

**Installation Qualification, Performance,  
Qualification and Operational  
Qualification  
VECTOR** VEC5DIFF

(Serial no: **08405192205GA**)

Fully Automated Hematology Analyzer

For

**CHITRANSH PATHOLOGY LAB,**

Civil Lines Lalitpur Uttar Pradesh

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#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646 5000.

Visit us: <http://www.horiba.com/in/>

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

- I. Performance Qualification.
- II. Performance Certificate.

### **Section 5 Attachments**

**General Instructions:**

- Tulip Diagnostics Pvt. Ltd. is responsible for installation of VECTOR VECSDIFF, Fully 5 part PartAutomated Hematology Analyzer, at CHITRANSH PATHOLOGY LAB. As per the attached protocol.
- An authorized Tulip Diagnostics Pvt. Ltd., representative will physically check the system and proceed for the installation.
- This installation protocol will be followed as specified by the manufacturer.
- Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.
- An authorized Tulip Diagnostics Pvt. Ltd. representative will also perform the precision check on the system to check if it is as per the claim of the manufacturer.
- The results obtained for Calibration, QC & Precision checks will be verified by the qualified trained employee of
- CHITRANSH PATHOLOGY LAB along with an authorized Tulip Diagnostics Pvt. Ltd., representative.
- On completion of the Installation all the necessary documents of the System checks will be used to evaluate the instrument installation in accordance with the manufacturer's protocol and intended use.
- An authorized Tulip Diagnostics Pvt. Ltd., representative will verify the documents of the system checks and approve the same.
- Successful completion of this protocol will verify that this instrument has been installed in accordance with the intended usage.

**Report Sign Off**

Prepared by:	Tulip Diagnostics Pvt. Ltd.		
Name:	SANJEEV		
Title; Engineer at Customer support	Sign: 	Date: 04/11/2019	
Approved by:			
Name:	Mr.pankaj		
Title: Lab Incharge	Sign: 	Date: 04/11/2019	

# VECTORVEC5DIFF

(Serial no: **08405192205GA**)

Fully Automated Hematology Analyzer

## Installation Qualification

For

**CHITRANSH PATHOLOGY LAB,**

Civil Lines Lalitpur Uttar Pradesh

---

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646 5000.

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**A. Installation Qualification****1. Installation Requirement :**

Sr. No.	Description	Compliance (Yes/No)
1.	Environmental conditions: Indoor Location not exposed to sunlight, water and vibration free platform. Temperature of 16°C to 34°C and maximum relative humidity of 80%.	yes
2.	Physical Space Requirement: 36(W) x 36(D) x 53(H)cm with at least 20 cm space at the back of the instrument from the wall.	yes
3.	Electrical Requirements: Power supply - 100Vac- 240 Vac +/- 10%. Power consumption – Maximum 150VA with earth less than 3 V.	yes
4.	UPS connection available.	yes

**2. The instrument has been checked for the following:**

Sr. No.	Verification	Provided (Yes/No)
1.	Instrument is identified Instrument Serial No. : 08405192205GA	Yes
2.	Manufacturer's specifications: Technical and Physical Requirement	Yes
3.	Accessories / consumables are listed as per checklist ( Provided along)	Yes
4.	System checked for any External / physical damage.	Yes
5.	Instrument User Manual (Soft Copy)	Yes

*M/*

### 3. Equipment Description :

VECTORVEC5DIFF, Fully Automated Hematology Analyzer

Instrument Identification	Verified Yes/No
Equipment Type : Hematology Analyzer	Yes
Model : VECTORVEC5DIFF	Yes
Manufacturer : HORIBA Medical, France	Yes
Marketed By : HORIBA Medical - Tulip Diagnostics Pvt. Ltd.	Yes
Equipment # : One	Yes
Serial Number : 08405192205GA	Yes
Dimensions : 36(W) x 36(D) x 53(H)	Yes
Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz Power Consumption: 150 VA	Yes

### 4. Accessories/Consumables :

The accessories were supplied with the instrument as per the check list. Check & verified in case they are found to be in order.

