



# Akshat Biomedicals (p) Ltd

Regd. Office: 352, Katewa Nagar, New Sanganer Road, Sodala, Jaipur-302019 • akshatindia@hotmail.com  
B.O.: 95/G1, Devi Nagar, New Sanganer Road, Sodala, Jaipur-302019 • Ph.: +91 141 2297075 | Factory: 121, Solitaire Industrial Park, RIICO, Bagru (Jaipur)

## Installation Certificate For AXIOM-21 Sr. No. 3020ET01360

This is to certify that instrument AXIOM-21 sr. no.:- 3020ET01360 is successfully installed and Commissioned at, JAIPUR and the installation protocol/ checklist have been successfully completed for the above instrument.

Date of Installation : 23/04/2018

AKSHAT BIOMEDICALS (P) LTD, Technical services Department

Name : SAGAR SHARMA

Designation : Service Engineer

Customers Name : RELIABLE DIAGNOSTIC CENTRE

Address : KOTA, RAJASTHAN

Instrument Model : AXIOM-21

Serial no. : 3020ET01360

Date of Installation : 23/04/2018



Initial Inspection of the unit carried out and the details are as follows:

System Condition Report: Found the system to have been delivered in satisfactory condition and no External physical damaged observed on the same, Package was kept in good condition as per the Directional Indicators like not tilt, indicating the system has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

Found all the required accessories as required.

External Requirement for installation:

1. Input voltage of 220v-240v/50Hz or 60 Hz
2. Recommended operating Temperature is 15-30 degree Celsius, with in Relative Humidity 30-85% And Atmospheric pressure 70-106kpa.



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Carried out all the installation procedures as per the installation procedure and checklists.

Carried out all the necessary checks and alignments'.

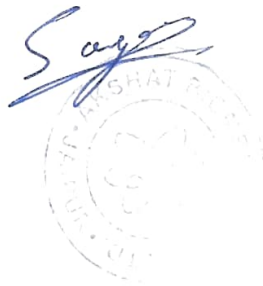
Carried out all the necessary system checks and tests.

Handover the instrument for operators Training And Qualifications

AKSHAT BIOMEDICALS (P) LTD., Technical Services Department

Name : SAGAR SHARMA

Designation : Service Engineer





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## Installation Certificate for AXIOM-21 Sr. No.:- 3020ET01360

This is to certify that the instrument AXIOM-21 Sr. No.:- 3020ET01360 is successfully installed and Commissioned at RELIABLE DIAGNOSTIC CENTRE, KOTA, RAJASTHAN and the Installation Protocol/ checklist has been Successfully completed for the above Instrument.

Date of installation : 23/04/2018

AKSHAT BIOMEDICALS (P) LTD., Technical Services Department

Name : Sagar Sharma

Designation : Service Engineer



Installation Qualification for AXIOM-21 Sr. No.:- 3020ET01360

Customer Name : RELIABLE DIAGNOSTIC CENTRE  
Address : KOTA, RAJASTHAN

Instrument Name : AXIOM-21  
Serial No. : 3020ET01360

**Initial Inspection of the unit carried out and the details are as follows**

**System Condition Report :** Found the system to have been delivered in satisfactory condition and no External physical damaged observed on the same, Package was kept in good condition as per the Directional Indicators like not tilt , indicating the system has not been subjected to mechanical shocks or stored in any manner , so as to cause any damage to the same.

Found all the accessories as required.



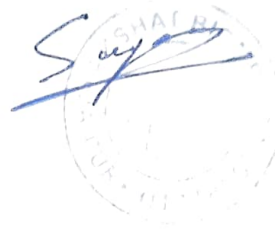
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1. Verified all the Mechanical Movements : Done
2. Verified Hydraulics : Done
3. Verified Electrical Systems : Done
4. Verified the all reagents System : Done

## AKSHAT BIOMEDICALS (P) LTD. , Technical Service Department

Name : Sagar Sharma  
Designation : Service Engineer  
Date : 23/04/2018



### Instrument Setup

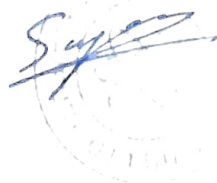
1. Assembled the instrument accessories.
  2. Removed the shipping Clamps.
  3. Connected the REAGENTS.
  4. Connected the REGENT TUBING.
  5. Connected the power cord and connection cord.
6. Initialise the machine and follow the installation procedure.

### Operational Instection

1. Checked and found mechanical movements OK.
2. Checked and found Hydraulics OK.
3. Checked and found electrical OK.
4. Checked with Control and Samples, Results Are found OK.

## AKSHAT BIOMEDICALS (P) LTD. , Technical Service Department

Name : Sagar Sharma  
Designation : Service Engineer





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Checked and found all controls to be within the acceptable SD.

## System Certification:

Study data has determined that the system described in this document either meets the necessary criteria outlined in this performance qualification protocol, or exceptional conditions have been identified documentation include.

The system is ready for specific usage.

