WELDON BIOTECH INDIA PVT. LTD.

Inspiration for Life Sciences

INSTALLATION REPORT

Customer Name: PATHOCON DIAGNOSTICS
Address: #10/A-1, 1st 'R' Block, Rajajinagar, Near Mahalakshmi Metro Station, Bengaluru
Pin code: 560010
Report No
Date: 23/09/2024
Time: 04:00 pm
State: Karnataka

Contact Person: Mr. Srinivas
Contact Number: +91 9845605376
Designation
Department: Lab.

Email ID: Info.pathocon@gmail.com
Instrument Supplied from: Anjan Distributors, Blr

Call Type: ☐ Installation ☑ Application training	Instrument Model: Welcoust 3t Serial Number: 230396BCC0203
Installation date: 23/Sep/2024 Warranty period: 2 Year's.	Warranty Start date: 23/Sep/2024 Warranty End date: 22/Sep/2026
Extra Terms	→ Distributor placed the Instrument under "RSC"
Customer Remarks	
Engineer Remarks	↳ Instrument Successfully Installed & User training given to End User. ↳ Run the QC sample. Instrument working fine.
Customer Signature & Seal: 23/09/24 PATHOCON DIAGNOSTICS # 10/A-1, 1st 'R' Block, Rajajinagar BENGALURU-560 010	Engineer Name: P. KARUPPASAMY Contact number: +91 8122456762 Sign: P. Karuppasamy 23/Sep/2024

Corp.Office: 37-E, First Floor, Patparganj, Opp. Usha Enclave, Mayur Vihar, Phase-I, Delhi-110091 (INDIA)
Ph.: +91-11-22790839, 22794809, Fax: +91-11-22794807, Helpline (24x7): 8800499300210
Email: info@weldonbiotech.com, Website: www.weldonbiotech.com
GSTIN: 07AACCW5207G1ZJ, D.L. No.: 30/6/06, 20B & 21B, ISO: 9001:2015
Manufacturing Facility: Plot No.31, Sector-2, I.I.E., SIDCUL, Haridwar (Uttrakhand), Pin: 249403
Ph.: 01334-239441, 42, Helpline (24x7): 8006223479, Email: mfg@weldonbiotech.com
GSTIN: 05AACCW5207G1ZH

Installation Qualification for Welcount 3+

Customer Name : **PATHOCON DIAGNOSTICS**

Address : At Nanjappa's, # 10/A-1, 1st 'R' Block, Rajajinagar,
Near Mahalakshmi Metro Station, Bengaluru - 560010

Instrument Name : **Welcount 3+**

Serial Number : **2303960BCC0203**

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. The Tilt-indicator and the Shock-indicators on the Packaging were found to be in Good Condition, indicating the System has nót been subjected to mechanical shocks or stored in any manner, to cause any damage to the same.

Found all the required accessories as required.

Installation Procedure & Checklist Attached for records.

External Requirements for Installation:

1. Input voltage of 220V-240V / 50Hz or 60Hz.
2. Recommended Operating Temperature is 15-30 °C, with Relative Humidity 30-85% and Atmospheric Pressure 70-106 kPa.

WELDON, Technical Service Department

U. Mur

Name : Balamuralikanth. U

Designation : Manager – Product Specialist

Date : 04/11/2024

Installation Certificate for Welcount 3+

This is to certify that the **Welcount 3+** Instrument Serial No.**2303960BCC0203** is successfully Installed and Commissioned at WELDON, Chennai and the Installation Protocol / checklist has been successfully completed for the above instrument.

WELDON, Technical Service Department

Name : Balamuralikanth. U

Designation : Manager - Product Specialist

Date : 04/11/2024

Installation Qualifications for Welcount 3+

Carried out all the Installation Procedures as per the Installation Procedure & Checklists.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Checked the counts by running the samples and found OK.

Checked sample mixing alignment and aspiration found OK.

