

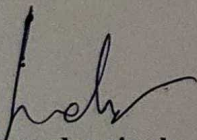
## Certificate of Calibration

**Customer Name** : Dr.Reetu's Path Lab  
**Model** : Biochemistry Analyser, Erba Chem-7  
**Serial No.** : S170917  
**Calibration Date** : 17-7-2021  
**Next Calibration Due Date** : 16-07-2022

*With reference to the Semi Automated Biochemistry Analyser, Model :ERBA CHEM-7 bearing Sr. No. S170917 at Dr.Reetu's Path lab, on inspection of the instrument it is observed that the results are well within the range and instrument is working fine.*

*Instrument is properly calibrated.*

Thanking you,  
For **Transasia Bio-Medicals Ltd.**



**Devender singh**  
**Sr.Service engineer**

**TRANSASIA  
ERBA CHEM-7  
SEMI-AUTOMATED BIO-CHEMISTRY  
ANALYZER**

**INSTRUMENT QUALIFICATION  
DOCUMENT  
FOR  
“DR. REETU’S PATH LAB”**

**BALLABHGARH.**

# Installation Qualification for ErbaCHEM-7

**Customer Name** :DR. REETU'S PATH LAB.

**Address** :BALLABHGARH

**Instrument Model**:CHEM-7

**Serial Number**:S170917

**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.

<b>Sr No.</b>	<b>Description</b>	<b>Qty</b>
1.	POWER CORD 3 PIN 250V/6A	1
2.	USER MANUAL - CHEM-7 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-7	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.S170917 is successfully installed and commissioned at DR. REETU'S PATH LAB and the Installation Protocol / checklist has been successfully completed for the above instrument.

**For TBM, Technical Services Department**

**Name** : Mr. DILIP YADAV  
**Designation** : SERVICE ENGINEER  
**Date** :

# **Installation Qualification for ErbaCHEM-7**

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. Dilip Yadav

**Designation:** SERVICE ENGINEER

**Date:**

# Installation Report for ErbaCHEM-7

**Customer Name** :DR. REETU'S PATH LAB

**Department** : Laboratory

**Contact Person** :DR. REETU NAGE

**Instrument Model** :CHEM-7

**Serial Number** :S170917

**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 DepartmentCustomer Detail

Name:MR. DEVENDER SINGHName: DR. REETU NAGE

Designation: SERVICE ENGINEER Designation: HOD

Signature :Signature :

Date : Date:

# 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 Customer Detail

Name: MR. DEVENDER SINGH Name : DR. REETU NAGE

Designation: SERVICE ENGINEER Designation: HOD.

Signature : Signature :

Date : Date:

# **Operational Qualification For CHEM-7**

## **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:        Transasia bio-medicals ltd.

Name: Mr. Dilip Yadav  
Designation: SERVICE ENGINEER

Customer Authorization: DR. REETU'S PATH LAB.

Name: DR. REETU NAGE  
Designation: HOD.

**Company Representative Sign:-**\_\_\_\_\_

**Date:-** \_\_\_\_\_

**Customer Sign:-**\_\_\_\_\_

**Date:-** \_\_\_\_\_



# Operational Qualification for CHEM-7

**[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: \_\_\_\_\_

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	<b>Range</b>
Gains									<b>30000-200000</b>
Offset									<b>-5000 to +5000</b>

**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 Customer Detail**

Name: MR. DEVENDER SINGH Name : DR. REETU NAGE

Designation: SERVICE ENGINEER Designation: HOD

Signature : Signature :

Date : Date:

## Performance Qualifications for CHEM-7

### 1. PRECISION CHECK:

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

### 2. KINETIC, END-POINT MODE CHECK :

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.

Data attach separately.

Protocol performed By:-

**TBM, Technical Services Department**

**CUSTOMER DETAIL**

#### TBM, Technical Services Department Customer Detail

Name : Vikas Dagar

Name: DR. REETU NAGE

Designation: Application Specialist

Designation: HOD.

