

1/5/2015 - TSO Update, 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 #
<u>S50903</u>		MVista® Blastomyces Quantitative Antigen EIA	1/5/2015	1
<u>S50392</u>		MVista® Histoplasma Quantitative Ag EIA Non-Urine	1/5/2015	2

DISCONTINUED 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>S52252</u>	Partial DMD Del./Dup. Only-Males	2/2/2015	3

Due to these assays being performed by outside vendors, we are unable to use our normal method of communication. Some of the changes listed in this document may be effective in less than 30 days. Please note the individual effective dates below, as these changes may require **IMMEDIATE ACTION**.

Test Changes

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

MVista® Blastomyces Quantitative Antigen EIA	
Effective Date	1/5/2015
Former Test Name	<i>Blastomyces Antigen Urine</i>
Test Code	S50903
Specimen Requirements	Preferred: 2 mL (0.5 mL minimum) random urine collected in a sterile screw cap container Acceptable: 2 mL (0.8 mL minimum) CSF collected in a sterile screw cap container 2 mL (1.2 mL minimum) serum 2 mL (1.2 mL minimum) plasma collected in a sodium heparin (green-top) tube, EDTA (lavender-top) tube, or 3.2% sodium citrate (light blue-top) tube 2 mL (0.5 mL minimum) BAL collected in a sterile screw cap container
Reject Criteria	Samples in transport media, fixative or isolator tubes ; specimens with particulate matter or viscosity; tissue, biopsy, sputum, tracheal aspirate, FNA, bone marrow aspirate, or stool
Instructions	Indicate specimen type and date drawn on test request form. Two unique patient identifiers required on specimen container. Ship to arrive Monday-Friday using a next day delivery service or 2nd day service. Do not ship by first class mail. List all antifungal agents patient is receiving.
Transport Temperature	Refrigerated
Specimen Stability	Room temperature: 48 hours Refrigerated: 14 days Frozen: Indefinite
Units Of Measure	ng/mL
Always Message	Reference interval: None Detected

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	<p>Results reported as ng/mL in 0.2 - 14.7 ng/mL range Results above the limit of detection but below 0.2 ng/mL are reports as 'Positive, Below the Limit of Quantification' Results above 14.7 ng/mL are reported as 'Positive, Above the Limit of Quantification'</p> <p>This test was developed and its performance characteristics determined by MiraVista Diagnostics. It has not been cleared or approved by the FDA; however, FDA clearance or approval is not currently required for clinical use. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.</p> <p>Abbreviations C = Cancelled U = Unable to Test QNS = Quantity Not Sufficient for Testing</p>																
Interface Mapping	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Type</th> <th>Result Name</th> <th>Unit of Measure</th> </tr> </thead> <tbody> <tr> <td>107642</td> <td>Prompt-Result</td> <td>Specimen Type</td> <td></td> </tr> <tr> <td>107643</td> <td></td> <td>Result</td> <td>ng/mL</td> </tr> <tr> <td>107644</td> <td></td> <td>Interpretation</td> <td></td> </tr> </tbody> </table>	Result Code	Type	Result Name	Unit of Measure	107642	Prompt-Result	Specimen Type		107643		Result	ng/mL	107644		Interpretation	
Result Code	Type	Result Name	Unit of Measure														
107642	Prompt-Result	Specimen Type															
107643		Result	ng/mL														
107644		Interpretation															

MVista® Histoplasma Quantitative Ag EIA Non-Urine	
Effective Date	1/5/2015
Former Test Name	Histoplasma AG Non-Urine
Test Code	S50392
Specimen Requirements	<p>Preferred: 2 mL (1.2 mL minimum) serum</p> <p>Acceptable: 2 mL (0.8 mL minimum) CSF collected in a sterile screw cap container 2 mL (1.2 mL minimum) plasma collected in a sodium heparin (green-top) tube, EDTA (lavender-top) tube, or 3.2% sodium citrate (light blue-top) tube 2 mL (0.5 mL minimum) BAL collected in a sterile screw cap container</p>
Reject Criteria	Samples in transport media, fixative or isolator tubes ; specimens with particulate matter or viscosity; tissue, biopsy, sputum, tracheal aspirate, FNA, bone marrow aspirate, or stool
Instructions	<p>Indicate specimen type and date drawn on test request form. Two unique patient identifiers required on specimen container. Ship to arrive Monday-Friday using a next day delivery service or 2nd day service. Do not ship by first class mail. List all antifungal agents patient is receiving.</p>
Transport Temperature	Refrigerated
Specimen Stability	<p>Room temperature: 48 hours Refrigerated: 14 days Frozen: Indefinite</p>
Units Of Measure	ng/mL
Always Message	<p>Reference interval: None Detected</p> <p>Results reported as ng/mL in 0.4 - 19 ng/mL range Results above the limit of detection but below 0.4 ng/mL are reports as 'Positive, Below the Limit of Quantification' Results above 19 ng/mL are reported as 'Positive, Above the Limit of Quantification'</p> <p>This test was developed and its performance characteristics determined by MiraVista Diagnostics. It has not been cleared or approved by the FDA; however, FDA clearance or approval is not currently required for clinical use. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.</p>

	Abbreviations C = Cancelled U = Unable to Test QNS = Quantity Not Sufficient for Testing			
Interface Mapping	Result Code	Type	Result Name	Unit of Measure
	105805	Prompt-Result	Specimen Type	
	105806		Result	ng/mL
	105985		Interpretation	

Discontinued Tests

Partial DMD Del./Dup. Only-Males	
Effective Date	2/2/2015
Test Code	S52252