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Wishing you a happy holiday season from all of us at Northern Plains Laboratory

COVID Testing Validation

By Rhonda Burgard, Client Services Supervisor

Laboratories implementing COVID testing are required to do the following:

- Perform validation studies for accuracy. The number of samples to be used may be determined by the laboratory director.
- Perform quality control testing. An IQCP is not required for tests that have FDA Emergency Use Authorization (EUA). If a test does not have an EUA it is considered highly complex and QC must be performed each day of testing.
- Report all results, both positive and negative to state health departments
- Be enrolled in proficiency testing or perform an alternate accuracy assessment twice a year.
- Cease testing of any tests on the FDA's "Removed/Do not Distribute" test list. If using a test that does not have EUA approval disclaimer comments must be added. Additional information may be found on the COLA website at www.colacentral.com.

Quality Corner- Waived Testing

By Rhonda Burgard, Client Services Supervisor

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) simple, low risk tests are classified as "waived tests" and performed with no routine regulatory oversight in physician's offices and various other locations. Sites performing only waived tests comprise 58% of the approximately 180,000 laboratory testing sites in the United States.

Laboratory tests are important if the diagnosis and treatment of the patient. With the increasing number of waived tests available, the Center for Medicare and Medicaid Services (CMS) has expressed concern about the quality of test results being produced. During a survey of 4214 waived testing sites the following issues were identified:

- Personnel and Training- No education of training is required is required for the director or testing personnel for waived testing. The survey found that much of the waived testing is being performed by nurses or medical assistants (75%). High turn-over rates and a lack of training were identified as problems.
- Testing Practices- 21% of testing locations did not perform quality control (QC) as specified and 5% did not perform calibration or function

checks as required. 6% of locations were using expired kits/reagents and 3% of locations failed to adhere to proper storage/temperature conditions. 45% of locations did not track kit lot numbers and expirations or have documentation of QC and/or patient testing results.

As a result of this survey the Centers for Disease Control has developed the "Ready? Set? Test? Patient Testing is Important. Get the right results" booklet for waived testing locations. This booklet along with a waived testing self-assessment checklist can be found at www.cdc.gov/clia/Resources/Waived Tests/.

Some of the recommendations in the booklet are:

- Promote and offer opportunities for employee training and continuing education.
- Comply with OSHA standards for the safety and health of employees.
- Make sure the testing environment has adequate space, lighting, temperature and humidity levels.
- Make sure the best test is selected for use and that manufacturer's instructions are available for testing personnel and are followed exactly as described.
- Conduct internal and external quality assessment to make sure your test systems are functioning properly.
- Make sure all QC and test results are recorded at the time of testing.

Reference: Good laboratory practices for Waived Testing Sites Survey Findings www.cola.org.

CMS Extension of CLIA Certificate Expiration Dates

By Rhonda Burgard, Client Services Supervisor

Effective, August 27, 2020 CMS announced that it had extended the expiration date to December 13, 2020 for all CLIA certificates that were set to expire this year. CMS will not be printing new CLIA certificates that indicate the extended expiration date. Additional information can be found at www.cms.gov/Regulations-and-Guidance/Legislation/ CLIA/CLIA Laboratory Demographic information.

Competency for New Test Methods

By Rhonda Burgard, Client Services Supervisor

Many laboratories have implemented COVID testing in 2020. Please remember if you have added a new test, staff performing the test are required to document competency at 6 months and again at 12 months. You will need to add the new test to your orientation and competency checklists.

AACC's Guide to Lab Test Utilization

By Rhonda Burgard, Client Services Supervisor

AACC Academy and Science and Practice Core Committee have developed a test utilization resource focusing on commonly misused tests in hospitals in clinics. Improper test utilization can result in poor patient outcomes and waste in the healthcare system.