Handed over the Instrument for Operators Training & Qualifications

For WELDON, Technical Service Department

Name: Balamuralikanth. U

Designation: Manager - Product Specialist

Date: 04/11/2024

Installation Report for Welcount 3+

Customer Name : PATHOCON DIAGNOSTICS

Department : Laboratory

Contact Person : DR. G.N. KESHAVA MURTHY

Instrument Model : **Welcount 3+**

Serial Number : **2303960BCC0203**

Date of Installation : **04/11/2024**

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

WELDON, Technical Service Department:

Name : Balamuralikanth. U

Designation : Manager Product Specialist

Signature :

Date: 04/11/2024

Customer Details:

Name: PATHOCON DIAGNOSTICS

Contact Person : DR. G.N. KESHAVA MURTHY

Designation : Pathologist & Medical Director

Signature :

Date : 04/11/2024

PATHOCON DIAGNOSTICS
10/A-1, 1st 'R' Block, Rajajinagar
BENGALURU-560 010

Operations Qualifications for Welcount 3+

1. Verified the power connections : Done
2. Verified the barcode reader : Done
3. Verified sample holder rotation : Done
4. Verified the QC and Samples results : Done
5. Verified reagents tubing's and connection : Done

WELDON, Technical Service Department

U. Mur

Name : Balamuralikanth. U

Designation : Manager - Product Specialist

Date : 04/11/2024

Instrument Setup

1. Assembled the instrument accessories.
2. Removed the Robotic Arm Protection sheets.
3. Removed the Opener Unit fixing screws.
4. Connected all the all-position tubing's.
5. Installed the printer & printing test passed.

Operational Inspection

1. Checked samples runs and found OK.

WELDON, Technical Service Department

Name : Balamuralikanth. U

Designation : Manager - Product Specialist

Date : 04/11/2024

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 conditions have been identified and documentation included.

Exceptional conditions, if any, have been addressed.

The System is ready for specific usage.

Protocol Performed By: WELDON BIOTECH INDIA PVT LTD

Name: Balamuralikanth. U

Designation: Manager - Product Specialist

Customer Authorization: PATHOCON DIAGNOSTICS

Name: DR. G.N. KESHAVA MURTHY

Designation: Pathologist & Medical Director

Balamuralikanth. U

Company Representative Name & Sign

Date: 04/11/2024

DR. G.N. KESHAVA MURTHY

Customer Name & Sign

Date: 04/11/2024

PATHOCON DIAGNOSTICS
10/A-1, 1st 'R' Block, Rajajinagar
BENGALURU-560 010

PQ SCHEDULE

The following activities mentioned below must be performed to complete the performance qualification.

Contents:

Evaluation methods for Whole Blood Mode

1. Precision
2. Accuracy
3. Carryover
4. Limit of Blank
5. Limit of Detection and Limit of Quantitation
6. Linearity
7. QC Run

PERFORMANCE QUALIFICATION PROCEDURE

Performance Qualification

1. **Precision Check**

   Procedure for Precision Testing

   Requirements: - 1 Peripheral Blood sample

   1. Set the analyser to WB Mode, analyse Peripheral Blood for 11 consecutive times. The coefficient of variation of counting for each analysing parameter should meet the following condition.
   2. Input the data into the provided table. Calculate Mean, SD and CV%.
   3. Compare these values with the performance criteria for Within-run Precision Table.
   4. Acceptable Variation are as follows:

Precision Check Limit

Parameters	Performance
WBC ($10^3/\mu L$)	3.0 % or less
RBC ($10^6/\mu L$)	1.5 % or less
HGB (g/dL)	1.5 % or less
HCT (%)	1.5 % or less
PLT-I ($10^3/\mu L$)	4.0 % or less

5. Attach the ledger report of the result in the final report.

2. **Accuracy Check**

Procedure for Accuracy Check Testing

Requirements: - CBC-3D, R&D Haematology Control L2

1. Set the analyser to WB Mode, analyze CBC-3D QC for 11 consecutive times.
2. Input the data into the provided table. Calculate Mean and Calculate % difference from Target mentioned in Lot Assay sheet.
3. Acceptable Variation are as follows:

Accuracy Check Limit

Parameters	Performance
WBC-D ($10^3/\mu L$)	± 3.0 % or less
RBC ($10^6/\mu L$)	± 2.0 % or less
HGB (g/dL)	± 2.0 % or less
HCT (%)	± 3.0 % or less
PLT-I ($10^3/\mu L$)	± 5.0 % or less

4. Attach the ledger report of the result in the final report.

3. **Carryover – Analysis Results & Calculation**

Procedure for Carryover Check testing
Requirements: - CBC-3D QC Level 3 & Diluent

1. Analyse CBC-3D QC Level 3 for 3 times consecutively to obtain high concentrations of cells to get 3 values (H1, H2, H3).
2. Then analyse Diluent for 3 times consecutively to obtain low concentrations of cells to get 3 values (L1, L2, L3)
3. Calculate the carryover rate using the following formula.

