Northern Plains Laboratory

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Quality Corner- Microbiology Test Codes and Specimen Collection

By Rhonda Burgard, Client Services Supervisor

Nothing is more important to the effectiveness of a laboratory test than a specimen that has been appropriately selected, collected and transported.

Ordering the correct test code for a microbiology specimen and providing the appropriate information for the site and source of the specimen can assist the microbiology staff in choosing the correct media to enhance the growth of any organisms. Any additional information that can be provided, including mechanism of injury, antibiotic history or patient diagnostic history may also assist the microbiologist in their identification. For example, a wound of the arm may be processed differently depending on the patient history or mechanism of injury, i.e. a human bite wound, a fall from bicycle onto gravel or a skin lesion post chemotherapy.

Some of the most common type of microbiology specimens are:

- Urine Culture (UC): Collect using sterile technique. Providing good patient education on the appropriate cleansing technique is key in reducing urine culture contamination rates. Indicate if the specimen is a midstream, clean catch, catherized, cytoscopic or suprapubic urine specimen. Samples should be transported to the laboratory within one hour or placed in BD boric acid urine transport media.
- Throat Culture (TC): Insert the Aimes kit culture swab behind the uvula and swab both tonsillar fauces and the posterior pharynx and also any ulceration, exudate, lesion or area of inflammation. Only pathogenic organisms of the throat will be identified. If the provider is looking for yeast infection order the test code (FUNG)
- Respiratory Culture (RC): For sputum collection instruct the patient to cough deeply and produce lower respiratory tract fluid. A gram stain will be performed and any specimens with increased epithelial cells will be rejected.
- Abscess/ Deep tissue wounds (AC): This test code includes a gram stain, an aerobic and anaerobic culture. Cleanse the area around the wound with sterile saline or 70% alcohol. If possible, aspirate exudate from the wound with a needle and syringe. Alternately, a swab may be placed deep into the lesion and a sample collected. Transport in anaerobic transport media (e swab).
- Miscellaneous culture (MC) This code does not include anaerobic culture. Most superficial wounds fall into this category. Cleanse the area around the site well to avoid skin contamination. Susceptibility testing

is performed when 3 or fewer potential pathogens are identified.
- Eye/Ear Culture (EYERC) Please indicate the site and source of the specimen collected. It is helpful for microbiology staff to know if the sample is drainage, a surface lesion or from the conjunctiva of the eye.
- Genital Culture (GENC): Collected by the provider from the patient's urethra, Bartholin, vagina or cervix. Standard of practice for detection of bacterial vaginosis is based on gram stain or molecular testing (VAGP), not culture. If molecular testing is not ordered, samples for culture should be sent on Aimes media.
- Stool Culture (FC) Raw stool needs to be place in Cary-Blair transport media within 30 min to 1 hour after collection.
- Ova and Parasite (OVP and OPFA) The OVP test code tests for *Giardia lamblia* and *Cryptosporidium* and is used for patients that have not traveled outside of the United States. The OPFA test code is used if the patient has traveled outside the United States. Patient history is very important and assists in parasitic identification.

Additional information can be found in the NPL Test Catalog at www.northernplainslab.com under the specimen collection tag. For optimal specimen processing please also write the source/site on the specimen label.

CAP Certificate

By Rhonda Burgard, Client Services Supervisor

The most recent version of the Pathology Consultants Physician Office Laboratory CAP certificate is enclosed in this mailing.

COLA Criteria Changes

By Rhonda Burgard, Client Services Supervisor

COLA has made the following changes to their 2019 criteria for accreditation:

- Has the laboratory established requirements for specimen acceptability, including storage temperature and specimen age requirements? (new standard)
- As part of the method evaluation, has the laboratory evaluated the potential risk of carryover between samples, and does the procedure include identification, investigation and correction of errors due to carryover? (new standard)

Proficiency testing (PT) is required for all regulated analytes and each accredited laboratory's PT scores are required to be released to COLA. When expected PT scores are not received by COLA it is considered "non-participation" and is considered a PT failure.

PSA SCREENING

By: Patti Schmidt, CPC, Billing Supervisor

PSA screening tests (PSAS) are only covered by Medicare and the Alternative Medicare plans once per year. The testing cannot be done earlier than exactly one year prior to the last one done. Please verify in the patient's record when the last PSA was performed before ordering the test again. The diagnostic PSA's (PSAD) can be performed more often as long as there is an appropriate diagnosis to warrant the testing or an ABN is signed by the patient.

