

**IMPERIAL DIAGNOSTIC & CO.,**

50, Chinnamuthu 1st Street, E.K. Valasu, ERODE - 638 011.

**Installation /Validation Report****Semi Auto Chemistry Analyser – AutoLab Versa****IQ / OQ / PQ Documents****Customer Address : Sri Amman Digital Xrays & ECG Micro Lab****Contact Person: Velusamy**

118, R.S. Road, Opp. Govt. Hospital,

**Mbl No : 9865342005**

Perundurai -638052

**Serial No : S1906175****Installation date :07.06.2020****Installation Qualification****Transport damage**

Package damaged :  Yes  No  
 Parts damaged  Yes  No

If yes, please specify :

Initial check	Number	Part description
---------------	--------	------------------

Parts missing ?

(Check against packing list)

 Yes → Please specify parts No

\*Please return parts , including a malfunction report

 Line Voltage / Main Supply : 220 – 240 V :231 V Grounding Voltage ( 0-5 V ) : 1V Room Air conditioned :  Yes  No Stabiliser /UPS : Offline UPS

Rating : &gt; 1 KVA (Page 1 of 2)

**(We recommend connecting Autulab Versa to UPS OF 1 KVA )**

The system Described meets all the criteria outlined in this installation qualification Documents .All items have been checked & Installation has been completed.

The system is ready for Performing Operational Qualification.

Performer : KANNAN

Reviewer : SARAVANAN

Date : 10.06.2022

**IMPERIAL DIAGNOSTIC & CO**  
 No.11, Sri Annai Towers,  
 Chinnamuthu 2nd Street, E.K. Valasu.  
 Erode - 638 011.

For **IMPERIAL DIAGNOSTIC & CO**

*B. K. Annamalai*  
 Proprietor

# IMPERIAL DIAGNOSTIC & CO.,

50, Chinnamuthu 1st Street, E.K. Valasu, ERODE - 638 011.

## Installation/Validation Report

Semi Auto Chemistry Analyser - Auto Lab Versa IQ / OQ / PQ Documents

Customer Address : Sri Amman Digital Xrays & ECG Micro Lab

Contact Person: Velusamy

118, R.S. Road, Opp. Govt. Hospital,

Mbl No : 9865342005

Perundurai - 638052

Serial No : S1906175

Installation date: 07.06.2020

### Operation Qualification

- Connect the instrument to the waste container.
- Switch ON the system ,Check the initializing process.
- Check gain and background values for all filters.
- Check aspiration volume.
- Set system and test parameter.
- Run calibration and QC cycle.
- Check normal procedure to shut down the analyser.

### Tests /Comments (if any):

The instruments is performing in the prescribed standards; validation of the same has been performed.

This is to certify that the instrument can be used for operational analysis.

The system described meets all the criteria outlined in this installation qualification Documents.

All items have been checked & Installation has been completed .

The system is ready for Performing Performance Qualification.

Performer: KANNAN

DATE: 10.06.2022

For IMPERIAL DIAGNOSTIC & CO

*B. K. Annamalai*  
Proprietor

Reviewer: SARAVANAN  
*Saravanan*  
IMPERIAL DIAGNOSTIC & CO  
No.11, Sri Annai Towers,  
Chinnamuthu 2nd Street, E.K. Valasu,  
Erode - 638 011.

**IMPERIAL DIAGNOSTIC & CO.,**

50, Chinnamuthu 1st Street, E.K. Valasu, ERODE - 638 011.

Semi Auto Chemistry Analyser – AutoLab Versa

IQ / OQ / PQ Documents

Installation/ Validation Report

Customer Address : Sri Amman Digital Xrays &amp; ECG Micro Lab

Contact Person: Velusamy

118, R.S. Road, Opp. Govt. Hospital,

Mbl No : 9865342005

Perundurai -638052

Serial No : 51906175

Installation date : 07.06.2022**Performance Qualification****NORMAL CONTROL:**

Control Manufacture : SPINREACT

QC Name : Spintrol "H" Normal Human Serum

LOT : 34589

Expiry : 2023-06

Method	Parameter	Range	Values Obtain	Status
End Point	Total Cholesterol	82.6-111	98	OK
End Point	GLUCOSE	88.4-120	102	OK
Fixed time	Creatinine	0.82-1.18	1.1	OK
Fixed time	UREA(BERTHELOT)	35.9-48.5	41	OK
Kinetic	SGOT	41.4-59.6	51	OK
Kinetic	SGPT	39.5-56.9	49	OK

**ABNORMAL CONTROL:**

Control Manufacture : SPINREACT

QC Name : Spintrol "H" Normal Human Serum

LOT : 16575

Expiry : 2023-06

Method	Parameter	Range	Values Obtain	Status
End Point	Total Cholesterol	156-210	187	OK
End Point	GLUCOSE	200-270	234	OK
Fixed time	Creatinine	3.27-4.71	3.90	OK
Fixed time	UREA(BERTHELOT)	106-144	123	OK
Kinetic	SGOT	118-170	141	OK
Kinetic	SGPT	91-131	113	OK

**REMARKS:** The system meets all criteria outlined in this Performance Qualification Documents.

All the required parameters have been checked and instruments is ready for regular use.

Performer: KANNAN

Date: 10.06.2022

Reviewer: SARAVANAN

**IMPERIAL DIAGNOSTIC & CO**  
 No.11, Sri Annai Towers,  
 Chinnamuthu 2nd Street, E.K. Valasu,  
 Erode - 638 011.

For **IMPERIAL DIAGNOSTIC & CO**

*B. R. Arun*  
 Proprietor

# IMPERIAL DIAGNOSTIC & CO.,

50, Chinnamuthu 1st Street, E.K. Valasu, ERODE - 638 011.

## CERTIFICATE

This is to certify that the following instrument have been validated as per the manufacturer's protocol & is found to be working satisfactorily.

**Certificate No** : 202201ER005  
**Instrument Name** : Semi Auto Chemistry Analyser  
**Model** : CHEM-7  
**Serial No** : S1906175  
**Marketed By** : IMPERIAL DIAGNOSTIC & CO.,

The Validation is valid from 10.06.2022 to 09.06.2023

For IMPERIAL DIAGNOSTIC & CO. *S. S. S.*  
IMPERIAL DIAGNOSTIC & CO  
No.11, Sri Annal Towers,  
Chinnamuthu 2nd Street, E.K. Valasu.  
Erode - 638 011.

*B. R. Ramya*  
Proprietor