Volume 16 Issue 76 401 North 9th Street, Bismarck ND 58501-4507 Sept 2020

Welcome to Dr. Elena Rodgers-Rieger

By Rhonda Burgard, Client Services Supervisor

Dr. Elena Rodgers-Rieger is a new pathologist affiliated with Pathology Consultants PC and Northern Plains Laboratory. She has greater than ten years of experience in surgical pathology, cytopathology, and clinical pathology. Dr. Rodgers-Rieger has experience in clinical lab directorships and lab and hospital physician leadership. She received her doctor of medicine degree from the University of North Dakota and completed her residency training in Anatomic and Clinical Pathology at the University of Minnesota. Her fellowship training in Surgical Pathology was completed at the University of Minnesota. Dr. Rodgers-Rieger is licensed to practice medicine in North Dakota, South Dakota and Minnesota and is a member of the College of American Pathologists and American Society of Clinical Pathology.

Northern Plains Laboratory Non-consulting visits

By Rhonda Burgard, Client Services Supervisor

Each year Northern Plains Laboratory (NPL) consultants make an educational visit to each non-consulting location. Because of COVID-19 transmission concerns, NPL regretfully announces we will not make any non-consulting visits in 2020. Your business is important to us, and if you have any issues or concerns with NPL service or have any questions for the consulting medical technologists please contact NPL client services at 701-530-5700.

Quality Corner- Improving Laboratory Practices using the LEAN Model

By Rhonda Burgard, Client Services Supervisor

In today's healthcare environment it is important for all laboratories to improve both the quality and efficiency of their operations. Laboratories are being asked to do things more accurately, faster and quicker with fewer people.

One way these goals can be accomplished is by the use and implementation of LEAN tools for improving workflow, efficiency and quality.
Lean is a systematic approach to identifying and eliminating waste through improvement in process workflow. Waste is any task that requires time, costs, or work and adds no value to the system.
Some examples of waste are:

- Waiting times between steps of a process.
- Wasted movement of materials or specimens from one work area to another. Excessive manual paperwork or electronic keystrokes.
- Over-production which includes unnecessary re-testing, overly sensitive instrumentation, performing testing not specifically requested and excessive review of results.
- Waste of inventory which includes having more supplies on hand than needed.
- Defects which includes wrong patient/wrong test, missing or inaccurate information, degraded samples and patient complaints.
- Waste of overproduction which includes allowing specimens to sit while waiting for downstream processes to have capacity.
- Waste of miss-utilization of skills that includes not taking advantage of people's expertise, not cross training and not taking advantage of continuous improvement ideas and activities.

There are several tools that can be used to identify and reduce waste in a system. Some of these are:

- Value Stream Mapping which is diagraming the workflow in a process from start to finish and identifying waiting times, transportation wastes and other impediments to efficiency of the system. It can also include diagramming laboratory lay out and specimen movement and identifying optimal laboratory design.
- Point of Use Storage which includes having the needed supplies and reagents at the point of testing and eliminating excess inventory.
- SS System which includes removing clutter from the workspace and standardizing workspace layouts
- Visual Management which includes visual clues for specimen drop off and for the push and pull of specimen flow.
- Standard Work which includes determining best work practices which are followed by everyone.
- Mistake-proofing which includes creating processes that allow tasks to be completed correctly and accurately 100% of the time.

Laboratories that implement LEAN practices often see a 30-60% reduction in turn-around times, a 30-60% reduction in inventory requirements and a 40-50% reduction in costs due to enhanced efficiencies.

Reference: Mayo Clinic LEAN Simulation Workshop

Utilization Management

By Rhonda Burgard, Client Services Supervisor

Homocysteine: Homocysteine may be elevated in patients with a vitamin B12 or folate deficiency. Elevated homocysteine levels may also be correlated with an increased risk of heart attack and stroke. Homocysteine, Total is not recommended for risk assessment of cardiovascular disease or venous thromboembolism, but it is an acceptable screening test for disorders of methionine metabolism (e.g., congenital hyperhomocysteinemia).

Bence Jones Protein: Kappa/Lambda Quantitative Free Light Chains with Ratio, Serum and Kappa and Lambda Free Light Chains (Bence Jones Protein), Quantitative, Urine aid in the evaluation and management of multiple myeloma and related disorders. These tests typically do not need to be repeated if serum protein electrophoresis (SPEP) results are consistent with previous findings.

Catecholamine and Metanephrines: Metanephrines, Plasma (Free) and Metanephrines, Fractionated by HPLC-MS/MS, The use of a urine specimen detects most cases of pheochromocytoma. Fractionated Plasma Catecholamine's is usually unnecessary and should be performed as a follow-up test only if a patient exhibits clinical symptoms of excess catecholamine secretion. Vanillylmandelic Acid (VMA), Urine is useful only in diagnosing neuroblastoma but not in diagnosing pheochromocytoma.

