

# Application Sheet

## CMV IgM

**REF 51103**

## Instrument: HumaReader HS

**REF 16670**

### Setting:

**CMVM\_51103\_R2**

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 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

The validation criteria are checked automatically. If the criteria fail, no result will be displayed.

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Corresponding to the IFU the blank value is subtracted automatically.

The application requires the definition of 1 well as cut-off control, although the assay does not comprise one. Since the software does not calculate results for controls the value has to be calculated individually. The COV is included in the report or can be calculated according to the IFU.