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EIGHTCHECK-3WP ASSAY SHEET

Normal Level

LOT **9005 0822**

13-Apr-2019

Model		WBC	RBC	HGB		HCT	MCV	MCH		MCHC		PLT
		[10^3/μL]	[10^6/μL]	[g/dL]	[mmol/L]	[%]	[fL]	[pg]	[amol]	[g/dL]	[mmol/L]	[10^3/uL]
K-800 K-1000	Range	8.5	4.55	12.9	8.0	36.9	82.3	29.8	1851	38.2	23.7	261
		7.3	4.25	12.1	7.6	32.1	74.5	27.0	1675	34.2	21.3	193
K-4500 [1)]	Mean	7.9	4.40	12.5	7.8	34.5	78.4	28.4	1763	36.2	22.5	227
	Limit %	8.0	3.50	3.0	3.0	7.0	5.0	5.0	5.0	5.5	5.5	15
K-4500 Closed Mode	Range	8.5	4.62	13.0	8.1	37.1	82.3	30.1	1869	38.9	24.2	253
		6.5	4.18	12.0	7.5	31.9	74.5	26.7	1657	33.5	20.8	187
	Mean	7.5	4.40	12.5	7.8	34.5	78.4	28.4	1763	36.2	22.5	220
	Limit %	13.0	5.00	4.0	4.0	7.5	5.0	6.0	6.0	7.5	7.5	15
KX-21N KX-21	Range	8.0	4.53	13.0	8.0	36.9	82.6	30.5	1893	39.3	24.4	260
		7.0	4.19	12.2	7.6	31.7	74.8	27.3	1695	34.1	21.2	192
	Mean	7.5	4.36	12.6	7.8	34.3	78.7	28.9	1794	36.7	22.8	226
	Limit %	7.0	4.00	3.0	3.0	7.5	5.0	5.5	5.5	7.0	7.0	15
	Limit #	0.5	0.17	0.4	0.2	2.6	3.9	1.6	99	2.6	1.6	34
pocH-100i	Range	7.8	4.73	12.8	8.0	39.0	85.0	28.7	1783	36.2	22.5	260
		6.6	4.27	11.6	7.2	33.2	75.4	25.5	1581	31.4	19.5	192
	Mean	7.2	4.50	12.2	7.6	36.1	80.2	27.1	1682	33.8	21.0	226
	Limit %	9.0	5.00	5.0	5.0	8.0	6.0	6.0	6.0	7.0	7.0	15
	Limit #	0.6	0.23	0.6	0.4	2.9	4.8	1.6	101	2.4	1.5	34
XP series	Range	7.8	4.52	12.7	7.8	36.3	81.6	29.9	1853	38.9	24.2	265
		6.8	4.18	11.9	7.4	31.3	73.8	26.7	1659	33.9	21.0	195
	Mean	7.3	4.35	12.3	7.6	33.8	77.7	28.3	1756	36.4	22.6	230
	Limit %	7.0	4.00	3.0	3.0	7.5	5.0	5.5	5.5	7.0	7.0	15
	Limit #	0.5	0.17	0.4	0.2	2.5	3.9	1.6	97	2.5	1.6	35

