

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - April 2024 -

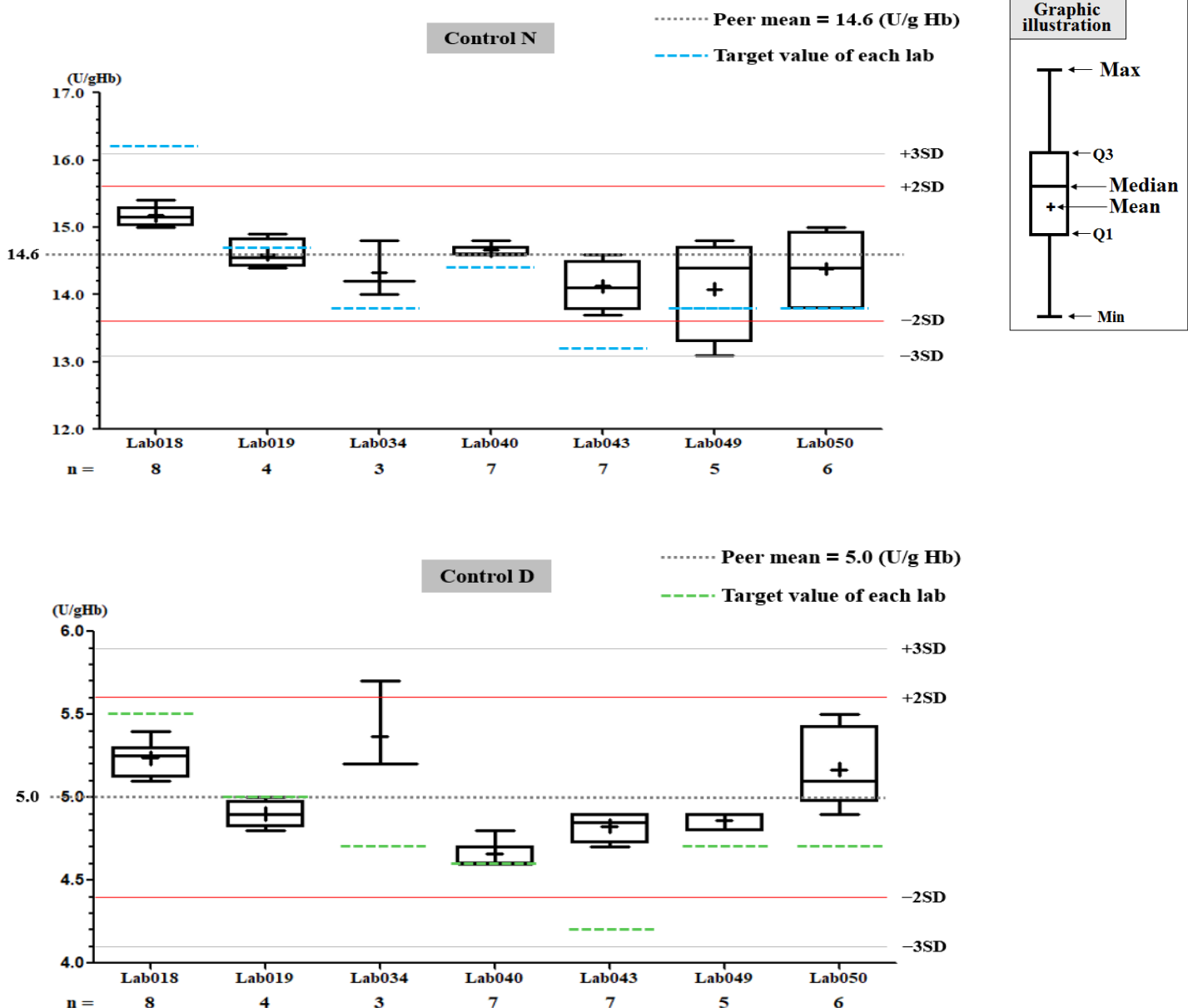
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:BJ0922N) | Control D (Lot No.: BJ0922D) |
|-----------------------------|--------------------------------|---------------------------------|
| Labs | 7 | 7 |
| Received results number (n) | 37 | 37 |
| Median | 14.6 (U/g Hb) | 4.9 (U/g Hb) |
| Mean | 14.6 (U/g Hb) | 5.0 (U/g Hb) |
| SD | 0.5 | 0.3 |
| CV | 3.4% | 6.0% |
| Range of G6PD | 13.1 ~ 15.4 (U/g Hb) | 4.6 ~ 5.7 (U/g Hb) |
| Range of Hb | 2.0 ~ 2.7 (g/dL) | 1.8 ~ 2.3 (g/dL) |

