

arkray healthcare PVt. Ltd.

Plot no. 336, 338, 340, Road no. 3, G.I.D.C.,

Sachin 394 230, (Surat), India. Telephone: 0261-239 7712 to 15 Fascimile: 0261-239 7719, URL http://www.arkray.co.in

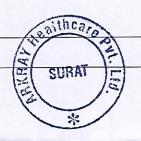
Installation / Operation/Performance Qualification Certificate. <u>Auto Chem Xact Pro</u>

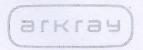
System Description:

Type of Analyzer Auto Chem Xact Pro (Fully Automatic Bio-Chemistre		
Model	Xact Pro	
Serial Number	1250619167	
Marketed in India By	ARKRAY HEALTHCARE PVT LTD.	

Instrument Delivery:

Date of Delivery	20/11/2020





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Installation Qualification Certificate.

AutoChem Xat Pro	Received	Undamaged	
Accessories	Received	Undamaged	

Assembly and Installation:	
Place of Installation	G1 Pathology Laboratory
	Sr No 14/4, Vadgaon Khurd, Pune
Date of Installation : 25-11-2020	
Analyzer Serial No : 1250619167	
Installed By : Mr. Vijay Patil	
Initial Check Up / Auto Self Diagnosis	Passed
Auto Chem Xat Pro is successfully installed	ed and is in a fully working condition.
WO DE SURAT SURAT	
For, Arkray Healthcare Pvt Lid	Customer's Signature and Stamp

Regd. Office: 701/702, Opulence.6th Road, TPS III , Santacruz(East) Mumbai-400 055 INDIA :telephone: +91 – 22-6155 9355 ; facsimile: +91-22-61559356: CIN NO: U51507MH2007PTC175112



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OPERATIONAL QUALIFICATION (OQ)

Auto Chem Xact Pro

Analyzer Serial No: 1250619167

Date	•	25/11/2020	
Duie		43/11/4040	

OPERATIONAL PARTS	Working	Not Working
Reagent/Sample Tray Movement	O.K	
Cuvvete Tray Movement	O.K.	
Reagent Refrigeration Section	O.K.	
Cuvvete section Temperature (37 C)	O.K.	
Mixer Arm Movement	O.K.	
Sample Arm Movement	O.K.	
Reagent /Sample liquid level detection	O.K.	
Waste & DI water sensor	O.K.	
Optical Section	O.K.	
External computer & Software	O.K.	

All the parts of Auto Chem Xact Pro are in working condition & Operation of analyzer is according to given specifications at the user's environment.

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CIN NO :U51507MH2007PTC175112



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Plot no. 536, 338, 340, Road no. 3, G.I.D.C., Sachin 594 230, (Surat), India, Telephonec, 0261-239 7712 to 15 Fascimile: 0261 239 7719, URL http://www.arkray.co.in

PERFORMANCE QUALIFICATION (PQ)

Auto Chem Xact Pro SN: 1250619167 Date: 26/06/2021

Calibration: Calibration done with Multi calibrator C.f.a.s. Verification of the instrument results is done and in rage.

Randox Control Lot (1416)	Results	Range of Control		
Glucose	116.0	(92.0-128.0) mg/dl		
ALP	178.64	(152.0-206.0) IU/L		
Creatnine	1.51	(1.22-1.86) mg/dl		
Trig	94.85	(78.90-108.70) mg/dl		
SGOT	51.09	(36.00-54.00) IU/L		
Cholesterol	155.56	(136.0-176.0) mg/dl		
Total Protein	5.46	(4.64-6.92) g/dl		

The results obtained are satisfactory. This is to certify that AutoChem Xact Pro is working OK & results are within recommended range

For, Arkray Healthcare

Customer's Signature and Stamp

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SURAT



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PERFORMANCE QUALIFICATION (PQ)

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Randox Control	Results	Range of Control	
Lot (1416)		Mange of Control	
Glucose	116.0	(92.0-128.0) mg/dl	
ALP	178.64	(152.0-206.0) IU/L	
Creatnine	1.51		
Trig	94.85	(1.22-1.86) mg/dl	
SGOT	51.09	(78.90-108.70) mg/dl	
Cholesterol		(36.00-54.00) IU/L	
Total Protein	155.56	(136.0-176.0) mg/dl	
	5.46	(4.64-6.92) g/dl	

The results obtained are satisfactory. This is to certify that AutoChem Xact Pro is working OK & results are within recommended range

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SURAT

QC results

From:

24-06-2021

To:

28-06-2021

Level:

No.	Item	Lot number	Result	Check date	Check time	Flag	QC range
66	SGOT	VDOX 1416	51.09	26-06-2021	12:13:56	+2SD	36.00-54.00
69	CREAT	NDOX 1416	1.51	26-06-2021	12:10:27	-1SD	1.22-1.86
71	URIC	NDOX 1416	5.55	26-06-2021	12:11:34	-1SD	5.04-6.56
72	TP	NDOX 1416	5.46	26-06-2021	12:11:35	-1SD	4.64-6.92
73	SGPT	NDOX 1416	44.06	26-06-2021	12:13:21	+1SD	32.00-50.00
77	UREA	NDOX 1416	45.69	26-06-2021	12:44:18	+1SD	36.50-49.30
78	GLU	NDOX 1416	116	26-06-2021	13:35:58	+1SD	92.00-128.00
79	TBIL	NDOX 1416	1.98	26-06-2021	12:45:14	-1SD	1.66-2.58
80	ALP	NDOX 1416	178.64	26-06-2021	12:42:31	-1SD	152.00-206.00
81	CHOL	NDOX 1416	155.56	26-06-2021	12:18:40	-1SD	136.00-176.00
82	TG	NDOX 1416	94.85	26-06-2021	12:18:22	+1SD	78.90-108.70
83	LDH	NDOX 1416	229.99	26-06-2021	12:16:00	+2SD	181.00-245.00
84	DBIL	1DOX_1416	1.56	26-06-2021	12:14:17	+2SD	1.01-1.57

arkray healthcare PVt. Ltd.

