A WIPRO GE HEALTHCARE INVESTED COMPANY

CALIBRATION CERTIFICATE

CUSTOMER NAME: WELFARE MEDICAL FOUNDATION VILLOO POONAWALA MEMORIAL HOSPITAL LABORATORY

ANALYZER: DIALAB AUTOLYSER	***INSTALLATION DATE: 13/10/2016***
SERIAL NO: 47152972	***CALIBRATION DATE: 13/04/2022***
CALIBRATION DUE DATE: 13/04/2023	

This is to certify the analyser has been checked & calibrated for the following parameters

TEST PARAMETER	*TARGET VALUE & RANGE*	*OBTAIN VALUE*
Input Voltage	230 V – 240 V	235
Optical Transmission for All Cuvettes	Up TO 100 %	100%
Cuvette Temperature	37 degree +/- 0.3	36.9
Reagent Cooling Temperature	4 – 10 Degree Centigrade	7 Degree Centigrade
12 V Lamp Supply	12 V +/- 0.3 V	12.2 V
5 V Supply	5 V +/- 0.3 V	5.1 V
24 V Supply	24 V +/- 0.3 V	24.2 V

Following Mechanical Checks has been Carried Out.

CHECK CARRIED OUT	*RESULT*

Washing piston Centering in Cuvette	OK
Reagent / Sample probe Centering in Both Reagent Positions	OK
Reagent/ Sample probe Centering in Sample Positions	OK
Reagent / Sample probe Centering in Wash Station	OK

CALIBRATION AND MAINTAINANCE PROCEDURES

MAINTAINANCE:

- Instrument was checked for cleanliness.
- Cuvettes were cleaned externally with distilled water & hypo chloride in 1:1 proportion

  Extra wash, Wash Cuvette & Wash cuvette with water is given.
- Checked the working of Washing Piston for Aspiration & Despising.
- Performed Zeroing on water.
- Cleaned Reagent / Sample probe.
- Diluter Prime is carried out.

CALIBRATION:

- Input supply and lamp voltage for the machine was found adequate using the multimeter.
- Cuvette Temperature is indicated in operating software.
- Reagent compartments cooling temperature is indicated in operating software.

Precision Check: The CV's obtained are in acceptable range (<± 5.0% CV). Calibrations of routine tests were also done & the results of controls & samples found satisfactory.

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LIST OF MATERIALS REQUIRED FOR PRECISION CHECK

Sr. No.	Name of the Material	Lot Number	Expiry Date
1	Dialab Urea Auto, Urease/GLDH	030221	2023-09-26
2	Dialab Albumin, BCG	090421	2023-10-20
3	Dialab GPT(ALT), mod. IFCC	120521	2022-11-10
4	Randox Human Assayed Multi-Sera LEVEL 3	1195UE	2025-04-28

Precision: –

Intra-Assay Variation: – Run Randox Human Assay Multi-Sera Level 3 control 10 times each (in one run) for one end point, one fixed time & one kinetic assay.

Sr. No.	ALBUMIN	UREA	SGPT
1	3.01	132	145
2	2.89	129	143
3	2.98	132	143
4	2.97	124	146
5	3.04	129	144
6	2.81	128	137
7	2.94	124	142
8	2.92	131	141
9	3.01	128	144
10	2.98	130	145
MEAN	**2.95**	**128.7**	**143**
SD	**0.07**	**2.87**	**2.58**
%CV	**2.29**	**2.23**	**1.80**
ACCEPTANCE	**<5%**	**<5%**	**<5%**
STATUS	**ACCEPTABLE**	**ACCEPTABLE**	**ACCEPTABLE**

Report Sign Off:

Calibration Done By: Mr. Nitin Phadtare

PRECISION RUN DONE WITH DIALAB REAGENTS ON 13-04-2022

Sample No.	Albumin	SGPT	Urea
1	3.01	145	132
2	2.89	143	129
3	2.98	143	132
4	2.97	146	124
5	3.04	144	129
6	2.81	137	128
7	2.94	142	124
8	2.92	141	131
9	3.01	144	128
10	2.98	145	130
MEAN	2.955	143	128.7
SD	0.067864	2.581989	2.869379
%CV	2.29659	1.805587	2.229509

Results

New Factor = 34.6

#1 STD001 (Standard) (13-04-22 16:02)

