

INSTALLATION RATING / COMPLETION FORM

ACCOUNT DETAILS

Account Name	Doctors Laboratory		
Address	14-Q2, Nethaji By-Pass Road		
City	Dharmapuri		
State	Tamilnadu	ZIP Code	636701
Dr In-Charge at site	Dr. K. balan , Ph.D.,/ Dr. Gandhi , Ph.D.,		
Dr In-Charge Contact No	9787103287		
Email ID	doctorslaboratorys@gmail.com		

FIELD PERSONNEL DETAILS

RSM	Sinu Joseph	AM - Scientific Support	Karthik Lakshmanan
Primary CSE	Pradeep Leveal	Primary AM - CRM	Sanjay A
Secondary CSE	Deepak	Secondary AM - CRM	Sathish Shankar

INSTALLATION DATE AND TIME STAMPS

FSE Start Date & Time	31.01.2022 11:00	FAS Start Date & Time	07.02.2022 11:00
FSE End Date & Time	01.02.2022 15:00	FAS End Date & Time	09.02.2022 19:00
FSE Total Site Visits	2	FAS Total Site Visits	3
FSE Total Site Hrs	14	FAS Total Site Hrs	24

INSTRUMENT DETAILS

Instrument Category	CHEMISTRY	Instrument Model	AUTOPAK 300
Serial No	908020039	Installation Notification No	728106286417
LIS Vendor	NOT APPLICABLE	Water Source	IN-HOUSE

FSE INSTALL RATINGS - ELECTRICAL & MECHANICAL INSTALLATION

AUTOPAK 300				
Delivery Quality	Site Preparation	Hardware Quality	S/W Quality	Adjustments
5	5	5	5	5
EM No of Visit Days	FSE Travel Hrs			2
2				

FAS INSTALL RATINGS - METHOD INSTALLATION & TRAINING

Install Ratings: 5 = Outstanding; 4 = Good; 3 = Acceptable; 2 = Fair; 1=Poor			
Method Calibration	Consumables Delivery	Training	No of Methods Installed
5	5	5	5
Appn & Trng visit days	FAS Travel Hrs		1
3			

PART REPLACEMENT, IF ANY

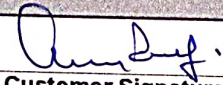
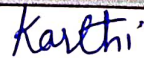
Part Replaced	Part Number
Part Replaced	Part Number

FSE and FAS Comments: For any rating 4 or less, please provide details ; Any other comments

Installation Completion Date and Time 09.02.2022 19:00

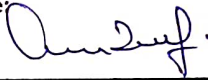
CUSTOMER REMARKS ON OVERALL INSTALLATION

I hereby agree that above statements are correct and instrument has been installed to our satisfaction.

 Customer Signature and Date	 Signature of Siemens Service Representative
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DOCTORS LABORATORY
 14-Q2, Nethaji By-pass Road
 Dharmapuri-636 701.

AUTOPAK 300 IQ, OQ, PQ Guideline and Documentation

Name/Address of Lab: Doctors Laboratory	
Phone: 9787103287	Contact Person: Dr. K. Balan, Ph.D.,/ Dr. Gandhi, Ph.D.,
FAX: NA	Contact Email: doctorslaboratorys@gmail.com
Instrument Model: AUTOPAK 300	Instrument Serial #: 908020039
Installation Date: 09.02.2022	Software Revision #: NA
Install FSE / FAS Name: Mr. Pradeep Leveal Mr. Karthik Lakshmanan	Signature: 

DOCTORS LABORATORY
14-Q2, Nethaji By-pass Road
Dharmapuri-635 701.

Instrument Installation Qualification:

The Installation Qualification (IQ) procedure verifies that the equipment and its sub-systems have been installed in accordance with the specifications. These requirements must all be satisfied before the IQ can be completed and the qualification process is allowed to progress to the Operational Qualification (OQ) procedure.

INSTALLATION QUALIFICATION CHECKLIST:

Shipping Boxes Received

- No external damage.

Documentation

- Matched Serial # Packing List.
 Matched Serial # Final Check Report.
 Operator's Manual.

Accessories

- As per attached list.

