

Get Up and Running Faster. Stay Up and Running Longer.

**THE WORLD'S ONLY PURPOSE-BUILT QC SOLUTION FOR CLINICAL
NEXT-GENERATION SEQUENCING**

Next-generation sequencing (NGS) offers great promise as one of the most powerful diagnostic tools for improving human health. However, the NGS workflow is complex, spanning several days and involving multiple steps, reagents, instruments, operators, and software tools. As a result, clinical genomics laboratories often struggle with successfully validating and operationalizing clinical NGS assays that are fully compliant with CAP/AMP guidelines. Particularly because they necessitate the monitoring of dozens of quality metrics to ensure optimal assay performance.

To address these challenges, it is important for clinical genomics laboratories to utilize a robust QC strategy including:

- The ability to consistently monitor performance of every step in the workflow and relevant variants in a panel over time
- Incorporating a sustainable source of truth-set reference materials
- Using a purpose-built QC software solution for reviewing the many QC metrics required by industry guidelines such as CAP/AMP

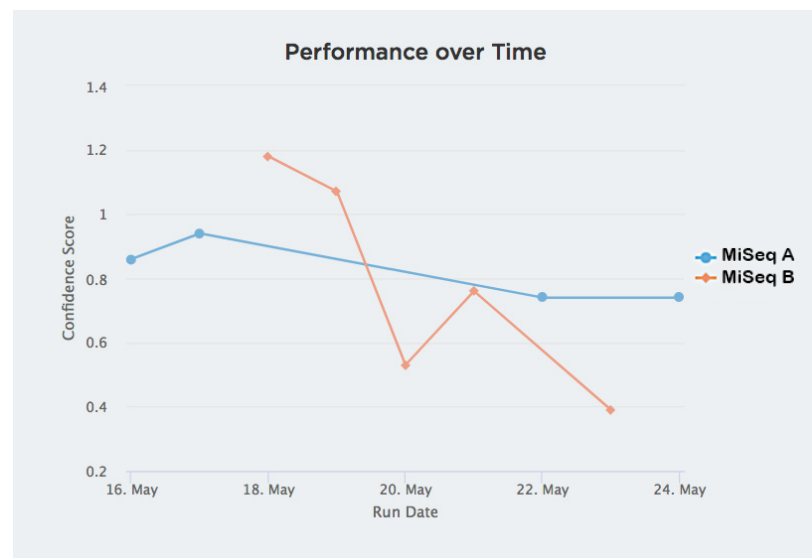
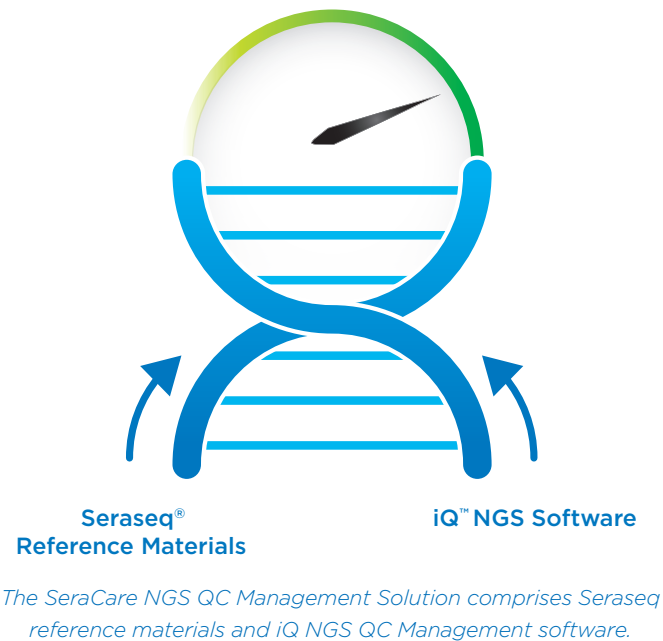
SeraCare offers the world's only fit-for-purpose clinical NGS QC management solution which includes iQ NGS - a cloud-based cockpit featuring a single integrated environment for tracking, trending, troubleshooting, and reporting NGS QC data - and Seraseq reference materials which are designed for the unique demands of NGS.

REDUCE ASSAY DOWNTIME WITH PROACTIVE MONITORING AND TROUBLESHOOTING

It's critical to catch errors and quickly remedy their root causes before patient results are delayed or affected. An industry-wide survey found that 52% of clinical NGS labs experience at least 12 days of downtime for troubleshooting per year¹. SeraCare's exclusive Confidence Score™ cuts troubleshooting time from hours to minutes. This single, quantitative assessment of your assay's performance aggregates the data from highly multiplexed Seraseq reference materials. The Confidence Score enables you to spot and address overarching trends in assay performance by understanding drift and performance across reagent lots, instruments, and operators.

