

Version: 1.23

Calibration Certificate

Calibration of the **V Chem Next** (Semi Auto Biochemistry Analyzer) has been carried out as per the recommendations of the principle company.

Customer Name: DR. DASGUPTAS EYE CLINIC & LABORATORY, ROHINI, DELHI.

Date of Installation: 07/04/2023.

Calibration Date: 08/04/2023.

MODEL: V Chem Next

| TEMPRETURE | |
|------------|--------|
| 37°C | Passed |

Sr. No: ES1052206CN241

| | AD VALUE | |
|--------------|-------------|--------|
| AD Value | 35000-55000 | Passed |
| OFFSET value | 0-4000 | Passed |
| GAIN value | 1-255 | Passed |

OD linear range is **0-3.0A**

Next Calibration Due On: 07/10/2023.

18/J

Tested By: Checked By



Performance Qualification

MODEL: V Chem Next | Sr. No: ES1052206CN241 | Version: 1.23 | Date: 08-04-2023

PQ is performed at

DR. DASGUPTAS EYE CLINIC & LABORATORY, ROHINI, DELHI

According to the assay results that are comprised in this document the VCHEM NEXT system can be approved for the routine operation.

System released for routine operation.

| PERFORMANCE CALIBRATION | | | |
|-------------------------|--------|--------------|--------|
| LOT No: MB052303 | | | |
| TEST | TARGET | RANGE | RESULT |
| GLU | 92.46 | 76.74-108.18 | 104.42 |
| CRE | 1.10 | 0.91-1.29 | 1.10 |
| SGOT | 45.23 | 37.54-52.92 | 49.4 |
| SGPT | 43.50 | 36.11-50.90 | 46.7 |
| UREA | 46.56 | 38.64-54.48 | 44.42 |

Note: Performance of the parameters are subject to traceability of Reagents, Manufacturer or Supplier.

| VP ZON | • |
|--------|---|
| (x) | |

Tested By: Checked By:





Operational Qualification

| MODEL: VCHEM NEXT | Sr. No: ES1052206CN241 | Version: 1.23 | Date: 08-04-2023 |
|-------------------|------------------------|---------------|------------------|
|-------------------|------------------------|---------------|------------------|

Operational Qualification Protocol run at DR. DASGUPTAS EYE CLINIC & LABORATORY, ROHINI, DELHI.

| # | Description | Status |
|---|-------------------------------------|--------|
| 1 | Blank/Optics | Passed |
| 2 | Assays(Parameter) Calibration | Passed |
| 3 | Assay (Parameter) Control – BioNORM | Passed |
| 4 | Assays(Parameter) Samples(Patient) | Passed |

I confirm that the above specified analyzer V Chem Next (Semi Auto Biochemistry Analyzer) is installed properly and its performance is within the specification.

Tested By: Checked By:





Installation Qualification

| MODEL: VCHEM NEXT | Sr. No: ES1052206CN241 | Version: 1.23 | Date: 07-04-2023 |
|-------------------|------------------------|---------------|------------------|
|-------------------|------------------------|---------------|------------------|

Installation of V Chem Next (Semi Auto Biochemistry Analyzer) at DR. DASGUPTAS EYE CLINIC & LABORATORY, F-26/10, SECTOR 7, ROHINI, DELHI.

The Installation Checklist is as given below:-

| # | Position | Action | Status |
|---|--------------|--|--------|
| 1 | Unpacking | Unpack the Complete System | OK |
| 2 | Inventory | Check Accessories | OK |
| 3 | Installation | Connection Of waste Pipeline Connection Of the Equipment | ОК |
| 4 | Service | Action /Hardware Test Check Blank/Optics | ОК |
| 5 | User | Start Work Procedure Blank Test Run QC Run Samples/Check Reproducibility Stop Work Procedure | ОК |

A

Tested By: Checked By

DR. DAS GUPTA LABORATORIES

| Sample ID: Test Name: | 0002 |
|--------------------------|---------------------|
| Abs. : | SGPT |
| Result: | -0.0264 |
| Unit: | 46.7 U/L |
| Ref. Low: | 36.0 |
| Ref. High: | 50.0 |
| Test/Date: | 08/04/2023 12:11:12 |

DR. DAS GUPTA LABORATORIES

| Sample ID: | 0002 |
|------------|---------------------|
| Test Name: | SGOT |
| Abs. : | -0.0279 |
| Result: | 49.4 |
| Unit: | U/L |
| Ref. Low: | 37.0 |
| Ref. High: | 52.9 |
| Test/Date: | 08/04/2023 12:16:29 |

DR. DAS GUPTA LABORATORIES

| Sample ID: | 0004 |
|--------------|--------|
| Test Name: | U_ACID |
| Abs. : | 0.1178 |
| Result: | 5.86↑ |
| Unit: | mg/dl |
| Ref. Low: | 4.10 |
| Ref. High: | 5.80 |
| 110111111111 | 10.00. |

Test/Date: 08/04/2023 12:22:10

Result: 0.0214
Unit: 1.10
Ref. Low: mg/dl
Ref. High: 0.80
Test/Date: 0.9/04/2002 15

Test/Date: 08/04/2023 12:47:3

DR. DAS GUPTA LABORATORIES

Sample ID: 0007
Test Name: GLU
Abs.: 0.3718
Result: 104.421
Unit: mg/dl
Ref. Low: 74.00
Ref. High: 100.00

Test/Date: 08/04/2023 13:15:0

3/04/2023 12:23:50

DR. DAS GUPTA LABORATORIES

Sample ID: 0004 Test Name: TG Abs. : 0.3754 Result: 98.574 Unit: mg/dl Ref. Low: 25,000 Ref. High: 160,000 Test/Date: 08/04/2023 12:26:17

DR. DAS GUPTA LABORATORIES

Sample ID:

Test Name:

Abs. :

Result:

Unit:

Ref. Low:

Ref. High:

0001

UREA

0.0433

44.42

mg/dl

38.00

54.00

Test/Date: 08/04/2023 12: