



Calibration Certificate

Customer Name: Checkpoint Healthcare Pvt Ltd

Address of Customer: Mayur Vihar Delhi

Model : CHEM5x

Serial No. : S2208181

Calibration Done Date : 15/07/2023

Calibration Due Date : On or Before 14/07/2024

This is to certify that we have calibrated the Semi-Automatic Biochemistry Analyzer Model: CHEM5x bearing Sr. No. S2208181 and on inspection of the instrument gains. It is observed that the results are well within the range and instrument is working fine.

Thanking you,

For

Transasia Bio-Medicals Ltd.



Lavkush Lal ★

Sr. Application Specialist




Calibration Data			
Diffraction Grating Data			
S.N.	Filter	Gain Values	OK/Yes/No
1	340	133182	OK
2	405	142934	OK
3	505 ^u	141950	OK
4	546	154089	OK
5	578	147927	OK
6	630	137945	OK

Thanking you,

For

Transasia Bio Medicals Ltd.

Lavkush Lal
A circular blue ink stamp with the text 'Transasia Bio Medicals Ltd.' around the perimeter and 'New Delhi' in the center. A small star is at the bottom of the stamp.

Lavkush Lal

Sr. Application Specialist

Offset
Calibration data

FILTER	OFFSET	GAIN
340	-00344	133182
405	-00629	142934
505	-00322	141950
546	-00447	154089
578	-00738	147927
630	-00162	137945

Offset
Calibration data

FILTER	OFFSET	GAIN
340	-00344	133182
405	-00629	142934
505	-00322	141950
540	-00447	154089
576	-00738	147927
630	-00162	137945

TRANSASIA
ERBA Chem 5X
SEMI-AUTOMATED BIO-CHEMISTRY
ANALYZER
INSTRUMENT QUALIFICATION DOCUMENT
FOR
"Checkpoint Healthcare Pvt Ltd"



TRANSASIA BIOMEDICALS LIMITED			TRANSASIA[®] Bio-Medicals Ltd.
IQQQPQ of Erba CHEM 5X (Checkpoint Healthcare Pvt Ltd)			
Instrument Name	CHEM 5X	SN	S2208181

Installation Qualification for Erba Chem5X NS

Customer Name : Checkpoint Healthcare Pvt Ltd

Address : Mayur Vihar Delhi

Instrument Model : CHEM 5X

Serial Number : S2208181

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report:

Found the System to have been delivered in satisfactory condition.

Confirmed and found all the required accessories as per dispatch note as per table below.

Sr No.	Description	Qty
1.	POWER CORD 3 PIN 250V/6A	1
2.	USER MANUAL - Chem-5X New Scheme (Domestic)	1
3.	THERMAL PRINTER PAPER ROLL (57mm x30mt.)	1
4.	RECTANGULAR POLY. MICRO CUVETTE	5
5.	ALLEN KEY 3MM	1
6.	T200y Pipet Tips Series 200ul(Yellow)	100
7.	T1000b Pipet Tips Series 1000ul(Blue)	100
8.	ROUND GLASS MICROCUVETTES	5
9.	DUST COVER FOR Chem-5 XNS	1
10.	TEST TUBE HOLDER (with*O-ring)	1
11.	Pipette Stand (Plastic)	1
12.	PROLINE SINGLE CHANNEL VARAIBLE VOLUME MECHANICAL PIPETTES 5UL - 50UL (CAT. NO 720020)	1
13.	PROLINE SINGLE CHANNEL VARAIBLE VOLUME MECHANICAL PIPETTE 100UL - 1000UL (CAT. NO 720060)	1
14.	ERBA WASH (4 X 50 ML)	1

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA[®] Bio-Medicals Ltd.
IQOQPQ of Erba CHEM 5X (Checkpoint Healthcare Pvt Ltd)			
Instrument Name	CHEM 5X	SN	S2208181

Installation Procedure & Checklist Attached for records.

External Requirements for Installation:

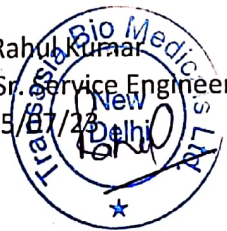
1. Input voltage of 220V-240V / 50Hz or 60Hz.
2. Perfect earthing was provided at power source with all applicable local Requirement (A grounded, power plug only should be used). The voltage between earth and neutral should not exceed more than 3V.


Installation Certificate for

This is to certify that the Instrument Serial No.S2208181 is successfully installed and commissioned at Checkpoint Healthcare Pvt Ltd and the Installation Protocol / checklist has been successfully completed for the above instrument.