Some of the tests identified by the committee as over utilized are:

- 72 Hour Quantitative Fecal Fat: This test is not indicated in the differentiation of pancreatic diseases, including pancreatitis, cystic fibrosis and cancer, and should be used with caution in the evaluation of malabsorption. Often, results from 72 hour quantitative fecal fat testing do not provide significant clinical value and do not provide additional information on the causation of malabsorption. Test results are highly sensitive to dietary requirements which may significantly impact the test interpretation.
- Anti-Gliadin Antibody (AGA) Assay: This test is not recommended for the detection of celiac disease. It has low diagnostic accuracy and is considered outdated. The Immunoglobulin A (IgA) anti-tissue transglutaminase (tTG) antibody is the preferred test and has 95% or higher sensitivity and specificity for celiac disease. Tests for antibodies against the deamidated peptide of gliadin (anti-DGP) have replaced the AGA test.
- CK-MB: Routine measurement of CKMB is no longer indicated in the assessment of patients with a possible acute coronary syndrome. Troponin I or T are superior markers of myocardial injury.
- Vitamin B12 or Cobalamin: Screening for Vitamin B12 deficiency should only be performed if risk factors are present which include gastric or small intestine resections, inflammatory bowel disease, use of metformin for more than 4 months, use of proton pump inhibitors or histamine H2 blockers for more than 12 months, strict vegetarians and adults older than 75 years.
- 25-hydroxyvitamin D, and 1, 25-dihydroxyvitamin D: These test should only be ordered for individuals at risk of vitamin D deficiency including breastfed infants, older adults, those with limited sun exposure, dark skin, inflammatory bowel disease and other malabsorption disorders, obesity or gastric bypass. These tests should not be ordered as population screening tests. 1, 25-dihydroxyvitamin D should not be ordered to evaluate vitamin D status and only ordered to monitor acquired or inherited disorders of vitamin D metabolism. There are rarely any indications for ordering both 25-hydroxyvitamin D and 1, 25-dihydroxyvitamin D.

Additional information can be found at: www.labtestsonline.org/optimal-testing-aaccs-guide-lab-test-utilization.

Cold Weather Shipping

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. Primary serum tubes arriving frozen will have the following comment appended based manufacture recommendations and an internal study performed at NPL: "Primary collection tube received frozen. Internal studies indicate that sodium and chloride may have a negative bias of approximately 7%."

If sending EDTA specimens for CBC's, please wrap them in bubble bags 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. Do not remove the plastic liners from the Styrofoam containers.

If winter weather makes it impossible for the courier companies to travel, NPL will send a HVR memo and/or call the impacted clients. If your facility will be closed due to adverse weather conditions, please notify NPL client services at 701-530-5700.

Satisfaction Survey

By Rhonda Burgard, Client Services Supervisor

Customer satisfaction surveys were mailed in early November. If you have not already returned your survey, please do so by December 11th, 2020. Thank you.

AABB Standards 32nd Edition Changes

By Rhonda Burgard, Client Services Supervisor

The American Association of Blood Banks has just released the 32nd Edition of the Standards for Blood Banks and Transfusion Services. Some of the changes include:

- 1.4.1 The transfusion service shall have a policy to address inventory shortages.
- 3.5.2.4 If there is an instrument malfunction or failure investigation should include a determination if other equipment is similarly affected.
- 3.9.6 The facility must have measures in place to minimize the risk of an internal or external data breach.
- 5.8.5 Donor unit testing now includes testing in some states for *Babesia* spp.
- 5.14.2 If an Rh type discrepancy is detected and the transfusion is necessary before resolution, only Rh-negative Red Blood Cells shall be issued to patients of childbearing potential.
- 5.16.2.1.1 The computer system shall be an FDA 510(k) cleared medical device.
- 5.19.3 The transfusion service shall have a policy regarding the use of washed cellular products.
- 6.2C Alarm investigation documentation must be kept for 5 years.
- 8.2 Blood utilization should include the use of group O and group O Rh (D) negative RBCs and AB plasma.

