ARUP LABORATORIES

IMMEDIATE CHANGE HOT LINE: Effective January 4, 2016

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-9 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.

New Test 2001597 Arbovirus Antibodies, IgG and IgM, CSF ARBOCSF GM

*This test performed at ARUP Laboratories.
Testing unavailable since October 2014 due nationwide reagent backorder. Reagents now in stock.
Testing is diagnostically important and in demand by clinicians.

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Tue, Fri
Reported: 1-5 days

Specimen Required: Collect: CSF.
Specimen Preparation: Transfer 4 mL CSF to an ARUP Standard Transport Tube. (Min: 2.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, heat-inactivated, or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
	St. Louis Encephalitis Antibody, IgG by IFA, CSF	Less than 1:1
	California Encephalitis Antibody, IgG by IFA, CSF	Less than 1:1
	Eastern Equine Encephalitis Antibody, IgG by IFA, CSF	Less than 1:1
	Western Equine Encephalitis Antibody, IgG by IFA, CSF	Less than 1:1
	West Nile Virus Antibody, IgG by ELISA, CSF	1.29 IV or less: Negative - No significant level of West Nile virus IgG antibody detected. 1.30-1.49 IV: Equivocal - Questionable presence of West Nile virus IgG antibody detected. Repeat testing in 10-14 days may be helpful. 1.50 IV or greater: Positive - Presence of IgG antibody to West Nile virus detected, suggestive of current or past infection.
	St. Louis Encephalitis Antibody, IgM by IFA, CSF	Less than 1:1
	California Encephalitis Antibody, IgM by IFA, CSF	Less than 1:1
	Eastern Equine Encephalitis Antibody, IgM by IFA, CSF	Less than 1:1
	Western Equine Encephalitis, Antibody, IgM by IFA, CSF	Less than 1:1
	West Nile Virus Antibody, IgM by ELISA, CSF	0.89 IV or less: Negative - No significant level of West Nile virus IgM antibody detected. 0.90-1.10 IV: Equivocal - Questionable presence of West Nile virus IgM antibody detected. Repeat testing in 10-14 days may be helpful. 1.11 IV or greater: Positive - Presence of IgM antibody to West Nile virus detected, suggestive of current or recent infection.

Interpretive Data: Refer to report.

See Compliance Statement B: www.aruplab.com/CS

CPT Code(s): 86651 x2; 86652 x2; 86653 x2; 86654 x2; 86789; 86788

New York DOH approval pending. Call for status update.

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

New Test 2001594 Arbovirus Antibodies, IgG and IgM, Serum ARBOSER GM

*This test performed at ARUP Laboratories.
Testing unavailable since October 2014 due nationwide reagent backorder. Reagents now in stock.
Testing is diagnostically important and in demand by clinicians.

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Tue, Fri
Reported: 1-5 days

Specimen Required: Collect: Serum Separator Tube (SST). Also acceptable: Plain Red.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.2 mL) Parallel testing is preferred and convalescent specimens **must** be received within 30 days from receipt of acute specimens. **Mark specimens plainly as "acute" or "convalescent."**
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
	St. Louis Encephalitis Antibody, IgG by IFA, Serum	Less than 1:16
	California Encephalitis Antibody, IgG by IFA, Serum	Less than 1:16
	Eastern Equine Encephalitis Antibody, IgG by IFA, Serum	Less than 1:16
	Western Equine Encephalitis Antibody, IgG by IFA, Serum	Less than 1:16
	West Nile Virus Antibody, IgG by ELISA, Serum	1.29 IV or less: Negative - No significant level of West Nile virus IgG antibody detected. 1.30-1.49 IV: Equivocal - Questionable presence of West Nile virus IgG antibody detected. Repeat testing in 10-14 days may be helpful. 1.50 IV or greater: Positive - Presence of IgG antibody to West Nile virus detected, suggestive of current or past infection.
	St. Louis Encephalitis Antibody, IgM by IFA, Serum	Less than 1:16
	California Encephalitis Antibody, IgM by IFA, Serum	Less than 1:16
	Eastern Equine Encephalitis Antibody, IgM by IFA, Serum	Less than 1:16
	Western Equine Encephalitis Antibody, IgM by IFA, Serum	Less than 1:16
	West Nile Virus Antibody, IgM by ELISA, Serum	0.89 IV or less: Negative - No significant level of West Nile virus IgM antibody detected. 0.90-1.10 IV: Equivocal - Questionable presence of West Nile virus IgM antibody detected. Repeat testing in 10-14 days may be helpful. 1.11 IV or greater: Positive - Presence of IgM antibody to West Nile virus detected, suggestive of current or recent infection.

