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Automated Urinalysis Testing

By Todd Pace, Core Lab Supervisor

Northern Plains Laboratory is pleased to announce the acquisition and implementation of the Iris IQ 200 Elite Workcell. The Iris IQ200 is a fully automated bench-top microscopy analyzer coupled with an Iris Automated Urine Chemistry analyzer. This instrumentation allows for complete urine chemistry and microscopic examination in one step.

The urine chemistry analyzer performs the “dipstick” portion of the urinalysis. This portion of the analyzer performs 9 chemistries plus specific gravity by refractometer, color and clarity.

The microscopic module uses Auto-Particle Recognition to count and classify cells, casts, yeast, bacteria and mucus in the urine sample. It also uses a digital camera to take 500 photos of the elements in each urine sample. This is equivalent to viewing 320 fields. This microscopic analysis is reviewed and verified on screen, greatly reducing the amount of time the technologists must spend at the microscope. Digital images for each sample can also be stored electronically and recalled at any time.

Specimen stability is 30 minutes at room temperature or 24 hours at refrigerated (2-8C) temperatures. If delay is anticipated or refrigeration is not possible, stability may be extended to 5 days if a Stabilur tablet is added to the specimen. Please add the

order comment “ Stabilur tablet added”. Specimens sent in urine culture kits are not acceptable for routine urinalysis.

The implementation of the Iris IQ200 Elite Workcell is expected to decrease urinalysis turn around times as well as help to standardize urine microscopic examination results. The automated quantitation and morphologic classification of elements in the urine gives the laboratory more detailed, accurate and efficient results.

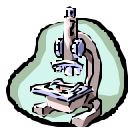


Mayo and ARUP Laboratories Changes

By: Rhonda Burgard, Client Services Supervisor

Mayo Medical Laboratories has discontinued adding text messages to reports indicating that the test method or reference range has changed. All changes to methodology or reference ranges can be found on the Mayo website at www.mayomedicallaboratories.com.

ARUP Laboratory has recently converted to the Millennium system. This conversion created some issues with ordering and report printing that have now been corrected. If you experience any problems with reports or have any other IT concerns please contact Paul Nelson **immediately** at 1-800-659-0395 or Rhonda Burgard at 701-530-5704.



Quality Corner

Purchasing and Inventory Management

By: Rhonda Burgard, Client Services Supervisor

Purchasing and inventory management of critical supplies, reagents and services is essential to high-quality laboratory operation.

The organization needs to define the necessary characteristics or functional requirements for critical supplies and reagents and communicate these expectations with prospective vendors. Vendors may be selected based on criteria such as licensure, ISO certification, quality service delivery, price, and past history. Documentation should include a listing of critical supplies, reagents and services and completed evaluations for all approved vendors.

The laboratory should have processes and procedures for initial and ongoing reviews of all contracts for provision and delivery of supplies, reagents and services including reference laboratory services. In addition, contracts to provide critical supplies or services should be developed and reviewed to ensure that each party's expectations are defined. Documentation should include a copy of all agreements including any pricing or service delivery changes.

An inventory management system should be developed that tracks the receipt and evaluation, storage, and disposition of all critical supplies and reagents. The inventory management system should provide the ability to track re-order levels so that essential supply and reagent items are available when needed. Documentation should include the date the item was received, the lot number, and that acceptance and storage criteria were met.

Received supplies that affect the quality of service should not be used until they have been verified as complying with specified acceptance criteria.

There should be a process to tie individual supply and reagent lot numbers to a particular patient or process. Documentation should include the dates the item was in use and the final disposition.

Finally, there should be a mechanism to evaluate a vendor's materials or services. Documentation should include tracking of back orders, shipping delays, service delivery, product failures and recalls.

Efficient and cost effective laboratory operations need the uninterrupted availability of quality reagents, supplies and services. Setting expectations and building good relationships with vendors is essential to ensuring that this process occurs.

