Grand Challenges: Diagnostics for Neglected Tropical Disease – Lymphatic Filariasis

Annex 1: Target Product Profile for LF diagnostics

1. Table for LF Surveillance use case

	Obj	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
Table no. 1 **NOTE:** Need statements shown in *underline italics* are differentiated from those in the IDA Stopping use case.	Objective: To determine when there is evidence or absence of ongoing transmission/recrudescence, both post-MDA and post-validation	Need to be able to perform test in field *or* laboratory	Need to be able to discriminate targeted prevalence threshold in the tested area	Need to perform test with minimally skilled/trained technicians or central laboratory technicians	Need to have low cost for the test	*Need to detect marker indicative of early sign of exposure with rapid clearance post-treatment*	*Need to have sample readout that is unambiguous*	Need to be able to ship and store tests in ambient conditions	Need to be able to test all ages of subjects	Need to have a test that is "user friendly"	Need to have test with timely delivery lead times	Need to measure target in a population-based survey
1.1 Intended use	**X**											
1.2 Targeted population	**X**		**X**			**X**			**X**			**X**
1.3 Lowest infrastructure level		**X**		**X**				**X**				
1.4 Lowest level user		**X**		**X**	**X**					**X**		
1.5 Training requirements		**X**		**X**	**X**							
2.1 Portability		**X**									**X**	
2.2 Instrument/power requirement		**X**			**X**					**X**		
2.3 Water requirement		**X**								**X**		
2.4 Maintenance and calibration		**X**		**X**	**X**							
2.5 Sample type/collection		**X**		**X**					**X**			
2.6 Sample preparation/transfer device		**X**		**X**	**X**					**X**		

2.7 Sample volume		**X**								**X**		
2.8 Target analyte	**X**		**X**			**X**			**X**			
2.9 Type of analysis		**X**		**X**	**X**		**X**					
2.10 Detection		**X**		**X**	**X**		**X**					
2.11 Quality control										**X**		
2.12 Supplies needed		**X**		**X**	**X**					**X**		
2.13 Safety		**X**		**X**								
3.1 Species differentiation	**X**		**X**			**X**						**X**
3.2 Diagnostic/clinical sensitivity	**X**		**X**			**X**						**X**
3.3 Diagnostic/clinical specificity	**X**		**X**			**X**						**X**
3.4 Time to results		**X**									**X**	
3.5 Result stability		**X**		**X**			**X**			**X**	**X**	
3.6 Throughput		**X**									**X**	
3.7 Target shelf life/stability		**X**						**X**		**X**		
3.8 Ease of use		**X**		**X**						**X**		
3.9 Ease of results interpretation		**X**		**X**			**X**			**X**		
3.10 Operating temperature		**X**			**X**			**X**		**X**		
4.1 Shipping conditions		**X**			**X**			**X**				
4.2 Storage conditions		**X**			**X**			**X**				
4.3 Service and support		**X**		**X**	**X**							
4.4 Waste disposal		**X**			**X**							
4.5 Labeling				**X**						**X**		
5.1 Target pricing per test					**X**							
5.2 Capital cost		**X**			**X**					**X**		
5.3 Product lead times											**X**	**X**
5.4 Target launch countries	**X**											**X**
5.5 Product registration	**X**		**X**			**X**				**X**		

2. Table for IDA stopping decision use case

	Obj	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
Table no. 2 **NOTE:** Need statements shown in *underline italics* are differentiated from those in the surveillance use case.	Objective: To determine when stopping IDA-based MDA is safe/risk of recrudescence is sufficiently low	Need to be able to perform test in field *or* laboratory	Need to be able to discriminate targeted prevalence threshold in the tested area	Need to perform test with minimally skilled/trained technicians or central lab technicians	Need to have low cost for the test	*Need to detect marker indicative of infection with live adult worm*	*Need to have sample readout that is categorical (i.e., "Yes/No")*	Need to be able to ship and store tests in ambient conditions	Need to be able to test all ages of subjects	Need to have a test that is "user friendly"	Need to have test with timely delivery lead times	Need to measure target in a population-based survey
1.1 Intended use	**X**											
1.2 Targeted population	**X**		**X**			**X**			**X**			**X**
1.3 Lowest infrastructure level		**X**		**X**				**X**				
1.4 Lowest level user		**X**		**X**	**X**					**X**		
1.5 Training requirements		**X**		**X**	**X**							
2.1 Portability												
2.2 Instrument/power requirement		**X** **X**			**X**					**X**	**X**	
2.3 Water requirement		**X**								**X**		
2.4 Maintenance and calibration		**X**		**X**	**X**							
2.5 Sample type/collection		**X**		**X**					**X**			
2.6 Sample preparation/transfer device		**X**		**X**	**X**					**X**		
2.7 Sample volume		**X**								**X**		
2.8 Target analyte	**X**		**X**			**X**			**X**			
2.9 Type of analysis		**X**		**X**	**X**		**X**					

2.10 Detection		**X**		**X**	**X**		**X**					
2.11 Quality control										**X**		
2.12 Supplies needed		**X**		**X**	**X**					**X**		
2.13 Safety		**X**		**X**								
3.1 Species differentiation	**X**		**X**			**X**						**X**
3.2 Diagnostic/clinical sensitivity	**X**		**X**			**X**						**X**
3.3 Diagnostic/clinical specificity	**X**		**X**			**X**						**X**
3.4 Time to results		**X**									**X**	
3.5 Result stability		**X**		**X**			**X**			**X**	**X**	
3.6 Throughput		**X**									**X**	
3.7 Target shelf life/stability		**X**						**X**		**X**		
3.8 Ease of use		**X**		**X**						**X**		
3.9 Ease of results interpretation		**X**		**X**			**X**			**X**		
3.10 Operating temperature		**X**			**X**			**X**		**X**		
4.1 Shipping conditions		**X**			**X**			**X**				
4.2 Storage conditions		**X**			**X**			**X**				
4.3 Service and support		**X**		**X**	**X**							
4.4 Waste disposal		**X**			**X**							
4.5 Labeling				**X**						**X**		
5.1 Target pricing per test					**X**							
5.2 Capital cost		**X**			**X**					**X**		
5.3 Product lead times											**X**	**X**
5.4 Target launch countries	**X**											**X**
5.5 Product registration	**X**		**X**			**X**				**X**		

3. TPP for LF Surveillance use case

Surveillance				
Obj/ Need	**1. Product use summary**	**Ideal**	**Minimum**	**Background, annotation re requirement risk, etc**
Obj	1.1 Intended use	An *in vitro* point-of-care test for the detection of analyte specific to *Wuchereria bancrofti*, *Brugia malayi*, and *Brugia timori* to aid in the surveillance of defined geographic areas as to whether recurdescence has/has not occurred.	An *in vitro* test for the detection of analyte specific to *Wuchereria bancrofti*, *Brugia malayi*, and *Brugia timori* to aid in the surveillance of defined geographic areas as to whether recurdescence has/has not occurred.	
Obj,2,5,8, 11	1.2 Targeted population	All ages of individuals resident in the population living in the defined geographic area.	Same.	
1,3,7	1.3 Lowest infrastructure level	The test will be performed in health facilities under "zero-infrastructure" conditions including but not limited to community health centers, households, and outdoor conditions.	If the required levels of performance necessitate a laboratory-based test, tests can be performed in a regional or national diagnostic testing laboratory.	
1,3,4	1.4 Lowest level user	This test will be performed by health personnel, community health workers, and community volunteers.	If testing must be perfromed in a regional or national diagnostic testing laboratory, the test will be performed by trained laboratory technicians.	
1,3,4	1.5 Training requirements	One day for community volunteers and lay persons; testing job aid/instructions for use should be made available via the internet for download (i.e., are publicly available).	If testing must be performed in a regional or national diagnostic testing laboratory, less than one week for trained laboratory technicians; testing job aid/instructions for use should be made available via the internet for download (i.e., are publicly available).	
Obj/ Need	2. Design	Ideal	Minimum	Annotation
1,10	2.1 Portability	Highly portable with no specialized transport needs.	If needed to obtain the required levels of performance, a laboratory-based test is acceptable.	

