Seraseq®
Turner Syndrome (XO) Reference Material

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® Turner Syndrome (XO) Reference Material is intended for use with whole-genome or targeted Next Generation Sequencing (NGS) assays or microarray assays that screen for the sex chromosome aneuploidy called Turner Syndrome (XO) in cell-free (cfDNA) present in maternal blood. The Seraseq Turner Syndrome (XO) Reference Material created with matched (or related) maternal-fetal source material is intended as a reference material for research testing and Non-Invasive Prenatal Testing (NIPT) clinical laboratories to monitor DNA extraction, library preparation, sequencing, and aneuploidy detection under a given set of bioinformatics pipeline parameters. *For Research Use Only. Not for use in diagnostic procedures.*

SUMMARY
A well-designed quality control program can provide added confidence in the reliability of results obtained for unknown specimens. The use of independent reference products may provide valuable information concerning assay accuracy and bioinformatics pipeline analysis.

PRINCIPLES OF THE PROCEDURE
Seraseq Turner Syndrome (XO) Reference Material is ready-to-use in NGS or microarray assays starting with DNA extraction after plasma isolation. They should follow the same workflow as unknown clinical samples. The reference materials contain processed human cfDNA derived from matched maternal-fetal source material and is formulated in a commutable matrix (simulated plasma) that is compatible with varying test methods. The product is formulated to simulate a XO karyotype which is confirmed by external NIPT QC testing.

REAGENTS

Material No.	Product
0720-0952	Seraseq® Turner Syndrome (XO) Reference Material

Product consist of 1 vial: 20 ng/mL concentration, 1 mL fill volume.

WARNINGS AND PRECAUTIONS
For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq Turner Syndrome (XO) Reference Material and all materials derived from human blood products as though they are capable of transmitting infectious agents. Seraseq Turner Syndrome (XO) Reference Material is manufactured using processed human cfDNA. Purified cfDNA mixture is formulated in a commutable matrix (simulated plasma) containing human protein isolates (LGC Clinical Diagnostics' SeraCon™ Matribase).

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
Avoid contamination of the product when opening and closing the vials.

STORAGE INSTRUCTIONS
Store Seraseq Turner Syndrome (XO) Reference Material refrigerated at 2 – 8°C. Do not freeze. Samples are designed to be single use only and should not be reused.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION
Seraseq Turner Syndrome (XO) Reference Material is a mixture of human genomic DNA (maternal and fetal). It should appear as a clear to pale yellow liquid. Alterations in this appearance may indicate instability or deterioration of the product and vials should be discarded.

PROCEDURE
Materials Provided
Seraseq Turner Syndrome (XO) Reference Material is produced from cfDNA extracted from pregnant patient source sample carrying a fetus with confirmed Turner syndrome. Material is further processed to maintain natural cfDNA size profile of both fetus and maternal DNA of approximately 170 base pairs in average (Figure 1). The DNA is stabilized and introduced into a dilution of LGC Clinical Diagnostics' SeraCon™ Matribase (simulated plasma). One (1) mL is provided per tube at 20 ng/mL concentration.

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. Mix by vortexing to ensure a homogeneous solution and spin gently (a few seconds) to collect liquid at the bottom of the tube. Do not centrifuge at high speed or for extended time as this may result in a non-homogeneous suspension.
Seraseq Turner Syndrome (XO) Reference Material may be inserted into workflows in a manner consistent with plasma fractions prior to extraction. Following extraction, Seraseq Turner Syndrome (XO) Reference Material should go through the entire library preparation, sequencing, and analysis in parallel with test specimens. Refer to standard assay procedures in order to determine the amount of material to use.

Quality Control
Seraseq Turner Syndrome (XO) Reference Material is designed to simulate a Turner Syndrome state but does not have assigned values for aneuploidy or fetal fraction. There are many reasons why assays may observe deviation from the representative data which may or may not be of significance. It is therefore recommended that each laboratory qualify the use of Seraseq Turner Syndrome (XO) Reference Material with each assay system prior to its routine use.

