

# Para 12® Extend



Multi-Parameter Assayed Hematology Control<sup>1</sup>

2020-04-06

350307-37  
2019-08

Rx Only

Open-vial stability 30 days<sup>2</sup>

Instrument <sup>3</sup> Abbott CELL-DYN® 1400*, 1600, 1700		CONTROL <sup>5</sup> L		CONTROL <sup>5</sup> N		CONTROL <sup>5</sup> H	
		LOT 92730422		LOT 92730423		LOT 92730424	
Parameter <sup>4</sup>		$\bar{x}$	+/-	$\bar{x}$	+/-	$\bar{x}$	+/-
WBC	10 <sup>9</sup> /L	2.5	0.4	8.9	1.0	22.3	2.5
LYM	10 <sup>9</sup> /L	1.4	0.6	2.5	1.2	3.3	2.0
LYM	%	54.2	10.0	27.6	9.0	14.6	6.0
MID	10 <sup>9</sup> /L	0.2	0.2	0.6	0.3	1.6	1.2
MID	%	6.3	4.5	7.2	5.0	7.2	5.0
GRAN	10 <sup>9</sup> /L	1.0	0.8	5.8	2.0	17.4	3.5
GRAN	%	39.5	10.0	65.2	9.0	78.2	8.0
RBC	10 <sup>12</sup> /L	2.34	0.20	4.22	0.25	5.22	0.30
HGB	g/dL	5.7	0.5	11.1	0.7	15.3	1.0
[HGB]	g/L	57	5	111	7	153	10
HCT	%	17.6	2.0	34.6	4.5	45.4	4.5
[HCT]	L/L	0.176	0.020	0.346	0.045	0.454	0.045
MCV	fL	75	6	82	7	87	7
MCH	pg	24.4	2.5	26.3	2.5	29.3	2.5
MCHC	g/dL	32.4	3.5	32.1	3.5	33.7	3.5
[MCHC]	g/L	324	35	321	35	337	35
RDW	%	21.2	5.0	20.4	5.0	18.3	5.0
PLT	10 <sup>9</sup> /L	71	25	240	35	646	85
MPV	fL	NA	NA	9.3	1.5	9.1	1.5

Instrument <sup>3</sup> Abbott CELL-DYN® 1800**		CONTROL <sup>5</sup> L		CONTROL <sup>5</sup> N		CONTROL <sup>5</sup> H	
		LOT 92730422		LOT 92730423		LOT 92730424	
Parameter <sup>4</sup>		$\bar{x}$	+/-	$\bar{x}$	+/-	$\bar{x}$	+/-
WBC	10 <sup>9</sup> /L	2.0	0.4	7.1	1.0	17.5	2.5
LYM	10 <sup>9</sup> /L	1.1	0.6	2.0	1.2	2.6	2.0
LYM	%	54.4	10.0	28.3	9.0	14.9	6.0
MID	10 <sup>9</sup> /L	0.2	0.2	0.6	0.3	1.6	1.2
MID	%	8.8	6.0	9.0	5.0	9.0	5.0
GRAN	10 <sup>9</sup> /L	0.8	0.8	4.5	2.0	13.3	3.5
GRAN	%	36.8	10.0	62.7	9.0	76.1	8.0
RBC	10 <sup>12</sup> /L	2.40	0.20	4.21	0.25	5.12	0.30
HGB	g/dL	5.6	0.5	11.2	0.7	15.3	1.0
[HGB]	g/L	56	5	112	7	153	10
HCT	%	18.5	2.0	35.4	4.5	46.1	4.5
[HCT]	L/L	0.185	0.020	0.354	0.045	0.461	0.045
MCV	fL	77	6	84	7	90	7
MCH	pg	23.3	2.5	26.6	2.5	29.9	2.5
MCHC	g/dL	30.3	3.5	31.6	3.5	33.2	3.5
[MCHC]	g/L	303	35	316	35	332	35
RDW	%	20.9	5.0	19.6	5.0	17.6	5.0
PLT	10 <sup>9</sup> /L	67	25	225	35	604	85
MPV	fL	NA	NA	9.4	1.5	9.6	1.5

