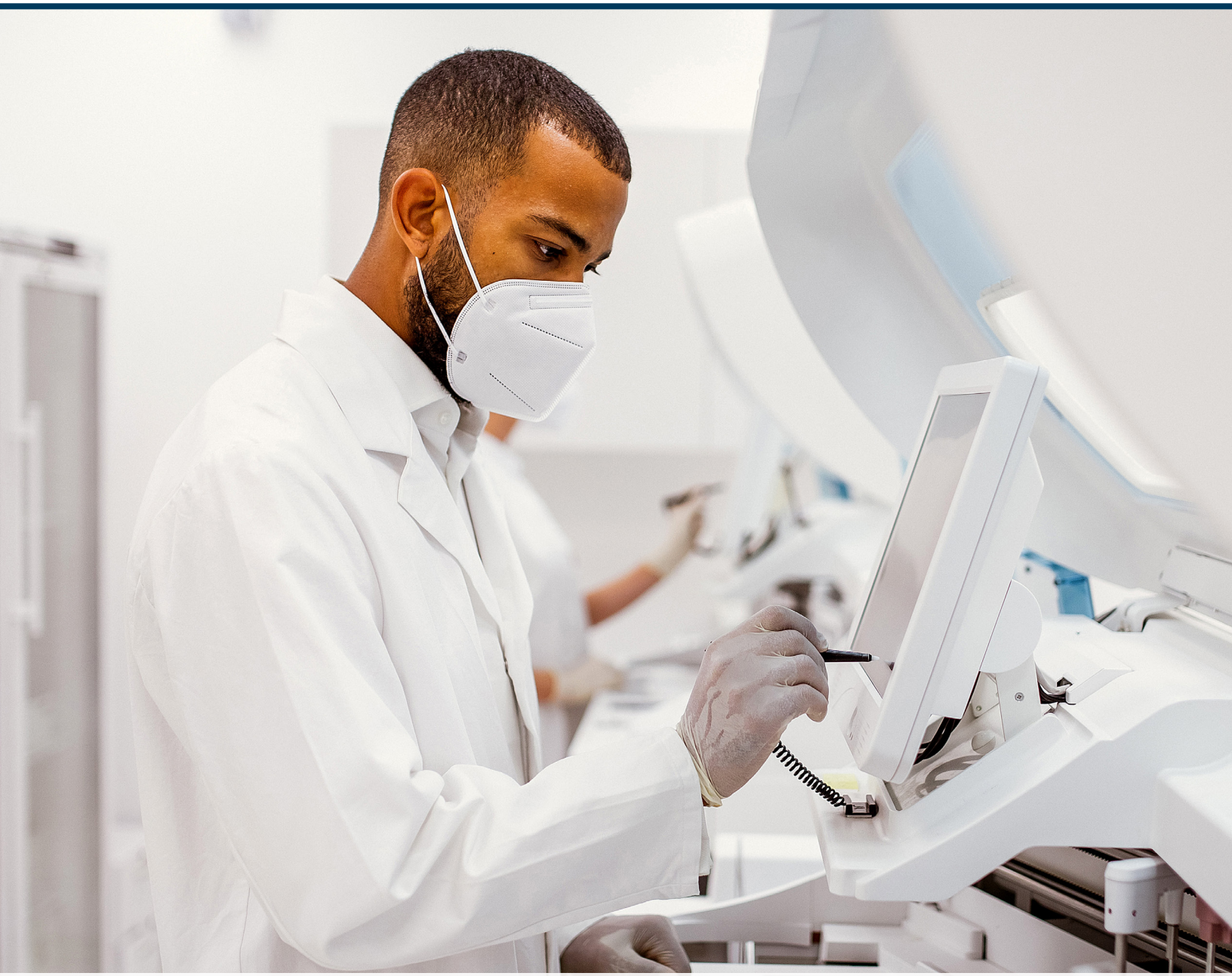
CLINICAL DIAGNOSTICS

Seraseq®

Reference Materials for
NGS Oncology Applications



Enabling the promise of precision medicine

seracare

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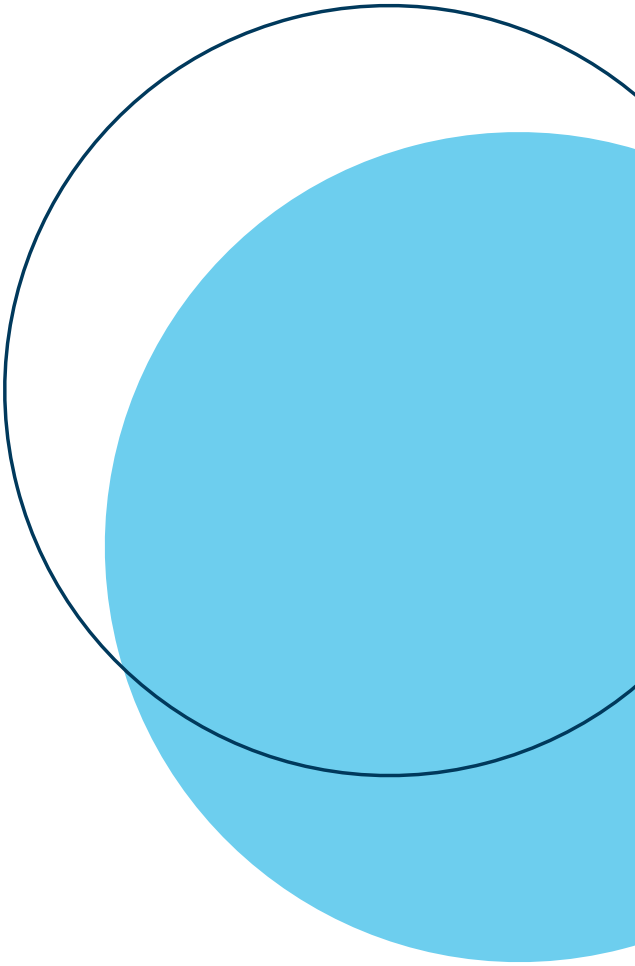


COMPLEX NGS ASSAYS REQUIRE SOPHISTICATED, GROUND-TRUTH REFERENCE MATERIALS

Assays based on next-generation sequencing (NGS) technologies are being increasingly used in clinical oncology. NGS assays profile genetic variations 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 workflow 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 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 or tumor cell lines with engineered biosynthetic nucleic acid targets, addressing the needs of a wide range of targeted and comprehensive sequencing panels, including DNA- and RNA-seq.