### 5. Preventive Maintenance :

The routine preventive maintenance of the system will be carried out by an authorized Tulip Diagnostics Pvt. Ltd., engineer at a specified time interval as recommended by the manufacturer.

### 6. Spare Parts :

Tulip Diagnostics Pvt. Ltd strongly recommends the end user to maintain a basic consumable parts onsite to minimize down time due to minor failures. Spare parts as provided in the installation kit.

**B. Installation Procedure:**

1. Putting the system at the predefined and pre inspected location (Having suitable Working Conditions).
2. Removal of the internal packing material of the system.
3. Place the Instrument on the bench top (Vibration free).
4. Connect the Power cord to the VECTORVEC5DIFF.
6. Turn on the inbuilt Printer.
7. All the operating software has been loaded in to VECTORVEC5DIFF.
8. Now from back side of the instrument turn the power switch ON. VECTORVEC5DIFF goesthrough its power up and self-test sequence.
9. The VECTORVEC5DIFF login menu is displayed after the Start up cycle is completed. Enter thecredentials.

### C. INSTALLATION CERTIFICATE:

Instrument Name : VECTORVEC5DIFF



Serial Number : 08405192205GA

Customer Details : Chitransh pathology Lab

Laboratory with complete address: Civil Lines Lalitpur Uttar Pradesh

Installation Date : 04/11/2019

Warranty expires on : 03/11/2024

Prepared by:	Tulip Diagnostics Pvt. Ltd.		
Name:	Sanjeev		
Title: Engineer at Customer support	Sign: 	Date:04/11/2019	
Approved by:	Chitransh pathology Lab		
Name:	Mr.pankaj		
Title: Lab Incharge	Sign: 	Date:04/11/2019	

#### Deviation:

Conclusion: Instrument has been qualified for Installation. Hence it has been taken for Operational Qualification.



**A. Operational Qualification****1. Instrument Identification:**

Instrument Name : VECTORVEC5DIFF

Serial Number : 08405192205GA

**2. Following is the list of actions performed and verified for running the system routinely.**

Sr. No.	Test Name	Test Purpose	Method	Observation
1.	SYSTEM SWITCH ON	TO CHECK THE ERROR FREE POWER UP.	Switch on the main, switch on the system. Login into yumizen Application software. Start up cycle is performed. Login in as User and check for the Screen Errors.	Ok
2.	STARTUP CYCLE	TO CHECK THE BACK GROUND IS OK.	Run a startup cycle from the main menu; check if the background is in the acceptable range.	Ok
3.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.	Ok
4.	REAGENT STATUS	TO CHECK ADEQUATE REAGENT IS AVAILABLE FOR ANALYSIS	Manually check in the reagent bottles or else change the reagent from the Status Menu.	Ok

5.	SAMPLE ANALYSIS	TO CHECK PROPER FUNCTIONING OF SAMPLE ANALYSIS	1. To run Stat/ Manual sample, press on sample identification and enter the sample ID and press on validate.	Ok
6.	ARCHIVE AND CURRENT REPORTS	TO RECOVER THE SAMPLE RESULT FROM ARCHIVE AND CURRENT REPORTS	Press on Results History icon and view the current results. To view archived reports, Select Archive results and select the date of the reports and view the report.	Ok
7.	QUALITY CONTROL DATA	TO RECOVER QUALITY CONTROL DATA AND LJ GRAPH	Press on QC Icon from the Main Menu and select the Lot No. To view on QC Runs , Click on Dates .	Ok
8..	FLAGS AND ALARMS	TO CHECK THE PROPER FLAGS AND ALARMS FOR SAMPLES	Run sample to verify alarms and flags.	Ok

### **B. Operational Training Record**

**Operator Training:** The users responsible for the operation of this instrument will be trained on the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented and the training records will be filled as indicated below:

### **C. Operator Maintenance Protocol**

**OPERATIONAL CERTIFICATE:**

Instrument Name : VECTORVEC5DIFF

Serial Number : 08405192205GA

Customer Details : Chitransh pathology Lab  
Laboratory with complete address : Civil Lines Lalitpur Uttar Pradesh

