Application Sheet

Toxo IgG

REF 51209

Instrument: Elisys Uno

REF 17350

Setting:

TOXOG_51209_CO_R5
TOXOG_51209_QT_readout_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.

Material Required

Material	REF	Comments
Toxo IgG	51209	
Reagent Rack, Infect. Diseases & Steroids & Autoimmune Elisys Uno	17359/2	all reagents
Sample Rack (12 mm) Elisys Uno or Sample Rack (13 mm) Elisys Uno	17359/7 or 17359/8	Sample and dilution; according to sample collection tube
Sample vials 2 ml	17350/16	Sample dilution

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 processing and evaluation of the test is realized by two complementary settings. TOXOG_51209_CO_R5 provides the processing and interpretation of the test. The report displays the calculated S/COV ratio in the "Concentration" column. Do not confuse the S/Co ratio with the International Units.

According to the IFU positive samples can be analysed quantitatively. To do this, the already processed and analysed MTP of the CO-run can be re-evaluated by using the setting TOXOG_51209_QT_readout_R5. The readout-setting has to be started subsequently after the CO-Setting. Therefore, please reset the shown racks and the plate in the software. The processed microplate of the first run has to remain in the plate carrier. Allocate the samples of the first run (already shown in the sample tab) to the readout-setting. As usual activate the buttons Add Test, Calibrate and Request. Confirm the note "EIA assay(s) with no wash. Continue?" with "YES". The position of CC, PCL, PCM, PCH, NC and samples on the corresponding racks are displayed in the software. The controls and samples are pipetted only virtually (volume 0 µl), the bottles do not have to be positioned on the racks anymore. The virtual pipette step and the photometric measurement only take a few minutes. Concentrations below 1.6 IU/ml and above 65 IU/ml are calculated by extrapolation and should be considered as "out of range". The readout-setting also shows concentrations of negative and equivocal specimens, these results have to be ignored.

Due to the usable space on the racks the number of samples that can be processed is limited to 48.

For technical reasons, the assay step „start incubation time" in the setting TOXOG_51209_CO_R5 requires to define a corresponding reagent. This reagent only exists in the software, there is no reagent bottle for it. However, this virtual reagent needs to be allocated to a position on the reagent rack, any position can be chosen. Do not place any other reagent bottle on this position while the virtual bottle is allocated to it.