



INSTALLATION QUALIFICATION

For

Semi Automated Urine Chemistry Analyzer

MODEL : MISPA URISKAN 100 PLUS

AGAPPE DIAGNOSTICS LTD

ADL/MO/SER/040/20-21

ADL/FO/MCD/CO/076/2020/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

CORPORATE OFFICE / REAGENT PLANT
Agappe Hills, Pattimattom (PO), Dist. Ernakulam, Kerala - 683 562, India.
Tel: +91 484 286 7000 | Email: agappe@agappe.in

MUMBAI [REGISTERED OFFICE]
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Tel: +91 22 4300 8000 | Email: mumbaioffice@agappe.in

EQUIPMENT PLANT
X/588-CB, Block No. 32, KINFRA Small Industrial Park,
Nellad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

DELHI OFFICE
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New Delhi - 110 015, India.
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KOLKATA OFFICE
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Tel: +91 33 4003 0451 | Email: kolkataoffice@agappe.in

BANGALORE OFFICE
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TABLE OF CONTENTS

S No.	Contents	Page No.
I	Approval of the IQ procedure	3
II	Instructions	4
III	Scope	5
IV	Installation Qualification	6
V	Comments	9
VI	System Certification	10

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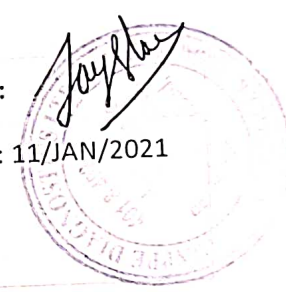


I. APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE

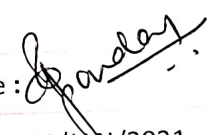
Both SHRUTI CLINICAL LABORATORY, JUHU & AGAPPE DIAGNOSTICS LTD are jointly responsible for the installation of MISPA URISKAN 100 PLUS with serial number 105375201222 at Shruti Clinical Laboratory , No: 203, Royal Chambers , N. S Road No: 1, Opposite Club Millennium, Juhu - 400049 "at as per the attached Installation Qualification protocol.

Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.

Name	:	Jay Shah	Signature :	
Title	:	Engineer - Customer Service	Date	: 11/JAN/2021
Company	:	AGAPPE DIAGNOSTICS LTD		




Validation Team from "SHRUTI CLINICAL LABORATORY, JUHU "

Name:	:	DR KRISHNA / ^{OR} PAYAL	Signature :	
Designation	:	QUALITY MANAGER	Date	: 11/JAN/2021
Department	:	CLINICAL		

Customer Authorizations:

Name : SHRUTI CLINICAL PATHOLOGY,
 Title : INSTALLATION QUALIFICATION ;
 Site : JUPP, MUMBAI

Signature: 

Date : 11/01/2021
 ADL/FO/MCD/CO/076/2020/R00

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II. INSTRUCTIONS

1. An authorized **AGAPPE DIAGNOSTICS LTD.** representative will check and enter the specific data as outlined in the Installation Qualification. Each result will be noted and dated.
2. The concerned employees of will verify each result and sign in each page. The member of the validation team will carry this out.
3. All deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the IQ protocol. All resolution to such problems will also be noted in the **COMMENTS** section, and must be resolved prior to issuance of a **SYSTEM CERTIFICATION**.

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III. SCOPE

This Installation Qualification protocol will be performed at **SHRUTI CLINICAL LABORATORY, JUHU**. This Installation protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage. Trained, knowledgeable personnel will perform qualification studies. Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

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IV. INSTALLATION QUALIFICATION

A. Instrument Identification

Verified Date: 11-01-2021

1. Model Name : Mispa Uriskan 100 Plus

B. Serial Number : 105375201222

Following is a list of accessories /consumables verified:

S No.	Component	Present (Yes/No)	Verified By	Comments
01	Analyzer Main unit	Yes	Jay Shah	OK
02	Power Chord	Yes	Jay Shah	OK

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1. INSTALLATION CHECKS

Purpose: To make sure that the instrument is received with all the major components necessary for operation

S No.	Component	(Yes/No)	Verified By	Comments
1	Major components and accessories are present	Yes	Jay Shah	OK
2	There is no physical damage to the components	Yes	Jay Shah	OK
3	Ambient temperature is available	Yes	Jay Shah	OK
4	Instrument is installed in the table leveled properly	Yes	Jay Shah	OK
5	Power supply is correct	Yes	Jay Shah	OK
6	Electric connections are tight, weatherproof & earthed	Yes	Jay Shah	OK
7	Analyzer unit installed as per the manufacturers recommendations	Yes	Jay Shah	OK

Summary:

The information is recorded against each data and the deviations if any is justified / explained properly.

