

Installation Qualification, Performance, Qualification and Operational Qualification

ABX **Micros 60/ES60**

(Serial no: **904ESOH14853**)

Three Part Hematology Analyzer

For

CARE DIAGNOSTICS,

3rd cross, Neeladri Nagar, Electronic City Phase I, opposite
to ICICI Bank, Bengaluru, Karnataka 560100.

HORIBA
Medical

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General Instructions:

- HORIBA India Pvt.Ltd. is responsible for installation of Micros ES60, Three Part Hematology Analyzer, at **CARE DIAGNOSTICS, BANGALORE** per the attached protocol.
- An authorized HORIBA 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.
- After the installation of the system, Instrument calibration & QC will be performed by the authorized HORIBA India Pvt. Ltd. representative.
- An authorized HORIBA 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 **CARE DIAGNOSTICS, BANGALORE** along with an authorized HORIBA 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 HORIBA 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:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	RAJESH A		
Title:	Sign:	Date: 10/2/20	
EXECUTIVE SERVICE ENGINEER			
Reviewed by:	CARE DIAGNOSTICS, BANGALORE		
Name:	SUDHARSHAN . M		
Title:	Sign:	Date: 10/2/20	
			
Approved by:	CARE DIAGNOSTICS, BANGALORE		
Name:	DR. MEENU . E.V		
Title:	Sign:	Date: 10/2/20	
			

HORIBA Medical

ABX Micros 60/ES60
(Serial no: **904ESOH14853**)
Three Part Hematology Analyzer

Design Qualification

For

CARE DIAGNOSTICS,

**3rd cross, Neeladri Nagar, Electronic City Phase I, opposite
to ICICI Bank, Bengaluru, Karnataka 560100.**




A. Design Qualification

This is to certify that Hematology analyzer specially designed for perform the following parameters.

1. WBC = White Blood Cell Count
2. RBC = Red Blood Cell Count
3. HGB = Hemoglobin Concentration
4. HCT = Hematocrit
5. MCV = Mean Corpuscular Volume
6. MCH = Mean Corpuscular Hemoglobin
7. MCHC = Mean Cellular Hemoglobin Concentration
8. PLT = Platelet Count
9. RDW-CV = Red Cell Distribution Width (Coefficient Of Variation)
10. PDW = Platelet Distribution Width
11. MPV = Mean Platelet Volume
12. PCT = Plateletcrit
13. GRAN# = Granulocyte Count
14. LYMPH# = Lymphocyte Count
15. MONO# = Monocyte Count
16. GRAN% = Granulocyte Percent
17. LYMPH% = Lymphocyte Percent
18. MONO% = Monocyte Percent

B. DESIGN CERTIFICATE:

Instrument Name : MICROS ES60.
Serial Number : 904ESOH14853
Customer Details : CARE DIAGNOSTICS, BANGALORE.
With complete address 3rd cross, Neeladri Nagar, Electronic City Phase I,
Opposite to ICICI Bank, Bengaluru, Karnataka 560100.
Installation Date : 10/02/2020
Warranty expires on : 09/02/2021

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Rajesh A		
Title: EXECUTIVE SERVICE ENGINEER	Sign: 	Date:	10/2/20
Reviewed by:	CARE DIAGNOSTICS, BANGALORE		
Name:	SUDHARSHAN M		
Title:	Sign: 	Date:	10/2/20
Approved by:	CARE DIAGNOSTICS, BANGALORE		
Name:	DR. MEENU. E.V		
Title:	Sign: 	Date:	10/2/20

Deviation:

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

HORIBA Medical

ABX Micros 60/ES60
(Serial no: **904ES0H14853**)
Three Part Hematology Analyzer

Installation Qualification

For

CARE DIAGNOSTICS,

**3rd cross, Neeladri Nagar, Electronic City Phase I, opposite
to ICICI Bank, Bengaluru, Karnataka 560100.**

A. Installation Qualification

1. Installation Requirement :

Sr. No.	Description	Compliance (Yes/No)	Verified by & Date
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	[Signature] 10/2/20
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	[Signature] 10/2/20
3.	Electrical Requirements: Power supply - 100Vac- 240 Vac +/- 10%. Power consumption – Maximum 150VA with earth less than 3 V.	Yes	[Signature] 10/2/20
4.	UPS connection available.	Yes	[Signature] 10/2/20

