
Enzo
Life Sciences
OPTIMIZE BIOPROCESS.
MAXIMIZE PROFITABILITY.
Innovative assays for biotherapeutics development

Enabling Solutions for Bioprocessing Optimization

Development of a single drug, whether it is a new chemical entity or a biological therapeutic, requires significant investment of resources. Each step of the process from early discovery through production and delivery must be fully explored, characterized, and understood. Enzo Life Sciences offers a unique set of assays that provide solutions for biotherapeutic characterization, aggregate detection, and contaminant detection for optimizing process development, formulation, in-house QC testing, lot-to-lot reproducibility, and more. Our aim is to deliver tools that make drug development more efficient, more cost-effective, and more successful.

NEW!

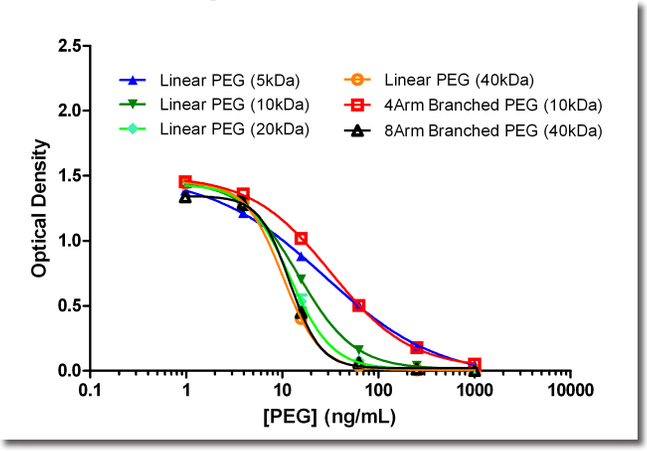
PEGylated Protein ELISA Kit for Quantitative Detection of a Diverse Set of PEGylated Molecules

The sensitive PEGylated Protein ELISA kit allows for quantitative detection of a diverse set of PEGylated molecules in plasma, serum, tissue and other biological samples using a competitive ELISA format. The assay is applicable for drug development and pharmaceutical manufacturing applications including drug formulations, pharmacokinetics analysis, drug comparison, lead candidate identification, lot release criteria and in-process QC studies.

- Validated for a wide range of MW linear and branched PEGs, both in free form and when conjugated to proteins
- Sensitive assay measures < 1ng/ml of PEGylated molecules
- Quantify PEGylated target molecules in complex matrices to monitor drug levels or its accumulation in tissue
- High throughput format allows analysis of up to 35 samples in duplicate in just 2 hours

PRODUCT	PRODUCT #	SIZE
PEGylated Protein ELISA Kit	ADI-900-213	1 x 96 wells

Sensitive Detection of Low and High Molecular Weight PEG molecules



The PEGylated Protein ELISA kit detects several PEG molecules of different molecular weight: linear PEG between 1 and 40kDa, and branched PEG including 4 arm 10kDa, and 8 arm 40kDa. The larger the molecular weight PEG molecule, the higher the kit sensitivity.

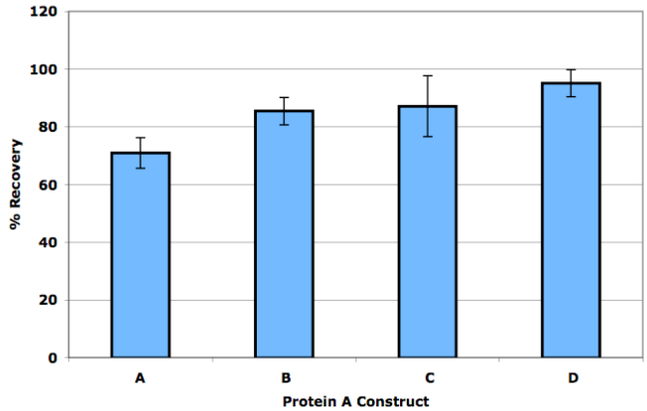
Protein A ELISA Kit for Residual Contaminant Detection

The Protein A ELISA kit is a sensitive and reproducible sandwich assay to quantify Protein A residuals in monoclonal antibody preparations. The *Staphylococcus aureus* 42kDa cell wall constituent Protein A is commonly used to purify IgG from large-scale antibody preparations. The extensively validated ELISA kit enables efficient detection of natural and recombinant Protein A constructs with up to 100% recovery.

