



Foundation One CDx Testing

What is Foundation one CDX?

- Foundation One CDx is the first FDA-approved, tissue-based broad companion diagnostic (CDx) that is clinically and analytically validated for solid tumors.
- The test is designed to provide physicians with clinically actionable information — both to consider appropriate therapies for patients and understand results with evidence of resistance — based on the individual genomic profile of each patient's cancer.
- Test results include microsatellite instability (MSI) and tumor mutational burden (TMB) to help inform immunotherapy decisions, and loss of heterozygosity (LOH) for ovarian cancer patients.

In which Indications Foundation one CDX test can be recommended?

- All solid tumors

How many genes are tested in Foundation test?

Foundation Medicine tests look at more than 300 cancer-related genes:

- Foundation One CDx (324 genes interrogated from a tissue sample)
- Foundation One Liquid CDx (over 300 genes* interrogated from a simple blood draw)
- Foundation One Heme (406 DNA and 265 RNA genes interrogated from a variety of sample options)

What is Comprehensive Genomic Profiling (CGP)?

CGP is technique by which we can identify all 4 types of genomic alterations (Base substitutions, Insertion Deletions, Copy number alterations and rearrangements) through single test. We also get TMB, MSI and LOH for ovarian cancer.

- Comprehensive genomic profiling (CGP) — also known as biomarker testing or tumor profiling.

- CGP is a method of cancer testing that can find the mutations in your cancer's DNA that may be causing your cancer to grow.
- The mutations in your cancer's DNA may help your doctor identify a targeted therapy, immunotherapy, or clinical trial that is right for you.

How is comprehensive genomic profiling different from single-gene or “hot spot” testing?

- Single biomarker testing identifies alterations that are confined to a single gene, potentially missing clinically relevant mutations in additional genes.
- Gene hotspot testing may test multiple genes at a time but is confined to commonly altered regions within those genes, resulting in potentially missing other clinically relevant classes of alterations.
- Comprehensive genomic profiling detects the four main classes of genomic alterations across a broader panel of genes, oftentimes hundreds. It does whole exome sequencing of the targeted genes and hence identifies more alterations than other NGS tests.

What is the depth and read of foundation one testing?

- Usually Foundation One CDx has a depth of around 600 which is sufficient to get a 99.99% accuracy. This is validated and published in Nature. Also, this is unique coverage and not copy of the same reads.

How is Foundation One is different from existing competitor offerings in India?

- Foundation One CDx and other profiles from FMI are clinically and analytically validated and the validation publications are available in public domain. FMI is the only company which has both, solid and liquid biopsy which is FDA approved.
- FMI liquid biopsy panels are most comprehensive and covers over 300 genes
- FMI reports are trusted globally, and any physician sitting in Europe and US can give opinion based on the report.
- FMI finds more alterations than Hot Spot tests being offered by other companies in India.

What is the commercial information of Foundation One Testing?

S. No.	Test Name	Test Code	MRP	Technique	Specimen	Special Instructions for Sample Collection	TAT / Reported on
1	Foundation One CDx	SMO10328	260000	Next Generation Sequencing (NGS)	FFPE Tissue block	Foundation One TRF- Duly signed & stamped	22nd working Day by 7:00 p.m.

2	Foundation One Heme for haematological malignancies & Sarcomas	SMO10329	310000			by concerned physician for sample processing (must)	30th working Day by 7:00 p.m.
3	Foundation One Liquid	SP10125	260000		"USE ONLY TUBES PROVIDED INSIDE THE FACT SPECIMEN COLLECTION KIT.OTHER TUBES WILL NOT BE ACCEPTED" TOTAL VOLUME- 8.5ml per tube (2 tubes in one kit)	Patient Consent Form – Dully signed by patient for sample processing (must)	22nd working Day by 7:00 p.m.

Report will come to Patient or Treating Physician or Doctor?

- The report of patient will be directly emailed to patient and treating Physician or Doctor, on the provided email id. The report is highly confidential.

In the Paraffin Block, For Foundation One Testing, how much tumor percentage is required?

- In the Paraffin Block the minimum required tumor percentage of 20% or more. If the sample is from liver, the tumor content should be over 30%.