

Seraseq[®] Lymphoma DNA Products

The first comprehensive reference material for NGS-based lymphoid assay development, validation, and routine QC use

INTRODUCTION

Lymphoma is cancer of the lymphatic system and represents about a third of all hematological disorders. In the US, ~5% of all cancers are diagnosed with this malignancy, which is the largest demography of blood cancers. While there are many subtypes of this disease, the two most notables are Hodgkin's Lymphoma (HL) and Non-Hodgkin's Lymphoma (NHL), which impact children as well as adults. According to the 2020 report of cancer diseases in the US by the National Cancer Institute (NCI), ~700,000 Americans are living with this disease, with ~80,000 newly diagnosed, and ~20,000 deaths.

To help clinical labs performing NGS-based lymphoid testing better develop, characterize, validate and routinely assess lymphoid diseases by NGS assays, SeraCare has developed the Seraseq Lymphoma DNA Mutation Mix, Seraseq FFPE Lymphoma Reference Material and Seraseq ctDNA Lymphoma DNA Mutation Mix, the first set of comprehensive lymphoid cancer NGS assay reference materials. These unique products include clinically important SNVs, INDELs and gene fusions important in lymphoma disease diagnosis and prognosis. Variants are present against a single well-characterized genomic background (GM24385) at clinically relevant allele frequencies, precisely quantitated by digital PCR assays.

FEATURES AND BENEFITS

- Develop and validate Lymphoid-based NGS assays with confidence using a highly multiplexed reference material containing biomarkers important in Lymphoma cancers.
- Provide robust sensitivity to detect clinically-relevant mutations at variant allele frequencies that establish and validate assay LoD claims.
- Mutation targets are quantitated using highly sensitive digital PCR as well as a custom NGS assay.
- All mutations are blended against GM24385 human genomic DNA as background 'wild-type' material.
- Available as purified gDNA, ctDNA, and FFPE curls for end-to-end assay performance monitoring.
- Manufactured in GMP-compliant and ISO 13485-certified facilities.

HIGHLIGHTS

Highly multiplexed reference material containing clinically significant variants primarily found in lymphoid tumors

First-to-market reference standard for lymphoma diseases

High-quality manufactured reference material; guarantees consistent ground truth

ORDERING INFORMATION

Material #	Product	Concentration	Fill Volume	Total Mass
0710-2202	Seraseq FFPE Lymphoma DNA Reference Material	1 FFPE curl/vial	10 µm	>100 ng*
0710-2203	Seraseq Lymphoma DNA Mutation Mix	15 ng/µl	25 µl	375 ng
0710-3184	Seraseq ctDNA Lymphoma Mix AF0.1%	10 ng/µl	25 µl	250 ng
0710-3183	Seraseq ctDNA Lymphoma Mix AF0.5%	10 ng/µl	25 µl	250 ng
0710-3182	Seraseq ctDNA Lymphoma Mix AF1%	10 ng/µl	25 µl	250 ng
0710-3181	Seraseq ctDNA Lymphoma Mix WT	10 ng/µl	25 µl	250 ng

* Based on Qiagen QIAamp DNA FFPE Tissue Kit and the Qubit dsDNA HS Assay.

MUTATIONS PRESENT IN THE SERASEQ® LYMPHOMA PRODUCTS

5' partner	3'partner	Variant Type
NPM1	ALK	Translocation
HSP90AA1	BCL6	Translocation
CCND1	CDC42BPB	Translocation
BIRC3	MALT1	Translocation
MYC	IGH	Translocation
TBL1XR1	TP63	Translocation

Gene	Nucleic acid change	Amino Acid Change	Variant Type
BCL2	c.302G>C	p.G101A	SNV
BRAF	c.1799T>A	p.V600E	SNV
DNMT3A	c.2645G>A	p.R882H	SNV
EZH2	c.1922A>T	Y641F	SNV
IDH2	c.515G>A	p.R172K	SNV
MYD88	c.794T>C	p.L265P	SNV
CXCR4	c.1013C>G	p.S338X	SNV
CXCR4	c.1013C>A	p.S338X	SNV
NOTCH1	c.7541_7542del	p.P2514Rfs*4	Del
NOTCH2	c.7198C>T	p.R2400*	SNV
RHOA	c.50G>T	p.G17V	SNV
SF3B1	c.2098A>G	p.K700E	SNV
STAT3	c.1919A>T	p.Y640F	SNV
STAT3	c.1982A>T	p.D661V	SNV
STAT3	c.1940A>T	p.N647I	SNV
STAT5B	c.1994A>T	p.Y665F	SNV
STAT5B	c.1924A>C	p.N642H	SNV
TP53	c.743G>A	p.R248Q	SNV
TP53	c.820del	p.V274Ffs*71	Del
TP53	c.818G>A	p.R273H	SNV

ABOUT US

SeraCare offers a comprehensive portfolio of reference materials for oncology and reproductive health, designed and manufactured to meet the precision demanded by NGS assays. The portfolio includes high quality ground-truth RNA, ctDNA and genomic DNA-based reference materials that are NGS platform agnostic for tumor profiling, immuno-oncology, liquid biopsy, NIPT and germline cancer assay workflows. **For more information visit seracare.com**