Model		W-SCR/ LYM [%]	W-MCR/ MXD [%]	W-LCR/ NEUT [%][2)]	W-SCC/ LYM [10^3/μL][2]	W-MCC/ MXD [10^3/μL][2]	W-LCC/ NEUT [10^3/μL][2)]	W-SMV [fL]	W-LMV [fL]	RDW-CV [%]	RDW-SD [fL]	PDW [fL]	MPV [fL]	P-LCR [%]	PCT [%]
K-1000 K-4500 [1)]	Range	31.1	12.8	64.0	2.5	1.0	5.2	62.3	199.0	13.9	31.7	9.1	10.5	27.0	
		27.1	9.4	55.6	2.1	0.8	4.2	43.3	169.6	10.3	23.5	7.5	8.9	9.0	
	Mean	29.1	11.1	59.8	2.3	0.9	4.7	52.8	184.3	12.1	27.6	8.3	9.7	18.0	
	Limit %	7.0	15.0	7.0	10.0	15.0	10.0	18.0	8.0	15.0	15.0	10.0	8.0	50.0	
K-4500 Closed Mode	Range	31.1	12.8	64.0	2.4	0.9	5.0	62.3	199.0	13.9	31.7	9.1	10.5	27.0	
		27.1	9.4	55.6	2.0	0.7	4.0	43.3	169.6	10.3	23.5	7.5	8.9	9.0	
	Mean	29.1	11.1	59.8	2.2	0.8	4.5	52.8	184.3	12.1	27.6	8.3	9.7	18.0	
	Limit %	7.0	15.0	7.0	10.0	15.0	10.0	18.0	8.0	15.0	15.0	10.0	8.0	50.0	
KX-21N KX-21	Range	34.0	13.4	63.9	2.5	1.0	5.0	73.0	224.9	12.5	40.5	9.9	10.3	25.2	
		25.2	8.0	55.5	1.9	0.6	4.0	50.8	166.3	9.3	29.9	8.1	8.7	8.4	
	Mean	29.6	10.7	59.7	2.2	0.8	4.5	61.9	195.6	10.9	35.2	9.0	9.5	16.8	
	Limit %	15.0	25.0	7.0	15.0	25.0	10.0	18.0	15.0	15.0	15.0	10.0	8.0	50.0	
	Limit #	4.4	2.7	4.2	0.3	0.2	0.5	11.1	29.3	1.6	5.3	0.9	0.8	8.4	
pocH-100i	Range	33.7	12.8	64.9	2.4	0.9	4.9	77.9	231.4	17.1	48.8	10.1	11.2	31.0	
		24.9	7.2	56.5	1.8	0.5	3.9	54.1	171.0	12.7	36.0	8.3	9.6	7.8	
	Mean	29.3	10.0	60.7	2.1	0.7	4.4	66.0	201.2	14.9	42.4	9.2	10.4	19.4	
	Limit %	15.0	28.0	7.0	15.0	28.0	12.0	18.0	15.0	15.0	15.0	10.0	8.0	60.0	
	Limit #	4.4	2.8	4.2	0.3	0.2	0.5	11.9	30.2	2.2	6.4	0.9	0.8	11.6	
XP series	Range	33.6	13.4	64.3	2.4	1.0	4.8	73.3	223.7	12.0	39.8	9.7	10.4	25.4	0.31
		24.8	8.0	55.9	1.8	0.6	4.0	50.9	165.3	8.8	29.4	7.9	8.8	8.4	0.13
	Mean	29.2	10.7	60.1	2.1	0.8	4.4	62.1	194.5	10.4	34.6	8.8	9.6	16.9	0.22
	Limit %	15.0	25.0	7.0	15.0	25.0	10.0	18.0	15.0	15.0	15.0	10.0	8.0	50.0	43.0
	Limit #	4.4	2.7	4.2	0.3	0.2	0.4	11.2	29.2	1.6	5.2	0.9	0.8	8.5	0.09

Remarks:
1) K-4500: Open Mode assay values
2) These parameters values should be used as a reference only.

CE IVD

Please refer to the package insert for the handling procedure for EIGHTCHECK-3WP.

