

NIST issues first standard reference material for quantitative analysis of glycans

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Credit: National Institute of Standards and Technology

NIST Standard Reference Material (SRM) 3655 helps biopharmaceutical manufacturers perform measurements of glycan molecules in their protein drug products, including the monoclonal antibodies (mAbs) that currently dominate the biopharma market. Because differences in glycan structures can affect the safety and efficacy of a mAb, glycan profiles are considered a "critical quality attribute"—a key property used to assess biopharmaceutical product

quality. Therefore, it is important that biopharmaceutical manufacturers and regulators have confidence in their analyses of the glycans in a drug product.

SRM 3655 is the first standard for the quantitative assessment of glycans; It is traceable to the International System of Units (SI) and can be used as a calibrant for the measurement of N-linked glycans on mAbs with limited analytical bias. Mass fractions for 13 glycans—some of the most common and abundant on mAbs—were determined by gravimetry and confirmed by [mass spectrometry](#). The mass fraction and molar concentration values for the glycans are NIST Certified Values, meaning that the investigators have the highest [confidence](#) in data accuracy in that all known or suspected sources of bias have been fully investigated or accounted for by NIST.

This SRM helps the biopharmaceutical industry assess the consistency of manufacturing processes, and provides a clearer understanding of the glycan structures and content on drug products. It can also be used by researchers investigating glycomics or cancer.

A unit of 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 known mass fraction. A unit of SRM 3655 consists of thirteen 0.5 mL vials each containing approximately 0.2 mL of solution, frozen.

Details were published as an NIST Special Publication.

More information: Mark Lowenthal, Certification of Standard Reference Material® 3655 Glycans in Solution (Frozen), *NIST Special Publication* (2022). [DOI: 10.6028/NIST.SP.260-224](https://doi.org/10.6028/NIST.SP.260-224)

Provided by National Institute of Standards and Technology

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