

Technical Specifications Series - 5

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Prequalification of in vitro diagnostics:



IVDs that are:

- Safe
- appropriate
- Affordable
- Good quality
- Resource-limited settings



Technical guidance series

TGS 1 - Standards applicable to the WHO Prequalification of in vitro diagnostic medical device

TGS 2 - Establishing stability of in vitro diagnostic medical devices

Annex to TGS 2 - Establishing component stability for in vitro diagnostic medical devices. Case study: single-use-buffer vials for rapid diagnostic tests - **Draft**

TGS 3 - Principles of performance studies

TGS 4 - Test method validation for in vitro diagnostic medical devices

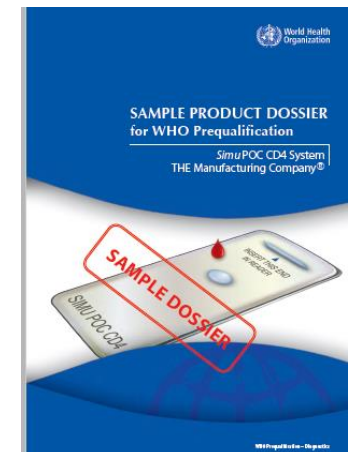
TGS 5 - Designing instructions for use for in vitro diagnostic medical devices

TGS 6 - Panels for quality assurance and quality control of in vitro diagnostic medical devices

TGS 7 - Risk management for manufacturers of in vitro diagnostic medical devices - **Draft open for public comment**

Sample dossiers

- Sample Product Dossier for a CD4 IVD
- Sample Product Dossier for an IVD intended for HIV self-testing
- Sample Product Dossier for a qualitative nucleic acid-based testing technology for HIV-1 and HIV-2 to detect HIV-1 and HIV-2
- Sample Product Dossier for a quantitative nucleic acid-based testing technology to measure HIV-1 RNA



Technical specifications series

TSS 1 - Technical Specification Series to WHO Prequalification - Diagnostics Assessment: HIV rapid diagnostic tests for professional use and/or self-testing

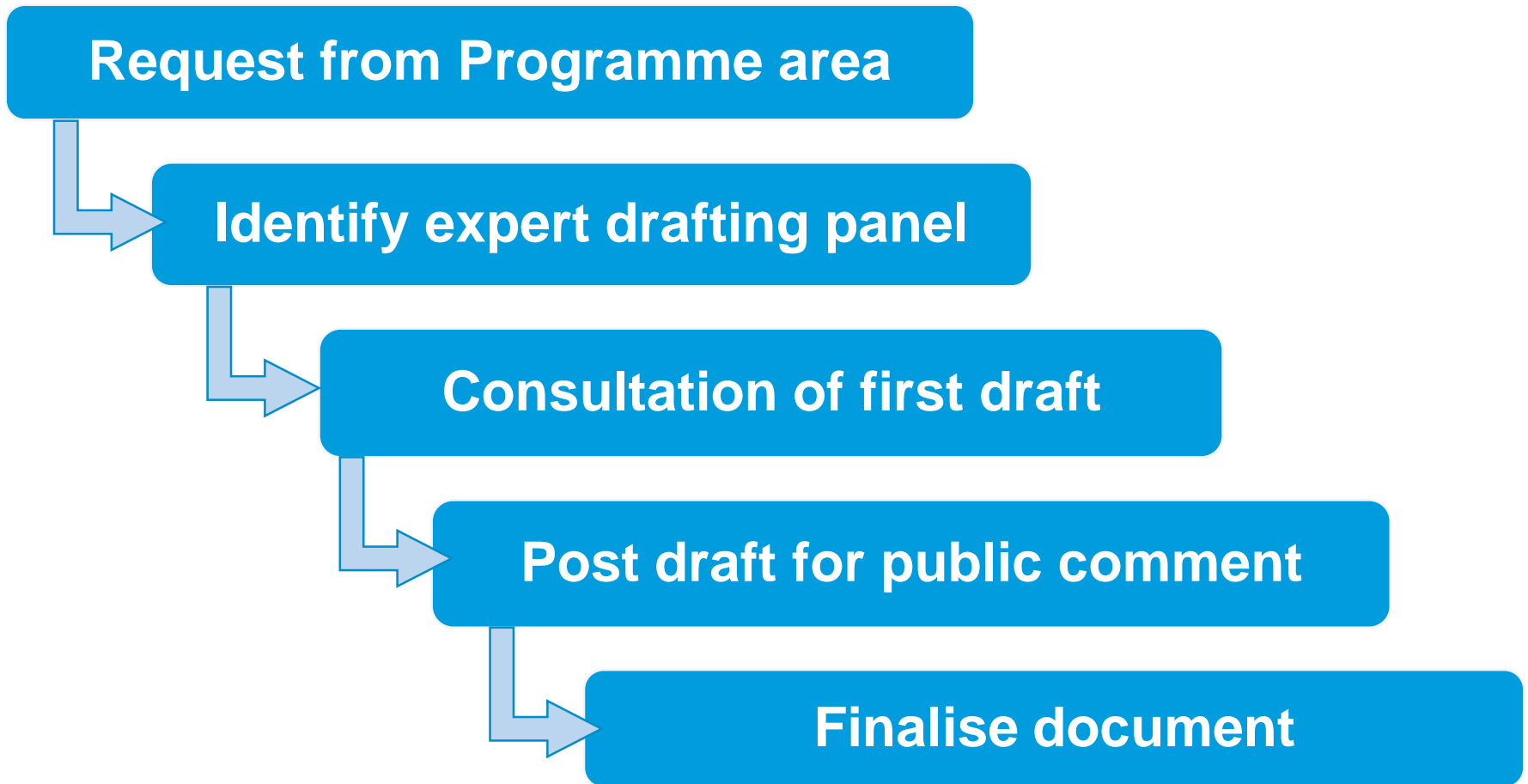
TSS 2 - Technical Specification Series for submission to WHO Prequalification - Diagnostic Assessment: IVD to identify Glucose-6-phosphate dehydrogenase (G6PD) activity

