

**Installation Qualification, Performance,  
Qualification and Operational  
Qualification**

**HUMA COUNT 5D**

(Serial no:**N11041742031**)

Fully Automated Hematology Analyzer

For

**DOC OPD LABS ,  
NOIDA**

---

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

Visit us: [http://www.HUMAN .com/in/](http://www.HUMAN.com/in/)

---

## **Table of Contents:**

### **Section 1 General Instructions**

### **Section 2 Installation Qualification**

- I. Installation Qualification.
- II. Installation Procedure.
- III. Installation Certificate.

### **Section 3 Operational Qualification**

- I. Operational Qualification.
- II. Operational Training Record.
- III. Operator Maintenance Protocol.
- IV. Operational Certificate.

### **Section 4 Performance Qualifications**

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

### **Section 5 Attachments**

## **Table of Contents:**

### **Section 1 General Instructions**

### **Section 2 Installation Qualification**

- I. Installation Qualification.
- II. Installation Procedure.
- III. Installation Certificate.

### **Section 3 Operational Qualification**

- I. Operational Qualification.
- II. Operational Training Record.
- III. Operator Maintenance Protocol.
- IV. Operational Certificate.

### **Section 4 Performance Qualifications**

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

### **Section 5 Attachments**

## **Table of Contents:**

### **Section 1 General Instructions**

### **Section 2 Installation Qualification**

- I. Installation Qualification.
- II. Installation Procedure.
- III. Installation Certificate.

### **Section 3 Operational Qualification**

- I. Operational Qualification.
- II. Operational Training Record.
- III. Operator Maintenance Protocol.
- IV. Operational Certificate.

### **Section 4 Performance Qualifications**

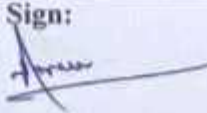
- I. Performance Qualification.
- II. Performance Certificate.

### **Section 5 Attachments**

**General Instructions:**

- HUMAN India Pvt. Ltd. is responsible for installation of HUMA COUNT 5D Fully 6 part Part Automated Hematology Analyzer, at DOC OPD LABS. As per the attached protocol.
- An authorized HUMAN India 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 HUMAN India 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
- DOC OPD LABS along with an authorized HUMAN India 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 HUMAN India 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.

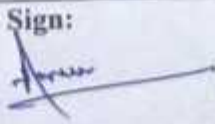
**Report Sign Off**

<b>Prepared by:</b>	HUMAN Medical - HUMAN India Pvt. Ltd.		
<b>Name:</b>	RAHUL RAJPUT		
<b>Title; Engineer at Customer support</b>	<b>Sign:</b>	<b>Date: 04/06/2022</b>	
<b>Approved by:</b>			
<b>Name:</b>	Mr. ARUN KUMAR		
<b>Title: Lab Incharge</b>	<b>Sign:</b> 	<b>Date: 04/06/2022</b>	

**General Instructions:**

- HUMAN India Pvt. Ltd. is responsible for installation of HUMA COUNT 5D Fully 6 part Part Automated Hematology Analyzer, at DOC OPD LABS. As per the attached protocol.
- An authorized HUMAN India 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 HUMAN India 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
- DOC OPD LABS along with an authorized HUMAN India 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 HUMAN India 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:	HUMAN Medical - HUMAN India Pvt. Ltd.		
Name:	RAHUL RAJPUT		
Title; Engineer at Customer support	Sign:	Date: 04/06/2022	
Approved by:			
Name:	Mr. ARUN KUMAR		
Title: Lab Incharge	Sign: 	Date: 04/06/2022	

**HUMA COUNT 5D**  
(Serial no:**N11041742031**)  
Fully Automated Hematology Analyzer

For

**DOC OPD LABS ,**  
NOIDA

---

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

Visit us: [http://www.HUMAN .com/in/](http://www.HUMAN.com/in/)

---

## 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)
	Instrument is identified Instrument Serial No. : <b>N11041742031</b>	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



### 3. Equipment Description :

HUMA COUNT 5D, Fully Automated Hematology Analyzer

<b>Instrument Identification</b>	<b>Verified Yes/No</b>
Equipment Type : Hematology Analyzer	Yes
Model : HUMA COUNT 5D	Yes
Manufacturer : HUMAN Medical, France	Yes
Marketed By :HUMAN Medical - HUMAN India Pvt. Ltd.	Yes
Equipment # : One	Yes
Serial Number : <b>N11041742031</b>	Yes
Dimensions : 36(W) x 36(D) x 53(H)	Yes
Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz	Yes
Power Consumption: 150 VA	

### 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 HUMAN India Pvt. Ltd., engineer at a specified time interval as recommended by the manufacturer.

### 6. Spare Parts :

HUMAN India 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 HUMA COUNT 5D.
6. Turn on the inbuilt Printer.
7. All the operating software has been loaded in to HUMA COUNT 5D.
8. Now from back side of the instrument turn the power switch ON. HUMA COUNT 5D goesthrough its power up and self-test sequence.
9. The HUMA COUNT 5D login menu is displayed after the Start up cycle is completed. Enter the credentials.

