TARGET PRODUCT PROFILE
for scabies to start and stop mass drug administration

World Health Organization

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Writer: Christopher Hanna, Global Project Partners, LLC, United States of America and Michael Marks, London School of Hygiene and Tropical Medicine, United Kingdom of Great Britain and Northern Ireland

Contributors: Olivier Chosidow, Henri-Mondor University Hospital, France; James McCarthy, University of Melbourne, Australia; Wendemagegn Enbiale, Bahir Dar University, Ethiopia; Daniel Engelman, Murdoch Children's Research Institute, Australia; Jodie McVernon, Doherty Institute, University of Melbourne, Australia; Andrew Steer, Murdoch Children's Research Institute, Australia

WHO Staff: Dr Kingsley Asiedu, Dr Daniel Argaw Dagne, Dr Anthony Solomon, Department of Neglected Control of Neglected Tropical Diseases.

Scabies is an ectoparasitic disease that is found worldwide. There are approximately 400 million cases a year.

1. Epidemiology

Scabies is caused by infestation with the human ectoparasite *Sarcoptes scabei* var *hominis*. Worldwide, the highest burden of the disease is in low-and-middle income settings *(1, 2)*. Scabies is particularly common among young children. Infestation is associated with skin lesions and severe itch which profoundly impacts quality of life. Individuals with scabies are at increased risk of secondary bacterial skin infection (impetigo), and this may result in more severe complications (such as necrotizing soft tissue infections and bacteraemia) and also to immunologically mediated phenomena including glomerulonephritis and rheumatic fever; these complications are not theoretical or rare – rather, they are frequent sequelae of scabies, particularly in highly-endemic populations.

2. Public health response

In 2019, WHO held a first informal consultation on a framework for the public health control of scabies *(3)*. In areas where the prevalence of scabies is particularly high, the best available evidence supports the use of ivermectin-based mass drug administration (MDA) to control scabies. This strategy consists of two doses of oral ivermectin delivered 7–14 days apart (with 5% topical permethrin offered to individuals in whom ivermectin is contraindicated) *(4)*.

On the basis of current best evidence, the informal recommendation is to start MDA in settings where the community prevalence of scabies is ≥ 10%. The current informal recommendation is to conduct 3–5 rounds of MDA before re-assessing the burden of the disease. If the prevalence of scabies is < 2%, then MDA can be stopped.

In 2021, the first national programmes were initiated in Fiji and the Solomon Islands supported by the World Scabies Programme. The new road map for neglected tropical diseases 2021–2030 has set a target for 25 countries to have rolled out MDA for scabies control by 2030 (5).

3. Available diagnostic tools

Currently, clinical examination is the mainstay of scabies diagnosis. In high-income settings, dermatoscopy and other diagnostic tests are occasionally used to supplement clinical examination. However, these tests are insensitive and not practical for field use within community-based programmes. Other diagnostic tests such as polymerase chain reaction (PCR) remain at a developmental stage.

4. The WHO Diagnostic Technical Advisory Group for Neglected Tropical Diseases

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. At its 12th meeting (Geneva, 29–30 April 2019), the WHO Strategic and Technical Advisory Group for Neglected Tropical Diseases, the principal advisory group to WHO on the control of neglected tropical

diseases (NTDs), decided to establish a single WHO working group to ensure use of a unified approach to identify and prioritize diagnostic needs, and to inform WHO strategies and guidance on the subject of NTD diagnostics *(6)*.

At its inaugural meeting (Geneva, 30–31 October 2019), the Diagnostic Technical Advisory Group for Neglected Tropical Diseases (DTAG) discussed priorities for the year ahead as well as how to manage the complexity of supporting the diagnostics agenda across the entirety of the WHO NTD portfolio. Recommendations were made, based on the understanding that they would be reviewed at the next meeting, as it had been made clear that all NTDs had diagnostic needs that would have to be addressed in due course.

One of the recommendations was to prepare target product profiles (TPPs) for diagnostics to support emerging scabies control programmes and, specifically, TPPs for both starting and stopping MDA.

These TPPs are therefore focused on diagnosis of 'common scabies' and not crusted scabies.

