

**Certificate of Calibration**

**Customer Name:** FAMILY HOSPITAL AND RESEARCH CENTER, DEPARTMENT OF PATHOLOGY, KANPUR, U.P.

**Model:** Semi-Automated Bio Chemistry Analyzer Erba CHEM 5 PLUS V2

**Serial No.:** N110517

**Calibration done date:** 08/04/2021

**Next Calibration Date:** 07/04/2022

**Lab In charge:** Dr. A.K. Gupta

*This is to certify that above mentioned product has been verified of calibration By*

*Checking Lamp Voltage*

*Checking gain of Photo meter for all Filters*

*Checking sipping volume of peristaltic pump- 2195*

*Cuvette temperature physical: 37°C*

Filter	PRE-CHANNEL
340	169811
405	168531
450	168647
505	167634
546	167981
578	166824
630	165952
670	165783

*Followed by calibration of all the three types of chemistries (picked up GLI CREAT and SGPT) and QC run with satisfactory values of QC*

Calibration at site performed by Mr. Saurabh Tripathi

Authorized Signatory  
(Mr. Saurabh Tripathi)  
Sr. Service Engineer  
For Transasia Bio-Medicals Ltd.

*Saurabh*

RAW-MATERIAL

08/04/21 05:34:40  
LAB TECH R P OJHA

GLU Reagent OD 0.0903

MEAN 84.0 RANGE 72.0 - 96.0

GLU STD O.D. 0.4351  
CONC : 100 mg/dL  
FACTOR: 290.02

000028 GLU 75.17 mg/dL

08/04/21 05:43:19  
LAB TECH R P OJHA

CRE DELTA STD O.D. 0.0858  
CONC : 2 mg/dL  
FACTOR: 23.310

MEAN 1.70 RANGE 1.20 - 2.20

000029 CRE 2.24 mg/dL H

08/04/21 05:50:26  
LAB TECH R P OJHA

000030 GPT 25.28 U/L

FILTER	GAIN	OFFSET
340	011457	-03548
405	005897	-03373
450	014509	-03512
505	029311	-03483
546	026463	-03257
578	022641	-03414
630	040871	-03483
670	042116	-03319

**TRANSASIA BIO-MEDICALS LTD.**

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08/04/21 20:00:38  
LAB TECH R P OJHA

**TRANSASIA**  
**ERBA Chem-5 PLUS v2**  
SEMI-AUTOMATED BIO-CHEMISTRY  
ANALYZER  
INSTRUMENT QUALIFICATION DOCUMENT  
FOR  
"FAMILY HOSPITAL AND RESEARCH CENTER, DEPARTMENT OF PATHOLOGY, KANPUR,  
U.P. "

## Installation Qualification Erba Chem5 PLUS v2

**Customer Name** : FAMILY HOSPITAL AND RESEARCH CENTER, DEPARTMENT OF PATHOLOGY, KANPUR, U.P.

**Address** : A-9., AWAS VIKAS, HANSPURAM, HAMIRPUR ROAD, NAUBASTA , KANPUR

**Instrument Model** : Semi-Automated Bio Chemistry Analyzer Erba CHEM-5 PLUS v2

**Serial Number** : N110517

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-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. **N110517** is successfully installed and commissioned at **FAMILY HOSPITAL AND RESEARCH CENTER, DEPARTMENT OF PATHOLOGY, KANPUR, U.P.** and the Installation Protocol / checklist has been successfully completed for the above instrument.

**For TBM, Technical Services Department**

**Name** : MR. Saurabh Tripathi  
**Designation** : Sr. Service Engineer

*Saurabh*

**Date** : 30/06/2011

## Installation Qualification Erba Chem5 PLUS v2

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. Saurabh Tripathi

Designation: Sr. Service Engineer

Date: 30/06/2011

*Saurabh*

## Installation Report Erba Chem 5 plus v2

Customer Name : FAMILY HOSPITAL AND RESEARCH CENTER, Department of Pathology , Kanpur UP

Department : PATHOLOGY  
Contact Person : Dr. A.K. Gupta

Instrument Model : Erba Chem-5 plus V2

Serial Number : N110517


Date of Installation: 30/06/2011

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 : Mr. Saurabh Tripathi


Designation: Sr. Service Engineer

Signature : 

Date : 30/06/2011

### Customer Detail

Name : Dr. A.K. Gupta

Signature : 

Date : 30/06/2011


## 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 : Mr. Saurabh Tripathi


Designation: Sr. Service Engineer

Signature : 

Date : 30/06/2011

### Customer Detail

Name : Dr. A.K. Gupta

Signature : 

Date : 30/06/2011

### **TRANSASIA BIO-MEDICALS LTD.**

# Operational Qualification For Erba Chem5 plus v2

## 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: Mr. Saurabh Tripathi  
Designation: Sr. Service Engineer

Customer Authorization:

Name: Dr. A.K. Gupta



Company Representative Sign:-



Customer Sign:-

Date:- 30/06/2011

Date:- 30/06/2011



# Operational Qualification for Erba Chem5 plus

## v2

### [A] FUNCTIONAL CHECK :

#### 1. PUMP CALIBRATION

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

2195

#### 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)

OK

#### 3. KEY FUNCTIONS

(Confirm all keys function & keys functioning are smooth)

OK

#### 4. BUZZER

(Buzzer beeps when key is pressed)

OK

#### 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)

OK

#### 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)

#### 7. GAIN CHECK FOR ALL FILTERS

Filter	PRE-CHANNEL
340	169783
405	168544
450	168273
505	167871
546	167352
578	166253
630	165241
670	165734



8. Checked Hardware test and found OK.

9. Checked Date & time and found OK.

10. Checked printer test and found OK.

OK

OK

**TBM, Technical Services Department**

Name : Mr. Saurabh Tripathi

Designation : Sr. Service Engineer

Signature : 

Date : 30/06/2011

**Customer Details**

Name : Dr. A.K. Gupta

Signature : 

Date: 30/06/2011

## Performance Qualifications for Erba Chem5plusV2

### 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.	83.92
2.	84.76
3.	85.52
4.	86.03
5.	86.13
6.	87.06
7.	87.89
8.	88.65
9.	89.74
10	90.12
Mean	86.982
SD	2.085
CV%	2.397

#### Conclusion:

The result for all the performance tests carried out for the instrument meets the acceptance criteria. Hence the instrument is qualified for the performance.

Protocol performed By:- Mr. Rajat Sharma

**TBM, Technical Services Department**

**TBM, Technical Services Department**

Name : Mr. Rajat Sharma

Designation: Application Specialist

Signature :



Date : 30/06/2011

#### CUSTOMER DETAIL

##### Customer Detail

Name : Dr. A.K. Gupta

Signature :



Date : 30/06/2011

30/06/11 01:13:46  
LAB TECH R P OJHA

000009 GLU 83.92 mg/dl

000010 GLU 84.76 mg/dl

000011 GLU 85.52 mg/dl

000012 GLU 86.03 mg/dl

000013 GLU 86.13 mg/dl

000014 GLU 87.06 mg/dl

000015 GLU 87.89 mg/dl

000016 GLU 88.65 mg/dl

000017 GLU 89.74 mg/dl

000018 GLU 90.12 mg/dl

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