TARGET PRODUCT PROFILE
for a diagnostic test to confirm leprosy in individuals with clinical signs and symptoms

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Writer: Christopher Hanna, Global Project Partners, LLC, United States of America

Contributors: Sundeep Chaitanya Vedithi, American Leprosy Mission, United Kingdom of Great Britain and Northern Ireland; Isra Cruz, National School of Public Health, Spain; Camilla Ducker, Tro Da Global Health Consulting, United Kingdom of Great Britain and Northern Ireland; Petra Kukkaro, Novartis, Switzerland; Andie Tucker, Global Partnership of Zero Leprosy, United States of America.

WHO staff: Kingsley Asiedu, Daniel Argaw Dagne, Jose Antonio Ruiz Postigo, Anthony Solomon, WHO Department of Neglected Control of Neglected Tropical Diseases; Erwin Cooreman, Venkata Ranganadha Rao Pemmaraju, WHO Regional Office for South-East Asia.

Declarations of interest

The writer and contributors signed the WHO Declaration of Interest which were reviewed by the Skin NTDs Team. Dr Petra Kukkaro works for Norvatis which provides the multi-drug therapy for leprosy elimination. The interests declared were assessed and deemed to be non-specific and did not constitute a conflict of interest.

1. Epidemiology

Leprosy, also known as Hansen's disease, is a chronic infectious disease caused by *Mycobacterium leprae* or, in some cases, by *Mycobacterium lepromatosis*. The bacteria is likely transmitted via tiny droplets (aerosols) from the nose and mouth during close and frequent contact with untreated cases. In some circumstances, skin-to-skin contact has also been implicated. Close and frequent contact increase the risk of contacts developing leprosy. Stigmatization and discrimination impede the life of an individual suffering from leprosy; overcoming them is an essential part of leprosy control. As with other neglected tropical diseases (NTDs), the occurrence of leprosy is often related to socioeconomic determinants of health.

M. leprae multiplies slowly and the incubation period of the disease averages 5 years. Symptoms may occur within 1 year but can also take up to 20 years or longer to appear. The disease mainly affects the skin, the peripheral nerves, the mucosal surfaces of the upper respiratory tract and the eyes. Leprosy is known to occur at all ages, from early infancy to advanced old age. It is curable with multidrug therapy (MDT) and treatment administered in the early stages can prevent disability. Untreated, leprosy can cause progressive and permanent damage to the skin, nerves, limbs and eyes.

Despite the available treatment, more than 200 000 new leprosy patients were diagnosed globally in 2019, with more than 120 countries reporting cases (including non-autochthonous cases); 80% of the burden is in India, Brazil and Indonesia. Early case detection is important to help contain the spread of infection and prevent disabilities.

2. Public health response

Leprosy is an age-old disease, described in the literature of ancient civilizations. Throughout history, people afflicted by leprosy have often been ostracized by their communities and families. The first treatment for leprosy became available in the 1940s with the development of dapsone. In the 1960s, however, *M. leprae* started to develop resistance to this medicine. In the early 1960s, rifampicin and clofazimine were discovered and were added to the treatment regimen, which was labelled MDT. In 1981, WHO recommended that all patients be treated with MDT. The currently recommended MDT regimen consists of dapsone, rifampicin and clofazimine for multibacillary (MB) cases, whereas treatment for paucibacillary (PB) comprises only dapsone and rifampicin. The treatment lasts for 12 months for MB and 6 months for PB. MDT kills the pathogen, thereby curing the patient.

In the new WHO road map for neglected tropical diseases for 2021–2030 ("the road map"), leprosy is targeted for elimination (interruption of *M. leprae* transmission). The following critical actions, among others, are required to reach the 2030 targets for leprosy:

- Update country guidelines to include use of single-dose rifampicin for post-exposure prophylaxis (PEP) for contacts; advance research on new preventive approaches.
- Continue investment into research for diagnostics for disease and infection; develop surveillance strategies, systems and guidelines for case-finding and treatment; ensure resources for validation.
- Ensure medicines supply, including access to MDT, prophylactic drugs, single-dose rifampicin, second-line treatments and medicines to treat reactions; monitor adverse events (pharmacovigilance) and resistance to antibiotics.

