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The SomaScan® Assay v4.0, v4.1, v5.0 Stability

The SomaScan v4.0, v4.1, and v5.0 Assays are run using 96 well plates; eleven wells are allocated for control samples used to control for batch effects and to estimate the accuracy, precision, and buffer background of the assay over time. Five pooled calibrator replicates, three pooled quality control (QC) replicates, and three buffer replicates are run on every plate.

The SomaScan v4.0, v4.1, and v5.0 Assays are read using Agilent hybridization, scan, and feature extraction technology. Twelve hybridization control SOMAmer® Reagents are added alongside SOMAmer Reagents to be measured from the biological samples and controls of each well during the SOMAmer Reagent elution step to control for readout variability.

The control samples are run repeatedly during assay qualification and robust point estimates are generated and stored as references for each SOMAmer Reagent's result for the calibrator and QC samples. The results are to be used as references throughout the life of the SomaScan v4.0, v4.1, and v5.0 Assays. Plate calibration is performed by calculating the ratio of the calibrator reference RFU value to the plate-specific calibrator replicate median RFU value for each SOMAmer Reagent.

The resulting ratio distribution is decomposed into a plate scale factor defined by the median of the distribution and a vector of SOMAmer Reagent-specific calibration scale factors. Normalization of QC replicates and samples is performed using adaptive normalization by maximum likelihood (ANML) with point and variance estimates from a normal U.S. population.

Post calibration accuracy is estimated using the ratio of the QC reference RFU value to the plate-specific QC replicate median RFU value for each SOMAmer Reagent. The resulting QC ratio distribution provides a robust estimate of accuracy for each SOMAmer Reagent on every plate. Reporting for the SomaScan v4.0, v4.1, and v5.0 Assays include all control sample results, plate scale factors, calibration scale factors, QC reference ratios, and summary assay acceptance criteria for all plates on which collaborator samples were run.

Plate-specific acceptance criteria: Plate scale factor between 0.4-2.5 and 85% of QC ratios between 0.8 and 1.2 must be met prior to release. More details regarding the qualification can be found in the SomaScan Technical Note.

In addition to standard acceptance criteria, alternate assay summary metrics including calibration scale factor percent outside of 0.6-1.4, QC sample total precision and 5 plate running precision, and buffer background or estimated lower limit of detection (eLOD) are monitored for failures or trends over time on a daily basis by Production Bioinformatics, Assay Services, and Assay Development team members. Failures, trends, or observed anomalies are reported to Quality Assurance.

Triplicate QC samples run on each plate have been used to evaluate production stability over time since the launch of the SomaScan v4.0 Assay. As of November of 2023 for the SomaScan v5.0 Assay, the Coefficients of Variation (CVs) for 32 replicates of the QC samples are below 4.5% for half of reagents and CVs for 90% of the reagents are below 9.6% (median = 4.5%, 90th percentile = 9.6%).

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The SomaScan Assay v4.0, v4.1, 5.0 Stability

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