LGC seracare

ENABLING THE PROMISE OF
PRECISION MEDICINE

SERASEQ® REFERENCE MATERIALS FOR NGS ONCOLOGY APPLICATIONS

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Complex NGS assays require sophisticated, ground-truth reference materials

Assays based on next-generation sequencing (NGS) technologies are being increasingly used in clinical oncology. NGS assays profile genetic mutations to enable precision diagnostics, personalized treatment selection, stratification of patients for clinical trials, and disease monitoring.

To be effective, these assays must capture the breadth of genomic events present in cancerous cells. This complexity can make the development and validation of NGS assays challenging.

A critical component of a robust NGS assay is the reference material, which ensures the test is performing as expected and delivers confidence in results used to monitor treatment and guide patient outcomes. Not all reference materials are created equal, and selection of the provider is a key consideration when a new assay is developed and validated.

Reference materials from LGC SeraCare are the industry gold standard

As the leading provider of off-the-shelf and custom oncology-focused reference materials, we support precision oncology NGS assay validation, giving you increased confidence in the clinical deployment of these assays to analyze actionable and challenging variants in patient samples.

Benefits of Seraseq Reference Materials

Highly multiplexed, patient-like reference materials combine well-characterized, normal cell lines with engineered biosynthetic DNA targets, addressing the needs of a wide range of targeted sequencing panels, including DNA- and RNA-seq.

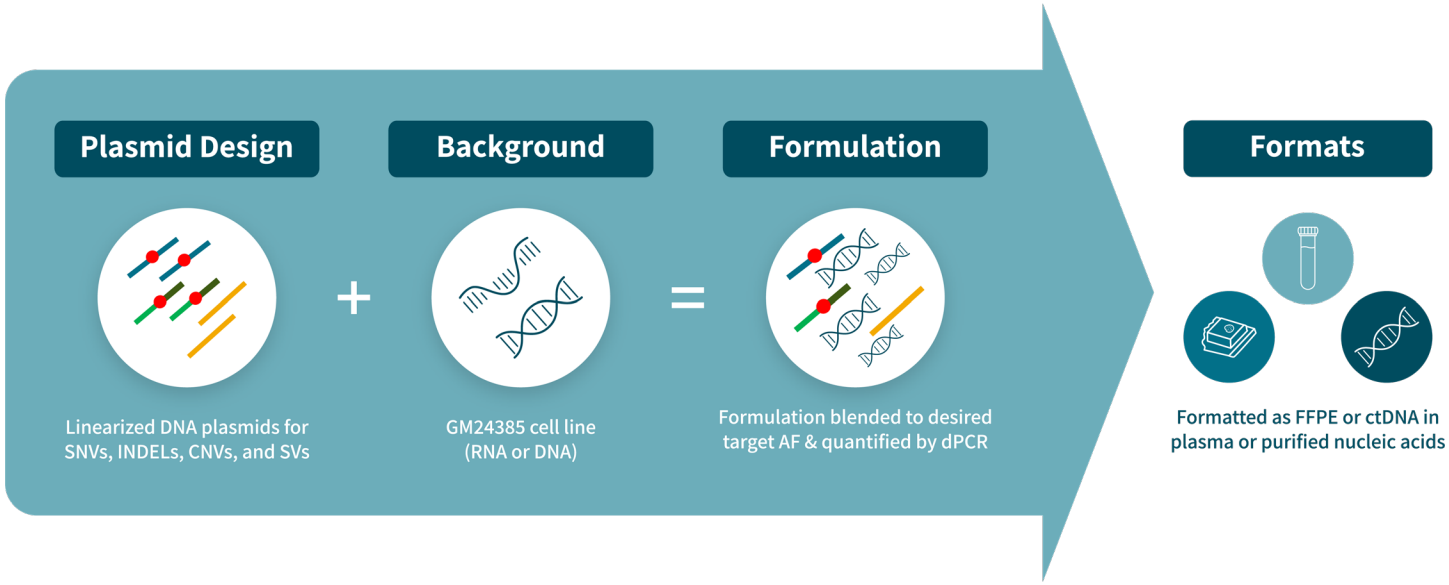
Improve the consistency of assay performance and increase confidence in results when developing, validating, and implementing NGS assays for cancer diagnosis, treatment monitoring and patient stratification.