2. The instrument has been checked for the following:

Sr. No.	Verification	Provided (Yes/No)	Verified by & Date
1.	Instrument is identified Instrument Serial No. : 904ESOH14853	Yes	[Signature] 10/2/20
2.	Manufacturer's specifications: Technical and Physical Requirement	Yes	[Signature] 10/2/20
3.	Accessories / consumables are listed as per checklist(Provided along)	Yes	[Signature] 10/2/20
4.	System checked for any External / physical damage.	Yes	[Signature] 10/2/20
5.	Instrument User Manual (Soft Copy)	Yes	[Signature] 10/2/20

3. Equipment Description :

Micros ES60, Three Part Hematology Analyzer

Instrument Identification	Verified Yes/No	Verified by / Date
Equipment Type : Hematology Analyzer	YES	R 10/2/20
Model : Micros ES60	YES	R 10/2/20
Manufacturer : HORIBA Medical, France	YES	R 10/2/20
Marketed By :HORIBA Medical - HORIBA India Pvt. Ltd.	YES	R 10/2/20
Equipment # : One	YES	R 10/2/20
Serial Number : 904ESOH14853	YES	R 10/2/20
Dimensions : 36(W) x 36(D) x 53(H)	YES	R 10/2/20
Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz Power Consumption: 150 VA	YES	R 10/2/20

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.

Qualified Trained employee name	Verified By	Date
SUDHARSAN, M	DR. MANU, EV	10/2/20

5. Preventive Maintenance :

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

6. Spare Parts :




HORIBA 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 preinspected location (Having suitable Working Conditions).
2. Removal of the internal packing material of the system.
3. Place the Instrument on the benchtop (Vibration free).
4. Connect the Power cord to the Micros ES60.
6. Turn on the inbuilt Printer.
7. All the operating software has been loaded in to Micros ES60.
8. Now from back side of the instrument turn the power switch ON. Micros ES60 goes through its power up and self-test sequence.
9. The Micros ES60 login menu is displayed after the Start up cycle is completed. Enter the credentials.

C. INSTALLATION CERTIFICATE:

Instrument Name : MICROS ES60.
Serial Number : 904ESOH14853
Customer Details : CARE DIAGNOSTICS, BANGALORE.
With complete address 3rd cross, Neeladri Nagar, Electronic City Phase I,
Opposite to ICICI Bank, Bengaluru, Karnataka 560100.
Installation Date : 10/02/2020
Warranty expires on : 09/02/2021

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Rajesh A		
Title: Executive Service Engineer	Sign: 	Date: 10/2/20	
Reviewed by:	CARE DIAGNOSTICS, BANGALORE		
Name:	SUDHARSHAN . M		
Title:	Sign: 	Date: 10/2/20	
Approved by:	CARE DIAGNOSTICS, BANGALORE.		
Name:	DR. MEENU . E.V		
Title:	Sign: 	Date: 10/2/20	

Deviation:

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

HORIBA Medical

ABX Micros 60/ES60
(Serial no: **904ES0H14853**)
Three Part Hematology Analyzer

Operational Qualification

For

CARE DIAGNOSTICS,

**3rd cross, Neeladri Nagar, Electronic City Phase I, opposite
to ICICI Bank, Bengaluru, Karnataka 560100.**







A. Operational Qualification

1. Instrument Identification:

Instrument Name : MICROS ES60

Serial Number : 904ESOH14853

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

Sr. No.	Test Name	Test Purpose	Method	Observation	Verified Sign/Date
1.	SYSTEM SWITCH ON	TO CHECK THE ERROR FREE POWER UP.	Switch on the main, switch on the system. Login into Micros Application software. Startup cycle is performed .Login in as User and check for the Screen Errors.		 10/2/20
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.		 10/2/20
3.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.		 10/2/20
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.		 10/2/20
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.		 10/2/20
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.		 10/2/20

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. and press on Print Icon to print LJ graph. To view on QC Runs, Click on Data's.		<i>[Signature]</i> 10/2/20
8..	FLAGS AND ALARMS	TO CHECK THE PROPER FLAGS AND ALARMS FOR SAMPLES	Run sample to verify alarms and flags.		<i>[Signature]</i> 10/2/20