Reference:

A Quality Management System Model for Health Care, Approved Guideline, Second Edition, CLSI HS1-A2 November 2004

New Test Codes

By Deb Smith, LIS Coordinator

The following new test codes have been added to the NPL test catalog:

RITU	Ritalin, Urine
BORDP	Bordetella, PCR
ANAR	ANA Reflex (ARUP test)
LPSRA	Lupus Comp Reflex panel
EBVQP	EBV Quant PCR, W Bld
SERQL	Seroquel
AAQPA	Amino Acid Quant. Plasma

Inactivated codes are:

AO- Acridine Orange
AFBSM- Modified AFB Stain

Advance Beneficiary Notice (ABN)

By Ann Oie, Compliance Officer

An Advance Beneficiary Notice (ABN) is a notice that is given to a beneficiary if there is reason to believe that Medicare will not pay for a test.

Effective March 1, 2009, providers must use the revised Advance Beneficiary Notice of Noncoverage (ABN) (CMS-R-131) form launched last year. Northern Plains Laboratory began using this revised ABN in July 2008.

INSTRUCTIONS FOR COMPLETING AN ABN

The ABN must be verbally reviewed with the beneficiary or their representative and any questions that they have must be answered before it is signed.

Asterisked fields are required.

*** Patient Name:**

Enter the first and last name of the beneficiary. If the middle initial is available, that should also be entered. This field is mandatory.

Identification Number:

Enter a number that will relate back to the specific date of service and/or test. This field is optional. NPL suggests using the requisition number. This is NOT the beneficiary's Medicare number.

*** Test(s):**

Enter the name/description of the test(s) for which the ABN is being completed. Write multiple tests on separate lines. This field is mandatory.

*** Reason Medicare May Not Pay:**

Enter the reason why Medicare may deny payment for the test. This is mandatory.

Possible reasons include:

- Medicare does not pay for these test(s) for your condition
- Medicare does not pay for these tests as often as this (denied as too frequent)

- Medicare does not pay for experimental or research tests

There must be at least one reason applicable to each test listed even though the same reason may apply to multiple tests.

*** Estimated Cost:**

Enter the estimated cost for the test. The "Estimated Cost" is a mandatory field. If the "Estimated Cost" is not written on the ABN form, the ABN will not be considered valid, and NPL will bill a recovery fee back to the client.

*** Options:**

The beneficiary or representative must select only 1 of the 3 options. The three options explain the beneficiary's possible choices regarding the test(s) that may be denied payment by Medicare. Selection of one option is mandatory.

Additional Information:

This field may be used for additional clarification that would be of use to the beneficiary.

*** Signature:**

Signature of the beneficiary or representative is mandatory. The signature indicates that they have received and understand the content of the notice.

*** Date:**

Enter the date the ABN was signed by the beneficiary or representative. This field is mandatory.

When all required fields have been completed and the form has been signed and dated, a copy should be given to the beneficiary or representative. Send the original notice to NPL or Path PC. As of March 1, 2009, the new form must be used.

If NPL or Path PC receives an old version of the ABN, a recovery fee will be billed back to the client facility. For questions, contact NPL or Path PC at 701-222-2480 or 800-659-0395.

Differential Blood Smears

By: Rhonda Burgard, Client Services Supervisor

EDTA (ethylenediaminetetraacetic acid) inhibits the clotting process by removing calcium from the whole blood sample. EDTA can cause morphological changes in blood cells when present in significant concentrations. K₂EDTA is the preferred anticoagulant for specimen collection for cell counting and sizing.

If a tube is not filled to its full volume of draw, the additive to blood specimen ratio is affected, resulting in too high of a concentration of EDTA. This high concentration may cause the red cells to shrink and may create red cell morphology artifact. An excess of EDTA also affects both erythrocytes and leukocytes by causing membrane damage.

The amount of time between specimen collection and preparation of the differential smear may also affect the test results. Smears made from EDTA tubes at room temperature for more than 5 hours also often have unacceptable levels of artifact of the blood cells (echinocytic RBC's, spherocytes, and necrobiotic leukocytes). High quality blood smears can be made from EDTA tubes as long as they are made within 2-3 hours of the blood draw.