Acceptance criteria:

PARAMETER

PASS ✓

FAIL

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2. INSTRUMENT INSTALLATION

Date of Installation: 11/01/2021

Installed by: Jay Shah

S No.	Parameter	Done by	Comments
01	Installation of the main unit	Jay Shah	ok

Acceptance criteria System should be "Ready" for use

PARAMETER PASS ✓ FAIL

Parameter values for verification: System found "Ready" for use

3: Movement of Strip reader

Purpose: To check the movement of strip holder.

Procedure:

S No.	Activity	Done By	Date
01	Check strip holder movement	Jay Shah	11-01-2021

Acceptance criteria:

- No error Messages displayed
- Strip holder move when strip is kept and Start key is pressed.

PARAMETER PASS ✓ FAIL

Parameter values for verification: No Error Messages

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V. COMMENTS

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VI. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline in this Installation Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Operational Qualification.

Report Performed By: **AGAPPE DIAGNOSTICS LTD.**

Representative

Name : Jay Shah

Designation : Engineer - Customer Service

Company : AGAPPE DIAGNOSTICS LTD.

Signature :

Date :

11/JAN/2021



Customer Authorizations: **SHRUTI CLINICAL LABORATORY**

Name : DR PAYAL PANDEY

Designation : QUALITY MANAGER

Title : INSTALLATION QUALIFICATION

Signature :

Date :

Payal Pandey

11/01/2021

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MODEL : MISPA URISKAN 100 PLUS

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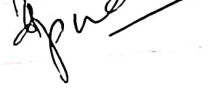
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Name	: Jay Shah	Signature :		
Title	: Engineer - Customer Service	Date		: 11/JAN/2021
Company	: AGAPPE DIAGNOSTICS LTD.			

Validation Team from: from "SHRUTI CLINICAL LABORATORY, JUHU "

Name:	: DR PAYAL PANDEY	Signature :	
Designation	: QUALITY MANAGER	Date	: 11/01/2021
Department	: CLINICAL PATHOLOGY		

Customer Authorizations:

Name: SHRUTI CLINICAL LABORATORY
Title : OPERATIONAL QUALIFICATION
Site : JVDD, MUMBAI

Signature: 
Date : 11/01/2021

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2. The concerned employees of **SHRUTI CLINICAL LABORATORY, JUHU** will verify each result and sign in each page. The member of the validation team will carry this out.
3. All deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the OQ protocol. All resolution to such problems will also be noted in the **COMMENTS** section, and must be resolved prior to issuance of a **SYSTEM CERTIFICATION**.

ADL/FO/MCD/077/2020/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

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Tel: +91 484 286 7000 | Email: agappe@agappe.in

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Email: bangaloreoffice@agappe.in



III. SCOPE

This Operational Qualification will be performed on **SHRUTI CLINICAL LABORATORY, JUHU** . This Installation protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage. Trained, knowledgeable personnel will perform qualification studies. Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

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IV. OPERATION QUALIFICATION

Verified Date : 11-01-2021

A. Instrument Identification

1. Model Name : MISPA Uriskan 100 Plus
2. Serial Number : 105375201222

B. Following is a list of tests to be performed and verified

Test No.	Test Name	Test purpose	Verified By and date
01	Start up	To make the equipment ready for operation	Jay Shah 11/JAN/2021
02	Daily maintenance	To clean appropriate modules	Jay Shah 11/JAN/2021
03	QC check	To confirm that the system and reagents are acceptable and working within specifications	Jay Shah 11/JAN/2021
04	Reproducibility check	To check the precision [CV %]	Jay Shah 11/JAN/2021
05	Shut down procedure	To shut down the system	Jay Shah 11/JAN/2021

Test 01: Starting the system

Purpose: To make the instrument READY for operation

Summary:

Instrument checks functioning of different parts of the instrument automatically; if there is an error code, initialize the system and follow corrective action instructions provided for the error message.

