

Adalimumab (Humira®) – ADA ELISA

Cat# SB-06-024

For the qualitative determination of antibodies to adalimumab 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.
Positive Control	Chicken anti-adalimumab.
Sensitivity	Detection limit of 84 ng/mL.
Drug Tolerance	Tolerance up to 7.3 µg/mL.
Sample Pre-Treatment	Drug tolerance can be improved with acid dissociation. For further details please contact tec@somrubioscience.com .
Precision	Intra-assay precision ranges from 3 to 7%. Inter-assay mean precision is 12%. Determined by analysis of samples at 500 ng/mL in 6 replicates, on 6 different occasions.
Rheumatoid Factor (RF) Interference	If high levels of RF are expected, a sample pre-treatment step may be incorporated into the assay. For further details please contact tec@somrubioscience.com .
Interpretation of Results	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.
Statistical CutPoint	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 .
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.