



Abbott Diagnostics Medical Pvt. Ltd.
No. 404, BPTP Park Centra, NH - 8,
Sector - 30, Opp. 32nd Milestone,
Gurugram Haryana 122001, India
T: +91 124 4569000
F: +91 124 4569011

UROMETER-120

Installation Qualification



Abbott Diagnostics Medical Pvt. Ltd.
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INSTRUMENT ORIGIN AND IDENTIFICATION

Instrument Name : UROMETER-120

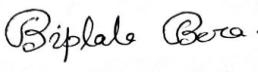
Manufacturer : SD STANDARD DIAGNOSTICS, INC.

Serial Number : 12211621

Customer : LUPIN DIAGNOSTICS
KIRAN PLAZA, 84 DISTRICT CENTRE
CHANDRASHEKHARPUR, BHUBANESWAR 751016

The undersigned performer certifies that the Installation Qualification Protocol has been successfully completed for the instrument stated above.

Engineer/Application for Abbott Diagnostics Medical Pvt. Ltd.

Signature : 

Name : Biplab Bera

Designation : Manager Application - East

Company : Abbott Diagnostics Medical Pvt. Ltd.

Authorized Personnel for Lupin Diagnostics

Signature :

Name : Mr. Manas Kumar Sahoo

Designation : Lab Manager

ENVIRONMENT & SITE

Instrument Parameter	Reference	Compliance	
		Y	N
Place on a level surface in an area free from excess dust, vibration, strong magnetic field, direct sunlight, excessive moisture or large Temperature fluctuation.	Operator Manual	Y	
Leave the sufficient clearance (10 cm) both side of the unit for adequate air circulation	Operator Manual	Y	

INSTRUMENT DELIVERY AND DOCUMENTATION

Unpack the instrument carefully. Are any items missing against the Packing List? **NO**

Packing List - Annexure A. Check and Verify

If **YES**, state missing items: _____

Is there any damage to the instrument or accessories? **NO**

Yes

No



If yes: Description of damage: _____

Corrective action: _____

Manufacturer informed:

Yes

No



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Is all standard documentation included?

	Present	Missing
Operator Manual (OM)	√ <input type="checkbox"/>	<input type="checkbox"/>
Warranty Card	√ <input type="checkbox"/>	<input type="checkbox"/>

Additional Documentation (if any) requested:

Description:

Provided: YES/NO



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Installation Qualification: Summary Report

Instrument:		Manufacturer:	SD STANDARD DIAGNOSTICS, INC
UROMETER-120			
Assessment of Complete Installation Qualification			
No Deviations	<input checked="" type="checkbox"/>	Deviations	<input type="checkbox"/> <i>(list below)</i>
Deviations	Impact on Operation		Justification for Acceptance

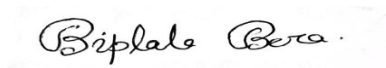
Successful completion of the preceding activities and checks indicates that this instrument has been satisfactorily delivered and installed. The instrument has passed the Installation Qualification procedure and may now be submitted for Operational Qualification

	Name	Signature	Date
Complete By (for Abbott)	Mr. Biplab Bera	<i>Biplab Bera</i>	05/12/2023
Deviations Approved By			
IQ Approved and Accepted By	Mr. Manas Kumar Sahoo		05/12/2023

ANNEXURE A – PACKING LIST

<u>ITEM</u>	<u>RECEIVED(Y/N)</u>
1. Instrument	Y
2. User's Manual	Y
3. Packaging List	Y
4. Power Cable and Adapter	Y
5. RS-232 serial cable	Y
6. Printer Paper	Y

For **Abbott Diagnostics Medical Pvt. Ltd.**



Name & Signature: Mr. Biplab Bera

Designation: Manager Application - East

For **Lupin Diagnostics**

Name & Signature: Mr. Manas Kumar Sahoo

Designation: Lab Manager



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UROMETER-120

Performance Qualification



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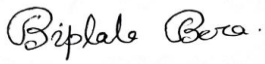
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CERTIFICATE OF PERFORMANCE QUALIFICATION

Instrument Name : UROMETER-120
Make : SD STANDARD DIAGNOSTICS, INC.
Serial Number : 12211621
Customer : LUPIN DIAGNOSTICS
KIRAN PLAZA, 84 DISTRICT CENTRE
CHANDRASHEKHARPUR, BHUBANESWAR 751016

The undersigned performer certifies that the Performance Qualification Protocol has been successfully completed for the instrument stated above.