Gamma-GT	<IFCC>	115	U/L (	0.062)	[]
Albumin	<BCG>	3.56	g/dL (	0.279)	[]
Gamma-GT	<IFCC>	115	U/L (	0.063)	[]
Albumin	<BCG>	3.56	g/dL (	0.263)	[]
LDH-L	<IFCC>	262	U/L (	0.025)	[]
LDH-L	<IFCC>	262	U/L (	0.024)	[]
Creatinine	<Enzymatic, PAP>	3.89	mg/dL (	0.093)	[]
Urea	<UV Urease>	107	mg/dL (	0.203)	[]
Urea	<UV Urease>	107	mg/dL (	0.216)	[]
Creatinine	<Enzymatic, PAP>	3.89	mg/dL (	0.093)	[]
GPT (ALT)	<mod. IFCC>	97.3	U/L (	0.059)	[]
GPT (ALT)	<mod. IFCC>	97.3	U/L (	0.059)	[]
GOT (AST)	<mod. IFCC>	108	U/L (	0.065)	[]
GOT (AST)	<mod. IFCC>	108	U/L (	0.065)	[]
Bilirubin Direct	<DCA>	2.47	mg/dL (	0.172)	[]
Bilirubin Direct	<DCA>	2.47	mg/dL (	0.174)	[]
Uric Acid	<enzym.,color.,TBHBA>	5.01	mg/dL (	0.150)	[]
CK-NAC	<opt. DGKC/IFCC>	354	U/L (	0.086)	[]
Uric Acid	<enzym.,color.,TBHBA>	5.01	mg/dL (	0.140)	[]
CK-NAC	<opt. DGKC/IFCC>	354	U/L (	0.085)	[]

Standardization for CK-NAC performed!
New Factor = 4148

Standardization for Creatinine performed!
New Factor = 51.0
New Shift = -0.057

#2 STD002 (Standard) (13-04-22 16:12)

Creatinine	<Enzymatic, PAP>	0.000	mg/dL (	0.010)	[]
Creatinine	<Enzymatic, PAP>	0.000	mg/dL (	0.023)	[]
Bilirubin Direct	<DCA>	0.000	mg/dL (	0.002)	[]
Bilirubin Direct	<DCA>	0.000	mg/dL (	0.001)	[]

Standardization for Bilirubin Direct performed!
New Factor = 14.8
New Shift = -0.029

CRP	<Turbidimetric>	22.0	mg/L	(0.083)	(1st Result).	[]
		21.0	mg/L	(0.080)	0.000 - 6.00	[-
Urea	<UV Urease>	52.5	mg/dL	(0.103)	17.0 - 43.0	[+

#1 AUTOBATCH001 PRECISION (Routine) (13-04-22 18:43)

Albumin	<BCG>	3.01	g/dL	(0.228)	3.50 - 5.20	[-
Urea	<UV Urease>	132	mg/dL	(0.258)	17.0 - 43.0	[+
GPT (ALT)	<mod. IFCC>	145	U/L	(0.088)	0.000 - 41.0	[+

#2 AUTOBATCH002 (Routine) (13-04-22 18:44)

Urea	<UV Urease>	129	mg/dL	(0.253)	17.0 - 43.0	[+]
Albumin	<BCG>	2.89	g/dL	(0.219)	3.50 - 5.20	[-]
GPT (ALT)	<mod. IFCC>	143	U/L	(0.087)	0.000 - 41.0	[+]

#3 AUTOBATCH003 (Routine) (13-04-22 18:45)

Urea	<UV Urease>	132	mg/dL	(0.259)	17.0 - 43.0	[+]
Albumin	<BCG>	2.98	g/dL	(0.226)	3.50 - 5.20	[-]
GPT (ALT)	<mod. IFCC>	148	U/L	(0.090)	0.000 - 41.0	[+]

#4 AUTOBATCH004 (Routine) (13-04-22 18:45)

Urea	<UV Urease>	124	mg/dL	(0.242)	17.0 - 43.0	[+]
Albumin	<BCG>	2.97	g/dL	(0.225)	3.50 - 5.20	[-]
GPT (ALT)	<mod. IFCC>	142	U/L	(0.086)	0.000 - 41.0	[+]

#5 AUTOBATCH005 (Routine) (13-04-22 18:46)

Urea	<UV Urease>	129	mg/dL	(0.253)	17.0 - 43.0	[+]
Albumin	<BCG>	3.04	g/dL	(0.231)	3.50 - 5.20	[-]
GPT (ALT)	<mod. IFCC>	144	U/L	(0.088)	0.000 - 41.0	[+]

GPT (ALT)	<mod. IFCC>	144	U/L	(0.087)	0.000 - 41.0	

#6 AUTOBATCH006 (Routine) (13-04-22 18:52)

