Annexure A: Technical Specification

Tender Specifications for single Syphilis and dual HIV/Syphilis RDTs

Definition:

The **single syphilis RDT** is a rapid, qualitative in-vitro diagnostic (IVD) which will be used for point-of-care syphilis screening in known HIV positive individuals.

The **dual HIV/syphilis RDT** is a rapid, qualitative IVD which will be used for point-of-care simultaneous HIV and syphilis screening in individuals with HIV negative or unconfirmed status.

1. Pre-Screening suitability:

a) **Dual HIV/Syphilis and Single Syphilis RDTs**: Only dual HIV/Syphilis and single Syphilis RDTs that appear on the WHO LIST OF PREQUALIFIED IN-VITRO DIAGNOSTIC PRODUCTS are eligible for this tender https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/.

b) *Quality Management System (QMS) certification:* **ISO13485-2016** certification (https://www.iso.org) or an equivalent QMS recognised by a regulatory authority which is a member of the Global Harmonization Task Force (GHTF).

c) *Adherence to Regulation:* Bidders are required to adhere to the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended and the Regulation relating to Medical Devices and IVDs (2016). Non-compliance with these conditions will invalidate the bid.

d) *Licencing:* Manufacturers, distributors and wholesalers, as referred to in Section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), must obtain a licence for the manufacturing, importing, exporting, distribution and wholesaling of medical devices and IVDs, as issued by the South African Health Products Regulatory Authority (SAHPRA).

e) *Batch documentation:* Proof of the production, invoicing, and shipping documents of a minimum of three different test kit batches / lot numbers must be provided to NICD.

2. Assays:

Single syphilis RDT: The RDT must be an immunochromatographic assay, comprising synthetic peptides and/or recombinant antigens that detect antibodies (IgG and IgM) to Syphilis (*Treponema pallidum)* in human serum, plasma, and/or whole blood.

Each test must have an internal quality control mechanism, such as a control (validation) line.

Dual HIV/syphilis RDT: The RDT must simultaneously screen for HIV and syphilis using one specimen. The test must be an immunochromatographic assay, comprising synthetic peptides and/or recombinant antigens that detect antibodies (IgG and IgM) specific to HIV 1&2 and Syphilis (*Treponema pallidum)* in human serum, plasma, and/or whole blood.

Each test must have an internal quality control mechanism, such as a control (validation) line.

3. Packaging:

Only the manufacturer's original name of the test kit device will be accepted for the traceability of the test kit and reagents, packaging and labelling.

Test kit batch/lot number and expiry date must appear on each test foil, box of tests and outer shipping carton. Labelling should conform to GHTF documents "Labelling and Instructions for Use for IVD Medical Devices".

a) The name of the test kit must be the same on the documentation submitted for the tender as it appears on the test device. The test device as well as the kit packaging should also have the same kit name.

b) Additional equipment and reagents required for the test must be provided including buffer solution, pipettes that are standardised and deliver the expected volumes, lancets (single-use, auto-safety, retractable needle 23g, 2.2mm depth, blade cutting, ultrasonically welded) and swabs (70 % isopropyl alcohol) eg. A box of 25 test devices must contain sufficient buffer solution, 25 pipettes, 25 lancets, 25 swabs and a Package Insert.

4. Test kit operation & performance:

a) The test method/process should not be complex and must be completed in a maximum of 3 steps. The instructions for use (IFU) must include clear instructions for testing with each matrix (serum/plasma and specifically whole

blood). Serum/Plasma is used for evaluation purposes and the protocol for serum/plasma must be included in the IFU. Volume for whole, serum or plasma should be an exact volume without a volume range e.g. 2 – 3 drops. The instructions must be in English.

b) **Dual HIV/Syphilis RDT**: The test kit must have high clinical and analytical performance in reputable laboratory evaluations, as follows (Using WHO optimal requirements):

	HIV	Syphilis
Sensitivity	≥ 99%	≥ 98%
Specificity	≥ 99%	≥ 98%

c) **Single Syphilis RDT:** The test kit must have high clinical and analytical performance in reputable laboratory evaluations, as follows (Using WHO optimal requirements):

	Syphilis
Sensitivity	≥ 98%
Specificity	≥ 98%

d) The number of weak positives must be less than 5%. A weak positive is a known sample that gives a weak reaction on the syphilis test strip when a band is significantly fainter or weaker than the procedural control observed.

e) The number of invalid results must be less than 1%.

f) Inter-reader variability of test kits must be less than 5%. Inter-reader variability is analysed by two different operators who read the final results independently.

g) The maximum time duration for the test result must be 20 minutes for either positive or negative results. The IFU must indicate a specified incubation time duration. No duration ranges will be accepted e.g. 5-20 minutes is not acceptable. One incubation time duration is required.

5. Test kit storage & shelf-life:

a) The storage temperature of the test kits and reagents should allow safe storage in any South African rural clinic that has no heating or refrigeration (safe to store between 2°C and 30°C). Operating temperature should be ambient temperature i.e. between 18°C and 30°C.

b) The guaranteed shelf-life for the test and buffer solution must be greater than 12 months on delivery at all delivery sites countrywide.

6. Training:

a) Training for 1-2 days must be provided by the supplier in each province prior to supplying test kits. Costs incurred, including test kits used for demonstration purposes, will be carried by the supplier.

b) Training must also be provided to other Government Departments (Correctional and Military Services) and users in each province. Costs incurred, including test kits used for demonstration purposes, will be carried by the supplier.

c) Suppliers must also be available to assist provinces with training as the need arises. Costs incurred, including test kits used for demonstration purposes, will be carried by the supplier.

7. Quality Control:

It is compulsory for all winning Bidders to participate in the Post Market Surveillance as follows:

a) Prior to any batches/lot numbers being distributed to testing sites the supplier will provide a minimum of 100 test devices to the NICD for assessment.

b) No batch/lot number may be distributed in South Africa without the necessary post-production Post Market Surveillance Report from the NICD.

c) A compulsory fee for the assessment of post-production batches will be applied by the NICD and paid for by the supplier.

8. Supplier lead time:

The supplier will be expected to deliver stock to all provinces allocated within four weeks lead time after the commencement of the contract.