





**DETAILS OF CONTROL RUN**

Instrument Model : Mispa Count X - 3 Part Hematology Analyzer  
 Serial No : 2121100020338  
 Date of Control Run : 05/FEB/2024  
 Control Used : Agappe Quality Control  
 Lot No : *AG8642 / 231041*  
 Expiry : *23/04/2024*

The results of repeatability test are summarized in the following table. Refer the attached control sheets for details.

Sample No	WBC K/ $\mu$ L	RBC M/ $\mu$ L	HGB g/dL	HCT (%)	PLT K/ $\mu$ L
1	7.3	4.2	12.8	33.83	2332
2	7.2	4.25	12.81	33.9	236
3	7.2	4.2	2.7	33.6	235
Instrument Mean	7.23	4.21	12.76	33.76	233
Range	(7.6) $\pm$ 0.8	3.98( $\pm$ 0.4)	12.8( $\pm$ 0.9)	32.3( $\pm$ 4.7)	243( $\pm$ 32)
CV %	0.79	0.68	0.45	0.45	0.65

This is to certify that the above-mentioned product has been calibrated for CBC parameters (WBC, RBC, HGB, HCT, PLT) according to the standard operating procedure given by Agappe.

The control run after calibration shows good repeatability and precision

Next Calibration due on **04/AUG/2024**

For **AGAPPE DIAGNOSTICS LTD.**

*S. Pravin*  
*5/2/24*  
 Authorized Signatory



**Name:** Rangani Raj Kumar

**Designation:** Assistant Manager – Customer Service

**AGAPPE DIAGNOSTICS LTD.** ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

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ADU/CO/QAD/075/2023-24

MUMBAI DISTRICT  
CERTIFIED LABORATORY

TO WHOMSOEVER IT MAY CONCERN

Certificate of Traceability

Agappe Hematology Calibrator, manufactured by R&D Systems, is used for the calibration of Mispa Count X Instrument and the assigned values are traceable to standard reference methods

The White Blood Cell (WBC) and Red Blood Cell (RBC) are analyzed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

Hemoglobin is measured using the Clinical Laboratory Standards Institute (CLSI) recommended reagent for the hemoglobin cyanide (cyanmethemoglobin) method (1). Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations (1).

The hematocrit (packed cell volume) is measured using plain glass microhematocrit tubes (not coated with anticoagulant) centrifuged for 5 minutes in a micro hematocrit centrifuge according to the CLSI H7-A3 document (2). No correction is made for trapped plasma.

Platelets are assayed using a hemocytometer and phase contrast optics.

For Agappe Diagnostics Ltd.

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YOUR BEST PARTNER IN DIAGNOSTICS

Calibration  
Date 07/02/2014 01:45:03  
Model Calibration Jr 30  
Serial 691000159  
Version 3.9  
Completed 11:34:26  
FPGA firmware 1.03  
PIC boot 0.4  
PIC main 2.2

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WBC=0.95 RBC=0.95 HGB=1.00  
MCV=1.00 RDWc=1.00 PLT=1.00  
MPV=1.00

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MPV=1.00

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