DIAGNOSTIC TARGET PRODUCT PROFILE

for monitoring and evaluation of soil-transmitted helminth control programmes

World Health Organization

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1. Introduction

Soil-transmitted helminths are a group of intestinal worms that include *Ascaris lumbricoides* (giant roundworm), *Trichuris trichiura* (whipworm), and *Ancylostoma* spp. (*A. duodenale, A. ceylanicum*) and *Necator americanus* (hookworms). Despite the clear biological differences among the different species, their transmission is characterized by the same sequence of events: (i) infected individuals excrete worm eggs through their stool in soil; (ii) under optimal conditions of moisture and temperature the excreted eggs develop into infectious stages; and (iii) finally, infection occurs through oral uptake (*Ascaris, Ancylostoma* and *Trichuris*) or skin penetration (*Ancylostoma* and *Necator*) of these infectious stages (embryonated eggs and third stage larvae) that reside in the soil and/or in the environment (referring to their common name).

2. Epidemiology

It is estimated that 800 million people worldwide are infected with at least one species of soil-transmitted helminth, resulting in a global disease burden of more than 3 million disability-adjusted life years. Given the route of transmission, these infections and their associated disease burden predominate in (sub)tropical countries where optimal climate conditions for egg survival and larval development in the environment, poor socioeconomic status and lack of appropriate access to water, sanitation and hygiene facilitate transmission. Attributable morbidity is mainly associated with infections of moderate-to-heavy intensity and mainly affects children and women of reproductive age. Effects include impaired growth and cognitive development, malnutrition, anaemia and school absenteeism in children, and malnutrition and anaemia in women.

3. Public health response

In areas where soil-transmitted helminths are endemic, the World Health Organization (WHO) recommends preventive chemotherapy with a single tablet of an anthelminthic medicine (400 mg albendazole or 500 mg mebendazole), which is periodically administered to both preschool-aged and school-aged children and to other populations at risk. Both medicines are safe for healthy people who do not have infections; it is more cost-effective to treat all populations at risk than to test and treat each individual. The frequency of large-scale deworming is based on the observed prevalence of any of the species, as measured by Kato-Katz thick smear on stool samples, and whether or not this prevalence exceeds a predefined decision threshold. For example, at the start of the preventive chemotherapy programme, it is recommended to distribute medicines twice a year when the prevalence is at least 50% and once a year when the prevalence is at least 20%. During the implementation phase, the prevalence of any soil-transmitted helminth infection is periodically re-evaluated to verify whether objectives are being met, and, if necessary, to adjust the frequency of administration (observed prevalence ≥ 50%: 3 rounds of preventive chemotherapy per year; > 50% observed prevalence ≥ 20%: maintain frequency of preventive chemotherapy; > 20% observed prevalence ≥ 10%: 1 round of preventive chemotherapy per year; > 10% observed prevalence ≥ 2%: 1 round of preventive chemotherapy for 2 years; observed prevalence < 2%: no preventive chemotherapy).

However, this is insufficient to interrupt transmission without additional measures such as increased access to clean water and sanitation and education as well as behavioural change, or by expanding preventive chemotherapy to entire communities. As a result, WHO guidelines for most countries target reducing the prevalence of moderate-to-heavy intensity infections to < 2% (in preschool-aged and school-aged children), which is the target defined for elimination of soil-transmitted helminthiases as a public health problem.

