



CALIBRATION REPORT

To.

Sadbhavana Pathology Lab,
Pune.

Dear Sir,

As per requirement instrument re calibrated and details are as below:

1. Instrument: Bio-chemistry Analyzer EC-5plusV2 S.N- **S200619**
2. Range of the instrument: Optical density Linear form 0-2.5
3. Date of Calibration - 17/06/2021
4. Next Calibration Due- 16/06/2022

Test Voltages / Test Temperature -

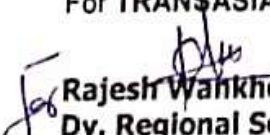
Test Voltage	Actual Voltage	Ok / Not Ok
Logic 5 V	4.9V	OK
Lamp Voltage (11.5V – 12V)	11.68V	OK
SMPS 16.5 -18.5	17.8	OK
Flowcell Temperature	20°C, 40°C, 37°C ,OFF	ALL OK

Sr.No.	Filters	Pre Channel	Log Channel
1	340	113789	0.6025
2	405	126634	0.4622
3	450	126622	0.5071
4	505	178114	0.5125
5	546	168093	0.4165
6	578	157354	0.3286
7	630	159546	0.4155
8	670	175124	0.3555

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

Yours faithfully,

For TRANSASIA BIO-MEDICALS LTD.


Rajesh Wankhede
Dy. Regional Service Manager



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TRANSASIA
ERBA Chem 5 V210K
SEMI-AUTOMATED BIO-CHEMISTRY
ANALYZER
INSTRUMENT QUALIFICATION DOCUMENT
FOR
"Sadbhavana Pathology Laboratory, Manchar"

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Installation Qualification for ERBA CHEM-5 V210

Customer Name : Sadbhavana Pathology Laboratory, Manchar

Address : Solapur

Instrument Model : Erba Chem5plusV2

Serial Number : S200619

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
	POWER CORD 3 PIN 250V/5A	1
	USER MANUAL - Erba V2 10K (Domestic)	1
	THERMAL PRINTER PAPER ROLL (57mm x30mt.)	1
	RECTANGULAR POLY. MICRO CUVETTE	5
	ALLEN KEY 3MM	1
	T200y Pipet Tips Series 200ul(Yellow)	100
	T1000b Pipet Tips Series 1000ul(Blue)	100
	ROUND GLASS MICROCUVETTES	5
	TEST TUBE HOLDER (with O ring)	1
	Pipette Stand (Plastic)	1
	PROLINE SINGLE CHANNEL VARIABLE VOLUME MECHANICAL PIPETTES 5UL - 50UL (CAT. NO 720020)	1
	PROLINE SINGLE CHANNEL VARIABLE VOLUME MECHANICAL PIPEPITE 100UL - 1000UL (CAT. NO 720060)	1
	ERBA WASH (4 X 50 ML)	1

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Installation Procedure & Checklist Attached for records.



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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. S200619 is successfully installed and commissioned at **Sadbhavana Pathology Laboratory, Manchar** and the Installation Protocol / checklist has been successfully completed for the above instrument.

For TBM, Technical Services Department

Name : Hemant Punse
Designation : Sr. Service Engineer
Date :



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Installation Qualification for ERBA CHEM-5 V210N



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: Hemant Punse
Designation: Sr. Service Engineer
Date:



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Installation Report for ERBA CHEM-5 V210K

Customer Name : Sadbhavana Pathology Laboratory, Manchar

Department : Pathology

Contact Person :

Instrument Model : Erba Chem-5 V2 10K

Serial Number : S200619

Date of Installation:

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 : Hemant Punse

Designation: Sr. Service Engineer

Signature :

Date :



Customer Detail

Name : Sanket Rode

Designation: Proprieter

Signature : *Rode*

Date : 8/09/21



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
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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 : Hernant Punse
Designation: Sr. Service Engineer
Signature : 
Date :



Customer Detail

Name : Sonket Rode
Designation: Proprieter
Signature : 
Date : 8/09/21

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Operational Qualification For ERBA CHEM-5



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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: Hemant Punse
Designation: Sr. Service Engineer

Customer Authorization:

Name:
Designation:

Company Representative Sign: _____
Date: _____

Customer Sign: [Signature]
Date: 8/09/21





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Operational Qualification for ERBA CHEM-5

[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	450	505	546	578	600	670	Range
Gains	40,000	35,000	45,000	50,000	55,000	60,000	50,000	75,000	30,000-200,000
Offset	1000	1500	1200	1400	1500	4000	+4000	3000	-5000 to +5000

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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 : Hemant Punse
Designation : Sr. Service Engineer
Signature :
Date :



Customer Details

Name : Sanket Rode
Designation : Rode Proprietor
Signature :
Date: 8/09/21





Performance Qualifications for ERBA CHEM-5 V210K

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	40.00		41.00	
CHOL	0.0	200.00		199.00	
CRET	0.0	2.00		2.01	

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

000088 GLU 99.74 mg/dl

000089 GLU 101.9 mg/dl H

000090 GLU 99.21 mg/dl

000091 GLU 101.1 mg/dl H

000103 GLU 97.50 mg/dl

08/09/21 16:30:18

000104 GLU 98.88 mg/dl

000102 GLU 96.91 mg/dl

08/09/21 16:17:49

000101 GLU 105.0 mg/dl H

000097 GLU 96.81 mg/dl

000098 GLU 95.79 mg/dl



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 : Hemant Punse
Designation: Sr. Service Engineer
signature :
Date :

Name : *Sanket Rode*
Designation: *Proprieter*
Signature : *[Signature]*
Date : *8/09/21*

