



TRANSASIA
ERBA Chem 5X NS
SEMI-AUTOMATED BIO-CHEMISTRY
ANALYZER
INSTRUMENT QUALIFICATION DOCUMENT
FOR
"Orbit Health Care & Diagnostic Centre, Gurgaon"

Installation Qualification for Erba Chem5X NS



Customer Name : Orbit Health Care & Diagnostic Centre, Gurgaon
Address : 325/11, Old Railway Road, Opp. Gupta Medicos, Gurgaon
Instrument Model : Chem5X
Serial Number : S2105131
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-5X 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-5 XNS	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.



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. S2105131 is successfully installed and commissioned at _____ and the Installation Protocol / checklist has been successfully completed for the above instrument.

For TBM, Technical Services Department

Name : VARUN ARORA *Varun*
Designation : Sr. Service Engineer
Date : *1/8/22*

Installation Qualification for Erba Chem X NS



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: VARUN ARORA *Varun*

Designation: Sr. Service Engineer

Date: *1/8/22*

Installation Report for Erba Chem 5X NS



Customer Name : Orbit Health Care & Diagnostic Centre, Gurgaon

Department : Lab

Contact Person : Mr. Pawan

Instrument Model : Erba Chem-5X NS

Serial Number : S2105131

Date of Installation: 18-06-21

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 : Varun Arora

Designation: Sr. Service Engineer

Signature : *Varun Arora*

Date : 18/06/22

Customer Detail

Name : *Pawan Kumar*

Designation: *OWNER*

Signature : *Pawan Kumar*

Date : 01/08/22

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 : Varun Arora
Designation: Sr. Service Engineer
Signature : *Varun Arora*
Date : 01/08/22

Customer Detail

Name : *Raman Kumar*
Designation: *owner*
Signature : *R*
Date : 01/08/22

Operational Qualification For Erba Chem



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. Ravi Kumar Sah
Designation: Application Specialist

Customer Authorization:

Name:
Designation:

Company Representative Sign:-

Date:- 1/8/22

Customer Sign:-

Date:- 01/08/22

Operational Qualification for Erba ChemSx NS



UNMATCHED SERVICE
SINCE 1979...

[A] **FUNCTIONAL CHECK :**

1. PUMP CALIBRATION

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

2175

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)

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	505	546	578	630	Range
Gains	155K	167K	162K	153K	145K	158K	30000-200000
Offset	OK	OK	OK	OK	OK	OK	-5000 to +5000

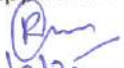
8. Checked Hardware test and found OK.

OK




9. Checked Date & time and found OK.
10. Checked printer test and found OK.

TBM, Technical Services Department

Name : Mr. Ravi Kumar Sah
Designation : Application Specialist
Signature : 
Date : 4/8/22

Customer Details

Name : Pawan Kumar
Designation : OWNER
Signature : 
Date: 01/08/22



Performance Qualifications for Erba Chem5X NS

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.	100.3
2.	100.5
3.	100.4
4.	100.2
5.	100.2
6.	100.4
7.	100.5
8.	100.9
9.	100.9
10	100.9
Mean	100.6
SD	0.5
CV%	0.5 %

Protocol performed By:-



TBM, Technical Services Department

TBM, Technical Services Department

Name : Mr. Ravi Kumar Sah
Designation: Application Specialist
Signature : 
Date : 18/22

CUSTOMER DETAIL

Customer Detail

Name : 
Designation: OWNER
Signature : 
Date : 01/08/22



Ref : TBMNZ-1/430/21-22

Dated : 18-06-21

Calibration Certificate

Customer Name : Orbit Health Care & Diagnostic Centre, Gurgaon

Model : Erba Chem 5X

Serial No. : S2105131

Calibration Date : 18-06-21

Calibration Due Date : 17-06-22

This is to certify that we have calibrated the Semi Automated Biochemistry Analyser , Model : Erba Chem 5X bearing Sr. No. S2105131 and 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.

Varun
Varun Arora
Sr. Service Engineer



Ref : TBMNZ-1/765/22-23

Dated : 18-06-22

Calibration Certificate

Customer Name : Orbit Health Care & Diagnostic Centre, Gurgaon

Model : Erba Chem 5X

Serial No. : S2105131

Calibration Date : 17-06-22

Calibration Due Date : 16-06-23

This is to certify that we have calibrated the Semi Automated Biochemistry Analyser , Model : Erba Chem 5X bearing Sr. No. S2105131 and 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.**

Varun
Varun Arora
Sr. Service Engineer

ERBA NORM 8C

LOT - S062243 &

EXP - 11/2024.