- Superior sensitivity detecting 1ppm of Protein A residuals in human IgG
- Flexible detection with 4 different Protein A constructs
- Contamination analysis and measurement of Protein A variants in monoclonal antibody preparations
- Time and value savings with results in < 3 hours and low cost per test

PRODUCT	PRODUCT #	SIZE
Protein A ELISA Kit	ADI-900-057	1 x 96 wells

Detect Natural and Recombinant Protein A Variants



Assay recognition of different Protein A constructs, post-boiling. Resulting concentrations were interpolated from kit standard curve. Percent recovery calculated by dividing observed concentration by expected concentration (A & B: n=9, C & D: n=12) for several Protein A constructs (A: Natural Protein A from *S. Aureus*; B: Recombinant Protein A from *E. coli*; C: Recombinant Cys-Protein A from *E. coli*; and D: Recombinant alkaline-resistant Protein A variant from *E. coli*).

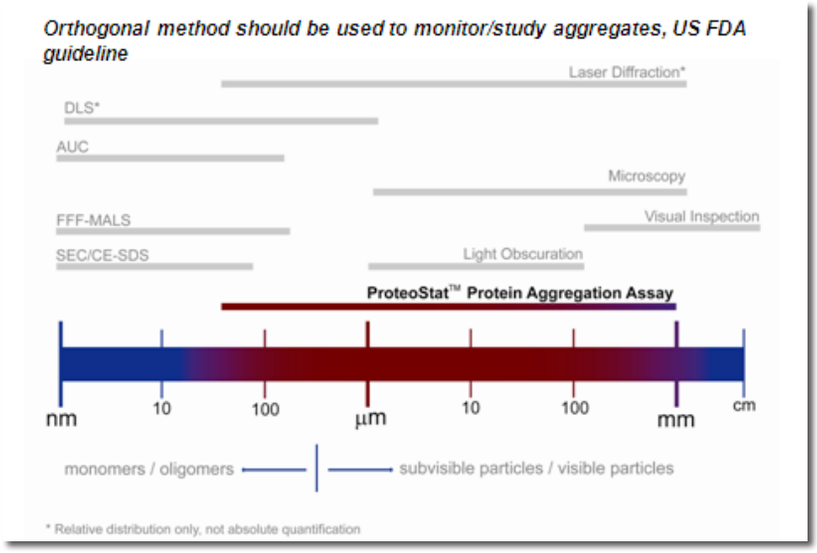
ProteoStat® Protein Aggregation Assay for Quantitative Detection of Protein Aggregates

The ProteoStat® Protein Aggregation Assay is a simple, sensitive, homogenous fluorescent microplate assay. The novel molecular rotor dye used detects a broad range of different protein aggregates from visible to subvisible particles

- Works over a wide pH and ionic strength range and is compatible with commonly used buffers and excipients
- Provides a convenient, complementary orthogonal method for cross-validation of instrumentation-intensive techniques
- Useful assay to troubleshoot protein damage, from protein development through manufacturing stages

PRODUCT	PRODUCT #	SIZE
ProteoStat® Protein Aggregation Assay	ENZ-51023	For 2 x 96 wells
ProteoStat® Protein Aggregation Standards	ENZ-51039	For 2 x 96 wells

Use to Detect Protein Aggregates from Visible to Subvisible Particles



ProteoStat® Protein Refolding & Aggregation Sensing Kit for Identification of Optimal Refolding Conditions

The ProteoStat® Protein Refolding & Aggregation Sensing Kit is a simple, sensitive, homogeneous assay for screening protein refolding parameters. The assay is enabled by a novel molecular rotor dye.

