PHYSICIANS LABORATORY SERVICES

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PLS UPDATE

JANUARY 2016

TRICHOMONAS VAGINALIS CDC GUIDELINES

The pathogen Trichomonas vaginalis has been linked to pelvic inflammatory disease, female infertility, premature births, low birth weights, and increased risk of HIV infection. T. vaginalis infections may be asymptomatic in up to 50% of infected women; the percentage may be even higher in men.

This FDA-approved Aptima Trichomonas vaginalis test offers higher sensitivity for Trichomonas vaginalis compared with slower, technically demanding culture and techniques. The Center for Disease Control (CDC) and Association of Public Health Laboratories (APHL) suggest testing for Trichomonas vaginalis using highly sensitive techniques in women with vaginal discharge. Screening is also suggested in high prevalence settings such as sexually transmitted disease clinics, correctional facilities, and high risk sexual behavior.

Physicians Laboratory offers nucleic acid amplification testing for Trichomonas vaginalis. This test is performed on the same platform on which we currently perform testing for Neisseria gonorrhoeae and Chlamydia trachomatis.

Test #	Test Name	CPT Codes
1987	Trichomonas vaginalis DNA Amplified	87661
2000	Chlamydia/GC/Trichomonas Panel by PCR	87491, 87591, 87661

Acceptable Specimen Types:

Liquid Based Pap Vial / Aptima Urine / Aptima Swab

TEST #8204: ANTI-MULLERIAN HORMONE – NOW PERFORMED IN-HOUSE

Effective January 4, 2016, Physicians Laboratory Services is pleased to announce that "Anti-Mullerian Hormone" (AMH) will now be performed in-house. This test is used as an aid in monitoring ovarian reserve in fertility assessment. AMH is only produced in small ovarian follicles and blood levels can provide an indirect measure of the size of the pool of growing and/or remaining follicles, or eggs in the ovaries.

Women with many small follicles as well as females with polycystic ovary syndrome have higher AMH levels, while women who are approaching menopause tend to have low AMH values. Higher AMH values tend to have better response to ovarian stimulation for in-vitro fertilization and have a greater chance of producing more mature eggs for retrieval. While AMH levels do provide information concerning egg quantity, they do not provide information concerning egg quality.

Any questions concerning AMH can be directed to Dr. Gregory Post or the Special Chemistry department.

IONIZED CALCIUM – IMPROVED EFFICACY IN DETECTING PRIMARY HYPERPARATHYROIDISM

Measurement of calcium is used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms). Calcium ions are important in the transmission of nerve impulses, as a cofactor in several enzyme reactions, in the maintenance of normal muscle contractility, and in the process of coagulation.

Serum calcium exists in three forms: 1) free calcium ion, Ca^{2+}, 50%, 2) protein bound calcium, 45% and 3) complexed calcium, mainly with citrate, 5%. The ionized calcium is physiologically most significant and direct measurement of ionized calcium is now suggested in many ambulatory conditions, including patients in the later stages of chronic kidney disease, patients with suspected hyperparathyroidism, MEN1, multiple myeloma, Paget's disease/osteoporosis as well as other diseases which affect protein levels or pH of the blood.

In histologically proven hyperparathyroidism, Ionized Calcium has been demonstrated to detect 20 – 40 % more cases when compared to total calcium. The efficacy is higher in younger patients with better renal function. The test is available as a single ordered test or as part of a profile with PTH.

Test # 9410 Ionized Calcium CPT 82330
2.0 mL (0.5 mL) Serum Separator Tube UNOPENED. Separate samples must be submitted when multiple tests are ordered.

Test #2342 PTH w/ Ionized Calcium CPT 83970, 82330
2.0 mL (0.5 mL) Serum Separator Tube UNOPENED for the Ionized Calcium AND 1.0 mL (0.5mL) Serum for the PTH. 2 separate serum separator tubes must be submitted for this order. One tube must be unopened.

