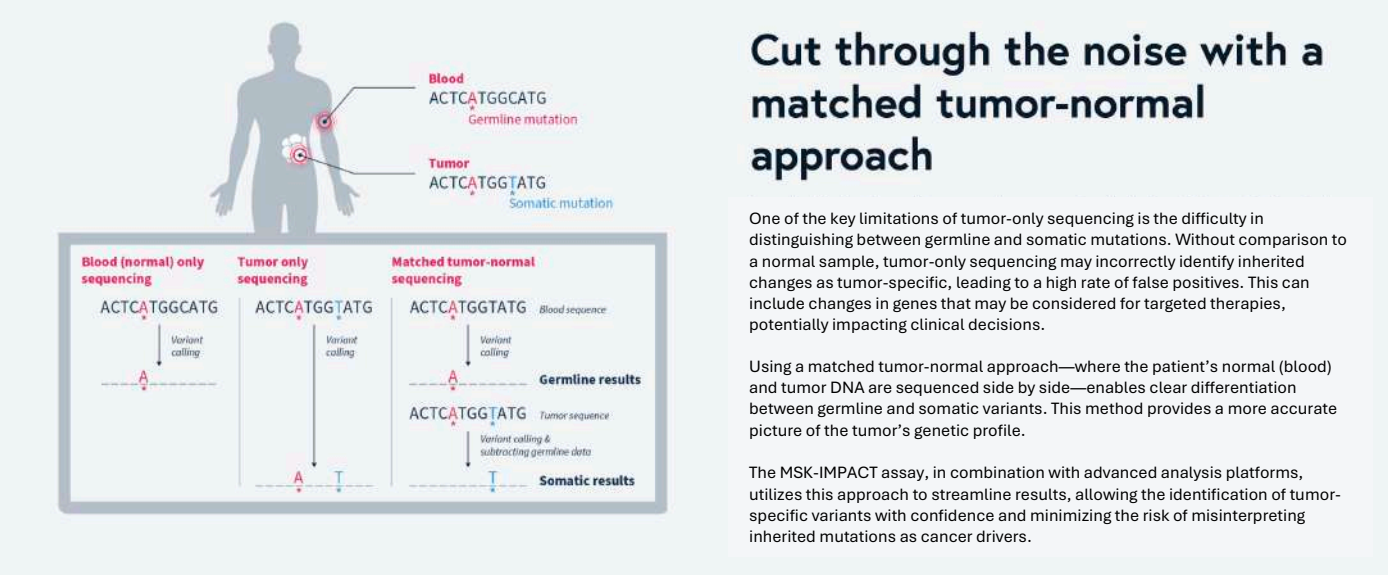
NEW TEST UPDATE June 24, 2025

Comprehensive Genomic Profiling (CGP) with MSK-IMPACT™

We are pleased to announce that the **MSK-IMPACT™** test (Integrated Mutation Profiling of Actionable Cancer Targets) is now available in-house at the National Reference Laboratory (NRL). This advanced Comprehensive Genomic Profiling (CGP) assay has been locally validated for the first time using the SOPHiA DDM™ platform. With this milestone, we are bringing precision oncology closer to patients in the UAE and the wider region.

What is MSK-IMPACT™?

MSK-IMPACT™ is a cutting-edge next-generation sequencing (NGS) test developed by **Memorial Sloan Kettering Cancer Center** (MSKCC) and authorized by the FDA as a Class II in vitro diagnostic (IVD) device. It offers detailed profiling of somatic mutations across **505 cancer-related genes** and includes matched normal analysis to distinguish germline variants (see figure below).



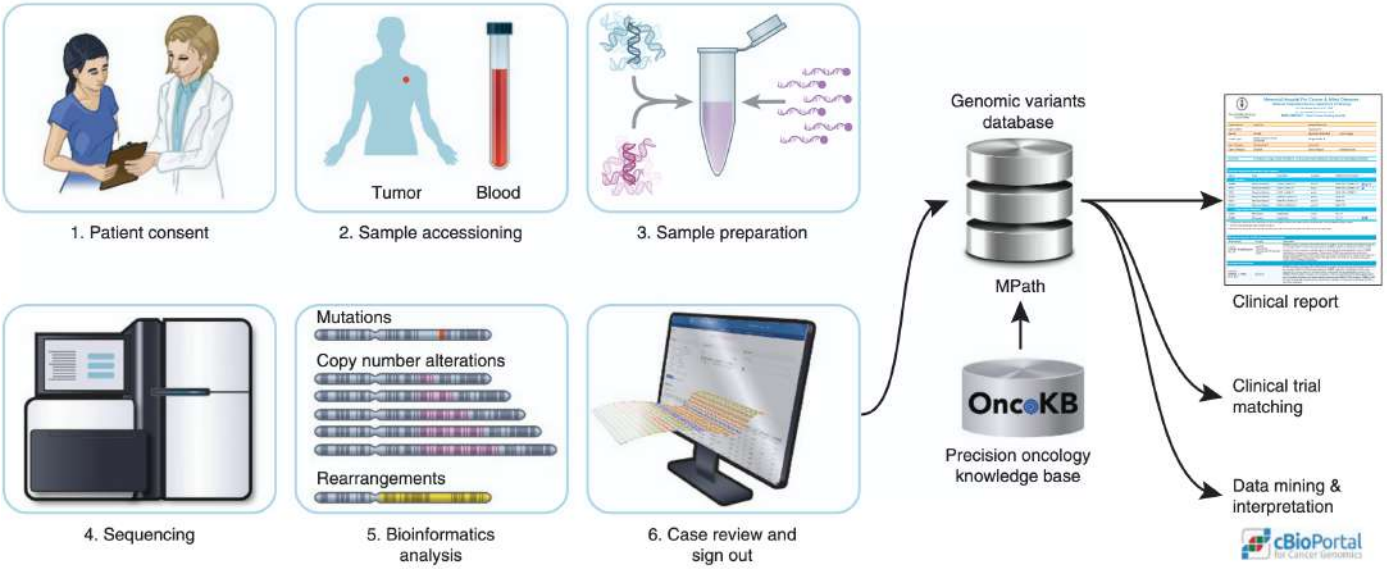
Now available at NRL, this test enables clinicians to access high-quality genomic information with faster turnaround times, supporting more informed decision-making across a wide range of **solid tumors.**

