HOTLINE: Effective September 8, 2020

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
3	2008665	*Babesia* Species by PCR			x									
3	0065078	*Bordetella pertussis* by PCR			x									
3	0065080	*Bordetella pertussis/parapertussis* by PCR			x									
8	0060774	Chlamydia trachomatis and Neisseria gonorrhoeae by Transcription-Mediated Amplification (TMA), M4/UTM												x
3	2002838	*Clostridium difficile* toxin B gene (tcdB) by PCR				x								
4	2013661	Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants			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	2000138	Cytology, ThinPrep Pap Test with Reflex to Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep	x	x					x	x		x		
4	2000136	Cytology, ThinPrep Pap Test and Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep (for routine co-testing in women over 30)	x	x					x	x		x		
4	0060040	Cytomegalovirus by Qualitative PCR			x									
4	2008555	Cytomegalovirus by Qualitative PCR, Saliva			x									
4	0051813	Cytomegalovirus by Quantitative PCR			x									
5	2006966	Cytomegalovirus, Quantitative PCR with Reflex to Drug Resistance Testing by Sequencing			x									
5	2007862	*Ehrlichia* and *Anaplasma* Species by PCR			x									
5	0050246	Epstein-Barr Virus by Qualitative PCR			x									
5	0051352	Epstein-Barr Virus by Quantitative PCR			x									
8	3002026	Explify Respiratory Pathogen Detection by Next Generation Sequencing												x
5	0097720	Factor V Leiden (*F5*) R506Q Mutation			x									
5	2011148	Herpes Simplex Virus (HSV) by PCR with Reflex to HSV (HSV-1/HSV-2) Subtype by PCR			x									
5	2010095	Herpes Simplex Virus (HSV-1/HSV-2) Subtype by PCR			x									
5	0060041	Herpes Simplex Virus by PCR			x									
5	2002429	HLA-B*57:01 for Abacavir Sensitivity			x									
6	3003005	Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep											x	
8	2007894	Human Papillomavirus (HPV) Genotypes 16 and 18/45 by Transcription-Mediated Amplification (TMA), ThinPrep												x
8	2007890	Human Papillomavirus (HPV), High Risk by Transcription-Mediated Amplification (TMA) with Reflex to HPV Genotypes 16 and 18/45 by TMA, ThinPrep												x
8	2007893	Human Papillomavirus (HPV), High Risk by Transcription-Mediated Amplification (TMA), ThinPrep												x
8	2011940	Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, ThinPrep												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
6	2013008	Periprosthetic Joint Infection (PJI) Detection (Synovasure)			x						x			
6	3002598	Phosphatidylethanol (PEth), Whole Blood, Quantitative					x	x						
7	0056060	Prothrombin (*F2*) c.*97G>A (G20210A) Pathogenic Variant			x									
7	0051368	RhD Gene (*RHD*) Copy Number			x									
7	2008670	Tick-Borne Disease Panel by PCR, Blood			x									
7	3001801	Toxigenic Clostridium difficile by LFA with Reflex to PCR, Stool				x								
7	0060042	Varicella-Zoster Virus by PCR			x									

2008665 ***Babesia* Species by PCR** **BABPCR**

Performed: Sun-Sat
Reported: 2-6 days

0065078 ***Bordetella pertussis* by PCR** **BPERT**

Performed: Sun-Sat
Reported: 2-7 days

0065080 ***Bordetella pertussis/parapertussis* by PCR** **BORD PCR**

Performed: Sun-Sat
Reported: 2-7 days

2002838 ***Clostridium difficile* toxin B gene (tcdB) by PCR** **CDIFF PCR**

Specimen Required: Collect: Soft or liquid stool.
Specimen Preparation: Transfer 1 mL stool to a clean, unpreserved transport vial (ARUP Supply# 40910). Available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 0.5 mL).
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Specimens in media or preservatives.
Stability (collection to initiation of testing): Ambient: 48 hours; Refrigerated: 5 days; Frozen: 1 week

2013661 **Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants** **CF VAR**

Performed: Sun-Sat
Reported: 5-14 days

2000138 **Cytology, ThinPrep Pap Test with Reflex to Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep** **TR REQUEST**