Instrument <sup>3</sup> Beckman Coulter® Ac-T™ Series / Ac-T diff™/ Ac-T diff 2™		CONTROL <sup>5</sup> L		CONTROL <sup>5</sup> N		CONTROL <sup>5</sup> H	
		LOT 92730422		LOT 92730423		LOT 92730424	
Parameter <sup>4</sup>		$\bar{x}$	+/-	$\bar{x}$	+/-	$\bar{x}$	+/-
WBC	10 <sup>9</sup> /L	2.3	0.4	8.3	1.0	21.7	2.5
LYM	10 <sup>9</sup> /L	1.2	0.6	2.3	1.2	3.1	2.0
LYM	%	54.2	10.0	27.2	9.0	14.2	6.0
MID	10 <sup>9</sup> /L	0.2	0.2	0.8	0.3	2.2	1.2
MID	%	8.6	6.0	9.4	5.0	10.1	5.0
GRAN	10 <sup>9</sup> /L	0.9	0.8	5.3	2.0	16.4	3.5
GRAN	%	37.2	10.0	63.4	9.0	75.7	8.0
RBC	10 <sup>12</sup> /L	2.24	0.20	4.10	0.25	5.17	0.30
HGB	g/dL	5.4	0.5	10.8	0.7	15.0	1.0
[HGB]	g/L	54	5	108	7	150	10
HCT	%	17.4	2.0	34.2	4.5	46.3	4.5
[HCT]	L/L	0.174	0.020	0.342	0.045	0.463	0.045
MCV	fL	77.6	6.0	83.3	7.0	89.5	7.0
MCH	pg	24.1	2.5	26.3	2.5	29.0	2.5
MCHC	g/dL	31.0	3.5	31.6	3.5	32.4	3.5
[MCHC]	g/L	310	35	316	35	324	35
RDW	%	18.6	5.0	18.1	5.0	15.4	5.0
PLT	10 <sup>9</sup> /L	66	25	217	35	567	85
MPV	fL	9.4	1.5	9.6	1.5	9.7	1.5

Instrument <sup>3</sup> Mindray BC-3200		CONTROL <sup>5</sup> L		CONTROL <sup>5</sup> N		CONTROL <sup>5</sup> H	
		LOT 92730422		LOT 92730423		LOT 92730424	
Parameter <sup>4</sup>		$\bar{x}$	+/-	$\bar{x}$	+/-	$\bar{x}$	+/-
WBC	10 <sup>9</sup> /L	2.1	0.4	7.9	1.0	20.3	2.5
LYM	10 <sup>9</sup> /L	1.1	0.6	2.0	1.2	2.6	2.0
LYM	%	51.0	10.0	25.1	9.0	12.9	6.0
MID	10 <sup>9</sup> /L	0.2	0.2	0.7	0.3	1.8	1.2
MID	%	8.5	6.0	8.4	5.0	8.7	5.0
GRAN	10 <sup>9</sup> /L	0.9	0.8	5.3	2.0	15.9	3.5
GRAN	%	40.5	10.0	66.5	9.0	78.3	8.0
RBC	10 <sup>12</sup> /L	2.33	0.20	4.21	0.40	5.30	0.40
HGB	g/dL	5.6	0.5	11.1	1.0	15.5	1.2
[HGB]	g/L	56	5	111	10	155	12
HCT	%	18.4	2.5	36.1	4.5	48.1	4.5
[HCT]	L/L	0.184	0.025	0.361	0.045	0.481	0.045
MCV	fL	78.8	6.0	85.8	7.0	90.8	7.0
MCH	pg	24.0	2.5	26.4	2.5	29.2	2.5
MCHC	g/dL	30.4	3.5	30.7	3.5	32.2	3.5
[MCHC]	g/L	304	35	307	35	322	35
RDW	%	15.8	5.0	15.2	5.0	13.9	5.0
PLT	10 <sup>9</sup> /L	80	25	218	35	546	85
MPV	fL	8.9	1.5	8.6	1.5	8.6	1.5

