Field Diagnostic Test for Animal African Trypanosomosis (AAT)

GALVmed
Protecting Livestock – Improving Human Lives

Target Product Profile (TPP)

A reliable and reproducible field test for diagnosis of *T. congolense* and *T. vivax* infection in ruminants

Attribute	Ideal TPP (Wants)	Minimum TPP (Needs)
1 **Goal of Test**	Diagnosis of *T. congolense* and *T. vivax* either as single or combined infections in any host species of interest AND distinguish between current (active) and past infection.	Diagnosis of *T. congolense* and *T. vivax* either as single or combined infections in cattle. No differentiation between *T. vivax* and *T. congolense* For treatment: Must be able to differentiate between current and past infection. In some cases this is not required i.e. zero grazed then differentiation not required for diagnosis. Also antibody detection useful for disease monitoring.
2 **Reference Test**	Parasitological and molecular testing (parasite mRNA or DNA) for *T. congolense* and *T. vivax.*	Parasitological and molecular testing (parasite mRNA or DNA) for *T. congolense* and *T. vivax.*
3 **Sensitivity**	*T. congolense* and *T. vivax* 100%.	*T. congolense* and *T. vivax* >90%.
4 **Specificity**	*T. congolense* and *T. vivax* 100%. No interference with other related blood parasites (Anaplasmosis, Babesiosis, Theileriosis and/or other species of trypanosomes including *T. b. brucei* and *T. theileri*).	*T. congolense* and *T. vivax* >85%. No interference with other related blood parasites (Anaplasmosis, Babesiosis, Theileriosis and/or other species of trypanosomes including *T. brucei brucei* and *T. theileri*).
5 **Reproducibility**	100%.	>90%.
6 **Biological principle**	Not predetermined.	Not predetermined.
7 **Quality Control**	Control line required as quality control indicator.	Control line required as quality control indicator.
8 **Test Result & Interpretation**	Visual readout that directs treatment without data interpretation.	Visual readout that directs treatment without data interpretation.
9 **Specimen Type**	Whole blood with or without anticoagulant.	Whole blood with anticoagulant.
10 **Sample preparation**	None.	None.

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11 Special Handling or Equipment	None required. Reader device for quantification.	Timing device.
12 Refrigeration	None required.	Below 30°C
13 Power	None required.	None required.
14 Stability	36 months at ≤30°C/75%RH.	18 months at ≤30°C/75%RH.
15 Water	None required.	None required.
16 Training	Minimal: visual and intuitive instructions; no language requirements to perform test and no more than 1 page of instructions (only pictures no words).	Minimal: visual and intuitive instructions; no more than 1 page of instructions (mainly pictures, few words). Brief training.
17 Time to result	5 min /test.	<30min /test.
18 Duration of valid result	5 – 10 min (time from when result is valid to when result is no longer readable/valid).	≥2 min (time from when result is valid to when result is no longer readable/valid).
19 Precautions	Safe specimen management.	Safe specimen management.
20 Steps to test result	2 steps or less to test result.	Not predetermined.
21 Results Record	Place to write or identify livestock on test if required, and place to write test result.	None.
22 Test Pack Size	10 tests/pack. Each individual test device sealed in robust foil packaging.	100 tests/pack.
23 Retail price to end user	<US$1.00/test. Below cost of treatment.	<US$2.00 per test. Preferably below cost of treatment.