

9/3/2015 - 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>92777</u>		QNatal™ Advanced	9/8/2015	1

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 #
<u>S50964</u>		Amaranth FD&C Red #2	9/3/2015	1

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 information that is changing appears in bold text in this update. Former test names and test codes have been italicized.

QNatal™ Advanced	
Clinical Significance	The NIPS screens for fetal chromosomal abnormalities: trisomy 21, 18 and 13, as well as fetal sex. In addition, when a clear result is seen, will also report fetal sex aneuploidies and select microdeletions, including 22q (DiGeorge syndrome), 15q (Prader-Willi/Angelman syndromes), 11q (Langer-Giedion syndrome), 5p (Cridu-chat syndrome), 4p (Wolf-Hirschhorn syndrome), and 1p36 deletion syndrome as an additional finding.
Effective Date	9/8/2015
Test Code	<i>92777</i>
Instructions	Do not draw before 10 weeks gestation. Use Streck tubes only. Volume 20 mL (16 mL minimum) whole blood collected in two Streck cell-free (black/tan tiger top) glass tubes (10 mL in each tube).
Set-up/Analytic Time	Set up: Wed-Sat; Report available: 7 days Plasma separation 7 days a week
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Test Send Out (Referrals)

Amaranth FD&C Red #2	
Effective Date	9/3/2015
Test Code	<i>S50964</i>
Additional Information	The vendor has discontinued this assay with no recommended alternative.