

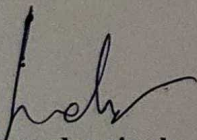
Certificate of Calibration

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, FARIDABAD

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.

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:

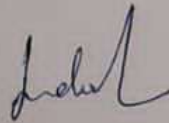
1. Input voltage of 220V-240V / 50Hz or 60Hz.
2. Perfect earthing was provided at power source with all applicable local requirement (A grounded, power plug only should be used). The voltage between earth and neutral should not exceed more than 3V.

Installation Certificate for

This is to certify that the Instrument Serial No.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. DEVENDER SINGH
Designation : SERVICE ENGINEER
Date : 07/11/2017



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.

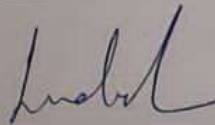
Carried out all the necessary system checks and tests.

Performed all due maintenance activities.

Handed over the Instrument for Operators Training & Qualifications

For TBM, Technical Services Department

Name: MR. DEVENDER SINGH
Designation: SERVICE ENGINEER
Date: 07/11/2017



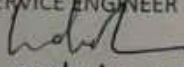
Installation Report for ErbaCHEM-7


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 Department Customer Detail

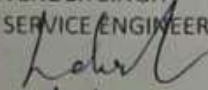
Name: MR. DEVENDER SINGH
Designation: SERVICE ENGINEER
Signature : 
Date : 07/11/2017


Name: DR. REETU NAGE
Designation: HOD
Signature :  - Dr Reetu Nage
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
Designation: SERVICE ENGINEER
Signature : 
Date : 07/11/2017

Name : DR. REETU NAGE
Designation: HOD.
Signature : 
Date:

Dr Reetu Jadhav Nage

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.

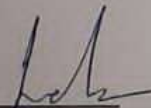
The System is ready for specific usage.

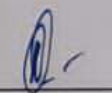
Protocol Performed By: Transasia bio-medicals ltd.

Name: MR. DEVENDER SINGH
Designation: SERVICE ENGINEER

Customer Authorization: DR. REETU'S PATH LAB.

Name: DR. REETU NAGE
Designation: HOD.

Company Representative Sign:- 
Date:- 07/11/2017

Customer Sign:-  Dr Reetu
Jadhav
Nage
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: 37°C

Temperature Range: (A) 37° C ± 0.1°C
(B) 57.5 KΩ to 59.0 KΩ using temperature jig)

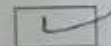
Check temperature in RUN TEST mode for temperatures:

1. 37° C: _____ 2. 30° C: _____ 3. 25° C: _____

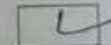
7. GAIN CHECK FOR ALL FILTERS

Filter	340	405	450	505	546	578	600	670	Range
Gains									30000-200000
Offset									-5000 to +5000

8. Checked Hardware test and found OK.



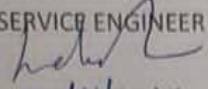
9. Checked Date & time and found OK.




10. Checked printer test and found OK.



TBM, Technical Services Department Customer Detail

Name: MR. DEVENDER SINGH
Designation: SERVICE ENGINEER
Signature : 
Date : 07/11/2017

Name : DR. REETU NAGE 
Designation: HOD
Signature : Dr Reetu Jadhav Nage
Date:

22 July 2014

Traceability Statement

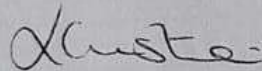
To Whom It May Concern

Catalogue Number: CAL2350, CAL2351

Each batch of serum is distributed to approximately 3000 laboratories worldwide and values are assigned by a consensus of results obtained by these laboratories. The Calibration values for each instrument have been determined in at least 10 independent laboratories.

Values are verified against a master lot of calibrator which is traceable to reference methods or reference materials. In some cases, values may be assigned at Randox Laboratories in comparison to a master lot of calibrator which is traceable to reference methods or reference materials listed in the following table.

For and on behalf of Randox Laboratories Limited.