Key Highlights of MSK-IMPACT™ CGP Assay

- **Extensive Genomic Coverage:** Targets 505 genes associated with solid tumors, including high-priority oncogenes and tumor suppressors such as ***TP53, EGFR, BRCA1/2, KRAS, BRAF, ALK, PIK3CA***, and more.
- **Multiple Variant Types Detected:**
  - Single Nucleotide Variants (**SNVs**) & Insertion/Deletions (**Indels**) in 505 genes
  - Copy Number Alterations (**CNAs**) in 490 genes
  - Gene Fusions and Rearrangements of 23 genes (e.g. *ALK, ROS1, RET, NTRK1/2/3*)
  - Microsatellite Instability (**MSI**) and Tumor Mutational Burden (**TMB**)
  - Germline analysis of 27 genes (when matched normal blood provided)
  - Tumor-Infiltrating Clonal Hematopoiesis (when matched normal blood provided)
- Low allelic fraction detection (≤5% variant allele fraction) with ≥500× median coverage.
- **Turnaround Time:** 14 calendar days
- **Clinical Reporting:**
  - Variants classified per AMP/ASCO/CAP and ESMO guidelines.
  - Matched with clinical actionability via OncoKB, an FDA-recognized knowledge base.
  - Detailed therapeutic, prognostic, and diagnostic interpretations included.

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Overview of MSK-IMPACT Clinical Workflow (PMID: 28481359)



1. Patients provide informed consent for paired tumor–normal sequence analysis
2. A blood sample is submitted as a source of normal DNA along with FFPE tumor sample.
3. DNA is extracted from tumor and blood samples using automated protocols, and sequence libraries are prepared
4. Sequencing is done using hybridization probes targeting all coding exons of genes and select introns of recurrently rearranged genes.
5. Following sequencing, paired reads are analyzed through a custom bioinformatics pipeline that detects multiple classes of genomic rearrangements.
6. Results are loaded into a genomic variants database powered by SOPHIA DDM, where they are manually reviewed for quality and accuracy. Genomic alterations are reported in the electronic medical record. The data can also be used for automated clinical trial matching and automatically uploaded to the cBioPortal for data mining and interpretation.

Clinical Applications

Ideal for patients with:

- Advanced or metastatic solid tumors
- Cancer of unknown primary (CUP)
- Resistance to standard therapies
- Need for multiple actionable targets for treatment stratification
- Eligibility for enrolment in precision oncology trials

Why Choose In-House Comprehensive Genomic Profiling (CGP) at NRL?

- **Accreditations:** Fully accredited by College of American Pathologists and ISO 15189:2022
- **Proven Reliability:** Backed by rigorous in-house validation studies, ensuring high analytical accuracy and confidence in every result
- **Faster Results:** Local testing ensures quick and dependable turnaround times
- **Seamless Integration:** Complete diagnostic workflow—from expert anatomical pathology to advanced molecular and genomic analysis
- **Clinical Relevance:** Testing aligned with NCCN, WHO, and ClinGen guidelines for actionable insights
- **Specialized Expertise:** Team of subspecialist pathologists, experienced bioinformaticians, and clinical scientists

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Test Requirements

Test Name	**MSK-IMPACT Comprehensive Genomic Profiling, NGS, Varies**
Order Code	17233055
CPT Code	88381; 81455
Clinical indication	Solid tumors (e.g., lung, breast, colon, prostate, brain, ovary, pancreas)
Sample Type	**TUMOR** • Formalin-Fixed Paraffin-Embedded (FFPE) tissue block (preferred) OR • 10 unstained FFPE sections on uncharged slides in a sterile container (minimum 5 µm sections), along with an H&E-Stained Slide for tumor cell content assessment OR • Decalcified FFPE bone sample: Only EDTA decalcification is accepted OR • Core needle biopsy: 3-5 fresh cores from the tumor **CYTOLOGY** Cytology smear: 3 from FNA with minimum of 3,000 cells. Do not coverslip. **BLOOD** 3-5 mL Peripheral Whole Blood in EDTA (strongly recommended) for genomic DNA from White Blood Cells (WBC)
Container	Sterile container; EDTA for Peripheral Blood
Sample Volume	10 Unstained Sections (5 µm sections) plus H&E stained section; Blood, 3-5mL
Transport Conditions	Room Temperature for Unstained Sections; Refrigerated for Blood
Storage	Room Temperature for Unstained Sections; Refrigerated for Blood
Turnaround Time	14 Days
Methodology	Next Generation Sequencing (NGS) – Illumina
Rejection Criteria	**TUMOR** 1. Fresh frozen tissue 2. Low tissue content in FFPE blocks 3. Tissue with low tumor nuclei content <20%. **BLOOD** 1. Hemolyzed peripheral blood specimen 2. Peripheral blood collected in EDTA container

For more information, please contact:

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