Para 12® Extend

CE 2797 IVD

STRECK

Multi-Parameter Assayed Hematology Control[1]

Rx Only

Open-vial stability 30 days[2]

2027-05-24

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2024-07

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Instrument [3] Horiba® ABX Micros® 60 / Horiba® ABX Micros® ES 60 / Siemens® ADVIA® 60		CONTROL[5] L LOT 63200422		CONTROL[5] N LOT 63200423		CONTROL[5] H LOT 63200424	
Parameter [4]		$\bar{x}$	+/-	$\bar{x}$	+/-	$\bar{x}$	+/-
WBC	10^9/L	2.2	0.4	8.7	0.6	20.6	2.5
LYM	10^9/L	1.4	0.5	3.2	0.5	4.2	1.5
LYM	%	63.3	8.0	36.4	6.0	20.5	6.0
MID	10^9/L	0.2	0.2	0.5	0.3	1.1	1.0
MID	%	4.5	4.5	5.7	5.0	5.2	5.0
GRAN	10^9/L	0.8	0.8	5.0	1.0	15.3	3.0
GRAN	%	32.8	8.0	58.0	7.0	74.3	8.0
RBC	10^{12}/L	2.15	0.15	4.06	0.20	5.11	0.25
HGB	g/dL	5.3	0.5	11.1	0.6	15.7	0.7
[HGB]	g/L	53	5	111	6	157	7
HCT	%	15.5	2.0	32.9	3.0	45.5	4.0
[HCT]	L/L	0.155	0.020	0.329	0.030	0.455	0.040
MCV	fL	72	6	81	6	89	6
MCH	pg	24.7	2.0	27.3	2.0	30.7	2.0
MCHC	g/dL	34.2	3.0	33.7	3.0	34.5	3.0
[MCHC]	g/L	342	30	337	30	345	30
RDW	%	17.9	5.0	15.7	5.0	14.5	5.0
PLT	10^9/L	77	15	220	30	561	60
MPV	fL	9.7	1.5	9.1	1.5	8.8	1.5

Instrument [3] Beckman Coulter® Ac•T Series / Ac•T diff/ Ac•T diff 2		CONTROL[5] L LOT 63200422		CONTROL[5] N LOT 63200423		CONTROL[5] H LOT 63200424	
Parameter [4]		$\bar{x}$	+/-	$\bar{x}$	+/-	$\bar{x}$	+/-
WBC	10^9/L	2.3	0.4	9.0	1.0	21.4	2.5
LYM	10^9/L	1.2	0.6	2.4	1.2	2.9	2.0
LYM	%	53.8	10.0	27.2	9.0	13.4	6.0
MID	10^9/L	0.2	0.2	0.8	0.3	1.9	1.2
MID	%	6.8	6.0	8.9	5.0	8.8	5.0
GRAN	10^9/L	0.9	0.8	5.8	2.0	16.6	3.5
GRAN	%	39.4	10.0	63.9	9.0	77.8	8.0
RBC	10^{12}/L	2.19	0.20	4.12	0.25	5.16	0.30
HGB	g/dL	5.2	0.5	11.4	0.7	16.0	1.0
[HGB]	g/L	52	5	114	7	160	10
HCT	%	16.2	2.0	34.1	4.5	46.6	4.5
[HCT]	L/L	0.162	0.020	0.341	0.045	0.466	0.045
MCV	fL	73.8	6.0	82.7	7.0	90.4	7.0
MCH	pg	23.7	2.5	27.7	2.5	31.0	2.5
MCHC	g/dL	32.1	3.5	33.4	3.5	34.3	3.5
[MCHC]	g/L	321	35	334	35	343	35
RDW	%	20.0	5.0	17.0	5.0	15.5	5.0
PLT	10^9/L	66	25	205	35	539	85
MPV	fL	9.3	1.5	9.5	1.5	9.6	1.5

