

Byovet Medical & Technologies Pvt. Ltd.,

Redefining Veterinary Diagnostics

Record of Analyzer Installation, Check, Accept and training

User Name iQURE BIOMEDICAL SYSTEMS PVT LTD

Address 13/1, 2ND FLOOR, 1ST MAIN ROAD, KHM BLOCK, GANGANAGAR, RT NAGAR, BANGALORE-560032

Product Name HAEMATOLOGY ANALYSER

Model SMART DX

Serial Number 48600003

Qty 1

Date of Installation 24.01.2021

Warranty Period 24.01.2021 TO 23.01.2022

Check and Accept PRODUCT ACCESSORIES, QUALIFICATION MATERIALS, MANUALS, CERTIFICATES AND OTHERS ARE COMPLETE.

Training **TRAINER:** JAGADISH **DATE OF TRAINING:** 25.01.2021

Customer Opinion INSTALLATION DONE SUCCESSFULLY

Date 25.01.2021

Signature of Check and accept

Warranty Notes:

1. This record also used as warranty certificate. Please ke
2. This record is in duplicate. The first one maintained by the installation engineer, and the second one is maintained by the customer.
3. Please refer to manuals about warranty service.



3-9-534/2/A, Srirama Hills, Mansurabad, Hyderabad-500068.
Website: www.byovet.com E-mail: info@byovet.com

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SMART DX HAEMATOLOGY SYSTEM OPERATIONAL QUALIFICATION

Customer Name : **IQURE BIOMEDICAL SYSTEMS PVT LTD**
13/1, 2ND FLOOR, 1ST MAIN ROAD, KHM BLOCK, GANGANAGAR,
RT NAGAR, BANGALORE, KARNATAKA-560032

THE FOLLOWING CHECKS AND SETUPS ARE CARRIED OUT FOR **BYOVET SMART DX HEMATOLOGY ANALYZER** FOR OPERATIONAL QUALIFICATION.

- | | |
|--|--------------------------|
| 1. DEFINE SETUP AS PER LABORATORY REQUIREMENTS | <input type="checkbox"/> |
| • Q.C | |
| • SAMPLE | |
| • SYSTEM OPTIONS | |
| • PRINTER AND MEMORY | |
| 2. PERFORM DIAGNOSTIC (SLOW SPEED AND HIGH SPEED) | <input type="checkbox"/> |
| CHECK FOR SHEAR VALVE | |
| 3. PERFORM DIAGNOSTIC CHECK FOR TUBINGS AND VALVE | <input type="checkbox"/> |
| 4. PERFORM BACKGROUND TEST FOR DILUENT AND LYSE | <input type="checkbox"/> |
| 5. PERFORM 2 POINT PRIMING SOLUTION | <input type="checkbox"/> |
| 6. PERFORM CONDITIONING BY USING FRESH WHOLE BLOOD | <input type="checkbox"/> |
| 7. PERFORM SAMPLE ASPIRATION IN BACKGROUND CHECK | <input type="checkbox"/> |
| 8. PERFORM FULL 2 POINT CALIBRATION | <input type="checkbox"/> |
| (CALIBRATION PERFORMED BY THE INSTRUMENT ITSELF FOR REGULAR USAGE) | |
| 9. HANDING INSTRUMENT AND USER TRAINING | <input type="checkbox"/> |
| 10. CHECKED FOR TRUE VALUE CHECK (QC LOW) | <input type="checkbox"/> |
| (REFER PERFORMANCE QUALIFICATION FOR DETAILS) | |
| 11. THE SYSTEM IS READY FOR SPECIFIC USAGE. | <input type="checkbox"/> |

Company Name	BYOVET MEDICAL TECHNOLOGIES PVT LTD	Page 1 of 1
Equipment Name	SMART DX	Serial No: 48600003
OPERATIONAL QUALIFICATION (OQ)		



Byovet Medical & Technologies Pvt. Ltd.,

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SMART DX HAEMATOLOGY SYSTEM PERFORMANCE QUALIFICATION

Following procedure was carried out as part of the performance qualification:

1. **Calibration of Assay**
 - a. Analytes calibrated and checked for **WBC, RBC, HGB, MCV, PLT, MPV, RDW-CV, RDW-SD**
 - b. Checked and found all calibration are valid curve.
2. **Internal Quality Control Performance**
 - a. RANDOX Hematology Control
 - b. Checked and found controls are within the acceptable limits.
3. **Precision Study**
 - a. Run precision for **WBC, RBC, HGB, MCV, PLT, MPV, RDW-CV, RDW-SD**
 - b. Assays of 10 replicates was carried out, CV% obtained are within the acceptable limit for the assay
 - c. See print outs attached

Company Name	BYOVET MEDICAL TECHNOLOGIES PVT LTD	Page 1 of 3
Equipment Name	SMART DX PERFORMANCE QUALIFICATION (PQ)	Serial No: 48600003



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Website: www.byovet.com

E-mail: info@byovet.com

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Export

Save

Ref. Value	1	2	3	4	5	6	7	8	9	10	Mean	SD	New Cal(%)	Cal%
	8.4	8.3	8.3	8.3	8.4	8.3	8.0	8.7	8.3	8.4	8.3	0.1567	****	100.0
	4.30	4.20	4.25	4.29	4.22	4.24	4.16	4.23	4.19	4.26	4.23	0.0437	****	85.0
	14.1	14.0	14.4	14.3	14.1	14.0	13.9	14.4	14.0	14.1	14.1	0.1766	****	80.0
	90.7	90.9	91.2	91.2	91.0	91.1	90.6	90.7	90.8	90.8	90.9	0.2160	****	100.0
	270	230	230	236	260	234	220	213	221	208	232	19.6004	****	85.0

154312

lot

alibrator

PLT

MCV

HGB

RBC

WBC

Save

Export

Ref. Value	1	2	3	4	5	6	7	8	9	10	Mean	SD	New Cal(%)	Cal%
	90.7	90.9	91.2	91.2	91.0	91.1	90.6	90.7	90.8	90.8	90.9	0.2160	0.2160	100.0
	270	230	230	236	260	234	220	213	221	208	232	19.6004	19.6004	85.0
	8.0	8.1	8.2	8.1	8.3	8.1	8.0	8.2	8.2	8.0	8.1	0.1032	0.1032	100.0
	10.1	9.6	9.5	10.0	9.5	9.5	9.6	9.6	10.1	9.0	9.7	0.3374	0.3374	100.0
	37.9	35.2	35.2	40.6	37.9	40.6	35.2	40.6	46.0	35.2	38.4	3.5547	3.5547	100.0

Calibrator

Lot

154312

RDW_SD

RDW_CV

MPV

PLT

MCV