

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), specify tissue: \_\_\_\_\_  FFPE tissue Block (Block no. ....)  
 Fresh Frozen Tissue  Saliva  Other sample type (specify site) \_\_\_\_\_  DBS/FTA

Whole Blood in Streck Tubes 2x 10ml

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. Kumudini Fernando** D.O.B. **DD MM YY** Age\*: **69Y/F** Gender\*: **M / F**  
(In Capital Letters)  
 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\* **11/3/2025 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.

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: \_\_\_\_\_

**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. Kumudini Fernando

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.

06 MAR 2025

Co. Kumbura, 1100  
bri...

Ca Annet 2018

Low / Low Risk

Blood - Sample

MM - 2732 (PCR)

~~MM 1513~~



Dr. Neville Fernando  
Teaching Hospital



CONFIDENTIAL RADIOLOGY REPORT

ULTRA SOUND SCAN

NAME OF THE PATIENT: Mrs. Kumudini Fernando	AGE: 69Y	GENDER: F
REFERRED BY : Dr. Mahendra Perera		
BHT / INV NO : 453632		

ULTRA SOUND SCAN OF THE ABDOMEN AND PELVIS

Liver is normal in size and shape. Echo pattern is Normal. Intra hepatic ducts and the C.B.D. are within normal limits. **There are multiple hypo-echoic, round focal lesions in all the segments each measuring around 15-10mm. Larger hypo-echoic area around the ligamentum Teres 6.1 x 3.2cm.**

Few porta-hepatic nodes largest 11 x 8mm. No portal vein compression or thrombosis.  
Upper para aortic nodes largest aorto-caval 13 x 8mm.

**Gall bladder is contracted despite fasting.**

Right kidney - 9.6cm

Left kidney - 9.7cm **Mid pole cortical calcification**

Both kidneys shows normal cortical echogenicity and normal cortico medullary demarcation.

No evidence of intra renal calculi or hydronephrosis seen.

No solid focal lesions are seen in the kidneys.

No supra renal masses.

Pancreas is normal in size and echogenicity.

Spleen is not enlarged. Echo pattern is uniform.

Bladder is normally distended. No bladder wall thickening, diverticulae or vesical calculi seen.

**Uterus is anteverted and normal. Endometrial thickness measuring 6mm.** No focal lesions.

No adenexal masses.

No free fluid.

**COMMENTS:**

- Appearance are of multiple liver metastatic deposits with porta hepatic and para aortic lympho adenopathy.
- Endometrium is thickened for the late menopausal female.
- Chest X-ray reviewed- focal nodule in right mid zone overlapping right 3<sup>rd</sup> rib. Suggest CCT chest and abdomen pelvis.

Date: 4 March 2025

  
Dr. (Mrs.) INDUNI DOUGLAS  
MBBS, MD - Radiology  
SLMC - 22084  
Consultant Radiologist

Dr. (Mrs.) Induni Douglas (MBBS, MD)  
(Consultant Radiologist)

### Fluorescent In Situ Hybridisation (FISH) REPORT: FISH for Her2 gene amplification

<b>Patient Name</b>	Kumudini Fernando	<b>Requesting Clinician</b>	Dr. Mahendra Perera
<b>Gender</b>	Female	<b>Hospital Information</b>	Forté Diagnostics Pvt Ltd
<b>Age/Date of Birth</b>	62 Years /	<b>Sample Received</b>	One FFPE block labelled as AS414A3
<b>Sample ID/MGM ID</b>	195050/MGM-FI-290-18	<b>Time of Fixation</b>	Not available.
<b>Order ID(s)</b>	71053	<b>Samples Received(Date &amp; Time)</b>	23-08-2018 12:07 pm
<b>Clinical Indication</b>	Invasive ductal carcinoma, NST	<b>Report Date</b>	31-08-2018 4:48 pm

### RESULT SUMMARY

Assay Name	Probe	ISCN 2018
HER2 gene Amplification	PathVysion HER2 DNA probe	nuc ish(D17Z1x1≈2,D17S1215x4≈20) [60]

#### Interpretation:

Tumor cells showed evidence of HER2 gene amplification

### DETAILED REPORT



Representative image of tumor cell showing two spectrum, green (CEP 17) and scattered spectrum orange (HER2 gene) signals indicating HER2 gene amplification.

