

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA01	
Details of Non-conformance: SOPs not visible and acknowledged by the laboratory staff personnel.		
Immediate action: N/A		
Classification of NC Major <input checked="" type="radio"/> Minor <input type="radio"/>	Reference no of relevant guide/Standard/requirement 4.3	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: 04/02/2021	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause: The SOP's are kept on the Laboratory Manager desktop and not accessible to staff personnel. Therefore, staff can read or acknowledge the SOP's.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The SOP's are printed and now available to all staff personnel and have been acknowledged.		
Date: <u>04/08/2021</u> Sign: <u>gditshego</u>		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <u>04/02/2021</u> Sign: <u>[Signature]</u> (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/> Comment:		
Quality Officer/HOS Signature: <u>[Signature]</u> Date: <u>04/08/21</u>		

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA02	
Details of Non-conformance: IQC and patient raw data not signed from the machine print out.		
Immediate action: N/A		
Classification of NC Major <input type="radio"/> Minor <input checked="" type="radio"/>	Reference no of relevant guide/Standard/requirement 5.6	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: 04/02/2021	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause: The technical staff need to ensure that they sign raw data as a form of verifying and accepting the result from the machine. Staff did not know they must initial/sign the machine raw data.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Laboratory now signs raw data; this was implemented immediately.		
Date: <u>05/02/2021</u> Sign: <u>[Signature]</u> gditshego		
Resumption of testing YES <input checked="" type="radio"/> NO <input type="radio"/> N/A		
Date: <u>05/02/2021</u> Sign: <u>[Signature]</u> (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: <u>[Signature]</u> Date: <u>05/02/2021</u>		

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA03	
Details of Non-conformance:		
Running of EQA samples in duplicate and not signing the raw data. Immediate action: N/A		
Classification of NC Major <input type="radio"/> Minor <input checked="" type="radio"/>	Reference no of relevant guide/Standard/requirement 5.6	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: 04/02/21	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause:		
Technical staff was running FBC EQA samples in duplicate, this was done in the closed and open mode. And there was no signature of person who worked on the sample.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The laboratory has stopped running samples in duplicate, as the closed & open mode uses the same sample processes. This was implemented in the following up FBC EQA sample. Sample C14/S3.		
Date: <u>04/03/21</u> Sign: <u>gditshego</u>		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <u>04/03/21</u> Sign: _____ (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: <u>[Signature]</u> Date: <u>09/03/21</u>		

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA04	
Details of Non-conformance:		
No evidence of EQA review communication amongst laboratory technical staff.		
Immediate action:		
N/A		
Classification of NC Major <input type="radio"/> Minor <input checked="" type="radio"/>	Reference no of relevant guide/Standard/requirement 5.6	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: <i>04/02/2021</i>	Signature: gditshego <i>U</i>
Section II (Attach Supporting Evidence)		
Root Cause:		
The technical staff was not being updated on their EQA performance, the EQA was only signed off by the QM.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The performance of EQA is now being communicated to all technical staff members. The was evident with EQA report of C14/S2.		
Date: <i>04/03/21</i> Sign: <u>gditshego</u>		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <i>04/03/21</i> Sign: <i>[Signature]</i> (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness		
Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: <i>[Signature]</i> Date: <i>04/03/21</i>		

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA05	
Details of Non-conformance:		
<p>No EQA roaster visible for running of EQA samples, with the names of the technical lab staff. Therefore, no return was seen with sample C18/11 Chemistry. EQA sample was submitted late – therefore a non-return.</p>		
Immediate action:		
N/A		
Classification of NC Major <input checked="" type="radio"/> Minor <input type="radio"/>	Reference no of relevant guide/Standard/requirement 5.6	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: 04/02/2021	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause:		
The laboratory had not put up a roaster for running of EQA samples. Therefore, staff members were not aware on when samples should be submitted to RIQAS.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The laboratory now has a roaster they use, with all technical staff included.		
Date: <u>04/3/21</u> Sign: <u>gditshego</u>		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <u>04/8/21</u> Sign: _____ (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: <u>[Signature]</u> Date: <u>4/8/21</u>		


Section:		
SECTION NC NO: INTERNAL AUDIT	TIA06	
Details of Non-conformance:		
TIA06- No communication documented for the no return EQA sample. (see TIA04) Similar NC.		
Immediate action:		
N/A		
Classification of NC Major <input type="radio"/> Minor <input checked="" type="radio"/>	Reference no of relevant guide/Standard/requirement 5.6	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: 04/02/21	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause: The technical staff was not being updated on their EQA performance, the EQA was only signed off by the QM.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The performance of EQA is now being communicated to all technical staff members including "Non return". The was evident with EQA report of C14/S2.		
Laboratory does do CA with no-returns and failed EQA.		
Date: <u>04/03/21</u> Sign: <u>gditshego</u>		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <u>04/03/21</u> Sign: <u>Ditshego</u> (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: <u>[Signature]</u> Date: <u>04/03/21</u>		

Section: Request Form		
SECTION NC NO: INTERNAL AUDIT	TIA07	
Details of Non-conformance:		
No centrifuge maintenance log was available at time of audit.		
Immediate action:		
N/A		
Classification of NC Major <input type="radio"/> Minor <input checked="" type="radio"/>	Reference no of relevant guide/Standard/requirement 5.3	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: <i>04/02/21</i>	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause:		
The laboratory was maintaining the centrifuge daily, by wiping it done. However, no records was available at the time of audit.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The laboratory has added the centrifuge maintenance onto the daily decontamination schedule. The staff are now recording centrifuge maintenance daily.		
Date: <i>10/02/21</i> Sign: _____gditshego_____		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <i>16/02/21</i> Sign: <i>[Signature]</i> (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness		
Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: <i>[Signature]</i> Date: <i>25/02/21</i>		

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA08	
Details of Non-conformance:		
<p>There was no reagent traceability and QC aliquots were not labelled with lot number and in use date while stored in the freezer.</p>		
Immediate action:		
<p>Immediate action was taken with new lot of IQC.</p>		
Classification of NC Major <input type="radio"/> Minor <input checked="" type="radio"/>	Reference no of relevant guide/Standard/requirement 5.3.2	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: <i>04/02/2021</i>	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause:		
<p>The IQC aliquoted were stored in trays in the freezer without any date in use or lot number, therefore could not be traceable. The reagents put in use could not be traceable on the reagent/ consumable log sheet.</p>		
<p>Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/></p>		
<p>The laboratory has started being consistent with recording the reagents on the reagent log sheet. And aliquoted IQC has a date put in use and lot number labelled on the tray.</p>		
Date: <u><i>06/02/21</i></u> Sign: <u>gditshego</u>		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <u><i>06/02/21</i></u> Sign: <u><i>[Signature]</i></u> (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: <u><i>[Signature]</i></u> Date: <u><i>06/02/21</i></u>		

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA09	
Details of Non-conformance:		
At time of audit the laboratory did not have IQC in place for ABO & Rh.		
Immediate action:		
Classification of NC Major <input checked="" type="checkbox"/> Minor <input type="checkbox"/>	Reference no of relevant guide/Standard/requirement 5.6	Was test halted? Yes NO <input checked="" type="checkbox"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: 04/02/21	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause:		
The laboratory does not have iqc in place for Blood grouping. The lab occasionally sends blood group to referral lab as form of confirmation.		
Corrective Action(s) taken: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>		
The laboratory has done a PO to sanbas for the purchase of cells as a form of IQC and reverse method. The laboratory has asked a referring lab to give us cells until the order arrives.		
Date: <u>22/02/21</u> Sign: <u>gditshego</u>		
Resumption of testing YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> N/A		
Date: <u>22/02/21</u> Sign: <u>[Signature]</u> (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness		
Corrective Action effective: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>		
Comment:		
Quality Officer/HOS Signature: <u>[Signature]</u> Date: <u>22/02/21</u>		

Section:			
SECTION NC NO: INTERNAL AUDIT		TIA10	
Details of Non-conformance:			
TIA10- At the time audit, the laboratory was using expired reagents, and this was not documented in an SOP.			
Immediate action:			
N/A			
Classification of NC Major <input type="radio"/> Minor <input checked="" type="radio"/>		Reference no of relevant guide/Standard/requirement 5.3.2	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego		Date: <i>04/02/2021</i>	Signature: gditshego
Section II (Attach Supporting Evidence)			
Root Cause:			
The laboratory technical staff have been using expired reagents, but not expired IQC. This is permitted in the laboratory, only if the expired reagents perform well after running of IQC. However, this was not documented.			
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>			
The Quality Manager has now documented the use of expired reagents is allowed in the Laboratory SOP, only if IQC passes.			
Date: <u><i>04/03/21</i></u> Sign: <u>gditshego</u>			
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A			
Date: <u><i>04/3/21</i></u> Sign: <u><i>[Signature]</i></u> (lab director/manager)			
Section III (Attach Supporting Evidence)			
Effectiveness			
Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>			
Comment:			
Quality Officer/HOS Signature: <u><i>[Signature]</i></u> Date: <u><i>09/3/21</i></u>			

