

Immediate Change HOTLINE: Effective August 6, 2018

### MEDICARE COVERAGE OF LABORATORY TESTING

Please remember when ordering laboratory tests that are billed to Medicare/Medicaid or other federally funded programs, the following requirements apply:

1. Only tests that are medically necessary for the diagnosis or treatment of the patient should be ordered. Medicare does not pay for screening tests except for certain specifically approved procedures and may not pay for non-FDA approved tests or those tests considered experimental.
2. If there is reason to believe that Medicare will not pay for a test, the patient should be informed. The patient should then sign an Advance Beneficiary Notice (ABN) to indicate that he or she is responsible for the cost of the test if Medicare denies payment.
3. The ordering physician must provide an ICD-10 diagnosis code or narrative description, if required by the fiscal intermediary or carrier.
4. Organ- or disease-related panels should be billed only when all components of the panel are medically necessary.
5. Both ARUP- and client-customized panels should be billed to Medicare only when every component of the customized panel is medically necessary.
6. Medicare National Limitation Amounts for CPT codes are available through the Centers for Medicare & Medicaid Services (CMS) or its intermediaries. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

The CPT Code(s) for test(s) profiled in this bulletin are for informational purposes only. The codes reflect our interpretation of CPT coding requirements, based upon AMA guidelines published annually. CPT codes are provided only as guidance to assist you in billing. ARUP strongly recommends that clients reconfirm CPT code information with their local intermediary or carrier. CPT coding is the sole responsibility of the billing party.

The regulations described above are only guidelines. Additional procedures may be required by your fiscal intermediary or carrier.

Hotline Page #	Test Number	Summary of Changes by Test Name	Name Change	Methodology	Performed/Reported Schedule	Specimen Requirements	Reference Interval	Interpretive Data	Note	CPT Code	Component Change	Other Interface Change	New Test	Inactive
2	<a href="#">0092566</a>	Bullous Pemphigoid Antigens (180 kDa and 230 kDa), IgG (Pricing Change Only)												
2	<a href="#">2010905</a>	Collagen Type VII Antibody IgG by ELISA (Pricing Change Only)												
2	<a href="#">0092572</a>	Cutaneous Direct Immunofluorescence, Biopsy (Pricing Change Only)												
2	<a href="#">0090649</a>	Desmoglein 1 and Desmoglein 3 Antibodies in Pemphigus, IgG (Pricing Change Only)												
3	<a href="#">2010921</a>	Eosinophil Granule Major Basic Protein, Tissue (Pricing Change Only)												

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3	<a href="#">2010902</a>	Epidermal Transglutaminase (etG/tTG3) Antibody, IgA by ELISA (Pricing Change Only)												
3	<a href="#">0092057</a>	Epithelial Basement Membrane Zone Antibody IgA (Pricing Change Only)												
3	<a href="#">0092056</a>	Epithelial Basement Membrane Zone Antibody IgG (Pricing Change Only)												
3	<a href="#">0090266</a>	Epithelial Cell Surface Antibody IgG (Pricing Change Only)												
3	<a href="#">0090299</a>	Epithelial Skin Antibody (Pricing Change Only)												
3	<a href="#">0091161</a>	Gamma-Hydroxybutyric Acid (GHB), Urine - Screen with Reflex to Confirmation/Quantitation							x			x		
3	<a href="#">0092283</a>	Herpes Gestationis Factor (Complement-Fixing Basement Membrane Zone Antibody IgG) (Pricing Change Only)												
3	<a href="#">0055655</a>	Methylenetetrahydrofolate Reductase (MTHFR), 2 Variants	x	x			x	x						
4	<a href="#">0092107</a>	Paraneoplastic Pemphigus Antibody Screen (Pricing Change Only)												
4	<a href="#">0092001</a>	Pemphigoid Antibody Panel - Epithelial Basement Membrane Zone Antibodies, IgG and IgA, BP180 and BP230 Antibodies, IgG (Pricing Change Only)												
4	<a href="#">0092106</a>	Pemphigus Antibody IgA (Pricing Change Only)												
4	<a href="#">0090650</a>	Pemphigus Antibody Panel - Epithelial Cell Surface Antibodies and Desmoglein 1 and Desmoglein 3 Antibodies, IgG (Pricing Change Only)												
4	<a href="#">0056200</a>	Thrombotic Risk, DNA Panel		x	x	x	x							

**[0092566](#) Bullous Pemphigoid Antigens (180 kDa and 230 kDa), IgG BP180 230G**

**HOTLINE NOTE:** There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.

**[2010905](#) Collagen Type VII Antibody IgG by ELISA COLLAG 7**

**HOTLINE NOTE:** There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.

**[0092572](#) Cutaneous Direct Immunofluorescence, Biopsy CUTDIF**

**HOTLINE NOTE:** There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.

**[0090649](#) Desmoglein 1 and Desmoglein 3 Antibodies in Pemphigus, IgG IGG DESMOG**

**HOTLINE NOTE:** There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.

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<a href="#"><u>2010921</u></a>	<b>Eosinophil Granule Major Basic Protein, Tissue</b>	<b>EGMBP TIS</b>
<b>HOTLINE NOTE:</b> There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.		
<a href="#"><u>2010902</u></a>	<b>Epidermal Transglutaminase (etG/tTG3) Antibody, IgA by ELISA</b>	<b>EPI TRANS</b>
<b>HOTLINE NOTE:</b> There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.		
<a href="#"><u>0092057</u></a>	<b>Epithelial Basement Membrane Zone Antibody IgA</b>	<b>EBMZ IGA</b>
<b>HOTLINE NOTE:</b> There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.		
<a href="#"><u>0092056</u></a>	<b>Epithelial Basement Membrane Zone Antibody IgG</b>	<b>EBMZ IGG</b>
<b>HOTLINE NOTE:</b> There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.		
<a href="#"><u>0090266</u></a>	<b>Epithelial Cell Surface Antibody IgG</b>	<b>IGG EPI AB</b>
<b>HOTLINE NOTE:</b> There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.		
<a href="#"><u>0090299</u></a>	<b>Epithelial Skin Antibody</b>	<b>EPITHELIAL</b>
<b>HOTLINE NOTE:</b> There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.		
<a href="#"><u>0091161</u></a>	<b>Gamma-Hydroxybutyric Acid (GHB), Urine - Screen with Reflex to Confirmation/Quantitation</b>	<b>GHB U</b>

