Immediate Change HOTLINE: Effective June 4, 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	0098880	*Chlamydia* Antibody Differentiation (Lymphogranuloma Venereum) by Microimmunofluorescence			x						x			
7	2006356	Chronic Granulomatous Disease (*CYBB* Gene Scanning and *NCF1* Exon 2 GT Deletion) with Reflex to *CYBB* Sequencing												x
3	3000544	Chronic Granulomatous Disease Panel (*CYBB* Sequencing and *NCF1* Exon 2 GT Deletion)											x	
7	2006361	Chronic Granulomatous Disease, X-Linked (*CYBB*) Gene Scanning with Reflex to Sequencing												x

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
4	3000541	Chronic Granulomatous Disease, X-Linked (*CYBB*) Sequencing											x	
4	2006238	Diamond-Blackfan Anemia (*RPS19*) Sequencing				x								
4	2008326	Hydrocarbon and Oxygenated Volatiles Panel, Blood							x		x			
5	2014683	LeukoStrat CDx *FLT3* Mutation Detection by PCR				x								
7	0091088	Methyprylon, Serum or Plasma												x
5	2006054	Mitochondrial Disorders Panel (mtDNA Sequencing, Nuclear Genes Sequencing and Deletion/Duplication)	x						x					
5	2014059	Prostate-Specific Kallikrein, 4Kscore				x					x			
7	0099411	Schistosoma Antibody, IgG												x
6	3000582	*Schistosoma* Antibody, IgG, Serum											x	

0098880 ***Chlamydia* Antibody Differentiation (Lymphogranuloma Venereum) by Microimmunofluorescence** **LYMPH VEN**

Performed: Varies
Reported: 3-4 days

HOTLINE NOTE: There is a component change associated with this test.
Remove component 0098696, C. trachomatis (L2) IgG.
Remove component 0098697, C. trachomatis (L2) IgA.
Remove component 0098698, C. trachomatis (L2) IgM.
Remove component 0098699, C. trachomatis (L2) Interpretation.
Add component 3000348, C. trachomatis (L1) IgG.
Add component 3000349, C. trachomatis (L1) IgA.
Add component 3000350, C. trachomatis (L1) IgM.
Add component 3000351, C. trachomatis (L1) Interpretation.

New Test	**3000544**	**Chronic Granulomatous Disease Panel (*CYBB* Sequencing and *NCF1* Exon 2 GT Deletion)**	**CGD PAN**

Methodology: Polymerase Chain Reaction/ Sequencing/ High Resolution Melt Analysis
Performed: Sun-Sat
Reported: Within 2 weeks

Specimen Required: Collect: Lavender (EDTA), Pink (K_2EDTA), Yellow (ACD).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 6 months

Interpretive Data:
Background Information for Chronic Granulomatous Disease Panel (*CYBB* Sequencing and *NCF1* Exon 2 GT Deletion):
Characteristics of Chronic Granulomatous Disease (CGD): A primary immunodeficiency disorder characterized by recurrent, severe bacterial and fungal infections of the skin, lymph nodes, liver, lungs, bones, or visceral organs. Dysregulated inflammatory responses result in granulomas.
Incidence: Approximately 1 in 250,000 births.
Inheritance: X-linked recessive for *CYBB*; de novo variants in 10-20 percent of affected males. Autosomal recessive for *NCF1*.
Cause: Pathogenic variants in the X-linked *CYBB* gene (60-70 percent), pathogenic variants in autosomal recessive genes *NCF1* (25 percent), *CYBA* (Less than 5 percent), *NCF2* (Less than 5 percent) and *NCF4* (very rare).
Clinical Sensitivity: Up to 78 percent for CGD
Methodology: Bidirectional sequencing of the *CYBB* coding region and intron-exon boundaries. Polymerase Chain Reaction/High-Resolution Melt Analysis to assess for the common *NCF1* c.75_76delGT variant.
Analytical Sensitivity: 99 percent for *CYBB* and homozygous *NCF1* c.75_76delGT deletion, 90 percent for heterozygous *NCF1* c.75_76delGT deletion.
Analytical Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Regulatory region variants, deep intronic variants, and large duplications will not be detected in patients of either sex; large deletions will not be detected in females. Variants in *NCF1* other than c.75_76delGT are not evaluated. Because of potential recombination between *NCF1* and its pseudogenes, the lack of detection of the c.75_76delGT variant does not rule out carrier status for autosomal recessive CGD.

CPT Code(s): 81479

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.

