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.
New Test 2011958  Ashkenazi Jewish (BRCA1 and BRCA2) 3 Mutations  AJ BRCA

*This test performed at ARUP Laboratories. Activation of ARUP-developed testing due to recent Supreme Court ruling disallowing exclusive patenting of the BRCA genes.

Methodology: Polymerase Chain Reaction/Fragment Analysis
Performed: Varies
Reported: 7-10 days

Specimen Required: Collect: Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B). 
Specimen Preparation: Transport 3 mL whole blood (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

Background information for Ashkenazi Jewish (BRCA1 and BRCA2) 3 Mutations:
Characteristics: Individuals with a mutation have an increased risk for early onset cancer of the breast, ovary, fallopian tubes, peritoneum, cervix, uterus, pancreas and prostate.
Incidence: Approximately 1 in 36 (2.74 percent) of individuals of Ashkenazi Jewish descent.
Inheritance: Autosomal dominant.
Penetrance: Risk by age 70 for breast cancer is 56 percent, ovarian cancer 16 percent, and prostate cancer 16 percent.
Cause: Pathogenic germline BRCA1 or BRCA2 gene mutations.
Mutations Tested: BRCA1 gene c.68_69delAG; p.Glu23ValfsTer17 legacy nomenclature (185delAG or 187delAG) and c.5266dupC; p.Gln1756ProfsTer74 legacy nomenclature (5382insC or 5385insC); BRCA2 gene c.5946delT; p.Ser1982ArgfsTer22 legacy nomenclature (6174delT).
Clinical Sensitivity: 97 percent of BRCA1 and BRCA2 gene mutations in Ashkenazi Jewish individuals are detected by this 3 mutation panel.
Methodology: PCR and fragment analysis.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: This test has a detection rate of <1 percent for BRCA1 and BRCA2 mutations in individuals who are not of Ashkenazi Jewish descent. BRCA1 and BRCA2 gene mutations, other than those targeted, will not be detected. Rare diagnostic errors may occur due to primer site mutations.

Note:

CPT Code(s): 81212

New York DOH Approved. Call for status update.

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

**Methodology:** Polymerase Chain Reaction/Sequencing

**Performed:** Sun- Sat

**Reported:** 14-21 days

**Specimen Required:**
- **Collect:** Lavender (EDTA), pink (K$_2$EDTA), or yellow (ACD Solution A or B).
- **Specimen Preparation:** Transport 3 mL whole blood. (Min: 1 mL)
- **Storage/Transport Temperature:** Refrigerated
- **Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

**Reference Interval:**

**Interpretive Data:**

**Background Information for Breast and Ovarian Hereditary Cancer Syndrome (BRCA1 and BRCA2) Sequencing**

**Characteristics:** Female carriers of BRCA1 mutations have a breast cancer risk of 57 percent and ovarian cancer risk of 40 percent by age 70. Female carriers of BRCA2 mutations have a breast cancer risk of 49 percent and ovarian cancer risk of 18 percent by age 70. BRCA1 mutation carriers may also be at increased risk for fallopian, peritoneal, cervical, uterine, and pancreatic cancer. BRCA2 mutation carriers may be at increased risk for pancreatic, stomach, gallbladder, bile duct, and melanoma cancers. Men with BRCA1 mutations are at increased risk for breast cancer and possibly pancreatic, prostate, and testicular cancers while male carriers of BRCA2 mutations are at increased risk for breast, pancreatic and prostate cancers.

**Prevalence:** 1 in 500 individuals have a BRCA1 or BRCA2 mutation; 5-10 percent of breast cancer and 10-15 percent of ovarian cancer are caused by germline BRCA1 or BRCA2 mutations.

**Inheritance:** Autosomal dominant.

**Cause:** Pathogenic germline mutations in several genes cause hereditary breast and ovarian cancer (HBOC) syndrome. Mutations in tumor suppressor genes, BRCA1 and BRCA2, are causative for 20-60 percent of HBOC.

