

**TRANSASIA<sup>®</sup>**

Transasia Bio-Medicals Ltd., 109-110, 1st Floor, Deep Shikha Building, Rajendra Place, New Delhi - 110 008  
Tel: 011 - 25732223 Fax: 011-25785451 Email: nz1@transasia.co.in CIN: U33110MH1985PLC036198



**TRANSASIA**  
**ERBA Chem 7**

SEMI-AUTOMATED BIO-CHEMISTRY  
ANALYZER  
INSTRUMENT QUALIFICATION DOCUMENT  
FOR  
“\_SHREE PATH LAB\_”

Page 1 of 9

## 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



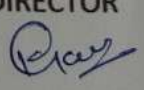
## Instrument Setup

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.

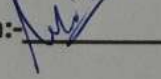
**The System is ready for specific usage.**

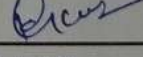
### Protocol Performed By:

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 $\mu$ 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



# TESTNCAL LABORATORY

(A DIVISION OF TESTING & CALIBRATION INDIA (OPC) PVT. LTD)

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9001:2015

## Calibration Certificate

Certificate/ULR No.: TNC/2022/2/42

Page 1 of 1

Customer Details		Instrument Receipt Date	1-Jan-2022
<b>M/S SHREE PATH LAB</b>		SRF No.	ISO/JC/21-22/317
First Floor, Ratan Ultrasound Centre Opposite Government Girls School Circular Road, Rewari Haryana Pin Code : 123401		Date of Calibration	1-Jan-2022
		Next Calibration Date	31-Dec-2022
		Certificate Issue Date	3-Jan-2022
A) Identification On UUC (Unit Under Calibration)			
Instrument Name	Digital Thermo Hygrometer	Make / Model No.	HTC-1/---
Range	-50 to 70 °C, 10 to 99 % RH	Instrument Condition	SATISFACTORY
Least Count	0.1°C, 1% RH	Location of Calibration	At Site
Serial No.	---	Location	Shree Path Lab Rewadi
Instrument ID.	DTM-01	Parameter	Thermal
<b>ENVIRONMENTAL CONDITION</b>	Temperature:- 24±2 °C,Relative Humidity: - 55±10%	Calibration Reference Standard	---
		Calibration Procedure	TNC-05/T/01

### Details of Test Equipments Used

Name	I.D. NO./ SR NO	Certificate/ULR No.	Valid upto
RH & Temperature Sensor with Indicator	TNC/T/C/007/17	CC210121000000413F	11/03/2022

### Calibration Results (Temperature)

Sr.No.	UUC Value (°C)	Standard Value (°C)	Deviation (°C)	Uncertainty at k=2 at 95 % Confidence Level (±) (°C)
1	10.0	10.01	0.01	0.48
2	20.0	20.04	0.04	0.48
3	30.0	30.06	0.06	0.48
4	40.0	40.07	0.07	0.48
5	50.0	50.08	0.08	0.48

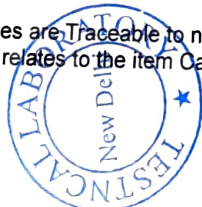
### Calibration Result (Humidity)

Sr.No.	UUC Value (%RH)	Standard Value ((%RH))	Deviation ((%RH))	Uncertainty at k=2 at 95 % Confidence Level (±) (%RH)
1	20	20.00	0.00	1.7
2	30	30.02	0.02	1.7
3	40	40.04	0.04	1.7
4	50	50.06	0.06	1.7
5	80	80.10	0.10	1.7
6	90	90.21	0.21	1.7

Note:

- The Calibration results reported in this certificate are valid at the time of and the started condition of measurement.
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P -17 F03-00

Issued & Approved By

*(Signature)*  
CEO

Testncal Laboratory  
Plot No. 113, Pocket A2, Sector-17  
Dwarka, New Delhi-110075



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## Calibration Certificate

Certificate/ULR No.: CC205522000000893F Page 1 of 1

<b>Customer Details</b>		Instrument Receipt Date	1-Jan-2022
<b>M/S SHREE PATH LAB</b>		SRF No.	TNC1/JC/21-22/130
First Floor, Ratan Ultrasound Centre Opposite Government Girls School Circular Road, Rewari Haryana Pin Code : 123401		Date of Calibration	1-Jan-2022
		Next Calibration Date	31-Dec-2022
		Certificate Issue Date	3-Jan-2022

<b>A) Identification On UUC (Unit Under Calibration)</b>			
Instrument Name	Incubator	Make / Model No.	---/---
Range	0 to 110 °C	Instrument Condition	SATISFACTORY
Least Count	As per Instruments	Location of Calibration	At Site
Serial No.	---	Location	Shree Path Lab Rewadi
Instrument ID.	INC-02	Parameter	°C
<b>ENVIRONMENTAL CONDITION</b>	Temperature:- 25±2 °C,Relative Humidity: - 50±10%	Calibration Reference Standard	ITS-90
		Calibration Procedure	TNC-06-T 2.0