1,4,9	2.2 Instrument/power requirement	Self-contained kit operates independent of any mains power.	If a laboratory-based test is required, access to mains power is acceptable.	
1,9	2.3 Water requirement	Self-contained kit operates independent of any water supply.	If a laboratory-based test is required, access to laboratory grade water is acceptable.	
1,3,4	2.4 Maintenance and calibration	No maintenance required (i.e., disposable) and no calibration required.	If a laboratory-based test is required, periodic maintenance and calibration of any instrumentation must be available in the countries, and should not be needed more frequently than once a year.	
1,3,8	2.5 Sample type/collection	Peripheral whole blood from finger stick.	If a laboratory-based test is required, peripheral whole blood from finger stick, EDTA/heparinized sample, or DBS. No venipuncture sampling!	If EDTA/heparinized sample, would need to ensure there is the ability to either transport immediately or store suitably.
1,3,4,9	2.6 Sample preparation/transfer device	Sample preparation should not exceed transfer of sampled whole blood to the testing device, either directly or by use of a predefined and provided device (e.g., inverted cup, transfer loop, etc; may provide their own validated transfer device.)	If a laboratory-based test is required, preparation of serum/plasma from EDTA/heparin anticoagulated blood *or* elution from DBS is acceptable.	
1,9	2.7 Sample volume	1-10 uL	1-100 µL	
Obj,2,5,8	2.8 Target analyte	Antibody(s) or other biomarker(s) specific for early exposure/transmission potential of *Wuchereria bancrofti (W.b), Brugia malayi (B.m),* or *Brugia timori (B.t)*	Same.	Antibody-based markers are expected to provide the earliest sign of exposure, so discovery and validation of such a marker would need to identify an antibody with rapid clearance post-treatment. Alternatively, note that a (non-antibody) marker to detect live/viable worm would also be useful in post-validation surveillance. However, current antigen-based biomarkers such as

				CFA or other IgG-based biomarkers possess half-life kinetics that enable determination of *exposure to W.b, B.m*, or *B.t* which: a) may have occurred years prior and, b) may or may not still be an active infection/viable parasite. For these reasons and since it may take significant time/effort for biomarker discovery and validation, this is a **high-risk** requirement.
1,3,4,6	2.9 Type of analysis	Quantitative	Qualitative	Quantitative assay may provide additional information regarding overall "decay" of biomarker levels/concentration within a sampled population.
1,3,4,6	2.10 Detection	High contrast, clear result for naked eye; indoor and outdoor reading of a signal that provides unambiguous determination of a qualitative measure.	If a laboratory-based test is required, may include instrument-based detection of a signal that provides unambiguous determination of a quantitative measure.	
9	2.11 Quality control	· Exogenous process control indicator · Colorimetric or other indicator to identify excessive heat/humidity exposure	· Exogenous process control indicator	**NOTE/QUESTION:** there would need to be definition of how endogenous positive controls should/would be used if they are to be included with a test.
1,3,4,9	2.12 Supplies needed	All reagents and supplied included in kit, with minimal import restrictions (e.g., animal-free)	Same	
1,3	2.13 Safety	Auto-retracting sterile lancet for blood draw in the case of finger-stick sampling; normal use does not create any	If a laboratory-based test is required, auto-retracting sterile lancet for blood draw in the case of finger-stick or DBS sampling; normal use does not	

		additional hazards to the operator when observing Universal Blood Safety precautions.	create any additional hazards to the operator when observing Universal Blood Safety precautions.	
Obj/ Need	3. Performance	Ideal	Minimum	Annotation
Obj,2,5,11	3.1 Species differentiation	*W.b, B.m,* or *B.t*	Same	There should be no interference from other filarial parasites such as *Loa loa*, *Onchocerca volvulus*, *Mansonella* spp., etc. (Potential for interference may not be applicable in parts of the world not endemic for these non-lymphatic filarial parasites.)
Obj,2,5,11	3.2 Diagnostic/clinical sensitivity	>99% sensitivity	>85% sensitivity	In the context of post-validation surveillance, it will be important to identify remaining focii of potential transmission. Information on early exposure to LF from population-based surveys (e.g. TAS, DHS, MICS, PHIA, etc.), as well as the epidemiologic situation, will be useful in guiding more targeted village-based surveillance efforts to identify remaining transmission focii. While there is no WHO target for surveillance, researchers have proposed a provisional threshold of 5% antibody prevalence in children (Rao et al PLOS NTDs 2014), where an antibody analyte was used as the basis for assigning this as a **high-risk** "Ideal" requirement. The sensitivity calculations here presume that a