INTERPRETATION OF RESULTS
Detection of Turner Syndrome (XO) may vary with different types of tests and different test kit lots. Since the reference material does not have an assigned value, the laboratory must establish a range for each lot of Seraseq Turner Syndrome (XO) 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 change in bioinformatics pipeline parameters.

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LIMITATIONS OF THE PROCEDURE
Seraseq Turner Syndrome (XO) Reference Material MUST NOT BE SUBSTITUTED FOR THE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

TEST PROCEDURES and *INTERPRETATION OF RESULTS* provided by manufacturers of test kits must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. Seraseq Turner Syndrome (XO) Reference Material is not a calibrator and should not be used for assay calibration.

Note that Seraseq Turner Syndrome (XO) Reference Material may not be compatible with certain NIPT methods based on the specific assays design and methodology.

Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS
Specific detection of chromosome abnormality will vary among different assays, different procedures, different lot numbers, and different laboratories. Each laboratory should establish its own acceptance criteria. For example, the acceptable range for each variant might include all values within two standard deviations of the mean of 20 data points obtained in 20 runs[2].

SPECIFIC PERFORMANCE CHARACTERISTICS
Seraseq Turner Syndrome (XO) Reference Material has been designed for use with NGS sequencing procedures for the purposes of evaluating assay performance. Seraseq Turner Syndrome (XO) Reference Material does not have assigned values. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory.

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. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline– Fourth Edition. CLSI document C24, 2016.

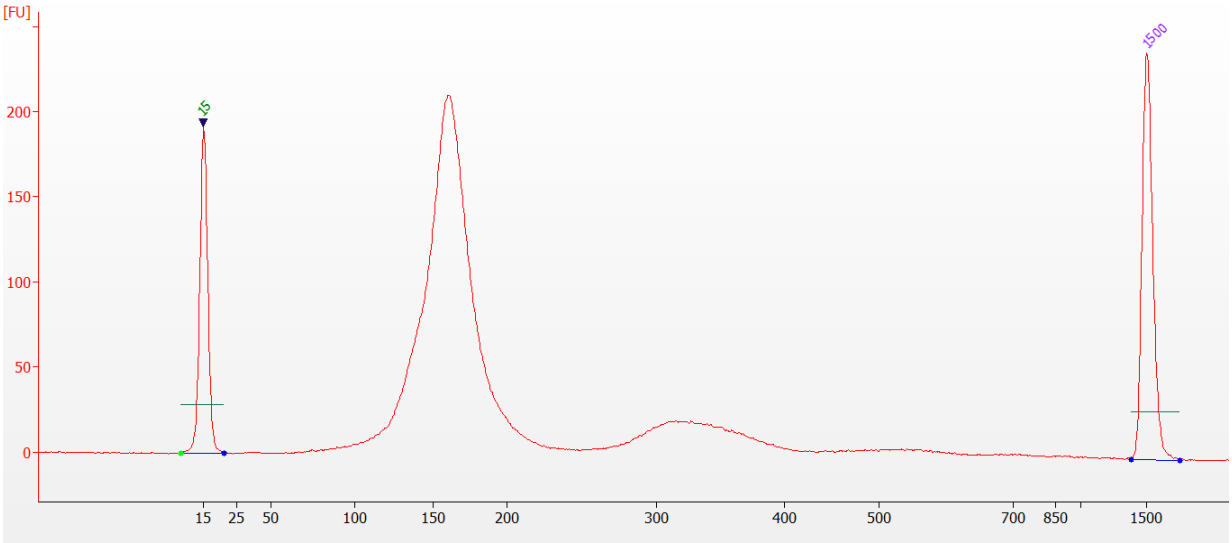

Figure-1: Representative cfDNA size distribution for Seraseq® Turner Syndrome (XO) Reference Material (X-axis represents base pairs, Y-axis represents relative units). Peak size was observed at 161 bp.

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