Protein A ELISA Kit

Certificate of Analysis

Manufacturing Information

Lot Number: EAXXXXXX
Part Number: 9000-1

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 Kits. 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 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 Kits has been tested in our QC Laboratory and meets the following specifications:

Performance Criteria	Specification
Correlation coefficient of linear standard curve fit	0.985 or greater
Correlation coefficient of four parameter logistical standard curve fit	0.990 or greater
OD value for 1.6 ng/mL Standards	0.900 OD or greater at 450 nm
OD value for 0 ng/mL Standards	0.150 OD or lower at 450 nm
CV of 0 ng/mL Standards	Less than 18% with no more than four masked outliers
CV of other Standard Curve points	Less than 12% with no more than four total outliers for the Standard Curves
Hot Wells	No more than four total
OD = Ontical Density	CV = Coefficient of Variation

OD = Optical Density CV = Coefficient of Variation

EXAMPLE	EXAMPLE
Quality Assurance	Date

Document Number: QA-FM-9002-05

