

Seraseq[®] Myeloid DNA and RNA Fusion Reference Materials

THE FIRST COMPREHENSIVE REFERENCE MATERIALS FOR NGS-BASED MYELOID ASSAY DEVELOPMENT, VALIDATION, AND QC

HIGHLIGHTS

SINGLE-SAMPLE, MULTIPLEXED FORMAT; PATIENT- LIKE SAMPLE PERFORMANCE.

23 DNA MUTATIONS AND NINE FUSION RNA VARIANTS QUANTITATED WITH DIGITAL PCR; ASSURES ACCURATE, AND CONSISTENT DETECTION OF CLINICALLY RELEVANT MUTATIONS

HIGH-QUALITY MANUFACTURED REFERENCE MATERIAL; CONSISTENT GROUND TRUTH

INTRODUCTION

Blood cancers, such as acute myeloid leukemia (AML) and chronic myeloid leukemia (CML), are estimated to affect millions of people around the world, but current diagnosis methods are time-consuming and expensive. Molecular analysis of myeloid cancers is rapidly shifting from traditional singleplex methods such as FISH and qPCR, to highly multiplexed NGS assays. To ensure confidence in assay performance across the diverse types of mutations prevalent for myeloid cancers, clinical labs need to overcome the challenge of sourcing relevant mutations and the high expense associated with singleplex samples such as residual patient specimens and cell lines.

To help clinical labs performing NGS-based myeloid testing thoroughly understand and characterize their assays, SeraCare has developed the Seraseq Myeloid Mutation DNA Mix and Seraseq Myeloid Fusion RNA Mix, the first set of comprehensive myeloid cancer NGS reference materials. These unique products include a wide range of mutation types, from simple but clinically important SNVs, to gene fusions. To maximize compatibility with existing and emerging myeloid assays, the new products contain 23 DNA mutations (including FLT3 ITDs and NPM1) along with nine fusion RNAs (including BCR-ABL and PML-RARA). Variants are present against a single well-characterized genomic background (GM24385) at clinically relevant allele frequencies which are precisely quantified using highly sensitive digital PCR assays.

KEY GENES INCLUDED

ABL1	BRAF	CEBPA	IDH1
ASXL1	CBL	FLT3	JAK2
BCR-ABL	EVT6-ABL1	PCM1-JAK2	PML-RAR α

FEATURES AND BENEFITS

- Develop and validate your assay with confidence using the most comprehensive patient-like reference materials in the market for myeloid cancers
- Ensure robust sensitivity using a single sample with clinically-relevant mutations across a range of variant allele frequencies that establish and challenge your limit of detection (LOD)
- Mutation targets precisely quantitated with digital PCR and blended with single well-characterized GM24385 human genomic DNA as background 'wild-type' material
- Manufactured in GMP-compliant, ISO 13485-certified facilities

ABOUT SERACARE

TRUSTED SUPPLIER TO THE DIAGNOSTIC TESTING INDUSTRY FOR OVER 30 YEARS.

HIGH-QUALITY CONTROL PRODUCTS, RAW BIOLOGICAL MATERIALS, AND IMMUNOASSAY REAGENTS.

INNOVATIVE TOOLS AND TECHNOLOGIES TO PROVIDE ASSURANCE IN DIAGNOSTIC ASSAY PERFORMANCE AND TEST RESULTS.

FOR MORE INFORMATION, PLEASE VISIT OUR WEBSITE: WWW.SERACARE.COM.

23 DNA MUTATIONS IN THE SERASEQ MYELOID MUTATION DNA MIX

Gene ID	HGVS
ABL1	c.944C>T
ASXL1	c.1900_1922del23
BRAF	c.1799T>A
CALR	c.1092_1143del52
CBL	c.1259G>A
CBL	c.1139T>C
CEBPA	c.68_69insC
CEBPA	c.939_940insAAG
CSF3R	c.1853C>T
FLT3	c.1759_1800dup
FLT3	duplication of chr13:28,608,250-28,608,277 (hg19), insGCCCC between duplicated and native seq
FLT3	c.2503G>T
IDH1	c.394C>T
JAK2	c.1849G>T
JAK2	c.1624_1629delAATGAA
MPL	c.1544G>T
MYD88	c.794T>C
NPM1	c.863_864insTCTG
SF3B1	c.2098A>G
SF3B1	c.1998G>T
SRSF2	c.284_307del24
U2AF1	c.101C>T

NINE RNA FUSIONS IN THE SERASEQ MYELOID FUSION RNA MIX

Gene ID	HGVS
BCR-ABL1	BCR{NM_004327.3}:r.1_3378_ABL1{NM_005157.3}:r.83_5384
ETV6-ABL1 (transcript 1)	ETV6{NM_001987.4}:r.1_737_ABL1{NM_007313.2}:r.576-5881
ETV6-ABL1 (transcript 2)	ETV6{NM_001987.4}:r.1_1283_ABL1{NM_007313.2}:r.576-5881
FIPIL1-PDGFRFA	FIPIL1{NM_030917.3}:r.1_1109_PDGFRFA{NM_006206.5}:r.2037_6590
MYST3-CREBBP	MYST3{NM_006766.4}:r.1_3803_CREBBP{NM_004380.2}:r.290_10197
PCMI-JAK2	PCMI{NM_006197.3}:r.1_4365_JAK2{NM_004972.3}:r.2008_5285
PML-RAR α	PML{NM_033238.2}:r.1_1786_ins134bp_RARA{NM_000964.3}:r.657_3301
RUNX1-RUNX1T1	RUNX1 {NM_001754.4}: r.1-803_ RUNX1T1 {NM_004349.3}:r.419-7420
TCF3-PBX1	TCF3{NM_003200.3}:r.1_1519_PBX1{NM_002585.3}:r.729_6918

For detailed variant information, visit www.seracare.com/myeloid

ORDERING INFORMATION

Each part code is available for individual purchase.

Product	Format	Part Code	Frequency	Concentration	Volume	Total Mass
Seraseq Myeloid Mutation DNA Mix	NO EXTRACTION REQUIRED Purified DNA in buffer	0710-0408	As low as 5%	15 ng/ μ L	25 μ L	375 ng
Seraseq Myeloid Fusion RNA Mix	NO EXTRACTION REQUIRED Purified RNA in buffer	0710-0407	NA	15 ng/ μ L	25 μ L	375 ng

