

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.

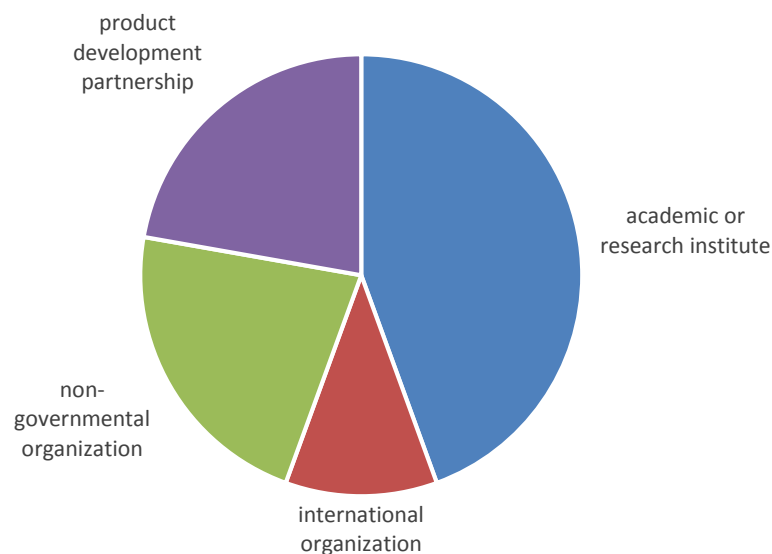
To facilitate consensus building around this TPP, a Delphi-like survey process was used. For each TPP feature, an agreement percentage was calculated. Agreement was scored on a scale ranging from 1 to 5 (1-disagree, 2-somewhat disagree, 3-neither agree nor disagree, 4-mostly agree, 5-fully agree). Participants 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	<ol style="list-style-type: none"> 1) Patients with symptoms suggestive of HAT presenting at health care facilities for assessment 2) 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	<ol style="list-style-type: none"> 1) Health care facilities at all levels of the health system, including decentralized facilities with no laboratory infrastructure 2) 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. gambiense</i> and <i>T.b. rhodesiense</i>) to identify	Screening people at risk for <i>T.b. gambiense</i> HAT to identify suspects. A positive result will require further		67% (desired)/ 89% (minimal)

	suspects. A positive result will require further testing to confirm cases.	testing to confirm cases.		
Target molecule Analyte to be detected	Host antibodies against antigens that are expressed by both <i>T.b. gambiense</i> and <i>T.b. rhodesiense</i>	Host antibodies against antigens that are expressed by <i>T.b. gambiense</i>		56% (desired)/ 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 preparation	None or fully integrated	Centrifugation or sedimentation		89% (desired)/ 56% (minimal)
REPRODUCIBILITY				
Inter-test reproducibility	Kappa >95%	Kappa >90%	Comparing results obtained with different tests on identical	100% (desired)/ 89% (minimal)

			samples by the same reader	
Inter-reader reproducibility	Kappa >95%	Kappa >90%	Comparing results obtained with the same test on identical samples by different readers	100% (desired) / 89% (minimal)
TEST PROCEDURE				
Number of steps to be performed by operator	<3 No timed step	<5 1 timed step	Excluding sample collection steps	78% (desired)/ 78% (minimal)
Need for operator to transfer a precise volume of sample	No	Yes, using a disposable transfer device		100% (desired)/ 100% (minimal)
Time to result	≤5 min	≤20 min	Excluding sample collection	78% (desired)/ 78% (minimal)
Internal control	Included	Included		78% (desired)/ 89% (minimal)
SAMPLING				
Volume of sample required	≤5 µl	≤20 µl		78% (desired)/ 78% (minimal)
Sample preparation	None or fully integrated	None or fully integrated		89% (desired)/ 44% (minimal)
Throughput	Single test	Single test		67% (desired)/ 89% (minimal)
RELATED EQUIPMENT				
Auxiliary equipment	None	Portable reader device		89% (desired)/ 67% (minimal)
Power Requirements	None	Battery-operated portable reader device		89% (desired)/ 78% (minimal)
Need for maintenance/spare parts	None	Portable reader device		100% (desired)/ 67% (minimal)
MANUFACTURING REQUIREMENTS				
Cost of manufacturing device/test (for single use device)	<0.50 USD per test	<1 USD per test		89% (desired)/ 78% (minimal)
Expected scale of manufacture	3 million tests per year	1 million tests per year		56% (desired)/ 44% (minimal)
OPERATIONAL CHARACTERISTICS				

Operating conditions	1-50°C, 90% humidity	1–40°C, 70% humidity		89% (desired)/ 78% (minimal)
Kit stability	24 months at 40°C, 90% humidity + 1 week at 50°C	12 months at 30°C, 70% humidity		89% (desired)/ 56% (minimal)
In use stability	>2 hours after opening the pouch	>½ hour after opening the pouch		100% (desired)/ 100% (minimal)
Reagents reconstitution	All reagents ready to use	All reagents ready to use		100% (desired)/ 89% (minimal)
End user profile	Primary health care worker, without any formal laboratory training	Primary health care worker, without any formal laboratory training		100% (desired)/ 78% (minimal)
Biosafety requirement	No need for biosafety cabinet. Standard biosafety precautions for handling potentially infectious materials.	No need for biosafety cabinet. Standard biosafety precautions for handling potentially infectious materials.		100% (desired)/ 100% (minimal)
Training needs	Less than half a day for any level health care worker	Less than 2 hours for any level health care worker		78% (desired)/ 44% (minimal)