Spring 2018

AEL
AMERICAN ESOTERIC LABORATORIES
A Sonic Healthcare Company

AEL Update

Contents

Lab Week!

Medical Laboratory Professionals Week was April 22- 28, 2018. AEL would like to celebrate all medical laboratory professionals and pathologists who play a vital role in health care and patient advocacy!

Alert

Please note that Medicare beneficiaries will be receiving new cards over the next year. Medicare Beneficiary Identifiers (MBI) will need to be updated in your systems as patients present for services to be covered.

Vitamin Assay Panels

Medicare Coverage Changes

Local Coverage Determination Policy for Vitamin B12, Folic Acid, and Homocysteine (CPT: 82607, 82746, and 83090)

Medicare now considers vitamin assay panels (more than one vitamin assay) a screening procedure and therefore, non-covered. Assays for micronutrient testing for nutritional deficiencies that include multiple tests for vitamins are not considered necessary. Medicare reimburses for covered clinical laboratory studies that are reasonable and necessary for the diagnosis or treatment of an illness. Many vitamin deficiency problems can be determined from the patient's history and physical examination. Most vitamin deficiencies are suggested by specific clinical findings and may be corrected with supplemented vitamins. Clinical findings may indicate the need for laboratory testing for a specific vitamin deficiency. Any diagnostic evaluation should be targeted at the specific vitamin deficiency suspected and not a general screen. Other clinical states such as malabsorption syndrome may also lead to vitamin deficiencies.

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CMS

Medicare Advantage Plans

According to CMS, Medicare Advantage Plans must cover all of the services that original Medicare covers. However, if you are a provider for a Medicare Advantage Plan, you should know that changes have been made for the plans recently. Many plans require referrals to specialists and unless the referral is done, the patient may not receive full benefits and will have increased out of pocket expense. Many of these plans work in-network and any referrals must be to a participating provider or facility. The plan can also choose not to cover the costs of services that are not deemed medically necessary under Medicare.

The traditional ABN that has been used for Medicare patients for years is not valid for Medicare Advantage Plans.

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2018 CPT Code Changes

The American Medical Association (AMA) has made Current Procedural Terminology (CPT) code changes to the 2018 edition of the CPT coding manual. AEL has implemented these changes effective January 1, 2018.

Below is the list of affected tests with their associated updates.

Code	Test Name	Former CPT	2018 CPT
IDH12	IDH1 And IDH2 Mut Analysis, Exon 4	81403x2	81120; 81121
BCRABL1	BCR-ABL 1 Kinase Dom Mutation	81479	81170
G6PD MUT	Glucose-6-Phosphate Dehydrogenase 2	81479	81247
TPMG	Thiopurine Methytransferase Genotype	81401	81335
BGSEQ	Beta Globin(HBB) Gene Sequencing	81404	81364
TGFBR1	TGFBR1 Mutation Analysis	81405x2	81405
QACET	Acetone, Quantitative	80320/G0480	82010
ZIKAM	Zika Virus IgM Ab Capture(Mac)	86790	86794
PEANUT	Allergen Peanut Component Panel	86003x5	86008x5
ZIKASU	Zika Serum And Urine Pcr	87798x2	87662x2

Vitamin D continued from page 1

For Medicare beneficiaries vitamin testing may not be used for routine screening. Once a beneficiary has been shown to be vitamin deficient, further testing is medically necessary only to ensure adequate replacement has been accomplished. Thereafter, annual testing may be appropriate depending upon the indication and other mitigating factors. Assays of vitamin testing, not otherwise classified (84591), are not covered since all clinically relevant vitamins have specific assays.

The following are laboratory tests for which frequency limitations will be specified **[note this should be all the CPT codes in the list below, except for those that are non-covered]:** * Vitamins and metabolic function assays: 25-OH Vitamin D-3, Carnitine, Vitamin B-12, Folic Acid (Serum), Homocystine, Vitamin B-6, Vitamin B-2, Vitamin B-1, Vitamin E, Fibrinogen, High-Sensitivity C-Reactive Protein and Lipoprotein associated phospholipase A 2 (Lp-PLA 2); Vitamin A; Vitamin K; and Ascorbic acid.