Platelet clumping or platelet satellitism may result if the EDTA tube is not adequately mixed or if the patient has an underlying thrombocytopenic disorder. Collection of the specimen in an anticoagulant other than EDTA may allow an accurate platelet count to be obtained. Over filling the EDTA tube may result in clotting which causes thrombin release and a falsely low platelet count. When a test result shows a low platelet count a differential smear should be made to help determine if the low platelet

count is due to a patient condition or specimen mixing.

WBC counts remain stable for 3 days when the specimen is stored at room temperature. Slight vacuolization of monocytes and neutrophils may be seen in EDTA specimens stored for 3-4 hours at room temperature. Only minimal changes are seen in specimens stored for 12 hours at 4°C.

Reference:

BD Diagnostics Tech Talk, January 2009

Glycosylated Hemoglobin (HA1C) Specimen Change

By: Rhonda Burgard, Client Services Supervisor

Whole blood EDTA specimens that have been frozen will now be acceptable for GHGB (A1C) testing.

Discontinuation of Routine SSA Testing on Urinalysis

By: Todd Pace, Core Laboratory Supervisor

Northern Plains Laboratory discontinued routinely confirming dipstick urinalysis for protein using the Sulfo-Salicylic Acid (SSA) precipitation test. The presence or absence of protein in the urine sample will still be reported from the dipstick urinalysis result.

In the past, our policy was to perform SSA testing on all specimens submitted for urinalysis on patients older than 50 years old. This was performed because the SSA method is more sensitive for globulin proteins than the dipstick method.

SSA testing will still be performed in our laboratory. If this testing is desired, please order as a separate test using the test code **USSA** along with the urinalysis testing.

Implementation of IDMS traceable Creatinine Measurements

By: Todd Pace, Core Laboratory Supervisor

The National Kidney Disease Education Program, NKDEP, launched the Creatinine Standardization Program to reduce inter-laboratory variation in creatinine assay calibration and to provide more accurate estimates of the glomerular filtration rate (eGFR).

To comply with the recommendations of the NKDEP, Northern Plains Laboratory implemented instrument software changes standardizing creatinine measurements to a reference material that is traceable to the internationally accepted isotope dilution mass spectrometry (IDMS) method. To prevent rounding errors in eGFR calculations, creatinine measurements will be reported to two decimal places. The IDMS-traceable MDRD (Modification of Diet in Renal Disease Study) equation should be used to calculate the eGFR as recommended by the NKDEP. These changes will improve the accuracy of the eGFR reported.

Correlation studies performed at Northern Plains Laboratory demonstrate no significant difference ($r=0.9995$) in creatinine values from the current calibration compared to the IDMS method.

Refer to the NKDEP website for more information: www.nkdep.nih.gov.

Questions or comments should be directed to Todd Pace at Northern Plains Laboratory (701-530-5721) or to Laurie Linz, MD (701-530-6745).

Supply Provision

By Rhonda Burgard, Client Services Supervisor

Northern Plains Laboratory recently completed a supply provision study.

83% of supply orders placed prior to 1330 are mailed the same day. However, only 38% of supply orders are received prior to 1330. Orders placed after 1330 are filled the next business day, which means orders received after 1330 on Friday are not mailed until the following Monday.

58% of supply orders are received by the ordering location the day after they are mailed. The range from mailed to order receipt was 1-5 days with an average delivery time of 2 days. Supplies mailed on Friday had the longest delivery times.

To expedite supply delivery it is best to place your supply order prior to 1330 Monday-Thursday. In most cases this should provide a 1-2 day delivery time.

Approximately 10% of supply orders exceeded the new maximum supply limits and were modified. The most common type of supply order reduced was: PAP supplies, Styrofoam containers, toner and labels. Clients are encouraged to place weekly supply orders and maximum levels are designed to allow you to stock a minimum of 3-4 weeks of any inventory item on your shelves. If you need to exceed maximum supply limits please add a comment to your supply order. If a supply order not on the maximum supply list is reduced, you should receive a phone call from NPL prior to the order being filled.

NPL encourages you to contact us if you notice any defects with supplies or have any concerns about supply provision. If you have any questions or concerns please contact Rhonda Burgard at rburgard@primecare.org or 701-530-5704 or Wanda Giedd at wgiedd@primecare.org or 701-530-5725.

