

7/27/2012 - Immediate Action, Quest Diagnostics Nichols Institute, Valencia

TEST CHANGES				
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	Former Test Code	Test Name	Effective Date	Page #
16898		SureSwab® Bacterial Vaginosis DNA, Quantitative RT-PCR	7/27/2012	1

Test Changes

The following test changes will be effective on the dates indicated below. **Please note that only the information that is changing appears in this update.** Former test names and test codes have been italicized.

SureSwab® Bacterial Vaginosis DNA, Quantitative RT-PCR							
Effective Date	7/27/2012						
Test Code	16898						
Reference Range	<table border="1"> <tr> <td>BV Category: Lactobacillus species: Atopobium vaginae: Megasphaera species: Gardnerella vaginalis:</td> <td>NOT SUPPORTIVE Accompanies report Accompanies report Accompanies report Accompanies report</td> </tr> </table>	BV Category: Lactobacillus species: Atopobium vaginae: Megasphaera species: Gardnerella vaginalis:	NOT SUPPORTIVE Accompanies report Accompanies report Accompanies report Accompanies report				
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Always Message	<p>NOT SUPPORTIVE OF BV: The pattern of results is not supportive of a diagnosis of BV: 1) Presence of Lactobacillus spp., G. vaginalis levels less than 6.0 log cells/mL, and absence of A. vaginae and Megasphaera spp; or 2) Absence of all targeted organisms; or 3) Absence of Lactobacillus spp. plus G. vaginalis detected at levels less than 6.0 log cells/mL and absence of A. vaginae and Megasphaera spp.</p> <p>EQUIVOCAL FOR BV: The pattern of results is neither supportive nor not supportive of a diagnosis of BV. The patient may be in transition into or out of BV: Presence of Lactobacillus spp. plus G. vaginalis (greater or equal to 6.0 log cells/mL) and/or one of the other BV-associated pathogens</p> <p>SUPPORTIVE OF BV: The pattern of results is supportive of a diagnosis of BV: Absence of Lactobacillus spp. and presence of G. vaginalis greater than or equal to 6.0 log cells/mL and/or one or both of the other BV-associated pathogens.</p> <p>Concentration for Lactobacilli (L. acidophilus/ crispatus, L. jensenii) are collectively reported under the term "Lactobacillus spp.", as these species are among the peroxide producing Lactobacilli thought to be protective against bacterial vaginosis. Atopobium vaginae, Megasphaera spp., and Gardnerella (greater than 6.0 log cells/mL) have been associated with vaginosis when present in the absence of peroxidase producing Lactobacilli.</p> <p>This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. Performance characteristics refer to the analytical performance of the test.</p>						
Performing Site	Quest Diagnostics Nichols Institute, Valencia						
CPU Mappings	<table border="1"> <tr> <td colspan="2">Reporting Title: SURESWAB,BACT VAGINOSIS,PCR</td> </tr> <tr> <th>Result Code</th> <th>Result Name</th> </tr> <tr> <td>86008580 86005968 86005970 86005971 86005972</td> <td>BV Category: Lactobacillus species Atopobium vaginae Megasphaera species Gardnerella vaginalis</td> </tr> </table>	Reporting Title: SURESWAB,BACT VAGINOSIS,PCR		Result Code	Result Name	86008580 86005968 86005970 86005971 86005972	BV Category: Lactobacillus species Atopobium vaginae Megasphaera species Gardnerella vaginalis
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Tests Affected	<table border="1"> <tr> <th>Test Codes:</th> <th>Name:</th> </tr> <tr> <td>16491</td> <td>SureSwab®, Vaginosis, CT/NG</td> </tr> </table>	Test Codes:	Name:	16491	SureSwab®, Vaginosis, CT/NG		
Test Codes:	Name:						
16491	SureSwab®, Vaginosis, CT/NG						

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17333	SureSwab®, Vaginosis/Vaginitis Plus
15509	SureSwab®, Bacterial Vaginosis/Vaginitis