** Additional inclusion of Vitamin D (with limited coverage not otherwise specified).*

Medicare won't cover more than one test per year, per beneficiary except as noted below. Certain tests may exceed the stated frequencies, when accompanied by a diagnosis fitting the exception description for exceeding the once per annum max.

- Vitamin B-12 (82607) and folate (82746) can be tested up to four times per year for malabsorption syndromes (K90.9) or deficiency disorders (D81.818, D81.819, E53.8, D51.0, D51.1, D51.2, D51.3, D51.8, D51.9, D52.0, D52.1, D52.8 and D52.9).

- Vitamin B-12 (82607) can only be tested four times per year for postsurgical malabsorption (K91.2). If you are ordering these test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required. For more info please call AEL Customer Service or your AEL Representative.

Vitamin causes interference during laboratory testing

Laboratory tests such as immunoassays use antibodies to detect and quantitate analytical compounds and often use a biotin linker to enhance sensitivity and accuracy. High dose biotin taken within 1 or 2 days or lower dose biotin taken within a few hours prior to sampling may affect the accuracy of laboratory testing for those assays that include a biotin component.

As a consequence, the US Food and Drug Administration (FDA) has issued a Safety Communication: The FDA Warns that Biotin May Interfere with Lab Tests (https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm586505.htm).

What does this mean for patients and providers?

- Patients on high dose supplements of biotin, such as hair/nail/skin supplements, should refrain from taking them in the 24 hours prior to laboratory testing.
- These supplements may or may not indicate they contain biotin prominently.
- Patients taking prescribed mega dose regiments (>150 mg biotin) should refrain from taking the supplement for 24-48 hours prior to laboratory testing, upon the advice of their physician.
- Patients and physicians should review any lab test result that does not match the clinical presentation and consider if biotin interference is present.

Background information:

- Biotin, or vitamin B7, is often found in multi-vitamins, prenatal vitamins, and dietary supplements, which may not be clear from the name of the supplement.
- Patients and clinicians should be aware that a number of immunoassay lab tests, including but not limited to cardiovascular diagnostic tests, thyroid tests, and certain other hormone tests, may be affected by biotin interference.
- The US recommended daily allowance (US RDA) for biotin is 0.03 mg.
    - The amount of biotin often found in multivitamins does not typically cause significant interference.
    - Supplements containing high biotin levels including those marketed for hair, skin, and nail benefits may contain 5-20 mg of biotin (200-600 times US RDA).
    - Biotin levels higher than the recommended daily allowance may cause significant interference with affected lab tests.

References:

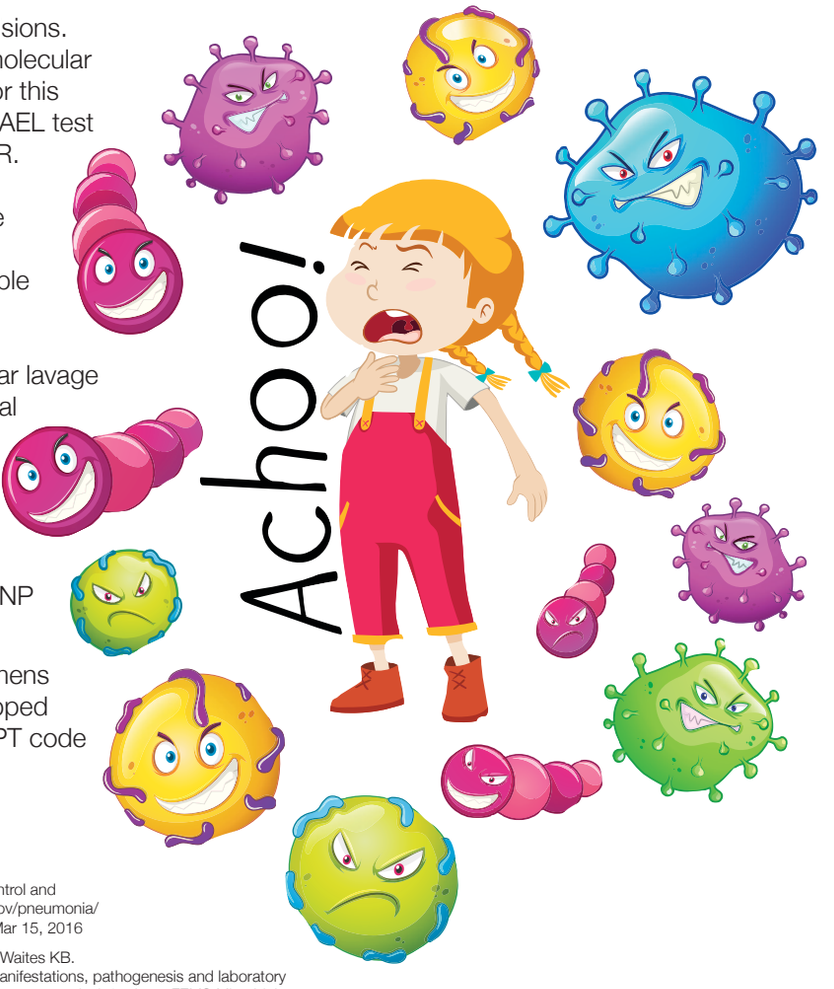
1. The FDA Warns that Biotin May Interfere with Lab Tests: FDA Safety Communication. Date Issued: 11/28/2017 https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm586505.htm
2. Kummer, S et al. Biotin Treatment Mimicking Graves' disease. NEJM 2016; 375:704-706.
3. Paxton, Anne. Beauty fad's ugly downside: test interference. CAP Today. September 2016.

PCR vs. Culture For Mycoplasma Testing

Mycoplasma pneumoniae is an 'atypical' bacterium (the singular form of bacteria) that commonly causes infections of the respiratory system. The most common type of illness caused by these bacteria, especially in children, is tracheobronchitis, commonly called a chest cold. This illness is often seen with other upper respiratory tract symptoms, like a sore throat. Sometimes *M. pneumoniae* infection can cause pneumonia, a more serious infection of the lungs, which may require treatment or care in a hospital.

M. pneumoniae infections are sometimes referred to as *walking pneumonia.* Some experts estimate that between 1 and 10 out of every 50 cases of community-acquired pneumonia (lung infections developed outside of a hospital) in the United States is caused by *M. pneumoniae*. However, not everyone who is exposed to *M. pneumoniae* develops pneumonia. The culture method for detection sometimes results in slow growth and has a high potential for false negatives. The advantage of culture is that it provides clinical isolates for genotyping and susceptibility testing. The advantages of the molecular test methods include higher sensitivity and specificity. Detection is rapid and results can be obtained in time to guide treatment decisions. To order the molecular test method for this organism use AEL test code MPNPCR. The preferred specimen type is sputum but other acceptable specimen types include bronchoalveolar lavage (BAL), bronchial brushings, CSF, pleural fluid, lung washes, tracheal aspirates and NP swab.

The specimens should be shipped frozen. The CPT code is 87581.



References:

Centers for Disease Control and Prevention. www.cdc.gov/pneumonia/atypical/mycoplasma. Mar 15, 2016

Atkinson TP, Balish MF, Waites KB. Epidemiology, clinical manifestations, pathogenesis and laboratory detection of Mycoplasma pneumoniaeinfections. FEMS Microbiol Rev. 2008;32:956–73.

Thurman KA, et al. Comparison of laboratory diagnostic procedures for detection of Mycoplasma pneumoniae in community outbreaks. Clin Infect Dis. 2009;48:1244–9.

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Instead of the ABN, you should ask the plan for a written advance coverage decision to make sure a service is medically necessary and will be covered. If the plan will not pay for a service you need, the patient may be responsible for all of the costs if your office did not ask for an advance coverage decision.