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:




Sr. No.	Operators	Designation	Name & Sign of the Trainer.	Date
1.	SUDHARSAN . M	LAB MANAGER	<i>[Signature]</i> PRASANNA	10/2/20
2.	PRAVIN KUMAR . U	LAB TECH	<i>[Signature]</i> PRASANNA	10/2/20
3.	K. RAMANJANEYULU	LAB TECH	<i>[Signature]</i> PRASANNA	10/2/20
4.	NASIM AKRAM . M.S	LAB TECH	<i>[Signature]</i> PRASANNA	10/2/20
5.	TEJAS	LAB TECH	<i>[Signature]</i> PRASANNA	10/2/20
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
16.				

C. Operator Maintenance Protocol

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

D. OPERATIONAL CERTIFICATE:

Instrument Name : MICROS ES60.
Serial Number : 904ESOH14853
Customer Details : CARE DIAGNOSTICS, BANGALORE.
With complete address 3rd cross, Neeladri Nagar, Electronic City Phase I,
Opposite to ICICI Bank, Bengaluru, Karnataka 560100.
Installation Date : 10/02/2020
Warranty expires on : 09/02/2021

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Rajesh A		
Title: Executive Service Engineer	Sign: 	Date:	10/2/20
Reviewed by:	CARE DIAGNOSTICS, BANGALORE		
Name:	SUDHARSHAN M		
Title:	Sign: 	Date:	10/2/20
Approved by:	CARE DIAGNOSTICS, BANGALORE		
Name:	DR. MEENU E ✓		
Title:	Sign: 	Date:	10/2/20

Deviation:

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



ABX Micros 60/ES60
(Serial no: **904ES0H14853**)
Three Part Hematology Analyzer

Performance Qualification

For

CARE DIAGNOSTICS,
3rd cross, Neeladri Nagar, Electronic City Phase I, opposite
to ICICI Bank, Bengaluru, Karnataka 560100.

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

Instrument Name : MICROS ES60.

Serial Number : 904ESOH14853

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: 904ESOH14853

Parameters	Acceptable Range	Observed Value	Verified by Sign/Date
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.1	<i>[Signature]</i> 10/2/20
RBC $10^6/\text{mm}^3$	$\leq 0.02 \times 10^6/\text{mm}^3$	0	<i>[Signature]</i> 10/2/20
HGB g/dL	$\leq 0.3 \text{ g/dl}$	0	<i>[Signature]</i> 10/2/20
PLT $10^3/\text{mm}^3$	$\leq 10 \times 10^3/\text{mm}^3$	0	<i>[Signature]</i> 10/2/20

Conducted By: *[Signature]* RAJESH AVerified By: *[Signature]*

- **Calibration:** To calibrate the Instrument using calibrator (ABX Minocal) and verify the same.

Procedure: Go to Quality Assurance icon on main screen and then Calibration icon. Run Calibrator (ABX Minocal) 11 times, without taking the values of first run, calibrate the instrument using average of the last 5 runs. Run Calibrator as a sample to verify the calibration.

Lot: CX443; **Expiry:** 05/03/2020.

Serial No: 904ESOH14853

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	9.1	8.60	3.1	<3.5%	PASSED
RBC	4.52	4.60	0.54	<2%	PASSED
HGB	14.1	14.1	0.2	<1%	PASSED
HCT	39.6	39.9	0.6	<2%	PASSED
PLT	250	297	2	<5%	PASSED

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 Minotrol MX421; Exp: 05/04/2020.

Serial No: 904ESOH14853

Level I: Low Control

Parameters	Target	Tolerance	Observed Value Dated 14/02/2020	Comments
RBC 10 ⁶ /mm ³	2.40	0.15	2.45	Passed
HGB g/dL	6.00	0.40	5.90	Passed
HCT %	16.6	2.00	16.9	Passed
MCV μm ³	69.0	4.00	69.0	Passed
MCH pg	25.0	2.00	23.9	Passed
MCHC g/dL	36.2	3.00	34.7	Passed
RDW %	14.5	3.00	14.1	Passed
PLT 10 ³ /mm ³	73.0	20.0	82.0	Passed
MPV μm ³	9.00	2.00	9.10	Passed
WBC 10 ³ /mm ³	1.90	0.40	1.80	Passed
LYM%	66.0	8.00	63.0	Passed
LYM #	1.25	0.40	1.10	Passed
MON %	8.50	6.00	9.30	Passed
MON #	0.20	0.20	0.10	Passed
GRA %	25.5	7.00	27.7	Passed
GRA#	0.48	0.40	0.60	Passed