MRSA/SA SSTI BY PCR

By Ron Piatz, Research and Development

Northern Plains Laboratory (NPL) is pleased to announce the addition of the Cepheid Xpert MRSA/SA Skin and Soft Tissues Infection Assay (MRSA/SA SSTI Assay) to our in house test menu. The MRSA/SA SSTI assay is an automated DNA test for simultaneously detecting methicillin-resistant *Staphylococcus aureus* (MRSA) and methicillin-sensitive *Staphylococcus aureus* (MSSA) directly from swabs collected from skin and soft tissue infections. This assay utilizes real-time polymerase chain reaction (PCR) methodology, which allows for rapid results with an assay time of one hour.

The most common cause of skin and soft tissue infections is *Staph aureus* with MRSA representing over 50% of these infections in parts of the U.S. The tremendous increase of both hospital acquired and community acquired MRSA in skin and soft tissue infections require a change in management of these infections. Current laboratory methods can take 48-72 hours to determine if a SSTI is caused by MSSA or MRSA. Rapidly identifying the causative pathogen allows for targeted antimicrobial therapy and allows for immediate isolation and infection control measures. The MRSA/SA SSTI assay will be performed 24 hours per day, seven days per week.

Possible MRSA/SA SSTI assay results are listed below:

MRSA POSITIVE/SA POSITIVE: MRSA by PCR positive
MRSA negative/MSSA negative: MRSA and MSSA by PCR negative
MRSA negative/MSSA POSITIVE: MSSA (not MRSA) by PCR positive

Reflex aerobic bacterial culture will be performed regardless of assay results. The

option of ordering this test without the reflex is available by specifying "No Reflex" when requesting.

Specimen:

Swab specimens of skin and soft tissue infections collected with a Copan double swab (red cap). The Copan double swab is the only acceptable collection device for this test. Following collection, sample is stable for 24 hours at room temperature or up to 5 days when stored at 2-8C.

Special Considerations or Limitations:

The MRSA/SA SSTI Assay is not intended to monitor treatment for MRSA/SA infections or to be used for surveillance cultures.

For questions, please contact NPL at 701-530-5700 or 1-800-645-1003.

Test code	CPT Code	Test Name	Specimen Requirement	Reference Range
SSTIP	87640 87641	MRSA/SA SSTI by PCR	Swab of Infection	MRSA: Negative MRSA: Negative

New Surgical Pathology Request Forms

By Deanne Knutson, Pathology Supervisor

Pathology Consultants, PC now has a new, revised surgical pathology request form available. The form offers the option to list all Physicians / Providers, along with their first names, that are a part of the patient's care. With multiple physicians bearing the same last name, providing the first name helps maintain our commitment to our patients to make certain that pathology reports are sent to all the appropriate Providers.

To prevent formalin leakage, when sending surgical specimens please ensure that the vial lid and package closure is securely sealed.

Susceptibility Testing on GBS

By: Renae Baltzer, Microbiology Supervisor

NPL has started performing susceptibility tests on Group B beta hemolytic streptococci (GBS) isolated from vag/rectal cultures from obstetric patients and on isolates from invasive or surgical sites in other patients. There is still no known resistance to Penicillin, the typical treatment for GBS. However, resistance is increasing to Erythromycin and Clindamycin which are the recommended drugs in a penicillin allergic patient. National reports site resistance of GBS to Erythromycin and Clindamycin of up to 38% and 22% respectively. Data from NPL, (99 isolates) shows 48% resistance to Erythromycin and 48% resistance to Clindamycin.

Celiac Disease Testing

By Rhonda Burgard, Client Services Supervisor

Celiac Disease or gluten sensitive enteropathy (GSE) is a non-allergic immune mediated sensitivity in genetically susceptible individuals to gluten in wheat or related proteins found in barley and rye. The disorder is characterized by chronic inflammation and flattening of the intestinal mucosa, resulting in malabsorption syndrome. Patients with celiac disease may suffer from diarrhea, gastrointestinal problems, anemia, fatigue, psychiatric problems or may be asymptomatic. All GSE patients have an increased risk of lymphoma. A gluten-free diet may control GSE and associated risks.