The new standards also address the addition of some new component types:

- Whole blood leukocyte reduced
- Pathogen-reduced plasma
- Pathogen-reduced platelets
- Cold stored platelets

Additional information can be found on the AABB website at AABB.org

Reference: 32nd Edition of the Standards for Blood Banks and Transfusion Services

Herpes Simplex Virus & Varicella Zoster Virus Amplified Molecular

By Ron Piatz, Research and Development

Northern Plains Laboratory (NPL) is pleased to announce the addition of the Quidel Solana Herpes Simplex Virus 1 (HSV-1), Herpes Simplex Virus 2 (HSV-2) and Varicella-Zoster Virus (VZV) assay to our in house test menu. The Solana HSV 1+2/VZV Assay is an in vitro diagnostic test, using isothermal amplification technology (helicase-dependent amplification, HDA), for the qualitative detection and differentiation of HSV-1, HSV-2 and VZV DNA isolated and purified from cutaneous or mucocutaneous lesion samples obtained from symptomatic patients suspected of active infection.

HSV-1 and HSV-2 are DNA viruses that can cause lesions at a variety of cutaneous and mucocutaneous sites. These lesions can be a result of the primary infection by the virus or they can result from a reactivation of the latent virus, causing recurrent episodes of the disease. HSV-1 and HSV-2 are genetically and antigenically distinct forms of HSV. HSV-2 is the most common cause of genital infections, due to venereal transmission; HSV-1 is commonly associated with other disease locations although both serotypes have been shown to cause disease in all locations of the body.

Primary VZV infection results in chickenpox (varicella), which may rarely result in complications including encephalitis or pneumonia. Even when clinical symptoms of chickenpox have resolved, VZV remains dormant in the nervous system of the infected person (virus latency). In approximately 10 to 20% of cases, VZV reactivates later in life producing shingles.

Specimen:
Collect vesicle swab or fluid from cutaneous or mucocutaneous lesions. Place swab or fluid in Universal Transport Media (UTM) or Viral Transport Media immediately. Specimens are stable at room temperature (up to 30°C) for up to 48 hours and at 2-8°C or –20°C for up to 7 days.

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

Test Code	CPT Code	Test Name	Specimen	Reference Range
HVZAM	87529(x2) 87798	HSV & VZV Amplified Molecular	Swab in UTM or VTM	Negative
HSVAM	87529(x2)	HSV Amplified Molecular	Swab in UTM or VTM	Negative
VZVAM	87798	VZV Amplified Molecular	Swab in UTM or VTM	Negative

Blood Culture Identification

By Ron Piatz, Research and Development

Northern Plains Laboratory (NPL) is switching to an enhanced BioFire Blood Culture Identification 2 (BCID2) Panel. The BCID2 panel uses an aliquot of blood from a positive blood culture bottle to test for 43 targets associated with bloodstream infections, including gram-negative bacteria, gram-positive bacteria, yeast, and 10 antimicrobial resistance genes—all with one test and with results available in about an hour from positive blood culture.
The BioFire BCID2 Panel

features broadened inclusivity for *Enterobacterales*, new assays for fungal and anaerobic pathogens, and additional identification of coagulase-negative *Staphylococcus* species.

The BioFire BCID2 Panel menu includes seven additional resistance genes, including carbapenemases and colistin resistance genes. An MREJ assay allows for more specific MRSA identification. See the complete listing below:

GRAM-NEGATIVE BACTERIA

Acinetobacter calcoaceticus baumannii complex
*Bacteroides fragilis******
Enterobacterales
- *Enterobacter cloacae* complex
- *Escherichia coli*
- *Klebsiella aerogenes******
- *Klebsiella oxytoca*
- *Klebsiella pneumoniae* group
- *Proteus*
- *Salmonella******
- *Serratia marcescens*

Haemophilus influenzae
Neisseria meningitidis
Pseudomonas aeruginosa
*Stenotrophomonas maltophilia******

GRAM-POSITIVE BACTERIA

*Enterococcus faecalis******
*Enterococcus faecium******
Listeria monocytogenes
Staphylococcus
- *Staphylococcus aureus*
- *Staphylococcus epidermidis******
- *Staphylococcus lugdunensis******