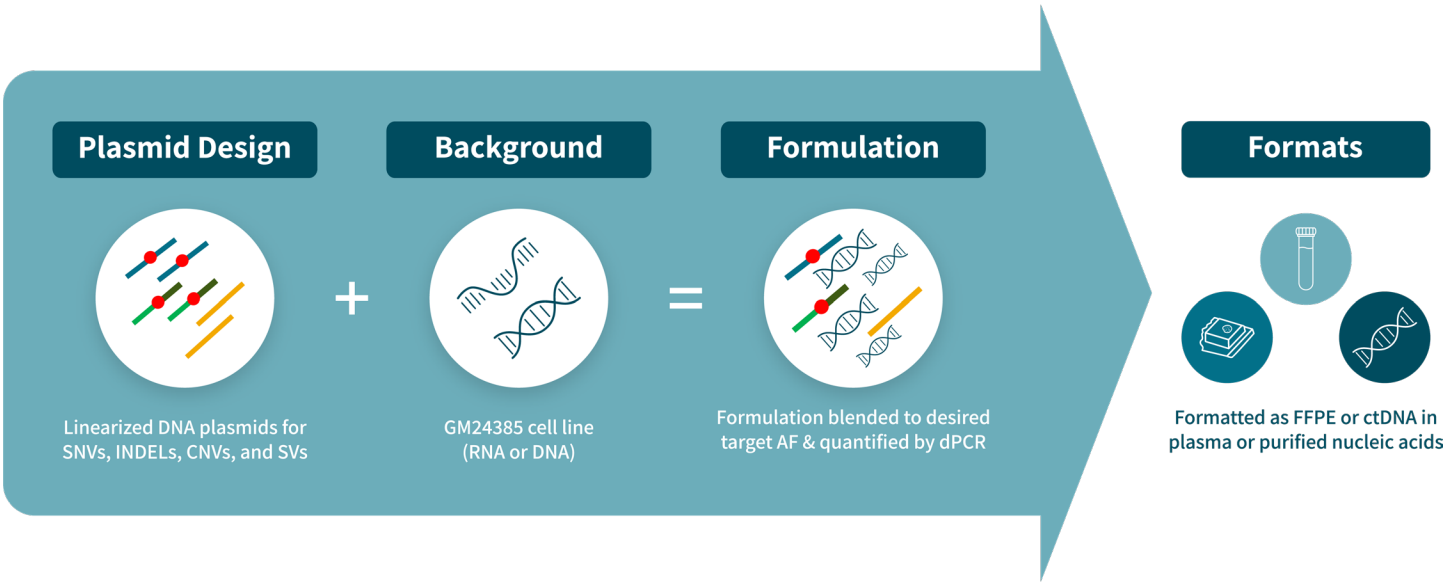
Improve the consistency of performance and increase confidence in results when developing, validating, and implementing NGS assays for cancer diagnosis, profiling, treatment monitoring and patient stratification.

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), plasma encapsulated ctDNA, as well as FFPE and cover all variant types: SNVs, INDELs, CNVs, SVs and RNA fusions, in addition to complex genomic signatures.

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 materials are formulated based on a biosynthetic construct approach, with a construct harboring one or more variants designed at a typical construct length of 800 bp for SNV, INDEL, SV, or fusion, or as a full-length gene for CNVs and large deletions. A highly multiplexed DNA or in vitro-transcribed RNA (IVT-RNA) pool containing the variants is blended at specific allele frequencies by spiking into a wild-type genomic DNA or RNA background of the well-characterized GM24385 cell line or a tumor-derived 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
Wild-type TNA/FFPE
CNVs DNA/FFPE
BRCA1/2 DNA/FFPE
HRD DNA/FFPE
Fusion RNA/FFPE
NTRK RNA/FFPE
Whole Transcriptome RNA-Seq
Endometrial Cancer DNA

HEME DISORDER:

Myeloid DNA/RNA/ctDNA
Lymphoma DNA/FFPE/ctDNA

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 v4
ctDNA MRD
ctDNA Complete™
ctDNA v2
ctDNA Extraction Reference Material
Methylated ctDNA
ctDNA ESR1
ctDNA Prostate ctDNA Myeloid
ctDNA Lymphoma
cfRNA

ENSURE CONSISTENCY, REPRODUCIBILITY, AND CONFIDENCE OF TUMOR PROFILING ASSAYS

SOLID TUMOR

- Available in a wide range of products and formats, solid tumor DNA reference materials include up to 112 clinically relevant variants across all variant types. Focused BRCA1/2 reference materials comprise 20 variants including large genomic rearrangements (LGRs) and the other consisting of 2 exon deletions spanning the whole gene sequences.
- SeraCare has developed unique reference materials for evaluating genomic instability resulting from homologous recombination deficiency (HRD). These comprehensive tumor-normal matched HRD reference materials have been characterized by NGS and microarray assays with various HRD algorithms to support development, validation, and clinical application of genome-wide NGS HRD assays.
- Fusion RNA reference materials with up to 30 unique fusions, including sarcoma and less common fusions, are available to meet different needs, such as pan-cancer profiling, solid tumor screening, targeted RNA panels, whole transcriptome RNA-seq, and cancer type- and gene-specific applications.
- Reference materials for challenging detection of copy number variations (CNVs), available as a general solid tumor offering spanning 12 full length clinically-relevant gene amplifications, or partial or complete copy losses in 7 clinically relevant genes.

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

HEME DISORDER

- Myeloid DNA, ctDNA and RNA reference materials offer up to 25 important myelogenous leukemia variants and 9 gene fusions, respectively, for analysis by hematology-focused targeted NGS assays.
- Lymphoma DNA, FFPE and ctDNA reference materials incorporate 26 lymphoma variants for analysis of lymphoid cancers.

IDENTIFY PATIENTS MOST LIKELY TO RESPOND TO TREATMENT WITH GREATER CONFIDENCE

IMMUNO-ONCOLOGY

SeraCare partnered with industry experts to develop a portfolio of immuno-oncology reference materials 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 reference materials.

