Seraseq®

FFPE Lymphoma DNA Reference Material

Package Insert

PLEASE NOTE:
THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

NAME AND INTENDED USE

The Seraseq® FFPE Lymphoma DNA Reference Material product is a reference material formulated for use with Next Generation Sequencing (NGS) assays that detect somatic mutations in hematologic disorder patient samples. This product is intended for use as a reference material in the development, validation and routine laboratory tests used to detect lymphoma disease gene variants by NGS assays under a given set of bioinformatics pipeline parameters. Product is *For Research Use Only. Not for use in diagnostic procedures*.

REAGENTS

Material Number	Product Name
0710-2202	Seraseq® FFPE Lymphoma DNA Reference Material

Product consist of one 10µm FFPE curl per vial.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq FFPE Lymphoma DNA Reference Material product as though it is capable of transmitting infectious agents. This product is formulated using an engineered human cell line derived from GM24385, which is a B-lymphocytic, male cell line from the Genome in a Bottle (GIAB) Project.

Safety Precautions

Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling reference materials and human specimens[1]. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are being handled. Clean any spillage by immediately wiping with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

Handling Precautions

Do not use Seraseq FFPE Lymphoma DNA Reference Material product beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

STORAGE INSTRUCTIONS

Store Seraseq FFPE Lymphoma DNA Reference Material at 2-8°C. After opening, record the date opened and the expiration date on the vial.

PROCEDURE

Materials Provided

Seraseq FFPE Lymphoma DNA Reference Material consists of engineered cells which have been formalin treated and embedded in paraffin to create an FFPE block, which is then sectioned into 10 µm curls. One 10µm FFPE curl is provided per vial.

Materials Required but not Provided

Seraseq FFPE Lymphoma DNA Reference Material require extraction. Refer to instructions supplied by manufacturers of the extraction kit to be used.

Instructions for Use

Allow the product vial to come to room temperature before use. Seraseq FFPE Lymphoma DNA Reference Material must go through an extraction process. Refer to your assay procedures in order to determine the amount of extracted material to use in library preparation.

EXPECTED RESULTS & INTERPRETATION OF RESULTS

Seraseq FFPE Lymphoma DNA Reference Material is compatible with commercially available nucleic acid extraction methods commonly used for FFPE specimens. Average DNA extraction yields per FFPE curl (10 µm) when using either Promega's Maxwell RSC FFPE DNA kit or Qiagen's QIAamp DNA FFPE Tissue kit, quantitated by Thermo Fisher's Qubit dsDNA HS assay, are provided in Table 1 below.

Table 1: Representative DNA extraction yield per 10µm FFPE curl

	Average Yield per 10µm curl (ng)	
FFPE Block	**Qiagen QIAamp DNA FFPE Tissue**	**Promega Maxwell RSC DNA FFPE**
Average (ng)	193 ± 44	124 ± 11

Table 2 lists the gene variants represented in the Seraseq FFPE Lymphoma DNA Reference Material. Detection of mutations may differ across different NGS panels and different test reagent lots. While the presence and frequency of each mutation in this product was confirmed during manufacture using functional NGS and/or digital PCR assays, there may be differences in observed allele frequencies due to assay characteristics. Seraseq FFPE Lymphoma DNA Reference Material does not have assigned values for allele frequencies of the mutations present in the product. Each laboratory must establish an assay-specific expected value for each mutation and each lot of Seraseq FFPE Lymphoma DNA Reference Material. When results for the product are outside of the established acceptance range, it may indicate unsatisfactory test performance. Possible sources of error include: deterioration of test kit reagents, operator error, faulty performance of equipment, contamination of reagents, or changes in bioinformatics pipeline parameters. Additional support documents are available by contacting us at CDx.Marketing@LGCGroup.com

LIMITATIONS OF THE PROCEDURE

Seraseq FFPE Lymphoma DNA Reference Material MUST NOT BE SUBSTITUTED FOR THE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS. *TEST PROCEDURES* provided by manufacturers must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. This product is offered for Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly. Seraseq FFPE Lymphoma DNA Reference Material is not a calibrator and should not be used for assay calibration. These materials are not whole-process controls and do not evaluate the methods used for specimen extraction. Adverse shipping and/or storage conditions or use of outdated product may produce erroneous results.

REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

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Table 2: List of 26 DNA gene variants in the Seraseq FFPE Lymphoma DNA Reference Material

#	5' partner	3'partner	Variant Type	
1	NPM1	ALK	Translocation	
2	HSP90AA1	BCL6	Translocation	
3	CCND1	CDC42BPB	Translocation	
4	BIRC3	MALT1	Translocation	
5	MYC	IGH	Translocation	
6	TBL1XR1	TP63	Translocation	
#	**Gene**	**Nucleic acid change**	**Amino Acid Change**	**Variant Type**
7	BCL2	c.302G>C	p.G101A	SNV
8	BRAF	c.1799T>A	p.V600E	SNV
9	DNMT3A	c.2645G>A	p.R882H	SNV
10	EZH2	c.1922A>T	Y641F	SNV
11	IDH2	c.515G>A	p.R172K	SNV
12	MYD88	c.794T>C	p.L265P	SNV
13	CXCR4	c.1013C>G	p.S338X	SNV
14	CXCR4	c.1013C>A	p.S338X	SNV
15	NOTCH1	c.7541_7542del	p.P2514Rfs*4	Del
16	NOTCH2	c.7198C>T	p.R2400*	SNV
17	RHOA	c.50G>T	p.G17V	SNV
18	SF3B1	c.2098A>G	p.K700E	SNV
19	STAT3	c.1919A>T	p.Y640F	SNV
20	STAT3	c.1982A>T	p.D661V	SNV
21	STAT3	c.1940A>T	p.N647I	SNV
22	STAT5B	c.1994A>T	p.Y665F	SNV
23	STAT5B	c.1924A>C	p.N642H	SNV
24	TP53	c.743G>A	p.R248Q	SNV
25	TP53	c.820del	p.V274Ffs*71	Del
26	TP53	c.818G>A	p.R273H	SNV