

Performance Report

Sr. No.	Description
1.	<p data-bbox="581 800 1187 905">VDx Reagents – Nihon Kohden 3 Part Hematology Analyzers</p> <p data-bbox="849 974 922 1024">v/s</p> <p data-bbox="524 1104 1247 1209">Reference Reagents – Nihon Kohden 3 Part Hematology Analyzer</p>

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Details of Reagents

Type of Reagents	3 Part Hematology Reagents
Instrument Model	Nihon Kohden - Celltac α
Reference Reagents	Nihon Kohden Reference Reagents
Diluent	Lot No : 225422 Expiry Date: 02-2024
Hemolynac-3N	Lot No : 225354 Expiry Date: 01-2024

Details of Tests Conducted

Sr. No.	Tests Conducted
1	Background Test
2	Coefficient of Correlation: Accuracy
3	Quality Control (Low, Normal & High)
4	Coefficient of Variation: Precision (VDx Genius Compatible reagents)
5	Coefficient of Variation: Precision (Genius Reference reagents)

Background

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot- HVDNK221011 VDx Lyse-NK Lot- HVLNK221002 VDx Cleaner-NK Lot- HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot-225422 Hemolynac-3N Lot-225354
WBC (10 ³ /μL)	0.0	0.0
RBC (10 ⁶ /μL)	0.0	0.0
HGB (g/dL)	0.0	0.0
HCT (%)	0.0	0.0
MCV (fL)	0.0	0.0
MCH (pg)	0.0	0.0
MCHC (g/dL)	0.0	0.0
PLT (10 ³ /μL)	0.0	0.0
Lym #	0.0	0.0
Mon#	0.0	0.0
Gran#	0.0	0.0
Lym%	0.0	0.0
Mon%	0.0	0.0
Gran%	0.0	0.0
RDW (%)	0.0	0.0
PCT (%)	0.0	0.0
MPV (fL)	0.0	0.0
PDW (%)	0.0	0.0

Coefficient of Correlation Studies

- I. The objective was to determine the correlation between the results obtained with the developed Vanguard compatible Nihon Kohden reagent and the Reference Nihon Kohden reagents.
- II. The Coefficient of Correlation (“r”) was calculated for each major parameter of the Complete Blood Count.
- III. The data has been presented in the form of:
 - 1 Sample size
 - 2 Mean x (\bar{x})
 - 3 Mean y (\bar{y})
 - 4 Intercept (a)
 - 5 Slope (b)
 - 6 Regression line equation
 - 7 Value of “r”
 - 8 Linear Regression Graph
 - 9 Raw Data of values
 - 10 Histograms will be made available at the time of visit

Note: The correlation coefficient, is a numerical value between -1 and 1 that expresses the strength of the linear relationship between two variables. When “r” is closer to 1 it indicates a strong positive relationship. A value of 0 indicates that there is no relationship. Values close to -1 signal a strong negative relationship between the two variables.

Correlation coefficient formula: There are many formulas to calculate the correlation coefficient (all yielding the same result). We used the following:

$$r = \frac{n \sum_{i=1}^n x_i y_i - \sum_{i=1}^n x_i \sum_{i=1}^n y_i}{\sqrt{(n \sum_{i=1}^n x_i^2 - (\sum_{i=1}^n x_i)^2)(n \sum_{i=1}^n y_i^2 - (\sum_{i=1}^n y_i)^2)}}$$

Where n is the total number of samples, x_i (x_1, x_2, \dots, x_n) are the x values and y_i are the y values.

Coefficient of Correlation (“r”): WBC

x = Nihon Kohden Reference Reagents for Celltac α, 3 Part Hematology Analyzer.
y = VDX Reagents for Celltac α, 3 Part Hematology Analyzer.

