
14
C-6

DR. BRA INSTITUTE ROTARY CANCER HOSPITAL
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-110029

Ref. No.F.1/IRCH/MR/2023-2024

Dated 25 OCT 2023

ESTIMATE CERTIFICATE

TO WHOM IT MAY CONCERN

This is to certify that Mr. Mayank Mehta, Age 9 years, Male, S/o Sh. Gautam Kumar Mehta, (UHID-107028596 & IRCH No. 275884/22) is a known case of **Acute Myeloid Leukemia** and is under treatment with Medical Oncology at DR. BRA IRCH, AIIMS since 04.10.2023.

The approximate cost for his treatment would be Rs. 10,00,000/- (Rupees Ten Lakhs Only). The item-wise breakup of the expenditure is as under:-

S.No.	Name of Medicines with dosage/Consumables Required for treatment/operation	Duration of treatment	Approx. Cost	Name of Procedure
1.	Bone Marrow transplant-Busulfan -Melphalan - Cyclophosphamide	06 month	Rs. 10,00,000/-	Allogenic HSCT
	Total approximate cost of the treatment		**Rs. 10,00,000/-**	

The cheque/draft may be sent in favour of **"DR. BRA IRCH, AIIMS, Ansari Nagar, New Delhi-29 (IRCH Patient Treatment Account)"**
(NB: This estimate certificate is valid for six months from the date of issue)

(SIGNATURE BY CONSULTANT)

SANEER BAKSHI
आचार्य एवं विभागाध्यक्ष/Professor & Head
चिकित्सा अर्बुदविज्ञान विभाग/Deptt. of Medical Oncology
डॉ. बी.आर.ए. आई.आर.सी.एच., अ.भा.आ.सं. नई दिल्ली-29
Dr. B.R.A. I.R.C.H., A.I.I.M.S., New Delhi-29
डीएमसी पंजीकृत सं/DMC Registration No. 18936

(COUNTER SIGNED BY HOD)

(COUNTER SIGNED BY M.S.)

चिकित्सा अधीक्षक/MEDICAL SUPERINTENDENT
अ.भा.आ.सं. अस्पताल/A.I.I.M.S. HOSPITAL
डॉ बी आ.अ.सं.रो.कें.अ./Dr. B.R.A., I.R.C.H.
नई दिल्ली-110029/New Delhi-110029

81166

डॉ. बी. आर. अम्बेडकर संस्थान रोटरी कैंसर अस्पताल
Dr. B.R. Ambedkar Institute Rotary Cancer Hospital
अ.भा.आ.सं अस्पताल/A.I.I.M.S. Hospital

OPR-6

बहिरंग रोगी विभाग/Out Patient Department

[illegible] PROHIBITED IN HOSPITAL PREMISES

DR. B.R.A. IRCH,AIIMS,NEW DELHI

IRCH No. 305416 — Reg.Date 04/10/2023

Clinic Fwd: Lymphoma Leukemia Clinic — Clinic No. 2023/72109

Dept. MEDICAL ONCOLOGY

General

UHID-107028594

नाम

Name: MAYANK MEHTA — Sex/Age: M/9Y

S/O- GAUTAM KUMAR MEHTA — Room 13 (Shift Morning)

Phone No. 8447690330

Address H.NO-13 GRAM-LUPUNG POST- LUPUNG THANA KATKAMSANDI , HAZARIBAGH, JHARKHAND, Pin 825319, INDIA

केन्द्रीय पंजीकृत सं./O.P.D. Regn. No.

...ी	लिंग Sex	आयु Age	जन्म तिथि/Date of Birth

दिनांक/Date	उपचार/Treatment
23/2/24	Re AML planned for HSCT.
	D/w Dr DP sir.
	Plan
	– collect DSA report.
	– High resolution HLA typing ē brother. (नित्यूष्ण)
	– CMV IgG for Donor recipient.
Wt- 25kg	– Feeds 5L only, will need 15 L for Haplo. MSSO (15L) kindly facilitate
CAC IPS.	– R/w c̄ above reports on 8/3/24.
	– Dental/ENT clearance.
	– Can go home to arrange funds.

