

Protein A ELISA Kit for Detection of MabSelect SuRe™ Ligand

Certificate of Analysis

Manufacturing Information

Lot Number: EZXXXXXX
Part Number: 9333-1
Date Manufactured: Month dd, yyyy
Expiration Date: Month dd, yyyy

The above Lot was manufactured according to Repligen's standard protocols for the production, testing and release of Protein A ELISA Kit for Detection of MabSelect SuRe™ Ligand. The Quality Assurance batch records for this Lot are available for review at Repligen's facility in Waltham, Massachusetts.

Kit Performance & Certification Information

Quality Control testing is performed according to the procedure described in the Protein A ELISA Kit for Detection of MabSelect SuRe™ Ligand User Guide. ELISA plates were read on a microplate reader with the wavelength set at 450 nm.

Repligen certifies that the above lot of Protein A ELISA Kit for Detection of MabSelect SuRe™ Ligand has been tested in a QC Laboratory and meets the following specifications:

Performance Criteria	Specification
Correlation coefficient of linear regression standard curve fit ⁽¹⁾	0.985 or greater
Correlation coefficient of four parameter logistical standard curve fit	0.990 or greater
OD ₄₅₀ value for 1.6 ng/mL standards	0.900 OD or greater at 450 nm
Signal-to-noise ratio ⁽²⁾ ($\frac{1.6 \text{ ng/mL Std OD}_{450}}{\text{Zero Std OD}_{450}}$)	6.0 or greater
CV of 0 ng/mL standards ⁽³⁾	Less than 18%
CV of other standard curve points ⁽³⁾	Less than 12%

OD = Optical Density

CV = Coefficient of Variation

EXAMPLE

QA Signature

EXAMPLE

Date

1. This Protein A ELISA Kit for Detection of MabSelect SuRe™ Ligand was designed and tested to meet the highest level of performance represented by a linear standard curve. Other curve fitting algorithms, such as the four parameter logistical fit or an exponential curve fit, may be used to mathematically represent the standard curve. Each laboratory should use an appropriate method that has been validated for their application.
2. Many factors can affect performance of the ELISA assay and produce nonlinear standard curves and low signal to noise ratios. Please refer to Repligen's ELISA troubleshooting guide that can be found on Repligen's Web site at www.repligen.com.
3. The determination and elimination of outlier data points should be made using an appropriate statistical method.

MabSelect SuRe™ is a trademark of GE Healthcare Companies

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