

**TRANSASIA<sup>®</sup>**

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**Calibration Certificate**

Customer Name : Delvin Path Lab

Address of Customer: Noida GB Nagar UP

Model : CHEM 7

Serial No. : N100119

Calibration Done Date : 11/01/2024

Calibration Due Date : On or Before 10/01/2025

*This is to certify that we have calibrated the Semi-Automatic Biochemistry Analyzer Model: CHEM7 bearing Sr. No. N100119 and on inspection of the instrument gains. It is observed that the results are well within the range and instrument is working fine.*

Thanking you,

For

Transasia Bio-Medicals Ltd.

Rahul Kumar

Sr Service Engineer

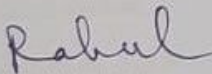


Calibration Data			
S.N.	Filter	Gain Values	OK/Yes/No
1	340	11537	OK
2	405	18649	OK
3	450	30721	OK
4	505	33292	OK
5	546	26861	OK
6	578	26608	OK
7	600	27955	OK
8	670	35143	OK

Thanking you,

For

Transasia Bio-Medicals Ltd.

  
Rahul Kumar

Sr Service Engineer



## Calibration Certificate

Customer Name : Delvin Path Lab

Address of Customer: Noida GB Nagar UP

Model : CHEM 7

Serial No. : N100119

Calibration Done Date : 12/01/2023

Calibration Due Date : On or Before 11/01/2024

*This is to certify that we have calibrated the Semi-Automatic Biochemistry Analyzer Model: CHEM7 bearing Sr. No. N100119 and on inspection of the instrument gains. It is observed that the results are well within the range and instrument is working fine.*

Thanking you,

For

Transasia Bio-Medicals Ltd.

Rahul Kumar

Sr Service Engineer



Calibration Data			
S.N.	Filter	Gain Values	OK/Yes/No
1	340	31640	OK
2	405	20785	OK
3	450	32679	OK
4	505	41852	OK
5	546	35644	OK
6	578	29876	OK
7	600	28541	OK
8	670	39782	OK

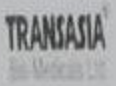
Thanking you,

For


Transasia Bio-Medicals Ltd.

Rahul Kumar

Sr Service Engineer

TRANSASIA BIOMEDICALS LIMITED			
IQOQPQ of Erba CHEM7 (Delvin Path Lab Noida)			
Instrument Name	CHEM7	SN	N100119

**TRANSASIA**  
**ERBA Chem 7**  
 SEMI-AUTOMATED BIO-CHEMISTRY  
 ANALYZER  
**INSTRUMENT QUALIFICATION DOCUMENT**  
 FOR  
 "Delvin Path Lab Noida GB Nagar"

TRANSASIA BIOMEDICALS LIMITED			
IQOQPQ of Erba CHEM7 (Delvin Path Lab Noida)			
Instrument Name	CHEM7	SN	N100119

## Installation Qualification for Erba Chem7

Customer Name : Delvin Path Lab Noida GB Nagar  
Address : Noida

Instrument Model : CHEM7  
Serial Number : N100119


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 50UL - 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

TRANSASIA BIOMEDICALS LIMITED			
IQOQPQ of Erba CHEM7 (Delvin Path Lab Noida)			
Instrument Name	CHEM7	SN	N100119

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**

This is to certify that the Instrument Serial No. N100119 is successfully installed and commissioned at Delvin Path Lab Noida GB Nagar and the Installation Protocol / checklist has been successfully completed for the above instrument.

**For TBM, Technical Services Department**

**Name** : Rahul Kumar  
**Designation** : Sr. Service Engineer  
**Date** : 12/01/2023

TRANSASIA BIOMEDICALS LIMITED			
IQOQPQ of Erba CHEM7 (Delvin Path Lab Noida)			
Instrument Name	CHEM7	SN	N100119

## 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 : Rahul Kumar  
 Designation : Sr. Service Engineer  
 Date : 12/01/2023



TRANSASIA BIOMEDICALS LIMITED			
IQOQPQ of Erba CHEM7 (Delvin Path Lab Noida)			
Instrument Name	CHEM7	SN	N100119

## Installation Report for Erba Chem 7

**Customer Name** : Delvin Path Lab Noida GB Nagar

**Department** : Laboratory

**Contact Person** : Dr Achala Agarwal

**Instrument Model** : Erba Chem-7

**Serial Number** : N100119

**Date of Installation**: 12/01/2023

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** : Rahul Kumar

**Designation**: Sr. Service Engineer


**Signature** : 

**Date** : 12/01/2023


### Customer Detail

**Name** : Dr Achala Agarwal

**Designation**: Lab Director

**Signature** : 

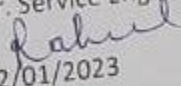
**Date** : 12/01/2023

TRANSASIA BIOMEDICALS LIMITED			
IQOQPQ of Erba CHEM7 (Delvin Path Lab Noida)			
Instrument Name	CHEM7	SN	N100119