Instrument <sup>3</sup> Mindray BC-3600		CONTROL <sup>5</sup> L		CONTROL <sup>5</sup> N		CONTROL <sup>5</sup> H	
		LOT	92730422	LOT	92730423	LOT	92730424
Parameter <sup>4</sup>		ȳ	+/-	ȳ	+/-	ȳ	+/-
WBC	10 <sup>9</sup> /L	1.9	0.4	6.8	1.0	17.3	2.5
LYM	10 <sup>9</sup> /L	1.0	0.6	1.9	1.2	2.5	2.0
LYM	%	54.4	10.0	27.9	9.0	14.7	6.0
MID	10 <sup>9</sup> /L	0.2	0.2	0.6	0.3	1.7	1.2
MID	%	8.7	6.0	9.5	5.0	9.9	5.0
GRAN	10 <sup>9</sup> /L	0.9	0.8	4.3	2.0	13.0	3.5
GRAN	%	36.9	10.0	62.6	9.0	75.4	8.0
RBC	10 <sup>12</sup> /L	2.32	0.20	4.29	0.40	5.38	0.40
HGB	g/dL	5.2	0.5	10.6	1.0	15.0	1.2
[HGB]	g/L	52	5	106	10	150	12
HCT	%	17.2	2.5	34.0	4.5	45.1	4.5
[HCT]	L/L	0.172	0.025	0.340	0.045	0.451	0.045
MCV	fL	74.0	6.0	79.3	7.0	83.8	7.0
MCH	pg	22.4	2.5	24.7	2.5	27.9	2.5
MCHC	g/dL	30.2	3.5	31.2	3.5	33.3	3.5
[MCHC]	g/L	302	35	312	35	333	35
RDW	%	16.3	5.0	15.8	5.0	14.9	5.0
PLT	10 <sup>9</sup> /L	72	25	231	35	608	85
MPV	fL	8.3	1.5	8.2	1.5	8.2	1.5

Instrument <sup>3</sup> ERMA PCE-210		CONTROL <sup>5</sup> L		CONTROL <sup>5</sup> N		CONTROL <sup>5</sup> H	
		LOT	92730422	LOT	92730423	LOT	92730424
Parameter <sup>4</sup>		ȳ	+/-	ȳ	+/-	ȳ	+/-
WBC	10 <sup>9</sup> /L	2.0	0.4	7.6	0.7	20.2	2.5
LYM	10 <sup>9</sup> /L	1.0	0.5	1.9	0.5	2.4	1.5
LYM	%	50.8	8.0	25.0	6.0	11.8	6.0
MID	10 <sup>9</sup> /L	0.2	0.2	0.4	0.3	1.0	1.0
MID	%	6.0	6.0	5.0	5.0	5.0	5.0
GRAN	10 <sup>9</sup> /L	0.9	0.8	5.3	1.0	16.9	3.0
GRAN	%	44.7	8.0	70.3	7.0	83.9	8.0
RBC	10 <sup>12</sup> /L	2.34	0.20	4.21	0.25	5.20	0.35
HGB	g/dL	5.2	0.8	10.8	0.9	15.2	1.0
[HGB]	g/L	52	8	108	9	152	10
HCT	%	17.3	2.0	34.6	4.5	44.9	4.5
[HCT]	L/L	0.173	0.020	0.346	0.045	0.449	0.045
MCV	fL	74.1	6.0	82.2	7.0	86.4	7.0
MCH	pg	22.2	2.5	25.7	3.0	29.2	3.0
MCHC	g/dL	30.0	3.5	31.2	3.5	33.8	3.5
[MCHC]	g/L	300	35	312	35	338	35
RDW	%	23.5	5.0	23.3	5.0	21.5	5.0
PLT	10 <sup>9</sup> /L	86	25	239	45	582	85
MPV	fL	9.9	1.5	9.4	1.5	9.2	1.5
PDW	%	10.8	3.0	11.8	1.7	12.0	1.7

Instrument <sup>3</sup> Nihon Kohden Celltac α MEK-6400 Series / MEK-6500		CONTROL <sup>5</sup> L		CONTROL <sup>5</sup> N		CONTROL <sup>5</sup> H	
		LOT	92730422	LOT	92730423	LOT	92730424
Parameter <sup>4</sup>		ȳ	+/-	ȳ	+/-	ȳ	+/-
WBC	10 <sup>9</sup> /L	2.1	0.4	7.7	0.6	20.1	2.5
LYM	10 <sup>9</sup> /L	1.4	0.5	2.7	0.5	4.9	1.5
LYM	%	67.9	11.0	35.7	6.0	24.4	6.0
MID	10 <sup>9</sup> /L	0.2	0.2	0.6	0.3	1.9	1.0
MID	%	6.0	6.0	7.6	5.0	9.3	5.0
GRAN	10 <sup>9</sup> /L	0.8	0.8	4.4	1.0	13.3	3.0
GRAN	%	26.4	11.0	56.7	7.0	66.3	8.0
RBC	10 <sup>12</sup> /L	2.25	0.15	4.14	0.20	5.10	0.25
HGB	g/dL	5.4	0.5	11.0	0.6	15.2	0.7
[HGB]	g/L	54	5	110	6	152	7
HCT	%	16.7	2.0	32.7	3.0	42.8	4.0
[HCT]	L/L	0.167	0.020	0.327	0.030	0.428	0.040
MCV	fL	74	6	79	6	84	6
MCH	pg	24.0	2.0	26.6	2.0	29.8	2.0
MCHC	g/dL	32.3	3.0	33.6	3.0	35.5	3.0
[MCHC]	g/L	323	30	336	30	355	30
RDW	%	18.8	5.0	18.6	5.0	16.9	5.0
PLT	10 <sup>9</sup> /L	81	15	261	30	660	60
PCT	%	0.06	0.03	0.19	0.06	0.50	0.20
MPV	fL	7.5	1.5	7.4	1.5	7.5	1.5
PDW	%	14.5	5.5	13.8	3.7	13.7	2.7