$$“r” = 0.987$$

Sample size: 9

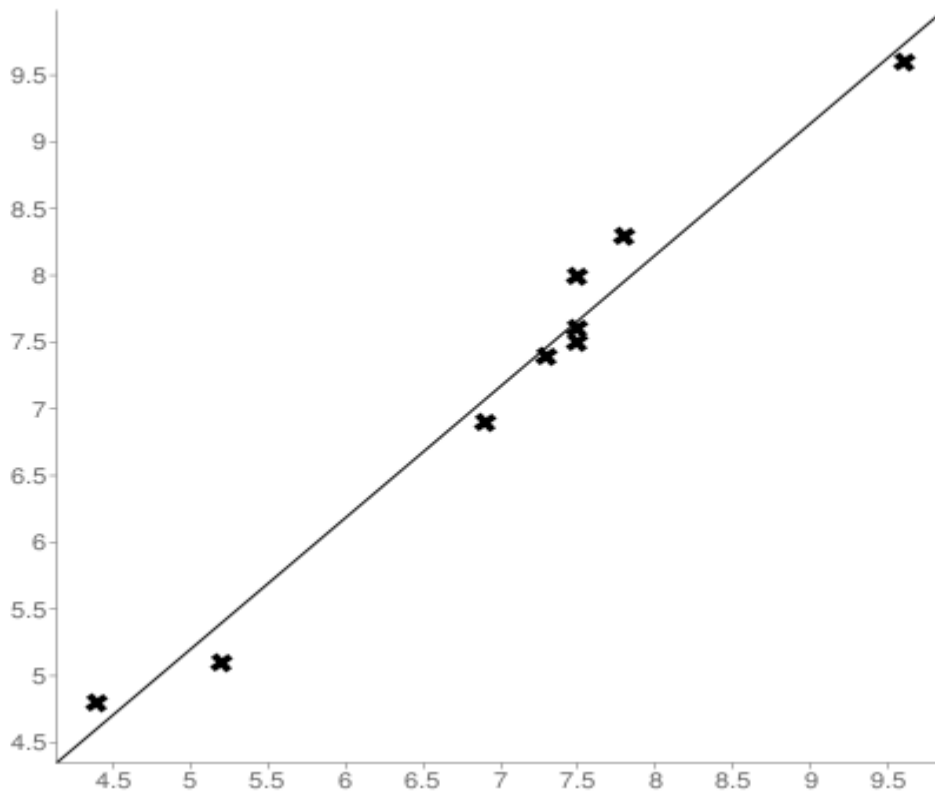
Mean x (\bar{x}): 7.07777777777778

Mean y (\bar{y}): 7.24444444444444

Intercept (a): 0.26261602344897

Slope (b): 0.98644357596482

Regression line equation: $y=0.26261602344897+0.98644357596482x$

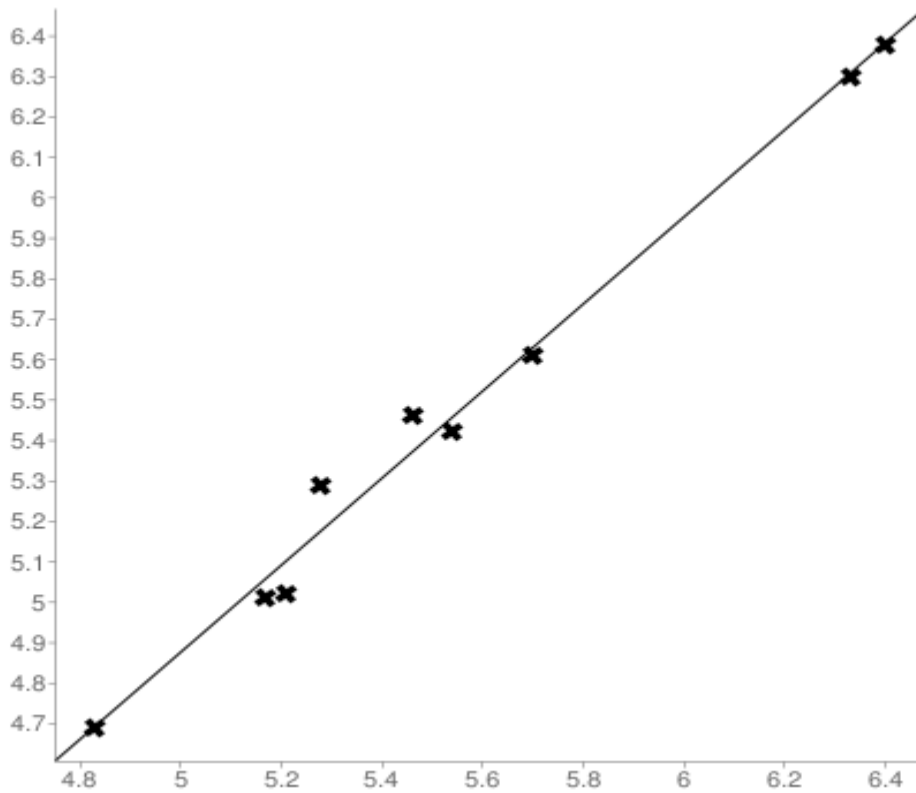


Coefficient of Correlation (“r”): RBC

x = Nihon Kohden Reference Reagents for Celltac α, 3 Part Hematology Analyzer.
y = VDX Reagents for Celltac α, 3 Part Hematology Analyzer.