Urea	<UV Urease>	126	mg/dL	(0.251)	17.0 - 43.0	
Albumin	<BCG>	2.81	g/dL	(0.214)	3.50 - 5.20	
GPT (ALT)	<mod. IFCC>	137	U/L	(0.083)	0.000 - 41.0	

#7 AUTOBATCH007 (Routine) (13-04-22 18:53)

Urea	<UV Urease>	124	mg/dL	(0.242)	17.0 - 43.0	
Albumin	<BCG>	2.94	g/dL	(0.223)	3.50 - 5.20	
GPT (ALT)	<mod. IFCC>	142	U/L	(0.086)	0.000 - 41.0	

#8 AUTOBATCH008 (Routine) (13-04-22 18:54)

Urea	<UV Urease>	131	mg/dL	(0.256)	17.0 - 43.0	
Albumin	<BCG>	2.92	g/dL	(0.222)	3.50 - 5.20	
GPT (ALT)	<mod. IFCC>	141	U/L	(0.086)	0.000 - 41.0	

#9 AUTOBATCH009 (Routine) (13-04-22 18:54)

Urea	<UV Urease>	128	mg/dL	(0.251)	17.0 - 43.0	
Albumin	<BCG>	3.01	g/dL	(0.229)	3.50 - 5.20	
GPT (ALT)	<mod. IFCC>	144	U/L	(0.087)	0.000 - 41.0	

#10 AUTOBATCH010 (Routine) (13-04-22 18:55)

Urea	<UV Urease>	130	mg/dL	(0.264)	17.0 - 43.0	
Albumin	<BCG>	2.98	g/dL	(0.228)	3.50 - 5.20	
GPT (ALT	<mod. IFCC>	145	U/L	(0.088)	0.000 - 41.0	

ages

		139	U/L	(0.092)	113 - 171	[]
rin Direct	<DCA>	1.90	mg/dL	(0.134)	1.75 - 2.61	[]

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IQ, OQ AND PQ OF AUTOLYSER

CUSTOMER:

Welfare Medical Foundation Villoo Poonawalla Memorial Hospital Laboratory

I.Q.

INSTALLATION QUALIFICATION PROTOCOL

Instrument/Model: **Dialab Autolyser**

Serial Number: **47152972**

Location: **Pune**

Date of Protocol: **13/04/2022**

1. AIM OF THE IQ PROTOCOL

Aim of the present protocol is to define the qualifications and the acceptance standard in order to verify the correct installation of the Dialab Autolyser.

The good outcome of the procedure ensures that the system is installed according to the parameters and the standard of the manufacturer. The result of the installation activity is the base for the subsequent operational qualification protocol.

The installation qualification will verify the main parts of the instrument and the presence of the necessary documentation. It will also check the ambient conditions, the power supply, and the placement of the instrument that must be in the compliance with the indications reported in the documentation supplied to the customer.

The service engineer that is authorised carries out all the tests as indicated in the present I.Q and the results are written dated and signed.

The customer has to check that all the controls are correct and will subscribe the validity and the acceptance date.

2. PROTOCOL IQ APPROVAL

The protocol is prepared by the company Dialab. The control and checking of the activity here must be accomplished by the laboratory personnel.

Procedure checked by	Approval sign	Date
Lab QC staff		13/04/2022
Lab Manager		13/04/2022

3. EXECUTOR OF THE IQ APPROVAL

Technical support personnel	Company	Sign	Date
Zubin K Patell	Genworks Health Pvt. Ltd.		13/04/2022
Nitin Phadtare	Genworks Health Pvt. Ltd.		13/04/2022

The service engineers here above indicated have trained the staff for the use of the instrument and the operations described in the I.Q Protocol.

4. INSTALLATION QUALIFICATION

A) INSTRUMENT AND ACCESSORIES:

- Clinical Chemistry Analyzer Dialab **Autolyser**: Serial No.: **47152972**
- PC
- Monitor

B) DOCUMENTATION LIST:

The following documentation is supplied with the instrument

- Operator's Manual

Manual	Available	Not Available
Operator's Manual	✓	–

C) PREINSTALLATION CHECKS:

During the pre-installation visit the laboratory area should be inspected in the light of the following requirements:

Activity	Checked	Compliance	Not Compliance
Temperature of the laboratory between 18 and 32°C	25°C	✓	
Relative humidity of the laboratory between 10% to 90%	78%	✓	
Main power supply : voltage between 100 to 240 V_{AC}	200 V_{AC}	✓	
Main power supply : frequency between 50 and 60 Hz	55 Hz	✓	
Presence of good ventilation (minimum: 20 cm from wall)	25 cm	✓	
No presence of vibration	Yes	✓	
No direct exposure to light, heat, air streams & draught	Yes	✓	

