Boule Con-Diff

CONTROL

IVD

Control	Lot	
Tri-Level	22610-1K	2027-03-04
Low	22610-11	2027-03-04
Normal	22610-12	2027-03-04
High	22610-13	2027-03-04

Open vial stability 14 days [1]

MEDONIC

Medonic M-series/M32

		CONTROL	L	CONTROL	N	CONTROL	H
		LOT	22610-11	LOT	22610-12	LOT	22610-13
		Mean [2]	± Range [3]	Mean [2]	± Range [3]	Mean [2]	± Range [3]
RBC	10^{12}/L	2.23	0.12	4.16	0.18	5.08	0.22
MCV	fL	67.9	5.0	83.7	5.0	93.3	5.0
RDW	%	15.0	4.0	12.3	4.0	12.6	4.0
Hct	%	15.1	2.5	34.8	3.0	47.4	3.5
Plt	10^9/L	86	15	226	30	508	60
MPV	fL	11.7	1.5	11.7	1.5	11.9	1.5
WBC	10^9/L	3.5	0.3	8.6	0.6	20.7	1.8
Hgb	g/dL	5.5	0.3	12.2	0.4	16.3	0.5
MCH	pg	24.7	1.5	29.3	1.5	32.1	1.5
MCHC	g/dL	36.4	3.0	35.1	3.0	34.4	3.0
Lymph#	10^9/L	1.5	0.4	4.0	0.6	12.5	1.5
Mid#	10^9/L	0.2	0.3	0.6	0.5	1.3	1.0
Gran#	10^9/L	1.8	0.8	4.0	1.0	6.9	2.5
Lymph	%	43.9	7.0	46.1	5.0	60.4	5.0
Mid	%	5.4	5.0	7.1	5.0	6.4	5.0
Gran	%	50.7	7.0	46.8	5.0	33.2	5.0

	1	2	3
bg	Трайност на отворен флакон 14 дни (bg)	Средно	Обхват
hr	Stabilnost otvorene bočice 14 dani (hr)	Sredstvo	Raspon
cs	Stabilita otevřené ampulky 14 dny (cs)	Průměr	Rozsah
da	Åben rør stabilitet 14 dage (da)	Middelværdi	Område
et	Stabiilsus avatud viaalis 14 päevade (et)	Keskmine	Vahemik
fr	Stabilité en flacon ouvert 14 jour (fr)	Moyenne	Intervalle
de	Stabilität geöffneter Flaschen 14 tage (de)	Mittelwert	Bereich
el	Διατήρηση δείγματος μετά την αποσφράγιση 14 ημέρα (el)	Μέση	Αναμενόμενο εύρος α
it	Stabilità della fiala aperta 14 giorni (it)	Media	Intervallo
lv	Atvērt flakonu stabilitāti 14 dienas (lv)	Nozīmē	Diapazons
lt	Stabilumas atidarius buteliuką 14 dienas (lt)	Vidurkis	Intervalas
no	Åpen rør/glass stabilitet 14 dager (no)	Middelverdi	Område
pl	Trwałość po otworzeniu fiolki 14 Liczba dni (pl)	Średnia	Zakres
pt	Estabilidade após abertura do frasco 14 dias (pt)	Média	Intervalo
ro	Termenul de valabilitate al fiolei desfăcute 14 zile (ro)	Medie	Interval
ru	Стабильность вскрытого флакона 14 дней (ru)	Среднее	диапазон
sr	Proizvod stabilan nakon otvaranja pakovanja 14 dana (sr)	Srednja vrednost	Opseg
sk	Stabilita otvorenej injekčnej liekovky 14 dní (sk)	Priemer	Rozsah
sl	Stabilita otvorenej injekčnej liekovky 14 dni (sl)	Povprečno	Območje
es	Estabilidad de la cápsula abierta 14 dias (es)	Media	Intervalo
sv	Hållbarhet för öppnad flaska 14 dagar (sv)	Medelvärde	Intervall
tr	Açık şişe stabilitesi 14 gün (tr)	Ortalama	Aralığı

www.boule.com

Boule Medical AB
Fagerstagatan 7
SE-163 53 Spånga,
Sweden

25121-8

For Medonic M-series / M32 with barcode reader

M-Series:
1. In the Main Menu go to “Q/C Menu” “*Enter Con/Cal” “ Control/Calibrator Assay Value Input”*
2. Scan in each blood calibrator/control column by column, sequence 1 to 9

M32:
1. In the Main Menu go to “Quality Control” “Input Assays”
2. Scan in each blood calibrator / control column by column, sequence 1 to 9

Instr.:	M-series	Instr.:	M-series	Instr.:	M-series
Lot:	22610-11	Lot:	22610-12	Lot:	22610-13
Prod.:	Con-Diff Low	Prod.:	Con-Diff Norm	Prod.:	Con-Diff High
ID:	2261011+	ID:	2261012+	ID:	2261013+
Exp.:	4-Mar-2027	Exp.:	4-Mar-2027	Exp.:	4-Mar-2027

1:	BoulevCBAV2	BoulevCBAV2	BoulevCBAV2
2:	2261011+	2261012+	2261013+
3:	27030400001153030000	27030400002153030000	27030400003153030000
4:	10004029700000000000	10004029500000000000	10004029400000000000
5:	22312679500550315125	41618837501220434830	50822933501630547435
6:	08615117152471536430	22630117152931535130	50860119153211534430
7:	03503015040020301808	08606040060060504010	20718125150131006925
8:	15040439700545050770	12340461500715046850	12640604500645033250
9:	11112782230875915448	11118509287912281486	11111427039272832863

3.

