

**FLT3 MUTATION TESTING**  
**#91837**

**EXPLANATION OF CHANGE:** Effective immediately, Unit Code 91837, FLT3 Mutation Testing, referred to LabPMM, will be updated to reflect the following changes:

	<b>CURRENT</b>	<b>NEW</b>
Unit Code Always Message:	<p>Assay Description</p> <p>Multiplex 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.</p> <p>This test was developed and its performance characteristics determined by the Laboratory for Personalized Molecular Medicine. 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 of Personalized Molecular Medicine is CLIA certified to perform high complexity testing.</p>	<p>This test was developed and its performance characteristics determined by the Laboratory for Personalized Molecular Medicine. 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 of Personalized Molecular Medicine is CLIA certified to perform high complexity testing.</p>

QUESTIONS: Contact Mayo Medical Laboratories  
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