Check www.medicare.gov for more information about the Medicare Advantage Plans or check with your specific plan representative.

Testing Update

Discontinuation of Random Microalbumin (MLBU)

In accordance with the National Kidney Foundation (NKF) and other laboratory societies, American Esoteric Laboratory has discontinued the use of the Random Microalbumin (MLBU) test code effective April 9, 2018.

The recommended test is the Albumin Creatinine Ratio, Random Urine (MACR). AEL also offers the Microalbumin, Timed Urine (MLBT). The term Microalbumin is no longer recommended and will be referred to as Albumin.

AEL Updated Reference Ranges

In order to improve patient care, AEL performed a review of test reference ranges and implemented these updates on March 5, 2018. Please contact the laboratory if you have any questions about these updates.

Test Name	Sex	Min. Age (>=)	Max. Age (<)	Range	Unit
Sodium	F/M	0Y	115Y	135 - 146	mEq/L
Chloride	F/M	0Y	115Y	95 - 107	mEq/L
Carbon Dioxide	F/M	0Y	115Y	19 - 31	mEq/L
Anion Gap	F/M	0Y	115Y	10 - 19	mEq/L
Glucose	F/M	0Y	115Y	70 - 99	mg/dL
Phosphorus	F/M	15Y	115Y	2.5 - 4.5	mg/dL
Bilirubin Total	F/M	0D	1D	2 - 6	mg/dL
	F/M	1D	2D	6 - 10	
	F/M	3D	1M	4 - 8	
	F/M	1M	17Y	<= 1.0	
	F/M	17Y	150Y	<= 1.2	
Bilirubin Direct	F	0D	115Y	<= 0.3	mg/dL
Bilirubin Indirect	F/M	17Y	115Y	<= 1.2	mg/dL
AST (SGOT)	F	18Y	115Y	9 - 40	U/L
	M	18Y	115Y	9 - 50	
ALT (SGPT)	F	18Y	115Y	5 - 40	U/L
	M	7Y	115Y	5 - 50	
Creatine Kinase-CK	F	18Y	115Y	28 - 176	U/L
	M	18Y	115Y	31 - 336	
GGT	F	0Y	115Y	0 - 40	U/L
	M	0Y	115Y	0 - 60	
LDH	F	15Y	115Y	123 - 214	U/L
	M	15Y	115Y	135 - 225	
Lipase	F/M	0Y	115Y	13 - 60	U/L
Gentamicin Trough	F/M	0Y	115Y	0.5 - 2	ug/mL
Gentamicin Peak	F/M	0Y	115Y	6 - 10	ug/mL

Test Name	Sex	Min. Age (>=)	Max. Age (<)	Range	Unit
Gentamicin Random	F/M	0Y	115Y	0.5 - 10	ug/mL
Tobramycin Peak	F/M	0Y	115Y	6 - 10	ug/mL
Tobramycin Random	F/M	0Y	115Y	0.5 - 10	ug/mL
Vancomycin Random	F/M	0Y	115Y	10 - 40	ug/mL
Digoxin	F/M	0Y	115Y	0.6 - 2.0	ng/mL
Lithium	F/M	0Y	115Y	0.6 - 1.2	mmol/L
Phenobarbital	F/M	0Y	115Y	10 - 40	ug/mL
Theophylline	F/M	5M	115Y	10 - 20	ug/mL
Valproic Acid	F/M	0Y	115Y	50 - 125	ug/mL
TSH	F/M	20Y	115Y	0.4 - 4.1	uIU/mL
T3, total	F/M	20Y	115Y	80 - 200	ng/dL
Free T3	F/M	18Y	115Y	2.2 - 4.2	pg/mL
Free T4	F/M	20Y	115Y	0.8 - 1.9	ng/dL
SHBG	F	18Y	21Y	24 - 125	nmol/L
	F	21Y	50Y	25 - 122	
	F	50Y	115Y	17 - 125	
	M	18Y	21Y	15 - 56	
	M	21Y	50Y	17 - 56	
	M	50Y	115Y	19 - 76	
ASO TITER	F/M	17Y	115Y	<= 200	IU/mL
Creatinine-Random Urine	F	0Y	115Y	28 - 217	mg/dL
	M	0Y	115Y	39 - 259	

Note: Total T3 result units have been updated to ng/dL from ng/mL. Results in ng/dL are 100 fold higher than ng/mL results.

