



CERTIFICATE OF CALIBRATION

Customer Name : Dr Kaushik Path Labs
Address of the customer : 1/2284, Main Mandir Road, Ramnagar, Sahadara
Instrument Model : BC 2800 - 3 Part Hematology Analyzer
Serial No. : RQ-42113214
Date of Installation : ...17/02/2014
Date of Calibration : 07/Mar/2022

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

The reference instruments used for value assignment are managed by the traceability system in Shenzhen Mindray Bio – Medical Electronics Co., Ltd, and these are traceable to the International Standards such as ICSH/WHO, NCCLS.

For AGAPPE DIAGNOSTICS LTD.



Vijender

Authorized Signatory
Name : Vijender Pratap Singh
Designation : Engineer - Customer Service

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

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DETAILS OF CONTROL RUN

Instrument Model : BC 2800 - 3 Part Hematology Analyzer
 Serial No : RQ-42113214
 Date of Control Run : 03/03/2022
 Control Used : D Check D Hematology Control (Vanguard Diagnostics Pvt. Limited)
 Lot No : 140301
 Expiry : 05/09/2022

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

Sample No	WBC K/ μ L	RBC M/ μ L	HGB g/dL	MCV fL	PLT K/ μ L
1	2.5	2.67	7.7	85.7	78
2	2.5	2.63	7.6	85.7	86
3	2.4	2.61	7.6	85.1	81
Instrument Mean	2.4	1.16	7.6	85.5	81
Range	0.06	0.03	0.06	0.35	4.04
CV %	2.34	1.16	0.76	0.41	4.95