D) MINIMUM SW / HW REQUIREMENT OF THE PC DIALAB AUTOLYSER

HW Requirement	Compliance	Not Compliance
Hard Disk Min 5gb free	✓	
Min RAM Memory: 1Gb (2Gb for Windows &)	✓	
Pentium Dual core processor	✓	
USB 1, version 2.0 for communication with the analyzer	✓	
CD ROM, DVD Reader	✓	
Host Communication RS232 or LAN(TCP/IP)	✓	

SW Requirement	Compliance	Not Compliance
Operative System Windows 2000 Professional, Windows XP Professional, Windows Vista Professional, Windows 7 Professional, Win 10	✓	
Acrobat Reader	✓	

E) POSITIONING OF THE INSTRUMENT

Ventilation	Compliance	Not Compliance
It's necessary to keep a space of at least 20 cm around the analyzer.	✓	

5. I.Q CONCLUSIONS

Completed the controls and the verification of the tests described in the IQ protocol and considered the positive results we certify that the Dialab Autolyser is correctly installed according to the instrument specifications.

Approved By	Sign	Date
Genworks technical representative		13/04/2022
Lab Manager		13/04/2022

6. ATTACHMENT

a) Training Record

CUSTOMER:

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Welfare Medical Foundation Villoo Poonawalla Memorial Hospital Laboratory

O.Q.

OPERATIONAL QUALIFICATION PROTOCOL

Instrument/Model: Dialab Autolyser

Serial Number: 47152972

Location: Pune

Date of Protocol: 13/04/2022

1. OPERATIONAL QUALIFICATION PROTOCOL – OQ

This protocol is drawn and authorized by the QA of the Dialab GmbH.

2. PROTOCOL OQ APPROVAL

The control and the checking of the activity here reported must be accomplished by the laboratory personnel.

Procedure checked by	Approval sign	Date
Lab QC staff		13/04/2022
Lab Manager		13/04/2022

3. EXECUTOR OF THE PROTOCOL OQ

Technical support personnel	Company	Sign	Date
Zubin K Patell	Genworks Health Pvt. Ltd.		13/04/2022
Nitin Phadtare	Genworks Health Pvt. Ltd.		13/04/2022

The service engineers here above indicated have trained the staff for the use of the instrument and the operations described in the O.Q Protocol

4. PURPOSE OF THE OQ PROTOCOL

Purpose of the present protocol is to define the qualifications and the acceptance standard in order to verify the operatively and functionality of the Dialab Autolyser. The good outcome of the procedure ensures that the system functions according to the parameters and the standard of the manufacturer.

A specialist authorized by Dialab will perform the necessary procedures, as outlined in this OQ and each result will be written, dated and signed. A person appointed by the client, verify that all checks are correct and will sign the validity and the date of acceptance.

5. REQUIREMENT

5.1 Verification of the state of the instrument: The Dialab Autolyser must be subjected to regular maintenance program in order to keep the instrument in good operative condition.

The daily, weekly and monthly maintenance operations are described in chapter no. 18 of operator manual and must be carried out by laboratory personnel.

6. OPERATIONAL QUALIFICATION

The Operational Qualification procedure involves the following steps:

Turn on the instrument: Purpose of the test is to verify that after turning on the Dialab Autolyser it carries out all the internal control operations and movement of the modules. The main menu should be available after a few while with no error messages.

Actions	Compliance	Not Compliance
Washing Piston Valve passed	✓	
Arm liquid sensor	✓	
Diluter valve, Peristaltic pump and needle	✓	
Wait till the instrument turn in "READY" status	✓	

Note: The "ready" status of the instrument is reached after approximately 20 minutes.