**Genes Tested:** BRCA1 and BRCA2.

**Clinical Sensitivity:** Approximately 90 percent of BRCA1 and BRCA2 mutations.

**Methodology:** Bidirectional sequencing of the entire BRCA1 and BRCA2 coding regions and intron-exon boundaries.

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

**Limitations:** BRCA1 and BRCA2 gene regulatory region mutations, deep intronic mutations, and large deletions/duplications will not be detected. Other genes causing HBOC are not tested. Rare diagnostic errors can occur due to primer site mutations.

**Note:**

**CPT Code(s):** 81211

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test 2011915 Breast and Ovarian Hereditary Cancer Syndrome (BRCA1 and BRCA2) Deletion/Duplication

*This test performed at ARUP Laboratories.
Activation of ARUP-developed testing due to recent Supreme Court ruling disallowing exclusive patenting of the BRCA genes.

Methodology: Multiplex Ligation-dependent Probe Amplification
Performed: Varies
Reported: Within 2 weeks

Specimen Required: Collect: Lavender (EDTA), pink (K2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:
Background Information for Breast and Ovarian Hereditary Cancer Syndrome (BRCA1 and BRCA2) Deletion/Duplication
Characteristics: Female carriers of BRCA1 mutations have a breast cancer risk of 57 percent and ovarian cancer risk of 40 percent by age 70. Female carriers of BRCA2 mutations have a breast cancer risk of 49 percent and ovarian cancer risk of 18 percent by age 70. BRCA1 mutation carriers may also be at increased risk for fallopian, peritoneal, cervical, uterine, and pancreatic cancer. BRCA2 mutation carriers may be at increased risk for pancreatic, stomach, gallbladder, bile duct, and melanoma cancers. Men with BRCA1 mutations are at increased risk for breast cancer and possibly pancreatic, prostate, and testicular cancers while male carriers of BRCA2 mutations are at increased risk for breast, pancreatic and prostate cancers.
Prevalence: 1 in 500 individuals has a BRCA1 or BRCA2 mutation; 5-10 percent of breast cancer and 10-15 percent of ovarian cancer are caused by germline BRCA1 or BRCA2 mutations.
Inheritance: Autosomal dominant.
Cause: Pathogenic germline mutations in several genes cause hereditary breast and ovarian cancer (HBOC) syndrome. Mutations in tumor suppressor genes, BRCA1 and BRCA2, are causative for the majority of HBOC.
Genes Tested: BRCA1 and BRCA2.
Clinical Sensitivity: Approximately 10 percent of BRCA1 and BRCA2 mutations.
Methodology: Multiplex ligation-dependent probe amplification (MLPA) to detect large BRCA1 and BRCA2 locus and intragenic deletions/duplications.
Analytical Sensitivity and Specificity: 99 percent.
Limitations: Rare diagnostic errors can occur due to probe site mutations. Breakpoints for large deletions/duplications will not be determined. BRCA1 and BRCA2 base pair substitutions, small deletions/duplications, deep intronic, and regulatory region mutations will not be detected. Other genes causing HBOC syndrome are not tested.

Note: CPT Code(s): 81213
New York DOH approval pending. Call for status update.

HOT LINE NOTE: Refer to the Test Mix Addendum for interface build information.
**New Test** 2011949  **Breast and Ovarian Hereditary Cancer Syndrome (BRCA1 and BRCA2) Sequencing and Deletion/Duplication**  **BRCA FGA**

*This test performed at ARUP Laboratories. Activation of ARUP-developed testing due to recent Supreme Court ruling disallowing exclusive patenting of the BRCA genes.*

Additional Technical Information

**Methodology:** Polymerase Chain Reaction/Sequencing/Multiplex Ligation-dependent Probe Amplification

**Performed:** Sun-Sat  
**Reported:** 21-28 days

**Specimen Required:**  
**Collect:** Lavender (EDTA), pink (K₂EDTA), or yellow (ACD Solution A or B).  
**Specimen Preparation:** Transport 3 mL whole blood. (Min: 2 mL)  
**Storage/Transport Temperature:** Refrigerated  
**Stability (collection to initiation of testing):** Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