5. Purpose of the TPP

Currently there is no formal WHO guideline on scabies MDA. A provisional strategy for the control of scabies was developed at the WHO Informal Consultation in Manilla (2019). The major areas of consensus were on strategies when the prevalence of scabies was high (≥ 10%) and therefore the initial programmatic needs are framed around these areas.

The purpose of this TPP is to lead to development of new diagnostic tools to measure when there is evidence to support starting and/or stopping ivermectin-based MDA.

For starting MDA, when deployed as part of an appropriately-powered population-based survey, the test must be able to demonstrate that the surveyed prevalence exceeds the defined prevalence threshold of 10% in a designated geographical area with a specified probability.

For stopping MDA, when deployed as part of an appropriately-powered population-based survey, the test must be able to demonstrate that the surveyed prevalence is below the defined prevalence threshold of 2% in a designated geographical area with a specified probability.

It is recognized that the evidence informing these TPPs is at a more preliminary stage than that for other NTDs and that there is likely to be ongoing evolution of programme targets and survey/mapping strategies that will influence the parameters offered in this document.

6. Audiences engaged and external consultations to develop the TPP

In order to initiate the development of TPPs for scabies, Mr Christopher Hanna and Dr Michael Marks gathered together a group of six experts on scabies. The group was divided into a group of clinical experts on scabies and a group on experts on diagnostics. After discussions a draft TPP was developed by Mr Christopher Hanna and Dr Michael Marks. The draft was submitted to the D-TAG group chair, Dr Patrick Lammie, for comments before finalization and publication for the online consultation and adapted based on their comments. It was then published on the WHO website for public consultation from 1 to 31 October 2021. No feedback was received. The draft document was therefore considered final.

References

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3. WHO informal consultation on a framework for scabies control, meeting report. World Health Organization Regional Office for the Western Pacific, Manila, Philippines, 19–21 February 2019. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/9789240008069, accessed 3 February 2022).

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6. Souza AA, Ducker C, Argaw D, King JD, Solomon AW, Biamonte MA, et al. Diagnostics and the neglected tropical diseases roadmap: setting the agenda for 2030. Trans R Soc Trop Med Hyg. 2021; 115(2):129–35. doi:10.1093/trstmh/traa118.

Scabies Diagnosis TPP – Mass Drug Administration Start

1. Product use summary	Minimum	Ideal	Background, annotation re requirement risk, etc.
1.1 Intended use	An in vitro laboratory-based test that detects *S. scabiei*-specific analyte(s) for the purpose of "scabies mapping" to identify areas with ≥ 10% disease prevalence.	An in vitro point-of-care test that detects *S. scabiei*-specific analyte(s) for the purpose of "scabies mapping" to identify areas with ≥ 10% disease prevalence.	
1.2 Targeted population	All ages of individuals resident in the population living in the defined geographical area.	All ages of individuals resident in the population living in the defined geographical area.	
1.3 Lowest infrastructure level	For a laboratory-based test, tests can be performed in a peripheral health facility/referral centre, regional or national diagnostic testing laboratory.	The test will be performed under "zero-infrastructure" conditions including but not limited to schools, community health centres, households and outdoor conditions.	
1.4 Lowest level user	For a laboratory-based test, the test will be performed by trained laboratory technicians.	For a point-of-care test, the test will be performed by health personnel, community health workers and community volunteers.	
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).	For a point-of-care test, ≤ 1 day for health personnel, 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).	NOTE: it should not be 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); rather, job aids/instructions for use should always be available via the Internet.
2. Design	Minimum	Ideal	Annotation
2.1 Portability	For a laboratory-based test, specific portability and transport requirements should not be beyond those associated with standard laboratory equipment.	For a point-of-care test, highly portable with no specialized transport needs.	"Portability" implies those characteristics described in 2.2–2.4 as well as no locational limitations as to where the test can be performed.
2.2 Instrument/ power requirement	For a laboratory-based test, access to mains power is acceptable.	For a point-of-care test, self-contained kit operates independent of any mains power.	
2.3 Water requirement	For a laboratory-based test, access to laboratory-grade water is acceptable.	For a point-of-care test, self-contained kit operates independent of any water supply.	
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-care test, no maintenance required (i.e. disposable) and no calibration required.	
2.5 Sample type/ collection	Peripheral whole blood from finger stick, collected urine or skin swabs of a suspected area.	Peripheral whole blood from finger stick or collected urine.	"Ideal" differs from "Minimum" by elimination of sampling via skin swabbing.