Test Utilization- Pharmacogenetics Testing

By Rhonda Burgard, Client Services Supervisor

Genetic variations associated with drug response or drug disposition may predispose a patient to be at risk for drug-related toxicity, nonstandard dose requirements, or lack of therapeutic benefit. Pharmacogenetics testing should be considered before prescribing select drugs or when investigating adverse drug reaction or therapeutic failure.

Adverse drug reactions (ADR) include both therapeutic failure and potentially life-threatening toxicities. ADR's are classified as Type 1 (dose dependent) and Type 2 (not dose dependent).

In Type 1 ADR, the drug accumulates instead of being eliminated as expected. Pharmacogenetics testing can identify the association between a gene variant that affects the activity of a specific drug and the targeted therapeutic dose of that drug and the likelihood of an ADR.

Patients that are poor metabolizers of a drug will have reduced drug activation and therapeutic failure is likely. Or the drug may have poor inactivation and dose related toxicity is possible.

Patients that are rapid metabolizers of a drug will have accelerated drug activation which may lead to excess accumulation and possible toxicity. Or, they may have accelerated drug elimination and therapeutic failure.

In Type 2 ADR, the person has inherited a specific gene variant and when administered a trigger drug, regardless of dose, may have an adverse reaction.

The Clinical Pharmacogenetics Implementation Consortium (CPIC) has published dosing guidelines involving CYP genotypes. See https://cpicpgx.org/guidelines

Examples of some genetic tests that provide pharmacogenetic information are:

Drug	Genetic Test	Action when Variant is detected
Codeine, Tramadol, Oxycodone, Tamoxifen	CYP2D6 Cytochrome P450 Panel	Possible dose adjustment
Phenytoin, Carbamazepine, Lamotrigine	HLA-B*15:02	Possible dose adjustment
Interferon	IL28B	Increased risk of disease progression
Abacavir Sensitivity	HLA-B*57:01	Hypersensitivity to drug detected-prescribe alternate drug
Allopurinol Hypersensitivity	HLS-B*58:01	Risk of severe cutaneous adverse reactions-prescribe alternate drug
Antidepressants Nortriptyline, TCS, SSRI's and Clopidogrel (Plavix)	CYP2D6, CYP2C19 Cytochrome P450 Panel	Dose adjustment
Atazanavit	UGT1A1	Useful in dose planning
Tacrolimus	CYP3A5 CYP 3A4, Cytochrome P450 Panel	Possible dose adjustment
Thiopurine	TPMT, NUDR15	Possible dose adjustment
Warfarin Sensitivity	CYP2Cd, CYP2C9, CYP4F2, VKORC1	Possible dose adjustment

Reference: ARUP Consult: The Physicians Guide to Lab Test Selection and Interpretation Germline Pharmacogenetics- PGX

Waived Testing Requirements

By Rhonda Burgard, Client Services Supervisor

Waived tests are defined as tests that are so simple to perform and produce accurate results so reliably as to make the likelihood or erroneous results negligible. The number of waived testing sites has grown from 44% of all clinical laboratory testing sites in 1993 to 71% today. The number of waived tests has also grown from 8 in 1993 to more than 130 today. With the increase in waived testing the American Association of Clinical Chemists (AACC) is urging Congress to direct HHS to conduct a study on the quality of testing and make recommendations for improvement,

Waived tests are exempt from CMS requirements for personal qualification, training and competency, proficiency testing and quality assessment. However, Joint Commission, The College of American Pathologists and COLA accreditation checklists all have standards related to waived testing. The following deficiencies were identified during recent COLA inspections:

- 12% did not have current product inserts for testing they were performing.
- 21% did not check the product insert for changes upon receipt.
- 21% did not perform quality control as required by the manufacturer and 35% did not maintain logs with results of quality control testing,
- 18% did not use correct units of measure for reporting results and 31% did not maintain a log of tests performed.
- 6% were using expired reagents or control materials,
- 3% had improper storage conditions,
- 6% did not performs required follow-up confirmatory tests.
- 5% did not performs required function or calibration checks,
- 45% did not document the name, lot number and expiration dates of kits in use.
- 9% did not require a written order or requisition before performing the test,

It is recommended each waived testing laboratory have at least one person responsible for testing oversight. Personnel performing testing should be trained and competent before reporting patient test results. Each laboratory should have written policies and procedures, which may be current package inserts, for all testing performed and log sheets for documentation kit lot numbers, dates of use and expiration dates, daily recording of storage temperatures, external and internal quality control results and patient test results. All patient test results should be reported with the accompanying reference (normal) ranges. While proficiency testing is not required for waived testing it is good laboratory practice.

Reference: COLA inSights Spring 2019 edition Clinical Laboratory News, Jan/Feb 2019 edition.