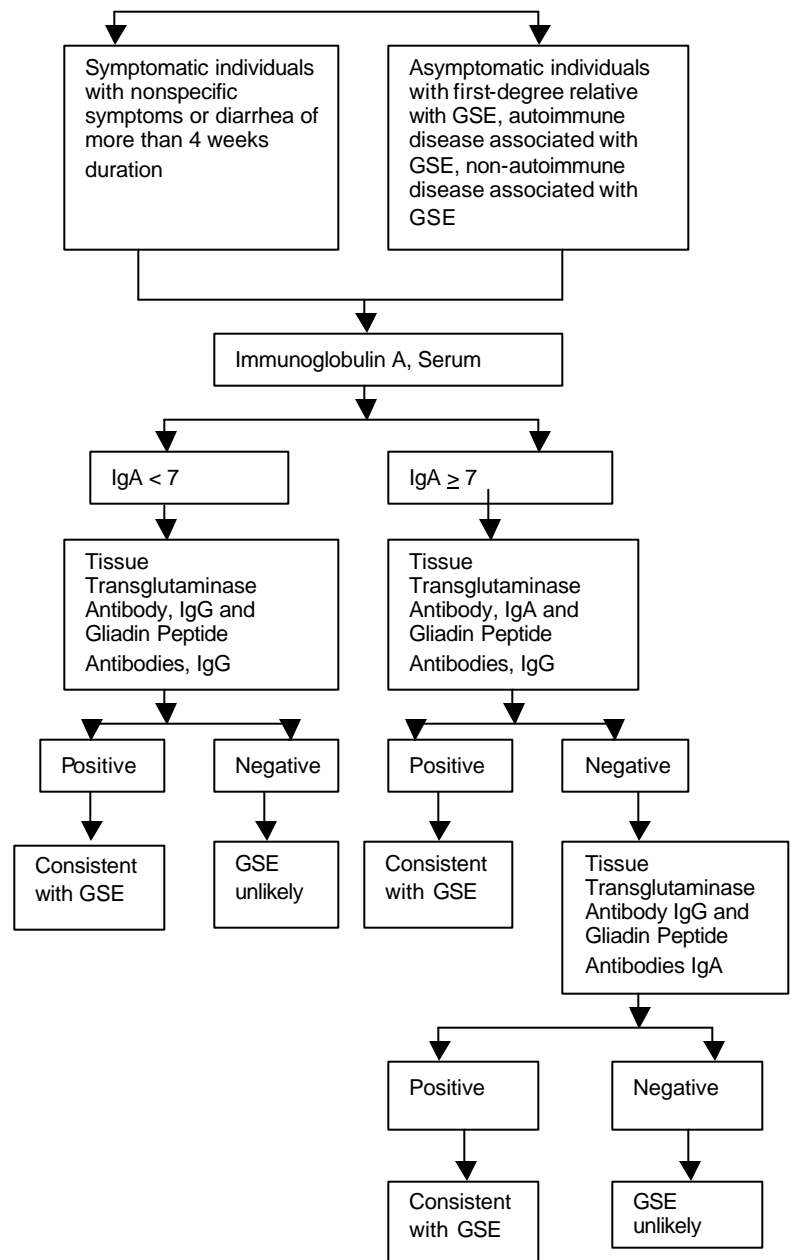
The following algorithm can be used to assist in the diagnosis of celiac disease. Please note that if the Celiac Disease Reflexive panel (ARUP test 0051065) is ordered Gliadin Peptide Ab IgG and IgA tests may be automatically added depending on the test results. Transglutaminase Ab, IgA (ARUP test

0050734) also reflexes Endomysial Antibody IgA. Caution should be used when ordering these panels so that duplicate testing is avoided.

Reference:

AARUP Consult Celiac Disease at www.arupconsult.com.

Celiac Disease (GSE) Testing Indications



New Quality Report

By Rhonda Burgard, Client Services Supervisor

Enclosed in this mailing is an example of a new quality report that will be provided quarterly on a site-specific basis. This information can be used to monitor trends pertaining to specimen collection and transport, test requests, test results and reporting and customer satisfaction.

