Seraseq®

FFPE MSI-High Reference Material

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® FFPE MSI-High Reference Material 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

Material Number	Product Name`
0710-2236	Seraseq® FFPE MSI-High Reference Material

Product consist of one 10µm FFPE curl per vial.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq FFPE MSI-High Reference Material product as though it is capable of transmitting infectious agents. This product is formulated from a diseased uterine/cervical cancer cell line (https://www.atcc.org/products/htb-31).

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 FFPE MSI-High Reference Material product beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

STORAGE INSTRUCTIONS

Store Seraseq FFPE MSI-High Reference Material at 2-8 °C. After opening, record the date opened and the expiration date on the vial.

PROCEDURE

Materials Provided

Seraseq FFPE MSI-High Reference Material consists of human diseased cells that were formalin treated and embedded in paraffin to create an FFPE block, and then sectioned into 10 µm curls. One 10 µm FFPE curl is provided per vial.

Materials Required but not Provided

Seraseq FFPE MSI-High Reference Material require 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. Seraseq FFPE MSI-High Reference Material must go through an extraction process. Refer to your assay procedures in order to determine the amount of extracted material to use in library preparation.

EXPECTED RESULTS & INTERPRETATION OF RESULTS

Seraseq FFPE MSI-High Reference Material is compatible with commercially available nucleic acid extraction methods commonly used for FFPE specimens. DNA extraction yields per FFPE curl (10 µm) when using either Promega's Maxwell RSC FFPE DNA kit or Qiagen's QIAamp DNA FFPE Tissue kit, quantitated by Thermo Fisher's Qubit dsDNA HS assay, are provided in Table 1 below

Table 1: Representative DNA extraction yield per 10µm FFPE curl.

	Yield per 10µm curl (ng)	
FFPE Block	**Qiagen QIAamp DNA FFPE Tissue (ng)**	**Promega Maxwell RSC DNA FFPE (ng)**
1	593	272
2	492	298
3	620	300
Average (ng)	**568 ± 117**	**290 ± 39**

Table 2 provides MSI analysis result for the Seraseq FFPE MSI-High Reference Material 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 FFPE MSI-High Reference Material. 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 by contacting us at CDx.Marketing@LGCGroup.com

LIMITATIONS OF THE PROCEDURE

Seraseq FFPE MSI-High Reference Material 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 FFPE MSI-High Reference Material 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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Table 2: MSI status determination for the Seraseq FFPE MSI-High Reference Material based on the TSO500 Assay.

Product Name	Material Number	Av. MSI Sites Detected	Av. Unstable MSI sites	Av. MSI Score*	MSI Call
Seraseq® FFPE MSI-High Reference Material	0710-2236	119 105	90 75	75.6 71.4	MSI-High MSI-High

**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.*