				goal of surveillance is to measure a <5% threshold at the village-level. **NOTE:** need to have means for validating sensitivity, e.g., standardized sample panels or suitable reference materials.
Obj,2,5,11	3.3 Diagnostic/clinical specificity	>99.8% specificity	>98.8% specificity	In the context of post-validation surveillance, it will be important to identify remaining focii of potential transmission. Information on early exposure to LF from population-based surveys (e.g. TAS, DHS, MICS, PHIA, etc.), as well as the epidemiologic situation, will be useful in guiding more targeted village-based surveillance efforts to identify remaining transmission focii. While there is no WHO target for surveillance, researchers have proposed a provisional threshold of 5% antibody prevalence in children (Rao et al PLOS NTDs 2014), where an antibody analyte was used as the basis for assigning this as a **high-risk** "Ideal" requirement. The specificity calculations

				here presume that a goal of surveillance is to measure a <5% threshold at the village-level. **NOTE:** need to have means for validating specificity e.g., standardized sample panels or suitable reference materials.
1,10	3.4 Time to results	<0.5 hour to developed test result	If a laboratory test is required, <48 hours to developed test result	Laboratory tests assume there will be a workflow into which tests will need to be introduced, i.e., same-day results may not be viable.
1,3,6,9,10	3.5 Result stability	Developed test result remains stable for 24 hours	Developed test result remains stable for 0.5 hour	Ability to interpret final test results in a manner not constrained by timed steps helps greatly in resource-constrained settings
1,10	3.6 Throughput	≥ 10 tests per hour	If a laboratory test is required, 120 tests per day If field-based test, ≥ seven tests per hour	
1,7,9	3.7 Target shelf life/stability	≥24 months, 4 C - 40 C, 50% RH (no cold chain required); temperature excursion/prolonged deviation of 50 C for two weeks acceptable.	≥18 months, 4 C - 40 C, 50% RH (laboratory test may require cold chain); temperature excursion/prolonged deviation of 50 C for two weeks acceptable.	
1,3,9	3.8 Ease of use	One timed step; ten or less user steps, instructions for use should include diagram of method and results interpretation. For field-based test, must be able to use in an unprotected external environment.	If a laboratory test is required, five or fewer timed steps; fifteen or less user steps, instructions for use should include diagram of method and results interpretation.	Example lab test with more than one timed step and multiple user steps would include a standard colorimetric ELISA. For field-based test, must also be able to add a label to the test device.

1,3,6,9	3.9 Ease of results interpretation	Interpreted by unaided eye, does not require discrimination of one color from another	If a laboratory test is required, results can be interpreted by a suitable instrument.	
1,4,7,9	3.10 Operating temperature	15 C - 50 C	May have to control temperature for laboratory-based test	
Obj/Need	4. Product Configuration	Ideal	Minimum	Annotation
1,4,7	4.1 Shipping conditions	Conformance to applicable requirements of ASTM D4169-05 and ISO 11607-1:2006 (or equivalent); no cold-chain shipping required.	If a laboratory-based test is required, cold-chain shipping (e.g., 0-4 C) is acceptable.	
1,4,7	4.2 Storage conditions	Ambient storage conditions, 4 C - 40 C; no cold storage required	If a laboratory-based test is required, cold storage is acceptable	
1,3,4	4.3 Service and support	None required (though can be made available).	If laboratory-based test, support must be available from manufacturer.	
1,4	4.4 Waste disposal	Does not include material that cannot be disposed of in normal laboratory biohazard waste streams.	Same	
3,9	4.5 Labeling and instructions for use (IFUs)	Compliance required per CE Mark and WHO PQ; Product Insert shall be available in relevant local language(s) and shall include Instructions for Use (IFUs) for the test	Same	Need to confirm that WHO PQ will process NTD Dx dossiers
Obj/Need	5. Product cost and channels	Ideal	Minimum	Annotation
4	5.1 Target pricing per test	<$2	(TBD)	Should be room for special pricing in special circumstances (e.g., population subset testing for MDA stopping decisions)
1,4,9	5.2 Capital cost	No capital costs	If laboratory-based test, capital cost should not exceed $5,000 per instrument	Capital cost reflects pricing for unused microtiter plate reader (absorbance, colorimetry), but would be equally applicable to other devices. **NOTE:** assumes lab already stood up, may be more if lab not established.

