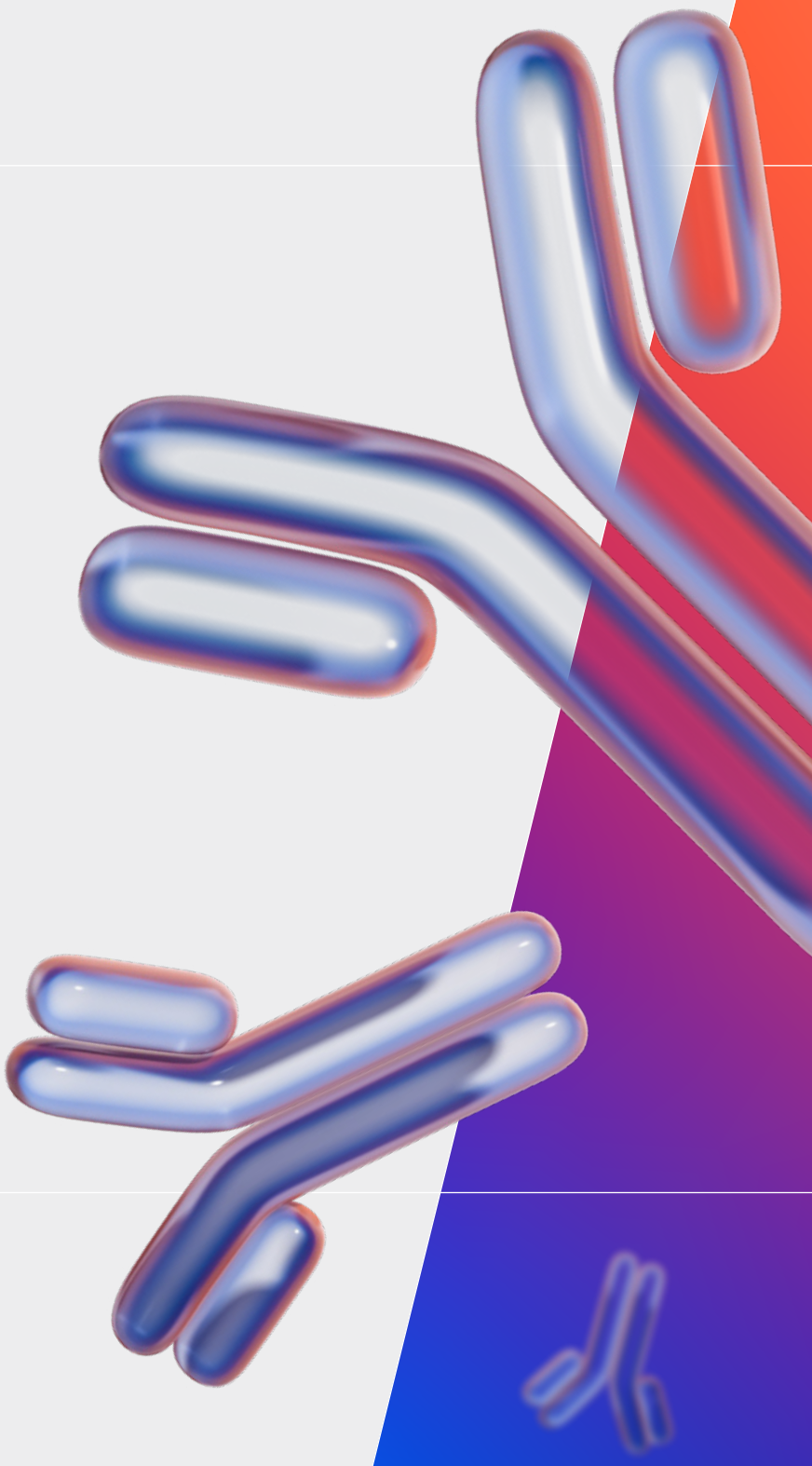
R&D systems
by bio-techne

USP mAb Reference Standards



R&D Systems now offers five monoclonal antibody U.S. Pharmacopeia (USP) Reference Standards to overcome the limited availability of consistent, highly characterized mAb standards and to provide a range of reference products with different physicochemical properties.

These USP mAb Reference Standards (RSs) aid in mAb development and manufacturing and:

- Provide a means to evaluate and monitor the performance of assays which measure physicochemical critical quality attributes (CQAs) of monoclonal antibody therapeutics
- Facilitate adoption of leading-edge analytical technologies by providing well-characterized standards
- Assist in reducing assay variability by providing materials for assay controls
- Are supported by USP quality and lifecycle management, including ongoing suitability for use studies for the lifetime of the RSs

TABLE 1

General information for the four non-compendial USP mAb Reference Standards

	USP mAb 001, monoclonal IgG1	USP mAb 002, monoclonal IgG1	USP mAb 003, monoclonal IgG1	USP mAb 004, monoclonal IgG4
USP Catalog #	1445539	1445547	1445595	1457499
CAS #	174722-31-7	216974-75-3	912628-39-8	189261-10-7
MW	~147,000 Da	~150,000 Da	~146,000 Da	~149,000 Da
Theoretical pI*	8.7	8.1	8.1	7.8
Experimental pI (cIEF)**	9.2	7.8	7.7	7.5
Experimental pI (icIEF)**	9.2	7.9	7.8	7.7
Package size	200 µL solution (2 mg protein content)	200 µL solution (2 mg protein content)	200 µL solution (2 mg protein content)	200 µL (4.5 mg protein content)

Table 1. * Calculated using ProtParam (ExPASy) without glycosylation **Per USP In-house methods, see charge variant application note for more details.

