

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - August 2022 -

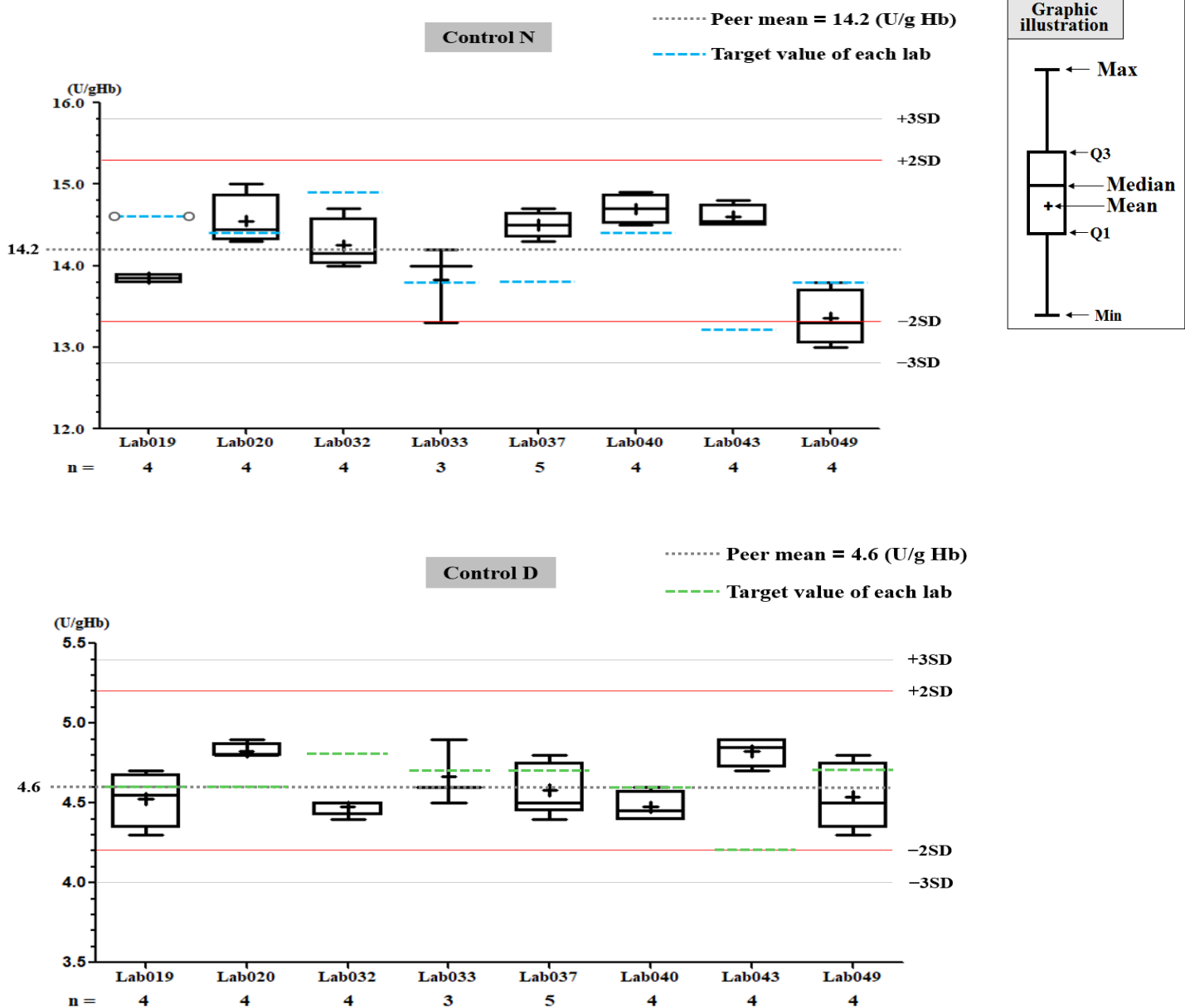
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:BJ0922N) | Control D (Lot No.: BJ0922D) |
|-----------------------------|--------------------------------|---------------------------------|
| Labs | 8 | 8 |
| Received results number (n) | 33 | 33 |
| Median | 14.3 (U/g Hb) | 4.6 (U/g Hb) |
| Mean | 14.2 (U/g Hb) | 4.6 (U/g Hb) |
| SD | 0.5 | 0.2 |
| CV | 3.5% | 4.3% |
| Range of G6PD | 13.0 ~ 15.0 (U/g Hb) | 4.3 ~ 4.9 (U/g Hb) |
| Range of Hb | 2.0 ~ 3.1 (g/dL) | 1.9 ~ 2.7 (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