Procedure:

- Check the room temperature Instrument works in ambient temperature.
- Switch on the Mispa Uriskan 100 Plus by pressing the main switch
- Wait for the instrument to get ready after initialization.
- If not, initialize by again after solving the error displayed
- Follow instructions provided for the error message

Acceptance criteria: System to display **READY** status

PARAMETER **PASS** FAIL

Parameter values for verification: "READY" on Status Area

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**Test 02: Daily Maintenance**

Purpose: To clean appropriate modules so as per the daily maintenance protocol

Method: Refer detailed procedure for Daily Maintenance

S No.	Activity	Done by	Date
01	Clean out side area	Jay Shah	11/JAN/2021
02	Clean the strip holder	Jay Shah	11/JAN/2021
03	Check the strip movement	Jay Shah	11/JAN/2021
04	Perform Quality Control	Jay Shah	11/JAN/2021

Acceptance criteria System should be "Ready" after daily maintenance without any error

PARAMETER PASS ✓ FAIL

Parameter values for verification: System found "Ready" after daily maintenance

Test 3: QC check

Purpose: To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.

Procedure:

S No.	Activity	Done By	Date
01	Test by controls	Jay Shah	11/JAN/2021

Acceptance criteria: QC results within specified limits mentioned on the control product insert

PARAMETER PASS ✓ FAIL

Parameter values for verification: QC values within $\pm 2SD$

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Test 4: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Prepare control material/ sample	Jay Shah	11/JAN/2021
02	Run triplicates	Jay Shah	11/JAN/2021

Acceptance criteria: Results CV within specified limits

PARAMETER **PASS** ✓ FAIL

Parameter values for verification: CV% within the limits

Test 5: Shut down

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Remove used strips from strip table	Jay Shah	11/JAN/2021
02	Switch off the instrument	Jay Shah	11/JAN/2021

Acceptance criteria: Shut down without any error

PARAMETER **PASS** ✓ FAIL

Parameter values for verification: Shut down without any error

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V: OPERATIONAL PROCEDURE

A. Certificate of Training

1. Technician Training

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

S No.	Training program	Initials	Date
1	Instrument Setup	Jay Shah	11/JAN/2021
2	System Operation	Jay Shah	11/JAN/2021
3	Training on proper pipetting and strip placement on strip table	Jay Shah	11/JAN/2021

2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

S No.	Operators	Department	Initials	Date
①	SHANTI VERMA	CLINICAL LABORATORY	Shanti	11/01/2024

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VI. COMMENTS

AGAPPE

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VII. SYSTEM CERTIFICATION

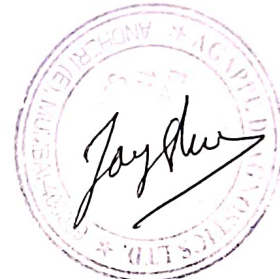
Study data has determined that the system described in this document either meets all criteria outline in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Performance Qualification.

Report Performed By: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : Jay Shah

Designation : Engineer - Customer Service

Signature : ,



Company : AGAPPE DIAGNOSTICS LTD.

Date

: 11/JAN/2021

Customer Authorizations: 6

Name : SHRUTI CLINICAL LABORATORY

CDR PAYAL PANDEY

Designation : QUALITY MANAGER

Signature

: *[Handwritten Signature]*

Title : OPERATIONAL QUALIFICATION

Date

: 11/01/2021

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REPRODUCIBILITY CHECK

①
 001111
 2021-01-11 09:29:46

UBG	Normal	3.4 μmol/L
BIL	Neg	Neg
KET	Neg	Neg
BLD	Neg	Neg
PRO	Trace	Trace
MALB		0.15 g/L
NIT	Neg	Neg
LEU	3+	>=500Leu/μL
GLU	Neg	Neg
SG	1.020	
PH	6.0	

②
 001111
 2021-01-11 09:29:05

UBG	Normal	3.4 μmol/L
BIL	Neg	Neg
KET	Neg	Neg
BLD	Neg	Neg
PRO	Trace	Trace
MALB		Neg
NIT		Neg
LEU	2+	125Leu/μL
GLU	Neg	Neg
SG	1.025	
PH	6.0	

③
 001111
 2021-01-11 09:34:46

UBG	Normal	3.4 μmol/L
BIL	Neg	Neg
KET	Neg	Neg
BLD	Neg	Neg
PRO	Trace	Trace
MALB		0.15 g/L
NIT	Neg	Neg
LEU	3-	>=500Leu/μL
GLU	Neg	Neg
SG	1.010	
PH	6.0	

