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Quality Corner- Canceled Tests

By Rhonda Burgard, Client Services Supervisor

The most common reasons for canceled tests at NPL in 2018 were:

- **The specimen was hemolyzed or clotted.** All blood samples should be mixed 6-8 times by gentle inversion after drawing. Some causes of hemolysis are:
  - Not allowing the alcohol on the venipuncture site to dry.
  - Inadequate venous access
  - Shaking instead of gentle mixing of the collection tube.
  - Too small of a needle size.
- **The specimen was quantity not sufficient.** When sending specimens, especially those that may require reflex testing or those that require aliquoting, do not send just the minimum volume required for testing. Samples for coagulation should be filled to the fill line on the specimen tube. Samples for hematology should be filled to 10% of the stated volume.
- **The specimen was an inappropriate specimen type**. Make sure to use the appropriate tubes for collection of lead and trace free element specimens. CG/chlamydia specimens should be sent on the transport swab and the cleansing swab discarded.
- **The specimen transport condition was not appropriate.** Access the Northern Plains Laboratory test catalog at www.northernplainslab.com for the appropriate specimen transport temperatures and packaging instructions. Remember some specimens must be protected from light during transport.
- **There was a specimen labeling error.** All specimens should be labeled at the patient bedside with two unique identifiers. Make sure the patient information on the specimen tube and on the requisition are an exact match.

Canceled tests delay patient care. By paying close attention to specimen collection and transport requirements cancelation of tests may be avoided.

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/

NDPHL New Collection kit for *B. pertussis*

By Ron Piatz, Research and Development

The North Dakota Department of Health, Division of Microbiology, no longer accepts the small plastic tube for *Bordetella pertussis* testing. Due to a methodology change, Universal Transport Media (UTM) is now the specimen of choice. The new Helicase-Dependent Amplification (HDA) assay will detect *Bordetella pertussis* along with *Bordetella parapertussis.*

Collection & Handling

1. The *Bordetella species* collection kit (supply item # 800976), provided by the Division of Microbiology, includes:
   a. One universal transport media tube.
   b. One sterile Dacron® polyester, **small-tipped swab** suitable for the collection of nasopharyngeal specimens.
2. The specimen of choice is a nasopharyngeal swab in universal transport media. (See picture below for proper collection of specimens)

   a. Gently pass the flocked swab through the nose and into the posterior nasopharynx.
   b. Rotate the swab on the nasopharyngeal membrane 5-6 times and allow it to remain in place for 10-15 seconds.
   c. Remove the swab and repeat the procedure in the other nare using the same swab.
   d. Remove cover from the UTM, place the swab in the liquid and snap the swab shaft off at the score and leave the swab inside the vial. Replace the cap; be sure to tighten securely to prevent leakage.
   e. Label the UTM with patient label or patient's name/date of birth.
   Note: Specimens received on large (culture type) swabs are assumed to be from the nose and not the nasopharynx regardless of the source given on the specimen label.
3. Return the universal transport media to the zip-lock plastic biohazard bag that contained the collection supplies.
4. Complete requisition and forward the sample in UTM to NDPHL within 4 days of collection at refrigerator temperature. If longer, send UTM frozen.

NPL information:

Test Code	CPT Codes	Test Name	Specimen	Reference Range
PERTP	87798	Bordetella pertussis / parapertussis by HDA	Nasopharyngeal Swab	Negative

Add-on Orders

By Rhonda Burgard, Client Services Supervisor

Orders added on to a specimen must be requested by the facility collecting the specimen even if the order is placed by a provider from another facility. Please contact the collecting facility to add-on your order.

Anion Gap Reporting

By Ron Piatz, Research and Development

Northern Plains Laboratory is now reporting serum anion gaps on all chemistry panels that include sodium, chloride and CO2 results. The **Anion gap** is the calculated difference between commonly measured cations and anions in the serum. Thus, the anion gap reflects the difference in unmeasured cations and anions.

Elevated anion gaps are seen in conditions such as renal failure, ketoacidosis, lactic acidosis and toxic agents (poisoning). Low anion gaps are associated with conditions such as multiple myeloma, hyponatremia, hypoalbuminemia, and bromide ingestion.

Formula:
Anion Gap = Sodium – (Chloride + CO2)

Reference Range: 7 – 15 mEq/L

For interfaced clients, the added result code will be “ANGAP”. For additional testing information, please contact NPL at 701-530-5700 or 1-800-645-1003.

