Northern Plains Laboratory

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Quality Corner- CMS Proposes Changes to Proficiency Testing

By Rhonda Burgard, Client Services Supervisor

On February 4th, 2019 the Centers for Medicare and Medicaid Services (CMS) published new proposed rules for proficiency testing in the Federal Register that expands the list of regulated analytes for proficiency testing and defined new criteria for acceptable performance for proficiency testing.

The proposed rule includes the addition of several chemistry analytes to the regulated analyte listing as well as elimination of a few analytes.

The acceptable criteria for acceptable performance is proposed to be tightened for several chemistry and hematology analytes. For transfusion medicine the acceptable criteria for antibody detection is proposed to be changed from 80% to 100%

In microbiology, which includes bacteriology, mycology, parasitology and virology, CMS is proposing that new required categories that include (as appropriate); Gram stain including bacterial morphology, direct bacterial antigen detection, bacterial toxin detection, detection and identification of bacteria which includes one of the following: Detection of growth or no growth in culture media or identification of bacteria to the highest level that the laboratory reports results on patient specimens, and antimicrobial susceptibility or resistance testing on select bacteria. There are also specific requirements in the proposed rule that the proficiency samples must include representatives of the major groups of medically important aerobic and anaerobic bacteria. The requirement for "mixed" flora is proposed to be reduced from 50% to 25%.

Please be watch for the release of the final rule sometime in mid to late 2019.

The proposed rule is available on-line at https://www.federalregister.gov/documents/2019/02/04/2018-28363.

Vitamin D Testing

By Patti Schmidt, Billing Supervisor

Effective January 1, 2019, BCBS established a policy for payment of the Vitamin D assay. Per their rationale, Vitamin D testing is only appropriate in higher risk patients (ex. Osteoporosis, chronic kidney disease, long term high risk medications known to lower Vitamin D, known vitamin D deficiency). Routine screening or complaints of fatigue are not considered appropriate reasons for testing. BCBS will not reimburse for the testing and NPL will not be able to bill the patient. The medical policy is located at: http://wwww.bcbsndmedicalpolicy.com/documents/vitamin-d-assay/. Please share this information with your providers.

ARUP Offers Two New Assays for Autoimmune Neuropathy

By Rhonda Burgard, Client Services Supervisor

ARUP now offers two new assays to aid in the diagnosis of CNS demyelinating disease or autoimmune encephalitis.

Test # 3001277 Myelin Oligodendrocyte Glycoprotein (MOG) Antibody, IgG by IFA with Reflex to Titer, Serum

Test # 3001283 Autoimmune CNS Demyelinating Disease Reflexive Panel

Aquaporin-4 receptor (AQP4) and myelin oligodendrocyte glycoprotein (MOG) antibody testing is used for diagnosis and evaluation of neuromyelitis optica (NMO), acute myelitis, spinal cord lesions, autoimmune encephalitis, or NMOSD.

The indirect fluorescent antibody assay utilized full-length MOG transfected cell lines for the detection and semi-quantification of MOG IgG antibody. This methodology compares highly to FACS methodology, with an overall agreement of 98.8%.

Mayo Medical Laboratories Phlebotomy Training Modules

By Rhonda Burgard, Client Services Supervisor

Mayo Clinic Laboratories is implementing a series of phlebotomy training modules that are free to access and offer 1.0 PACE credit/module. The first module is entitled “Fundamentals of Phlebotomy” and is available at https://news.mayocliniclabs.com/on-demand/.

Additional phlebotomy related topics that are available on the Mayo website are:

- Phlebotomy Top Gun: Order of Draw-Do We Still Care?
- Blood Cultures: Present and Future Challenges
- Pseudo hyperkalemia
- Drawing Blood From a Patient Receiving Intravenous Fluids
- Arterial Punctures
- Measuring Potassium in Capillary Blood Samples
- From Pediatrics to Geriatrics (Pediatric Phlebotomy)
- Phlebotomy Training and Competency Assessment

ARUP Chart Format Change for Benzodiazepines

By Rhonda Burgard, Client Services Supervisor

ARUP has modified how cutoff values and interpretative comments appear on the report for Benzodiazepines, Urine, Quantitative (Test code BNZQU). Drug components will be re-ordered in the report. The main interpretive comment will be moved from the diazepam drug result field to the last drug reported, alpha-hydrozymidazolam. The cutoff values for each drug component will now appear in their own individual interpretative data section rather than in one all-inclusive paragraph.