   % Carryover = [(L1- L3)/ (H3 – L3)] x 100 (%)
4. Compare this value with the performance criteria for carryover rate.
5. Acceptable Variation are as follows:

Carryover check Limit

Parameters	Performance
WBC-D ($10^3/\mu L$)	1.0 % or less
RBC ($10^6/\mu L$)	1.0 % or less
HGB (g/dL)	1.0 % or less
HCT (%)	1.0 % or less
PLT-I ($10^3/\mu L$)	1.0 % or less

6. Attach the ledger report of the result in the final report.

4. **LoB**

1. Cellpack DCL was analyzed 11 times and LoB was Calculated as follows
2. LoB (Limit of Blank) = Average + 1.645 X SDb

5. **LoD & LoQ**

1. Peripheral blood was diluted with CELL PACK DCL to the following Target consistencies

Target Consistencies

Parameter	WBC (x10^3/µL)	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	PLT (x10^3/µL)
Sample 1	0	0	0	0	1
Sample 2	0.01	0.01	0	0.1	1

2. Each diluted Blood was analyzed 10 times consecutively and LoD & LoQ were calculated as follows

LoDi = LoB + 1.645 X SDdi

Where,

SDdi = Standard Deviation in the consecutive measurement of the sample

LoD (Limit of Detection) = Average of LoDi

LoQ (Limit of Quantitation) = Maximum Value of LoDi

6. **Linearity Check**

Patient sample with high counts was analyzed and actual values were plotted against expected values.

7. **QC RUN**

Run **CBC-3D, R&D Hematology** Trilevel QC and check the QC values.

1. **Precision (Whole Blood Mode)**

Peripheral blood is analysed 11x. The first run was excluded and the Average, SD, and CV% were calculated. Judgement is applicable only if the condition is satisfied.

Welcount 3+ SN: 2303960BCC0203					
Run	WBC (x10^3/µL)	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	PLT-I (x10^3/µL)
	Sample 1	Sample 1	Sample 1	Sample 1	Sample 1
~~1~~	~~6.37~~	~~5.13~~	~~14.6~~	~~43.6~~	~~198~~
2	6.37	5.15	14.6	43.6	197
3	6.5	5.03	14.5	42.5	199
4	6.18	5.11	14.5	43.2	193
5	6.35	5.12	14.6	43.3	196
6	6.33	5.12	14.5	43.3	192
7	6.12	5.03	14.5	42.3	197
8	6.23	5.15	14.5	43.4	195
9	6.11	5.10	14.5	42.9	190
10	6.34	5.12	14.5	43.1	185
11	6.49	5.20	14.6	43.7	202
Average	**6.30**	**5.11**	**14.5**	**43.1**	**194.60**
SD	**0.14**	**0.05**	**0.0**	**0.4**	**4.84**
CV%	**2.2**	**1.0**	**0.3**	**1.0**	**2.5**
Criteria	**≤ 3.0 %**	**≤ 1.5 %**	**≤ 1.5 %**	**≤ 1.5 %**	**≤ 4.0 %**
Condition	WBC ≥ 4.00x10^3/µL	RBC ≥ 4.00x10^6/µL	NA	NA	PLT ≥ 100x10^3/µL
Judgement	Pass	Pass	Pass	Pass	Pass

2. Accuracy (Whole Blood Mode)

CBC-3D, R&D Check Level 2 is analyzed 6x. The first run is excluded and the Average, % Difference, and Difference from target values are calculated.

