Asiri AOI Cancer Centre (Private) Limited.
No.21, Kirimandala Mw, Colombo 5 T. +94 11 452 4400 E. asiriaoi@asiri.lk

Credence Genomics (Pvt) Ltd
No 12 -3/2, Sunethradevi Road, Kohuwala, Sri Lanka
Tel: +94 11 2 89 06 87 / +94 11 2 81 83 70
Hotline: +94 710 38 00 11
Email: info@credencegenomics.com
Web: www.credencegenomics.com
Company Registration No PV78459

Patient Name	: N. S. Jayashinghe	**Date Specimen Obtained**	: 30.09.2022
DOB / Age	: 30.10.1962	**Date Specimen Received**	: 30.09.2022
Sample Reference No	: SC69545	**Reporting Date**	: 08.10.2022
Gender	: Female	**Referring Physician**	: Dr. Mahendra Perera
Specimen Type	: Paraffin Block	**Referring Facility**	: Asiri Surgical Hospital

TEST PERFORMED – P53(IHC)

INDICATION FOR TEST – Not Provided

IMMUNOHISTOCHEMISTRY STUDIES

MARKERS (CLONES)	RESULT	IMAGES
P53 (BP 53-12)	NEGATIVE	

TECHNICAL NOTE:

All immunohistochemistry markers have been evaluated in the context of appropriate positive and negative controls. A result is considered uninterpretable as a result of the type of fixative used (non 10% neutral buffered formalin), time to fixation (> 1 hour), duration of fixation (> 6 hr or < 72 hour), strong decalcification, or inappropriate staining of normal internal or external assay controls. An alternative sample for retesting is then usually recommended. These assays have not been validated on decalcified specimens

This report was reviewed and approved on **08.10.2022** by

Dr. Padmapani Padeniya
M.B.B.S | MSc in Clinical Genetics
Geneticist and Genetic Counsellor
Senior Lecturer
Department of Anatomy
Faculty of Medicine
University of Kelaniya

CONFIDENTIAL LABORATORY REPORT

Member of Clinical and Laboratory Standards Institute, U.S.A.

Asiri Hospital Holdings PLC, 181, Kirula Road, Narahenpita, Colombo 05
T. +94 11 452 3355-7 F. +94 11 452 3358 prlab@asiri.lk

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ENZYME IMMUNOASSAY

UHID	: 120226935	
REFERENCE No.	: 01 0489 26/09/22	
SAMPLE DATE & TIME	: 26/09/2022 11:57	AGE : 59 Y/F
REPORT DATE & TIME	: 29/09/2022 09:47	AHH2002546 / ASH5255
PATIENT	: MRS. N.S. JAYASINGHE	
REFERRED BY	: DR.MAHENDRA PERERA	

TEST	RESULT		FLAG	REFERENCE VALUE
CA 15-3	11.50	u/ml		

Comment :-

Expected value :

6.4 - 58

Median 21.6

MLT

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Allred Score* for Estrogen and Progesterone Receptor Evaluation:

Proportion Score	Positive Cells, %	Intensity	Intensity Score
0	0	None	0
1	< 1	Weak	1
2	1 to 10	Intermediate	2
3	11 to 33	Strong	3
4	34 to 66		
5	>= 67		

* The Allred score combines the percentage of positive cells and the intensity of the reaction product in most of the carcinoma 9 .The 2 Scores are added together for a final score with 8 possible values.Scores of 0 and 2 are considered negative.Scores of 3 to 8 considered positive.

Note:

5. All immunohistochemistry markers have been evaluated in the context of appropriate positive and negative controls. A result isconsidered uninterpretable as a result of the type of fixative used (non 10% neutral buffered formalin), time to fixation (> 1 hour),duration of fixation(>6 hr or <72 hour),strong decalcification, or inappropriate staining of normal internal or external assay controls. An alternative sample for retesting is then usually recommended.
6. Assay has been performed on formalin fixed paraffin embedded tissue, using the polymer based detection system for Immunohistochemistry studies.
7. Cold ischemia and fixation time: Not known
8. Internal control: Present and stain as expected

References:

1. Allison KH, Hammond MEH, Dowsett M, et al. Estrogen and progesterone receptor testing in breast cancer: ASCO/CAP guideline update. Arch Pathol Lab Med doi: 10.5858/arpa.2019-0904-SA.

