

Calibration and Preventive Maintenance Not Required for Small Clinitek Urine Chemistry Analyzers

Clinitek Advantus™, Clinitek® 500, Clinitek® 50, Clinitek Status®, Clinitek Status®+ Analyzers

Calibration

Calibration chips and bars used on the small Clinitek Urine Chemistry analyzers do not require annual calibration. During instrument development, sufficient calibration chip/bar material for the product lifetime was obtained. Several samples from this single batch were tested on an Aviv reference spectrophotometer. The spectrophotometer was calibrated using tiles calibrated and value assigned by the National Institute of Standards and Technology (NIST). By calibrating the reference spectrophotometer with NIST traceable calibrators, we are able to show traceability to NIST.

The material used for the calibration chip/bar is not affected by sunlight, is chemically stable in contact with bleach and validated cleaners, and therefore does not degrade over time. If the calibration chip/bar is properly maintained and cleaned according to the respective analyzer's Operator's Manual, the original reflectance values are maintained.

No further calibration of the chip/bar material is necessary.

Preventive Maintenance

No Field Service preventive maintenance is required for any of the small Clinitek analyzers. All small Clinitek analyzers have recommended cleaning and routine maintenance procedures in their respective Operator's Manual and/or Quick Reference Guide. These procedures are intended for use by the customer only.

Trademark Information

Clinitek, Clinitek Status, and Clinitek Advantus are trademarks of Siemens Healthcare Diagnostics.

Installation Qualification for CT STATUS:

Customer Name	:	G1 PATHOLOGY LAB SERVICES
Address	:	10/4 VADGAON KHURD, SINHGAD ROAD; NEAR LOKMAT OFFICE NANDED CITY ROAD, PUNE-411041
Instrument Model	:	CLINITEK STATUS
Serial Number	:	302944

Initial Inspection of the Unit carried out and the details are as below:

System Condition Report:

Found the System to have been delivered in satisfactory condition and no external physical damaged observed on the same. The Tilt-Indicator and the Shock-Indicators on the Packaging were found to be in Good Condition, indicating the System has not been subjected to mechanical shocks or stored in any manner, to cause any damage to the same.

Found all the required accessories as required.

Installation Procedure & Checklist Attached for records.

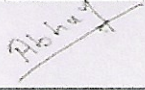
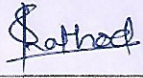
External requirements for Installation:

- 1 Input Voltage of 220V / 50 Hz (UPS out-put).
- 2 Recommended Operating temperatures is 22 – 26 Degree Celcius, with relative Humidity 20 – 80% (No Condensation).



Installation Certificate for CT STATUS

This is to certify that the CT STATUS Instrument Serial No. 302944 is successfully installed and Commissioned at SRL Diagnostics, Satna and the Installation Protocol / checklist has been successfully completed for the above Instrument.

SIEMENS Healthcare Pvt. Ltd.		Customer	
Name	Abhay Gautam	Name	SURAJ RATHOD
Designation	Support Engineer	Designation	Head of the Department
Signature		Signature	
Date	17/03/2021	Date	17/03/2021



Installation Qualifications for CT STATUS

- Carried out all the Installation Procedures as per the Installation Procedure & Checklists.
- Carried out all the necessary checks.
- Carried out all checks and tests for Movement for Moving Table.
- Carried out set up procedure as per the customer requirement.
- Checked the Touch Screen Calibration
- Handed over the Instrument for Operators Training & Qualifications.

For SIEMENS Healthcare Pvt. Ltd.

Name	Abhay Gautam
Designation	Support Engineer
Date	17.03.2021

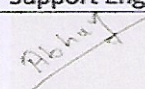



CT STATUS Installation Qualification (IQ)

Customer Name	G1 PATHOLOGY LAB SERVICES
Department	SURAJ RATHOD
Contact Person	Pathology
Instrument Model	CLINITEK STATUS
Serial Number	302944
Date of Installation	17.03.2021

Installation Checks & Protocol done as per Checklist attached.

The Instrument was installed and was found to be working satisfactorily. Preliminary Customer Training was provided, and standardization of some parameters was done. The results were found to be within the expected range and the System found to be working satisfactorily.

SIEMENS Healthcare Pvt. Ltd		Customer	
Name	Abhay Gautam	Name	SURAJ RATHOD
Designation	Support Engineer	Designation	Head of the Department
Signature		Signature	
Date	12.07.2021	Date	12.07.2021



Instrument Set Up

1. Take out the instrument from box and removed the packing carefully.
2. Plugged the Adaptor of the instrument to available Voltage Protection device.
3. Set up and configure the instrument.
4. Installed the Moving Table.
5. Installed the Printer Paper.

