MEDGENOME

Sy No 94/1C and 94/2, Tower-1, Veerasandra Village, Attibele Hobli,
Electronic City, Phase-1, Bangalore, Karnataka, 560100.

Fluorescent In Situ Hybridization (FISH) REPORT: FISH for Chronic Lymphocytic Leukemia (CLL) Panel- 6 markers (del6q, del17p, del13q, ATM del/Trisomy 11, Trisomy 12, IGH rearrangement)

Patient Name	I. Kathriarachchi	**Requesting Clinician**	Dr. Mahendra Perera
Gender	Female	**Hospital Information**	Aegle Omics Private Limited
Age/Date of Birth	65 Years	**Sample Source**	Peripheral Blood in Sodium Heparin.
Sample ID	9045266	**Samples Collected(Date & Time)**	25-03-2025 5:48 pm
Order ID(s)	1244031	**Samples Received(Date & Time)**	27-03-2025 11:40 am
Clinical Indication	Case of CLL.	**Report Date**	04-04-2025 5:02 pm
Collection Center/ Partner Lab	0		

RESULT SUMMARY

Sl no	Probe Name	FISH Result	ISCN 2020
1	IGH Gene Rearrangement	Positive	nuc ish(5'IGHx1,3'IGHx2)(5'IGH con 3'IGHx1)[140/200]
2	CEP12/D13S319 (13q14.2) (Tri12 and Del 13q)	Positive	nuc ish(D12Z3x3,D13S319x0~1)[120/200]
3	CEP6/MYB	Negative	nuc ish(CEP6,MYB)x2[198/200]
4	RB1/ATM	Negative	nuc ish(D11Z1,ATM)x2[198/200]
5	TP53/CEP17 (Del17p)	Negative	nuc ish(TP53,CEP17)x2[196/200]

Interpretation:

The FISH test is positive for Trisomy 12, Deletion 13q14.2 and IGH rearrangement and negative for Deletion 6q, Deletion 11q and Deletion 17p.

There is presence of IGH rearrangement with loss of spectrum green signal indicating deletion of IGHV segments within the green probe target as a result of normal somatic V-D-J recombination.Kindly correlate with clinical, hematological and cytogenetic findings.

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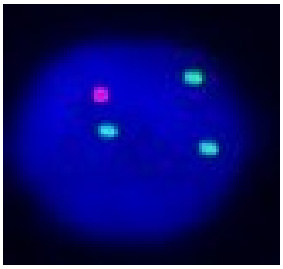
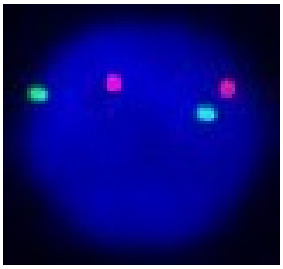
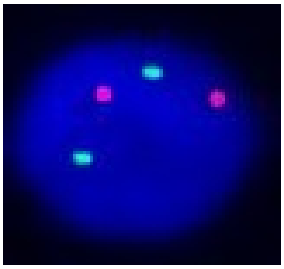
DETAILED REPORT



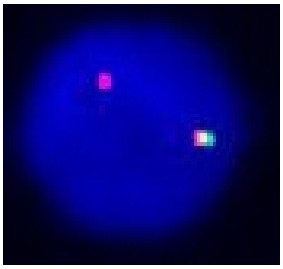
CEP12/D13S319 (13q14.2) (Tri12 and Del 13q)



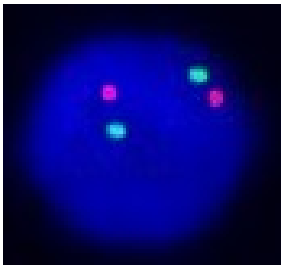
CEP6/MYB



TP53/CEP17 (Del17p)



IGH Gene Rearrangement



RB1/ATM

1) CEP12/D13S319 (13q14.2) (Tri12 and Del 13q) :

