

XQ-Series Commissioning Report

Customer: SEABIRD MEDICARE

Date: 27-Jun-2024

Model No: XQ-320

Serial No: 13073

1 BACKGROUND VERIFICATION

Background check was done by executing the Auto Rinsing. The results are as below :

Parameters	Results	Acceptable Range	Status
WBC \	0.0	≤ 0.3 X 10*3/uL	PASS
RBC	0	. ≤ 0.02 X 10*6/uL	PASS
HGB	0.0	≤ 0.1g/dL	PASS
PLT	0	≤ 10 X 10*3/uL	PASS

NOTE: Refer to the attached Background Check Screenshot.

2 CLOG LEVEL ADJUSTMENT FOR WBC AND RBC

Clog level results are as below:

Parameters	Results	Clog Value	Status
WBC Clog	100	100 ± 1.0	PASS
RBC Clog	100	100 ± 1.0	PASS

NOTE: Refer to the attached Clog Adjustments Screenshot.

3 HGB BLANK AND BLOOD ASPIRATION SENSOR BLANK ADJUSTMENTS

Blank results are as below:

Parameters	Results	Assay Value	Status
HGB Blank	5022	5000 ± 200	PASS
Aspiration Sensor Blank	5063	5000 ± 200	PASS

NOTE: Refer to the attached Blank Adjustments Screenshot.

4 BLOOD ASPIRATION SENSOR SPAN ADJUSTMENT

Parameter	Results	Assay Value	Status
Aspiration sensor	12898	13000 ± 500	PASS

ed Blood Aspiration Sensor Span Adjustment Screenshot.



5 SENSITIVITY ADJUSTMENT FOR WBC, RBC, PLT, AND HGB DETECTION

Material Used : El

EIGHTCHECK (Normal)

Lot No. : Expiry date : 41110822 27-Jul-2024

-5.1 WBC Sensitivity Adjustment

Assay Mean (W-SMV), Target (fL) Passing Criteria for Range (fL) Passing Criteria for W-SMV (fL) Passing Criteria for Ratio

60.5			
Less tha	n or equal	6.1	
57.5	to	63.5	
50	to +	150	

Range (fL)	W-SMV (fL)	Target (fL)	WBC Gain	Ratio
0.6	60.9	60.5	105	99.3
PASS	PASS	Assay Mean	For record purpose	PASS

NOTE: Refer to the attached Sensitivity Adjustment Screenshot.

5.2 RBC Sensitivity Adjustment

Assay Mean (MCV), Target (fL) Passing Criteria for Range (fL) Passing Criteria for MCV (fL) Passing Criteria for Ratio

76.2		
Less tha	n or equal	2.6
74.9	to	77.5
50	to .	150

Range (fL)	MCV (fL)	Target (fL)	RBC Gain -	Ratio
0.3	76.2	76.2	129	98.6
PASS	PASS	Assay Mean	For record purpose	PASS

NOTE: Refer to the attached Sensitivity Adjustment Screenshot.

5.3 PLT Sensitivity Adjustment

Assay Mean (MPV), Target (fL) Passing Oriteria for Range (fL) Passing Criteria for MPV (fL) Passing Criteria for Ratio

9.2			
Less tha	an or equal	0.9	
8.7	to	9.7	
50	to	150	

Range (fL)	MPV (fL)	Target (fL)	PLT Gain	Ratio
0.3	10.2	9.2	124	90.2
PASS	FAIL	Assay Mean	For record purpose	PASS

NOTE: Refer to the attached Sensitivity Adjustment Screenshot.

5.4 HGB Sensitivity Adjustment

Assay Mean (HGB), Target (g/dL) Passing Criteria for Range (g/dL) Passing Criteria for HGB (g/dL) Passing Criteria for Ratio

12.6			
Less tha	n or equal	0.5	
12.0	to	13.2	_
50	to	150	

Range (g/dL)	HGB (g/dL)	Target (g/dL)	Span Gain	Ratio
0.1	12.3	12.6	141	102.4
PASS	PASS	Assay Mean	For record purpose	PASS

NOTE: Refer to the attached Sensitivity Adjustment Screenshot.



6 WHOLE BLOOD MODE CALIBRATION Calibrator Used: SCS-1000

SCS-1000 41630525 Lot: Expiry: 14-Jul-2024

Refer to the attached Calibrator Calibration History Screenshot.

