

Calibration report

Product Name	Semi auto Biochemistry Analyzer	Model	URA
Tested Date	25.02.2023	SN	601631019IE
Customer Name	DELHI DIAGNOSTICS		

Parameter	expected result	Obtained result	Conclusion
Flowcel Temp	37° ±0.3° Celsius	37.01° Celsius	OK/ NOT OK
Flowcel aspiration volume	450ul ± 10% (450ul used as standard to measure in each parameter program)	460ul	OK/ NOT OK
340nm	AD values 2000 to 3800	2920	OK/ NOT OK
405nm	AD values 2000 to 3800	3020	OK/ NOT OK
500nm	AD values 2000 to 3800	3250	OK/ NOT OK
546nm	AD values 2000 to 3800	3050	OK/ NOT OK
578nm	AD values 2000 to 3800	3230	OK/ NOT OK
620nm	AD values 2000 to 3800	3090	OK/ NOT OK

Testing Result :	QC PASS
Remarks:	Instrument Calibrated as per factory standard and the performed check values are satisfactory
Next calibration on:	25.02.2024
The Tester:	The Auditor



Medsource Ozone Biomedicals Pvt. Ltd.

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URA IQ/OQ/PQ

IQ/OQ/PQ Protocol

Installation Qualification

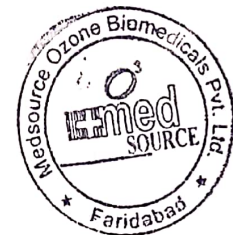
Operational Qualification

Performance Qualification

Instrument name: **URA**Serial No. **601631019 IE**D.O.I. : **06th April 2015****Customer Details****Delhi Diagnostic****Puran Enclave, 28/29 Chowk 1st Floor ,
Near Pooja Furniture ,Faridabad Haryana 121002**Contact number - **8010639426**Email id- **delhidiagnostics3456@gmail.com**

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Installation Qualification

To verify that the facilities provided for the installation of semi automated Biochemistry analyzer meets the requirements for the system and that all components of the system have been delivered, ready for installation in accordance with the standard for the system and other appropriate regulations.

Purpose: The purpose of the installation qualification (IQ) is to confirm that the instrument is installed as per the requirement.

S.No.	Parameter	Expected Result	Observed	Remarks
1	Ground voltage(voltage between neutral and earth)	< 3V	1.3 V	OK
2	Line voltage (voltage between line and neutral)	180V to 245V	228 V	OK
3	Capacity of UPS used	>400W	600VA	OK
4	Installation of peristaltic tube	Installed	OK	OK
Unpacking				
5	Package inspection	No damage.	NO DAMAGE SEEN	CHECKED
		Inspection of accessory supplied		CHECKED

- The analyzer passed the installation qualification
- The analyzer didn't pass the installation qualification

Special Note: Installation report attached.

Apurva M

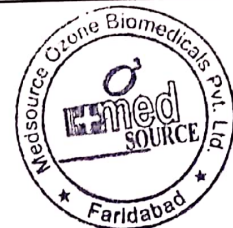
Engineer name and signature

N.K. Sharma

Customer name and signature

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SOLUTIONS
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URA IQ/OQ/PO

Operational Qualification

Purpose: The purpose of the operational qualification (OQ) is to ensure that the system can be operated as expected and to devise the standard operating procedure.

S no	Parameter	Expected result	Result
1	Switch ON the instrument	Software started without any error message	NO ERROR SEEN
2	Functionality of peristaltic system	Di water aspirated without any bubble in fluidic path	CHECKED
3	Functionality of halogen lamp	Lamp is glowing	CHECKED
4	Functionality of touch panel	Able to operate the software with touch.	N.A.
5	Functionality of Internal printer	Responding to print command	CHECKED
6	Functionality of flowcel temperature	Temperature reach $37 \pm 0.4^\circ\text{C}$ and stable	CHECKED
7	Programming of all reagents.	Installed	CHECKED
8	Training	Have all users has been properly trained on the safety, theory of operation and maintenance of the URA?	OK

- The analyzer passed the operational qualification
- The analyzer didn't pass the operational qualification

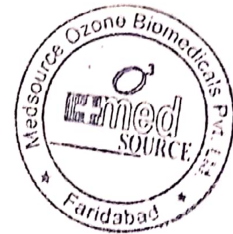
Special note:

Aspatakush

Engineer name and signature

N.K. Sharma

Customer name and signature



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