Instrument Location

- The analyzer is a heavy instrument (more than 95 Kg). At least two persons are needed to move it. The lifting arms must be used.
 The instrument is installed on a solid horizontal table that can support the weight of the instrument.
 The location is well-ventilated and dust free.
 The instrument is properly levelled.
 The instrument is not expose to direct sunlight.
 The instrument is not placed near or in front of heat sources.
 The pressure is above 600 hPa.
 The room temperature is lower than 27°C.
 Main electric is close to the instrument (less than two meters) and must fulfill local regulations.

- There is a free access to main switch and main cable's plug. A distance of 50 cm from the left side of instrument to nearest table or wall is advisable. The right side must have at least 30 cm of free space for ventilation purposes.
- The instrument must have 2.10 m of free space above it. Avoid using shelves, walls or screens above the instrument.
- Reagent storage under the instrument is easily accessible.
- Space for computer, printer and UPS to be hooked.

Power Requirements

- 100/240 Vac, 50/60 Hz, 600VA maximum.
- Female receptacle outlet with single-phase input power and ground.
- Building outlet properly grounded and electrical panel protected against power fluctuations.
- Confirmed third-wire earth ground capable of carrying full current of circuit.
- UPS system hooked up to properly rated and grounded outlet, battery is connected and powered on.

Connections and Setup

PC setup and connections

- Peripherals (mouse, keyboard) connected to the computer.
- Computer power cord connected.
- Power cord connected to UPS.
- USB/serial port adapter connected to computer and serial cable connected to instrument.

Instrument setup and connections

- Biohazard waste container tubing properly connected to container and to instrument.
- Biohazard waste container located on floor or shelf lower than instrument.
- Reagent tubing properly connected to all reagent containers and to instrument.
- Tubes cut to length in order to prevent a U shape below bottle level.
- Peristaltic pumps tubing connected.
- The plastic protection tube from the vertical shaft of the probe arm and tip protector removed.
- DI water and cleaner bottles filled.
- Instrument and scale connected to the computer.
- Instrument's power cord connected to instrument and plugged into electrical outlet.

Installation Qualification is now complete. You may begin the Operation Qualification Procedure.

OPERATION QUALIFICATION CHECKLIST:

The definition of operational qualification is: Establishing confidence that the equipment and sub-systems are capable of operating within the stated limits and tolerances. In practice, the operational qualification is the executed test protocol documenting that a system meets the defined requirements or that the system does what it's supposed to do.

Instrument and PC Startup:

- Computer powered on and USB/serial port adapter driver installed.
- Computer settings configured for proper date/time, display, hibernation and hard drive per installation guide.
- Windows activation performed when prompted.
- Windows updated prior to software installation.
- Software installed.
- Instrument turned on.
- Software started and reconnected (Do not initialize)
- Filter wheel calibrated (remember to remove cuvettes if any inserted).
- Reaction cuvettes inserted.
- Full mechanical calibration performed.

- System flush performed.
- Washer volume calibration performed.
- Photometer calibration performed.
- Scale calibrated.
- Initialization performed.

System tests:

In order to check whether the instrument works within given specification the instrument is equipped in a batch of tests to check analyzers performance. To ensure that the instrument meets all measuring requirements all the tests should pass.

All the System Tests protocols are included in the Operator's Manual (Chapter 9). Follow the instruction given in the OM as well as on the screen during performing the tests.

Reagent used for system tests:

1. Calibration set VA0003SL:
 - 5 g/l Potassium chromate
 - Sodium nitrate
 - 0,1 g/l Potassium chromate
 - 2 g/l Potassium chromate
2. Additive for Wash Solution VA0002SL
3. Cleaning Solution VA0000SL

Additional reagents:

1. Distilled water

System Tests results:

	Passed	Failed	Comments
• Temperature	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Stray light	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Noise	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Stability	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Tip pump	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Level detection	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Washer hydraulics	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Washer	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Dilution	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Photometer linearity	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Diluter linearity	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Clot detector	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Refer to the *Operator's Manual*, for detailed information regarding the reagents composition, storage requirements, usage, etc.