7 PRE-DILUTION MODE CALIBRATION
Calibrator Used: SCS-1000
Lot: 41630525 Expiry: 14-Jul-2024

7.1 Pre-Dilution Mode Calibration

No.	WBC	RBC	HGB	HCT	PLT
Run 2	7.09	3.90	11.9	31.2	187
Run 3	7.00	3.91	12.4	31.1	191
Run 4	7.16	3.98	12.2	31.8	192
Run 5	7.29	4.10	14.0	32.6	192
Run 6	6.85	4.01	12.6	32.0	191
Average (Run: 2 - 6)	7.08	3.98	12.6	31.7	190.6
Target	7.33	4.40	12.7	35.1	229
Current Comp%	100.0	100.0	100.0	100.0	100.0
New Comp %	103.6	110.7	100.6	110.7	120.1

NOTE: Refer to the attached Pre-Dilution Mode Calibration (Run: 2 - 6) Screenshot.

7.2 Post Pre-Dilution Mode Calibration Check

No.	WBC	RBC	1100	1 //	
Run 2			HGB	HCT	PLT
	7.29	4.51	12.8	36.3	228
Run 3	7.43	4.49	12.8	36.2	220
Run 4	7.36	4.47	12.7	36.1	230
Run 5	7.47	4.48	12.8	36.1	225
E Run 6	7.35	4.52	12.9	36.4	230
Average (Run: 2 - 6)	7.38	4.494	12.8	36.2	227
Target	7.33	4.40	12.7	35.1	
Delta Percent %	0.68	2.04	0.79	3.07	229
Limit %	3.58	2.79	1.39		1.05
Status	PASS	PASS	PASS	4.44 DASS	7.00

NOTE: 1. Refer to the attached Post Pre-Dilution Mode Calibration (Run: 2 - 6) Screenshot.

2. Delta Percent % indicates difference between Average (Run: 2 - 6) and Target



Expiry date:

27-Jul-2024

Eightcheck-3WP (Low) results :

		Eightcheck-3WP Assay Value				
Parameter	Result	Target	Limit	Min	Max	Status
WBC	3.5	3.3	0.4	2.9	3.7	PASS
RBC	2.7	2.7	0.2	2.5	2.9	PASS
HGB	6.2	6.4	0.3	6.1	6.7	PASS
HCT	18.4	18.1	1.5	16.6	19.6	PASS
MCV	67.2	67.5	4.1	63.4	71.6	PASS
MCH	22.6	23.9	1.7	22.2	25.6	PASS
MCHC	33.7	35.4	2.8	32.6	38.2	PASS
PLT	66.0	74.0	22.0	52.0	96.0	PASS

NOTE: Refer to the attached QC results Screenshot.

Eightcheck-3WP (Normal) results:

		Eightcheck-3WP Assay Value				1
Parameter	Result	Target	Limit	Min	Max	Status
WBC	7.5	7.2	0.5	6.7	7.7	PASS
RBC	4.7	4.6	0.2	4.4	4.8	PASS
HGB	12.2	12.6	0.4	12.2	13.0	PASS
HCT	35.9	35.3	2.6	32.7	37.9	PASS
MCV	76.1	76.2	3.8	72.4	80.0	PASS
. MCH	25.8	27.2	1.6	25.6	28.8	PASS
MCHC	34.0	35.7	2.5	33.2	38.2	PASS
PLT ·	189.0	217.0	33.0	184.0	250.0	PASS

NOTE: Refer to the attached QC results Screenshot.

'Eightcheck-3WP (High) results :

		Eigh	Eightcheck-3WP Assay Value				
Parameter	Result	Target	Limit	Min	Max	Status	
WBC	19.3	18.6	1.3	17.3	19.9	PASS	
RBC	5.5	5.6	0.3	5.3	5.9	PASS	
HGB	16.3	16.8	0.5	16.3	17.3	PASS	
HCT	46.1	46.8	3.5	43.3	50.3	PASS	
MCV	84.1	84.0	4.2	79.8	88.2	PASS	
MCH	29.7	30.2	1.8	28.4	32.0	PASS	
MCHC	35.4	35.9	2.5	33.4	38.4	PASS	
PLT	465.0	520.0	78.0	442.0	598.0	PASS	

NOTE: Refer to the attached QC results Screenshot.



9 CERTIFICATION

I/We certify that XQ-320 Serial No: 13073 has been successfully commissioned in accordance to the manufacturer's recommendations.

Report and Commissioning Performed By :

Signature (Engineer 1)

Name: Moudul

Date: 27 (6/24

Signature (Engineer 2)

Name: Vishou. Mk

Date: 27/6/24

Report Reviewed and Accepted By:

Signature (Customer)

Name: x 5 HANYA JIBU

Date: 27/6/24

Company Stamp : (Vendor) Company Stamp : (Customer)