TSS 3 - Technical Specification Series for submission to WHO Prequalification – Diagnostic Assessment: Malaria rapid diagnostic tests

TSS 4 - Technical Specification Series for submission to WHO Prequalification – Diagnostic Assessment: IVDs used for the detection of high-risk Human Papillomavirus (HPV) types in cervical cancer screening

TSS 5 - Technical Specification Series for submission to WHO Prequalification – Diagnostic Assessment: Rapid diagnostic tests used for surveillance and detection of an outbreak of cholera

Guidance development process



PART 1	Establishing analytical performance characteristics
1.1	Specimen types
1.1.1	Specimen types
1.2	Specimen collection, storage and transport
1.2.1	Specimen stability
1.3	Precision of measurement
1.3.1	Repeatability, reproducibility
1.4	Performance panels
1.4.1	Performance panels
1.5	Validation of reading times
1.5.1	Validation of reading times
1.6	Analytical sensitivity
1.6.1	Analytical Sensitivity
1.7	Establishment of reader cut-off
1.7.1	Establishment of reader cut-off
1.8	High dose hook effect
1.8.1	High dose hook effect
1.9	Analytical specificity
1.9.1	Potentially interfering substances
1.9.1.1	Endogenous
1.9.1.2	Exogenous
1.9.2	Cross-reactivity, including selectivity with non-virulent O1 strains of <i>V. cholerae</i>
1.10	Stability
1.10.1	Shelf-life (including transport stability).
1.10.2	In-use stability (open pack or open vial stability).
1.11	Flex studies
1.11.1	Flex studies/robustness

PART 2	Establishing clinical performance characteristics
2.1	Diagnostic sensitivity and specificity
2.1.1	Diagnostic sensitivity
2.1.2	Diagnostic specificity
2.2	Qualification of usability
2.2.1	Labelling comprehension study (including IFU)
2.2.2	Results interpretation study

TSS-5

<http://apps.who.int/iris/bitstream/10665/260469/1/9789241513715-eng.pdf>

WHO PREQUALIFICATION TEAM:
DIAGNOSTICS



World Health
Organization

Technical Specifications Series
for submission to WHO Prequalification –
Diagnostic Assessment

TSS-5

Rapid diagnostic tests (RDTs)
used for surveillance and
detection of an outbreak of
cholera

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