4. Available diagnostic tools

Traditionally, soil-transmitted helminths have been diagnosed by detecting worm-specific eggs in stool samples examined by microscope. Since the 1990s, WHO has recommended Kato-Katz as the diagnostic standard for quantifying eggs in stools. During the past decade, a variety of new diagnostic tests have been introduced to the field, including both microscopy-based (e.g. FECPAK^{G2} and (mini-) FLOTAC), and DNA-based methods (quantitative polymerase chain reaction (qPCR)). Each of these tests has important advantages and disadvantages over Kato-Katz. Important advantages are a clearer microscopic view (FECPAK^{G2} and (mini-)FLOTAC); a higher clinical sensitivity (proportion of infected individuals correctly diagnosed as infected ((mini-)FLOTAC, and qPCR); opportunities for automated egg counting and quality control (e.g. FECPAK^{G2}); and abilities to differentiate hookworm species and to simultaneously detect parasites other than soil-transmitted helminths (qPCR). Chief limitations of these novel tests are the need for well-equipped laboratories with well-trained, skilled technicians (e.g. FLOTAC and qPCR), the higher cost of processing large numbers of samples (FECPAK^{G2}, mini-FLOTAC and qPCR) and the lack of standardized protocols and commercially available kits (qPCR). This is in particular when samples are processed in a laboratory distant from the collection site. Currently, most technologies based on other biomarkers (e.g. antigens, antibodies and metabolites) or other sample matrices (e.g. serum and urine) are either not yet explored, in the research phase or only commercialized for certain worm species.

5. Diagnostic Technical Advisory Group

The WHO Department of Control of Neglected Tropical Diseases manages a diverse portfolio of 20 diseases and disease groups, each with its own unique epidemiological and diagnostic challenges. The Strategic and Technical Advisory Group for Neglected Tropical Diseases, WHO's principal advisory group for the control of these diseases, decided that a single working group would help to ensure a unified approach to identifying and prioritizing diagnostic needs and to informing the Organization's strategies and guidance on the subject.

Thus, the Diagnostic Technical Advisory Group was formed as an advisory group to the Department. At its first meeting (Geneva, Switzerland, 30-31 October 2019), members of the Group discussed priorities for the year ahead as well as how to manage the complexity of supporting the diagnostics agenda across the entirety of the portfolio of diseases. Recommendations were made, based on the understanding that they would be reviewed at the next meeting, as it had been made clear that all these diseases had diagnostic needs which would have to be addressed in due course.

One of the recommendations was to develop target product profiles for diagnostics for soil-transmitted helminthiases to facilitate monitoring and evaluation of control programmes.

6. Purpose of the target product profile

Health ministries currently lack effective tools for monitoring and evaluating programmes to control soil-transmitted helminths. Egg detection can be used, but the cost and challenges of obtaining samples and the need for trained personnel and equipment limit the frequency of monitoring.

The purpose of this target product profile is to lead the development of new diagnostic tools to facilitate programme decisions on whether (i) programmes should start preventive chemotherapy, (ii) move towards the next phase or ultimately stop preventive chemotherapy, based on WHO's decision algorithm and (iii) whether soil-transmitted helminths have been eliminated as a public health problem.

7. Summary of target product profile

The target product is an in vitro/ex vivo laboratory-based (minimum) or point-of-sampling (ideal) test that allows for quantitative detection of analytes specific to soil-transmitted helminths in all age groups. For laboratory-based tests, tests can be performed in regional or national diagnostic testing laboratories by trained laboratory technicians (< 1-week training); specific requirements for portability and transport should not exceed those of standard laboratory equipment. For point-of-sampling tests, health personnel and community health workers should be able to perform and interpret the test with only a single day of training; any equipment used for reading the test should be highly portable and battery powered if it needs electricity at all. The test should be specific (≥ 94%) to each *Ascaris, Trichuris* and hookworm and have a sensitivity of at least 60% for each of the three species of helminth, although different sensitivity/specificity combinations are possible. The test should allow for a throughput of at least seven samples per hour and its cost should not exceed US$ 3.

