

The NIST Biomanufacturing Program has made significant progress in antibody manufacturing and provides an approach to analytical measurements that can expedite the time to market of life-saving products and enable broader access to them.

NIST Biomanufacturing Reference Materials: Development, Applications, and Impact

Katharina S. Yandrofski, Megan H. Cleveland, Zvi Kelman,
Mike J. Tarlov, and John P. Marino



Katharina S.
Yandrofski



Megan H. Cleveland



Zvi Kelman



Mike J. Tarlov



John P. Marino

Monoclonal antibody (mAb) therapeutics, currently the largest and most successful biologic platform, harness the naturally evolved specificity of adaptive immunity to treat a variety of conditions such as cancer, autoimmune disorders, and infectious diseases (Kelley 2024). MAbs are complex, multidomain proteins with post-translational modifications (PTMs), including N-glycosylation, at a single site that can play a particularly important role in determining drug safety and efficacy (Schiel et al. 2014). These therapeutics are manufactured

Katharina S. Yandrofski is a physical science technician at the National Institute of Standards and Technology (NIST) and the Institute for Bioscience and Biotechnology Research (IBBR). Megan H. Cleveland is a research biologist at NIST. Zvi Kelman is a research biologist at NIST and IBBR. Mike J. Tarlov is a research chemist at NIST and IBBR. John P. Marino is a research chemist at NIST and IBBR.

using highly controlled bioprocesses that typically employ mammalian cells such as Chinese hamster ovary (CHO) or non-secreting murine myeloma as the production host (Kelley 2009; Li et al. 2010). During drug development, manufacture, formulation, and product release, a wide variety of analytical technologies are used to characterize mAb therapeutics and the processes used in their manufacture (Schiel et al. 2014; Schiel et al. 2015a; Schiel et al. 2015b). These methods are used to measure the critical quality attributes of a drug product related to its identity, purity, stability, potency, and safety and the critical process parameters in the manufacturing process. Due to their large size and the nature of cell-based production, mAbs, like other protein-based therapeutics, are inherently complex, heterogeneous products—defined by determined acceptable ranges of variance in measured critical quality attributes and critical process parameters (as described in guidelines developed by working committees of the International Conference on Harmonization, e.g., ICH5, ICH6, and ICH8) that correlate to performance of the therapeutic in clinical application (Schiel et al. 2014).

Around 2010, with the approaching patent expirations of the first innovator biologic medicines, it was recognized that reference materials (RMs) to support advances in the state-of-the-art in analytical and biophysical methods would benefit both innovator companies developing new medicines and emerging companies developing biosimilars, which are highly similar but not generic versions of biologic innovator drugs (Kozlowski 2009). At this time, it was also recognized that the National Institute of

Standards and Technology (NIST), working with industry and regulatory authorities, could assist in establishing a measurements and standards infrastructure to support a science-based regulatory path for bringing follow-on biosimilar therapeutics to the market.

In response, the NIST Biomanufacturing Program (<https://www.nist.gov/biomanufacturing>) was initiated in 2012 to address infrastructural measurement science problems and biopharmaceutical standard needs to support the development and manufacture of biologic medicines, with a focus on advancing state-of-the-art measurement science RMs, and standard reference materials (SRMs) that could support the development and manufacture of mAb therapeutics. NIST, a non-regulatory US government agency, cannot compel adoption of methods or technologies arising from its measurement science program nor the use of its RMs, so it relies on extensive stakeholder engagement and feedback to gain community consensus. Through such outreach, NIST identified broad infrastructural measurement challenges faced by the biopharmaceutical industry in mAb development and manufacture. NIST has worked to address these measurement challenges and foster innovation by leveraging pre-competitive collaborations and data sharing across academic, government, and industry stakeholder groups that are enabled by the availability of open access, publicly available RMs (figure 1). An example of the unique niche that NIST fills in supporting the biopharmaceutical ecosystem of the bioeconomy will