Instrument [3] Mindray® BC-3200		CONTROL[6] L LOT 63200422		CONTROL[5] N LOT 63200423		CONTROL[5] H LOT 63200424	
Parameter [4]		$\bar{x}$	+/-	$\bar{x}$	+/-	$\bar{x}$	+/-
WBC	10^9/L	2.1	0.4	8.6	1.0	20.0	2.5
LYM	10^9/L	1.1	0.6	2.2	1.2	2.4	2.0
LYM	%	50.8	10.0	25.6	9.0	12.2	6.0
MID	10^9/L	0.2	0.2	0.8	0.3	1.5	1.2
MID	%	7.6	6.0	8.8	5.0	7.6	5.0
GRAN	10^9/L	0.9	0.8	5.6	2.0	16.0	3.5
GRAN	%	41.6	10.0	65.6	9.0	80.2	8.0
RBC	10^{12}/L	2.25	0.20	4.17	0.40	5.25	0.40
HGB	g/dL	5.3	0.5	11.4	1.0	16.0	1.2
[HGB]	g/L	53	5	114	10	160	12
HCT	%	16.5	2.5	34.2	4.5	47.0	4.5
[HCT]	L/L	0.165	0.025	0.342	0.045	0.470	0.045
MCV	fL	73.4	6.0	82.1	7.0	89.5	7.0
MCH	pg	23.6	2.5	27.3	2.5	30.5	2.5
MCHC	g/dL	32.1	3.5	33.3	3.5	34.0	3.5
[MCHC]	g/L	321	35	333	35	340	35
RDW	%	16.8	5.0	14.7	5.0	13.5	5.0
PLT	10^9/L	82	25	219	35	548	85
MPV	fL	9.3	1.5	8.5	1.5	8.3	1.5

Instrument [3] Mindray® BC-3600		CONTROL[5] L LOT 63200422		CONTROL[5] N LOT 63200423		CONTROL[5] H LOT 63200424	
Parameter [4]		$\bar{x}$	+/-	$\bar{x}$	+/-	$\bar{x}$	+/-
WBC	10^9/L	2.1	0.4	8.1	1.0	18.6	2.5
LYM	10^9/L	1.1	0.6	2.3	1.2	2.8	2.0
LYM	%	54.4	10.0	29.0	9.0	15.1	6.0
MID	10^9/L	0.2	0.2	0.7	0.3	1.4	1.2
MID	%	7.1	6.0	8.3	5.0	7.4	5.0
GRAN	10^9/L	0.9	0.8	5.1	2.0	14.4	3.5
GRAN	%	38.5	10.0	62.7	9.0	77.5	8.0
RBC	10^{12}/L	2.20	0.20	4.14	0.40	5.20	0.40
HGB	g/dL	5.1	0.5	11.1	1.0	16.1	1.2
[HGB]	g/L	51	5	111	10	161	12
HCT	%	16.5	2.5	34.5	4.5	46.9	4.5
[HCT]	L/L	0.165	0.025	0.345	0.045	0.469	0.045
MCV	fL	75.0	6.0	83.3	7.0	90.1	7.0
MCH	pg	23.2	2.5	26.8	2.5	31.0	2.5
MCHC	g/dL	30.9	3.5	32.2	3.5	34.3	3.5
[MCHC]	g/L	309	35	322	35	343	35
RDW	%	16.6	5.0	15.2	5.0	14.0	5.0
PLT	10^9/L	72	25	225	35	587	85
MPV	fL	8.4	1.5	8.4	1.5	8.3	1.5

Streck
7002 S. 109 Street
La Vista, NE 68128 USA

EC REP
MEDIMARK® Europe
11, rue Emile Zola, BP 2332
38033 Grenoble Cedex 2, France

Instrument [3] ERMA PCE-210		CONTROL[5] L		CONTROL[5] N		CONTROL[5] H	
		LOT 63200422		LOT 63200423		LOT 63200424	
Parameter [4]		$\bar{x}$	+/-	$\bar{x}$	+/-	$\bar{x}$	+/-
WBC	10^9/L	2.0	0.4	8.7	0.7	22.0	2.5
LYM	10^9/L	1.0	0.5	2.1	0.5	2.3	1.5
LYM	%	48.8	8.0	24.0	6.0	10.4	6.0
MID	10^9/L	0.2	0.2	0.4	0.3	1.1	1.0
MID	%	6.0	6.0	5.0	5.0	5.0	5.0
GRAN	10^9/L	1.0	0.8	6.2	1.0	19.1	3.0
GRAN	%	47.6	8.0	71.8	7.0	86.6	8.0
RBC	10^{12}/L	2.31	0.20	4.32	0.25	5.59	0.35
HGB	g/dL	5.1	0.8	11.5	0.9	17.3	1.0
[HGB]	g/L	51	8	115	9	173	10
HCT	%	16.8	2.0	35.0	4.5	49.4	4.5
[HCT]	L/L	0.168	0.020	0.350	0.045	0.494	0.045
MCV	fL	72.9	6.0	81.1	7.0	88.4	7.0
MCH	pg	22.1	2.5	26.6	3.0	30.9	3.0
MCHC	g/dL	30.4	3.5	32.9	3.5	35.0	3.5
[MCHC]	g/L	304	35	329	35	350	35
RDW	%	22.5	5.0	20.1	5.0	18.7	5.0
PLT	10^9/L	86	25	220	45	570	85
MPV	fL	10.1	1.5	9.3	1.5	9.1	1.5
PDW	fL	10.8	3.0	11.8	1.7	11.6	1.7

