Seraseq®

Compromised FFPE WT (DNA/RNA) 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® Compromised FFPE WT (DNA/RNA) Reference Material is a full-process negative control reference material formulated for use with targeted Next Generation Sequencing (NGS) assays that detect mutations in DNA as well as RNA-based gene fusions in a wide range of cancer genes. This product is intended as a quality reference material for translational and disease research testing to monitor nucleic acid extraction, library preparation, sequencing, DNA mutations and RNA fusion detection under a given set of bioinformatics pipeline parameters. *For Research Use Only. Not for use in diagnostic procedures.*

REAGENTS

Table 1. Seraseq Compromised FFPE WT (DNA/RNA) Ref Mtrl

Material No.	Product
0710-1710	Seraseq® Compromised FFPE WT (DNA/RNA) RM

One 10 µm FFPE curl per vial

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq Compromised FFPE WT (DNA/RNA) Reference Material 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 (GIAB) 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 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 Compromised FFPE WT (DNA/RNA) Reference Material beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

STORAGE INSTRUCTIONS

Store Seraseq Compromised FFPE WT (DNA/RNA) Reference Material at 2-8 °C. Shelf life when stored under these conditions is two years from date of manufacture.

PROCEDURE

Materials Provided

Seraseq Compromised FFPE WT (DNA/RNA) Reference Material consists of cells which have been formalin treated to create a more damaged DNA and embedded in paraffin to yield an FFPE block, which is then sliced into 10 µm sections. One 10 µm FFPE curl is provided per vial.

Materials Required but not Provided

Seraseq Compromised FFPE WT (DNA/RNA) Reference Material product 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 Compromised FFPE WT (DNA/RNA) Reference Material must go through an extraction process. Refer to your usual assay procedures in order to determine the amount of extracted material to use in library preparation.

EXPECTED RESULTS & INTERPRETATION OF RESULTS

Seraseq Compromised FFPE WT (DNA/RNA) Reference Material is compatible with different commercially available nucleic acid extraction methods commonly used for FFPE specimens. We have used the Agencourt Formapure extraction kit paired with Qubit to quantify extracted yield of RNA, and the QIAamp FFPE Tissue kit paired with Qubit to quantify extracted DNA yield (see Table 2).

Table 2. Average yield from a 1x10 µm curl

RNA Yield / 10 µm curl (ng)	DNA Yield / 10 µm curl (ng)
1165.3 ± 43.1	205.1 ± 10.4

RNA yield from Agencourt Formapure
DNA yield from QIAamp FFPE Tissue Kit

Heterozygous Mutations Identified in the Product

Potentially pathogenic mutations and fusions are detected in the Seraseq Compromised FFPE WT (DNA/RNA) Reference Material when using ILMN TSO500 NGS panel. We provide these data in lot specific Technical Product Reports to establish that while this product is a wild-type reference sample the end user needs to be aware of the presence of variants in the sample[2]. 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.

LIMITATIONS OF THE PROCEDURE

Seraseq Compromised FFPE WT (DNA/RNA) 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 Compromised FFPE WT (DNA/RNA) Reference Material is not a calibrator and should not be used for assay calibration. 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.
2. Zook Justin M, Catoe D, McDaniel J, et al. Extensive sequencing of seven human genomes to characterize benchmark reference materials. Sci Data. 2016;3: 160025.

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