INSTRUMENT PERFORMANCE QUALIFICATION:

The definition of performance qualification is: Establishing confidence through appropriate testing that the installed product meets all performance requirements for functionality and safety and that results are effective and reproducible. In practice, the performance qualification is the executed test protocol documenting that a system meets the defined requirements to function in the clinical laboratory environment.

NEW INSTRUMENT VALIDATION:

All new instruments, upon installation, must be tested to validate the manufacturer's claims for accuracy and precision.

New operators will be instructed and assisted by the individual(s) who install and train the operator(s) in the routine use of the new analyzer. Instructions and guidance in the validation of accuracy and precision will as per the laboratory Protocols. These validations must be reviewed and approved by the Lab Director before the instrument can be used to test and report patient samples.

INSTRUMENT VALIDATION EVALUATION

Laboratory Name:	Doctors Laboratory
Address:	14-Q2, Nethaji By-Pass Road, Opp to Govt Hospital Dharmapuri-636701
Phone:	9787103287
Contact person:	Dr. K.Balan Ph.D.,
Contact email:	doctorslaboratory@gmail.com

Instrument Serial No.:	908020039	Date installed:	01.02.2022
Date(s) validated:	09.02.2022		

I have evaluated the validation data for this analyzer .

YES NO

Signature

I approve this instrument for use in this clinical lab. YES NO

Lab Director's Signature:

Signature

Date approved:

09/02/2022

DOCTORS LABORATORY
14-Q2, Nethaji By-pass Road
Dharmapuri-636 701.

DEPARTMENT OF CLINICAL BIOCHEMISTRY

PRECISION STUDY

Analyzer	AUTOPAK 300
S.No	908020039
Evaluation Date	09.02.2022
Material	BIORAD-ASSAYED CHEMISTRY
Lot No:	26470

S.No	Glucose(mg/dl)	Creatinine(mg/dL)	SGOT(U/L)	SGPT(U/L)	ALB(g/dL)
1	77.7	2.47	44.8	28.2	4.41
2	78.6	2.44	44.6	31.3	4.44
3	78.6	2.47	45.2	30.3	4.43
4	78.2	2.49	49.8	31.6	4.41
5	77.8	2.46	46.7	30.3	4.46
Mean	78.18	2.466	46.22	30.34	4.43
SD	0.43	0.02	2.16	1.33	0.02
CV%	0.55%	0.74%	4.68%	4.39%	0.48%
ACCEPTABLE CV	4.5	6	12.3	19.4	3.2
S.No	TP(g/dL)	ALP(U/L)	Tbil(mg/dL)	Chol(mg/dL)	Trig(mg/dL)
1	6.79	112.2	1.1	261	190.4
2	6.8	109.7	1.13	259	188.4
3	6.8	110	1.12	259	190
4	6.74	111.2	1.09	258	188.4
5	6.75	112.7	1.1	258	188.5
Mean	6.8	111.2	1.1	259.0	189.1
SD	0.03	1.32	0.02	1.22	0.98
CV%	0.43%	1.18%	1.48%	0.47%	0.52%
ACCEPTABLE CV	2.75	6.45	21.8	5.95	19.9
S.No	UA(mg/dL)				
1	5.09				
2	5.07				
3	5.12				
4	4.76				
5	5.01				
Mean	5.01				
SD	0.15				
CV%	2.90%				
ACCEPTABLE CV	8.6				

