



## CALIBRATION REPORT

To,  
Right Care Pathology Lab,Pune

DATE- 25/11/21

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 - 25 Nov 2021.
4. Next Calibration Due- 24 Nov 2022.

Quality Control Results-

Test Type	Test Results	Range
End Point (GLU)	99.00	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 LTD.

RAJESH WANKHEDE  
REGIONAL SERVICE MANAGER





**TRANSASIA**  
**ERBA Chem 5X NS**  
SEMI-AUTOMATED BIO-CHEMISTRY  
ANALYZER  
INSTRUMENT QUALIFICATION DOCUMENT  
FOR  
"Right Care Pathology Lab, Pune"



## 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 EC5X

**Serial Number** : S2010209

**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 VARIABLE VOLUME MECHANICAL PIPETTES 5UL - 50UL (CAT. NO 720020)	1
13.	PROLINE SINGLE CHANNEL VARIABLE VOLUME MECHANICAL PIPETTE 100UL - 1000UL (CAT. NO 720060)	1
14.	ERBA WASH (4 X 50 ML)	1

**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.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 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: Mukund Tonpe**

**Designation: SERVICE ENGINEER**

**Date: 25/11/2020**



## Installation Report for Erba Chem 5X NS

**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

### Customer Detail

**Name** : Mrs. Jyoti phadtare  
**Designation:** M.D  
**Signature** : Jphadtare  
**Date** : 25/11/2020





## 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 : Mukund Tomorrow.  
Designation: SERVICE ENGINEER  
Signature :  
Date : 25/11/2020

### Customer Detail

Name : Jyoti phadtare  
Designation: M.D  
Signature : J. Phadtare  
Date : 25/11/2020





## Operational Qualification For Erba Chem 5XNS

### 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 Sign: \_\_\_\_\_  
Date: -25/11/2020



Customer Sign: - [Signature]  
Date: - 25/11/2020





## 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°C

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:  2. 30° C:  3. 25° C:

**7. GAIN CHECK FOR ALL FILTERS**

Filter	340	405	505	546	578	630	Range
Gains	40,000	35,000	50,000	55,000	10,000	75,000	30000-200000
Offset	1000	1500	1400	1500	4000	3000	-5000 to +5000

**8. Checked Hardware test and found OK.**



9. Checked Date & time and found OK.

10. Checked printer test and found OK.

**TBM, Technical Services Department**

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

**Customer Details**

Name : MRS. Jyoti phadker  
Designation : M.D  
Signature : J. Phadker  
Date: 25/11/2020





UNMATCHED SERVICE  
SINCE 1979...

## 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	99.28
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.)

TEST	BLK OD	LEVEL 1		LEVEL 2	
SGPT	0.0	54.	00		
CHOL	0.0	124.	00		
CRET	0.0	1.40.	00		



PERFORMANCE TEST	DATA TRACEABILITY	REMARKS UNMATCHED SERVICE MEETS/DOES NOT MEET ACCEPTANCE
SGPT	yes	yes
CHOL	yes	yes
CRET	yes	yes.

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

Name : MRS. Jyoti phadtare  
Designation: M.D  
Signature : Jphadtare  
Date : 25/11/20.

