



**Aspen Diagnostics Pvt. Ltd.**

(Rapid Diagnostic Group Of Companies)



# **(ACON-U 500)**

**(Automatic Urinalysis System)**

**Installation Qualification**

**Operational Qualification**

**Performance Qualification**

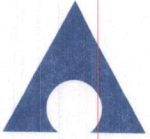
**(IQ/OQ/PQ)**

**KRSNAA Diagnostics Ltd.**

**The. Rohru, Dist. Shimla, Himachal Pradesh 171210**

**(By Aspen Diagnostic Pvt. Ltd)**





# Aspen Diagnostics Pvt. Ltd.

(Rapid Diagnostic Group Of Companies)



ISO 9001:2015  
CERTIFIED COMPANY

## CERTIFICATE OF INSTALLATION

Instrument Name : U 500  
Serial Number : 29711002F05  
Customer Name : Krsnaa Diagnostics Ltd.  
Address : The. Rohru, Dist. Shimla, Himachal Pradesh 171210

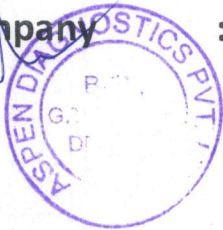
The undersigned performers certify that the Installation Qualification Protocol has been successfully completed for the instrument stated above.

### Technical Executive:

Signature :  
Name : Shankar Kumar  
Designation : Technical Executive  
Company : Aspen Diagnostics Pvt. Ltd.

### Quality Manager:

Signature :  
Name : Mr. Jagdish Kumar  
Designation : Lab Incharge  
Company : Krsnaa Diagnostics Ltd.





# Aspen Diagnostics Pvt. Ltd.

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Certificate No.: 30903/A/0001/UK/En  
ISO 9001:2015  
CERTIFIED COMPANY

## INSTALLATION REPORT

**Customer Name** : Krsnaa Diagnostics Ltd.  
**Place** : The. Rohru, Dist. Shimla, Himachal Pradesh 171210  
**Department** : Laboratory  
**Contact Person** : Mr. Jagdish Kumar  
**Instrument Name** : U 500  
**Serial Number** : 29711002F05  
**Date of Installation** : 14.09.2022  
**Warranty Expiry** : Under Warranty

The Analyzer was installed along with the necessary standard accessories. All basic requirements and adjustments were checked and are found to be satisfactory. The preliminary standardization of the analyzer and the training were provided to the complete satisfaction of the customer. The analyzer is found to be working satisfactorily.

For Aspen Diagnostics Pvt. Ltd.

**Rajaram Krishnamurthy**  
**National Service Manager**



## INSTALLATION QUALIFICATION

### IQ PROTOCOL

System Unpacking

System Checking: For any Damages All accessories as per check List verification

Space Requirement

Power Requirement

Reagents, Control, Calibrators verification.

### 1. SYSTEM UNPACKING& 2. SYSTEM CHECKING

Un packed U 500 instrument carefully and checked for any physical Damages.

### 3. ACCESSORIES CHECK-

Checked all accessories as per check List & found it alright.

### 4. SPACE REQUIREMENT-

Checked site for proper space allocation. At least 100 CM on each side and enough room for the below mentioned dimensions:

DIMENSIONS	
Parameter	Analyzer OV
Width(cm)	36.6
Depth (cm)	28.3
Height (cm)	19.5
Weight (Kg)	4.0





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## 5. POWER REQUIREMENT –

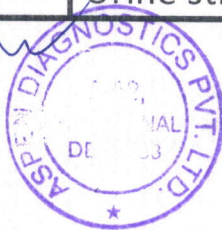
Requirement	Acceptable Range	Observed Ranged
Input Voltage	220 + / - 10 V	225 V
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15 C – 30 C	23

## 6. REAGENTS, CALIBRATORS, CONTROL CHECK

Name	Check	Remark
Urine Strips	Yes	Ok
Negative Control	Yes	Ok
Positive Control	Yes	Ok
Cleaning Solution	Yes	Ok

## PRE-INSTALLATION VERIFICATION REPORT :-

PRE-INSTALLATION VERIFICATION REPORT		
S/N	Parameter	Remark
1	Unpacking Instrument	OK
2	System Checking for damages	OK
3	Accessories check	OK
4	Space Check	OK
5	Power Check	OK
6	Urine strips check	OK





## OPERATIONAL QUALIFICATION

The Operational Qualification procedure specifies the methodology for installation of specified system after successful installation qualification. Successful completion of procedure identifies that system is ready for operation and subsequent performance analysis.