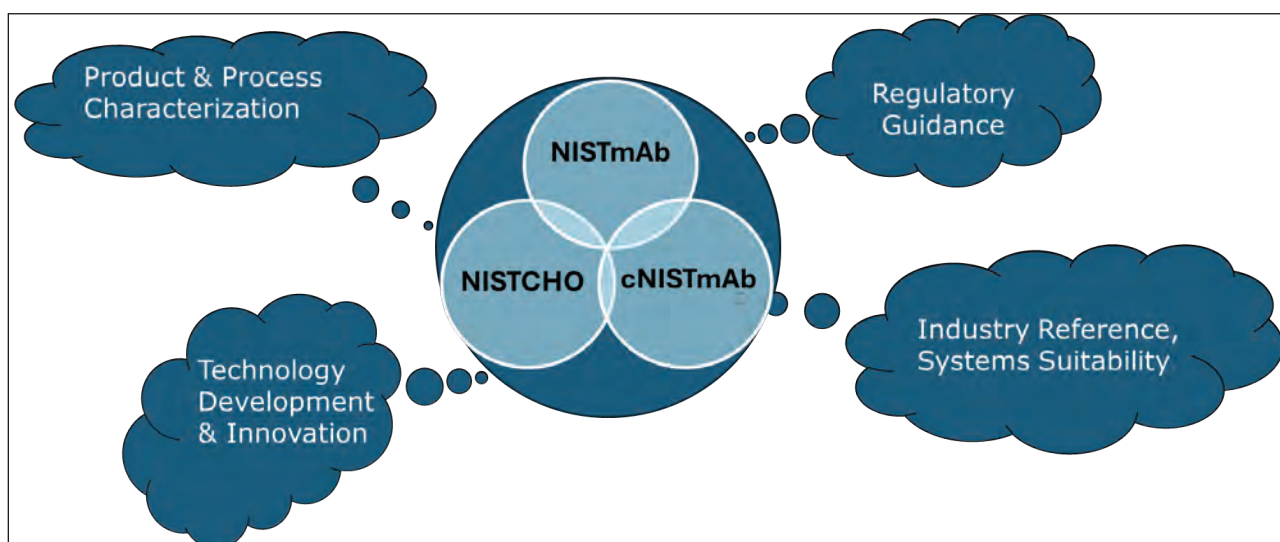


FIGURE 1 Examples of stakeholder value that can be provided by well characterized, widely available, accepted biomanufacturing reference materials in supporting commerce and innovation.

be described in terms of three novel biopharmaceutical RMs (RM 8671 NISTmAb, RM 8675 NISTCHO, and RM 8672 cNISTmAb) and related measurement science and technology innovation that has been enabled by the availability of these standards (Cleveland et al. 2025; Dahodwala et al. 2025; Mouchahoir and Schiel 2018; Schiel and Turner 2018; Schiel et al. 2018; Turner et al. 2018; Turner and Schiel 2018; Yandrofski et al. 2022; Yandrofski et al. 2023).

NIST Biomanufacturing Reference Materials

Biopharmaceutical companies typically rely on in-house reference standards, derived from well-characterized lots of drug products, to establish product-specific specifications when developing new drugs. These in-house standards, together with challenge materials typically derived from controlled physical or chemical degradation of drug products, are used for analytical method qualification and validation. While these materials serve an essential role in product-specific mAb drug development and lifecycle management within a pharmaceutical company, in-house standards are often limited in broader use in the evaluation of analytical methods and for collaborative studies due to intellectual property limitations. Additionally, while commercial mAbs can, in principle, be used as standards since they are stable and well characterized, the industry does not normally make data used to characterize these therapeutics publicly accessible. A publicly available, well-characterized mAb RM addresses these limitations and provides the biopharmaceutical stakeholder community with a unique resource.

