PHYSICIANS LABORATORY SERVICES

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PLS UPDATE

JANUARY 2015

Changes to HPV CPT Codes:

Effective 01/01/2015, the AMA created new CPT Codes for HPV testing. These codes are as follows:

87623	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low risk types
87624	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types
87625	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), types 16 and 18 only, includes type 45 if performed

The CPT codes for the following tests have been modified effective 01/01/2015:

Test #	Test Name	Old CPT Code	New CPT Code
7613	HPV High Risk Screen	87621	87624
7614	HPV High Risk Screen w/ Reflex to 16/18	87621	87624
7683	HPV Genotype16/18	87621	87625
7658	HPV Type Detect 3.0 Sequencing (Sendout)	87798, 87621	87798, 87624

New Cytology Tests ~ Effective February 1, 2015:

Insurance companies are becoming increasingly strict with payment for HPV testing. With the introduction of the new CPT codes listed above, we are anticipating that our facility will only receive payment when the ordering physician follows the recommendations of ACOG and ASCCP guidelines. At the request of our providers, we have developed three new tests that will automatically reflex based on the most current guidelines. The guidelines, reflex criteria and new test numbers are listed below for your review:

SUMMARY OF ACOG CERVICAL CANCER SCREENING RECOMMENDATIONS

Age of Patient	Pap	HPV High Risk Screen	HPV Genotype 16/18
Age <21	Not Recommended	Not Recommended	Not Recommended
Age 21-29	Pap every 3 years	HPV High Risk Screen if Pap is ASCUS	Not Recommended
Age 30-65	If screening only by Pap, testing is recommended every three years.	Preferred Method ~ Co-testing using the combination of Pap and HPV High Risk Screen. Test again in 5 years if both results are negative and patient is low-risk.	If the Pap result is normal and the HPV High Risk Screen is positive, HPV 16/18 Genotype is recommended.
Age >65	Screening should be discontinued after age 65 for women with adequate negative prior screening results and no history of CIN2 or higher.		

REFERENCES

1. American College of Obstetricians and Gynecologists. Screening for Cervical Cancer. ACOG Practice Bulletin. No. 131, November 2012.
2. Cervical Cancer Screening Guidelines for Average-Risk Women, 2012, http://www.cdc.gov/cancer/cervical/pdf/guidelines.pdf
3. HPV Genotyping Clinical Update. 2009, American Society for Colposcopy and Cervical Pathology.
4. Saslow, D et al. ACS-ASCCP-ASCP Screening Guidelines. Journal of Lower Genital Tract Disease, Volume 16, Number 3, 2012, p. 4.

PAP W/ REFLEX TO HPV PER ACOG GUIDELINES

Criteria for reflex Testing:

- Age 30-65: Co-testing ~ Pap plus HPV High Risk Screen. If Pap is normal and HPV High Risk Screen is positive, a reflex to HPV 16/18 Genotype will be performed.
- Age 21-29: Pap performed. If Pap result is ASCUS, reflex to HPV High Risk Screen.

3615 Pap, ThinPrep® Image w/ Reflex to HPV (ACOG Guidelines)
3616 Pap, ThinPrep® w/ Reflex to HPV (ACOG Guidelines)
3617 Pap, SurePath™ w/ Reflex to HPV (ACOG Guidelines)

Note: Tests 3615, 3616, and 3617 will not reflex to HPV testing for patients less than 21 years of age and greater than 65 years of age. Please call client services if you would like to add on HPV testing.

SITUATIONS WHERE HPV DNA TESTING & GENOTYPING ARE NOT RECOMMENDED

~Per ASCCP HPV Genotyping Clinical Update~

- Adolescents, defined as women 20 years and younger (regardless of their Cytology results).
- Women 21 years and older with ASC-H, LSIL, or HSIL cytology (note: "reflex" HPV testing is acceptable in postmenopausal women with LSIL)
- Routine screening in women before the age of 30 years
- In women considering vaccination against HPV
- For routine STD Screening
- As part of a sexual assault workup
- HPV 16/18 genotyping is not recommended for women with ASC-US
- HPV is not recommended as the initial screening test for women 30 years and older

HPV Order Changes for Interface Clients and Copia Users ~ Effective February 1, 2015:

Interface Clients:

In order to use the new tests listed above, you will need to add these order choices to your EMR systems. If you have questions or need assistance, please call our I.T. department at 402-731-4145.

