

ELISAPro Validation: *Mycobacterium paratuberculosis* (MAP) Antibody Test Kit, ELISA

Each assay undergoes the following series of tests:

Timing:

Confirms testing is completed according to assay circular, timing based per sample with a well-to-well precision of <15 seconds.

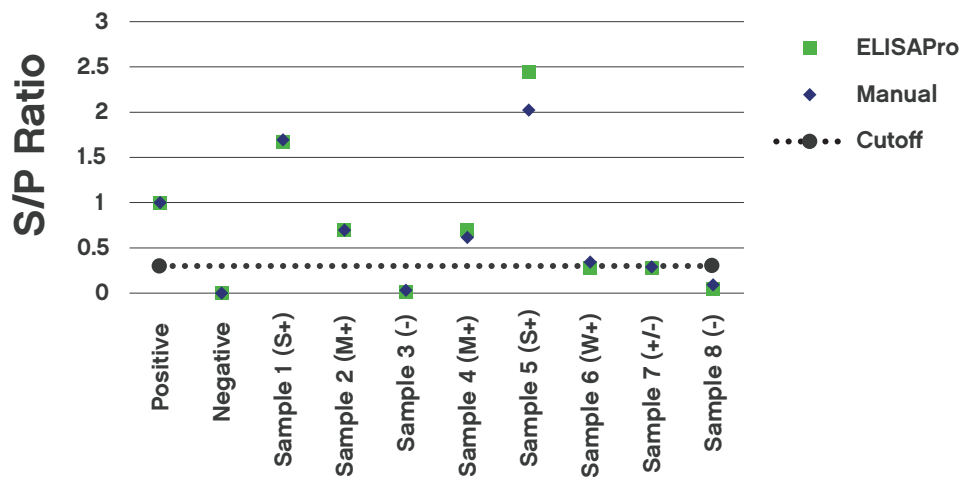
Result:

	Well 1	Well 32	Well 64
Sample	0:30:08	0:30:04	0:30:04
Conjugate	0:30:08	0:30:04	0:30:04
Substrate	0:10:08	0:10:07	0:10:08

ELISAPro vs Manual:

Compares the data from ELISAPro to data obtained manually from two technicians for confirmation of concordance using an internal, well-characterized sample set.

Result:



Cross-contamination:

Confirms there is no well-to-well cross-contamination due to carry-over of samples.

Result:

The assay was negative for cross-contamination (data not shown).

Conclusion:

In accordance with OIE standards, VMRD has demonstrated that the ELISAPro adequately performs VMRD's MAP Antibody Test Kit, ELISA, and produces data that is equivalent to that obtained using traditional methods using a well-characterized panel of samples. Each sample and control met pre-determined criteria for both methods.