

Get the most out of the Seraseq® Reproductive Health Reference Materials

Why and How to Use Them

LGC SeraCare provides reference materials for preimplantation genetic testing (PGT-A) and non-invasive prenatal testing (NIPT). They are formulated to easily fit into your laboratory workflow. PGT-A materials are formulated as gDNA in buffer, while the NIPT materials are formulated as encapsulated cfDNA material in plasma-like matrix. Research Use Only.

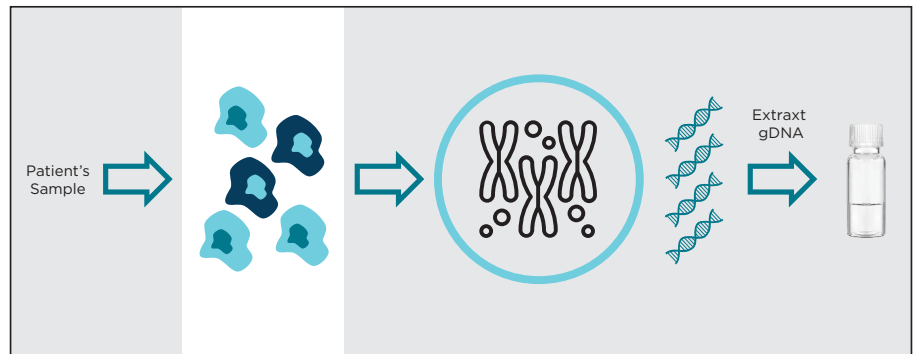
Why Choose LGC SeraCare Reproductive Health Reference Materials?

LGC SeraCare reference materials are manufactured to the highest standards in GMP-compliant and ISO 13485-certified facilities. They are used globally by laboratories as well as proficiency providers.

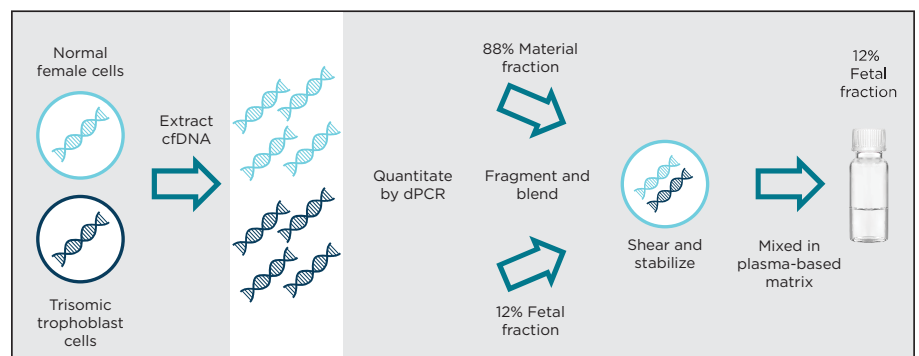
Using reference materials specifically formulated for reproductive health will help you to proactively monitor the laboratory's workflow. It provides a way to:

- Compare methods
- Compare workflows
- Train your staff

Evaluating multiple methods using the same exact material makes it an objective comparison of performance. Any changes in a workflow due to an upgrade of the method can also be easily compared by using Seraseq reference materials. Training new staff is very important and using reference materials makes the process easier and comparable not just across the operators, but also over time. These reference materials are also a great way to troubleshoot your assays that are deployed across multiple sites.



1A: PGT-A Reference Materials are prepared from trophoblast cell lines obtained from pregnancies with chromosomal anomalies. Cells were karyotyped and gDNA was prepared in a buffer at concentrations reflecting blastocyst sampling.



1B: NIPT Reference Materials are prepared from a sample of maternal plasma containing maternal and fetal cfDNA. Plasma samples were collected from pregnant women. cfDNA was isolated, amplified via a proprietary method, encapsulated and formulated in a plasma matrix.

How to Use Seraseq PGT-A Reference Materials in Your Workflow

PGT-A starts with a biopsy of an embryo of collecting 1-10 cells. The collected cells are then analyzed for aneuploidy. There are multiple tests for PGT-A, including PCR, arrays, and NGS. gDNA has been used successfully as a surrogate starting material for PGT-A by proficiency testing providers. LGC SeraCare-created materials fit the currently used model for PGT-A reference materials.

gDNA in our products is developed from karyotyped trisomic cells, also previously used in our legacy NIPT materials. This new product allows the laboratories to develop, compare, validate, or monitor the assays for PGT-A. The same materials can also be used for training or proficiency testing. The amount of DNA in a microliter of this product represents approximately the amount of DNA equivalent to 5-10 cells collected during an embryo biopsy. This makes it easy to add the material to multiple PGT-A test workflows.

LGC SeraCare PGT-A reference materials have been tested by multiple methods, including microarrays and NGS-based assays.

How to use Seraseq NIPT Reference Materials in Your Workflow

SeraSeq NIPT reference materials are processed the same way as the patient samples. Each vial is formulated as a 1 mL sample containing approximately the same amount of cfDNA as 4 mL of plasma obtained from a 10 mL blood draw. Different NIPT assays use different starting volumes of plasma, between 1 mL and 4 mL.

One of the most common questions when it comes to using the materials is: How can they be diluted to suit the input volume required? The most common ways

of adjusting the volume are with PBS or LGC SeraCare Matribase. If needed, the volume of the sample can be customized to fit your workflow better. The second most common question is about the recovery of the cfDNA during the extraction. In this case, there is variability between the methods used and between the labs using the same method. It is a good idea to determine what percent recovery is normal for your method and NIPT assay. Our product reports describe yield per sample for a single extraction and quantification scenario; measured yields may vary with methods but our materials have been designed and verified to be compatible with most major NIPT tests on the market.

The best reference materials for NIPT assays should also be similar to patient samples in the way they look and perform.

SeraSeq NIPT reference materials are developed from blood draws sourced from pregnant women with fetal ploidy status confirmed by one or more methods. The manufacturing process preserves the fetal fraction of the original sample, the SNP content of mother and fetus, as well as the size difference between the fetal and maternal cfDNA. This makes our materials look and perform like the real patient samples they were derived from.

SeraSeq NIPT maternal matched materials vary in the fetal fraction depending on the starting sample and are assessed for fetal fraction before release and this information is provided in the Technical Product Report (TPR). However, it is important to mention that fetal fraction assessment significantly varies across the NIPT methods. Therefore, a value provided should be used as a guide only and empirically determined for NIPT methods not described on the TPR.

LEARN MORE

To learn more about Seraseq NIPT and PGT-A Reference Materials, visit <https://www.seracare.com/Controls---Reference-Materials-NGS-Reproductive-Health/>.

Contact us at **508.244.6400** and **800.676.1881** or email info@seracare.com.