With a wide range of formats, we can meet your exact needs. Reference materials are available as purified nucleic acid [DNA, RNA, or circulating tumor DNA (ctDNA)], plasma encapsulated ctDNA, as well as FFPE formats, and cover all variant types: SNVs, INDELs, CNVs, SVs and RNA fusions.

Reduce the time needed to develop and validate a new assay – without sacrificing quality with the unique design of our reference materials.

Seraseq Reference Material Design Process

Seraseq reference material is based on a biosynthetic plasmid-based approach, with a linearized plasmid harboring a single variant designed at a typical construct length of 800 bp for SNV, INDEL, SV, or fusion, or at a full-length gene for CNV. A highly multiplexed DNA plasmid or in vitro-transcribed RNA (IVT-RNA) pool containing the variants is blended at specific allele frequencies and spiked into a wildtype genomic DNA or RNA background of the well-characterized GM24385 cell line. Introduced variants are quantified by dPCR at all production steps and the final Seraseq product is tested by dPCR and NGS assays.



Solutions for Precision Oncology NGS Applications

Disease Profiling

Solid Tumor:

- Tumor DNA/FFPE
- Fusion RNA/FFPE
- Wildtype TNA/FFPE
- CNVs DNA/FFPE
- NTRK RNA/FFPE
- Whole Transcriptome RNA-Seq

Heme Disorder:

- Myeloid DNA/RNA
- Lymphoma DNA/FFPE

Immuno-Oncology Treatment Response

Tumor Mutational Burden:

- Tissue TMB gDNA/FFPE
- Blood TMB ctDNA
- TMB Reference Panel

Microsatellite Instability:

- MSI Reference Panels
- MSI-High gDNA/FFPE

Disease Monitoring

Liquid Biopsy:

- ctDNA v2
- ctDNA Complete™
- ctDNA MRD Panel

Ensure consistency, reproducibility, and confidence of tumor profiling assays

Solid Tumor

- Tumor DNA reference materials include up to 40 clinically relevant variants across all variant types.
- A variety of fusion RNA reference materials with up to 22 unique fusions are available to meet different needs, including pan-cancer profiling, solid tumor screening, targeted RNA panels, whole transcriptome RNA-seq, and cancer type- and gene-specific applications.
- GM24385 cell line-based wildtype reference material, available as either purified DNA and RNA or as FFPE, provides negative controls for all solid tumor products in end-to-end NGS workflows.

Seraseq disease profiling reference materials, available as purified DNA/RNA or FFPE, incorporate key variants from solid tumor and hematological malignancies.

Heme Disorder

- Myeloid DNA and RNA reference materials offer 23 important myelogenous leukemia variants and 9 gene fusions, respectively, for analysis by heme-based targeted NGS assays.
- Lymphoma DNA and FFPE reference materials incorporate 26 lymphoma variants for analysis of lymphoid cancers.

Identify patients most likely to respond to treatment with greater confidence

Immuno-oncology

LGC SeraCare partnered with industry experts to develop a portfolio of immuno-oncology reference standards using orthogonal analysis by whole exome sequencing (WES) and NGS targeted panels. These tumor mutational burden (TMB) and microsatellite instability (MSI) reference materials support the harmonization and validation of NGS assays for identifying patients most likely to respond to a treatment regimen. Our portfolio includes the industry's first tissue TMB (tTMB) and blood TMB (bTMB) reference materials, in addition to tumor-only and tumor-normal matched MSI controls.

