Northern Plains Laboratory

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Quality Corner- Choosing a New Laboratory Analyzer

By Rhonda Burgard, Client Services Supervisor

When choosing a new laboratory analyzer there are several questions to consider:

- What is the complexity of my laboratory? The analyzer or test chosen must fit within the CLIA complexity: waived, moderate or highly complex, assigned to your laboratory.
- What are the testing needs of my laboratory? Look at the test menu available on the analyzer for the best fit to your laboratory.
- What specimen type and/or sample size is required?
- What is the hourly output and turn-around time of test results? For laboratories with large test volumes or in urgent care settings faster outputs may be desirable.
- Can STAT samples be programmed to bypass routine samples?
- Is primary tube sampling available, does the instrument have a barcode reader and does the instrument perform automatic dilutions when required? These features allow for walk away capability that allows staff to perform other testing.
- Are there features on the analyzer that will prevent operation when maintenance or calibration is overdue or when QC is not within acceptable limits? These are desirable safety features that prevent patient results being reported when there are issues with instrument function.
- What are the space, electrical requirement and water source requirements for the instrument? It is important that the laboratory have adequate space, water source, ventilation and electrical capabilities for the new instrument.
- How much down time is there for this instrument? The manufacturer should be able to provide documentation for the average time required for maintenance, scheduled service, unscheduled service, calibration and shutdown time. It is also important to know how quickly a service representative can be available both remotely and on-site.
- What is the cost/test for this analyzer? The cost/test should include the cost of the instrument, purchase or rental, including the cost of any interfaces, cost of installation and staff training annualized over 5-7 years depending on the expected life of the instrument. The cost/ test should also include the annual cost of service contracts, cost of reagents, calibrators and QC material, cost of proficiency testing and cost of parts and supplies divided by the annual volumes of tests. Consider the cost of labor required for instrument operation and

maintenance. Compare the total cost/tests over a 5-7 year period for the different analyzers being considered.
- Are there any other items to consider? Ask for references from other users of the instruments you are considering.

Finding the answers to these questions during the purchase process will allow the laboratory to make the best decision for a cost effective analyzer that meets their operational needs.

Test Utilization

By Rhonda Burgard, Client Services Supervisor

Choosing Wisely is an initiative of the ABIM Foundation that seeks to advance a national dialogue on avoiding unnecessary medical tests, treatments and procedures. Some of their recent recommendations are:

- Do not order urine cultures unless patients have symptoms consistent with urinary tract infection. (American Society for Microbiology)
- Do not order a Lyme immunoblot without a positive Lyme Enzyme Immunoassay (EIA) screening test. Do not order Lyme serology on patients with a primary erythema migrans lesion. (American Society for Microbiology)
- Do not request routinely extended incubation of blood cultures in suspected endocarditis. (American Society for Microbiology)
- Avoid using hemoglobin to evaluate patients for iron deficiency in susceptible populations. Instead use ferritin. (American Society for Clinical Laboratory Science)
- Do not order a factor V Leiden mutation assay as the initial test to identify a congenital cause of a thrombotic event. Order a phenotypic activated protein C resistance (APCR) ratio assay. (American Society for Clinical Laboratory Science)
- Do not repeat Hepatitis C virus antibody testing in patients with a previous positive Hepatitis C virus (HCV) test. Order Hepatitis C viral load testing for assessment of active versus resolved infection. (American Society for Clinical Pathology)
- Do not use plasma catecholamine to evaluate a patient for pheochromocytoma or paraganglioma. Use plasma free metanephrines or urinary fractionated metanephrines. (American Society for Clinical Pathology)
- Do not routinely test for community gastrointestinal stool pathogens in hospitalized patients who develop diarrhea after day 3 of hospitalization. (American Society for Clinical Pathology)
- Do not order red blood cell folate levels at all. In adults, consider folate supplementation instead of serum folate testing in patients with macrocytic anemia. (American Society for Clinical Pathology)
- Do not screen for genital herpes simplex virus (HSV) infection in asymptomatic adults, including pregnant women. (American Academy of Family Physicians)

Additional information can be found at https://www.choosingwisely.org

CMS Guidance for COVID-19 Test Systems

By Rhonda Burgard, Client Services Supervisor

Because many COVID-19 test systems have been released with emergency use authorization (EUA) CMS has issued a document that clarifies the CLIA requirements for these tests.

