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.

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

Available Now

This test performed at ARUP Laboratories.

Patient History For Cystic Fibrosis (CF) Testing

Additional Technical Information

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Sun-Sat
Reported: 5-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background information for Cystic Fibrosis (*CFTR*), 165 Pathogenic Variants:
Characteristics of Classic Cystic Fibrosis (CF): Chronic sino-pulmonary disease, gastrointestinal malabsorption/pancreatic insufficiency, and obstructive azoospermia. Symptoms of mild CF are often limited to a single organ system such as isolated pancreatitis, bilateral absence of the vas deferens, nasal polyposis, or bronchiectasis.
Incidence: 1 in 2,300 Ashkenazi Jewish, 1 in 2,500 Caucasians, 1 in 13,500 Hispanics, 1 in 15,100 African Americans, 1 in 35,100 Asians.
Inheritance: Autosomal recessive.
Penetrance: High for severe and moderately severe pathogenic variants, variable for mild pathogenic variants.
Cause: Two pathogenic *CFTR* variants on opposite chromosomes.
Pathogenic Variants Tested: Variants are listed by standard nomenclature. Legacy names are also provided for the 23 recommended ACMG variants. c.1A>G, p.Met1Val; c.14C>T, p.Pro5Leu; c.54-5940_273+10250del21kb, p.Ser18ArgfsX16 ; c.115C>T, p.Gln39X; c.178G>T, p.Glu60X; c.200C>T, p.Pro67Leu; c.223C>T, p.Arg75X; c.254G>A (Legacy G85E), p.Gly85Glu; c.262_263delTT, p.Leu88IlefsX22; c.273+1G>A, Intronic; c.274-1G>A, Intronic; c.274G>A, p.Glu92Lys; c.274G>T, p.Glu92X; c.292C>T, p.Gln98X; c.313delA, p.Ile105SerfsX2; c.325_327delTATinsG, p.Tyr109GlyfsX4; c.328G>C, p.Asp110His; c.349C>T, p.Arg117Cys; c.350G>A (Legacy R117H), p.Arg117His; c.366T>A, p.Tyr122X; c.442delA, p.Ile148LeufsX5; c.489+1G>T (Legacy 621+1G>T); c.509G>A, p.Arg170His; c.531delT, p.Ile177MetfsX12; c.532G>A, p.Gly178Arg; c.579+1G>T (Legacy 711+1G>T); c.579+5G>A, Intronic; c.579+3A>G, Intronic; c.580-1G>T, Intronic; c.595C>T , p.His199Tyr; c.613C>T, p.Pro205Ser; c.617T>G, p.Leu206Trp; c.658C>T, p.Gln220X; c.720_741delAGGGAGAATGATGATGAAGTAC, p.Gly241GlufsX13; c.803delA, p.Asn268IlefsX17; c.933_935delCTT, p.Phe312del; c.948delT, p.Phe316LeufsX12; c.988G>T, p.Gly330X; c.1000C>T (Legacy R334W), p.Arg334Trp; c.1001G>T, p.Arg334Leu; c.1007T>A, p.Ile336Lys; c.1021T>C, p.Ser341Pro; c.1022_1023insTC, p.Phe342HisfsX28; c.1040G>A, p.Arg347His; c.1040G>C (Legacy R347P), p.Arg347Pro; c.1052C>G, p.Thr351Ser; c.1054C>T, p.Arg352Trp; c.1055G>A, p.Arg352Gln; c.1081delT, p.Trp361GlyfsX8; c.1116+1G>A, Intronic; c.1127_1128insA, p.Gln378AlafsX4 ; c.1153_1154insAT, p.Asn386IlefsX3; c.1202G>A, p.Trp401X; c.1203G>A, p.Trp401X; c.1209+1G>A, Intronic; c.1329_1330insAGAT, p.Ile444ArgfsX3 ; c.1364C>A (Legacy A455E), p.Ala455Glu; c.1393-1G>A, Intronic; c.1397C>A, p.Ser466X ; c.1397C>G, p.Ser466X; c.1400T>C, p.Leu467Pro; c.1418delG, p.Gly473GlufsX54; c.1438G>T, p.Gly480Cys; c.1466C>A, p.Ser489X; c.1475C>T, p.Ser492Phe; c.1477C>T, p.Gln493X; c.1486T>G, p.Trp496Gly; c.1519_1521delATC (Legacy I507del), p.Ile507del; c.1521_1523delCTT (Legacy F508del), p.Phe508del; c.1545_1546delTA, p.Tyr515X; c.1558G>T, p.Val520Phe; c.1572C>A, p.Cys524X; c.1573C>T, p.Gln525X; c.1585-1G>A (Legacy 1717-1G>A); c.1585-8G>A, Intronic; c.1624G>T (Legacy G542X), p.Gly542X ; c.1645A>C, p.Ser549Arg; c.1646G>A, p.Ser549Asn; c.1647T>G, p.Ser549Arg; c.1651G>A, p.Gly551Ser; c.1652G>A (Legacy G551D), p.Gly551Asp; c.1654C>T, p.Gln552X; c.1657C>T (Legacy R553X), p.Arg553X; c.1675G>A, p.Ala559Thr; c.1678A>G, p.Arg560Gly; c.1679G>A, p.Arg560Lys; c.1679G>C (Legacy R560T), p.Arg560Thr; c.1680-1G>A , Intronic; c.1703delT, p.Leu568CysfsX4; c.1721C>A, p.Pro574His; c.1753G>T, p.Glu585X; c.1766+1G>A (Legacy 1898+1G>A); c.1766+3A>G, Intronic; c.1792_1798delAAAACTA , p.Lys598GlyfsX11; c.1923_1931del9insA, p.Ser641ArgfsX5; c.1973_1985del13insAGAAA, p.Arg658LysfsX4; c.2012delT, p.Leu671X; c.2051_2052delAA, p.Lys684ThrfsX4; c.2051_2052delAAinsG, p.Lys684SerfsX38; c.2052delA (Legacy 2184delA), p.Lys684AsnfsX38; c.2125C>T, p.Arg709X; c.2128A>T, p.Lys710X; c.2175_2176insA, p.Glu726ArgfsX4; c.2195T>G, p.Leu732X; c.2215delG, p.Val739TyrfsX16; c.2290C>T, p.Arg764Ter; c.2453delT, p.Leu818TrpfsX3; c.2464G>T, p.Glu822X; c.2490+1G>A , Intronic; c.2491G>T, p.Glu831X ; c.2506G>T, p.Asp836Tyr; c.2537G>A, p.Trp846X; c.2551C>T, p.Arg851X; c.2583delT, p.Phe861LeufsX3; c.2657+5G>A (Legacy 2789+5G>A); c.2668C>T, p.Gln890X ; c.2737_2738insG, p.Tyr913X; c.2780T>C, p.Leu927Pro; c.2810_2811insT, p.Val938GlyfsX37; c.2834C>T, p.Ser945Leu; c.2875delG, p.Ala959HisfsX9; c.2900T>C, p.Leu967Ser; c.2908G>C, p.Gly970Arg; c.2988+1G>A (Legacy 3120+1G>A); c.2988G>A, Intronic; c.2989-1G>A, Intronic; c.3038C>A, p.Pro1013His; c.3039delC, p.Tyr1014ThrfsX9; c.3067_3072delATAGTG, p.Ile1023_Val1024del; c.3140-26A>G, Intronic; c.3194T>C, p.Leu1065Pro; c.3196C>T, p.Arg1066Cys; c.3197G>A, p.Arg1066His; c.3230T>C, p.Leu1077Pro; c.3266G>A, p.Trp1089X; c.3276C>A, p.Tyr1092X; c.3276C>G, p.Tyr1092X; c.3297C>A, p.Phe1099Leu; c.3302T>A, p.Met1101Lys; c.3310G>T, p.Glu1104X; c.3472C>T, p.Arg1158X; c.3484C>T (Legacy R1162X), p.Arg1162X; c.3528delC (Legacy 3659delC), p.Lys1177SerfsX15; c.3587C>G, p.Ser1196X; c.3611G>A, p.Trp1204X; c.3612G>A, p.Trp1204X; c.3659delC, p.Thr1220LysfsX8; c.3717+12191C>T (Legacy 3849+10kbC>T); c.3731G>A, p.Gly1244Glu; c.3744delA, p.Lys1250ArgfsX9; c.3752G>A, p.Ser1251Asn; c.3763T>C, p.Ser1255Pro; c.3764C>A, p.Ser1255X; c.3773_3774insT, p.Leu1258PhefsX7; c.3846G>A (Legacy W1282X), p.Trp1282X; c.3873+1G>A, Intronic; c.3909C>G (Legacy N1303K), p.Asn1303Lys; c.3937C>T, p.Gln1313X; c.3964-78_4242+577del, Exon 22-23 del; c.4028delG, p.Gly1343Alafs*4; c.4046G>A, p.Gly1349Asp; c.4077_4080delTGTTinsAA, p.Val1360delfsX?; c.4111G>T, p.Glu1371X; c.4251delA, p.Glu1418ArgfsX14; c.1679+1.6kbA>G. The IVS-5 variant, c.1210−12[5], will be reported when R117H is detected and in individuals that are reported to be symptomatic.