The proprietary nature of commercial mammalian cell-based manufacture of mAb therapeutics also severely limits sharing of industrial cell lines and a company's internal process knowledge and data. As described for the drug product standards, it was recognized that a publicly available, well-characterized reference production host cell line, representative of a CHO host cell used by the industry for mAb manufacturing, would greatly benefit the biopharmaceutical stakeholder community. This tool allows evaluation of all aspects of the processes, methods, and instruments used in controlled commercial biomanufacturing. This living cell RM can also be used in collaborative, pre-competitive studies and benchmarking of new bioprocess technologies, including new continuous and process-intensive manufacturing methods, cell culture media, process analytical technologies, and other technologies used in upstream and downstream processes employed in the manufacture of mAbs.

NIST's Approach to Biomanufacturing Reference Material Development

Under the NIST Biomanufacturing Program, NIST has focused on the development of RMs that can be used for ensuring that analytical methods for mAbs provide consistent results across methods and labs. NIST also anticipates that its RMs may be used to benchmark emerging analytical technologies, thus accelerating the development and adoption of new and advanced analytical and biophysical methods needed to address the unique challenges of characterizing these complex and heterogeneous protein-based drugs.

To identify and establish broad consensus around the development of mAb and CHO RMs, NIST extensively engaged stakeholders (industry, regulatory and other government agencies, and academic institutions) through workshops, roundtables, and other forums. Once a decision was made to pursue these RMs, NIST faced an immediate challenge of sourcing an appropriate, stable material in the amount required for developability into a NIST RM that would be available for wide distribution over many years to the stakeholder community.

***A publicly available,
well-characterized
mAb reference material
addresses these limitations and
provides the biopharmaceutical
stakeholder community with a
unique resource.***

In this respect, NIST has benefited from partnerships with industry stakeholders who have provided typical industry materials through material transfer agreements. In the case of NISTmAb, NIST received a pharmaceutical-grade mAb drug substance through a material transfer agreement with MedImmune (now AstraZeneca) for the expressed purpose of its development into RM 8671 NISTmAb. For NISTCHO, MilliporeSigma and the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) partnered with NIST to develop an industry-relevant,

open-access CHO cell line with limited constraints that expresses a mAb with the same primary sequence as the NISTmAb, referred to as cNISTmAb. The NISTCHO cell line produced by MilliporeSigma was transferred to NIST through a material transfer agreement for development into RM 8675 NISTCHO. For cNISTmAb, NIST has a contractual agreement with MilliporeSigma to manufacture cNISTmAb (expressed from NISTCHO) for transfer to NIST for development into RM 8672, cNISTmAb, a complementary monoclonal antibody RM to RM 8671 NISTmAb. Through its ability to distribute candidate RMs, unencumbered by intellectual property restrictions, with stakeholder communities, NIST is able to use crowdsourcing as an approach for characterization of these materials through pre-competitive, collaborative interlaboratory studies.

These studies generate deep characterization data on each material, including information on stability and homogeneity, and establish fit-for-purpose uses for the RM. For NISTmAb, the initial crowdsourcing approach yielded extensive characterization data on primary structure, PTMs, higher-order structure, and biophysical properties that were described in a series of articles that were compiled into a three-volume American Chemical Society book series (Schiel et al. 2014). NISTmAb, NISTCHO, and cNISTmAb, like all NIST RMs, are designed to be fit for an intended use and determined to be sufficiently homogeneous and stable by assigning non-certified measurement values and uncertainties (Beauchamp et al. 2020). A RM information sheet (NIST 2023) includes these values and is distributed with each unit of the RM, which is sold on a cost recovery basis through the NIST Office of Reference Materials or through certified third-party distributors.

