Point of Care Testing (POCT) Inspection Checklist- Final

Name of the Facility: _____

Date of Inspection:_____/_____/_____

Ref.	Description	Yes	No	N/A	Remarks
5	**STANDARD ONE: GENERAL REQUIREMENTS**				
5.2	Licensed health facilities shall list the POCTs offered and have them visibly placed for patient access and have a documented quality control program.				
6	**STANDARD TWO: HEALTH FACILITY REQUIREMENTS**				
6.6	The basic POCT list includes the following, but not limited to:				
6.6.1	Blood glucose glucometer				
6.6.2	HbA1c measurement				
6.6.3	Urine pregnancy tests				
6.6.4	Haemoglobin and Haematocrit (by finger prick)				
6.6.5	Urine dip stick for urine analysis				
6.6.6	Cardiac Troponin (FDA and/CE marked analysers) for myocardial infarction detection, Myoglobin and Fatty Acid Binding Protein (FABP)				
6.6.7	Full Blood count/ Complete Blood count				
6.6.8	D-dimer test				
6.6.9	Bilirubinometer				
6.6.10	Blood gas analyser with electrolytes				
6.6.11	Prothrombin Time (PT) and International Normalized Ratio (INR) for coagulation study				
6.6.12	Molecular POCT testing (NEAR Technology) CLIA Waived (FDA approved)				

6.6.13	COVID-19				
6.6.14	Flu A/B				
6.6.15	Streptococcal A				
6.6.16	RSV				
6.6.17	Rapid test kits for infectious disease limited to:				
a	Influenza virus- nasal swabs				
b	Rapid Strep A- nasal swabs				
c	Respiratory Syncytial Virus (RSV)- nasal swabs/ nasal wash				
d	Adeno virus- nasal swab				
e	Rota Virus- in stool				
f	Adenovirus- in stool				
g	Malarial antigen- in blood				
h	Dengue Rapid Detection Test				
i	Giardia- in stool				
j	Cryptosporidium- in stool.				
k	COVID-19 Antigen (Nasal/Nasopharyngeal)				
l	H pylori - Stool				
m	Faecal Occult Blood – Stool				
n	Norovirus – Stool				
6.6.18	Molecular (PCR/NAT) genetic test for the following:				
a	HBC/HCV PCR (for virus detection)				
b	HIV PCR (for virus detection)				
9	**STANDARD FIVE: EQUIPMENT SELECTION AND IMPLEMENTATION**				
9.5	The SOPs shall include:				
9.5.1	Principle of normal operation techniques				
9.5.2	Health and safety requirements				
9.5.3	Specimens required, patient sample and request form identification criteria and specimen handling				

9.5.4	Hazard warning and safety information				
9.5.5	Contra-indications and limitations of the instrument and technique				
9.5.6	Perform of routine operations such as maintenance and routine internal and external decontamination				
9.5.7	Basic troubleshooting if an instrument malfunction is recognised				
9.5.8	Preparation of reagents and other materials				
9.5.9	Calibration				
9.5.10	Quality control procedures				
9.5.11	Sample analysis procedures				
9.5.12	Reporting of results, including abnormal results				
9.5.13	Documentation/transmission of results				
9.5.14	Criteria for referral of samples				
9.5.15	Criteria for Critical Values and/or unusual values and reporting				
9.5.16	Limitations of the procedure				
9.5.17	Reference values				
9.5.18	Specimen storage, stability and transfer to a clinical laboratory				
9.5.19	Safe disposal of reagents and biological material				
9.5.20	Safe handling of all specimens and spillages				
9.5.21	Sample collection				
9.5.22	Clinical utility and limitations				
9.5.23	Reagent storage				
9.5.24	Technical limitations of the device				
9.5.25	Response to results that fall outside of predefined limits				
9.5.26	Infection control practices/policy with special reference to hand held devices				

9.5.27	Correct documentation and maintenance of results.				