- **Quality Control**- You must follow the manufacturer's instructions listed in the IFU for quality control. For instructions that state to follow "local, state, and/or federal regulations", the laboratory needs to follow non-waived CLIA quality control requirements, two levels of quality control daily, or develop an IQCP.
- **Specimen type-** You must follow the specimen type rules listed in the manufacturer's EUA and CDC guidelines. Any laboratory that alters the specimen type must be CLIA certified for high complexity testing, establish performance specifications and be in compliance with high complexity requirements.
- **Personnel**- Staff performing testing must meet the CLIA requirements for waived, moderate or high complexity testing depending on the test method/kit used. In North Dakota, personnel performing testing must be licensed by the Board of Clinical Laboratory Practice or exempt.
- **FDA cleared or approved test systems**-A test list of manufacturer's with EUA for COVID-19 testing is available on the FDA website. Do not use tests that have not received this approval.
- **Requisitions**-For non-waived testing there must be a written or electronic request for patient testing from an authorized provider.
- **Multiple sites**-The laboratory needs a separate CLIA application for each laboratory location, however CMS has permitted a laboratory to extend its existing CLIA certificate to operate a temporary/overflow location that is off-site (i.e. parking lot).
- **Reporting requirements**- CLIA inspectors will complete a focused survey for compliance with the CMS SARS-CoV-2 reporting requirements that all results, both positive and negative be reported for molecular, antigen and serology testing. Laboratory policy and procedures must address COVID reporting requirements.

Reference: CMS Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories Surveyor Guidance for New and Modified CLIA Requirements Related to SARS-CoV-2 Test Result Reporting. 1-8-2021

Biomarkers and Laboratory Tests Used in the Treatment of COVID-19 (SARS-CoV-2)

By Rhonda Burgard, Client Services Supervisor

Patients with COVID-19 illness can be classified by the severity of the clinical findings, response to therapy and clinical outcomes into three categories. The stages based on increasing severity are:

- Stage 1: Early infection which lasts from 2-14 days during which the virus multiplies. Primary symptoms are mild and nonspecific, such as fever and cough. 75% of patients that are diagnosed with COVID-19 remain in this stage and prognosis is excellent.
- Stage 2: The pulmonary phase is part of the viral response phase in

which the virus causes symptoms by cell infiltration and destruction. Patients may develop viral pneumonia with cough, fever and possible hypoxia. This group, about 20% of those diagnosed, may require hospitalization and may require mechanical ventilation.

- Stage 3: About 5% of patients diagnosed with COVID-19 progress to a hyper inflammatory phase. Symptoms include acute respiratory distress syndrome, heart failure, septic shock, secondary infections, coagulopathy, acute cardiac and kidney injury.

For stage 2 and 3 patients' biomarkers like Interleukin-6 (IL-6), Procalcitonin, Troponin, B-type natriuretic peptide (BNP), Ddimer and Ferritin are important in monitoring patient prognosis and treatment.

Interleukin-6 is a marker of severe inflammatory response and abnormal release of circulating cytokines such and interferons, interleukins and tumor necrosis factors which are involved in the inflammatory process. IL-6 may also be used as a predictor for respiratory failure and the potential need for a ventilator.

Procalcitonin (PCT) is a marker for the inflammatory response to bacteria, enabling the provider to differentiate between bacterial infection and other nonbacterial causes of lower respiratory tract infection. High PCT levels may be associated with the potential for septic shock and acute respiratory failure.

Troponin and BNP are a markers for myocardial injury. Patients with high baseline troponin and BNP values may have poorer outcomes than those patients with normal values.

Ddimer is used for the diagnosis of clot formation and breakdown and is a predictor for disseminated intravascular coagulation (DIC).

Ferritin is an indicator of severe inflammation. High levels are associated with worse clinical outcomes.

The clinical laboratory and the information that it provides is important in the diagnosis, treatment and monitoring of patients diagnosed with COVID-19 infections.

Reference: MLO, Jan 2021, Immunodiagnostic Tests

CMS Extends Expiration Dates on Certificates of Compliance and Accreditation

By Rhonda Burgard, Client Services Supervisor

CMS has issued a hold on routine, recertification surveys for hospital laboratories until February 20th, 2021. At that time CMS will determine if they will extend the hold for another 30 days. This ruling does not affect laboratories not affiliated with hospitals.

On Jan 1, 2021 CLIA extended the expiration dates on Certificates of Compliance and Accreditation to March 31st, 2021 for laboratories with certificates expiring before that date. If routine surveys are placed on hold past February 20th, CLIA has indicated they will extend the expiration dates again.