TMB

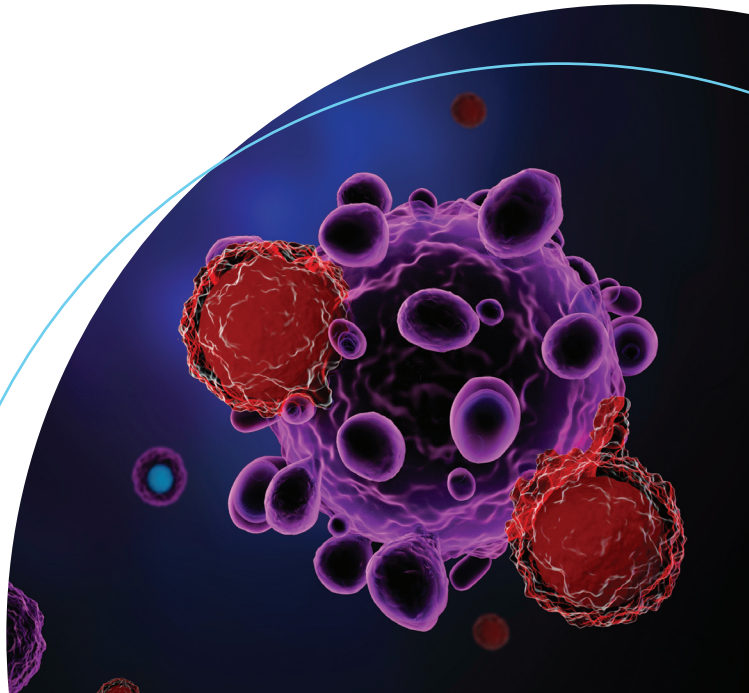
- Tissue TMB reference materials are derived from tumor-normal matched human cell lines and characterized by WES and a TMB analysis pipeline (tumor-normal mode) to determine their empirical TMB scores.
- Supports TMB analysis and scoring harmonization between gold-standard WES and targeted NGS panels.
- Expanded TMB reference panel with a single genomic background covers TMB scores from 5 to 50.
- Available as 100% purified DNA tumor/normal set or 30% tumor FFPE format.

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.

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.



DEVELOP AND VALIDATE LIQUID BIOPSY ASSAYS, MONITOR RESIDUAL DISEASE TESTING WITH PRECISION

DISEASE MONITORING

The wide range of Seraseq cell-free nucleic acid reference materials enables the assessment of cfDNA extraction yield, as well as sensitivity and specificity of assays that profile tumors in plasma and monitor the presence of tumor- specific variants or methylation in ctDNA of patients undergoing therapy. Our disease monitoring portfolio has recently been expanded to support epigenetic studies with our Methylated ctDNA product line.

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

ctDNA v4, ctDNA COMPLETE™, ctDNA v2

- ctDNA reference materials containing dozens of actionable mutations, including SNVs, INDELs, translocations. ctDNA v4 and ctDNA Complete™ also includes CNVs.
- Patient-like sized blend of contrived ctDNA constructs and background wild-type DNA.
- Available in a range of AFs from 0.1% to 5% as purified DNA Mix or plasma encapsulated ctDNA.

ctDNA MRD

- 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 the TMB Score 26 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.

cfRNA

- cfRNA Reference standard containing actionable fusions across multiple cancer types
- Patient-like fragment-sized blend of contrived cfRNA constructs and background wild-type RNA
- Available in mutation mix format in buffer

NEW DISEASE STATE FOCUSED REFERENCE MATERIALS

ctDNA ESR1

- 22 clinically relevant mutations in ESR1 and PIK3CA
- All variants present at 1% variant allele frequency (VAF) with WT sample available to dilute and challenge limit of detection
- All DNA mutations leading to clinically relevant amino acid substitutions in the ligand binding domain of ESR1 (e.g. 3 different DNA sequences leading to a Y537S amino acid substitution) are present

ctDNA PROSTATE

- 48 clinically relevant mutations including SNVs, INDELs, translocations and CNVs
- Emphasis on homologous recombination repair (HRR) pathway mutations typically found in castration resistant metastatic prostate cancer (mCRPC)
- Variants present at 1% or 0.5% Variant Allele Frequency (VAF)

ENDOMETRIAL CANCER

- 32 clinically relevant mutations including SNVs, INDELs, and CNVs
- Variant coverage spanning across all major molecular subtypes of endometrial cancer, including POLE mutations
- Variants present at 10% Variant Allele Frequency (VAF)

FULL PROCESS REFERENCE MATERIALS

Seraseq reference materials feature nucleic acids embedded in plasma-like or FFPE matrices that closely mimic patient-like sample characteristics. They are designed to support end-to-end assay workflows and are ideal for establishing isolation protocols as well as evaluating analytical performance throughout the NGS process.

FFPE REFERENCE MATERIALS

- Includes up to 74 clinically relevant variants across all major variant types
- Primarily available as lightly fixed FFPE representing typical clinical fixation protocols (less degraded) with select products offered as Compromised FFPE with moderate fixation representing archival sample-like RIN/DIN values (more degraded)
- Available in 10uM curls

cfDNA REFERENCE MATERIALS

- Includes up to 93 clinically relevant variants across all major variant types
- Natural cfDNA-like size distribution (~170 bp) and patient-like sequencing performance
- cfDNA embedded in synthetic plasma
- Available in a range of AFs from 0.1% to 5%.

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.

Complementing our industry-leading portfolio of ready-to-use reference materials for NGS-based assays, SeraCare develops custom, highly-multiplexed solutions tailored to your workflow and unique specifications.

We tap into our comprehensive scientific knowledge and experience to quickly build NGS reference materials carrying clinically-actionable genomic variants or genomic signatures, for solid tumor and hematological malignancy profiling, liquid biopsy, and reproductive health. Custom reference materials give you unparalleled flexibility and scalability for validating your NGS workflow. Our biosynthetic spike-in technology and efficient, quality-controlled manufacturing let us provide a rapid turnaround time for your custom materials – typically 8-12 weeks.