**Reference Interval:**

**Interpretive Data:**

**Background Information for Breast and Ovarian Hereditary Cancer Syndrome (BRCA1 and BRCA2) Sequencing and Deletion/Duplication**

**Characteristics:** Female carriers of BRCA1 mutations have a breast cancer risk of 57 percent and ovarian cancer risk of 40 percent by age 70. Female carriers of BRCA2 mutations have a breast cancer risk of 49 percent and ovarian cancer risk of 18 percent by age 70. BRCA1 mutation carriers may also be at increased risk for fallopian, peritoneal, cervical, uterine, and pancreatic cancer. BRCA2 mutation carriers may be at increased risk for pancreatic, stomach, gallbladder, bile duct, and melanoma cancers. Men with BRCA1 mutations are at increased risk for breast cancer and possibly pancreatic, prostate, and testicular cancers while male carriers of BRCA2 mutations are at increased risk for breast, pancreatic and prostate cancers.

**Prevalence:** 1 in 500 individuals have a BRCA1 or BRCA2 mutation; 5-10 percent of breast cancer and 10-15 percent of ovarian cancer are caused by germline BRCA1 or BRCA2 mutations.

**Inheritance:** Autosomal dominant.

**Cause:** Pathogenic germline mutations in several genes cause hereditary breast and ovarian cancer (HBOC) syndrome. Mutations in tumor suppressor genes, BRCA1 and BRCA2, are causative for the majority of HBOC.

**Genes Tested:** BRCA1 and BRCA2.

**Clinical Sensitivity:** 20-60 percent of HBOC.

**Methodology:** Bidirectional sequencing and multiplex ligation-dependent probe amplification (MLPA) of the entire coding regions and intron-exon boundaries of the BRCA1 and BRCA2 genes.

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

**Limitations:** Rare diagnostic errors can occur due to primer or probe site mutations. Regulatory region mutations and deep intronic mutations will not be detected. Genes causing HBOC syndrome, other than BRCA1 and BRCA2, are not tested. Deletion/duplication breakpoints will not be determined.

**Note:**

**CPT Code(s):**  81211, 81213

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test 2011937 Human Papillomavirus (HPV) 16 and 18 Genotype by PCR, SurePath

This test performed at ARUP Laboratories. New platform provides genotyping on SurePath media.

Methodology: Qualitative Polymerase Chain Reaction
Performed: Mon, Wed, Fri
Reported: 1-5 days

Specimen Required: Collect: Cervical specimen with SurePath collection kit and place in SurePath media.
Specimen Preparation: Place each specimen in an individually sealed bag.
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: 3 months; Refrigerated: 3 month; Frozen: Unacceptable

Reference Interval: Negative

Interpretive Data: This test amplifies DNA of HPV16 and HPV18. The FDA has not approved the SurePath sample medium for HPV testing. Laboratories should collect and transport specimens according to the instructions of FDA-approved kits (ThinPrep medium).

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 HPV16 and/or HPV18 result does not exclude the presence of other high-risk HPV types, the possibility of future cytologic abnormalities, or 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.

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

Note:

CPT Code(s): 87625 x2

New York DOH approval pending. Call for status update.

HOT LINE NOTE: Refer to the Test Mix Addendum for interface build information.
New Test 2011942 Human Papillomavirus (HPV), High Risk by PCR, SurePath  SP HPV PCR

This test performed at ARUP Laboratories.
New platform provides significant performance improvement over current assay using SurePath media.

**Methodology:** Qualitative Polymerase Chain Reaction  
**Performed:** Mon, Wed, Fri  
**Reported:** 1-5 days

**Specimen Required:**  
**Collect:** Cervical, anal or vaginal specimens with SurePath collection kit and place in SurePath media.  
**Specimen Preparation:** Place each specimen in an individually sealed bag.  
**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: 3 months; Refrigerated: 3 month; Frozen: Unacceptable

**Reference Interval:** Negative

**Interpretive Data:**  
This test amplifies DNA of 14 high-risk HPV types associated with cervical cancer and its precursor lesions (HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68). The FDA has not approved the SurePath sample medium for HPV testing. Laboratories should collect and transport specimens according to the instructions of FDA-approved kits (ThinPrep medium).  