Clinical Sensitivity: Ashkenazi Jewish 96 percent; Caucasian 92 percent; Hispanic 80 percent; African American 78 percent; Asian American 55 percent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity & Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Only the 165 pathogenic *CFTR* variants listed above will be interrogated.

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

Note: The 165-variant test includes the 23 pathogenic CF variants recommended by the American College of Medical Genetics for population carrier screening.

CPT Code(s): 81220

New York DOH approval pending. Call for status update.

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

New Test **2013663** **Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants with Reflex to Sequencing** **CF VAR SEQ**

Available Now
This test performed at ARUP Laboratories.

Patient History For Cystic Fibrosis (CF) Testing

Additional Technical Information

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring/Sequencing
Performed: Sun-Sat
Reported: 7-28 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution).
Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background information for Cystic Fibrosis (*CFTR*), 165 Pathogenic Variants with Reflex to Sequencing:
Characteristics of Classic Cystic Fibrosis (CF): Chronic sino-pulmonary disease, gastrointestinal malabsorption/pancreatic insufficiency, and obstructive azoospermia. Symptoms of mild CF are often limited to a single organ system such as isolated pancreatitis, bilateral absence of the vas deferens, nasal polyposis, or bronchiectasis.
Incidence: 1 in 2,300 Ashkenazi Jewish, 1 in 2,500 Caucasians, 1 in 13,500 Hispanics, 1 in 15,100 African Americans, 1 in 35,100 Asians.
Inheritance: Autosomal recessive.
Penetrance: High for severe and moderately severe pathogenic variants, variable for mild pathogenic variants.
Cause: Two pathogenic *CFTR* variants on opposite chromosomes.