10,11	5.3 Product lead times	<4 weeks	<6 weeks	"Lead time" includes fulfillment *and* delivery of ordered tests to procurer. **NOTE:** May be adjusted to longer lead times provided shelf life is of sufficient duration, e.g., two years.
Obj,11	5.4 Target launch countries	WHO prioritized countries	Same	
Obj,2,5,9	5.5 Product registration (i.e., substantiation to regulatory body of product claims)	· CE Mark · Any registration required for export from country of origin (e.g., KFDA) · WHO PQ · Country-level registration (if required/ applicable for target countries)	Same	Need to confirm that WHO PQ will process NTD Dx dossiers

4. TPP for IDA stopping decision use case

Stopping Decision				
Obj/Need	**1. Product use summary**	**Ideal**	**Minimum**	**Background, annotation re requirement risk, etc**
Obj	1.1 Intended use	An *in vitro* point-of-care test for the detection of analyte specific to *Wuchereria bancrofti*, *Brugia malayi*, and *Brugia timori* to aid in decision-making in defined geographic areas for stopping mass drug administration of IDA.	An *in vitro* test for the detection of analyte specific to *Wuchereria bancrofti*, *Brugia malayi*, and *Brugia timori* to aid in decision-making in defined geographic areas for stopping mass drug administration of IDA.	
Obj,2,5,8, 11	1.2 Targeted population	All ages of individuals resident in the population living in the defined geographic area.	Same.	
1,3,7	1.3 Lowest infrastructure level	The test will be performed in health facilities under "zero-infrastructure" conditions including but not limited to community health centers, households, and outdoor conditions.	If the required levels of performance necessitate a laboratory-based test, tests can be performed in a regional or national diagnostic testing laboratory.	
1,3,4	1.4 Lowest level user	This test will be performed by health personnel, community health workers, and community volunteers.	If testing must be perfromed in a regional or national diagnostic testing laboratory, the test will be performed by trained laboratory technicians.	
1,3,4	1.5 Training requirements	One day for community volunteers and lay persons; testing job aid/instructions for use should be made available via the internet for download	If testing must be performed in a regional or national diagnostic testing laboratory, less than one week for trained laboratory technicians; testing job aid/instructions for use should be made available via the internet for download (i.e., are publicly available).	

		(i.e., are publicly available).		
Obj/Need	2. Design	Ideal	Minimum	Annotation
1,10	2.1 Portability	Highly portable with no specialized transport needs.	If needed to obtain the required levels of performance, a laboratory-based test is acceptable.	
1,4,9	2.2 Instrument/power requirement	Self-contained kit operates independent of any mains power.	If a laboratory-based test is required, access to mains power is acceptable.	
1,9	2.3 Water requirement	Self-contained kit operates independent of any water supply.	If a laboratory-based test is required, access to laboratory grade water is acceptable.	
1,3,4	2.4 Maintenance and calibration	No maintenance required (i.e., disposable) and no calibration required.	If a laboratory-based test is required, periodic maintenance and calibration of any instrumentation must be available in the countries, and should not be needed more frequently than once a year.	
1,3,8	2.5 Sample type/collection	Peripheral whole blood from finger stick.	If a laboratory-based test is required, peripheral whole blood from finger stick, EDTA/heparinized sample, or DBS. No venipuncture sampling!	If EDTA/heparinized sample, would need to ensure there is the ability to either transport immediately or store suitably.
1,3,4,9	2.6 Sample preparation/transfer device	Sample preparation should not exceed transfer of sampled whole blood to the testing device, either directly or by use of a predefined and provided device (e.g., inverted cup, transfer loop, etc; may provide their own validated transfer device.)	If a laboratory-based test is required, preparation of serum/plasma from EDTA/heparin anticoagulated blood *or* elution from DBS is acceptable.	
1,9	2.7 Sample volume	1-10 uL	1-100 µL	