### Details of Test Equipments Used

Name	I.D. NO./ SR NO	Certificate/ULR No.	Valid upto
4-Wire RTD with Indicator	TN/T/C/005/17	CC317221000000028F	09/02/2022

### Calibration Results

Sr.No.	UUC Value (°C)	Standard Value (°C)	Deviation (°C)	Uncertainty at k=2 at 95 % Confidence Level (±)
1	10.0	10.01	0.01	0.48
2	40.0	40.02	0.02	0.48
4	50.0	50.04	0.04	0.48
5	70.0	70.07	0.07	0.48
5	110.0	110.09	0.09	0.48

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## Calibration Certificate

Certificate/ULR No.: CC205522000000894F

Page 1 of 1

Customer Details		Instrument Receipt Date	1-Jan-2022
M/S SHREE PATH LAB First Floor, Ratan Ultrasound Centre Opposite Government Girls School Circular Road, Rewari Haryana Pin Code : 123401		SRF No.	TNC1/JC/21-22/130
		Date of Calibration	1-Jan-2022
		Next Calibration Date	31-Dec-2022
		Certificate Issue Date	3-Jan-2022
A) Identification On UUC (Unit Under Calibration)			
Instrument Name	Centrifuge	Make / Model No.	---/---
Range	0 to 3500 rpm	Instrument Condition	SATISFACTORY
Least Count	10 rpm	Location of Calibration	At Site
Serial No.	---	Location	Shree Path Lab Rewadi
Instrument ID.	CEN-01	Parameter	Speed
ENVIRONMENTAL CONDITION	Temperature: 25±2°C, Relative Humidity: 50±10%	Calibration Reference Standard	IS: 12508
		Calibration Procedure	TNC -02-RPM 2.0

### Details of Test Equipments Used

Name	I.D. NO./ SR NO	Certificate/ULR No.	Valid upto
Dig. Tachometer	TNC/RPM/C/002/19	CC233921000001239F	10/02/2022

### Calibration Results

Sl. No.	UUC Value (rpm)	Std. Value (rpm)	Error (rpm)	Uncertainty at k=2, ± %
1	100	100	0	1.65
2	500	501	-1	0.45
3	1000	1002	-2	0.19
4	2000	2003	-3	0.19
5	3500	3504	-4	0.19

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(Amit Kumar)  
CEO

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Dwarka, New Delhi-110075

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CC-2055

## Calibration Certificate

Certificate/ULR No.: CC205522000000895F

Page 1 of 1

Customer Details		Instrument Receipt Date	1-Jan-2022
M/S SHREE PATH LAB First Floor, Ratan Ultrasound Centre Opposite Government Girls School Circular Road, Rewari Haryana Pin Code : 123401		SRF No.	TNC1/JC/21-22/130
		Date of Calibration	1-Jan-2022
		Next Calibration Date	31-Dec-2022
		Certificate Issue Date	3-Jan-2022

### A) Identification On UUC (Unit Under Calibration)

Instrument Name	Micropipette	Make / Model No.	Dragon Lab/---
Range	100 to 1000 µl	Instrument Condition	SATISFACTORY
Least Count	5 µl	Location of Calibration	At Laboratory
Serial No.	YE199AL0541492	Location	Shree Path Lab Rewadi
Instrument ID.	Pipette-01	Parameter	Volume
ENVIRONMENTAL CONDITION	Temp:- ( 24±2)°C, RH: - (50±10)%	Calibration Reference Standard	ISO 8655
		Calibration Procedure	TNC-02-V 2.0

### Details of Test Equipments Used

Name	I.D. NO./ SR NO	Certificate/ULR No.	Valid upto
Weights E2 Class (1 mg to 200 g)	TNC/M/C/002/17	FL/C/M/11012021-C001	16/01/2024
Digital Weighing Balance	TNC/C/M/001/17	CC205522000000049F	02/01/2023

### Calibration Results

Nominal Volume (µl)	Measured mean volume (µl)	Error (µl)	Uncertainty at k=2 (µl)
1000	1000.89	-0.89	9.0
500	500.24	-0.24	9.0
100	100.37	-0.37	2.2

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(Amit Kumar)  
CEO

Testncal Laboratory  
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## Calibration Certificate

Certificate/ULR No.: CC205522000000896F Page 1 of 1

Customer Details		Instrument Receipt Date	1-Jan-2022
<b>M/S SHREE PATH LAB</b>		SRF No.	TNC1/JC/21-22/130
First Floor, Ratan Ultrasound Centre Opposite Government Girls School Circular Road, Rewari Haryana Pin Code : 123401		Date of Calibration	1-Jan-2022
		Next Calibration Date	31-Dec-2022
		Certificate Issue Date	3-Jan-2022

### A) Identification On UUC (Unit Under Calibration)

Instrument Name	Micropipette	Make / Model No.	Oxpette/---
Range	5 to 50 µl	Instrument Condition	SATISFACTORY
Least Count	1 µl	Location of Calibration	At Laboratory
Serial No.	---	Location	Shree Path Lab Rewadi
Instrument ID.	Pipette-02	Parameter	Volume
<b>ENVIRONMENTAL CONDITION</b>	Temp:- ( 24±2)°C, RH: - (50±10)%	Calibration Reference Standard	ISO 8655
		Calibration Procedure	TNC-02-V 2.0

