Melanoma Panel

Indication: Targeted next generation sequencing assay for detection of hot spot mutations in cancer-related genes. The following genes/regions are included in the panel. Additional genes will be evaluated when requested.

BRAF Exon 15 (AA 581-606) including p.V600E detection

NRAS Exons 2-3 (AA 1-19, 38-62)

KIT Exons 11, 13, 17 (AA 550-587, 641-664, 814-828)

Exons 2, 9, 10, 14, 15, 18 (AA 51-88, 502-514, 515-549, 670-707, 715-745, 838-

866)

PDGFRA Exons 12, 14, 15, 18 (AA 552-589, 659-668, 673-711, 823-854)

GNA11 Exons 4-7 (AA 159-172, 172-202, 202-216, 255-297, 304-349, 349-360)

GNAQ Exons 4- 7 (AA 159-202, 202-210, 210-263, 261-297, 297-325, 326-360, 355-360)

Testing Method: Amplicon based targeted next generation sequencing.

Test Parameters:

<u>Diagnostic sensitivity</u>: This assay is designed to detect known single nucleotide variants only within defined regions. Nucleotide insertions and deletions more than 25bp or outside of the defined regions may not be detected. Gene rearrangements are not detected.

<u>Technical sensitivity</u>: This assay may not detect certain mutations if the proportion of tumor cells in the sample studied is less than 5%.

Turnaround Time: 5-10 business days

Sample Requirements: The presence of adequate tumor in the material submitted for analysis should be confirmed by a surgical pathologist. A section from archival paraffin material or frozen surgical biopsies should be confirmed to contain > 50% tumor by a surgical pathologist. If the submitted material for analysis contains < 50% of tumor, areas of predominant tumor will be microdissected to enrich for neoplastic cells.

- Formalin-fixed, paraffin-embedded tissue
- 5-6 tissue sections (please include H&E slide and a copy of pathology report)
- Cytology slides
- Fresh frozen tissue (ship frozen)

CPT Codes: 81445, **G0452**. 88381 may apply.