3. Available diagnostic tools

Leprosy is classified as Paucibacillary (PB) or Multibacillary (MB), based on the number of skin lesions, the presence of nerve involvement and the identification of bacilli in slit-skin smear. The WHO guidelines for the diagnosis, treatment and prevention of leprosy[1] recommend no further tests in addition to standard methods for diagnosis of leprosy. The diagnosis is based on the presence of at least one of three cardinal signs: these are:

(i) definite loss of sensation in a pale (hypopigmented) or reddish skin patch;

(ii) thickened or enlarged peripheral nerve with loss of sensation and/or weakness of the muscles supplied by that nerve;

(iii) presence of acid-fast bacilli in a slit-skin smear.

With the dwindling clinical expertise in leprosy, clinical diagnosis of indeterminate, pure neuritic and certain cases of PB and MB leprosy with confusing clinical signs can be challenging. Therefore, a number of point-of-care and laboratory assays have been developed and tested in various patient and control groups to supplement clinical diagnostic methods. These assays encompass both direct (pathogen) and indirect (host response) detection of the disease, utilizing various technologies such as enzyme-linked immunosorbent assays (ELISA), lateral flow assays (LFA) and polymerase chain reaction (PCR)-based assays. However, most of the currently developed tools are only of research grade and are not available commercially for broad use in clinical settings. Additionally, some of these tools face various challenges such as: low diagnostic accuracy for PB leprosy, lack of standardization and high level of complexity/ needed instrumentation for most primary health-care settings.

To date, only a few leprosy diagnostic assays detecting *M. leprae,* or immune responses to it, are authorized for *in-vitro* diagnostic use and are commercially available. Hain Lifescience GmbH (Nehren, Germany) has a test system for the identification of *M. leprae* and its resistance to rifampicin, ofloxacin and dapsone. GenoType LepraeDR, a PCR-based DNA strip technology, requires three separate instruments; as such, it is not suitable for use in low-resource settings.

OrangeLife (Rio de Janeiro, Brazil), in collaboration with the Infectious Disease Research Institute (Seattle, USA) has developed a qualitative LFA to detect *M. leprae* specific IgM antibodies against PGL-1 and IgG antibodies to LID-1. CTK Biotech (San Diego, USA) has developed qualitative GOLD-LFA, utilizing the same antigens as OrangeLife. However, both of these assays are for research use only and may no longer be available at this time.

Once appropriate diagnostic tools are developed, it would be imperative to ensure that products stay on the market, as efforts to eliminate leprosy would be hampered if tests are not maintained. Mechanisms to secure commitment from vendors should be explored.

4. WHO Diagnostic Technical Advisory Group for Neglected Tropical Diseases

The WHO Department of Control of Neglected Tropical Diseases (WHO/NTD) 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 Strategic and Technical Advisory Group for Neglected Tropical Diseases, the principal advisory group to WHO for the control, elimination and eradication of

[1] Guidelines for the diagnosis, treatment and prevention of leprosy. New Delhi: World Health Organization Regional Office for South-East Asia; 2018 (https://apps.who.int/iris/handle/10665/274127, accessed 9 May 2022).

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.

The Diagnostic Technical Advisory Group (DTAG) was thus formed as an advisory group to WHO/NTD. At its inaugural meeting (30–31 October 2019, Geneva, Switzerland), DTAG members 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 on the understanding that they would be reviewed at the next meeting, as it had been made clear that all NTDs had diagnostic needs which would have to be addressed in due course.

The diagnostic needs for leprosy, as determined by the DTAG, are:

- detection of *M. leprae* infection – to provide prophylaxis to those most at risk;
- screening for potential leprosy cases – to better identify individuals with suggestive signs of leprosy;
- diagnosis of leprosy – to confirm diagnosis of all forms of leprosy (especially indeterminate and PB leprosy);
- prediction of future disease - to identify those at risk of disability; and
- diagnosis of nerve function loss – to recognize early nerve function changes that can lead to sensorimotor neuropathy associated with leprosy.

5. WHO Technical Advisory Group on Leprosy

At its 17th meeting, the WHO Technical Advisory Group on Leprosy (TAG-Leprosy) discussed topics related to *M. lepromatosis*, zoonotic leprosy, environmental sources of *M. leprae* and target product profiles (TPPs) related to diagnostics. Further research was recommended in the following areas:

- researchers to find a reliable diagnostic test/tests for confirming leprosy in symptomatic as well as asymptomatic individuals (e.g., household contacts);
- more epidemiological and bacteriological research studies to understand the role of *M. lepromatosis* in transmission of infection;
- more studies to understand the extent of zoonotic transmission to humans caused by infected animals and its spread among animals; and
- further research studies on environmental sources of *M. leprae* and their role in transmission of infection.