PRODUCT GUIDE & LISTING

Application	Product Group		Description	DNA	RNA	ctDNA	cfRNA	FFPE	Genes	Variant Types
Disease Profiling	Solid Tumor DNA/RNA	Tumor Mutation v2	28 pan cancer genes/ translocations, 40 variants; AF: 10%, 7%, or 4%	●					AKT1, APC, ATM, BRAF, CTNNB1, EGFR, ERBB2, FGFR3, FLT3, FOXL2, GNA11, GNAQ, GNAS, IDH1, JAK2, KIT, KRAS,MPL, NPM1, NRAS, PDGFRA, PIK3CA, PTEN, RET, SMAD4,TP53, NCOA4::RET, TPR::ALK	SNV, INDEL, SV
		Tumor Mutation v3	86 genes/translocations, 112 variatns; AF: 10%, 7%, or 4%	●					AKT1, APC, AR, ARID1A, ATM, BARD1, BRAF, BRCA1, BRCA2, BRIP1, CDK12, CDKN2A, CHEK1, CHEK2, CTNNB1, EGFR, ERBB2, ESR1, EZH2, FANCA, FANCL, FGFR3, FOXL2, HRAS, IDH1, IDH2, KIT, KRAS, MAP2K1, MAP4K3, MET, MLH1, MRE11, MSH2, MSH6, MTOR, NBN, NF1, NRAS, NTRK1, NTRK2, NTRK3, PALB2, PDGFRA, PIK3CA, PIK3R1, PMS2, PTCH1, PTEN, PTPN11, RAD51C, RAD51D, RAD54L, RAF1, RB1, RET, SLC7A8, SMAD4, SMARCB1, STK11, TERT, TP53, TSC1, TSC2, VHL, ZNF2, CD74::NRG1, CD74::ROS1, COL1A1::PDGFB, EML4::ALK, ETV6::NTRK3, FGFR2::BICC1, FGFR3::TACC3, NCOA4::RET, PML::NTRK2, TPM3::NTRK1, AKT2, CCND1, CCNE1, CDK4, FGF19, FGF3, FGF4, FGFR1, MYC, MYCN	SNV, INDEL, SV, CNV
		Solid Tumor FFPE	58 pan cancer genes/ translocations, 74 variants, AF: ~4-45%					●	AR, ATM, BRCA1, BRCA2, CDKN2A, CHEK1, CHEK2, EGFR, ERBB2, ESR1, FGFR3, HRAS, IDH1, IDH2, KIT, KRAS, MAP2K1, MAP4K3, MET, MLH1, MSH2, MSH6, MTOR, NF1, NTRK1, NTRK2, NTRK3, PALB2, PDGFRA, PIK3CA, PIK3R1, PMS2, PTCH1, PTEN, RAD51C, RAD51D, RAF1, RB1, RET, SLC7A8, SMARCB1, STK11, TERT, TP53, TSC1, TSC2, VHL, ZNF2, CD74::NRG1, CD74::ROS1, COL1A1::PDGFB, EML4::ALK, ETV6::NTRK3, FGFR2::BICC1, FGFR3::TACC3, NCOA4::RET, PML::NTRK2, TPM3::NTRK1	SNV, INDEL, SV
		Compromised Tumor	17 solid tumor genes/ translocations, 34 variants; AF: ~2-40%					●	AKT1, ALK, BRAF, BRCA1, BRCA2, EGFR, ERBB2 (CNV), KIT, KRAS, MET (CNV), MYC (CNV), NRAS, PIK3CA, TP53, CD74::ROS1, EML4::ALK, NCOA4::RET	SNV, INDEL, SV, CNV
		Integration FFPE	14 solid tumor genes/ translocations; AF: >1%					●	ALK, BRAF, BRCA1, EGFR, ERBB2, FGFR3, KIT, KRAS, NRAS, PDGFRA, RET, TP53, CCDC6-RET, FGFR3-TACC3, TPM3-NTRK1	SNV, INDEL, Translocation
		Endometrial Cancer	16 genes, 32 variants; AF: ~10%	●					POLE, MSH2, MLH1, MSH6, PMS2, TP53, PTEN, PIK3CA, KRAS, CTNNB1, AKT1, POLD, ARID1A, FBXW7, PPP2R1A, ERBB2	SNV, INDEL, CNV
		HRD	High- or low-positive and negative. 4 HRR genes, 8 variants; AF: ~1-40%	●				●	ATM, BRIP1, RAD51C, RAD51D	SNV, INDEL
		BRCA1/2 LGR	20 variants; AF: 10-50%	●				●	BRCA1, BRCA2	SNV, INDEL
		BRCA1/2 Exon Deletion	2 genes; AF: 60%	●					BRCA1, BRCA2	Large Deletions
		Inherited Cancer v1	7 solid tumor genes, 24 variants; AF: 50%	●				●	BRCA1, BRCA2, CDKN2A, MLH1, MSH2, MSH6, PMS2	SNV, INDEL
		Inherited Cancer v2	55 cancer-predisposing genes, 61 variants; AF: 50%	●					APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2,BRIP1, CDH1, CDK4, CDKN1B, CDKN2A, CHEK2, DICER1,EPCAM, FH, FLCN, HOXB13, KIT, MAX, MEN1, MET, MITF, MLH1, MSH2, MSH2 Boland Inversion 3', MSH6, MUTYH, NBN, NF1, NF1, NTHL1, PALB2, PDGFRA, PMS2, POLD1, POLE, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, STK11, TMEM127, TP53, TSC1, TSC2, VHL	SNV, INDEL, SV, Inversion

Key: ● = available as FPPE ● = available in 0.1x Tris-EDTA buffer ● = available in 0.1x 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
AF: allele frequency
MRD: minimal residual disease
MSI: microsatellite instability
TMB: Tumor Mutational Burden
RM: reference material
TF: tumor fraction
v: version
WT: wild-type