Thyroid Function Screening: For initial thyroid function screening in non-pregnant individuals, order Thyroid Stimulating Hormone with reflex to Free Thyroxine. For pregnant women, the optimal method of thyroid screening is Thyroxine, Free (Free T4), rather than TSH/free T4 combination. Triiodothyronine, Free (Free T3), and Triiodothyronine, Total (Total T3), should be ordered only for specific circumstances (e.g., abnormal TSH/normal free T4 and suspicion of thyroid disease). Thyroid panels containing obsolete tests such as T3 uptake and total T4 should not be ordered.

Francisella tularensis and Tick Bites!

By Robert Arndt, Microbiology supervisor

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 and the most common source for human infection)
- Skin contact with infected animals
- Drinking contaminated water
- Inhaling contaminated aerosols or agricultural and landscaping dust
- Laboratory exposure
- Exposed as a 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. Laboratory technologists may need prophylactic

antibiotic treatment if they have had potential exposure to Francisella in the laboratory. This can 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. Or, use the microbiology test code "MC" with a source of "tick bite (source code TICK)". It is critically important for the collecting/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.

Please share this information with your providers so they can be aware of this needed information.

Discontinued Tests

By Rhonda Burgard, Client Services Supervisor

The following tests were discontinued by Northern Plains Laboratory

Test name	NPL Test Code	Alternate ARUP Test Code
Hemosiderin	HEMOS	20222
Urine Scr 4 (Ord by MDC only)	US4	NA
Spun Hct (Ord by NPL only)	HCTM	NA
Eosinophil Count	EOSCT	NA
Buffy Coat	BUFFY	NA
Myoglobin	MYO	0020224

West Nile Virus Testing

By Rhonda Burgard, Client Services Supervisor

The North Dakota Public Health Laboratory no longer requires a West Nile Questionnaire be submitted with West Nile (Test code WNVP) testing. If you have any questions or concerns please contact Rhonda Burgard, Client Services Supervisor at 701-530-5700.

Shipping Boxes and Blue Ice Packs

By Rhonda Burgard, Client Services Supervisor

Please do not place packing tape across or around the blue shipping boxes. The Velcro closure is sufficient to hold the box closed and secure.

For compliance reasons, Northern Plains Laboratory (NPL) provided shipping boxes should only be used for shipping specimens to NPL. Do not use these boxes for shipping specimens to other laboratories.

We have noted that some of the current blue ice packs are not holding specimens at frozen temperatures. We are looking at alternate options for the blue ice packs. Until the current blue ice packs are replaced, please add additional frozen blue ice packs to your shipments (minimum of 4 ice packs).

New ABN Forms

By Rhonda Burgard, Client Services Supervisor

Enclosed in this mailing is the revised Advance Beneficiary Notice form that went into effect on Sept 1st, 2020. Please discard any old forms you have on file.

COVID-19 Reporting Requirements

By Rhonda Burgard, Client Services Supervisor

The CARES act requires any laboratory performing testing for COVID-19 to report the results from each test to the Department of Health and Human Services (HHS) as soon as possible but no later than August 1st. All data is to be reported thru state or local public health departments using existing reporting channels. Electronic submission is preferred but a predefined flat file format may also be acceptable. The following data elements must be collected and reported:

- Test ordered by the LOINC code provided by the CDC
- Device identifier
- Test result- use appropriate LOINC or SNOMED code
- Test result date
- Accession #/specimen id
- Patient age
- Patient race
- Patient ethnicity
- Patient sex
- Patient residence zip code
- Patient residence county
- Ordering provider name and NPI
- Ordering provider zip
- Performing facility name and/or CLIA number
- Performing facility zip code
- Specimen source- use appropriate LOINC, SNOMED-CT or SPM4 code
- Date test ordered
- Date specimen collected.

In addition the patient name, address, phone number, date of birth, ordering provider address and phone number may be reported. All facilities ordering and collecting specimens for COVID-19 testing must make every reasonable effort to collect this demographic information when either submitting samples or reporting results to the state health department. The following data fields are considered “ask on order entry” questions and should be entered at test request:

- First test (Y/N/U)
- Employed in healthcare (Y/N/U)
- Symptomatic as defined by CDC (Y/N/U) If yes, date of onset
- Hospitalized (Y/N/U)
- ICU (Y/N/U)
- Resident in congregate care setting (Y/N/U)
- Pregnant (Y/N/U)

Better understanding of what testing is being performed and the results obtained will help providers in decision making related to this public health emergency.

Reference: CMS document COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115

Personnel Training and Competency

By Rhonda Burgard, Client Services Supervisor

Proper employee training and on-going competency assessment programs are designed to help ensure laboratory testing is being performed correctly every time.

All new employees need orientation and training. They must be trained in the following areas:

- Assigned duties and responsibilities
- Laboratory policies and procedures for all tests they are authorized to perform.
- Laboratory quality assessment program

- OSHA and safety practices
- Laboratory computer system
- HIPPA protocols

All current employees need training whenever there is a new process or test implemented, a change to a current process or test method, or when the need for additional training is identified.