Note: Please refer Westgard Biological Variation Values for Acceptable CV

PREPARED BY

Artho

REVIEWED AND ACCEPTED BY

Artho

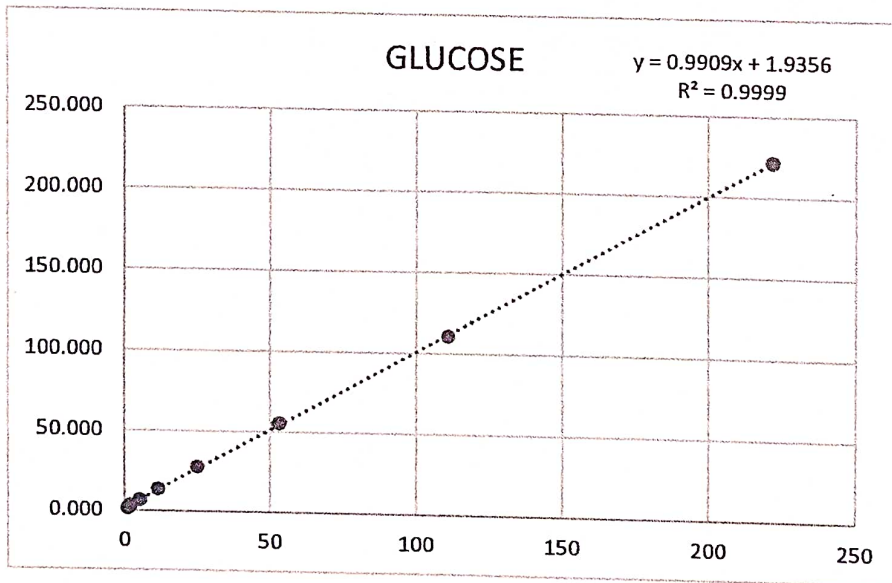
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Dharmapuri-636 701.

DEPARTMENT OF CLINICAL BIOCHEMISTRY

LINEARITY STUDY

Analyzer	AUTOPAK300
S.No	908020039
Assay	GLUCOSE
Evaluation Date	09.02.2022
Material	Serum

S.No	SNO	OBTAINED	EXPECTED
1	NEAT	221.8	221.800
2	1:02	110.9	110.900
3	1:04	53	55.450
4	1:08	24.9	27.725
5	1:16	11.5	13.863
6	1:32	5.1	6.931
7	1:64	2.1	3.466
8	1:128	1	1.733



SLOPE	0.9909
Coefficient Determination (R²)	0.9999
Linearity Range	1-400 mg/dL

Sample Id KARTHICK Date 09-02-2022 16:42:48

Ref. class ADULT

Patient Id

First name

MD.

Last name

Section

Birth date 30-12-1899

Bed

Method Id	Result	Units	Reference	Flags	Measurement Time
ALB APK	4.74	g/dL	3.50 - 5.20		09-02-2022 17:16:59
ALPA APK	67.8	U/L	-		09-02-2022 17:23:14
CHOL APK	169	mg/dL	20 - 200		09-02-2022 17:19:48
CREA APK	0.76	mg/dL	0.60 - 1.30		09-02-2022 17:16:59
GLU APK	118.3	mg/dL	70.0 - 100.0	H	09-02-2022 17:25:10
GOT APK	20.1	U/L	5.0 - 37.0		09-02-2022 17:20:21
GPT APK	25.9	U/L	5.0 - 41.0		09-02-2022 17:20:34
TBIL APK	1.16	mg/dL	0.30 - 1.20		09-02-2022 17:22:27
TPr APK	6.97	g/dL	6.60 - 8.70		09-02-2022 17:20:29
TRIG APK	193.3	mg/dL	20.0 - 150.0	H	09-02-2022 17:25:40
UrA APK	5.55	mg/dL	2.60 - 7.20		09-02-2022 17:20:49

Sample Id KARTHIK Date 09-02-2022 12:37:40

Ref. class ADULT

Patient Id

First name

MD.

Last name

Section

Birth date 30-12-1899

Bed

Method Id	Result	Units	Reference	Flags	Measurement Time
ALB APK	4.59	g/dL	3.50 - 5.20		09-02-2022 12:44:01
ALPA APK	68.5	U/L	-		09-02-2022 12:50:16
CHOL APK	171	mg/dL	20 - 200		09-02-2022 12:46:49
CREA APK	0.83	mg/dL	0.60 - 1.30		09-02-2022 12:44:01
GLU APK	114.8	mg/dL	70.0 - 100.0	H	09-02-2022 12:52:11
GOT APK	17.4	U/L	5.0 - 37.0		09-02-2022 12:47:23
GPT APK	24.5	U/L	5.0 - 41.0		09-02-2022 12:47:36
TBIL APK	1.22	mg/dL	0.30 - 1.20	H	09-02-2022 12:49:28
TPr APK	6.91	g/dL	6.60 - 8.70		09-02-2022 12:47:31
TRIG APK	187.1	mg/dL	20.0 - 150.0	H	09-02-2022 12:52:42
UrA APK	5.55	mg/dL	2.60 - 7.20		09-02-2022 12:47:51

