

1/10/2014 - Immediate Action, Quest Diagnostics Nichols Institute, Valencia

Revision Message!
 Please note: 1/31/14 communication revision for test code 91593- Prenat-IQ™, Noninvasive prenatal test (NIPT) and 91673- Panorama™ Prenatal Test (NY), the launch of these test changes will be held until further notice.

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 #
91593		Prenat-IQ™, Noninvasive Prenatal Test (NIPT)	2/10/2014	1

NY UPDATE
 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	Page #
91772	KIT D816, Mutation Analysis (Mastocytosis)	3
91673	Panorama™ Prenatal Test (NY)	3

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 #
S52235		Rabies Vaccine Response End-Point Titer	1/10/2014	4

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.

Redirect

Prenat-IQ™, Noninvasive Prenatal Test (NIPT)	
Revision Message!	Please note: The launch of this assay at Quest Diagnostics, San Juan Capistrano will be postponed until further notice effective 1/31/14.
Message	** This test is not available for New York patient testing ** For New York patient testing use test code 91673- Panorama™ Prenatal Test (NY), performed at Natera, Inc. listed in the New York section.
Clinical Significance	Fetal chromosomal aneuploidies for chromosomes 13, 18, 21 and X and Y, as well as triploidy, will be determined through this non-invasive test using plasma obtained from the mother's whole blood.
Effective Date	2/10/2014
Former Test Name	Panorama™ Prenatal Test
Test Code	91593
Specimen Requirements	10 mL (10 mL minimum) in each of 2 tubes of whole blood collected in a Streck cell-free (black/tan tiger top) glass tube
Reject Criteria	Samples received past 4 days after draw; samples received refrigerated or frozen; gestational age is less than 9 weeks; pregnancy is not a singleton; pregnancy resulted from a donor egg; mother w/a non autologous bone marrow transplant; hemolysis

Instructions	<p>** This test is not available for New York patient testing. ** Whole blood: Store at 18°-26° C; Must be received in the laboratory within 4 days of draw. Please completely fill (x2) Streck BCT collection tubes. USE ONLY STRECK BCT COLLECTION TUBE (Streck, item#167568). Paternal Buccal Swab is acceptable if submitted along with the whole blood. If submitting Paternal Buccal Swab do not order a separate test. Submit samples together Specific DNA collection kit must be used: Request Quest Client supply part# 169045 Buccal Swab, DNA Collection Kit, For Celera</p>																																																																																															
Specimen Stability	<p>Room temperature: 4 days Refrigerated and Frozen: Unacceptable</p>																																																																																															
Set-up/Analytic Time	<p>Set up: Daily; Report available: 10 days</p>																																																																																															
Always Message	<p>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>																																																																																															
Assay Category	<p>Laboratory Developed Test</p>																																																																																															
Performing Site	<p>This test previously performed at Natera, Inc. will now be performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.</p>																																																																																															
CPU Mappings	<table border="1"> <thead> <tr> <th data-bbox="505 905 667 953">Result Code</th> <th data-bbox="667 905 984 953">Type</th> <th data-bbox="984 905 1308 953">Result Name</th> <th data-bbox="1308 905 1511 953">Unit of Measure</th> </tr> </thead> <tbody> <tr> <td data-bbox="505 953 667 1001">86010322</td> <td data-bbox="667 953 984 1001">Prompt-Result (no return)</td> <td data-bbox="984 953 1308 1001">EDD</td> <td data-bbox="1308 953 1511 1001"></td> </tr> <tr> <td data-bbox="505 1001 667 1050">86009329</td> <td data-bbox="667 1001 984 1050"></td> <td data-bbox="984 1001 1308 1050">Gestational Age</td> <td data-bbox="1308 1001 1511 1050">weeks</td> </tr> <tr> <td data-bbox="505 1050 667 1098">86010323</td> <td data-bbox="667 1050 984 1098">Prompt-Result</td> <td data-bbox="984 1050 1308 1098">Maternal Weight</td> <td data-bbox="1308 1050 1511 1098"></td> </tr> <tr> <td data-bbox="505 1098 667 1146">86009331</td> <td data-bbox="667 1098 984 1146">Prompt-Result</td> <td 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	86009348		T13 Comments	
	86009351		MX Age Based Risk	
	86009353		MX Panorama Risk Score	
	86009354		MX Result	
	86009364		MX Comments	
	86010327		TR/VT Result	
	86010328		TR/VT Comments	
	86009359		Message	
	86009349		Testing Methodology	
	86009350		Limitations	
	86009363		Approved By:	
Additional Information	Removed Reference analyte.			

New York Patient Testing Update

KIT D816, Mutation Analysis (Mastocytosis)	
Message	** This test is <i>not available</i> for New York patient testing.**
Effective Date	1/10/2014
Test Code	91772

Panorama™ Prenatal Test (NY)																															
Revision Message!	Please note: This reactivation of this test will be postponed until further notice effective 1/31/14.																														
Message	For non-New York patient testing, use test code 91593- Prenat-IQ™, Noninvasive Prenatal Test (NIPT)																														
Effective Date	2/10/2014																														
Test Code	91673																														
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86009334		T21 Age Based Risk																													
86009336		T21 Panorama Risk Score																													
86009337		T21 Result																													

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86009338		T21 Comments
86009339		T18 Age Based Risk
86009341		T18 Panorama Risk Score
86009342		T18 Result
86009343		T18 Comments
86009344		T13 Age Based Risk
86009346		T13 Panorama Risk Score
86009347		T13 Result
86009348		T13 Comments
86009351		MX Age Based Risk
86009353		MX Panorama Risk Score
86009354		MX Result
86009364		MX Comments
86010327		TR/VT Result
86010328		TR/VT Comments
86009359		Message
86009349		Testing Methodology
86009350		Limitations
86009330		Reference
86009363		Approved By:

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**.

Rabies Vaccine Response End-Point Titer	
Message	***TSO LABORATORY RESTRICTIONS*** This vendor is not Florida or New York Certified. Therefore, this code is not available to Florida or New York Clients.
Effective Date	1/10/2014
Test Code	S52235
Always Message	<p>Rabies Neutralizing Antibody Titration (RFFIT) Result Verified By:</p> <p>Susan M. Moore, Managing Director Rabies Laboratory KSVDL</p> <p>In humans, a result of 0.5 IU/mL or higher is considered an acceptable response to rabies vaccination according to the World Health Organization (WHO) guidelines; see WHO and Advisory Committee on Immunization Practices documents for additional guidance. Also, there is more information at www.vet.ksu.edu/rabies. (Note: the symbol ">" means "greater than" and ">=" means "greater than or equal to") Results are confidential personal health information. All</p>

disclosures must be in accordance with HIPAA.