“r” = 0.993

Sample size: 9
Mean x (\bar{x}): 5.54666666666667
Mean y (\bar{y}): 5.46444444444444
Intercept (a): -0.50417128625391
Slope (b): 1.0760725476019
Regression line equation: $y = 1.0760725476019x - 0.50417128625391$



Coefficient of Correlation (“r”): Hemoglobin

x = Nihon Kohden Reference Reagents for Celltac α, 3 Part Hematology Analyzer.
y = VDX Reagents for Celltac α, 3 Part Hematology Analyzer.

$$“r” = 0.997$$

Sample size: 9

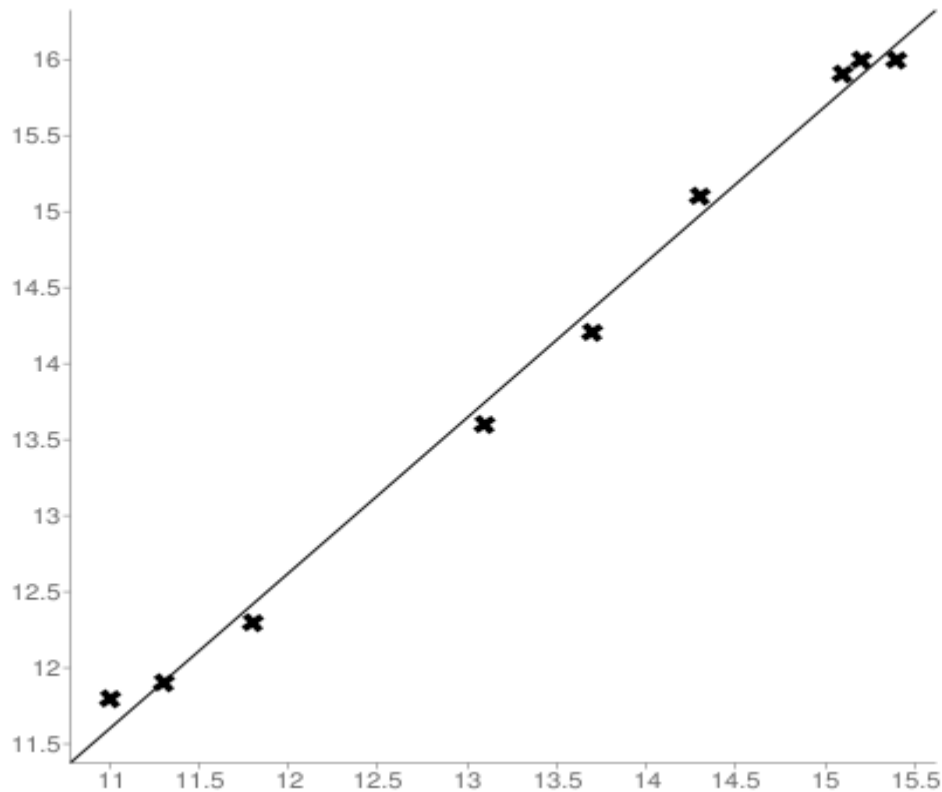
Mean x (\bar{x}): 13.4333333333333

Mean y (\bar{y}): 14.0888888888889

Intercept (a): 0.34939876957523

Slope (b): 1.0227908277405

Regression line equation: $y=0.34939876957523+1.0227908277405x$

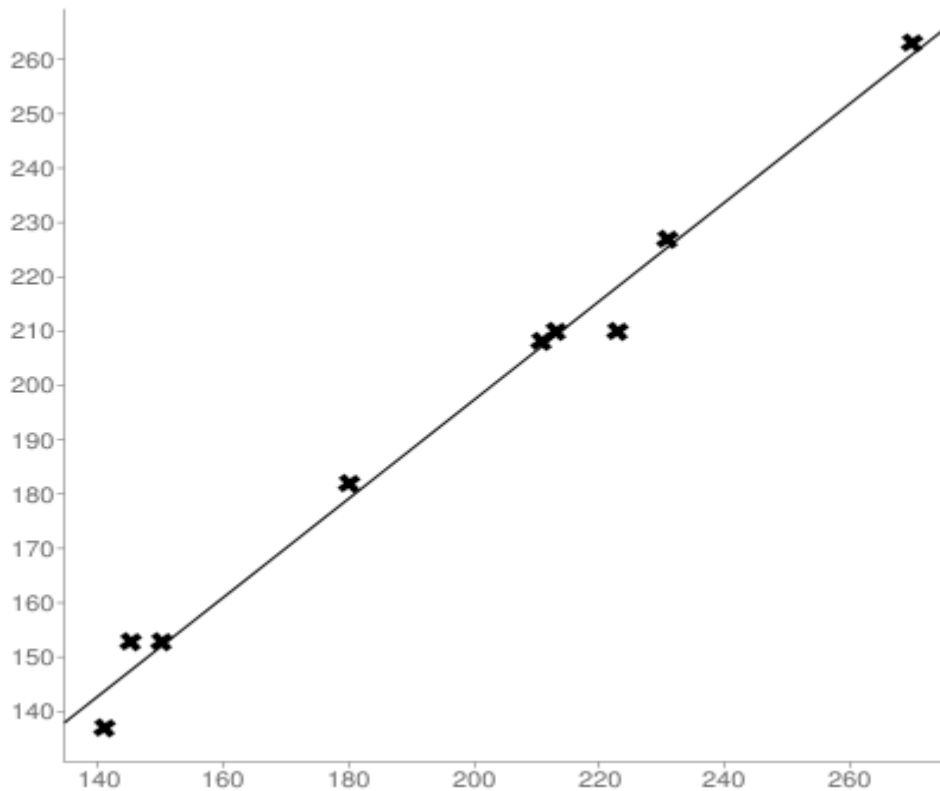


Coefficient of Correlation (“r”): Platelets

x = Nihon Kohden Reference Reagents for Celltac α, 3 Part Hematology Analyzer.
y = VDX Reagents for Celltac α, 3 Part Hematology Analyzer.

$$“r” = 0.993$$

Sample size: 9
Mean x (\bar{x}): 196
Mean y (\bar{y}): 193.66666666667
Intercept (a): 15.653619370217
Slope (b): 0.90822983314515
Regression line equation: $y = 15.653619370217 + 0.90822983314515x$



Coefficient of Correlation (“r”): MCV

x = Nihon Kohden Reference Reagents for Celltac α, 3 Part Hematology Analyzer.
y = VDX Reagents for Celltac α, 3 Part Hematology Analyzer.

