

Byovet Medical & Technologies Pvt. Ltd.,

Redefining Veterinary Diagnostics

Record of Analyzer Insatallation, 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

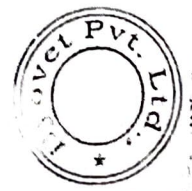
Customer Opinion INSTALLATION DONE SUCCESSFULLY

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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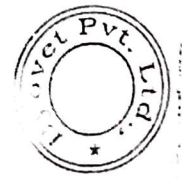
SMART DX HAEMATOLOGY SYSTEM OPERATIONAL QUALIFICATION

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**
 - Q.C
 - SAMPLE
 - SYSTEM OPTIONS
 - PRINTER AND MEMORY
- 2. PERFORM DIAGNOSTIC (SLOW SPEED AND HIGH SPEED) CHECK FOR SHEAR VALVE**
- 3. PERFORM DIAGNOSTIC CHECK FOR TUBINGS AND VALVE**
- 4. PERFORM BACKGROUND TEST FOR DILUENT AND LYSE**
- 5. PERFORM 2 POINT PRIMING SOLUTION**
- 6. PERFORM CONDITIONING BY USING FRESH WHOLE BLOOD**
- 7. PERFORM SAMPLE ASPIRATION IN BACKGROUND CHECK**
- 8. PERFORM FULL 2 POINT CALIBRATION**
(CALIBRATION PERFORMED BY THE INSTRUMENT ITSELF FOR REGULAR USAGE)
- 9. HANDING INSTRUMENT AND USER TRAINING**
- 10. CHECKED FOR TRUE VALUE CHECK (QC LOW)**
(REFER PERFORMANCE QUALIFICATION FOR DETAILS)
- 11. THE SYSTEM IS READY FOR SPECIFIC USAGE.**

Company Name	BYOVET MEDICAL TECHNOLOGIES PVT LTD	Page 2 of 3
Equipment Name	SMART DX	Serial No: 48600003
Operational Qualification		



SMART DX Haematology System Performance Qualification

Following procedure was carried out as part of the performance Qualification:-

1. Calibration of Assay

Analytes Calibrated and checked for **WBC, RBC, HGB, MCV, PLT, MPV, RDW-CV, RDW-SD**

Checked and found all calibration are valid Curve.

2. Internal Quality Control Performance.

RANDOX Haematology Control

Checked and found Controls are within the acceptable limits.

3. Precision Study

Run Precision for **WBC, RBC, HGB, MCV, PLT, MPV, RDW-CV, RDW-SD**

Assays of 10 replicates was carried out, CV% obtained

Are within the acceptable limit for the assay

See print outs attached.

4. Carryover Check

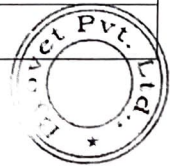
Performed the Carryover study in **SMART DX** as per BCI protocols

See printout attached

4. BYOVET Methodology & Range

See print outs attached

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



Calibrator

Lot

154312

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

Save

Export

Operator: JAGADISH

Next ID: 431797

Mode: whole blood

2021-01-25 13:06

Calibrator

Lot:

154312

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

Save

Export

operator: JAGADISH

Next ID: 431797

Mode: whole blood

2021-01-25 13:07