[signature] SR. DF.

वरिष्ठ रेजिडेंट/SENIOR RESIDENT

13/3/24 - DSA testing - SAB

- Flu ~~22/3/24~~ in BMT OPD ~~c~~ DSA
  22/3/24 ~~c~~ CBC repeat

wt = 25 kg - Donor file to make in BMT OPD.

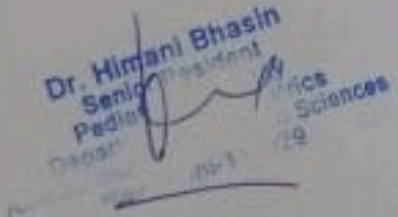
- ~~CBC/DLC/RETIC~~ available

22/3/24 Repeat DSA = ~~(nil)~~ for both class I & II
(16/3/24)

adv

- Dental & ENT clearance for HSCT
- To meet ot from flwr on 28/3/24 @11am BMT unit
  (Dr Deb / Dr Shubham)

Dental:- - Can consider tooth extraction after flu feels labs (CBC)



MC-3055

Client
Gurugram
Pathkind Diagnostics Pvt. Ltd.
Plot No. 55-56, Udhyog Vihar Ph-IV, Gurugram - 122015

Processed By
Pathkind Diagnostics Pvt. Ltd.
Plot No. 55-56, Udhyog Vihar Ph-IV, Gurugram - 122015

Name	: **Mst. MAYANK MEHTA IRCH-305416**	Billing Date	: 05/10/202319:30:17
Age	: 9 Yrs	Sample Collected on	: 05/10/2023 11:00:55
Sex	: Male	Sample Received on	: 05/10/2023 19:36:40
P. ID No.	: P1000100018251	Report Released on	: 25/10/2023 14:55:13
Accession No	: **100023010696**	Barcode No.	: 995326627, 995326626
Referring Doctor	: DR SAMEER BAKSHI		
Referred By	:	Ref no.	:

Report Status - Final

Test Name	Result	Biological Ref. Interval	Unit

2. Naval Daver, Richard F. Schlenk, Nigel H. Russell & Mark J. Levis. Targeting FLT3 mutations in AML: review of current knowledge and evidence. Leukemia 2019. Vol 33; 299-312
3. Alexander J Ambinder , Mark Levis . A. Potential targeting of FLT3 acute myeloid leukemia. Review Haematologica. 2021 Mar 1;106 (3):671-681

Note: This Test has been validated and its performance evaluated at Pathkind Diagnostics Pvt Ltd

** End of Report**

Dr. Sarjana Dutt
PhD
Director Molecular Biology & Cytogenetics

Dr. Avijit Guha
Scientist (Molecular)
PhD (Molecular)

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Acute myeloid leukemias (AMLs) are a heterogeneous group of disorders characterized by the clonal expansion of myeloid blasts (eg, undifferentiated myeloid precursors) in the peripheral blood, bone marrow, and/or other tissues, which results in impaired hematopoiesis and bone marrow failure.
Gene alterations, along with translocations and inversions, carry prognostic importance in AML. In addition to large chromosomal rearrangements, molecular changes have also been implicated in the development of AML. In fact, genetic mutations are identified in more than 97% of cases, often in the absence of any large chromosomal abnormality. A comprehensive evaluation of several molecular markers (eg, *FLT3, NPM1, CEBPA, KIT, IDH1* and *IDH2*) is important for risk assessment and prognostication in certain patients with AML and may guide treatment decisions.