Target product profile for soil-transmitted helminth monitoring and evaluation

Obj/Need	1. Product use summary	Minimum	Ideal	Background, annotation re requirement risk, etc.
Obj	1.1 Intended use	An in vitro/ex vivo laboratory-based test for detecting analytes specific to soil-transmitted helminths (STHs) to aid in monitoring and evaluating control efforts including verifying whether STH infcetions have been eliminated as a public health problem.	An in vitro/ex vivo point-of-sampling test for the detection of analytes specific to soil-transmitted helminths (STHs) to aid in monitoring and evaluating control efforts including verifying whether STH infections have been eliminated as a public health problem.	
Obj,3,9	1.2 Targeted population	All age groups of individuals in the defined geographical area.	Same.	
1,2,5,8,11	1.3 Lowest infrastructure level	For a laboratory-based test, tests can be performed in a regional or national diagnostic testing laboratory.	For a point-of-sampling test, the test will be performed under "zero-infrastructure" conditions including but not limited to schools, community health centers, households, and outdoor conditions.	
1,2,5,6,9,11	1.4 Lowest level user	For a laboratory-based test, the test will be performed by trained laboratory technicians.	For a point-of-sampling test, the test will be performed by trained health personnel and community health workers.	
1,2,5,6,9,11	1.5 Training requirements	For a laboratory-based test, < 1 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 at all times).	For a point-of-sampling test, ≤ 1 day for trained health personnel and community health workers; testing job aid/instructions for use should be made available via the Internet for download (i.e. are publicly available at all times).	NOTE: It is not a *requirement* to have Internet access to obtain job aids/instructions for use since these must be included with the test itself (per Requirement 4.5), but rather that job aids/instructions for use should always be available via the Internet.
Obj/Need	2. Design	Minimum	Ideal	Annotation
1,2,5	2.1 Portability	For a laboratory-based test, specific portability and transport requirements should not be beyond those associated with standard laboratory equipment typically available for testing clinical samples.	For a point-of-sampling test, highly portable with no specialized transport needs.	
1,5	2.2 Instrument/ power requirement	For a laboratory-based test, access to mains power is acceptable.	For a point-of-sampling test, self-contained kit operates independent of any mains power.	
1,2,5,6	2.3 Water requirement	For a laboratory-based test, access to laboratory grade water is acceptable.	For a point-of-sampling test, self-contained kit operates independent of any water supply.	
1,2,5,6	2.4 Maintenance and calibration	For a laboratory-based test, periodic maintenance and calibration of any instrumentation must be available in the countries, and should not be needed more frequently than once a year.	For a point-of-sampling test, no maintenance required (i.e. disposable) and no calibration required.	
1,2,3,7,9,11	2.5 Sample type/ collection	Test can be performed on stool, urine or other validated sample types (e.g. peripheral blood) that are fresh (i.e. < 12 h at ambient conditions.)	Test can be performed on urine or other validated sample types (e.g. peripheral blood) without the need for stool, and have the ability to be stored or preserved.	

1,2,5,7,9	2.6 Sample preparation/transfer device	For a laboratory-based test, sample preparation should not exceed transfer of the specimen to a suitably designed sample transport device, either directly or by use of a predefined and provided device (e.g. inverted cup, screen-and-template, disposable fixed-volume transfer pipet, etc; may also provide their own validated transfer device) for final processing at a laboratory. Any devices required are provided with the test kit.	For a point-of-sampling test, sample preparation should not exceed transfer of the specimen to the testing device, either directly or by use of a predefined and provided device (e.g. inverted cup, screen-and-template, disposable fixed-volume transfer pipet, etc.) that is provided with the test kit.	
1,2,3,5,7,9,11	2.7 Sample quantity	Stool: < 1 g Urine: < 10 mL Blood/serum: < 50 µL	Stool: < 0.1 g Urine: < 1 mL Blood/serum: < 10 µL	("<" introduced per Vlaminck comment.) The "sample quantity" is the amount required to run the test, hence specimen collection may require more than is shown. Also note that the quantities shown here are for both "minimum" and "ideal" sample type conditions (shown in Requirement 2.5).
Obj,4,10	2.8 Target analyte	Biomarker(s) specific for current active patent infection from *A. lumbricoides*, *T. trichiura* and hookworm only	Same, but differentiate between hookworm species	Biomarkers based on antigens or other types (e.g. some nucleic acid-based markers) will presumably provide more favourable half-life kinetics and thus enable more accurate determination of currently active patent STH infection in all age groups, and should be species-specific to enable programme decision-making. As there are no readily available markers known that meet these requirements and are capable of meeting the remainder of the TPP requirements, this is considered a high-risk requirement. NOTE: "Other biomarkers" may also include faecal eggs (e.g. as for Kato-Katz) provided the remaining requirements within the TPP can be met.
2,4,5,6,7,10	2.9 Type of analysis	Quantitative	Same	Detection of active STH infections for monitoring and evaluation must be able to determine infection intensity, i.e. light, moderate and heavy intensity infections (as currently defined by Kato-Katz). Other markers may give rise to other definitions of infection intensity, which may be correlated to eggs per gram (epg). · *A. lumbricoides*: **light**: 1-4999 epg; **moderate**: 5000-49 999 epg; **heavy**: ≥ 50 000 epg · *T. trichiura*: **light**: 1-999 epg; **moderate**: 1000-9999 epg; **heavy**: ≥ 10 000 epg · Hookworm: **light**: 1-1999 epg; **moderate**: 2000-3999 epg; **heavy**: ≥ 4000 epg The test should be able to detect and classify infection intensities with a diagnostic sensitivity and specificity equal to those 3.2 and 3.3 (see Levecke et al., 2020 PLoS NTD).

