TARGET PRODUCT PROFILE

for a diagnostic test to detect *Mycobacterium leprae* infection among asymptomatic household and familial contacts of leprosy patients

World Health Organization

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Contents

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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 in the constitute a conflict of interest.

1. Epidemiology

Leprosy remains a significant health problem in endemic tropical countries where about 200,000 new cases are reported annually from more than 155 WHO Member States and territories. The stable incidence rates during the past 15 years and the occurrence of about 10% of paediatric cases among newly detected leprosy cases annually indicate ongoing transmission of the disease in endemic countries. Leprosy is caused by an obligate intracellular bacilli, *Mycobacterium leprae* and, in some cases, by *Mycobacterium lepromatosis*. Transmission of leprosy bacilli is poorly understood, and existing evidence suggests that inhalation of aerosols containing *M. leprae* is the main route of transmission. In some circumstances, skin-to-skin contact has also been implicated in transmission. To date, there is no conclusive evidence that the shedding of bacteria into the environment by an active case can lead to subsequent infection of individuals.

Owing to the chronicity of *M. leprae* infection, individuals in close contact with leprosy cases may harbour infection before clinical signs appear. During this latent period, infection without any clinical signs can eventually progress towards manifesting overt clinical signs and symptoms of leprosy. Limited evidence suggests that subclinically infected individuals may transmit *M. leprae* to other individuals in close physical contact. Those at highest risk are household and family contacts. Hence it is vital to detect *M. leprae* infection primarily in the household and among familial contacts of leprosy cases in order to determine individuals who require an enhanced regimen of post-exposure prophylaxis (PEP) and to prevent *M. leprae* transmission.

In the new WHO road map for neglected tropical diseases 2021–2030 ("the road map"), leprosy is targeted for elimination (interruption of *M. leprae* transmission). Guidelines for contact tracing and interrupting transmission with appropriate prophylactic interventions have also been developed. However, the precise mechanisms of action of these interventions have not yet been studied, and the long-term consequences of the interventions are not known.

2. Public health response

Research and field observations indicate that the risk of developing leprosy is significantly higher among household and familial contacts of leprosy cases than among individuals with no known contact with leprosy cases. With the stable incidence rates, it is clear that passive case detection and treatment with multidrug therapy (MDT) alone cannot interrupt ongoing transmission of the disease.

Large-scale clinical trials with single-dose rifampicin (SDR) given as PEP to contacts of newly diagnosed patients with leprosy have shown a 50–60% reduction in the risk of developing leprosy among these contacts over the following 2 years. Leprosy PEP is now being introduced into national programmes. In 2020, WHO published technical guidance for implementation of contact tracing and PEP. [1] With a view to administering more efficacious PEP against leprosy, the road map identifies the following critical actions, among others, required to achieve the 2030 targets:

- 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; and
- ensure resources for validation.

[1] Leprosy/Hansen disease: contact tracing and post-exposure prophylaxis. New Delhi: World Health Organization Regional Office for South-East Asia; 2020 (https://apps.who.int/iris/handle/10665/336679, accessed 9 May 2022).

The WHO technical guidance provides information on the importance of active case detection and contact examination, the efficacy of chemoprophylaxis, and the feasibility and acceptability of chemoprophylaxis. A diagnostic test that can help to identify high-risk individuals with *M. leprae* infection who require an enhanced PEP regimen than just SDR-PEP will assist in planning and implementing various PEP interventions and can contribute to interrupting *M. leprae* transmission.

3. Available diagnostic tools

Research has produced many leads in terms of molecular and immunodiagnostics for *M. leprae* infection. A molecular or immunodiagnostic test that can detect *M. leprae* infection may aid in identifying individuals who require an enhanced PEP regimen rather than just SDR-PEP in order to prevent progression to overt disease and consequent disability. Additionally, tests for confirmatory diagnosis of leprosy (and classification thereof) in individuals with limited clinical signs as well as tests for pre- and post-elimination surveillance to ascertain if transmission has been interrupted, are required.

Antibodies against *M. leprae* cell-wall components have been extensively studied with the goal of developing immunodiagnostics for leprosy for more than three decades. Antibodies against the antigenic part of the *M. leprae*-specific phenolic glycolipid molecule (PGL-I) were detected in many populations in areas endemic for leprosy. Despite the presence of PGL-I antibodies in more than 50% of individuals in hyperendemic areas, the majority of those with a positive antibody titre never develop leprosy, as noted from various prospective cohort studies.

