

Date: 16/02/2022

CALIBRATION CERTIFICATE

TO WHOM SOEVER IT MAY CONCERN

This is to Certify That The Analyzer Bearing the Serial no: **S2110167** Has Installed by us

At **KG Diagnostics, Tenkasi.** Has Been Calibrated on 16-Feb-2022 And Verified To Control Values.

LOT NO 99			
TEST	MEAN	SD	DV
GLUCOSE	88.8	4.4	87.0
UREA	56.5	3.8	53.9
CREATINIE	1.66	0.10	1.73
TGL	47.5	2.5	44.7
T.PRO	5.2	0.2	5.0
ALB	2.84	0.17	2.76

The Next Calibration Due is on or Before : 15-Feb-2023

For TRANSASIA BIO MEDICALS LTD



P.Ramachandran
Sr.Application Specialist

TRANSASIA BIO-MEDICALS LTD.

TRANSASIA BIO-MEDICAL LTD.

CHEM 5X

SR. NO :S2110167

IQ,OQ AND PQ

For

KG DIAGNOSTICS, TENKASI

Marketed by:
Transasia Bio-Medicals Ltd.,
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI - 400 072

TRANSASIA BIO-MEDICALS LTD.

Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai - 400 072 Tel.: (022) 40309000, Fax : (022) 2857 3030
Email : transasia@transasia.co.in Website : www.transasia.co.in

Installation Qualification for Erba Chem5X NS

Customer Name : KG DIAGNOSTICS

Address : 5-294(3) A.P.S Complex, Madurai Main Road, Tenkasi

Instrument Model : CHEM 5X

Serial Number : S2110167

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

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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. S2110167 is successfully installed and commissioned at KG DIAGNOSTICS and the Installation Protocol / checklist has been successfully completed for the above instrument.

For TBM, Technical Services Department

Name : Mr. A.GanesaMoorthi
Designation : Service Engineer
Date :16/02/2022

TRANSASIA BIO-MEDICALS LTD.

Installation Qualification for Erba Chem5X NS

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: Mr. A.GanesaMoorthi
Designation: Service Engineer
Date: 16/02/2022

Installation Report for Erba Chem 5X NS

Customer Name : KG DIAGNOSTICS

Department : LAB

Contact Person : MR.LAKSHMANAN

Instrument Model : Erba Chem-5X NS

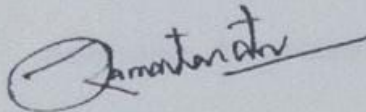
Serial Number : S2110167

Date of Installation: 16/02/2022

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 : P.RAMACHANDRAN
Designation: Sr.Application Specialist

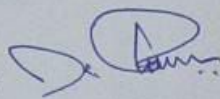


Signature :

Date :16/02/2022

Customer Detail

Name : K.LAKSHMANAN
Designation : LAB - TECH

Signature : 

Date : 16.02.2022

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 : P.RAMACHANDRAN

Designation: Sr.Application Specialist

Signature :

Date :16/02/2022

Customer Detail

Name : K.LAKSHMANAN

Designation: LAB TECH

Signature :

Date : 16.2.2022

TRANSASIA BIO-MEDICALS LTD.

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 : P.RAMACHANDRAN

Designation: Sr.Application Specialist

Signature :

Date :16/02/2022

Customer Detail

Name : K.LAKSHMANAN

Designation: LAB TECH

Signature :

Date : 16.2.2022

TRANSASIA BIO-MEDICALS LTD.

Operational Qualification For Erba Chem5X NS

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:

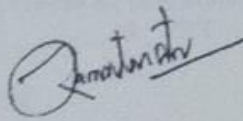
Name: P.RAMACHANDRAN
Designation: Sr.Application Specialist

Customer Authorization:

Name: Mr.Lakshmanan
Designation: Lab Technician

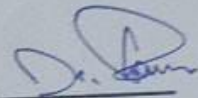
Company Representative Sign:-

Date: 16/02/2022



Customer Sign:-

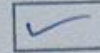
Date:- 16/02/2022



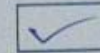
Operational Qualification for Erba Chem5X NS

[A] FUNCTIONAL CHECK :
1. PUMP CALIBRATION

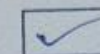
(Calibrate the peristaltic pump and record the count range from 1800 to 2700)


2. PRINTER TEST

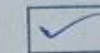
(To carry out printer function test from maintenance menu and to confirm that all characters printed w/o gap & are clearly readable:- Last line must be above paper cutter)


3. KEY FUNCTIONS

(Confirm all keys function & keys functioning are smooth)


4. BUZZER

(Buzzer beeps when key is pressed)


5. PERISTALTIC PUMP ASSEMBLY

(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

 Temperature Range: (A) $37^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$

 (B) 57.5 K Ω to 59.0 K Ω using temperature jig)

Check temperature in RUN TEST mode for temperatures:

 1. 37°C : _____ 2. 30°C : _____ 3. 25°C : _____

7. GAIN CHECK FOR ALL FILTERS

Filter	340	405	505	546	578	630	Range
Gains	38000	42000	49000	62000	69500	74000	30000-200000
Offset	-5100	-6150	-6110	-5980	-5510	-6512	-5000 to +5000

8. Checked Hardware test and found OK.



9. Checked Date & time and found OK.



10. Checked printer test and found OK.


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TBM, Technical Services DepartmentName :
Designation :
Signature :
Date :**Customer Details**Name :
Designation :
Signature :
Date:**Performance Qualifications for Erba Chem5X NS****1. PRECISION CHECK:**

(After performing Glucose calibration, prepare Glucose reaction solution of one concentration of around 5ml and aspirate this reaction 500 μ l 10 times and note down readings and calculate CV. CV should be below 3%)

Sr. No.	Concentration mg/dl
1.	93.2
2.	91.8
3.	93.5
4.	90.9
5.	91.6
6.	91.8
7.	92.8
8.	92.2
9.	93.1
10	92.8
Mean	95.59
SD	4.78
CV%	3%

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2. KINETIC, END-POINT MODE CHECK :

(Process the Biochemistry check with reagents and controls as per the kit insert literatures.)

TEST	BLK OD	LEVEL 1				LEVEL 2			
		LOT NO 99				LOT NO 88			
		MEAN	SD	DV	SD	MEAN	SD	DV	SD
GLUCOSE	0.0421	88.8	4.43	93	< 1SD	267	13.3	274	< 1SD
UREA	0.0702	56.6	3.77	54	< -1SD	135	6.67	140	< 1SD
TGL	0.0239	47.8	2.4	50	< 1SD	211	10.6	223	< 2SD
T.PRO	0.1220	5.14	0.21	5.2	< 1SD	8.18	0.33	8.4	< 1SD
ALB	0.0276	2.84	0.17	2.95	< 1SD	4.55	0.27	4.60	< 1SD
CREATININE	0.0000	1.60	0.10	1.51	< -1SD	4.91	0.29	5.05	< 2SD

PERFORMANCE TEST	DATA TRACEABILITY	REMARKS MEETS/DOES NOT MEET ACCEPTANCE
SGPT		
CHOL		
CRET		

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:-

TBM, Technical Services Department

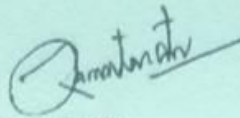
CUSTOMER

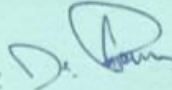
DETAIL TBM, Technical Services Department

Customer Detail

Name : P.RAMACHANDRAN
Designation: Sr.Application Specialist

Name : K. LAKSHMANAN
Designation: LAB. TECH

Signature : 
Date : 16/02/2022

Signature : 
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