



CERTIFICATE OF CALIBRATION

Customer Name : Dr. Akanksha Gupta, Rewari

Model : Erba Chem 7

Serial No. : S180140

Calibration Date : 10/02/2022

Calibration Due Date : 09/02/2023

This is to certify that we have calibrated the Semi Automated Biochemistry Clinical Chemistry Analyzer, Model: Erba Chem 7 bearing Sr. No. S180140 and on inspection of the instrument it is observed that the results are well within the range and instrument is working satisfactorily.

Thanking you,

For **Transasia Bio-Medicals Ltd.**

Pawan Bizla

Sr. Area Service Manager

M: +91-9812780002

E mail: p.bizla@transasia.co.in



CALIBRATION CERTIFICATE

1 NAME OF HOSPITAL : Dr. Akanksha Gupta, Rewari
2 MODEL : ERBA CHEM 7
3 SR NO. : S180140
4 RANGE OF THE INSTRUMENT : OPTICAL DENSITY LINEAR FORM 0-2.5
5 DATE OF CALIBRATION : 10/02/2022
6 NEXT DUE DATE : 09/02/2023

TEST VOLTAGES / TEST TEMPERATURE

TEST VOLTAGE	ACTUAL VOLTAGE	OK/ NOT OK
LOGIC 5V	5.02V	OK
LAMP VOLTAGE (11.5V-12V)	11.75V	OK
SMPS V (17-19V)	18.50V	OK
FLOWCELL TEMPERATURE	25C,30C,37C, OFF	ALL OK
PUMP CALIBRATION		OK



TRANSASIA[®]

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TRANSASIA
ERBA Chem 7

SEMI-AUTOMATED BIO-CHEMISTRY
ANALYZER
INSTRUMENT QUALIFICATION DOCUMENT
FOR
“_SHREE PATH LAB_”

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Installation Qualification for Erba Chem7

Customer Name : SHREE PATH LAB
Address : FIRST FLOOR, INSIDE RATAN DIAGNOSTICS, CIRCULAR ROAD,
REWARI, HARYANA.
Instrument Model : CHEM-7
Serial Number : S180140
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. S180140 is successfully installed and commissioned at SHREE PATH LAB and the Installation Protocol / checklist has been successfully completed for the above instrument.

For TBM, Technical Services Department

Name : MOHIT GILL
Designation : SERVICE ENGINEER
Date : 06-04-2022



Installation Qualification for Erba Chem7

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: MOHIT GILL

Designation: SERVICE ENGINEER

Date: 06-04-2022

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Installation Report for Erba Chem 7

Customer Name : SHREE PATH LAB

Department : LAB

Contact Person : DR. AKANKSHA GUPTA

Instrument Model : Erba Chem-7

Serial Number : S180140

Date of Installation: 19-09-2018

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 : MOHIT GILL

Designation: SERVICE ENGINEER

Signature :

Date : 06-04-2022

Customer Detail

Name : DR. KAMAL KANT

Designation: DIRECTOR

Signature :


Date : 06/04/2022



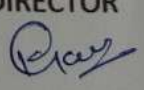
Instrument Setup

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 : MOHIT GILL
Designation: SERVICE ENGINEER
Signature : 
Date : 06-04-2022

Customer Detail

Name : DR. KAMAL KANT
Designation: DIRECTOR
Signature : 
Date : 06/04/2022



Operational Qualification For Erba Chem7

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.

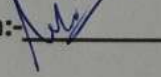
The System is ready for specific usage.

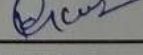
Protocol Performed By:

Name: MOHIT GILL
Designation: SERVICE ENGINEER

Customer Authorization:

Name: DR. KAMAL KANT
Designation: DIRECTOR

Company Representative Sign: 
Date: 06.04.2022

Customer Sign: 
Date: 06/04/2022



Operational Qualification for Erba Chem7

[A] FUNCTIONAL CHECK :

PUMP CALIBRATION

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

OK

1. 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

2. KEY FUNCTIONS

(Confirm all keys function & keys functioning are smooth)

OK

3. BUZZER

(Buzzer beeps when key is pressed)

OK

4. 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



5. 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: _____

6. GAIN CHECK FOR ALL FILTERS

Filter	340	405	450	505	546	578	600	670	Range
Gains	35000	27142	41060	43153	58143	52000	61234	48004	30000-200000
Offset	4918	3712	3800	-3214	3643	-2158	4817	-4160	-5000 to +5000