Assay EIGHTCHECK-3WP Normal AP
Part No 350312
CX483964C

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EIGHTCHECK-3WP ASSAY SHEET

High Level

LOT **9004 0823**

13-Apr-2019

Model		WBC	RBC	HGB		HCT	MCV	MCH		MCHC		PLT
		[10^3/μL]	[10^6/μL]	[g/dL]	[mmol/L]	[%]	[fL]	[pg]	[amol]	[g/dL]	[mmol/L]	[10^3/uL]
K-800 K-1000	Range	21.2	5.54	17.3	10.7	48.7	89.3	33.0	2046	38.7	24.0	580
		18.0	5.16	16.3	10.1	42.3	80.7	29.8	1852	35.1	21.8	446
K-4500 1)	Mean	19.6	5.35	16.8	10.4	45.5	85.0	31.4	1949	36.9	22.9	513
	Limit %	8.0	3.50	3.1	3.1	7.0	5.0	5.0	5.0	5.0	5.0	13
K-4500 Closed Mode	Range	21.0	5.64	17.6	10.9	48.9	89.3	33.3	2066	39.7	24.6	563
		16.2	5.06	16.0	9.9	42.1	80.7	29.5	1832	34.1	21.2	433
	Mean	18.6	5.35	16.8	10.4	45.5	85.0	31.4	1949	36.9	22.9	498
	Limit %	13.0	5.50	4.5	4.5	7.5	5.0	6.0	6.0	7.5	7.5	13
KX-21N KX-21	Range	20.9	5.52	17.7	11.0	48.8	89.8	34.0	2108	40.3	25.0	641
		18.1	5.10	16.5	10.2	42.0	81.2	30.4	1888	35.1	21.8	493
	Mean	19.5	5.31	17.1	10.6	45.4	85.5	32.2	1998	37.7	23.4	567
	Limit %	7.0	4.00	3.5	3.5	7.5	5.0	5.5	5.5	7.0	7.0	13
	Limit #	1.4	0.21	0.6	0.4	3.4	4.3	1.8	110	2.6	1.6	74
pocH-100i	Range	19.9	5.78	17.6	10.9	51.6	92.1	32.2	1997	37.6	23.3	610
		16.7	5.22	16.0	9.9	44.0	81.7	28.8	1789	32.6	20.3	450
	Mean	18.3	5.50	16.8	10.4	47.8	86.9	30.5	1893	35.1	21.8	530
	Limit %	9.0	5.00	5.0	5.0	8.0	6.0	5.5	5.5	7.0	7.0	15
	Limit #	1.6	0.28	0.8	0.5	3.8	5.2	1.7	104	2.5	1.5	80
XP series	Range	19.5	5.50	17.2	10.7	47.9	88.5	33.1	2056	39.8	24.7	620
		16.9	5.08	16.0	9.9	41.3	80.1	29.7	1842	34.6	21.5	478
	Mean	18.2	5.29	16.6	10.3	44.6	84.3	31.4	1949	37.2	23.1	549
	Limit %	7.0	4.00	3.5	3.5	7.5	5.0	5.5	5.5	7.0	7.0	13
	Limit #	1.3	0.21	0.6	0.4	3.3	4.2	1.7	107	2.6	1.6	71

Model		W-SCR/ LYM [%]	W-MCR/ MXD [%]	W-LCR/ NEUT [%]2)	W-SCC/ LYM [10^3/μL]2	W-MCC/ MXD [10^3/μL]2	W-LCC/ NEUT [10^3/μL]2)	W-SMV [fL]	W-LMV [fL]	RDW-CV [%]	RDW-SD [fL]	PDW [fL]	MPV [fL]	P-LCR [%]	PCT [%]
K-1000 K-4500 1)	Range	36.0	18.9	53.5	7.3	3.7	10.8	63.0	201.6	13.1	35.4	9.2	10.5	27.8	
		31.2	13.9	46.5	5.9	2.7	8.8	43.8	171.8	9.7	26.2	7.6	8.9	9.2	
	Mean	33.6	16.4	50.0	6.6	3.2	9.8	53.4	186.7	11.4	30.8	8.4	9.7	18.5	
	Limit %	7.0	15.0	7.0	10.0	15.0	10.0	18.0	8.0	15.0	15.0	10.0	8.0	50.0	
K-4500 Closed Mode	Range	38.6	20.5	57.5	7.4	3.9	11.2	63.0	216.6	13.5	36.3	10.1	10.7	29.6	
		28.6	12.3	42.5	5.0	2.3	7.4	43.8	156.8	9.3	25.3	6.7	8.7	7.4	
	Mean	33.6	16.4	50.0	6.2	3.1	9.3	53.4	186.7	11.4	30.8	8.4	9.7	18.5	
	Limit %	15.0	25.0	15.0	20.0	25.0	20.0	18.0	16.0	18.0	18.0	20.0	10.0	60.0	
KX-21N KX-21	Range	40.0	20.1	52.5	7.8	3.9	10.6	73.6	227.5	12.1	42.7	9.9	10.3	25.7	
		29.6	12.1	45.7	5.8	2.3	8.6	51.2	168.1	8.9	31.5	8.1	8.7	8.5	
	Mean	34.8	16.1	49.1	6.8	3.1	9.6	62.4	197.8	10.5	37.1	9.0	9.5	17.1	
	Limit %	15.0	25.0	7.0	15.0	25.0	10.0	18.0	15.0	15.0	15.0	10.0	8.0	50.0	
	Limit #	5.2	4.0	3.4	1.0	0.8	1.0	11.2	29.7	1.6	5.6	0.9	0.8	8.6	
pocH-100i	Range	39.9	20.6	52.6	7.4	3.7	10.1	77.6	233.7	16.9	51.9	10.5	11.1	30.9	
		29.5	11.6	45.8	5.4	2.1	7.9	54.0	172.7	12.5	38.3	8.5	9.5	7.7	
	Mean	34.7	16.1	49.2	6.4	2.9	9.0	65.8	203.2	14.7	45.1	9.5	10.3	19.3	
	Limit %	15.0	28.0	7.0	15.0	28.0	12.0	18.0	15.0	15.0	15.0	10.0	8.0	60.0	
	Limit #	5.2	4.5	3.4	1.0	0.8	1.1	11.8	30.5	2.2	6.8	1.0	0.8	11.6	
XP series	Range	39.8	19.8	53.1	7.2	3.6	9.9	73.9	225.5	11.4	41.4	9.8	10.5	26.7	0.77
		29.4	11.8	46.1	5.4	2.2	8.1	51.3	166.7	8.4	30.6	8.0	8.9	8.9	0.31
	Mean	34.6	15.8	49.6	6.3	2.9	9.0	62.6	196.1	9.9	36.0	8.9	9.7	17.8	0.54
	Limit %	15.0	25.0	7.0	15.0	25.0	10.0	18.0	15.0	15.0	15.0	10.0	8.0	50.0	43.0
	Limit #	5.2	4.0	3.5	0.9	0.7	0.9	11.3	29.4	1.5	5.4	0.9	0.8	8.9	0.23