### Details of Test Equipments Used

Name	I.D. NO./ SR NO	Certificate/ULR No.	Valid upto
Weights E2 Class (1 mg to 200 g)	TNC/M/C/002/17	FL/C/M/11012021-C001	16/01/2024
Digital Weighing Balance	TNC/C/M/001/17	CC205522000000049F	02/01/2023

### Calibration Results

Nominal Volume (µl)	Measured mean volume (µl)	Error (µl)	Uncertainty at k=2 (µl)
50.00	50.25	-0.25	0.3
20.00	0.40	19.60	19.6
10.00	0.10	9.90	9.9

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CEO

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## Calibration Certificate

Certificate/ULR No.: CC20552200000897F

Page 1 of 1

### Customer Details

**M/S SHREE PATH LAB**  
First Floor, Ratan Ultrasound Centre Opposite Government Girls  
School Circular Road, Rewari Haryana Pin Code : 123401

Instrument Receipt Date	1-Jan-2022
SRF No.	TNC1/JC/21-22/130
Date of Calibration	1-Jan-2022
Next Calibration Date	31-Dec-2022
Certificate Issue Date	3-Jan-2022

### A) Identification On UUC (Unit Under Calibration)

Instrument Name	Digital Temperature Indicator with	Make / Model No.	Mextech/---
Range	Sensor -10 to 110 °C	Instrument Condition	SATISFACTORY
Least Count	0.1°C	Location of Calibration	At Site
Serial No.	---	Location	Shree Path Lab Rewadi
Instrument ID.	DTI-01	Parameter	Thermal
ENVIRONMENTAL CONDITION	Temperature:- 25±2 °C,Relative Humidity: - 50±10%	Calibration Reference Standard	ITS-90
		Calibration Procedure	TNC-06-T 2.0

### Details of Test Equipments Used

Name	I.D. NO./ SR NO	Certificate/ULR No.	Valid upto
4-Wire RTD with Indicator	TN/T/C/005/17	CC317221000000028F	09/02/2022

### Calibration Results

Sr.No.	UUC Value (°C)	Standard Value (°C)	Deviation (°C)	Uncertainty at k=2 at 95 % Confidence Level (±)
1	20.0	20.05	0.05	0.48
2	40.0	40.15	0.15	0.48
3	60.0	60.21	0.21	0.48
4	80.0	80.24	0.24	0.48
5	110.0	110.33	0.33	0.48

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## Calibration Certificate

Certificate/ULR No.: CC205522000000898F Page 1 of 1

<b>Customer Details</b>		Instrument Receipt Date	1-Jan-2022
<b>M/S SHREE PATH LAB</b>		SRF No.	TNC1/JC/21-22/130
First Floor, Ratan Ultrasound Centre Opposite Government Girls School Circular Road, Rewari Haryana Pin Code : 123401		Date of Calibration	1-Jan-2022
		Next Calibration Date	31-Dec-2022
		Certificate Issue Date	3-Jan-2022

### A) Identification On UUC (Unit Under Calibration)

Instrument Name	Digital Temperature Indicator with Sensor	Make / Model No.	Mextech/---
Range	0 to 110 °C	Instrument Condition	SATISFACTORY
Least Count	0.1°C	Location of Calibration	At Site
Serial No.	---	Location	Shree Path Lab Rewadi
Instrument ID.	DTI-02	Parameter	Thermal
<b>ENVIRONMENTAL CONDITION</b>	Temperature:- 25±2 °C, Relative Humidity: - 50±10%	Calibration Reference Standard	ITS-90
		Calibration Procedure	TNC-06-T 2.0

### Details of Test Equipments Used

Name	I.D. NO./ SR NO	Certificate/ULR No.	Valid upto
4-Wire RTD with Indicator	TN/T/C/005/17	CC317221000000028F	09/02/2022

### Calibration Results

Sr.No.	UUC Value (°C)	Standard Value (°C)	Deviation (°C)	Uncertainty at k=2 at 95 % Confidence Level (±)
1	20.0	20.04	0.04	0.48
2	40.0	40.14	0.14	0.48
3	60.0	60.22	0.22	0.48
4	80.0	80.26	0.26	0.48
5	110.0	110.32	0.32	0.48

Note: -

- The Calibration results reported in this certificate are valid at the time of and the started condition of measurement.
- This report should not be reproduced except in full without our prior permission in writing.
- Calibration certificate without signature are not valid and this certificate is inteded of only for guidance and not for legel purpose or for advertisement.
- All our certificates are Traceable to national/International standard.
- This Certificate relates to the item Calibrated. Totaliability of Testncal Laboratory. will be limited to the invoiced amount only.

Calibrated By



Issued & Approved By   
(Amit Kumar)  
CEO

Testncal Laboratory  
Plot No. 113, Pocket A2, Sector-17  
Dwarka, New Delhi-110075