



## DEFINING PRODUCT NEEDS: PERFORMANCE REQUIREMENTS

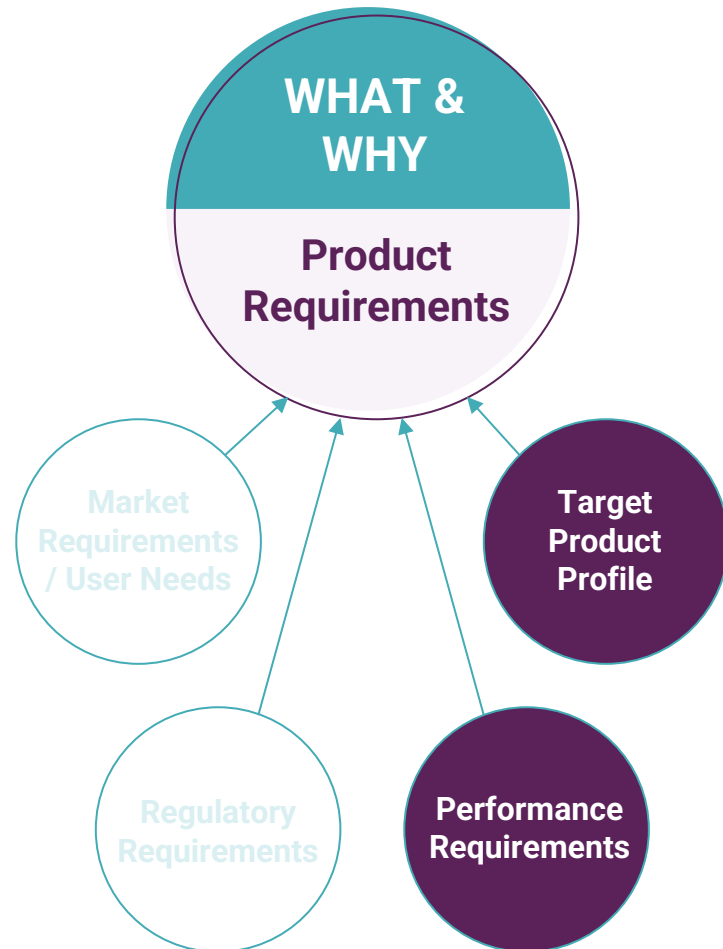
◆ Olga Ordeig



# TOPICS

- 1 Performance Requirements
- 2 Target Product Profile for Diagnostics: what is it, who does it and how to use it
- 3 Target Product Profile vs Product Requirement Document
- 4 Other resources

# PRODUCT REQUIREMENTS



Examples of relevant categories/aspects for product requirements consideration:

<b>Market Need</b> Why is the product needed?	<b>Intended Use</b> Purpose of your device What the test does / how it works	<b>Indications for Use</b> Circumstances under which the test will be used
<b>Target Markets</b> Where is the test going to be sold?	<b>Procurement</b> Who will buy the product?	<b>Target Settings</b> Where the test will be used?
<b>Target Analyte</b> Which analyte to test?	<b>Specimen Type</b> (e.g. swap, urine, blood...)	<b>Analytical &amp; Clinical Performance</b> (e.g. LoD, sen., spe.)
<b>Operational Characteristics</b> (e.g. shelf life, stability)	<b>Test Format</b> (e.g. LFT, strip, ELISA)	<b>Target COGs</b> What is the target cost?
<b>Device Classification</b> Based on Risk associated with Intended Use of test	<b>Waste Management</b> Test disposal after use	<b>Digital / Connectivity</b> Data storage, sharing...

