

USP Monoclonal Antibody (mAb) Standards



USP offers a growing portfolio of well characterized monoclonal antibody (mAb) reference standards and associated characterization data

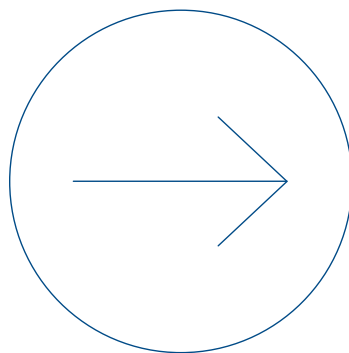
- Provide a means to reliably measure quality attributes and characterize components of biologics
- Facilitate the advancement of leading-edge analytical technologies that define quality for the industry
- Reduce the variability that is inherently challenging in biological products

USP mAbs are supported by USP quality and lifecycle management including ongoing suitability for use studies for the lifetime of the reference standards.

USP mAb Standards*

Cat # 1445550	Monoclonal IgG Suitability
Cat # 1445539	Monoclonal IgG1, mAb 001 RS*
Cat # 1445547	Monoclonal IgG1, mAb 002 RS*
Cat # 1445595	Monoclonal IgG1, mAb 003 RS*

*New Applications for USP mAb Reference Standards: Resolving Charge Variants



Characterization Data

New in Feb 2022:

Resolving Charge Variants

- Capillary isoelectric focusing (cIEF) using Sciex PA800Plus
- Imaged capillary isoelectric focusing (icIEF) using ProteinSimple Maurice and iCE3
- Size exclusion chromatography (SEC)
- Capillary electrophoresis sodium dodecyl sulfate (CE-SDS) reduced
- Capillary electrophoresis sodium dodecyl sulfate (CE-SDS) non-reduced
- Intact mass analysis
- N-Glycan analysis using CE-LIF and HILIC-FLR-MS

Example Applications

- Internal assay control
- Independent control material for method development
- Standardization of physico-chemical testing
- Training activities
- Method transfer activities
- Optimization of platform methods (eg. glycan analysis)

To order

Visit <https://www.usp.org/biologics/reference-standards>

For more information

Visit us online at <https://www.usp.org/biologics/reference-standards/igg> to learn more

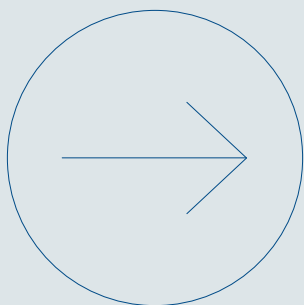
[usp.org/biologics](https://www.usp.org/biologics)

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Supporting Resources

USP Education Courses	<ul style="list-style-type: none">• USP's Work Supporting Multi-Attribute Methods for Biologics• What's New in Biologics? Focus on USP's Monoclonal Antibody Reference Standards• Analysis of Charge Variants in Biologics• Assays to Evaluate Fragment Crystallizable (Fc)-Mediated Effector Function• Full course list available: https://www.usp.org/biologics/education
USP Infographic	Ensuring quality in monoclonal antibody development with USP standards
USP Tech Note	New USP monoclonal antibody standards
USP Certificates	Enhanced USP Certificates can be found on the USP store for applicable USP mAb standards



About USP

USP is an independent scientific organization that collaborates with the world's top experts in health and science to develop quality resources and standards for medicines, dietary supplements, and food ingredients. Through our resources, standards, advocacy and education, USP helps increase the availability of quality medicines, supplements and foods for billions of people worldwide.