④
 001111
 2021-01-11 09:32:58

UBG	Normal	3.4 μmol/L
BIL	Neg	Neg
KET	Neg	Neg
BLD	Neg	Neg
PRO	Trace	Trace
MALB		0.15 g/L
NIT		Neg
LEU	3+	>=500Leu/μL
GLU	Neg	Neg
SG	1.015	
PH	6.0	

⑤
 001111
 2021-01-11 09:31:26

UBG	Normal	3.4 μmol/L
BIL	Neg	Neg
KET	Neg	Neg
BLD	Neg	Neg
PRO	Trace	Trace
MALB		0.15 g/L
NIT		Neg
LEU	3+	>=500Leu/μL
GLU	Neg	Neg
SG	1.020	
PH	6.0	

PERFORMED BY: [Signature]
 CHECKED BY: [Signature]

QC CHECK

Level-1

02007
2021-01-11 09 16 51

URG	Normal	3.1 mmol/L
BIL	Neg	Neg
KET	Neg	Neg
BLD	Neg	Neg
PRO	Neg	Neg
HALB		Neg
NIT		Neg
LEU	Neg	Neg
GLU	Neg	Neg
SG	1.025	
PH	6.0	

Level-2

020072
2021-01-11 09 22 54

UBB	1+	34 mmol/L
BIL	2+	31 mmol/L
KET	±	0.5 mmol/L
BLD	2+	20 Ery µL
PRO	4+	>=200 µg/L
HALB		20 132 L
NIT		Pos
LEU	3+	=500 Leu µL
GLU	Neg	Neg
SG	1.015	
PH	7.5	

PERFORMED BY: [Signature]

CHECKED BY: [Signature]

DATE : 01-11-21 REPRODUCIBILITY CHECK

SR NO.	TEST NAME	VALUE
1	UBG	3.4
2	UBG	3.4
3	UBG	3.4
4	UBG	3.4
5	UBG	3.4
	MEAN	3.4
	SD	0
	CV%	0

SR NO.	TEST NAME	VALUE
1	SG	1.02
2	SG	1.025
3	SG	1.01
4	SG	1.015
5	SG	1.02
	MEAN	1.018
	SD	0.0
	CV	0.56

SR NO.	TEST NAME	VALUE
1	PH	6
2	PH	6
3	PH	6
4	PH	6
5	PH	6
	MEAN	6
	SD	0.0
	CV	0.0

Performed by: Dr. P. H.Check by: J. H.

www.agappe.com



AGAPPE

PERFORMANCE QUALIFICATION

For

Semi Automated Urine Chemistry Analyzer

MODEL : MISPA URISKAN 100 PLUS

AGAPPE DIAGNOSTICS LTD.

ADL/MO/SER/040/20-21

ADL/FO/MCD/078/2020/R00

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YOUR BEST PARTNER IN DIAGNOSTICS



PERFORMANCE QUALIFICATION

For

Semi Automated Urine Chemistry Analyzer

MODEL : MISPA URISKAN 100 PLUS

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ADL/MO/SER/040/20-21

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TABLE OF CONTENTS

S No.	Contents	Page No.
I	Approval of the PQ procedure	3
II	Instructions	4
III	Scope	5
IV	Performance Qualification	6
V	Comments	10
VI	System Certification	11

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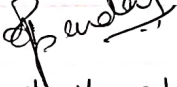
I. APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE

Both SHRUTI CLINICAL LABORATORY, JUHU & AGAPPE DIAGNOSTICS LTD are jointly responsible for the installation of MISPA URISKAN 100 PLUS with serial number 105375201222 at Shruti Clinical Laboratory , No: 203, Royal Chambers , N. S Road No: 1, Opposite Club Millennium, Juhu - 400049 "as per the attached PERFORMANCE Qualification protocol.

Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.


Name	:	Jay Shah	Signature :	
Title	:	Engineer - Customer Service	Date : 11/JAN/2021	
Company	:	AGAPPE DIAGNOSTICS LTD.		