Instrument [3] HTI® MicroCC-20 Plus		CONTROL[5] L		CONTROL[5] N		CONTROL[5] H	
		LOT 63200422		LOT 63200423		LOT 63200424	
Parameter [4]		$\bar{x}$	+/-	$\bar{x}$	+/-	$\bar{x}$	+/-
WBC	10^9/L	2.0	0.4	7.5	0.6	16.9	2.5
LYM	10^9/L	1.1	0.5	2.3	0.5	2.7	1.5
LYM	%	56.3	8.0	30.8	6.0	15.9	6.0
MID	10^9/L	0.2	0.2	0.8	0.3	1.6	1.0
MID	%	8.3	4.5	10.2	5.0	9.4	5.0
GRAN	10^9/L	0.8	0.8	4.4	1.0	12.6	3.0
GRAN	%	35.4	8.0	59.0	7.0	74.7	8.0
RBC	10^{12}/L	2.14	0.15	3.99	0.20	4.96	0.25
HGB	g/dL	5.4	0.5	11.2	0.6	15.6	0.7
[HGB]	g/L	54	5	112	6	156	7
HCT	%	16.7	2.0	34.2	3.0	46.1	4.0
[HCT]	L/L	0.167	0.020	0.342	0.030	0.461	0.040
MCV	fL	78.2	6.0	85.7	6.0	92.9	6.0
MCH	pg	25.2	2.0	28.1	2.0	31.5	2.0
MCHC	g/dL	32.3	3.0	32.7	3.0	33.8	3.0
[MCHC]	g/L	323	30	327	30	338	30
RDW	%	14.9	5.0	13.7	5.0	13.7	5.0
RDW-SD	fL	42.3	3.5	43.4	8.4	46.3	3.7
PLT	10^9/L	84	25	229	30	561	60
PCT	%	0.06	0.02	0.17	0.17	0.57	0.57
MPV	fL	7.7	1.5	7.6	1.5	7.7	1.5
PDW	%	9.9	1.9	10.1	2.0	9.8	1.4
P-LCR	%	13.0	13.0	10.0	10.0	8.6	6.7

Instrument [3] Nihon Kohden® Celltac α MEK-6400 Series / MEK-6500		CONTROL[5] L		CONTROL[5] N		CONTROL[5] H	
		LOT 63200422		LOT 63200423		LOT 63200424	
Parameter [4]		$\bar{x}$	+/-	$\bar{x}$	+/-	$\bar{x}$	+/-
WBC	10^9/L	2.2	0.4	8.5	0.6	20.5	2.5
LYM	10^9/L	1.6	0.5	3.9	0.5	5.8	1.5
LYM	%	71.8	11.0	45.5	6.0	28.1	6.0
MID	10^9/L	0.2	0.2	0.8	0.3	2.0	1.0
MID	%	8.5	6.0	9.5	5.0	9.7	5.0
GRAN	10^9/L	0.8	0.8	3.8	1.0	12.8	3.0
GRAN	%	19.8	11.0	44.9	7.0	62.2	8.0
RBC	10^{12}/L	2.23	0.15	4.12	0.20	5.13	0.25
HGB	g/dL	5.2	0.5	11.2	0.6	15.9	0.7
[HGB]	g/L	52	5	112	6	159	7
HCT	%	16.5	2.0	33.8	3.0	45.7	4.0
[HCT]	L/L	0.165	0.020	0.338	0.030	0.457	0.040
MCV	fL	74	6	82	6	89	6
MCH	pg	23.3	2.0	27.2	2.0	31.0	2.0
MCHC	g/dL	31.5	3.0	33.1	3.0	34.8	3.0
[MCHC]	g/L	315	30	331	30	348	30
RDW	%	19.7	5.0	17.6	5.0	16.1	5.0
PLT	10^9/L	76	15	228	30	594	60
PCT	%	0.06	0.03	0.17	0.06	0.43	0.20
MPV	fL	7.4	1.5	7.3	1.5	7.3	1.5
PDW	%	14.4	5.5	13.5	3.7	13.1	2.7

