

Next-Generation Sequencing Panel

for Solid Tumors

Overview

Focus::Oncomine™ is designed to cover hotspot mutations of 35 unique genes in various different types of solid tumors including but not limited to lung cancer, colorectal cancer, skin cancer, breast cancer, bladder cancer, and thyroid cancer. The assay utilizes sequencing of DNA targets allowing detection of 989 hotspot variants, including single nucleotide variants (SNVs), with a very low input DNA material. The assay is designed to detect hotspot mutations that have clinical utility in prognosis or diagnosis or therapeutic implications in various solid tumors. The biomarkers included in Focus::Oncomine™ were selected based on information in the Oncomine Knowledgebase and confirmed with industry-leading pharmaceutical partners. The results of the assay should be interpreted in the context of available clinical, pathologic, and laboratory information.

Clinical Utility

This assay can be used to provide treatment guidance for solid tumors such as lung, colon, skin, breast, and bladder cancers and diagnosis/prognosis use in thyroid cancer.

Methodology and Interpretation

DNA extracted from FFPE material or blood/bone marrow specimen is used in this assay. Primers specific to each target region amplifies the region to be sequenced using Ampliseq library preparation technology. After bead based purification, the library is sequenced in massively parallel sequencing using PGM sequencer (Thermo Fisher). Sequencing reads are aligned, annotated, and reported along with their clinical interpretation provided by Oncomine Knowledgebase reporter.

Gene List for Mutation Detection (35)

AKT1, ALK, AR, BRAF, CDK4, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ESR1, FGFR2, FGFR3, GNA11, GNAQ, HRAS, IDH1, IDH2, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, NRAS, PDGFRA, PIK3CA, RAF1, RET, ROS1, SMO.

Limitations

The analytical sensitivity is 5% for mutation detection in DNA panel.

Specimen Requirements

FFPE block or 5-10 FFPE sections at 10 µm thickness on positively coated slides shipped at room temperature, with H&E slide(s). Please submit 15 sections for small biopsies. The tumor tissue must be ≥ 20% tumor cells for accurate test results.

TAT 7-10 days

CPT Codes 81445

CGI Laboratory Licensure

CAP (Laboratory #: 7191582 AU-ID: 1434060 (NJ); 8033768 AU-ID: 1636028 (NC); 7209131 AU-ID: 1506668 (CA)), CLIA (Certificate #: 31D1038733 (NJ); 34D1009209 (NC); 05D1066073 (CA)), New Jersey (CLIS ID #: 0002299), New York State (PFI: 8192), Pennsylvania (031978), Florida (800018142), Maryland (1395), California (COS00800558) (CA).

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v. 05.06.16