

\* Kinetic, End-Point Mode check:  
ERBA CHEM-5-V210K

07/01/21 10:23:33

000185 CRE 2.99 mg/dl H  
LINEAR REACTION

07/01/21 10:45:13

000189 CHO 341.0 mg/dl H

07/01/21 11:00:01

000190 SPT 132.1 IU/l H  
LINEAR REACTION

## 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 : Mr. Aman Thapa  
Designation: Sr. Service Engineer  
Signature :  
Date :

### Customer Detail

Name : Dr. Gagandeep Singh  
Designation: Pathologist  
Signature :  
Date : 09/07/2021

# Operational Qualification For ERBA CHEM-5 V210K

## System Certification:

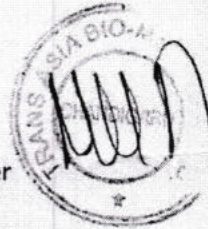
Study data has determined that the System described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional conditions, if any, have been addressed.

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

Protocol Performed By:

Name: Mr. Aman Thapa  
Designation: Sr. Service Engineer



Customer Authorization:

Name: Dr. Gagandeep Singh  
Designation: Pathologist

Company Representative Sign:- \_\_\_\_\_  
Date:- \_\_\_\_\_

Customer Sign:- \_\_\_\_\_  
Date:- 07/01/21

# Operational Qualification for ERBA CHEM-5 V210K

## [A] FUNCTIONAL CHECK :

### 1. PUMP CALIBRATION

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

OK

### 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: OK 2. 30°C: OK 3. 25°C: OK

### 7. GAIN CHECK FOR ALL FILTERS

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



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 : Mr. Aman Thapa  
Designation : Sr. Service Engineer  
Signature :  
Date :

**Customer Details**

Name : Dr Gagandeep Singh  
Designation : Pathologist  
Signature :  
Date: 02/01/2021

## Performance Qualifications for ERBA CHEM-5 V210K

### 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%)

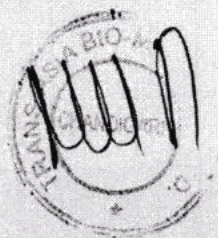
Sr. No.	Concentration mg/dl
1.	192.9
2.	192.7
3.	192.8
4.	192.8
5.	193.6
6.	193.1
7.	193.3
8.	193.4
9.	193.2
10	193.2
<b>Mean</b>	<b>193.1</b>
<b>SD</b>	<b>0.29</b>
<b>CV%</b>	<b>0.15</b>

### 2. KINETIC, END-POINT MODE CHECK :

(Process the Biochemistry check with reagents and controls as per the kit insert literatures.)

TEST	BLK OD	Control Result	Mean Value	Range
SGPT	0.00	132.1	132.36	105.89-158.83
CHOL	0.0081	341	327.72	278.56-376.88
CRET	0.00	2.99	3.15	2.49-3.81

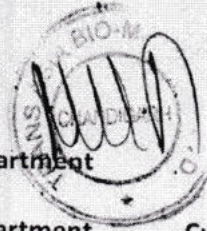
PERFORMANCE TEST	DATA TRACEABILITY	REMARKS MEETS/DOES NOT MEET ACCEPTANCE
SGPT	Multical	Meet
CHOL	Multical	Meet
CRET	Multical	Meet



**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:-



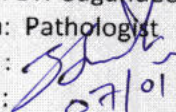
**TBM, Technical Services Department**

**CUSTOMER DETAIL**

**TBM, Technical Services Department**

Name : Aman Thapa  
Designation: Sr. Service Engineer  
Signature :  
Date :

**Customer Detail**

Name : Dr. Gagandeep Singh  
Designation: Pathologist  
Signature :   
Date : 07/11/2021

\* Precision check :  
ERBA CHEM -5 V210K

07/01/21 09:58:42

000174 CHO 192.9 mg/dl

000175 CHO 192.7 mg/dl

000176 CHO 192.8 mg/dl

000177 CHO 192.8 mg/dl

000178 CHO 193.6 mg/dl

000179 CHO 193.1 mg/dl

000180 CHO 193.3 mg/dl

000181 CHO 193.4 mg/dl

000182 CHO 193.2 mg/dl

000183 CHO 193.2 mg/dl

000184 CHO 193.4 mg/dl



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. S190179 is successfully installed and commissioned at Dr. Singh Path Lab, Rupnagar and the Installation Protocol / checklist has been successfully completed for the above instrument.

For TBM, Technical Services Department

Name : Mr. Aman Thapa  
Designation : Sr. Service Engineer  
Date :



## Installation Qualification for ERBA CHEM-5 V210K

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.

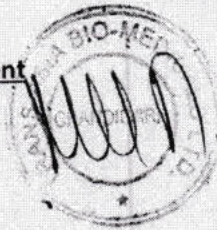
Handed over the Instrument for Operators Training & Qualifications

For TBM, Technical Services Department

Name: Mr. Aman Thapa

Designation: Sr. Service Engineer

Date:



## Installation Report for ERBA CHEM-5 V210K

**Customer Name** : Dr. Gagandeep Singh

**Department** : Laboratory

**Contact Person** : Dr. Gagandeep Singh

**Instrument Model** : Erba Chem-5 V2 10K

**Serial Number** : S190179

**Date of Installation:** 01<sup>st</sup> Mar 2019

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** : Mr. Aman Thapa

**Designation:** Sr. Service Engineer

**Signature** :

**Date** :

### Customer Detail

**Name** : Dr. Gagandeep Singh

**Designation:** Pathologist

**Signature** :

**Date** :

*[Handwritten signature]*  
7/01/2021

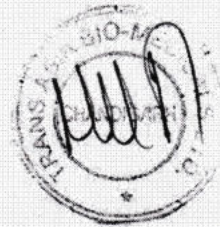
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UNMATCHED SERVICE  
SINCE 1979...

**TRANSASIA**  
**ERBA Chem 5 V210K**  
SEMI-AUTOMATED BIO-CHEMISTRY  
ANALYZER  
INSTRUMENT QUALIFICATION DOCUMENT  
FOR  
**"Dr. Singh Path Lab"**



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## Installation Qualification for ERBA CHEM-5 V210K

**Customer Name** : Dr. Singh Path Lab

**Address** : Rupnagar

**Instrument Model** : Chem 5+V2

**Serial Number** : S190179

**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 – ECS V2 10K (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.	TEST TUBE HOLDER (with O-ring)	1
10.	Pipette Stand (Plastic)	1
11.	PROLINE SINGLE CHANNEL VARAIBLE VOLUME MECHANICAL PIPETTES 5UL - 50UL (CAT. NO 720020)	1
12.	PROLINE SINGLE CHANNEL VARAIBLE VOLUME MECHANICAL PIPETTE 100UL - 1000UL (CAT. NO 720060)	1
13.	ERBA WASH (4 X 50 ML)	1