NISTmAb (RM 8671): An IgG1 κ Antibody Standard

In 2016, NIST took its first step in introducing biopharmaceutical standards to the public when it released the first of its kind IgG1 κ monoclonal antibody RM, RM 8671 NISTmAb. NISTmAb was an ideal candidate for development into a RM to fill the need for an industry-wide test material for analytical method control and evaluation of the performance of emerging technologies used to characterize critical quality attributes of mAbs. Among classes of mAb biotherapeutics, the IgG1 κ subclass and allotype is the most prevalent in both clinical use and development. In addition to meeting the requirements for establishing a NIST RM, a biopharmaceutical industry-like approach to characterization and life-cycle management

was used in the development of the RM 8671 NISTmAb material (Turner and Schiel 2018). The initial characterization of the material (Schiel et al. 2014) was performed on a single production lot, NISTmAb Primary Sample 8670, which is now held in reserve as the NIST in-house primary standard. Additional lots of the material were pooled, homogenized, and vialled at 10 mg/mL as RM 8671 NISTmAb (Schiel and Turner 2018). RM 8671 NISTmAb was found to be homogeneous and stable and assigned non-certified values using test methods (e.g., UV, SEC, CE-SDS, CZE, and DLS) qualified by NIST and representative of industry best practices (Schiel et al. 2018; Schiel and Turner 2018; Turner et al. 2018). As with all NIST RMs, a stability verification is performed every five years to evaluate homogeneity and stability by repeating the qualified methods used for initial value assignment to demonstrate that the assigned values still fall within the originally reported limits of uncertainty. The first renewal of RM 8671 NISTmAb was carried out in 2020 (Yandrofski et al. 2023), and the second is currently underway in 2025.

NISTCHO (RM 8675): Clonal CHO-K1 Cell Line Producing cNISTmAb (RM 8672)

Building upon the experience of NISTmAb as an industry-representative standard, two new complementary RMs are currently being developed under the NIST Biomanufacturing Program: (1) NISTCHO, a first-of-its-kind, open-access living RM, a CHO-K1 producer of a non-originator NISTmAb, and (2) cNISTmAb, the non-originator product expressed by NISTCHO. A reference CHO host cell line that could be used as a general reference for product manufacturing was identified by engaging the community through the NSF Industry-University Cooperative Research Center Advanced Mammalian Biomanufacturing Innovation Center as a highly desirable RM for NIST to develop. Furthermore, it was recognized that it would be of value to link the CHO host cell RM to the well-characterized NISTmAb RM. Thus, the NISTCHO RM 8675 was engineered to express the same amino acid sequences as the heavy and light chains of the NISTmAb RM 8671.

To inform the development of RM 8675 NISTCHO, NIST released a research-grade test material (i.e., a candidate RM material) to the public in 2023, which was quickly taken up for use by early adopters who provided feedback to NIST on use cases and its fit-for-purpose. Following industry best practices, NIST contracted the production of a master and working cell banks for the

