MEDGENOME
CAP ACCREDITED
258/A, 3rd Floor, Narayana Nethralaya Building, Narayana Health City,
Hosur Road, Bommasandra, Bangalore, Karnataka, India – 560 099
(Toll Free) 1800 103 3691 techsupport@medgenome.com
www.medgenome.com customersupport@medgenome.com

Sample Receipt Details:

POD : _____ Temp : _____

Date & Time : _____ Sample Type : _____

CS Name & Sign: _____ Logistics Name & Sign : _____

Prenatal Sample ☐Yes ☐No Bill type MOU Retail Research

TEST REQUISITION FORM

Disease Segment* _____

Each sample must be accompanied by this completed requisition. * Fields are mandatory

Test Details

ESR1 gene testing by NGS -Liquid Biopsy (Hot Spot Mutations)

Test Name:* _____ Test Code:* MGM2732

Sample type:

- ☐ Blood (in EDTA tube)
- ☐ Blood (in streck tube)
- ☐ DNA, Specify Source: _____
- ☐ Buccal swab
- ☐ Amniotic Fluid
- ☐ CVS
- ☐ Cultured CV
- ☐ Cultured amniocytes
- ☐ Fetal Blood (PUBS)
- ☐ Maternal blood for MCC (please send for prenatal studies)
- ☐ Products of Conception (POC), specifiy tissue: _____
- ✱ FFPE tissue Block (Block no. .....)
- ☐ DBS/FTA
- ☐ Fresh Frozen Tissue
- ☐ Saliva
- ☐ Other sample type (specify site) _____

Patient had a blood transfusion ☐Yes ■No Date of last transfusion __/__/__ (minimum 3 days of wait time is required for genetic testing)

Has he/she undergone allogenic bone marrow transplant: ☐Yes ☐No.

Patient Details

Name:* Mrs. Malani Gunawardena (In Capital Letters) D.O.B. DD MM YY Age:* 85Y/F Gender:* M / F

Address: .....

Phone:..... E-mail I.D: .....

Clinician Details

Clinician's Name:* Dr. Mahendra Perera Hospital Affiliation: Aegle Omics Pvt Ltd

Address: ..... Phone : .....

..... Email id : .....

Date of sample collection* 10/4/2024 YY

I understand that the current analysis is limited to variants which co-relate with disease phenotype/symptoms/terms as mentioned in the clinical details provided by me. Incidental findings which may or may not be actionable are not routinely reported. They can however be provided on request after informed consent from the patient/guardian. As disease phenotype may evolve over time, the appearance of new symptoms/signs may alter test results or their significance: MedGenome laboratories cannot be held responsible for this. A re-analysis or a re-test may be required due to the former; this will be performed (if deemed necessary) at an additional cost. I am authorised to order the above tests as I am the treating physician/consulting physician in this case. I confirm that the patient/guardian (in case of minors) has been provided complete information regarding the test, including its limitations in a language of their understanding.

Dr. MAHENDRA PERERA
MBBS (Cey), MD (Col), Dip RT
Consultant in Clinical Oncology
& Radiotherapy

Medical Professional Signature* Date: Place:

Clinical notes/diagnosis:

Disease affection status Yes NO Parental consanguinity present Yes NO Age of manifestation: _____

Affected Siblings Yes NO Details: _____

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techsupport@medgenome.com
customersupport@medgenome.com
www.medgenome.com
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GOVERNING LAW, JURISDICTION AND DISPUTE RESOLUTION

These Terms and Conditions and this Test Requisition Form shall be governed by and construed in accordance with Indian law and the courts in Bangalore shall have exclusive injunctive jurisdiction. In the event of any dispute, controversy or claim whatsoever arising from these Terms and Conditions and/or this Test Requisition Form, the parties shall undertake to make every effort to reach an amicable settlement within fifteen (15) days upon reference of the dispute by any party through discussions among the concerned representatives of parties, failing which the dispute, controversy or claim shall be settled by Arbitration by a Sole Arbitrator appointed by the 'President-Arbitration Centre-Karnataka', Bangalore as per Indian Arbitration and Conciliation Act, 1996 as amended from time to time. The venue of arbitration shall be Bangalore and it shall be conducted in English language. The award passed by the Sole Arbitrator shall be final and binding upon the parties.

NOTICE

All notices, statements or other communication required or permitted to be given or made shall be in writing and in English language. Such notices will deliver by hand or sent by prepaid post with recorded delivery, or facsimile transmission addressed to the intended recipient at the address mentioned in this Test Requisition Form.