Installation Date : 04/11/2019

Warranty expires on : 03/11/2024

Prepared by:	Tulip Diagnostics Pvt. Ltd.		
Name:	Sanjeev		
Title: Engineer at Customer support	Sign:	Date:04/11/2019	
Approved by:	Chitransh pathology Lab		
Name:	Mr. pankaj		
Title: Lab incharge	Sign:	Date:04/11/2019	

**Deviation:**

**Conclusion:** Instrument has been qualified for Operational. Hence it has been taken for Performance Qualification.

**A. Performance Qualification****A. Instrument Identification:**

Instrument Name : VECTORVEC5DIFF


Serial Number : 08405192205GA

**B. Following is the list of test to be performed and verified**

- **Blank Reference cycle:** To verify the Startup Cycle of the instrument.

Serial No: 08405192205GA

Parameters	Acceptable Range	Observed Value
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.0
RBC $10^6/\text{mm}^3$	$\leq 0.02 \times 10^6/\text{mm}^3$	0.00
HGB g/Dl	$\leq 0.3 \text{ g/dl}$	0.0
PLT $10^3/\text{mm}^3$	$\leq 10 \times 10^3/\text{mm}^3$	0

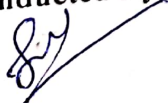
Conducted By:  
Verified By:  


- **Precision Study:** Precision is checked by running blood sample in 10 replicates & getting CV% in within acceptance.

Serial No: 08405192205GA

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	0.6	
HGB g/dL	< 1.5	0.5	
HCT %	< 2.0	0.7	
PLT $10^3/\text{mm}^3$	< 5.0	3.9	
WBC $10^3/\text{mm}^3$	< 2.5	1.2	
GRA %	< 4	2.0	
LYM%	< 10	1.3	
MON%	< 20	6.4	

Conducted By:



Verified By:



- **Control Runs:** The quality of the analyzer is checked by running three levels of Controls & getting the values in the range as per the kit insert.
  - **Lot:** ABX Difftrol; PX421; Exp: 10/12/2021.

Serial No: 08405192205GA

LEVEL	STATUS
LOW (PX 424L)	OK
NORMAL (PX 424N)	OK
HIGH (PX 424H)	OK

Conducted By:



Verified By:



- **Carryover Study:** Carry over is checked by running quality controls (Low & high) in 3 replicates & getting CV% in within acceptance.
  - Carry Over % =  $(L1-L3) * 100 / (H3-L3)$ .

Serial No: 08405192205GA

Parameters	WBC $10^3/\text{mm}^3$	RBC $10^6/\text{mm}^3$	HGB g/dL	HCT %	PLT $10^3/\text{mm}^3$
Carry Over (%)	0.5	0.9	0	0.6	0.2
Manufacturer acceptable CV%	<1%	<1%	<1%	<1%	<1%
Status	Passed	Passed	Passed	Passed	Passed

Conducted By:





Verified By:



**B. PERFORMANCE CERTIFICATE:**

Instrument Name : VECTORVEC5DIFF  
 Serial Number : 08405192205GA  
 Customer Details : Chitransh pathology Lab  
 Laboratory with complete address : Civil Lines Lalitpur Uttar Pradesh  
 Installation Date : 04/11/2019  
 Warranty expires on : 03/11/2024

Prepared by:	Tulip Diagnostics Pvt. Ltd.		
Name:	Sanjeev		
Title: Engineer at Customer support	Sign:		04/11/2019
Approved by:	Chitransh pathology Lab		
Name:	Mr. Pankuj		
Title: Lab Incharge	Sign:		Date: 04/11/2019

**Deviation:**

**Conclusion:** Instrument has been qualified for Performance.

**ATTACHMENTS**

Attachment No	Document Title	Page Nos.	Verified By Sign/Date



**CALIBRATION DATA**

SMP NO/TIME	WBC	RBC	HGB	HCT	PLT
SCS1	6.80	4.41	12.3	34.00	258
SCS2	6.90	4.42	12.3	34.00	261
SCS3	6.90	4.38	12.3	33.60	257
SCS4	6.70	4.36	12.3	33.40	259
SCS5	6.80	4.42	12.3	33.90	264
<b>MEAN</b>	<b>6.82</b>	<b>4.398</b>	<b>12.30</b>	<b>33.78</b>	<b>259.8</b>
Acceptable Limits	6.51 - 7.09	4.320 - 4.497	12.11 - 12.36	33.06 - 34.55	250.3 - 276.7
<b>Result</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>

(Traceability System) :  
 The traceability system of Tulip Hematology analyzers are shown in attached sheet.

