

Test Update 876

Posted Date 05/08/2024 **Effective Date** 06/04/2024 **Update Type** <u>New Tests</u> **CPT Code** 81272, 88381-TC, G0452-26, 88381-26

KIT and PDGFRA Mutation for GIST

Order Code: GISTN

Fee Code: NA128, NA037 (CPT 81272, 88381-TC, G0452-26, 88381-26)

The MLabs Molecular Diagnostics Laboratory will begin offering KIT and PDGFRA Mutation for GIST by Next-Generation Sequencing (NGS) effective June 4, 2024. This test will replace the KIT Mutation – Exons 9, 11, 13, 17 and PDGFRA Mutation for GIST assays.

<u>Collection Instructions</u>: For formalin-fixed, paraffin-embedded tissue, a block containing an area with a high percentage of neoplastic cells (for micro-/macro-dissection) is preferred. Unstained, UNBAKED slides (5-8, 10-micron slides; 10-15 if few neoplastic cells are present) with associated H&E-stained slide are also acceptable. Decalcified tissue or other fixatives will be accepted and the assay attempted; however, these specimens may result in failed testing due to degraded nucleic acid. A Diff-Quik or Papanicolaou stained aspirate smear (preferable containing a high percentage and overall number of neoplastic cells) is also acceptable. Both blocks and slides should be stored at room temperature.

<u>Test Limitations</u>: This test will detect only the mutations within specific gene regions. A negative result does not rule out the presence of a mutation outside of the sequenced regions or a low-level mutation below the sensitivity of detection (approximately 5% variant allele frequency).

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