tTMB

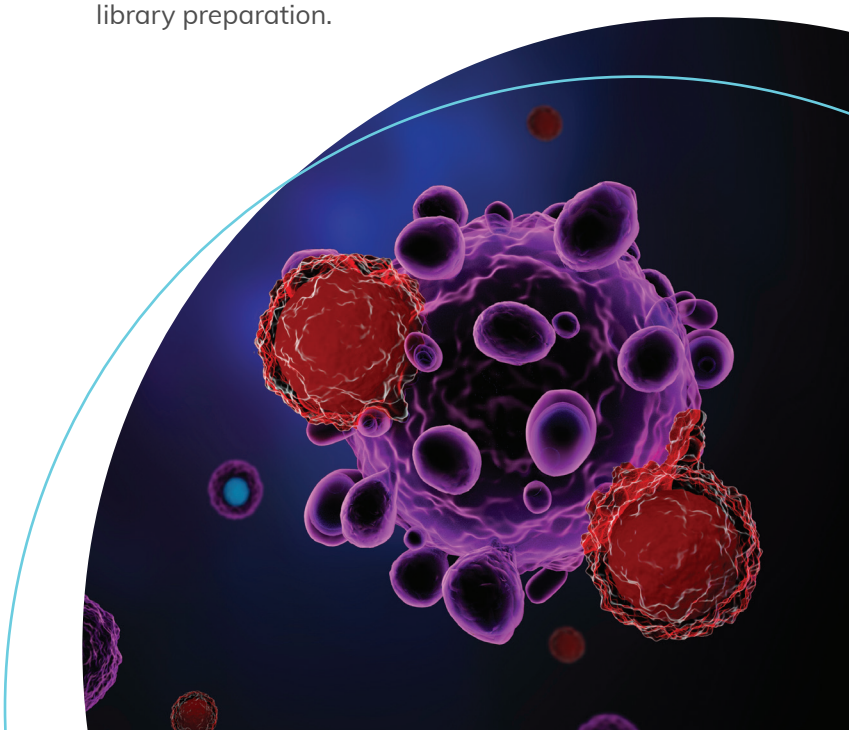
- Tissue TMB reference materials are derived from tumor-normal matched human cell lines and characterized by WES and a TMB analysis pipeline (tumor-normal mode) to determine their empirical TMB scores.
- Supports TMB analysis and scoring harmonization between gold-standard WES and targeted NGS panels.
- Available as 100% purified DNA tumor/normal set or 30% tumor FFPE format.

bTMB

- Blood TMB reference materials are derived from human diseased and matched-normal cell lines and are characterized by a comprehensive genomic profiling panel.
- Extracted genomic DNA is blended at three tumor fractions (0%, 0.5% and 2%), fragmented and sized to mimic patient ctDNA.
- Available as purified ctDNA ready for NGS library preparation.

MSI

- Tumor-normal matched MSI reference materials (available as DNA at AF 5% or AF 20%) support deployment of molecular and genomic MSI assays interrogating tumor microsatellite stability status.
- Tumor only MSI-High products (DNA/FFPE) enable validation of MSI-High calls using NGS assays including MSI scoring.



Develop and validate liquid biopsy assays, monitor residual disease testing with precision

Disease Monitoring

The ctDNA minimal residual disease (MRD) reference material allows the assessment of sensitivity and specificity at ultra-low variant allele frequencies (AFs) required for NGS-based ctDNA assays that monitor the presence of tumor-specific variants in patients undergoing therapy.

With patent-pending cfDNA technology, we ensure the most patient-like ctDNA sizing, better variant coverage, and improved library complexity to support liquid biopsy NGS assay development, validation, and routine analysis.

ctDNA v2 & ctDNA Complete™

- ctDNA reference materials containing 40 pan-cancer markers (ctDNA v2) or 25 solid tumor-focused markers including CNVs (ctDNA Complete).
- Patient-like sized blend of contrived ctDNA constructs and background wildtype DNA.
- Available in a range of AFs from 0.1% to 5% as purified DNA Mix or plasma encapsulated ctDNA.

ctDNA MRD Panel

- An ultra-sensitive ctDNA reference material for NGS-based MRD assay LoD validation and detection/monitoring of patient-derived mutations over a therapeutic time course.
- Derived from a diseased cell line harboring a high number of somatic variants, its SNP-matched normal cell line, and additional biosynthetic DNA variants of therapeutic utility.
- The tumor/normal DNAs are blended to four tumor fractions (0.5%, 0.05%, 0.005% and 0%), fragmented and sized to mimic patient ctDNA; all blends are characterized by NGS.

Accelerate your NGS assay development and validation with flexible and scalable solutions

Expert-designed custom reference materials supporting the entire NGS assay lifecycle

Produced in ISO 13485 certified, cGMP compliant, US FDA audited facilities, our custom reference materials are traceable from sourcing through processing and delivery to provide you with the highest level of confidence.

We design and produce sophisticated, highly multiplexed reference materials tailored to your specifications. With our custom services, you have a high degree of flexibility, access to our technical and scientific experts, and a rapid turnaround time for your unique requirements and complex biomarkers.

Select from a library of existing variants and variant types (>400 variants across >60 genes) or new variants that we can synthesize for you. Let us configure the reference material to your exact requirements.