	Welcount 3+ SN: 2303960BCC0203				
R&D QC		Lot No: B1124		Expiry Date	05022025
Run	WBC (x10^3/µL)	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	PLT-I (x10^3/µL)
~~1~~	~~4.83~~	~~4.62~~	~~13.4~~	~~38.2~~	~~252~~
2	4.77	4.6	13.4	38.1	255
3	4.87	4.62	13.4	38.1	250
4	5.04	4.7	13.5	38.7	275
5	5.19	4.66	13.4	38.5	261
6	4.88	4.67	13.4	38.5	252
Average	4.90	4.650	13.420	38.3	258
Target	4.60	4.60	13.6	38.2	260
% Difference	3.1	1.1	-1.3	0.5	-0.5
Difference	0.3	0.05	-0.18	0.2	-1.4
Criteria	± 4 % or ± 0.40 x 10^3/µL	± 2 % or ± 0.03 x 10^6/µL	± 2 % or ± 0.2 g/dL	± 3 % or ± 1.0 HCT	± 5 % or ± 10 x 10^3/µL
Judgement	Pass	Pass	Pass	Pass	Pass

3. Carryover (Whole Blood Mode)

Control blood level-3 is analysed 3x consecutively to obtain high concentrations (H1-H3). Then Diluent is analyzed 3x consecutively to obtain low concentrations (L1-L3). The % Carryover is calculated as follows:

$$\% \text{ Carryover} = \frac{L1 - L3}{H3 - L3} \times 100$$

Welcount 3+ SN: 2303960BCC0203					
Sample 1	**WBC (x10^3/µL)**	**RBC (x10^6/µL)**	**HGB (g/dL)**	**HCT (%)**	**PLT (x10^3/µL)**
H1	13.73	5.38	17.2	46.8	526
H2	14.70	5.24	17.0	45.5	493
H3	14.49	5.35	17.0	46.5	511
L1	0	0	0	0	0
L2	0	0	0	0	0
L3	0	0	0	0	0
% Carryover	0.00	0.00	0.0	0.0	0.0
Criteria	≤ 1.0 %	≤ 1.0 %	≤ 1.0 %	≤ 1.0 %	≤ 1.0 %
Judgement	Pass	Pass	Pass	Pass	Pass

4. Limit of Blank (Whole Blood Mode)

Diluent is analysed 11x consecutively. The first run is excluded, and the LoB is calculated as follows:

LoB (Limit of Blank) = Average + 1.645 x SDb
SDb = Standard deviation in the consecutive measurement of the sample

Welcount 3+ SN: 2303960BCC0203					
Run	WBC (x10^3/µL)	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	PLT-I (x10^3/µL)
1	0.00	0.00	0.0	0	0
2	0.00	0.00	0.0	0	0
3	0.00	0.00	0.0	0	0
4	0.00	0.00	0.0	0	0
5	0.00	0.00	0.0	0	0
6	0.00	0.00	0.0	0	0
7	0.00	0.00	0.0	0	0
8	0.00	0.00	0.0	0	0
9	0.00	0.00	0.0	0	0
10	0.00	0.00	0.0	0	0
11	0.00	0.00	0.0	0	0
Average	0.00	0.00	0.0	0.00	0
SDb	0.00	0.00	0.0	0.00	0
LoB	0.00	0.00	0.0	0.00	0

5. Limit of Detection and Limit of Quantitation (Whole Blood Mode)

Peripheral blood is diluted with Diluent to the following target consistencies:

Parameter	WBC (x10^3/µL)	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	PLT (x10^3/µL)
Sample 1	0.04	0.01	0.0	0.2	1.9
Sample 2	0.05	0.01	0.1	0.3	2.6

Each diluted sample is analyzed 11x consecutively. The first run is excluded and the LoD and LoQ are calculated as follows:

LoDi = LoB + 1.645 x SDdi

SDdi = Standard deviation in the consecutive measurement of the sample

LoD (Limit of Detection) = Average of LoDi

LoQ (Limit of Quantitation) = Maximum value of LoDi

Welcount 3+ SN: 2303960BCC0203						
Run	WBC (x10^3/µL)		RBC (x10^6/µL)		HGB (g/dL)	
	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2
1	0.06	0.17	0.05	0.16	0.2	0.4
2	0.08	0.19	0.05	0.15	0.1	0.4
3	0.00	0.15	0.05	0.15	0.1	0.5
4	0.00	0.18	0.05	0.16	0.1	0.4
5	0.00	0.18	0.05	0.16	0.1	0.4
6	0.00	0.17	0.05	0.15	0.1	0.4
7	0.00	0.18	0.05	0.15	0.1	0.4
8	0.00	0.16	0.05	0.15	0.1	0.4
9	0.00	0.16	0.06	0.16	0.1	0.4
10	0.06	0.16	0.05	0.15	0.1	0.4
11	0.00	0.16	0.05	0.16	0.1	0.4
Average	0.01	0.17	0.05	0.15	0.1	0.4
SDdi	0.03	0.01	0.00	0.01	0.0	0.0
LoDi	0.05	0.02	0.01	0.01	0.00	0.05
LoD	0.04		0.01		0.0	
LoQ	0.05		0.01		0.1	

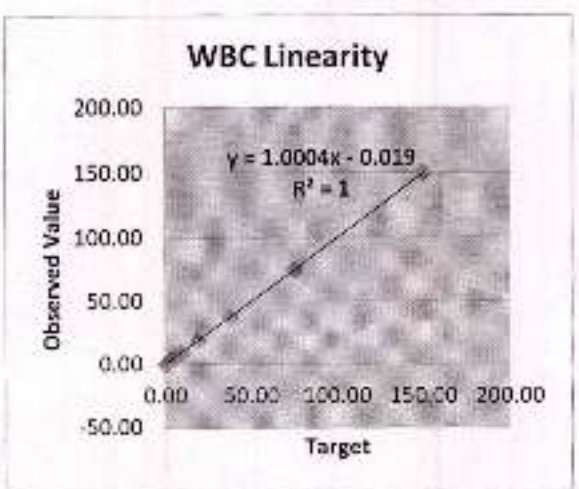
Welcount 3+ SN: 2303960BCC0203				
Run	HCT (%)		PLT-I (x10^3/μL)	
	Sample 1	Sample 2	Sample 1	Sample 2
~~1~~	~~0.4~~	~~1.3~~	~~5~~	~~9~~
2	0.0	1.2	5	5
3	0.4	1.2	5	7
4	0.4	1.3	7	10
5	0.4	1.3	5	7
6	0.4	1.2	6	5
7	0.4	1.2	6	5
8	0.4	1.2	5	5
9	0.5	1.3	5	6
10	0.0	1.2	5	6
11	0.4	1.3	5	5
Average	0.33	1.24	5	6
SDdi	0.18	0.05	1	2
LoDi	0.29	0.08	1.15	2.62
LoD	0.2		1.9	
LoQ	0.3		2.6	

*The availability of functions depends on your system configuration

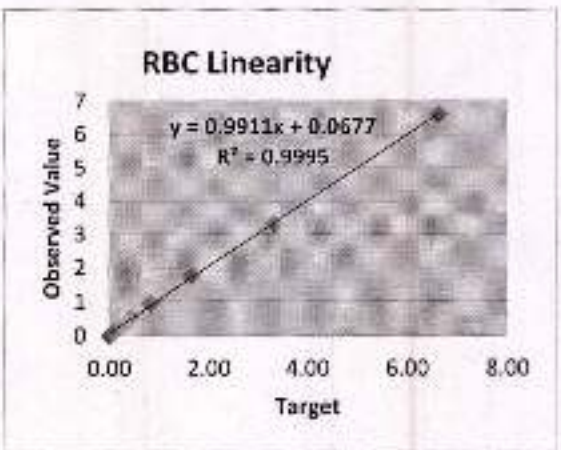
6. Linearity Check

Patient sample with high counts was analyzed and actual values were plotted against expected values.

