

12/19/2013 - 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 #
<u>6110</u>		Quantiferon®-TB Gold, (Draw Site Incubated)	12/30/2013	1

REDIRECTS				
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 #
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<u>17396</u>	S51548	HLA-B High Resolution	12/30/2013	2
<u>17394</u>	S51409	HLA-DQB1 High Resolution	12/30/2013	3
<u>17393</u>	S52488	HLA-DRB1 High Resolution	12/30/2013	4

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 #	
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SEND OUTS				
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 #
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<u>S41530</u>		Oligosaccharide Screen, Urine	1/6/2014	5

Due to the background information related to these changes, we are unable to use our normal method of communication. These changes listed in this document are effective in less than 30 days. Please note the individual effective dates below, as some of these changes require IMMEDIATE ACTION.

## 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.

Quantiferon®-TB Gold, (Draw Site Incubated)	
Effective Date	12/30/2013
Former Test Name	<i>Quantiferon®-TB Gold, (Client Incubated)</i>
Test Code	6110

Performing Site	Quest Diagnostics Nichols Institute, Valencia
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**Redirects**

<b>HLA-A High Resolution</b>					
Effective Date	12/30/2013				
Former Test Name	HLA-A High Resolution SBT Typing				
Former Test Code	S51547				
Test Code	17397				
Specimen Requirements	<p><b>Preferred:</b> 14 mL (7 mL minimum) whole blood collected in an EDTA (lavender-top) tube</p> <p><b>Acceptable:</b> Whole blood collected in an ACD (yellow-top) tube</p> <p><b>Pediatric volume:</b> 0-1 year: 3 mL 1-5 years: 5 mL 5-10 years: 7 mL &gt;10 years: 14 mL</p>				
Reject Criteria	Received room temperature > 14 days, received refrigerated or frozen, hemolysis				
Instructions	Samples cannot be shipped on Saturday or the day before a holiday.				
Specimen Stability	Room temperature: 14 days Refrigerated and Frozen: Unacceptable				
Set-up/Analytic Time	Set up: Mon-Sat; Report available: 5-7 days				
Reference Range	Accompanies report				
Always Message	These tests were developed and their performance characteristics were determined by BloodCenter of Wisconsin. They have not been cleared by the FDA. However, this approval is not required.				
Methodology	Direct DNA Sequencing, Polymerase Chain Reaction				
Assay Category	Laboratory Developed Test				
Performing Site	This test previously performed at Quest Diagnostics Nichols Institute, Chantilly will now be performed at Blood Center of Wisconsin.				
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86010571</td> <td>HLA-A High Resolution</td> </tr> </tbody> </table>	Result Code	Result Name	86010571	HLA-A High Resolution
Result Code	Result Name				
86010571	HLA-A High Resolution				

<b>HLA-B High Resolution</b>	
Effective Date	12/30/2013
Former Test Name	HLA-B High Resolution SBT Typing
Former Test Code	S51548
Test Code	17396
Specimen Requirements	<p><b>Preferred:</b> 14 mL (7 mL minimum) whole blood collected in an EDTA (lavender-top) tube</p>

	<p><b>Acceptable:</b> Whole blood collected in an ACD (yellow-top) tube</p> <p><b>Pediatric volume:</b> 0-1 year: 3 mL 1-5 years: 5 mL 5-10 years: 7 mL &gt;10 years: 14 mL</p>				
Reject Criteria	Received room temperature > 14 days, received refrigerated or frozen, hemolysis				
Instructions	Samples cannot be shipped on Saturday or the day before a holiday.				
Specimen Stability	Room temperature: 14 days Refrigerated and Frozen: Unacceptable				
Set-up/Analytic Time	Set up: Mon-Sat; Report available: 5-7 days				
Reference Range	Accompanies report				
Always Message	These tests were developed and their performance characteristics were determined by BloodCenter of Wisconsin. They have not been cleared by the FDA. However, this approval is not required.				
Methodology	Direct DNA Sequencing, Polymerase Chain Reaction				
Assay Category	Laboratory Developed Test				
Performing Site	This test previously performed at Quest Diagnostics Nichols Institute, Chantilly will now be performed at Blood Center of Wisconsin.				
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86010576</td> <td>HLA-B High Resolution</td> </tr> </tbody> </table>	Result Code	Result Name	86010576	HLA-B High Resolution
Result Code	Result Name				
86010576	HLA-B High Resolution				

HLA-DQB1 High Resolution	
Effective Date	12/30/2013
Former Test Name	HLA-DQB1 High Resolution SBT Typing
Former Test Code	S51409
Test Code	17394
Specimen Requirements	<p><b>Preferred:</b> 14 mL (7 mL minimum) whole blood collected in an EDTA (lavender-top) tube</p> <p><b>Acceptable:</b> Whole blood collected in an ACD (yellow-top) tube</p> <p><b>Pediatric volume:</b> 0-1 year: 3 mL 1-5 years: 5 mL 5-10 years: 7 mL &gt;10 years: 14 mL</p>
Reject Criteria	Received room temperature > 14 days, received refrigerated or frozen, hemolysis
Instructions	Sample cannot be shipped on Saturday or the day before a holiday.
Specimen Stability	Room temperature: 14 days Refrigerated and Frozen: Unacceptable
Set-up/Analytic Time	Set up: Mon-Sat; Report available: 5-7 days
Reference Range	Accompanies report
Always Message	These tests were developed and their performance characteristics were determined by BloodCenter of Wisconsin. They have not been cleared by the FDA. However, this approval is not required.