Signature :

Signature :

Date :

Date:

17/07/21 09:39:36

036292 UAC 9.59 mg/dl H

17/07/21 09:43:12

CRE DELTA STD O.D. 0.0783  
NET O.D. : 0.0583  
CONC : 2.0 mg/dl  
FACTOR : 29.283

LINEAR REACTION

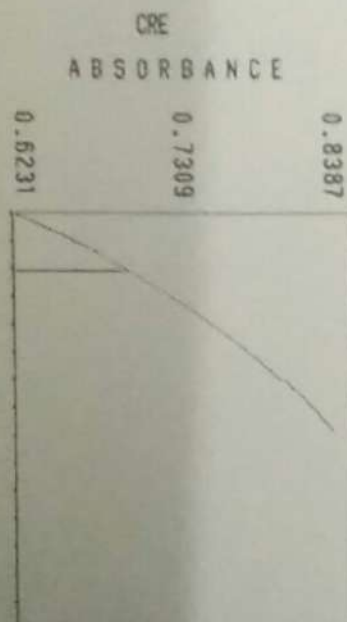
036293 CRE 1.90 mg/dl H

LINEAR REACTION

036294 CRE 3.88 mg/dl H

LINEAR REACTION

036294 CRE 3.88 mg/dl H



X Axis:1Unit = 10sec  
SAMPLE O.D. Initial= 0.6982  
DELTA SAMPLE O.D. = 0.1405

036294 CRE 3.88 mg/dl H

LINEAR REACTION

17/07/21 09:48:04

036295 BIT 3.98 mg/dl H

17/07/21 09:10:17

URE DELTA STD O.D. -0.101  
NET O.D. : -0.103  
CONC : 50.0 mg/dl  
FACTOR : -485.4

LINEAR REACTION

036281 URE 58.73 mg/dl H

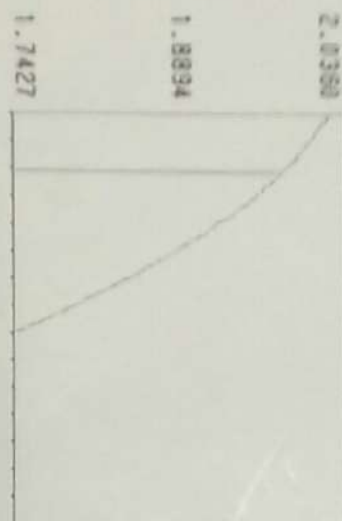
LINEAR REACTION

036282 URE 123.8 mg/dl H

LINEAR REACTION

036282 URE 123.8 mg/dl H

URE  
ABSORBANCE



X Axis:1Unit = 10sec  
SAMPLE O.D. Initial= 1.9956  
DELTA SAMPLE O.D. = -0.253

036282 URE 123.8 mg/dl H

LINEAR REACTION

17/07/21 09:31:35

ALB Reagent (B) -0.028

ALB STD O.D. 0.7490  
NET O.D. : 0.7770  
CONC : 3.6 g/dl  
FACTOR : 1.7872

17/07/21 09:33:39

GLU STD O.D. 0.3749  
NET O.D. : 0.2876  
CONC : 100.0 mg/dl  
FACTOR : 347.71

036285 GLU 309.8 mg/dl H

036287 GLU 352.4 mg/dl H

17/07/21 09:35:52

CHO STD O.D. 0.3350  
NET O.D. : 0.3107  
CONC : 200.0 mg/dl  
FACTOR : 643.71

036288 CHO 254.6 mg/dl H

036289 CHO 297.3 mg/dl H

17/07/21 09:37:39

PRO STD O.D. 0.3641  
NET O.D. : 0.2251  
CONC : 6.0 g/dl  
FACTOR : 26.655

036290 PRO 9.01 g/dl H

17/07/21 09:30:09

ALB STD O.D. 0.4343  
NET O.D. : 0.3430  
CONC : 3.6 g/dl  
FACTOR : 10.496

036284 ALB 4.09 g/dl