*The statistic results are calculated from all labs reported in this month

** G6PD Method = Medicon reagent kit, 37°C

II. The distribution of G6PD reported for each lab in this survey



G6PD 定量檢驗內部品管統計結果及 SDI 分佈圖

選擇 LotNo : BJ0922N (2021-01-01 ~ 2100-12-31) Change

列印圖表

檢驗單位 : **Lab019**

| QC Control Lot No. | Control N | | Control D | |
|--------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | BJ0922N | | BJ0922D | |
| 檢驗期間 | Month (2024/04) | CUM (2023/11/01~2024/04/30) | Month (2024/04) | CUM (2023/11/01~2024/04/30) |
| 累計點數 (N) | 4 | 26 | 4 | 26 |
| 累計平均值 (Mean) U/gHb | 14.6 | 14.8 | 4.9 | 5.0 |
| 累計標準差 (SD) | 0.2 | 0.3 | 0.1 | 0.1 |
| 累計變異係數 (CV) % | 1.4 | 2.0 | 2.0 | 2.0 |
| 目標值 (Target) U/gHb | 14.7 | 14.7 | 5.0 | 5.0 |
| 總誤差 (TE) % | 3.4 | 4.7 | 6.1 | 4.0 |
| 可容許總誤差 (TEa) % | 20 | 20 | 20 | 20 |
| σ | >6 | >6 | >6 | >6 |

誤差 (Bias)% = { [| 累計平均值 (Mean) - 目標值 (Target) |] / 目標值 (Target) } x 100%

總誤差 (TE, Total Error)% = 誤差 (Bias)% + 2 x 累計變異係數 (CV)

σ (Sigma) = (TEa% - 誤差 (Bias)%) / 累計變異係數 (CV)

月統計 : 2024 04 Change ; 累計期間 (CUM) : 自 2023 11 01 至 2024 04 30 Change

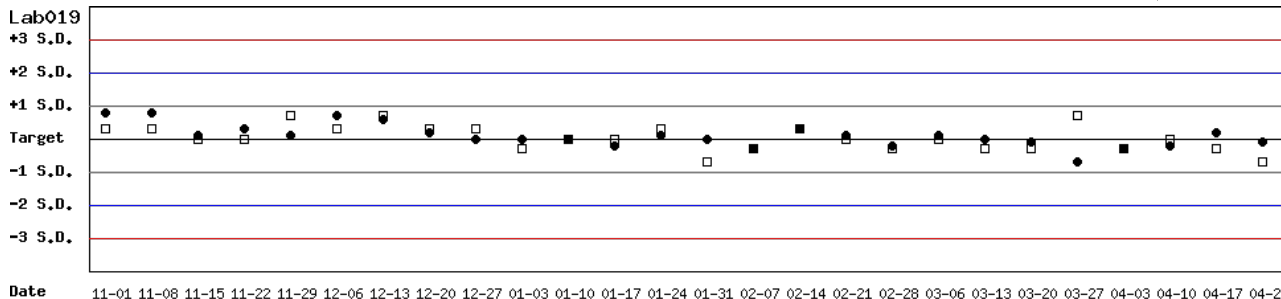
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Control N 及 Control D SDI 分佈圖

Lot No.: BJ0922N ; 檢驗期間 : 2023-11-01 至 2024-04-30 ; 目標值 (Target) : 14.7 ; 參考標準差 (SD) : 0.90 (●)

Lot No.: BJ0922D ; 檢驗期間 : 2023-11-01 至 2024-04-30 ; 目標值 (Target) : 5.0 ; 參考標準差 (SD) : 0.30 (□)