Level II: Normal Control

Parameters	Target	Tolerance	Observed Value Dated 14/02/2020	Comments
RBC 10 ⁶ /mm ³	4.59	0.18	4.60	Passed
HGB g/dL	13.5	0.5	13.3	Passed
HCT %	37.2	2.5	37.1	Passed
MCV μm ³	81.0	4.0	81.0	Passed
MCH pg	29.4	2.0	28.9	Passed
MCHC g/dL	36.3	3.0	35.8	Passed
RDW %	14.0	3.0	13.3	Passed
PLT 10 ³ /mm ³	263	40	268	Passed
MPV μm ³	8.40	2.0	8.60	Passed
WBC 10 ³ /mm ³	7.80	0.8	7.50	Passed
LYM %	36.0	5.0	34.4	Passed
LYM #	2.81	0.40	2.50	Passed
MON %	6.00	4.0	6.60	Passed
MON #	0.47	0.30	0.40	Passed
GRA %	58.0	6.0	59.0	Passed
GRA #	4.52	0.60	4.60	Passed

Level III: High Control

Parameters	Target	Tolerance	Observed Value Dated-14/02/2020	Comments
RBC $10^6/\text{mm}^3$	5.72	0.20	5.71	Passed
HGB g/dL	18.4	0.6	18.5	Passed
HCT %	50.3	3.0	50.8	Passed
MCV μm^3	88.0	4.0	89.0	Passed
MCH pg	32.2	2.0	32.3	Passed
MCHC g/dL	36.6	3.0	36.4	Passed
RDW %	13.5	3.0	13.8	Passed
PLT $10^3/\text{mm}^3$	565	45	538	Passed
MPV μm^3	8.30	2.0	8.10	Passed
WBC $10^3/\text{mm}^3$	20.8	1.6	20.1	Passed
LYM %	18.00	5.0	17.3	Passed
LYM #	3.74	1.0	3.50	Passed
MON %	4.00	4.0	4.80	Passed
MON #	0.83	0.8	0.90	Passed
GRA %	78.0	7.0	77.9	Passed
GRA #	16.22	1.4	15.9	Passed

↓
Conducted By:Verified By: 

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

Serial No: 904ESOH14853

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	1.09	PASS
HGB g/dL	< 1.5	0.55	PASS
HCT %	< 2.0	1.23	PASS
PLT $10^3/\text{mm}^3$	< 5.0	2.44	PASS
WBC $10^3/\text{mm}^3$	< 2.5	1.27	PASS

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: 904ESOH14853

Parameters	WBC 10 ³ /mm ³	RBC 10 ⁶ /mm ³	HGB g/dL	PLT 10 ³ /mm ³
Carry Over (%)	0.5	-0.6	0.0	-2.0
Manufacturer acceptable CV%	<2%	<2%	<2%	<2%
Status	Passed	Passed	Passed	Passed

Conducted By: Verified By: 

B. PERFORMANCE CERTIFICATE:

Instrument Name : MICROS ES60.
Serial Number : 904ESOH14853
Customer Details : CARE DIAGNOSTICS, BANGALORE.
With complete address 3rd cross, Neeladri Nagar, Electronic City Phase I,
Opposite to ICICI Bank, Bengaluru, Karnataka 560100.
Installation Date : 10/02/2020
Warranty expires on : 09/02/2021

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Rajesh A		
Title: EXECUTIVE ENGINEER	SERVICE	Sign: 	Date: 10/2/20
Reviewed by:	CARE DIAGNOSTICS, BANGALORE		
Name:	SUDHARSHAN . M		
Title:	Sign: 	Date: 10/2/20.	
Approved by:	CARE DIAGNOSTICS, BANGALORE		
Name:	DR. MEENU . E . V		
Title:	Sign: 	Date: 10/2/20	

Deviation:

Conclusion: Instrument has been qualified for Performance.

