Northern Plains Laboratory

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Quality Corner- Laboratory Safety

By Rhonda Burgard, Client Services Supervisor

The Occupational Safety and Health Administration (OSHA) has safety guidelines that are designed to protect the more than 500,000 laboratory workers from exposure to workplace hazards.

Laboratory safety plans should include the following elements

- Chemical safety: Limiting exposure to hazardous chemicals by labeling of containers, availability of chemical Safety Data Sheets, appropriate transport and storage of chemicals, exposure monitoring, spill detection and clean-up and offering all employees chemical safety training.
- Biological safety: The CDC estimates more than 200 pathogens can be transmitted from exposure to blood. The Bloodborne Pathogen Standard (29 CFR 1910, 1030) requires employers to protect workers from infection with human bloodborne pathogens in the workplace. The employer must have a written exposure control plan, offer the Hepatitis B vaccine, offer biological safety training and provide the appropriate personal protective equipment (PPE) for employees.
- Physical safety: The laboratory should be evaluated for physical hazards including slips/trips/falls, fire and electrical risks. Fire alarms and extinguishers must be readily accessible and staff trained on their activation and use. Equipment that is damaged or undergoing service or maintenance must be labeled with a “lockout” tag.
- Radiation safety: Exposure to radiation is to be monitored and limited.

The most common threats to laboratory safety include the improper use of PPE and failure to follow protocols defined in chemical and biohazard safety plans. Engineering controls should be put in place to reduce risks. These may include biological and radiation signage, biological safety cabinets, chemical fume hoods, removing chemicals not in use, and ergonomic evaluations of the workspace to reduce the chances of injury.

The laboratory should build a culture of safety by doing the following:

- Conduct safety orientation, training and competency assessment for all employees
- Enforce safe work practices and conduct periodic safety audits
- Correct unsafe conditions
- Investigate workplace accidents
- Designate a laboratory safety officer that is responsible for the overall administration of the safety program.

Reference: OSHA Laboratory Safety Guidance, 2011

COLA Criteria Updates

By Rhonda Burgard, Client Services Supervisor

There have been changes to the 2020 COLA Accreditation Manual published in May 2020 in the ORG, PT, PST, IH, MSPEC, and QC sections of the manual. Some of the changes are listed below:

- All test procedures must be signed biennially by the Laboratory Director or delegated in writing to a qualified designee.
- For any proficiency scores of less than 100% the results must be evaluated and there must be documentation of corrective action.
- Test results must include the reference range and other pertinent information (i.e. test method) used for interpretation.
- Controls must be verified by repetitive testing to verify that they meet the manufacturer's established parameters for mean and standard deviation. This does not apply to single use test devices or when controls and reagents come packaged together as a unit. Five values are considered adequate to verify a range when performing parallel testing.
- Screening assays that are reported by the laboratory as qualitative (positive/negative) based on a cutoff or threshold must that verify the accuracy of the assay at the cutoff level at least every six months. This criteria applies to rapid toxicology tests. If the assay is calibrated with three or more calibrators every six months this criteria does not apply.
- Criteria must be established for when a manual cell count must be performed to verify an automated differential count.
- Transfusion medicine-All antiglobulin tests (IgG or polyspecific) must be checked with IgG coated red cells. All anti-complement reagents must be checked with C3-coated red cells.
- Transfusion medicine- Alarm checks must be performed at least quarterly and documentation include that the alarms sound as expected.
- Transfusion medicine-There must be a written procedure to verify the accuracy of thermometers used to monitor blood storage and they must be verified prior to use and annually.
- Transfusion medicine-The laboratory must have a procedure for reporting biological deviations to the FDA
- Transfusion medicine- All transfusion personnel must have initial training and annual continuing education in tasks relating to administration of blood and blood components.
- Transfusion medicine- There must be a written procedure in place to identify potential Rh immune globulin candidates and all Rh immune globulin candidates must be tested after delivery for fetomaternal hemorrhage that may require greater than the standard dose of Rh immune globulin

Reference: COLA Technical Bulletins, May 18th 2020

Drug Interference

By Rhonda Burgard, Client Services Supervisor

Eltrombopag, a drug used to treat thrombocytopenia and/or aplastic anemia may interfere with the Siemens Total Bilirubin assay causing a positive bias with Total Bilirubin results. No interference with the Direct Bilirubin assay has been identified.

New CDC Recommendations for Hepatitis C Virus Screening

By Rhonda Burgard, Client Services Supervisor

Hepatitis virus (HCV) infection is a major source of morbidity and mortality in the United States. HCV is transmitted through exposure to infectious blood or body fluids. While there is no vaccine for hepatitis C, there are new antiviral treatments that can result in a virologic cure in most infected individuals.