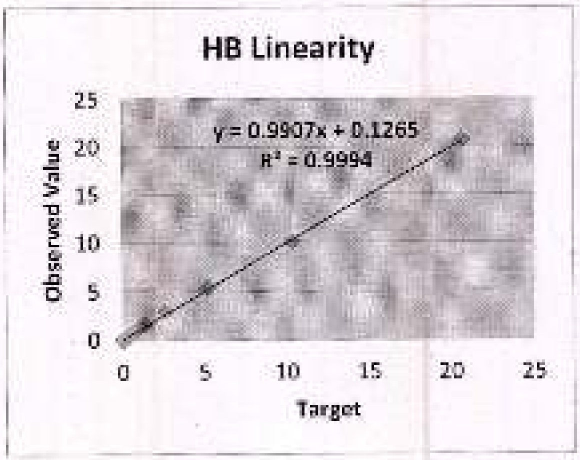
WBC	Target	Observed	Status
Neat	150.00	150.00	Pass
1:2 Dil	75.00	75.20	Pass
1:4 Dil	37.50	37.30	Pass
1:8 Dil	18.75	18.70	Pass
1:16 Dil	9.38	9.32	Pass
1:32 Dil	4.69	4.60	Pass
1:64 Dil	2.34	2.40	Pass
1:128 Dil	1.17	1.19	Pass
1:256 Dil	0.59	0.60	Pass
1:512 Dil	0.29	0.29	Pass
1:1024 Dil	0.15	0.14	Pass
Blank	0.00	0.00	Pass
WBC Correlation: 1.0			



RBC	Target	Observed	Status
Neat	6.61	6.61	Pass
1:2 Dil	3.31	3.31	Pass
1:4 Dil	1.65	1.76	Pass
1:8 Dil	0.83	0.96	Pass
1:16 Dil	0.41	0.53	Pass
1:32 Dil	0.21	0.26	Pass
1:64 Dil	0.10	0.16	Pass
1:128 Dil	0.05	0.07	Pass
Blank	0.00	0.00	Pass
RBC Correlation: 0.9995			



HB	Target	Observed	Status
Neat	20.7	20.7	Pass
1:2 Dil	10.4	10.1	Pass
1:4 Dil	5.2	5.4	Pass
1:8 Dil	2.6	2.9	Pass
1:16 Dil	1.3	1.6	Pass
1:32 Dil	0.6	0.8	Pass
1:64 Dil	0.3	0.4	Pass
1:128 Dil	0.2	0.2	Pass
1:256 Dil	0.1	0.1	Pass
Blank	0.0	0.0	Pass
HB Correlation:0.9994			



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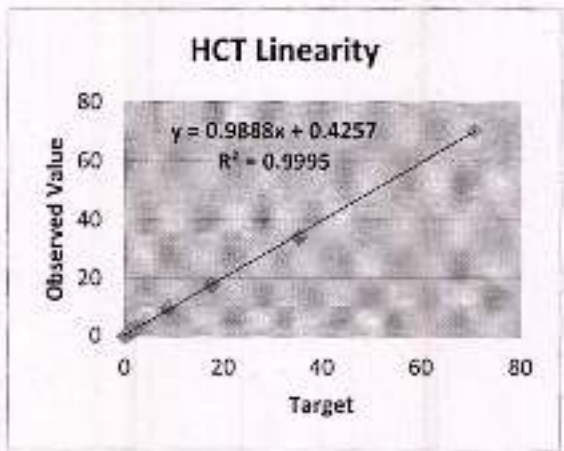
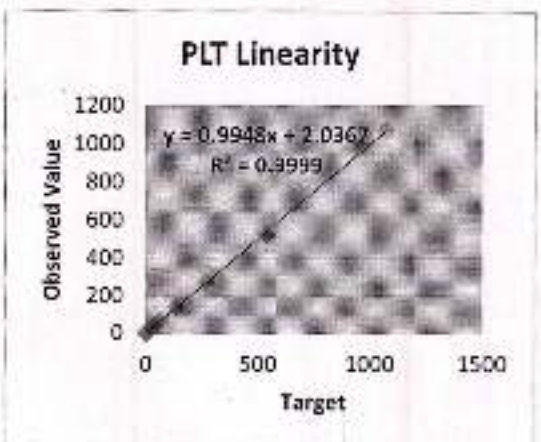
Manufacturing Facility: Plot No. ... 249403

HCT	Target	Observed	Status
Neat	70.6	70.6	Pass
1:2 Dil	35.3	34.3	Pass
1:4 Dil	17.7	18.0	Pass
1:8 Dil	8.8	9.8	Pass
1:16 Dil	4.4	5.4	Pass
1:32 Dil	2.2	2.6	Pass
1:64 Dil	1.1	1.5	Pass
1:128 Dil	0.6	0.7	Pass
Blank	0.0	0.0	Pass
HCT Correlation: 0.9995			