This report was reviewed and approved on **07.10.2022** by

Dr. Padmapani Padeniya
M.B.B.S | MSc in Clinical Genetics
Geneticist and Genetic Counsellor
Senior Lecturer
Department of Anatomy
Faculty of Medicine
University of Kelaniya

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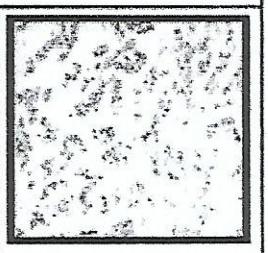
4. Progesterone Receptor (PR)

Diagnosis:

Markers	Result		Interpretation	Image
PgR(PGR 636)	% of cells with nuclear staining in the invasive component of the tumor	90	Positive	
	Intensity of staining	Strong		
	Allred score	8		

Clinical rationale of ER/PR testing:

PgR Significance:

Hormone receptor status is determined primarily to identify patients who may benefit from hormonal therapy. About 75% to 80% of invasive breast cancers are positive for ER and PgR, including almost all well-differentiated cancers and most moderately differentiated cancers, and studies have shown a substantial survival benefit from endocrine therapy among patients with ER-positive tumors. True ER-negative, PgR-positive carcinomas are extremely rare, but patients with such tumors are also considered eligible for hormonal therapy. Receptor status is only a weak prognostic factor.

Reporting Results of Estrogen Receptor (ER) and Progesterone Receptor (PgR) Testing:

Result	Criteria	Comments
Positive	Immunoreactive tumor cells present (≥1%)	Invasive carcinomas with 1 to 10% of cells staining for ER(not PgR) are reported as "Low Positive" and the following report comment is recommended: "The cancer in this sample has a low level(1-10%) of ER expression by IHC. There are limited data on the overall benefit of endocrine therapies for patients with low level (1-10%) ER expression but they currently suggest possible benefit, so patients are considered eligible for endocrine treatment. There are data that suggest invasive cancers with these result are heterogeneous in both behavior and biology and often have gene expression profiles more similar to ER negative cancers." The Low Positive designation applies only to invasive carcinoma, and is not used for Progesterone receptor or DCIS.
Negative	< 1% immunoreactive tumor cells present	

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3. Ki-67

Diagnosis:

Markers	Result		Image
Ki-67 (MIB-1)	% of positive nuclei	20	

Technical Note:

1. Ki-67 is a nuclear protein found in all phases of the cell cycle and is a marker of cell proliferation. The monoclonal antibody MIB-1 is the most commonly used antibody for assessing Ki-67 in formalin-fixed paraffin-embedded tissue sections. The percentage of Ki-67 positive tumor cells determined by IHC is often used to stratify patients into good and poor prognostic groups, but there is a lack of consensus on scoring, definition of low versus high expression, an appropriate cut point for positivity, or which part of the tumor should be scored (eg, leading edge, hot spots, overall average).26 There is also a paucity of data on the effects of preanalytic variables (e.g., ischemic time, length of fixation, antigen retrieval) on Ki-67 staining. For these reasons, routine testing of breast cancers for Ki-67 expression is not currently recommended by either ASCO or the National Comprehensive Cancer Network (NCCN).
2. All immunohistochemistry markers have been evaluated in the context of appropriate positive and negative controls. A result is considered uninterpretable as a result of the type of fixative used (non 10% neutral buffered formalin), time to fixation (> 1hour), duration of fixation (> 6 hr or < 72 hour), strong decalcification, or inappropriate staining of normal internal or external assay controls. An alternative sample for retesting is then usually recommended.
3. Assay has been performed on formalin fixed paraffin embedded tissue, using the polymer based detection system for Immunohistochemistry studies.
4. Cold ischemia and fixation time: Not known

References:

1. Dowsett M, Nielsen TO, A'Hern R, et al. Assessment of Ki67 in breast cancer: recommendations from the International Ki67 in breast cancer working group. J Natl Cancer Inst. 2011;103(22):1656-1664.

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Note:

1. If the initial HER2 test result in a core needle biopsy specimen of a primary breast cancer is negative, a new HER2 test may be ordered on the excision specimen if one of the following is observed:-
    1. Tumor is grade 3
    2. Amount of invasive tumor in the core biopsy specimen is small
    3. Resection specimen contains high-grade carcinoma that is morphologically distinct from that in the core

    There is doubt about the handling of the core biopsy specimen (long ischemic time, short time in fixative, different fixative), or the test is suspected by the pathologist to be negative on the basis of testing error.
2. Unusual staining patterns of HER2 IHC are considered HER2 equivocal. IHC staining moderate to intense but incomplete (basolateral or lateral) or circumferential IHC staining that is intense in <10% of tumor cell.
3. All immunohistochemistry markers have been evaluated in the context of appropriate positive and negative controls. A result is considered uninterpretable as a result of the type of fixative used (non 10% neutral buffered formalin), time to fixation (> 1 hour), duration of fixation (> 6 hour or < 72 hour), strong decalcification, or inappropriate staining of normal internal or external assay controls. An alternative sample for retesting is then usually recommended.
4. Assay has been performed on formalin fixed paraffin embedded tissue, using the polymer based detection system for Immunohistochemistry studies.
5. Cold ischemia and fixation time: Not known

References:

1. Wolff AC, Hammond MEH, Allison KH, et al. HER2 testing in breast cancer: American Society of Clinical Oncology/College of American Pathologists clinical practice guideline focused update. Arch Pathol Lab Med. 2018;142(11):1364-1382.