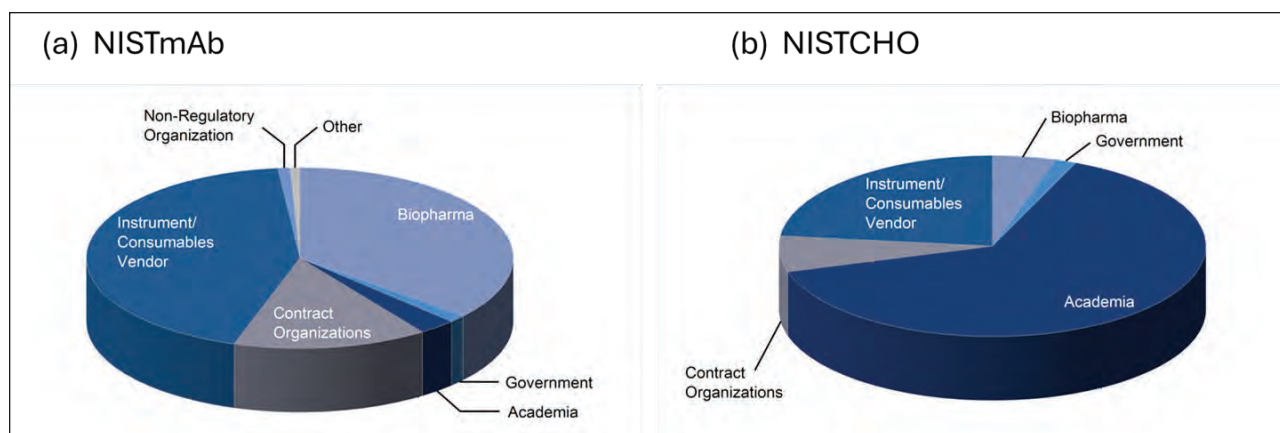


FIGURE 2 Stakeholder uptake of NIST biomaterials reference materials based upon sales and distribution metrics from the NIST Office of Reference Materials: (a) NISTmAb and (b) NISTCHO.

NISTCHO, the latter of which would then be developed by NIST into RM 8675 NISTCHO, to the contract research organization Eurofins Lancaster Laboratories to be produced under good manufacturing practices conditions. The development and initial characterization of the NISTCHO material followed industry practices and norms for clonal selection, genetic stability, and high titer (Dahodwala et al. 2025). The assigned values for NISTCHO will be based on the copy number ratio of the mAb genes (heavy chain, light chain) and integration sites to known CHO genes using digital PCR.

NIST is also developing RM 8672 cNISTmAb based on the IgG1k monoclonal antibody expressed by NISTCHO. This RM is a companion to RM 8671 NISTmAb that will have assigned reference values and be maintained through a life-cycle management system that mimics industry best practices similar to those used for NISTmAb. As the cNISTmAb is produced in CHO cells, it has distinguishing PTMs, such as glycosylation (Luo and Zhang 2024), as compared to the original RM 8671 NISTmAb that was produced in non-secreting murine myeloma cells. Having this RM provides direct coupling of process to product using the predominant industry production host CHO cell, as well as a close comparator molecule with distinguishing PTMs relative to the original NISTmAb RM.

Applications of NISTmAb, NISTCHO, and cNISTmAb

The NISTmAb, NISTCHO, and cNISTmAb RMs are used by stakeholders (figure 2) in a variety of applications, including serving as a system suitability sample, establishing method or instrument performance, bridging analyti-

cal test methods, and assisting in method qualification. NISTmAb, which has been available to the public for almost 10 years, has been used extensively to evaluate the best practices and develop innovative analytical technologies. Based on NIST Office of Reference Materials sales over this time, we find that biopharmaceutical companies and analytical instrument vendors make up more than 50% of the stakeholder uptake for NISTmAb. Roughly a third of the distributed material is used by mid-to-major biopharmaceutical companies as a method performance standard to support implementation of analytical assays for characterization of mAb products and to monitor analytical and manufacturing processes to ensure consistent product quality and safety. Moreover, NISTmAb is used by biopharmaceutical companies as a method performance standard to ensure quality and consistent manufacturing of mAb products, including use as a test material for development of physicochemical characterization and methods, a system suitability standard, and an analytical cross-check material when a test method deviation is observed. Approximately 20% of distributed NISTmAb is used by analytical instrument vendors to benchmark the performance of new analytical technologies and methods that have been described in application notes and patent applications. To date, NIST has been featured or used in over 100 application notes by instrument vendors. Instrument vendors and others have also used NISTmAb in over 130 US patent applications to demonstrate the performance of new analytical methods and technologies.

NISTCHO is currently scheduled to be released as RM 8675 by summer 2025. During its release as a research-

grade test material, NISTCHO was used as a test material to demonstrate process analytical methods, downstream purification methods, and emerging bioprocess workflows, such as continuous manufacturing and process intensification strategies. Additionally, NISTCHO has been widely used by community colleges and other educational institutions for use in the development of workforce training programs that will provide students with the unique opportunity to gain laboratory experience with a CHO production host cell line that is representative of current industry standards (Fredericks et al. 2024; Nadour et al. 2024).

