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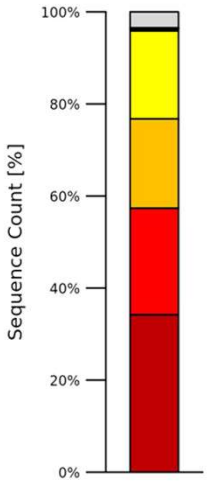
Laboratory Director
CLIA # 22D2300979

Patient Name	PTLastName, PTFirst	Treatment Date	01-Oct-2023	ProtaGene ID	SampleID
MRN	10000000003	Collection Date	23-Apr-2024	Visit #	6-month
DOB	05-Jan-2020	Received Date	24-Apr-2024	Treatment	LYFGENIA™
Gender	M	Analysis Date	01-May-2024	Facility Sample ID	88-888-88892
Diagnosis	CALD	Approval Date	02-May-2024	Facility Name	QTC Name
Referring Physician	First Last, MD	Sample Type	Blood		

INTEGRATION SITE (IS) ANALYSIS SUMMARY REPORT

Test Summary: IS analysis as routine safety evaluation to monitor for potential oncogenesis determined IS locations in DNA of the provided sample and their relative abundance as clonality measurement by S-EPTS/LM-PCR, next-generation sequencing, and bioinformatical analysis.

Result: IS profile is presented as relative contributions of the ten most abundant IS.



Rank	Gene	Freq. [%]	Location
Top1	MIB1	34.189	18-19440045
Top2	LOC101060019	23.163	2+67192774
Top3	MECOM	19.410	3+169089416
Top4	OXCT1	19.108	5+41785394
Top5	EHD2	0.336	19+48237796
Top6	KMT2A	0.225	11-118348583
Top7	PALM	0.041	19-702353
Top8	NEAT1	0.025	11+65206059
Top9	ZNF384	0.024	12-6797269
Top10	ZBTB34	0.018	9+129644388
#All Other mapp. IS	1646	3.462	

Seq Count 10 strongest	198210
Seq Count all other mapp. IS	7108
Total Seq Counts Used	205318

Caption: Gene name corresponds to RefSeq identification of genes located next to (or at) the IS. Location contains the chromosome number, sequence orientation (plus or minus strand), and locus of the IS (based on human reference genome hg19).

Comments: While increasing IS contribution may be associated with an increased risk of a malignancy, it will not *a priori* result in a malignancy. Therefore, regular IS testing and timely trigger of enhanced monitoring is essential mitigation measure.

Note that sequencing reads mapping to multiple locations in the reference genome have been removed from analysis. Frequency of the high contributing IS were not substantially changed. IS test results should not be the sole basis for patient management. Results should be interpreted in consultation with a qualified licensed health care practioner.

Approval: Result was reviewed and approved by the Laboratory Director, Pertti Toivola, PhD.