1. This test is designed to detect *FLT3* mutations in acute myeloid leukemia (AML). *FLT3* mutation incidence is 20-30 percent in cytogenetically normal AML and represents an important diagnostic and prognostic marker.
2. Up to 70 percent of *FLT3*-mutated patients harbor internal tandem duplication (ITD) mutations in exon 14 of the juxtamembrane domain and 30 percent demonstrate tyrosine kinase domain (TKD) D835 mutations in exon 20. Aspartic acid at amino acid 835 most often changes either to Tyrosine (D835Y) or Valine (D835V).
3. This test is designed to detect both ITD and D835 mutations. The presence of *FLT3* mutations is associated with a poor prognosis, unless it occurs concurrently with an NPM mutation
4. *FLT3* Positive AMLs are candidates for treatment with Midostaurin in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation

Methodology, Test Attributes and Limitations:
Whole Blood/ BM DNA was extracted using commercial Kit. The Mutation analysis was carried out using an LDT. PCR reactions were carried out to amplify the region involved in ITD and D835 point mutations. The amplified product for D835 was digested with EcoRV and resolved on gel electrophoresis.
Samples must be received at the laboratory under appropriate conditions within 72hrs of aspiration to ensure preservation of high molecular weight DNA. PCR is a highly sensitive technique; reasons for apparently contradictory results may be due to improper quality control during sample collection, selection of inappropriate specimen and/or presence of PCR inhibitors.
FLT3 mutations other than ITD and D835 will not be detected with this assay. Results of this test must always be interpreted within the patient's clinical context and in conjunction with other relevant data and should not be used alone for a diagnosis of malignancy. A negative result does not definitely exclude the possibility of an *FLT3* mutation below the detection limit of this test and does not exclude the possibility of rare forms of *FLT3* mutations not detectable by this methodology.

References:

1. M Carmen Chillón, Carina Fernández, Ramón García-Sanz, Ana Balanzategui et al. FLT3-activating mutations are associated with poor prognostic features in AML at diagnosis. Hematol J. 2004; 5(3):239-46.

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However, only those cases with Double or Biallelic mutations (one in each allele) show improved prognosis.

3. Screening for *CEBPA* mutations offers a means for risk stratification in AML patients with normal karyotype.

Methodology, Test Attributes and Limitations:
Whole Blood DNA was extracted using commercial Kit. This assay is based upon PCR and Gene Sequencing of *CEBPA* (RefSeq NM_004364). The analytical sensitivity of the test allows detection of the mutation when the mutant clone comprises at least 18-20% of the total genomic DNA.
Samples must be received at the laboratory under appropriate conditions within 72hrs of aspiration to ensure preservation of high molecular weight DNA. PCR is a highly sensitive technique; reasons for apparently contradictory results may be due to improper quality control during sample collection, selection of inappropriate specimen and/or presence of PCR inhibitors.
Results of this test must always be interpreted within the patient's clinical context and in conjunction with other relevant data and should not be used alone for a diagnosis of malignancy.

Note: This Test has been developed and its performance evaluated at Pathkind Diagnostics Pvt. Ltd.

FLT3 Mutation Detection

Sample: Whole Blood EDTA

FLT3 (ITD & D835) Mutation Detection Assay (Qualitative)

Specimen: EDTA Whole Blood
Methodology: PCR & Gel Electrophoresis
Mutations Screened in: *FLT3* gene (Ref Seq NC_000013.11)

Gene/ Exon	Mutation Screened	Effect of Mutation	Molecular Status
FLT3/ Exon 14	ITD	Pathogenic	Detected
FLT3/ Exon 20	D835	Pathogenic	Not Detected

Result & Interpretation:
ITD Mutation was DETECTED in the *FLT3* gene of the sample provided.

Clinical Information:

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Results of this test must always be interpreted within the patient's clinical context and in conjunction with other relevant data and should not be used alone for a diagnosis of malignancy.

CEBPA Mutation Detection

Sample: Whole Blood EDTA

CEBPA Mutation Analysis

Specimen: EDTA Whole Blood
Methodology: PCR & Sequencing
Mutations Screened in: Entire Coding Region of *CEBPA* gene (RefSeq NM_004364)

Nature of Mutation	Effect of Mutation	Molecular Status
None	No effect on Prognosis	No Mutation Detected
Single Mutation	No effect on Prognosis	###
Double Mutation	Positive effect on Prognosis	###

Result:
No mutations were detected in the coding region of the *CEBPA* gene.