“r” = 0.998

Sample size: 9

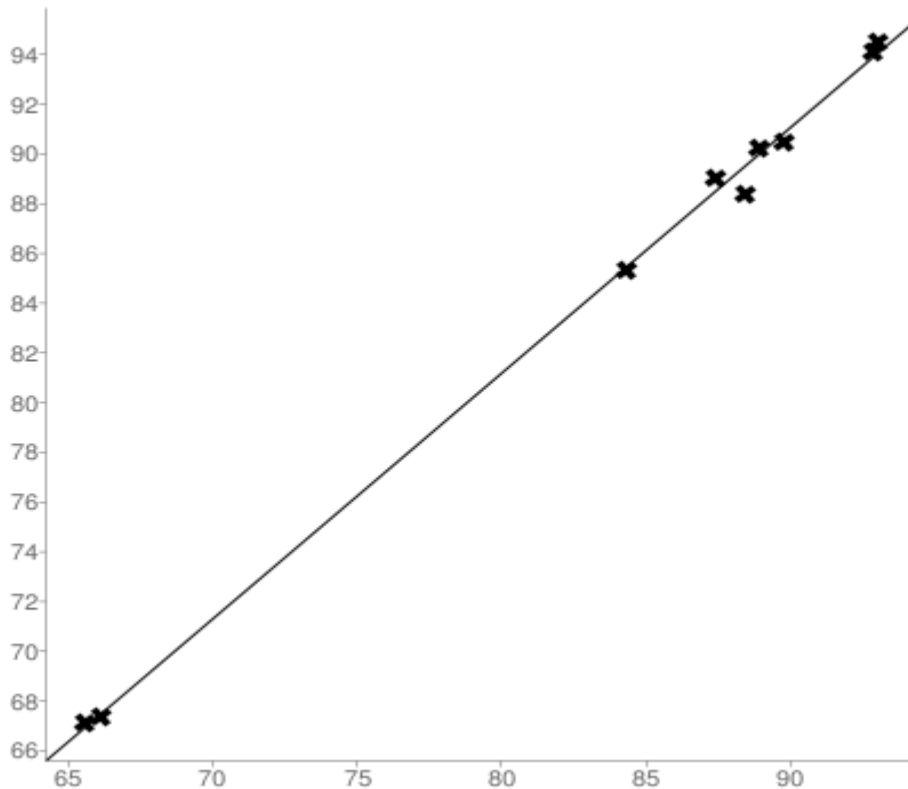
Mean x (\bar{x}): 84.044444444444

Mean y (\bar{y}): 85.166666666667

Intercept (a): 2.1377009693544

Slope (b): 0.98791736022714

Regression line equation: $y = 2.1377009693544 + 0.98791736022714x$



Coefficient of Correlation (“r”): HCT

x = Nihon Kohden Reference Reagents for Celltac α, 3 Part Hematology Analyzer.
y = VDX Reagents for Celltac α, 3 Part Hematology Analyzer.

$$“r” = 0.987$$

Sample size: 9

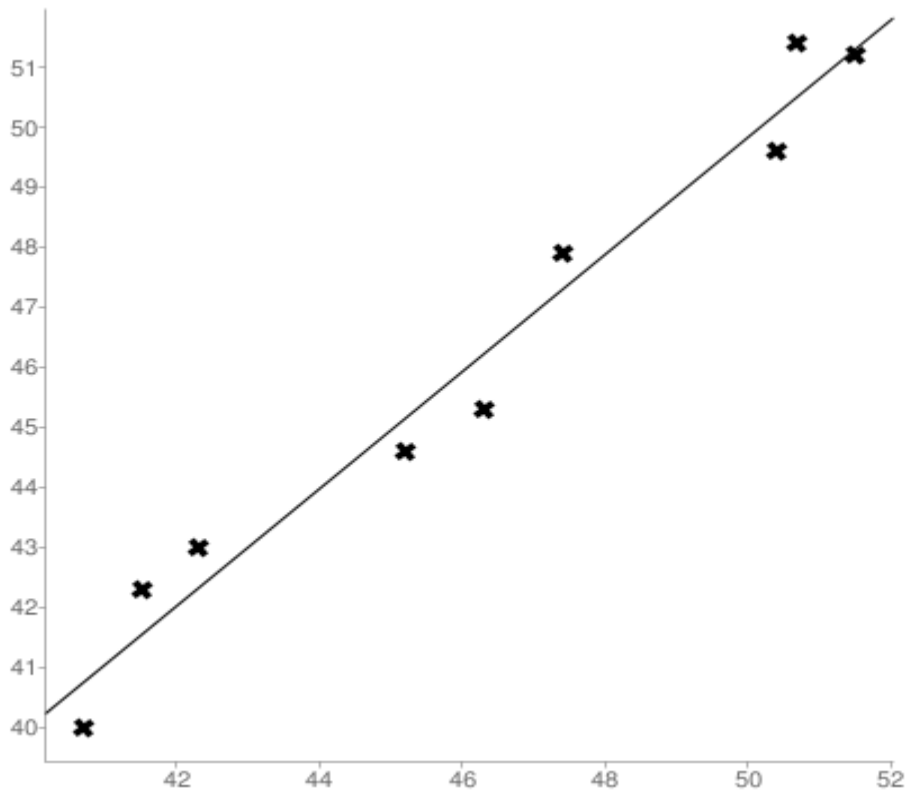
Mean x (\bar{x}): 46.222222222222

Mean y (\bar{y}): 46.144444444444

Intercept (a): 1.052301884325

Slope (b): 0.97555116115643

Regression line equation: $y = 1.052301884325 + 0.97555116115643x$



Performance with Hematology 3rd Part Controls

Diagon D Check D