The trainer should be a qualified individual with technical laboratory experience who regularly performs the process or test procedure.

The laboratory should develop a training checklist for each lab position that includes observation of the trainee performing:

- Specimen collection and handling
- Preparation, labeling, use and storage of reagents, controls and standards
- Instrument operation, maintenance, function checks and calibration
- Step by step performance of the test procedure
- Quality control procedures and corrective action of unacceptable QC results.
- Interpretation and reporting of test results including calculations, reference ranges and critical results. Recognition of inconsistent test results.
- Quality assessment procedures.

Competency assessment is the means to confirm that training was effective and that personnel are capable of following established policies and procedures. Competency checklists and orientation checklists may have a similar format but should be separate and distinct documents.

Competency assessments should occur every six months for the first year and annually thereafter. For example: If an employee completes initial training in Jan 2020, the six month competency recheck would be due in July 2020 and another competency recheck due in Jan 2021. After that time, the employee would then complete an annual competency based on the laboratory's competency program deadlines.

Competency checklists must include the following required elements for each test method:

- Direct observation of test performance
- Review of testing worksheets, quality control records, proficiency testing and maintenance records
- Direct observation of instrument maintenance and function checks
- Monitoring the recording and reporting of test results
- Assessment of test performance by testing of previously analyzed samples, split samples or proficiency testing samples.
- Assessment of problem solving skills.

Individuals acting as Technical Consultants, Clinical Consultants and Technical Supervisors must also have their competency assessed. Competency forms for those positions are available on the COLA website.

Reference: Cola Lab Guide 15: Personnel Training and Competency Assessment
CMS: What Do I Need to Do to Assess Personnel Competency

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.

Supply Item Shortages

By Rhonda Burgard, Client Services Supervisor

There is a national shortage of plastics which are used to make biohazard bags (supply item #801003). Currently we are recycling non-contaminated bags.

There is a shortage of Aimes transport media and Universal Transport Media (UTM) that is used for the collection of ureaplasma/mycoplasma and Herpes virus specimens. If you have excess Aimes or UTM in stock, or any that are near their expiration date, please return them to Northern Plains Laboratory. There is also a shortage of 2.7 ml sodium citrate tubes. Supply orders for these items may be reduced until alternate supply items are available.

Because of a nationwide shortage of instrument pipettes for the Aptima GC/chlamydia test (test code CNGAM), GC/chlamydia testing is temporarily being sent to ARUP laboratories. Order codes and testing supplies remain unchanged. However, testing supplies for GC/chlamydia testing are also on backorder. Supply orders may be reduced based on availability.

New Guidance from the FDA for SARS-CoV-2 testing

By Rhonda Burgard, Client Services Supervisor

Recently several different platforms and methodologies for COVID-19 molecular, antigen and antibody testing have become available. When implementing COVID-19 testing for use on symptomatic and asymptomatic patients, please consider the following recommendation in the August 24th, 2020 FDA Frequently Asked Questions (FAQs) about testing for SARS-CoV-2

testing asymptomatic individuals for COVID-19

Q: Does the FDA have recommendations for health care providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19?

A: An asymptomatic individual may be suspected of COVID-19 by their health care provider for various reasons, such as known exposure or working in a high-risk environment. Such use is within the authorized indications for use of tests intended for individuals suspected of COVID-19 by their health care provider. For health care providers who are ordering an authorized SARS-CoV-2 diagnostic test to be used off-label (outside the authorization) to screen asymptomatic individuals not suspected of having COVID-19, we recommend they consider the information below.

Although the current available literature suggests that symptomatic individuals with COVID-19 and asymptomatic individuals without known exposure may have similar levels of viral genetic material, there is limited data on the distribution of viral loads in individuals with and without symptoms across demographics, different settings, and specimen types. Therefore, when screening asymptomatic individuals, health care providers should consider using a highly sensitive test, especially if rapid turnaround times are available. If highly sensitive tests are not feasible, or if turnaround times are prolonged, health care providers may consider use of less sensitive point-of-care tests, even if they are not specifically authorized for this indication (commonly referred to as “off-label”). For congregate care settings, like nursing homes or similar settings, repeated use of rapid point-of-care testing may be superior for overall infection control compared to less frequent, highly sensitive tests with prolonged turnaround times.

If less sensitive tests, such as some rapid point-of-care tests, are used, health care providers should be aware of the performance of the tests and may want to consider different testing approaches, such as serial testing. “Negative” results should be considered as “presumptive negative,” and health care providers should consider them in the context of clinical observations, patient history, and epidemiological information. Thus, if there is a significant new outbreak in a congregate care facility or high clinical suspicion of an infection in an individual resident, a negative point-of-care test should be confirmed with a highly sensitive molecular test (refer to CDC guidelines). It is not necessary to perform confirmatory high-sensitivity molecular tests on individuals with negative antigen test or other point-of-care test results if they are obtained during routine screening or surveillance.

Reference https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#general.