As the biopharmaceutical industry trends towards using other platform-based approaches, such as mRNA and cell and gene therapy products, in developing new therapeutics, there will be opportunities for NIST to follow a similar path to provide reference materials to the community for use in advancing these emerging modalities.

As previously mentioned, NIST biomanufacturing RMs also enable collaborative, precompetitive research studies between academic, industry, government, and regulatory agencies. For example, NISTmAb has found wide use in interlaboratory studies (Yandrofski et al. 2022) of current and emerging analytical technologies, including studies of two-dimensional nuclear magnetic resonance (2D-NMR) (Brinson et al. 2018) and hydrogen-deuterium exchange mass spectroscopy (Hudgens et al. 2019) for higher-order structure analysis, the multi-attribute method for detecting PTMs (Mouchahoir et al. 2021),

and glycosylation analysis using different analytical methods (De Leoz et al. 2020). Interlaboratory studies are designed to provide important insights into the current state-of-the-art performance and variability of analytical methods between different methods, instruments, operators, or sites. Results from these studies serve to promote harmonization and best practices and reveal potential limitations in analytical instrumentation and methods. Lastly, these community exercises support benchmarking and foster collaboration across the stakeholder community to promote adoption of emerging measurement technologies. With the more recent availability of NISTCHO and cNISTmAb, we anticipate that these RMs will be used similarly to NISTmAb and expand the type and scope of interlaboratory studies that can be carried out to address broad infrastructural measurement challenges faced by industry. Importantly, the use of publicly available, non-intellectual-property-constrained materials like NISTmAb, cNISTmAb, and NISTCHO in these studies allows free exchange of materials and data sharing among participants.

Conclusions

Well-characterized, industry-representative materials like the NISTmAb, NISTCHO, and cNISTmAb form a complementary set of RMs that can benefit the entire biomanufacturing research community and help drive progress across the field of manufacturing of biopharmaceutical products by underpinning quality measurements that support an accelerated time to market and broader access to these life-saving drug products. These RMs can serve broad purposes including support for the evaluation and adoption of new analytical technologies, applications in method development and performance evaluation, and roles in fostering community collaboration through inter-laboratory studies and workforce development. In addition to the mAb and CHO RMs, additional RMs have been developed under the NIST Biomanufacturing Program to meet the specific needs of the industry, such as protein glycosylation and glycan analysis (SRM 3655, Glycans) (Lowenthal et al. 2022) and aggregated proteinaceous particle measurements (RM 8634, Ethylene Tetrafluoroethylene for subvisible particles [Ripple et al. 2019]) and SRM 1989 for visible particles (Telikepalli et al. 2025). The success of the NIST Biomanufacturing Program and RM development stems from the convening power of NIST to unite diverse stakeholders with varied perspectives and expertise to establish community consensus. NIST also benefits from its stakeholder community

through candidate material donations and in-kind donations of time and resources to crowdsourcing exercises for material characterization and other interlaboratory collaborative studies. This public-private partnership and the generous participation of scientists and experts from industry, academia, and other government agencies have been invaluable to NIST's mission to develop RMs and advance measurement science for biopharmaceutical products and manufacturing.

Taken together, NISTmAb, NISTCHO, and cNISTmAb provide a roadmap for how platform RMs are developed and widely disseminated through stakeholder engagement and can find broad application in biopharmaceutical development and manufacturing. As the biopharmaceutical industry trends towards using other platform-based approaches, such as mRNA and cell and gene therapy products, in developing new therapeutics, there will be opportunities for NIST to follow a similar path to provide RMs to the community for use in advancing these emerging modalities.

Acknowledgement

The authors would like to acknowledge the significant contributions of former NIST program leader J. Schiel and industry leaders, Mark Schenerman, Britta Anderson, and Frank Swartzwelder to the NIST biomanufacturing standards program.

Disclaimer

The mention of commercial equipment, instruments, materials or companies does not imply recommendation or endorsement by the National Institute of Standards and Technology, nor does it imply that the materials or equipment identified are necessarily the best available for the purpose. All company specific information contained in this presentation is publicly available.