### OQ PROTOCOL

System Connections

Customizing the Analyzer Software

System Booting, Initialization & Check

Maintenance Procedures.

Customer Training – Operation & Maintenance.

### 1. SYSTEM CONNECTION –

SYSTEM CONNECTIONS			
S/N	Name	Check	Remark
1	Autoloader	Installation Manual	OK
2	Input Power supply	Connect	OK
3	Cleaning Solution Tube & Sensor	Operating Manual	





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## 2. REAGENT & WASTE Management-

Please refer to the User Manual and the Kit Literature supplied with the instrument.

## 3. CUSTOMIZING ANALYZER SOFTWARE –

CUSTOMIZING ANALYZER SOFTWARE			
S/N	Parameters	Check	Remark
1	Date & Time	Operating Manual	Ok
2	Reagents	Operating Manual	Ok
3	Reference Ranges	Operating Manual	Ok
4	Reference Units	Operating Manual	Ok
5	Printing format	Operating Manual	Ok
6	Creating New User	Operating Manual	Ok

## 4. SYSTEM BOOTING ,INITIALIZATION& CHECK-

Power ON System and check for successful initialization of the instrument.

## 5.MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/N	Parameters	Check	Remark
1	Using Maintenance Menu	Operator Manual	





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## PERFORMANCE QUALIFICATION-

### QC Done with U 500 Urine Strips

Lot No.: URS2040049 Exp. Date: 22-02-2024

### QC NAME: U500 Urinalysis Control

<u>QC Name</u>	<u>Lot No.</u>	<u>Expiry</u>
<u>Positive Control</u>	<u>87742</u>	<u>31-07-2023</u>

<u>Item-Parameter</u>	<u>Range</u>	<u>Results Obtained</u>
<u>Glucose</u>	<u>± to 3+</u>	<u>3+</u>
<u>Bilirubin</u>	<u>1+ to 3+</u>	<u>3+</u>
<u>Ketone</u>	<u>± to 2+</u>	<u>1+</u>
<u>Blood</u>	<u>1+ to 3+</u>	<u>3+</u>
<u>Protein</u>	<u>1+ to 3+</u>	<u>3+</u>
<u>Urobilinogen</u>	<u>1+ to 3+</u>	<u>3+</u>
<u>Leukocytes</u>	<u>1+ to 3+</u>	<u>3+</u>
<u>Specific Gravity</u>	<u>1.005 to 1.025</u>	<u>1.015</u>
<u>Ph</u>	<u>6.0 to 8.0</u>	<u>6.5</u>
<u>Nitrite</u>	<u>Positive</u>	<u>Positive</u>

*Rafiq*





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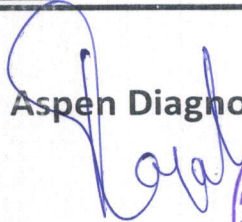
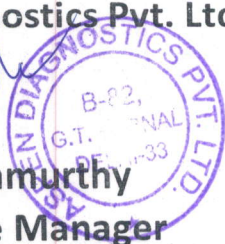
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QC NAME:U 500(Urinalysis Control)

Qc Name	Lot No.	Expiry
Negative Control	87741	31-07-2023

Item-Parameter	Range	Results Obtained
<u>Glucose</u>	Negative	Negative
<u>Bilirubin</u>	Negative	Negative
<u>Ketone</u>	Negative	Negative
<u>Blood</u>	Negative	Negative
<u>Protein</u>	Negative	Negative
<u>Urobilinogen</u>	3.4 to 17umol/L	Negative
<u>Leukocytes</u>	Negative	Negative
<u>Specific Gravity</u>	1.005 to 1.025	1.02
<u>pH</u>	5.0 to 7.0	6.0
<u>Nitrite</u>	Negative	Negative

For Aspen Diagnostics Pvt. Ltd.

**Rajaram Krishnamurthy**  
National Service Manager