Pathogenic Variants Tested: Variants are listed by standard nomenclature. Legacy names are also provided for the 23 recommended ACMG variants. c.1A>G, p.Met1Val; c.14C>T, p.Pro5Leu; c.54-5940_273+10250del21kb, p.Ser18ArgfsX16 ; c.115C>T, p.Gln39X; c.178G>T, p.Glu60X; c.200C>T, p.Pro67Leu; c.223C>T, p.Arg75X; c.254G>A (Legacy G85E), p.Gly85Glu; c.262_263delTT, p.Leu88IlefsX22; c.273+1G>A, Intronic; c.274-1G>A, Intronic; c.274G>A, p.Glu92Lys; c.274G>T, p.Glu92X; c.292C>T, p.Gln98X; c.313delA, p.Ile105SerfsX2; c.325_327delTATinsG, p.Tyr109GlyfsX4; c.328G>C, p.Asp110His; c.349C>T, p.Arg117Cys; c.350G>A (Legacy R117H), p.Arg117His; c.366T>A, p.Tyr122X; c.442delA, p.Ile148LeufsX5; c.489+1G>T (Legacy 621+1G>T); c.509G>A, p.Arg170His; c.531delT, p.Ile177MetfsX12; c.532G>A, p.Gly178Arg; c.579+1G>T (Legacy 711+1G>T); c.579+5G>A, Intronic; c.579+3A>G, Intronic; c.580-1G>T, Intronic; c.595C>T , p.His199Tyr; c.613C>T, p.Pro205Ser; c.617T>G, p.Leu206Trp; c.658C>T, p.Gln220X; c.720_741delAGGGAGAATGATGATGAAGTAC, p.Gly241GlufsX13; c.803delA, p.Asn268IlefsX17; c.933_935delCTT, p.Phe312del; c.948delT, p.Phe316LeufsX12; c.988G>T, p.Gly330X; c.1000C>T (Legacy R334W), p.Arg334Trp; c.1001G>T, p.Arg334Leu; c.1007T>A, p.Ile336Lys; c.1021T>C, p.Ser341Pro; c.1022_1023insTC, p.Phe342HisfsX28; c.1040G>A, p.Arg347His; c.1040G>C (Legacy R347P), p.Arg347Pro; c.1052C>G, p.Thr351Ser; c.1054C>T, p.Arg352Trp; c.1055G>A, p.Arg352Gln; c.1081delT, p.Trp361GlyfsX8; c.1116+1G>A, Intronic; c.1127_1128insA, p.Gln378AlafsX4 ; c.1153_1154insAT, p.Asn386IlefsX3; c.1202G>A, p.Trp401X; c.1203G>A, p.Trp401X; c.1209+1G>A, Intronic; c.1329_1330insAGAT, p.Ile444ArgfsX3 ; c.1364C>A (Legacy A455E), p.Ala455Glu; c.1393-1G>A, Intronic; c.1397C>A, p.Ser466X ; c.1397C>G, p.Ser466X; c.1400T>C, p.Leu467Pro; c.1418delG, p.Gly473GlufsX54; c.1438G>T, p.Gly480Cys; c.1466C>A, p.Ser489X; c.1475C>T, p.Ser492Phe; c.1477C>T, p.Gln493X; c.1486T>G, p.Trp496Gly; c.1519_1521delATC (Legacy I507del), p.Ile507del; c.1521_1523delCTT (Legacy F508del), p.Phe508del; c.1545_1546delTA, p.Tyr515X; c.1558G>T, p.Val520Phe; c.1572C>A, p.Cys524X; c.1573C>T, p.Gln525X; c.1585-1G>A (Legacy 1717-1G>A); c.1585-8G>A, Intronic; c.1624G>T (Legacy G542X), p.Gly542X ; c.1645A>C, p.Ser549Arg; c.1646G>A, p.Ser549Asn; c.1647T>G, p.Ser549Arg; c.1651G>A, p.Gly551Ser; c.1652G>A (Legacy G551D), p.Gly551Asp; c.1654C>T, p.Gln552X; c.1657C>T (Legacy R553X), p.Arg553X; c.1675G>A, p.Ala559Thr; c.1678A>G, p.Arg560Gly; c.1679G>A, p.Arg560Lys; c.1679G>C (Legacy R560T), p.Arg560Thr; c.1680-1G>A , Intronic; c.1703delT, p.Leu568CysfsX4; c.1721C>A, p.Pro574His; c.1753G>T, p.Glu585X; c.1766+1G>A (Legacy 1898+1G>A); c.1766+3A>G, Intronic; c.1792_1798delAAAACTA , p.Lys598GlyfsX11; c.1923_1931del9insA, p.Ser641ArgfsX5; c.1973_1985del13insAGAAA, p.Arg658LysfsX4; c.2012delT, p.Leu671X; c.2051_2052delAA, p.Lys684ThrfsX4; c.2051_2052delAAinsG, p.Lys684SerfsX38; c.2052delA (Legacy 2184delA), p.Lys684AsnfsX38; c.2125C>T, p.Arg709X; c.2128A>T, p.Lys710X; c.2175_2176insA, p.Glu726ArgfsX4; c.2195T>G, p.Leu732X; c.2215delG, p.Val739TyrfsX16; c.2290C>T, p.Arg764Ter; c.2453delT, p.Leu818TrpfsX3; c.2464G>T, p.Glu822X; c.2490+1G>A , Intronic; c.2491G>T, p.Glu831X ; c.2506G>T, p.Asp836Tyr; c.2537G>A, p.Trp846X; c.2551C>T, p.Arg851X; c.2583delT, p.Phe861LeufsX3; c.2657+5G>A (Legacy 2789+5G>A); c.2668C>T, p.Gln890X ; c.2737_2738insG, p.Tyr913X; c.2780T>C, p.Leu927Pro; c.2810_2811insT, p.Val938GlyfsX37; c.2834C>T, p.Ser945Leu; c.2875delG, p.Ala959HisfsX9; c.2900T>C, p.Leu967Ser; c.2908G>C, p.Gly970Arg; c.2988+1G>A (Legacy 3120+1G>A); c.2988G>A, Intronic; c.2989-1G>A, Intronic; c.3038C>A, p.Pro1013His; c.3039delC, p.Tyr1014ThrfsX9; c.3067_3072delATAGTG, p.Ile1023_Val1024del; c.3140-26A>G, Intronic; c.3194T>C, p.Leu1065Pro; c.3196C>T, p.Arg1066Cys; c.3197G>A, p.Arg1066His; c.3230T>C, p.Leu1077Pro; c.3266G>A, p.Trp1089X; c.3276C>A, p.Tyr1092X; c.3276C>G, p.Tyr1092X; c.3297C>A, p.Phe1099Leu; c.3302T>A, p.Met1101Lys; c.3310G>T, p.Glu1104X; c.3472C>T, p.Arg1158X; c.3484C>T (Legacy R1162X), p.Arg1162X; c.3528delC (Legacy 3659delC), p.Lys1177SerfsX15; c.3587C>G, p.Ser1196X; c.3611G>A, p.Trp1204X; c.3612G>A, p.Trp1204X; c.3659delC, p.Thr1220LysfsX8; c.3717+12191C>T (Legacy 3849+10kbC>T); c.3731G>A, p.Gly1244Glu; c.3744delA, p.Lys1250ArgfsX9; c.3752G>A, p.Ser1251Asn; c.3763T>C, p.Ser1255Pro; c.3764C>A, p.Ser1255X; c.3773_3774insT, p.Leu1258PhefsX7; c.3846G>A (Legacy W1282X), p.Trp1282X; c.3873+1G>A, Intronic; c.3909C>G (Legacy N1303K), p.Asn1303Lys; c.3937C>T, p.Gln1313X; c.3964-78_4242+577del, Exon 22-23 del; c.4028delG, p.Gly1343Alafs*4; c.4046G>A, p.Gly1349Asp; c.4077_4080delTGTTinsAA, p.Val1360delfsX?; c.4111G>T, p.Glu1371X; c.4251delA, p.Glu1418ArgfsX14; c.1679+1.6kbA>G. The IVS-5 variant, c.1210−12[5], will be reported when R117H is detected and in individuals that are reported to be symptomatic.
Clinical Sensitivity of 165-Variant Test: Ashkenazi Jewish 96 percent; Caucasian 92 percent; Hispanic 80 percent; African American 78 percent; Asian American 55 percent.
Clinical Sensitivity for Sequencing: 97 percent.
Methodology for 165-Variant Test: Polymerase Chain Reaction (PCR) and fluorescence monitoring.
Methodology for Sequencing: Bidirectional sequencing of the *CFTR* coding region and intron-exon boundaries.
Analytical Sensitivity & Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Pathogenic *CFTR* promoter variants and large gene deletions/duplications will not be detected.