INDEPENDENT PARTIES

All parties effected hereunder are independent entities and neither of the parties are an agent, employee or joint venture of the other and they shall not represent themselves as such to any third parties.

REFUND

Refund of fees for any reason has to be claimed by the Patient or the guardians of the Patients within 90 days from the date of delivery of report.

Patient/Guardian Authorization

By my signature below I attest to the following:

I have read and I understand the information provided on this form.

Patient Consent (sign here or on the consent document)

☐ I have read the Informed Consent document and I give permission to MedGenome to perform genetic testing as described. I also give permission for my specimen / genetic data to be used in (de-identified) studies at MedGenome to improve genetic testing for other patients.

By agreeing to this informed consent below, I am confirming that I understand the benefits, risks and limitations associated with genetic testing. Furthermore, I am affirming that I recognize the seriousness of conditions for which {I am/my child} being tested, and that disease descriptions, prognoses, and treatment options have been made available to me by {my/my child's} health care provider. Finally, if I have the legal authorization to provide this informed consent on behalf of another person, I am attesting that the sample provided belongs to that person.

Patient/Guardian Name: Mrs. Malani Gunawardena

First Name | Middle Name | Last Name | Date of Birth: mm/dd/yyyy

Patient/Guardian Signature* | Date: | Place:

Father Name | Mother Name

Signature* | Date and time | Signature* | Date and time

Relationship with the proband

Note :

Signature of both parents is requested for prenatal testing.

For trio testing, each parent should provide separate informed consent for the sequencing of his or her sample.

MeGenome may reserve the right to send you communications on genetics / genomics periodically. The team may also connect with you to seek consent for your active participation in certain programs & communications.

*Fields are mandatory

ASIRI SURGICAL HOSPITAL | AOI AMERICAN ONCOLOGY INSTITUTE PRECISION CANCER CARE

Comprehensive Cancer Care Centre

07 APR 2023

Dr. MAHENDRA PERERA
MBBS (Cey) MD (Colo) Dip RT
Consultant in Clinical Oncology
& Radiotherapy
Principal Investigator - Clinical Trials

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

CŌRE DIAGNOSTICS™

Your Test Results

MC-2256

Case Number:	**102240032625**
Patient Name:	**MALANI L GUNAWARDENA**
Age/Sex:	**84 yrs/Female**
Patient Location:	**Colombo**
Hospital Name:	**Melsta Laboratories (Private) Limited**
Physician Name:	**Dr. Mahendra Perera**
Date & Time of Accessioning:	**01/03/2024 18:58 Hrs**
Date & Time of Reporting:	**06/03/2024 18:28 Hrs**

TEST NAME

Estrogen receptor (ER), Progesterone Receptor (PR), Ki-67, P53, HER2

SPECIMEN INFORMATION

Received three paraffin blocks. Test performed on block no. DC-9298 (B)

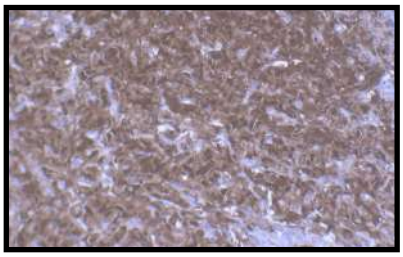
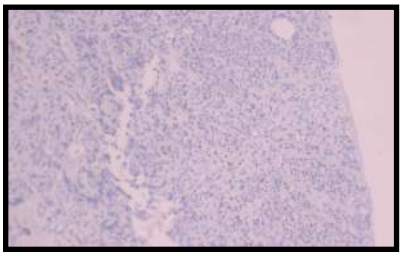
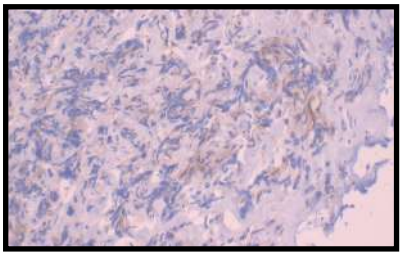
CLINICAL HISTORY

Previous mastectomy for left breast carcinoma. Mass in the left chest wall.

METHODOLOGY

Immunohistochemistry.