Operational Inspection

1. Checked the Movement of Moving Table
2. Checked the Calibration of Touch Screen.
3. Checked the Lamps Voltage.
4. Checked the Movement of Strip.
5. Checked the Instrument with Check-stick.

For SIEMENS Healthcare Pvt. Ltd.

Name : Abhay Gautam

Designation : Support Engineer

Date : 12.07.2021



Operations Qualifications for CT STATUS

- | | |
|---|--------|
| 1. Verified the Calibrations of Touch Screen | : Done |
| 2. Carried out set-up of parameters | : Done |
| 3. Carried out Daily Cleaning Procedures | : Done |
| 4. Carried out manual set-up | : Done |
| 5. Carried out Calibration of Moving Table | : Done |
| 6. Imparted Operator's training and maintenance | : Done |



Operational Qualification:

System certification

Study Data has determined that the System described in this document either meets all criteria outlined in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included.

Exceptional conditions, if any, have been addressed.

The System is ready for specific usage.

Protocol Performed By: **For SIEMENS Healthcare Pvt. Ltd.**

Name : Abhay Gautam

Designation : Support Engineer

Date : 12.07.2021

Customer Authorization:

Name : SURAJ RATHOD

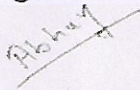
Designation : Head of the Department

Company Representative Name & Sign : Customer Name & Sign

Name: Abhay Gautam

Date : 12.07.2021

Signature:



Name: SURAJ RATHOD

Date : 12.07.2021

Signature:



Performance Qualifications for CT STATUS

Controls

Checked and found all level Controls to be within the acceptable SD

Datasheet of Calibration and Controls attached.

Kit: Multistix 10SG

Controls: Positive Controls and Negative Controls

Materials used for Performance Qualification:

Sl. No	Name of the material	Lot Number	Expiry date
1	Multistix 10SG	30031020	03-22
2	Positive Control	PC0361120P	28-02-22
3	Negative Control	N C03611201N	28-02-22



Negative Control:

Parameters→	GLU	BIL	KET	pH	PRO	UBG	NIT	LEU	SG	BLO
Ranges	Negative	Negative	Negative	6.0 - 7.5	Negative	3.2-16 μmol/L	Negative	Negative	1.015 - 1.025	Negative
RUN 1	Negative	Negative	Negative	7.0	Negative	3.2 μmol/L	Negative	Negative	1.020	Negative
RUN 2	Negative	Negative	Negative	7.0	Negative	3.2 μmol/L	Negative	Negative	1.015	Negative
RUN 3	Negative	Negative	Negative	7.0	Negative	3.2 μmol/L	Negative	Negative	1.020	Negative
RUN 4	Negative	Negative	Negative	7.0	Negative	3.2 μmol/L	Negative	Negative	1.020	Negative
RUN 5	Negative	Negative	Negative	7.0	Negative	3.2 μmol/L	Negative	Negative	1.015	Negative

Positive Control:

Parameters→	GLU	BIL	KET	pH	PRO	URO	NIT	LEU	SG	BLO
Ranges	5.5 – 28 mmol/L	Positive	Positive	≥ 8.0	Trace – 1.0g/L	16 – 33 μmol/L	Positive	Small - Large	≤ 1.006	Large
RUN 1	14 mmol/L	Large	1.5 mmol/L	≥ 9.0	1.0 g/L	33 μmol/L	Positive	500 Leu/μL	1.015	200 Ery/μL
RUN 2	14 mmol/L	Large	1.5 mmol/L	≥ 9.0	1.0 g/L	33 μmol/L	Positive	500 Leu/μL	1.015	200 Ery/μL
RUN 3	14 mmol/L	Large	3.9 mmol/L	8.5	1.0 g/L	33 μmol/L	Positive	500 Leu/μL	1.015	200 Ery/μL
RUN 4	14 mmol/L	Large	3.9 mmol/L	8.5	1.0 g/L	33 μmol/L	Positive	500 Leu/μL	1.015	200 Ery/μL
RUN 5	14 mmol/L	Large	1.5 mmol/L	8.5	1.0 g/L	33 μmol/L	Positive	15 Leu/μL	1.025	200 Ery/μL



Performance Qualification:

System certification

Study Data has determined that the System described in this document either meets all criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

Exceptional conditions, if any, have been addressed.

The System is ready for specific usage.

Protocol Performed By : SIEMENS Healthcare Pvt. Ltd.

Name : Abhay Goutam

Designation : Support Engineer

Customer Authorization :

Name : SURAJ RATHOD

Designation : Head of the Department

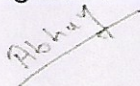
Company Representative Name & Sign

Customer Name & Sign

Name: Abhay Goutam

Date : 12/07/2021

Signature:



Name: SURAJ RATHOD

Date : 12/07/2021

Signature