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

Note: The 165-variant test includes the 23 pathogenic CF variants recommended by the American College of Medical Genetics for population carrier screening. If only one pathogenic variant is identified, then *CFTR* gene sequencing will be added. Additional charges apply.

CPT Code(s): 81220; if reflexed, add 81223

New York DOH approval pending. Call for status update.

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

New Test **2013664** **Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants with Reflex to Sequencing and Reflex to Deletion/Duplication** **CFVAR COMP**

Available Now
This test performed at ARUP Laboratories.

Patient History For Cystic Fibrosis (CF) Testing

Additional Technical Information

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring/Sequencing/Multiplex Ligation-dependent Probe Amplification
Performed: Sun-Sat
Reported: 7-35 days

Specimen Required: Collect: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution).
Specimen Preparation: Transport 3 mL whole blood. (Min: 2 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background information for Cystic Fibrosis (*CFTR*), 165 Pathogenic Variants with Reflex to Sequencing and Reflex to Deletion/Duplication:
Characteristics of Classic Cystic Fibrosis (CF): Chronic sino-pulmonary disease, gastrointestinal malabsorption/pancreatic insufficiency, and obstructive azoospermia. Symptoms of mild CF are often limited to a single organ system such as isolated pancreatitis, bilateral absence of the vas deferens, nasal polyposis, or bronchiectasis.
Incidence: 1 in 2,300 Ashkenazi Jewish, 1 in 2,500 Caucasians, 1 in 13,500 Hispanics, 1 in 15,100 African Americans, 1 in 35,100 Asians.
Inheritance: Autosomal recessive.
Penetrance: High for severe and moderately severe pathogenic variants, variable for mild pathogenic variants.
Cause: Two pathogenic *CFTR* variants on opposite chromosomes.
Pathogenic Variants Tested: Variants are listed by standard nomenclature. Legacy names are also provided for the 23 recommended ACMG variants. c.1A>G, p.Met1Val; c.14C>T, p.Pro5Leu; c.54-5940_273+10250del21kb, p.Ser18ArgfsX16 ; c.115C>T, p.Gln39X; c.178G>T, p.Glu60X; c.200C>T, p.Pro67Leu; c.223C>T, p.Arg75X; c.254G>A (Legacy G85E), p.Gly85Glu; c.262_263delTT, p.Leu88IlefsX22; c.273+1G>A, Intronic; c.274-1G>A, Intronic; c.274G>A, p.Glu92Lys; c.274G>T, p.Glu92X; c.292C>T, p.Gln98X; c.313delA, p.Ile105SerfsX2; c.325_327delTATinsG, p.Tyr109GlyfsX4; c.328G>C, p.Asp110His; c.349C>T, p.Arg117Cys; c.350G>A (Legacy R117H), p.Arg117His; c.366T>A, p.Tyr122X; c.442delA, p.Ile148LeufsX5; c.489+1G>T (Legacy 621+1G>T); c.509G>A, p.Arg170His; c.531delT, p.Ile177MetfsX12; c.532G>A, p.Gly178Arg; c.579+1G>T (Legacy 711+1G>T); c.579+5G>A, Intronic; c.579+3A>G, Intronic; c.580-1G>T, Intronic; c.595C>T , p.His199Tyr; c.613C>T, p.Pro205Ser; c.617T>G, p.Leu206Trp; c.658C>T, p.Gln220X; c.720_741delAGGGAGAATGATGATGAAGTAC, p.Gly241GlufsX13; c.803delA, p.Asn268IlefsX17; c.933_935delCTT, p.Phe312del; c.948delT, p.Phe316LeufsX12; c.988G>T, p.Gly330X; c.1000C>T (Legacy R334W), p.Arg334Trp; c.1001G>T, p.Arg334Leu; c.1007T>A, p.Ile336Lys; c.1021T>C, p.Ser341Pro; c.1022_1023insTC, p.Phe342HisfsX28; c.1040G>A, p.Arg347His; c.1040G>C (Legacy R347P), p.Arg347Pro; c.1052C>G, p.Thr351Ser; c.1054C>T, p.Arg352Trp; c.1055G>A, p.Arg352Gln; c.1081delT, p.Trp361GlyfsX8; c.1116+1G>A, Intronic; c.1127_1128insA, p.Gln378AlafsX4 ; c.1153_1154insAT, p.Asn386IlefsX3; c.1202G>A, p.Trp401X; c.1203G>A, p.Trp401X; c.1209+1G>A, Intronic; c.1329_1330insAGAT, p.Ile444ArgfsX3 ; c.1364C>A (Legacy A455E), p.Ala455Glu; c.1393-1G>A, Intronic; c.1397C>A, p.Ser466X ; c.1397C>G, p.Ser466X; c.1400T>C, p.Leu467Pro; c.1418delG, p.Gly473GlufsX54; c.1438G>T, p.Gly480Cys; c.1466C>A, p.Ser489X; c.1475C>T, p.Ser492Phe; c.1477C>T, p.Gln493X; c.1486T>G, p.Trp496Gly; c.1519_1521delATC (Legacy I507del), p.Ile507del; c.1521_1523delCTT (Legacy F508del), p.Phe508del; c.1545_1546delTA, p.Tyr515X; c.1558G>T, p.Val520Phe; c.1572C>A, p.Cys524X; c.1573C>T, p.Gln525X; c.1585-1G>A (Legacy 1717-1G>A); c.1585-8G>A, Intronic; c.1624G>T (Legacy G542X), p.Gly542X ; c.1645A>C, p.Ser549Arg; c.1646G>A, p.Ser549Asn; c.1647T>G, p.Ser549Arg; c.1651G>A, p.Gly551Ser; c.1652G>A (Legacy G551D), p.Gly551Asp; c.1654C>T, p.Gln552X; c.1657C>T (Legacy R553X), p.Arg553X; c.1675G>A, p.Ala559Thr; c.1678A>G, p.Arg560Gly; c.1679G>A, p.Arg560Lys; c.1679G>C (Legacy R560T), p.Arg560Thr; c.1680-1G>A , Intronic; c.1703delT, p.Leu568CysfsX4; c.1721C>A, p.Pro574His; c.1753G>T, p.Glu585X; c.1766+1G>A (Legacy 1898+1G>A); c.1766+3A>G, Intronic; c.1792_1798delAAAACTA , p.Lys598GlyfsX11; c.1923_1931del9insA, p.Ser641ArgfsX5; c.1973_1985del13insAGAAA, p.Arg658LysfsX4; c.2012delT, p.Leu671X; c.2051_2052delAA, p.Lys684ThrfsX4; c.2051_2052delAAinsG, p.Lys684SerfsX38; c.2052delA (Legacy 2184delA), p.Lys684AsnfsX38; c.2125C>T, p.Arg709X; c.2128A>T, p.Lys710X; c.2175_2176insA, p.Glu726ArgfsX4; c.2195T>G, p.Leu732X; c.2215delG, p.Val739TyrfsX16; c.2290C>T, p.Arg764Ter; c.2453delT, p.Leu818TrpfsX3; c.2464G>T, p.Glu822X; c.2490+1G>A , Intronic; c.2491G>T, p.Glu831X ; c.2506G>T, p.Asp836Tyr; c.2537G>A, p.Trp846X; c.2551C>T, p.Arg851X; c.2583delT, p.Phe861LeufsX3; c.2657+5G>A (Legacy 2789+5G>A); c.2668C>T, p.Gln890X ; c.2737_2738insG, p.Tyr913X; c.2780T>C, p.Leu927Pro; c.2810_2811insT, p.Val938GlyfsX37; c.2834C>T, p.Ser945Leu; c.2875delG, p.Ala959HisfsX9; c.2900T>C, p.Leu967Ser; c.2908G>C, p.Gly970Arg; c.2988+1G>A (Legacy 3120+1G>A); c.2988G>A, Intronic; c.2989-1G>A, Intronic; c.3038C>A, p.Pro1013His; c.3039delC, p.Tyr1014ThrfsX9; c.3067_3072delATAGTG, p.Ile1023_Val1024del; c.3140-26A>G, Intronic; c.3194T>C, p.Leu1065Pro; c.3196C>T, p.Arg1066Cys; c.3197G>A, p.Arg1066His; c.3230T>C, p.Leu1077Pro; c.3266G>A, p.Trp1089X; c.3276C>A, p.Tyr1092X; c.3276C>G, p.Tyr1092X; c.3297C>A, p.Phe1099Leu; c.3302T>A, p.Met1101Lys; c.3310G>T, p.Glu1104X; c.3472C>T, p.Arg1158X; c.3484C>T (Legacy R1162X), p.Arg1162X; c.3528delC (Legacy 3659delC), p.Lys1177SerfsX15; c.3587C>G, p.Ser1196X; c.3611G>A, p.Trp1204X; c.3612G>A, p.Trp1204X; c.3659delC, p.Thr1220LysfsX8; c.3717+12191C>T (Legacy 3849+10kbC>T); c.3731G>A, p.Gly1244Glu; c.3744delA, p.Lys1250ArgfsX9; c.3752G>A, p.Ser1251Asn; c.3763T>C, p.Ser1255Pro; c.3764C>A, p.Ser1255X; c.3773_3774insT, p.Leu1258PhefsX7; c.3846G>A (Legacy W1282X), p.Trp1282X; c.3873+1G>A, Intronic; c.3909C>G (Legacy N1303K), p.Asn1303Lys; c.3937C>T, p.Gln1313X; c.3964-78_4242+577del, Exon 22-23 del; c.4028delG, p.Gly1343Alafs*4; c.4046G>A, p.Gly1349Asp; c.4077_4080delTGTTinsAA, p.Val1360delfsX?; c.4111G>T, p.Glu1371X; c.4251delA, p.Glu1418ArgfsX14; c.1679+1.6kbA>G. The IVS-5 variant, c.1210−12[5], will be reported when R117H is detected and in individuals that are reported to be symptomatic.