Instrument <sup>3</sup> HTI MicroCC-20 Plus		CONTROL <sup>5</sup> L		CONTROL <sup>5</sup> N		CONTROL <sup>5</sup> H	
		LOT	92730422	LOT	92730423	LOT	92730424
Parameter <sup>4</sup>		ȳ	+/-	ȳ	+/-	ȳ	+/-
WBC	10 <sup>9</sup> /L	2.1	0.4	7.2	0.6	17.8	2.5
LYM	10 <sup>9</sup> /L	1.2	0.5	2.1	0.5	2.8	1.5
LYM	%	55.7	8.0	29.4	6.0	15.7	6.0
MID	10 <sup>9</sup> /L	0.2	0.2	0.8	0.3	2.3	1.0
MID	%	10.2	4.5	11.7	5.0	12.7	5.0
GRAN	10 <sup>9</sup> /L	0.8	0.8	4.2	1.0	12.7	3.0
GRAN	%	34.1	8.0	58.9	7.0	71.5	8.0
RBC	10 <sup>12</sup> /L	2.17	0.15	4.03	0.20	5.05	0.25
HGB	g/dL	5.6	0.5	11.1	0.6	15.2	0.7
[HGB]	g/L	56	5	111	6	152	7
HCT	%	17.5	2.0	34.4	3.0	45.1	4.0
[HCT]	L/L	0.175	0.020	0.344	0.030	0.451	0.040
MCV	fL	80.8	6.0	85.4	6.0	89.4	6.0
MCH	pg	25.8	2.0	27.5	2.0	30.1	2.0
MCHC	g/dL	32.0	3.0	32.3	3.0	33.7	3.0
[MCHC]	g/L	320	30	323	30	337	30
RDW	%	14.2	5.0	13.8	5.0	13.1	5.0
PLT	10 <sup>9</sup> /L	84	25	235	30	552	60
MPV	fL	8.0	1.5	7.9	1.5	7.9	1.5

Instrument <sup>3</sup> ABX Micros 60 / Siemens Advia 60		CONTROL <sup>5</sup> L		CONTROL <sup>5</sup> N		CONTROL <sup>5</sup> H	
		LOT	92730422	LOT	92730423	LOT	92730424
Parameter <sup>4</sup>		ȳ	+/-	ȳ	+/-	ȳ	+/-
WBC	10 <sup>9</sup> /L	2.2	0.4	8.0	0.6	20.5	2.5
LYM	10 <sup>9</sup> /L	1.3	0.5	2.6	0.5	3.9	1.5
LYM	%	61.0	8.0	32.8	6.0	19.1	6.0
MID	10 <sup>9</sup> /L	0.2	0.2	0.7	0.3	1.9	1.0
MID	%	7.4	4.5	8.6	5.0	9.2	5.0
GRAN	10 <sup>9</sup> /L	0.8	0.8	4.7	1.0	14.7	3.0
GRAN	%	31.6	8.0	58.6	7.0	71.7	8.0
RBC	10 <sup>12</sup> /L	2.17	0.15	4.03	0.20	5.10	0.25
HGB	g/dL	5.4	0.5	10.9	0.6	14.9	0.7
[HGB]	g/L	54	5	109	6	149	7
HCT	%	16.1	2.0	32.2	3.0	43.4	4.0
[HCT]	L/L	0.161	0.020	0.322	0.030	0.434	0.040
MCV	fL	74	6	80	6	85	6
MCH	pg	24.9	2.0	27.0	2.0	29.2	2.0
MCHC	g/dL	33.5	3.0	33.9	3.0	34.4	3.0
[MCHC]	g/L	335	30	339	30	344	30
RDW	%	16.9	5.0	16.9	5.0	14.9	5.0
PLT	10 <sup>9</sup> /L	73	15	217	30	565	60
MPV	fL	10.3	1.5	9.8	1.5	9.6	1.5