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

The control run after calibration shows good repeatability and precision

Next Calibration due on **06/Sep/2022**

For **AGAPPE DIAGNOSTICS LTD.**

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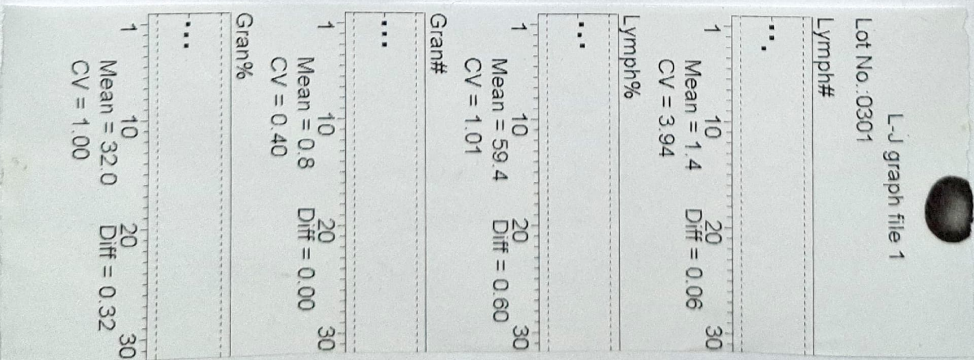
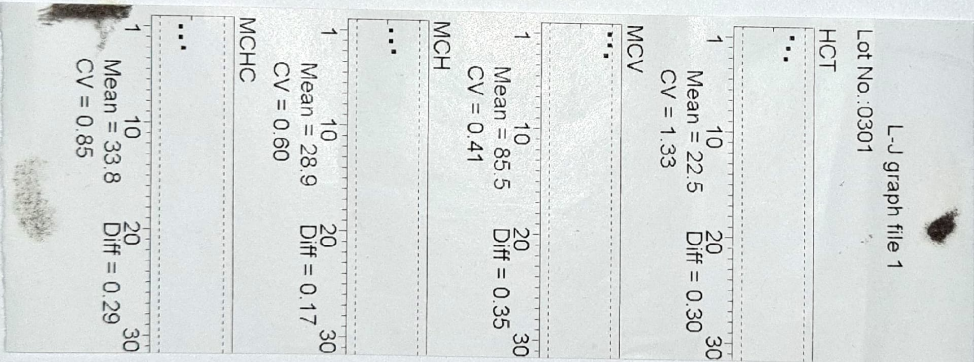