Before using the analyzer, it is recommended to perform the preliminary checks outlined below. Some of these checks should be performed daily and others are periodically.

a) Maintenance Operations

Actions	Periodicity	Done
Verify that there is sufficient washing solution in the external tank for the needs of the working day. **The washing solution is prepared by adding to double distilled H2O the Surface Active Agent – tensioactive - 1ml per liter of water (i.e. ratio 1:1000).** See technical specifications regarding double distilled water below.	Daily	✓
Check that the waste containers are empty or that they are of sufficient capacity for at least containing washing solution corresponding to the daily waste liquid volume.	Daily	✓
Zeroing on photometer	Twice a day (A reminder message will appear 20 min after start up and then after 6 hours)	✓
Wash cuvettes with proper solution	Daily	✓
Extra wash of cuvettes with acid & alkali soln.	Weekly	✓
Replacement of tubes and peristaltic pump	As and when required	✓
Photometric Lamp	1500 working hrs	✓
Replacement of dilutor's piston seal	As and when required	✓

b) <u>OPTICAL TRANSMISSION (MEASUREMENT AND CHECKING OF CUVETTE BLANK)</u>

After zeroing on photometer, it indicates the percentage of transparency of the cuvettes. The cuvettes with poor transparency (40% less than the mean of calculated O.T) are highlighted and will automatically eliminate it and work with one less cuvette.

Actions	Compliance	Not Compliance
Carry out zeroing on photometer	✓	
Verify that O.T data are within the range	✓	

7. O.Q CONCLUSIONS

Completed the controls and the verification of the tests described in the OQ protocol and considered the positive results we certify that the Dialab Autolyser is operating well according to the instrument specifications.

Approved By	Sign	Date
Genworks Technical representative		13/04/2022
Lab Manager		13/04/2022

8. ATTACHMENT

a) Results of the Optical Transmission (Raw Data)

CUSTOMER:

A WIPRO GE HEALTHCARE INVESTED COMPANY

Welfare Medical Foundation Villoo Poonawalla Memorial Hospital Laboratory

P.Q.

PERFORMANCE QUALIFICATION PROTOCOL

Instrument/Model: Dialab Autolyser

Serial Number: 47152972

Location: Pune

Date of Protocol: 13/04/2022

1. **PERFORMANCE QUALIFICATION PROTOCOL – PQ**

This protocol is drawn and authorized by the QA of the Dialab GmbH.

2. **PROTOCOL PQ APPROVAL**

The control and the checking of the activity here reported must be accomplished by the laboratory personnel.

Procedure checked by	Approval sign	Date
Lab QC staff		13/04/2022
Lab Manager		13/04/2022

3. EXECUTOR OF THE PROTOCOL PQ

Technical support personnel	Company	Sign	Date
Zubin K Patell	Genworks Health Pvt. Ltd.		13/04/2022
Nitin Phadtare	Genworks Health Pvt. Ltd.		13/04/2022

The service engineers here above indicated have trained the staff for the use of the instrument and the operations described in the P.Q Protocol.

4. REQUIREMENT

The purpose is to put the reagents **(Urea D00715, Albumin D00204 and GPT {ALT} D00640)** on board that will be used in the next step. For reagent loading please refer to Dialab Autolyser Operator's Manual.

Reagent: Urea
Cat. No.: D00715

Lot No: 030221
Expiry Date: 2023-09-26

Reagent: Albumin
Cat. No.: D00204
Lot No: 090421
Expiry Date: 2023-10-20

Reagent: GPT (ALT)
Cat. No.: D00640
Lot No: 120521
Expiry Date: 2022-11-10

Action	Compliance	Not Compliance
Put the reagents bottles on-board according to the procedure in the Operator's Manual	✓	
Verify the application of the reagents (Urea, Albumin & ALT) according to Dialab protocol	✓	

5. PREPARE THE MATERIALS FOR CALIBRATION AND CONTROLS

The purpose is to prepare the calibrator and control serum that will be used during the present protocol.

Calibrator: DIACAL AUTO
Cat. No.: D98485SV

7. CHECKING WITH CONTROL SERUM

Carry out 10 replicates for control serum and insert the target and the range data of the control serum that you are using into the table below. (Consult insert sheet of the controls)

The mean value of the 10 replicates must be inside the acceptable range: the obtained %CV must be lower than the expected %CV.

RANDOX HUMAN ASSAYED MULTI-SERA - LEVEL 3

TEST	Mean Value (10 replicates)	%CV	%CV Expected	Target Value (insert sheet)	Acceptable Range
Urea	128.7	2.23	<=5.0	122	103 – 141
Albumin	2.95	2.30	<=5.0	2.96	2.52 – 3.40
ALT/SGPT	143	1.81	<=5.0	142	113 – 171

*Note: Every single replicate must be within the acceptable range.

8. P.Q CONCLUSIONS

Completed the controls of the tests described in the PQ protocol and considered the positive results we certify that the Dialab Autolyser is performing well according to the instrument specifications and parameters of the constructor.

Approved By	Sign	Date
Genworks Technical Representative		13/04/2022
Lab Manager		13/04/2022

9. ATTACHEMENT

a) Control Results (Raw Data)