單位 : Lab019



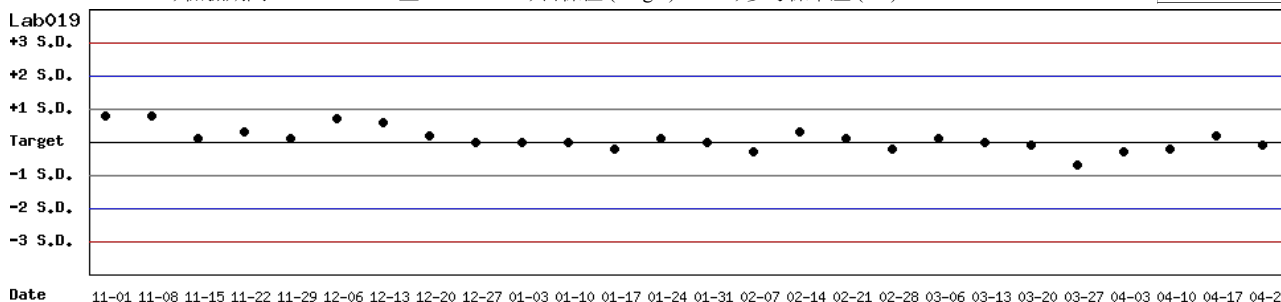
月統計 : 2024 04 Change ; 累計期間 (CUM) : 自 2023 11 01 至 2024 04 30 Change

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Control N SDI 分佈圖

Lot No.: BJ0922N ; 檢驗期間 : 2023-11-01 至 2024-04-30 ; 目標值 (Target) : 14.7 ; 參考標準差 (SD) : 0.90

單位 : Lab019



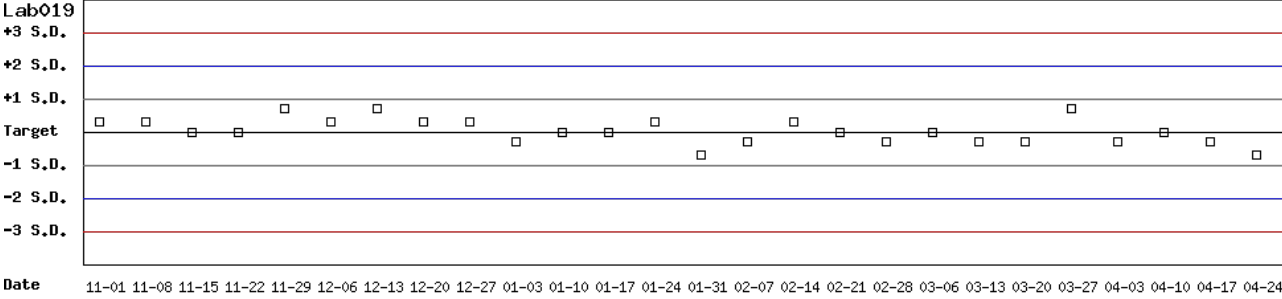
月統計 : 2024 04 Change ; 累計期間 (CUM) : 自 2023 11 01 至 2024 04 30 Change

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Control D SDI 分佈圖

Lot No.: BJ0922D ; 檢驗期間 : 2023-11-01 至 2024-04-30 ; 目標值 (Target) : 5.0 ; 參考標準差 (SD) : 0.30

單位 : Lab019



月統計 : 2024 ▾ 04 ▾ Change ; 累計期間 (CUM) : 自 2023 ▾ 11 ▾ 01 ▾ 至 2024 ▾ 04 ▾ 30 ▾ Change

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Peer Group Statistics (Table 1)

Select LotNo : BJ0922N (2021-01-01 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 1

Monthly

Month : 2024 04 Change

| UnitID ↑ | Reagent Kit (Code) ↑ | Control N (Lot No.: BJ0922N) | | | | | | | | Control D (Lot No.: BJ0922D) | | | | | | | |
|---|--|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|
| | | Target (U/gHb) | Mean (U/gHb) | n for Mean | SD | CV (%) | TE (%) | TEa (%) | σ | Target (U/gHb) | Mean (U/gHb) | n for Mean | SD | CV (%) | TE (%) | TEa (%) | σ |
| Lab018 | 5 | 16.2 | 15.2 | 8 | 0.2 | 1.3 | 8.8 | 20 | >6 | 5.5 | 5.2 | 8 | 0.1 | 1.9 | 9.3 | 20 | >6 |
| Lab019 | 5 | 14.7 | 14.6 | 4 | 0.2 | 1.4 | 3.4 | 20 | >6 | 5.0 | 4.9 | 4 | 0.1 | 2.0 | 6.1 | 20 | >6 |
| Lab034 | 5 | 13.8 | 14.3 | 3 | 0.4 | 2.8 | 9.2 | 20 | 5.8 | 4.7 | 5.4 | 3 | 0.3 | 5.6 | 26.0 | 20 | 0.9 |
| Lab040 | 5 | 14.4 | 14.7 | 7 | 0.1 | 0.7 | 3.4 | 20 | >6 | 4.6 | 4.7 | 7 | 0.1 | 2.1 | 6.4 | 20 | >6 |
| Lab043 | 5 | 13.2 | 14.1 | 4 | 0.4 | 2.8 | 12.5 | 20 | 4.7 | 4.2 | 4.8 | 4 | 0.1 | 2.1 | 18.5 | 20 | 2.7 |
| Lab049 | 5 | 13.8 | 14.1 | 5 | 0.7 | 5.0 | 12.1 | 20 | 3.6 | 4.7 | 4.9 | 5 | 0.1 | 2.0 | 8.3 | 20 | >6 |
| Lab050 | 5 | 13.8 | 14.4 | 6 | 0.5 | 3.5 | 11.3 | 20 | 4.5 | 4.7 | 5.2 | 6 | 0.2 | 3.8 | 18.3 | 20 | 2.5 |
| Total | - | - | 14.6 | 37 | 0.5 | 3.4 | - | - | - | - | 5.0 | 37 | 0.3 | 6.0 | - | - | - |