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA11	
Details of Non-conformance:		
TIA11- The temperature charts in the laboratory were not labelled e.g., room temp etc. and no temp range was stated on the chart.		
Immediate action:		
N/A		
Classification of NC Major <input type="radio"/> Minor <input checked="" type="radio"/>	Reference no of relevant guide/Standard/requirement 5.2	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: 04/02/21	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause:		
The temperature charts were available in the lab, however, they did not have temperature ranges and not labelled eg. Room, fridge, freezer etc.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The laboratory is now using labelled temperature charts with temp ranges stated on the charts.		
Date: <u>04/03/21</u> Sign: <u>gditshego</u>		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <u>04/03/21</u> Sign: _____ (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness		
Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature:  Date: <u>04/03/21</u>		

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA12	
Details of Non-conformance:		
<p>The laboratory staff have not documented temperature readings consistently on the temperature charts and Equipment maintenance logs have blanks as well.</p>		
Immediate action:		
N/A		
Classification of NC Major <input type="radio"/> Minor <input checked="" type="radio"/>	Reference no of relevant guide/Standard/requirement 5.2/ 5.3	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: 04/03/21	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause:		
The lab staff have not been consistent in recording temperature readings. This inconsistency has been observed with the Equipment maintenance logs as well.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The laboratory supervisor has been monitoring the recordings, evidence that staff are recording the temp charts & maintenance logs is available. See current maintenance logs and temp charts. Sundays & Public Holidays are highlighted as such.		
Date: <u>04/03/21</u> Sign: <u>gditshego</u>		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <u>04/03/21</u> Sign: _____ (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness Corrective Action effective: YES <input type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: <u>[Signature]</u> Date: <u>04/03/21</u>		

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA13	
Details of Non-conformance:		
At time of audit some lab staff could not show auditor how to read temperature readings from thermometer.		
Immediate action:		
N/A		
Classification of NC Major <input type="radio"/> Minor <input checked="" type="radio"/>	Reference no of relevant guide/Standard/requirement 5.2	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: 04/02/21	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause:		
All laboratory staff have been trained how to read temperatures, however at time of audit when they were asked, they could not read the min & max readings and reset the thermometer.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Retraining had been arranged for all staff member, and they are all competent to use the thermometer and read the temperature readings.		
Date: 9/02/21 Sign: gditshego		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: 09/02/21 Sign: (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: 11/02/21 Date: <i>[Signature]</i>		



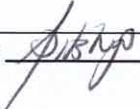
Section:		
SECTION NC NO: INTERNAL AUDIT	TIA14	
Details of Non-conformance:		
At the time of the audit the laboratory was using uncontrolled forms, such as the reagent & consumable forms.		
Immediate action:		
N/A		
Classification of NC Major <input type="radio"/> Minor <input checked="" type="radio"/>	Reference no of relevant guide/Standard/requirement 4.3	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: <i>4/02/2021</i>	Signature: gditshogo <i>Ditshego</i>
Section II (Attach Supporting Evidence)		
Root Cause:		
At the time of audit, the laboratory had not yet added these forms as part of the SOP. Hence, they were not controlled.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The forms have been allocated to an SOP and are now controlled.		
Date: <u><i>04/03/21</i></u> Sign: <u>gditshogo</u>		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <u><i>04/03/2021</i></u> Sign: <u><i>Ditshego</i></u> (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness		
Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: <u><i>[Signature]</i></u> Date: <u><i>09/08/2021</i></u>		

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA15	
Details of Non-conformance:		
Staff personal files were incomplete (training log not signed, no job description, No hep immunity records)		
Immediate action:		
N/A		
Classification of NC Major <input type="radio"/> Minor <input checked="" type="radio"/>	Reference no of relevant guide/Standard/requirement 5.1	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: <i>04/02/2021</i>	Signature: gditshego <i>[Signature]</i>
Section II (Attach Supporting Evidence)		
Root Cause:		
At the time of audit, the personnel files were available, however not all files had job description and Hep immunity records, these had not been printed and put in files. The training log was just not available for J.Kubheka and the T. Kubheka all other files had training logs.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The staff personnel files have been corrected, all required information has been included in all laboratory staff files.		
Date: <i>04/03/21</i> Sign: _____gditshego_____		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <i>04/08/21</i> Sign: <i>[Signature]</i> (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness		
Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		

Quality Officer/HOS Signature: *[Signature]* Date..... 09/03/2021.....