Validation Team from SHRUTI CLINICAL LABORATORY

Name:	:	DR PAYAL PANDEY	Signature :	
Designation	:	QUALITY MANAGER	Date : 11/01/2021	
Department	:	CLINICAL PATHOLOGY		

Customer Authorizations:

Name : SHRUTI CLINICAL LABORATORY (DR PAYAL PANDEY)
 Title : PERFORMANCE QUALIFICATION
 Site : JVPD , MUMBAI

Signature: 
 Date : 11/01/2021

ADL/FO/MCD/078/2020/R00

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

CORPORATE OFFICE / REAGENT PLANT
 Agappe Hills, Pattimattom (PO), Dist. Ernakulam, Kerala - 683 562, India.
 Tel: +91 484 286 7000 | Email: agappe@agappe.in

EQUIPMENT PLANT
 X/588-CB, Block No. 32, KINFRA Small Industrial Park,
 Nellad, Cochin, Kerala, India - 686 721. Tel: +91 484 276 7477.

KOLKATA OFFICE
 406, Merlin Matrix, Plot No-10, Block-DN, Sector V,
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 Tel: +91 33 4003 0451 | Email: kolkattoffice@agappe.in

MUMBAI [REGISTERED OFFICE]
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 S-6, 11th Floor, Red Cross Bhavan, No:26 Race Course Road,
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 Email: bangaloreoffice@agappe.in



II. INSTRUCTIONS

1. An authorized **AGAPPE DIAGNOSTICS LTD** representative will check and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.
2. The concerned employees of **SHRUTI CLINICAL LABORATORY, JUHU** will verify each result and sign in each page. The member of the validation team will carry this out.
3. All deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the PQ protocol. All resolution to such problems will also be noted in the **COMMENTS** section, and must be resolved prior to issuance of a **SYSTEM CERTIFICATION**.

ADL/FO/MCD/078/2020/R00

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III. SCOPE

This Performance Qualification protocol will be performed on the Mispa Uriskan 100 plus at **SHRUTI CLINICAL LABORATORY, JUHU** . This Performance protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage. Trained, knowledgeable personnel will perform qualification studies. Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

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IV PERFORMANCE QUALIFICATION

Verified Date: 11/JAN/2021

A. Instrument Identification

1. Model Name : MISPA Uriskan 100 Plus
2. Serial Number : 105375201222

B. Following is a list of tests to be performed and verified

Test No.	Test Name	Test purpose	Verified By and date
01	Start up	To make the equipment ready for operation	Jay Shah 11/JAN/2021
02	Daily maintenance	To clean appropriate modules	Jay Shah 11/JAN/2021
03	QC check	To confirm that the system and reagents are acceptable and working within specifications	Jay Shah 11/JAN/2021
04	Reproducibility check	To check the precision [CV %]	Jay Shah 11/JAN/2021
05	Shut down procedure	To shut down the system	Jay Shah 11/JAN/2021

Test 01: Starting the system

Purpose: To make the instrument READY for operation

Summary: Instrument checks functioning of different parts of the instrument automatically; if there is an error code, initialize the system and follow corrective action instructions provided for the error message.

Procedure:

- Check the room temperature and switch on the Air Conditioner
- Switch on the Mispa Uriskan 100 Plus by pressing the main switch
- Wait for the instrument to get ready after initialization
- If not, initialize again after solving the error displayed
- Follow instructions provided for the error message

Acceptance criteria: System to show main menu without any error message

PARAMETER PASS FAIL

Parameter values for verification: "System boots to Main Menu without any error message"

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**Test 02: Daily Maintenance**

Purpose: To clean appropriate modules so as per the daily maintenance protocol

Method:

Refer detailed procedure for Daily Maintenance

S No.	Activity	Done by	Date
01	Clean out side area	Jay Shah	11/JAN/2021
02	Clean the strip holder	Jay Shah	11/JAN/2021
03	Check the strip movement	Jay Shah	11/JAN/2021
04	Perform Quality Control	Jay Shah	11/JAN/2021

Acceptance criteria System should be "Ready" after daily maintenance without any error

PARAMETER **PASS** FAIL

Parameter values for verification: System found "Ready" after daily maintenance

Test 3: QC check

Purpose: To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.

