



Monoclonal antibody Reference Standards

Background

Therapeutic monoclonal antibodies (mAbs) are biologics that have been used for decades to treat various conditions, including rheumatoid arthritis, asthma, as well as various cancers and infectious diseases. During the COVID-19 pandemic, monoclonal antibody treatments were utilized to treat people infected with severe COVID-19 infection. New mAb products hold great promise to treat those infected with future pandemic pathogens and potentially as prophylaxis to protect consumers from infection. In 2021, the market size for mAbs in the U.S. was \$111 billion and is expected to grow to \$243 billion by 2028.

mAbs are proteins produced in a laboratory that function like the antibodies made by the body's immune system in response to infection. mAb therapeutics are made using cell-based manufacturing processes. The complexity of the manufacturing process and the structure of mAb molecules make characterization for consistent quality and stability challenging for manufacturers.

Opportunity to strengthen quality

As applications for mAb treatments continue to grow, manufacturers need ways to verify the quality of mAb therapeutics. Because many manufacturers are familiar with USP standards for medicine quality, they view USP as a trusted resource for solutions to their mAb characterization challenges. USP's mAb standards help ensure consistency and reproducibility of analytical methods.

USP solutions

USP mAb Reference Standards can serve as a positive control or system suitability standard for analytical quality testing procedures. They can be used as an independent control material for method development, training, method transfer, and as an internal assay control.

- Four mAb Reference Standards
 - Monoclonal IgG System Suitability
 - Monoclonal IgG1, mAb001
 - Monoclonal IgG1, mAb002
 - Monoclonal IgG1, mAb003
- General Chapter <129> *Analytical Procedures of Recombinant Therapeutic Monoclonal Antibodies*

- [USP–NF General Chapter 129 Analytical Procedures for Recombinant Therapeutic Monoclonal Antibodies webinar](#)
- [What’s New in Biologics? Focus on USP’s Monoclonal Antibody Reference Standards webinar](#)
- [Characterization of Biotherapeutics webinar](#)

Why it’s important

mAbs are a growing class of therapeutics that offer new treatment options to patients. mAbs can contain variations and impurities that manufacturers must measure and control to ensure the therapeutic benefit to patients. USP standards provide a way to reliably measure quality attributes and characterize components of mAb therapeutics, enabling manufacturers to verify their quality.

Web resources

- <https://www.usp.org/biologics/reference-standards/igg>
- <https://www.usp.org/news/mab-rs-release>
- <https://store.usp.org/home>
- [What are Monoclonal Antibodies? Video with John Kokai-Kun, Ph.D.](#)
- [mAb technical note](#)