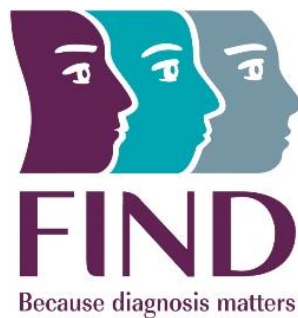


**Target Product Profile:
Rapid test for diagnosis of malaria and
screening for human African
trypanosomiasis (HAT)**

February 2017



TARGET PRODUCT PROFILE 5:

Rapid test for diagnosis of malaria and screening 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.

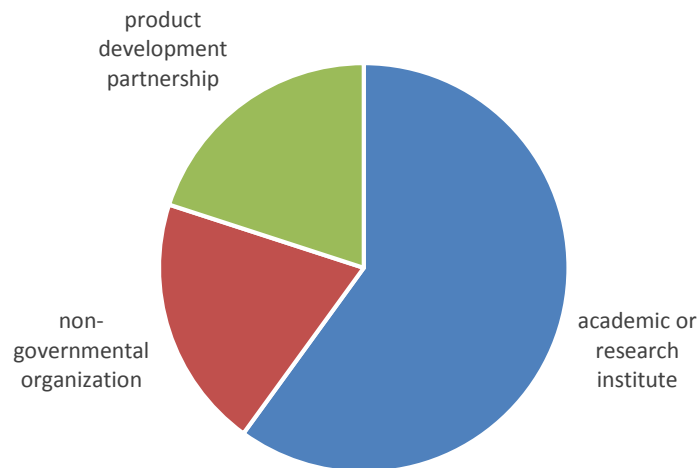
To facilitate consensus building around this TPP, a Delphi-like survey process was used. For each TPP feature, an agreement percentage was calculated. Agreement was scored on a scale ranging from 1 to 5 (1-disagree, 2-somewhat disagree, 3-neither agree nor disagree, 4-mostly agree, 5-fully agree). Participants 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: 5 (response rate: 23%)

Organization types: academic or research institute (3; 60%), non-governmental organization (1; 20%), product development partnership (1; 20%)



- 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
Rapid test for diagnosis of malaria and screening for HAT

**Survey
results**

Key Features	Desired Target	Minimally Accepted Target	Annotation	Consensus score
PRIORITY FEATURES				
Target Population	People living in regions that are endemic for both HAT and malaria	Patients with symptoms suggestive of HAT or malaria presenting at health care facilities for assessment, living in regions that are endemic for both HAT and malaria		80% (desired)/ 80% (minimal)
Target use setting	Health care facilities at all levels of the health system, including decentralized facilities with no laboratory infrastructure	Health care facilities at all levels of the health system, including decentralized facilities with no laboratory infrastructure	The test could also be used by mobile teams	100% (desired)/ 100% (minimal)
Intended use	Diagnosis of <i>P. falciparum</i> malaria and screening for HAT (both <i>T.b. gambiense</i> and <i>T.b. rhodesiense</i>) in populations at risk for both diseases. A positive HAT result will require further testing to confirm disease.	Diagnosis of <i>P. falciparum</i> malaria and screening for HAT (both <i>T.b. gambiense</i> and <i>T.b. rhodesiense</i>) in populations at risk for both diseases. A positive HAT result will require further testing to confirm disease.		80% (desired)/ 80% (minimal)

Target molecule Analyte to be detected	1) Host antibodies against antigens that are expressed by both <i>T.b. gambiense</i> and <i>T.b. rhodesiense</i> <i>P. falciparum</i> antigen	1) Host antibodies against antigens that are expressed by <i>T.b. gambiense</i> <i>P. falciparum</i> antigen		80% (desired)/ 80% (minimal)
Clinical Sensitivity	1) HAT: 100% of confirmed cases Malaria: 95%	1) HAT: 90% of confirmed cases Malaria: 95%	1) HAT: Based on freshly collected samples. Case confirmation based on a combination of routine methods. 2) Malaria: PCR as reference method.	80% (desired)/ 80% (minimal)
Clinical specificity	1) HAT: >99% 2) Malaria: >99.5%	1) HAT: 95% 2) Malaria: 99%	1) Based on freshly collected samples. Controls to be confirmed as negative using a combination of routine methods. Malaria: PCR as reference method.	180% (desired)/ 60% (minimal)
Type of analysis	Qualitative	Qualitative		100% (desired)/ 100% (minimal)
Reading system	Visual	Portable reader device		80% (desired)/ 60% (minimal)
Sample type	Whole blood	Whole blood		80% (desired)/ 80% (minimal)
Sample preparation	None or fully integrated	None or fully integrated		80% (desired)/ 80% (minimal)

REPRODUCIBILITY

Inter-test reproducibility	Kappa >95%	Kappa >90%	Comparing results obtained with different tests on identical samples by the same reader	60% (desired)/ 60% (minimal)
Inter-reader reproducibility	Kappa >95%	Kappa >90%	Comparing results obtained with the same test on identical samples by different readers	60% (desired)/ 60% (minimal)
TEST PROCEDURE				
Number of steps to be performed by operator	<3 No timed step	<5 1 timed step	Excluding sample collection steps	60% (desired)/ 40% (minimal)
Need for operator to transfer a precise volume of sample	No	Yes, using a disposable transfer device		100% (desired)/ 80% (minimal)
Time to result	≤5 min	≤20 min	Excluding sample collection	100% (desired)/ 100% (minimal)
Internal control	Included	Included		80% (desired)/ 80% (minimal)
SAMPLING				
Volume of sample required	≤5 µl	≤20 µl		60% (desired)/ 80% (minimal)
Sample preparation	None or fully integrated	Sedimentation and/or adding reagent		80% (desired)/ 20% (minimal)
Throughput	Single test for HAT and malaria	Single test for HAT and malaria		60% (desired)/ 60% (minimal)
RELATED EQUIPMENT				
Auxiliary equipment	None	Portable reader device		80% (desired)/ 60% (minimal)
Power Requirements	None	Battery-operated portable reader device		100% (desired)/ 80% (minimal)
Need for maintenance/spare parts	None	Portable reader device		100% (desired)/ 80% (minimal)
MANUFACTURING REQUIREMENTS				
Cost of manufacturing	<0.50 USD per test	<1 USD per test		60% (desired)/ 60% (minimal)

device/test (for single use device)				
Expected scale of manufacture	5 million tests per year	2 million tests per year		60% (desired)/ 60% (minimal)
OPERATIONAL CHARACTERISTICS				
Operating conditions	1-50°C, 90% humidity	1-40°C, 70% humidity		80% (desired)/ 80% (minimal)
Kit stability	24 months at 40°C, 90% humidity + 1 week at 50°C	12 months at 30°C, 70% humidity		60% (desired)/ 40% (minimal)
In use stability	>2 hours after opening the pouch	>½ hour after opening the pouch		80% (desired)/ 80% (minimal)
Reagents reconstitution	All reagents ready to use	All reagents ready to use		8% (desired)/ 80% (minimal)
End user profile	Primary health care worker, without any formal laboratory training	Primary health care worker, without any formal laboratory training		80% (desired)/ 80% (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	≤2 hours for any level health care worker	≤4 hours for any level health care worker		80% (desired)/ 60% (minimal)