2.6 Sample preparation/ transfer device	· Sample preparation for whole-blood finger stick or urine should not exceed transfer of sample to the testing device. · Sample preparation for skin swabs should not exceed transfer of the swab to a sample processing tube holding no more than 500 µL of processing buffer, an aliquot of which is transferred to the testing device after a defined period of time. · Transfer of the sample volume to the testing device shall occur by use of a predefined and provided single-use transfer device (e.g. inverted cup, disposable fixed-volume transfer pipet).	· Sample preparation for whole-blood finger stick or urine should not exceed transfer of sample to the testing device. · Transfer of the sample volume to the testing device shall occur by use of a predefined and provided single-use transfer device (e.g. inverted cup, disposable fixed-volume transfer pipet).	"Ideal" differs from "Minimum" by elimination of sampling via skin swabbing.
2.7 Sample volume	1–100 uL	1–10 µL	"Sample volume" represents that volume which is introduced to the test device itself.
2.8 Target analyte	**Biomarker(s) specific for current active infection from *Sarcoptes scabiei*.**	**Biomarker(s) specific for current active infection from *Sarcoptes scabiei*.**	**NOTE**: In this context a "biomarker" is presumed to be a biochemical moiety whose diagnostic detection is considered to be *distinct from* identification of the *S. scabiei* mite ***or*** identification of its vestiges, e.g. burrows, faecal pellets or eggs, upon physical examination of the patient. 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 current active infection from/viability of *S. scabiei* in all age groups. IgG-based serology biomarkers typically possess half-life/ sero-conversion kinetics that enable determination of prior infection, unless they have been explicitly identified and characterized as being correlated to active infection. Even though other markers have been investigated (e.g. nucleic acid-based, Ab serology-based), qualification and validation of these will require significant time and effort going forward. For this reason, this is a **high-risk** requirement.
2.9 Type of analysis	Qualitative	Qualitative	

2.10 Detection	For laboratory-based tests, may include instrument-based detection of a signal that provides unambiguous determination of a qualitative measure.	For point-of-care tests, results shall be a high contrast, clear result for naked eye; indoor and outdoor reading of a signal that provides a definitive result without the need for color discrimination.	Same as above.
2.11 Quality control	· Internal process control indicator	· Internal process control indicator · Colorimetric or other indicator to identify excessive heat/humidity exposure	For further consideration (i.e. beyond TPP scope): definition of how endogenous positive controls should/would be used if they are to be included with a test, e.g. will there be a community-wide quality panel, centralized reporting of results?
2.12 Supplies needed	All reagents and supplies included in test kit, including those needed for sample collection and processing, with minimal import restrictions (e.g. animal-free).	All reagents and supplies included in test kit, including those needed for sample collection and processing, with minimal import restrictions (e.g. animal-free).	
2.13 Safety	Normal use of the test does not create any additional hazards to the operator when observing Universal Blood Safety/Body Fluid precautions.	Normal use of the test does not create any additional hazards to the operator when observing Universal Blood Safety/Body Fluid precautions.	
3. Performance	Minimum	Ideal	Annotation
3.1 Species differentiation/detection	*S. scabiei*	*S. scabiei*	There should be no interference/nonspecific signals as a result of other common human ectoparasites, in particularly other mite species that may include (but are not limited to): · *Dermatophagoides* spp. (e.g. the common dust mites *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*) · *Demodex* spp. (e.g. *Demodex foliculorum*) · *Cheyletus* spp. (e.g. *Cheyletus eruditus*) · *Tyrophagus* spp. (e.g. *Tyrophagus putrescentiae* and *Tyrophagus longior*) · *Pediculus* spp. (e.g. the common louse species *Pediculus humanus* and *Pediculus humanus capitis*) · *Phthirius* spp. (e.g. *Phthirius pubis*) · *Cimex* spp. (e.g. the common bed bug *Cimex lectularius*)
3.2 Time to results	< 2 h to developed test result	< 0.5 h to developed test result	
3.3 Result stability	Developed test result remains stable for 0.5 h	Developed test result remains stable for 24 h	Ability to interpret final test results in a manner not constrained by timed steps helps greatly in resource-constrained settings.
3.4 Throughput	For laboratory-based tests, ≥ 100 tests/day per tester	For point-of-care tests, ≥ 10 individuals tested/h per tester	"Throughput" represents how many tests can be run in parallel within an hour and is *separate from* the time to results.