Clinical Sensitivity for 165-Variant Test: Ashkenazi Jewish 96 percent; Caucasian 92 percent; Hispanic 80 percent; African American 78 percent; Asian American 55 percent.
Clinical Sensitivity for Sequencing and Deletion/Duplication: 97 and 99 percent, respectively.
Methodology for 165-Variant Test: Polymerase chain reaction (PCR) and fluorescence monitoring.
Methodology for Sequencing: Bidirectional sequencing of the *CFTR* coding region and intron-exon boundaries.
Methodology for Deletion/Duplication: Multiplex ligation-dependent probe amplification (MLPA) to detect large *CFTR* coding region deletions/duplications.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. The breakpoints of large deletions/duplications will not be determined. Regulatory region and intronic variants will not be detected.

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

Note: The 165-variant test includes the 23 pathogenic CF variants recommended by the American College of Medical Genetics for population carrier screening. If only one pathogenic variant is identified, then *CFTR* gene sequencing will be added. After *CFTR* gene sequencing, if less than two pathogenic variants are identified, then *CFTR* deletion/duplication will be added. Additional charges apply.

CPT Code(s): 81220; if reflexed to Sequencing, add 81223; if reflexed to Del/Dup, add 81222

New York DOH Approval pending. Call for status update.

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

New Test 2013662 Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants, Fetal CF VAR FE

Available Now
This test performed at ARUP Laboratories.

Time Sensitive

Additional Technical Information

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Sun-Sat
Reported: 7-10 days

Specimen Required: Collect: **Fetal Specimen:** Two T-25 flasks of cultured amniocytes at 80 percent confluency. ***If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**
Maternal Specimen: Lavender (EDTA), pink (K_2EDTA), or yellow (ACD Solution).
Specimen Preparation: **Cultured amniocytes**: Fill flasks with culture media. Transport two T-25 flasks of cultured amniocytes at 80 percent confluency. Backup cultures must be retained at the client's institution until testing is complete.
Maternal Specimen: Transport 3 mL whole blood. (Min. 1 mL)
Storage/Transport Temperature: **Cultured amniocytes**: **CRITICAL ROOM TEMPERATURE.** Must be received within 48 hours of shipment due to lability of cells.
Maternal Specimen: Refrigerated.
Unacceptable Conditions: **Maternal Specimen**: Plasma or serum. Specimens collected in sodium heparin or lithium heparin tubes.
Remarks: **Maternal sample is recommended for proper test interpretation; order Maternal Cell Contamination (ARUP test code 0050608).** Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.
Stability (collection to initiation of testing): **Fetal:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable
Maternal: Ambient: 72 hours; Refrigerated: 2 weeks; Frozen: 1 month.

Reference Interval: By report

Interpretive Data:

Background information for Cystic Fibrosis (*CFTR*), 165 Pathogenic Variants, Fetal
Characteristics of Classic Cystic Fibrosis (CF): Chronic sino-pulmonary disease, gastrointestinal malabsorption/pancreatic insufficiency, and obstructive azoospermia. Symptoms of mild CF are often limited to a single organ system such as isolated pancreatitis, bilateral absence of the vas deferens, nasal polyposis, or bronchiectasis.
Incidence: 1 in 2,300 Ashkenazi Jewish, 1 in 2,500 Caucasians, 1 in 13,500 Hispanics, 1 in 15,100 African Americans, 1 in 35,100 Asians.
Inheritance: Autosomal recessive.
Penetrance: High for severe and moderately severe pathogenic variants, variable for mild pathogenic variants.
Cause: Two pathogenic *CFTR* variants on opposite chromosomes.
Pathogenic Variants Tested: Variants are listed by standard nomenclature. Legacy names are also provided for the 23 recommended ACMG variants. c.1A>G, p.Met1Val; c.14C>T, p.Pro5Leu; c.54-5940_273+10250del21kb, p.Ser18ArgfsX16 ; c.115C>T, p.Gln39X; c.178G>T, p.Glu60X; c.200C>T, p.Pro67Leu; c.223C>T, p.Arg75X; c.254G>A (Legacy G85E), p.Gly85Glu; c.262_263delTT, p.Leu88IlefsX22; c.273+1G>A, Intronic; c.274-1G>A, Intronic; c.274G>A, p.Glu92Lys; c.274G>T, p.Glu92X; c.292C>T, p.Gln98X; c.313delA, p.Ile105SerfsX2; c.325_327delTATinsG, p.Tyr109GlyfsX4; c.328G>C, p.Asp110His; c.349C>T, p.Arg117Cys; c.350G>A (Legacy R117H), p.Arg117His; c.366T>A, p.Tyr122X; c.442delA, p.Ile148LeufsX5; c.489+1G>T (Legacy 621+1G>T); c.509G>A, p.Arg170His; c.531delT, p.Ile177MetfsX12; c.532G>A, p.Gly178Arg; c.579+1G>T (Legacy 711+1G>T); c.579+5G>A, Intronic; c.579+3A>G, Intronic; c.580-1G>T, Intronic; c.595C>T , p.His199Tyr; c.613C>T, p.Pro205Ser; c.617T>G, p.Leu206Trp; c.658C>T, p.Gln220X; c.720_741delAGGGAGAATGATGATGAAGTAC, p.Gly241GlufsX13; c.803delA, p.Asn268IlefsX17; c.933_935delCTT, p.Phe312del; c.948delT, p.Phe316LeufsX12; c.988G>T, p.Gly330X; c.1000C>T (Legacy R334W), p.Arg334Trp; c.1001G>T, p.Arg334Leu; c.1007T>A, p.Ile336Lys; c.1021T>C, p.Ser341Pro; c.1022_1023insTC, p.Phe342HisfsX28; c.1040G>A, p.Arg347His; c.1040G>C (Legacy R347P), p.Arg347Pro; c.1052C>G, p.Thr351Ser; c.1054C>T, p.Arg352Trp; c.1055G>A, p.Arg352Gln; c.1081delT, p.Trp361GlyfsX8; c.1116+1G>A, Intronic; c.1127_1128insA, p.Gln378AlafsX4 ; c.1153_1154insAT, p.Asn386IlefsX3; c.1202G>A, p.Trp401X; c.1203G>A, p.Trp401X; c.1209+1G>A, Intronic; c.1329_1330insAGAT, p.Ile444ArgfsX3 ; c.1364C>A (Legacy A455E), p.Ala455Glu; c.1393-1G>A, Intronic; c.1397C>A, p.Ser466X ; c.1397C>G, p.Ser466X; c.1400T>C, p.Leu467Pro; c.1418delG, p.Gly473GlufsX54; c.1438G>T, p.Gly480Cys; c.1466C>A, p.Ser489X; c.1475C>T, p.Ser492Phe; c.1477C>T, p.Gln493X; c.1486T>G, p.Trp496Gly; c.1519_1521delATC (Legacy I507del), p.Ile507del; c.1521_1523delCTT (Legacy F508del), p.Phe508del; c.1545_1546delTA, p.Tyr515X; c.1558G>T, p.Val520Phe; c.1572C>A, p.Cys524X; c.1573C>T, p.Gln525X; c.1585-1G>A (Legacy 1717-1G>A); c.1585-8G>A, Intronic; c.1624G>T (Legacy G542X), p.Gly542X ; c.1645A>C, p.Ser549Arg; c.1646G>A, p.Ser549Asn; c.1647T>G, p.Ser549Arg; c.1651G>A, p.Gly551Ser; c.1652G>A (Legacy G551D), p.Gly551Asp; c.1654C>T, p.Gln552X; c.1657C>T (Legacy R553X), p.Arg553X; c.1675G>A, p.Ala559Thr; c.1678A>G, p.Arg560Gly; c.1679G>A, p.Arg560Lys; c.1679G>C (Legacy R560T), p.Arg560Thr; c.1680-1G>A , Intronic; c.1703delT, p.Leu568CysfsX4; c.1721C>A, p.Pro574His; c.1753G>T, p.Glu585X; c.1766+1G>A (Legacy 1898+1G>A); c.1766+3A>G, Intronic; c.1792_1798delAAAACTA , p.Lys598GlyfsX11; c.1923_1931del9insA, p.Ser641ArgfsX5; c.1973_1985del13insAGAAA, p.Arg658LysfsX4; c.2012delT, p.Leu671X; c.2051_2052delAA, p.Lys684ThrfsX4; c.2051_2052delAAinsG, p.Lys684SerfsX38; c.2052delA (Legacy 2184delA), p.Lys684AsnfsX38; c.2125C>T, p.Arg709X; c.2128A>T, p.Lys710X; c.2175_2176insA, p.Glu726ArgfsX4; c.2195T>G, p.Leu732X; c.2215delG, p.Val739TyrfsX16; c.2290C>T, p.Arg764Ter; c.2453delT, p.Leu818TrpfsX3; c.2464G>T, p.Glu822X; c.2490+1G>A , Intronic; c.2491G>T, p.Glu831X ; c.2506G>T, p.Asp836Tyr; c.2537G>A, p.Trp846X; c.2551C>T, p.Arg851X; c.2583delT, p.Phe861LeufsX3; c.2657+5G>A (Legacy 2789+5G>A); c.2668C>T, p.Gln890X ; c.2737_2738insG, p.Tyr913X; c.2780T>C, p.Leu927Pro; c.2810_2811insT, p.Val938GlyfsX37; c.2834C>T, p.Ser945Leu; c.2875delG, p.Ala959HisfsX9; c.2900T>C, p.Leu967Ser; c.2908G>C, p.Gly970Arg; c.2988+1G>A (Legacy 3120+1G>A); c.2988G>A, Intronic; c.2989-1G>A, Intronic; c.3038C>A, p.Pro1013His; c.3039delC, p.Tyr1014ThrfsX9; c.3067_3072delATAGTG, p.Ile1023_Val1024del; c.3140-26A>G, Intronic; c.3194T>C, p.Leu1065Pro; c.3196C>T, p.Arg1066Cys; c.3197G>A, p.Arg1066His; c.3230T>C, p.Leu1077Pro; c.3266G>A, p.Trp1089X; c.3276C>A, p.Tyr1092X; c.3276C>G, p.Tyr1092X; c.3297C>A, p.Phe1099Leu; c.3302T>A, p.Met1101Lys; c.3310G>T, p.Glu1104X; c.3472C>T, p.Arg1158X; c.3484C>T (Legacy R1162X), p.Arg1162X; c.3528delC (Legacy 3659delC), p.Lys1177SerfsX15; c.3587C>G, p.Ser1196X; c.3611G>A, p.Trp1204X; c.3612G>A, p.Trp1204X; c.3659delC, p.Thr1220LysfsX8; c.3717+12191C>T (Legacy 3849+10kbC>T); c.3731G>A, p.Gly1244Glu; c.3744delA, p.Lys1250ArgfsX9; c.3752G>A, p.Ser1251Asn; c.3763T>C, p.Ser1255Pro; c.3764C>A, p.Ser1255X; c.3773_3774insT, p.Leu1258PhefsX7; c.3846G>A (Legacy W1282X), p.Trp1282X; c.3873+1G>A, Intronic; c.3909C>G (Legacy N1303K), p.Asn1303Lys; c.3937C>T, p.Gln1313X; c.3964-78_4242+577del, Exon 22-23 del; c.4028delG, p.Gly1343Alafs*4; c.4046G>A, p.Gly1349Asp; c.4077_4080delTGTTinsAA, p.Val1360delfsX?; c.4111G>T, p.Glu1371X; c.4251delA, p.Glu1418ArgfsX14; c.1679+1.6kbA>G. The IVS-5 variant, c.1210−12[5], will be reported when R117H is detected and in individuals that are reported to be symptomatic.
Clinical Sensitivity: Ashkenazi Jewish 96 percent; Caucasian 92 percent; Hispanic 80 percent; African American 78 percent; Asian American 55 percent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.
Analytical Sensitivity & Specificity: 99 percent.
Limitations: Diagnostic errors can occur due to rare sequence variations. Only the 165 pathogenic *CFTR* variants listed above will be interrogated.

