

Application Sheet

Toxo IgG

REF 51209

Instrument: HumaReader Single plus

REF 18000

Setting:

TOXG_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.

An automated qualitative evaluation is done by the instrument. If quantitative values are needed, they have to be calculated by the user according to the IFU.

Please note that the reader needs special positioning of controls. The pipetting scheme differs from IFU. PCL and PCH cannot be interpreted by the reader. For this reason, they have to be considered as samples.

Well Position	Layout of test
A1	Blank
B1/C1	NC
D1/E1	PCM
F1/G1	CC
H1/A2	PCL (sample 1 + 2)
B2/C2	PCH (sample 3 + 4)
D2...	Samples

The validity criterion “ $MNC \leq MCC$ ” must be checked manually. The OD values displayed in the report are reduced by the blank value.