

CLINITEK Status⁺
Analyzer



INSTRUMENT DETAILS



Micropath Laboratory,
OmPlaza, Konda Lane,
Laxmipuri, Kolhapur, 416002.

INSTRUMENT NAME	Clinitek Status ⁺
INSTRUMENT NUMBER	ML/INST - 04
SERIAL NUMBER	355987
MODEL NUMBER	Status ⁺
MANUFACTURER'S NAME	Siemens
VENDOR NAME	Siemens Healthcare Pvt. Ltd
INSTALLATION DATE	02/07/2024
DATE ENTERING IN TO SERVICE	02/07/2024
LOCATION	Kolhapur

Installation Qualification for CT STATUS⁺

Customer Name : Micropath Laboratory
Address : A/D G-13, Om Plaza, Konda Lane,
Laxmipuri, Kolhapur, Maharashtra - 416002.
Instrument Model : CLINITEK STATUS⁺
Serial Number : 355987

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, so as to cause any damage to the same.

Found all the required accessories as required.

Installation Procedure & Checklist

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 Qualifications for CT STATUS+

- 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.

Instrument Set Up

- Take out the instrument from box and removed the packing carefully;
- Plugged the Adaptor of the instrument to available Voltage Protection device;
- Set up and configure the instrument;
- Installed the Moving Table;
- Installed the Printer Paper;

Siemens Healthcare Pvt. Ltd.

Name : Sampat Lokhande

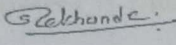
Designation : Service Engineer

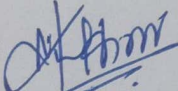
Date : 02/07/2024

CT STATUS Installation Qualification (IQ)

Customer Name : Micropath Laboratory
Department : Pathology
Contact Person : Miss. Madhuri Savekar
Instrument Model : CT-Status +
Serial Number : 355987.
Date of Installation : 02/07/2024

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,
Name : Sampat Lokhande
Designation : Service Engineer
Signature : 
Date : 02/07/2024

Micropath Laboratory
Name : Dr Manisha Kulkarni
Designation: Consultant Pathologist
Signature: 
Date: 02/07/2024

CT STATUS + Operational Qualification (OO)

Operational Inspection

- Checked the Movement of Moving Table
- Checked the Calibration of Touch Screen;
- Checked the Lamps Voltage;
- Checked the Movement of Strip;
- Quality Control Processed for verification

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 |

Siemens Healthcare Pvt. Ltd.

Name : Sampat Lokhande

Designation : Service Engineer

Date : 02/07/2024

Operational Qualification Report

Equipment name : CLINITEK STATUS+


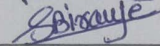
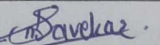
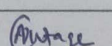

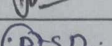
Equipment Serial No : 355987

Table 1 - Materials used for Performance Qualification

S. No	Name of the material	Lot Number	Expiry date
1	Multi Stix 10SG	30250324	31/08/2025
2	Negative Control	N0632034N	30/04/2025
3	Positive Control	P0632034P	30/04/2025

Table 2 – Training

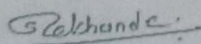
The following staffs are trained on operation, maintenance and routine trouble shooting of Clinitek Status+ - Semi automated urine chemistry analyzer

S. No	Name of the Trainee	Signature with date
1.	Miss. Sushma Korlekar	 02/07/24
2.	Miss. Sujata Biranje	 02/07/24
3.	Miss. Madhuri Savekar	 02/07/24
4.	Mr. Omkar Lokhande	
5.	Mr. Avadhoot Ghatage	 2/7/24
6.	Miss. Madhavi Pandhav	 2/7/24
7.	Mr. Pratik Nalawade	 2/7/24.

Name of the Trainer: Sampat Lokhande

Designation: Service Engineer

Sign and date: 02/07/2024



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: Siemens Healthcare Pvt. Ltd.,

Name : Sampat Lokhande

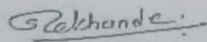
Designation : Service Engineer

Customer Authorization: Micropath Laboratory

Name : Dr Manisha Kulkarni

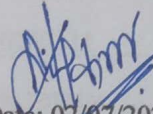
Designation : Consultant Pathologist

Company Representative Name & Sign:
Sampat Lokhande



Date: 02/07/2024

Customer Name & Sign
Dr Manisha Kulkarni



Date: 02/07/2024

Performance Qualifications for CT STATUS +

Procedure

Accuracy and Precision assay

Run all control levels 05 times each and document in the table 1 and 2 for accuracy and precision study.

