

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 certified 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.

RM 8675 is intended to provide a publicly accessible, industry relevant monoclonal antibody expressing cell line for biomanufacturing research and development. This RM can be used for a variety of purposes that may include assessing the performance of bioprocess measurement systems and bioprocess technologies associated with monoclonal antibody production or use in biomanufacturing educational and training programs.

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
<a href="#">3655</a>	Glycans in Solution (Frozen)	13 vials	<i>13 certified mass fraction values for glycans</i>
<a href="#">8230</a>	<i>Saccharomyces cerevisiae</i> NE095 Cells for Cell Counting and DNA-based Detection (freeze-dried)	16 vials (12 yeast, 4 matrix)	<i>Cells per vial and Colony Forming Units (CFU) per vial</i>
<a href="#">8634</a>	Ethylene Tetrafluoroethylene for Particle Size Distribution and Morphology	20 mL	<i>particle size distribution and particle morphology</i>
<a href="#">8671</a>	NISTmAb, Humanized IgG1k; Monoclonal Antibody	1 vial x 800 µL	<i>Concentration, size and charge heterogeneity, identity confirmation</i>
<a href="#">8675</a>	NISTCHO, Clonal CHO-K1 Cell Line Producing cNISTmAb	1 vial x 1 mL	<i>Copy Number Ratios of NISTCHO Specific Genes to Reference Genes in the CHO-K1 Genome</i>

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