Clinical Information:
Acute myeloid leukemias (AMLs) are a heterogeneous group of disorders characterized by the clonal expansion of myeloid blasts (eg, undifferentiated myeloid precursors) in the peripheral blood, bone marrow, and/or other tissues, which results in impaired hematopoiesis and bone marrow failure.
While cytogenetic aberrations detected at the time of diagnosis are the most used prognostic feature, approximately 50% of AML cases show a normal karyotype, which is considered an intermediate-risk feature. A comprehensive evaluation of several molecular markers (eg, *FLT3*, *NPM1*, *CEBPA*, *KIT*, *IDH1* and *IDH2*) is important for risk assessment and prognostication in certain patients with AML and may guide treatment decisions.

1. *CEBPA* (CCAAT/enhancer-binding protein alpha) is a transcription factor important for myeloid differentiation and suppression of proliferation. *CEBPA* mutations define the provisional category of "Acute Myeloid Leukemia with mutated *CEBPA*" in the 2008 WHO Classification of Tumors of Haematopoietic and Lymphoid Tissues.
2. Mutations in *CEBPA* are found in 10-15% of cases of cytogenetically normal AML and are associated with a favorable prognosis.

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Test Name	Result	Biological Ref. Interval	Unit

Mutations Screened in: Exon 12 of *NPM1* gene (RefSeq NM_002520)

Gene/ Exon	Mutation Screened	Effect of Mutation	Molecular Status
NPM1/ Exon 12	Mutations A, B & D	Pathogenic	Mutation 'A' Detected

Result & Interpretation:
Mutation 'A' was observed in exon 12 of *NPM1* gene.

Clinical Information:
Acute myeloid leukemias (AMLs) are a heterogeneous group of disorders characterized by the clonal expansion of myeloid blasts (eg, undifferentiated myeloid precursors) in the peripheral blood, bone marrow, and/or other tissues, which results in impaired hematopoiesis and bone marrow failure.
While cytogenetic aberrations detected at the time of diagnosis are the most used prognostic feature, approximately 50% of AML cases show a normal karyotype, which is considered an intermediate-risk feature. A comprehensive evaluation of several molecular markers (eg, *FLT3, NPM1, CEBPA, KIT, IDH1* and *IDH2*) is important for risk assessment and prognostication in certain patients with AML and may guide treatment decisions.

1. An *NPM1* alteration is a common finding in de novo AML (25%-30% of cases) and consists of small insertion (typically 4 base pair) or insertion/deletion events involving exon 12.
2. Three variants are highly recurrent, termed types A, B, and Dand together account for approximately 90% of *NPM1* alterations in de novo AML.
3. Thus, in patients with newly diagnosed AML, those with normal karyotype, no *FLT3* variant, and a *NPM1* alteration are considered to have a better prognosis than patients in the same group with neoplasms lacking a *NPM1* alteration.
4. Furthermore, the presence of a *NPM1* alteration serves as a sensitive marker for evaluating minimal disease and therapeutic response following treatment

Methodology, Test Attributes and Limitations:
Whole Blood DNA was extracted using commercial Kit. The Kit utilizes real-time quantitative PCR (qPCR) double-dye oligonucleotide hydrolysis principle, in which specific primers and an internal double-dye probe with a reporter and a quencher (FAM™-TAMRA™) for the amplification reactions is being used. In addition, a 3'-end modified phosphate oligonucleotide is used that perfectly matches the wild-type NPM1 gene and does not allow polymerization. This test is designed to detect NPM1-mutant transcripts of types A, B, and D only. Samples must be received at the laboratory under appropriate conditions within 72hrs of aspiration to ensure preservation of high molecular weight DNA. PCR is a highly sensitive technique; reasons for apparently contradictory results may be due to improper quality control during sample collection, selection of inappropriate specimen and/or presence of PCR inhibitors.