For TBM, Technical Services Department

Name : Rahul Kumar
Designation : Sr. Service Engineer
Date : 15/07/2023



TRANSASIA BIOMEDICALS LIMITED			
IQOQPQ of Erba CHEM 5X (Checkpoint Healthcare Pvt Ltd)			
Instrument Name	CHEM 5X	SN	S2208181

Installation Qualification for Erba Chem5X

Carried out all the Installation Procedures as per the Installation Procedure & Checklists.

Connected the Peristaltic Pump tubing correctly & placed the end of the waste tubing coming out of the analyzer into the waste bottle provided for collecting waste.

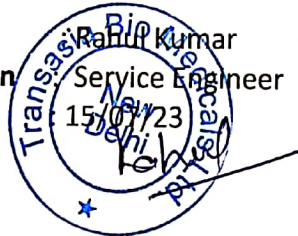
Carried out all the necessary system checks and tests.


Performed all due maintenance activities.

Handed over the Instrument for Operators Training & Qualifications

For TBM, Technical Services Department

Name: Raj Kumar
 Designation: Service Engineer
 Date: 15/07/23



TRANSASIA BIOMEDICALS LIMITED			
IQOQPQ of Erba CHEM 5X (Checkpoint Healthcare Pvt Ltd)			
Instrument Name	CHEM 5X	SN	S2208181

Installation Report for Erba Chem 5X

Customer Name : Checkpoint Healthcare Pvt Ltd

Department : Laboratory
Contact Person : Kuber Singh


Instrument Model : Erba Chem-5X NS

Serial Number : S2208181

Date of Installation: 06/09/2021


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

TBM, Technical Services Department

Name : Ravi Kumar
Designation : Service Engineer
Signature : 
Date : 15/07/2023



Customer Detail

Name : Kuber Singh
Designation : Lab Tech.
Signature : 
Date : 15/07/2023

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA [®] Bio-Medicals Ltd.
IQOQPQ of Erba CHEM 5X (Checkpoint Healthcare Pvt Ltd)			
Instrument Name	CHEM 5X	SN	S2208181


Instrument Setup

1. Assembled the instrument accessories.
2. Connected the 3/2 pin cord (with earth terminal) of the external SMPS to the mains socket & checked the output of the SMPS it should be 18V DC +/- 1.0 V DC.
3. Connected the Peristaltic Pump tubing & placed the end of the waste tubing coming out of the analyzer into the waste bottle provided for collecting the waste.
4. Mounted the printer paper.

TBM, Technical Services Department

Name : Rahu Kumar
 Designation : Service Engineer
 Signature : 
 Date : 15/07/23

Customer Detail

Name : Kuber Singh
 Designation : Lab Tech.
 Signature : 
 Date : 15/07/2023

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA [®] Bio-Medicals Ltd.
IQOQPQ of Erba CHEM 5X (Checkpoint Healthcare Pvt Ltd)			
Instrument Name	CHEM 5X	SN	S2208181

Operational Qualification For Erba Chem5X

System Certification:

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

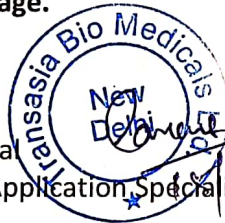
Exceptional conditions, if any, have been addressed.

The System is ready for specific usage.

Protocol Performed By: TBM

Name: Lavkush Lal

Designation: Sr. Application Specialist



Customer Authorization:

Name: Kuber Singh

Designation: Lab Tech.

KS

15/07/2023

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA [®] Bio-Medicals Ltd.
IQOQPQ of Erba CHEM 5X (Checkpoint Healthcare Pvt Ltd)			
Instrument Name	CHEM 5X	SN	S2208181

Operational Qualification for Erba Chem5X

[A] FUNCTIONAL CHECK :

- OK
1. **PUMP CALIBRATION** OK
 (Calibrate the peristaltic pump and record the count range from 1800 to 2700)
 2. **PRINTER TEST** OK
 (To carry out printer function test from maintenance menu and to confirm that all characters printed w/o gap & are clearly readable:- Last line must be above paper cutter)
 3. **KEY FUNCTIONS** OK
 (Confirm all keys function & keys functioning are smooth)
 4. **BUZZER** OK
 (Buzzer beeps when key is pressed)
 5. **PERISTALTIC PUMP ASSEMBLY** OK
 (Confirm rotor rotates smoothly without jerk, and placement of peristaltic tubing Remains at the centre of the bush and should not be touching the end support or rotor base)
 6. **TEMPERATURE CHECK**
 Cuvette temperature physical: 37.1
 Temperature Range: (A) 37° C ± 0.1°C
 (B) 57.5 KΩ to 59.0 KΩ using temperature Jig
 Check temperature in RUN TEST mode for temperatures:
 1. 37° C: OK 2. 30° C: OK 3. 25° C: OK
 7. **GAIN CHECK FOR ALL FILTERS:** OK