Date: 14/02/2020

CALIBRATION CERTIFICATE

This is to state that the hematology cell counter model **MICROS ES 60** bearing **Serial no: 904ESOH14853** at **CARE DIAGNOSTICS, BANGALORE, Karnataka state**, was calibrated with Calibrator on **14/02/2020**.

The Calibration Coefficient is automatically generated after calibration. Subsequently controls were processed and found them in respective range.

Calibrator Used: **ABX MINOCAL**
Lot No.: **CX 443**
Expiry Date: **05/03/2020**

Sr. No	Tested Parameter	Remarks
1	Startup / Blank Cycle	Passed
2	Repeatability/ Precision	Passed
3	Calibration	Passed
4	Quality Control	Passed

Next calibration cycle is due on **13/02/2021**.

YESHWANTH PADASHETTY



ENGINEER CUSTOMER SUPPORT

Horiba Medical.



LOT CX 443 **Rev 1** **CAL** **(Exp.) 2020-03-05**
(YYYY-MM-DD)

PARAMETRES PARAMETERS	UNITES UNITS	Minilysebio								TOLERANCES TOLERANCE	
		MICROS	MICROS	MICROS	MICROS	MICROS	MICROS	PENTRA	PENTRA		
GB WBC	$10^3/\text{mm}^3 \cdot 10^9/l$	ES60	CRP 200								± 0.2
GR RBC	$10^6/\text{mm}^3 \cdot 10^{12}/l$	9.1	8.9	9.2							± 0.06
	g/dl	4.52	4.50	4.54							± 0.2
HB HGB	g/l	14.1	13.6	14.1							± 2
	mmol/l	141	136	141							± 0.12
	%	8.76	8.46	8.76							± 1.0
HT HCT	l/l	39.6	39.4	39.7							± 0.010
	$10^3/\text{mm}^3 \cdot 10^9/l$	0.396	0.394	0.397							± 10
PLAQ. PLTS		250	235	245							± 0.5
VPM MPV	$\mu\text{m}^3 ; \text{fl}$	8.3	8.1	8.8							

LOT

MX 421 L

CONTROL L

Rev.1



(Exp.)

2020-04-05
[YYYY-MM-DD]

PARAMETRES PARAMETERS	UNITES UNITS	MICROS										TOLERANCES TOLERANCE
		ES60	CRP 300	MICROS	MICROS	MICROS	MICROS	ARGOS - HELIOS	PENTRA	PENTRA	PENTRA	
Minilysebio												
										60 BP - 60 TP		
GB WBC	$10^3/mm^3 \cdot 10^9/l$	1.9	1.8							1.9		± 0.4
GR RBC	$10^6/mm^3 \cdot 10^{12}/l$	2.40	2.35							2.38		± 0.15
	g/dl	6.0	5.9							5.8		± 0.4
HB HGB	g/l	60	59							58		± 4
	mmol/l	3.73	3.65							3.60		± 0.25
HT HCT	%	16.6	16.2							16.4		± 2.0
	l/l	0.166	0.162							0.164		± 0.020
VGM MCV	$\mu m^3 \cdot fl$	69	69							69		± 4
	p9	25.0	25.0							24.4		± 2.0
TGMH MCH	fmol	1.55	1.55							1.51		± 0.12
	g/dl	36.2	36.3							35.3		± 3.0
	g/l	362	363							353		± 30
CCMH MCHC	mmol/l	22.50	22.52							21.93		± 1.86
	%	14.5	14.0							14.0		± 3.0
IDR RDW	$10^3/mm^3 \cdot 10^9/l$	73	73							76		± 20
PLAQ PLTS	$\mu m^3 \cdot fl$	9.0	8.5							8.9		± 2.0
VPM MPV	#	1.25	1.18							1.25		± 0.40
LYMPHO	%	66.0	65.7							66.0		± 8.0
	#	0.20	0.18							0.20		± 0.20
MONO	%	8.5	10.0							8.0		± 6.0
	#	0.48	0.44							0.49		± 0.40
GRANULO	%	25.5	24.5							26.0		± 7.0

LOT

MX 421 N
Rev 1

CONTROL N

(Exp.)