Streptococcus
- *Streptococcus agalactiae*
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes*

YEAST

Candida albicans
*Candida auris******
Candida glabrata
Candida krusei
Candida parapsilosis
Candida tropicalis
*Cryptococcus neoformans/gattii******

ANTIMICROBIAL RESISTANCE GENES

Carbapenemases
IMP*****
KPC
OXA-48-like*****
NDM*****
VIM*****

Colistin Resistance

*mcr-1******

ESBL

CTX-M*****

Methicillin Resistance

mecA/C
mecA/C & MREJ (MRSA) *****

Vancomycin Resistance

vanA/B

*** Indicates a new target on the BioFire BCID2 Panel**

Specimen:

The BioFire BCID2 Panel is performed directly on positive blood culture samples that demonstrate the presence of organisms as determined by Gram stain.

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

Test Code	CPT Code	Test Name	Specimen
BCIDP	87150(x33)	Blood Culture Identification by PCR	Aliquot from a positive blood culture bottle.

High Sensitivity Troponin I

By Rhonda Burgard, Client Services Supervisor

Siemens Healthcare has notified Dimension users that the current Dimension EXL Cardiac Troponin I (TNI) assay reagents will not be offered for purchase after November 30, 2021. This reagent will be replaced with the Dimension EXL High-Sensitivity Troponin I (TNIH) assay. Please note that there are significant differences between the two assays including units of measure, gender specific reference ranges, and serial testing protocols.

Laboratories making this conversion should work with your Laboratory Director and Clinical Consultant to establish test protocols and to offer provider education.

SARS-COV-2 IgG Antibody

By Ron Piatz, Research and Development

Northern Plains Laboratory (NPL) is pleased to announce the addition of the Access SARS-CoV-2 IgG assay to our in house test menu. The Access SARS-CoV-2 IgG assay is a paramagnetic particle, chemiluminescent immunoassay intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum or plasma. This assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

Note: The Access SARS-CoV-2 IgG assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

Specimen:
Collect: Serum separator tube. Also acceptable: Plasma from Li Heparin, EDTA or Citrate tube.

Transport: Spun gel serum separator tube or 0.5 mL serum or plasma in a Standard Transport Tube, refrigerated. If specimen will not arrive within 48 days of collection, send frozen.

Unacceptable Conditions: Lipemic or hemolyzed samples.

Stability: Room temperature: 8 hours, Refrigerated: 48 hours, Frozen: 30 days (Avoid Freeze/thaw cycles)

NPL Reference Range: Non-Reactive

Test Code	CPT Code	Test Name	Specimen Requirements
CVABG	86769	SARS-COV2-IGG AB	0.5 mL serum/plasma

Reimbursement Based on Medical Necessity

By Patti Schmidt, Billing Supervisor

Blue Cross/Blue Shield of North Dakota has begun to follow Medicare guidelines for some tests deemed to not be medically necessary. The two high volume tests affected by this ruling are the Vitamin D assay and COVID-19 antibody test. Blue Cross/Blue Shield will not reimburse for these tests, and the patient cannot be billed, unless the patient signs an Advance Member

Notice form available on the Northern Plains Laboratory website at www.northernplainslab.com.

For Covid-19 Antibody testing: an Advance Member Notice form should be submitted with all samples from patients with Blue Cross/Blue Shield insurance. The estimated cost is $62.00

For Vitamin D testing, except for diagnosis code E55.9 (known Vitamin D deficiency): an Advance Member Notice form should be submitted with all samples from patients with Blue Cross/Blue Shield insurance. Please reference the Blue Cross Blue Shield laboratory test policies and coverage at www.bcbsnd.com/providers/policies-precertification. Vitamin D is listed under the uncategorized section. The estimated cost is $119.00.

Please share this information with your providers.

Any questions may be directed to the Northern Plains Laboratory billing office at 701-222-2480 or 1-800-659-0395.

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