01/08/22 19:17:03

000108 AST 47.91 IU/l H
LINEAR REACTION

01/08/22 19:23:06

000109 ALT 49.33 IU/l H
LINEAR REACTION

01/08/22 19:29:47

000110 ALP 98.95 IU/l
LINEAR REACTION

01/08/22 19:33:55

01/08/22 20:02:13

000123 URE 41.21 mg/dl
LINEAR REACTION

01/08/22 20:35:15

000124 CRE 1.30 mg/dl
LINEAR REACTION

01/08/22 20:38:17

000125 ALB 2.41 g/dl L

01/08/22 20:42:30

000126 CHO 139.9 mg/dl

01/08/22 20:47:04

000127 TRIG 70.50 mg/dl

01/08/22 20:48:12

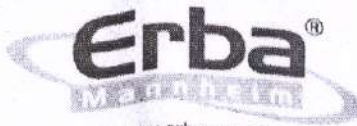
000128 TPRO 6.06 g/dl L

01/08/22 20:50:18

000129 URIC 5.25 mg/dl

000290	GLU	100.3	mg/dl	H
000291	GLU	100.5	mg/dl	H
000292	GLU	100.4	mg/dl	H
000293	GLU	100.2	mg/dl	H
000294	GLU	100.2	mg/dl	H
000295	GLU	100.4	mg/dl	H
000296	GLU	100.5	mg/dl	H
000297	GLU	100.9	mg/dl	H
000298	GLU	100.9	mg/dl	H
000299	GLU	101.9	mg/dl	H

ERBA NORM
CONTROL FOR BIOCHEMISTRY
Assayed Values for ERBA Reagents,



LIQUID STABLE REAGENTS / POWDER REAGENTS & SYSTEM PACK REAGENTS IN NORMAL RANGE
For *in vitro* diagnostic use only

Website : www.erbamannheim.com

INTENDED USE
ERBA NORM

PRINCIPLE OF THE PROCEDURE

This human serum control is to be used for assessment of method precision & techniques in use and treated in the same way as an unknown specimen that would be used in accordance with the direction of the assay procedure.

The results obtained for the control are to be compared with the assigned values given in the "assay data" section of the insert and an evaluation made by standard statistical techniques to determine if the procedure is within the control limits.

It is recommended that each laboratory establish its own means and acceptable ranges. Values provided in the insert should be used as reference.

COMPOSITION

The Control serum is prepared from human serum with chemical additives and tissue extracts of human and animal origin. Bacteriostatic agents have been added. The control is provided in lyophilized form for increase stability.

WARNING

It is recommended that this product be handled with same precautions used for patient specimen.

The blood donations used for production were tested by CE-marked test kits and found to be non-reactive for HBsAg, anti-HIV 1/2 and anti-HCV. In addition HCV and HIV have been tested by PCR. Despite of that the danger of infection for biological material can not be excluded with certainty.

During the work all principles of personal hygiene are to be maintained.

When the bottle is broken the contaminated place must be disinfected.

RECONSTITUTION

1. Allow the vial and AQUA-4 (supplied in the kit) to attain room temperature. Add exactly 5ml of AQUA-4 and allow to stand for 30 minutes at rest in a high-protected place. Swirl occasionally.
2. Swirl the contents gently to ensure homogeneity before using as sample for testing. Avoid formation of foam.

STORAGE & STABILITY

Prior to reconstitution

The controls should be stored at 2-8°C and is stable till the expiry date printed on the label. Protect from light.

After reconstitution

The constituents when protected from light and contamination are stable:

1 day	at +18 °to +25 °C
1 week	at +2 to +8 °C (Bilirubin: 1 day)
1 month	at -20 °C

LIMITATIONS

The results obtained using the control are dependent upon several factors. Erroneous results can occur from reconstitution inaccuracy and the technique errors associated with the assay procedure. The serum is not compatible for use with o-Tolidine Glucose procedures. Improper storage or handling of the control can also affect the results. If there is a visible evidence of microbial growth in a vial, do not use that vial.