Obj,2,5,8	2.8 Target analyte	**Antigen(s) or other biomarker(s) specific for current infection from/viability of *Wuchereria bancrofti (W.b), Brugia malayi (B.m),* or *Brugia timori (B.t)***	**Same.**	Biomarkers based on antigens or other types (e.g., certain nucleic-acid based markers) will presumably provide more favorable half-life kinetics that enable more accurate determination of *current* infection from/viability of *W.b, B.m or B.t* in all age groups. However, **current** antigen-based biomarkers such as CFA or other IgG-based biomarkers possess half-life kinetics that enable determination of *prior* infection from/viability of *W.b, B.m*, or *B.t* which may or may not still be an active infection/viable parasite, and discovery and validation of alternative markers may require significant time/effort. For this reason, this is a **high-risk** requirement.
1,3,4,6	2.9 Type of analysis	Qualitative	Qualitative	
1,3,4,6	2.10 Detection	High contrast, clear result for naked eye; indoor and outdoor reading of a signal that provides a "yes/no" result	If a laboratory-based test is required, may include instrument-based detection of a signal that provides a "yes/no" result.	
9	2.11 Quality control	· Exogenous process control indicator · Colorimetric or other indicator to identify excessive heat/humidity exposure	· Exogenous process control indicator	**NOTE/QUESTION:** there would need to be definition of how endogenous positive controls should/would be used

				if they are to be included with a test.
1,3,4,9	2.12 Supplies needed	All reagents and supplied included in kit, with minimal import restrictions (e.g., animal-free)	Same	
1,3	2.13 Safety	Auto-retracting sterile lancet for blood draw in the case of finger-stick sampling; normal use does not create any additional hazards to the operator when observing Universal Blood Safety precautions.	If a laboratory-based test is required, auto-retracting sterile lancet for blood draw in the case of finger-stick or DBS sampling; normal use does not create any additional hazards to the operator when observing Universal Blood Safety precautions.	
Obj/Need	**3. Performance**	**Ideal**	**Minimum**	**Annotation**
Obj,2,5,11	3.1 Species differentiation	*W.b, B.m,* or *B.t*	Same	There should be no interference from other filarial parasites such as *Loa loa*, *Onchocerca volvulus*, *Mansonella* spp., etc. (Potential for interference may not be applicable in parts of the world not endemic for these non-lymphatic filarial parasites.)
Obj,2,5,11	3.2 Diagnostic/clinical sensitivity	"Single test" approach: >60% sensitivity "Confirmatory test" approach: >82% sensitivity	"Single test" approach: >40% sensitivity "Confirmatory test" approach: >73% sensitivity	Current WHO TAS guidance is to measure a <2% prevalence threshold (1% in Aedes areas) in a population. Considering the new infection/viable worm analyte proposed (2.8) that is a more direct measure of transmission potential, and taking into consideration recent operational research that has

				found LF recrudescence post-MDA, a more stringent threshold of <1% prevalence is proposed. The sensitivity calculations are based on testing this 1% threshold and consider two potential scenarios: 1) a "single test" approach in which a new RDT is developed that replaces the current tools in the TAS and 2) a "confirmatory test" approach in which the new diagnostic is used as a confirmatory assay on individuals testing FTS/BRT positive during the TAS. **NOTES:** since the analyte has yet to be defined there is no basis for assigning a level of risk here (which may be low or high); need to have means for validating sensitivity, e.g., standardized sample panels or suitable reference materials.

Obj,2,5,11	3.3 Diagnostic/clinical specificity	"Single test" approach: >99.7% specificity "Confirmatory test" approach: >99% specificity	"Single test" approach: >99.5% specificity "Confirmatory test" approach: >83% specificity	Current WHO TAS guidance is to measure a <2% prevalence threshold (1% in Aedes areas) in a population. Considering the new infection/viable worm analyte proposed (2.8) that is a more direct measure of transmission potential, and taking into consideration recent operational research that has found LF recrudescence post-MDA, a more stringent threshold of <1% prevalence is proposed. The specificity calculations are based on testing this 1% threshold and consider two potential scenarios: 1) a "single test" approach in which a new RDT is developed that replaces the current tools in the TAS and 2) a "confirmatory test" approach in which the new diagnostic is used as a confirmatory assay on individuals testing FTS/BRT positive during the TAS. **NOTES:** since the analyte has yet to be defined there is no basis for assigning a level of risk here (which may be low or high); need to have means for