Product Guide

Application	Type	Product	Description	DNA	RNA	ctDNA	FFPE	Variant Types
Disease Profiling	Solid Tumor	Tumor Mutation DNA Mix v2	28 pan-cancer genes; AF: 7 or 10%	●				40 variants: SNVs, INDELs, SVs
		Tri-Level Tumor Mutation DNA Mix v2	28 pan-cancer genes; AF: 4, 7, or 10%	●				40 variants: SNVs, INDELs, SVs
		CNV Mix (Breast or Lung & Brain)	+3, +6, or +12 copies	●				Breast: ERBB2, FGFR3, MYC; Lung & Brain: EGFR, MET, MYCN
		Fusion RNA Mix v4 & FFPE Tumor Fusion RNA v4 RM	~1,500 copies/µl		●		●	18 pan-cancer fusion genes
		Whole Transcriptome RNA Seq Mix	>20,000 copies/µl		●			22 pan-cancer fusion genes
		NTRK Fusion RNA Mix & FFPE NTRK Fusion RNA RM	>1,000 copies/µl		●		●	15 NTRK1/2/3 fusion genes
		Compromised FFPE Tumor DNA RM	15 solid tumor genes; patient-like RM	●			●	34 variants: SNVs, INDELs, SVs, CNVs
		Compromised FFPE WT (DNA/RNA) RM	GM24385 cell line-based negative control	●	●		●	N/A
		TNA (DNA/RNA) WT Mix & FFPE WT (DNA/RNA) RM	GM24385 cell line-based negative control	●	●		●	N/A
	Heme Disorder	Lymphoma DNA Mutation Mix & FFPE Lymphoma DNA RM	14 lymphoid (HL/NHL) cancer genes; AF: ~10%	●			●	26 variants: SNVs, INDELs, SVs
		Myeloid Mutation DNA Mix	16 myeloid (AML/MDS) genes; AF: 5, 10, or 15%	●				23 variants: SNVs, INDELs
		Myeloid Fusion RNA Mix	>1,000 copies/µl		●			9 myeloid (AML/MDS) fusion genes
Immuno-Oncology	TMB	gDNA TMB Mix & FFPE TMB RM	tumor-normal matched RM; TMB Score: 7, 9, 13, 20, or 26	●			●	filtered non-synonymous TMB variants
		Blood TMB Mix	TF: 0%, 0.5%, 2%; TMB Score: 7, 13, 20, or 26			●		filtered non-synonymous TMB variants
	MSI	gDNA MSI-High Mix & FFPE MSI-High RM	MSI-High tumor cell line; MSI score: ~77	●			●	multiple MSI loci
		MSI Reference Panel Mix	5 Bethesda MSI markers; AF: 5 or 20%	●				BAT-25, BAT-26, NR-21, NR-24, MONO-27 loci
Disease Monitoring	Liquid Biopsy	ctDNA Mutation Mix v2	28 pan-cancer genes; AF: 0, 0.125, 0.25, 0.5, 1, or 2%			●		40 variants: SNVs, INDELs, SVs
		ctDNA Complete™ RM	16 solid tumor genes; AF: 0, 0.1, 0.5, 1, 2.5, or 5%			●		25 variants: SNVs, INDELs, SVs, CNVs
	MRD	ctDNA MRD Panel Mix	TF: 0, 0.005, 0.05, and 0.5%			●		>600 variants: SNVs, INDELs, CNVs

Key: ● = available ● = available in Tris-EDTA buffer ● = available in Tris-EDTA buffer or Plasma options

Abbreviations:
CNV: copy number variation
INDEL: insertion-deletion
SNV: single nucleotide variant
SV: structural variant
ctDNA: circulating tumor DNA
FFPE: formalin-fixed paraffin-embedded
gDNA: genomic DNA
TNA: total nucleic acid
AF: allele frequency
MRD: minimal residual disease
MSI: microsatellite instability
TMB: Tumor Mutational Burden
RM: reference material
TF: tumor fraction
v: version
WT: wildtype

