Seraseq®
Solid Tumor CNV Mix

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
Seraseq® Solid Tumor CNV Mix products are reference materials formulated for use with targeted Next Generation Sequencing (NGS) assays that detect amplifications in human samples. This product is intended as reference material of clinically actionable Copy Number Variations (CNVs) analyzed by solid tumor NGS assays under a given set of bioinformatics pipeline parameters. *For Research Use Only. Not for use in diagnostic procedures.*

REAGENT
Table 1. Different levels of amplification are available as individual products for Seraseq Solid Tumor CNV Mix.

Material No.	Product
0710-2866	Seraseq® Solid Tumor CNV Mix, +3 copies
0710-2867	Seraseq® Solid Tumor CNV Mix, +6 copies
0710-2868	Seraseq® Solid Tumor CNV Mix, +12 copies

WARNINGS AND PRECAUTIONS
For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle the Seraseq Solid Tumor CNV Mix product as though it is capable of transmitting infectious agents.

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 Solid Tumor CNV Mix product beyond expiration date. Avoid contamination of the product when opening and closing the vials.

STORAGE INSTRUCTIONS
Store the Seraseq Solid Tumor CNV Mix product at -20°C.

PROCEDURE
Materials Provided
Seraseq Solid Tumor CNV Mix consists of genomic DNA purified from GM24385 cell line and biosynthetic DNA constructs. The DNA is in 1 mM Tris, 0.1 mM EDTA pH 8.0 with 10 mM Potassium Chloride. 20 µL is provided per vial and the concentration is 10 ng/µL.

Materials Required but not Provided
Refer to instructions supplied by manufacturers of the test kits to be used.

Instructions for Use
Allow the product vial to come to room temperature before use. Refer to your assay procedures to determine the amount of material to use in library preparation.

EXPECTED RESULTS & INTERPRETATION OF RESULTS
Table 2 indicates the target genes with copy number gains present in the Seraseq Solid Tumor CNV Mix reference materials. See batch-specific technical product report for observed CNV values. The additional copies are present in a synthetic DNA construct of approximately 130 kilobases surrounding the genes of interest. Table 3 specifies regions of the BRAF, EGFR and MET genes that may be present at higher-than-expected number of copies. Detection of gene amplification levels (copies) may differ across different NGS targeted assays as well as different test consumable lots. While the level of amplification of the CNV targets in this product is confirmed during manufacture by orthogonal assays - digital PCR and NGS systems - there may be slight variation in amplification levels due to platform/assay differences. Each laboratory must establish an assay-specific expected value for each target CNV from each lot of the Seraseq Solid Tumor CNV Mix reference materials. If CNV calls for the Seraseq product are outside the established acceptance range, it may indicate unsatisfactory test performance. Possible sources of error may include degradation of test kit reagents, operator error, faulty performance of equipment, contamination of assay reagents, or change in bioinformatics pipeline parameters. Additional support documents are available online at www.seracare.com/oncology.

Table 2. Gene Targets and Estimated CNVs*

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

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 Solid Tumor CNV Mix product MUST NOT BE SUBSTITUTED FOR THE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

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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 are 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 copy numbers. The Seraseq Solid Tumor CNV Mix product 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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