3.5 Target shelf-life/ stability	For laboratory-based tests, ≥ 18 months at 2–4 °C.	≥ 18 months, 2–40 °C, 75% relative humidity (no cold chain required); temperature excursion/prolonged deviation of 50 °C for 2 weeks is acceptable.	"Minimum" target shelf-life/stability is applicable *only* to laboratory-based tests, whereas "Ideal" target shelf-life/stability applies to any test format.
3.6 Ease of use	For laboratory-based tests, ≤ 5 timed steps; ≤ 15 user steps. Instructions for use should include diagram of method and interpretation of results.	For laboratory-based tests, ≤ 1 timed step; ≤ 5 user steps. Instructions for use should include diagram of method and interpretation of results. For point-of-care tests, must be able to use in an unprotected external environment.	This is in relation to the test operation *only*.
3.7 Ease of results interpretation	For laboratory-based tests, a definitive "Yes/No" result can be interpreted by a suitable instrument that meets requirements defined in 2.10 "Minimum".	For point-of-care tests, a definitive "Yes/No" result can be interpreted by eye that meets requirements defined in 2.10 "Minimum".	
3.8 Operating temperature	15–40 °C, 75% relative humidity	15–40 °C, 75% relative humidity	
4. Product configuration	Minimum	Ideal	Annotation
4.1 Shipping conditions	For laboratory-based tests, conformance to applicable requirements of ASTM D4169-05 and ISO 11607–1:2006 (or equivalent); cold-chain shipping (e.g. 0–4 °C) is acceptable for any test components/consumables used in the laboratory.	For point-of-care tests, conformance to applicable requirements of ASTM D4169-05 and ISO 11607-1:2006 (or equivalent); no cold-chain shipping required.	
4.2 Storage conditions	For laboratory-based tests, cold storage is acceptable for any *laboratory*-based testing components/ consumables.	Ambient storage conditions, 2–40 °C; no cold storage required.	"Minimum" storage conditions are applicable *only* to *laboratory*-based tests, whereas "Ideal" storage conditions apply to any test format.
4.3 Service and support	For laboratory-based tests, support must be available from manufacturer for any *laboratory*-based equipment and/or procedures.	For point-of-care tests, none required.	
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.	
4.5 Labelling and instructions for use (IFUs)	Compliance required per in vitro diagnostic regulation (IVDR) requirements and WHO prequalification (PQ) 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 IFUs for the test. Must provide accurate material safety data sheet information on components that are potentially toxic.	Compliance required per in vitro diagnostic devices requirements 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 IFUs for the test. Must provide accurate material safety data sheet information on components that are potentially toxic.	WHO PQ label/IFU guidance should be applied, regardless of whether test is prequalified by WHO or not.

5. Product cost and channels	Minimum	Ideal	Annotation
5.1 Target pricing per test	< US$ 3	< US$ 1	Actual price details will depend on other factors separate from the test itself, which include shipping, storage, quantities purchased and other factors commonly encountered in national procurement for NTD programmes.
5.2 Capital cost	For laboratory-based tests, capital costs may vary but should not exceed US$ 5000.	For point-of-care tests, none required.	
5.3 Product lead times	< 8 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. 2 years. Purpose for information is to address design decisions that can impact line/process design for production, and hence impact lead times.
5.4 Targeted countries	WHO prioritized countries	WHO prioritized countries	
5.5 Product registration (i.e. substantiation to regulatory body of product claims)	· CE Mark/IVDR (or other SRA) *as relevant* · Any registration required for export from country of origin (e.g. KMFDS from Korea) · WHO PQ, *if required/applicable* · Country-level registration (if required/applicable for target countries)	· CE Mark/IVDR (or other SRA) *as relevant* · Any registration required for export from country of origin (e.g. KMFDS from Korea) · WHO PQ, *if required/applicable* · Country-level registration (if required/applicable for target countries)	Need to confirm that WHO PQ will process dossiers for NTD diagnostics.