Persons with acute HCV infection are typically either asymptomatic or have a mild clinical illness. Jaundice only occurs in 20-30% of infected individuals. Up to 46% of people believed to be infected resolve their infection without sequelae. However, 5-25% may develop cirrhosis and an increased risk for hepatocellular cancer. The Center for Disease Control (CDC) estimates that only 10% of the actual number of HCV cases are detected each year.

CDC recommends testing for HCV infection among the following groups:

- Once for all adults $\geq$ 18 yrs. of age
- All pregnant women-each pregnancy
- All persons with risk factors including IV drug use, HIV, hemodialysis, transfusions prior to 1992, clotting factor recipients prior to 1987, healthcare workers with an exposure and children born to infected mothers.

The CDC recommends screening for the anti-HCV antibody and if positive testing by PCR for HCV RNA to identify chronic infection.

Reference: CDC Recommendations for Hepatitis C Screening among Adults-United States 2020

Test Utilization
Warfarin Sensitivity Genotyping

By Rhonda Burgard, Client Services Supervisor

Warfarin (Coumadin) is an anticoagulant reduces the body's ability to form blood clots by blocking the formation of vitamin K–dependent clotting factors. Factors that affect the body's response to warfarin include age, gender, body mass, diet, medications and genetic variants. Over dosing or under dosing of warfarin can lead to bleeding or thrombosis.

Genetic testing for warfarin sensitivity may be indicated for individuals prior to starting warfarin therapy, individuals with a personal or family history of difficulty with warfarin and patients taking warfarin that are difficult to maintain in therapeutic ranges.

An estimated 40-63% of the variability in therapeutic warfarin dose is accounted for by the CYP2C9*2*3 and VKORC1*2 variant alleles. The CYP4F2*3 allele is associated with an increased warfarin dose requirement. CYP2C/8/9 variants are associated with a reduced rate of warfarin catabolism, which is associated with a decreased dose requirement and increased time to achieve a steady dosage rage.

The ability to accurately dose patients on warfarin based on their genetic information reduces the risk of bleeding or clotting in this vulnerable patient population.

Reference: ARUP Laboratories Consult: Warfarin Sensitivity

COVID-19 Testing

By Rhonda Burgard, Client Services Supervisor

Coronaviruses are a large family of viruses that are common in humans and in many different species of animals, Rarely, animal coronaviruses can infect people and then spread between people such as with SARS-CoV, MERS-CoV, and now with SARS-CoV-2 (COVID-19)

Viral transmission happens during close exposure to a person infected with COVID-19 via respiratory droplets produced when an infected person coughs or sneezes. The virus may also be transmitted by touching a surface contaminated with the virus and then touching the mouth, nose, or eyes.

Because of the increased risk to public health from the COVID-19 virus, the Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for several different COVID-19 tests from a variety of manufacturers. CLIA requirements for verification of test performance must be followed before placing these EUA tests into use. Manufacturer's directions for quality control must be followed, however IQCP are not required. Serology tests that are on the market, that have been released without an Emergency Use Authorization by the FDA, are considered highly complex.

Personnel collecting and testing specimens for COVID-19 testing must follow the CDC recommendations for biosafety. This includes wearing personal protective equipment (PPE), including lab coats, gloves, masks, and eye protection. It is recommended all testing be performed under a biological safety cabinet (BSC) or behind a Plexiglas barrier. Specimen collection and testing areas should be disinfected frequently.

Two types of tests for COVID-19 are available:

- Molecular Diagnostic (PCR) Tests- These tests detect viral RNA and are recommended to determine current infection. Specimens for molecular testing include nasal pharyngeal swab (Best viral recovery), nasal mid-turbinate swab and oropharyngeal swab (Least amount of virus recovered). [2]
- Serology Tests- These tests measure the amount of antibodies present when the body is responding to a COVID-19 infection, typically within 8-11 days after the onset of symptoms. Some serology tests detect both IgM (early infection) and IgG (resolved infection) and others IgG only. Evidence of protective immunity is not currently available and according to the literature results should not be used to make staffing decisions or decisions regarding the need for PPE. Serological tests should not be used to diagnose infection. [3]

A second wave of COVID-19 infection is expected this fall or early winter. It is important that laboratories be prepared with an adequate amount of PPE and test capacity.

Reference:

1. **COLA Technical Bulletin COVID-19 Testing Fact Sheet**
2. **Comparative accuracy of oropharyngeal and nasopharyngeal swabs for diagnosis of COVID-19 www.cebm.not/covid-19**
3. **IDSA Antibody Testing Primer 4-20-2020**

ARUP Change to Monoclonal Protein Test

By Rhonda Burgard, Client Services Supervisor

ARUP new test: Monoclonal Protein Study, Expanded Panel, Serum (NPL test code: IFLCA / ARUP # 2002715)**.** This is the most comprehensive and preferred test to aid in the diagnosis and management of monoclonal gammopathies, including multiple myeloma. Use to detect, quantify, and characterize serum monoclonal protein. Includes protein immunofixation electrophoresis, quantitative immunoglobulins, Kappa & Lambda free light chains and an SPEP/IFE interpretation.