Northern Plains Laboratory Test Catalog Changes

By Rhonda Burgard, Client Services Supervisor

The Northern Plains Laboratory Test Catalog now contains an electronic “hot link” to Mayo Medical Laboratory test catalog information. In addition, this link to the Mayo Medical Laboratory test catalog also offers access to Mayo test algorithms and educational offerings.

Since clients that search for test information in the NPL Connect (HVR) will have tests display that “hot link” to both ARUP and Mayo test catalogs, NPL will no longer update the NPL Test Catalog with ARUP and Mayo specimen requirements and reference interval changes. You will note that when exiting the search screen, only basic test information will display.

Northern Plains Laboratory has also recently reviewed the Test Catalog and updated reference ranges, specimen requirements and CPT codes for tests done internally at NPL.

New information on “Laboratory Tests Used for Monitoring Anticoagulants” has been added to the NPL Test Catalog under the General Information section. Please review and share with your medical staff as needed.

If you have any questions or concerns please contact Rhonda Burgard, Client Services Supervisor at 701-530-5700

Calibration and Calibration Verification Requirements

By Rhonda Burgard, Client Services Supervisor

CLIA has changed the exceptions for calibration verification and now lists factory or manufacturer calibrated test systems as an exception to the calibration verification requirements.

CLIA §493.1255 Standard: Calibration and calibration verification procedures
(b) Perform and document calibration verification procedures – . . .
EXCEPTIONS: . . .
5. Calibration verification is not required on: Instruments that are factory or manufacturer calibrated . . .

COLA has similar language in their inspection checklist.

COLA CA2 Is calibration verification performed, according to the manufacturer’s instructions…..

EXCEPTIONS
- For automated cell counters, calibration verification is met if the lab follows manufacturer’s instruction for instrument operation and performs a minimum of two (2) levels of QC each day of testing. NOTE: This exception does not apply to centrifugal Hematology analyzers.
- For test systems which the laboratory performs three (3) levels of NIST traceable controls (low, mid, and high range) more than once each day of testing and follows manufacturer’s instructions, the requirement for calibration verification is met.
- For instruments that are factory calibrated and do not allow user calibration, calibration verification is not required.

Tick Bites!

By Robert Arndt, Microbiology Supervisor

Now that summer is finally here, the ticks are out and roaming the countryside. Infections from tick bites are very important to the Microbiology laboratory as they may potentially be caused by Francisella tularensis. Francisella tularensis is a slow growing tiny gram-negative coccobacilli that generally may cause infections in rabbits, hares, and rodents which can then be transmitted to humans. Infections with F. tularensis happen in a number of ways:

- Tick and deer fly bites (transient host for the bacteria)
- Skin contact with infected animals
- Drinking contaminated water
- Inhaling contaminated aerosols or agricultural and landscaping dust
- Laboratory exposure
- Exposed as an result of bioterrorism

As you can see above, tick bites are a primary vector for this disease, and if you look towards the bottom of the list, laboratory exposure is also a primary mode of infection. At Northern Plains Laboratory, we have never had a laboratory associated infection caused by this bacteria. However, we have had technologists that have had to be prophylactically treated just to be safe.

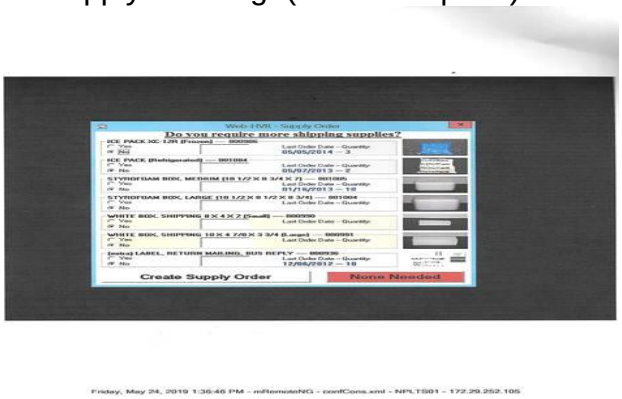
Exposure may occur when the microbiology lab does not have sufficient information (such as knowing the site was a Tick Bite) to work up this suspected organism. Please remember to provide information, such as Site: Lt Shoulder Wound from Tick Bite. There is minimal risk of exposure when collecting the patient sample if proper PPE is used. However, once the organism has grown on an agar plate, the risk of exposure is increased for laboratorians.

Therefore, it is important for the collecting and ordering entities of wound culture samples, to provide the microbiology lab with the most accurate source/site descriptions possible so that the Microbiology laboratory can accurately isolate and report out infectious isolates in a timely, efficient and safe manner.

