

Liquid Biopsy Solutions Overview

REFERENCE MATERIALS AND QC SOFTWARE FOR LIQUID BIOPSY ASSAY, VALIDATION, DEVELOPMENT, AND QUALITY CONTROL MANAGEMENT

Ensuring accuracy at extreme levels of sensitivity is crucial to the clinical utility of low-plex qPCR and highly multiplexed NGS-based liquid biopsy assays. These tests demand purpose-built, patient-like reference materials and the ability to easily track and trend QC metrics over time to ensure their sensitivity and troubleshoot performance drift before critical patient results are impacted.

BETTER ASSAYS AND MORE THOROUGH VALIDATIONS

- Highly multiplexed Seraseq® ctDNA reference materials give you more data per run
- Confidently assess your assay's concordance with tissue-based tests with allele frequencies up to 5%
- Natural cfDNA-like size distribution and efficient library preparation enhances NGS workflow performance and data quality

ENSURE ASSAY SENSITIVITY AND ACCURACY

- Determine your assay's lower limit-of-detection with orthogonally validated allele frequencies down to 0.1%
- Confidently establish your assay's ability to detect SNVs, INDELs, CNVs, and SVs with reference materials featuring the broadest coverage of all variant types
- Expert-designed constructs contain up to 40 clinically relevant variants tied to diagnosis, disease progression monitoring, and therapeutic selection

ENHANCE CONFIDENCE IN THE QUALITY OF YOUR RESULTS

- Quickly and easily track and trend your assay's QC data to instantly detect performance drift and determine sources of variability with iQ™ NGS QC Management software and Seraseq biosynthetic reference materials
- SeraCare's exclusive Confidence Score™ gives you at-a-glance insight into your assay's workflow performance
- Prepare for regulatory inspections in just a few clicks to sign-off on QC metrics and generate a fully compiled and ready-to-submit report

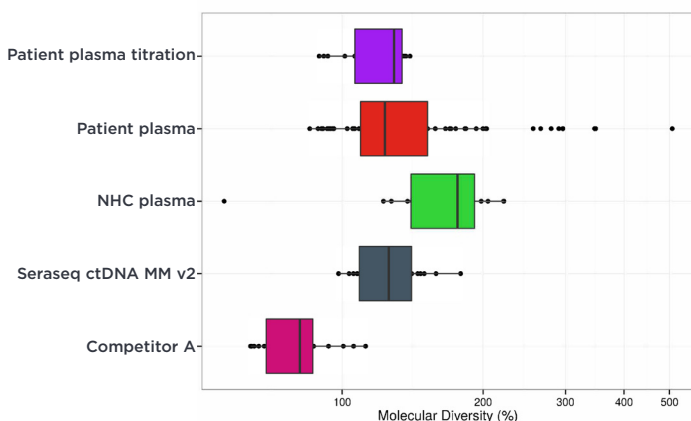


Figure 1: The Seraseq ctDNA Mutation Mix v2 reference standards and cancer patient plasma samples have comparable post-sequencing molecular diversity of barcoded molecules relative to mass input by Qubit™ (330 cps/ng) [J Larsen, et. al., Poster#: 5574, 2018 AACR Meeting, Chicago, IL]. Molecular diversity is plotted for all amplicons in all samples; the median number of unique MBCs across all amplicons >100% of expectation based on input DNA quantities, indicating a highly efficient workflow. Data courtesy of Asuragen, Inc.

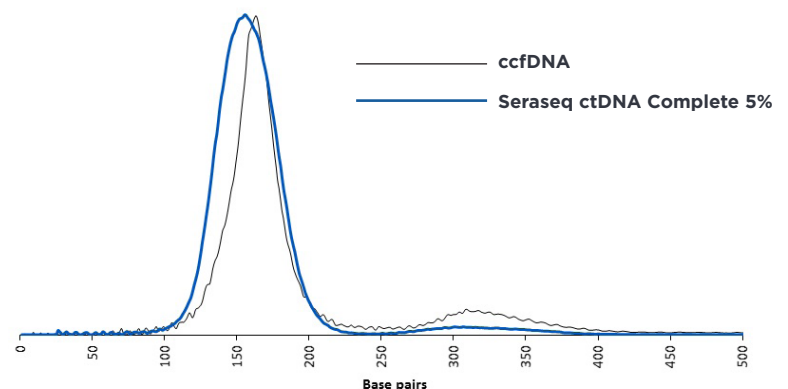


Figure 2: Representative DNA fragment size distribution for the Seraseq ctDNA Complete™ Mutation Mix AF5% versus natural circulating cell-free DNA (ccfDNA)

COMPREHENSIVE SOLUTIONS ACROSS ALL PHASES OF THE NGS WORKFLOW

Seraseq ctDNA Reference Materials

- **Seraseq ctDNA v2**

- The most comprehensive DNA variants in a single reference sample - 40 variants - SNVs, INDELS, and SVs
- Patient-like material provides ground-truth variant analysis and optimized assay performance

- **Seraseq ctDNA Complete**

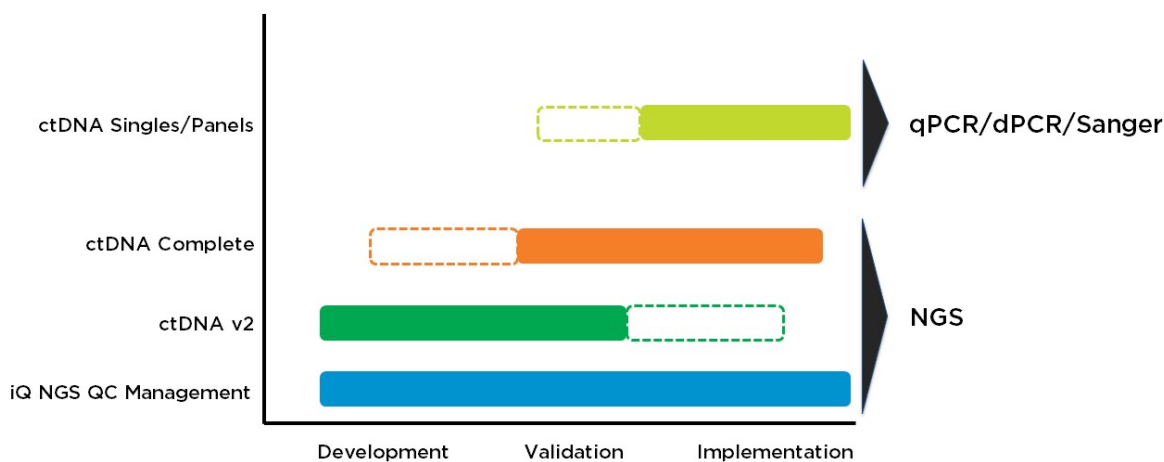
- Most complete content of clinically relevant DNA variant types in a single reference sample - SNVs, INDELS, CNVs, and SVs
- Broadly compatible with commercially available assays to accelerate validation and clinical implementation

- **Seraseq ctDNA Gene Panels**

- Disease-focused, single-gene, low-plex reference standards for cancer diagnostic assay testing for targeted therapies, or clinical trial stratification of cancer patients - EGFR (T790M, L858R, ex19 del), KRAS (G12D), and more
- Ensures consistent, high quality patient sample test results

iQ NGS QC Management Software

- Maximize uptime by proactively tracking and trending assay performance across a broader representation of relevant biology
- Decrease QC implementation time with preloaded CAP/AMP NGS metrics
- Simplify QC review process with one simple, integrated environment that spans the entire NGS workflow



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/ctDNA to learn more.



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