Lauziata Christie
Product Registration Manager

ANDOX

CALIBRATION SERA TRACEABILITY

Analyte	Reference Material	Ref. Lab Values
Acid Phosphatase (Total)	Internal Master Calibrator	
Acid Phosphatase (Prostatic)	Internal Master Calibrator	
Acid Phosphatase (Non-Prostatic)	Internal Master Calibrator	
Albumin	DA470	
Aldolase	Internal Master Calibrator	
ALP DEA	Internal Master Calibrator	
ALP AMP	Internal Master Calibrator	
ALT with PP	IFCC 454	
ALT without PP	JSCC TS01/TS02	
Amylase (PNPG7)	BCR476/Epsilon NADH	
Pancreatic Amylase	BCR476/Epsilon NADH	
AST with PP	Internal Master Calibrator	
AST without PP	AD457	
Bicarbonate	SRM351	
Bile Acids	Internal Master Calibrator	
Bilirubin (Direct)	Internal Master Calibrator	
Bilirubin (Total)	Internal Master Calibrator	
Butyryl Cholinesterase	Molar absorptivity	
Calcium CPC	NIST 909b + SRM956b	Atomic Absorption Spectroscopy
Calcium Arsenazo III	NIST 909b + SRM956b	Atomic Absorption Spectroscopy
Chloride	NIST 909b	Coulometry
Cholesterol	NIST 909b, MIST 1952a	ID-GC/MS
CK	AD455	
CKMB	IFCC-455	
Copper	Seronorm Trace elements	
Creatinine	NIST 909b level 2/ SRM967 level 2	ID-GC/MS
Glucose GOD	NIST 917b, NIST965a	ID-GC/MS
Glucose Hexokinase	NIST 917b, NIST965a	
γ -GT	AD452 and JSCC TS01/TS02	
GLDH (DGKC)	Internal Master Calibrator	
α -HBDH (DGKC)	Internal Master Calibrator	
Hydroxybutyrate	Internal Master Calibrator	
Iron	Internal Master Calibrator	
LDH P-L	Internal Master Calibrator	
LDH L-P	AD453	
TIBC	Internal Master Calibrator	
Lactate	Gravimetric	
LAP	Internal Master Calibrator	
Lithium	Reference lab.	Atomic Absorption Spectroscopy
Lipase	Internal Master Calibrator	
Magnesium	NIST 909b	Atomic Absorption Spectroscopy
Osmolality	Internal Master Calibrator	
Phosphorous	NIST 18611g	
Potassium ISE	NIST 909b	Flame photometry
Sodium ISE	NIST 909b	Flame photometry
Total Protein	SRM927d	Photometry
Triglycerides	Internal Master Calibrator	ID-GC/MS
Urea	NIST 909b	
Uric Acid	NIST 909b	ID-GC/MS
Zinc	Internal Master Calibrator	