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA16	
Details of Non-conformance:		
Some analysers do not have maintenance log (Access & cobas C111)		
Immediate action:		
N/A		
Classification of NC Major <input type="radio"/> Minor <input checked="" type="radio"/>	Reference no of relevant guide/Standard/requirement 5.3	Was test halted? Yes <input type="radio"/> NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: 04/02/2021	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause:		
The laboratory had not documented a maintenance log for the Access by mistake. The cobas C111 maintenance log was misplaced at time of audit.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The QM has created a maintenance log for the Access as per the operator's manual. Cobas C111 maintenance log is now available for recordings.		
Date: 20/02/21 Sign: _____gditshego_____		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: 20/02/21 Sign: _____(lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: _____ Date: _____		

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA17	
Details of Non-conformance:		
<p><i>recording @ 06/2/21</i> Inconsistency of actioning the daily QC and weekly LJ graphs and detailed root cause not given when there was non-conformance.</p>		
Immediate action:		
YES		
Classification of NC Major <input checked="" type="radio"/> Minor <input type="radio"/>	Reference no of relevant guide/Standard/requirement 5.6	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: <i>04/02/2021</i>	Signature: gditshego <i>[Signature]</i>
Section II (Attach Supporting Evidence)		
Root Cause:		
At time of audit the laboratory was not actioning IQC immediately, and no evidence of proper root cause was taken by the lab. No evidence that this was done weekly.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The technical staff have started to check LJ graphs weekly, and proper CA and root cause is performed on failed IQC.		
Date: <u><i>06/02/21</i></u> Sign: <u>gditshego</u>		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <u><i>06/02/21</i></u> Sign: <u><i>[Signature]</i></u> (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: <u><i>[Signature]</i></u> Date: <u><i>05/02/21</i></u> <u><i>[Signature]</i></u>		

Section:		
SECTION NC NO: INTERNAL AUDIT		TIA18
Details of Non-conformance:		
Reagent log must accommodate the QC and requires a column for in use date.		
Classification of NC Major <input checked="" type="radio"/> Minor <input type="radio"/>	Reference no of relevant guide/Standard/requirement 5.3.2	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: 04/02/2021	Signature: gditshego 
Section II (Attach Supporting Evidence)		
Root Cause:		
The reagent log had not accommodated the date put in use of reagents, and QC acceptability column.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The reagents log, has date put in use and QC column, the reagent log is available on the SOP.		
Date: <u>24/02/2021</u> Sign: <u>gditshego</u>		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <u>24/02/2021</u> Sign:  (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness		
Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature:  Date: <u>26/02/21</u>		

Section:		
SECTION NC NO: INTERNAL AUDIT		TIA19
Details of Non-conformance:		
Not all machines had IQC records attached after service.		
Immediate action:		
N/A		
Classification of NC Major <input checked="" type="radio"/> Minor <input type="radio"/>	Reference no of relevant guide/Standard/requirement 5.3	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: 04/02/2021	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause:		
The laboratory was not keeping track of the IQC records after machines services.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
The laboratory manager to print job cards from supplier immediately and technical staff to attach IQC immediately after service. This will be monitored with next service.		
Date: <u>04/08/2021</u> Sign: <u>gditshego</u>		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <u>04/03/2021</u> Sign: <u>[Signature]</u> (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/> Comment:		
Quality Officer/HOS Signature: <u>[Signature]</u> Date: <u>09/08/21</u>		

Section:		
SECTION NC NO: INTERNAL AUDIT	TIA21	
Details of Non-conformance:		
Incorrect % solution prepared for the disinfectant and the in-use date not updated for the bleach solution prepared to decontaminate the benches.		
Immediate action:		
YES		
Classification of NC Major <input checked="" type="radio"/> Minor <input type="radio"/>	Reference no of relevant guide/Standard/requirement 5.3.2	Was test halted? Yes NO <input checked="" type="radio"/> n/a Signature/Date:
Name of reporter/Identifier: Gugu Ditshego	Date: 04/02/2021	Signature: gditshego
Section II (Attach Supporting Evidence)		
Root Cause:		
At the time of audit, the staff members were preparing a disinfectant solution, however they were not sure of % dilution. And date prepared was not recorded anywhere.		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
A procedure on how to prepare the disinfectant solution has been documented. The date of preparation is now recorded on the bottle.		
Date: <u>25/02/21</u> Sign: <u>gditshego</u>		
Resumption of testing YES <input type="radio"/> NO <input checked="" type="radio"/> N/A		
Date: <u>25/02/21</u> Sign: <u>[Signature]</u> (lab director/manager)		
Section III (Attach Supporting Evidence)		
Effectiveness Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: <u>[Signature]</u> Date: <u>25/02/21</u>		