Procedure:

S No.	Activity	Done By	Date
01	Test by controls	Jay Shah	11/JAN/2021

Acceptance criteria: QC results within specified limits mentioned on the control product insert

PARAMETER **PASS** FAIL

Parameter values for verification: QC values within $\pm 2SD$

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Test 4: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Prepare control material/ sample	Jay Shah	11/JAN/2021
02	Run triplicates	Jay Shah	11/JAN/2021

Acceptance criteria: Results CV within specified limits

PARAMETER **PASS** FAIL

Parameter values for verification: CV% within the limits

Test 5: Shut down

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Remove used strips from strip table	Jay Shah	11/JAN/2021
02	Switch off the instrument	Jay Shah	11/JAN/2021

Acceptance criteria: Shut down without any error

PARAMETER **PASS** FAIL

Parameter values for verification: Shut down without any error

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**H. Operational procedure:**

a. Certificate of Training

1. Technician Training

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

S No.	Training program	Initials	Date
1	Instrument Setup	Jay Shah	11/JAN/2021
2	System Operation	Jay Shah	11/JAN/2021
3	Training on proper pipetting and strip placement on strip table	Jay Shah	11/JAN/2021

2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

S No.	Operators	Department	Initials	Date
①	MS SHANTI VERMA	CLINICAL PATHOLOGY	Shanti	11/01/2021

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V. COMMENTS

AGAPPE

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VI. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed.

The system is ready for specified usage.

Report Performed By: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : Jay Shah
 Designation : Engineer - Customer Service Signature : Jay Shah
 Company : AGAPPE DIAGNOSTICS LTD. Date : 11/JAN/2021



Customer Authorizations: Shruti Clinical Laboratory

Name : DR PAYAL PANDEY
 Designation : QUALITY MANAGER Signature : Payal Pandey
 Title : PERFORMANCE QUALIFICATION Date : 11/01/2021

ADL/FO/MCD/078/2020/R00

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REPRODUCIBILITY CHECK

①
 001111
 2021-01-11 09:29:46

UBG	Normal	3.4 μmol/L
BIL	Neg	Neg
KET	Neg	Neg
BLD	Neg	Neg
PRO	Trace	Trace
MALB		0.15 g/L
NIT	Neg	Neg
LEU	3+	>=500Leu/μL
GLU	Neg	Neg
SG	1.020	
PH	6.0	

②
 001111
 2021-01-11 09:29:09

UBG	Normal	3.4 μmol/L
BIL	Neg	Neg
KET	Neg	Neg
BLD	Neg	Neg
PRO	Trace	Trace
MALB		Neg
NIT		Neg
LEU	3+	125Leu/μL
GLU	Neg	Neg
SG	1.025	
PH	6.0	

③
 001111
 2021-01-11 09:24:46

UBG	Normal	3.4 μmol/L
BIL	Neg	Neg
KET	Neg	Neg
BLD	Neg	Neg
PRO	Trace	Trace
MALB		0.15 g/L
NIT	Neg	Neg
LEU	3-	>=500Leu/μL
GLU	Neg	Neg
SG	1.010	
PH	6.0	

④
 001111
 2021-01-11 09:32:58

UBG	Normal	3.4 μmol/L
BIL	Neg	Neg
KET	Neg	Neg
BLD	Neg	Neg
PRO	Trace	Trace
MALB		0.15 g/L
NIT		Neg
LEU	3+	>=500Leu/μL
GLU	Neg	Neg
SG	1.015	
PH	6.0	

⑤
 001111
 2021-01-11 09:21:26

UBG	Normal	3.4 μmol/L
BIL	Neg	Neg
KET	Neg	Neg
BLD	Neg	Neg
PRO	Trace	Trace
MALB		0.15 g/L
NIT	Neg	Neg
LEU	3+	>=500Leu/μL
GLU	Neg	Neg
SG	1.020	
PH	6.0	

PERFORMED BY: T. B. S. P. A.
 CHECKED BY: J. J. J.

QC CHECK

Level-1

02007
2021-01-11 09 16 51

UBG	Normal	3.1	µmol/L
BIL	Neg		
KET	Neg		
BLD	Neg		
PRO	Neg		
MALB			
NIT			
LEU	Neg		
GLU	Neg		
SG	1.025		
PH	6.0		

Level-2

020072
2021-01-11 09 22 54

UBG	1+	34	µmol/L
BIL	2+	51	µmol/L
KET	±	0.5	mmol/L
BLD	2+	20	Ery/µL
PRO	4+	>=20	g/g/L
MALB		>C	13x/L
NIT			Pos
LEU	3+	=500	Leu/µL
GLU	Neg		
SG	1.015		
PH	7.5		