Bias (%) = [(| Mean - Target |) / Target] x 100%

TE : Total Error(%) = Bias (%) + 2 × CV (%)

σ (Sigma) = [TEa% - Bias (%)] / CV (%)

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Cumulative

Cumulative : from 2021 01 01 to 2024 04 30 Change

| UnitID ↑ | Reagent Kit (Code) ↑ | Control N (Lot No.: BJ0922N) | | | | | | | | Control D (Lot No.: BJ0922D) | | | | | | | |
|---|--|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|
| | | Target (U/gHb) | Mean (U/gHb) | n for Mean | SD | CV (%) | TE (%) | TEa (%) | σ | Target (U/gHb) | Mean (U/gHb) | n for Mean | SD | CV (%) | TE (%) | TEa (%) | σ |
| Lab018 | 5 | 16.2 | 15.3 | 70 | 0.5 | 3.3 | 12.1 | 20 | 4.4 | 5.5 | 5.4 | 70 | 0.1 | 1.9 | 5.5 | 20 | >6 |
| Lab019 | 5 | 14.7 | 14.5 | 109 | 0.6 | 4.1 | 9.6 | 20 | 4.5 | 5.0 | 4.8 | 109 | 0.3 | 6.3 | 16.5 | 20 | 2.5 |
| Lab020 | 5 | 14.4 | 14.4 | 85 | 0.5 | 3.5 | 6.9 | 20 | 5.7 | 4.6 | 4.7 | 85 | 0.2 | 4.3 | 10.7 | 20 | 4.1 |
| Lab022 | 5 | 14.4 | 14.4 | 27 | 0.5 | 3.5 | 6.9 | 20 | 5.7 | 4.6 | 4.7 | 27 | 0.3 | 6.4 | 14.9 | 20 | 2.8 |
| Lab028 | 5 | 15.2 | 15.1 | 34 | 1.1 | 7.3 | 15.2 | 20 | 2.6 | 4.9 | 4.9 | 34 | 0.3 | 6.1 | 12.2 | 20 | 3.3 |
| Lab032 | 5 | 14.9 | 14.3 | 153 | 0.4 | 2.8 | 9.6 | 20 | 5.7 | 4.8 | 4.5 | 153 | 0.2 | 4.4 | 15.1 | 20 | 3.1 |
| Lab033 | 5 | 13.8 | 13.6 | 81 | 0.7 | 5.1 | 11.7 | 20 | 3.6 | 4.7 | 4.6 | 81 | 0.3 | 6.5 | 15.2 | 20 | 2.7 |
| Lab034 | 5 | 13.8 | 14.5 | 6 | 0.3 | 2.1 | 9.2 | 20 | >6 | 4.7 | 5.3 | 6 | 0.2 | 3.8 | 20.3 | 20 | 1.9 |
| Lab037 | 5 | 13.8 | 14.5 | 59 | 0.5 | 3.4 | 12.0 | 20 | 4.4 | 4.7 | 4.7 | 59 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Lab040 | 5 | 14.4 | 14.8 | 104 | 0.2 | 1.4 | 5.5 | 20 | >6 | 4.6 | 4.6 | 104 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab043 | 5 | 13.2 | 13.9 | 136 | 1.1 | 7.9 | 21.1 | 20 | 1.9 | 4.2 | 4.6 | 136 | 0.4 | 8.7 | 26.9 | 20 | 1.2 |
| Lab049 | 5 | 13.8 | 14.4 | 207 | 0.6 | 4.2 | 12.7 | 20 | 3.7 | 4.7 | 4.7 | 207 | 0.3 | 6.4 | 12.8 | 20 | 3.1 |
| Lab050 | 5 | 13.8 | 14.2 | 13 | 0.7 | 4.9 | 12.8 | 20 | 3.5 | 4.7 | 5.3 | 13 | 0.3 | 5.7 | 24.1 | 20 | 1.3 |
| Total | - | - | 14.4 | 1084 | 0.8 | 5.6 | - | - | - | - | 4.7 | 1084 | 0.3 | 6.4 | - | - | - |