PLT	Target	Observed	Status
Neat	1072	1072	Pass
1:2 Dil	536	526	Pass
1:4 Dil	268	271	Pass
1:8 Dil	134	137	Pass
1:16 Dil	67	72	Pass
1:32 Dil	34	37	Pass
1:64 Dil	17	19	Pass
1:128 Dil	8	10	Pass
1:256 Dil	4	5	Pass
Blank	0	0	Pass
PLT Correlation:0.9999			



7. QC RUN

CBC-3D, R&D Hematology Trilevel QC processed, obtained QC values are in within a range. QC passed and printout attached.

Final Conclusion and deviation verified by:

Prepared & Checked By: **Balamuralikanth. U** **Manager – Product Specialist**	**Sign:**	**Date:04/11/2024**
Approved by:	**PATHOCON DIAGNOSTICS**	
Name:	**DR. G.N. KESHAVA MURTHY**	
Title: **Pathologist & Medical Director**	**Sign:** PATHOCON DIAGNOSTICS # 10/A-1, 1st 'R' Block, Rajajinagar BENGALURU-560 010	**Date:04/11/2024**

Deviation: None.

Conclusion: This report certifies that the instrument Weldon Welcount-3+ Automated Hematology Analyzer **S.No: 23039608CC0203** is qualified to perform as per manufacturer's specifications.

（ / ）全自动三分类血细胞分析仪出厂检验报告单

（ BCC-3960 ） Automatic Hematology Analyzer Certificate of Analysis

YQ/JG/DB0212-007

仪器型号 Instrument Model	BCC-3960	仪器号 Instrument No.	2303960BCC0203 2012817-20221217110154	出厂日期 Date of Manufacture	2024.02.07
客户名称 Client Name	/				

空白检测 Blank Test	
分析仪空白计数应符合RBC≤0.02×10¹²/L,WBC≤0.2×10⁹/L，HGB≤1g/L，PLT≤5×10⁹/L Analyzer blank count should meet: RBC≤0.02×10¹²/L,WBC≤0.2×10⁹/L，HGB≤1g/L，PLT≤5×10⁹/L	是否合格 Qualified or not √
分析仪可比性 Analyzer Comparability	
分析仪可比性应符合以下标准：RBC不超过±2%；WBC不超过±3.0%；HGB不超过±2%；PLT不超过±5.0%；HCT/MCV不超过±2.0% Analyzer comparability should meet: RBC no more than±2%; WBC no more than ±3.0%; HGB no more than ±2%; PLT no more than±5.0%; HCT/MCV no more than±2.0%	是否合格 Qualified or not √
重复性检测 Repeatability Test	
分析仪重复性应符合：WBC（3.5-6.9）×10⁹/L≤3.0%；WBC（7.0-15）×10⁹/L≤2.0%；RBC≤1.5%；HGB≤1.5%；PLT（100-149）×10⁹/L≤5.0%；PLT（150-500）×10⁹/L≤4.0%；HCT≤1.5%；MCV≤1.0% Analyzer repeatability should meet: WBC（3.5-6.9）×10⁹/L≤3.0%；WBC（7.0-15）×10⁹/L≤2.0%；RBC≤1.5%；HGB≤1.5%；PLT（100-149）×10⁹/L≤5.0%；PLT（150-500）×10⁹/L≤4.0%；HCT≤1.5%；MCV≤1.0%	是否合格 Qualified or not √

安全性检验 Safety Test		
序号 No.	检测项目 Test Item	是否合格 Qualified or not
1	绝缘耐压检测 Insulation withstand voltage test	√
2	接地电阻检测 Grounding Resistance Test	√
3	漏电流检验项 Leakage current test	√

包装检验 Packing Inspection		
序号 No.	检验项目 Inspection Item	是否合格 Qualified or not
1	外观检验 Appearence Inspection	√
2	标识检验 Sticker Inspection	√
3	封箱检验 Sealing Inspection	√

检验结果： Test Result:	合格□ Qualified√	不合格□ Unqualified□
备注： Remarks:	划"√"为合格，划"×"为不合格 Put a tick "√" if qualified; and a cross "×" if unqualified.	