PRODUCT GUIDE & LISTING CONTINUED

Application	Product Group		Description	DNA	RNA	ctDNA	cfRNA	FFPE	Genes	Variant Types
Disease Profiling	Solid Tumor DNA/RNA	CNV	>2 additional copies	●				●	AKT2, BRAF, EGFR, ERBB2, FGFR3, KIT, KRAS, MET, MYC, MYCN, NTRK1, PIK3CA	CNV
		Copy loss - complete or partial	Partial or complete gene copy loss	●					CDKN2A, CDKN2B, CYP2D6, MAP2K4, MINPP1, MTAP, PTEN, TP53	CNV
		WT Control	GM24385-based negative control	●	●			●	N/A	N/A
		Tumor Fusion v4	18 solid tumor fusions; ~1,500 copies/µL		●			●	CCDC6::RET, CD74::ROS1, EGFR Variant III, EGFR::SEPTIN14, EML4::ALK, ETV6::NTRK3, FGFR3::BAIAP2L1, FGFR3::TACC3, KIF5B::RET, LMNA::NTRK1, MET ex 14 Skipping, NCOA4::RET, PAX8::PPARG, SLC34A2::ROS1, SLC45A3::BRAF, TFG::NTRK1, TMPRSS2::ERG, TPM3::NTRK1	Fusion
		Sarcome Plus RNA Fusion	30 solid tumor fusions including 10 sarcoma-related fusions; ~1000 copies/µL		●				EWSR1::ERG, KIF5B::ALK, CD74::NRG1, EZR::ROS1, PRKAR1A::RET, STRN::ALK, TPM3::ALK, AR-V7, BRD4::NUTM1, RANBP2::ALK, TPM3::ROS1, EWSR1::FLI1, EWSR1::ETV1, PAX3::FOXO1, SDC4::ROS1, EWSR1::WT1, FGFR1::TACC1, FGFR2::CCDC6, SLC45A3::ERG, SND1::BRAF, TMPRSS2::ETV1, TRIM24::BRAF, TRIM24::RET, EWSR1::ATF1, FGFR3::TACC3, KIAA1549::BRAF, PAX7::FOXO1, SS18::SSX1, SS18::SSX2, COL1A1::PDGFB	Fusion
		NTRK Fusion	15 fusions for NTRK1, NTRK2, and NTRK3; >1000 copies/µL		●			●	AFAP1::NTRK2, BTBD1::NTRK3, ETV6::NTRK3 (4 isoforms), IRF2BP2::NTRK1, LMNA::NTRK1, NACC2::NTRK2, PAN3::NTRK2, QKI::NTRK2, SQSTM1::NTRK1, TFG::NTRK1, TPM3::NTRK1, TRIM24::NTRK2	Fusion
	Heme Disorder	Whole Transcriptome	22 pan cancer fusions; >20,000 copies/µL		●				BCR::ABL1, CCDC6::RET, CD74::ROS1, EML4::ALK, ETV6::ABL1 (2 isoforms), ETV6::NTRK3, FGFR3::TACC3, KIF5B::RET, LMNA::NTRK1 (2 isoforms), MEF2D::CSF1R, MET ex 14 Skipping, NACC2::NTRK2, NCOA4::RET, PML::RARA, RUNX1::RUNX1T1, SLC34A2::ROS1, SLC45A3::BRAF, TCF3::PBX1, TMPRSS2::ERG, TPM3::NTRK1	Fusion
		Lymphoma	20 lymphoid cancer genes/translocations, 26 variants; AF: ~10%	●		●		●	BCL2, BRAF, CXCR4, DNMT3A, EZH2, IDH2, MYD88, NOTCH1, NOTCH2, RHOA, SF3B1, STAT3, STAT5B, TP53, BIRC3::MALT1 , CCND1::CDC42BPB, HSP90AA1::BCL6, MYC::IGH, NPM1::ALK, TBL1XR1::TP63	SNV, INDEL, SV
		Myeloid Mutation	16 myeloid genes, 23 variants; AF: 5%, 10%, or 15%	●					ABL1, ASXL1, BRAF, CALR, CBL, CEBPA, CSF3R, FLT3, IDH1, JAK2, MPL, MYD88, NPM1, SF3B1, SRSF2, U2AF1	SNV, INDEL
		Myeloid Fusion	9 myeloid fusions; >1,000 copies/µL		●				BCR::ABL1, ETV6::ABL1 (2 isoforms), FIP1L1::PDGFRA, KAT6A::CREBBP, PCM1::JAK2, PML::RARA, RUNX1::RUNX1T1, TCF3::PBX1	Fusion
		Myeloid ctDNA	17 myeloid genes, 25 variants; AF: 0%, 0.1%, 0.5%, or 1%			●			ABL1, ASXL1, BRAF, CALR, CBL, CEBPA, CSF3R, EZH2, FLT3, IDH1, IDH2, JAK2, MPL, MYD88, NPM1, SF3B1, SRSF2	SNV, INDEL

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TF: tumor fraction
v: version
WT: wild-type