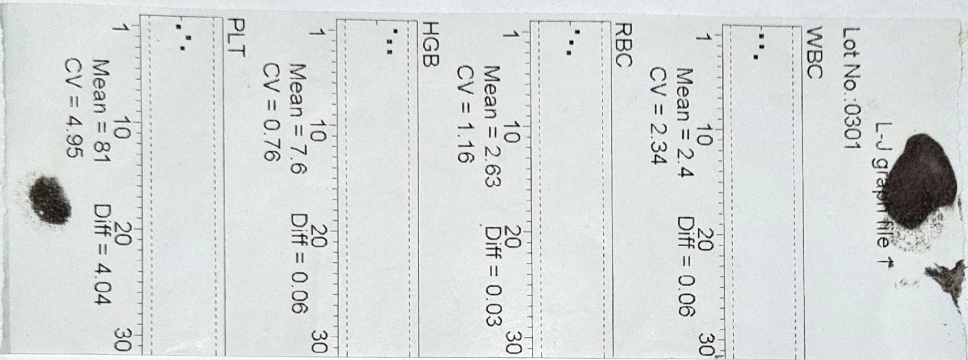
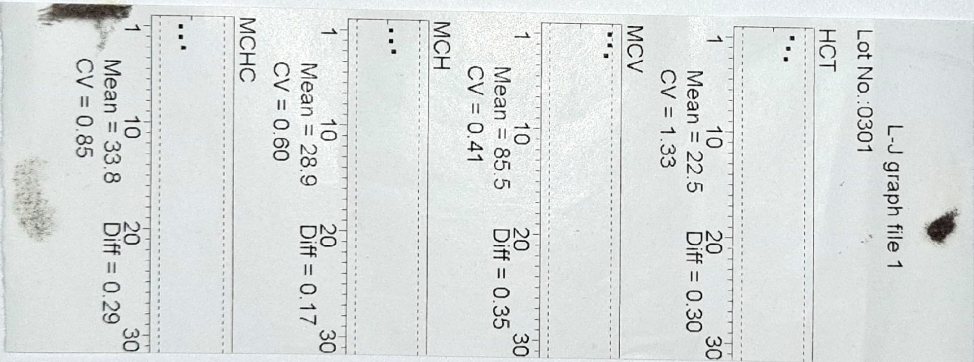
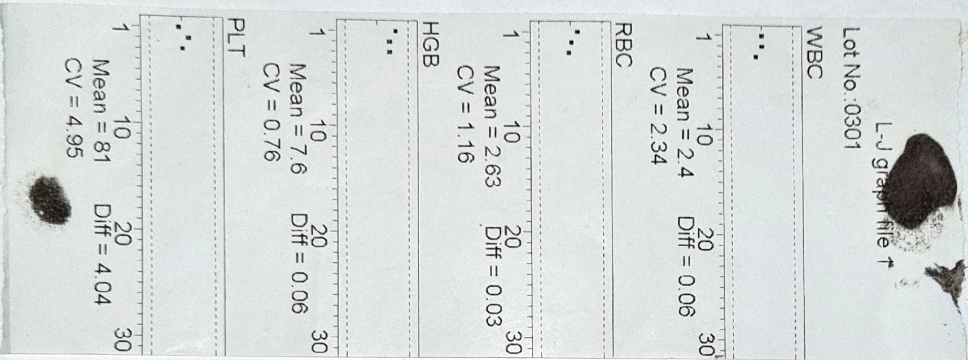
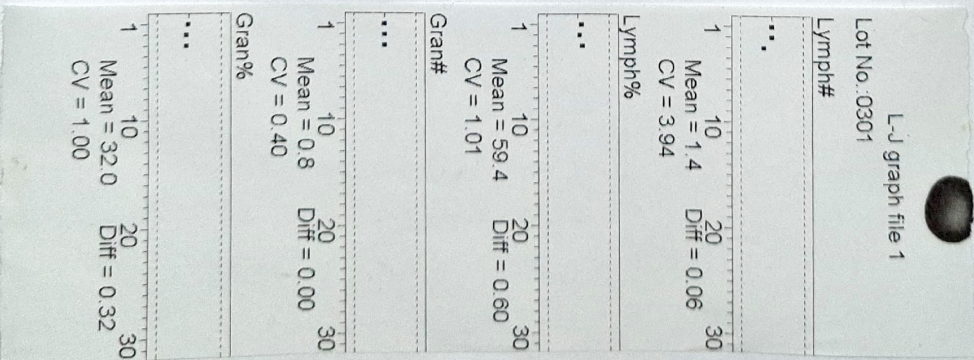
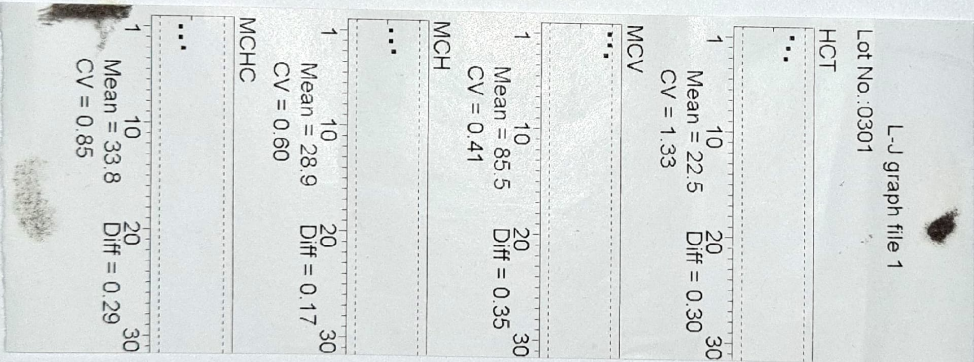
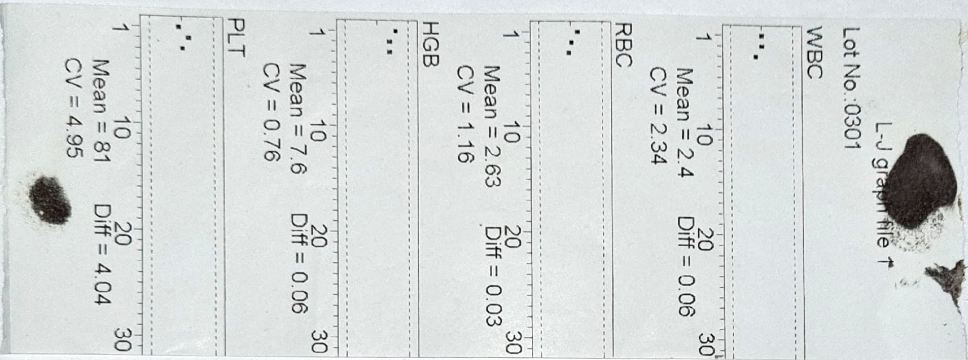
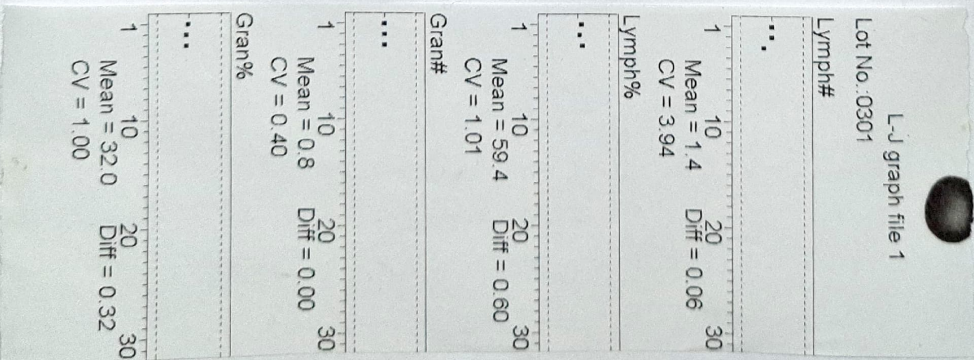
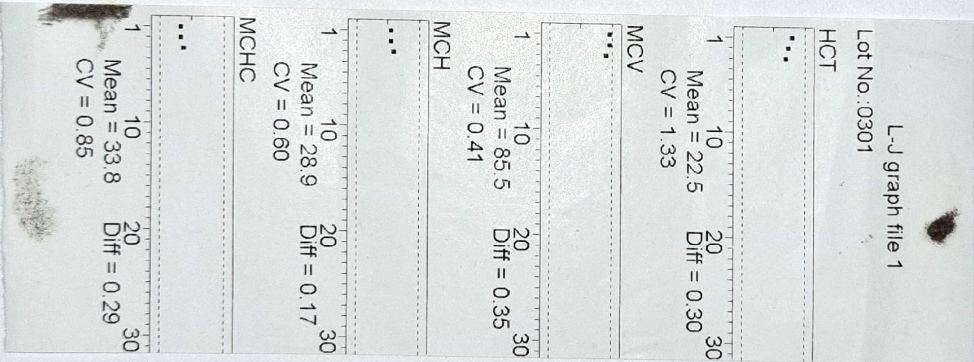
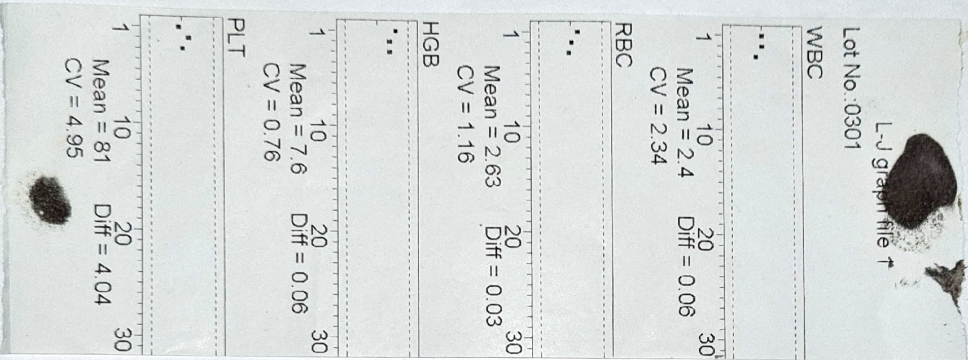
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QC Table 1			
No	1	2	3
Time	03-07	03-07	03-07
WBC	11:42	11:48	11:51
RBC	2.5	2.4	2.4
HGB	2.67	2.63	2.61
PLT	7.7	7.6	7.6
Lymph#	1.5	1.5	1.4
Lymph%	59.4	58.8	60.0
Gran#	0.8	0.8	0.8
Gran%	32.4	31.8	31.9
HCT	22.8	22.5	22.2
MCV	85.7	85.7	85.1
MCH	28.8	28.8	29.1
MCHC	33.7	33.7	34.2





