

# Boule Con-Diff

CONTROL

IVD



Open vial stability 14 days <sup>1</sup>

| Control   | Lot      |            |
|-----------|----------|------------|
| Tri-Level | --       | --         |
| Low       | 22505-41 | 2025-10-03 |
| Normal    | 22505-42 | 2025-10-03 |
| High      | 22505-43 | 2025-10-07 |

## MEDONIC

| CONTROL              |                     | L                 |                      |
|----------------------|---------------------|-------------------|----------------------|
| LOT                  |                     | 22505-41          |                      |
| Medonic M-series/M32 |                     | Mean <sup>2</sup> | ± Range <sup>3</sup> |
| RBC                  | 10 <sup>12</sup> /L | 2.25              | 0.12                 |
| MCV                  | fL                  | 70.0              | 5.0                  |
| RDW                  | %                   | 15.2              | 4.0                  |
| Hct                  | %                   | 15.8              | 2.5                  |
| Plt                  | 10 <sup>9</sup> /L  | 81                | 15                   |
| MPV                  | fL                  | 11.1              | 1.5                  |
| WBC                  | 10 <sup>9</sup> /L  | 3.3               | 0.3                  |
| Hgb                  | g/dL                | 5.8               | 0.3                  |
| MCH                  | pg                  | 25.8              | 1.5                  |
| MCHC                 | g/dL                | 36.7              | 3.0                  |
| Lymph#               | 10 <sup>9</sup> /L  | 1.4               | 0.4                  |
| Mid#                 | 10 <sup>9</sup> /L  | 0.2               | 0.3                  |
| Gran#                | 10 <sup>9</sup> /L  | 1.7               | 0.8                  |
| Lymph                | %                   | 43.8              | 7.0                  |
| Mid                  | %                   | 5.0               | 5.0                  |
| Gran                 | %                   | 51.2              | 7.0                  |

| CONTROL |  | N                 |                      |
|---------|--|-------------------|----------------------|
| LOT     |  | 22505-42          |                      |
|         |  | Mean <sup>2</sup> | ± Range <sup>3</sup> |
|         |  | 4.18              | 0.18                 |
|         |  | 83.6              | 5.0                  |
|         |  | 12.6              | 4.0                  |
|         |  | 34.9              | 3.0                  |
|         |  | 237               | 30                   |
|         |  | 11.1              | 1.5                  |
|         |  | 8.3               | 0.6                  |
|         |  | 12.3              | 0.4                  |
|         |  | 29.4              | 1.5                  |
|         |  | 35.2              | 3.0                  |
|         |  | 3.9               | 0.6                  |
|         |  | 0.5               | 0.5                  |
|         |  | 3.9               | 1.0                  |
|         |  | 46.5              | 5.0                  |
|         |  | 6.5               | 5.0                  |
|         |  | 47.0              | 5.0                  |

| CONTROL |  | H                 |                      |
|---------|--|-------------------|----------------------|
| LOT     |  | 22505-43          |                      |
|         |  | Mean <sup>2</sup> | ± Range <sup>3</sup> |
|         |  | 5.03              | 0.22                 |
|         |  | 89.7              | 5.0                  |
|         |  | 13.1              | 4.0                  |
|         |  | 45.1              | 3.5                  |
|         |  | 547               | 60                   |
|         |  | 11.5              | 1.5                  |
|         |  | 20.4              | 1.8                  |
|         |  | 15.5              | 0.5                  |
|         |  | 30.8              | 1.5                  |
|         |  | 34.4              | 3.0                  |
|         |  | 12.5              | 1.5                  |
|         |  | 1.2               | 1.0                  |
|         |  | 6.7               | 2.5                  |
|         |  | 61.3              | 5.0                  |
|         |  | 5.9               | 5.0                  |
|         |  | 32.8              | 5.0                  |

1  
bg Трайност на отворен флакон 14 дни (bg)  
hr Stabilität otvorene bočice 14 dni (hr)  
cs Stabilita otevřené ampulky 14 dní (cs)  
da Åben rør stabilitet 14 dage (da)  
et Stabilsus avatud viaalis 14 päevade (et)  
fr Stabilité en flacon ouvert 14 jour (fr)  
de Stabilität geöffnete Flaschen 14 tage (de)  
el Διατήρηση δείγματος μετά την αποσφράγιση 14 ημέρα (el)  
it Stabilità della fiala aperta 14 giorni (it)  
lv Atvērt flakonu stabilitāti 14 dienas (lv)  
lt Stabilitumas atidarius buteliuką 14 dienas (lt)  
no Åpen rør/glass stabilitet 14 dager (no)  
pl Trwałość po otwarciu fiolek 14 Liczba dni (pl)  
pt Estabilidade após abertura do frasco 14 dias (pt)  
ro Termenul de valabilitate al fiolei desfăcute 14 zile (ro)  
ru Стабильность вскрытого флакона 14 дней (ru)  
sr Proizvod stabilan nakon otvaranja pakovanja 14 dana (sr)  
sk Stabilita otvorenej injekčnej liekovky 14 dní (sk)  
sl Stabilita otvorene injekčnej liekovky 14 dni (sl)  
es Estabilidad de la cápsula abierta 14 días (es)  
sv Hållbarhet för öppnad flaska 14 dagar (sv)  
tr Açık şişe stabilitesi 14 gün (tr)

