

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

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 #
<a href="#">91593</a>		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 #
<a href="#">91772</a>	KIT D816, Mutation Analysis (Mastocytosis)	3
<a href="#">91673</a>	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 #
<a href="#">S52235</a>		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)	
Message	<b>** 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.</b>
Clinical Significance	<b>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.</b>
Effective Date	<b>2/10/2014</b>
Former Test Name	<i>Panorama™ Prenatal Test</i>
Test Code	91593
Specimen Requirements	10 mL ( <b>10 mL minimum</b> ) in each of 2 tubes of whole blood collected in a Streck cell-free (black/tan tiger top) glass tube
Reject Criteria	<b>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</b>
Instructions	<p><b>** This test is not available for New York patient testing. **</b></p> <p><b>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).</b></p> <p><b>Paternal Buccal Swab is acceptable if submitted along with the whole blood. If submitting Paternal Buccal Swab do not order a separate test.</b></p> <p><b>Submit samples together</b></p> <p><b>Specific DNA collection kit must be used:</b>  <b>Request Quest Client supply part# 169045</b>  <b>Buccal Swab, DNA Collection Kit, For Celera</b></p>

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Specimen Stability	<b>Room temperature: 4 days</b> Refrigerated and Frozen: Unacceptable			
Set-up/Analytic Time	<b>Set up: Daily; Report available: 10 days</b>			
Always Message	<b>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.</b>			
Assay Category	<b>Laboratory Developed Test</b>			
Performing Site	<b>This test previously performed at Natera, Inc. will now be performed at Quest Diagnostics Nichols Institute, San Juan Capistrano.</b>			
CPU Mappings	<b>Result Code</b>	<b>Type</b>	<b>Result Name</b>	<b>Unit of Measure</b>
	<b>86010322</b>	<b>Prompt-Result (no return)</b>	<b>EDD</b>	
	86009329		Gestational Age	<b>weeks</b>
	86010323	Prompt-Result	Maternal Weight	
	86009331	Prompt-Result	Gender Of Fetus Requested	
	<b>86010324</b>	<b>Prompt-Result (no return)</b>	<b>Paternal swab submitted?</b>	
	<b>86010325</b>	<b>Prompt-Result (no return)</b>	<b>Paternal name</b>	
	<b>86010326</b>	<b>Prompt-Result (no return)</b>	<b>Paternal DOB</b>	
	<b>86010419</b>		<b>Paternal Swab Received?</b>	
	86009366		Gender of Fetus	
	86009365		% Fetal Fraction	<b>%</b>
	86009333		NIPT Interpretation	
	86009334		T21 Age Based Risk	
	86009336		T21 Panorama Risk Score	
	86009337		T21 Result	
	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	

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	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 <b>not available</b> for New York patient testing.**
Effective Date	1/10/2014
Test Code	91772

Panorama™ Prenatal Test (NY)																																																				
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	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**.

<b>Rabies Vaccine Response End-Point Titer</b>	
Message	<b>***TSO LABORATORY RESTRICTIONS*** This vendor is not Florida or New York Certified. Therefore, this code is not available to Florida or New York Clients.</b>
Effective Date	<b>1/10/2014</b>
Test Code	S52235
Always Message	<p>Rabies Neutralizing Antibody Titration (RFFIT) Result Verified By:</p> <p><b>Susan M. Moore, Managing Director</b>  <b>Rabies Laboratory KSVDL</b></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 <a href="http://www.vet.ksu.edu/rabies">www.vet.ksu.edu/rabies</a>. (Note: the symbol "&gt;" means "greater than" and "&gt;=" means "greater than or equal to") Results are confidential personal health information. All disclosures must be in accordance with HIPAA.</p>