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 #**
S49734		Limulus Amebocyte Lysate (Endotoxin)	2/17/2014	1
14530		Lp-PLA2 (Lipoprotein-Associated Phospholipase A2)	2/17/2014	2
35079		Hereditary Hemochromatosis DNA Mutation Analysis	3/17/2014	2

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		3

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 that only the information that is changing appears in this update.** *Former test names and test codes have been italicized.*

Limulus Amebocyte Lysate (Endotoxin)	
Effective Date	**2/17/2014**
Test Code	S49734
Specimen Requirements	5 ml Aqueous solutions used in patient management or cell cultures for clinical trials. **Submitted in a nonpyrogenic plastic leakproof container**. Do not send in a glass tube.
Reject Criteria	Specimens sent in glass tubes; **body fluids**
Specimen Stability	**Room temperature and Refrigerated: Unacceptable** **Frozen: 30 days**
Reference Range	**Level Detected** / **Interpretation** **<0.05 EU/mL** — **None detected** **<0.25 EU/mL** — **Maximum allowable level for dialysis water** **0.125 EU/mL** — **Action level for dialysis water** **<0.50 EU/mL** — **Maximum allowable level for dialysis fluid** **0.25 EU/mL** — **Action level for dialysis fluid** **<0.25 EU/mL** — **USP acceptable limits for injectable or irrigation water** **<0.50 EU/mL** — **USP acceptable limits for inhalatory water** **2.00 EU/mL** — **Acceptable upper limit for hemo-dialysis reuse water**
Always Message	**The LAL is used as a quantitative test to detect gram-negative endotoxin in aqueous solutions used in patient management. The LAL assay is not recommended for serum or plasma samples due to the**

	presence of inhibitory factors. It is essential to maintain specimen sterility and prevent false positive results from exogenous gram negative bacteria.
Methodology	**Kinetic**
Performing Site	Focus Diagnostics, Inc.

Lp-PLA2 (Lipoprotein-Associated Phospholipase A2)	
Effective Date	**2/17/2014**
Test Code	14530
Reject Criteria	Samples stored and shipped room temperature; **Samples received at -20°C**
Instructions	Specimens should be centrifuged and separated within 2 hours of venipuncture. Serum separator tubes are acceptable**. Store samples refrigerated prior to courier pick-up. Transport on dry ice.** **For longer term storage samples must be maintained below -60°C.**
Specimen Stability	Room temperature: Unacceptable Refrigerated: 14 days **Frozen -20°C: Unacceptable** Frozen -70°C: 30 days
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 3 days**
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Hereditary Hemochromatosis DNA Mutation Analysis	
Message	****This test is not approved for New York patient testing. For New York patient testing, use test code 36193*****
Clinical Significance	**Hereditary Hemochromatosis (HH) is an inherited disorder wherein the body accumulates excess iron. This test establishes HH diagnosis in individuals with abnormal iron study results and identifies at-risk family members.**
Effective Date	**3/17/2014**
Test Code	35079
Specimen Requirements	Preferred: 5 mL (3 mL minimum) whole blood collected in an EDTA (lavender-top) tube Acceptable: 5 mL (3 mL minimum) whole blood collected in an EDTA (royal blue-top), sodium heparin (green-top), ACD solution B (yellow-top) or **ACD solution A (yellow-top)** tube **Extracted DNA: Please call 1-866-GENE-INFO (1-866-436-3463) for additional information**.
Instructions	**Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship room temperature immediately. Do not freeze.** **Extracted DNA: Please call 1-866-GENE-INFO (1-866-436-3463) for additional information.**
Set-up/Analytic Time	**Set up: Tues, Thurs, Sat; Report available: 7 days**
Methodology	**Fluorescent Restriction Fragment Length Polymorphism, Polymerase Chain Reaction (PCR)**
Performing Site	**This test previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano will now be performed at Quest Diagnostics Nichols Institute, Chantilly.**
CPU Mappings	**Result Code** / **Result Name** **85987560** / DNA Mutation Analysis

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	
Message	***** This test is now available for New York State patient testing**** **Please note:** this test is still restricted for Florida patient testing.
Test Code	S52235