The USP monoclonal IgG1 (USP mAb 001, USP mAb 002, USP mAb 003) Reference Standards are recombinant humanized IgG1s expressed in Chinese hamster ovary (CHO) cell culture and manufactured using industry standard upstream production and downstream purification. The Reference Standards have been rigorously tested and the results were evaluated during multi-laboratory studies using the methods described in USP General Chapter **<129> Analytical Procedures for Recombinant Therapeutic Monoclonal Antibodies**.

FIGURE 1

Charge profile of USP mAb Reference Standards determined by icIEF on the Maurice system

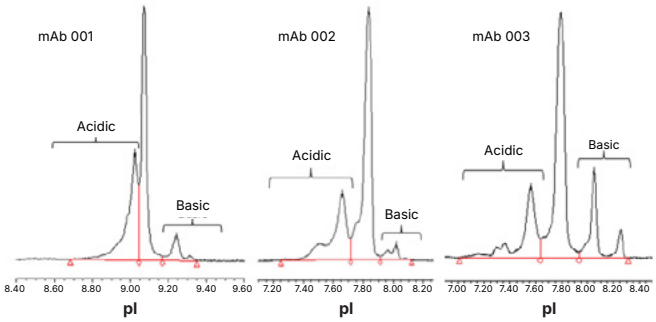


Figure 1. Electropherograms of USP mAb Reference Standards are representative of two instrument models, multiple preparations, and multiple injections from three independent laboratories.

The new USP mAb 004 (monoclonal IgG4) standard expands this portfolio by providing an additional well-characterized monoclonal antibody reference material for analytical method development, qualification, and routine performance monitoring. Characterized using orthogonal analytical techniques, USP mAb 004 exhibits distinct charge variant and molecular size profiles that support the evaluation of critical quality attributes (CQAs) throughout the biotherapeutic development and manufacturing lifecycle. Representative icIEF and CE-SDS electropherograms generated on the Maurice™ platform are shown below.

FIGURE 2

Charge profile of USP mAb 004 Reference Standard on the Maurice system

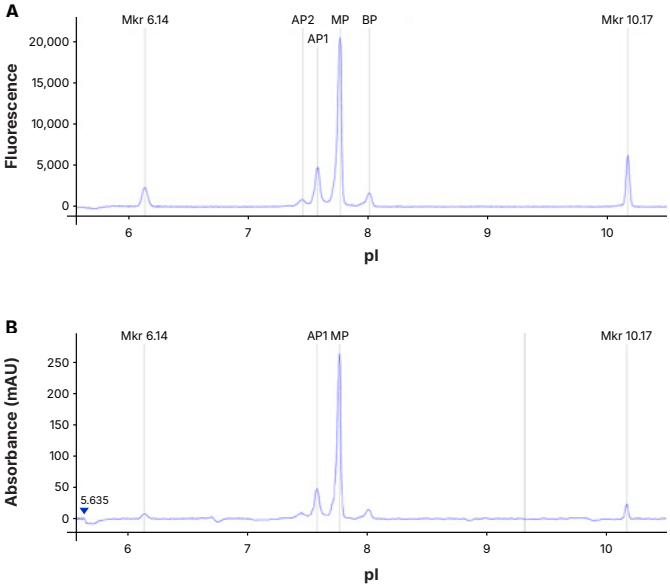


Figure 2. Native fluorescence (NF) electropherogram **(A)** and Focused Absorbance (Abs) charge profile **(B)** of USP mAb 004 acquired by icIEF on the Maurice system.

FIGURE 3

Size and purity analysis of USP mAb4 Reference Standard on the Maurice System

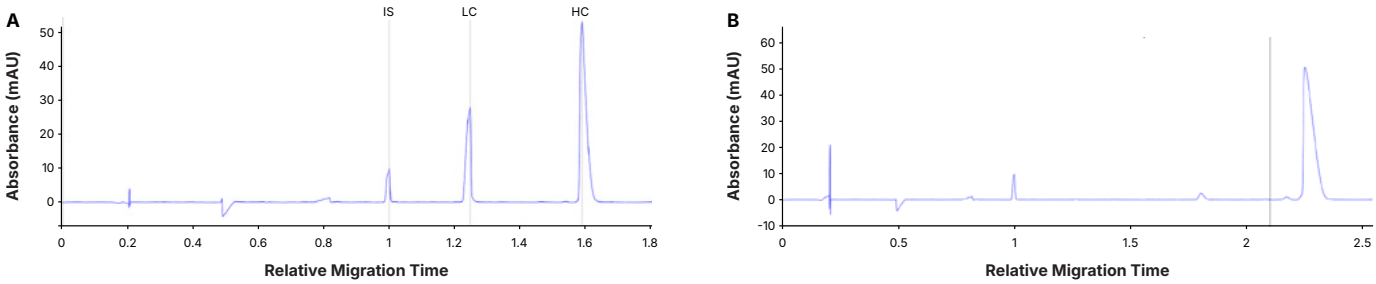


Figure 3. Non-reduced **(A)** and Reduced **(B)** electropherogram of USP mAb 004 using CE-SDS on the Maurice system.