Bias (%) = [(| Mean - Target |) / Target] x 100%

TE : Total Error(%) = Bias (%) + 2 × CV (%)

σ (Sigma) = [TEa% - Bias (%)] / CV (%)

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| Reagent Kit | Reagent Code |
|-------------|--------------|
| Medicon | 5 |

Peer Group Statistics (Table 2)

Select LotNo : BJ0922N (2021-01-01 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 2

Control N Month vs. Cumulative

| | | Control N (Lot No.: BJ0922N) | | | | | | | | | | | | | | | |
|-------------------------|-------------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|----------------|-----------------------------|------------|-----|--------|--------|---------|-----|
| | | Month (2024/04) | | | | | | | | | CUM (2021/01/01-2024/04/30) | | | | | | |
| UnitID <small>↑</small> | Reagent Kit (Code) <small>↑</small> | Target (U/gHb) | Mean (U/gHb) | n for Mean | SD | CV (%) | TE (%) | TEa (%) | σ | Target (U/gHb) | Mean (U/gHb) | n for Mean | SD | CV (%) | TE (%) | TEa (%) | σ |
| Lab018 | 5 | 16.2 | 15.2 | 8 | 0.2 | 1.3 | 8.8 | 20 | >6 | 16.2 | 15.3 | 70 | 0.5 | 3.3 | 12.1 | 20 | 4.4 |
| Lab019 | 5 | 14.7 | 14.6 | 4 | 0.2 | 1.4 | 3.4 | 20 | >6 | 14.7 | 14.5 | 109 | 0.6 | 4.1 | 9.6 | 20 | 4.5 |
| Lab020 | 5 | 14.4 | - | 0 | - | - | - | 20 | - | 14.4 | 14.4 | 85 | 0.5 | 3.5 | 6.9 | 20 | 5.7 |
| Lab022 | 5 | 14.4 | - | 0 | - | - | - | 20 | - | 14.4 | 14.4 | 27 | 0.5 | 3.5 | 6.9 | 20 | 5.7 |
| Lab028 | 5 | 15.2 | - | 0 | - | - | - | 20 | - | 15.2 | 15.1 | 34 | 1.1 | 7.3 | 15.2 | 20 | 2.6 |
| Lab032 | 5 | 14.9 | - | 0 | - | - | - | 20 | - | 14.9 | 14.3 | 153 | 0.4 | 2.8 | 9.6 | 20 | 5.7 |
| Lab033 | 5 | 13.8 | - | 0 | - | - | - | 20 | - | 13.8 | 13.6 | 81 | 0.7 | 5.1 | 11.7 | 20 | 3.6 |
| Lab034 | 5 | 13.8 | 14.3 | 3 | 0.4 | 2.8 | 9.2 | 20 | 5.8 | 13.8 | 14.5 | 6 | 0.3 | 2.1 | 9.2 | 20 | >6 |
| Lab037 | 5 | 13.8 | - | 0 | - | - | - | 20 | - | 13.8 | 14.5 | 59 | 0.5 | 3.4 | 12.0 | 20 | 4.4 |
| Lab040 | 5 | 14.4 | 14.7 | 7 | 0.1 | 0.7 | 3.4 | 20 | >6 | 14.4 | 14.8 | 104 | 0.2 | 1.4 | 5.5 | 20 | >6 |
| Lab043 | 5 | 13.2 | 14.1 | 4 | 0.4 | 2.8 | 12.5 | 20 | 4.7 | 13.2 | 13.9 | 136 | 1.1 | 7.9 | 21.1 | 20 | 1.9 |
| Lab049 | 5 | 13.8 | 14.1 | 5 | 0.7 | 5.0 | 12.1 | 20 | 3.6 | 13.8 | 14.4 | 207 | 0.6 | 4.2 | 12.7 | 20 | 3.7 |
| Lab050 | 5 | 13.8 | 14.4 | 6 | 0.5 | 3.5 | 11.3 | 20 | 4.5 | 13.8 | 14.2 | 13 | 0.7 | 4.9 | 12.8 | 20 | 3.5 |
| Total | - | - | 14.6 | 37 | 0.5 | 3.4 | - | - | - | - | 14.4 | 1084 | 0.8 | 5.6 | - | - | - |

