MSK's Next-Generation Sequence Testing

Taking a closer look. Making a bigger impact.

MSK-IMPACT® is a targeted DNA sequencing test available to cancer patients. It can detect mutations and other critical changes in the most important cancer genes using DNA from tumor tissue and matched healthy cells.

MSK-ACCESS℠ is a "liquid biopsy" test that can detect many of these same mutations with ultra-high sensitivity in cell-free DNA collected from blood plasma.

Both tests are used in precision diagnosis and matching patients to available therapies or clinical trials that will benefit them most.

Memorial Sloan Kettering Cancer Center

To learn more, please contact
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MSK-IMPACT®

- A **tumor tissue test** that directly compares cancerous and normal DNA for accurate diagnosis; a separate MSK-IMPACT®-Heme assay exists for leukemias and lymphomas
- A high throughput, targeted DNA sequencing panel for somatic mutations as well as germline and clonal hematopoiesis mutations
- Solid tumor CGP test run on >50,000 consented* cases to date (latest version run on 505 genes); heme test run on >5,000 consented* cases to date (latest version run on 468 leukemia and lymphoma genes)
- The most published assay in oncology, with 575+ research publications by MSK investigators

OVERVIEW

- Comprehensive genomic profiling test for 505 genes with clinical relevance for solid tumors (FFPE tissue)
- Probes optimized to maximize depth and uniformity of coverage

VALIDATION

- First next-generation sequencing (NGS) tumor profiling test (academic or commercial) to receive New York State Department of Health approval and FDA Class II authorization (of 486 gene test)
- 77,000+ tumors and matched normal tissue sequenced in a clinical setting — standardized analysis and format

DISTINGUISHING FEATURES

- Comprehensive analysis pipeline — mutations, copy number alterations, rearrangements, microsatellite instability (MSI), tumor mutational burden (TMB), germline variants, clonal hematopoiesis
- Tumor-normal comparison distinguishes somatic mutations from inherited variants, resulting in reduced noise, increased accuracy for TMB, and identification of cancer risk
- Large population-scale data set across all cancers enables better interpretation and contextualization of results
- Potential to include OncoKB℠** and/or hotspot annotations

VALUE

- Identify driver mutations
- Match patients to approved targeted therapies
- Match patients to clinical trials by likelihood of response

MSK-ACCESS℠

- A **liquid biopsy test** that directly compares cancerous and normal DNA for accurate diagnosis
- Liquid biopsy test of **129 genes** run on almost 4,000 MSK consented* cases since launch in 2019

OVERVIEW

- Liquid biopsy test to noninvasively detect tumor-derived mutations in blood plasma (cell-free DNA)
- Includes selected exons of 129 genes, introns of 10 genes, and additional content for detecting mutations, structural rearrangements, copy number alterations, and MSI
- Wide variety of clinical applications: genomic profiling, disease monitoring, resistance, surveillance

VALIDATION

- Received New York State Department of Health approval
- 5,500+ cell-free DNA and matched white blood cell samples sequenced in a clinical setting — standardized analysis and format

DISTINGUISHING FEATURES

- Designed and optimized based on >25,000 tumors sequenced by MSK-IMPACT® to include the most informative and frequently mutated genomic targets
- Inclusion of matched normal enables identification and filtering of germline variants and clonal hematopoiesis mutations (provides an advantage over many commercial tests)
- Automatic inclusion of preexisting tumor data to increase sensitivity for mutation detection
- Potential to include OncoKB℠** and/or hotspot annotations to enable clinical interpretation of variants identified by assays

VALUE

- Identifying driver mutations
- Matching patients to approved targeted therapies
- Matching patients to clinical trials by likelihood of response
- Monitoring circulating tumor DNA levels and disease burden throughout treatment
- Early detection of resistance variants

*Patients have consented to their data being used in research to advance science

**A portion of MSK's Oncology Knowledge Base (OncoKB℠) has been recognized by the FDA as a source of valid scientific evidence for level 2 (clinical significance) and level 3 (potential clinical significance) biomarkers. Under the FDA's database recognition program, test developers can use these data to support the clinical validity of tumor profiling tests in premarket submissions.