References

- Beauchamp CR, Camara JE, Carney J, Choquett SJ, Cole KD, DeRose PC, Diewer DL, Epstein MS, Kline MC, Lippa KA, and 9 others. 2020. Metrological Tools for the Reference Materials and Reference Instruments of the NIST Material Measurement Laboratory. NIST Special Publication 260-136. <https://doi.org/10.6028/NIST.SP.260-136-2020>
- Brinson RG, Marino JP, Delaglio F, Arbogast LW, Evans RM, Kearsley A, Gingras G, Ghasriani H, Aubin Y, Pierens GK, and 39 others. 2019. Enabling adoption of 2D-NMR for the higher order structure assessment of monoclonal antibody therapeutics. *MAbs* 11(1):94-105.
- Cleveland MH, Karageorgos IL, Marino JP, Tarlov MJ, Yandrowski KS, Zangmeister RA, Kelman Z. 2025. Recommended nomenclature convention for the NISTCHO cell line and its product monoclonal antibody, cNISTmAb. *MAbs* 17(1): 2490789.
- Dahodwala H, Hodzic I, Slesarev A, Cutak B, Kuzin A, Lal R, Liu J, Mahon J, Narasimhan LN, Onuska J, and 10 others. 2025. Development and characterization of the NISTCHO reference cell line. *Biotechnology Journal* 20: e70012. doi: 10.1002/biot.70012.
- De Leoz MLA, Diewer DL, Fung A, Liu L, Yau HK, Potter O, Staples GO, Furuki K, Frenkel R, Hu Y, and 137 others. 2020. NIST interlaboratory study on glycosylation analysis of monoclonal antibodies: Comparison of results from diverse analytical methods. *Molecular Cell Proteomics* 19(1):11-30.
- Fredericks JT, Milligan S, Doshi H, Bryans M. 2024. Comparison of cryopreservation conditions on the performance of NISTCHO Cells. *Journal of Advanced Technological Education (JATE)* 3(2):29-36.
- Hudgens JW, Gallagher ES, Karageorgos I, Anderson KW, Filliben JJ, Huang RY, Chen G, Bou-Assaf GM, Espada A, Chalmers MJ, and 27 others. 2019. Interlaboratory comparison of hydrogen-deuterium exchange mass spectrometry measurements of the Fab fragment of NISTmAb. *Analytical Chemistry* 91(11):7336-45.
- Kelley B. 2009. Industrialization of mAb production technology: The bioprocessing industry at a crossroads. *MAbs* 1(5):443-52.
- Kelley B. 2024. The history and potential future of monoclonal antibody therapeutics development and manufacturing in four eras. *MAbs* 16(1):2373330.
- Kozlowski S. Testimony before the Subcommittee on Technology and Innovation, Committee on Science and Technology, U.S. House of Representatives 2009. Online at: <https://www.govinfo.gov/content/pkg/CHRG-111hhr52285/html/CHRG-111hhr52285.htm>.
- Li F, Vijayasankaran N, Shen AY, Kiss R, Amanullah A. 2010. Cell culture processes for monoclonal antibody production. *MAbs* 2(5):466-79.
- Lowenthal M, Toman B, Lang BE, Phinney KW. 2022. Certification of Standard Reference Material® 3655 Glycans in Solution (Frozen). NIST Special Publication 260-224. doi: 10.6028/NIST.SP.260-224.
- Luo S, Zhang B. 2024. Benchmark glycan profile of therapeutic monoclonal antibodies produced by mammalian cell expression systems. *Pharmaceutical Research* 41:29-37.
- Mouchahoir T, Schiel JE. 2018. Development of an LC-MS/MS peptide mapping protocol for the NISTmAb. *Analytical and Bioanalytical Chemistry* 410:2111-2126.

