

## 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<br>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

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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