The TAG-Leprosy also recommended the development of two TPPs for tests to assess bacteriological cure and to assess infection levels in the community to assist in ascertaining interruption of transmission.

6. Purpose of the Target product profile (TPP)

As the number of leprosy cases is reducing, so too is the clinical expertise even in endemic countries. This often leads to delay or misdiagnosis and delayed initiation of MDT. Early detection and treatment of leprosy are important to prevent disability but may also aid in breaking the transmission chain.

As identified in both the road map and the DTAG meeting report, a test confirming (or ruling out) leprosy of all types, including indeterminate and PB leprosy, is of high priority. The purpose of this TPP is to guide the development of a tool that can be used at all health-care levels where MDT is prescribed, to aid health-care providers in deciding when to initiate treatment. The clinical validation of such a test should take into account performance requirements for the entire spectrum of leprosy, including manifestations with low levels of bacilli. Although ideally such a test would be available as a point-of-care test, it is recognized that to reach the required sensitivity and specificity, laboratory-based testing might be required.

The TPP target performance characteristics were modelled to reduce health-care provider delays in diagnosis as a function of diagnostic performance. In the modelling, prevalence of leprosy in tested populations assumed endemicity levels similar to household contacts, as this would be the most likely group to seek medical consultation. It was observed through modelling that, to have a meaningful impact on reduction on time to diagnosis, very high stringency around specificity is required. It is of note that in cases where performance requirements are high and cannot be met with a single test, a combined, two-step test approach may be used to achieve the required testing specificity.

7. Audiences engaged and external consultations to develop the diagnostic TPP

To initiate the development of a diagnostic TPP for leprosy, Dr Sundeep Chaitanya Vedithi and Dr Petra Kukkaro identified priority areas and consulted a group of experts under the Leprosy Diagnostic Working Group of the Global Partnership for Zero Leprosy. The Working Group brought together experts in laboratory science, clinical aspects of leprosy and representatives from stakeholder groups in the leprosy community. After discussions with the Group, a TPP was drafted by Mr Christopher Hanna, Dr Sundeep Chaitanya Vedithi and Dr Petra Kukkaro. The draft was reviewed by members of the Working Group and submitted to the DTAG chair, Dr Patrick Lammie, for comments before finalization and posting on the WHO website for public consultation (30 November to 20 December 2021). In addition to the public online consultation, the TAG-Leprosy also reviewed the TPP, provided comments and made suggestions on use case narratives for incorporation by the Working Group chairs Dr Sundeep Chaitanya Vedithi and Dr Petra Kukkaro. The final document was reviewed by the DTAG subgroup chair on skin NTDs, Dr Isra Cruz, and a WHO staff representative, Dr Pemmaraju Ranganatha Rao.

TPP for a diagnostic test to confirm leprosy in individuals with clinical signs and symptoms

