

# Seraseq® ctDNA Extraction Reference Materials

The first comprehensive reference material for validation and performance monitoring of cfDNA extraction yield

## INTRODUCTION

Preparation of a liquid biopsy sample starts with a blood draw from a patient followed by extraction of cfDNA from plasma. The concentration of cfDNA in a blood draw can vary greatly from patient to patient, but reference materials are typically built to a single cfDNA concentration. Additionally, extraction kits do not provide robust feedback about root cause of extractions resulting in lower than expected yield which increases the challenge of decoupling extraction kit performance from pre-analytic sample handling.

LGC Clinical Diagnostics has produced the Seraseq ctDNA Extraction Reference Materials to allow clinical labs to validate and assess performance of cfDNA extractions in a more comprehensive manner. The ctDNA Extraction Reference Materials are available at concentrations of 20, 50 and 80 ng/mL in synthetic plasma. In addition to being useful as total cfDNA extraction reference materials, the samples contain four EGFR variants present at 1% ctDNA to represent tumor ctDNA. Each kit comes with 4x single use vials for ease of use at an affordable price point.

## FEATURES AND BENEFITS

- Validate and monitor performance of cfDNA extractions using well-defined, precisely built reference materials
- Available in 20, 50 and 80 ng/mL concentrations to more accurately represent the range of cfDNA yields expected from patient samples
- Mutation targets are quantitated using highly sensitive digital PCR
- Affordably priced for routine use
- EGFR variants present at 1% to evaluate detection of pathogenic variants and quantitation of percent tumor detection
- All mutations are blended against GM24385 human genomic DNA as background 'wild-type' material
- Manufactured in GMP-compliant and ISO 13485-certified facilities

## HIGHLIGHTS

Multiple concentrations mimicking cfDNA between 20-80 ng/mL of plasma

Monitor a range of sample yields while confirming downstream variant detection

Consistently performing with batch-specific yield information provided

## ORDERING INFORMATION

Material #	Product	Concentration*	Fill Volume	Total Mass
0710-3294	Seraseq® ctDNA Extraction Reference Material 20 ng/mL	20 ng/mL	4 x 1 mL	80 ng
0710-3295	Seraseq® ctDNA Extraction Reference Material 50 ng/mL	50 ng/mL	4 x 1 mL	200 ng
0710-3296	Seraseq® ctDNA Extraction Reference Material 80 ng/mL	80 ng/mL	4 x 1 mL	320 ng

\* Concentration targets are based on Qiagen QIAamp ccfDNA Kit extraction yield measured by the Qubit dsDNA BR Assay.

## EXTRACTION YIELDS OBSERVED WITH DIFFERENT EXTRACTION METHODS

Material	QIAamp (ng/mL)	Maxwell RSC (ng/mL)	MagMax (ng/mL)	Zymo MAGICBead (ng/mL)	Nucleosnap cfDNA (ng/mL)
ctDNA Extraction RM 80ng/mL	87.00	55.39	79.13	54.3	64.83
ctDNA Extraction RM 50ng/mL	57.83	41.23	57.71	39.47	45.57
ctDNA Extraction RM 20ng/mL	35.36	23.86	29.87	24.87	24.87

\*Observations are from a representative batch of each material indicated. Batch-specific QIAamp data is included on the Technical Product Report. The extraction with MagMax was performed manually.

## MUTATIONS PRESENT IN THE SERASEQ® CTDNA EXTRACTION REFERENCE MATERIAL PRODUCTS

Gene	Nucleotide Change	Protein Change
EGFR	c.2236_2250del	p.E746_A750del
EGFR	c.2155G>A	G719S
EGFR	c.2369C>T	p.T790M
EGFR	c.2573T>G	p.L858R

## ABOUT US

SeraCare offers a comprehensive portfolio of reference materials for oncology and reproductive health, designed and manufactured to meet the precision demanded by NGS assays. The portfolio includes high quality ground-truth RNA, ctDNA and genomic DNA-based reference materials that are NGS platform agnostic for tumor profiling, immuno-oncology, liquid biopsy, NIPT and germline cancer assay workflows. **For more information visit [seracare.com](https://seracare.com)**