We hope that you will find this information useful. If you have any questions or concerns please contact Rhonda Burgard at rburgard@primecare.org or 701-530-5704

ARUP specimen transport for stools

By Rhonda Burgard, Client Services Supervisor

Effective immediately ARUP laboratories will no longer transport stool specimens in one-gallon containers. Please request an ARUP stool collection and shipping kit if you will be sending a stool sample > 500 mL. Smaller stool samples can continue to be sent in sterile screw topped urine containers.

CLSI Microbiology Changes

By Ron Piatz, Research and Development

CLSI has released three new documents

- M100-S19 – Susceptibilities (updated yearly)
- M02-A10 – Disk diffusion (updated every 3 yrs)
- M07-A8 – MIC (updated every 3 years)

Some of the document changes include:

- Disk diffusion and MIC tables are now combined on the M100 tables.
- Results from one drug should not be used to predict results for another drug unless there is an “or” connecting them in CLSI tables. However, extrapolating may be appropriate if there is reliable recent data available to support the decision.
- Drugs for which there are “susceptible only” breakpoints can be reported as

“non-susceptible” if the “non-susceptible results are confirmed with a CLSI reference method.

Staphylococcus species:

- Before reporting Penicillin susceptible Staphylococci as susceptible (MIC = 0.12 ug/ml or zone diameter = 29mm), confirm with an induced beta-lactamase test.
- Cefoxitin is better at determining oxacillin resistance than oxacillin. Use cefoxitin as a surrogate (i.e. test cefoxitin but report oxacillin.) Oxacillin disk diffusion test for coagulase-negative Staphylococcus has been eliminated.
- Detection of Vancomycin Intermediate Staph aureus (VISA) using disk diffusion is not recommended for detecting vancomycin resistance in Staphylococci. (Use an alternative method.)
- Added a recommendation to test for high-level mupirocin resistance in *S. aureus*. (Perform only when requested)

Enterobacteriaceae

- Added screening and confirmatory tests for carbapenemases (enzyme that hydrolyze or inactivates carbapenems.) Carbapenems are antibiotics such as imipenem, meropenem, doripenem, and ertapenem. An example of a carbapenemase is KPC (*Klebsiella pneumoniae* carbapenemase)
- Enterobacteriaceae that are resistant to cefotaxime, ceftriaxone, and/or cefazidime and have elevated carbapenem MICs or reduced zone are suspicious for carbapenemase production. The modified Hodge test can be used to confirm carbapenemase production. (New QC organisms are available.)
- New cephalosporin breakpoints coming in late 2009 or 2010.

Changes to the Northern Plains Laboratory Critical Call Policy

By Rhonda Burgard, Client Services Supervisor

Effective immediately the following changes to the Northern Plains Laboratory Critical Call policy have been implemented:

- Critical test result information will not be left on voicemail. The provider or laboratory will be contacted directly.
- **All** critical values including subsequent critical values on the same test will now be called. The only exceptions to this policy are hematology results per specific physician request and critical BUN and creatinine values on kidney dialysis patients.
- If NPL is unable to reach the provider or laboratory the new escalation policy calls for an NPL pathologist to determine the appropriate action and/or to attempt to contact the patient directly.

Enclosed in this mailing is an updated list on NPL Critical Laboratory Values. In December a form for Critical Value Notification was distributed to each client site. If you have not returned the form we encourage you to do so. If you need additional forms please contact Northern Plains Laboratory client services at 701-530-5700.

Northern Plains Laboratory Reflex Testing Policy

By Rhonda Burgard, Client Services Supervisor

In the setting of pertinent positive tests, the laboratory has historically ordered and performed selected additional tests (reflex tests) that were deemed appropriate to ensure quality patient management. These reflex tests are consistent with regional and national standards of practice.

Enclosed in this newsletter you will find Northern Plains Laboratory's 2009 approved list of reflex tests. Please note on your requisition or call Northern Plains Laboratory at 1-701-530-5700 if you do not want a specific reflex test performed.

Updated CLIA Certificates

By Rhonda Burgard, Client Services Supervisor

Enclosed in this mailing are updated Northern Plains Laboratory, ARUP Laboratory and Mayo Medical Laboratory CLIA certificates. Additional copies can be found on each facility's website.