IMMUNOHISTOCHEMISTRY STUDIES

MARKERS (CLONES)	RESULT	IMAGES
ER (BH292)	**80%, STRONG POSITIVE**	
PR (BH357)	**5% , MODERATE POSITIVE**	
HER2 NU (BH228)	**SCORE 1+ , NEGATIVE**	

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COLLEGE of AMERICAN PATHOLOGISTS
AU-ID-2010258

Dr. Samriti, MD
Reg. No. 40685

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Your Test Results

MC-2256

Case Number:	**102240032625**
Patient Name:	**MALANI L GUNAWARDENA**
Age/Sex:	**84 yrs/Female**
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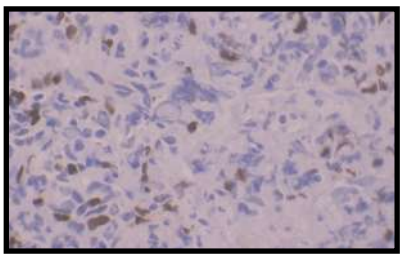
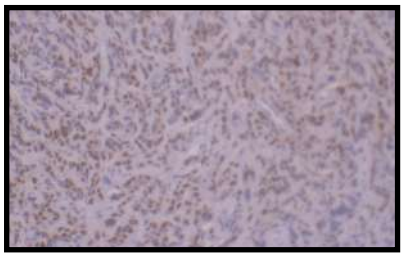
Physician Name:	**Dr. Mahendra Perera**
Date & Time of Accessioning:	**01/03/2024 18:58 Hrs**
Date & Time of Reporting:	**06/03/2024 18:28 Hrs**

IMMUNOHISTOCHEMISTRY STUDIES

MARKERS (CLONES)	RESULT	IMAGES
Ki67 (BH360)	**30%**	
P53 (BP53-12)	**50% STRONG POSITIVE**	

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.

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Dr. Samriti, MD
Reg. No. 40685

Question?

Contact us at **+91 124 4615 615**

Toll Free Helpline **+91 8882899999**

CONDITIONS OF REPORTING

1. The tests are carried out in the lab with the presumption that the specimen belongs to the patient named or identified in the bill/test request form.
2. The test results relate specifically to the sample received in the lab and are presumed to have been generated and transported per specific instructions given by the physicians/laboratory.
3. The reported results are for information and are subject to confirmation and interpretation by the referring doctor.
4. Some tests are referred to other laboratories to provide a wider test menu to the customer.
5. Core Diagnostics Pvt. Ltd. shall in no event be liable for accidental damage, loss, or destruction of specimen, which is not attributable to any direct and mala fide act or omission of Core Diagnostics Pvt. Ltd. or its employees. Liability of Core Diagnostics Pvt. Ltd. for deficiency of services, or other errors and omissions shall be limited to fee paid by the patient for the relevant laboratory services.

CORE Diagnostics National Reference Lab - Gurugram (102)

406, Udyog Vihar, Phase III, Gurgaon 122016

CORE Diagnostics Lab - New Delhi (103)

C-13, Green Park Extension, New Delhi – 110016

CORE Diagnostics Lab - Bangalore (105)

1st Floor, KMK Tower, 142 KH Road, Bangalore - 560027

CORE Diagnostics Lab - Lucknow (109)

J.S. Tower, Plot No. K-702, Sector-K, Ashiyana,

Near Raj Luxmi Sweets, Lucknow-226012

CORE Diagnostics Lab - Bhubaneswar (108)

Plot No. 249, Near Police Academy, AIIMS Nagar,

Patrapada, Bhubaneswar-751019

The test was processed in Lab 102.

mamma CŌRE

BRCA1 & 2 Somatic Gene Sequencing Report

Specimen Type	
FFPE Block - DC/9298 B	
Specimen Collection Date & Time	Date & Time of Accessioning
28/02/2024 00:00 Hrs	01/03/2024 18:58 Hrs

Case Number:	**102240032625**
Patient Name:	**Malani L. Gunawardena**
Dob/Sex:	**84 Yrs/Female**
Patient Location:	**Colombo**
Hospital Name:	**Melsta Laboratories Pvt Ltd**
Physician Name:	**Dr. Mahendra Perera**
Date & Time of Reporting:	**18/03/2024 12:10 Hrs**

TEST INFORMATION

The ***BRCA1*** and ***BRCA2 somatic* gene sequencing test** aims is a Next Generation Sequencing (**NGS)** based test in order to determine pathogenic and likely pathogenic **Single Nucleotide Variants (SNVs)** and **small Insertion/ Deletions (Indels),** that are clinically relevant for PARPi therapy.

CLINICAL HISTORY

Ca. Left Breast, Family history-Not available.

RESULTS

- **Negative**

Genes Tested	Mutation Detected
BRCA1	No clinically relevant variant identified
BRCA2	No clinically relevant variant identified

**In the Index patient, due to highly fragmented DNA, many pathogenic/likely pathogenic/VUS mutations have been identified, but nothing can be ruled out and reported as a true variant. Clinical correlation is recommended. Genetic counseling is recommended for the accurate interpretation of test results.