Interpretive Data: Refer to report.

CPT Code(s): 86651 x2; 86652 x2; 86653 x2; 86654 x2; 86789; 86788

New York DOH Approved.

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

New Test **2001596** **Arbovirus Antibodies, IgG, CSF** **ARBO CSF G**

*This test performed at ARUP Laboratories.
Testing unavailable since October 2014 due nationwide reagent backorder. Reagents now in stock.
Testing is diagnostically important and in demand by clinicians.

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Tue, Fri
Reported: 1-5 days

Specimen Required: Collect: CSF.
Specimen Preparation: Transfer 4 mL CSF to an ARUP Standard Transport Tube. (Min: 1.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma. Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
	St. Louis Encephalitis Antibody, IgG by IFA, CSF	Less than 1:1
	California Encephalitis Antibody, IgG by IFA, CSF	Less than 1:1
	Eastern Equine Encephalitis Antibody, IgG by IFA, CSF	Less than 1:1
	Western Equine Encephalitis Antibody, IgG by IFA, CSF	Less than 1:1
	West Nile Virus Antibody, IgG by ELISA, CSF	1.29 IV or less: Negative - No significant level of West Nile virus IgG antibody detected. 1.30-1.49 IV: Equivocal - Questionable presence of West Nile virus IgG antibody detected. Repeat testing in 10-14 days may be helpful. 1.50 IV or greater: Positive - Presence of IgG antibody to West Nile virus detected, suggestive of current or past infection.

Interpretive Data: See Compliance Statement B: www.aruplab.com/CS

CPT Code(s): 86651; 86652; 86653; 86654; 86789

New York DOH approval pending. Call for status update.

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

New Test 2001593 Arbovirus Antibodies, IgG, Serum ARBO SER G

*This test performed at ARUP Laboratories.
Testing unavailable since October 2014 due nationwide reagent backorder. Reagents now in stock.
Testing is diagnostically important and in demand by clinicians.

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Tue, Fri
Reported: 1-5 days

Specimen Required: Collect: Serum Separator Tube (SST). Also acceptable: Plain Red.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL) Parallel testing is preferred and convalescent specimens **must** be received within 30 days from receipt of acute specimens. **Mark specimens plainly as "acute" or "convalescent."**
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, hemolyzed, or severely lipemic, specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
	St. Louis Encephalitis Antibody, IgG by IFA, Serum	Less than 1:16
	California Encephalitis Antibody, IgG by IFA, Serum	Less than 1:16
	Eastern Equine Encephalitis Antibody, IgG by IFA, Serum	Less than 1:16
	Western Equine Encephalitis Antibody, IgG by IFA, Serum	Less than 1:16
	West Nile Virus Antibody, IgG by ELISA, Serum	1.29 IV or less: Negative - No significant level of West Nile virus IgG antibody detected. 1.30-1.49 IV: Equivocal - Questionable presence of West Nile virus IgG antibody detected. Repeat testing in 10-14 days may be helpful. 1.50 IV or greater: Positive - Presence of IgG antibody to West Nile virus detected, suggestive of current or past infection.

CPT Code(s): 86651; 86652; 86653; 86654; 86789

New York DOH Approved.

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

New Test **2001595** **Arbovirus Antibodies, IgM, CSF** **ARBO CSF M**

*This test performed at ARUP Laboratories.
Testing unavailable since October 2014 due nationwide reagent backorder. Reagents now in stock.
Testing is diagnostically important and in demand by clinicians.