Remarks:
1) K-4500: Open Mode assay values
2) These parameters values should be used as a reference only.

CE IVD

Please refer to the package insert for the handling procedure for EIGHTCHECK-3WP.

Assay EIGHTCHECK-3WP High AP
Part No 350313
BP823483C

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BB453911D
Part No 350466

EIGHTCHECK-3WP ASSAY SHEET
Normal Level
For pocH-100i

LOT **9005 0822**

13-Apr-2019

		Mean	Limit #
WBC	[10^3/µL]	7.2	0.6
RBC	[10^6/µL]	4.50	0.23
HGB	[g/dL]	12.2	0.6
HGB	[mmol/L]	7.6	0.4
HCT	[%]	36.1	2.9
MCV	[fL]	80.2	4.8
MCH	[pg]	27.1	1.6
MCH	[amol]	1682	101
MCHC	[g/dL]	33.8	2.4
MCHC	[mmol/L]	21.0	1.5
PLT	[10^3/µL]	226	34
W-SCR / LYM	[%]	29.3	4.4
W-MCR / MXD	[%]	10.0	2.8
W-LCR / NEUT 1)	[%]	60.7	4.2

		Mean	Limit #
W-SCC / LYM 1)	[10^3/µL]	2.1	0.3
W-MCC / MXD 1)	[10^3/µL]	0.7	0.2
W-LCC / NEUT 1)	[10^3/µL]	4.4	0.5
W-SMV	[fL]	66.0	11.9
W-LMV	[fL]	201.2	30.2
RDW-CV	[%]	14.9	2.2
RDW-SD	[fL]	42.4	6.4
PDW	[fL]	9.2	0.9
MPV	[fL]	10.4	0.8
P-LCR	[%]	19.4	11.6

1) These parameters values should be used as a reference only.

