

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 and Run self check	Software started with no error message	OK
2	Check the reagent cooling	Reagent components starts cooling	OK
3	Position of Probe	Probe should be in the wash station	OK
4	Functionality of Probe level sensor	Responding with green LED ON/OFF	OK
5	Functionality of probe collision sensor	Aligned with 1mm height of sensor	OK
6	Installation of all system pack reagents, Calibration and QC data	Installed	OK
7	Place any of three reagent bottle and test volume	All volumes have to be recognized.	OK
8	Training	Have all users been properly trained on the safety, theory of operation and maintenance of the Csense 100?	OK

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

Special note:

Praveen Kumar

Engineer name and signature

Customer name and signature



Installation Qualification

To verify that the facilities provided for the installation of fully 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	0.1V	SATISFACTORY
2	Line voltage (voltage between line and neutral)	180V to 245V	234V	SATISFACTORY.
3	Capacity of online ups	>1000W	5KVA	SATISFACTORY.
Unpacking				
Caution: Unpacking and lifting is 2 persons job				
4	Package inspection	No damage and sealed	OK	OK
		Inspection of accessory supplied	OK	OK
		Accessory box included computer	OK	OK

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

Special Note: Installation report attached.

[Handwritten Signature]

Engineer name and signature

Customer name and signature



Medsource Ozone Biomedicals Pvt. Ltd.

Corporate office: Plot No109, HSIIDC, Sector-31,
Faridabad - 121003 (Haryana), Phone: +91-129-4286600/612
Email mail@ozonebio.com, Website: www.ozonebio.com.



Medsources Ozone Biomedicals Pvt. Ltd.

INSTRUMENT INSTALLATION REPORT

Hospital/Lab Name: **OLIVE HEART & DIAGNOSTIC**
 Address: **SECTOR 117 TDI AIRPORT ROAD** District: **MOHALI** State: **PUNJAB**
 Pin: **140055** Ph. No.: **9988897049** Email ID: **olivePathology@gmail.com**
 Model: **C Sense 100** Instrument: **Fully Automatic Analyzer**
 Serial No.: **312100111** Challan No.: _____ Date: _____
 Invoice No.: _____ Date: _____
 S.C. No.: _____ Date: _____ Instrument Delivery Date: _____ Instrument Installation Date: **30/06/2021**
 Customer Code: _____ (for office use only) _____
 Re-Installation report made by: **ATAY** Report No.: _____ Date: _____ Site Status: **Ready/ Not Ready**
 Warranty: **2 Year** (Warranty starts either from the date of delivery or installation of instrument whichever is earlier)
 Contact Person: _____

S/N	NAME	DESIGNATION	PHONE/CELL NO.	EMAIL ID
	Dr. Suchita Gupta	Owner	9988897049	olivePathology@gmail.com

Site Output Voltage: (Kindly check the recommended power supply voltage range mentioned Backside of the instrument or in Service or User manual and should be maintain the same always)
234V
 Power Source: **DIRECT UPS / CVT Online** (Source voltage should be constant)
 Site Earthing Voltage: (Earthing voltage should be 0 VAC, otherwise suggest customer to take the necessary steps for it)
 Line/Neutral: **234V** Line/Earth: **0.1V** Line/Neutral: **233V** (leakage voltage should be 0 VAC)
 Humidity: **OK** Site condition: **OK** Ventilation: **OK** Room Size: _____
 Engineers Remarks regarding power source and Site conditions and suggestion to customers : _____

Tests Performed :

TEST NAME	RESULT	REMARKS
ALB	4.48	OZO PATH:- All Qc in Range
CHOL	228	
OT	74.1	
PT	85.1	
TP	6.35	
UREA	50	

Person's Trained : **Miss Asti, Mrs Rajni,**

Customer's Remarks: _____

Engineer's Remarks : **Instrument Installed Successfully**
Machine Ready to test

Service Engineer Name : **ATAY KUMAR** Authorized Signatory :-
 Signature: _____ Name: _____
 Date(DD/MM/YY) **Atay 30/06/2021** (with Seal), Date : _____

Note : 1. Please fill the form in Capital Letters only 2. Annexure is mandatory 3. Subject to Faridabad Jusisdiction
 Imp.: Please note that in case of non-compliance of above points report shall not be accepted at H.O.
 HEAD OFF. : Plot No. 109 HSIIDC Sector- 31, Faridabad - 121003 Haryana (INDIA)
 REGD. OFF. : 238, Santnagar, East of Kailash, Delhi - 110065 (INDIA)
 Mob.: 09650064495, E-mail : mail@ozonebio.com, service@ozonebio.com, Website: www.ozonebio.com

Performance Qualification

Purpose: The purpose of the performance qualification (PQ) is to confirm that the instrument is installed and performed as per requirement.

S no	Parameter	Expected result	Obtained value	Result
1	AD Values of 340nm	30,000 to 60,000	50848	OK
2	AD Values of 405nm	30,000 to 60,000	51408	OK
3	AD Values of 450nm	30,000 to 60,000	51888	OK
4	AD Values of 510nm	30,000 to 60,000	51368	OK
5	AD Values of 546nm	30,000 to 60,000	52432	OK
6	AD Values of 578nm	30,000 to 60,000	51480	OK
7	AD Values of 630nm	30,000 to 60,000	52168	OK
8	AD Values of 700nm	30,000 to 60,000	52160	OK
9	Accuracy study	The results of both QC samples should be in the specified range	YES	OK
10	Precision study	The CV in % should be lesser than 5% for each test	YES	RESULTS ATTACHED.