2020-04-05
(YYYY-MM-DD)

PARAMETRES PARAMETERS	UNITES UNITS	Minitlysebio										TOLERANCES TOLERANCE	
		ES60	MICROS CRP 200	MICROS	MICROS	MICROS	ARGOS-HELOS	PENTRA	PENTRA	PENTRA	PENTRA		
GB WBC	$10^3/\text{mm}^3 \cdot 10^9/\text{l}$	7.8	7.3	7.8	7.8	7.8							± 0.8
GR RBC	$10^6/\text{mm}^3 \cdot 10^{12}/\text{l}$	4.59	4.55	4.61	4.61	4.61							± 0.18
	g/dl	13.5	13.4	13.5	13.5	13.5							± 0.5
HB HGB	g/l	135	134	135	135	135							± 5
	mmol/l	8.38	8.32	8.38	8.38	8.38							± 0.31
HT HCT	%	37.2	36.9	37.3	37.3	37.3							± 2.5
	l/l	0.372	0.369	0.373	0.373	0.373							± 0.025
VGM MCV	$\mu\text{m}^3 \cdot \text{fl}$	81	81	81	81	81							± 4
TGMH MCH	pg	29.4	29.5	29.3	29.3	29.3							± 2.0
	fmol	1.83	1.83	1.82	1.82	1.82							± 0.12
CCMH MCHC	g/dl	36.3	36.4	36.2	36.2	36.2							± 3.0
	g/l	363	364	362	362	362							± 30
	mmol/l	22.55	22.58	22.45	22.45	22.45							± 1.86
IDR RDW	%	14.0	13.5	14.0	14.0	14.0							± 3.0
PLAC. PLTS	$10^3/\text{mm}^3 \cdot 10^9/\text{l}$	263	260	268	268	268							± 40
VPM MPV	$\mu\text{m}^3 \cdot \text{fl}$	8.4	8.0	8.5	8.5	8.5							± 2.0
LYMPHO	#	2.81	2.71	2.77	2.77	2.77							± 0.40
	%	36.0	37.1	35.5	35.5	35.5							± 5.0
MONO	#	0.47	0.45	0.47	0.47	0.47							± 0.30
	%	6.0	6.2	6.0	6.0	6.0							± 4.0
GRANULO	#	4.52	4.15	4.56	4.56	4.56							± 0.60
	%	58.0	56.8	58.5	58.5	58.5							± 6.0

Ref: TEMP-0830 Rev.39 FRONT / RECTO 1300060626

PARAMETRES PARAMETERS	UNITES UNITS	MINILYSEBIO										TOLERANCES TOLERANCE			
		MICROS ES60	MICROS CRP 200	MICROS	MICROS	MICROS 60 RP - 60 IRP	ARGOS - HELIOS	PENTRA	PENTRA	PENTRA	PENTRA				
GB WBC	$10^3/mm^3 \cdot 10^9/l$	20.8	19.6			20.8									± 1.6
GR RBC	$10^6/mm^3 \cdot 10^{12}/l$	5.72	5.62			5.69									± 0.20
	g/dl	18.4	17.8			18.4									± 0.6
HB HGB	g/l	184	178			184									± 6
	mmol/l	11.43	11.05			11.43									± 0.37
HT HCT	%	50.3	49.5			50.1									± 3.0
	l/l	0.503	0.495			0.501									± 0.030
VGM MCV	$\mu m^3 \cdot fl$	88	88			88									± 4
	pg	32.2	31.7			32.3									± 2.0
TGMH MCH	fmol	2.00	1.97			2.01									± 0.12
	g/dl	36.6	36.0			36.7									± 3.0
CCMH MCHC	g/l	366	360			367									± 30
	mmol/l	22.70	22.35			22.82									± 1.86
IDR RDW	%	13.5	13.5			13.5									± 3.0
PLAQ_PLTS	$10^7/mm^3 \cdot 10^9/l$	565	545			574									± 45
VPM MPV	$\mu m^3 \cdot fl$	8.3	8.0			8.5									± 2.0
	#	3.74	3.64			3.74									± 1.00
LYMPHO	%	18.0	18.6			18.0									± 5.0
	#	0.83	1.27			0.83									± 0.80
MONO	%	4.0	6.5			4.0									± 4.0
	#	16.22	14.69			16.22									± 1.40
GRANULO	%	78.0	75.0			78.0									± 7.0

LOT: MX 421 H H CONTROL H

(Exp.)

2020-04-05
 (YYYY-MM-DD)