Low, Normal & High Controls

Lot No : 1V0901

Expiry : 05.03.2023

Diagon D Check D
(Low Control, Lot - 1V0901, Exp.- 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot- HVDNK221011 VDx Lyse-NK Lot- HVLNK221002 VDx Cleaner-NK Lot- HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot-225422 Hemolynac-3N Lot-225354	Range
WBC (10 ³ /μL)	2.5	2.4	1.8 - 2.8
RBC (10 ⁶ /μL)	2.53	2.51	2.32 - 2.72
HGB (g/dL)	6.9	6.4	6.5 - 7.5
HCT (%)	21.5	20.5	18.6 - 24.6
MCV (fL)	85.0	81.7	79.7 - 91.7
MCH (pg)	27.3	25.5	24.1 - 31.7
MCHC (g/dL)	32.1	31.2	27.7 - 37.3
PLT (10 ³ /μL)	70	70	51 - 101
Lym #	1.6	1.5	NA
Mon#	0.2	0.2	NA
Gran#	0.7	0.7	NA
Lym%	63.8	62.6	NA
Mon%	8.3	7.3	NA
Gran%	27.9	30.1	NA
RDW (%)	18.1	18.6	11.9 - 21.9
PCT (%)	0.08	0.07	NA
MPV (fL)	10.8	10.6	4.4 - 10.4
PDW (%)	13.5	14.3	11.7 - 17.7

