Immediate Action Update August 3, 2011

Business Unit: Quest Diagnostics Nichols Institute, Valencia

Table of Contents

Summary of Test Changes

Test Name	Test Code(s)	Performing Site	Test Code	Test Name	Specimen Requirements	Shipping Temperature	Specimen Stability	Units of Measure	Reference Range	Methodology	CPT Codes	Reject Criteria	Other (see listing)
Pain Management, Alcohol Metabolites, with Confirmation, Urn	**16910**												X

The CPT Codes provided in this document are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed. Any Profile/panel component may be ordered separately. Reflex tests are performed at an additional charge.

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 codes and test names have been italicized.

Pain Management, Alcohol Metabolites, with Confirmation, Urn		
Effective Date	**August 1, 2011**	
Test Code:	**16910**	
Additional Information:	**Added component**	
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**	
CPU Interface Mapping: Add component	**Result Code:**	**Result Name:**
	82000625	**Please Note**

Test Redirects

FLT3 (ITD) and D835 Variant Detection by PCR ****** This test is not available for New York patient testing. There is not a recommended alternative for NY patient testing available at this time.******		
Effective Date	**August 1, 2011**	
Test Code:	**S52494**	
CPT Code(s):	**83891, 83898 (x2) 83892, 83909 (x2), 83912**	
Former Test Name:	***FLT3 & NPM1 GENOTYPR***	
Former Test Code:	***5038***	
Specimen Requirements:	**Type:**	**Peripheral blood collected in EDTA (lavender-top) tube. The sample requirements are PB or BM (Heparin, EDTA or ACD anticoagulants), isolated DNA and isolated frozen cells (i.e. left-over flow cytometry specimens). For PB and BM, submit 0.5 mL of sample (although any amount received will be run). Fixed cells or tissue are unacceptable. Submit PB and BM samples within 7 days of draw. Primary samples received after 7 days of draw will be run (with a disclaimer), but if the sample is QNS the lab will charge for testing. Primary samples that are greater than 14 days after draw will not be run.**
	Opt Volume:	
	Min Volume:	**5.0 mL 0.5 mL**
Transport Temperature:	**Room temperature**	
Specimen Stability:	**Room Temperature: 72 hours Refrigerated: 7 days Frozen: Unacceptable**	
Set-Up/Analytic Time:	**Set-up: Mon-Fri; Report Available: 4-5 days Vendor does not accept samples Sat/Sun/Holidays**	
Reference Ranges:	**FLT3 ITD FLT3 D835**	**Negative Negative**
Methodology:	**Polymerase Chain Reaction**	
Always Message:	**PCR for both the Internal Tandem Duplication (ITD) and the D835 mutation was performed on DNA isolated from the**	

	patient sample using fluorescently labeled primers specific for the areas immediately surrounding the ITD and D835 mutations. The PCR product for the ITD is directly run on an ABI 3130x1 genetic analyzer and size of the product determined. The D835 mutation PCR product is cut with the EcoRV restriction enzyme, run on the ABI 3130x1 genetic analyzer, and the sizes of the digested PCR products are determined. This assay has an analytical sensitivity of 5 FLT3 variant containing cells in 100 total cells. **This test was developed and its performance characteristics determined by the Laboratory for Personalized Molecular Medicine(TM). It has not been cleared or approved by the U.S. Food and Drug Administration. However, such approval is not required for clinical implementation, and test results have been shown to be clinically useful. The Laboratory for Personalized Molecular Medicine(TM) is CLIA certified to perform high complexity testing.** **This test was performed under the direction of William B. Praxton,MD,PhD,FCAP** ***FLT3 Mutation Testing is performed pursuant to patents licensed from Takara Bio of Otsu, Japan.** ***NPM1 Mutation Testing is performed pursuant to patents licensed from TrovaGene of San Diego, CA.**	
Performing Site:	**LabPMM, Laboratory for Personalized Molecular Medicine**	
CPU Interface Mapping:	**Result Code:**	**Result Name:**
	113471	**FLT3 ITD**
	113472	**FLT3 D835**
	113473	**Comment**
	113474	**Interpretation**

Test Discontinuations

FLT3 & NPM1 GenotypR™	
Effective Date	**August 1, 2011**
Test Code:	**5038**
Additional Information:	**Suggested Alternate: S52494 -FLT3 (ITD) and D835 Variant Detection by PCR**
Performing Site:	**LabPMM, Laboratory for Personalized Molecular Medicine**

FLT3 & NPM1 GenotypR™ – Paraffin Block	
Effective Date	**August 1, 2011**
Test Code:	**5038BK**
Additional Information:	**No alternate available.**
Performing Site:	**Quest Diagnostics Nichols Institute, Valencia**