				validating sensitivity, e.g., standardized sample panels or suitable reference materials.
1,10	3.4 Time to results	<0.5 hour to developed test result	If a laboratory test is required, <48 hours to developed test result	Laboratory tests assume there will be a workflow into which tests will need to be introduced, i.e., same-day results may not be viable.
1,3,6,9,10	3.5 Result stability	Developed test result remains stable for 24 hours	Developed test result remains stable for 0.5 hour	Ability to interpret final test results in a manner not constrained by timed steps helps greatly in resource-constrained settings
1,10	3.6 Throughput	≥ 10 tests per hour	If a laboratory test is required, 120 tests per day If field-based test, ≥ seven tests per hour	
1,7,9	3.7 Target shelf life/stability	≥24 months, 4 C - 40 C, 50% RH (no cold chain required); temperature excursion/prolonged deviation of 50 C for two weeks acceptable.	≥18 months, 4 C - 40 C, 50% RH (laboratory test may require cold chain); temperature excursion/prolonged deviation of 50 C for two weeks acceptable.	
1,3,9	3.8 Ease of use	One timed step; ten or less user steps, instructions for use should include diagram of method	If a laboratory test is required, five or fewer timed steps; fifteen or less user steps, instructions for use should include diagram of method and results interpretation.	Example lab test with more than one timed step and multiple user steps would include a standard

		and results interpretation. For field-based test, must be able to use in an unprotected external environment.		colorimetric ELISA. For field-based test, must also be able to add a label to the test device.
1,3,6,9	3.9 Ease of results interpretation	Interpreted by unaided eye, does not require discrimination of one color from another	If a laboratory test is required, results can be interpreted by a suitable instrument.	
1,4,7,9	3.10 Operating temperature	15 C - 50 C	May have to control temperature for laboratory-based test	
Obj/Need	**4. Product Configuration**	**Ideal**	**Minimum**	**Annotation**
1,4,7	4.1 Shipping conditions	Conformance to applicable requirements of ASTM D4169-05 and ISO 11607-1:2006 (or equivalent); no cold-chain shipping required.	If a laboratory-based test is required, cold-chain shipping (e.g., 0-4 C) is acceptable.	
1,4,7	4.2 Storage conditions	Ambient storage conditions, 4 C - 40 C; no cold storage required	If a laboratory-based test is required, cold storage is acceptable	
1,3,4	4.3 Service and support	None required (though can be made available).	If laboratory-based test, support must be available from manufacturer.	
1,4	4.4 Waste disposal	Does not include material that cannot be disposed of in normal laboratory biohazard waste streams.	Same	
3,9	4.5 Labeling and instructions for use (IFUs)	Compliance required per CE Mark and WHO PQ; Product Insert shall be available in relevant local language(s) and shall include Instructions for Use (IFUs) for the test	Same	Need to confirm that WHO PQ will process NTD Dx dossiers
Obj/Need	**5. Product cost and channels**	**Ideal**	**Minimum**	**Annotation**
4	5.1 Target pricing per test	Single test: <$2 Confirmatory test: <$2	Single test: <$3 Confirmatory test: <$5 (higher?)	Should be room for special pricing in special circumstances (e.g., population

				subset testing for MDA stopping decisions)
1,4,9	5.2 Capital cost	No capital costs	If laboratory-based test, capital cost should not exceed $5,000 per instrument	Capital cost reflects pricing for unused microtiter plate reader (absorbance, colorimetry), but would be equally applicable to other devices. **NOTE:** assumes lab already stood up, may be more if lab not established.
10,11	5.3 Product lead times	<4 weeks	<6 weeks	"Lead time" includes fulfillment *and* delivery of ordered tests to procurer. **NOTE:** May be adjusted to longer lead times provided shelf life is of sufficient duration, e.g., two years.
Obj,11	5.4 Target launch countries	WHO prioritized countries	Same	
Obj,2,5,9	5.5 Product registration (i.e., substantiation to regulatory body of product claims)	· CE Mark · Any registration required for export from country of origin (e.g., KFDA) · WHO PQ · Country-level registration (if required/ applicable for target countries)	Same	Need to confirm that WHO PQ will process NTD Dx dossiers