CE IVD

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AP631315D
Part No 350467

EIGHTCHECK-3WP ASSAY SHEET
High Level
For pocH-100i

LOT **9004 0823**

13-Apr-2019

		Mean	Limit #
WBC	[10^3/µL]	18.3	1.6
RBC	[10^6/µL]	5.50	0.28
HGB	[g/dL]	16.8	0.8
HGB	[mmol/L]	10.4	0.5
HCT	[%]	47.8	3.8
MCV	[fL]	86.9	5.2
MCH	[pg]	30.5	1.7
MCH	[amol]	1893	104
MCHC	[g/dL]	35.1	2.5
MCHC	[mmol/L]	21.8	1.5
PLT	[10^3/µL]	530	80
W-SCR / LYM	[%]	34.7	5.2
W-MCR / MXD	[%]	16.1	4.5
W-LCR / NEUT 1)	[%]	49.2	3.4
W-SCC / LYM 1)	[10^3/µL]	6.4	1.0
W-MCC / MXD 1)	[10^3/µL]	2.9	0.8
W-LCC / NEUT 1)	[10^3/µL]	9.0	1.1
W-SMV	[fL]	65.8	11.8
W-LMV	[fL]	203.2	30.5
RDW-CV	[%]	14.7	2.2
RDW-SD	[fL]	45.1	6.8
PDW	[fL]	9.5	1.0
MPV	[fL]	10.3	0.8
P-LCR	[%]	19.3	11.6

1) These parameters values should be used as a reference only.

CE IVD

Assay pocH-100i EIGHTCHECK-3WP AP High

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AS899580D
Part No 350612

EIGHTCHECK-3WP ASSAY SHEET
Normal Level
For XP series

LOT **9005 0822**

13-Apr-2019

		Mean	Limit #
WBC	[10^3/µL]	7.3	0.5
RBC	[10^6/µL]	4.35	0.17
HGB	[g/dL]	12.3	0.4
HGB	[mmol/L]	7.6	0.2
HCT	[%]	33.8	2.5
MCV	[fL]	77.7	3.9
MCH	[pg]	28.3	1.6
MCH	[amol]	1756	97
MCHC	[g/dL]	36.4	2.5
MCHC	[mmol/L]	22.6	1.6
PLT	[10^3/µL]	230	35
W-SCR / LYM	[%]	29.2	4.4
W-MCR / MXD	[%]	10.7	2.7
W-LCR / NEUT [1)]	[%]	60.1	4.2

		Mean	Limit #
W-SCC / LYM [1)]	[10^3/µL]	2.1	0.3
W-MCC / MXD [1)]	[10^3/µL]	0.8	0.2
W-LCC / NEUT [1)]	[10^3/µL]	4.4	0.4
W-SMV	[fL]	62.1	11.2
W-LMV	[fL]	194.5	29.2
RDW-CV	[%]	10.4	1.6
RDW-SD	[fL]	34.6	5.2
PDW	[fL]	8.8	0.9
MPV	[fL]	9.6	0.8
P-LCR	[%]	16.9	8.5
PCT	[%]	0.22	0.09

1) These parameters values should be used as a reference only.

CE IVD

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AG131837D
Part No 350613

EIGHTCHECK-3WP ASSAY SHEET
High Level
For XP series

LOT **9004 0823**

13-Apr-2019

		Mean	Limit #
WBC	[10^3/µL]	18.2	1.3
RBC	[10^6/µL]	5.29	0.21
HGB	[g/dL]	16.6	0.6
HGB	[mmol/L]	10.3	0.4
HCT	[%]	44.6	3.3
MCV	[fL]	84.3	4.2
MCH	[pg]	31.4	1.7
MCH	[amol]	1949	107
MCHC	[g/dL]	37.2	2.6
MCHC	[mmol/L]	23.1	1.6
PLT	[10^3/µL]	549	71
W-SCR / LYM	[%]	34.6	5.2
W-MCR / MXD	[%]	15.8	4.0
W-LCR / NEUT 1)	[%]	49.6	3.5

		Mean	Limit #
W-SCC / LYM 1)	[10^3/µL]	6.3	0.9
W-MCC / MXD 1)	[10^3/µL]	2.9	0.7
W-LCC / NEUT 1)	[10^3/µL]	9.0	0.9
W-SMV	[fL]	62.6	11.3
W-LMV	[fL]	196.1	29.4
RDW-CV	[%]	9.9	1.5
RDW-SD	[fL]	36.0	5.4
PDW	[fL]	8.9	0.9
MPV	[fL]	9.7	0.8
P-LCR	[%]	17.8	8.9
PCT	[%]	0.54	0.23

1) These parameters values should be used as a reference only.

CE IVD