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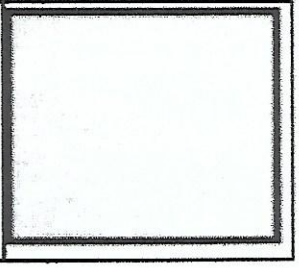
2. HER2

Diagnosis:

Markers(Clones)	Result		Interpretation	Image
Her-2/neu (EP-3)	No staining observed	Score 0	NEGATIVE	

Comments

HER-2-Significance:

The HER2 gene is responsible for the formation of HER2 Protein, which is a Human growth Factor Receptor. A positive HER2 test result would mean over expression of Her2 protein and is seen in about 20% of breast carcinomas.

Various studies have shown that these HER2 positive tumors have aggressive growth, metastasize faster and have less favorable prognosis than HER2 negative tumors.

However, they have shown to have good response to AntiHER2 therapy (either monoclonal antibodies or relevant tyrosine kinase inhibitors).

Table 4. Reporting results of HER2 Testing by Immunohistochemistry(IHC)

Result	Criteria
Negative (Score 0)	No staining observed or Membrane stating that is incomplete and is faint/barely perceptible and within ≤10% of tumor cells
Negative(Score 1+)	Incomplete membrane staining that is faint/barely perceptible and within >10% of tumor cells*
Equivocal (Score 2+)	Weak to moderate complete membrane staining in >10% of tumor cells or Complete membrane staining that is intense but within ≤10% of tumor cells*
Positive (Score 3+)	Complete membrane staining that is intense and >10% of tumor cells*

* Readly appereciated using a low-power objective and observed within a homogeneous and contiguous population of invasive tumor cells.

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Note:

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Credence Genomics (Pvt) Ltd
No 12 -3/2, Sunethradevi Road, Kohuwala, Sri Lanka
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Reporting Results of Estrogen Receptor (ER) and Progesterone Receptor (PgR) Testing:

Result	Criteria	Comments
Positive	Immunoreactive tumor cells present (≥1%)	Invasive carcinomas with 1 to 10% of cells staining fo ER(not PgR) are reported as "Low Positive" and th following report comment is recommended: "The cancer in this sample has a low level(1-10%) of E expression by IHC. There are limited data on the overa benefit of endocrine therapies for patients with low level (1-10%) ER expression but they currently suggest possibl benefit, so patients are considered eligible for endocrin treatment. There are data that suggest invasive cancers wit these result are heterogeneous in both behavior and biolog and often have gene expression profiles more similar to E negative cancers." The Low Positive designation applies onl to invasive carcinoma, and is not used for Progesteron receptor or DCIS.
Negative	< 1% immunoreactive tumor cells present	

Allred Score* for Estrogen and Progesterone Receptor Evaluation:

Proportion Score	Positive Cells, %	Intensity	Intensity Score
0	0	None	0
1	< 1	Weak	1
2	1 to 10	Intermediate	2
3	11 to 33	Strong	3
4	34 to 66		
5	>= 67		

* The Allred score combines the percentage of positive cells and the intensity of the reaction product in mo of the carcinoma 9 .The 2 Scores are added together for a final score with 8 possible values.Scores of 0 and are considered negative.Scores of 3 to 8 considered positive.

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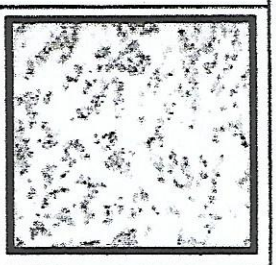
Patient Name	: N. S. Jayashinghe	**Date Specimen Obtained**	: 30.09.2022
DOB / Age	: 30.10.1962	**Date Specimen Received**	: 30.09.2022
Sample Reference No	: SC69545	**Reporting Date**	: 07.10.2022
Gender	: Female	**Referring Physician**	: Dr. Mahendra Perera
Specimen Type	: Paraffin Block	**Referring Facility**	: Asiri Surgical Hospital

TEST PERFORMED – gSeek Breast Panel (ER, PR, KI-67, HER2neu)

INDICATION FOR TEST – Not Provided

1. Estrogen receptor (ER)

Diagnosis:

Markers	Result		Interpretation	Image
ER (EP-1)	% of cells with nuclear staining in the invasive component of the tumor	90	Positive	
	Intensity of staining	Strong		
	Allred score	8		

Clinical rationale of ER/PR testing:

ER Significance

Hormone receptor status is determined primarily to identify patients who may benefit from hormonal therapy. About 75% to 80% of invasive breast cancers are positive for ER and PgR, including almost all well-differentiated cancers and most moderately differentiated cancers, and studies have shown a substantial survival benefit from endocrine therapy among patients with ER-positive tumors. True ER-negative, PgR-positive carcinomas are extremely rare, but patients with such tumors are also considered eligible for hormonal therapy. Receptor status is only a weak prognostic factor.