Scabies Diagnosis TPP – Mass Drug Administration Stop

1. Product use summary	Minimum	Ideal	Background, annotation re requirement risk, etc.
1.1 Intended use	An in vitro laboratory-based test that detects *S. scabiei*-specific analyte(s) for the purpose of "scabies mapping" to identify areas with < 2% disease prevalence.	An in vitro point-of-care test that detects *S. scabiei*-specific analyte(s) for the purpose of "scabies mapping" to identify areas with < 2% disease prevalence.	
1.2 Targeted population	All ages of individuals resident in the population living in the defined geographical area.	All ages of individuals resident in the population living in the defined geographical area.	
1.3 Lowest infrastructure level	For a laboratory-based test, tests can be performed in a peripheral health facility/referral centre, regional or national diagnostic testing laboratory.	The test will be performed under "zero-infrastructure" conditions including but not limited to schools, community health centers, households and outdoor conditions.	
1.4 Lowest level user	For a laboratory-based test, the test will be performed by trained laboratory technicians.	For a point-of-care test, the test will be performed by health personnel, community health workers and community volunteers.	
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).	For a point-of-care test, ≤ 1 day for health personnel, 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).	NOTE: it should not be 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); rather, job aids/instructions for use should always be available via the Internet.
2. Design	Minimum	Ideal	Annotation
2.1 Portability	For a laboratory-based test, specific portability and transport requirements should not be beyond those associated with standard laboratory equipment.	For a point-of-care test, highly portable with no specialized transport needs.	"Portability" implies those characteristics described in 2.2-2.4 as well as no locational limitations as to where the test can be performed.
2.2 Instrument/ power requirement	For a laboratory-based test, access to mains power is acceptable.	For a point-of-care test, self-contained kit operates independent of any mains power.	
2.3 Water requirement	For a laboratory-based test, access to laboratory grade water is acceptable.	For a point-of-care test, self-contained kit operates independent of any water supply.	
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-care test, no maintenance required (i.e. disposable) and no calibration required.	
2.5 Sample type/ collection	Peripheral whole blood from finger stick, collected urine or skin swabs of a suspected area.	Peripheral whole blood from finger stick or collected urine.	"Ideal" differs from "Minimum" by elimination of sampling via skin swabbing.

2.6 Sample preparation/ transfer device	· Sample preparation for whole-blood finger stick or urine should not exceed transfer of sample to the testing device. · Sample preparation for skin swabs should not exceed transfer of the swab to a sample processing tube holding no more than 500 µL of processing buffer, an aliquot of which is transferred to the testing device after a defined period of time. · Transfer of the sample volume to the testing device shall occur by use of a predefined and provided single-use transfer device (e.g. inverted cup, disposable fixed-volume transfer pipet).	· Sample preparation for whole-blood finger stick or urine should not exceed transfer of sample to the testing device. · Transfer of the sample volume to the testing device shall occur by use of a predefined and provided single-use transfer device (e.g. inverted cup, disposable fixed-volume transfer pipet).	"Ideal" differs from "Minimum" by elimination of sampling via skin swabbing.
2.7 Sample volume	1–100 uL	1–10 µL	"Sample volume" represents that volume which is introduced to the test device itself.
2.8 Target analyte	**Biomarker(s) specific for current active infection from *Sarcoptes scabiei*.**	**Biomarker(s) specific for current active infection from *Sarcoptes scabiei*.**	NOTE: In this context a "biomarker" is presumed to be a biochemical moiety whose diagnostic detection is considered to be distinct from identification of the *S. scabiei* mite or identification of its vestiges, e.g. burrows, faecal pellets or eggs, upon physical examination of the patient. 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 current active infection from/viability of *S. scabiei* in all age groups. IgG-based serology biomarkers typically possess half-life/ sero-conversion kinetics that enable determination of prior infection, unless they have been explicitly identified and characterized as being correlated to active infection. Even though other markers have been investigated (e.g. nucleic acid-based, Ab serology-based), qualification and validation of these will require significant time and effort going forward. For this reason, this is a **high-risk** requirement.
2.9 Type of analysis	Qualitative	Qualitative	
2.10 Detection	For laboratory-based tests, may include instrument-based detection of a signal that provides unambiguous determination of a qualitative measure.	For point-of-care tests, results shall be a high contrast, clear result for naked eye; indoor and outdoor reading of a signal that provides a definitive result without the need for colour discrimination.	Same as above.

