review of worksheets, QC records, PT results and maintenance records.
- Direct observation of performance of instrument maintenance and function checks.
- Analysis of previously analyzed samples.
- Assessment of problem solving skills.

Tests that are run on the same instrument may be grouped together as a "test method" as long as there are no unique aspects or procedures associated with that test. Quizzes or case studies can be used to document competency for problem solving, calculations, or for unique aspects

(dilutions for example) that may be associated with a particular test.

CLIA does not require competency assessment of personnel only performing waived testing and/or phlebotomy. However, even though there is not a specific requirement for competency documentation, it is good laboratory practice to ensure personnel are following manufacturer's instructions and are reporting out accurate test results. Provider-performed microscopy (PPM) is non-waived, and individuals performing these tests must have their competency assessed using all six-assessment methods annually.

Testing personnel failing to participate in competency assessment or not achieving acceptable competency scores must have remediation documented. **If proficiency samples are used for competency, corrective action for testing personnel with unacceptable proficiency testing scores (<80% for most analytes) must have remediation implemented and documented**.

Competency of clinical consultants, technical consultants, technical supervisors and general supervisors must reflect their oversight responsibilities. Forms are available from Northern Plains Laboratory that can be used for competency assessment for these positions. If you would like a copy of these forms, please contact NPL consulting services at 701-530-5700.

Your laboratory director should is responsible for review and approval of all training and competency activities and should review and sign all completed orientation and competency forms.

References: www.com.gov/clia/reg/toc.aspx
42 CFR Part 493.1413 (b)(8) and 493.151 (b)(8)

Quality Assessment

By Rhonda Burgard, Client Services Supervisor

An effective quality assurance (QA) plan monitors quality for the entire laboratory process, from the time the physician orders the laboratory test to until the results are recorded in the patient record and reported to the appropriate provider.

Several types of documents can be used to document the quality of laboratory operations:

- Internal- Quality control, instrument calibration, new test/reagent validation and instrument maintenance records.
- Internal- Quality audits. Annual quality audits should include at a minimum a pre-analytical, analytical and post-analytical audit.
- External- Proficiency documentation, consulting trip reports, accreditation inspection reports

Annually, summarize your quality activities, including a list of improvements implemented as a result of the quality program. The laboratory director must review the quality program annually to determine it has been effective in improving laboratory operations.