Similarly, *M. leprae* nucleic acids were detected with varying sensitivity across multibacillary and paucibacillary leprosy cases and even in household contacts, paving a way for the development of more precise molecular detection tools. Many studies identified highly specific and repetitive elements in the genome of *M. leprae* as suitable DNA targets for molecular diagnostics.

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 Leprae DR, a PCR-based DNA strip technology, requires three separate instruments; as such, is not suitable for use in low-resource settings.

Orange Life (Rio de Janeiro, Brazil), in collaboration with the Infectious Disease Research Institute (Seattle, USA), has developed a qualitative lateral flow assay (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 Orange Life. However, both of these assays are for research use only and may no longer be available at this time.

Development and implementation of point-of-care, field-friendly diagnostic tests to detect *M. leprae* infection therefore require concerted efforts between technology developers and field/programme-level implementing partners.

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 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 WHO 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* (and *M. lepromatosis* in ideal cases) 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 paucibacillary 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)

Prior to attracting developers and companies to invest in producing innovative diagnostics for leprosy, a TPP is essential to recognize and document gaps, priority areas for diagnostics, use cases, needs statements and requirements for ideal and optimal test scenarios for each of these priority areas.

The Leprosy Diagnostic Working Group of the Global Partnership for Zero Leprosy, in partnership with DTAG and in technical consultation with the Bill & Melinda Gates Foundation, developed this TPP using existing technical and modelling resources to pave a way for a future with effective diagnostics for leprosy.

A point-of-care, field-friendly diagnostic tool is required to detect infection with *M. leprae* (and *M. lepromatosis* in ideal cases) among contacts of leprosy cases, especially those who are household or blood-related contacts. Such a diagnostic can detect *M. leprae* and *M. lepromatosis* infection at subclinical stage, enabling programmes to intervene with appropriate chemoprophylactic or immunoprophylactic tools to prevent progression to clinical leprosy and curb transmission. However, if clinical leprosy is suspected, the individual should move into an appropriate diagnostic pathway to determine the need for MDT. Given the expansion of PEP interventions in countries endemic for leprosy, a guiding diagnostic tool is essential to decide on those individuals needing enhanced PEP interventions as well as to monitor the effect/efficiency of the intervention at an individual level. This TPP was developed with a view to defining the ideal and optimal characteristics of the diagnostics that will be used to detect *M. leprae* and *M. lepromatosis* infection among household and familial contacts of leprosy cases.

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 draft TPP was developed 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 online public 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 detect *Mycobacterium leprae* infection among asymptomatic household and familial contacts of leprosy patients

1. Product use summary	**Minimum**	**Ideal**	**Background, annotation re requirement risk, etc.**
1.1 Intended use	A point-of-care test for the detection of analyte specific to *M. leprae* or host response to *M. leprae* to enable detection of subclinical *M. leprae* infections.	A point-of-care test for the detection of analyte specific to *M. leprae* and *M. lepromatosis* or host response to *M. leprae* and *M. lepromatosis* to enable detection of subclinical *M. leprae* and *M. lepromatosis* infections.	"Subclinical infections" are characterized by asymptomatic individuals infected with *M. leprae* or *M. lepromatosis* for whom the infection can either progress to an overt disease or may resolve without causing any symptoms.
1.2 Targeted population	All ages of family and household contacts of confirmed leprosy cases.	All ages of family and household contacts of confirmed leprosy cases.	In some situations, might also expand to community contacts if the ring around a patient is defined.
1.3 Lowest infrastructure level	The test will be performed under "zero-infrastructure" conditions including but not limited to households, community health centres and, potentially, outdoor conditions..	The test will be performed under "zero-infrastructure" conditions including but not limited to households, community health centres and, potentially, outdoor conditions.	"Zero infrastructure' conditions are those where no prior requirements must be fulfilled for proper operation of the test.
1.4 Lowest level user	This test will be performed by health personnel, community health workers and community volunteers.	For a point-of-care test, the test will be performed by health personnel, community health workers and community volunteers.	
1.5 Training requirements	One day or less for health personnel, community health workers and community volunteers; testing job aid/instructions for use should be made available via the Internet for download (i.e. are publicly available).	One day or less for health personnel, community health workers and community volunteers; 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	Highly portable with no specialized transport needs.	Highly portable with no specialized transport needs.	"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	Self-contained kit operates independent of any mains power.	Self-contained kit operates independent of any mains power.	
2.3 Water requirement	Self-contained kit operates independent of any water supply.	Self-contained kit operates independent of any water supply.	

