

SeraCare Cancer Solutions Overview

REFERENCE MATERIALS AND QC SOFTWARE FOR CLINICAL NGS ASSAY, VALIDATION, DEVELOPMENT AND QUALITY CONTROL MANAGEMENT

SeraCare's comprehensive suite of patient-like **Seraseq[®]** reference materials and quality management solutions accelerate development, streamline validation, and ensure confidence in results for today's demanding NGS-based clinical oncology assays.

Assay Development



DEVELOP ASSAYS FASTER

- Broadest selection of clinically relevant variants offering coverage of all variant types
- Highly multiplexed - significantly more data per sequencing run
- Customize your own reference materials from a library of over 240 variants covering all variant types (SNVs, INDELS, CNVs, SVs) at virtually any allele frequency

Assay Validation



LAUNCH ON TIME AND ON BUDGET

- Each reference material batch is accurately quantitated — ddPCR and NGS QC provides important information on LOD, sensitivity, and specificity
- Regulatory-compliant analytical validation materials — accepted by New York State, the FDA, and other regulatory bodies
- iQ[™] NGS QC Management software offers QC workflow templates with pre-loaded CAP/AMP-recommended metrics to establish performance and proficiency prior to test launch

Lab QC Operations



ENSURE CONFIDENCE IN YOUR RESULTS

- Monitor assay performance and quickly reveal sources of variability (e.g., reagent lots, instrument calibration, operator experience) with SeraCare's Confidence Score[®] - a comprehensive precision metric powered by our highly multiplexed Seraseq[®] reference materials
- Easily and simply review QC data for your entire NGS workflow in one integrated environment
- Quickly generate comprehensive QC reports for audits and inspections

WHEN TO USE REFERENCE MATERIALS

Multiplexed reference materials are important throughout an assay's entire lifecycle. This reference guide details when to use multiplexed Seraseq NGS reference materials as your primary reference material, and when they should supplement the use of patient samples.

Assay Selection	Primary Reference Material	Supplementary Reference Material	Validation	Primary Reference Material	Supplementary Reference Material
Sample preparation	Seraseq	Patient samples	Accuracy	Patient samples	Seraseq
Library preparation	Seraseq	Patient samples	Precision	Seraseq	Patient samples
Sequencing	Seraseq	Patient samples	Reproducibility	Seraseq	Patient samples
Bioinformatics pipeline	Seraseq	Patient samples	Reference range	Patient samples	Seraseq
			Minimum input amount (ng of DNA)	Seraseq	Patient samples
			Limit of detection	Patient samples	Seraseq
			Analytical specificity	Patient samples	Seraseq
			Analytical sensitivity	Seraseq	Patient samples
Operations	Primary Reference Material	Supplementary Reference Material	Reporting	Primary Reference Material	Supplementary Reference Material
Daily runs quality control	Seraseq	Patient samples	QC metrics	Seraseq	Patient samples
New operators	Seraseq	Patient samples	QC reports for CAP inspections	Seraseq	Patient samples
New reagents	Seraseq	Patient samples			
New instruments	Seraseq	Patient samples			
Annual competency	Seraseq	Patient samples			

About SeraCare

SeraCare is a trusted partner and worldwide supplier to the diagnostic testing industry for over 30 years, advancing the development of molecular and serology diagnostics with innovative technology, quality controls, reagents, and biological materials. As an ISO 13485-certified manufacturer with advanced molecular manufacturing and packaging capabilities, SeraCare is a leader in reference materials to enable the promise of precision medicine and ensure correct results for NGS-based test providers. Visit www.seracare.com/cancer to learn more.

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