- Mouchahoir T, Schiel JE, Rogers R, Heckert A, Place BJ, Ammerman A, Li X, Robinson T, Schmidt B, Chumsae CM, and 88 others. 2021. New peak detection performance metrics from the MAM consortium interlaboratory study. *Journal of the American Society for Mass Spectrometry* 32(4):913–28.
- Nadour S, Clement K, Doshi H, Bryans M. 2024. Assessing the stability of NISTCHO Cells in long-term culture. *Journal of Advanced Technological Education (JATE)* 3(2):81–88.
- NIST [National Institute of Standards and Technology]. 2023. Reference material 8671: NISTmAb, Humanized IgG1k Monoclonal Antibody, Oct 25. <https://tsapps.nist.gov/srmext/certificates/8671.pdf>.
- Ripple D, Telikepalli S, Steffens K, Carrier M, Montgomery C, Ritchie N, Lu J. 2019. Reference Material 8634: ethylene tetrafluoroethylene for particle size distribution and morphology. NIST Special Publication 260-193. <https://doi.org/10.6028/NIST.SP.260-193>.
- Schiel JE, Davis DL, Borisov OB, eds. 2014. *State-of-the-Art and Emerging Technologies for Therapeutic Monoclonal Antibody Characterization. Volume 1, Monoclonal Antibody Therapeutics: Structure, Function, and Regulatory Space*. American Chemical Society.
- Schiel JE, Davis DL, Borisov OB, eds. 2015a. *State-of-the-Art and Emerging Technologies for Therapeutic Monoclonal Antibody Characterization. Volume 2, Biopharmaceutical Characterization: The NISTmAb Case Study*. American Chemical Society.
- Schiel JE, Davis, DL, Borisov OB, eds. 2015b. *State-of-the-Art and Emerging Technologies for Therapeutic Monoclonal Antibody Characterization. Volume 3, Defining the Next Generation of Analytical and Biophysical Techniques*. American Chemical Society.
- Schiel JE, Turner A. 2018. The NISTmAb reference material 8671 lifecycle management and quality plan. *Analytical and Bioanalytical Chemistry* 410(8):2067–78.
- Schiel JE, Turner A, Mouchahoir T, Yandrofski K, Telikepalli S, King J, DeRose P, Ripple D, Phinney K. 2018. The NISTmAb Reference Material 8671 value assignment, homogeneity, and stability. *Analytical and Bioanalytical Chemistry* 410(8):2127–39.
- Telikepalli S, Ripple D, Carrier M, Steffens K, Newton D, Montgomery C, Ritchie N, Asmar A, Halter M. 2025. Certification of Standard Reference Material® 1989 Monodisperse Irregularly Shaped Epoxy-based Particles (Nominal 100 nm, 150 nm, 220 nm). NIST Special Publication 260. <https://doi.org/10.6028/NIST.SP.260-255>.
- Turner A, Schiel JE. 2018. Qualification of NISTmAb charge heterogeneity control assays. *Analytical and Bioanalytical Chemistry* 410:2079–93.
- Turner A, Yandrofski K, Telikepalli S, King J, Heckert A, Filliben J, Fipple D, Schiel JE. 2018. Development of orthogonal NISTmAb size heterogeneity control methods. *Analytical and Bioanalytical Chemistry* 410:2095–2110.
- Yandrofski K, Mouchahoir T, De Leoz ML, Duewer D, Hudgens JW, Anderson KW, Arbogast L, Delaglio F, Brinson RG, Marino JP, and 3 others. 2022. Interlaboratory studies using the NISTmAb to advance biopharmaceutical structural analytics. *Frontiers in Molecular Biosciences* 9:876780.
- Yandrofski K, Schiel J, Mouchahoir T, Telikepalli S, Heckert N, Ripple D, DeRose P, Phinney K, Marino J. 2023. Humanized monoclonal antibody IgG1k, NISTmAb RM 8671 summary of 5-year stability verification (5YSV). NIST Special Publication 260-237. <https://doi.org/10.6028/NIST.SP.260-237>.