PERFORMED BY: DEPT

CHECKED BY: JULIA

DATE : 01-11-21 REPRODUCIBILITY CHECK

SR NO.	TEST NAME	VALUE
1	UBG	3.4
2	UBG	3.4
3	UBG	3.4
4	UBG	3.4
5	UBG	3.4
	MEAN	3.4
	SD	0
	CV%	0

SR NO.	TEST NAME	VALUE
1	SG	1.02
2	SG	1.025
3	SG	1.01
4	SG	1.015
5	SG	1.02
	MEAN	1.018
	SD	0.0
	CV	0.56

Performed by: ~~Tripa~~
 Check by: Julu

SR NO.	TEST NAME	VALUE
1	PH	6
2	PH	6
3	PH	6
4	PH	6
5	PH	6
	MEAN	6
	SD	0.0
	CV	0.0



Calibration Certificate

ADL/MO/SER/04722-23

Customer Name : Shruti Clinical Laboratory, Juhu
 Instrument : Uriskan 100 plus Urine Analyzer
 Model : Uriskan
 Instrument Serial Number : 105375201222
 Date Of Installation : 11/01/2021
 Calibration Date : 13/07/2022
 Calibration Due on : 12/01/2023

Technical Specifications

Wave Length : 525nm, 572nm, 610nm & 660nm
 Test Speed : 514 Specimen/Hour
 Data Memory : 2000 Patient results and 50 Quality Control Records
 Temperature : 15 °C - 30 °C
 Optimal Temperature : 20 °C - 25 °C
 Relative Humidity : ≤ 80 %
 Communication Interface : RS 232 Serial Port
 Power Supply : 100-240 VAC 50/60 Hz
 Power Supply : 40 VA
 Fuse : 250 V 1.5 A
 Printer : Internal Thermal Printer

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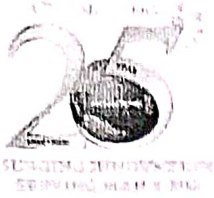
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LEVEL-01

020071
2022-07-13 15:51:50

UBG	Normal	0.4 umol/L
BIL	Neg	Neg
KET	Neg	Neg
BLD	Neg	Neg
PRO	Neg	Neg
MALB		Neg
NIT		Neg
LEU	Neg	Neg
GLU	Neg	Neg
SG	>= 1.030	
PH	6.0	

Calibration Details

Level 01

Parameter Name	Short Name	Result
Urobilinogen	UBG	0.4 u
Bilirubin	BIL	Neg
Ketone	KET	Neg
Blood	BLD	Neg
Protein	PRO	Neg
Micro Albumin	MALB	Neg
Nitrite	NIT	Neg
Leucocytes	LEU	Neg
Glucose	GLU	Neg
Specific Gravity	SG	>= 1.030
PH	PH	6.0

Appropriate Reagent Strip : URISTIK H8
 : URISTIK H10
 : URISTIK H11



Signature

AGAPPE DIAGNOSTICS LTD.

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Level 02

020073
2022-07-10 15:54:04

UBG	1+	34 μ mol/L
BIL	2+	51 μ mol/L
KET	±	0.5 mmol/L
BLD	2+	80 Ery μ L
PRO	3+	\geq 3.0 g/L
MALB		$>$ 0.15 g/L
NIT		Pos
LEU	3+	\geq 500 Leu μ L
GLU	1+	5.5 mmol/L
SG	1.020	
PH	7.5	

Calibration Details

Level 02
Parameter Name

Short Name

Result

Urobilinogen

UBG

34 μ mol/L

Bilirubin

BIL

51 μ mol/L

Ketone

KET

0.5 mmol/L

Blood

BLD

80 Ery/ μ L

Protein

PRO

\geq 3.0 g/L

Micro Albumin

MALB

$>$ 0.15 g/L

Nitrite

NIT

POS

Leucocytes

LEU

\geq 500 Leu/ μ L

Glucose

GLU

5.5 mmol/L

Specific Gravity

SG

1.020

PH

PH

7.5

Appropriative Reagent Strip

: URISTIK H8

: URISTIK H10

: URISTIK H11



AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

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Bangalore - 560 001. Tel: +91 80 2728 8385



Performance Check up

Section	Check /Clean
Work Table	Clean
Calibration Strip Box	Check
Screen Unit	check
Key board	check
Power Supply	check
Optical Detector	check
Photocoupler	check
Stepping motors	check
Sensitivity Setting	check

This is to certify that we have calibrated the instrument N1600100H0281 and on inspection of the instrument it is observed that the instrument is working fine.

Thanking you,

For Agappe Diagnostics Ltd,.



Shiv Shankar Ramashraya Varma



Authorised signatory

Name: Shiv Shankar Ramashraya Varma

Designation: Senior Engineer

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

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