Seraseq®
FFPE Solid Tumor CNV Reference Material

Package Insert

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

NAME AND INTENDED USE

The Seraseq® FFPE Solid Tumor CNV Reference Material (RM) product is a full-process reference material formulated for use with targeted Next Generation Sequencing (NGS) assays that detect copy number variations (CNVs) in human solid tumor samples. This product is intended for use as a reference material in the development, validation, and routine use of laboratory tests designed to detect clinically actionable CNVs by NGS assays under a given set of bioinformatics pipeline parameters.
For Research Use Only. Not for use in diagnostic procedures.

REAGENT

Table 1. Seraseq FFPE Solid Tumor CNV RM

Material No.	Product
0710-2865	Seraseq® FFPE Solid Tumor CNV RM

One 10 µm FFPE curl per vial

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle the Seraseq FFPE Solid Tumor CNV RM 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 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 up 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 the Seraseq FFPE Solid Tumor CNV RM product beyond expiration date. Avoid contamination of the product when opening and closing the vials.

STORAGE INSTRUCTIONS

Store the Seraseq FFPE Solid Tumor CNV RM at 2-8°C. Shelf life when stored under this condition is two years from date of manufacture.

PROCEDURE

Materials Provided

The Seraseq FFPE Solid Tumor CNV RM 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 10 µm FFPE curl is provided per vial, and each kit includes 1 vial.

Materials Required but not Provided

The Seraseq FFPE Solid Tumor CNV RM product requires DNA 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. The Seraseq FFPE Solid Tumor CNV RM product must go through a DNA extraction process. Refer to your assay procedures to determine the amount of extracted material to use in library preparation.

EXPECTED RESULTS & INTERPRETATION OF RESULTS

The Seraseq FFPE Solid Tumor CNV RM product is compatible with commercially available nucleic acid extraction methods commonly used for FFPE specimens. The product is designed to give a minimum yield of 100 ng DNA per curl when using the AutoGen XTRACT Genomic DNA FFPE One-Step Kit and the Qubit dsDNA HS Assay.

DNA Integrity Number (DIN) is calculated from DNA extracted using the AutoGen XTRACT Genomic DNA FFPE One-Step Kit and assessed using the Agilent gDNA ScreenTape Assay. Batch specific DIN value can be found in the Technical Product Report.

Table 2 lists the CNVs in the Seraseq FFPE Solid Tumor CNV RM product. Detection of CNVs may differ across different NGS assays and different test reagent lots. The copy number of each CNV in this product is examined during manufacture using digital PCR (dPCR) and/or NGS assays. Variation in copy numbers for each CNV exists so that this product is deemed as qualitative. There may be differences in observed copy numbers due to assay characteristics. Each laboratory must establish an assay-specific expected value for each CNV and lot of the Seraseq FFPE Solid Tumor CNV RM prior to its routine use. 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 online at www.seracare.com/oncology.

Table 2: Gene Targets*

AKT2	BRAF	EGFR	ERBB2	FGFR3	KIT
KRAS	MET	MYC	MYCN	NTRK1	PIK3CA

*Each gene in the table is present at >3 additional copies verified by dPCR.

BRAF, EGFR, and MET genes are amplified using two synthetic constructs with a small region of overlap between the constructs. Assays targeting this overlapping region may report higher amplification levels. Table 3 specifies the overlapping regions of the BRAF, EGFR, and MET genes.

Table 3: Amplified overlapping regions of BRAF, EGFR, and MET

Gene	Chr	GRCh37 Amplified Location	GRCh37 Gene Location
BRAF	7	140303580_140516241 140505751_140669283	140413128_140624729
EGFR	7	55075561_55231755 55213103_55316773	55086710_55279321
MET	7	116302716_116418397 116372111_116489445	116312250_116438431

LIMITATIONS OF THE PROCEDURE

The Seraseq FFPE Solid Tumor CNV RM product 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. These products are offered for Research Use Only. Not for use in diagnostic procedures. Data is provided for informational purposes. LGC Clinical Diagnostics SeraCare does not claim that others can duplicate test results exactly. Note that based on your particular assay protocol and regions interrogated, targets other than the 12 annotated in these products may be detected at varying allele frequencies and copy numbers. The Seraseq FFPE Solid Tumor CNV RM product is not a calibrator and should not be used for assay calibration. Adverse shipping and/or storage conditions or use of outdated products 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.

LGC Clinical Diagnostics, Inc. | 37 Birch Street, Milford, MA 01757 USA
Phone: +1 508.244.6400 | Toll Free (US Only) 800.676.1818
info@seracare.com | www.seracare.com

14234-01 March 2023