

# Application Sheet

**fPSA**

**REF 52035**

**Instrument: HumaReader Single plus**

**REF 18000**

**Setting:**

**fPSA\_52035\_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 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 validation criteria for CAL F ( $\geq 1.3$  and difference of duplicates  $\leq 10\%$ ) are not checked by the device. Each assay run must be performed with its calibration curve. When the reading is started a dialogue asks if the calibrator values from the previous reading should be used. The option "Discard" must be selected to continue.