

6/2/2014 - 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 #
<u>92140</u>	BRCAvantage™, Ashkenazi Jewish Screen with Reflex BRCAvantage™, Comprehensive	6/9/2014	1

New Test Offerings

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

BRCAvantage™, Ashkenazi Jewish Screen with Reflex BRCAvantage™, Comprehensive							
Clinical Significance	This reflexive test screens for the presence of 3 mutations which account for approximately 90% of the BRCA1 and BRCA2 mutations found in Ashkenazi Jews. Should the results be negative, the test will reflex to comprehensive testing for detection of mutations in the BRCA1 and BRCA2 genes which are the most common causes of hereditary breast and ovarian cancers.						
Effective Date	6/9/2014						
Test Code	92140						
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. 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	See individual assays						
Always Message	<p>BRCAvantage™, Ashkenazi Jewish Screen: 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.</p> <p>For more information on this test, go to: http://education.questdiagnostics.com/faq/FAQ121 (This link is being provided for informational/educational purposes only.)</p> <p>BRCAvantage™, Comprehensive: 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.</p> <p>For more information on this test, go to: http://education.questdiagnostics.com/faq/FAQ120 (This link is being provided for informational/educational purposes only.)</p>						
Methodology	Fluorescent Polymerase Chain Reaction, Next Generation Sequencing and Multiplex Ligation-dependent Probe Amplification (MLPA)						
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano						
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Type</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Result Code	Type	Result Name			
Result Code	Type	Result Name					

86007572	Prompt-Result (no return)	Ethnicity:
86010095	Prompt-Result (no return)	Known Family BRCA Mutation
86010128	Prompt-Result (no return)	Spec. Familial Mutation
86010096	Prompt-Result (no return)	Spec. Familial Del/Dup
86010078		Interpretation Summary
86010079		BRCA1/2 Ashkenazi Mutation
86010080		BRCA1/2 Mutations Interp
86010081		Comprehensive Interp
86010121		Additional Information
*TR 92140-2-Interpretation Summary		
Result Code	Result Name	
86010068	Interpretation Summary	
*TR 92140-3-BRCA1 Sequencing		
Result Code	Result Name	
86010069	BRCA1 Sequencing	
86010070	BRCA1 Seq Interp	
*TR 92140-4-BRCA1 Del/Dup		
Result Code	Result Name	
86010071	BRCA1 Del/Dup	
86010072	BRCA1 Del/Dup Interp	
*TR 92140-5-BRCA2 Sequencing		
Result Code	Result Name	
86010073	BRCA2 Sequencing	
86010074	BRCA2 Seq Interp	
*TR 92140-6-BRCA2 Del/Dup		
Result Code	Result Name	
86010075	BRCA2 Del/Dup	
86010076	BRCA2 Del/Dup Interp	
*TR 92140-7-Comprehensive Report		
Result Code	Result Name	
86010077	Comprehensive Interp	
*TR 92140-8-Additional Information		
Result Code	Result Name	
86010120	Additional Information	
<p>*TR (True Reflexing Flag) CPU interface clients: If you are set up to use our True Reflexing option, build the unit codes with the TR flag (indicated above) separately.</p>		

Additional Information	<p>If BRCAvantage™ Ashkenazi Jewish Screen is negative, then BRCAvantage™, Comprehensive will be performed at an additional charge (CPT code(s): 81211, 81213).</p> <p>Pricing Message: Negotiated pricing on 91864 -BRCAvantage™, Ashkenazi Jewish Screen will be applied to code 92140. Negotiated pricing on 91863 - BRCAvantage™, Comprehensive will be applied to code 92140-2</p>
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