**C. INSTALLATION CERTIFICATE:**

Instrument Name : HUMA COUNT 5D

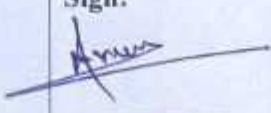
Serial Number : N11041742031

Customer Details : DOC OPD LABS

address : NOIDA

Installation Date : 04/06/2022

Warranty expires on : 03/06/2023

Prepared by:	HUMAN Medical - HUMAN India Pvt. Ltd.		
Name:	Rahul Rajput		
Title: Engineer at Customer support	Sign:	Date: 04/06/2022	
Approved by:	DOC OPD LABS		
Name:	Mr. Arun Kumar		
Title: Lab Incharge	Sign: 	Date: 04/06/2022	

**Deviation:**

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

**HUMA COUNT 5D**  
(Serial no: **N11041742031**)  
Fully Automated Hematology Analyzer

For

**DOC OPD LABS ,**  
NOIDA

---

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646 5000.  
Visit us: <http://www.HUMAN.com/in/>

---

## A. Operational Qualification

### 1. Instrument Identification:

Instrument Name : HUMA COUNT 5D

Serial Number : N11041742031

### 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**

**Maintenance and Troubleshooting:** Perform Concentration Cleaning as advised by the HUMAN Medical Representative .Run a Shutdown cycle before switching off the analyzer .

**OPERATIONAL CERTIFICATE:**

Instrument Name : HUMA COUNT 5D.

Serial Number : N11041742031


Customer Details : DOC OPD LABS

Laboratory with complete address NOIDA

Installation Date : 04/06/2022

Warranty expires on : 03/06/2023

Prepared by:	HUMAN Medical - HUMAN India Pvt. Ltd.
Name:	Rahul Rajput

Title: Engineer at Customer support	Doc opd labs	Date: 04/06/2022
Approved by:	DOC OPD LABS	
Name:	Mr. Arun kumar	
Title: Lab incharge	Sign: 	Date: 04/06/2022

**Deviation:**

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



**HUMA COUNT 5D**  
(Serial no: **N11041742031**)  
Fully Automated Hematology Analyzer

For

**DOC OPD LABS ,**  
NOIDA

**Performance Qualification**

For

---

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

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

---

**A. Performance Qualification**

**A. Instrument Identification:**

Instrument Name : HUMA COUNT 5D

Serial Number : N11041742031

**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: 907YOXH02566

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: 

- **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 Diffrol; PX421; **Exp:** 10/12/2023.

Serial No: N11041742031

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

Conducted By:

Verified By: 

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

Serial No: **N11041742031**

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	
	< 10	1.3	
LYM%			
MON%	< 20	6.4	

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 % =  $(L1-L3) \times 100 / (H3-L3)$ .

Serial No: **N11041742031**

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

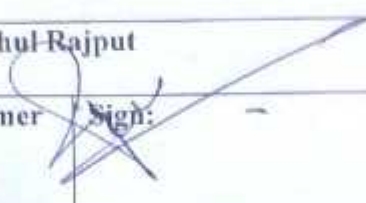

Conducted By:

Verified By: 

**B. PERFORMANCE CERTIFICATE:**

Instrument Name : HUMA COUNT 5D  
 Serial Number : N11041742031  
 Customer Details : DOC OPD LABS  
 complete address ,NOIDA

Installation Date : 04/06/2022  
 Warranty expires on : 03/06/2023.

Prepared by:	HUMAN Medical - HUMAN India Pvt. Ltd.		
Name:	Rahul Rajput		
Title:Engineer at Customer support	Sign:		Date:04/06/2022
Approved by:	DOC OPD LABSLaboratory		
Name:	Mr.Arun Kumar		
Title: Lab Incharge	Sign:		Date:04/06/2022

**Deviation:**

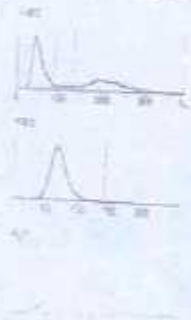
**Conclusion:** Instrument has been qualified for Performance.

**ATTACHMENTS**

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

L-J Results(Plate 1)  
 Lot No. 100001  
 Time: 11-11-2022 17:32

WBC	2.9	2.3 - 3.3
Lymph#	1.4	1.0 - 1.8
Gran#	1.0	0.7 - 1.7
Lymph%	52.4	36.5 - 64.1
Gran%	41.8	27.7 - 57.5
HGB	7.4	6.0 - 7.9
HCT	2.69	2.28 - 2.79
HCT	30.3	18.2 - 24.2
MCV	75.8	75.0 - 87.8
MCH	27.5	25.0 - 32.0
MCHC	36.4	30.3 - 39.9
PLT	73	64 - 104



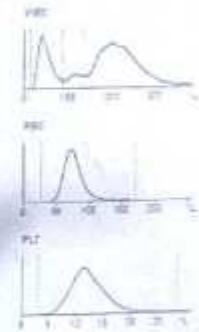
L-J Results(Plate 2)  
 Lot No. 100001  
 Time: 11-11-2022 17:32

WBC	7.7	7.0 - 9.0
Lymph#	2.3	1.8 - 3.4
Gran#	4.9	4.3 - 6.9
Lymph%	29.9	20.4 - 42.2
Gran%	63.6	44.0 - 81.0
HGB	12.3	11.7 - 12.9
RBC	4.30	3.77 - 4.37
HCT	34.7	32.0 - 40.0
MCV	80.6	82.4 - 94.4
MCH	28.6	26.4 - 34.0
MCHC	35.4	29.4 - 38.2
PLT	206	192 - 282



L-J Results(Plate 3)  
 Lot No. 100001  
 Time: 11-11-2022 17:32

WBC	17.8	15.9 - 20.9
Lymph#	4.2	2.0 - 7.0
Gran#	12.4	9.0 - 18.8
Lymph%	23.8	18.0 - 35.2
Gran%	69.2	48.8 - 90.8
HGB	15.3	14.4 - 18.0
RBC	5.11	4.47 - 5.27
HCT	42.3	39.0 - 48.0
MCV	82.8	83.4 - 95.4
MCH	29.9	27.4 - 35.0
MCHC	36.1	30.1 - 39.7
PLT	448	440 - 570



*[Handwritten signature]*