D-Check D

CONTROL

ASSAY VALUES AND EXPECTED RANGES

Vizsgálati értékek és várható tartományok

LOT: 1V0301



05-09-2022

Instruments:		Diagon D-Cell 60, D-Cell 60CS; Mindray BC-3200, BC-3000Plus, BC-2900, BC-2800, BC-1800					
Parameter		CONTROL "Low"		CONTROL "Normal"		CONTROL "High"	
		LOT: 1V0301		LOT: 1V0301		LOT: 1V0301	
		Mean ± Limit	Range Variation	Mean ± Limit	Range Variation	Mean ± Limit	Range Variation
WBC	10 ⁹ /L	2,5 ± 0,5	2,0 - 3,0	8,5 ± 1,0	7,5 - 9,5	18,7 ± 2,5	16,2 - 21,2
RBC	10 ¹² /L	2,62 ± 0,20	2,42 - 2,82	4,54 ± 0,30	4,24 - 4,84	5,70 ± 0,40	5,30 - 6,10
Hgb	g/dL	7,4 ± 0,5	6,9 - 7,9	13,4 ± 0,6	12,8 - 14,0	17,7 ± 0,8	16,9 - 18,5
	g/L	74 ± 5	69 - 79	134 ± 6	128 - 140	177 ± 8	169 - 185
Hct	%	21,0 ± 3,0	18,0 - 24,0	38,3 ± 4,0	34,3 - 42,3	50,9 ± 4,5	46,4 - 55,4
	L/L	0,210 ± 0,030	0,180 - 0,240	0,383 ± 0,040	0,343 - 0,423	0,509 ± 0,045	0,464 - 0,554
MCV	fL	80,2 ± 6,0	74,2 - 86,2	84,5 ± 6,0	78,5 - 90,5	89,3 ± 6,0	83,3 - 95,3
MCH	pg	28,3 ± 3,8	24,5 - 32,1	29,4 ± 3,8	25,6 - 33,2	31,0 ± 3,8	27,2 - 34,8
MCHC	g/dL	35,3 ± 4,8	30,5 - 40,1	34,8 ± 4,8	30,0 - 39,6	34,7 ± 4,8	29,9 - 39,5
	g/L	353 ± 48	305 - 401	348 ± 48	300 - 396	347 ± 48	299 - 395
RDW-SD	fL	42,0 ± 8,0	34,0 - 50,0	44,1 ± 9,0	35,1 - 53,1	47,3 ± 10,0	37,3 - 57,3
RDW-CV	%	14,6 ± 5,0	9,6 - 19,6	14,9 ± 5,0	9,9 - 19,9	15,1 ± 5,0	10,1 - 20,1
Pit	10 ⁹ /L	80 ± 25	55 - 105	230 ± 45	185 - 275	463 ± 65	398 - 528
MPV	fL	11,6 ± 3,0	8,6 - 14,6	11,5 ± 3,0	8,5 - 14,5	11,6 ± 3,0	8,6 - 14,6
PDW	%	13,4 ± 3,0	10,4 - 16,4	13,4 ± 3,0	10,4 - 16,4	13,4 ± 3,0	10,4 - 16,4
PCT	%	0,092 ± 0,050	0,042 - 0,142	0,265 ± 0,100	0,165 - 0,365	0,536 ± 0,200	0,336 - 0,736
LYMPH#	10 ⁹ /L	1,5 ± 0,4	1,1 - 1,9	2,8 ± 1,0	1,8 - 3,8	4,3 ± 2,4	1,9 - 6,7
MID#	10 ⁹ /L	0,2 ± 0,2	0,0 - 0,4	1,0 ± 0,8	0,2 - 1,8	2,6 ± 2,0	0,6 - 4,6
GRAN#	10 ⁹ /L	0,8 ± 0,3	0,5 - 1,1	4,7 ± 0,7	4,0 - 5,4	11,8 ± 3,5	8,3 - 15,3
LYMPH%	%	57,6 ± 14,4	43,2 - 72,0	32,5 ± 11,4	21,1 - 43,9	23,3 ± 8,1	15,2 - 31,4
MID%	%	9,7 ± 7,3	2,4 - 17,0	12,7 ± 10,1	2,6 - 22,8	13,9 ± 11,2	2,7 - 25,1
GRAN%	%	32,7 ± 11,4	21,3 - 44,1	54,8 ± 16,4	38,4 - 71,2	62,8 ± 18,8	44,0 - 81,6

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IVD