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA[®] Bio-Medicals Ltd.
IQQQPQ of Erba CHEM 5X (Checkpoint Healthcare Pvt Ltd)			
Instrument Name	CHEM 5X	SN	S2208181

8. Checked Hardware test and found OK.

OK

9. Checked Date & time and found OK.

OK

10. Checked printer test and found OK.

OK

TBM, Technical Services Department

Name : Lavkush Lal
 Designation: Application Specialist
 Signature
 Date



Customer Detail

Name : Kuber Singh
 Designation: Lgg Tech.
 Signature :
 Date : 15/07/2023

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA [®] Bio-Medicals Ltd.
IQOQPQ of Erba CHEM 5X (Checkpoint Healthcare Pvt Ltd)			
Instrument Name	CHEM 5X	SN	S2208181

Performance Qualifications for Erba Chem5X

1. PRECISION CHECK:

(After performing Glucose, Cholesterol, Triglyceride calibration, prepare reaction solution of one concentration of around 5ml and aspirate this reaction 500µl 11 times and note down readings and calculate CV. CV should be below 3%)

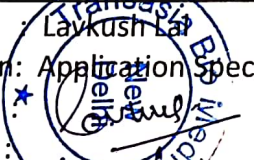
Precision data attached.

Conclusion:


The result for all the performance tests carried out for the instrument meets/does not meet the acceptance criteria. Hence the instrument is/ is not qualified for the performance.

Protocol performed By:- Lavkush Lal (Sr. Application Specialist Transasia Biomedicals Ltd)

TBM, Technical Services Department

Name : Lavkush Lal
 Designation: Application Specialist
 Signature : 
 Date : 15/07/2023

Customer Detail

Name : Kuber Singh
 Designation: Lg Tech
 Signature : 
 Date : 15/07/2023

Intra Assay Precision Study

Parameters	Glu	Chol	Tgl	Uric	BIT	Prot
Replications	Results	Results	Results	Results	Results	Results
Rep1	248.6	242.3	100.7	12.85	4.37	8.49
Rep2	249.6	233.7	98.58	11.14	4.43	8.63
Rep3	247.1	232.5	95.7	10.74	4.14	8.89
Rep4	241.6	233	94.65	11.02	4.49	8.84
Rep5	237.1	232.7	95.9	10.6	4.26	8.8
Rep6	237.1	232.2	99.11	10.27	4.3	8.74
Rep7	236.3	240.4	96.67	10.54	4.25	8.7
Rep8	238	238.3	97.65	10.93	4.22	8.69
Rep9	245.5	233.9	98.58	10.49	4.14	8.69
Rep10	237.1	234.9	100.7	10.07	4.18	8.71
Mean	241.80	235.39	97.82	10.87	4.28	8.72
SD	3.46	3.62	1.52	0.10	0.12	0.11
CV%	1.43	1.54	1.55	0.92	2.80	1.29
Limit %	< 3.0	< 3.0	< 3.0	< 5.0	< 3.0	< 3.0

Site Name - Checkpoint Healthcare Pvt Ltd

Instrument SN - S2208181

Analysis Date - 15 July 2023

Handwritten signature/initials

Carryover worksheet

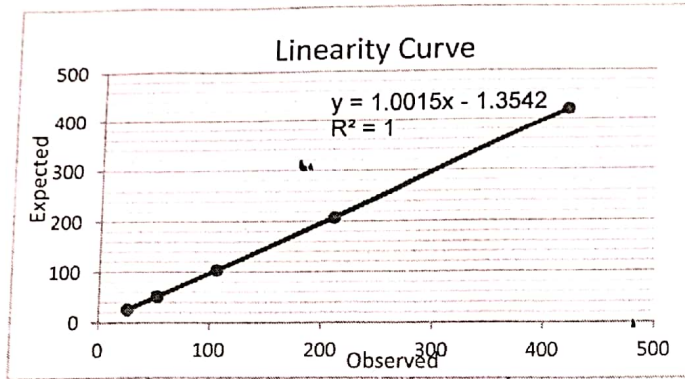
Interpretation of results :

1) If (L1-L3) is equal to a negative number or zero then stop as there is no evidence of carryover.