1,2,5,6	2.10 Detection	· High contrast, clear result detected with *unaided or aided eye* (the latter may include/entail use of a laboratory-based test) where the signal provides a definitive "yes/no" result. · Signal povides indication of infection intensity *category* (i.e. light, moderate or heavy intensity).	· High contrast, clear result detected with *unaided* eye; indoor and outdoor reading of a signal that provides a definitive "yes/no" result. · Provides indication of infection intensity with an actual egg count/non-categorical result.	Same as above.
2,4,6,10,12	2.11 Quality control	· Exogenous process control indicator (e.g. control line on a rapid diagnostic test, control well in an enzyme-linked immunosorbent assay, etc.)	· Exogenous process control indicator (e.g. control line on a rapid diagnostic test, control well in an enzyme-linked immunosorbent assay, etc.). · Colourimetric or other indicator to identify excessive heat/humidity exposure of the test kits.	**For further consideration (i.e. beyond TPP scope)**: definition of how universal standard operating procedures and endogenous positive controls should/would be used (e.g. if they are to be included with a test, will there be a community-wide proficiency panel, centralized reporting of results, etc.) are subject to programme-based quality assurance strategies.
1,2,5,6,8,9	2.12 Supplies needed	All reagents and supplies included in test kit, with minimal import restrictions (e.g. animal-free)	Same	
1,2,5,9,11	2.13 Safety	Standard self-collection vessel, swab or wipe for stool collection; standard self-collection vessel for urine sampling; 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/body fluid precautions.	Same	
Obj/Need	3. Performance	Minimum	Ideal	Annotation
Obj,4,12	3.1 Species differentiation/detection	*A. lumbricoides*, *T. trichiura* and hookworm (*A. duodenale* and *N. americanus*) only	*A. lumbricoides, T. trichiura, Ancylostoma* spp and *N. americanus* (hookworms are differentiated)	· Within "minimum", species differentiation should be achieved between *A. lumbricoides, T. trichiua* and hookworm (i.e. *A. duodenale* and *N. americanus* do NOT need to be differentiated from one another) · Can be achieved with polymerase chain reaction and microscopy for "minimum" requirements when it relates to specificity, so strictly speaking this is not a "high-risk" requirement. · Note that *Ancylostoma* spp. include *A. duodenale* and *A. ceylanicum*."
Obj,4,10	3.2 Diagnostic/clinical sensitivity	≥ 60%	Same	**Overview of Dx performance modelling**: · Modelled the impact of sensitivity and specificity on the error (risk) to either uneccesary continue with the programme strategy or prematurely shift to the next phase of the programme. · Have assumed risk of < 25% to mistakenly conclude that treatment must continue as before and a risk of < 5% to mistakenly reduce treatment to a lower level of intervention when, in fact, preventive chemotherapy should continue.

