3/10/2015 - Special Communication, 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 #**
92777	**QNatal™ Advanced**	4/13/2015	

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 #**
92530	MaterniT21™ Plus (T21Q)	4/13/2015	

Dear Valued Client,

We are pleased to announce the availability of our Quest Diagnostics laboratory developed test for noninvasive prenatal screening, QNatal™ Advanced NIPS. This test has been developed, validated and is performed exclusively at Quest Diagnostics.

As a result, Quest will no longer offer the MaterniT21® PLUS prenatal test from Sequenom Laboratories. QNatal™ Advanced is a medically equivalent test with some enhancements. QNatal™ Advanced screens for common fetal aneuploidies including trisomies 21, 18, and 13 as well as fetal sex aneuploidies and select copy number variants. In addition, QNatal™ Advanced accurately measures and reports fetal fraction. The test methodology includes full end to end automation and a high depth of sequencing at 10 million reads.

QNatal Advanced™ NIPS is the latest addition to our extensive menu of Quest developed prenatal genetic screens and diagnostic tests for fetal aneuploidy. Our team of expert medical geneticists and genetic counselors can provide full continuity in evaluating your patients for risk of fetal chromosomal abnormalities.

New Test Offering

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

QNatal™ Advanced	
Message	***** This test is not available for New York patient testing. For New York patient testing use test code 91933-MaterniT21™ Plus (NY). *****
Clinical Significance	**The NIPT tests for fetal chromosomal abnormalities for trisomy 21, 18 and 13. In addition when a clear result is seen, will also report fetal sex aneuploidies, trisomy 16 and 22, and select microdeletions, including 22q (DiGeorge syndrome), 15q (Prader-Willi/Angelman syndromes), 11q (Jacobsen syndrome), 8q (Langer-Giedion syndrome), 5p (Cri-du-chat syndrome), 4p (Wolf-Hirschhorn syndrome), and 1p36 deletion syndrome as an additional finding.**
Effective Date	**4/13/2015**
Test Code	**92777**
CPT Codes	**81420**
Specimen Requirements	**10 mL (8 mL minimum) whole blood collected in each of two separate Streck cell-free (black/tan tiger top) tube**
Instructions	**Do not draw before 10 weeks gestation. Use Streck tubes only.**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 7 days** **Refrigerated and Frozen: Unacceptable**

Set-up/Analytic Time	**Set up: Daily; Report available: 7-8 days**
Reference Range	**Accompanies report**
Methodology	**Next Generation Sequencing**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**

Interface Mapping

Result Code	Type	Result Name	Unit of Measure
86010421	Prompt-Result (no return)	Collection Date	
86012060	Prompt-Result (no return)	EDD	
86012061	Prompt-Result	Number of Fetuses?	
86012062	Prompt-Result (no return)	Maternal Height (Feet)	ft
86012063	Prompt-Result (no return)	Maternal Height (Inches)	in
86012064	Prompt-Result (no return)	Maternal Weight (lbs)	lbs
86012065	Prompt-Result	Advanced Maternal Age?	
86012066	Prompt-Result	Abnormal MSS?	
86012067	Prompt-Result	Abnormal US?	
86012068	Prompt-Result	Personal/Fam History?	
86012069	Prompt-Result (no return)	Opt Out Microdels?	
86012070	Prompt-Result (no return)	Opt Out Fetal Sex?	
86012071	Prompt-Result (no return)	Additional Comments	
86012072		Interpretation	
86012073		Trisomy 21 (T21)	
86012074		Trisomy 18 (T18)	
86012075		Trisomy 13 (T13)	
86012076		Y Chromosome	
86012077		Y Chr. Interpretation	
86012078		Sex Chromosome	
86012079		Sex Chromosome Interp	
86012080		Microdeletion	
86012081		Microdeletion Interp	
86012082		Gestational Age (in weeks)	
86012083		Gestational Age (in days)	
86012084		Fetal Fraction	
86012085		Laboratory Comments	
86012086		Limitations	
86012087		Specifications	
86012088		Methodology	

Discontinued Test

MaterniT21™ Plus (T21Q)	
Effective Date	**4/13/2015**
Test Code	92530
Additional Information	The recommended alternative is test code 92777-QNatal™ Advanced in the New Test Offering section.