Bias (%) = [(| Mean - Target |) / Target] x 100%

TE : Total Error(%) = Bias (%) + 2 × CV (%)

σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2024 04 Change

Cumulative : from 2021 01 01 to 2024 04 30 Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: BJ0922D) | | | | | | | | | | | | | | | |
|-------------------------|-------------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|----------------|-----------------------------|------------|-----|--------|--------|---------|-----|
| | | Month (2024/04) | | | | | | | | | CUM (2021/01/01-2024/04/30) | | | | | | |
| UnitID <small>↑</small> | Reagent Kit (Code) <small>↑</small> | Target (U/gHb) | Mean (U/gHb) | n for Mean | SD | CV (%) | TE (%) | TEa (%) | σ | Target (U/gHb) | Mean (U/gHb) | n for Mean | SD | CV (%) | TE (%) | TEa (%) | σ |
| Lab018 | 5 | 5.5 | 5.2 | 8 | 0.1 | 1.9 | 9.3 | 20 | >6 | 5.5 | 5.4 | 70 | 0.1 | 1.9 | 5.5 | 20 | >6 |
| Lab019 | 5 | 5.0 | 4.9 | 4 | 0.1 | 2.0 | 6.1 | 20 | >6 | 5.0 | 4.8 | 109 | 0.3 | 6.3 | 16.5 | 20 | 2.5 |
| Lab020 | 5 | 4.6 | - | 0 | - | - | - | 20 | - | 4.6 | 4.7 | 85 | 0.2 | 4.3 | 10.7 | 20 | 4.1 |
| Lab022 | 5 | 4.6 | - | 0 | - | - | - | 20 | - | 4.6 | 4.7 | 27 | 0.3 | 6.4 | 14.9 | 20 | 2.8 |
| Lab028 | 5 | 4.9 | - | 0 | - | - | - | 20 | - | 4.9 | 4.9 | 34 | 0.3 | 6.1 | 12.2 | 20 | 3.3 |
| Lab032 | 5 | 4.8 | - | 0 | - | - | - | 20 | - | 4.8 | 4.5 | 153 | 0.2 | 4.4 | 15.1 | 20 | 3.1 |
| Lab033 | 5 | 4.7 | - | 0 | - | - | - | 20 | - | 4.7 | 4.6 | 81 | 0.3 | 6.5 | 15.2 | 20 | 2.7 |
| Lab034 | 5 | 4.7 | 5.4 | 3 | 0.3 | 5.6 | 26.0 | 20 | 0.9 | 4.7 | 5.3 | 6 | 0.2 | 3.8 | 20.3 | 20 | 1.9 |
| Lab037 | 5 | 4.7 | - | 0 | - | - | - | 20 | - | 4.7 | 4.7 | 59 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Lab040 | 5 | 4.6 | 4.7 | 7 | 0.1 | 2.1 | 6.4 | 20 | >6 | 4.6 | 4.6 | 104 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab043 | 5 | 4.2 | 4.8 | 4 | 0.1 | 2.1 | 18.5 | 20 | 2.7 | 4.2 | 4.6 | 136 | 0.4 | 8.7 | 26.9 | 20 | 1.2 |
| Lab049 | 5 | 4.7 | 4.9 | 5 | 0.1 | 2.0 | 8.3 | 20 | >6 | 4.7 | 4.7 | 207 | 0.3 | 6.4 | 12.8 | 20 | 3.1 |
| Lab050 | 5 | 4.7 | 5.2 | 6 | 0.2 | 3.8 | 18.3 | 20 | 2.5 | 4.7 | 5.3 | 13 | 0.3 | 5.7 | 24.1 | 20 | 1.3 |
| Total | - | - | 5.0 | 37 | 0.3 | 6.0 | - | - | - | - | 4.7 | 1084 | 0.3 | 6.4 | - | - | - |

Bias (%) = [(| Mean - Target |) / Target] x 100%

TE : Total Error(%) = Bias (%) + 2 × CV (%)

σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2024 04 Change

Cumulative : from 2021 01 01 to 2024 04 30 Change

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| Reagent Kit | Reagent Code |
|-------------|--------------|
| Medicon | 5 |