2.11 Quality control	· Internal process control indicator	· Internal process control indicator · Colorimetric or other indicator to identify excessive heat/humidity exposure	For further consideration (i.e. beyond TPP scope): definition of how endogenous positive controls should/would be used if they are to be included with a test, e.g. will there be a community-wide quality panel, centralized reporting of results?
2.12 Supplies needed	All reagents and supplies included in test kit, including those needed for sample collection and processing, with minimal import restrictions (e.g. animal-free).	All reagents and supplies included in test kit, including those needed for sample collection and processing, with minimal import restrictions (e.g. animal-free).	
2.13 Safety	Normal use of the test does not create any additional hazards to the operator when observing Universal Blood Safety/Body Fluid precautions.	Normal use of the test does not create any additional hazards to the operator when observing Universal Blood Safety/Body Fluid precautions.	
3. Performance	Minimum	Ideal	Annotation
3.1 Species differentiation/detection	*S. scabiei*	*S. scabiei*	There should be no interference/nonspecific signals as a result of other common human ectoparasites, in particularly other mite species that may include (but are not limited to): · *Dermatophagoides* spp. (e.g. the common dust mites *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*) · *Demodex* spp. (e.g. *Demodex foliculorum*) · *Cheyletus* spp. (e.g. *Cheyletus eruditus*) · *Tyrophagus* spp. (e.g. *Tyrophagus putrescentiae* and *Tyrophagus longior*) · *Pediculus* spp. (e.g. the common louse species *Pediculus humanus* and *Pediculus humanus capitis*) · *Phthirius* spp. (e.g. *Phthirius pubis*) · *Cimex* spp. (e.g. the common bed bug *Cimex lectularius*)
3.2 Diagnostic/clinical sensitivity	*For initial clinical screen of Se=70%/Sp=70%*, confirmatory test sensitivity: ≥ **93%** *For initial clinical screen of Se=80%/Sp=80%*, confirmatory test sensitivity: ≥ **81%**	*For initial clinical screen*, single-test sensitivity: ≥ **80%**	*Assumptions made for performance requirements:* · The sensitivity performance values at left assume a 95% power of accurate detection of prevalence at 2%, i.e. there is a 5% risk of misclassifying actual prevalences of > 2% as being ≥ 2%. NOTE: As these levels of performance would require significant expertise to achieve and there are no existing tests that can meet this, it is considered a **high-risk** requirement.

