

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 #
91864	BRCAvantage™, Ashkenazi Jewish Screen	10/14/2013	1
91863	BRCAvantage™, Comprehensive	10/14/2013	2
91866	BRCAvantage™, Rearrangements	10/14/2013	3
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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	http://education.questdiagnostics.com/faq/FAQ121 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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86010079		BRCA1/2 Ashkenazi Mutation																	
86010080		BRCA1/2 Mutations Interp																	

	86010081		Comprehensive Interp
	86010121		Additional Information

BRCAVantage™, Comprehensive																																			
Message	** This test is not available for New York patient testing **																																		
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																																		
Test Code	91863																																		
CPT Codes	81211, 81213																																		
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. Send report of results for family member with known BRCA mutation.																																		
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Reference Range	Accompanies report																																		
Always Message	http://education.questdiagnostics.com/faq/FAQ120 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																																			

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

BRCAVantage™, Rearrangements	
Message	** This test is not available for New York patient testing **
Clinical Significance	This test detects large deletion/duplication mutations in the BRCA1 and BRCA2 genes which are not detectable by DNA sequencing.
Effective Date	10/14/2013
Test Code	91866
CPT Codes	81479, 81213
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. Send report of results for family member with known BRCA mutation.
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: 14 days from the time of receiving completed pre-authorization
Reference Range	Accompanies report
Always Message	http://education.questdiagnostics.com/faq/FAQ122 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	Multiplex Ligation-dependent Probe Amplification (MLPA)																																																															
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano																																																															
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BRCAVantage™, Single Site	
Message	** This test is not available for New York patient testing **
Clinical Significance	This test detects the presence of known familial mutations in the BRCA1 or BRCA2 gene in tested patients.
Effective Date	10/14/2013
Test Code	91865
CPT Codes	81215 BRCA1 or 81217 BRCA2
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. Send report of results for family member with known BRCA mutation.
Transport Temperature	Room temperature
Specimen Stability	Room temperature and Refrigerated: 8 days

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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																														
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Always Message	http://education.questdiagnostics.com/faq/FAQ123 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.																														
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