Engineer/ Application for Abbott Diagnostics Medical Pvt. Ltd.

Signature : 
Date : 05/12/2023
Name : Mr. Biplab Bera
Designation : Manager Application - East
Company : Abbott Diagnostics Medical Pvt. Ltd.

Authorized Personnel for Lupin Diagnostics

Signature :
Date :
Name : Mr. Manas Kumar Sahoo
Designation : Lab Manager

TRIGGER FOR PERFORMANCE QUALIFICATION

Installation	√ <input type="checkbox"/>	Routine Maintenance	√ <input type="checkbox"/>
Functional Tests	√ <input type="checkbox"/>		

FUNCTIONAL TESTS:

TEST	Accepted Ranges	Not Done	Pass	Fail
Self-calibration value	As per given criteria		√	
Key Board	-easy operate		√	
Centering check	In and out of strip loader plate		√	
Printer	Visible printing		√	

% CV TESTING

Table 1 – Accuracy and Precision Testing

QC Material Name : Level 1&2(Randox)

Lot # : 1258UC(L-1) / 1259UC(L-2)

Expiry Date : 30/11/2024 & 31/05/2024

Parameter	BLD	BIL	URO	KET	Pro	Nit	Glu	pH	S.G	LEU	Remarks
Positive Control(PC) Range	1+ _ 3+	1+ _3+	2+_4+	Trace_2+	Trace _2+	Pos	1+ _4+	6.5 _≥8.5	1.005 _1.020	1+ _2+	
Negative Control(NC) Range	Neg	Neg	Neg	Neg	Neg	Neg	Neg	5.0 _6.5	1.015 _1.030	Neg	
Run 1 (PC)	3+	3+	4+	+	+	Pos	3+	8.0	1.025	++	
Run 2 (PC)	3+	3+	4+	2+	+	Pos	3+	8.5	1.020	+	
Run 3 (PC)	3+	3+	4+	2+	+	Pos	3+	8.0	1.020	+	
Run 4	3+	3+	4+	+	+	Pos	2+	8.5	1.020	+	

(PC)											
Run 5 (PC)	3+	3+	4+	+	+	Pos	3+	8.5	1.025	2+	
Mean	3	3	2.6	1	1.6	NA	3.4	8.3	1.020	1	
SD	0	0	.4	0	.49		.49	.3	0	0	

Parameter	BLO	BIL	URO	KET	Pro	Nit	Glu	pH	S.G	LEU	Remarks
Run 1 (NC)	-(Neg)	-(Neg)	norm	-(Neg)	-(Neg)	-(Neg)	-(Neg)	<5.5	1.015	-(Neg)	
Run 2 (NC)	-(Neg)	-(Neg)	norm	-(Neg)	-(Neg)	-(Neg)	-(Neg)	<5.5	1.015	-(Neg)	
Run 3 (NC)	-(Neg)	-(Neg)	norm	-(Neg)	-(Neg)	-(Neg)	-(Neg)	<5.5	1.020	-(Neg)	
Run 4 (NC)	-(Neg)	-(Neg)	norm	-(Neg)	-(Neg)	-(Neg)	-(Neg)	<5.5	1.020	-(Neg)	
Run 5(NC)	-(Neg)	-(Neg)	norm	-(Neg)	-(Neg)	-(Neg)	-(Neg)	<5.5	1.025	-(Neg)	
MEAN	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
SD	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	



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TEST	Accepted Ranges	Not Done	Pass	Fail
Positive Control	< 5 %		√	
Negative Control	< 5 %		√	

Comments: Controls are tested 5 times and result of same attached separately.