ID-GC/MS - Isotope Dilution-Gas Chromatography-Mass Spectrometry

28/11/19 10:02:33
030480 URE 39.60 mg/dl

URE
ABSORBANCE

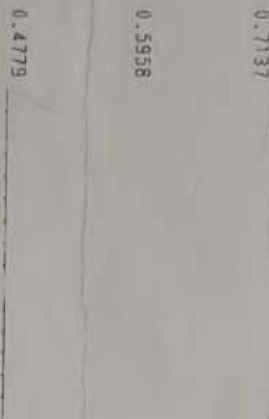


X Axis: 1Unit = 10sec
SAMPLE O.D. Initial = 0.2705
DELTA SAMPLE O.D. = -0.083

030489 URE 39.60 mg/dl

030470 CRE 1.35 mg/dl

CRE
ABSORBANCE



X Axis: 1Unit = 10sec
SAMPLE O.D. Initial = 0.5571
DELTA SAMPLE O.D. = 0.156

030471 CRE 1.35 mg/dl

LINEAR REACTION

28/11/19 10:08:46

ALB STD O.D. 0.5207
NET O.D. : 0.5458
CONC : 49.2 g/dl
FACTOR : 143

030471 ALB 54.38 g/dl ✓ H

HYPERACTIVE SAMPLE

28/11/19 10:21:28

030472 GLL 93.92 mg/dl ✓

28/11/19 10:22:36

PRO STD O.D. 0.4248
NET O.D. : 0.3113
CONC : 69.6 g/dl
FACTOR : 223.58

030473 PRO 74.25 g/dl ✓ H

HYPE c

28/11/19 10:09:13

030475 CHO 84.04 mg/dl

28/11/19 10:10:23

030475 BIL 1.64 mg/dl

DR REETU'S PATH LAB - BALLABGARH

VERIFICATION FORMAT - PRECISION TESTING
(Recording schedule - 3 Monthly)

Doc No. DRPL / TECH / FR / 11
Issue 1, Rev: 00 Dated: 01 10 2018

Date 7/10/2019

Department Biochemistry

Readings	TEST PARAMETERS AS PER NABL SCOPE							Done By	Verified By	Remarks
	Glucose	Urea	Creatinin	Bilirubin	Protein	Albumin	Cholesterol			
1	97.94	43.60	1.06	0.59	6.35	2.47	73.63	Deepchand	(Signature)	OK
2	97.54	44.0	1.07	0.51	6.18	2.57	64.31	Deepchand	(Signature)	OK
3	90.44	40.0	0.92	0.62	5.83	2.70	69.17	Deepchand	(Signature)	OK
4	90.53	39.20	0.96	0.66	6.05	2.53	75.05	Deepchand	(Signature)	OK
5	91.16	38.40	0.95	0.56	5.79	2.53	79.08	Deepchand	(Signature)	OK
Mean	93.52	41.04	0.99	0.59	6.04	2.56	72.25	Deepchand	(Signature)	OK
SD	3.86	2.59	0.07	0.06	0.24	0.09	5.68	Deepchand	(Signature)	OK
% CV	4.13	6.30	6.89	9.73	3.90	3.36	7.86	Deepchand	(Signature)	OK
Remarks										

- Acceptance Criteria: % CV - Within 5% for Hematology and 10% for Clinical Biochemistry

