

Transasia Blo - Medicals Ltd., Transasia House, & Chandivali Studio Road, Andheri (E), Mumbai - 400 072 Tel: +91 22 4030 9000 Fax: +91 22 2857 3030

CALIBRATION REPORT

To, Right Care Pathology Lab,Pune

DATE- 10/02/23

Dear Sir,

As desired by you please find enclosed herewith the Calibration report:

- 1. Instrument: Bio-chemistry Analyzer EC-5X S.N- S2010209.
- 2. Range of the instrument: Optical density Linear form 0-2.5.
- 3. Date of Calibration 10 Feb 2023.
- 4. Next Calibration Due- 09 Feb 2024.

Quality Control Results-

Test Type	Test Results	Range
End Point (GLU)	<u>9</u> 9.00	80.2-108.2
Fix Time (URE)	33.2	29.85-37.85
Kinetic (SGPT)	44.2	37.5-52.5

All values are with in Range as per Quality control ERBA NORM.

Thanking you and assuring of our prompt attention at all times.

Yours faithfully, For TRANSASIA BIO-MEDICALS

RAJESH WANKHEDE



www.transasla.co.in



TRANSASIA ERBA Chem 5X NS

SEMI-AUTOMATED BIO-CHEMISTRY ANALYZER INSTRUMENT QUALIFICATION DOCUMENT FOR "Right Care Pathology Lab, Pune"



www.transasia.co.in

Page 1 of 9



Installation Qualification for Erba Chem5X NS

Customer Name : Right Care Pathology Lab

:

Address

1st & 2nd Floor, Tanishq Building, near Sai Sanskruti Apt., Near Bank of Maharashtra, Sinhgad College Road, Ambegaon Bk Pune-46

Instrument Model: ERBA EC5XSerial Number: S2010209Initial 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

Installation Procedure & Checklist Attached for records.

Page 2 of 9





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.S2010209 is successfully installed and commissioned atAddress:-

1st & 2nd Floor, Tanishq Building, near Sai Sanskruti Apt., Near Bank of Maharashtra, Sinhgad College Road, Ambegaon Bk Pune-46 and the Installation Protocol / checklist has been successfully completed for the above instrument.

For TBM, Technical Services Department

Name	: Mukund Tonpe
Designation	: SERVICE ENGINEER
Date	: 25/11/2020





Installation Qualification for Erba Chem 5% ANSERVIC

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: Mukund Tonpe Designation: SERVICE ENGINEER Date: 25/11/2020



Page 4 of 9



Installation Report for Erba Chem 5%

Customer Name : Right Care Pathology Lab

Department : Contact Person :

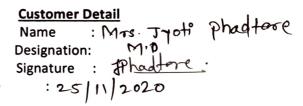
Instrument Model : Erba Chem-5X NS Serial Number : S2010209 Date of Installation: 25/11/2020

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 : Mukund Tonpe Designation: SERVICE ENGINEER Signature : Date : 25/11/2020

Date











- 1. Assembled the instrument accessories.
- 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

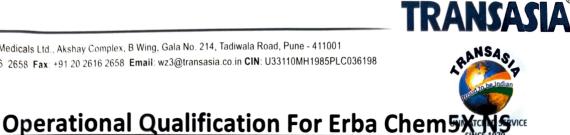
Name: Mukund Tomorrow.Designation: SERVICE ENGINEERSignatureDate:25/11/2020



Custom	<u>er Detail</u>
Name	: Tyoti phadlooc
Designation	" M.P.
Signature	: Jphadtore
Date :	25/11/2020
	25 111 2020



Page 6 of 9



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: MANDAR SUMANT **Designation: APPLICATION SPECILIST**

Customer Authorization: Name: **Designation:**

Company Representative Sig Date:-25/11/2020



Customer Sign:-Date:- 25



Page 7 of 9

Operational Qualification for Erba Chem5X

[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. PERISTALIC 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

Temperature Range: (A) 37° C± 0.1°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	40,000	35000	50,000	55000	10,000	75000	30000-200000
Offset	1000	1500	1400	1500	4000	3000	-5000 to +5000

8. Checked Hardware test and found OK.

HO : Transasia Bio - Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai - 400 072,



_	_	_	







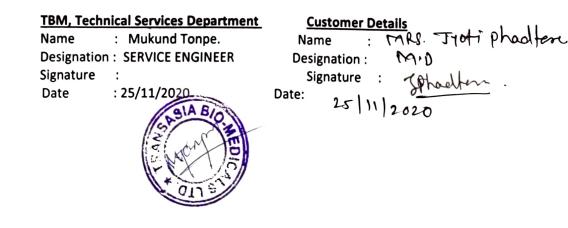




9. Checked Date & time and found OK.

•

10. Checked printer test and found OK.



Page 9 of 9





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 500µl 10 times and note down readings and calculate CV. CV should be below 3%)

Sr. No.	Concentration mg/dl
1.	99.74
2.	101.9
3.	99.21
4.	101.1
5.	97.50
6.	98.88
7.	96.91
8.	105.0
9.	96.81
10	95.72
Mean	gg. 28
SD	2.81
CV%	2·83

2. KINETIC, END-POINT MODE CHECK :

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

		LE	VEL 1	LEVEL 2
TEST	BLK OD			
SGPT	0.0	54.	00	
(HOL	0.0	124.	00	
(RET	0.0	1.40 .	00	



Page 10 of 9





PERFORMANCE TEST	DATA TRACEABILITY	REMARKS MEETS/DOES NOTE MEET ACCEPTANCE
SGPT	Yes	Yes
CHOL	Yes	Yes
CRET	Yes	yes.

Conclusion:

1

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.

Date

Protocol performed By:-

TBM, Technical Services Department

TBM, Technical Services Department

Name : Mukund Tonpe Designation: SERVICE ENGINEER Signature : Date :25/11/2020

Son Martin Contraction

CUSTOMER DETAIL

<u>Customer Detail</u> Name : MRS. Jjoti phadfore. Designation: M.D Signature : Jphadfore. ²25/11/20.

