





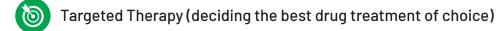




Clinical Application:

Prognostic and Predictive biomarker for platinum-based chemotherapy and PARP inhibitor therapy

Test Utility



- Disease prognostication (impact on overall survival rate of breast and ovarian cancer patients)
- Tumor profiling has the advantage of detecting both germline and somatic mutations together in a single assay for any given patient. Reflex testing on blood sample is recommended to confirm the germline predisposition
- Hereditary risk assessment (presence of personal or family history)
 - Platinum based chemotherapy has been shown to be more effective in Ovarian Cancer patients with HRR mutations (Germline/somatic)[2]
 - Mutation in HRR genes (HRR defective tumors) in Triple Negative Breast Cancer in predictive of complete Pathological Response in these tumors [3]





CLINICAL SIGNIFICANCE

The cancer genome atlas study shows that 17% of high grade serous ovarian cancer had germline BRCA1/2 mutations, while 28% had somatic mutations in the broader category i.e., HRR genes that includes BRCA1/2 as well as other genes such as CDK12, RAD51C, PPP2R2A, CHEK1, RAD51B, RAD51D, CHEK2, RAD51L, BARD1, BRIP1, ATM, FANCL, PALB2 [1]

Who should be tested?



Individual diagnosed with Breast cancer and suspected to have BRCA1/2 mutation



Any woman diagnosed with epithelial ovarian, fallopian tube, and peritoneal cancers can undergo genetic testing as per SGO recommendation



Women with ovarian cancer who may benefit from PARPi maintenance therapy



Women with ovarian cancer resistant to platinum therapy



Men with castration resistant prostate cancer who have progressed in prior treatment



Patients with pancreatic cancer who may have suspected BRCA1/2 mutations

Sensitivity and Specificity NGS based HRR testing:

100%

Limit of Detection 5% and 10%

for SNIV

for Short indels (<10bp)

TEST NAME	TEST CODE	PRICE	TAT
NEXTGEN HRR GENE PANEL	Н0874	25300	4 WEEKS
Genes Covered:			
ATM	BRIP1	FANCL	RAD51C
BARD1	CDK12	PALB2	RAD51D
BRCA1	CHEK1	PPP2R2A	RAD54L
BRCA2	CHEK2	RAD51B	