Application Sheet

IMTEC-dsDNA-Antibodies

REF ITC59001

Instrument: HumaReader HS

REF 16670

Setting:

dsDNA_ITC59001_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 validation criterion for NC is programmed based on absorption values in consideration of the equivalence of cut-off and CAL2 (NCx < STD2).

If NC and PC should be reported with concentration values, the respective wells should be set as "samples". In this case the validation criteria for both, NC and PC, have to be checked by the user.

The validation criteria of CAL5 (STD5 ≥ 0.6) and the checking of raising absorbance values of CAL1 up to CAL5 are realized correctly by HumaReader HS. If the criteria fail, no result will be displayed.

Human

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