· The sensitivity/specificity combinations shown are representative of "minimum" and "ideal" Se/Sp combinations that will provide sufficient decision-making for this use case across six different programme thresholds that range between 1-50% (i.e, 1, 2, 5, 10, 20 and 50%). It is important to note that these thresholds represent the *true* underlying prevalence and not the observed prevalence. Assuming a true underlying prevalence for programme decisions was essential to facilitate comparison across many different sensitivities (Se) and specificities (Sp). The additional programme thresholds of 1% and 5% were included because the Sp of the current diagnostic standard (Kato-Katz thick smear) is not 100%, and hence the true underlying prevalence might be overestimated in situations where the true underlying prevalence is approaching zero.

· "Ideal" Se/Sp combinations are those with the least amount of uncertainty around three or more of these thresholds, and "minimum" Se/Sp combinations are those with the least amount of uncertainty around less than three thresholds; examples of these combinations are below:

Minimum		Ideal	
Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)
≥ 60	99	≥ 60	99
≥ 62	98	≥ 69	98
≥ 63	97	≥ 77	97
≥ 84	96	≥ 92	96
≥ 85	95	≥ 98	95
≥ 86	94		

· Current test formats that meet other TPP characteristics do not consistently achieve these sensitivity and specificity requirements across the species specified. For this reason it is considered a **high-risk** requirement. It is also important to specify that these performance requirements should be validated in an area representative for the region to which the pending decision-making refers.

· At present quantitative polymerase chain reaction (qPCR), FLOTAC and other techniques may be capable of meeting sensitivity requirements in low endemic areas, but they may not be able to meet other requirements.

				· **NOTE: Absence of a gold standard**. The group did not feel comfortable with putting forward a comparator. Indeed, there is no gold standard nor is it straightforward to identify which current diagnostic method (or combination of methods) can be put forward as an alternative comparator. For example, qPCR has shown to outcompete any current diagnostic method but as recently illustrated it is probably the least standardized (Cools et al., PLoS NTD 2020; 2021; different DNA-extraction methods and qPCR protocols) – which makes it impossible to unequivocally define the comparator. The fact that the sensitivity may depend on infection intensity and that the criteria to define intensity of infections are based on egg counts derived from Kato-Katz method further complicate such recommendations. As this is a cross-cutting issue across the different neglected tropical diseases, the Diagnostic Technical Advisory Group recommended establishing a working group to address this issue.
Obj,4,10	3.3 Diagnostic/ clinical specificity	≥ 99%	Same	· See notes above. · The "minimum" and "ideal" specificity requirements shown were selected on the basis of their providing the least uncertainty around the 1% programme threshold, i.e. the threshold that is driving the diagnostic requirements.
1,2,7	3.4 Time to results	< 4 h to developed test result	< 0.5 h to developed test result	
1,2,12	3.5 Result stability	Developed test result remains stable for 0.5 h	Developed test result remains stable for at least 24 h	Ability to interpret final test results in a manner not constrained by timed steps helps greatly in resource-constrained settings.
1,2,7	3.6 Throughput	For laboratory-based tests, ≥ 100 tests/day per tester; for field-based tests, ≥ 7 tests/h per tester	For field-based tests, ≥ 10 tests/h per tester	"Throughput" represents how many tests can be run within an hour by one person and is *separate from* the time to results.
1,2,5,8,12	3.7 Target shelf-life/ stability	For a laboratory-based test, ≥ 18 months at 2-10 °C (via cold-chain storage).	≥ 24 months, 2-40 °C, 50% relative humidity with no cold chain required; temperature excursion/prolonged deviation of 50 °C for 2 weeks should be acceptable.	
1,2,5,7	3.8 Ease of use	· One timed step; ≤ 10 user steps, instructions for use should include diagram of method and results interpretation. · If a point-of-sampling test, it must be able to be used in an unprotected external environment.	· One timed step; ≤ 5 user steps, instructions for use should include diagram of method and results interpretation. · If a point-of-sampling test, it must be able to be used in an unprotected external environment.	