Diagon D Check D
(Normal Control, Lot - 1V0901, Exp.- 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot- HVDNK221011 VDx Lyse-NK Lot- HVLNK221002 VDx Cleaner-NK Lot- HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot-225422 Hemolynac-3N Lot-225354	Range
WBC (10 ³ /μL)	7.2	7.1	6.0 - 8.0
RBC (10 ⁶ /μL)	4.56	4.47	4.26 - 4.86
HGB (g/dL)	13.6	12.7	12.8 - 14.0
HCT (%)	40.7	38.5	36.6 - 45.6
MCV (fL)	89.3	86.1	82.9 - 96.9
MCH (pg)	29.8	28.4	25.5 - 33.1
MCHC (g/dL)	33.4	33.0	27.7 - 37.3
PLT (10 ³ /μL)	226	214	196 - 286
Lym #	3.2	3.0	NA
Mon#	0.3	0.3	NA
Gran#	3.7	3.8	NA
Lym%	43.8	42.7	NA
Mon%	4.5	4.7	NA
Gran%	51.7	52.6	NA
RDW (%)	17.2	17.6	11.4 - 21.4
PCT (%)	0.24	0.21	NA
MPV (fL)	10.4	10.0	4.6 - 10.6
PDW (%)	12.5	12.9	10.3 - 16.3

Diagon D Check D
(High Control, Lot - 1V0901, Exp.- 05.03.2023)

Parameters	All Reagents: Vanguard Diagnostics VDx Diluent-NK Lot- HVDNK221011 VDx Lyse-NK Lot- HVLNK221002 VDx Cleaner-NK Lot- HVRNK220905	All Reagents: Nihon Kohden as Reference Diluent Lot-225422 Hemolynac-3N Lot-225354	Range
WBC (10 ³ /μL)	17.7	17.7	14.4 - 19.4
RBC (10 ⁶ /μL)	5.59	5.54	5.13 - 5.93
HGB (g/dL)	17.5	16.8	16.4 - 18.0
HCT (%)	53.0	51.0	47.6 - 56.6
MCV (fL)	94.8	92.1	87.2 - 101.2
MCH (pg)	31.3	30.3	27.3 - 34.9
MCHC (g/dL)	33.0	32.9	28.2 - 37.8
PLT (10 ³ /μL)	488	483	447 – 617
Lym #	6.0	6.3	NA
Mon#	0.7	0.7	NA
Gran#	11.0	10.7	NA
Lym%	34.0	17.4	NA
Mon%	4.0	0.5	NA
Gran%	62.0	57.9	NA
RDW (%)	17.2	15.5	11.1 - 21.1
PCT (%)	0.55	0.22	NA
MPV (fL)	11.3	15.7	4.7 - 10.7
PDW (%)	11.2	16.3	10.3 - 16.3

