6. Technical specification series (TSS)

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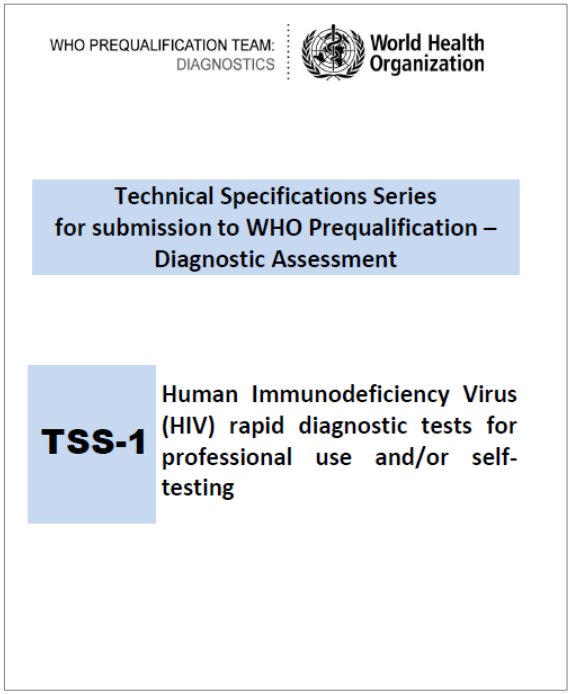
Technical specification series (TSS)

- Each TSS document is tailored to a specific pathogen/type of assay
- Summarize minimum performance evaluation criteria for meeting prequalification requirements.
- Manufacturers must comply with the technical specifications in the relevant TSS document (within three years of its publication).



Where to find them:

https://extranet.who.int/pqweb/vitro-diagnostics/technical-specifications-series

Technical specification series (TSS)

- in development -

Public consultation closed (Q4 2019):

- TSS-10: In Vitro Diagnostic (IVDs) medical devices used for the qualitative and quantitative detection of **Hepatitis C RNA**
- TSS-11: In Vitro Diagnostic (IVDs) medical devices used for the q**uantitative** detection of **HIV-1 nucleic acid**
- TSS-12: In Vitro Diagnostic (IVDs) medical devices used for the **qualitative** detection of **HIV-1 and HIV-2 nucleic acid**

Anticipated publishing date: Q1 2021

Technical specification series (TSS)

- in development -

Public consultation closed (Q1 2020):

- TSS-13: Rapid diagnostic tests to detect **Hepatitis B virus 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 virus nucleic acid**

Public consultation open (closing Dec 1, 2020):

- TSS-7 Annex 1: Qualification of usability for **self-testing** with rapid diagnostic tests to detect **hepatitis C antibody**

  https://extranet.who.int/pqweb/news/draft-tss-7-annex-1-qualification-usability-self-testing-rapid-diagnostic-tests-detect

Anticipated publishing date: Q1 2021

PRE PANDEMIC

WHO Prequalification of In Vitro Diagnostics Update

Issue 28
Q4 2019

IN THIS ISSUE:

1. PREQUALIFIED IVDs
2. EXPANSION OF THE PREQUALIFICATION OF IN VITRO DIAGNOSTICS SCOPE

2020: Haemoglobin (point of care) and glucose meters and test strips

2021: Tuberculosis, yellow fever, dengue fever, gonorrhoea and chlamydia

2022: Measles, rubella, leishmaniasis and schistosomiasis

2023: Mycoplasma genitalium and onchocerciasis

Technical specification series (TSS)

In preparation (2020/2021):

- TSS-16: POC IVD to detect **haemoglobin** (quantitative)
- TSS-xx: **M. tuberculosis**, Lateral flow urine lipoarabinomannan assay (LF-LAM)

Planned (2021/2022):

- SARS-CoV-2 ?? (EUL guidance exists for NAT, Ag RDT & Ab RDTs/IA)
- Blood glucose meter/test systems (POC)
- M. tuberculosis
  - PCR assay with & without resistance detection
  - Lateral flow urine lipoarabinomannan assay (LF-LAM)
- Dengue/Yellow fever
  - PCR assay
  - Serology