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Quality Corner: Inspection Preparation

By Rhonda Burgard, Client Services Supervisor

To prepare for a laboratory inspection begin by obtaining the appropriate inspection checklist from your accreditation agency.

Six months prior to your inspection: Complete a self-inspection by reviewing your Standard Operating Procedures (SOP's), forms and laboratory records for compliance with the checklist standards. This review will allow you to identify any gaps in documentation or performance and implement corrective action prior to the inspection. As you review the standards, note on the checklist which procedures and/or locations of forms that link to each standard. These notations will assist the surveyor in completion of their checklist on the day of your inspection.

One week prior to your expected inspection date, notify HR that the surveyor will want to review employee HR files for licensure and credentials and notify administration that a surveyor will be on-site. Gather and review supporting documentation for your inspection. This may include:

- Completed Quality Assurance (QA) audits. Make sure there is at a minimum a pre-analytical, analytical, and post-analytical audit.
- Proficiency testing results. Review to make sure there is documentation of corrective action for any unacceptable results and all non-graded results have been self-graded.
- Employee competency documentation. Make sure there is documentation for all six elements of competency for each test method.
- Copies of laboratory reports by the clinical consultant to make sure they include flags for abnormal results and reference ranges for all tests.
- Procedure manuals including a policy correction of reports with missing or incorrect information.
- Documentation of verification of calculations including INR calculations
- Documentation of twice annual correlations for tests done on multiple instruments
- An audit all supplies and reagents for appropriate dating and labeling.
- All new or modified test performance verification including review and approval by the laboratory director prior to implementation of the test.
- A written blood borne pathogen exposure control plan and documentation of annual training

On the day of the inspection:

- Identify the location that your surveyor will work at.

- Gather together QA and proficiency documents, QC temperature and maintenance records, instrument/test validation and calibration documentation, SOP's, and competency documentation and deliver to the surveyor.
- Provide the surveyor a copy of your self-inspection checklist and supporting documentation.

The surveyor should during the course of the inspection tell you which deficiencies they are noting. This will allow you to provide the inspector with additional information, if available.

At summation the surveyor will list all recommendations and deficiencies noted. You will have a defined timeframe to respond to the accreditation agency with your plan of corrective action and supporting documentation.

The ten most frequently citations by COLA surveyors in 2014-2015 were

- Lack of acceptable competency assessments on all applicable staff.
- The Laboratory Director not obtaining a minimum of four lab related CEU's every 2 years.
- Not implementing IQCP
- Not following manufacturer's directions for QC on waived tests.
- The Laboratory Director not fulfilling the proficiency testing responsibilities of the position.
- Lack of documentation that proficiency testing results were reviewed with staff.
- The Laboratory Director not fulfilling the QC or QA responsibilities of the position.
- The Technical Consultant not fulfilling the responsibilities of the position.
- Not performing calibration verification as required.
- Protocol not followed for lot change of thromboplastin (Incorrect information input for INR calculation)
- Not monitoring quality control by plotting and reviewing weekly.

Reference: COLA Technical Bulletin 2016-1 and 2016-2

Changes in the 30th Edition of AABB Standards for Blood Banks and Transfusion Services

By Rhonda Burgard, Client Services Supervisor

The following is a list of some of the revised or new standards found in the 30th Edition of AABB Standards for Blood Banks and Transfusion Services:

3.7.3 Activation of the alarm shall initiate a process for immediate **action**, investigation and appropriate corrective action.

5.11.24 The transfusion service shall have a policy to reduce the risk of misidentification of patient pre transfusion samples.

5.19.7 The BB/TS shall have a policy for responding to requests for products for patients identified by the ordering physician or other authorized health care professional as being at increased risk for TACO.

5.17.1.2.1 If the neonate is discharged and readmitted, pre-transfusion testing shall be performed using the neonate's serum or plasma.

False Positive Troponin Results

By Rhonda Burgard, Client Services Supervisor

Cardiac troponin I (cTnI) and T (cTnT) are sensitive and specific markers of myocardial cell damage and have replaced creatine kinase MB as the preferred marker for acute myocardial injury (AMI). Troponin consists of 3 single chain polypeptides- troponin C which binds calcium ions, troponin I which binds to actin and inhibits actin myosin interactions and troponin T which binds tropomyosin and facilitates contraction.

Only one assay is available for troponin T (Roche Diagnostics). However, several different assays are available for Troponin I. There is no standardization of troponin I results from one assay to another and cutoff values for elevated results vary from manufacturer to manufacturer. Results from one manufacturer should not be compared to those from another.

While troponin tests are used to identify AMI, a variety of other conditions may also be associated with elevated troponin levels including acute pulmonary embolism, acute or severe heart failure, myocarditis, sepsis, acute pericarditis, renal failure, hypovolemia, and cerebrovascular accidents.

False positive troponin values may also be caused by:

- Heterophile antibodies
- Human anti-mouse antibodies
- Autoantibodies
- Fibrin clots
- Rheumatoid factor
- Microparticles in the specimen
- Interferences from high bilirubin, alkaline phosphatase, hemoglobin and lipemia
- Immunocomplex formation
- Analyzer malfunction

The incidence of false positive results is estimated to range from 0.19% to 3.1% depending on the assay used.