D-Check D

CONTROL

ASSAY VALUES AND EXPECTED RANGES

Vizsgálati értékek és várható tartományok

LOT: 1V0901**05-03-2023**

Instruments:		NIHON KOHDEN MEK-7222 (1)					
Parameter		CONTROL "Low"		CONTROL "Normal"		CONTROL "High"	
		LOT: 1V0901		LOT: 1V0901		LOT: 1V0901	
		Mean ± Limit	Range Variation	Mean ± Limit	Range Variation	Mean ± Limit	Range Variation
WBC	10 ⁹ /L	2,3 ± 0,5	1,8 - 2,8	7,0 ± 1,0	6,0 - 8,0	16,9 ± 2,5	14,4 - 19,4
RBC	10 ¹² /L	2,52 ± 0,20	2,32 - 2,72	4,56 ± 0,30	4,26 - 4,86	5,53 ± 0,40	5,13 - 5,93
Hgb	g/dL	7,0 ± 0,5	6,5 - 7,5	13,4 ± 0,6	12,8 - 14,0	17,2 ± 0,8	16,4 - 18,0
	g/L	70 ± 5	65 - 75	134 ± 6	128 - 140	172 ± 8	164 - 180
Hct	%	21,6 ± 3,0	18,6 - 24,6	41,1 ± 4,5	36,6 - 45,6	52,1 ± 4,5	47,6 - 56,6
	L/L	0,216 ± 0,030	0,186 - 0,246	0,411 ± 0,045	0,366 - 0,456	0,521 ± 0,045	0,476 - 0,566
MCV	fL	85,7 ± 6,0	79,7 - 91,7	89,9 ± 7,0	82,9 - 96,9	94,2 ± 7,0	87,2 - 101,2
MCH	pg	27,9 ± 3,8	24,1 - 31,7	29,3 ± 3,8	25,5 - 33,1	31,1 ± 3,8	27,3 - 34,9
MCHC	g/dL	32,5 ± 4,8	27,7 - 37,3	32,5 ± 4,8	27,7 - 37,3	33,0 ± 4,8	28,2 - 37,8
	g/L	325 ± 48	277 - 373	325 ± 48	277 - 373	330 ± 48	282 - 378
RDW-CV	%	16,9 ± 5,0	11,9 - 21,9	16,4 ± 5,0	11,4 - 21,4	16,1 ± 5,0	11,1 - 21,1
Plt	10 ⁹ /L	76 ± 25	51 - 101	241 ± 45	196 - 286	532 ± 85	447 - 617
MPV	fL	7,4 ± 3,0	4,4 - 10,4	7,6 ± 3,0	4,6 - 10,6	7,7 ± 3,0	4,7 - 10,7
PDW	%	14,7 ± 3,0	11,7 - 17,7	13,3 ± 3,0	10,3 - 16,3	13,3 ± 3,0	10,3 - 16,3

(1) Assay Values were obtained on analyzer using DIAGON reagents.

(1) DIAGON reagensek használata során kapott értékek.


 DIAGON Ltd.
 48-52., Baross Str.
 Budapest, Hungary
 H-1047


Coefficient of Variation:

Precision (VDx Reagent)

1. Fresh blood sample was collected and tested with the VDx Nihon Kohden Reagents on Celltac alpha, 3 Part Hematology Analyzer.
2. The sample was tested in 06 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh Blood Sample, n = 06

Precision Evaluation report of VDx Nihon Kohden compatible reagent on Celltac alpha, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC (10 ³ /μL)	4.8	4.6	4.8	4.5	4.6	4.5					4.63	0.14	0.03	2.95
RBC (10 ⁶ /μL)	5.07	5	5.03	4.98	5.02	5.03					5.02	0.03	0.01	0.61
HGB (g/dL)	13.6	13.5	13.6	13.4	13.5	13.5					13.52	0.08	0.01	0.56
HCT (%)	45	44.5	44.5	44.4	44.7	44.7					44.63	0.22	0.00	0.48
MCV (fL)	88.8	89	88.5	89.2	89	88.9					88.90	0.24	0.00	0.27
MCH (pg)	26.8	27	27	26.90	26.90	26.80					26.90	0.09	0.00	0.33
MCHC (g/dL)	30.2	30.3	30.6	30.20	30.20	30.20					30.28	0.16	0.01	0.53
PLT (10 ³ /μL)	146	143	138	141	142	149					143.17	3.87	0.03	2.70
Lym #	1.8	1.9	1.8	1.8	1.9	1.7					1.82	0.08	0.04	4.14
Mon#	0.3	0.3	0.3	0.3	0.3	0.3					0.30	0.00	0.00	0.00
Gran#	2.5	2.4	2.7	2.4	2.4	2.5					2.48	0.12	0.05	4.71
Lym%	40.2	40.6	37.3	41.0	40.4	37.7					39.53	1.60	0.04	4.05
Mon%	6.5	6.0	6.3	6.5	6.4	6.5					6.37	0.20	0.03	3.09
Gran%	53.3	53.4	56.4	51.9	53.2	55.8					54.00	1.73	0.03	3.20
RDW (%)	15.7	15.6	15.6	15.7	15.9	15.2					15.62	0.23	0.01	1.48
PCT (%)	0.28	0.28	0.27	0.26	0.27	0.28					0.27	0.01	0.03	2.99
MPV (fL)	19.30	19.7	19.8	19.6	18.7	19					19.35	0.43	0.02	2.23
PDW (%)	16.00	16.20	16.00	16.20	16.00	16.00					16.07	0.10	0.01	0.64

Coefficient of Variation:

Precision (Nihon Kohden Reference Reagent)

1. Fresh blood sample was collected and tested with the Nihon Kohden Reference Reagents on Celltac alpha, 3 Part Hematology Analyzer.
2. The sample was tested in 07 replicates to study Precision.
3. Coefficient of Variation (CV %) was calculated.