For questions or further information, please contact your Customer Service Associate (CSA), Customer Service: 901.405.8200, Dr. Fred Bugg: 901.432.8545 or Dr. Jess Evans 901.432.8605.

Testing Update

Updated 6-Part CBC Automated Differential

The automated WBC differential is changing from an automated 5-part differential to a 6-part differential effective May 7, 2018. This updated 6-part differential includes all the categories of the 5-part differential plus a new category: IMMATURE GRANULOCYTES (IG). The IG category includes metamyleocytes, myelocytes, and promyelocytes but not bands. Bands are included in the neutrophil category. Both increased bands and IG have been associated with the "left shift" but bands have historically been difficult to evaluate precisely due to subjective interpretive variation from person to person by manual differential. Automated IG counts are objective which are more precise and reproducible by our new Sysmex hematology analyzers. The components of the 6-part differential will be reported as both absolute counts (k/uL) and percentages (%). IG is an important indicator of infection and inflammation. However, IG may also be elevated in myeloproliferative neoplasms, stress and other conditions that stimulate bone marrow.

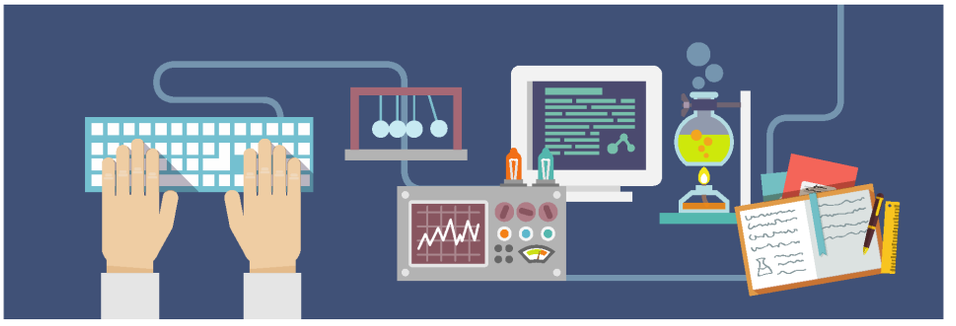
Testing Update

Discontinuation of H. Pylori Antibody Testing

The American Gastroenterological Association and the American College of Gastroenterology no longer recommend serologic antibody testing for either primary diagnosis (patients with active infection) or to confirm the eradication of H. pylori.

It has been recognized that the serological antibody tests do not distinguish a currently active infection with a past exposure or an infection that has been cured. Limitations of serological antibody tests include:

- Poor positive predictive value
- Poor performance characteristics for sensitivity and specificity compared to alternative tests
- Inability to differentiate active from past infection
- Inability to assess successful eradication following treatment



Current algorithms for the non-invasive assessment of patient for possible H. pylori infection no longer include serologic evaluation. The associations cited above have recommended the Urea Breath Test (HPBT) or the Fecal Antigen Test (PYLOS) as the initial step in the evaluation of possible H. pylori infection. Please remember the HPBT test requires a specialized collection kit. AEL Customer Service Representatives will be glad to instruct office personnel on proper HPBT collection. The CPT code for the HPBT is 83013. If you perform the collection for this test in your office the CPT code for the breath collection is 83014. The PYLOS test is a stool collection in a clean plastic stool container. The CPT code is 87338. AEL will be providing educational information to all clients currently ordering the serological tests with a targeted date of July 2, 2018 for discontinuation of the antibody testing. Please call Dr. Fred Bugg: 901.432.8545 or Dr. Jess Evans 901.432.8605 or your AEL representative with questions.