New Test 3000541 Chronic Granulomatous Disease, X-Linked (*CYBB*) Sequencing CYBB FGS

Methodology: Polymerase Chain Reaction/ Sequencing
Performed: Sun-Sat
Reported: Within 2 weeks

Specimen Required: Collect: Lavender (EDTA), Pink (K2EDTA), Yellow (ACD).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 1 month; Frozen: 6 months

Interpretive Data:
Background Information for Chronic Granulomatous Disease, X-Linked (*CYBB*) Sequencing:
Characteristics of chronic granulomatous disease (CGD):
A primary immunodeficiency disorder characterized by recurrent, severe bacterial and fungal infections of the skin, lymph nodes, liver, lungs, bones, or visceral organs. Dysregulated inflammatory responses result in granulomas.
Incidence: Approximately 1 in 250,000 births.
Inheritance: X-linked recessive for *CYBB*; de novo variants in 10-20 percent of affected males.
Cause: Pathogenic variants in the X-linked *CYBB* gene (60-70 percent), pathogenic variants in autosomal recessive genes *NCF1* (25 percent), *CYBA* (Less than 5 percent), *NCF2* (Less than 5 percent) and *NCF4* (very rare).
Clinical Sensitivity: 51-60 percent for CGD.
Methodology: Bidirectional sequencing of the *CYBB* coding region and intron-exon boundaries.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Regulatory region variants, deep intronic variants, and large duplications will not be detected in patients of either sex; large deletions will not be detected in females. Variants in genes other than *CYBB* are not evaluated.

CPT Code(s): 81479

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.

2006238 Diamond-Blackfan Anemia (*RPS19*) Sequencing RPS19 FGS

Specimen Required: Collect: Lavender (EDTA). Also acceptable: Pink (K_2EDTA).
Specimen Preparation: Transport 5 mL whole blood. (Min: 2 mL)
Storage/Transport Temperature: Refrigerated. Protect from extreme temperatures.
Remarks: **Clinical indication or reason for testing is required.**
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 week; Frozen: Unacceptable

2008326 Hydrocarbon and Oxygenated Volatiles Panel, Blood HYDRO OX B

Note: Acetaldehyde is an unstable compound post-collection and will both form and degrade under certain sample handling conditions. Even when extreme precautions are taken to maintain the integrity of Acetaldehyde during sample collection, transport and analysis, the results will be affected under typical collection and laboratory procedures.

Test includes: Benzene, Ethybenzene , Styrene, Toluene, Xylenes (o,m,p), n-Heptane, n-Hexane, Methylpentanes (2- and 3- Isomers), Pentane, n-Butanol, Ethanol, Isopropanol, n-Propanol, Methanol, Acetaldehyde, Acetone, Methyl Ethyl Ketone, Methyl Isobutyl Ketone, Methyl n-Butyl Ketone, Ethyl Acetate, Diethyl Ether, and Methyl Tertiary Butyl Ether.

HOTLINE NOTE: There is a component change associated with this test.
Remove component 0091149, Methyl Acrylate

2014683 LeukoStrat CDx *FLT3* Mutation Detection by PCR — FLT3 CDX

Specimen Required: Collect: Green (Sodium Heparin).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL) **OR** 1 mL bone marrow. (Min: 0.25 mL) **Separate specimens must be submitted when multiple tests are ordered.**
Storage/Transport Temperature: Refrigerated.
Remarks: Specimen type required.
Unacceptable Conditions: Specimens in Bone Marrow Transport Media. Grossly hemolyzed or clotted specimens.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

2006054 Mitochondrial Disorders Panel (mtDNA Sequencing, Nuclear Genes Sequencing and Deletion/Duplication) — MT PANEL

Note: *Genes tested by Sequencing: MT-ATP6, MT-ATP8, MT-CO1, MT-CO2, MT-CO3, MT-CYB, MT-ND1, MT-ND2, MT-ND3, MT-ND4, MT-ND4L, MT-ND5, MT-ND6, MT-RNR1, MT-RNR2, MT-TA, MT-TC, MT-TD, MT-TE, MT-TF, MT-TG, MT-TH, MT-TI, MT-TK, MT-TL1, MT-TL2, MT-TM, MT-TN, MT-TP, MT-TQ, MT-TR, MT-TS1, MT-TS2, MT-TT, MT-TV, MT-TW, MT-TY, ABCB7, ACAD9, ACADL, ACADM, ACADS, ACADVL, ACAT1, ADCK3, APTX, ASS1, ATPAF2, BCKDHA, BCKDHB, BCS1L, C10orf2, COQ2, COQ9, COX10, COX15, COX4I2, COX6B1, CPT1A, CPT2, CYCS, DARS2, DBT, DGUOK, DLAT, DLD, DNAJC19, DNM1L, ETFA, ETFB, ETFDH, ETHE1, FASTKD2, FH, FXN, GFER, GFM1, HADH, HADHA, HADHB, HMGCL, HMGCS2, HSPD1, ISCU, LARS2, LRPPRC, MCCC2, MFN2, MPV17, MRPS16, MRPS22, NDUFA1, NDUFA11, NDUFA2, NDUFAF1, NDUFAF2, NDUFAF3, NDUFAF4, NDUFAF5, NDUFS1, NDUFS2, NDUFS3, NDUFS4, NDUFS6, NDUFS7, NDUFS8, NDUFV1, NDUFV2, OPA1, OXCT1, PC, PCK2, PDHA1, PDHB, PDHX, PDP1, PDSS1, PDSS2, PINK1, POLG, POLG2, PPM1B, PREPL, PUS1, RARS2, RRM2B, SCO1, SCO2, SDHAF1, SDHB, SDHC, SDHD, SLC22A5, SLC25A13, SLC25A15, SLC25A19, SLC25A20, SLC25A22, SLC25A3, SLC25A4, SLC3A1, SPG7, SUCLA2, SUCLG1, SUOX, SURF1, TAZ, TIMM8A, TK2, TMEM70, TMPO, TRMU, TSFM, TUFM, TYMP, UQCRB, UQCRQ, WFS1*