Assayed Values Using LIQUID STABLE REAGENTS / POWDER REAGENTS LOT No.: S062243 EXPIRY: 11/2024

ABBR.	PARAMETERS	METHODOLOGY	UNITS	Values for Liquid Reagents			Values for Powder Reagents		
				Value	Interval	1 SD	Value	Interval	1 SD
ALB	Albumin	BCG	g/dl	3.41	2.90-3.92	0.17			
ALP	Alkaline phosphatase	AMP	U/l	101.31	81.05-121.57	6.75	96.98	77.58-116.38	6.47
ALT/GPT	ALT/SGPT	IFCC	U/l	57.47	45.98-68.96	3.83	51.87	41.50-62.24	3.46
AMY	Amylase	CNPG3	U/l	68.78	55.02-82.53	4.59	48.20	38.56-57.84	3.21
AST/GOT	AST/SGOT	IFCC	U/l	51.31	41.05-61.57	3.42	46.76	37.41-56.11	3.12
BID	Bilirubin Direct	DIAZO	mg/dl	0.96	0.72-1.19	0.08			
BIT	Bilirubin Total	DIAZO	mg/dl	1.47	1.10-1.83	0.12			
CA	Calcium	ARSENAZO III	mg/dl	7.93	6.34-9.51	0.53			
		OCPC	mg/dl	7.78	6.22-9.33	0.52			
CL	Chloride	MERCURIC THIOCYANATE	mmol/l	105.00	89.25-120.75	5.25			
CHOL	Cholesterol	CHOD-PAP	mg/dl	129.56	110.13-148.99	6.48	160.10	136.09-184.12	8.01
CK	Creatinine kinase NAC	DGKC	U/l	113.73	85.30-142.16	9.48	120.50	90.38-150.63	10.04
CK MB	Creatinine kinase MB	IMMUNO	U/l	30.64	22.98-38.30	2.55	20.50	15.38-25.63	1.71
CREA	Creatinine	JAFFE'S	mg/dl	1.03	0.82-1.25	0.07			
GGT	Gamma-glutamyl transferase	GLUPA-C	U/l	30.51	22.94-38.09	2.53	30.13	22.65-37.61	2.49
GLU	Glucose	GOD-POD	mg/dl	88.90	75.57-102.24	4.45	92.14	78.32-105.96	4.61
HDL	HDL Cholesterol	DIRECT	mg/dl	39.13	31.31-46.96	2.61			
		Phosphotungstic Acid	mg/dl	16.00	12.8-19.2	1.07			
LDL	LDL Cholesterol	DIRECT	mg/dl	59.33	47.47-71.20	3.96			
LDH-P	Lactate dehydrogenase-P	DGKC	U/l	386.32	309.06-463.58	25.75	289.50	231.6-347.40	19.30
LIP	Lipase	ADVANCE HEMOGEN	U/l	58.03	43.53-72.54	4.84			
MG	Magnesium	XYLIDYL BLUE	mg/dl	1.95	1.64-2.26	0.10			
PHOS	Phosphorus	UV-MOLYBDATE	mg/dl	5.34	4.54-6.14	0.27			
TP	Total Protein	BIURET	g/dl	6.39	5.43-7.35	0.32			
TGL	Triglycerides	GPO	mg/dl	93.52	79.49-107.55	4.68			
	Triglycerides -SR	GPO	mg/dl	124.50	105.83-143.18	6.23	73.00	62.05-83.95	3.65
UREA	Urea	UREASE-GLDH	mg/dl	40.50	34.43-46.58	2.03	40.36	34.30-46.41	2.02
UA	Uric Acid	URICASE	mg/dl	5.50	4.67-6.32	0.27			
	Uric Acid-SR	URICASE	mg/dl	5.53	4.70-6.36	0.28	6.17	5.24-7.09	0.31

* Note: a) For End Point Assay-Values obtained after calibration using respective calibrator. b) For Bilirubin and Kinetic Assay-Values obtained using fixed factor. c) Assay Temperature =37°C

Manufactured by : **TRANSASIA BIO-MEDICALS LTD.**, Khaliyan No. 235, Khasra No.24, Namthang Elaka, Mahakuma Namchi, South Sikkim - 737132.
In Technical Collaboration with : **ERBA diagnostics Mannheim GmbH**, Mannheim, Germany