If you choose not to use the new tests, you must clearly indicate on the requisition, which pap smear test you want ordered, as well as the specific HPV reflex criteria you want followed. This must be indicated on every order to avoid unnecessary phone calls to your facility. Examples are listed below:

Unacceptable: Pap Smear, ThinPrep® w/ Reflex to HPV if ASCUS
The example above does not make it clear whether the pap smear should reflex to High Risk Screen only or High Risk Screen w/ Reflex to 16/18 Genotype.

Acceptable: #3516 Pap Smear, ThinPrep® w/ Reflex to HPV High Risk Only if ASCUS
This example clearly states the test number and which HPV test should be ordered if the Pap smear is ASCUS

If you do not clearly indicate that you want HPV High Risk Screen w/ reflex to 16/18 Genotype on the requisition, we will only perform the HPV High Risk Screen and the genotype will not be reported.

Copia Users:

Effective February 1, 2015, the new Cytology tests will be available to order. If you choose to continue to use the original Pap smear tests, the system will require you to choose whether you want testing to reflex to HPV High Risk Only or HPV High Risk w/ reflex to 16/18 Genotype.

If you have any questions regarding the Pap smear and HPV changes, please contact Kacey Moreland at (800)642-1117 or kmoreland@physlab.com.

Pap Test Lubricating Jelly:

For clients that utilize the Hologic ThinPrep® Pap Test, there is a new, carboner-free lubricant on the market. Aseptic Control Product's Pap Test Lubricating Jelly has been tested and deemed acceptable for use with the ThinPrep® vial. Pap Test Lubricating Jelly is available directly from:

Aseptic Control Products, Inc.
3831 Industrial Ave. Unit D
Rolling Meadows, IL 60008
Phone: (800)448-0131
info@acpmedicalinc.com

Peanut Component Allergen Testing:

More than 3 million people, 1% of the population, in the U.S. report being allergic to peanuts, tree nuts or both. Only 1 out of 5 patients will outgrow the allergy, but the peanut allergy is the most common cause of food related deaths. There are five distinct components in peanuts which can cause an allergic reaction. The severity of the reaction is dependent on which components an individual reacts to upon exposure. The components are listed below.

Peanut Components	Physical Characteristics/Clinical Observations	Risk
Ara h1 – Storage Protein Ara h2 – Storage Protein Ara h3 – Storage Protein	Associated with systemic reactions Stable to heat and digestion Highest risk for severe reactions to exposure	Highest
Ara h9 – Lipid Transfer Protein	Associated with both systemic and local reactions Semi-stable to heat and digestion Associated with allergies to peach and peach-related fruits	Intermediate
Ara h8 – PR10 Protein	Associated with local reaction (oral allergy syndrome, OAS) Labile to heat and digestion (cooked food often tolerated) Associated with allergies to birch and birch-related tree pollen	Lowest

Ara h1, 2, 3 are proteins found in the seeds and are stable to heat and digestion. Cooking or ingestion does not break these proteins down. They are responsible for the most severe allergic reactions to peanut exposure.

Ara h9 (Lipid Transfer Protein – LTP) is semi-stable to heat and digestion, but adequately cooked foods may be tolerated. This component is most commonly associated with mild or systemic reactions, in addition to oral allergy syndrome (OAS).

Ara h8 is a heat labile protein and cooked foods are often tolerated. A positive test for this allergen by itself is often associated with mild and local symptoms such as OAS.

The ImmunoCap® Peanut Component Allergen Test helps to assess a patient's level of risk of a life-threatening reaction, and may reassure patients when the risk for allergic symptoms is low and when they will most likely experience mild or localized reactions upon exposure to peanut. The test helps the health care provider identify primary allergic sensitization versus symptoms caused by cross-reactivity. Knowing the reaction to the different peanut components provides clarity regarding the patient's risk of an allergic reaction and helps target effective management.

#1370 Peanut Component Panel

Performed:	Monday-Friday
Performing Lab:	PLS Omaha Hematology
Requirements:	3.0 mL Serum, Refrigerate
CPT:	86003 X 5

Name change from Hepatitis Profile 3" to "Hepatitis Profile Chronic" – Test #2795:

The current panel for chronic hepatitis includes the following tests:

Hepatitis B Core Total	Hepatitis Bs Antigen	Hepatitis C Antibody
Hepatitis B Core IgM	Hepatitis Bs Antibody	Hepatitis A IgM

Hepatitis B and C are associated with chronic disease. A chronic hepatitis B carrier is defined by a positive Hepatitis Bs Antigen and Hepatitis B Core Total for a duration > 6 months. Hepatitis C is associated with chronicity rates as high as 80-90% following infection and a positive antibody should be followed up with a molecular test for viremia. Hepatitis A is not associated with chronicity and the IgM only implies recent infection. Hepatitis A Total Antibody should be ordered to determine if seroconversion and immunity has occurred.