INTERPRETATION

- **No clinically relevant variant was identified in the *BRCA1* or *BRCA2* genes by NGS.**

RECOMMENDATIONS

- Genetic counseling is recommended for the patient.
- The test results should be interpreted in the context of the patient's medical evaluation, family history, and racial/ethnic back-ground in order to arrive at accurate diagnosis, prognosis or for therapeutic decisions.

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Aditi Aggarwal, Molecular Scientist

Dr. Shivani Sharma
DCP, DNB, DipRCPath. Reg. No. 1906

Dr. Rahul Katara, Ph.D.

CŌRE DIAGNOSTICS™

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BRCA1 & 2 Somatic Gene Sequencing Report

Case Number: **102240032625** Patient Name: **Malani L. Gunawardena** Ordering Physician Name: **Dr. Mahendra Perera**

ADDITIONAL INFORMATION

Test details:

The CORE Diagnostics BRCA Panel includes *BRCA1* and *BRCA2* genes associated with hereditary breast and ovarian cancer (HBOC) syndrome and to a lesser extent other cancers such as prostate cancer, pancreatic cancer, and melanoma. The test utilizes Oncomine BRCA Research Assay, which is based on the proven Ion AmpliSeq technology. The assay has been validated on clinical research samples and provides 100% exonic coverage, including flanking intronic sequences with high average depth of coverage (>500X).

For the index patient, Percent reads on target was 93.03% with a 89.20% Target base coverage at 500X.

Genomic DNA is isolated from the blood sample and quantified using Qubit Fluorometer. Approximately 20 ng DNA is used for target amplification. The amplified DNA is subjected to adapter ligation and Ion Xpress™ Barcode generation for specific library preparation. The generated high quality library is subjected to next generation sequencing (NGS) on the ION S5 sequencing platform. The output sequences are aligned to the human reference genome hg19 (GRCh37). The alignments and variant calling is done using the ION S5 torrent server. Variants are identified and interpreted using Ion Reporter Software. The identified variant(s) is(are) annotated according to HGVS sequence variant nomenclature. Multiple in-silico predictors, such as SIFT, PolyPhen, MutationTaster, NNSPLICE, and ASSP etc. are used for variant impact on the protein function. Population and literature databases such as dbSNP, Exome Aggregation Consortium (ExAC), genome Aggregation Database (gnomAD), ClinVar, HGMD and PubMed etc are used for variant summary and classification. Variants are labelled based on the American College of Medical Genetics (ACMG) recommendations for 5-tier variant classification system: Pathogenic, Likely Pathogenic, Variant of Uncertain Significance (VUS), Likely Benign and Benign. Clinically relevant variants identified by NGS are continuously validated in-house by a second independent method (Sanger) for quality aspects; therefore those variants which do not meet our internal QC criteria (based on extensive validation processes) are confirmed by Sanger sequencing.

Limitations and disclaimer:

Despite all precautions taken, the error (administrative and technical) associated with these types of molecular diagnostic tests can be as high as 1% to 2%. Rare polymorphisms may be present that could lead to false negative or false positive results. The quality of sequencing and coverage varies between regions; many factors such as homopolymers, GC-rich regions etc. influence the quality of sequencing and coverage. This may result in an occasional error in sequence reads or lack of detection of a particular genetic variant. Variants that have not been confirmed by an independent analysis could represent technical artifacts. Not all variants detected may be listed in the report. Inclusion of variants is dependent upon our assessment of their clinical significance. Additionally, the presence of a pathogenic/likely pathogenic variant may not be predictive of response to therapy in all patients. The selection of any potential treatment/course of action based on this report rests solely within the decision and judgment of the treating physician and patient. Decisions on patient care should be based on the independent medical judgment of the treating physician based upon all available clinical information, according to the applicable standard of care and should not be based solely on the tests and information contained in this report. Accurate interpretation of this report is dependent on provided detailed clinical history of the patient. In the event of unavailability of detailed clinical history, the lab cannot guarantee the accuracy of the interpretation. The classification of variants can change over the time. Please feel free to contact CORE Diagnostics (info@corediagnostics.in) in future to determine if there have been any changes in classification of any reported variants.

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Aditi Aggarwal, Molecular Scientist

Dr. Shivani Sharma
DCP, DNB, DipRCPath. Reg. No. 1906

Dr. Rahul Katara, Ph.D.

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Patrapada, Bhubaneswar-751019

The test was processed in Lab 102.