

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® TNA (DNA/RNA) WT Mix product is a wild-type reference material formulated for use with Next Generation Sequencing (NGS) assays that detect somatic 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 under a given set of bioinformatics pipeline parameters. Product is *For Research Use Only. Not for use in diagnostic procedures.*

REAGENTS

Table 1. Seraseq TNA (DNA/RNA) WT Mix

Material No.	Product
0710-1580	Seraseq® TNA (DNA/RNA) WT Mix

1 kit = 2 vials (1x 500 ng DNA; 1x 500 ng RNA), 2x 25 ng/µL conc.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.

CAUTION: Handle Seraseq TNA (DNA/RNA) WT Mix product as though it is capable of transmitting infectious agents. This product is 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 specimens¹. 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 TNA (DNA/RNA) WT Mix beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

STORAGE INSTRUCTIONS

Store Seraseq TNA (DNA/RNA) WT Mix at -70°C. Shelf life when stored under these conditions is two years from date of manufacture.

PROCEDURE

Materials Provided

Seraseq TNA (DNA/RNA) WT Mix consists of DNA and RNA purified from GM24385 human cell line. The purified DNA and RNA are provided in individual vials, maintained in 1 mM Tris 0.1 mM EDTA pH 8.0 aqueous buffer or 1 mM Tris HCl pH 8.0 aqueous buffer, respectively. These materials are ready to use in NGS assays in steps that follow DNA and RNA isolation. No further purification or DNA/RNA isolation is needed.

Materials Required but not Provided

Seraseq TNA (DNA/RNA) WT Mix is ready for use as direct input into a NGS library preparation step. Refer to instructions supplied by manufacturers of the extraction kit to be used.

Instructions for Use

Thaw the product vials on ice. Mix by vortexing to ensure a homogenous solution and spin briefly. Seraseq TNA (DNA/RNA) WT Mix may be input directly into RNA or DNA 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

Seraseq TNA (DNA/RNA) WT Mix product is a reference material for use directly into DNA or RNA sequencing library preparation step.

Heterozygous Mutations Identified in the Product

Potentially pathogenic mutations and fusions were detected in the Seraseq TNA (DNA/RNA) WT Mix when using either the ArcherDx Solid Tumor or ILMN's TSO500 NGS panels. This data is available upon request. While this product is a wild-type reference sample the end user needs to be aware of the presence of variants in the sample. 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 TNA (DNA/RNA) WT 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 TNA (DNA/RNA) WT Mix is not a calibrator and should not be used for assay calibration. This material is not 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.