

Application Sheet

Toxo IgG

REF 51209

Instrument: HumaReader HS

REF 16670

Setting:

TOXOG_QT_51209_R5

TOXOG_CO_51209_R5

For all essential product information, please refer to the User Manual of the analyzer and the instructions for use for reagents, controls and calibrators. Please refer to the instruction for use for performance data.

This Application Sheet provides additional information regarding the use of the assay on the HUMAN ELISA analyzer.

The parameters defined in this application sheet have been developed to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may negatively affect the performance and results of the assay. The user is responsible for the validation of any modification to the protocol here described.

Additional Notes

Due to a change of the Toxo IgG ELISA kit (REF 51209), the setting version R4 or lower should only be used up to LOT 20001. Please use setting version R5 or higher when using LOT 20002 or higher.

The results should be interpreted with regard to a cut-off value. Therefore use the cut-off assay file first. If needed, perform a second, quantitative measurement.

To run the same plate first with the cut-off assay and then with the quantitative assay, please apply the controls and standards as described in the quick guide and assign the control or standard names according to the following table in the user software:

| Well | Apply controls according to IFU / Quick Guide | Layout of test: | |
|-------|---|--|---|
| | | Qualitative assay file (TOXOG_QT_51209_R5) | Quantitative assay file (TOXOG_CO_51209_R5) |
| A1 | Blank | B | B1 |
| B1/C1 | NC | NC1 | NC1 |
| D1/E1 | CC | CR1 | S1 |
| F1/G1 | PCL | PC1 | S2 |
| H1/A2 | PCM | PC2 | S3 |
| B2/C2 | PCH | PC3 | S4 |

The QT assay is programmed to get concentrations for all samples in the report. For this reason all results are shown with concentrations. Concentrations below 1.6 IU/ml and above 65 U/ml are marked with “< S1*” and “> S4*”.

The OD values displayed in the report are reduced by the blank value.