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Tue, Fri
Reported: 1-5 days

Specimen Required: Collect: CSF.
Specimen Preparation: Transfer 4 mL CSF to an ARUP Standard Transport Tube. (Min: 1.5 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Contaminated, heat-inactivated, or hemolyzed specimens.
Stability (collection to initiation of testing): Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
	St. Louis Encephalitis Antibody, IgM by IFA, CSF	Less than 1:1
	California Encephalitis Antibody, IgM by IFA, CSF	Less than 1:1
	Eastern Equine Encephalitis Antibody, IgM by IFA, CSF	Less than 1:1
	Western Equine Encephalitis, Antibody, IgM by IFA, CSF	Less than 1:1
	West Nile Virus Antibody, IgM by ELISA, CSF	0.89 IV or less: Negative - No significant level of West Nile virus IgM antibody detected. 0.90-1.10 IV: Equivocal - Questionable presence of West Nile virus IgM antibody detected. Repeat testing in 10-14 days may be helpful. 1.11 IV or greater: Positive - Presence of IgM antibody to West Nile virus detected, suggestive of current or recent infection.

Interpretive Data: See Compliance Statement B: www.aruplab.com/CS

CPT Code(s): 86651; 86652; 86653; 86654; 86788

New York DOH approval pending. Call for status update.

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

New Test 2001592 Arbovirus Antibodies, IgM, Serum ARBO SER M

*This test performed at ARUP Laboratories.
Testing unavailable since October 2014 due nationwide reagent backorder. Reagents now in stock.
Testing is diagnostically important and in demand by clinicians.

Methodology: Semi-Quantitative Indirect Fluorescent Antibody/Semi-Quantitative Enzyme-Linked Immunosorbent Assay
Performed: Tue, Fri
Reported: 1-5 days

Specimen Required: Collect: Serum Separator Tube (SST). Also acceptable: Plain Red.
Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.15 mL) Parallel testing is preferred and convalescent specimens **must** be received within 30 days from receipt of acute specimens. **Mark specimens plainly as "acute" or "convalescent."**
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma. Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval:

Test Number	Components	Reference Interval
	St. Louis Encephalitis Antibody, IgM by IFA, Serum	Less than 1:16
	California Encephalitis Antibody, IgM by IFA, Serum	Less than 1:16
	Eastern Equine Encephalitis Antibody, IgM by IFA, Serum	Less than 1:16
	Western Equine Encephalitis Antibody, IgM by IFA, Serum	Less than 1:16
	West Nile Virus Antibody, IgM by ELISA, Serum	0.89 IV or less: Negative - No significant level of West Nile virus IgM antibody detected. 0.90-1.10 IV: Equivocal - Questionable presence of West Nile virus IgM antibody detected. Repeat testing in 10-14 days may be helpful. 1.11 IV or greater: Positive - Presence of IgM antibody to West Nile virus detected, suggestive of current or recent infection.

CPT Code(s): 86651; 86652; 86653; 86654; 86788

New York DOH Approved.

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

2005400 *FLT3* Mutation Detection by PCR FLT3 MUTAT

Performed: Varies
Reported: 3-10 days

2011806 *FLT3* Signal Ratio Mutation Detection by PCR FLT3-SR

Performed: Varies
Reported: 3-10 days

2010232 Non-Invasive Prenatal Testing for Fetal Aneuploidy (Panorama) with Microdeletions NIPTANEUMD

HOT LINE NOTE: There is a clinically significant charting name change associated with this test.
Change the charting name of component 2010354 from del 22q11 (DiGeorge/VCFS) to 22q11.2 deletion syndrome.

New Test **2013142** **Non-Invasive Prenatal Testing for Fetal Aneuploidy with 22q11.2 Microdeletion (Panorama)** **NIPTANEU22**

Patient History & Informed Consent for Non-Invasive Prenatal Testing (NIPT)

Additional Technical Information

Methodology: Targeted Sequencing with SNPs
Performed: Varies
Reported: 12-14 days

Specimen Required: Patient Prep:
Collect: Whole blood in Cell-Free DNA BCT Tube. All specimens must be collected using the NIPT ANEU kit (ARUP Supply #50223). Available online through eSupply or contacting ARUP Client Services at (800) 522-2787.
Required Specimen: Maternal specimens must be collected in 2 Cell-Free DNA BCT tubes.
Optional Specimen: Paternal specimens must be collected in buccal brush.
Specimen Preparation: Transport 20 mL maternal blood in Cell-Free DNA BCT Tube (ARUP Supply #50223) and optional paternal buccal brush. (Min: 16 mL) Available online through eSupply or contacting ARUP Client Services at (800) 522-2787. A paternal specimen is requested but is not required for testing. The paternal specimen cannot be tested alone and must be provided along with the maternal blood. Do not send the buccal brush separately.
Storage/Transport Temperature: Room temperature.
Remarks: Patient History and Informed Consent for Non-Invasive Prenatal Testing (NIPT) form required.
Unacceptable Conditions:
Stability (collection to initiation of testing): Ambient: 5 days; Refrigerated: Unacceptable; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data: Refer to report.

