

Application Sheet

IMTEC-TPO-Antibodies

REF ITC85020

Instrument: HumaReader HS

REF 16670

Setting:

TPO_ITC85020_R4

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

The concentration of the PC must be checked manually since the target values are batch specific. The concentration of the NC must also be checked by the user.

Since the software does not calculate results for controls, the wells of PC and NC should be set as "samples". The setting requires the definition of at least 1 well as "CR" (cut-off control), although the assay does not comprise one. Possibly the measurement does not start before one "CR" is located to an empty well.

The validation criteria for CAL5 with a minimum absorbance value of 0.6 ($STD5 \geq 0.6$) and the checking of raising absorbance values of CAL1 up to CAL5 are checked automatically by HumaReader HS. If the criteria fail, no result will be displayed.