**Note:** If Gamma-Hydroxybutyric Acid Screen is detected, then confirmation testing will be added at no additional charge.

**HOTLINE NOTE:** There is a reflexive pattern change associated with this test.

Add reflex to 2006520, Specific Gravity Confirmation, Urine

<a href="#"><u>0092283</u></a>	<b>Herpes Gestationis Factor (Complement-Fixing Basement Membrane Zone Antibody IgG)</b>	<b>HG FACTOR</b>
<b>HOTLINE NOTE:</b> There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.		
<a href="#"><u>0055655</u></a>	<b>Methylenetetrahydrofolate Reductase (<i>MTHFR</i>), 2 Variants</b>	<b>MTHFR PCR</b>

**Methodology:** Polymerase Chain Reaction/Fluorescence Monitoring

**Reference Interval: Negative:** Neither of the *MTHFR* variants tested, c.665C>T (previously designated C677T) and c.1286A>C (previously designated A1298C), were detected. Other causes of elevated homocysteine levels were not evaluated.

**Interpretive Data:**

**Background Information for Methylenetetrahydrofolate Reductase (*MTHFR*), 2 Variants:**

**Characteristics:** Variants in the *MTHFR* gene may reduce enzyme activity contributing to hyperhomocysteinemia. Although hyperhomocysteinemia was previously reported to be a risk factor for many conditions, especially venous thrombosis and cardiovascular disease, recent meta-analysis casts doubt on whether lifelong moderate homocysteine elevation has an effect on cardiovascular disease. The American College of Medical Genetics Practice Guidelines indicate that individuals with elevated homocysteine and two copies of the c.665C>T variant have an odds ratio of 1.27 for venous thromboembolism. Thus, they recommend *MTHFR* genotyping not be ordered as part of a routine evaluation for recurrent pregnancy loss or thrombophilia due to questionable clinical significance.

**Incidence:** The allele frequency of the c.665C>T variant is 0.35 in European Caucasians, 0.5 in Hispanics, and 0.12 in African Americans.

**Inheritance:** Autosomal recessive; two copies of the c.665C>T variant may be a contributing factor to hyperhomocysteinemia.

**Variants Tested:** c.665C>T(p.Ala222Val) and c.1286A>C(p.Glu429Ala). (legacy names, C677T and A1298C, respectively).

**Clinical Sensitivity:** Undefined; hyperhomocysteinemia is caused by genetic, physiologic and environmental factors. *MTHFR* variants are only one contributing factor.

**Methodology:** Polymerase chain reaction (PCR) and fluorescence monitoring.

**Analytical Sensitivity & Specificity:** 99 percent.

**Limitations:** Only two *MTHFR* gene variants (c.665C>T and c.1286A>C) are tested. Diagnostic errors can occur due to rare sequence variations.

See Compliance Statement C: [www.aruplab.com/CS](http://www.aruplab.com/CS)

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**0092107**      **Paraneoplastic Pemphigus Antibody Screen**      **PARA PEMPH**

**HOTLINE NOTE:** There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.

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**0092001**      **Pemphigoid Antibody Panel - Epithelial Basement Membrane Zone Antibodies, IgG and IgA, BP180 and BP230 Antibodies, IgG**      **PGOID PAN**

**HOTLINE NOTE:** There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.

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**0092106**      **Pemphigus Antibody IgA**      **IGA PEMPHI**

**HOTLINE NOTE:** There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.

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**0090650**      **Pemphigus Antibody Panel - Epithelial Cell Surface Antibodies and Desmoglein 1 and Desmoglein 3 Antibodies, IgG**      **PEMPHI PAN**

**HOTLINE NOTE:** There is a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.

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**0056200**      **Thrombotic Risk, DNA Panel**      **THROMDNA**

**Methodology:** Polymerase Chain Reaction/**Fluorescence Monitoring**  
**Performed:** Sun-Sat  
**Reported:** 2-6 days

**Specimen Required:** Collect: Lavender (EDTA), pink (K<sub>2</sub> EDTA) or yellow (ACD Solution A or B).  
 Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)  
 Storage/Transport Temperature: Refrigerated.  
 Unacceptable Conditions: Plasma or serum; collection of specimen in sodium heparin tubes.  
 Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month.

**Reference Interval:**

Test Number	Components	Reference Interval
0097720	Factor V Leiden (F5) R506Q Mutation	Negative: This sample is negative for factor V Leiden, R506Q mutation.
0055655	Methylenetetrahydrofolate Reductase (MTHFR), 2 Variants	Negative: Neither of the MTHFR variants tested, c.665C>T (previously designated C677T) and c.1286A>C (previously designated A1298C), were detected. Other causes of elevated homocysteine levels were not evaluated.
0056060	Prothrombin (F2) c.*97G>A (G20210A) Pathogenic Variant	