## Protocol Performed By:

Name : Sagar Sharma

Designation : Service Engineer

## PERFORMANCE QUALIFICATON DONE BY

Name : LOKESH SHARMA

Designation : DIRECTOR

## Operational Qualification:

### System Certification:

Study data has determined that the system described in this document either meets all criteria outlined in this Operational Protocol, or exceptional have been identified and documentation include.

Exceptional Conditions, if any have been addressed.

The System is ready for specific usage.

Protocol Performed By : Name : Sagar Sharma  
: Designation: Service Engineer





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## CALIBRATION RECORD

INSTEUMENT MODEL	AXIOM-21	Sr. No.	3020ET01360
TYPE	AXIOM-21 AUTOMATED HEMATOLOGY ANALYZER	INSTALLED AT	RELIABLE DIAGNOSTIC CENTRE
CALIBRATOR USED	HQ - CAL	Calibrator Lot No	KK102
		Calibrator Expiry	05/09/2021

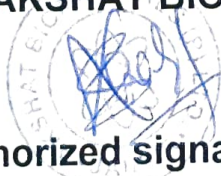
### Enclosed:-

1. Assay Sheet of HQ-Cal AXIOM Hematology (Lot- KK102, Expiry- 2021-09-05)

Calibration done - 05/07/2021

Next Calibration Due - 04/07/2022

FOR AKSHAT BIOMEDICALS (P) LTD.

  
( Authorized signatory )



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## Calibrator

Lot No. KK102

EXPIRY

05-09-2021

Parameter	WBC	RBC	HCb	MCV	PLT
Target	9.23	4.57	13.6	87.5	272
1	9.02	4.61	13.7	87.8	265
v2	9.14	4.65	14	87.6	266
v3	9.09	4.58	13.8	87.6	275
v4	8.93	4.68	13.9	87.9	266
v5	9.14	4.54	13.8	87.8	271
v6	9.23	4.63	13.9	87.6	264
v7	9.12	4.66	13.9	87.5	273
v8	9.18	4.70	14.1	87.7	274
v9	9.19	4.56	13.8	88.0	264
v10	9.03	4.57	13.7	87.3	267
v11	9.12	4.54	13.8	87.5	269
Mean	9.11	4.61	13.84	87.66	269.25
CV(%)	0.95	1.11	0.8	0.2	1.8
Calibration Factor	99.00	101	101	100	98
Calibration Factor	100.00	100.00	100.00	100.00	100.00



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## External Requirement for Installation:

3. Input voltage of 220V-240V/50Hz or 60Hz.
4. Recommended operating Temperature is 15-30 degree Celsius with in relative Humidity 30-85% and Atmospheric pressure 70-106kpa.

Installation Qualification for AXIOM-21 Sr. No. :- 3020ET01360

Carried out all the installation procedures as per the installation procedure and checklists.

Carried out all the necessary checks and alignments.

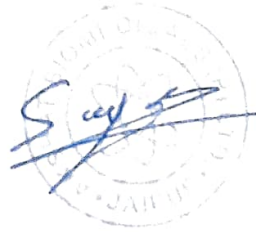
Carried out all the necessary system checks and Qualifications.

Handover the instrument for Operation Training and Qualification.

**AKSHAT BIOMEDICALS (P) LTD. , Technical Service Departments**

Name : Sagar Sharma

Designation : Service Engineer







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Sanganeer Industrial Park, RIIICO, Bagru (Jaipur)

## INSTALLATION QUALIFICATION (IQ)

**INSTRUMENT NAME :-** AXIOM-21 AUTOMATED HEMATOLOGY ANALYZER

**Model No. :-** AXIOM-21

**SR. NO :-** 3020ET01360

**Prepared By :-** Sagar Sharma

**Date:-** 23/04/2018

**Customer Name** : RELIABLE DIAGNOSTIC CENTRE

**Address** : KOTA , RAJASTHAN

**Instrument Model** : AXIOM-21

**Serial No.** : 3020ET01360

**Date Of Installation** : 23/04/2018

The instrument was installed and was found to be working satisfactory. Preliminary Customer Training was provided and standardization of the parameters were done. The results were found to be within the expected range and system found to be working satisfactorily.

**AkshatBiomedicals (P) Ltd**

**Technical Services Department**

**Name** : Sagar Sharma **Customer Name:** RELIABLE DIAGNOSTIC CENTRE

**Designation** : Service Engineer

**Contact person:** VIJAY NAGAR

**Signature** :  **Designation** : Lab Technician





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## OPERATIONAL QUALIFICATION (OQ)

**INSTRUMENT NAME** :- AXIOM-21 AUTOMATED HEMATOLOGY ANALYZER

Model No. :- AXIOM-21

SR. NO :- 3020ET01360

Prepared By :- Sagar Sharma Date:- 23/04/2018

### System Certification:

Study data has determined that the system described in this documents either meets all criteria outlined in this operational protocol, or exceptional conditions have been identified and documentation included.

Exceptional conditions, if any have been addressed.