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 HPV high-risk result does not exclude the possibility of future cytologic abnormalities, or 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.

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

**Note:**

**CPT Code(s):** 87624

New York DOH approval pending. Call for status update.

**HOT LINE NOTE:** Refer to the Test Mix Addendum for interface build information.
New Test  2011947  Human Papillomavirus (HPV), High Risk by PCR, ThinPrep  TP HPV PCR

This test performed at ARUP Laboratories.
New FDA-approved platform for HPV high-risk screening on ThinPrep media.

Methodology:  Qualitative Polymerase Chain Reaction
Performed:  Mon, Wed, Fri
Reported:  1-5 days

Specimen Required:  Collect: Cervical, anal or vaginal specimens with brush or spatula from ThinPrep kit and place in PreservCyt Media.
Specimen Preparation: Place each specimen in an individually sealed bag.
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: 6 months; Refrigerated: 6 month; Frozen: Unacceptable

Reference Interval:  Negative

Interpretive Data:  This test amplifies DNA of 14 high-risk HPV types associated with cervical cancer and its precursor lesions (HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68). 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 possibility of future cytologic HSIL or 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

HOT LINE NOTE: Refer to the Test Mix Addendum for interface build information.
New Test  | 2011933  | Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, SurePath  | SP HPV1618

This test performed at ARUP Laboratories.
New platform provides high-risk HPV result and genotyping on SurePath media.

Methodology: Qualitative Polymerase Chain Reaction
Performed: Mon, Wed, Fri
Reported: 1-5 days

Specimen Required:
- Collect: Cervical specimen with SurePath collection kit and place in SurePath media.
- Specimen Preparation: Place each specimen in an individually sealed bag.
- 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: 3 months; Refrigerated: 3 month; Frozen: Unacceptable

Reference Interval: Negative

Interpretive Data:
This test amplifies DNA of HPV16, HPV18 and 12 other high-risk HPV types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) associated with cervical cancer and its precursor lesions. The FDA has not approved the SurePath sample medium for HPV testing. Laboratories should collect and transport specimens according to the instructions of FDA-approved kits (ThinPrep medium).

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 possibility of future cytologic HSIL or 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.

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

Note:
CPT Code(s): 87624, 87625 x2

New York DOH approval pending. Call for status update.

HOT LINE NOTE: Refer to the Test Mix Addendum for interface build information.
**New Test** 2011940  **Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, ThinPrep**

This test performed at ARUP Laboratories.
New FDA-approved platform for primary HPV screening on ThinPrep media.

**Methodology:** Qualitative Polymerase Chain Reaction

**Performed:** Mon, Wed, Fri

**Reported:** 1-5 days

**Specimen Required:**
- **Collect:** Cervical specimen with brush or spatula from ThinPrep kit and place in PreservCyt Media.
- **Specimen Preparation:** Place each specimen in an individually sealed bag.
- **Storage/Transport Temperature:** Refrigerated.
- **Remarks:** Specimen source required.
- **Unacceptable Conditions:** Bloody or dark brown specimens. Specimens in any media other than indicated above.

**Reference Interval:** Negative

**Interpretive Data:** This test amplifies DNA of HPV16, HPV18 and 12 high-risk HPV types associated with cervical cancer and its precursor lesions (HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68). 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 possibility of future cytologic HSIL or 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, 87625 x2

New York DOH approved.

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

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**Delete** 2011866  **Integrated BRAC Analysis (BRCA1 and BRCA2)**

Effective April 13, 2015

**HOT LINE NOTE:** Delete this test and refer to Breast and Ovarian Hereditary Cancer Syndrome (BRCA1 and BRCA2) Sequencing and Deletion/Duplication (2011949).