

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

Each assay undergoes the following series of tests:

Timing

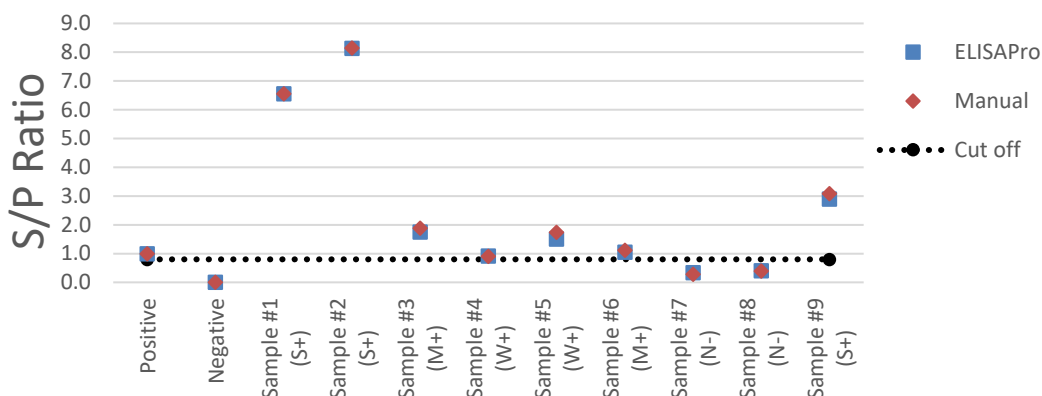
Confirms testing is completed according to assay circular, timing based per sample with a well-to-well precision of < 15 seconds

Result:

	Well 1	Well 32
Sample	0:30:09	0:30:03
Conjugate	0:30:08	0:30:05
Substrate	0:10:08	0:10:12

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 carryover 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, with goat serum, 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.