Methodology: Microscopy/Qualitative Nucleic Acid Amplification

Note: In addition to the ThinPrep Pap Test, Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep (ARUP test code 3003005) will be performed and reported under a separate accession. Additional charges apply. The Pap Test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

CPT Code(s): 88142; if reviewed by pathologist add 88141. If reflexed, add 87624

HOTLINE NOTE: There is a reflexive pattern change associated with this test.
Add reflex to 3003005, Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep
Remove reflex from 2007890, Human Papillomavirus (HPV), High Risk by Transcription-Mediated Amplification (TMA) with Reflex to HPV Genotypes 16 and 18/45 by TMA, ThinPrep

2000136 **Cytology, ThinPrep Pap Test and Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep (for routine co-testing in women over 30)** **TH REQUEST**

Methodology: Microscopy/Qualitative Nucleic Acid Amplification

Note: In addition to the ThinPrep Pap Test, Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep (ARUP test code 3003005) will be performed and reported under a separate accession. Additional charges apply. The Pap Test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

CPT Code(s): 88142; if reviewed by pathologist add 88141; 87624

HOTLINE NOTE: There is a reflexive pattern change associated with this test.
Add reflex to 3003005, Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep
Remove reflex from 2007890, Human Papillomavirus (HPV), High Risk by Transcription-Mediated Amplification (TMA) with Reflex to HPV Genotypes 16 and 18/45 by TMA, ThinPrep

0060040 **Cytomegalovirus by Qualitative PCR** **CMVPCR**

Performed: Sun-Sat
Reported: 2-5 days

2008555 **Cytomegalovirus by Qualitative PCR, Saliva** **CMVPCR SAL**

Performed: Sun-Sat
Reported: 2-5 days

0051813 **Cytomegalovirus by Quantitative PCR** **CMV QNT**

Performed: Sun-Sat
Reported: 2-5 days

2006966	**Cytomegalovirus, Quantitative PCR with Reflex to Drug Resistance Testing by Sequencing**	**CMV QNT GR**

Performed: Sun-Sat
Reported: 6-9 days

2007862	***Ehrlichia* and *Anaplasma* Species by PCR**	**EHR ANAPCR**

Performed: Sun-Sat
Reported: 2-6 days

0050246	**Epstein-Barr Virus by Qualitative PCR**	**EBVPCR**

Performed: Sun-Sat
Reported: 2-6 days

0051352	**Epstein-Barr Virus by Quantitative PCR**	**EBV QNT**

Performed: Sun-Sat
Reported: 2-6 days

0097720	**Factor V Leiden (*F5*) R506Q Mutation**	**FACV**

Performed: Sun-Sat
Reported: 3-8 days

2011148	**Herpes Simplex Virus (HSV) by PCR with Reflex to HSV (HSV-1/HSV-2) Subtype by PCR**	**HSVPCR RFX**

Performed: Sun-Sat
Reported: 2-6 days

2010095	**Herpes Simplex Virus (HSV-1/HSV-2) Subtype by PCR**	**HSVTYPEPCR**

Performed: Sun-Sat
Reported: 2-5 days

0060041	**Herpes Simplex Virus by PCR**	**HSVPCR**

Performed: Sun-Sat
Reported: 2-5 days

2002429	**HLA-B*57:01 for Abacavir Sensitivity**	**HLA-B5701**

Performed: Tue-Sat
Reported: 5-10 days

New Test **3003005** **Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep** **HPVNAA**

Click for Pricing

Methodology: Qualitative Nucleic Acid Amplification
Performed: Sun-Sat
Reported: 1-5 days

Specimen Required: Patient Prep: Females should avoid high concentrations of antifungal cream or contraceptive jelly, and should not douche prior to time of collection.
Collect: Cervical specimen with the ThinPrep Pap Test Collection kit
Storage/Transport Temperature: Refrigerated
Remarks: Specimen source required.
Unacceptable Conditions: Bloody or dark brown specimens. Specimens in any media other than indicated above.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month; Frozen: Unacceptable

Reference Interval: Negative

Interpretive Data:
This test detects high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) and differentiates HPV 16 and 18 associated with cervical cancer and its precursor lesions. Sensitivity may be affected by specimen collection methods, stage of infection, and the presence of interfering substances. Results should be interpreted in conjunction with other available laboratory and clinical data. A negative high-risk HPV result does not exclude the presence of other high-risk HPV types, the possibility of future cytologic abnormalities, underlying CIN2-3, or cancer.