Sample Id	G 1:128	Date	09-02-2022 18:21:50	Ref. class	ADULT
Patient Id					
First name		MD.			
Last name		Section			
Birth date	30-12-1899	Bed			
Method Id	Result	Units	Reference	Flags	Measurement Time
GLU APK	< 1.0mg/dL		70.0 - 100.0	LL,L,RL	09-02-2022 18:46:11

Sample Id	G 1:18	Date	09-02-2022 18:20:50	Ref. class	ADULT
Patient Id					
First name		MD.			
Last name		Section			
Birth date	30-12-1899	Bed			
Method Id	Result	Units	Reference	Flags	Measurement Time
GLU APK	24.9mg/dL		70.0 - 100.0	L	09-02-2022 18:35:21

Sample Id	G 1:2	Date	09-02-2022 18:19:37	Ref. class	ADULT
Patient Id					
First name		MD.			
Last name		Section			
Birth date	30-12-1899	Bed			
Method Id	Result	Units	Reference	Flags	Measurement Time
GLU APK	110.9mg/dL		70.0 - 100.0	H	09-02-2022 18:34:50

Sample Id	G 1:32	Date	09-02-2022 18:21:09	Ref. class	ADULT
Patient Id					
First name		MD.			
Last name		Section			
Birth date	30-12-1899	Bed			
Method Id	Result	Units	Reference	Flags	Measurement Time
GLU APK	5.1mg/dL		70.0 - 100.0	L	09-02-2022 18:35:31

Sample Id	G 1:4	Date	09-02-2022 18:20:06	Ref. class	ADULT
Patient Id					
First name		MD.			
Last name		Section			
Birth date	30-12-1899	Bed			
Method Id	Result	Units	Reference	Flags	Measurement Time
GLU APK	53.0mg/dL		70.0 - 100.0	L	09-02-2022 18:35:00

Sample Id	G 1:64	Date	09-02-2022 18:21:30	Ref. class	ADULT
Patient Id					
First name		MD.			
Last name		Section			
Birth date	30-12-1899	Bed			
Method Id	Result	Units	Reference	Flags	Measurement Time
GLU APK	2.1mg/dL		70.0 - 100.0	L	09-02-2022 18:35:41

Sample Id G 1:016

Date 09-02-2022 18:20:29

Ref. class ADULT

Patient Id

First name

MD.

Last name

Section

Birth date 30-12-1899

Bed

Method Id	Result	Units	Reference	Flags	Measurement Time
GLU APK	11.5mg/dL		70.0 - 100.0	L	09-02-2022 18:35:11

Sample Id PRECISION Date 08-02-2022 15:22:13

Ref. class ADULT

Patient Id PRECISION

First name MD.

