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Product Specification Data Sheet

Omalizumab (Xolair®) – PK ELISA Cat# SB-07-032

For the quantitative determination of omalizumab in human serum and plasma.

Detection Method	Colourmetric; absorbance at 450 nm with a reference at 650nm.
Storage	Kit ships at 2 to 8°C. Multiple storage temperatures upon arrival.
Calibrator	Xolair®
Sensitivity	Detection limit of 39 ng/mL.
Precision	Intra-assay precision ranges from 4 to 11%. Inter-assay mean precision is 13%. Determined by analysis of samples at 500 ng/mL in 6 replicates, on 6 different occasions.
Accuracy	Determined by analyzing three levels of quality control samples in 6 replicates on 6 different occasions. The Mean %bias is $\leq$ 20%.
Total Error	Calculated by adding the mean %bias with inter-assay variability (%CV). The Total Error is $\leq$ 24%
Hook Effect	No hook effect was observed up to 40,000 ng/mL of omalizumab.
Dilutional Linearity	Dilutional linearity was established up to 800 fold. Samples can be diluted up to 800-fold without any significant impact on the recovery of the samples.
Interpretation of Results	A calibration curve is constructed by plotting the absorbance values on a 4-point parameter fit curve. Concentration of omalizumab in test samples is interpolated from the calibration curve.
Safety Warnings and Precautions	All reagents and samples should be handled as if potentially hazardous and infectious. It is recommended that all kit reagents are handled by trained laboratory staff and are used in accordance with GLP.