ANNEXURE A01

Technical Specifications Criteria for HIV Rapid Kit Evaluations:

	Compliance
Pre-Award Technical Compliance	
1. **Pre-screen suitability:** Evidence of Independent Evaluations and/or kit lot productions must be provided. The evidence provided must include the following information:	
Pre-Award Technical Compliance	
a. Evidence of an independent evaluation by an internationally recognized agency: Prequalification by the WHO Prequalification of In Vitro Diagnostic Programme (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 kit lots) must be provided.	

	Compliance
1. The test kit must detect HIV 1 and HIV 2 antibodies. Devices detect for both antibodies simultaneously i.e. dual line (undifferentiated HIV-1 and HIV-2) or tri-line.	
2. 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). The IFU must include a revision/version number and date 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.	
3. The testing must not be complex and should be completed in a maximum of three steps	
4. Duration: • No duration ranges will be accepted e.g.5-20 minutes is not acceptable. • The IFU must indicate a specified incubation time duration • Only one incubation time duration is acceptable. The maximum time duration for the test result must be 20 minutes or less for either positive or negative results.	
5. The test kit must be user-friendly i.e. easy to perform. Sample and reagent volumes required for the test procedure must be specific. No reagent volume ranges will be accepted e.g. 2-5 drops of sample or 20 – 40 micolitre of sample or reagent is not acceptable. One volume (number of drops and or / measured volume) must be specified for both samples and reagent. The sample dropper must provide equivalent volume in drops to stated pipette volumes.	
6. The test device comprises of synthetic peptides and/ or recombinant proteins and detects for IgG and/or IgM and IgG	
7. Each test must have a control (validation) line (Procedural Control or IgG).	

	Compliance
8. Traceability of the test kits and Reagents, Packaging and Labelling including WHO PQ and/or Certifying Body reference number. Only the manufacturer's name of the test kit device will be accepted. a. 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 Global Harmonisation Task Force (GHTF) documents: "Labelling and Instructions for Use for IVD Medical Devices". b. Reagent batch/lot number must be the same as the test kit batch/lot number and must be printed together with the expiry date on the bottle marked with the products name. c. Additional equipment and reagents required for the test must be provided to include: • buffer/diluent, • 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) As an example, a box of 25 test devices must contain sufficient buffer/diluent, 25 pipettes, 25 Lancets, 25 Swabs and a Package Insert.	
9. The test kit must be highly sensitive and specific (≥ 99 % Sensitivity and 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.	
10. The number of weak positives must be less than 5 %. A Weak Positive is a sample that gives a weak reaction on an HIV test strip when a band is significantly fainter or weaker than the procedural control observed.	
11. The number of invalid results must be less than 5%.	
12. Inter-reader variability of test kits must be less than 5 %. The inter-reader variability is analysed by two different operators who read the final results independently.	

	Compliance
13. 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 room temperature. (between 18 ° C and 30° C).	
14. The guaranteed shelf-life for the test, reagents and additional equipment supplied (i.e. swabs and lancets) must be greater than 12 months on delivery at all delivery sites countrywide.	
15. Training: • Training for two to three days must be provided by the supplier in the allocated provinces prior to supplying test kits. • Training must also be provided to the Correctional Services, South African Police Services (SAPS) and Department of Defence (SANDF) in the allocated provinces. • Suppliers must also be available to assist provinces with training as and when the need arises. Supplier are advised that the costs for training including test kits used for demonstration purposes will be at the cost of the supplier(s).	
Post Award Compliance	
1. Post Marketing Surveillance It is compulsory for all successful bidders to participate in the Post Marketing surveillance as follows: • Prior to any batches/lot numbers being distributed to testing sites the supplier will provide a minimum of 150 test devices of the final batch to the NICD for assessment. • 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. • A compulsory fee for the assessment of 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.	