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Immuno-Oncology	TMB	Myeloid Fusion	9 myeloid fusions; >1,000 copies/µl		●				BCR::ABL1, ETV6::ABL1, FIP1L1::PDGFRA, KAT6A::CREBBP, PCM1::JAK2, PML::RARA, RUNX1::RUNX1T1, TCF3::PBX1	Fusion
		Tissue TMB	Tumor-normal matched RM; TMB score: 7, 9, 13, 20, or 26	●				●	N/A	N/A
		Blood TMB	TF: 0%, 0.5%, 2%; TMB score: 7, 13, 20, or 26			●			N/A	N/A
		TMB Reference Panel	Single genomic background; TMB score: 0, 5, 10, 30, and 50	●					N/A	N/A
	MSI	MSI-High	MSI-High tumor cell line; MSI score: ~77	●				●	N/A	N/A
		MSI Reference Panel	5 Bethesda MSI markers; AF: 5% or 20%	●					BAT-25, BAT-26, MONO-27, NR-21, NR-24	INDEL
Disease Monitoring	Liquid Biopsy	ctDNA v2	28 pan cancer genes/ translocations, 40 variants; AF: 0%, 0.125%, 0.25%, 0.5%, 1%, or 2%			●			AKT1, APC, ATM, BRAF, CTNNB1, EGFR, ERBB2, FGFR3, FLT3, FOXL2, GNA11, GNAQ, GNAS, IDH1, JAK2, KIT, KRAS, MPL, NPM1, NRAS, PDGFRA, PIK3CA, PTEN, RET, SMAD4, TP53, NCOA4::RET, TPR::ALK	SNV, INDEL, SV
		ctDNA Extraction Reference Material	4 variants; AF 1%; 20 ng/ml, 50 ng/ml, 80 ng/ml DNA			●			EGFR	SNV, INDEL
		ctDNA Complete	16 solid tumor genes/ translocations, 25 variants; AF: 0%, 0.1%, 0.5%, 1%, 2.5%, or 5%			●			AKT1, ALK, BRAF, BRCA1, BRCA2, EGFR, ERBB2 (CNV), KIT, KRAS, MET (CNV), MYC (CNV), NRAS, PIK3CA, CD74::ROS1, EML4::ALK, NCOA4::RET	SNV, INDEL, SV, CNV
		ctDNA v4	71 genes/translocations, 93 variants; AF 0%, 0.1%, 0.5%, or 5%			●			AKT1, AR, ATM, BRAF, BRCA1, BRCA2, CDKN2A, CHEK1, CHEK2, EGFR, ERBB2, ESR1, FGFR3, HRAS, IDH1, IDH2, KIT, KRAS, MAP2K1, MAP4K3, MET, MLH1, MSH2, MSH6, MTOR, NF1, NRAS, NTRK1, NTRK2, NTRK3, PALB2, PDGFRA, PIK3CA, PIK3R1, PMS2, PTCH1, PTEN, RAD51C, RAD51D, RAF1, RB1, RET, SLC7A8, SMARCB1, STK11, TERT, TP53, TSC1, TSC2, VHL, ZNF2, CD74::NRG1, CD74::ROS1, COL1A1::PDGFB, EML4::ALK, ETV6::NTRK3, FGFR2::BICC1, FGFR3::TACC3, NCOA4::RET, PML::NTRK2, TPM3::NTRK1, AKT2 (CNV), CCND1 (CNV), CCNE1 (CNV), CDK4 (CNV), FGF19 (CNV), FGF3 (CNV), FGF4 (CNV), FGFR1 (CNV), MYC (CNV), MYCN (CNV)	SNV, INDEL, SV, CNV
		ctDNA ESR1	2 genes, 22 variants; AF 0% and 1%			●			ESR1, PIK3CA	SNV, INDEL
		ctDNA Prostate	41 genes/translocations, 48 variants; AF 0%, 0.5%, or 1%			●			APC, AR, ATM, ATR, BARD1, BRAF, BRCA1, BRCA2, BRIP1, CDK12, CDKN2A, CHEK1, CHEK2, FANCA, FANCL, KIT, KRAS, MAP4K3, MLH1, MRE11, MSH2, MSH6, NBN, PALB2, PIK3CA, PIK3R1, PMS2, PTEN, RAD51B, RAD51C, RAD51D, RAD54L, RB1, SLC7A8, SPOP, TP53, ZNF2, SLC45A3::ETV1, TMPRSS2::ERG, CCND1 (CNV), MYC (CNV)	SNV, INDEL, SV, CNV
		cfRNA Fusion	19 solid tumor RNA fusions across 30 genes				●		CCDC6::RET, CD74::ROS1, EGFR Variant III, EGFR::SEPTIN14, EML4::ALK, ETV6::NTRK3, FGFR3::BAIAP2L1, FGFR3::TACC3, KIF5B::RET, LMNA::NTRK1, MET ex 14 Skipping, NCOA4::RET, PAX8::PPARG, SLC34A2::ROS1, SLC45A3::BRAF, TFG::NTRK1, TMPRSS2::ERG, FGFR1::TACC1, FGFR2:CCDC6	Fusion
	Methylation	Methylated ctDNA	<2% and >90% global CpG methylation			●			N/A	N/A
	MRD	ctDNA MRD	14 solid tumor genes/ translo- cations, 22 variants; TF: 0%, 0.005%, 0.05%, and 0.5%			●			AKT1, ALK, BRAF, BRCA1, BRCA2, EGFR, ERBB2, KIT, KRAS, NRAS, PIK3CA, CD74::ROS1, EML4::ALK, NCOA4::RET	SNV, INDEL, SV

Key: ● = available as FPPE ● = available in 0.1x Tris-EDTA buffer ● = available in 0.1x 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
AF: allele frequency
MRD: minimal residual disease
MSI: microsatellite instability
TMB: Tumor Mutational Burden
RM: reference material
TF: tumor fraction
v: version
WT: wild-type

PRODUCT LIST

Application	Product Group		Product Number	Product Name	Format	Fill in Size
Disease Profiling	Solid Tumor DNA/RNA	Tumor Mutation v2	0710-0094	Seraseq® Tumor Mutation DNA Mix v2 AF10 HC	DNA	1 x 25 µL, 25 ng/µL
			0710-0095	Seraseq® Tumor Mutation DNA Mix v2 AF7 HC	DNA	1 x 25 µL, 25 ng/µL
			0710-0097	Seraseq® Tri-Level Tumor Mutation DNA Mix v2 HC	DNA	1 x 25 µL, 25 ng/µL
		Tumor Mutation v3	0710-3460	Seraseq® Tumor Mutation DNA Mix v3 AF10%	DNA	1 x 15 µL, 25 ng/µL
			0710-3461	Seraseq® Tumor Mutation DNA Mix v3 AF7%	DNA	1 x 15 µL, 25 ng/µL
			0710-3462	Seraseq® Tumor Mutation DNA Mix v3 Tri-Level	DNA	1 x 15 µL, 25 ng/µL
		Solid Tumor FFPE	0710-3634	Seraseq® Solid Tumor FFPE DNA Reference Material	FFPE	1 x 10 µm curl
		Compromised Tumor	0710-1492	Seraseq® Compromised FFPE Tumor DNA RM	FFPE	1 x 10 µm curl
		HRD	0710-2643	Seraseq® FFPE HRD High-Positive RM	FFPE	1 x 10 µm curl
			0710-2644	Seraseq® FFPE HRD Negative RM	FFPE	1 x 10 µm curl
			0710-2645	Seraseq® FFPE HRD Low-Positive RM	FFPE	1 x 10 µm curl
			0710-2879	Seraseq® gDNA HRD High-Positive Mix	DNA	2 x 20 µL, 25 ng/µL
			0710-2880	Seraseq® gDNA HRD Low-Positive Mix	DNA	2 x 20 µL, 25 ng/µL
			0710-2881	Seraseq® gDNA HRD Negative Mix	DNA	2 x 20 µL, 25 ng/µL
		Integration FFPE	0710-4031	Seraseq® Integration Tumor FFPE DNA/RNA RM	FFPE	1 x 10 µm curl
			0710-4032	Seraseq® Integration WT FFPE DNA/RNA RM	FFPE	1 x 10 µm curl
		Endometrial Cancer	0710-4125	Seraseq® Endometrial Cancer DNA Mix	DNA	1 x 20 µL, 15 ng/µL
		BRCA1/2 LGR	0730-0564	Seraseq® FFPE BRCA1/2 LGR Reference Material	FFPE	1 x 10 µm curl
			0730-0567	Seraseq® gDNA BRCA1/2 LGR Somatic Mutation Mix	DNA	1 x 25 µL, 15 ng/µL
			0730-0568	Seraseq® gDNA BRCA1/2 LGR Inherited Mutation Mix	DNA	1 x 25 µL, 15 ng/µL
		BRCA1/2 Exon Deletion	0730-0570	Seraseq® BRCA1/2 Exon Deletions DNA Mix	DNA	1 x 25 µL, 15 ng/µL
		Inherited Cancer	0730-0003	Seraseq® Inherited Cancer DNA Mix v1	DNA	1 x 200 µL, 50 ng/µL
			0730-0069	Seraseq® Inherited Cancer DNA Mix v2	DNA	1 x 20 µL, 25 ng/µL
		CNV	0710-2865	Seraseq® FFPE Solid Tumor CNV Reference Materials	FFPE	1 x 10 µm curl
			0710-2866	Seraseq® Solid Tumor CNV Mix, +3 copies	DNA	1 x 20 µL, 10 ng/µL
			0710-2867	Seraseq® Solid Tumor CNV Mix, +6 copies	DNA	1 x 20 µL, 10 ng/µL
			0710-2868	Seraseq® Solid Tumor CNV Mix, +12 copies	DNA	1 x 20 µL, 10 ng/µL
			0710-4109	Seraseq® CNV Copy Loss DNA Mix	DNA	1 x 20 µL, 10 ng/µL