For quality assurance purposes, ARUP Laboratories will confirm the above result at no charge following delivery. Order Confirmation of Fetal Testing and include a copy of the original fetal report (or the mother's name and date of birth) with the test submission. Please contact an ARUP genetic counselor at (800) 242-2787 extension 2141 prior to specimen submission.

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

Note: The 165-variant test includes the 23 pathogenic CF variants recommended by the American College of Medical Genetics for population carrier screening.

CPT Code(s): 81220; 81265

New York DOH approval pending. Call for status update.

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

Delete **0050098** **Cystic Fibrosis (*CFTR*) 3199del6** **CF3199DEL6**

This test performed at ARUP Laboratories.
Inactivation due to discontinued kit by vendor.

HOT LINE NOTE: Delete this test and refer to Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants (2013661).

Delete **2001933** **Cystic Fibrosis (*CFTR*) 32 Mutations** **CF PAN**

This test performed at ARUP Laboratories.
Inactivation due to discontinued kit by vendor.

HOT LINE NOTE: Delete this test and refer to Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants (2013661).

Delete **2001968** **Cystic Fibrosis (*CFTR*) 32 Mutations with Reflex to Sequencing** **CF PAN-SEQ**

This test performed at ARUP Laboratories.
Inactivation due to discontinued kit by vendor.

HOT LINE NOTE: Delete this test and refer to Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants with Reflex to Sequencing (2013663).

Delete **2001967** **Cystic Fibrosis (*CFTR*) 32 Mutations with Reflex to Sequencing and Reflex to Deletion/Duplication** **CF COMPR**

This test performed at ARUP Laboratories.
Inactivation due to discontinued kit by vendor.

HOT LINE NOTE: Delete this test and refer to Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants with Reflex to Sequencing and Reflex to Deletion/Duplication (2013664).

Delete **2001969** **Cystic Fibrosis (*CFTR*) 32 Mutations, Atypical** **CF PAN 5T**

This test performed at ARUP Laboratories.
Inactivation due to discontinued kit by vendor.

HOT LINE NOTE: Delete this test and refer to Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants (2013661).

Delete **2001970** **Cystic Fibrosis (*CFTR*) 32 Mutations, Fetal** **CF PAN FE**

*This test performed at ARUP Laboratories.
Inactivation due to discontinued kit by vendor.

HOT LINE NOTE: Delete this test and refer to Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants, Fetal (2013662).

Delete **0056003** **Cystic Fibrosis (*CFTR*) 5T Mutation** **IVS-8**

*This test performed at ARUP Laboratories.
Inactivation due to discontinued kit by vendor.

HOT LINE NOTE: Delete this test and refer to Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants (2013661).

Delete **0056006** **Cystic Fibrosis Cis-Trans (*CFTR*) R117H and 5T Mutations** **CFCIS-TRAN**

*This test performed at ARUP Laboratories.
Inactivation due to discontinued kit by vendor.

HOT LINE NOTE: Delete this test and refer to Cystic Fibrosis (*CFTR*) 165 Pathogenic Variants (2013661).

2005400 ***FLT3* Mutation Detection by PCR** **FLT3 MUTAT**

HOT LINE NOTE: There is a component change associated with this test that affects interface clients only.

Delete 0081055 Lipoprotein-Associated Phospholipase A2 (PLAC) PLAC

Effective July 15, 2016

*This test performed at ARUP Laboratories.
Kit vendor has ceased business operations.
No replacement test available.

HOT LINE NOTE: Delete this test.

2012729 Non-Criteria Antiphospholipid Syndrome (APS) (aPs, aPt, aPs/aPt) Antibodies Panel NCAPS PAN

*This test performed at ARUP Laboratories.
Kit vendor for IgM component has ceased business operations
No replacement test available.

CPT Code(s): 86148 x2; 83516 x2; 86849

HOT LINE NOTE: There is a component change associated with this test that affects interface clients only. There is also a price change associated with this test. Please contact ARUP Client Services at (800) 522-2787 for additional information.

New Test 2013684 PD-L1 28-8 pharmDx by Immunohistochemistry with Interpretation, nivolumab (OPDIVO) 28-8 IP

*This test performed at ARUP Laboratories.
FDA-approved test with higher clinical relevance
for OPDIVO eligibility.

Available July 5, 2016

Methodology: Immunohistochemistry
Performed: Mon-Fri
Reported: 1-5 days

Specimen Required: Patient Prep:
Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen. Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808 recommended but not required), available online through eSupply using ARUP Connector contact ARUP Client Services at (800) 522-2787. (Min: 3 slides) If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report and indicate tissue site with the test order. For additional technical details, please contact ARUP Client Services at (800) 522-2787.
Unacceptable Conditions: Paraffin block with no tumor tissue remaining; specimens fixed in any fixative other than 10 percent neutral buffered formalin.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Reference Interval:

Interpretive Data: Refer to report.

Note: This test code includes pathologist interpretation.

CPT Code(s): 88342

New York DOH approval pending. Call for status update.

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

Delete **2004411** **Prothrombin Antibodies, IgG & IgM** **PROTHROMPN**

*This test performed at ARUP Laboratories.
Kit vendor has ceased business operations
No replacement test available.

HOT LINE NOTE: Delete this test.

Delete **0051303** **Prothrombin Antibody, IgM** **PROTHROM M**

*This test performed at ARUP Laboratories.
Kit vendor has ceased business operations
No replacement test available.

HOT LINE NOTE: Delete this test.