检验员： Tested by:

审核人： Checked by:

检验日期： Test Date: 2024.02.07

2A

DIRUI

DIRUI BCC-3900 ASSAY VALUES AND EXPECTED RANGES

Lot: 01124
Expiration: 2023-02-08

Instrument	Parameter		Level 1 Mean		Limit	Range			Level 2 Mean		Limit	Range			Level 3 Mean		Limit	Range		
DIRUI BCC-3900	WBC	10^9/L	1.7	±	0.5	1.2	-	2.2	4.6	±	1.0	3.6	-	5.6	11.0	±	2.5	8.5	-	13.5
	LYM%	%	70.5	±	10.0	60.5	-	80.5	54.5	±	11.0	43.5	-	65.5	28.5	±	7.0	21.5	-	35.5
	MXD%	%	10.0	±	8.0	2.0	-	18.0	10.5	±	9.0	1.5	-	19.5	3.5	±	3.5	0.0	-	7.0
	NEU%	%	19.5	±	14.0	5.5	-	33.5	35.0	±	12.0	23.0	-	47.0	68.0	±	9.0	59.0	-	77.0
	LYM#	10^9/L	1.2	±	0.2	1.0	-	1.4	2.5	±	0.5	2.0	-	3.0	3.1	±	0.8	2.3	-	3.9
	MXD#	10^9/L	0.2	±	0.2	0.0	-	0.4	0.5	±	0.5	0.0	-	1.0	0.4	±	0.4	0.0	-	0.8
	NEU#	10^9/L	0.3	±	0.3	0.0	-	0.6	1.6	±	0.6	1.0	-	2.2	7.5	±	1.0	6.5	-	8.5
	RBC	10^{12}/L	2.38	±	0.18	2.20	-	2.56	4.60	±	0.24	4.36	-	4.84	5.66	±	0.35	5.31	-	6.01
	HGB	g/L	60	±	4	56	-	64	136	±	6	130	-	142	184	±	8	176	-	192
	HCT	L/L	0.171	±	0.020	0.151	-	0.191	0.382	±	0.030	0.352	-	0.412	0.526	±	0.035	0.491	-	0.561
	MCV	fL	72.0	±	5.0	67.0	-	77.0	83.0	±	5.0	78.0	-	88.0	93.0	±	5.0	88.0	-	98.0
	MCH	pg	25.2	±	2.5	22.7	-	27.7	29.6	±	2.5	27.1	-	32.1	32.5	±	2.5	30.0	-	35.0
	MCHC	g/L	350	±	30	320	-	380	356	±	30	326	-	386	350	±	30	320	-	380
	RDW-CV	%	14.0	±	3.0	11.0	-	17.0	14.0	±	3.0	11.0	-	17.0	13.0	±	3.0	10.0	-	16.0
	RDW-SD	fL	33.5	±	10.0	23.5	-	43.5	36.0	±	10.0	26.0	-	46.0	37.5	±	10.0	27.5	-	47.5
	PLT	10^9/L	67	±	20	47	-	87	260	±	45	215	-	305	517	±	65	452	-	582
	PDW	fL	11.5	±	3.0	8.5	-	14.5	11.5	±	3.0	8.5	-	14.5	12.0	±	3.0	9.0	-	15.0
	MPV	fL	11.3	±	3.0	8.3	-	14.3	9.4	±	3.0	6.4	-	12.4	9.4	±	3.0	6.4	-	12.4
	P-LCR	%	26.5	±	10.0	16.5	-	36.5	22.0	±	10.0	12.0	-	32.0	22.5	±	10.0	12.5	-	32.5
	PCT	%	0.070	±	0.060	0.010	-	0.130	0.240	±	0.100	0.140	-	0.340	0.490	±	0.200	0.290	-	0.690
	P-LCC	10^9/L	18	±	12	6	-	30	57	±	25	32	-	82	116	±	35	81	-	151

DIRUI INDUSTRIAL CO.,LTD.

AS726-003 Rev. 12/21