1. Product use summary	Ideal	Minimum	Background, annotation re requirement risk, etc
1.1 Intended use	An in vitro **point-of-care** test to support decision for stopping mass drug administration and certifying areas with < 1% prevalence of analyte(s).	An in vitro **laboratory-based** test to support decision for stopping mass drug administration and certifying areas with < 1% of analyte(s).	Historically, different methods have been employed for different phases of the programme (nodules, skin snips, serology), and this has complicated the analysis of trends. A rapid diagnostic test with > 89% sensitivity and > 99.8% specificity may have the potential to support all of the following programme needs: mapping, monitoring and evaluation, stopping.
1.2 Targeted population	All ages of individuals resident in the population living in the defined geographical area.	Sentinel groups of school-aged children living in the defined geographical area.	
1.3 Lowest infrastructure level	The test will be performed under "zero-infrastructure" conditions including but not limited to community health centres, households and outdoor conditions.	If the required levels of performance necessitate a laboratory-based test, tests can be performed in a centralized laboratory.	
1.4 Lowest user level	This test will be performed by health personnel and community health workers.	If testing must be performed in a centralized laboratory, the test will be performed by trained laboratory technicians.	
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 centralized laboratory, < 2 weeks for training laboratory technicians; testing job aid/instructions for use should be made available via the Internet for download (i.e. are publicly available).	
2. Design	**Ideal**	**Minimum**	**Annotation**
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.	
2.2 Instrument/power requirement	Self-contained kit operates independently of any mains power.	If a laboratory-based test is required, access to mains power is acceptable.	
2.3 Water requirement	Self-contained kit operates independently of any water supply.	If a laboratory-based test is required, access to laboratory-grade water is acceptable.	
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.	
2.5 Sample type/collection	Peripheral whole blood from finger-stick or other easily collectable samples (e.g. urine, saliva).	If a laboratory-based blood test is required, peripheral whole blood from finger-stick, EDTA/heparinized sample, or dried blood spot. No venipuncture sampling.	If EDTA/heparinized sample, would need to ensure there is the ability to either transport immediately or store suitably.
2.6 Sample preparation/transfer device	Sample preparation should not exceed transfer of specimen 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 blood test is required, preparation of serum/plasma from EDTA/heparin anticoagulated blood or elution from dried blood spot is acceptable.	

2.7 Sample volume	If whole blood: 5–50 µL	If whole blood: 1–100 µL	
2.8 Target analyte	Antigen(s) or other biomarker(s) specific for live, adult *O. volvulus* female worms	Biomarker(s) to detect exposure to *O. volvulus.*	
2.9 Type of analysis	Quantitative	Qualitative	Even for an ideal case, qualitative may suffice.
2.10 Detection	High contrast, clear result for naked eye; indoor and outdoor reading of a signal.	If a laboratory-based test is required, may include instrument-based detection of a signal that provides a "yes/no" result.	
2.11 Quality control	A reference control sample shall be made available to verify that the test (lot) has retained its desired analytical sensitivity. If the test is a rapid diagnostic test, it will have a control line.	Same	The positive control can have a shelf life different from that of the assay.
2.12 Supplies needed	All reagents and supplies included in kit, with minimal import restrictions (e.g. animal-free)	Same	
2.13 Safety	All materials used for sampling must adhere to universal safety precautions. If lancets are included, they should be auto-retracting.	Same	
3. Performance	**Ideal**	**Minimum**	**Annotation**
3.1 Species differentiation	Can differentiate *O. volvulus* from *Wuchereria*, *Loa* and *Mansonella* spp.	Same	
3.2 Diagnostic/clinical sensitivity	≥ 89 %	Same	The test should detect at least 89% of people who have proven infection as demonstrated by the presence of microfilarial DNA in the skin. The sensitivity criteria and specificity criteria were calculated with the assumptions that mass drug administration can cease below a 1% prevalence threshold, and that overtreating is acceptable 10% of the time, while undertreating should not occur more than 5% of the time.
3.3 Diagnostic/clinical specificity	≥ 99.8%	Same	To be demonstrated with > 95% confidence
3.4 Time to results	< 0.5 h to developed test result	If a laboratory test is required, < 48 h to developed test result	48 h is based on eluting dried blood spots one day and running an enzyme-linked immunosorbent assay the following day. Does not include the time to ship/receive samples.
3.5 Result stability	Developed test result remains stable for 24 h	Developed test result remains stable for 0.5 h	Ability to interpret final test results in a manner not constrained by timed steps helps greatly in resource-constrained settings.
3.6 Throughput	≥ 10 tests per hour and per operator	If a laboratory test is required, 120 tests/day per operator. If field-based test, ≥ 7 tests/h per operator.	The 120 tests/day figure is based on running three enzyme-linked immunosorbent assay plates, each with 40 samples in duplicate.
3.7 Target shelf-life/stability	Stable for 36 months at 4–40 °C. Tolerates excursions to 50 °C for 2 weeks	If laboratory based: ≥ 12 months at 4 °C; temperature excursion of 50 °C for one week acceptable. If field deployable: Stable for 18 months at 4–37 °C; tolerates excursions to 50 °C for 1 week.	Acknowledging that other tests (e.g. filariasis test strip for lymphatic filariasis) have a 12-month shelf-life, logistical problems have been encountered with that test as well as with medicines having a 24-month shelf-life due to shipping, customs clearance, transport and/or field staff availability.
3.8 Ease of use	One timed step; ≤ 10 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, ≤ 5 timed steps; ≤ 15 user steps, instructions for use should include diagram of method and results interpretation.	