The System is ready for specific usage.

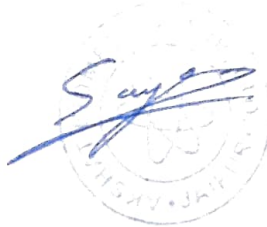
Protocol Performance : SagarShrama

Designation : Service Engineer

Customer Authorization : RELIABLE DIAGNOSTIC CENTRE KOTA, RAJASTHAN

Name: Sagar Sharma

Designation: Service Engineer



Company Representative Name And Sign

Customer Name And Sign

Date:- 23/04/2018 Date:-23/04/2018

Operations Qualification for AXIOM-21 Sr. No.:- 3020ET01360



## Performance Qualification for AXIOM-21 Sr. No. :- 3020ET01360

### Calibration Parameters

Checked and found all the control [parameters to be within the acceptable CV limits and in range.

Checked and found all the control to be within the acceptable SD.

### System Certification:

Study data determined that the system described in this documents either meets the necessary criteria outlined in this performance Qualification Protocol, or exceptional conditions have been identified and documents included.

The system is ready for specific usage.

### Protocol Performance By :

Name : SAGAR SHARMA

Designation : SERVICE ENGINEER



### PERFORMANCE QUALIFICATION DONE BY

Name : LOKESH SHARMA

Designation : DIRECTOR



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## PROCEDURAL QUALIFICATION (PQ)

<b>INSTRUMENT NAME :-</b>	AXIOM-21 FULLY AUTOMATED HEMATOLOGY ANALYZER
<b>Model No. :-</b>	AXIOM-21
<b>SR. NO :-</b>	3020ET01360
<b>Prepared By :- Sagar Sharma Date:- 23/04/2018</b>	

**Installation Qualification for AXIOM-21 Sr. No. :- 3020ET01360**

**Customer Name : RELIABLE DIAGNOSTIC CENTRE**  
**Address : KOTA, RAJASTHAN**  
**Instrument Model : AXIOM-21**  
**Serial No. : 3020ET01360**  
**Date of installation : 23/04/2018**

The instrument was installed and was found to be working satisfactory. Preliminary Customer Training was provided and standardization of the parameters were done. The results were found to be within the expected range and system found to be working satisfactorily.

**AKSHAT BIOMEDICALS (P) LTD. , Technical Services Departments**

**Name : Sagar Sharma Customer Name: RELIABLE DIAGNOSTIC CENTRE**

**Designation : Service Engineer Contact Person: VIJAY NAGAR**

**Signature :  Designation : Lab Technician**



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**Test Name:** Precision Testing

**Purpose:** To comply with specification and find deviation If any, if required to apply correction.

**Method:** To run normal sample 11 times consecutively and identify SD, CV and establish that it lies as per the manufacture's specs. To omit first run and to consider rest 10 runs and calculate SD & CV.

Sample No.	WBC	RBC	HGB	HCT	MCV	PLT
t-1	7.70	4.80	13.9	46.6	95.4	139
t-2	7.84	4.50	13.7	48.5	95.6	140
t-3	7.65	4.70	14.7	47.0	95.4	136
t-4	8.14	3.90	14.9	47.0	95.5	147
t-5	7.45	4.87	12.5	46.6	95.7	133
t-6	8.15	4.83	14.7	45.9	95.2	140
t-7	7.95	4.87	14.9	46.5	95.5	133
t-8	7.91	5.21	15.5	49.7	95.5	140
t-9	7.65	4.90	14.7	46.7	95.4	143
t-10	8.21	4.91	15.0	46.8	95.5	134
Mean	7.86	4.74	14.45	47.16	95.47	138.5
SD	0.6453	0.2327	0.2712	1.2670	1.2670	0.1337
CV%	1.538	2.451	1.823	2.686	0.140	3.286

**Authorization:**

**Name** : SAGAR SHARMA  
**Designation** : SERVICE ENGINEER  
**Date** : 23-04-2018







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**NAME OF THE INSTITUTION:- RELIABLE DIAGNOSTIC CENTRE**

**CARRYOVER WORKSHEET.**

Instrument Id: AXIOM-21, SN = 3020ET01360

Name of technical person: VIJAY NAGAR

Supervisor review: VIJAY NAGAR

Date performed : 05/07/2021

Carryover calculation:

$$\text{Carryover \%} = (L1-L3) / (H3-L3) * 100$$

Interpretation of results. :

1) If (L1-L3) is equal to a Negative number or zero Then stop as there is no Evidence of carryover.

2) The percentage Carryover effect should be Less than the imprecision Of the assay listed by Manufacture.

Instrument	Analytes				
	WBC	RBC	Plt	Hb	Hct
H1	14.5	4.62	244	11.6	35.5
H2	14.7	4.73	226	11.8	36.1
H3	14.7	4.75	242	11.8	36.3
L1	0	0	0	0	0
L2	0	0	0	0	0
L3	0	0	0	0	0
% age Carryover	0.00	0.00	0.00	0.00	0.00