Spectrum Green (G)	17p11.1-q11.1/CEP17	Spectrum Orange (O)	17q11.1-q12/HER2 gene
LocI Analysed	Ratio	Average HER2 Copy number	Result
HER2 / CEP 17	7.80	12.00	Positive

**Testing methodology:** FISH is molecular cytogenetic technique used to detect presence or absence and location of specific gene sequences. FISH involves co-denaturation and hybridization of fluorescent labelled specific DNA probes to target DNA sequence in the interphase cells. Paraffin-embedded tissue specimen should be deparaffinized and pre-treated to enhance tissue permeability. The excess unbound probe is removed during post hybridization washes. The sample is stained with DAPI (4', 6-Diamidino-2-phenylindole) a counter-stain to demarcate the nuclei. Each fluorescent labelled probe that hybridizes to region of interest in interphase cells are visualized as signal using suitable optical filters under Epi fluorescent microscope. 60 interphase cells are counted for each probe. Interpretation of results is done based on the signal patterns observed and the results of the test is reported. Appropriate controls are run in each batch along with the patient samples.

### Fluorescent In Situ Hybridisation (FISH) REPORT: FISH for Her2 gene amplification

<b>Patient Name</b>	Kumudini Fernando	<b>Requesting Clinician</b>	Dr. Mahendra Perera
<b>Gender</b>	Female	<b>Hospital Information</b>	Forte Diagnostics Pvt Ltd
<b>Age/Date of Birth</b>	62 Years /	<b>Sample Received</b>	One FFPE block labelled as A5414A3
<b>Sample ID/MGM ID</b>	195050/MGM-FI-290-18	<b>Time of Fixation</b>	Not available.
<b>Order ID(s)</b>	71053	<b>Samples Received(Date &amp; Time)</b>	23-08-2018 12:07 pm
<b>Clinical Indication</b>	Invasive ductal carcinoma, NST	<b>Report Date</b>	31-08-2018 4:48 pm

**Comments:** The pathVysion HER2 DNA probe kit II is USFDA approved kit and it is designed to detect amplification of the HER2 gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer tissue specimens. Results from the PathVysion Kit are intended for use as an adjunct to existing clinical and pathologic information currently used as prognostic factors in stage II, node-positive breast cancer patients. The PathVysion Kit is further indicated as an aid to predict disease-free and overall survival in patients with stage II, node-positive breast cancer treated with adjuvant cyclophosphamide, doxorubicin and 5-fluorouracil (CAF) chemotherapy. The PathVysion Kit is indicated as an aid in the assessment of patients for whom HERCEPTIN (Trastuzumab) treatment is being considered. The result interpretation is done according to ASCO-CAP 2013.

**Table 1: HER2 Result interpretation as per ASCO/CAP 2013 by Dual Probe ISH assay**

HER2/CEP17 ratio	Average copy number	Result
< 2.0	< 4 signals/cell	Negative
	>= 4 and < 6 signals/cell*	Equivocal
	>= 6 signals/cell*	positive
>= 2.0	>= 4 signals/cell*	
	< 4 signals/cell*	

\* should be observed in homogenous and contiguous population

**References:**

1. PathVysion HER2 DNA probe set II kit insert.
2. Wolff AC, Hammond ME, Hicks DG, et al. Recommendations for human epidermal growth factor receptor 2 testing in breast cancer; American Society of Clinical Oncology/College of American Pathologists. Arch Pathol Lab Med 2014;138(2):241-256.

**Disclaimers:**

1. The performance characteristics has been evaluated by Medgenome lab.
2. The finding of this test must be correlated with clinical diagnosis.
3. CAP recommends that the Specimens subjected to HER2 (ERBB2) testing should be fixed in 10% neutral buffered formalin for at least six hours and up to 72 hours. The volume of formalin should be at least 10 times the volume of the specimen. Decalcification solutions with strong acids should not be used.

**Enclosed : One block. Order was booked on 25.08.2018 and received by FISH department on 25.08.2018**

Prepared by:  
Deepika GS

*Signature*  
E. Venkataswamy, PhD  
Associate Director, QA

*Signature*  
Dr. Syed Muqlisur Rehman., MD (Path)  
Molecular Pathologist