Shrish Dixit

(Head- Products & Marketing)For  
 Tulip Diagnostics Pvt. Ltd

HIN/MED/2023-2024/103514  
19<sup>th</sup> May 2023

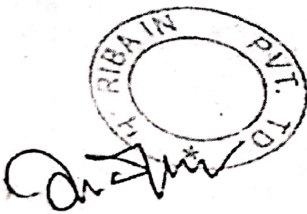
## CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer VectorVec5deff bearing serial number: 08405192205GA installed at CHITRANSH PATHOLOGY LAB as calibrated on 19<sup>th</sup> May 2023.

Calibrator : ABX MINOCAL  
Lot No. : CX440  
Expiry Date : 25<sup>th</sup> June 2023

The reports of Blank Cycle, Repeatability and Calibration Values were all found in acceptable range.

Next calibration cycle is due on 18<sup>th</sup> May 2024.



Shrish Dixit

(Head- Products & Marketing)  
For Tulip Diagnostics Pvt. Ltd

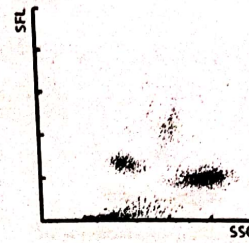
Sample No.: QC-31531401  
 Patient ID:  
 Name:  
 Sample Comment:

Ward: Adapter: 2

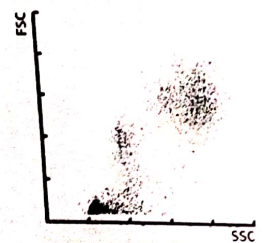
Pos.: 1 07/08/2023 10:25:45 WB  
 Doctor:  
 Birth: Sex:  
 Nickname: XN-L

WBC	2.59	[10 <sup>3</sup> /uL]		
RBC	2.29	[10 <sup>6</sup> /uL]		
HGB	5.8	[g/dL]		
HCT	16.9	[%]		
MCV	73.8	[fL]		
MCH	25.3	[pg]		
MCHC	34.3	[g/dL]		
PLT	68	[10 <sup>3</sup> /uL]		
RDW-SD	48.6	[fL]		
RDW-CV	17.9	[%]		
PDW	7.6	[fL]		
MPV	9.5	[fL]		
P-LCR	18.0	[%]		
PCT	0.06	[%]		
NEUT	1.22	[10 <sup>3</sup> /uL]	47.1	[%]
LYMPH	0.70	[10 <sup>3</sup> /uL]	27.0	[%]
MONO	0.20	[10 <sup>3</sup> /uL]	7.7	[%]
EO	0.31	[10 <sup>3</sup> /uL]	12.0	[%]
BASO	0.16	[10 <sup>3</sup> /uL]	6.2	[%]
IG	0.32	[10 <sup>3</sup> /uL]	12.4	[%]

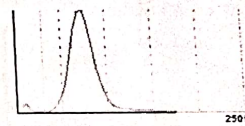
WDF



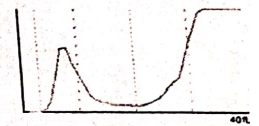
WDF-CBC



RBC



PLT



WBC IP Message

RBC IP Message

PLT IP Message

*Aslameo*

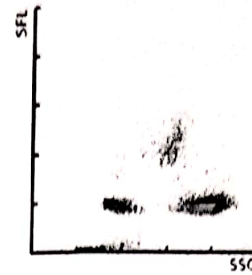
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Patient ID:  
Name:  
Sample Comment:

Ward: Adapter: 2

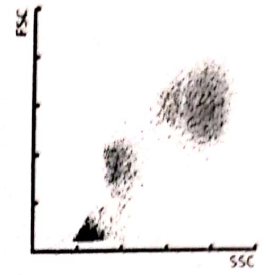
Pos.: 2 07/08/2023 10:26:47 WB  
Doctor:  
Birth: Sex:  
Nickname: XN-L

WBC	7.33	[10 <sup>3</sup> /uL]		
RBC	4.33	[10 <sup>6</sup> /uL]		
HGB	12.8	[g/dL]		
HCT	36.1	[%]		
MCV	83.4	[fL]		
MCH	29.6	[pg]		
MCHC	35.5	[g/dL]		
PLT	254	[10 <sup>3</sup> /uL]		
RDW-SD	44.6	[fL]		
RDW-CV	14.6	[%]		
PDW	7.3	[fL]		
MPV	8.8	[fL]		
P-LCR	12.5	[%]		
PCT	0.22	[%]		
NEUT	3.57	[10 <sup>3</sup> /uL]	48.7	[%]
LYMPH	1.76	[10 <sup>3</sup> /uL]	24.0	[%]
MONO	0.56	[10 <sup>3</sup> /uL]	7.6	[%]
EO	0.93	[10 <sup>3</sup> /uL]	12.7	[%]
BASO	0.51	[10 <sup>3</sup> /uL]	7.0	[%]
IG	0.92	[10 <sup>3</sup> /uL]	12.6	[%]

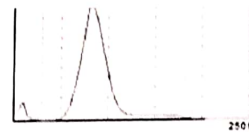
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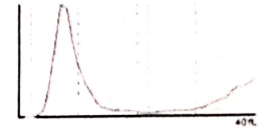
WDF - CBC



RBC



PLT



WBC IP Message

RBC IP Message

PLT IP Message

*Ashura*

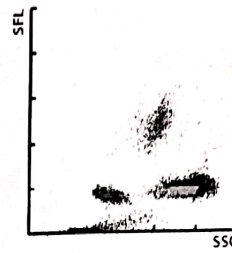
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Name:  
Sample Comment:

Ward: Adapter: 11

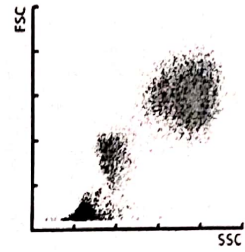
Pos.: 1 07/08/2023 15:46:10 WB  
Doctor:  
Birth: Sex:  
Nickname: XN-L

WBC	17.10	[10 <sup>3</sup> /uL]		
RBC	5.34	[10 <sup>6</sup> /uL]		
HGB	16.9	[g/dL]		
HCT	48.1	[%]		
MCV	90.1	[fL]		
MCH	31.6	[pg]		
MCHC	35.1	[g/dL]		
PLT	606	[10 <sup>3</sup> /uL]		
RDW-SD	46.3	[fL]		
RDW-CV	14.1	[%]		
PDW	7.5	[fL]		
MPV	8.6	[fL]		
P-LCR	10.3	[%]		
PCT	0.52	[%]		
NEUT	9.06	[10 <sup>3</sup> /uL]	52.9	[%]
LYMPH	3.21	[10 <sup>3</sup> /uL]	18.8	[%]
MONO	1.37	[10 <sup>3</sup> /uL]	8.0	[%]
EO	2.37	[10 <sup>3</sup> /uL]	13.9	[%]
BASO	1.09	[10 <sup>3</sup> /uL]	6.4	[%]
IG	2.68	[10 <sup>3</sup> /uL]	15.7	[%]

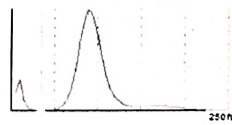
WDF



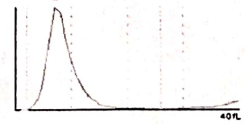
WDF-CBC



RBC



PLT



WBC IP Message

RBC IP Message

PLT IP Message

*Ashw...*