Product List

Application	Product Group	Material Number	Product	Size	Concentration (per Tube)
Disease Profiling	Solid Tumor DNA	0710-0094	Seraseq® Tumor Mutation DNA Mix v2 AF10 HC	1 x 25 µL	25 ng/µL
		0710-0095	Seraseq® Tumor Mutation DNA Mix v2 AF7 HC	1 x 25 µL	25 ng/µL
		0710-0097	Seraseq® Tri-Level Tumor Mutation DNA Mix v2 HC	1 x 25 µL	25 ng/µL
		0710-0137	Seraseq® FFPE WT (DNA/RNA) RM	1 x 10 µm curl	N/A
		0710-1710	Seraseq® Compromised FFPE WT (DNA/RNA) RM	1 x 10 µm curl	N/A
		0710-1580	Seraseq® Total Nucleic Acid WT (DNA/RNA) Mix	2 x 20 µL	25 ng/µL
		0710-1492	Seraseq® Compromised FFPE Tumor DNA RM	1 x 10 µm curl	N/A
		0710-0411	Seraseq® Breast CNV Mix, +3 copies	1 x 20 µL	10 ng/µL
		0710-0412	Seraseq® Breast CNV Mix, +6 copies	1 x 20 µL	10 ng/µL
		0710-0413	Seraseq® Breast CNV Mix, +12 copies	1 x 20 µL	10 ng/µL
		0710-0414	Seraseq® Lung & Brain CNV Mix, +3 copies	1 x 20 µL	10 ng/µL
		0710-0415	Seraseq® Lung & Brain CNV Mix, +6 copies	1 x 20 µL	10 ng/µL
		0710-0416	Seraseq® Lung & Brain CNV Mix, +12 copies	1 x 20 µL	10 ng/µL
	Solid Tumor RNA	0710-0496	Seraseq® FFPE Tumor Fusion RNA v4 RM	1 x 10 µm curl	N/A
		0710-0497	Seraseq® Fusion RNA Mix v4	1 x 25 µL	25 ng/µL
		0710-1031	Seraseq® FFPE NTRK Fusion RNA RM	1 x 10 µm curl	N/A
		0710-1696	Seraseq® NTRK Fusion RNA Mix	1 x 20 µL	25 ng/µL
		0710-2129	Seraseq® Whole Transcriptome RNA-Seq Mix	1 x 20 µL	50 ng/µL
	Heme Disorder	0710-2202	Seraseq® FFPE Lymphoma RM	1 x 10 µm curl	N/A
		0710-2203	Seraseq® gDNA Lymphona Mutation Mix	1 x 15 µL	25 ng/µL
		0710-0408	Seraseq® Myeloid Mutation DNA Mix	1 x 25 µL	15 ng/µL
		0710-0407	Seraseq® Myeloid Fusion RNA Mix	1 x 25 µL	15 ng/µL

