SAPIENS SG GENETIC DISEASES DIAGNOSTIC CENTER
MEDICAL ANALYSIS REPORT
LABORATORY LICENSE NO: GHDM-SM/34.39/01

Patient Name	:	**Sampling Location**	:
Gender	:	**Test Request Date**	:
Date Of Birth	:	**Sample Collection Date**	:
ID Number	:	**Sample Acceptance Date**	:
Protocol Number	:	**Report Approval Date**	:
Sample Number	:	**Report Release Date/Report Number**	:
Sample Type	:		

Refering Center / Physician :

Reason For Referral :

Test Name: t(15;17) (q22;q21) PML-RARA Fusion Analysis

Method: Quantitative Real Time PCR Analysis

Platform Used: Bio-Rad CFX96

Kit Used: Translocation Detection Kits for Leukemia, GENMARK, CE-IVD

DATA ANALYSIS RESULTS

POSITIVE,

The tested fusions (bcr1&2-bcr3) were **detected.**

INTERPRETATION:

As a result of RT-PCR analysis of RNA material extracted from patient's peripheral blood, t(15;17) (q22;q21) *PML-RARA* fusion translocation **was detected** (POSITIVE).

bcr1&2 breaks was calculated a 15 % and bcr3 break was calculated as 5 % according to kit manuel.

RECOMMENDATIONS:

The result should be evaluated together with clinical and other laboratory findings and recommended not for decision-making alone. Please refer to the technical features and restrictions section. Therapy decisions should be planned with a multidisciplinary approach.

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TECHNICAL SPECIFICATIONS and LIMITATIONS:

The kit has 'CE-IVD in vitro diagnostic' approved. It has the sensitivity to detect 5 copies of the BCR-ABL transcript in 50,000 ABL transcripts. (10-4= LOG 4).

The method may give false-negative results for mutations present in less than 1% of the sample examined. Reliable results depend on proper sample handling, transport and storage. This test was performed from the above mentioned material type. This sample was sent to our center with the record of the patient mentioned above. It is recommended to consider the influencing factors that may be involved in preanalytical errors before the material arrive to our institution. The responsibility of this process does not belong to our institution. The test does not include sample verification. There is the possibility of false positive-negative results within the technical characteristics - limitations of the method used. As with all laboratory tests, clinical findings should be prioritized; If necessary, additional tests / retests should be requested in case of clinical suspicion. As with all laboratory tests, it should not be used alone as a clinical decision maker. No comment can be made on the adequacy of the analysis, in patients for whom sufficient clinical data is not shared, and additional interpretation/recommendations cannot be made. Genetic counseling should be recommended before and after the test in all genetic screening.

GENERAL INFORMATION:

As a result of the t(15;17) translocation, the gene for retinoic acid receptor alpha (RARA) on 17q21 fuses with a transcription factor gene (promyelocytic leukemia or PML) on 15q22, giving rise to a PML/RARA gene fusion product. Acute Promyelocytic Leukemia (APL) is characterized by the reciprocal translocation t(15;17)(q22;q21) in ~90 % of cases. Fusion products with breakpoints are distinguished from each other and seen at different frequencies, bcr1, bcr2 and bcr3 isoforms can be detected with the test performed.

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Gene	Type	Variant		Break Point	Frequency
***PML-RARA* bcr1**	A	L	Long	Intron 6	55%
***PML-RARA* bcr2**	A	V	Varyant	Ekzon 6	5%
***PML-RARA* bcr3**	B	S	Short	Intron 3	40%

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