Hematology Reports

By Ron Piatz, Research and Development

Northern Plains Laboratory (NPL) has replaced our hematology analyzers with Sysmex XN-Series automated hematology analyzers. These new analyzers have advanced technology that will allow additional hematologic parameters to be reported. These new parameters may provide additional information concerning the patient’s hematologic status and should be correlated with other clinical findings.

Immature Granulocytes (IG)
The automated WBC differential, with the addition of Immature Granulocytes (IG), becomes a six-part WBC differential. Immature granulocytes (promyelocytes, myelocytes, metamyelocytes) >1.0% indicates the presence of immature white blood cells (left shift).

Reticulocyte Hemoglobin (RET-He)
Reticulocyte hemoglobin content (RET-H*e*) measures the amount of hemoglobin in the reticulocytes. The reticulocyte hemoglobin content indicates cell hemoglobinization, reflecting the quality of the newly produced reticulocytes. Ongoing reticulocyte production in the absence of sufficient iron eventually yields microcytic, hypochromic RBCs. Therefore, low RET-He results may be an early indicator of iron deficiency.

Immature Reticulocyte Fraction (IRF)
Immature Reticulocyte Fraction (IRF) is the rate of production of reticulocytes which is largely dependent on the bone marrow response to erythropoietin. Values above the normal range indicate an increase in RBC production in the bone marrow.

Immature Platelet Fraction (IPF)
The Immature Platelet Fraction (IPF) is a direct cellular measurement of thrombopoiesis. An elevated IPF indicates increased platelet production. A low platelet count and low IPF is consistent with a platelet production disorder. A high IPF and low platelet count is consistent with a platelet destruction disorder.

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

Prostate Health Index Test

By Rhonda Burgard, Client Services Supervisor

The Prostate Health Index test is an FDA approved test for prostate cancer screening. It is a multi-analyte test that improves the interpretation of an elevated PSA by using an algorithm that calculates the results of three tests (PSA, free PSA and p2PSA) into one score. These results provide more accurate diagnostic information which is used for determining which patients should proceed to biopsy.

New Sensitive Estradiol Reagent

By Ron Piatz, Research and Development

Beckman Coulter Diagnostics has introduced the Access Sensitive Estradiol assay. This new assay offers improved measurement of low levels of estradiol, such as those typically found in men, pediatric populations and post-menopausal women. Therefore, this new assay will enable accurate testing for estradiol in all patient populations. Northern Plains Laboratory (NPL) has evaluated and verified this assay and is pleased to announce the implementation of this new test method.

Questions or comments should be directed to Laurie Linz, MD or to Michelle Steiner at NPL 701-530-5720 or 1-800-645-1003

Test Code	Test Name	CPT Code	LOINC	Specimen
EST	Estradiol	82670	35384-7	0.5 mL serum or heparin plasma Stable 7 days at 2-8°C

NPL Estradiol Reference Ranges:

INTERVALS	Range of days from hLH peak (day 0)	SAMPLE TYPE	UNITS (pg/mL)
Pediatric 0 - <1 years old	N/A	Serum/heparin plasma	<15 – 38
Pre-puberty 1 - <12 years old			
Female	N/A	Serum/heparin plasma	<15 – 16
Male	N/A	Serum/heparin plasma	<15
Puberty 12 - <19 years old			
Female	N/A	Serum/heparin plasma	37 - 196
Male	N/A	Serum/heparin plasma	20 - 35
Adult Male	N/A	Serum/heparin plasma	<15 – 32
Adult Female:			
Early-Follicular	-14 to -10	Serum/heparin plasma	22 – 115
Mid Follicular	-9 to -4	Serum/heparin plasma	25 – 115
Ovulatory Peak	0	Serum/heparin plasma	32 – 517
Mid Luteal	+4 to +11	Serum/heparin plasma	37 – 246
Postmenopausal *	N/A	Serum/heparin plasma	<15 – 25
*Not on hormone therapy			

C. difficile by PCR with reflex to *C. difficile* Toxin by EIA

By Ron Piatz, Research and Development

Northern Plains Laboratory (NPL) has changed *C. difficile* testing methods from solely using a PCR molecular approach to a 2-step algorithm as recommended by the Infectious Disease Society of America. This 2-step algorithm will be beneficial in ruling out patients that are asymptomatic carriers of the C. difficile organism without detectable toxin production. The initial screening will be performed by a very sensitive, molecular PCR method with positive samples reflexed to *C. difficile* toxin by Enzyme Immunoassay (EIA). The PCR methodology will determine if *C. difficile* genes that code for toxin production are present in the stool sample and the EIA test will determine if the actual toxin produced by the *C. difficile* organisms is detected.