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.	
3.10 Operating temperature	15–40 °C	May have to control temperature for laboratory-based test.	
3.11 Equivalence of matrices	If the test is intended for one matrix (e.g. blood) but performance will be assessed in the laboratory with another matrix (e.g. serum), then equivalence between the two matrices shall be demonstrated.	Same	
4. Product configuration	**Ideal**	**Minimum**	**Annotation**
4.1 Shipping conditions	Conformance to applicable requirements of ASTM D4169-05 (for shipping) and ISO 11607-1:2006 (for sterile packaging, if needed); no cold-chain shipping required.	If a laboratory-based test is required, cold-chain shipping (e.g. 0–4 °C) is acceptable.	If a laboratory-based test is required, the samples preferrably should be able to be shipped to the laboratory at ambient temperature.
4.2 Storage conditions	Ambient storage conditions, 4–40 °C. Colourimetric or other indicators to identify excessive heat/humidity exposure.	If a laboratory-based test is required, cold storage is acceptable. Colourimetric or other indicators to identify excessive heat/humidity exposure.	It is recommended that the temperature indicator goes on the carton, while the moisture indicator should be inside the pouch (e.g. moisture indicating silica gel).
4.3 Service and support	None required (though can be made available).	If laboratory-based test, support must be available from the manufacturer.	
4.4 Waste disposal	Does not include material that cannot be disposed of in normal laboratory biohazard waste streams.	Same	
4.5 Labeling and instructions for use	Compliance required per in vitro diagnostic device regulation and, if applicable, WHO prequalification; product insert shall be available in relevant local language(s) and shall include instructions for use for the test; if appropriate, photos of example test results (i.e. positive, weak positive, negative) should be included in the instructions.	Same	
5. Product cost and channels	**Ideal**	**Minimum**	
5.1 Target pricing per test	< US$ 2	< US$ 3	Cost does not include personnel. Please note that requirements for cold-shipping may increase cost to beyond acceptable. For the test to be applicable also to monitoring and evaluation activities, the cost should be < US$ 2 (mass drug administration stopping decisions, which are done only once, tolerate a higher price-point than monitoring and evaluation activities that are repeatedly performed over a decade).
5.2 Capital cost	No capital costs	To be determined	
5.3 Product lead times	< 4 weeks	< 6 weeks	Time needed from receipt of purchase order to assays being ready to ship.
5.4 Target launch countries	N/A	N/A	
5.5 Product registration (i.e., substantiation to regulatory body of product claims)	· In vitro diagnostic device regulation · Any registration required for export from country of origin (e.g., KFDA) · WHO prequalifcation (in due course) · Country-level registration (if required/ applicable for target countries)	Same	An effort is ongoing to ensure that the WHO prequalification process will apply to NTDs. More and more countries are requiring registration of diagnostics within country, and the prequalification process would simplify things. As of 2020, a letter of no objection from the importing contry is used as a workaround, but this may not be a sustainable solution.

5.6 Procurement	Available for procurement from all endemic countries with no restriction.	Same	
5.7 Cost	· Standardized pricing quoted by manufacturer available to all stakeholders · Absence of distributor or third-party mark up	Same	