Last name Section

Birth date 08-02-2022 Bed

Method Id	Result	Units	Reference	Flags	Measurement Time
ALB APK	4.41g/dL		3.50 - 5.20		08-02-2022 15:34:45
ALB APK	4.44g/dL		3.50 - 5.20		08-02-2022 15:34:55
ALB APK	4.43g/dL		3.50 - 5.20		08-02-2022 15:35:05
ALB APK	4.41g/dL		3.50 - 5.20		08-02-2022 15:35:15
ALB APK	4.46g/dL		3.50 - 5.20		08-02-2022 15:35:26
ALPA APK	112.2U/L		-		08-02-2022 15:41:45
ALPA APK	109.7U/L		-		08-02-2022 15:41:53
ALPA APK	110.0U/L		-		08-02-2022 15:42:04
ALPA APK	111.2U/L		-		08-02-2022 15:42:12
ALPA APK	112.7U/L		-		08-02-2022 15:42:22
CHOL APK	261mg/dL		20 - 200	H	08-02-2022 15:32:07
CHOL APK	259mg/dL		20 - 200	H	08-02-2022 15:32:42
CHOL APK	259mg/dL		20 - 200	H	08-02-2022 15:32:49
CHOL APK	258mg/dL		20 - 200	H	08-02-2022 15:32:59
CHOL APK	258mg/dL		20 - 200	H	08-02-2022 15:33:09
CREA APK	2.47mg/dL		0.60 - 1.30	H	08-02-2022 15:29:20
CREA APK	2.44mg/dL		0.60 - 1.30	H	08-02-2022 15:30:21
CREA APK	2.47mg/dL		0.60 - 1.30	H	08-02-2022 15:30:33
CREA APK	2.49mg/dL		0.60 - 1.30	H	08-02-2022 15:30:46
CREA APK	2.46mg/dL		0.60 - 1.30	H	08-02-2022 15:31:01
GLU APK	77.7mg/dL		70.0 - 100.0		08-02-2022 15:37:29
GLU APK	78.6mg/dL		70.0 - 100.0		08-02-2022 15:39:09
GLU APK	78.6mg/dL		70.0 - 100.0		08-02-2022 15:39:19
GLU APK	78.2mg/dL		70.0 - 100.0		08-02-2022 15:39:29
GLU APK	77.8mg/dL		70.0 - 100.0		08-02-2022 15:39:39
GOT APK	44.8U/L		5.0 - 37.0	H	08-02-2022 15:39:26
GOT APK	44.6U/L		5.0 - 37.0	H	08-02-2022 15:39:40
GOT APK	45.2U/L		5.0 - 37.0	H	08-02-2022 15:39:51
GOT APK	49.8U/L		5.0 - 37.0	H	08-02-2022 15:40:05
GOT APK	46.7U/L		5.0 - 37.0	H	08-02-2022 15:40:17
GPT APK	28.2U/L		5.0 - 41.0		08-02-2022 15:40:30
GPT APK	31.3U/L		5.0 - 41.0		08-02-2022 15:40:44
GPT APK	30.3U/L		5.0 - 41.0		08-02-2022 15:40:55
GPT APK	31.6U/L		5.0 - 41.0		08-02-2022 15:41:08
GPT APK	30.3U/L		5.0 - 41.0		08-02-2022 15:41:24
TBIL APK	1.10mg/dL		0.30 - 1.20		08-02-2022 15:37:18
TBIL APK	1.13mg/dL		0.30 - 1.20		08-02-2022 15:37:25
TBIL APK	1.12mg/dL		0.30 - 1.20		08-02-2022 15:37:32
TBIL APK	1.09mg/dL		0.30 - 1.20		08-02-2022 15:37:52
TBIL APK	1.10mg/dL		0.30 - 1.20		08-02-2022 15:37:56
TPr APK	6.79g/dL		6.60 - 8.70		08-02-2022 15:34:48
TPr APK	6.80g/dL		6.60 - 8.70		08-02-2022 15:35:52
TPr APK	6.80g/dL		6.60 - 8.70		08-02-2022 15:36:00
TPr APK	6.74g/dL		6.60 - 8.70		08-02-2022 15:36:11
TPr APK	6.75g/dL		6.60 - 8.70		08-02-2022 15:36:21
TRIG APK	190.4mg/dL		20.0 - 150.0	H	08-02-2022 15:41:34
TRIG APK	188.4mg/dL		20.0 - 150.0	H	08-02-2022 15:41:44
TRIG APK	190.0mg/dL		20.0 - 150.0	H	08-02-2022 15:41:54
TRIG APK	188.4mg/dL		20.0 - 150.0	H	08-02-2022 15:42:03
TRIG APK	185.5mg/dL		20.0 - 150.0	H	08-02-2022 15:42:13
UrA APK	5.09mg/dL		2.60 - 7.20		08-02-2022 15:37:43
UrA APK	5.07mg/dL		2.60 - 7.20		08-02-2022 15:38:05
UrA APK	5.12mg/dL		2.60 - 7.20		08-02-2022 15:38:16
UrA APK	4.76mg/dL		2.60 - 7.20		08-02-2022 15:38:25
UrA APK	5.01mg/dL		2.60 - 7.20		08-02-2022 15:38:35