

Supplementary 4: Third draft TPP (January 2016) prepared by SD and shared with the working group prior to the face-to-face meeting.

Characteristic	Acceptable ("must")	Desired ("want")	Reference
SCOPE			
Goal	Rapid, biomarker-based best testing to differentiate between bacterial and non-bacterial infections to guide antimicrobial treatment.		Expert consensus
Target population	Children with non-severe, non-malarial fever presenting at (what?)	Total febrile population presenting with fever.	Gething <i>et. al.</i> 2010; WHO 2014 (IMCD);
Target level of health system	Tier 1 low level (passive case finding)		Maputo Declaration 2008
Target user	Healthcare worker	Trained lay person	Petti <i>et. al.</i> 2006
Price of individual test	10 USD	< 2 USD or equivalent to a course of antibiotic treatment	Expert consensus
Analytical sensitivity/LoD	Detection of a relevant bacterial/viral infection during the acute phase of the illness.	Detection of a relevant bacterial infection alone or as a co-infection with malaria, during the acute phase of the illness.	Not applicable
Diagnostic sensitivity to differentiate between bacterial and non-bacterial infections	Equal or better than 95%	Equal or better than 99%	Expert consensus
Diagnostic specificity	Equal or better than 80%	Equal or better than 90%	Expert consensus
TEST PROCEDURE			
Multiplexing	Marker(s)	Marker(s) plus pathogen specific testing (e.g. malaria)	Expert consensus
Ease of test performance	Not more than 2 timed steps during assay performance	One or no timed step during the assay.	Expert consensus
Sample type	Capillary blood Saliva		Expert consensus
Volume	100µL (~ 4 drops) for older children and adults; 50µL (~2 drops) for young children of capillary blood ~0.2-1mL for saliva.	25µL (~1 drop) of capillary blood ~0.2-1mL for saliva.	Expert consensus
Collection	Transfer device included in the test		Community based consensus
Additional sample preparation	1 sample-processing steps	None required	Expert consensus
Kit configuration	No additional reagents outside of the kit required		Community based consensus

Control material	Positive and negative and internal control provided with each test.		Community based consensus
Reagent preparation	Minimal of one additional step to prepare prior to use No (precise) measuring required.	No additional reagents required, everything is provided ready-to-use	Chua <i>et. al.</i> 2015
Time to result (per sample)	Less than 60min	Less than 20min	WHO meeting report-TPP for TB diagnostic
Hands on time	Total hands-on-time should be less than 5 min	Total hands on time should be less than 3 min	Expert consensus
Sample capacity	Capacity for parallel processing of <10 samples (?)		Expert consensus
Result stability	30 min	1 hour	n.a.
Analysis type	Qualitative	Quantitative	Expert consensus
OPERATIONAL CHARACTERISTICS			
Biosafety	No need for a biosafety cabinet; basic safety procedures need to be followed (standard PPE)		Laboratory Biosafety Manual, WHO 2014
Waste disposal	Biohazard waste	Testing device or compostable plastics for minimal environmental impact	n.a.
Storage conditions	12 month at fluctuating temperature (5-40°C) Up to 90% relative humidity No controlled temperature required	24 month at fluctuating temperature (5-50°C) Up to 90% relative humidity No controlled temperature required	Chua <i>et. al.</i> 2015
Operation conditions	Between 5°C - 40°C Up to 90% humidity	Between 5°C - 50°C Up to 90% humidity	Chua <i>et. al.</i> 2015
Shipping conditions	Shipping without cold chain		Expert consensus
Training requirements	Less than 2 days including proficiency panel	Less than half a day including proficiency panel	Chua <i>et. al.</i> 2015
Equipment (instrument external to test)	Small, portable or hand-held integrated instrument (<1kg) that must operate on battery	Instrumentation free.	Expert consensus
Power supply	Battery or solar powered	None required.	Chua <i>et. al.</i> 2015
Water supply	No external water required.		Community based consensus
External maintenance	Preventative maintenance at 2 year or >1000 samples; simple with only minimal expertise Maintenance alert should be included.	None required	Community based consensus
Calibration	Remote calibration or auto-calibration	No calibration required	Community based consensus
Internal process controls	Included		Chua <i>et. al.</i> 2015
Data interpretation and output	No interpretation required by user		Expert consensus

Connectivity	Wireless connectivity required	TPP in development at FIND/WHO
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