Run	Parameters					
	Prot	Trig	Glu	BIT	Chol	Uric
H1	7.27	119.4	223.4	3.55	232.6	10.51
H2	7.28	126.3	224.7	3.6	233.1	10.55
H3	7.35	126.9	224.7	3.64	233	10.56
L1	3.98	61.05	103.1	1.01	55.55	0.81
L2	4	62.76	104	1.04	56.42	0.85
L3	4	65.07	104.1	1.04	56.34	0.85
% Carryover	-0.60	-1.30	-0.83	-1.15	-0.45	-0.41
Limit %	< 2.0	< 2.0	< 2.0	< 2.0	< 2.0	< 2.0

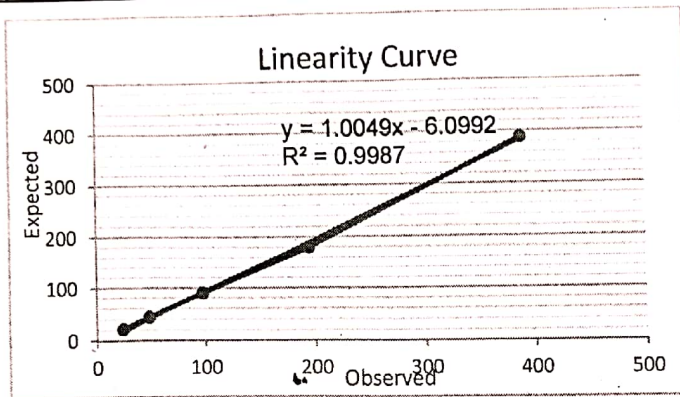
Site Name - Checkpoint Healthcare Pvt Ltd
 Instrument SN - S2208181
 Analysis Date - 15 July 2023

CHEM5x				
Linearity Curve with R Square Value				
Glucose				
Sr. No.	Dilutions	Expected Conc	Observed Conc	% Recovery
1	Neat	421.00	421.00	100.0
2	(1:2)	210.50	207.90	98.8
3	(1:4)	105.25	104.00	98.8
4	(1:8)	52.63	51.50	97.9
5	(1:16)	26.31	25.73	97.8



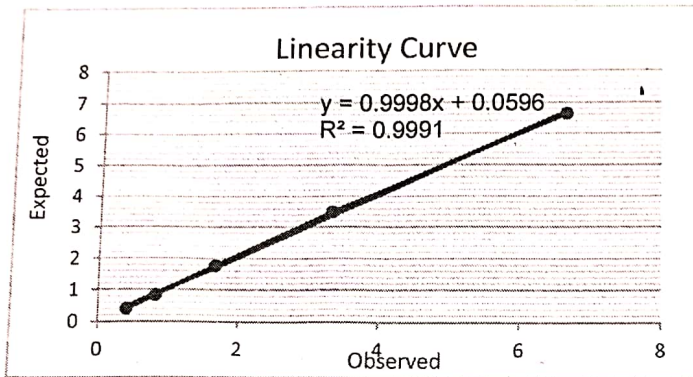
Site Name - Checkpoint Healthcare Pvt Ltd
Instrument SN - S2208181
Analysis Date - 15 July 2023

CHEM5x				
Linearity Curve with R Square Value				
Cholesterol				
Sr. No.	Dilutions	Expected Conc	Observed Conc	% Recovery
1	Neat	388.40	388.40	100.0
2	(1:2)	194.20	180.30	92.8
3	(1:4)	97.10	90.29	93.0
4	(1:8)	48.55	44.71	92.1
5	(1:16)	24.28	22.03	90.8



Site Name - Checkpoint Healthcare Pvt Ltd
 Instrument SN - S2208181
 Analysis Date - 15 July 2023

CHEM5x				
Linearity Curve with R Square Value				
Bilirubin Total				
Sr. No.	Dilutions	Expected Conc	Observed Conc	% Recovery
1	Neat	6.65	6.65	100.0
2	(1:2)	3.33	3.49	105.0
3	(1:4)	1.66	1.78	107.1
4	(1:8)	0.83 ³⁴	0.85	102.3
5	(1:16)	0.42	0.41	98.6



Site Name - Checkpoint Healthcare Pvt Ltd

Instrument SN - S2208181

Analysis Date - 15 July 2023