

10/15/2013 - New Release, Quest Diagnostics Nichols Institute, Valencia

NEW TESTS			
Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.			
Test Code	Test Name	Effective Date	Page #
<b>91864</b>	<b>BRCAvantage™, Ashkenazi Jewish Screen</b>	10/14/2013	1
<b>91863</b>	<b>BRCAvantage™, Comprehensive</b>	10/14/2013	2
<b>91866</b>	<b>BRCAvantage™, Rearrangements</b>	10/14/2013	3
<b>91865</b>	<b>BRCAvantage™, Single Site</b>	10/14/2013	4

## New Test Offerings

The following tests will be available through Quest Diagnostics on the dates indicated below.

BRCAvantage™, Ashkenazi Jewish Screen																			
Clinical Significance	This test detects 3 mutations which account for approximately 90% of the BRCA1 and BRCA2 mutations found in Ashkenazi Jews.																		
Effective Date	10/14/2013																		
Test Code	91864																		
CPT Codes	81212																		
Specimen Requirements	4 mL (2 mL minimum) whole blood collected in an EDTA (lavender-top) tube																		
Instructions	Whole Blood: Normal phlebotomy procedure; specimen stability is crucial. Store and ship room temperature immediately. Do not freeze.																		
Transport Temperature	Room temperature																		
Specimen Stability	Room temperature and Refrigerated: 8 days Frozen: Unacceptable																		
Set-up/Analytic Time	Set up: Mon, Wed, Fri; Report available: 7 days																		
Reference Range	Accompanies report																		
Always Message	<a href="http://education.questdiagnostics.com/faq/FAQ121">http://education.questdiagnostics.com/faq/FAQ121</a>  This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.																		
Methodology	Fluorescent Polymerase Chain Reaction																		
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano																		
CPU Mappings	<table border="1"> <thead> <tr> <th colspan="3">Reporting Title: BRCAVANTAGE ASHKENAZI SCREEN</th> </tr> <tr> <th>Result Code</th> <th>Type</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86007572</td> <td>Prompt-Result (no return)</td> <td>Ethnicity:</td> </tr> <tr> <td>86010078</td> <td></td> <td>Interpretation Summary</td> </tr> <tr> <td>86010079</td> <td></td> <td>BRCA1/2 Ashkenazi Mutation</td> </tr> <tr> <td>86010080</td> <td></td> <td>BRCA1/2 Mutations Interp</td> </tr> </tbody> </table>	Reporting Title: BRCAVANTAGE ASHKENAZI SCREEN			Result Code	Type	Result Name	86007572	Prompt-Result (no return)	Ethnicity:	86010078		Interpretation Summary	86010079		BRCA1/2 Ashkenazi Mutation	86010080		BRCA1/2 Mutations Interp
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86010080		BRCA1/2 Mutations Interp																	

	86010081		Comprehensive Interp
	86010121		Additional Information

BRCAVantage™, Comprehensive																																								
Message	<b>** This test is not available for New York patient testing **</b>																																							
Clinical Significance	This test detects mutations in the BRCA1 and BRCA2 genes which are the most common causes of hereditary breast and ovarian cancers.																																							
Effective Date	10/14/2013																																							
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CPT Codes	81211, 81213																																							
Specimen Requirements	4 mL (2 mL minimum) whole blood collected in an EDTA (lavender-top) tube																																							
Instructions	<b>Whole Blood: Normal phlebotomy procedure; specimen stability is crucial. Store and ship room temperature immediately. Do not freeze. Send report of results for family member with known BRCA mutation.</b>																																							
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Set-up/Analytic Time	Set up: Mon, Wed, Fri; Report available: 14 days from the time of receiving completed pre-authorization																																							
Reference Range	Accompanies report																																							
Always Message	<a href="http://education.questdiagnostics.com/faq/FAQ120">http://education.questdiagnostics.com/faq/FAQ120</a>  This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.																																							
Methodology	Next Generation Sequencing and Multiplex Ligation-dependent Probe Amplification (MLPA)																																							
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano																																							
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86010070	BRCA1 Seq Interp																																							
91863-3-BRCA1 Del/Dup																																								