QC Chart of Internal Quality Control (IQC) for G6PD Quantitative Test

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

Print Table

Lab033

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | BJ0922N | | BJ0922D | |
| Duration of the Analyzing | Month (2022/08) | CUM (2022/02/24~2022/08/31) | Month (2022/08) | CUM (2022/02/24~2022/08/31) |
| Runs (N) | 3 | 26 | 3 | 26 |
| Mean (U/gHb) | 13.8 | 13.7 | 4.7 | 4.7 |
| SD | 0.5 | 0.3 | 0.2 | 0.2 |
| CV (%) | 3.6 | 2.2 | 4.3 | 4.3 |
| Target Value (U/gHb) | 13.8 | 13.8 | 4.7 | 4.7 |
| Total Error (%) | 7.2 | 5.1 | 8.5 | 8.5 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | 5.6 | >6 | 4.7 | 4.7 |

Bias (%) = [(| Mean - Target |) / Target] x 100%
 TE : Total Error(%) = Bias (%) + 2 x CV (%)
 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2022 ▾ 08 ▾ Change ; Cumulative : from 2022 ▾ 02 ▾ 24 ▾ to 2022 ▾ 08 ▾ 31 ▾ Change

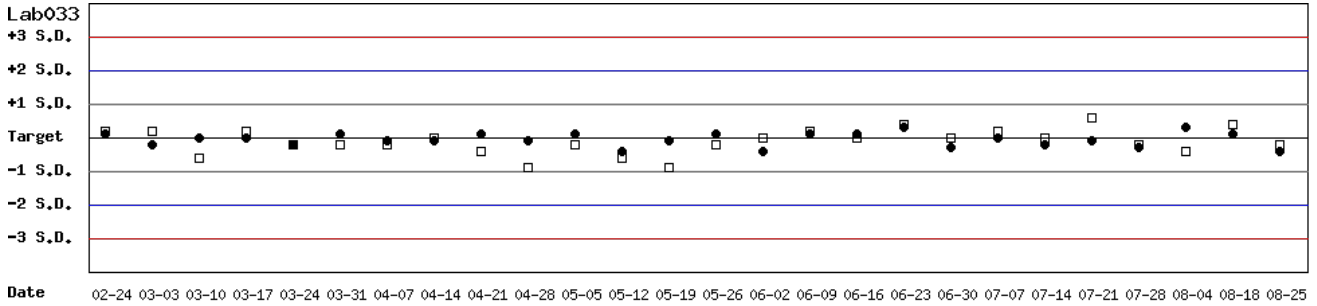
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-02-24 to 2022-08-31 ; Target : 13.8 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2022-02-24 to 2022-08-31 ; Target : 4.7 ; SD : 0.47 (□)

Lab033



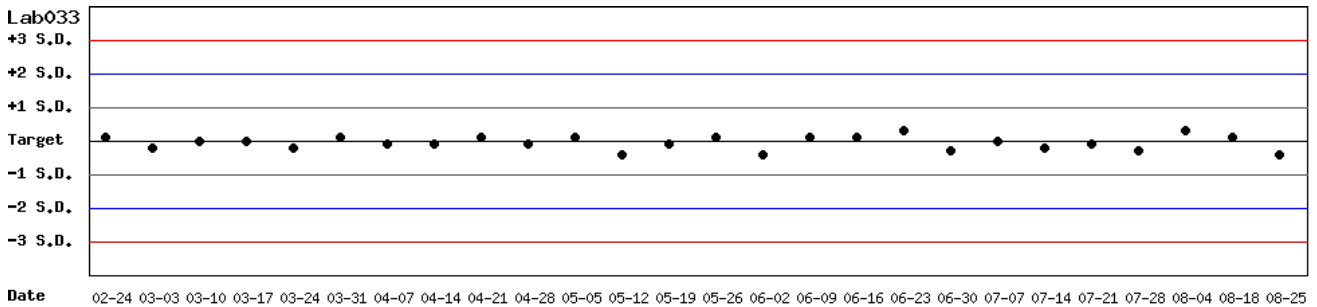
Month : 2022 ▾ 08 ▾ Change ; Cumulative : from 2022 ▾ 02 ▾ 24 ▾ to 2022 ▾ 08 ▾ 31 ▾ Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-02-24 to 2022-08-31 ; Target : 13.8 ; SD : 1.38