Instrument <sup>3</sup> Diatron <sup>®</sup> Abacus, Abacus Jr.		CONTROL <sup>5</sup> L		CONTROL <sup>5</sup> N		CONTROL <sup>5</sup> H	
		LOT	92730422	LOT	92730423	LOT	92730424
Parameter <sup>4</sup>		ȳ	+/-	ȳ	+/-	ȳ	+/-
WBC	10 <sup>9</sup> /L	2.3	0.4	8.0	0.6	19.5	2.5
LYM	10 <sup>9</sup> /L	1.3	0.5	2.2	0.5	2.9	1.5
LYM	%	56.5	8.0	28.0	6.0	14.9	6.0
MID	10 <sup>9</sup> /L	0.2	0.2	0.9	0.3	2.2	1.0
MID	%	8.4	6.0	11.2	5.0	11.3	5.0
GRAN	10 <sup>9</sup> /L	0.8	0.8	4.9	1.0	14.4	3.0
GRAN	%	35.5	8.0	60.8	7.0	73.7	8.0
RBC	10 <sup>12</sup> /L	2.30	0.15	4.10	0.20	5.03	0.25
HGB	g/dL	5.5	0.5	11.0	0.6	15.0	0.7
[HGB]	g/L	55	5	110	6	150	7
HCT	%	17.4	2.0	33.5	3.0	43.6	4.0
[HCT]	L/L	0.174	0.020	0.335	0.030	0.436	0.040
MCV	fL	75.5	6.0	81.8	6.0	86.6	6.0
MCH	pg	23.9	2.0	26.8	2.0	29.8	2.0
MCHC	g/dL	31.6	3.0	32.8	3.0	34.4	3.0
[MCHC]	g/L	316	30	328	30	344	30
RDW	%	19.3	5.0	18.8	5.0	16.8	5.0
PLT	10 <sup>9</sup> /L	68	15	238	30	613	60
PCT	%	NA	0.03	NA	0.06	NA	0.20
MPV	fL	9.9	1.5	9.9	1.5	10.0	1.5
PDW	%	NA	5.5	NA	3.7	NA	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 för flere parametere / 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

#### ȳ 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 / ± Intervall previsto / ± Förväntat intervall

#### I Jsi Units

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

#### \* CELL-DYN 1400 instruments disregard MID values.

Přístroje CELL-DYN ignorují hodnoty MID. / Les instruments CELL-DYN 1400 ignorent les valeurs MID. / CELL-DYN 1400 Geräte ignorieren MID-Werte. / Gli strumenti CELL-DYN 1400 ignorano i valori INTERMEDI. / CELL-DYN 1400-instrumenter ignorerer MID-verdier. / Analizator CELL-DYN 1400 nie liczą leukocytów MID (o objętości pomiędzy neutrofilami a limfocytami). / Los instrumentos CELL-DYN 1400 no toman en cuenta los valores de la población de células de tamaño mediano. / CELL-DYN 1400-instrument bortser från MID-värden.

#### \*\* CD-1800 MPV values may report intermittently with Para 12 Extend.

Hodnoty CD-1800 MPV se při použití Para 12 Extend mohou hlásit přerušovaně. / Lorsque le Para 12 Extend est utilisé sur le CD-1800, il se peut que les valeurs du volume plaquettaire moyen (VPM) soient rapportées d'une façon sporadique. / Bei Verwendung von Para 12 Extend werden die durchschnittlichen Thrombozytenwerte von CD-1800 unter Umständen unregelmäßig angegeben. / I valori del volume piastrinico medio possono essere refertati dal CD-1800 in modo intermittente quando si utilizza Para 12 Extend. / Bruk av Para 12 Extend kan medføre intermitterende CD-1800-rapportering av gjennomsnittlige blodplateverdier. / Para 12 Extend umożliwia okresowe podawanie wartości przez CELL-DYN 1800. / Con Para 12 Extend, la notificación de los volúmenes plaquetarios medios por parte del CD-1800 podría ser intermitente. / När Para 12 Extend används kan genomsnittliga trombocytvolymet som rapporteras av CELL-DYN 1800 rapporteras emellanåt.

#### 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 ses 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 sygnały 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.