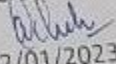
## Instrument Setup


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 : Rahul Kumar  
 Designation: Sr. Service Engineer  
 Signature :   
 Date : 12/01/2023

### Customer Detail

Name : Dr Achala Agarwal  
 Designation: Lab-Director  
 Signature :   
 Date : 12/01/2023

TRANSASIA BIOMEDICALS LIMITED			
IQOQPQ of Erba CHEM7 (Delvin Path Lab Noida)			
Instrument Name	CHEM7	SN	N100119

## Operational Qualification For Erba Chem7

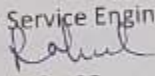
### System Certification:

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.

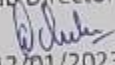
Exceptional conditions, if any, have been addressed.


The System is ready for specific usage.

### TBM, Technical Services Department

Name : Rahul Kumar  
 Designation: Sr. Service Engineer  
 Signature :   
 Date : 12/01/2023

### Customer Detail

Name : Dr Achaia Agarwal  
 Designation: Lab Director  
 Signature :   
 Date : 12/01/2023

TRANSASIA BIOMEDICALS LIMITED			
IQOQPQ of Erba CHEM7 (Delvin Path Lab Noida)			
Instrument Name	CHEM7	SN	N100119

## Operational Qualification for Erba Chem7

### [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)  $37^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$


(B) 57.5 K $\Omega$  to 59.0 K $\Omega$  using temperature Jig)

Check temperature in RUN TEST mode for temperatures:

1.  $37^{\circ}\text{C}$ : OK 2.  $30^{\circ}\text{C}$ : OK 3.  $25^{\circ}\text{C}$ : OK

7. GAIN CHECK FOR ALL FILTERS

- All filters gains values between 30000-200000
- All filters offset values between -5000 to +5000

TRANSASIA BIOMEDICALS LIMITED			
IQOQPQ of Erba CHEM7 (Delvin Path Lab Noida)			
Instrument Name	CHEM7	SN	N100119

8. Checked Hardware test and found OK.

OK

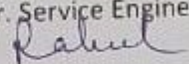
9. Checked Date & time and found OK.

OK

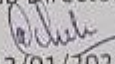
10. Checked printer test and found OK.

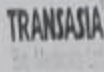
OK

**TBM, Technical Services Department**

Name : Rahul Kumar  
 Designation: Sr. Service Engineer  
 Signature :   
 Date : 12/01/2023

**Customer Detail**

Name : Dr Achala Agarwal  
 Designation: Lab Director  
 Signature :   
 Date : 12/01/2023

TRANSASIA BIOMEDICALS LIMITED			
IQOQPQ of Erba CHEM7 (Delvin Path Lab Noida)			
Instrument Name	CHEM7	SN	N100119

## Performance Qualifications for Erba Chem7

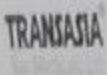
### 1. Calibration/Standard Check

Process Calibration of Glucose and found that the results of standards to be fine.

### 2. Precision Check

Run Precision of Glucose and CV % are within limits.

Glucose Precision	
S.N.	Results
1	100.7
2	101.4
3	101.7
4	102.2
5	103.1
6	103.2
7	103.6
8	104.0
9	104.5
10	100.4
11	100.7
12	100.9
13	101.2
14	101.4
15	101.6
16	102.2
17	102.3
18	102.4
19	102.7
20	102.8
<b>Mean</b>	<b>102.2</b>
<b>SD</b>	<b>1.2</b>
<b>CV%</b>	<b>1.1</b>

TRANSASIA BIOMEDICALS LIMITED			
IQOQPQ of Erba CHEM7 (Delvin Path Lab Noida)			
Instrument Name	CHEM7	SN	N100119

**Conclusion:**

The result for all the performance tests carried out for the instrument meets/does not meet the acceptance criteria. Hence the instrument is qualified for the performance

Protocol performed By:- Lavkush Lal

**TBM, Technical Services Department**

Name : Lavkush Lal  
 Designation: Sr. Application Specialist  
 Signature : *Lavkush*  
 Date : 12/01/2023

**Customer Detail**

Name : Dr Achala Agarwal  
 Designation: Lab Director  
 Signature : *Achala*  
 Date : 12/01/2023

\*\* End of Documents \*\*