Acceptance Criteria

Accuracy: All parameters should fall within the manufacturer specified reference range.

Precision: All parameters should be within the manufacturer specified reference range.

Note: Positive control ranges we have calculated on Plus System. Pack insert have different settings for ranges which we changed to Plus system for better understanding

Materials used for Performance Qualification

S. No	Name of the material	Lot Number	Expiry date
1	Multi Stix 10SG	30250324	31/08/2025
2	Level 1 Control – Negative	N0632034N	30/04/2025
3	Level 2 Control – Positive	P0632034P	30/04/2025

Table 1 – Accuracy and Precision Testing

QC Material Name : Negative Control

Lot # : N0632034N

Expiry Date : 30/04/2025

Parameter	GLU	BIL	KET	SG	BLD	PH	PRO	UBG	NIT	LEU
Ranges	Neg	Neg	Neg	1.010 – 1.025	Neg	6.0 – 7.0	Neg	0.2-1.0	Neg	Neg
Run 1	Neg	Neg	Neg	1.015	Neg	7.0	Neg	0.2	Neg	Neg
Run 2	Neg	Neg	Neg	1.015	Neg	7.0	Neg	0.2	Neg	Neg
Run 3	Neg	Neg	Neg	1.015	Neg	7.0	Neg	0.2	Neg	Neg
Run 4	Neg	Neg	Neg	1.015	Neg	7.0	Neg	0.2	Neg	Neg
Run 5	Neg	Neg	Neg	1.015	Neg	7.0	Neg	0.2	Neg	Neg

Remarks: All values are found in the Specified Ranges

Table 2 – Accuracy and Precision Testing

QC Material Name : Positive Control

Lot # : P0632034P

Expiry Date : 30/04/2025

Parameter	GLU	BIL	KET	SG	BLD	PH	PRO	UBG	NIT	LEU
Ranges	100-250mg/dl	≥ Small	≥ Trace	1.000 - 1.015	Moderate-Large	≥8.0	Trace-100mg/dl	≥2mg/dl	Positive	Trace – Moderate
Run 1	100	Large	40	1.010	Large	8.5	100	4.0	Positive	Small
Run 2	100	Large	40	1.010	Large	8.5	100	4.0	Positive	Small
Run 3	100	Large	40	1.010	Large	8.5	100	4.0	Positive	Small
Run 4	100	Large	40	1.010	Large	8.5	100	4.0	Positive	Trace
Run 5	100	Large	80	1.010	Large	8.5	100	4.0	Positive	Small

Remarks: All values are found in the specified Ranges.

Performance Qualification:

System certification

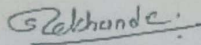
Study Data has determined that the System described in this document either meets all criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

The System is ready for specific usage.

Protocol Performed by: Siemens Healthcare Pvt. Ltd.,
Name : Sampat Lokhande
Designation : Service Engineer

Customer Authorization: Micropath Laboratory
Name : Dr. Manisha Kulkarni
Designation : Consultant pathologist

Company Representative Name & Sign
Sampat Lokhande



Date: 02/07/2024

Customer Name & Sign
Dr. Manisha Kulkarni



Date: 02/07/2024

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.

Siemens
Clinitek Status®

Serial Number: 355987

Patient Name: N1

Patient ID: N1

Multistix® 10 SG
Test date 07-02-2024
Time 5:06PM

Operator _____
Test number 0644
Color Not Entered
Clarity Not Entered

GLU Negative
BIL Negative
KET Negative
SG 1.015
BLO Negative
pH 7.0
PRO Negative
URO 0.2 E.U./dL
NIT Negative
LEU Negative

Siemens
Clinitek Status®

Serial Number: 355987

Patient Name: N2

Patient ID: N2

Multistix® 10 SG
Test date 07-02-2024
Time 5:08PM

Operator
Test number 0645

Color Not Entered

Clarity Not Entered

GLU Negative
BIL Negative
KET Negative
SG 1.015
BLO Negative
pH 7.0
PRO Negative
URO 0.2 E.U./dL
NIT Negative
LEU Negative