Genes tested by Deletion/Duplication: *ABCB7, ACAD9, ACADL, ACADM, ACADS, ACADVL, ACAT1, ADCK3, APTX, ASS1, ATPAF2, BCKDHA, BCKDHB, BCS1L, C10orf2, COQ2, COQ9, COX10, COX15, COX4I2, COX6B1, CPT1A, CPT2, CYCS, DARS2, DBT, DGUOK, DLAT, DLD, DNAJC19, DNM1L, ETFA, ETFB, ETFDH, ETHE1, FASTKD2, FH, FXN, GFER, GFM1, HADH, HADHA, HADHB, HMGCL, HMGCS2, HSPD1, ISCU, LRPPRC, MCCC2, MFN2, MPV17, MRPS16, MRPS22, NDUFA1, NDUFA11, NDUFAF1, NDUFAF2, NDUFAF3, NDUFAF4, NDUFAF5, NDUFS1, NDUFS2, NDUFS3, NDUFS4, NDUFS6, NDUFS7, NDUFS8, NDUFV1, NDUFV2, OPA1, OXCT1, PC, PCK2, PDHA1, PDHB, PDHX, PDP1, PDSS1, PDSS2, PINK1, POLG, POLG2, PPM1B, PREPL, PUS1, RARS2, RRM2B, SCO1, SCO2, SDHAF1, SDHB, SDHC, SDHD, SLC22A5, SLC25A13, SLC25A15, SLC25A19, SLC25A20, SLC25A22, SLC25A3, SLC25A4, SLC3A1, SPG7, SUCLA2, SUCLG1, SUOX, SURF1, TAZ, TIMM8A, TK2, TMEM70, TMPO, TRMU, TSFM, TUFM, TYMP, UQCRB, UQCRQ, WFS1*

2014059 Prostate-Specific Kallikrein, 4Kscore — 4KSCORE

Specimen Required: Collect: Serum Separator Tube (SST).
Specimen Preparation: Transfer 4 mL serum to an ARUP Standard Transport Tube. (Min: 3 mL)
Storage/Transport Temperature: Frozen.
Remarks: Test must be discussed with patient prior to ordering. Patient history, biopsy history and digital rectal exam (DRE) results are required for testing.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 72 hours; Frozen: 1 month

HOTLINE NOTE: There is a component change associated with this test.
Add component 3000586, 4K – Order Discussed with Patient
Add component 3000587, 4K – Patient History
Remove component 2014064, 4K – Negative Predictive Value (NPV)

New Test **3000582** ***Schistosoma* Antibody, IgG, Serum** **SCHISTO AB**

Methodology: Qualitative Enzyme Immunoassay
Performed: Varies
Reported: 3-8 days

Specimen Required: Collect: Serum Separator Tube (SST) or Plain Red.
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen
Unacceptable Conditions: Grossly hemolyzed or lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 1 month; Frozen: 1 month

Reference Interval: By report

Interpretive Data: Refer to report

CPT Code(s): 86682

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.

Immediate Change HOTLINE: Effective June 4, 2018

The following will be discontinued from ARUP's test menu on June 4, 2018.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
2006356	Chronic Granulomatous Disease (*CYBB* Gene Scanning and *NCF1* Exon 2 GT Deletion) with Reflex to *CYBB* Sequencing	Chronic Granulomatous Disease Panel (CYBB Sequencing and NCF1 Exon 2 GT Deletion) (3000544)
2006361	Chronic Granulomatous Disease, X-Linked (*CYBB*) Gene Scanning with Reflex to Sequencing	Chronic Granulomatous Disease, X-Linked (CYBB) Sequencing (3000541)
0091088	Methyprylon, Serum or Plasma	
0099411	Schistosoma Antibody, IgG	Schistosoma Antibody, IgG, Serum (3000582)