Ionized Calcium now Available as Single order or Panel with PTH:

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. Although more than 99% of body calcium exists in bones and teeth, it is the calcium in blood, which is of most concern clinically. The bones serve as a reservoir and the uptake and release of calcium from bone is under the control of the parathyroid hormone.

Serum calcium exists in three forms: 1) free calcium ions, Ca^{2+}, 50%, 2) protein bound calcium, 45% and 3) complexed calcium, mainly with citrate, 5%. The ionized calcium is physiologically the most significant. 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 hyperparathyroid disease, 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 will be available as a single ordered test or as part of a profile with PTH.

Effective February 1, 2015, Ionized Calcium will be performed in-house.

Ionized Calcium Test #9410

Specimen Requirements: Serum Separator Tube 2.0 mL. Submit entire sample **UNOPENED**.

PTH with Ionized Calcium Test #2342

Specimen Requirements: **TWO SEPARATE SPECIMENS MUST BE COLLECTED**

1. Ionized Calcium: Entire Serum Separator Tube **UNOPENED**. Refrigerated.
2. PTH: 1.0 mL Serum Frozen.

C-Difficile Update – Test #8187:

Clostridium difficile testing is performed at Physicians Lab, using an amplified DNA probe methodology which provides highly specific and sensitive results. Previously, C-Difficile testing was batched one to two times a day due to the methodology limitations. The microbiology department has updated the molecular platform allowing us to perform testing as soon as the specimen arrives in our Omaha location. Testing should always be limited to patients with >3 non-formed stools per 24-hour period, unless obstruction is suspected. Testing is available Monday-Friday 7am-10pm and Saturday-Sunday 7am-2pm.

Multiple testing from the same patient is to be discouraged, as patients may carry toxigenic C. difficile for months after clinical cure. This test method is not recommended for use as a "test of cure". Patient cure is determined by cessation of symptoms and return to formed stools.

Repeat testing following a positive test would be appropriate if the patient improves with therapy and relapses after the completion of a treatment regimen. Repeat testing following a negative test is not recommended due to the high sensitivity of the test. C. difficile culture with reflex to cytoxicity assay is another option for complicated cases or question of clinical relapse. For questions, contact the Microbiology Department.

CPT Code Updates:

On January 1, 2015, a complete list of all the 2015 CPT code updates was mailed to our clients. If you didn't receive this update or would like another copy, please email or call Kacey Moreland (800)642-1117 / kmoreland@physlab.com.
There was one error on this announcement. The correct CPT code is listed below:

Test #	Test Name	Old CPT Code	New AMA Code 2015	New CMS Code 2015
9346	GHB, Serum	80101	80304	G0431

Discontinued Tests:

#0725 Toxicology Drug Screen Urine

#2104 Drug Facilitated Sexual Assault Panel

#405 Leukocyte Alkaline Phosphatase (LAP)

The LAP test historically has been used to screen for chronic myelogenous leukemia (CML) and polycythemia vera (PV). The assay has poor sensitivity with other nonmalignant conditions causing false positive results. Newer, more specific assays have been developed and have replaced this obsolete test.

When working up a possible CML diagnosis, the recommendations are to test for:

- Qualitative RT-PCR for BCR/ABL
- FISH for BCR/ABL
- Karyotyping

To help establish the diagnosis of PV, the recommended tests are:

- Erythropoietin
- JAK2 mutation analysis

If you have any questions concerning this testing, please direct them to Gregory Post. Ph.D., our Director of Clinical Services at 800 642-1117.

Physicians Laboratory Website – Update to Test Directory:

WWW.PHYSLAB.COM
Physicians Laboratory is updating test requirements on our website to include patient preparation instructions, a preferred specimen type and detailed specimen processing information. Our goal is to make our website more user-friendly so that specimen collection requirements are clear and concise. All changes to our website will be completed by February 1, 2015. Other functionality that is available at www.physlab.com:

- CAP/CLIA Certificates
- Online Results
- Required Forms (ABN/Preauthorization/etc.)
- Supply Orders
- Past Technical Bulletins and Billing Updates

Technical Bulletins – Email Distribution:
Technical bulletins and billing updates are distributed via email by request. If you would like to receive notices by email, please contact Kacey Moreland at kmoreland@physlab.com or (800)642-1117 in order to have your name added to the distribution list.

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