Spectrum Green (G)	**CEP 12**	**Spectrum Orange (O)**	**D13S319 (13q14.2)**

Loci Analyzed	Signal Pattern	Normal Cut Off (%)	Percentage of Cells showing signal pattern	Result
CEP12/D13S319 (13q14.2) (Tri12 and Del 13q)	**3G/1O**	**> 2 %**	**60 %**	**Positive**

2) CEP6/MYB :

Spectrum Green (G)	**CEP6**	**Spectrum Orange (O)**	**MYB(6q23)**

Loci Analyzed	Signal Pattern	Normal Cut Off (%)	Percentage of Cells showing signal pattern	Result
CEP6/MYB	**2G/2O**	**>= 98 %**	**99 %**	**Negative**

3) TP53/CEP17 (Del17p) :

Spectrum Green (G)	**CEP17**	**Spectrum Orange (O)**	**TP53**

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Loci Analyzed	Signal Pattern	Normal Cut Off (%)	Percentage of Cells showing signal pattern	Result
TP53/CEP17 (Del17p)	2G2O	>= 98 %	98 %	Negative

4) IGH(14q32) :

Spectrum Green (G)	5'IGH	Spectrum Orange (O)	3'IGH

Loci Analyzed	Signal Pattern	Normal Cut Off (%)	Percentage of Cells showing signal pattern	Result
IGH(14q32)	2F/0G/0O	>= 98 %	30 %	Positive

5) RB1/ATM :

Spectrum Green (G)	RB1	Spectrum Orange (O)	ATM

Loci Analyzed	Signal Pattern	Normal Cut Off (%)	Percentage of Cells showing signal pattern	Result
RB1/ATM	2G/2O	> 98 %	99 %	Negative

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Testing methodology: FISH is a molecular cytogenetic technique used to detect the 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. The excess unbound probe is removed during post hybridization washes. The sample is stained with a DAPI (4',6-Diamidino-2-phenylindole) counter-stain to demarcate the nuclei. Each fluorescent labelled probe that hybridizes to region of interest in interphase cells is visualized as signal using suitable optical filters under Epi fluorescent microscope. 200 interphase cells are counted for each probe manually by two readers. Interpretation of results are done based on the signal patterns observed. Based on these interpretations, the results of the test are reported. Metasystems probes are used for the CLL panel. Trisomy 12 is a tricolor probe, it can detect trisomy 12 and deletion 13q.Appropriate controls are run along with patient samples.
Chronic lymphocytic leukemia is a neoplasm composed of monomorphic small mature B-Cells. About 80-905 of cytogenetic abnormalities are detceted by FISH or copy number arrays. As per WHO, the most common abnormalities seen in CLL are Del13q14.3, trisomy 12, Del11q22-23, Del17p13 and Del6q. NCCN guidelines recommends testing for t(11;14), Del 13q, Del 11q, +12,Del 17p by FISH. **If Del 17p/TP53 mutation is present, ibrutinib is given as first line treatment.**

(i)NCCN adopted Prognostic information for CLL based on Interphase FISH results:

Prognosis	Cytogenetic markers
Unfavorable	Del (17p) , del (11q)
Neutral	Normal, Trisomy 12
Favorable	Del (13q) as sole abnormality

References:

1. National comprehensive cancer care network. NCCN guidelines for Chronic lymphocytic leukemia or Small lymphocytic leukemia (CLL/SLL).Version 5.2018-March 26,2018.
2. WHO Classification of tumors of hematopoietic and lymphoid tissues, Revised edition 2017, 215-220.

Disclaimers:

1. This test was developed, and its performance characteristics determined by MedGenome. It has not been cleared or approved by the US Food and Drug Administration.
2. The finding of this test must be correlated with other clinical, haematopathological and cytogenetic findings for complete analysis.
3. Genetic changes other than those assayed cannot be ruled out on the basis of this testing.

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End of Report