- Identify optimal protein refolding conditions and maximize recovery of functional protein
- Comprehensive set of optimized screening reagents and conditions that facilitate protein refolding
- Rapid microplate screening using Design of Experiments (DOE)-valued approach to identify parameters that are critical to protein formulation

PRODUCT	PRODUCT #	SIZE
ProteoStat® Protein Refolding & Aggregation Sensing Kit	ENZ-51040	For 2 x 96 wells

Streamlined Microplate-based Workflow for Optimizing Protein Formulation

1° Fluorescent Screen for Aggregation

Parameters Assessed:
pH
Guanidine-HCl
L-arginine
Redox (DTT,GSH/GSSG)

↓ Confirm Activity

2° Fluorescent Screen for Aggregation

Excipients Assessed:
PEG, EDTA, $CaCl_2$
$MgCl_2$, NaCl, Tween
Sucrose, α-cyclodextrin

↓ Confirm Activity

Dialysis into Optimal Buffer Formulation

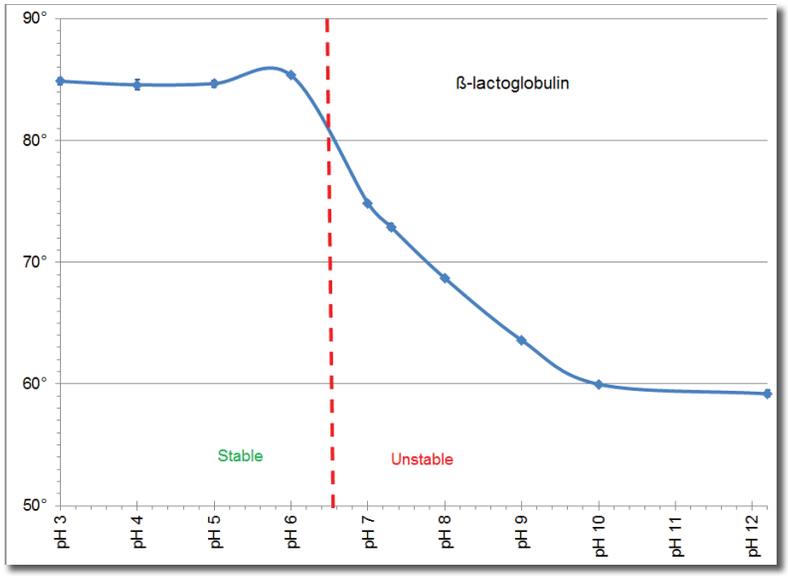
ProteoStat® Thermal Shift Stability Assay for Protein-based Pharmaceuticals

ProteoStat® Thermal Shift Stability Assay is a rapid, simple screening method based on a dye that detects protein aggregates. The assay does not require any prior knowledge of protein structure, sequence or ligand binding avidity. The Thermal Shift dye is based on a molecular rotor that has very low fluorescence in the absence of aggregated proteins, but fluoresces brightly when bound to protein aggregates. The assay is performed on a thermally regulated fluorimeter or RT PCR instrument.

- Perform accelerated screening for protein stability as a function of pH, ionic strength, and concentration
- Screen for ligand binding using a broad range of physiologically relevant compounds
- Screen protein variants to determine their relative stabilities or excipients to determine optimal protein storage conditions
- ProteoStat® dye is tolerant of detergents and hydrophobic compounds

Product	Product #	Size
ProteoStat® Thermal Shift Stability Assay Kit	ENZ-51027	400 assays

Monitor Protein Stability Via Shifts in Aggregation Temperature



Stability of a protein in different buffers: ß-Lactoglobulin was diluted into 50mM buffer at different pH in the presence of 150mM NaCl, and the aggregation temperature was determined using ProteoStat® dye.

Custom Services

A single, static catalog cannot hold all the necessary tools to meet the needs of an ever changing industry. Whether you require complex assay development or a novel reagent, contact us to help.

- Industry-proven high throughput plate coating capabilities ensure reproducible results for your host cell protein (HCP) screening process.
- Need to quantify an identified contaminant, or detect a specific PEGylated protein? Our immunoassay experts can keep your process moving with sensitive, specific custom assays built to your specifications on a variety of platforms.

Enzo® Life Sciences
scientists ***enabling*** scientists.

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