Siemens
Clinitek status®

Serial Number: 355987

Patient Name: N3

Patient ID: N3

Multistix® 10 SG
Test date 07-02-2024
Time 5:11PM

Operator _____
Test number 0646

Color Not Entered

Clarity Not Entered

GLU Negative

BIL Negative

KET Negative

SG 1.015

BLO Negative

pH 7.0

PRO Negative

URO 0.2 E.U./dL

NIT Negative

LEU Negative

Siemens
Clinitek Status®

Serial Number: 355987

Patient Name: N4

Patient ID: N4

Multistix® 10 SG
Test date 07-02-2024
Time 5:13PM

Operator _____
Test number 0647
Color Not Entered
Clarity Not Entered

GLU Negative
BIL Negative
KET Negative
SG 1.015
BLO Negative
pH 7.0
PRO Negative
URO 0.2 E.U./dL
NIT Negative
LEU Negative

Siemens
Clinitek Status®

Serial Number: 355987

Patient Name: N5

Patient ID: N5

Multistix® 10 SG

Test date 07-02-2024

Time 5:16PM

Operator _____

Test number 0648

Color Not Entered

Clarity Not Entered

GLU Negative

BIL Negative

KET Negative

SG 1.015

BLO Negative

pH 7.0

PRO Negative

URO 0.2 E.U./dL

NIT Negative

LEU Negative

Siemens
Clinitek Status®

Serial Number: 355987

Patient Name: P1

Patient ID: P1

Multistix® 10 SG
Test date 07-02-2024
Time 4:51PM

Operator _____
Test number 0637

Color Not Entered

Clarity Not Entered*

GLU Trace
BIL 3+
KET 2+
SG 1.010
BLO 3+
pH 8.5
PRO 2+
URO 4.0 E.U./dL
NIT Positive
LEU 1+

High pH may cause
falsely elevated PRO
results
Visibly bloody urine may
cause falsely elevated
PRO results

Siemens
Clinitek Status®

Serial Number : 355987

Patient Name : P2

Patient ID : P2

Multistix® 10 SG
Test date 07-02-2024
Time 4:54PM

Operator _____
Test number 0640
Color Not Entered
Clarity Not Entered

GLU Trace
BIL 3+
KET 2+
SG 1.010
BLO 3+
pH 8.5
PRO 1+
URO 4.0 E.U./dL
NIT Positive
LEU 3+

High pH may cause
falsely elevated PRO
results
Visibly bloody urine may
cause falsely elevated
PRO results

Siemens
Clinitek Status®

Serial Number: 355987

Patient Name: P3

Patient ID: P3

Multistix® 10 SG
Test date 07-02-2024
Time 4:57PM

Operator _____
Test number 0641
Color Not Entered
Clarity Not Entered

GLU Trace
BIL 3+
KET 2+
SG 1.015
BLO 3+
PH 8.5
PRO 1+
URO 4.0 E.U./dL
NIT Positive
LEU 1+

High pH may cause
falsely elevated PRO
results
Visibly bloody urine may
cause falsely elevated
PRO results

Siemens
Clinitek Status®

Serial Number: 355987

Patient Name: P4

Patient ID: P4

Multistix® 10 SG
Test date 07-02-2024
Time 4:59PM

Operator _____ 0642

Test number Not Entered

Color Not Entered

Clarity Not Entered

GLU Trace
BIL 3+
KET 2+
SG 1.010
BLO 3+
pH 8.5
PRO 2+
URO 4.0 E.U./dL
NIT Positive
LEU Trace

High pH may cause
falsely elevated PRO
results
Visibly bloody urine may
cause falsely elevated
PRO results

Siemens
Clinitek Status®

Serial Number: 355987

Patient Name: P5

Patient ID: P5

Multistix® 10 SG
Test date 07-02-2024
Time 5:02PM

Operator _____
Test number 0643
Color Not Entered
Clarity Not Entered

GLU Trace
BIL 3+
KET 2+
SG 1.010
BLO 3+
pH 7.5
PRO 1+
URO 4.0 E.U./dL
NIT Positive
LEU 3+

Visibly bloody urine may
cause falsely elevated
PRO results