# PERFORMANCE / OPERATIONAL REQUIREMENTS

Analytical & Clinical Performance	Test Procedure	Operational Characteristics	Instrument/reader characteristics
<ul style="list-style-type: none"> <li>Clinical sensitivity</li> <li>Clinical specificity</li> <li>Limit of detection</li> <li>Assay interference</li> <li>Cross-reactivity</li> <li>Test failure (invalid) rate</li> <li>Precision: Repeatability</li> <li>Precision: Reproducibility</li> </ul>	<ul style="list-style-type: none"> <li>Sample preparation</li> <li>Specimen collection</li> <li>Sample volume</li> <li>Test kit components</li> <li>User training</li> <li>Ease of use</li> <li>Sample-to-result time</li> <li>Stability valid result</li> </ul>	<ul style="list-style-type: none"> <li>Shelf Life</li> <li>Storage conditions</li> <li>Open test kit stability</li> <li>Operating range</li> <li>Shipping and transport conditions</li> <li>Biosafety</li> <li>Waste disposal</li> </ul>	<ul style="list-style-type: none"> <li>Size (W x H x B)</li> <li>Weight</li> <li>Power requirements</li> <li>Connectivity</li> <li>Data Export</li> <li>Service, maintenance</li> <li>Results processing</li> </ul>

# TARGET PRODUCT PROFILE (TPP) FOR DIAGNOSTICS

## WHAT IS IT?

Requirement documents for **products that are currently not available** on the market but that fulfil a priority need **in the context of Global Health**.

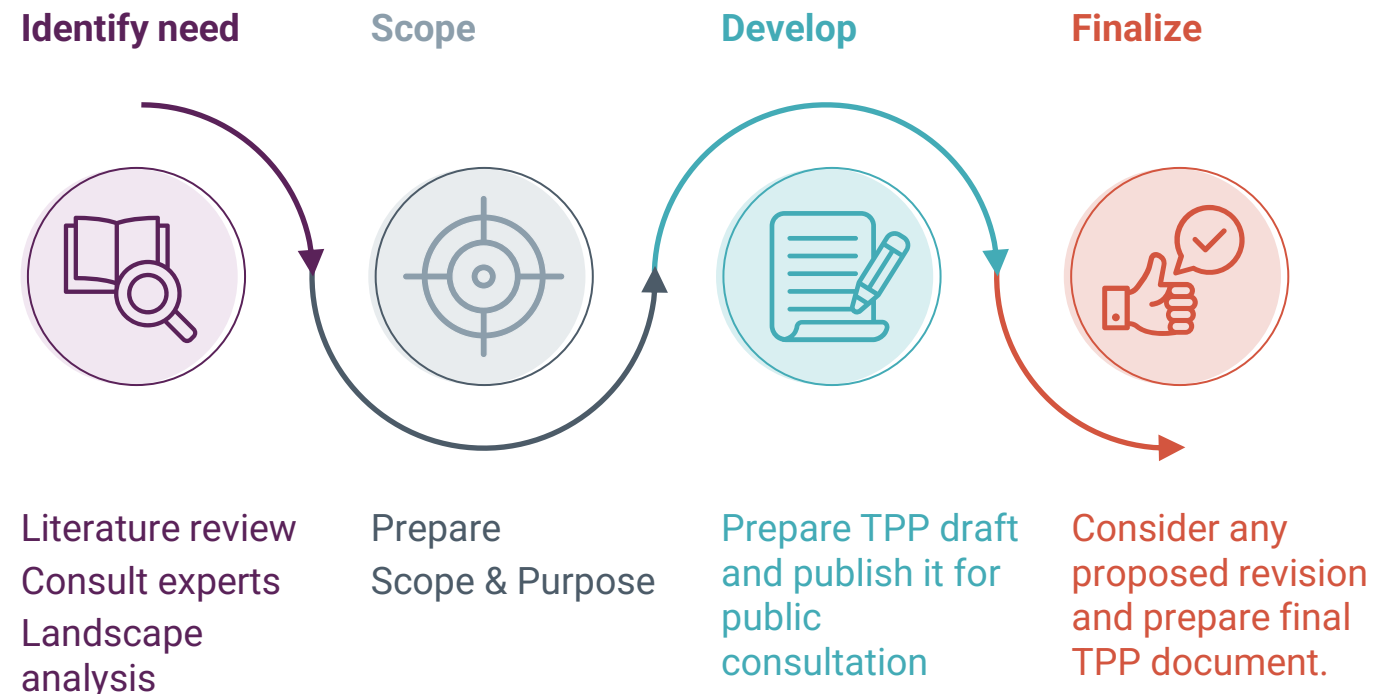
All TPPs are publicly available.