07/10/19 12:26:54

028965 URE 43.00 mg/dl

URE
ABSORBANCE

1.5823 1.6374 1.6924

X Axis:Unit = 10sec
SAMPLE O.D. Initial= 1.674
DELTA SAMPLE O.D. = -0.091

028965 URE 43.60 mg/dl

LINEAR REACTION

URE 44.00 mg/dl

URE
ABSORBANCE

-0.495 -0.440 -0.385

X Axis:Unit = 10sec
SAMPLE O.D. Initial= -0.403
DELTA SAMPLE O.D. = -0.092

028965 URE 44.00 mg/dl

RX ABSLIM UNDER
LINEAR REACTION

028965 URE 40.00 mg/dl

URE
ABSORBANCE

-1.428 -0.440 -0.392

X Axis:Unit = 10sec
SAMPLE O.D. Initial= -0.403
DELTA SAMPLE O.D. = -0.092

028965 URE 40.00 mg/dl

RX ABSLIM UNDER
LINEAR REACTION

028965 URE 39.20 mg/dl

URE
ABSORBANCE

-0.494 -0.444 -0.395

X Axis:Unit = 10sec
SAMPLE O.D. Initial= -0.414
DELTA SAMPLE O.D. = -0.080

028965 URE 39.20 mg/dl

RX ABSLIM UNDER
LINEAR REACTION

028965 URE 38.40 mg/dl

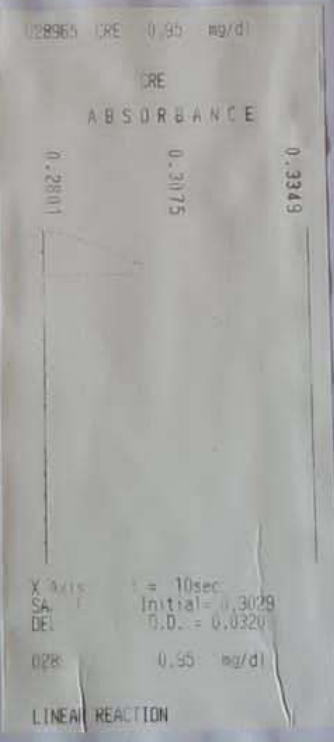
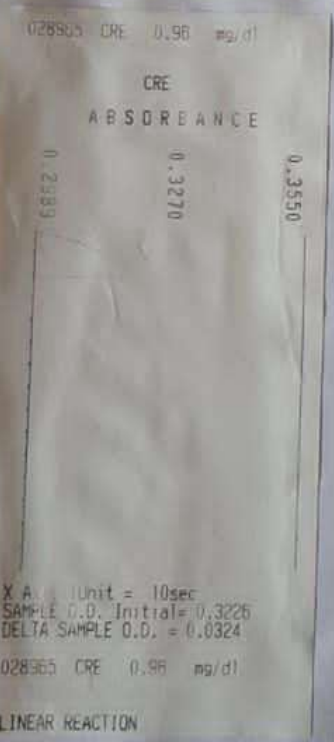
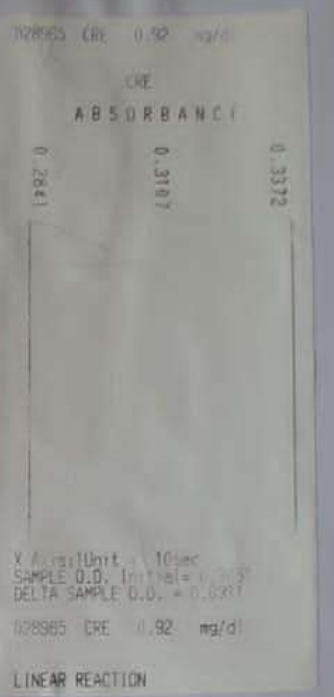
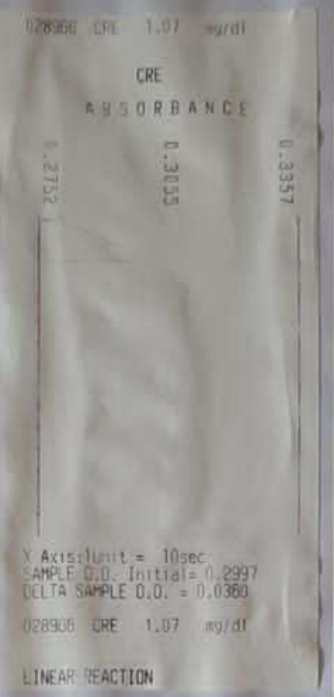
URE
ABSORBANCE

-0.417 -0.440 -0.394

X Axis:Unit = 10sec
SAMPLE O.D. Initial= -0.409
DELTA SAMPLE O.D. = -0.078

028965 URE 38.40 mg/dl

RX ABSLIM UNDER
LINEAR REACTION



Q

028965 BIT 1.91 g/dl L
028965 BIT 1.92 g/dl L
028965 BIT 1.90 g/dl L

07/10/19 13:48:12
028965 GLU 97.94 mg/dl
028965 GLU 97.54 mg/dl
028965 GLU 97.44 mg/dl
028965 GLU 97.44 mg/dl
028965 GLU 97.44 mg/dl

07/10/19 13:37:11
028965 PRO 5.36 g/dl L
028965 PRO 5.18 g/dl L
028965 PRO 5.83 g/dl L
028965 PRO 5.05 g/dl L
028965 PRO 5.79 g/dl L

07/10/19 13:47:11
028965 CHO 73.00 mg/dl
028965 CHO 64.00 mg/dl
028965 CHO 77.00 mg/dl
028965 CHO 75.05 mg/dl
028965 CHO 79.00 mg/dl

07/10/19 13:37:11
028965 ALB 2.47 g/dl L

028965 ALB 2.37 g/dl L
028965 ALB 2.31 g/dl L
028965 ALB 2.31 g/dl L
028965 ALB 2.31 g/dl L

