# **PROTEOSTAT® Protein aggregation** standards

## The only commercially available protein aggregation standards assay!

The PROTEOSTAT® Protein Aggregation standards are ideal for reliable and accurate quantification of protein aggregation in solution. The standards are used to determine low levels of aggregated protein in a sample by comparing the assay response of a test sample to that of the standard curve; comprised of standards with known concentrations of aggregated IgG. Protein test samples and protein aggregation standards should be analyzed in the same manner, by mixing them with detection reagent and using a fluorescence microplate reader to measure the fluorescence intensity values. As with any protein assay, different protein aggregates will elicit slightly greater or lesser fluorescence intensity response based upon their inherent amino acid composition and sequence. It is recommended that a standard curve be prepared each time the PROTEOSTAT® Protein Aggregation assay (Prod. No. ENZ-51023) is performed.

The PROTEOSTAT® Protein Aggregation standards contain stabilized, high-quality reference samples for generating an accurate standard curve. The standard curve is formulated from different amounts of aggregated IgG, combined with monomeric IgG. Once reconstituted, the samples contain 12.5%, 6.25%, 3.13%, 1.56%, 0.78%, 0.39%, 0.20% and 0% aggregated protein, while the total protein concentration of each standard is maintained at 1mg/ml. The total protein concentration of the IgG standard has been calibrated by direct comparison to an internal protein standard, in order to ensure lot-to-lot consistency and accuracy. Orthogonal characterization methods, including laser-based nanoparticle tracking and micro-flow imaging, have been employed to validate monomer integrity during manufacturing.

Citations: 2

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**Ordering Information** 

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ENZ-51039-KP002

2x96 wells

· Stabilized, high-quality reference IgG in known concentrations

• Developed for use with the PROTEOSTAT® Protein Aggregation Assay

• Easy to use - Simply add water!

Manuals, SDS & CofA

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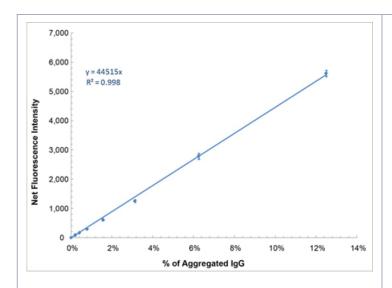


Figure 1: Typical standard curve produced using the PROTEOSTAT® Protein Aggregation standards.

### **Handling & Storage**

**Handling** Do not vortex or centrifuge at high speed. Avoid freeze-thaw cycles, as this can promote

further aggregation of the standards.

Short Term Storage -20°C

Long Term Storage -80°C

Shipping Blue Ice

#### Regulatory Status RUO - Research Use Only

#### **Product Details**

**Application** Fluorescent detection, Microplate

**Application Notes** This kit is ideal for reliable and accurate quantification of protein aggregation in solution.

The standards are used to determine low levels of aggregated protein in a sample by comparing the assay response of a test sample to that of the standard curve; comprised

of standards with known concentrations of aggregated IgG.

Contents A. PROTEOSTAT® Control (0.0% aggregate)

**B. PROTEOSTAT® Control** (0.20% aggregate)

C. PROTEOSTAT® Control (0.39% aggregate)

D. PROTEOSTAT® Control (0.78% aggregate)

E. PROTEOSTAT® Control (1.56% aggregate)

F. PROTEOSTAT® Control (3.13% aggregate)

**G. PROTEOSTAT<sup>®</sup> Control** (6.25% aggregate)

H. PROTEOSTAT® Control (12.5% aggregate)

Deionized Water, 5 ml

**Quality Control**A sample from each lot of PROTEOSTAT® Protein Aggregation Standards is used with

the procedures described in the user manual. Perform assay with 12.5% – 0%  $\,$ 

Aggregate in duplicate. Linear curve R-Square has to be greater than 0.95.

#### Technical Info / Product **Notes**

#### **Application Notes:**

Particle analysis of therapeutic protein formulations with ImageStreamX<sup>®</sup> Imaging Flow Cytometry and the PROTEOSTAT® Protein Aggregation Assay

Prediction of Aggregation Propensity and Monitoring of Aggregation of Antibody-Drug Conjugates (ADC) using ProteoStat<sup>®</sup> Reagents

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