Lab033



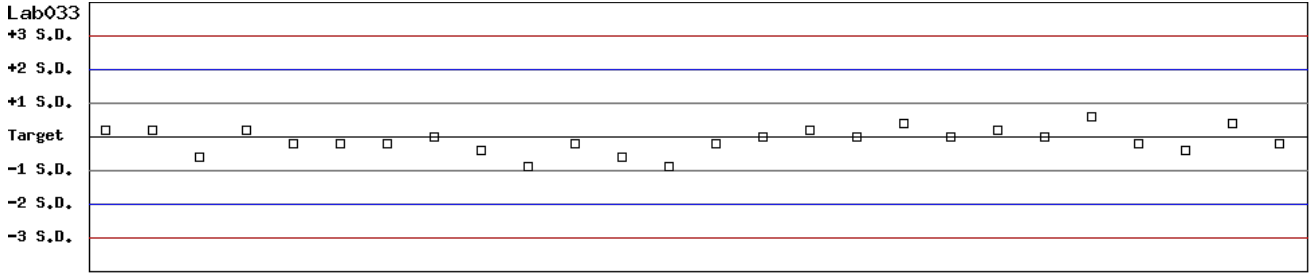
Month : 2022 ▾ 08 ▾ Change ; Cumulative : from 2022 ▾ 02 ▾ 24 ▾ to 2022 ▾ 08 ▾ 31 ▾ Change

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Control D SDI QC Chart

Lab033

Lot No.: BJ0922D ; Duration : 2022-02-24 to 2022-08-31 ; Target : 4.7 ; SD : 0.47



Date 02-24 03-03 03-10 03-17 03-24 03-31 04-07 04-14 04-21 04-28 05-05 05-12 05-19 05-26 06-02 06-09 06-16 06-23 06-30 07-07 07-14 07-21 07-28 08-04 08-11 08-18 08-25

Month : 2022 ▾ 08 ▾ Change ; Cumulative : from 2022 ▾ 02 ▾ 24 ▾ to 2022 ▾ 08 ▾ 31 ▾ 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 : 2022 08 Change

| UnitID <small>↑</small> | Reagent Kit (Code) <small>↑</small> | 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 |
| Lab019 | 5 | 14.6 | 13.9 | 4 | 0.1 | 0.7 | 6.2 | 20 | >6 | 4.6 | 4.5 | 4 | 0.2 | 4.4 | 11.1 | 20 | 4.1 |
| Lab020 | 5 | 14.4 | 14.6 | 4 | 0.3 | 2.1 | 5.5 | 20 | >6 | 4.6 | 4.8 | 4 | 0.1 | 2.1 | 8.5 | 20 | >6 |
| Lab032 | 5 | 14.9 | 14.3 | 4 | 0.3 | 2.1 | 8.2 | 20 | >6 | 4.8 | 4.5 | 4 | 0.1 | 2.2 | 10.7 | 20 | >6 |
| Lab033 | 5 | 13.8 | 13.8 | 3 | 0.5 | 3.6 | 7.2 | 20 | 5.6 | 4.7 | 4.7 | 3 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Lab037 | 5 | 13.8 | 14.5 | 5 | 0.2 | 1.4 | 7.8 | 20 | >6 | 4.7 | 4.6 | 5 | 0.2 | 4.3 | 10.8 | 20 | 4.2 |
| Lab040 | 5 | 14.4 | 14.7 | 4 | 0.2 | 1.4 | 4.8 | 20 | >6 | 4.6 | 4.5 | 4 | 0.1 | 2.2 | 6.6 | 20 | >6 |
| Lab043 | 5 | 13.2 | 14.6 | 4 | 0.1 | 0.7 | 12.0 | 20 | >6 | 4.2 | 4.8 | 4 | 0.1 | 2.1 | 18.5 | 20 | 2.7 |
| Lab049 | 5 | 13.8 | 13.4 | 5 | 0.3 | 2.2 | 7.4 | 20 | >6 | 4.7 | 4.5 | 5 | 0.2 | 4.4 | 13.1 | 20 | 3.6 |
| Total | - | - | 14.2 | 33 | 0.5 | 3.5 | - | - | - | - | 4.6 | 33 | 0.2 | 4.3 | - | - | - |