3.3 Diagnostic/clinical specificity	*For 1st clinical screen of Se=70%/Sp=70%*, confirmatory test specificity: ≥ **95%** *For 1st clinical screen of Se=80%/Sp=80%*, confirmatory test specificity: ≥ **93%**	*For no initial clinical screen*, single-test specificity: ≥ **99%**	*Assumptions made for performance requirements:* The sensitivity performance values at left assume a 95% power of accurate detection of prevalence at 2%, i.e. there is a 5% risk of misclassifying actual prevalences of > 2% as being ≥ 2%. **NOTE**: As these levels of performance would require significant expertise to achieve and there are no existing tests that can meet this, it is considered a **high-risk** requirement.
3.4 Time to results	< 2 h to developed test result	< 0.5 h to developed test result	
3.5 Result stability	Developed test result remains stable for 0.5 h	Developed test result remains stable for 24 h	Ability to interpret final test results in a manner not constrained by timed steps helps greatly in resource-constrained settings
3.6 Throughput	For laboratory-based tests, ≥ 100 tests/day per tester	For point-of-care tests, ≥ 10 individual tested/h per tester	"Throughput" represents how many tests can be run in parallel within an hour and is *separate from* the time to results.
3.7 Target shelf-life/stability	For laboratory-based tests, ≥ 18 months at 2–4 °C.	≥ 18 months, 2–40 °C, 75% relative humidity (no cold chain required); temperature excursion/prolonged deviation of 50 °C for 2 weeks is acceptable.	"Minimum" target shelf-life/stability is applicable *only* to laboratory-based tests, whereas "Ideal" target shelf-life/stability applies to any test format.
3.8 Ease of use	For laboratory-based tests, ≤ 5 timed steps; ≤ 15 user steps. instructions for use should include diagram of method and interpretation of results.	For laboratory-based tests, ≤ 1 timed step; ≤ 5 user steps. Instructions for use should include diagram of method and interpretation of results. For point-of-care tests, must be able to use in an unprotected external environment.	This is in relation to the test operation *only.*
3.9 Ease of results interpretation	For laboratory-based tests, a definitive "Yes/No" result can be interpreted by a suitable instrument that meets requirements defined in 2.10 "Minimum".	For point-of-care tests, a definitive "Yes/No" result can be interpreted by eye that meets requirements defined in 2.10 "Minimum".	
3.10 Operating temperature	15–40 °C, 75% relative humidity	15–40 °C, 75% relative humidity	

4. Product Configuration	Minimum	Ideal	Annotation
4.1 Shipping conditions	For laboratory-based tests, conformance to applicable requirements of ASTM D4169-05 and ISO 11607-1:2006 (or equivalent); cold-chain shipping (e.g. 0–4 °C) is acceptable for any test components/consumables used in the laboratory.	For point-of-care tests, conformance to applicable requirements of ASTM D4169-05 and ISO 11607-1:2006 (or equivalent); no cold-chain shipping required.	
4.2 Storage conditions	For laboratory-based tests, cold storage is acceptable for any *laboratory*-based testing components/consumables.	Ambient storage conditions, 2–40 °C; no cold storage required.	"Minimum" storage conditions are applicable *only* to *laboratory*-based tests, whereas "Ideal" storage conditions apply to any test format.
4.3 Service and support	For *laboratory*-based tests, support must be available from manufacturer for any laboratory-based equipment and/or procedures.	For point-of-care tests, none required.	
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.	
4.5 Labelling and instructions for use (IFUs)	Compliance required per in vitro diagnostic regulation (IVDR) requirements and WHO prequalification (PQ) 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 IFUs for the test. Must provide accurate material safety data sheet information on components that are potentially toxic.	Compliance required per in vitro diagnostic regulation (IVDR) requirements and WHO prequalification (PQ) 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 IFUs for the test. Must provide accurate material safety data sheet information on components that are potentially toxic.	WHO PQ label/IFU guidance should be applied, regardless of whether test is prequalified by WHO or not.

5. Product cost and channels	Minimum	Ideal	Annotation
5.1 Target pricing per test	< US$ 3	< US$ 1	Actual price details will depend on other factors separate from the test itself, which includes shipping, storage, quantities purchased and other factors commonly encountered in national procurement for NTD programmes.
5.2 Capital cost	For laboratory-based tests, capital costs may vary but should not exceed US$ 5000.	For point-of-care tests, none required.	
5.3 Product lead times	< 8 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. 2 years. Purpose for information is to address design decisions that can impact line/process design for production, and hence impact lead times.
5.4 Targeted countries	WHO prioritized countries	WHO prioritized countries	
5.5 Product registration (i.e. substantiation to regulatory body of product claims)	· CE Mark/IVDR (or other SRA) *as relevant* · Any registration required for export from country of origin (e.g. KMFDS from Korea) · WHO PQ, *if required/applicable* · Country-level registration (if required/applicable for target countries)	· CE Mark/IVDR (or other SRA) *as relevant* · Any registration required for export from country of origin (e.g. KMFDS from Korea) · WHO PQ, *if required/applicable* · Country-level registration (if required/applicable for target countries)	Need to confirm that WHO PQ will process dossiers for NTD diagnostics

Neglected tropical diseases
20 Avenue Appia
1211 Geneva 27
Switzerland

neglected.diseases@who.int

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

9789240045026