2  
Средно  
Sredstvo  
Průměr  
Middelværdi  
Keskmine  
Moyenne  
Mittelwert  
Μέση  
Media  
Nozīmē  
Vidurkis  
Middelverdi  
Średnia  
Média  
Medie  
Среднее  
Srednja vrednost  
Priemer  
Povprečno  
Media  
Medelvärde  
Ortalama

3  
Обхват  
Raspon  
Rozsah  
Område  
Vahemik  
Intervalle  
Bereich  
Αναμενόμενο εύρος α  
Intervallo  
Diapazons  
Intervalas  
Område  
Zakres  
Intervalo  
Interval  
диапазон  
Opseg  
Rozsah  
Območje  
Intervalo  
Intervall  
Arahğı

## 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  
Lot: 22505-41  
Prod.: Con-Diff Low  
ID: 2250541+  
Exp.: 3-Oct-2025

Instr.: M-series  
Lot: 22505-42  
Prod.: Con-Diff Norm  
ID: 2250542+  
Exp.: 3-Oct-2025

Instr.: M-series  
Lot: 22505-43  
Prod.: Con-Diff High  
ID: 2250543+  
Exp.: 7-Oct-2025



3.

# Boule Con-Diff

CONTROL

IVD



Open vial stability 14 days <sup>1</sup>

| Control   | Lot      |            |
|-----------|----------|------------|
| Tri-Level | --       | --         |
| Low       | 22505-41 | 2025-10-03 |
| Normal    | 22505-42 | 2025-10-03 |
| High      | 22505-43 | 2025-10-07 |

## SWELAB

| CONTROL               |                     | L                 |                      |
|-----------------------|---------------------|-------------------|----------------------|
| LOT                   |                     | 22505-41          |                      |
| Swelab Alfa/Alfa Plus |                     | Mean <sup>2</sup> | ± Range <sup>3</sup> |
| RBC                   | 10 <sup>12</sup> /L | 2.27              | 0.12                 |
| MCV                   | fL                  | 71.6              | 5.0                  |
| RDW                   | %                   | 14.3              | 4.0                  |
| Hct                   | %                   | 16.3              | 2.5                  |
| Plt                   | 10 <sup>9</sup> /L  | 84                | 15                   |
| MPV                   | fL                  | 11.9              | 1.5                  |
| WBC                   | 10 <sup>9</sup> /L  | 3.3               | 0.3                  |
| Hgb                   | g/dL                | 5.9               | 0.3                  |
| MCH                   | pg                  | 26.0              | 1.5                  |
| MCHC                  | g/dL                | 36.2              | 3.0                  |
| Lymph#                | 10 <sup>9</sup> /L  | 1.6               | 0.4                  |
| Mid#                  | 10 <sup>9</sup> /L  | 0.1               | 0.3                  |
| Gran#                 | 10 <sup>9</sup> /L  | 1.6               | 0.8                  |
| Lymph                 | %                   | 47.6              | 7.0                  |
| Mid                   | %                   | 3.2               | 5.0                  |
| Gran                  | %                   | 49.2              | 7.0                  |

| CONTROL |  | N                 |                      |
|---------|--|-------------------|----------------------|
| LOT     |  | 22505-42          |                      |
|         |  | Mean <sup>2</sup> | ± Range <sup>3</sup> |
|         |  | 4.17              | 0.18                 |
|         |  | 84.5              | 5.0                  |
|         |  | 11.3              | 4.0                  |
|         |  | 35.2              | 3.0                  |
|         |  | 243               | 30                   |
|         |  | 11.8              | 1.5                  |
|         |  | 8.4               | 0.6                  |
|         |  | 12.3              | 0.4                  |
|         |  | 29.5              | 1.5                  |
|         |  | 34.9              | 3.0                  |
|         |  | 4.2               | 0.6                  |
|         |  | 0.3               | 0.5                  |
|         |  | 3.9               | 1.0                  |
|         |  | 50.3              | 5.0                  |
|         |  | 3.6               | 5.0                  |
|         |  | 46.1              | 5.0                  |