## WHAT ARE USED FOR?

To ensure that R&D activities are **focused on relevant products** and designed for the contexts and needs of end-users by researchers, developers and manufacturers.

## HOW IS DONE?

It is a **consensus-based document** created by a large and diverse group of experts submitted to public consultation.



# TARGET PRODUCT PROFILE (TPP) FOR DIAGNOSTICS

## WHO DEVELOPS TPPs?

### World Health Organization (WHO):

A target product profile authored by WHO indicates that the organization determines there is a significant unmet health need for the product in question, and the product profile preferences promote the development of products with high public health impact and suitable for use in low to middle-income countries.

<https://www.who.int/tools/target-product-profile-database>

### Non-World Health Organization (WHO):

Several public health-oriented funders develop their own TPPs (e.g. UNICEF, PATH, GAVI, MSF, FIND, etc.) to fulfil needs in the context in which they operate.

## FIND TPP

FIND created **+40 TPPs** in close collaboration with WHO, for diagnostic tools for poverty-related diseases.

<https://www.finddx.org/tools-and-resources/rd-and-innovation/target-product-profiles/>

# TARGET PRODUCT PROFILE (TPP) FOR DIAGNOSTICS

## TPP KEY ELEMENTS:

- Intended use
- Target populations
- Performance (minimum and optimal)
- Operational characteristics (minimum and optimal)
- Costs (minimum and optimal)
- Regulatory pathway

## EXAMPLE

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Target Product Profiles for improved antimicrobial stewardship for gonococcal infection

# EXAMPLE

## N. GONORRHOEAE RDT

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### Target Product Profiles for improved antimicrobial stewardship for gonococcal infection