SENDOUT TEST #9780 VITAMIN D2, D3 25-HYDROXY DISCONTINUED

Effective immediately, the sendout test #9780 (Vitamin D2, D3 25-hydroxy) will be discontinued. This test measures the total amount of 25-hydroxy Vitamin D in serum and provides fractionated levels of the two isomers. The assay used by Physicians Laboratory Services (test #9277, Vitamin D 25-hydroxy) measures 100 % of the two isomers (D2 and D3) and provides identical information with a significant decrease in the cost of the test. The quantifiable value of Vitamin D in serum will not be affected with our assay no matter if one is supplemented with either oral form of isomer (D2 or D3). The lack of any statistical difference between the assays when measuring total Vit D 25-hydroxy makes the former test clinically insignificant.

CHANGES IN THE SPECIMEN LABELING AND SPECIMEN REJECTION POLICY

Proper specimen identification and labeling is a critical component of guaranteeing patient safety and providing high quality care in a clinical laboratory setting. In an effort to provide the highest quality care to our patients and clients, we are modifying our specimen labeling and specimen rejection policy.

All specimens, including all clinical and anatomic specimens, must be labeled with the patient's full first and last name and at least one other unique patient identifier such as date of birth, patient medical record number/clinic account number, or requisition number. Initials and nicknames will not be accepted. It is strongly recommended that all anatomic pathology specimens also have the date of collection and tissue source listed on the specimen container. Please note that these do not count as unique identifiers. It is also strongly recommended that the date of collection is listed on all clinical specimens. Please note that the information provided on the requisition and specimen must be identical.

Effective April 1, 2016, all mislabeled *retrievable* specimens will be rejected for testing. The client will be notified that the specimen has been rejected due to mislabeling and will be asked to recollect the specimen. Mislabeled *irretrievable* specimens will be held to minimize sample degradation while the labeling issue is being resolved. In the event of a mislabeled irretrievable specimen, a pathologist will speak with the ordering clinician and the "irretrievable specimen identification discrepancy form" will be completed. This form must be signed by the ordering provider before the specimen is processed. Please see the table below for definitions of retrievable and irretrievable specimens.

Retrievable specimens *(easily recollected from the patient without incurring harm and the recollected specimen is diagnostically equivalent to the original)*	**Irretrievable specimens** *(cannot be easily recollected from the patient, recollection of the specimen may negatively impact patient care, or the recollected specimen is not diagnostically equivalent to the original)*
• Throat swabs including nasopharyngeal swabs • Urine • Stool • Sputum • Blood (non-pediatric collections) • Arterial blood (drawn from arterial line) • Semen analysis • Nipple discharge if able to recollect	• Cerebrospinal fluid • Body fluids (non-urine) • Cord blood • Bone marrow • Wound cultures • Operating room cultures • Cultures taken before initiation of antibiotics • Arterial blood drawn from wrist • Anatomic pathology specimens o Biopsy o Resections o Pap smears o Fine needle aspirations

DHHS MEDICAID – NO LONGER COVERING QUAD SCREEN, FIRST TRIMESTER SCREENING & CYSTIC FIBROSIS

On October 1, 2015, Nebraska Medicaid made the decision to discontinue coverage for Genetic Testing and Counseling for an Unborn Child. The announcement states the following:

"Nebraska Medicaid covers items and services which are reasonable and necessary for the diagnosis and treatment of illness or injury (471 NAC 18-003.04). The regulations also state that Medicaid covers services provided to a client directly related for the diagnosis or treatment of the client's condition (471 NAC 1-002.02J).

Maternal serum and amniotic fluid tests which are not covered for the sole purpose of screening for genetic defects include, but are not limited to:

1. Alpha-Fetoprotein (AFP), Estriol, Inhibin A, and Human Chorionic Gonadotropin (hCG), better known as the Quad Screen Test;
2. Pregnancy-Associated Plasma Protein-A (PAPP-A) and hCG with a nuchal translucency ultrasound, better known as First Trimester Screening;
3. Cystic Fibrosis Screening; and
4. Amniocentesis."