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Test Name	Result	Biological Ref. Interval	Unit

Methodology: RTPCR & Gel Electrophoresis

Translocation Screened	Effect of Mutation	Molecular Status
PML-RARa/ t(15;17)(q22;q12)	Pathogenic	Not Detected

Result & Interpretation:
The hybrid transcript for *PML-RARa* was not detected in the leukocytes of the specimen.

Clinical Information:
PML-RARa or t(15;17)(q22;q12) is a balanced reciprocal translocation between *PML* gene on chromosome 15 & *RARa* gene on chromosome 17. This translocation is present in all cases of Acute Promyelocytic Leukemia/ AML-M3 & stratifies the patients for treatment with ATRA (all trans retinoic acid). At the genetic level, *RARa* breakpoints always occur in intron 2. *PML* breakpoints may occur in intron 6 (bcr1; 55-57%), exon 6 (bcr2; 3-5%) or intron 3 (bcr3; 40%).
This test detects the bcr1, bcr2, and bcr3 forms of the hybrid transcript.
The result of this test should be interpreted in correlation with the clinical and hematological parameters observed.

Methodology, Test Attributes and Limitations:
Whole Blood RNA was extracted using commercial Kit. This assay is based on the qualitative estimation of presence of *PML-RARa* hybrid transcript. The analytical sensitivity of this Test allows detection of 1 leukemic cell carrying the abnormal transcript in 10,000 normal cells. This Test is designed for diagnostic evaluation of the said transcript and should not be used for Monitoring purposes.
Samples must be received at the laboratory under appropriate conditions within 48hrs of aspiration to ensure preservation of RNA.
PCR is a highly sensitive technique; reasons for apparently contradictory results may be due to improper quality control during sample collection, selection of inappropriate specimen and/or presence of PCR inhibitors.

Note: This Test has been validated and its performance evaluated at Pathkind Diagnostics Pvt Ltd

NPM1 Mutation Detection

Sample: Whole Blood EDTA

NPM1 Mutation Analysis

Specimen: EDTA Whole Blood
Methodology: Real Time PCR

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Test Name	Result	Biological Ref. Interval	Unit

Methodology: RTPCR & Gel Electrophoresis

Translocation Screened	Effect of Mutation	Molecular Status
CBFB-MYH11/ inv16(p13q22)	Pathogenic	Not Detected

Result & Interpretation:
The hybrid transcript for *CBFB-MYH11* was not detected; hence the specimen is negative for inv16 mutation .
It may be noted that this RTPCR assay is designed to interrogate the presence of type A, D and E fusion transcripts only. A false negative due to the presence of other rare transcripts cannot be ruled out.

Clinical Information:
Pericentric inversion of chromosome 16, inv (16) (p13q22) is found in 8-9% cases of AML. It is most closely associated with AML-M4Eo. This inversion results in the fusion of *CBFB* gene to smooth muscle myosin heavy chain gene, *MYH11*. So far, 10 different *CBFB-MYH11* fusion transcripts have been reported. More than 85% cases have the transcript A; type D & E together represent another 10% cases. *CBFB-MYH11* or inv (16) positive AMLs are considered to have a good prognosis with more than 50% cases reaching CR. This RTPCR assay is designed to investigate the presence of type A, D and E transcripts only.
The result of this test should be interpreted in correlation with the clinical and hematological parameters observed.

Methodology, Test Attributes and Limitations:
Whole Blood RNA was extracted using commercial Kit. This assay is based on the qualitative estimation of presence of *CBFB-MYH11* hybrid transcript. The analytical sensitivity of this Test allows detection of 1 leukemic cell carrying the abnormal transcript in 100,000 normal cells. This Test is designed for diagnostic evaluation of the said transcript and should not be used for Monitoring purposes. Samples must be received at the laboratory under appropriate conditions within 48hrs of aspiration to ensure preservation of RNA. PCR is a highly sensitive technique; reasons for apparently contradictory results may be due to improper quality control during sample collection, selection of inappropriate specimen and/or presence of PCR inhibitors.

