105.6 - Biomanufacturing

SRM 3655 is intended primarily for use as a calibration standard for the measurement of enzymatically release N-linked glycans. Potential applications of SRM 3655 include the benchmarking and comparability of analytical techniques, as a material for ensuring system suitability, and for analytical method validation. This material may also be used to value-assign in-house calibrators or control materials. SRM 3655 consists of thirteen (13) aqueous solutions of glycans commonly associated with monoclonal antibody therapeutics. Each solution contains a purified free-reducing glycan at a certfied mass fraction.

RM 8230 is intended primarily for challenging, evaluating, and comparing analytical workflows involving nucleic acid-based detection. RM 8230 yeast cells have a noncoding sequence of nucleic acids stably inserted into their genome for targeted detection. Typical instrumentation for using this RM include polymerase chain reaction (PCR), quantitative PCR (qPCR), digital PCR (dPCR), and DNA sequencing technologies. In addition, this RM is characterized for total cells and may be used to support the assessment and comparison of microbial cell counting methods.

RM 8634 is intended primarily for use in validating the counting, sizing, and morphological analysis of liquid-borne particles over an approximate size range of 1 µm to 30 µm. RM 8634 is a suspension of highly polydisperse particles of irregular morphology that closely mimic the optical properties of aggregated proteinaceous particles. Thus, it is useful in determining instrumental response for particle counters used in biomanufacturing applications.

RM 8671 is intended primarily for use in evaluating the performance of methods for determining physicochemical and biophysical attributes of monoclonal antibodies. It also provides a representative test molecule for development of novel technology for therapeutic protein characterization.

PLEASE NOTE: The tables are presented to facilitate comparisons among a family of materials to help customers select the best SRM for their needs. For specific values and uncertainties, the certificate is the only official source.

SRM	Description	Unit Size	Parameters Reported
3655	Glycans in Solution (Frozen)	13 vials	13 certified mass fraction values for gylcans
8230	*Saccharomyces cerevisiae* NE095 Cells for Cell Counting and DNA-based Detection (freeze-dried)	16 vials (12 yeast, 4 matrix)	*Cells per vial and Colony Forming Units (CFU) per vial*
8634	Ethylene Tetrafluoroethylene for Particle Size Distribution and Morphology	20 mL	*particle size distribution and particle morphology*
8671	NISTmAb, Humanized IgG1k; Monoclonal Antibody	1 vial x 800 µL	*Concentration, size and charge heterogeneity, identity confirmation*

- Certified values are normal font.
- Non-certified and reference values are italicized.
- Information values and values of potential interest are within parentheses.