

Human-diagnostic ELISAs

The ELISA tests listed below consist of **29 kits for In Vitro diagnosis of autoimmune diseases** and **2 kits for the diagnosis of a Helicobacter pylori infection**.

These ELISA kits are **CE marked** and come in the standard format of 96 analyses. They all use **identical general reagents**, namely sample buffer, wash buffer, substrate and stop solution. Hence, one and the same sample dilution may be used for multiple assays; e.g. for simultaneous determination of Cardiolipin IgG and IgM.

All solutions are **ready to use** (exception: 10-fold wash buffer concentrate) and **color-coded**. The conjugate color (red, yellow or green) indicates the Ig-class detected, IgG, IgA or IgM, respectively. The color intensity of the blue calibrators reflects their corresponding concentration. The negative control is green, the positive red.

The solid phase features **break apart microwells** for economic use of the kit. It is packed in a foil bag with zip closure, useful for partial consumption of the solid phase. The frame of the microwell plate displays the parameter name.

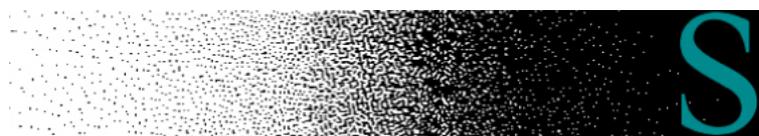
The sample is **serum or plasma**; **10 µL** are required throughout. It is **diluted 1:100** in the orange coloured sample buffer. **100 µL per microwell** is the fixed volume of sample, conjugate, substrate and stop solution.

The tests share one **common protocol: 3 x 30 minutes** incubation at room temperature and without shaking. Wash steps: unvariably 4 x 350 µL per microwell.

The tests have been **validated on the Dynex DS2** system and are accessible to other automated devices. The liquids come in polyethylene bottles with enough volume for automation. The detection system is **HRP/TMB, read at 450nm**.

The compact outer box is labelled on two adjacent sides for easy test kit identification in fridge stacks. Each product comes with **printed Directions for Use (also downloadable)**, including a Summary Flow Chart on the back, and a kit lot-specific Certificate of Analysis. Most of the tests offer the option of qualitative or quantitative evaluation.

The **excellent quality** of these products is reflected **by a very low number of complaints** over the years. Since more than a decade, we regularly participate in several international ring trials (UK: Neqas, US: CAP, Germany: Instand and Referenzinstitut für Bioanalytik) with **virtually no deviation of our results** from the respective intended response.



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