

IMMEDIATE HOT LINE: Effective March 2, 2015

#### 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.



Patient History For Breast and Ovarian Hereditary Cancer Syndrome (*BRCA1* and *BRCA2*) Genetic Testing



Additional Technical Information

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

**Specimen Required:** Collect: Lavender (EDTA), pink (K<sub>2</sub>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:** 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.

**New Test**      **2011954**      **Breast and Ovarian Hereditary Cancer Syndrome (*BRCA1* and *BRCA2*) Sequencing**      **BRCA FGS**

\*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  
**Performed:** Sun- Sat  
**Reported:** 14-21 days

**Specimen Required:** Collect: Lavender (EDTA), pink (K<sub>2</sub>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**      **BRCA DD**

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



Patient History For Breast and Ovarian Hereditary Cancer Syndrome (*BRCA1* and *BRCA2*) Genetic Testing



Additional Technical Information

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

**Specimen Required:** Collect: Lavender (EDTA), pink (K<sub>2</sub>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:** 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 (K<sub>2</sub>EDTA), 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.

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**New Test**      **2011937**      **Human Papillomavirus (HPV) 16 and 18 Genotype by PCR, SurePath**      **SP HPVGENO**

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](http://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.

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**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](http://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.

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**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.



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**New Test**      **2011933**      **Human Papillomavirus (HPV), High Risk with 16 and 18**      **SP HPV1618**  
**Genotype by PCR, SurePath**

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](http://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**      **TP HPV1618**

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.  
                                   Stability (collection to initiation of testing): Ambient: 6 months; Refrigerated: 6 month; Frozen: Unacceptable

**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.

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

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).