Previous data has determined that >80% of samples submitted for testing will test as *C. difficile* negative and thus will not require additional reflex testing. For those samples that test as *C. difficile* positive by PCR, the additional toxin test will confirm if active *C difficile* toxin production is taking place which indicates *C. difficile* infection. *C. difficile* PCR positive results with negative toxin test could indicate that the patient is a potential carrier of *C. difficile* but does not have *C. difficile* infection. As always, *C. difficile* test results should be correlated with the patient's clinical history.

Micro Test CDTOX will be reflexed if the result of Lab test GICPP (GI Panel) result component P0002 (Clostridium difficile toxin A/B) is Detected or Equivocal or if Micro Test CDP (C difficile toxin by PCR) is Positive.

Specimen collection remains unchanged:

- Collect 1 mL or 1 gm of liquid or unformed stool specimen in a clean container. Stool is stable for 3 days at 2-8°C. For longer stability, send frozen. **Note: Formed stool samples will be rejected.**

Additional CPT code, 87324, will be added to reflexed specimens and additional billing will apply.

Only patients that are *C. difficile* by PCR **and** *C. difficile* Toxin positive need to be reported to NHSN as positive patients.

Immunotherapy Interference with Blood Bank Serology Testing Results

By Rhonda Burgard, Client Services Supervisor

Immunotherapy works with the patient's own immune system to destroy cancer cells. Two new immunotherapy drugs Anti-CD 38 (Daratumumab) and Anti-CD 47, used for treatment of hematology and solid tumors, may interfere with blood bank serology testing including ABO back typing and antibody screening results. If discrepant results are obtained consider obtaining a patient diagnosis and medical history as part of your evaluation.

Reference: Transfusion https://onlinelibrary.wiley.com/doi/full/10.1111/trf.15033 for free access to the full article.

PAP and Human Papilloma Virus (HPV) Testing

By Rhonda Burgard, Client Services Supervisor

Northern Plains Laboratory and Pathology Consultants are pleased to announce a change regarding reporting of HPV results. When HPV testing is ordered, regardless of the PAP test result (co-testing), the HPV testing will now be performed at the same time as the PAP test instead of waiting for completion of the PAP test. This change should significantly reduce the turn-around time for HPV co-testing results. Please notify your providers that the HPV result will typically be reported before the PAP test result.

However, if HPV testing is ordered as reflex testing for an abnormal PAP test result (i.e. not ordered as co-testing), the process will not change. As always, if HPV was not originally ordered, but the provider would like to have HPV testing performed, HPV testing can be added on to any PAP test up to two weeks after the PAP test was received.

If your institution is billing for PAP and HPV testing please also notify your billing department. They may want to hold coding for the HPV test until the PAP diagnosis is available.

If you have any questions or concerns please contact Rhonda Burgard, Client Services Supervisor or Ron Piatz, Research and Development at 701-530-5700.

Critical Values

By Rhonda Burgard, Client Services Supervisor

If sending testing from a provider located outside of the ordering location please send contact information for that provider so that NPL is able to call any critical results. If the information is not provided, NPL will call the ordering facility with the critical value information.

Specimen Stability

By Rhonda Burgard, Client Services Supervisor

Several of the specimen type and stability requirements for chemistry testing have changed. Enclosed in this mailing is an updated listing of chemistry stability requirements for serum, plasma, urine, body fluid and whole blood specimens. Specimens exceeding stability limits may be used at the request of a provider or client account. A comment will be added to the test result “Specimen has exceeded recommended stability limits for this analyte. Test performed at the request of (provider name).” The comment is not intended to replace or supersede current policies on specimen rejection. If the specimen is very delayed or has exceeded storage temperature requirements it may still need to be canceled.

Additional information may be found in the NPL Test Catalog at www.northernplainslab.com. If you have any questions or concerns please contact the Northern Plains Client Services at 701-530-5700.

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