Abbreviations:

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gDNA: genomic DNA
TNA: total nucleic acid
AF: allele frequency
MRD: minimal residual disease
MSI: microsatellite instability
TMB: Tumor Mutational Burden
RM: reference material
v: version
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PRODUCT LIST CONTINUED

Application	Product Group		Product Number	Product Name	Format	Fill in Size
Disease Profiling	Solid Tumor DNA/RNA	Wild-type Control	0710-0137	Seraseq® FFPE WT (DNA/RNA) Reference Material	FFPE	1 x 10 µm curl
			0710-1580	Seraseq® TNA (DNA/RNA) WT Mix	DNA, RNA	2 x 20 µL, 25 ng/µL
			0710-1710	Seraseq® Compromised FFPE WT (DNA/RNA) RM	FFPE	1 x 10 µm curl
		Tumor Fusion v4	0710-0496	Seraseq® FFPE Tumor Fusion RNA v4 Reference Material	FFPE	1 x 10 µm curl
			0710-0497	Seraseq® Fusion RNA Mix v4	RNA	1 x 25 µL, 25 ng/µL
		Sarcoma Plus Fusion	0710-3809	Seraseq® Sarcoma Plus RNA Fusion Mix	RNA	1 x 20 µL, 25 ng/µL
		NTRK Fusion	0710-1031	Seraseq® FFPE NTRK Fusion RNA Reference Material	FFPE	1 x 10 µm curl
			0710-1696	Seraseq® NTRK Fusion RNA Mix	RNA	1 x 20 µL, 25 ng/µL
		Whole Transcriptome	0710-2129	Seraseq® Whole Transcriptome RNA Seq Mix	RNA	1 x 20 µL, 50 ng/µL
	Heme Disorder	Lymphoma	0710-2202	Seraseq® FFPE Lymphoma DNA Reference Material	FFPE	1 x 10 µm curl
			0710-2203	Seraseq® Lymphoma DNA Mutation Mix	DNA	1 x 25 µL, 15 ng/µL
			0710-3181	Seraseq® ctDNA Lymphoma Mix WT	ctDNA	1 x 25 µL, 10 ng/µL
			0710-3182	Seraseq® ctDNA Lymphoma Mix AF 1%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-3183	Seraseq® ctDNA Lymphoma Mix AF 0.5%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-3184	Seraseq® ctDNA Lymphoma Mix AF 0.1%	ctDNA	1 x 25 µL, 10 ng/µL
		Myeloid Mutation	0710-0408	Seraseq® Myeloid Mutation DNA Mix	DNA	1 x 25 µL, 15 ng/µL
		Myeloid Fusion	0710-0407	Seraseq® Myeloid Fusion RNA Mix	RNA	1 x 25 µL, 15 ng/µL
		Myeloid ctDNA	0710-2646	Seraseq® Myeloid ctDNA Mix WT	ctDNA	1 x 25 µL, 15 ng/µL
			0710-2647	Seraseq® Myeloid ctDNA Mix AF0.1%	ctDNA	1 x 25 µL, 15 ng/µL
			0710-2648	Seraseq® Myeloid ctDNA Mix AF0.5%	ctDNA	1 x 25 µL, 15 ng/µL
			0710-2649	Seraseq® Myeloid ctDNA Mix AF1%	ctDNA	1 x 25 µL, 15 ng/µL
Immuno-Oncology	TMB	Tissue TMB	0710-1307	Seraseq® FFPE TMB RM Score 26	FFPE	1 x 10 µm curl
			0710-1309	Seraseq® FFPE TMB RM Score 20	FFPE	1 x 10 µm curl
			0710-1618	Seraseq® FFPE TMB RM Score 13	FFPE	1 x 10 µm curl
			0710-1308	Seraseq® FFPE TMB RM Score 9	FFPE	1 x 10 µm curl
			0710-1310	Seraseq® FFPE TMB RM Score 7	FFPE	1 x 10 µm curl
			0710-1323	Seraseq® gDNA TMB Mix Score 26	DNA	2 x 10 µL, 50 ng/µL
			0710-1324	Seraseq® gDNA TMB Mix Score 20	DNA	2 x 10 µL, 50 ng/µL
			0710-1586	Seraseq® gDNA TMB Mix Score 13	DNA	2 x 10 µL, 50 ng/µL
			0710-1325	Seraseq® gDNA TMB Mix Score 9	DNA	2 x 10 µL, 50 ng/µL
			0710-1326	Seraseq® gDNA TMB Mix Score 7	DNA	2 x 10 µL, 50 ng/µL

Abbreviations:

