OncoStrands® HRD Test Result

Building A (G.01)
18-24 Ricketts Road
Mount Waverley
Victoria 3149
Australia

LifeStrands
Empowering lives with Genomics

Accredited for compliance with NPAAC standards and ISO 15189
NATA Accreditation Number: 21166

RCPA The Royal College of Pathologists of Australasia NATA

PATIENT INFORMATION	ORDERING PHYSICIAN	SPECIMEN INFORMATION	
Full Name:	Full Name:	Specimen Type:	FFPE Block
Date of Birth:	Institution:	Tissue:	Ovary
Sex at Birth:		Specimen ID:	SP23-XXXX-AX
Disease:		Ref. Laboratory:	Innoquest SG
Date Collected:	COPY TO	Date Ordered:	10/4/2023
LSG Accession ID:	Full Name:	Date Received:	10/4/2023
Ext. Accession ID:		Date Reported:	13/4/2023

CLINICAL DIAGNOSIS

Disease, staging, primary site, etc.

HRD STATUS: + POSITIVE

Positive HRD status = (**Positive GIS status)** and/or (**pathogenic/likely pathogenic *BRCA1/BRCA2* mutations)**

Negative HRD status = **(Negative GIS status)** and **(wild type *BRCA1/BRCA2* status)**

GIS Status*: **POSITIVE**

The Genomic Instability Score (GIS) is a measurement of genomic instability calculated from three genomic markers associated with homologous recombination deficiency (HRD) in cancer; loss of heterozygosity (LOH), telomeric allelic imbalance (TAI), and large-scale state transitions (LST).

Patient *Genomic Instability Score (GIS): 78
(A GIS of 42 or greater confers a positive GIS status.)

Tumour Mutation *BRCA1/BRCA2* Status: **POSITIVE**

Gene	Clinically Significant Mutation(s)	Interpretation
BRCA1	c.2433del (p.Lys812Argfs*3)	Deleterious
BRCA2	Not Detected	NA

Note: This result represents findings from all analysable *BRCA1/2* genomic regions only. Please note this assay cannot distinguish between germline and somatic *BRCA1/2* variants and so it may or may not reflect the germline status of this individual. Referral to clinical genetics services is recommended, if clinically applicable.

ASSAY DESCRIPTION

A molecular pathologist assessed the adequacy of submitted tissues for testing by reviewing tumour cellularity on H&E-stained section(s) and the size of tumour tissues. Genomic DNA was then extracted and quantified from accepted samples and was tested using the OncoStrands® HRD Test. OncoStrands® HRD Test is an in-house IVD test that uses the Illumina TruSight™ Oncology 500 (TSO500) HRD assay and targeted hybrid-capture based next generation sequencing chemistry

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to measure genomic instability in cancer, represented as a Genomic Instability Score (GIS). GIS is calculated using a proprietary algorithm developed by Myriad from Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions status. This test also identifies both *BRCA1* and *BRCA2* variants (single nucleotide variants, insertions and deletions, and large rearrangement variants) in the coding exons and intron/exon boundaries.

The results of the OncoStrands® HRD Test are used as an aid in identifying cancer patients with positive homologous recombination deficiency (HRD) status, who are eligible, because of a positive test result for deleterious or suspected deleterious mutations in *BRCA1* or *BRCA2* genes, or may become eligible, because of a positive test result for deleterious or suspected deleterious mutations in *BRCA1* or *BRCA2* genes or a positive Genomic Instability Score, for treatment with targeted therapy with PARP inhibitors like Olaparib (Lynparza®) or Niraparib (Zejula®) in accordance with the most recently approved therapeutic product labelling (Lynparza® is a registered trademark of AstraZeneca group of companies. Zejula® is a registered trademark of GSK).

Detection of deleterious or suspected deleterious *BRCA1* and *BRCA2* mutations and/or positive Genomic Instability Score in ovarian cancer patients is also associated with enhanced progression-free survival (PFS) from Zejula® (niraparib) maintenance therapy in accordance with the most recently approved therapeutic product labelling.

DISCLAIMER

This HRD Test is performed using the methodology developed by Illumina in collaboration with Myriad Genetics. The test is performed by LifeStrands Genomics Australia on a NATA accredited Illumina TruSight™ Oncology 500 (TSO500) assay backbone.

REFERENCE

1. Moore, K. et al. Maintenance olaparib in patients with newly diagnosed advanced ovarian cancer. N. Engl. J. Med. 379, 2495–2505 (2018).
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Reported by: _____

Designation:

Approved by: _____

Designation:

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