Supply Ordering

By Rhonda Burgard, Client Services Supervisor

Northern Plains Laboratory is discontinuing the supply order screen that displays when the send log is accessed. (See example 1) The HVR supply order button should be utilized for supply ordering. (See example 2).



Example 1

Example 2

Alert Values

By Rhonda Burgard, Client Services Supervisor

Effective 5/16/19, Northern Plains Laboratory has discontinued calling providers with the following urinalysis alert values:

- 3+ glucose
- 3+ ketones
- Cellular casts
- Polarizing fat with a high protein
- Oval fat bodies, fatty casts, or waxy casts
- More than 5 granular casts per low power field
- Diagnostic crystals such as leucine or cysteine
- Positive total reducing sugars in newborns
- Positive pregnancy tests on dermatology patients (Accutane)

Supervision of Personnel Performing Exempt Testing

By Rhonda Burgard, Client Services Supervisor

Effective August 1st, 2019, The North Dakota Board of Clinical Laboratory Practice regulations have been amended to allow supervision of individuals performing exempt tests to be supervised by the following personnel:

- An individual who is licensed by the board
- A physician licensed by the board of medicine
- An advanced practice registered nurse licensed by the board of nursing
- Other categories of individuals approved by the board by rule.

Personnel performing whole blood glucose waived tests as categorized by the Food and Drug Administration are exempt from North Dakota Board of Clinical Laboratory Practice licensure and regulatory requirements.

Reference: Sixty-sixth Legislative Assembly of North Dakota Senate bill NO. 2170

PNEUMONIA PANEL BY PCR (Test code: PNARC)

By Ron Piatz, Research and Development

Effective 6-18-19, Northern Plains Laboratory (NPL) is pleased to announce the addition of the FilmArray® Pneumonia Panel, to our in house test menu. The FilmArray® Pneumonia Panel is a rapid, multiplexed, nucleic acid test for the simultaneous detection and identification of multiple respiratory viral and bacterial nucleic acids, as well as select antimicrobial resistance genes, in sputum-like specimens (induced or expectorated sputum, or endotracheal aspirates) or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL) obtained from individuals suspected of lower respiratory tract infection. Some bacteria are reported semi-quantitatively with bins representing approximately 10^4, 10^5, 10^6, or ≥10^7 genomic copies of bacterial nucleic acid per milliliter (copies/mL) of specimen, to aid in estimating relative abundance of nucleic acid from these common bacteria within a specimen. This panel tests for the organisms listed below:

Bacteria reported with bins of 10^4, 10^5, 10^6, or ≥10^7 copies/mL		
Acinetobacter calcoaceticus-baumannii complex	Klebsiella oxytoca	Serratia marcescens
Enterobacter cloacae complex	Klebsiella pneumoniae group	Staphylococcus aureus
Escherichia coli	Moraxella catarrhalis	Streptococcus agalactiae
Haemophilus influenzae	Proteus spp.	Streptococcus pneumoniae
Klebsiella aerogenes	Pseudomonas aeruginosa	Streptococcus pyogenes

The following atypical bacteria, viruses, and antimicrobial resistance genes are reported qualitatively:

Atypical Bacteria		
Chlamydia pneumoniae	Legionella pneumophila	Mycoplasma pneumoniae
Viruses		
Adenovirus	Human Rhinovirus/ Enterovirus	Parainfluenza Virus
Coronavirus	Influenza A	Respiratory Syncytial Virus
Human Metapneumovirus	Influenza B	
Antimicrobial Resistance Genes		
CTX-M	NDM	*mecA/C* and MREJ
IMP	KPC	
OXA-48-like	VIM	

Specimen:

- **Bronchoalveolar lavage (BAL)-like specimens** including BAL and mini-BAL.
- **Sputum-like specimens –** induced/expectorated sputum, as well as endotracheal aspirate (ETA) Submit samples in a sterile container. Specimens are stable at refrigerated temperature for up to 24 hours at 2–8°C. Sputum samples will be evaluated for quality/acceptability prior to testing. Swab transports are unacceptable.

Note: Respiratory culture and Gram stain will be performed in conjunction with Pneumonia PCR panel.

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

Test Code	CPT Codes	Test Name	Specimen	Reference Range
PNARC	87486 87541 87581 87632 87798 x15	Pneumonia Panel by PCR	Sputum or Endotracheal Aspirates or Bronchoalveolar Lavage (BAL)	Neg