If the patient's elevated troponin result does not match the clinical picture of AMI the following steps are recommended:

- Check the sample for microparticles or clots. Re-centrifuge and re-assay
- Repeat the blood draw and re-test
- Check for hemolysis, lipemia, bilirubin
- Dilute the sample with a zero calibrator or a negative troponin patient sample to check for linearity of results to determine the presence of interfering heterophile antibodies.
- Send to another laboratory using a different assay method
- Check of instrument malfunction
- Submit the sample to manufacturer for work-up

Awareness of the possibility of a false positive troponin result may assist the provider in the management of patients without AMI and may spare the patient additional diagnostic procedures especially if the troponin result is not consistent with clinical diagnosis.

Reference: False Positive Cardiac Troponin Results in Patients Without Acute Myocardial Infarction, Lab Medicine 2006:37(9) 546-550

Changes in the 2016 COLA Accreditation Manual Requirements

By Rhonda Burgard, Client Services Supervisor

The following is a list of some of the revised or new standards found in the 2016 COLA Accreditation Manual:

- ORG 3: COLA must be notified within 30 days of any changes to test menu or personnel
- PER 5.1-5.6 (new): Does the laboratory competency program include direct observation of routine patient test performance, monitoring recording and reporting of test results, review of intermediate test results, direct observation of instrument maintenance, assessment of previously analyzed samples, and assessment of problem solving skills.
- PER 5.7 (new): Has the clinical consultant reviewed laboratory reports initially and following any changes
- PRE 20 (new): Does the laboratory have a policy describing what needs to be done if required information is missing from the laboratory requisition.
- MA 15: Are thermometers verified for accuracy before use.
- VER 15 (new) Are all studies for verification of performance evaluated by the laboratory director prior to implementation of the test.
- CA2: Is calibration performed according to the manufacturer's instructions including the number, type and concentration of materials used including low, medium and high values. Is calibration performed once every 6 months
- QC 10: Are manufacturer's instructions for the use of reagents, controls and kits followed
- CO 1-2: Does the laboratory have a mechanism to ensure the correct activity of the thromboplastin including determination of the patient reference range and mean with each change of lot number
- SU 3: Are no more than 12 sensitivity discs used on 150mm Kirby Bauer plates or 6 on 100mm plates
- PST 16.1 (new): Do reports of LDT include a statement indicating the test performance specifications were established by the laboratory and the test has not been approved by the FDA
- QA 23 (new) The laboratory QA plan must include annual verification of the INR calculation
- TS 7: Written procedures must detail proper storage temperatures and how they are to be monitored and controlled
- FAC 14 The facility must have a written blood borne pathogens exposure control plan.

NPL Seminar

By Rhonda Burgard, Client Services Supervisor

The Northern Plains Laboratory Seminar is scheduled for Sept 15th, 2016 at the Ramada Hotel in Bismarck. Enclosed in this mailing is the seminar agenda and registration forms. We hope you are able to attend.

Helicobacter pylori Serology Tests

By Rhonda Burgard, Client Services Supervisor

Effective June 6th, ARUP laboratories will inactive the serology test codes for *Helicobacter pylori* (Test codes HPYA, HPYG, HPYGA) and refer clients to the *Helicobacter pylori* Stool Antigen test (HPSA) performed in-house at Northern Plains Laboratory. Mayo Medical Laboratories also discontinued offering *Helicobacter pylori* serology tests in January, 2016.

This change is supported by the current diagnostic guidelines recommended by the American College of Gastroenterology (ACG) and the American Gastroenterology Association (AGA). Antibody tests cannot distinguish between active and past infection with adequate sensitivity and specificity. Despite older literature suggesting that IgG serology can be used as a test cure after 18 months, this has shown to be inaccurate. The stool antigen test has been cleared by the FDA for use as a test of eradication.

Many commercial insurance carriers have also discontinued reimbursement for *Helicobacter pylori* serology tests.

If *Helicobacter pylori* serology testing is ordered by the provider PAML laboratories will perform this test with a disclaimer. Order these tests using test codes HPYAX, HPYGX and HPAGX.

Reference: ARUP Test Alert Inactivation of *Helicobacter pylori* Serology tests.

Zika Virus

By Rhonda Burgard, Client Services Supervisor

The North Dakota Department of Health has validated the CDC Trioplex RT-PCR assay for Dengue virus, Chikungunya virus and Zika virus. This assay is available at the North Dakota Department of Health free of charge for ND residents.

Samples received for Trioplex testing will be analyzed based on the patient's travel history, symptom of onset, symptoms and pregnancy status. Depending on the information provided and/or Trioplex test results, some samples may be forwarded to the CDC for IgM serology testing.

Additional information on Zika virus can be found at www.ndhealth.gov/disease/zika/.

Urine Cups

By Rhonda Burgard, Client Services Supervisor

We are now purchasing urine cups from Medline. The cups are similar in appearance to our current urine cups. Please notify Northern Plains Laboratory Client Services at 701-530-5700 if you experience any problems with leaking samples.

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