Product List Continued

Application	Product Group	Material Number	Product	Size	Concentration (per Tube)
Immuno-Oncology	TMB	0710-1307	Seraseq® FFPE TMB RM Score 26	2 x 10 µm curl	N/A
		0710-1308	Seraseq® FFPE TMB RM Score 9	2 x 10 µm curl	N/A
		0710-1309	Seraseq® FFPE TMB RM Score 20	2 x 10 µm curl	N/A
		0710-1310	Seraseq® FFPE TMB RM Score 7	2 x 10 µm curl	N/A
		0710-1618	Seraseq® FFPE TMB RM Score 13	2 x 10 µm curl	N/A
		0710-1323	Seraseq® gDNA TMB Mix Score 26	2 x 10 µL	50 ng/µL
		0710-1324	Seraseq® gDNA TMB Mix Score 20	2 x 10 µL	50 ng/µL
		0710-1324	Seraseq® gDNA TMB Mix Score 9	2 x 10 µL	50 ng/µL
		0710-1326	Seraseq® gDNA TMB Mix Score 7	2 x 10 µL	50 ng/µL
		0710-1586	Seraseq® gDNA TMB Mix Score 13	2 x 10 µL	50 ng/µL
		0710-2087	Seraseq® Blood TMB Mix Score 7	3 x 20 µL	10 ng/µL
		0710-2088	Seraseq® Blood TMB Mix Score 13	3 x 20 µL	10 ng/µL
		0710-2089	Seraseq® Blood TMB Mix Score 20	3 x 20 µL	10 ng/µL
		0710-2090	Seraseq® Blood TMB Mix Score 26	3 x 20 µL	10 ng/µL
	MSI	0710-1675	Seraseq® MSI Reference Panel Mix AF5%	2 x 20 µL	15 ng/µL
		0710-1676	Seraseq® MSI Reference Panel Mix AF20%	2 x 20 µL	15 ng/µL
		0710-1670	Seraseq® gDNA MSI-High Mix	1 x 20 µL	25 ng/µL
		0710-2236	Seraseq® FFPE MSI-High RM	1 x 10 µm curl	N/A
Disease Monitoring	Liquid Biopsy	0710-0139	Seraseq® ctDNA Mutation Mix v2 AF2%	1 x 25 µL	10 ng/µL
		0710-0140	Seraseq® ctDNA Mutation Mix v2 AF1%	1 x 25 µL	10 ng/µL
		0710-0141	Seraseq® ctDNA Mutation Mix v2 AF0.5%	1 x 25 µL	10 ng/µL
		0710-0142	Seraseq® ctDNA Mutation Mix v2 AF0.25%	1 x 25 µL	10 ng/µL
		0710-0143	Seraseq® ctDNA Mutation Mix v2 AF0.125%	1 x 25 µL	10 ng/µL
		0710-0144	Seraseq® ctDNA Mutation Mix v2 WT	1 x 25 µL	10 ng/µL
		0710-0203	Seraseq® ctDNA Reference Material v2 AF2%	1 x 5 mL	25 ng/mL
		0710-0204	Seraseq® ctDNA Reference Material v2 AF1%	1 x 5 mL	25 ng/mL
		0710-0205	Seraseq® ctDNA Reference Material v2 AF0.5%	1 x 5 mL	25 ng/mL
		0710-0206	Seraseq® ctDNA Reference Material v2 AF0.25%	1 x 5 mL	25 ng/mL
		0710-0207	Seraseq® ctDNA Reference Material v2 AF0.125%	1 x 5 mL	25 ng/mL
		0710-0208	Seraseq® ctDNA Reference Material v2 WT	1 x 5 mL	25 ng/mL
		0710-0528	Seraseq® ctDNA Complete™ Mutation Mix AF5%	1 x 25 µL	10 ng/µL
		0710-0529	Seraseq® ctDNA Complete™ Mutation Mix AF2.5%	1 x 25 µL	10 ng/µL
		0710-0530	Seraseq® ctDNA Complete™ Mutation Mix AF1%	1 x 25 µL	10 ng/µL
		0710-0531	Seraseq® ctDNA Complete™ Mutation Mix AF0.5%	1 x 25 µL	10 ng/µL
		0710-0532	Seraseq® ctDNA Complete™ Mutation Mix AF0.1%	1 x 25 µL	10 ng/µL
		0710-0533	Seraseq® ctDNA Complete™ Mutation Mix WT	1 x 25 µL	10 ng/µL
		0710-0669	Seraseq® ctDNA Complete™ Reference Material AF5%	1 x 5 mL	25 ng/µL
		0710-0670	Seraseq® ctDNA Complete™ Reference Material AF2.5%	1 x 5 mL	25 ng/µL
		0710-0671	Seraseq® ctDNA Complete™ Reference Material AF1%	1 x 5 mL	25 ng/µL
		0710-0672	Seraseq® ctDNA Complete™ Reference Material AF0.5%	1 x 5 mL	25 ng/µL
		0710-0673	Seraseq® ctDNA Complete™ Reference Material AF0.1%	1 x 5 mL	25 ng/µL
		0710-0674	Seraseq® ctDNA Complete™ Reference Material WT	1 x 5 mL	25 ng/µL
	MRD	0710-2146	Seraseq® ctDNA MRD Panel Mix	4 x 20 µL	10 ng/µL

About LGC SeraCare, Part of LGC Clinical Diagnostics

LGC 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 and used as positive sample controls in tumor profiling, immuno-oncology, liquid biopsy, NIPT and germline cancer assay workflows.

LGC SeraCare is now part of LGC Clinical Diagnostics, Inc. LGC Clinical Diagnostics develops and manufactures over 3,650 catalog and custom-developed diagnostic quality solutions and component materials for the extended life sciences industry. We partner with IVD assay developers, and pharmaceutical, CRO and academic institutions in commercialization activities across the entire diagnostic pipeline - from concept and early stage research, through expedited product development and onwards into routine clinical use. Laboratory and diagnostic professionals across disciplines of clinical chemistry, immunochemistry, serology, molecular diagnostics, and clinical genomics rely on LGC's products to support accurate and reliable diagnostic results.