

Boule Con-Diff

CONTROL

IVD



| Control | Lot | |
|-----------|----------|------------|
| Tri-Level | -- | -- |
| Low | 22408-41 | 2025-01-06 |
| Normal | 22408-42 | 2025-01-06 |
| High | 22408-43 | 2025-01-06 |

Open vial stability 14 days ¹

MEDONIC

| Medonic M-series/M32 | | CONTROL | L |
|----------------------|---------------------|-------------------|----------------------|
| | | LOT | 22408-41 |
| | | Mean ² | ± Range ³ |
| RBC | 10 ¹² /L | 2.30 | 0.12 |
| MCV | fL | 65.7 | 5.0 |
| RDW | % | 15.2 | 4.0 |
| Hct | % | 15.1 | 2.5 |
| Plt | 10 ⁹ /L | 83 | 15 |
| MPV | fL | 11.1 | 1.5 |
| WBC | 10 ⁹ /L | 3.4 | 0.3 |
| Hgb | g/dL | 5.6 | 0.3 |
| MCH | pg | 24.3 | 1.5 |
| MCHC | g/dL | 37.1 | 3.0 |
| Lymph# | 10 ⁹ /L | 1.5 | 0.4 |
| Mid# | 10 ⁹ /L | 0.2 | 0.3 |
| Gran# | 10 ⁹ /L | 1.7 | 0.8 |
| Lymph | % | 44.3 | 7.0 |
| Mid | % | 6.2 | 5.0 |
| Gran | % | 49.5 | 7.0 |

| CONTROL | N | LOT | 22408-42 | Mean ² | ± Range ³ |
|---------|---|-----|----------|-------------------|----------------------|
| | | | | | |
| | | | | 4.12 | 0.18 |
| | | | | 86.0 | 5.0 |
| | | | | 14.2 | 4.0 |
| | | | | 35.4 | 3.0 |
| | | | | 238 | 30 |
| | | | | 11.8 | 1.5 |
| | | | | 8.6 | 0.6 |
| | | | | 12.4 | 0.4 |
| | | | | 30.1 | 1.5 |
| | | | | 35.0 | 3.0 |
| | | | | 4.0 | 0.6 |
| | | | | 0.6 | 0.5 |
| | | | | 4.0 | 1.0 |
| | | | | 46.6 | 5.0 |
| | | | | 6.8 | 5.0 |
| | | | | 46.6 | 5.0 |

| CONTROL | H | LOT | 22408-43 | Mean ² | ± Range ³ |
|---------|---|-----|----------|-------------------|----------------------|
| | | | | | |
| | | | | 5.08 | 0.22 |
| | | | | 92.7 | 5.0 |
| | | | | 14.3 | 4.0 |
| | | | | 47.1 | 3.5 |
| | | | | 533 | 60 |
| | | | | 11.6 | 1.5 |
| | | | | 20.7 | 1.8 |
| | | | | 16.1 | 0.5 |
| | | | | 31.7 | 1.5 |
| | | | | 34.2 | 3.0 |
| | | | | 12.5 | 1.5 |
| | | | | 1.3 | 1.0 |
| | | | | 6.9 | 2.5 |
| | | | | 60.5 | 5.0 |
| | | | | 6.2 | 5.0 |
| | | | | 33.3 | 5.0 |

1

| | |
|----|---|
| bg | Трайност на отворен флакон 14 дни (bg) |
| hr | Stabilnost otvorene bočice 14 dani (hr) |
| cs | Stabilita otevřené ampulky 14 dní (cs) |
| 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 | Διατήρηση 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 fiołki 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 otvorenej 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

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| | 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 |
| | Intervallo |
| | Intervall |
| | Aralığı |

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: 22408-41
 Prod.: Con-Diff Low
 ID: 2240841+
 Exp.: 6-Jan-2025

Instr.: M-series
 Lot: 22408-42
 Prod.: Con-Diff Norm
 ID: 2240842+
 Exp.: 6-Jan-2025

Instr.: M-series
 Lot: 22408-43
 Prod.: Con-Diff High
 ID: 2240843+
 Exp.: 6-Jan-2025



Boule Con-Diff

CONTROL

IVD



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Open vial stability 14 days ¹

SWELAB

| Swelab Alfa/Alfa Plus | CONTROL | | L |
|-----------------------|---------------------|----------------------|----------|
| | LOT | 22408-41 | 22408-41 |
| | Mean ² | ± Range ³ | |
| RBC | 10 ¹² /L | 2.31 | 0.12 |
| MCV | fL | 67.5 | 5.0 |
| RDW | % | 14.5 | 4.0 |
| Hct | % | 15.6 | 2.5 |
| Plt | 10 ⁹ /L | 83 | 15 |
| MPV | fL | 12.1 | 1.5 |
| WBC | 10 ⁹ /L | 3.3 | 0.3 |
| Hgb | g/dL | 5.7 | 0.3 |
| MCH | pg | 24.7 | 1.5 |
| MCHC | g/dL | 36.5 | 3.0 |
| Lymph# | 10 ⁹ /L | 1.6 | 0.4 |
| Mid# | 10 ⁹ /L | 0.2 | 0.3 |
| Gran# | 10 ⁹ /L | 1.5 | 0.8 |
| Lymph | % | 48.8 | 7.0 |
| Mid | % | 4.8 | 5.0 |
| Gran | % | 46.4 | 7.0 |

| CONTROL | N | |
|---------|-------------------|----------------------|
| | LOT | 22408-42 |
| | Mean ² | ± Range ³ |
| | 4.14 | 0.18 |
| | 87.7 | 5.0 |
| | 12.7 | 4.0 |
| | 36.3 | 3.0 |
| | 243 | 30 |
| | 12.8 | 1.5 |
| | 8.5 | 0.6 |
| | 12.4 | 0.4 |
| | 30.0 | 1.5 |
| | 34.2 | 3.0 |
| | 4.3 | 0.6 |
| | 0.4 | 0.5 |
| | 3.8 | 1.0 |
| | 50.8 | 5.0 |
| | 4.2 | 5.0 |
| | 45.0 | 5.0 |

| CONTROL | H | |
|---------|-------------------|----------------------|
| | LOT | 22408-43 |
| | Mean ² | ± Range ³ |
| | 5.09 | 0.22 |
| | 94.1 | 5.0 |
| | 13.1 | 4.0 |
| | 47.9 | 3.5 |
| | 548 | 60 |
| | 12.8 | 1.5 |
| | 20.4 | 1.8 |
| | 16.1 | 0.5 |
| | 31.6 | 1.5 |
| | 33.6 | 3.0 |
| | 13.0 | 1.5 |
| | 0.8 | 1.0 |
| | 6.6 | 2.5 |
| | 63.9 | 5.0 |
| | 3.8 | 5.0 |
| | 32.3 | 5.0 |

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| | Média |
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3

| | |
|--|---------------------|
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| | Intervalle |
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| | Område |
| | Zakres |
| | Intervalo |
| | Interval |
| | диапазон |
| | Orseg |
| | 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

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Lot: 22408-41
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ID: 2240841+
Exp.: 6-Jan-2025

Instr.: Swelab Alfa
Lot: 22408-42
Prod.: Con-Diff Norm
ID: 2240842+
Exp.: 6-Jan-2025

Instr.: Swelab Alfa
Lot: 22408-43
Prod.: Con-Diff High
ID: 2240843+
Exp.: 6-Jan-2025