Please contact Northern Plains Client Services at 701-530-5700 if you have any questions or concerns.

Abbott ID Now COVID-19 Update

By Rhonda Burgard, Client Services Supervisor

In May 2020, Abbott issued a Technical Brief indicating that negative results should be treated as presumptive and tested with an alternative FDA authorized molecular assay.

Northern Plains Laboratory recommends the following actions:

1. Add the recommended comment to your test results: *"Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with an alternative molecular assay."*
2. Revise your standard operating procedure to include the recommended actions for negative test results, updated information for sample collection and handling and changes to the test procedure.
3. Add the technical bulletin to the reference section of your SOP. Please contact NPL if you would like a copy of the technical bulleting.
4. Save the Technical Bulletin in your documents for validation
5. Send out a memo to providers

Please contact Northern Plains Client Services at 701-530-5700 if you have any questions or concerns

RPR Testing on an Automated Instrument.

By Robert Arndt, Microbiology Supervisor

In October of 2019, Northern Plains Laboratory transitioned to an automated instrument for performing RPR testing as well as bringing RPR titers in-house. You may have noticed an increased number of reactive RPR samples with this change, which is expected. First of all, the automated system is designed to be more sensitive than manual methods. It eliminates human bias and reads every sample using the same standard algorithm. Secondly, there are always expected biological false positives, which are positive for the type of tissue damage RPR identifies but not due to syphilis infections. There was a study published in the Journal of Clinical Microbiology in August of 2018 that compared a manual RPR method to the AIX1000 system that is used by our laboratory. "The sensitivity and specificity of the manual ASI card were 76.0% and 99.8%, respectively, while the sensitivity and specificity of the AIX100 were 100.0% and 99.4%, respectively (sensitivity $P = 0.03$)."[1]

Therefore, you will see more patients with potential false positive results that test positive for the RPR but are then negative for the TPPA testing. However, with the extremely high sensitivity of this method, the incidence of a false negative is decreased to almost zero compared to manual RPR methods, where the false negativity rate can be almost 25%. "Overall, the fully automated AIX1000 system demonstrated significantly enhanced sensitivity and specificity similar to that of the manual ASI RPR card test, making the AIX1000 system suitable for the laboratory diagnosis of syphilis in a clinical laboratory setting."[1]

Reference

1. Sanfilippo AM, Freeman K, Schmitz JL. 2018. Comparison of Manual and Fully Automated AIX1000 Rapid Plasma Reagin Assays for Laboratory Diagnosis of Syphilis, J of Clin Microbiology Vol 56 Issue 8: https://jcm.asm.org/content/jcm/early/2018/03/29/JCM.00214-18.full.pdf

Campylobacter Antigen

By Ron Piatz, Research and Development

Northern Plains Laboratory (NPL) has added stool Campylobacter Antigen testing to our in house test menu. The CAMPYLOBACTER QUIK CHEK™ test is a rapid membrane enzyme-linked immunosorbent assay for the qualitative detection of a Campylobacter-specific antigen in human fecal specimens. The CAMPYLOBACTER QUIK CHEK™ test is designed to detect C. jejuni, C. coli, C. lari, and C. upsaliensis from patients with signs and symptoms of gastroenteritis.

With traditional culture methods, *Campylobacter* species are slow-growing, requiring up to 72 hours before reaching a point where the culture can safely be reported as negative. By performing Campylobacter Antigen testing the same day the specimen is received, better turn-around times can be offered. Also, since Campylobacter is a fastidious organism, studies have reported up to a 25% false negative rate with traditional culture methods.

Specimen:

Stool specimen submitted in Cary Blair transport media, refrigerated. Fresh stool can be sent, if delivered to the laboratory within one hour of collection, for a stool culture including Campylobacter Antigen. For Campylobacter Antigen testing only, raw stool or stool in Cary- Blair transport media can be stored refrigerated for up to 96 hours, if longer, send frozen.

NPL Reference Range: Negative

Test Code	CPT Code	Test Name	Specimen Requirements
CAMAG	87449	Campylobacter Antigen by Immunoassay	Stool in Cary-Blair Transport
FSHGC	87045 87046(x2) 87899(x2) 87449	Stool Culture including Shiga Toxin & Campylobacter Antigen	Stool in Cary-Blair Transport

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

Supply Ordering and Utilization

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. Please do not use NPL provided supplies or shipping containers for testing sent to other reference laboratories. We request you 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 usually be filled the same day.

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.