1. Product use summary	Minimum	Ideal	Background, annotation re requirement risk, etc.
1.1 Intended use	A laboratory-based test for the detection of analyte specific to *M. leprae* (and *M. lepromatosis* in ideal cases) for the purposes of providing confirmation (or elimination) of clinical leprosy.	A point-of-care test for the detection of analyte specific to *M. leprae* (and *M. lepromatosis* in ideal cases) for the purposes of providing confirmation (or elimination) of clinical leprosy.	"Clinical leprosy" is characterized by individuals infected with *M. leprae* or *M. lepromatosis* who have any stage of the disease within the clinical leprosy spectrum, namely: **paucibacillary (PB)**, which includes: · tuberculoid (TT), · borderline tuberculoid (BT), · indeterminate (I) and · pure neuritic (PN) leprosy and **multibacillary (MB)**, which includes: · mid-borderline (BB), · borderline lepromatous (BL) and · lepromatous (LL) leprosy.
1.2 Targeted population	All age groups.	All age groups.	
1.3 Lowest infrastructure level	For a laboratory-based test, tests can be performed in a peripheral health facility/referral centre, primary care centres, tertiary care leprosy centres, regional or national diagnostic testing laboratory.	For a point-of-care test, the test will be performed under "zero-infrastructure" conditions including but not limited to schools, community health centres, ad hoc "skin camps", *plus* the locations for "minimum" 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, 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).	For a point-of-care test, one day or less 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 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); 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.	"For "minimum", the laboratory-based test will need to function with samples that have been collected up to 1 day prior. For "ideal", "portability" implies those characteristics described in 2.2–2.4 as well as no locational limitations 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	Capillary blood from finger stick, venous blood draw, collected urine, nasal swab, slit skin smears (SSS) and punch biopsies *if* the punch biopsy format allows for sub-millimetre biopsies.	Capillary blood from finger stick, collected urine or nasal swab.	"Ideal" differs from "Minimum" by elimination of SSS and punch biopsy sampling and venous blood draw. NOTE: Nasal swabs (or any other sample type) must be shown to generate results for current infection and not colonization.
2.6 Sample preparation/ transfer device	· Sample preparation should not exceed transfer of blood (capillary finger stick or venous draw), serum (from centrifuged venous blood for *lab-based tests*), collected urine, nasal swab, SSS or punch biopsy to a sample processing tube holding no more than 500 µL of extraction/ processing buffer, which is then 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 capillary finger stick blood or urine should not exceed transfer of sample to the testing device. · Sample preparation for nasal swab should not exceed transfer of nasal swab to a sample processing tube holding no more than 500 µL of extraction buffer, which is then transferred to the testing device after a defined duration. · 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 SSS and punch biopsy sampling and venous blood draw.

2.7 Sample volume	<100 uL	<10 µL	"Sample volume" represents the *volume introduced* to the test device itself; the *collected* sample volume may be larger than this.
2.8 Target analyte	Biomarker(s) specific for infection with *M. leprae*.	Biomarker(s) specific for infection with *M. leprae* and *M. lepromatosis*.	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 infection with *M. leprae* or *M. lepromatosis* in all age groups. Ab-based serology biomarkers may possess half-life kinetics that enable determination of prior infection from *M. leprae* or *M. lepromatosis*, but their half-life may preclude their use as markers of current infection or immune status. In addition, in all cases the biomarker applied must also consider the dependency on the sample type used. Even if other markers are discovered and proposed, their qualification and validation will require significant time and effort going forward. For this reason, this is a **high-risk** requirement.
2.9 Type of analysis	Semi-quantitative for determining bacilli load or immune status.	Quantitative for determining bacilli load or immune status.	· The ability to detect current *M. leprae* infections (and *M. lepromatosis* in "Ideal" situations) shall be independent of bacterial load/index. · Ultimate decision on treatment regimen will be based upon confirming leprosy infection and bacilli load with the test (assuming the infection is not yet cleared) or immune status combined with clinical evaluation; regimens are determined through consultation of the relevant leprosy treatment guidelines.
2.10 Detection	For laboratory-based tests, may include instrument-based detection of a signal that provides unambiguous determination of a semi-quantitative or quantitative measure.	For point-of-care tests, results shall be a high contrast, clear result for the naked eye; indoor and outdoor reading of a signal that provides an unambiguous semi-quantitative or quantitative result without the need for colour discrimination.	