Ebola Virus

By Rhonda Burgard, Client Services Supervisor

The North Dakota Department of Health has asked healthcare providers to contact the department immediately, at 800-211-4454 about any person being evaluated for Ebola and arrange diagnostic testing thru the Division of Microbiology.

Ebola virus is associated with fever and severe headaches, fatigue, muscle pain, vomiting, diarrhea, abdominal pain or unexplained hemorrhage. Patients with these symptoms should be asked about their travel history.

Reference: North Dakota Department of Health Health Alert Network Advisory

New Collection kit for Drug Panel, Urine Comprehensive

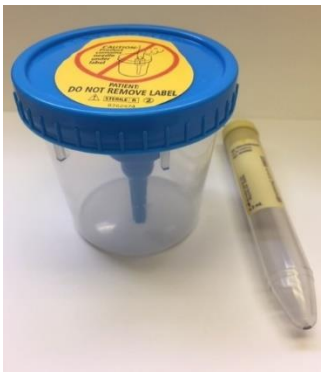
By Ron Piatz, Research and Development

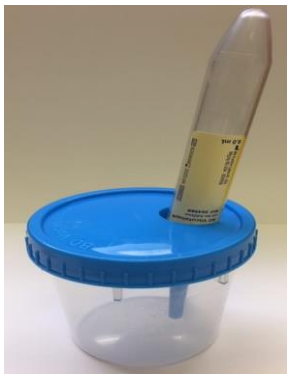
Northern Plains Laboratory has changed collection/transport kits for urine toxicology testing that is forwarded to MedScan Laboratories (Test code: M341C). The kit consists of a urine cup with an integrated transfer device plus a no additive 8.0 mL urine vacutainer tube (yellow cap). The patient will collect the urine sample utilizing the urine cup. Medical staff will then transfer some of the collected urine sample into the yellow-capped vacutainer tube by following the instructions below:

1. Label the yellow-capped urine transport tube with the same patient demographics as the urine cup.
2. Remove the yellow label located on top of the blue cap of the urine cup to expose the integrated transfer device.
3. Insert the yellow-capped tube into the integrated transfer device. The vacuum in the yellow-capped urine tube will transfer urine from the cup into the tube.
4. Send urine sample to NPL at refrigerated temperature (room temp is also acceptable). Recommended volume is 5 ml aliquot (1.0 ml min) of random urine.

Note: If the urine volume in the cup is insufficient to transfer urine into the yellow-capped tube, please send the urine cup to NPL.

Caution: The integrated transfer device does utilize a needle to puncture the yellow capped tube. Avoid contact and dispose of, appropriately.





Order NPL supply#: 801752
Description: Urinalysis Cup Kit, MedScan

Questions or comments should be directed to Ron Piatz or Rhonda Burgard at 701-530-5700 or 1-800-645-1003.

Supply Requests

By Rhonda Burgard, Client Services Supervisor

To remain in compliance with HIPPA laws, Northern Plains Laboratory (NPL) may only provide supplies used to collect and transport specimens tested and billed for by NPL. Please stock no more than a month's supply of any one supply item on your shelf and monitor your supply outdates. You may return any short dated supply items to NPL.

If possible, consolidate your supply orders into one weekly order. We encourage you to electronically place or fax your supply orders to the NPL rather than placing phone orders, which are sometimes ambiguous and difficult to interpret by mailroom staff. Orders sent to the mailroom prior to noon Monday-Friday typically will be filled the same day.

The newest version of the supply order form is enclosed in this newsletter. Please discard any old versions of this form.

If you have any questions or concerns please contact the Northern Plains Mailroom supervisor at 701-530-5700

Change to Cut-off Values for Measles IgG

By Rhonda Burgard, Client Services Supervisor

The manufacturer has changed the cut-off values for Measles IgG. This will affect interpretation of results for the following tests:

- Measles (Rubeola) Antibody, IgG (NPL test code MEASG, ARUP test code 0050380)
- Measles (Rubeola) Antibodies, IgG and IgM (NPL test code MEASL, ARUP test code 0050375)
- Measles (Rubeola) Antibody, IgG, CSF (ARUP test code 0054440)
- Encephalitis Panel with Reflex to Herpes Simplex Virus Types 1 and 2 Glycoprotein G-Specific Antibodies, IgG, Serum (ARUP test code 2008915) CSF (ARUP test code 2008916)
- Occupation Screen-MMR/VZV Antibody Assessment Panel, IgG (ARUP test code 2011375)

The new cut-off values are

- Positive- Result of 16.5 AU/mL or greater
- Equivocal-Result of 13.5 AU/mL up to 16.4 AU/mL
- Negative-Result of 13.4 AU/mL or less

If you have any questions or concerns please contact the Northern Plains client services at 701-530-5700

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