Methodology	<b>Direct DNA Sequencing, Polymerase Chain Reaction</b>					
Assay Category	<b>Laboratory Developed Test</b>					
Performing Site	<b>This test previously performed at Quest Diagnostics Nichols Institute, Chantilly will now be performed at Blood Center of Wisconsin.</b>					
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86010580</td> <td>HLA-DQB1 High Resolution</td> </tr> </tbody> </table>		Result Code	Result Name	86010580	HLA-DQB1 High Resolution
Result Code	Result Name					
86010580	HLA-DQB1 High Resolution					

<b>HLA-DRB1 High Resolution</b>					
Effective Date	<b>12/30/2013</b>				
Former Test Name	<i>HLA-DRB1 High Resolution SBT Typing</i>				
Former Test Code	<i>S52488</i>				
Test Code	<b>17393</b>				
Specimen Requirements	<p><b>Preferred:</b> 14 mL (7 mL minimum) whole blood collected in an EDTA (lavender-top) tube</p> <p><b>Acceptable:</b> Whole blood collected in an ACD (yellow-top) tube</p> <p><b>Pediatric volume:</b> 0-1 year: 3 mL 1-5 years: 5 mL 5-10 years: 7 mL &gt;10 years: 14 mL</p>				
Reject Criteria	<b>Received room temperature &gt; 14 days, received refrigerated or frozen, hemolysis</b>				
Instructions	<b>Samples cannot be shipped on Saturday or the day before a holiday.</b>				
Specimen Stability	<b>Room temperature: 14 days</b> <b>Refrigerated and Frozen: Unacceptable</b>				
Set-up/Analytic Time	<b>Set up: Mon-Sat; Report available: 5-7 days</b>				
Always Message	<b>These tests were developed and their performance characteristics were determined by BloodCenter of Wisconsin. They have not been cleared by the FDA. However, this approval is not required.</b>				
Methodology	<b>Direct DNA Sequencing, Polymerase Chain Reaction</b>				
Assay Category	<b>Laboratory Developed Test</b>				
Performing Site	<b>This test previously performed at Quest Diagnostics Nichols Institute, Chantilly will now be performed at Blood Center of Wisconsin.</b>				
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86010582</td> <td>HLA-DRB1 High Resolution</td> </tr> </tbody> </table>	Result Code	Result Name	86010582	HLA-DRB1 High Resolution
Result Code	Result Name				
86010582	HLA-DRB1 High Resolution				

**Discontinued Test**

<b>Trichomonas Direct Detection, DFA</b>	
Effective Date	<b>12/30/2013</b>

12/19/2013 - Immediate Action, Quest Diagnostics Nichols Institute, Valencia

Test Code	S44940
Additional Information	<p>This test will be discontinued due to reagent unavailability. The recommended alternatives are:</p> <p>For females:</p> <ul style="list-style-type: none"> <li>19550 (19550X) [4640]- SureSwab® Trichomonas vaginalis RNA, Qualitative TMA performed at Quest Diagnostics Nichols Institute, Valencia</li> </ul> <p>For males:</p> <ul style="list-style-type: none"> <li>90801- Trichomonas vaginalis RNA, Qualitative TMA, Males, performed at Quest Diagnostics Nichols Institute, Valencia</li> </ul>

**Test Send Outs (Referrals)**

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**.

<b>Prostaglandins D2, Serum or Plasma</b>	
Effective Date	12/30/2013
Test Code	S48755
Instructions	<p>3 ml serum or EDTA plasma should be collected and separated as soon as possible. Freeze specimen immediately after separation. Ship specimens frozen on dry ice.</p> <p>Patient Preparation: Patient should not be on aspirin, indomethacin, or anti-inflammatory medications, if possible, for at least 48 hours prior to collection of specimen.</p>
Transport Temperature	Frozen
Specimen Stability	Room temperature and Refrigerated: Unacceptable Frozen: 30 days

<b>Galactose-1-Phosphate (G-1-P), Erythrocytes</b>	
Effective Date	1/6/2014
Test Code	S48547NY
Set-up/Analytic Time	Set up: Wed; Report available: 8 days
Reference Range	<p>Non-galactosemic: 5-49 mcg/g of hemoglobin (&lt;1 mg/dL)</p> <p>Galactosemic on galactose restricted diet: 80-125 mcg/g of hemoglobin (1-4 mg/dL)</p> <p>Galactosemic on unrestricted diet: &gt;125 mcg/g of hemoglobin (&gt;4 mg/dL)</p>
Methodology	Ultraviolet, Enzymatic

<b>Oligosaccharide Screen, Urine</b>	
Effective Date	1/6/2014
Test Code	S41530
Additional Information	Discontinued due to low use, there is no recommended alternative.