Document Control #PT/F/041, Ver.07, Dt. 26.06.2019

TECHNICAL SERVICE REPORT

Report No.: 9099 Service Notification Number:				
Customer Name: G.ONE Pathology	tory.	Custo	omer No. / ID	
Address: Siphgad Road, Punce City: Punce State: Maharaski Contact Person: Tov. Rahw Tel./Fax. No.: Email ID Call Log Date: Call Attend Date: 25/1 Time: Time: 10.00 Sr. No.: 500 Site Voltage: 230V Ground Voltage: OK/No Problem reported:	BREA CHAR P.M.VI APPLI COUR WORK CAR	CATION		
Action taken: () rachine instal	lation & i	installing Po		
(ii) Pone mechanic		action U		
(ii) check earth		- 11 On kom	a La 1	
Done program	town	all Param		Calibratione
Details of tests performed (Attach Printout of Resu		J (V) Pas,	Cown 2	COADIA 1070
	RESULT OBTAIL	INED REMARKS		
Glu	98 mg/18	2 1 Vtg of earthing or		
1.00 A	100	70 -	<u> </u>	
Creat	1.72 mg	3 (1) train	ing of	
SGPT	46.5 ml	N	V ·	
		- (11) Cov	no Resu	
Following parts have been replaced / To re	placed	Name of persons trained during the call (installation Application)		
Part No. Description Qty Ra	ites (Ex taxes)	Name		Signature
		1) Labor		
		1 Rahul	· 42	alufe
		@ Monika	mam	MEKEE)
	Customer's remar	ks:		
Used from ☐ Company's Stock ☐ Customer's S	Stock			
Engineer's Remarks:				The state of the s
machine install successfully.				CES + G.7
Engineer's name: Vijay Pah'l		Customer's Name	ghadake	BUNE E
Signature: Salu		Stamp and Signatu	ıre:	(8) 10°

Please ensure filling and sending of Installation check list along with report at the time of Installation.

Single instrument report entry only and for single day report

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Sachin 394 230, (Surat). India, Telephone: 0261-6167777 Technical Support Cell (TSC) Telephone: 0261-6167711

Fax: 0261-6167778, URL http://www.arkray.co.in

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Certificate Of Warranty

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- 1. ARKRAY Warrants the following instrument sold by them against any defect in workmanship and materials for either 12 months after installation or 13 months after invoice whichever is earlier. ARKRAY Shall repair or replace any defective item free of charge during the warranty period, provided these items are used as prescribed by the operating instruction given in the Operator's Manual.
- 2. The warranty specifically excludes expandable and consumables like software, lamp, tubings, glassware, printer, fuse, etc. This warranty also excludes any accessories supplied with the instrument like CVT, personal computer, stabiliser, Pipettes, external printer, etc.,
- 3. ARKRAY Will provide services as per the following schedule during warranty period:
 - 1. One preventive maintenance service within four months after installation of instrument
 - 2. Unlimited number of Break Down services as and when required (i.e., whenever instrument faces any break down.)
- 4. ARKRAY Shall be absolved of any liability under this warranty under following cases:-
 - 1. If the product is not used in accordance with manufacturer's instruction.
 - 2. If the product is not regularly maintained as per standard instruction given in Operating Manual.
 - 3. If the product is used for purpose other than it is intended.
 - 4. Used with the equipment not approved by the ARKRAY.
 - 5. Warranty is void if the reagents and accessories are not used as per specifications of ARKRAY.
 - 6. If the instrument is repaired, modified, dis-assembled, reinstalled by any person other than ARKRAY approved service engineer.
 - 7. If the instrument is subject to neglect or accident, damaged due to accident, fire lightning, vandalism, water, power fluctuation or any other casualty.
 - 8. If all agreed terms and condition of Purchase contract is not fulfilled in agreed time limit.
- 5. The warranty is limited to repair and replacement of spares (excluding those items mentioned under clause (2) for restoration of satisfactory performance of instruments. It does not cover replacement of instrument once it is installed. The warranty shall not be extended under the circumstances where analyser remains unoperational under any reasons.
- Any dispute is subject to Surat Jurisdiction.

Customer Name	: GONE PATHOLOGY LABORATORY
Address	
	Sinhaad Road, Pune.
Instrument	BU 50619167
Serial Number	BU 50619167
Date of invoice	
Date of installation	28/11/2020
Name of Installing Engineer	Vijax Pagil
Warranty Period shall be conside	red either for 12 months after installation or 13 months after invoice whichever is earlier

For ARKPAY Healthcare Pvt. Ltd.,

Authorised Signatory

Signature of Installing Engineer

Seal & Signature of Customer

NOTE: Send us Installation Report and checklist duly filled in by you, enabling us to honour our warranty commitment successfully.

Thanks