Boule Con-Diff

CONTROL

IVD

Control	Lot	
Tri-Level	22610-1K	2027-03-04
Low	22610-11	2027-03-04
Normal	22610-12	2027-03-04
High	22610-13	2027-03-04

Open vial stability 14 days [1]

SWELAB

Swelab Alfa/Alfa Plus

		CONTROL	L
		LOT	22610-11
		Mean [2]	± Range [3]
RBC	10^{12}/L	2.24	0.12
MCV	fL	68.7	5.0
RDW	%	14.1	4.0
Hct	%	15.4	2.5
Plt	10^9/L	86	15
MPV	fL	12.2	1.5
WBC	10^9/L	3.4	0.3
Hgb	g/dL	5.6	0.3
MCH	pg	25.0	1.5
MCHC	g/dL	36.4	3.0
Lymph#	10^9/L	1.6	0.4
Mid#	10^9/L	0.1	0.3
Gran#	10^9/L	1.7	0.8
Lymph	%	47.5	7.0
Mid	%	3.6	5.0
Gran	%	48.9	7.0

CONTROL	N
LOT	22610-12
Mean [2]	± Range [3]
4.14	0.18
84.4	5.0
11.2	4.0
35.0	3.0
229	30
12.3	1.5
8.4	0.6
12.2	0.4
29.5	1.5
34.9	3.0
4.2	0.6
0.4	0.5
3.8	1.0
50.5	5.0
4.2	5.0
45.3	5.0

CONTROL	H
LOT	22610-13
Mean [2]	± Range [3]
5.03	0.22
94.4	5.0
11.7	4.0
47.5	3.5
525	60
12.6	1.5
20.4	1.8
16.3	0.5
32.4	1.5
34.4	3.0
13.1	1.5
0.8	1.0
6.5	2.5
64.2	5.0
4.1	5.0
31.7	5.0

	1	2	3
bg	Трайност на отворен флакон 14 дни (bg)	Средно	Обхват
hr	Stabilnost otvorene bočice 14 dani (hr)	Sredstvo	Raspon
cs	Stabilita otevřené ampulky 14 dny (cs)	Průměr	Rozsah
da	Åben rør stabilitet 14 dage (da)	Middelværdi	Område
et	Stabiilsus avatud viaalis 14 päevade (et)	Keskmine	Vahemik
fr	Stabilité en flacon ouvert 14 jour (fr)	Moyenne	Intervalle
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lv	Atvērt flakonu stabilitāti 14 dienas (lv)	Nozīmē	Diapazons
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no	Åpen rør/glass stabilitet 14 dager (no)	Middelverdi	Område
pl	Trwałość po otworzeniu fiolki 14 Liczba dni (pl)	Średnia	Zakres
pt	Estabilidade após abertura do frasco 14 dias (pt)	Média	Intervalo
ro	Termenul de valabilitate al fiolei desfăcute 14 zile (ro)	Medie	Interval
ru	Стабильность вскрытого флакона 14 дней (ru)	Среднее	диапазон
sr	Proizvod stabilan nakon otvaranja pakovanja 14 dana (sr)	Srednja vrednost	Opseg
sk	Stabilita otvorenej injekčnej liekovky 14 dní (sk)	Priemer	Rozsah
sl	Stabilita otvorenej injekčnej liekovky 14 dni (sl)	Povprečno	Območje
es	Estabilidad de la cápsula abierta 14 dias (es)	Media	Intervalo
sv	Hållbarhet för öppnad flaska 14 dagar (sv)	Medelvärde	Intervall
tr	Açık şişe stabilitesi 14 gün (tr)	Ortalama	Aralığı

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For Swelab Alfa / Alfa Plus with barcode reader

Alfa:
1. In the Main Menu go to “Q/C Menu” “*Enter Con/Cal” “ Control/Calibrator Assay Value Input”*
2. Scan in each blood calibrator/control column by column, sequence 1 to 9

Alfa Plus:
1. In the Main Menu go to “Quality Control” “Input Assays”
2. Scan in each blood calibrator / control column by column, sequence 1 to 9

Instr.:	Swelab Alfa	Instr.:	Swelab Alfa	Instr.:	Swelab Alfa
Lot:	22610-11	Lot:	22610-12	Lot:	22610-13
Prod.:	Con-Diff Low	Prod.:	Con-Diff Norm	Prod.:	Con-Diff High
ID:	2261011+	ID:	2261012+	ID:	2261013+
Exp.:	4-Mar-2027	Exp.:	4-Mar-2027	Exp.:	4-Mar-2027

1: BoulCBAV3 BoulCBAV3 BoulCBAV3

2: 2261011+ 2261012+ 2261013+

3: 27030400001153030000 27030400002153030000 27030400003153030000

4: 20014018000000000000 20014018000000000000 20014018000000000000

5: 22412687500560315425 41418844501220435030 50322944501630547535

6: 08615122152501536430 22930123152951534930 52560126153241534430

7: 03403016040010301708 08406042060040503810 20418131150081006525

8: 14140475700365048970 11240505500425045350 11740642500415031750

9: 11113775532635570609 11114452540932003350 11110958258582727947