POST FAULT RECTIFICATION

Is this Performance Qualification as a direct result of fault rectification?

YES

No

If YES;

Description of Fault	Reported On	Action Taken	Rectified On

Fault rectified by:

User

Specialized
Engineer

Return to
Manufacturer

Any measures advised to prevent reoccurrence:

.....

.....

.....

.....



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Performance Qualification: Summary Report

Instrument: UROMETER-120		Manufacturer: SD STANDARD DIAGNOSTICS, INC.	
Assessment of Complete Performance Qualification			
No Deviations	<input checked="" type="checkbox"/>	Deviations	<input type="checkbox"/> <i>(list below)</i>
Deviations	Impact on Operation		Justification for Acceptance

Successful completion of the preceding activities and checks indicates that this instrument has been satisfactorily delivered and installed. The instrument has passed the Performance Qualification and now be returned to use.

	Name	Signature	Date
Complete By (for Abbott)	Biplab Bera		05/12/2023
Deviations Approved By			
PQ Approved and Accepted By	Mr. Manas Kumar Sahoo		05/12/2023



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UROMETER-120

Operational Qualification



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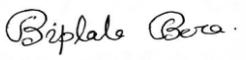
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CERTIFICATE OF OPERATIONAL QUALIFICATION

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Make : SD STANDARD DIAGNOSTICS, INC.
Serial Number : 12211621
Customer : LUPIN DIAGNOSTICS
KIRAN PLAZA, 84 DISTRICT CENTRE
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Engineer/ Application for Abbott Diagnostics Medical Pvt. Ltd.

Signature : 
Name : Mr. Biplab Bera
Designation : Manager Application - East
Company : Abbott Diagnostics Medical Pvt Ltd

Authorized Personnel for Lupin Diagnostics

Signature :
Name : Mr. Manas Kumar Sahoo
Designation : Lab Manager

SAFETY TESTS

Instrument Parameter	Specified Range	Reference	Compliance	
			Pass	Fail
Input voltages	100-240 V,50-60 HZ	Operator Manual	Pass	
Output voltages	12V-3A	Operator Manual-	Pass	
Humidity	≤ 80 % for temp. 30°C 50% for temp. 40°C	Operator Manual	Pass	
Ambient temperature	5°C to 40°C	Operator Manual	Pass	

PRE-RUN CHECKS

Pre-Run Check	Refer to	OK	Discrepancy	N / A
Check for Temperature	Operator Manual	√ <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Check for Humidity	Operator Manual	√ <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments(including Discrepancy):				

FUNCTIONAL TESTS

Functional Test	Reference	Pass	Fail
Key Board	Operator manual chapter 3.1	√ <input type="checkbox"/>	<input type="checkbox"/>
LCD display	Operator manual chapter 3.2 fig.3.2	√ <input type="checkbox"/>	<input type="checkbox"/>
Printer	Operator manual chapter 3.3	√ <input type="checkbox"/>	<input type="checkbox"/>
Run The Test	Operator manual chapter 3.4	√ <input type="checkbox"/>	<input type="checkbox"/>
Comments:			



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TRAINING

Date Instrument was released for use:			
Training Dates	From: 05/12/2023 To: 05/12//2023		
Operators Trained	Read Operators Manual	Received Operational Training	Signature
Mr. Manas Kumar Sahoo	Yes	Yes	
Mr. Priyabrata Sahoo	Yes	Yes	
Mr. Jitendra Kumar Mantry	Yes	Yes	
Mr. Chittaranjan Baral	Yes	Yes	
Comments: Trained Above lab personal for the routine operation and maintenance of the system.			



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Operational Qualification: Summary Report

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UROMETER -120			
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Deviations	Impact on Operation		Justification for Acceptance

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	Name	Signature	Date
Complete By (for Abbott)	Mr. Biplab Bera		05/12/2023
Deviations Approved By			
OQ Approved and Accepted By	Mr. Manas Kumar Sahoo		05/12/2023