

## Omalizumab (Xolair®) – ADA ELISA

Cat# SB-06-032

For the qualitative determination of antibodies to omalizumab in human serum and plasma.

<b>Description</b>	Sandwich enzyme immunoassay
<b>Detection Method</b>	Colourmetric
<b>Storage</b>	Kit ships at 2 to 8°C. Multiple storage temperatures upon arrival.
<b>Positive Control</b>	Rabbit/Human anti-Omalizumab <b>We designed this assay to use a human antibody (form biorad), but recently we ran our rabbit antibody in the assay and it looked good (see XOL-ADA 050). Do you want to make the switch to rabbit, or keep the human?</b>
<b>Sensitivity</b>	250 ng/mL
<b>Drug Tolerance</b>	<b>TBD</b>
<b>Sample Pre-Treatment</b>	Drug tolerance can be improved with acid dissociation. For further details please contact tec@somrubioscience.com
<b>Precision</b>	Intra-assay precision ranges from <b>3 to 7%</b> . <b>Inter-assay mean precision is 12%</b> . Determined by analysis of samples at 250 ng/mL in 6 replicates, on 6 different occasions.
<b>Interpretation of Results</b>	Results are reported as positive or negative relative to a pre-determined cutpoint. To determine the cutpoint, run 4-10 negative controls and calculate their mean, then add 2* standard deviations to the calculated mean.
<b>Statistical CutPoint</b>	We strongly recommend each lab develop their own statistical cutpoint in the appropriate study population using methodologies as described by G. Shankar, et al. (2008). (Recommendations for the Validation of Immunoassays Used for Detection of Host Antibodies Against Biotechnology Products. J. Pharmaceutical and Biomedical Analysis 48:1267–1281). For further details please contact tec@somrubioscience.com.
<b>Safety Warnings and Precautions</b>	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.