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PRODUCT LIST CONTINUED

Application	Product Group		Product Number	Product Name	Format	Fill in Size
		Blood TMB	0710-2087	Seraseq® Blood TMB Mix Score 7	ctDNA	3 x 20 µL, 10 ng/µL
			0710-2088	Seraseq® Blood TMB Mix Score 13	ctDNA	3 x 20 µL, 10 ng/µL
			0710-2089	Seraseq® Blood TMB Mix Score 20	ctDNA	3 x 20 µL, 10 ng/µL
			0710-2090	Seraseq® Blood TMB Mix Score 26	ctDNA	3 x 20 µL, 10 ng/µL
		TMB Reference Panel	0710-2463	Seraseq® gDNA TMB Reference Panel Mix	DNA	5 x 20 µL, 25 ng/µL
	MSI	MSI-High	0710-1670	Seraseq® gDNA MSI-High Mix	DNA	1 x 20 µL, 25 ng/µL
			0710-2236	Seraseq® FFPE MSI-High RM	FFPE	1 x 10 µm curl
		MSI Reference Panel	0710-1675	Seraseq® MSI Reference Panel Mix AF5%	DNA	2 x 15 µL, 20 ng/µL
			0710-1676	Seraseq® MSI Reference Panel Mix AF20%	DNA	2 x 15 µL, 20 ng/µL
Disease Monitoring	Liquid Biopsy	ctDNA v4	0710-3097	Seraseq® ctDNA Mutation Mix v4 AF0.1%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-3099	Seraseq® ctDNA Mutation Mix v4 AF0.5%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-3100	Seraseq® ctDNA Mutation Mix v4 AF5%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-3101	Seraseq® ctDNA Mutation Mix v4 WT	ctDNA	1 x 25 µL, 10 ng/µL
			0710-3989	Seraseq® ctDNA Reference Mat WT	ctDNA	1 x 5 mL, 25 ng/mL
			0710-3990	Seraseq® ctDNA Reference Mat AF5%	ctDNA	1 x 5 mL, 25 ng/mL
			0710-3991	Seraseq® ctDNA Reference Mat AF0.5%	ctDNA	1 x 5 mL, 25 ng/mL
			0710-3992	Seraseq® ctDNA Reference Mat AF0.1%	ctDNA	1 x 5 mL, 25 ng/mL
		ctDNA MRD	0710-2146	Seraseq® ctDNA MRD Panel Mix	ctDNA	4 x 20 µL, 10 ng/µL
			0710-3670	Seraseq® ctDNA MRD 0% Tumor	ctDNA	1 x 20 µL, 10 ng/µL
			0710-3671	Seraseq® ctDNA MRD 0.5% Tumor	ctDNA	1 x 20 µL, 10 ng/µL
			0710-3672	Seraseq® ctDNA MRD 0.05% Tumor	ctDNA	1 x 20 µL, 10 ng/µL
			0710-3673	Seraseq® ctDNA MRD 0.005% Tumor	ctDNA	1 x 20 µL, 10 ng/µL
		ctDNA v2	0710-0139	Seraseq® ctDNA Mutation Mix v2 AF2%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-0140	Seraseq® ctDNA Mutation Mix v2 AF1%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-0141	Seraseq® ctDNA Mutation Mix v2 AF0.5%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-0142	Seraseq® ctDNA Mutation Mix v2 AF0.25%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-0143	Seraseq® ctDNA Mutation Mix v2 AF0.125%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-0144	Seraseq® ctDNA Mutation Mix v2 WT	ctDNA	1 x 25 µL, 10 ng/µL
			0710-0203	Seraseq® ctDNA Reference Material v2 AF2%	ctDNA	1 x 5 mL, 25 ng/mL
			0710-0204	Seraseq® ctDNA Reference Material v2 AF1%	Plasma	1 x 5 mL, 25 ng/mL

Abbreviations:

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PRODUCT LIST CONTINUED

Application	Product Group		Product Number	Product Name	Format	Fill in Size
Disease Monitoring	Liquid Biopsy	ctDNA v2	0710-0205	Seraseq® ctDNA Reference Material v2 AF0.5%	Plasma	1 x 5 mL, 25 ng/mL
			0710-0207	Seraseq® ctDNA Reference Material v2 AF0.125%	Plasma	1 x 5 mL, 25 ng/mL
			0710-0208	Seraseq® ctDNA Reference Material v2 WT	Plasma	1 x 5 mL, 25 ng/mL
		ctDNA Complete	0710-0528	Seraseq® ctDNA Complete™ Mutation Mix AF5%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-0529	Seraseq® ctDNA Complete™ Mutation Mix AF2.5%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-0530	Seraseq® ctDNA Complete™ Mutation Mix AF1%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-0531	Seraseq® ctDNA Complete™ Mutation Mix AF0.5%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-0532	Seraseq® ctDNA Complete™ Mutation Mix AF0.1%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-0533	Seraseq® ctDNA Complete™ Mutation Mix WT (0%)	ctDNA	1 x 25 µL, 10 ng/µL
			0710-0669	Seraseq® ctDNA Complete™ Reference Material AF5%	Plasma	1 x 5 mL, 25 ng/mL
			0710-0670	Seraseq® ctDNA Complete™ Reference Material AF2.5%	Plasma	1 x 5 mL, 25 ng/mL
			0710-0671	Seraseq® ctDNA Complete™ Reference Material AF1%	Plasma	1 x 5 mL, 25 ng/mL
			0710-0672	Seraseq® ctDNA Complete™ Reference Material AF0.5%	Plasma	1 x 5 mL, 25 ng/mL
			0710-0673	Seraseq® ctDNA Complete™ Reference Material AF0.1%	Plasma	1 x 5 mL, 25 ng/mL
			0710-0674	Seraseq® ctDNA Complete™ Reference Material WT (0%)	Plasma	1 x 5 mL, 25 ng/mL
		ctDNA ESR1	0710-3565	Seraseq® ctDNA ESR1 Mutation Mix AF1%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-3564	Seraseq® ctDNA ESR1 Mix WT	ctDNA	1 x 25 µL, 10 ng/µL
		ctDNA Prostate	0710-3327	Seraseq® ctDNA Prostate Mix WT	ctDNA	1 x 25 µL, 10 ng/µL
			0710-3328	Seraseq® ctDNA Prostate Mix AF1%	ctDNA	1 x 25 µL, 10 ng/µL
			0710-3329	Seraseq® ctDNA Prostate Mix AF 0.5%	ctDNA	1 x 25 µL, 10 ng/µL
		Methylated ctDNA	0710-3089	Seraseq® Methylated ctDNA Mix	ctDNA	1 x 25 µL, 10 ng/µL
			0710-3088	Seraseq® Unmethylated ctDNA Mix	ctDNA	1 x 25 µL, 10 ng/µL
		ctDNA Extraction	0710-3294	Seraseq® ctDNA Extraction Reference Material 20 ng/mL	Plasma	4 x 1 mL, 20 ng/µL
			0710-3295	Seraseq® ctDNA Extraction Reference Material 50 ng/mL	Plasma	4 x 1 mL, 50 ng/µL
			0710-3296	Seraseq® ctDNA Extraction Reference Material 80 ng/mL	Plasma	4 x 1 mL, 80 ng/µL
		cfRNA	0710-4078	Seraseq® cfRNA Fusion Mix	cfRNA	1 x 25 µL, 10 ng/µL

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LGC CLINICAL DIAGNOSTICS

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