Note: This Test has been validated and its performance evaluated at Pathkind Diagnostics Pvt Ltd

 # PML-RARA t(15:17) RTPCR Qualitative
Sample: Whole Blood EDTA

PML-RARa Qualitative Assay

Specimen type: EDTA P Bld

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AML1-ETO (RUNX1-RUNX1T1) Qualitative Assay

Specimen type: EDTA P Bld
Methodology: RTPCR & Gel Electrophoresis

Translocation Screened	Effect of Mutation	Molecular Status
AML1-ETO/ t(8:21)(q22:q22.1)	Pathogenic	Not Detected

Result & Interpretation:
The hybrid transcript for *AML1-ETO* was not detected in the leukocytes of the specimen.

Clinical Information:
AML1-ETO or t(8:21)(q22:q22.1) is a balanced reciprocal translocation between *AML1* gene on chromosome 21 and *ETO* gene on chromosome 8. It is observed in 5-12% cases of AML and most closely associated with AML-M2, though it may rarely be seen in AML-M1 or M4. Immunophenotypically, a close association has been reported between expression of CD19 in AML and occurrence of *AML1-ETO* translocation. At the genetic level, *AML1* breakpoints are located within intron 5 and *ETO* breakpoint occur upstream of exon 2. Presence of the translocation denotes a good prognosis and patients often achieve CR in 85-90% cases
The result of this test should be interpreted in correlation with the clinical and hematological parameters observed.

Methodology, Test Attributes and Limitations:
Whole Blood RNA was extracted using commercial Kit. This assay is based on the qualitative estimation of presence of *AML1-ETO* hybrid transcript. The analytical sensitivity of this Test allows detection of 1 leukemic cell carrying the abnormal transcript in 100,000 normal cells. This Test is designed for diagnostic evaluation of the said transcript and should not be used for Monitoring purposes.
Samples must be received at the laboratory under appropriate conditions within 48hrs of aspiration to ensure preservation of RNA.
PCR is a highly sensitive technique; reasons for apparently contradictory results may be due to improper quality control during sample collection, selection of inappropriate specimen and/or presence of PCR inhibitors.

Note: This Test has been validated and its performance evaluated at Pathkind Diagnostics Pvt Ltd

 # Inv(16) RTPCR Qualitative

Inv16 (CBFB-MYH11) Qualitative Assay

Specimen type: EDTA P Bld

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Processed By
Pathkind Diagnostics Pvt. Ltd.
Plot No. 55-56, Udhyog Vihar Ph-IV, Gurugram - 122015

Name	: **Mst. MAYANK MEHTA IRCH-305416**	Billing Date	: 05/10/202319:30:17
Age	: 9 Yrs	Sample Collected on	: 05/10/2023 11:00:55
Sex	: Male	Sample Received on	: 05/10/2023 19:36:40
P. ID No.	: P1000100018251	Report Released on	: 25/10/2023 14:55:13
Accession No	: **100023010696**	Barcode No.	: 995326627, 995326626
Referring Doctor	: DR SAMEER BAKSHI		
Referred By	:	Ref no.	:

Report Status - Final

Test Name	Result	Biological Ref. Interval	Unit

AML Prognostication Panel
Hemat Disorder Karyotyping

Case Information :

Sample Type : WB-Heparin

Case ID : CG23-HM-292

Banding Method : GTG Banding

Banding Resolution : 450-550

Referral Reason : ? AML

No. of Cells Scored : 05

No. of Cells Karyotyped : 05

Result Karyotype : 46,XY[5]

Interpretation : A male karyotype with normal chromosome complement

Comment : Within the limits of standard cytogenetic methodologies for unstimulated cell culture, the karyotype shows normal G-banding pattern with apparently normal chromosome structure. The result is consistent with normal chromosome complement. Low grade mosaicism and cryptic translocations cannot be ruled out due to low metaphase count.

Recommendations : Nil

Limitations:
** The clinical interpretation of any test result should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results.*
** Low grade mosaicism cannot be ruled out.*

AML-ETO1 t(8;21) RTPCR Qualitative
Sample: Whole Blood EDTA
Method: RTPCR & Electrophoresis