Reports Print out	Expected	Remarks
Reports of both QC performed	Attached printout/ Saved file name and location	ATTACHED
Reports of precision study done	Attached printout/ Saved file name and location	ATTACHED

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

Special note:

[Handwritten signature]

Engineer name and signature

Customer name and signature



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To

NABL

Electrolytes not in scope in MELT
application

Olive
Heart & Diagnostics

Anshu

Director

Olive Heart and Diagnostics

Phone : 9478082657, 9041032657

- FULLY AUTOMATED LABORATORY WITH LATEST MACHINES

- HOME COLLECTION FACILITY AVAILABLE

📍 SCO 210, Sector 117, TDI, Airport Road,
Mohali (P.B.)

📍 Bungalow #120, Phase 3B1, Mohali (P.B.)
✉ olivepathology@gmail.com



Log No.

Medsource Ozone Biomedicals Pvt. Ltd.

Date : 20 01 22

Technical / Service Report

CUSTOMER DETAILS			SERVICE STATUS	
NAME & ADDRESS <p style="text-align: center; margin: 0;">DR. SUCHITA GUPTA Olive Pathology & Diagnostics Mohali (Punjab)</p>			<input type="checkbox"/> INSTALLATION <input type="checkbox"/> WARRANTY <input type="checkbox"/> AMC <input type="checkbox"/> CHARGEABLE CALL <input type="checkbox"/> P.M. VISIT <input type="checkbox"/> APPLICATION SUPPORT <input type="checkbox"/> COURTESY <input checked="" type="checkbox"/> CALIBRATION	
TEL. NO.:			WORK CARRIED OUT AT <input checked="" type="checkbox"/> SITE <input type="checkbox"/> SERVICE CENTRE	
NAME OF THE OPERATOR: Mrs. Rajini				
DATE OF INSTALLATION:				
MODEL: Censes-100		SR. NO.: 31210011		
PROBLEM REPORTED:			OBSERVATIONS: Required P.M.	
<p style="text-align: center; margin: 0;">———— No ————</p>				
ACTION TAKEN:			TO BE FILLED IN BY CUSTOMER <input checked="" type="checkbox"/> PREVENTIVE MAINTENANCE CARRIED OUT SATISFACTORILY <input type="checkbox"/> FAULT RECTIFIED & INSTRUMENT IS WORKING SATISFACTORILY <input type="checkbox"/> COMMENTS (IF ANY)	
Preventive Maintenance done, check the opticals Result output of the filter, cuvette output was satisfactory, calibration satisfactory. Quality control run satisfactory.				
FOLLOWING PARTS HAVE BEEN REPLACED				
PART NO.	DESCRIPTION	QTY.		
/	/	/		
ISSUED FROM : COMPANY'S STOCK <input type="checkbox"/> CUSTOMER'S STOCK <input type="checkbox"/>			DATE : 	
NOTE : Parts replaced chargeable except during warranty Period. Consumables like Printer Head, Lamp, tubings, paper rolls glass parts etc. Are not covered under warranty and hence are chargeable.				
ENGINEER'S REMARKS				
ENGINEER'S NAME :		BRANCH : H.O.		
SIGNATURE		RECEIVED ON :		
		CHECKED BY :		

OLIVE HEART AND DIAGNOSTICS

<i>DATE</i>	<i>TEST NAME</i>	<i>R. FACTOR</i>	<i>CONC.</i>
20-01-2022	UREA	1111.4674	123
20-01-2022	URIC ACID	49.7828	9.3
20-01-2022	TRIG	507.8482	253
20-01-2022	TOTAL PROTEIN	8.0505	4.43
20-01-2022	SGPT	2400.6862	144
20-01-2022	SGOT	2312.4064	151
20-01-2022	HDL-DIRECT	652.3539	69
20-01-2022	GLUCOSE	436.5052	276
20-01-2022	CREAT	107.4058	4
20-01-2022	ALBUMIN	5.063	2.89
20-01-2022	ALP	2116.4032	344
20-01-2022	BILI-TOTAL	100.0748	4.77
20-01-2022	BILI-DIRECT	19.4759	1.64
20-01-2022	CHOL	832.6983	275

QC information

Test time	QC Liquid	Item	Ave.	SD	Result	SD Range	In Control
2022-01-21 10:44	Randox P	UREA UV-OZ	120	12	126.83	96-144	Y
2022-01-21 10:43	Randox P	UA-OZ	9.29	1.21	9.42	6.87-11.71	Y
2022-01-21 10:42	Randox P	TRIG-OZ	255	41	291.05	173-337	Y
2022-01-21 10:42	Randox P	TP-OZ	4.39	0.88	4.37	2.63-6.15	Y
2022-01-21 10:41	Randox P	SGPT-OZ	139	27	144.34	85-193	Y
2022-01-21 10:41	Randox P	SGOT-OZ	157	32	153.84	93-221	Y
2022-01-21 10:40	Randox P	HDLc Direct	90.3	13.9	91.58	62.5-118.1	Y
2022-01-21 10:39	Randox P	GLU-OZ	279	43	299.43	193-365	Y
2022-01-21 10:39	Randox P	CREAT-OZ	4.24	0.85	3.11	2.54-5.94	Y
2022-01-21 10:38	Randox P	CHOL-OZ	273	36	279.24	201-345	Y
2022-01-21 10:38	Randox P	BIL-T-OZ	4.32	0.9	4.6	2.52-6.12	Y
2022-01-21 10:37	Randox P	BIL-D-OZ	1.51	0.32	1.51	0.87-2.15	Y
2022-01-21 10:36	Randox P	ALP-OZ	341	25.5	320.37	290-392	Y
2022-01-21 10:36	Randox P	ALB-OZ	2.89	0.43	3.29	2.03-3.75	Y