2.4 Maintenance and calibration	Any "field-friendly" equipment used for the test (e.g. sample incubator, reader) that allows for and meets other TPP requirements must require minimal maintenance and/or calibration (e.g. via return to manufacturer, running a standard).	No maintenance required (i.e. disposable) and no calibration required.	Any "field-friendly" equipment used for the test (e.g. incubator, reader) that allows for and meets other TPP requirements must be maintained and/or calibrated via return to manufacturer.
2.5 Sample type/ collection	Capillary blood from finger stick, venous blood draw, collected urine, nasal swab or slit skin smears (SSS).	Capillary blood from finger stick, collected urine or nasal swab.	"Ideal" differs from "Minimum" by elimination of SSS sampling and venous blood draw.
2.6 Sample preparation/ transfer device	· Sample preparation should not exceed transfer of blood (capillary finger stick or venous draw), collected urine, nasal swab or SSS 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 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 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 current subclinical infection with *M. leprae*.	Biomarker(s) specific for *current* subclinical 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 favorable half-life kinetics and thus enable more accurate determination of *current* subclinical 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. 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	Qualitative	Quantitative	The ability to detect current *M. leprae* or *M. lepromatosis* infections shall be independent of bacterial load/index.
2.10 Detection	High contrast, clear result for the naked eye; indoor and outdoor reading of a signal that provides a definitive result without the need for color discrimination.	High contrast, clear result for the naked eye; indoor and outdoor reading of a signal that provides a definitive result without the need for color discrimination.	
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, 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, including sample collection devices.
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	*M. leprae*	*M. leprae* and *M. lepromatosis*	· 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	.≥ 81%	.≥ 94%	*Assumptions made for diagnostic performance modelling in SIMCOLEP* · Contacts of an index patient are traced, screened and tested, which includes household contacts and four additional neighbouring households for an "Ideal" scenario (which accounts for SDR PEP interventions), whereas only household contacts are screened for a "Minimum" scenario. · After screening for clinical leprosy and initiation of multi-drug therapy, the remaining contacts are tested for infection; those who are positive receive enhanced PEP. In the "Ideal" scenario, those who are negative receive SDR, whereas in the "Minimum" scenario those who are negative receive no treatment. · Endemicity assumed to be "high", i.e. 30 per 100 000. · 75% reduction assumed after 12 years since the intervention in the "Ideal" scenario, whereas 75% reduction assumed after 13 years in the "Minimum" scenario. · Both "Minimum" and "Ideal" conditions assume 90% effectiveness of enhanced PEP.
3.3 Diagnostic/ clinical specificity	≥ 99.5%	≥ 99.9%	*Assumptions made for diagnostic performance modelling in SIMCOLEP* · 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	< 2 h to developed test result	< 0.5 h 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 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	≥ 7 individuals tested/h per tester	≥ 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	≥18 months, 2–40 °C, 75% relative humidity (no cold chain required); temperature excursion/prolonged deviation of 50 °C for 2 weeks acceptable.	≥ 24 months, 2–40 °C, 75% relative humidity (no cold chain required); temperature excursion/prolonged deviation of 50 °C for 2 weeks acceptable.	
3.8 Ease of use	≤ 2 timed steps; ≤ 8 user steps, instructions for use should include diagram of method and interpretation of results. Must be able to use in an unprotected external environment.	≤ 1 timed step; ≤ 5 user steps, instructions for use should include diagram of method and interpretation of results. 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	Should provide a definitive "yes/no" result achieved by meeting requirement defined in 2.10.	Should provide a definitive "yes/no" result achieved by meeting requirement defined in 2.10.	
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	Conformance to applicable requirements of ASTM D4169-05 and ISO 11607-1:2006 (or equivalent); no cold-chain shipping required.	Conformance to applicable requirements of ASTM D4169-05 and ISO 11607-1:2006 (or equivalent); no cold-chain shipping required.	
4.2 Storage conditions	Ambient storage conditions, 2–40 °C; no cold storage required.	Ambient storage conditions, 2–40 °C; no cold storage required.	
4.3 Service and support	None required.	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 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/In Vitro Diagnostic Regulation 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	< US$ 2000	< US$ 2000	
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 leprosy contact tracing and PEP administration programmes.	All areas endemic for leprosy	
5.5 Product registration (i.e. substantiation to regulatory body of product claims)	· CE Mark/In Vitro Diagnostic Regulation (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/In Vitro Diagnostic Regulation (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.

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