Target Product Profile: Screening test for human African trypanosomiasis (HAT)

February 2017





TARGET PRODUCT PROFILE 1:

Screening test for human African trypanosomiasis (HAT)

This target product profile (TPP) includes 31 test features. These features refer to specific requirements or specifications of the diagnostic tool to be developed. For each feature, both a desired (optimal) target and a minimally accepted target are defined in a table.

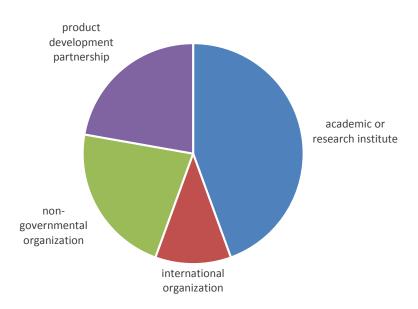
To facilitate consensus building around this TPP, a Delphi-like survey process was used. For each TPP feature, an agreement percentage was calculated. Agreement was scored on a scale ranging from 1 to 5 (1-disagree, 2-somewhat disagree, 3-neither agree nor disagree, 4-mostly agree, 5-fully agree). Participants were asked to provide comments when they did not agree with a statement (that is, when they scored a feature at 3 or lower).

Summary statistics on participants

Number of participants invited to complete the survey: 22

Number of participants who completed the survey: 7 (response rate: 32%)

Organization types: academic or research institute (4; 44.4%), international organization (1; 11.1%), non-governmental organization (2; 22.2%), product development partnership (2; 22.2%)



- 28 out of 31 features reached consensus (i.e. more than 50% of replies were either "Mostly agree" or "Fully agree")
- 3 features did not reach consensus (score of 50% or below) and were revised based on the comments provided by participants

TARGET PRODUCT PROFILE Screening test HAT

Survey results

Key Features	Desired Target	Minimally Accepted Target	Annotation	Consensus score	
	PRIORITY FEATURES				
Target Population	 Patients with symptoms suggestive of HAT presenting at health care facilities for assessment General population living in HAT endemic regions 	Patients with symptoms suggestive of HAT presenting to health care facilities for assessment		100% (desired)/ 78% (minimal)	
Target use setting	 Health care facilities at all levels of the health system, including decentralized facilities with no laboratory infrastructure Mobile teams conducting active screening 	Health care facilities at all levels of the health system, including decentralized facilities with no laboratory infrastructure		100% (desired)/ 89% (minimal)	
Intended use	Screening people at risk for HAT (both <i>T.b.</i> <i>gambiense</i> and <i>T.b.</i> <i>rhodesiense</i>) to identify	Screening people at risk for <i>T.b.</i> <i>gambiense</i> HAT to identify suspects. A positive result will require further		67% (desired)/ 89% (minimal)	

Target molecule	suspects. A positive result will require further testing to confirm cases. Host antibodies	testing to confirm cases. Host antibodies		56% (desired)/
Analyte to be detected	against antigens that are expressed by both <i>T.b.</i> <i>gambiense</i> and <i>T.b. rhodesiense</i>	against antigens that are expressed by <i>T.b.</i> gambiense		89% (minimal)
Clinical sensitivity	100% of parasitologically confirmed cases	90% of parasitologically confirmed cases	Based on freshly collected samples. Case confirmation based on a combination of routine parasitological methods.	78% (desired)/ 78% (minimal)
Clinical specificity	>99%	95%	Based on freshly collected samples. Controls to be confirmed as negative using a combination of routine parasitological methods.	100% (desired)/ 78% (minimal)
Type of analysis	Qualitative	Qualitative		100% (desired)/ 89% (minimal)
Reading system	Visual	Portable reader device		89% (desired)/ 56% (minimal)
Sample type	Whole blood, serum and plasma	Serum or plasma		78% (desired)/ 67% (minimal)
Sample	None or fully	Centrifugation or		89% (desired)/
preparation	integrated	sedimentation		56% (minimal)
Inter teet		REPRODUCIBILITY	Composing	1000((decircd))
Inter-test reproducibility	Карра >95%	Kappa >90%	Comparing results obtained with different tests on identical	100% (desired)/ 89% (minimal)

Inter-reader reproducibility Kappa >95% Kappa >90% Comparing results obtained with the same test on identical samples by different readers 100% (desired) / 89% (minimal) Number of steps to be performed by operator <3 1 Excluding sample collection steps 78% (desired) / 78% (minimal) Need for operator to ransfer a precise volume of sample No Yes, using a disposable transfer device 100% (desired) / 100% (minimal) Internal control Included Included Excluding sample collection 78% (desired) / 100% (minimal) Volume of sample ≤5 min ≤20 min Excluding sample collection 78% (desired) / 89% (minimal) Volume of sample Included Included Included 78% (desired) / 89% (minimal) Volume of sample ≤5 µl ≤20 µl 78% (desired) / 89% (desired) / 89% (minimal) Volume of sample Single test Single test 67% (desired) / 89% (desired) / 78% (minimal) Vex (Requirements None Portable reader device 89% (desired) / 67% (minimal) Need for maintenance/spare parts 0.00 <100% (des				samples by the	
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	manufacture	per year	per year		44% (minimal)

Operating conditions	1-50°C, 90%	1–40°C, 70%	89% (desired)/
	humidity	humidity	78% (minimal)
Kit stability	24 months at	12 months at	89% (desired)/
	40°C, 90%	30°C, 70%	56% (minimal)
	humidity + 1 week at 50°C	humidity	
In uno stability	>2 hours after	>1/2 hour after	100% (desired)/
In use stability	opening the	opening the	100% (minimal)
	pouch	pouch	100 % (minimar)
Reagents	All reagents	All reagents	100% (desired)/
reconstitution	ready to use	ready to use	89% (minimal)
End user profile	Primary health	Primary health	100% (desired)/
	care worker,	care worker,	78% (minimal)
	without any	without any	
	formal laboratory	formal laboratory	
	training	training	
Biosafety	No need for	No need for	100% (desired)/
requirement	biosafety	biosafety cabinet.	100% (minimal)
	cabinet.	Standard	
	Standard	biosafety	
	biosafety	precautions for	
	precautions for	handling	
	handling	potentially	
	potentially	infectious	
	infectious	materials.	
	materials.		
Training needs	Less than half a	Less than 2	78% (desired)/
	day for any level	hours for any	44% (minimal)
	health care	level health care	
	worker	worker	