2.11 Quality control	· Exogenous process control indicator (e.g. control line on a rapid diagnostic test (RDT), control well in an enzyme-linked immunosorbent assay (ELISA).	· Exogenous process control indicator (e.g. control line on an RDT, control well in an ELISA) · Colorimetric or other indicator to identify excessive heat/humidity exposure of the test kits	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, with minimal import restrictions (e.g., animal-free, reagents free from toxicity levels that trigger import restrictions).	All reagents and supplies included in test kit, with minimal import restrictions (e.g., animal-free, reagents free from toxicity levels that trigger import restrictions).	Assumed that all materials are included, but does not include sample collection devices.
2.13 Safety	Normal use does not create any additional hazards to the operator when observing Universal Blood Safety/ Body Fluid precautions.	Normal use 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	*M. leprae*	*M. leprae* and *M. lepromatosis*	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): · There should be particular focus to ensure no interference from other mycobacteria. · Due to co-endemicity of other mycobacteria (e.g. *M. tuberculosis*) as well as strong similarities in clinical presentation with other co-endemic skin diseases (e.g. post-kala-azar dermal leishmaniasis, which contributes to overall specificity), this is considered a **high-risk** requirement, i.e. the inherent challenges in meeting this requirement relative to current practices must be targeted and addressed to ensure the test's success.
3.2 Diagnostic/ clinical sensitivity	.≥ 90%	.≥ 90%	*Assumptions made for diagnostic performance modelling* · Modelled the effect of reducing health-care provider delays in diagnosis as a function of diagnostic performance. · Examined the effect of changing both sensitivity and specificity on the odds ratio surrounding the impact of diagnostic delay on the development of disability. In addition, the effect of changing both sensitivity and specificity on negative predictive value and positive predictive value for a range of new case prevalences among index case household contacts was also evaluated. · "Minimum" assumes a high-endemicity setting where the new case detection rates within household contacts of index cases are estimated to be 5%, while "ideal" assumes a low-endemicity setting where this same new case detection rate is 0.5%. NOTE: Validation of these performance requirements must take into consideration the presence of both MB *and* PB cases.
3.3 Diagnostic/ clinical specificity	.≥ 99%	.≥ 99.9%	*Assumptions made for diagnostic performance modelling* · Same as above. · This is considered a **high-risk** requirement, i.e. the inherent challenges in meeting this requirement relative to current practices must be targeted and addressed to ensure the test's success.

3.4 Time to results	< 4 h to developed test result	< 0.5 hour to developed test result	This requirement relates to the analysis of a sample with the test itself and *does not include* any additional time associated with sample collection, sample transport and storage, etc., which will vary considerably between test use conditions.
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.
3.6 Throughput	For laboratory-based tests, ≥ 100 tests/day per tester.	For field-based tests, ≥ 10 tests/h per tester.	"Throughput" represents how many tests can be run within an hour/day by one person and is *separate from* the time to results. NOTE: These throughput requirements *do not* infer that testing must be batched in all circumstances. As just one example, an ELISA-based test should not require the running of all 96 wells within a plate, so designs should consider flexibility when running tests, e.g. having 8-well strips as part of a 96-well plate design.
3.7 Target shelf-life/ stability	≥ 18 months, 4–40 °C, 75% relative humidity (RH); temperature excursion/prolonged deviation of 50 °C for 2 weeks acceptable.	≥ 24 months, 4–40 °C, 75% RH; temperature excursion/prolonged deviation of 50 °C for 2 weeks acceptable.	Requirements relate to test kits (i.e. consumables, whether point-of-care tests or specimen collection kits for laboratory-based testing) that are *used in the field*. NOTE: consumables *used in a laboratory* for laboratory-based testing procedures *may* require a cold chain.
3.8 Ease of use	For laboratory-based tests, ≤ 5 timed steps; ≤ 15 user steps, instructions for use should include diagram of method and results interpretation.	≤ 1 timed step; ≤ 5 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.	This is in relation to the test operation *only* and does not refer to sampling steps, sample storage steps, etc.
3.9 Ease of results interpretation	For laboratory-based tests, results can be definitively interpreted by a suitable instrument that meets requirements defined in 2.10 "Minimum".	For point-of-care tests, a definitively interpreted result is achieved by meeting requirements defined in 2.10 "Ideal".	
3.10 Operating temperature	20–40 °C, 75% RH	15–40 °C, 75% RH	

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.	
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. · Daily throughput needs are considered in the packaging so as to minimize the need to dispose of extraneous product waste.	
4.5 Labelling and instructions for use (IFUs)	Compliance required per relevant CE Mark/In Vitro Diagnostic Regulation (IVDR) requirements (or other SRA, e.g. 21 CFR 820) 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.	Compliance required per relevant CE Mark/IVDR requirements (or other SRA, e.g. 21 CFR 820) 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 prequalification 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 Target launch countries	Countries with areas endemic for leprosy	Countries with areas endemic for leprosy	
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. from Korean Ministry of Food and Drug Safety) · WHO prequalification, *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. from Korean Ministry of Food and Drug Safety) · WHO prequalification, *if required/applicable* · Country-level registration (if required/applicable for target countries)	Need to confirm the relevant product registration pathways with DTAG.

Neglected tropical diseases
World Health Organization
20 Avenue Appia
1211 Geneva 27
Switzerland

neglected.diseases@who.int

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

9789240073739