1,2,5	3.9 Ease of results interpretation	· Interpreted by *unaided* or *aided* eye (the latter may include/entail use of a laboratory-based test). · May require discrimination of one colour from another.	· Interpreted by *unaided* eye · Does not require discrimination of one color from another	
1,2,5,6,8	3.10 Operating temperature	15-40 °C, 75% relative humidity	Same	
Obj/Need	4. Product configuration	Minimum	Ideal	Annotation
1,6,8	4.1 Shipping conditions	· Conformance to applicable requirements of ASTM D4169-05 and ISO 11607-1:2006 (or equivalent) · For a laboratory-based test, cold-chain shipping is acceptable.	Conformance to applicable requirements of ASTM D4169-05 and ISO 11607-1:2006 (or equivalent) For point-of-sampling test, no cold-chain shipping should be required.	
1,2,5,6,8	4.2 Storage conditions	For laboratory-based tests, 2-10 °C cold storage acceptable.	Ambient storage conditions, 2-40 °C, 75% relative humidity; no cold storage required	
1,2,5,6	4.3 Service and support	For laboratory-based tests, support must be available from manufacturer for any *laboratory-based* equipment and/or procedures.	None required.	
1,2,6,9,11	4.4 Waste disposal	Does not include material that cannot be disposed of in normal laboratory biohazard waste streams.	· Does not include material that cannot be disposed of in normal laboratory biohazard waste streams. · Daily throughput needs are considered in the packaging so as to minimize package-related waste.	
2,10	4.5 Labelling and instructions for use	Compliance per CE/In Vitro Diagnostic Regulation and WHO prequalification guidance (see *WHO TGS-5: Designing instructions for use for in vitro diagnostic medical devices*); product insert shall be available in relevant local language(s) and shall include instructions for use for the test.	Same	WHO prequalification label/instructions for use guidance should be applied, regardless of whether test is WHO prequalified or not.
Obj/Need	5. Product cost and channels	Minimum	Ideal	Annotation
5,6	5.1 Target pricing per test	< US$ 3	< US$ 1	Price shown is sales price (i.e. is NOT COGS) and excludes any shipping costs. Actual price details to be captured if it can be estimated reasonably, as it will depend on various factors. "Minimum" based on meeting current Kato-Katz-level pricing, "ideal" based on key opinion leader feedback. The "minimum" cost requirement may enable higher pricing if its shown that the test provides greater cost-effectiveness to the programme as a whole and thus provides justification for a higher price.

1,5,6	5.2 Capital cost	For laboratory-based tests, capital costs should not exceed US$ 5000	For point-of-sampling tests, no capital costs required.	Capital cost reflects pricing for unused microtiter plate reader (absorbance, colourimetry), but would be equally applicable to other devices. NOTE: This assumes basic laboratory infrastructure, which is typically available for testing clinical samples, already exists. Costs to establish a laboratory de novo will require considerable additional cost not reflected in this document.
1,3	5.3 Product lead times	< 6 weeks	< 4 weeks	"Lead time" includes fulfillment *and* delivery of ordered tests kits to procurer; it does not include lead times associated with additional equipment that may be needed for laboratory-based tests. NOTE: May be adjusted to longer lead times provided shelf-life of test kits is of sufficient duration, e.g. 2 years.
Obj,4	5.4 Target launch countries	WHO prioritized countries	Same	
Obj,2,4	5.5 Product registration (i.e. substantiation to regulatory body of product claims)	· CE/In Vitro Diagnostic Regulation · Any registration required for export from country of origin (e.g. Korea Food and Drug Administration, etc.) · WHO prequalification (if required/applicable) · Country-level registration (if required/applicable for target countries)	Same	Need to confirm that WHO prequalification will process diagnostic dossiers for neglected tropical diseases.

Neglected tropical diseases
20 Avenue Appia
1211 Geneva 27
Switzerland

neglected.diseases@who.int

https://www.who.int/teams/control-of-neglected-tropical-diseases

9789240031227