

4/12/2013 - New Release, Quest Diagnostics Nichols Institute, Valencia

NEW 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 #
91673	Panorama™ Prenatal Test (NY)	4/12/2013	1

New Test Offerings

The following tests will be available through Quest Diagnostics on the dates indicated below.

Panorama™ Prenatal Test (NY)	
Message	For Non-New York patient testing, use test code 91593
Clinical Significance	This test detects the following fetal aneuploidies as early as 9 weeks of gestation: Trisomy 21 (Down Syndrome), Trisomy 18 (Edward Syndrome), Trisomy 13 (Patau Syndrome), and Monosomy X (Turner Syndrome). Panorama™ is the latest advance in a novel class of prenatal test: noninvasive prenatal test (NIPT). It uses cell free fetal DNA circulating in the plasma of the pregnant women to detect fetal aneuploidy. This technology is noninvasive and offers higher sensitivity and specificity than the current standard of care for screening tests. In December 2012, ACOG (The American College of Obstetricians and Gynecologists) issued a committee opinion on NIPT suggesting NIPT to be used as a primary screening test in women at increased risk of aneuploidy, or as a follow-up test for women with a positive first-trimester or second-trimester maternal serum screening result ¹⁻³ . References: Lo YM, Corbetta N, et al. Presence of fetal DNA in maternal plasma and serum. Lancet 1997; 350:485-7. ACOG Committee Opinion, Number 545, Dec 2012, Noninvasive prenatal testing for fetal Aneuploidy Zimmermann B, et al. Noninvasive prenatal aneuploidy testing of chromosomes 13, 18, 21, X, and Y, using targeted sequencing of polymorphic loci. Prenatal Diagnosis 2012, 32, 1233–1241
Effective Date	4/12/2013
Test Code	91673
CPT Codes	81599 Coding may vary depending on health plan or government payer requirements. CMS does not currently recognize MAAA CPT codes.
Specimen Requirements	20 mL (16 mL minimum) whole blood collected in 2 cell free Streck tubes per patient (glass tubes, black and tan stopper) Note: For pregnancy only. Test not performed for multiple gestations, pregnancies by egg donor or surrogacy.
Reject Criteria	Gross hemolysis; received frozen; received refrigerated; less than 8 mL in each tube; whole blood collected in tubes other than Streck Tube; greater than 5 days at room temperature
Instructions	Special instructions - only for New York State clients: NY State Department of Health requires that a “New York State Non-Permitted Laboratory Test Request Approval Form” be completed prior to patient testing. To obtain this form, please contact your Quest Diagnostics sales representative or local client services. Collect 10 mL in each tube (fill each tube at least 3/4 full) and maintain specimen at room temperature. Do not refrigerate or freeze. Ensure same day transportation, as processing of specimen is time sensitive.
Transport Temperature	Room temperature
Specimen Stability	Room temperature: 5 days Refrigerated and Frozen: Unacceptable
Set-up/Analytic Time	Set up: daily; Report available: 10 – 15 business days

Reference Range	Accompanies report																																																																															
Methodology	SNP Targeted Sequencing																																																																															
Performing Site	Natera, Inc.																																																																															
CPU Mappings	<table border="1"> <tr> <td>86009329</td> <td>Prompt Return</td> <td>Gestational Age</td> </tr> <tr> <td>86009331</td> <td>Prompt Return</td> <td>Gender of Fetus Requested</td> </tr> <tr> <td>86009366</td> <td></td> <td>Gender of Fetus</td> </tr> <tr> <td>86009365</td> <td></td> <td>% Fetal Fraction</td> </tr> <tr> <td>86009333</td> <td></td> <td>NIPT Interpretation</td> </tr> <tr> <td>86009334</td> <td></td> <td>T21 Age Based Risk</td> </tr> <tr> <td>86009336</td> <td></td> <td>T21 Panorama Risk Score</td> </tr> <tr> <td>86009337</td> <td></td> <td>T21 Result</td> </tr> <tr> <td>86009338</td> <td></td> <td>T21 Comments</td> </tr> <tr> <td>86009339</td> <td></td> <td>T18 Age Based Risk</td> </tr> <tr> <td>86009341</td> <td></td> <td>T18 Panorama Risk Score</td> </tr> <tr> <td>86009342</td> <td></td> <td>T18 Result</td> </tr> <tr> <td>86009343</td> <td></td> <td>T18 Comments</td> </tr> <tr> <td>86009344</td> <td></td> <td>T13 Age Based Risk</td> </tr> <tr> <td>86009346</td> <td></td> <td>T13 Panorama Risk Score</td> </tr> <tr> <td>86009347</td> <td></td> <td>T13 Result</td> </tr> <tr> <td>86009348</td> <td></td> <td>T13 Comments</td> </tr> <tr> <td>86009351</td> <td></td> <td>MX Age Based Risk</td> </tr> <tr> <td>86009353</td> <td></td> <td>MX Panorama Risk Score</td> </tr> <tr> <td>86009354</td> <td></td> <td>MX Result</td> </tr> <tr> <td>86009364</td> <td></td> <td>MX Comments</td> </tr> <tr> <td>86009359</td> <td></td> <td>Message</td> </tr> <tr> <td>86009349</td> <td></td> <td>Testing Methodology</td> </tr> <tr> <td>86009350</td> <td></td> <td>Limitations</td> </tr> <tr> <td>86009330</td> <td></td> <td>Reference</td> </tr> <tr> <td>86009363</td> <td></td> <td>Approved by:</td> </tr> </table>		86009329	Prompt Return	Gestational Age	86009331	Prompt Return	Gender of Fetus Requested	86009366		Gender of Fetus	86009365		% Fetal Fraction	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	86009359		Message	86009349		Testing Methodology	86009350		Limitations	86009330		Reference	86009363		Approved by:
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