ANNEXURE A02/A03:

Technical Specifications Criteria for Self-Screening HIV Rapid Diagnostic Kit Evaluations:

Technical Specifications Compliance	
1. Pre-Award Technical Compliance	**Compliance**
Pre-screen suitability. Evidence of Independent evaluations and/or kit lot productions must be provided. The evidence provided must include the following information: a. The test kit must appear on the WHO List of Prequalified In-Vitro Diagnostic Products as a "HIV RDT for Self-testing" type of assay (http://www.who.int/diagnosticslaboratory/evaluations/PQlist/en/en/ b. *Quality Management System (QMS) certification:* **ISO13485-2016** certification (https://www.iso.org). 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. The manufacturer must submit the regulatory version of the test kits it intends to supply the South African Government. Evidence of reproducibility across multiple test kit lots (e.g. including number of samples, type of specimens, number of kits lots must be provided.	
2. Product Specification	**3. Compliance**

1. The test kit must be a single-use device able to detect HIV 1 and HIV 2 antibodies simultaneously	
2. Instructions for use and labelling should be clear and easy to understand.	
3. Pictorial instructions for use (IFU) must be supplied with clear instructions for use with oral fluid or blood sample only. The instruction must be in English.	
4. Volume for oral fluid should be an exact volume without a volume range e.g 2-3 drops.	
5. The laboratory evaluation is conducted on serum samples, provide instructions for testing on serum/plasma in addition to oral fluid.	
6. The testing should be easy to follow and must be completed in a maximum of 5-6 steps	
7. Duration: a. No duration ranges will be accepted e.g.5-20 minutes is not acceptable. b. The IFU must indicate a specified incubation time duration c. Only one incubation time duration is acceptable. d. The maximum time duration for the test result must be 20 minutes or less for either positive or negative results.	
8. The test device must comprise synthetic peptides and/or recombinant proteins and detect for IgG and/or IgM+IgG.	
9. Each test must have a procedural (validation) control.	
a. Only the manufacturer's original name of the test kit device will be accepted for traceability. b. 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". c. Additional equipment and developer solution required for the test must be provided including test stand, vial of developer solution and an IFU/Package Insert. The IFU must include the version/revision number and date of the IFU.	

d. 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	
10. The test kit must have high analytical sensitivity and specificity (≥ 99 % Sensitivity and ≥ 99% Specificity) in Laboratory Evaluations completed by the NICD when compared to the standard laboratory based HIV-1/HIV-2 Enzyme-linked immunosorbant assay tests as a gold standard.	
11. The number of weak positives must be less than 5 %. A weak Positive is a known sample that gives a weak reaction on the HIV test strip when a band is significantly fainter or weaker than the procedural control observed.	
12. The number of invalid results must be less than 5 %.	
13. 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.	
14. 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 4° C and 30° C). Operating temperature should be room temperature i.e. between 18° C and 30 ° C).	
15. The guaranteed shelf-life for the test and developer solution must be greater than 12 months on delivery at all delivery sites countrywide	
16. Evidence of clinical studies for usability to be included as part of the submission.	
17. Training: a. Training for two to three days must be provided by the supplier in the allocated provinces prior to supplying test kits. b. Training must also be provided to the Correctional Services, South African Police Services, and Department of Defence (SANDF) in the allocated provinces. c. Suppliers must also be available to assist provinces with training as and when the need arises.	

d. Supplier are advised that the costs for training including test kits used for demonstration purposes will be at the cost of the supplier(s).	
4. **Post Award Compliance**	**Compliance**
1. Post Marketing surveillance It is compulsory for all successful bidders to participate in the Post Marketing surveillance as follows: a. Prior to any batches/lot numbers being distributed to testing sites the supplier will provide a minimum of 90 test devices of the final batch to the NICD for assessment. b. No batch / lot number may be distributed in South Africa without the necessary pre-production and post- production Post Market Surveillance Report from the NICD. c. A compulsory fee for the assessment of both pre and post- production batches will be applied by the NICD and paid for by the supplier.	
2. The supplier will be expected to deliver stock to all Provinces allocated within four weeks (lead time) after the commencement of the contract.	