IgG System Suitability Reference Standard

The USP IgG System Suitability Reference Standard enables analysts to efficiently evaluate system suitability criteria for aggregation and purity, which are critical quality attributes of mAbs, using methods outlined in USP General Chapter <129>. This standard is applicable during process development and routine method execution, ensuring consistent assay performance across different runs and days.

This USP Reference Standard is used to prepare a system suitability solution for the mobile phase as per USP Chapter <129> for the measurement of product-related impurities such as non-glycosylated molecules, half antibodies, and fragments by capillary sodium dodecyl sulfate (CE-SDS) electrophoresis.

FIGURE 4

Conducting the USP <129> protocol on Maurice using the IgG System Suitability Reference Standard

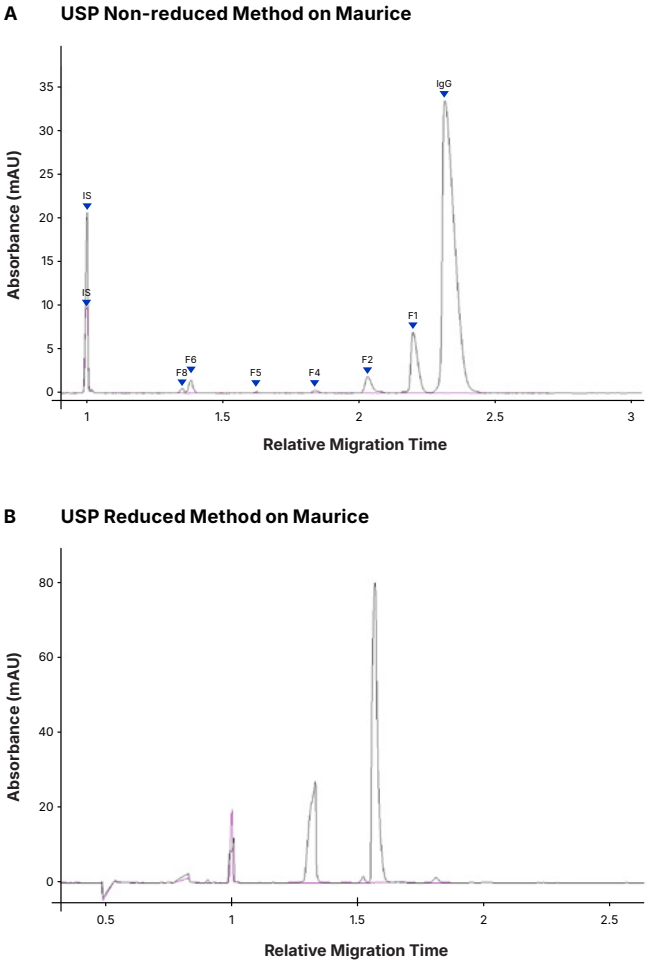


Figure 4. Results from the USP-recommended method on the Maurice system using **(A)** non-reduced CE-SDS method and **(B)** reduced CE-SDS method using the USP IgG System Suitability Reference Standard.

Characterization Data

- Capillary isoelectric focusing (cIEF)
- Imaged capillary isoelectric focusing (icIEF)
- Capillary electrophoresis sodium dodecyl sulfate (CE-SDS) (reduced and non-reduced)
- Intact (Protein) Mass by Spectrometry
- SE-HPLC (Size exclusion – High-performance liquid chromatography)
- N-Glycan analysis using Capillary electrophoresis – Laser Induced Fluorescence detection (CE-LIF) and Hydrophilic interaction chromatography – Fluorescence –Mass spectrometry (HILIC-FLR-MS)

Applications

- Internal assay control
- Independent control material for method development
- Standardization of physiochemical testing
- Training activities
- Method transfer activities
- Optimization of platform methods (e.g., glycan analysis)
- Higher order structure

TABLE 2

Ordering Information

Part No.	Description	Package Size
1445539	USP mAb 001, monoclonal IgG1	200 µl solution (2 mg protein content)
1445547	USP mAb 002, monoclonal IgG1	200 µl solution (2 mg protein content)
1445595	USP mAb 003, monoclonal IgG1	200 µl solution (2 mg protein content)
1457499	USP mAb 004, monoclonal IgG4	200 µl (4.5 mg protein content)
1445550	USP IgG System Suitability Standard	2 mg (lyophilized)

Learn more

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