| CONTROL |  | H                 |                      |
|---------|--|-------------------|----------------------|
| LOT     |  | 22505-43          |                      |
|         |  | Mean <sup>2</sup> | ± Range <sup>3</sup> |
|         |  | 5.00              | 0.22                 |
|         |  | 91.0              | 5.0                  |
|         |  | 11.8              | 4.0                  |
|         |  | 45.5              | 3.5                  |
|         |  | 563               | 60                   |
|         |  | 12.3              | 1.5                  |
|         |  | 20.3              | 1.8                  |
|         |  | 15.4              | 0.5                  |
|         |  | 30.8              | 1.5                  |
|         |  | 33.8              | 3.0                  |
|         |  | 13.0              | 1.5                  |
|         |  | 0.8               | 1.0                  |
|         |  | 6.5               | 2.5                  |
|         |  | 64.4              | 5.0                  |
|         |  | 3.7               | 5.0                  |
|         |  | 31.9              | 5.0                  |

1

|    |                                                           |
|----|-----------------------------------------------------------|
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| da | Åben rør stabilitet 14 dage (da)                          |
| et | Stabiilsus avatud vialis 14 päevade (et)                  |
| fr | Stabilité en flacon ouvert 14 jour (fr)                   |
| de | Stabilität geöffneter Flaschen 14 tage (de)               |
| el | Διάρθρωση δείγματος μετά την αποσφράγιση 14 ημέρα (el)    |
| it | Stabilità della fiala aperta 14 giorni (it)               |
| lv | Atvērt flakonu stabilitāti 14 dienas (lv)                 |
| lt | Stabilumas atidarius buteliuką 14 dienas (lt)             |
| no | Åpen rør/glass stabilitet 14 dager (no)                   |
| pl | Trwałość po otwarciu fiolek 14 dni (pl)                   |
| pt | Estabilidade após abertura do frasco 14 dias (pt)         |
| ro | Termenul de valabilitate al fiolei desfăcute 14 zile (ro) |
| ru | Стабильность вскрытого флакона 14 дней (ru)               |
| sr | Proizvod stabilan nakon otvaranja pakovanja 14 dana (sr)  |
| sk | Stabilita otvorenej injekčnej liekovky 14 dní (sk)        |
| sl | Stabilita otvorenej injekčneje liekovky 14 dni (sl)       |
| es | Estabilidad de la cápsula abierta 14 días (es)            |
| sv | Hållbarhet för öppnad flaska 14 dagar (sv)                |
| tr | Açık şişe stabilitesi 14 gün (tr)                         |

2

|                  |
|------------------|
| Sredno           |
| Sredstvo         |
| Průměr           |
| Middelverdi      |
| Keskmine         |
| Moyenne          |
| Mittelwert       |
| Μέση             |
| Media            |
| Nozīmē           |
| Vidurkis         |
| Middelverdi      |
| Średnia          |
| Média            |
| Medie            |
| Среднее          |
| Srednja vrednost |
| Priemer          |
| Povprečno        |
| Media            |
| Medelvärde       |
| Ortalama         |

3

|                     |
|---------------------|
| Обхват              |
| Raspon              |
| Rozsah              |
| Område              |
| Vahemik             |
| Intervalle          |
| Bereich             |
| Αναμενόμενο εύρος α |
| Intervallo          |
| Diapazons           |
| Intervalas          |
| Område              |
| Zakres              |
| Intervalo           |
| Interval            |
| диапазон            |
| Opseg               |
| Rozsah              |
| Območje             |
| Intervalo           |
| Intervall           |
| Aralığı             |

## 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

Lot: 22505-41

Prod.: Con-Diff Low

ID: 2250541+

Exp.: 3-Oct-2025

Instr.: Swelab Alfa

Lot: 22505-42

Prod.: Con-Diff Norm

ID: 2250542+

Exp.: 3-Oct-2025

Instr.: Swelab Alfa

Lot: 22505-43

Prod.: Con-Diff High

ID: 2250543+

Exp.: 7-Oct-2025

1:



B o u l e C B A V 3



B o u l e C B A V 3



B o u l e C B A V 3

2:



2250541+



2250542+



2250543+

3:



25100300001153030000



25100300002153030000



25100700003153030000

4:



20014018000000000000



20014018000000000000



20014018000000000000

5:



22712716500590316325



41718845501230435230



50022910501540545535

6:



08415119152601536230



24330118152951534930



56360123153081533830

7:



03303016040010301608



08406042060030503910



20318130150081006525

8:



14340476700325049270



11340503500365046150



11840644500375031950

9:



11118063451287346149



11116606366727339963



11116631858659417153