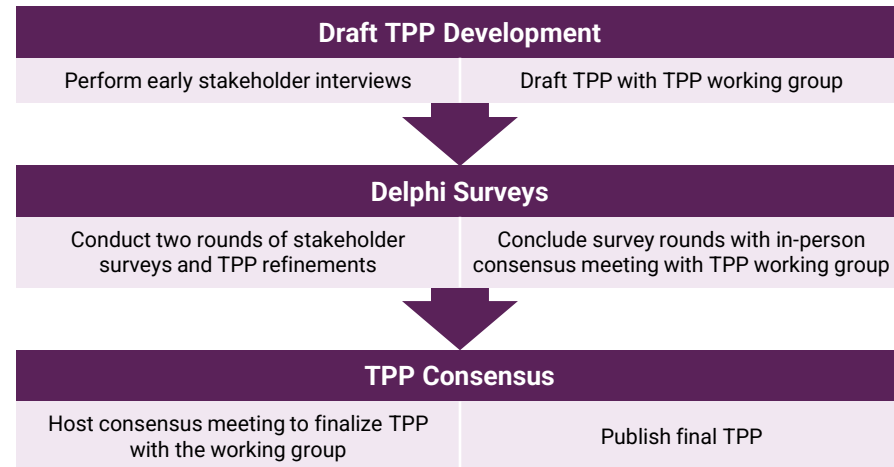





Figure 3: TPP development process

Characteristic	Minimal requirement	Optimal requirement
Scope of test		
 <b>Intended use</b>	To detect <i>Neisseria gonorrhoeae</i> (NG) only or NG and <i>Chlamydia trachomatis</i> (CT) infection to improve patient management and facilitate appropriate antibiotic use	Same as minimal, plus to assist in screening to identify previously undetected NG or NG and CT infections
 <b>Target use setting</b>	Primary health care setting including health posts (Level 1); to be used after initial clinical evaluation (referring to Step 2 in the WHO vaginal/urethral discharge flowchart) to guide treatment decision	
 <b>Test format / Equipment</b>	A non-instrumented, single-use, disposable diagnostic test preferred; ideally no additional power required for operation, but if required, batter power with 8-hour operation between charges Reader optional and only appropriate if its inclusion supports enhanced test performance	
Performance characteristics		
<b>Clinical sensitivity to predict resistance</b>	>80% required to achieve the minimal intended use for a non-molecular test >95% required to achieve the minimal intended use for a molecular test	>90% required to achieve the minimal intended use for a non-molecular test >95% required to achieve the minimal intended use for a molecular test
<b>Clinical specificity to predict resistance</b>	>95% required to achieve the minimal intended use	>98% required to achieve the optimal intended use
<b>Time to result</b>	≤30 minutes	≤10 minutes
Pricing		
<b>Target list price per test (excluding the cost of a reader)</b>	<\$3 USD for a low complexity test (e.g. rapid diagnostic test) that meets the minimal intended use and clinical sensitivity and specificity TPP specifications	<\$12 USD for moderate/high complexity test (e.g. disposable single-use molecular test) that meets the optimal intended use and clinical sensitivity and specificity TPP specifications



# TARGET PRODUCT PROFILE VS PRODUCT REQUIREMENT DOCUMENT

## PRODUCT REQUIREMENT DOCUMENT

## TARGET PRODUCT PROFILE

- |   |  |
|---|--|
| ◆ internal and confidential document        | → public guidance created by a broad number of experts |
| ◆ provide details on the specific product   | → is quite generic and sometimes test agnostic         |
| ◆ ranges (minimal to optimal) more specific | → ranges (minimal to optimal) often quite broad        |



The product should try to comply with TPP, acknowledging that sometime some characteristics may fall outside of TPP range.

# OTHER RESOURCES

◆ **Technical Specification Series (TSS)** describe WHO's interpretation of the minimum validation and verification studies to be undertaken by the manufacturer in support of in vitro diagnostic (IVD) performance claims.

**World Health Organization**  
Prequalification of Medical Products  
 IVDs, Medicines, Vaccines and Immunization  
 Devices, Vector Control

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IVD

In Vitro Diagnostics

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## Technical Specifications Series

The Technical Specifications Series (TSS) set out the performance evaluation criteria for meeting prequalification requirements. Each TSS document provides information on the minimum performance requirements for WHO prequalification that should be met by a manufacturer to ensure that the in vitro diagnostic that is being submitted for prequalification is safe and performs optimally. (A transition period is being applied for those products prequalified before the relevant TSS document was issued. Manufacturers must comply with the technical specifications in the relevant TSS document within three years of its publication.)

Compliance with prequalification technical specifications is verified during re-inspection. Failure to comply with the relevant technical specifications will result in the delisting of the product concerned from the WHO List of Prequalified IVDs.

- [TSS 1 - Human immunodeficiency virus \(HIV\) rapid diagnostic tests for professional and/or self-testing](#)
- [TSS 2 - In vitro diagnostic medical devices to identify glucose-6-phosphate dehydrogenase \(G6PD\) activity](#)
- [TSS 3 - Malaria rapid diagnostic tests](#)
- [TSS 4 - In vitro diagnostic medical devices used for the detection of high-risk human papillomavirus \(HPV\) types in cervical cancer screening](#)
- [TSS 5 - Rapid diagnostic tests used for surveillance and detection of an outbreak of cholera](#)
- [TSS 6 - Syphilis rapid diagnostic tests](#)
- [TSS 7 - see 2021 version update TSS 16 below](#)
- [TSS 8 - Immunoassays to detect hepatitis C antibody and/or antigen](#)
- [DRAFT TSS 9 - Immunoassays to detect HIV antibody and/or antigen](#)
- [TSS 10 - In vitro diagnostic medical devices used for the qualitative and quantitative detection of hepatitis C RNA](#)
- [TSS 11 - In vitro diagnostic medical devices used for the quantitative detection of HIV-1 nucleic acid](#)
- [TSS 12 - In vitro diagnostic medical devices used for the qualitative detection of HIV-1 and HIV-2 nucleic acid](#)
- [TSS 13 - Rapid diagnostic tests to detect hepatitis B surface antigen](#)
- [TSS 14 - Immunoassays to detect hepatitis B virus surface antigen](#)
- [TSS 15 - In vitro diagnostic medical devices used for the quantitative detection of hepatitis B DNA](#)
- [TSS 16 - Hepatitis C rapid diagnostic tests for professional use and/or self-testing, 2021 update](#)
- [TSS 17 - In vitro diagnostic medical devices used for the qualitative detection of Mycobacterium tuberculosis complex DNA and mutations associated with drug-resistant tuberculosis](#)

