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## Manufacturer declaration

Determination on APS conjugate (RDB2008 / RDB 2008 X / ELSP 5018) with the following lot numbers:

- 302-1
- 302-2
- 303-1
- 303-2
- 304-1

The above mentioned APS conjugate lots of GenID GmbH, distributed by AID GmbH, are part of our line-probe assays and EliSPot kits. The APS is used for the detection of biotinylated DNA amplificates or antigens via a chromogenic reaction.

In the above mentioned batches a loss of activity occurs, which may manifest itself in weak signals on the test strips or microtiter plate.

This usually leads to non-interpretable results. However, the risk of a false-negative or false-positive result caused by this is to be regarded as very low, since all control zones or positive control well (EliSpot) also develop only a weak signal strength and the test results must therefore be evaluated as invalid.

As a measure, the corresponding batches will be exchanged free of charge.

All still existing APS conjugates of these batches have to be disposed.