

**DISCOVER**  
**DIAGNOSE**  
**DEFEND**



**Clinical Testing For**

# **Breast & Reproductive Tract Cancer**



**India's Leading Super Specialised Laboratory Network**

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## Breast Cancer

### BRCA 1 & 2

- The test is based on Next generation sequencing on Ion torrent including 10 bp of intronic flanking sequences.
- All the gene mutations clinically related to disease will be reported if they are present in the specific patient sample (as Class 6).
- The report indicates the reference sequence and version number.
- The report provides the Pubmed ID of the reference (PMID), on which the interpretation was made, in case of pathogenic variations.

### Her2/neu by FISH

- Provide most accurate assessment of Herceptin (Trastuzumab) response.
- Advocated in all Her2/neu positive cases which has scores of +2 by IHC.
- Results are expressed in accordance with ASCO/CAP guidelines.

### MammaPrint+BluePrint Combination

- Identify molecular subtypes of patients who are at high risk of recurrence to help guide biologically centered treatment planning.
- Can lead to reclassification of up to 25% of tumors with potential therapeutic and prognostic implication, identify more clinically actionable biology.
- Reclassified of patients led to an improved distribution of response rates & a more accurate picture of which patients were likely to respond to neoadjuvant chemotherapy for breast cancer.

### Breast Cancer Prognosis Panel (1B) - ER, PR & Her2/neu

- A quantitative test to aid in making important therapeutic decisions in breast cancer.
- Identifies tumors potentially responsive to hormone therapy & Herceptin.
- Detailed interpretive results are reported along with a quantitative scoring in accordance with ASCO/CAP guidelines.

### Ki-67 by IHC

- Determine the benefit of chemotherapy in addition to hormone therapy in node negative ER positive breast cancer.
- A useful marker of cell proliferation and has been offered as a prognostic marker in early breast cancer.

### DNA Ploidy and cell cycle

- Determine prognosis of malignancies
- The panel analyses the proliferative potential of cancer cells by measuring the number of cells actively synthesizing DNA( S phase fraction SPF)

## Female Reproductive Tract Cancer

### HE 4 (Human Epididymis Protein 4)+ CA125

- Accurately determines the risk of malignancy.
- HE4+ CA125 combination has proven to be a more accurate predictor of malignant disease.
- Helps to triage patients to the appropriate specialist.
- Accurately stratified 89% of all epithelial ovarian tumors and low malignant potential tumors as high risk and 75% of all benign disease as low risk.
- The combination has a higher specificity and sensitivity than either marker alone.

### Liquid Based Cytology (LBC)

- High sensitivity and specificity as compared to conventional PAP smear.
- Better interpretation of results.
- Better specimen collection.

### Human Papilloma Virus DNA by Hybrid Capture (High/Low Risk)

- Screen patients with atypical squamous cells of undetermined significance (ASC-US) pap smear results to determine the need of referral to colposcopy.
- To assess the presence/absence of 13 HPV types( high risk) / 5 (low risk) HPV types.

### HPV Genotyping

- Detection of high-risk (HR) genotypes associated with the development of cervical cancer.
- Aids in targeting women with abnormal Pap smear results.
- Individual genotyping of human papillomavirus (HPV)-16 and/or HPV-18, if present.

### HPV by Hybrid Capture + LBC combo

- The combo includes HPV High risk, low risk and liquid based cytology.
- Combining LBC with HPV increased test sensitivity.

### Anti Mullerian Hormone (AMH)

- Assesses ovarian status including follicle development, ovarian reserve and ovarian responsiveness as part of evaluation of infertility.
- Assesses menopausal status, including premature ovarian failure.
- Assesses infants with ambiguous genitalia and other intersex conditions.

### Final Diagnosis Panel

- Performing comprehensive set of markers to establish exact diagnosis.
- IHC markers decided by the team of oncopathologists.
- Subsequent targeted approach leading to the final diagnosis.

**\*Also available  
Dual, Triple &  
Quadruple  
Marker Test**

## Test Information

Test Code	Test Name	Technique	Specimen	TAT / Reported on
SMO10058	BRCA-1 & 2 -complete sequencing test	Next Generation Sequencing	8-10 ml. Whole Blood EDTA.	21st working day
SFI10007	Her2/neu by FISH	FISH	Formalin Fixed Paraffin Embedded (FFPE) tissue block. Specify brief clinical details on TRF.	5th working day
SIH10004	Ki - 67 (IHC Marker)	Immunohistochemistry	Formalin Fixed Paraffin Embedded (FFPE) tissue block/Representative Tissue placed in Formalin sent at room temperature by courier. Polylysine coated slides are also acceptable (12-15 for FDP; For other panels depending upon the number of markers requested) with an additional H&E slide is required. Slides to be transported in proper slide mailers (plastic) with proper labelling.	4th working day
SP10043	Breast Cancer Prognosis Panel (1B) / ER, PR & Her2/neu			5th working day
SP10100	IHC Final Diagnosis Panel			
RP10183	Ovarian Cancer Panel (HE4+ CA125)	Chemiluminescence Microparticle Immunoassay (CMIA)	2 ml. (1 ml. Minimum) Serum from 1 SST (Gel Barrier Tube).	2nd working day
SCY10018	Liquid Based Cytology	Light Microscopy	Cervical scrapings in ThinPrep PreservCyt / SurePath liquid transport media	3rd working day
SMO10090	HPV DNA HR (High Risk) Test - (Hybrid Capture 2)	Hybrid Capture 2	Cervical scrapings/Genital Swabs in STM or in ThinPrep PreservCyt /SurePath liquid transport media	3rd working day
SMO10091	HPV DNA LR (Low Risk) Test - (Hybrid Capture 2)	Hybrid Capture 2		
SP10035	HPV DNA HR & LR - (Hybrid Capture 2) & LBC	Hybrid Capture 2 & Microscopy		
SMO10092	HPV Genotyping	PCR		15 working day
RIM10118	Anti Mullerian Hormone, MULLERIAN INHIBITING SUBSTANCE (MIS), Serum	ECLIA	2 ml. (1 ml. Minimum) Serum from 1 SST (Gel Barrier Tube).	Same working day
SMO10242	MammaPrint + Blueprint Combination	Microarray-based gene expression profile	Formalin-fixed paraffin-embedded tissue block or 10 unstained slides with a 5 micron section on each slide. Must contain at least 30% invasive tumor.	18th working day
SFC10053	DNA Ploidy & S-Phase, Solid Tumours (Flowcytometry)	Flow Cytometry	Paraffin embedded tissue block or Formalin Fixed Tissue	5th working day
RIM10114	Dual Test (1st Trimester)	Chemiluminescence Immunoassay (CLIA)	3 ml. (2 ml. Minimum) Serum from 1 SST (Gel Barrier Tube) taken from Pregnant Lady of pregnancy between 10 - 13 wks.	3rd working day
RIM10115	Triple Test (2nd Trimester)		3 ml. (2 ml. Minimum) Serum from 1 SST (Gel Barrier Tube) taken from Pregnant Lady of pregnancy between 14 -22 wks.	
RIM10116	Quadruple Test		2 ml. (1 ml. Minimum) Serum from 1 SST (Gel barrier tube).	4th working day