7. Checked Hardware test and found OK.

YE

9. Checked Date & time and found OK.

YE

10. Checked printer test and found OK.

YE

TBM, Technical Services Department

Name : MOHIT GILL

Designation : SERVICE ENGINEER

Signature : *Mohit*

Date : 06-04-2022

Customer Details

Name : DR. KAMAL KANT

Designation : DIRECTOR

Signature : *Kamal Kant*

Date: 06/04/2022

Performance Qualifications for Erba Chem7

1. PRECISION CHECK:

(After performing Glucose calibration, prepare Glucose reaction solution of one concentration of around 5ml and aspirate this reaction 500 μ l 10 times and note down readings and calculate CV. CV should be below 3%)

Sr. No.	Concentration mg/dl
1.	98.0
2.	97.4
3.	98.7
4.	99.2
5.	98.3
6.	100.4
7.	99.5
8.	101.3
9.	97.9
10	99.1
Mean	98.98
SD	0.50
CV%	$0.005 \times 100 = 0.5\%$



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	0.0045	39.45	40.25	80.20	80.65
CHOL	0.0052	200.10	199.80	300.05	300.10
CRET	0.0038	1.02	0.99	2.21	2.25

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

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:- Prem Singh

TBM, Technical Services Department

CUSTOMER DETAIL

TBM, Technical Services Department

Customer Detail

Name : SUNIL KUMAR

Name : DR. KAMAL KANT

Designation: APPLICATION SPECIALIST

Designation: DIRECTOR

Signature : *Sunil*

Signature : *Prem*

Date : 06.04.2022

Date : 06/04/2022



CHRISTIAN MEDICAL COLLEGE

DEPARTMENT OF CLINICAL BIOCHEMISTRY
CMC EXTERNAL QUALITY ASSURANCE SCHEME
MONTHLY SUMMARY REPORT - FEBRUARY 2022



PC-1024

Lab Name **SHREE PATH LAB** Lab No **14718**
Constituent Group **Chemistry II** Date of Result Entered : **19/02/2022**
PT item **Lyophilized Serum** Date of Report Published : **05/03/2022**

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants CV	SD	Your Value	SDI	U
1	GLUCOSE II	GOD-POD II	Any Analyser (Automation / Semi Automation)	1020	269.30	10.10	27.19	236 mg/dL	-1.22	1.70
2	UREA II	Urease UV / GLDH II	Any Analyser (Automation / Semi Automation)	612	29.53	13.54	4.00	26.38 mg/dL	-0.79	0.32
3	T.BILIRUBIN II	Diazonium Salt (Colorimetric) / Jendrassik II	Any Analyser (Automation / Semi Automation)	786	5.13	12.02	0.62	4.69 mg/dL	-0.71	0.04
4	T-PROTEIN II	Biuret - Colorimetric II	Any Analyser (Automation / Semi Automation)	782	5.64	9.45	0.53	6.06 g/dL	0.79	0.04
5	ALBUMIN II	BCG - Colorimetric II	Transasia / Erba	597	3.40	8.90	0.30	3.6 g/dL	0.66	0.02
6	URIC ACID II	Enzymatic / Uricase Colorimetric II	Any Analyser (Automation / Semi Automation)	774	4.73	18.22	0.86	4.95 mg/dL	0.26	0.06
7	CHOLESTROL II	CHOD-PAP II	Any Analyser (Automation / Semi Automation)	985	117.47	11.97	14.06	129.8 mg/dL	0.88	0.90
8	TRIGLYCERIDE II	GPO-PAP / Enzymatic Colorimetric / End Point II	Any Analyser (Automation / Semi Automation)	869	104.61	17.04	17.83	80.62 mg/dL	-1.35	1.21

SDI Range	Interpretation
Within -1.00 to +1.00	Excellent.
Within ± 1.01 to ± 2.00	Good.
Within ± 2.01 to ± 2.99	Accept with caution. Warning Signal.
Beyond ± 3.0	Unacceptable performance. Action Signal.

LAB ADDRESS :

SHREE PATH LAB
ABOVE RATAN ULTRASOUND, OPPOSITE GOVERNMENT GIRLS SCHOOL, CIRCULAR ROAD
REWARI
HARYANA123401

Coordinator Contact Details:
Email: clinqc@cmcvellore.ac.in
Contact Number: 0416-2283102

Pamela Christudoss
Dr. Pamela Christudoss
CMC EQAS Coordinator
Christian Medical College, Vellore

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

CMC EQAS does not sub contract any components

***** End of Report *****