Reference: Shelly Heilman, ND CLIA Surveyor, ND Department of Health

High Sensitivity Troponin Assays

By Rhonda Burgard, Client Services Supervisor

Several manufacturers are releasing new high-sensitivity Troponin (hs-cTn) assays. Compared to current Troponin (cTn) assays the new assays have:

- Different units of measure and different reference ranges for males and females.
- Are more sensitive but less specific than current troponin assays. The new high sensitivity assays may be able to detect cTn in a greater number of non-AMI subjects who are healthy or have other cardiac and non-cardiac causes of chest pain. This information may be used in the future to stratify the risk of cardiovascular disease in stable patients.
- May require serial studies that are shorter in duration than current troponin methods before patients are able to be discharged.
- Because there is no standardization of high sensitivity troponin methodology, values obtained from different assays and/or assay methods cannot be used interchangeably.

When validating the new high sensitivity troponin assays work closely with your implementation specialist. Samples tested using current troponin methods and/or on different instruments may not correlate well.

When implementing the new high sensitivity troponin assay, it is very important to make sure providers, nursing personnel, pharmacists and any affiliated clinics or nursing homes are aware of the change and the new reference ranges. Your vendor may be able to provide educational material for you to use.

Reference: Siemens Healthineers High Sensitivity Troponin I Assay
CLN, Feb 2021 A New Use for Cardiac Troponin

Annual Physician Notification

By Ann Oie, Compliance Officer

Northern Plains Laboratory, LLC, (NPL) is committed to conducting business in adherence with all applicable federal and state laws, and to comply with the program requirements of federal, state, and private health plans.

In accordance with the Office of the Inspector General Compliance Program Guidance for Clinical Laboratories, published on August 4, 1998, the 2021 Annual Physician Notice has been mailed to providers and is available online at: http://northernplainslab.com/wp-content/uploads/2021/02/NPL-Annual-Physician-Notice-2021.pdf

2020 Inspection Citations

By Rhonda Burgard, Client Services Supervisor

The COVID-19 pandemic altered the normal accreditation process in 2020. Some laboratory inspections were made on-site, while others were conducted virtually and still others have been delayed and will be conducted in 2021. Here is a listing of the most common citations from COLA, Joint Commission and/or CLIA 2020 inspections:

- Test results manually entered into a LIS or EMR are not reviewed by a second person. Failure to have all the required report elements (test methodology, reference ranges,

performing laboratory) on the reports.
- Failure to perform QC or to review QC weekly. Failure to store QC for the required length of time. Failure to perform calibration verification when required.
- Storage location and temperature for reagents including Glucola.
- Proficiency attestation not signed, no staff review of proficiency results and/or no documentation for proficiency outliers.
- The laboratory does not have a standard operating procedure for each test including criteria for differential stain, hemocytometer duplicate count criteria and tolerance limits for correlation studies.
- The transfusion director must review and sign the nursing policy for blood administration.
- Facility- Cracked laminate on counter surfaces, worn phlebotomy chairs, cracked tile on floor.
- Safety- Failure to wear appropriate PPE or to use barrier methods, hoods or shields as required.
- Competency- Failure to have completed competency documentation for the laboratory director and for some testing personnel.
- Quality- Failure to complete the required pre-analytical, analytical and post-analytical annual audits.

A pre-inspection checklist is available upon request from Northern Plains Laboratory consulting staff at 701-530-5700.

CK MB Test to be Discontinued

By Michelle Steiner, Core Lab Supervisor

Troponin is the preferred biomarker in diagnosing acute myocardial infarctions (AMI). The 2014 American Heart Association/American College of Cardiology guidelines conclude that CK-MB provides no additional value for diagnosing AMI (class III, level of evidence A).

Cardiac troponin has been the biomarker of choice owing to its nearly absolute myocardial tissue specificity and high clinical sensitivity for myocardial injury. In addition to high sensitivity and specificity, troponin provides stronger prognostic information.

Concomitant use of CK-MB and troponin can also negatively affect patient care if results conflict. CK-MB provides no incremental value over troponin in the diagnosis of acute coronary syndrome in patients with chronic renal disease. The most recent guidelines of the American Heart Association, the American College of Cardiology and the European Society of Cardiology support the use of troponin over CK-MB for diagnosing re-infarction.

Based on these recommendations, NPL has determined to discontinue CK-MB testing by summer 2021.