This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.
Note:

CPT Code(s): 87624

New York DOH Approved.

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

2013008 **Periprosthetic Joint Infection (PJI) Detection (Synovasure)** **SYNOVA PJI**

Performed: Varies
Reported: 3-5 days

HOTLINE NOTE: There is a component change associated with this test.
Add component 3003118, PJI Detection Anatomical Source

3002598 **Phosphatidylethanol (PEth), Whole Blood, Quantitative** **PETH**

Reference Interval: By Report

Interpretive Data:
Phosphatidylethanol (PEth) is a group of phospholipids formed in the presence of ethanol, phospholipase D and phosphatidylcholine. PEth is known to be a direct alcohol biomarker. The predominant PEth homologues are PEth 16:0/18:1 (POPEth) and PEth 16:0/18:2 (PLPEth), which account for 37-46% and 26-28% of the total PEth homologues, respectively. PEth is incorporated into the phospholipid membrane of red blood cells and has a general half-life of 4 - 10 days and a window of detection of 2 - 4 weeks. However, the window of detection is longer in individuals who chronically or excessively consume alcohol. Serial monitoring of PEth may be helpful in monitoring alcohol abstinence over time. PEth results should be interpreted in the context of the patient's clinical and behavioral history. Patients with advanced liver disease may have falsely elevated PEth concentrations (Nguyen VL et al 2018, Alcoholism Clinical & Experimental Research).

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

0056060 **Prothrombin (*F2*) c.*97G>A (G20210A) Pathogenic Variant** **PT PCR**

Performed: Sun-Sat
Reported: 3-8 days

0051368 **RhD Gene (*RHD*) Copy Number** **RHD**

Performed: Mon, Thu
Reported: 7-14 days

2008670 **Tick-Borne Disease Panel by PCR, Blood** **TICKPCR**

Performed: Sun-Sat
Reported: 2-6 days

3001801 **Toxigenic Clostridium difficile by LFA with Reflex to PCR, Stool** **CDIFF LFA**

Specimen Required: Collect: Stool.
Specimen Preparation: Transfer 5g stool to a clean, unpreserved transport vial (ARUP Supply# 40910) available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 1g)
Storage/Transport Temperature: Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions: Specimens preserved in Cary Blair/C&S media, formalin-based fixative (eg, Formalin, SAF) or alcohol-based fixative (eg, PVA, Totalfix, Alcorfix, etc).
Stability (collection to initiation of testing): Ambient 2 hours; Refrigerated 72 hours; Frozen 1 week

0060042 **Varicella-Zoster Virus by PCR** **VZVPCR**

Performed: Sun-Sat
Reported: 2-5 days

HOTLINE: Effective September 8, 2020

The following will be discontinued from ARUP's test menu on September 8, 2020.
Replacement test options are supplied if applicable.

Test Number	Test Name	Refer To Replacement
0060774	Chlamydia trachomatis and Neisseria gonorrhoeae by Transcription-Mediated Amplification (TMA), M4/UTM	Chlamydia trachomatis and Neisseria gonorrhoeae by Transcription-Mediated Amplification (TMA) (0060241)
3002026	Explify Respiratory Pathogen Detection by Next Generation Sequencing	Explify Respiratory RNA Pathogen Detection (3002971)
2007894	Human Papillomavirus (HPV) Genotypes 16 and 18/45 by Transcription-Mediated Amplification (TMA), ThinPrep	Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep (3003005)
2007890	Human Papillomavirus (HPV), High Risk by Transcription-Mediated Amplification (TMA) with Reflex to HPV Genotypes 16 and 18/45 by TMA, ThinPrep	Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep (3003005)
2007893	Human Papillomavirus (HPV), High Risk by Transcription-Mediated Amplification (TMA), ThinPrep	Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep (3003005)
2011940	Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, ThinPrep	Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by Nucleic Acid Amplification (NAA), ThinPrep (3003005)