Seraseq®
gDNA MSI-High 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
The Seraseq® gDNA MSI-High Mix product is a reference material formulated for use with Next Generation Sequencing (NGS) assays that detect microsatellites in human cancer patient samples. This product is intended for use as a reference material in the determination of the number of extended microsatellites in a cancer patient sample analyzed by NGS assays under a given set of bioinformatics pipeline parameters. Product is *For Research Use Only. Not for use in diagnostic procedures.*

REAGENTS

0710-1670: Seraseq gDNA MSI-High Mix
1 vial, 25 ng/µl concentration, 20 µl fill volume, and 500 ng total mass.

WARNINGS AND PRECAUTIONS
For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq gDNA MSI-High Mix product as though it is capable of transmitting infectious agents. This product consists of purified genomic DNA from a diseased breast cancer cell line.

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 gDNA MSI-High Mix product beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

STORAGE INSTRUCTIONS
Store Seraseq gDNA MSI-High Mix frozen at -20°C. Aliquoting of the product into low DNA binding tubes may be advisable to limit the number of freeze-thaw cycles. Shelf life when stored under these conditions is two years from date of manufacture.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION
Seraseq gDNA MSI-High Mix is formulated as a tumor only reference material, derived from expanded/cultured human cell line of a diseased (tumor) patient, and should appear as a clear liquid. Alterations in this appearance may indicate instability or deterioration of the product and vial should be discarded.

PROCEDURE
Materials Provided
Seraseq gDNA MSI-High Mix consists of high molecular weight DNA purified from a human diseased cell line. The purified DNA is present in a 1 mM Tris, 0.1 mM EDTA, pH 8.0 aqueous buffer. Material is ready to use in NGS assays in steps that follow DNA isolation. No further purification or DNA isolation is needed.

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

Instructions for Use
Thaw the product vial on ice. Mix by vortexing to ensure a homogenous solution and spin briefly. Seraseq gDNA MSI-High Mix may be input directly into library preparation following procedures used for clinical specimens. Refer to your assay procedures in order to determine the amount of material to use.

EXPECTED RESULTS & INTERPRETATION OF RESULTS
Table 1 provides MSI analysis result for the Seraseq gDNA MSI-High Mix product as determined by the TSO500 assay. Detection of microsatellites may differ across different NGS panels, and concomitantly the MSI score and MSI-High determination for this product by other targeted NGS panels may differ. Each laboratory must establish an expected MSI score for the Seraseq gDNA MSI-High Mix product. 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.

LIMITATIONS OF THE PROCEDURE
Seraseq gDNA MSI-High Mix 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 gDNA MSI-High Mix is not a calibrator and should not be used for assay calibration. This material is not a whole-process control and does not evaluate the method 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.

Table 1: MSI status determination for the Seraseq gDNA TMB Mix based on the TSO500 Assay.

Product Name	Material Number	Av. MSI Sites Detected*	Av. Unstable MSI sites*	Av. MSI Score*	MSI Call
Seraseq® gDNA MSI-High Mix	0710-1670	106	81	77.1	High

**MSI measurements are from replicate runs on the TSO500. MSI score is the ratio of the unstable MSI sites to the total number of sites detected (expressed as a percentage). The value must be >20% for an MSI-High result.*

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