<https://extranet.who.int/prequal/vitro-diagnostics/technical-specifications-series>

◆ **Technical Guidance Series (TGS)** contain valuable information on a range of issues that are encountered in the manufacture, verification, and validation of specific categories of IVD. TGS apply in to all IVDs that are eligible for WHO PQ.

**World Health Organization**  
Prequalification of Medical Products  
 IVDs, Medicines, Vaccines and Immunization  
 Devices, Vector Control

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## Technical Guidance Series

The Technical Guidance Series (TGS) was developed following a WHO consultation held in 2015 and attended by experts from national regulatory authorities, national reference laboratories, and WHO prequalification dossier reviewers and inspectors. The guidance series is a result of their efforts, and those of other international working groups, to provide clear information to manufacturers seeking WHO prequalification of in vitro diagnostics (IVDs).

TGS documents apply in principle to all IVDs that are eligible for WHO prequalification for use in WHO Member States. They should be read in conjunction with relevant international and national standards and guidance.

[TGS 1 Standards applicable to the WHO Prequalification of in vitro diagnostic medical devices](#); identifies standards and guidance relating to a range of issues that are encountered in the manufacture, verification, and validation of IVDs.

[TGS 2 Establishing stability of in vitro diagnostic medical devices](#); provides IVD manufacturers with guidance on possible approaches to determining stability and describes WHO prequalification requirements for stability testing.

- [Annex to TGS 2 Establishing component stability for in vitro diagnostic medical devices](#); provides recommendations for establishing the stability of components for IVDs, with examples on the change from establishing stability for multi-use dropper bottles to establishing stability for single-use vials.

[TGS 3 Principles of performance studies](#); identifies the key principles that apply when conducting and reporting the study design, results, and conclusion of analytical and clinical performance studies that support performance claims for IVDs undergoing assessment for WHO prequalification.

[TGS 4 Test method validation for in vitro diagnostic medical devices](#); provides guidance to manufacturers on the validation of the test methods used in establishing the design, development and manufacture of an IVD.

[TGS 5 Designing instructions for use for in vitro diagnostic medical devices](#); provides guidance to manufacturers on best practice when designing the instructions for use (IFU), which are an opportunity for the manufacturer to interact directly with end users and inform them about their product.

<https://extranet.who.int/prequal/vitro-diagnostics/technical-guidance-series>

# OTHER RESOURCES

- ◆ The **Common Specification (EU CS)** are a set of uniform and consistently requirements for class D (highest risk) in vitro diagnostic (e.g. HIV, HTLV, Hepatitis) in relation to the IVD Regulation 2017/746 (IVDR).

The screenshot displays the EUR-Lex website interface. At the top, the EUR-Lex logo and navigation links are visible. The main content area shows the details of Document 32022R1107, titled "Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council (Text with EEA relevance)". The document is in force and has a link to the data.europa.eu website. A sidebar on the left provides options to save, link, or download the document. At the bottom, a section for "Languages, formats and link to OJ" lists various languages and formats.

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C/2022/4498

OJ L 178, 5.7.2022, p. 3–56 (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)

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ELI: [http://data.europa.eu/eli/reg\\_impl/2022/1107/oj](http://data.europa.eu/eli/reg_impl/2022/1107/oj)

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## KEY TAKEAWAYS

1

If a TPP is available, use it as a reference to define your Product Requirements.

2

If a TPP is not available, use your market research and KOL consultation as well as available local and international guidance to define your Product Requirements.

3

If you are planning to submit for WHO PQ use TSS as a reference to define your PRD.

FIND 

QUESTIONS &  
FEEDBACK