1 Multi-Parameter Assayed Hematology Control
Kontrolní hematologické látky pro multiparametrickou analýzu / Contrôle dosé d'hématologie à paramètres multiples / Hämatologie-Kontrolle mit Sollwertzuweisung für mehrere Parameter / Controllo di analisi ematologica multi-parametro / Analysert hematologikontroll for flere parametrer / Wielo-parametrowa oznaczona kontrola hematologiczna. / Control hematológico ensayado de múltiples parámetros / Multiparameterkontroll för analyserad hematologi

2 Open-vial stability 30 days
Stabilita otevřené lékovky 30 dní / Stabilité en flacon ouvert 30 jours / Stabilität geöffneter Flaschen 30 tage / Stabiliteten til åpnet ampulle 30 dager / Stabilità della fiala aperta 30 giorni / Trwałość otwartego opakowania 30 liczba dni / Estabilidad de la cápsula abierta 30 días / Hållbarhet för öppen flaska 30 dagar

3 Instrument
Nástroj / Instrument / Gerät / Strumento / Instrument / Aparat / Instrumento / Instrument

4 Parameter
Parametr / Paramètre / Parameter / Parametro / Parameter / Parametr / Parámetro / Parameter

5 Control
Kontrola / Contrôle / Kontrolle / Controllo / Kontroll / Kontrola / Control / Kontroll

$\bar{X}$ Mean
Střední hodnota / Moyenne / Mittelwert / Media / Gjennomsnitt / Wartość średnia / Media / Medelvärde

+/- Expected Range
± očekávaný rozsah / ± Intervalle escompté / ± Erwartungsbereich / ± Range previsto / ± Forventet område / ± Zakres wartości oczekiwanych / ± Interval previsto / ± Förväntat intervall

[ ] SI Units
Mezinárodní soustava jednotek SI / Unitès SI / SI- Einheiten / Unitá SI / SI-måleenheter / Jednostki SI / Unidades SI / SI-enheter

Alarms or flags may be seen with Para 12 Extend. These alarms and flags may be disregarded if the control is performing within the assay ranges.

Alarmy nebo praporky upozornění lze vidět u Para 12 Extend. Tyto alarmy a praporky se mohou ignorovat, pokud je kontrola v rozmezích analýzy.

Des alarmes ou indicateurs peuvent être observés avec Para 12 Extend. Ces alarmes et indicateurs peuvent être ignorés si le contrôle se situe dans les intervalles d'essai.

Es ist möglich, dass mit dem Para 12 Extend Alarm- oder Warnmeldungen (Flags) erscheinen. Derartige Alarm- und Warnmeldungen können ignoriert werden, wenn die Kontrollwerte innerhalb der Assaybereiche liegen.

Allarmi e flag possono essere osservati con Para 12 Extend. Questi allarmi e queste flag possono essere ignorati se i valori del controllo si trovano all'interno dei range di analisi.

Alarmer eller flagg kan sees med Para 12 Extend. Disse alarmene og flaggene kan ignoreres hvis kontrollen utføres innenfor analyseområdene.

Przy użyciu Para 12 Extend mogą pojawić się alarmy lub sygnał/y ostrzegawcze. Jeśli wyniki badania kontroli mieszczą się w zakresie oznaczeń, ostrzeżenia te można zignorować.

Pueden verse alarmas o indicadores con Para 12 Extend. Pueden pasarse por alto estas alarmas e indicadores si el control está funcionando dentro de las gamas de análisis.

Larm eller flaggor kan ses med Para 12 Extend. Man kan ignorera dessa larm och flaggor om kontrollens prestanda ligger inom fastställda områden för analysen.

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