Note: Testing utilizes a single-nucleotide polymorphism (SNP)/informatics-based approach to detect fetal copy number for the five chromosomes responsible for the majority of live-birth aneuploidies (chromosomes 13, 18, 21, X, Y, and triploidy) and certain specific microdeletion syndromes (see current list of microdeletion syndromes listed under "Ordering Recommendations"). This is a screening test to help identify fetuses at risk for Down syndrome, trisomy 18, trisomy 13 and Turner syndrome, as well as fetuses affected with the specified microdeletion syndrome(s) listed. This test should not be considered diagnostic. All positive results should be confirmed by amniocentesis or CVS.

CPT Code(s): 81420; 88271 x72

New York DOH approval pending. Call for status update.

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

New Test **2013230** **Polychlorinated Biphenyls (PCB) Panel, Congeners, Serum or Plasma** **PCB PAN**

Available January 4, 2016

Methodology: Quantitative Gas Chromatography/Tandem Mass Spectrometry
Performed: Varies
Reported: 5-12 days

Specimen Required: Collect: Plain Red, Lavender (EDTA) or Pink (K_2 EDTA).
Specimen Preparation: Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 0.7 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month

Note:
Panel includes: 2,4,4'-Trichlorobiphenyl (PCB 28); 2,2',3,5'-Tetrachlorobiphenyl (PCB 44); 2,2',5,5'-Tetrachlorobiphenyl (PCB 52); 2,3',4,4'-Tetrachlorobiphenyl (PCB 66); 2,4,4',5-Tetrachlorobiphenyl (PCB 74); 2,2',4,5,5'-Pentachlorobiphenyl (PCB 101); 2,3',4,4',5-Pentachlorobiphenyl (PCB 118); 2,2',3,4,4',5'-Hexachlorobiphenyl (PCB 138); 2,2',4,4',5,5'-Hexachlorobiphenyl (PCB 153); 2,3,3',4,4',5-Hexachlorobiphenyl (PCB 156); 2,2',3,4,4',5,5'-Heptachlorobiphenyl (PCB 180).
Known Interferences: 2,2',3,4,4',5'-Hexachlorobiphenyl (PCB 138); 2,3,3',4,4',6-Hexachlorobiphenyl (PCB 158); 2,3,3',4',5,6-Hexachlorobiphenyl (PCB 163); 2,3,3',4',5',6-Hexachlorobiphenyl (PCB 164); 2,2',4,5,5'-Pentachlorobiphenyl (PCB 101); 2,2',3,4,6'-Pentachlorobiphenyl (PCB 89); 2,2',5,5'-Tetrachlorobiphenyl (PCB 52); 2,3',5',6-Tetrachlorobiphenyl (PCB 73); 2,3',4,4',5-Pentachlorobiphenyl (PCB 118); 2,3,3',4,5-Pentachlorobiphenyl (PCB 106); 2,3',4,4'-Tetrachlorobiphenyl (PCB 66); 3,3',5,5'-Tetrachlorobiphenyl (PCB 80); 2,4,4',5-Tetrachlorobiphenyl (PCB 74); 2,3,4,5-Tetrachlorobiphenyl (PCB 61).

CPT Code(s): 82441

New York DOH Approved.

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

Delete **0090789** **Polychlorinated Biphenyls, Blood** **POLYCHL B**

HOT LINE NOTE: Delete this test.

Delete **0090800** **Polychlorinated Biphenyls Quantitative, Serum or Plasma** **POLYCHL SP**

HOT LINE NOTE: Delete this test and refer to Polychlorinated Biphenyls (PCB) Panel, Congeners, Serum or Plasma (2013230).