<b>Result Code</b>	<b>Result Name</b>
86010071	BRAC1 Del/Dup
86010072	BRCA1 Del/Dup Interp
<b>91863-4-BRCA2 Sequencing</b>	
<b>Result Code</b>	<b>Result Name</b>
86010073	BRCA2 Sequencing
86010074	BRCA2 Seq Interp
<b>91863-5-BRCA2 Del/Dup</b>	
<b>Result Code</b>	<b>Result Name</b>
86010075	BRCA2 Del/Dup
86010076	BRCA2 Del/Dup Interp
<b>91863-6-Comprehensive Report</b>	
<b>Result Code</b>	<b>Result Name</b>
86010077	Comprehensive Interp
<b>91863-7-Additional Information</b>	
<b>Result Code</b>	<b>Result Name</b>
86010120	Additional Information

<b>BRCAVantage™, Rearrangements</b>	
Message	<b>** This test is not available for New York patient testing **</b>
Clinical Significance	This test detects large deletion/duplication mutations in the BRCA1 and BRCA2 genes which are not detectable by DNA sequencing.
<b>Effective Date</b>	<b>10/14/2013</b>
Test Code	<b>91866</b>
CPT Codes	<b>81479, 81213</b>
Specimen Requirements	<b>4 mL (2 mL minimum) whole blood collected in an EDTA (lavender-top) tube</b>
Instructions	<b>Whole Blood: Normal phlebotomy procedure; specimen stability is crucial. Store and ship room temperature immediately. Do not freeze. Send report of results for family member with known BRCA mutation.</b>
Transport Temperature	<b>Room temperature</b>
Specimen Stability	<b>Room temperature and Refrigerated: 8 days Frozen: Unacceptable</b>
Set-up/Analytic Time	<b>Set up: Mon, Wed, Fri; Report available: 14 days from the time of receiving completed pre-authorization</b>
Reference Range	<b>Accompanies report</b>
Always Message	<a href="http://education.questdiagnostics.com/faq/FAQ122">http://education.questdiagnostics.com/faq/FAQ122</a>  <b>This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.</b>

Methodology	Multiplex Ligation-dependent Probe Amplification (MLPA)																																																															
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano																																																															
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<b>BRCAVantage™, Single Site</b>	
Message	<b>** This test is not available for New York patient testing **</b>
Clinical Significance	This test detects the presence of known familial mutations in the BRCA1 or BRCA2 gene in tested patients.
<b>Effective Date</b>	<b>10/14/2013</b>
Test Code	<b>91865</b>
CPT Codes	<b>81215 BRCA1 or 81217 BRCA2</b>
Specimen Requirements	<b>4 mL (2 mL minimum) whole blood collected in an EDTA (lavender-top) tube</b>
Instructions	<b>Whole Blood: Normal phlebotomy procedure; specimen stability is crucial. Store and ship room temperature immediately. Do not freeze. Send report of results for family member with known BRCA mutation.</b>
Transport Temperature	<b>Room temperature</b>
Specimen Stability	<b>Room temperature and Refrigerated: 8 days</b>

	<b>Frozen: Unacceptable</b>																														
Set-up/Analytic Time	<b>Set up: Mon, Wed, Fri; Report available: 14 days from the time of receiving completed pre-authorization</b>																														
Reference Range	<b>Accompanies report</b>																														
Always Message	<p><a href="http://education.questdiagnostics.com/faq/FAQ123">http://education.questdiagnostics.com/faq/FAQ123</a></p> <p><b>This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.</b></p>																														
Methodology	<b>Next Generation Sequencing or Multiplex Ligation-dependent Probe Amplification (MLPA)</b>																														
Performing Site	<b>Quest Diagnostics Nichols Institute, San Juan Capistrano</b>																														
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