Physicians Laboratory did contact the Medicaid office to gain a better understanding of this decision. Our facility was informed that due to the low occurrence of positive results and expense of further testing, coupled with the fact that the results do not directly aid the unborn, the decision was made to no longer cover the testing.

Therefore, if the patient requests any of the tests listed above, the ordering facility **MUST INFORM THE PATIENT THAT TESTING WILL NOT BE COVERED BY MEDICAID AND OBTAIN A SIGNED ABN.** Failure to do so may result in charges being billed back to the ordering facility. An example of an ABN that can be used for Non-Medicare insurance providers is available on our website at www.physlab.com/forms/ABN_2016_Commercial.pdf.

Several of our clients have expressed concern over this decision; therefore, if you would like to send a detailed explanation to the Medicaid office as to why they should overturn this policy, please send all documentation to the following address:

Medicaid Director
NE Dept of Health & Human Services
PO Box 95026
Lincoln, NE 68509-5026

CPT CODE CHANGES, CORRECTIONS, AND CLARIFICATIONS

There were numerous CPT Code changes that took place on January 1, 2016. Physicians Laboratory distributed a bulletin to all clients that listed all of the tests that experienced modifications. If you did not receive a copy of this bulletin, please contact Kacey Moreland at kmoreland@physlab.com or 402-731-4145. There are a few corrections and additions to this bulletin:

#2190	Oxycodone, Urine	Correct CPT Code:	80300 (Medicare G0477)
#635	Fungus ID	Correct CPT Code:	Varies (87106 OR 87107)
			87106 used for definitive ID Yeast
			87107 used for definitive ID Mold
#608	Fungus Culture	Correct CPT Code:	Varies (Dependent on Source)
			87101 Culture, Fungi Isolation; Skin, Hair or Nail
			87102 Culture, Fungi Isolation; Other Source (Except Blood)
			** Additional CPT Codes Will Apply if ID Reported (See Above)**

CYTOLOGY UPDATES TO REPORTING

PAP SMEAR TESTING ~ As of July 2, 2015, Physicians Laboratory's diagnosis for benign-appearing endometrial cells in patients 40 years of age and older has been updated to comply with the new Bethesda System's recommendation that "benign-appearing endometrial cells be reported in women 45 years of age or older." (The Bethesda System for Reporting Cervical Cytology 93)

URINARY CYTOLOGY ~ As of January 1, 2016, Physicians Laboratory is utilizing the Paris System (TPS) for reporting Urinary Cytology. This system was developed to aid in the communication between pathologists and clinicians who investigate, diagnose and treat urothelial neoplasia. The TPS major diagnostic categories are:

-Unsatisfactory / Non-diagnostic

-Negative for High Grade Urothelial Carcinoma (NHGUC)

-Atypical Urothelial Cells (AUC)

-Suspicious for High Grade Urothelial Carcinoma (SHGUC)

-High Grade Urothelial Carcinoma (HGUC)

-Low Grade Urothelial Neoplasm (LGUN)

-Other malignancies, Primary and Secondary

If you have any questions regarding the Paris System (TPS) reporting system, please contact Angie Gedik (Cytology Supervisor) at agedik@physlab.com or (402)731-4145.

PHYSICIANS LABORATORY ~ WWW.PHYSLAB.COM

The Physicians Laboratory website www.physlab.com has been improved to allow for easier navigation. Clients can utilize the site for:

-Technical Bulletins

-Online Result Access

-Supply Orders

-Test Directory (Specimen Requirements & Stability / CPT Codes / Turn-Around-Time)

-Resources

-Forms (ABN, Preauthorization, Monthly Adjustments, Web Access Request)

We are always trying to enhance our services and welcome any recommendations for improvement. If you have any suggestions for additional functionality please contact Jeff Irwin jirwin@physlab.com (402) 933-1587.