Fresh, Blood Sample No- 1, n = 07

Precision Evaluation report of Reference Nihon Kohden reagent on Celltac alpha, 3 Part Hematology Analyzer														
Fresh Blood Sample														
Parameters	Ist	IIInd Repeat	IIIrd Repeat	IVth Repeat	Vth Repeat	VIth Repeat	VIIth Repeat	VIIIth Repeat	IXth Repeat	Xth Repeat	Mean	SD	CV	CV%
WBC (10 ³ /μL)	4.5	4.6	4.6	4.6	4.6	4.7	4.6				4.60	0.06	0.01	1.26
RBC (10 ⁶ /μL)	5.05	5.08	5.1	5.04	5.05	5.08	5.1				5.07	0.02	0.00	0.49
HGB (g/dL)	12.8	12.8	12.8	12.9	12.8	13.0	12.9				12.86	0.08	0.01	0.61
HCT (%)	43.8	44.2	44.4	44	44	44.4	44.6				44.20	0.28	0.01	0.64
MCV (fL)	86.7	87	87.1	87.3	87.1	87.4	87.5				87.16	0.27	0.00	0.31
MCH (pg)	25.3	25.2	25.1	25.6	25.3	25.6	25.3				25.34	0.19	0.01	0.75
MCHC (g/dL)	29.2	29	28.8	29.3	29.1	29.3	28.9				29.09	0.20	0.01	0.67
PLT (10 ³ /μL)	162	153	161	165	170	168	168				163.86	5.81	0.04	3.55
Lym #	1.7	1.7	1.6	1.7	1.7	1.7	1.8				1.70	0.06	0.03	3.40
Mon#	0.3	0.3	0.3	0.3	0.3	0.3	0.3				0.30	0.00	0.00	0.00
Gran#	2.5	2.6	2.7	2.6	2.6	2.7	2.4				2.59	0.11	0.04	4.13
Lym%	37.9	37.3	35.6	37.2	37.4	36.7	38.3				37.20	0.87	0.02	2.34
Mon%	6.3	6.6	6.5	7.0	7.0	6.6	6.6				6.66	0.26	0.04	3.86
Gran%	55.8	56.1	57.9	55.8	55.6	56.7	54.8				56.10	0.98	0.02	1.74
RDW (%)	15.8	15.8	15.8	15.5	15.2	15.7	15.1				15.56	0.30	0.02	1.92
PCT (%)	0.32	0.29	0.29	0.32	0.32	0.30	0.30				0.31	0.01	0.05	4.57
MPV (fL)	19.5	18.6	18.0	19.3	18.8	17.7	17.8				18.53	0.72	0.04	3.89
PDW (%)	16.5	15.9	16.3	16.0	16.0	16.7	16.7				16.30	0.34	0.02	2.10

Conclusions

1. The VDX Nihon Kohden 3 Part Hematology Reagents showed an excellent Coefficient of Correlation (“r”) using Nihon Kohden Original reagents as Reference.
2. All Measurable parameters showed values of “r” in the range of **0.987 to 0.998** displaying the highest degree of correlation between the reagents.
3. The VDX Nihon Kohden and the Nihon Kohden Reference 3 Part Hematology Reagents showed an excellent coefficient of Variation (CV %) for all parameters.
4. The CV % of Precision with the VDX Nihon Kohden reagents and the Nihon Kohden Reference reagents for the parameters are mentioned below.

Parameters	Nihon Kohden Reference Reagents (CV % of Precision)	VDx Nihon Kohden Reagents (CV % of Precision)
Measured Parameters	0.31% – 3.55%	0.27% - 2.95%
Calculated Parameters	0.00% - 4.57%	0.33% - 4.71%

5. Values obtained with 3rd Party controls from Diagon Hungary- Low, Normal & High were found to be within the specified ranges both for VDX Nihon Kohden 3 Part Hematology Reagents and Nihon Kohden Reference reagents.
6. **The VDX Nihon Kohden 3 Part Hematology Reagents were found to be accurate, precise and comparable with the Nihon Kohden reference reagents in all parameters identified for the evaluation.**