¹ <https://www.seracare.com/qcsurvey>

SeraCare's NGS QC Total Solution

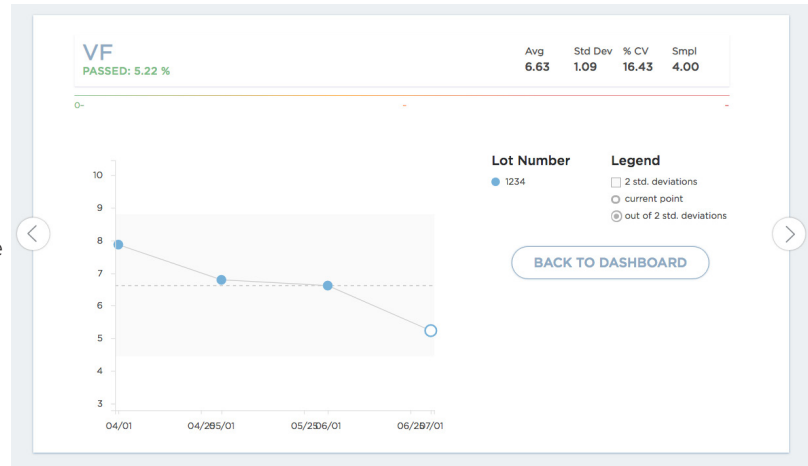


The SeraCare Confidence Score facilitates monitoring of assay performance over time and enables quick resolution of assay anomalies.

TRACK AND TREND PERFORMANCE ACROSS THE ENTIRE NGS WORKFLOW

Utilizing SeraCare's industry leading Seraseq reference materials, the iQ NGS QC Management solution provides an intuitive, highly visual cockpit for tracking and trending all aspects of the NGS workflow in a single, centralized environment. Sample and sequencing run data are also easily integrated with VCF information resulting in a streamlined solution for final QC review.

Final variant calls are impacted in different ways by each of the many dimensions of quality that cumulatively make up NGS run performance. Incorporating reference materials that best represent patient samples being tested with the proper mix of variants and variant types, along with associated quantitative metrics, is the key to truly comprehensive run performance assessments. Seraseq biosynthetic NGS reference materials provide:



Track and trend all aspects of the NGS workflow with one single, convenient, easy-to-use solution. LIMS data are also easily imported.

- Critical variants and variant types recommended by leading clinical genomics experts
- Precisely modulated allele frequencies allow for more accurate measures of assay performance
- Effortless integration with iQ NGS QC Management makes it easy to analyze and evaluate runs, no matter how much data

ENSURE CAP/AMP COMPLIANCE WITH PRE-DEVELOPED QC TEMPLATES AND REPORTS

SeraCare's iQ NGS QC Management solution provides pre-developed QC templates that include CAP/AMP recommended metrics to help your laboratory minimize the time needed to develop and incorporate a robust QC program that is ready for inspections by associations like the College of American Pathologists (CAP).

Quickly generate QC reports for inspections with just a few mouse clicks and choose from an array of pre-built reports for demonstrating the equivalency of instruments and operators at set intervals throughout the year to ensure quality and operational efficiency over time.

METRIC	VARIANT	THRESHOLDS	UNITS	INSTRUMENT
Bases exceeding the ...		PASS 75 - WARN - FAIL -	%	MiSeq
Mean on-target cover...		PASS 300 - WARN - FAIL -	Coverage	MiSeq
Mean insert size		PASS 300 - 500 WARN 250 - 300 FAIL -	Base Pairs	MiSeq

Mapping 3 metrics 17 May 2018

Variant Calls 60 metrics 17 May 2018

The SeraCare iQ NGS QC Management solution provides pre-developed workflows which are populated with CAP/AMP-recommended metrics.

REMOVE DOUBT. ADD CONFIDENCE.

With SeraCare's complete QC solution of Seraseq biosynthetic NGS reference materials and iQ NGS QC Management software, you'll spend less time wrangling with QC data and hunting down suitable remnant specimens, and more time running your lab. Trust SeraCare's 30-plus years of experience supporting clinical laboratories around the world with comprehensive solutions to their greatest QC challenges.

About SeraCare

SeraCare is a leading partner to global IVD manufacturers and clinical testing laboratories. Our expanding portfolio of QC products and technologies for genomic diagnostics includes reference materials for liquid biopsy, tumor sequencing, germline mutation testing, NIPT, and infectious disease. Today, SeraCare is advancing data integration with products for better QC and regulatory compliance. Visit www.seracare.com/QC to learn more.