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 2022 08 31 Change

| UnitID <small>↑</small> | Reagent Kit (Code) <small>↑</small> | 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 | 16.4 | 8 | 0.4 | 2.4 | 6.1 | 20 | >6 | 5.5 | 5.5 | 8 | 0.2 | 3.6 | 7.3 | 20 | 5.6 |
| Lab019 | 5 | 14.6 | 14.4 | 32 | 0.6 | 4.2 | 9.7 | 20 | 4.4 | 4.6 | 4.6 | 32 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab020 | 5 | 14.4 | 14.5 | 40 | 0.6 | 4.1 | 9.0 | 20 | 4.7 | 4.6 | 4.7 | 40 | 0.2 | 4.3 | 10.7 | 20 | 4.1 |
| Lab022 | 5 | 14.4 | 14.3 | 12 | 0.6 | 4.2 | 9.1 | 20 | 4.6 | 4.6 | 4.6 | 12 | 0.3 | 6.5 | 13.0 | 20 | 3.1 |
| 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 | 14.4 | 88 | 0.4 | 2.8 | 8.9 | 20 | 5.9 | 4.8 | 4.5 | 88 | 0.1 | 2.2 | 10.7 | 20 | >6 |
| Lab033 | 5 | 13.8 | 13.5 | 33 | 0.6 | 4.4 | 11.1 | 20 | 4.1 | 4.7 | 4.5 | 33 | 0.3 | 6.7 | 17.6 | 20 | 2.3 |
| Lab037 | 5 | 13.8 | 14.7 | 38 | 0.4 | 2.7 | 12.0 | 20 | 5.0 | 4.7 | 4.7 | 38 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Lab040 | 5 | 14.4 | 14.4 | 9 | 0.3 | 2.1 | 4.2 | 20 | >6 | 4.6 | 4.5 | 9 | 0.1 | 2.2 | 6.6 | 20 | >6 |
| Lab043 | 5 | 13.2 | 13.4 | 55 | 1.5 | 11.2 | 23.9 | 20 | 1.7 | 4.2 | 4.3 | 55 | 0.5 | 11.6 | 25.6 | 20 | 1.5 |
| Lab049 | 5 | 13.8 | 14.7 | 65 | 0.7 | 4.8 | 16.0 | 20 | 2.8 | 4.7 | 4.7 | 65 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Total | - | - | 14.4 | 414 | 1.0 | 6.9 | - | - | - | - | 4.6 | 414 | 0.3 | 6.5 | - | - | - |

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 (2022/08) | | | | | | | | CUM (2021/01/01~2022/08/31) | | | | | | | |
| UnitID ↑ | Reagent Kit (Code) ↑ | 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 | - | 0 | - | - | - | 20 | - | 16.2 | 16.4 | 8 | 0.4 | 2.4 | 6.1 | 20 | >6 |
| Lab019 | 5 | 14.6 | 13.9 | 4 | 0.1 | 0.7 | 6.2 | 20 | >6 | 14.6 | 14.4 | 32 | 0.6 | 4.2 | 9.7 | 20 | 4.4 |
| Lab020 | 5 | 14.4 | 14.6 | 4 | 0.3 | 2.1 | 5.5 | 20 | >6 | 14.4 | 14.5 | 40 | 0.6 | 4.1 | 9.0 | 20 | 4.7 |
| Lab022 | 5 | 14.4 | - | 0 | - | - | - | 20 | - | 14.4 | 14.3 | 12 | 0.6 | 4.2 | 9.1 | 20 | 4.6 |
| Lab028 | 5 | 15.2 | - | 0 | - | - | - | 20 | - | 15.2 | 15.1 | 34 | 1.1 | 7.3 | 15.2 | 20 | 2.6 |
| Lab032 | 5 | 14.9 | 14.3 | 4 | 0.3 | 2.1 | 8.2 | 20 | >6 | 14.9 | 14.4 | 88 | 0.4 | 2.8 | 8.9 | 20 | 5.9 |
| Lab033 | 5 | 13.8 | 13.8 | 3 | 0.5 | 3.6 | 7.2 | 20 | 5.6 | 13.8 | 13.5 | 33 | 0.6 | 4.4 | 11.1 | 20 | 4.1 |
| Lab037 | 5 | 13.8 | 14.5 | 5 | 0.2 | 1.4 | 7.8 | 20 | >6 | 13.8 | 14.7 | 38 | 0.4 | 2.7 | 12.0 | 20 | 5.0 |
| Lab040 | 5 | 14.4 | 14.7 | 4 | 0.2 | 1.4 | 4.8 | 20 | >6 | 14.4 | 14.4 | 9 | 0.3 | 2.1 | 4.2 | 20 | >6 |
| Lab043 | 5 | 13.2 | 14.6 | 4 | 0.1 | 0.7 | 12.0 | 20 | >6 | 13.2 | 13.4 | 55 | 1.5 | 11.2 | 23.9 | 20 | 1.7 |
| Lab049 | 5 | 13.8 | 13.4 | 5 | 0.3 | 2.2 | 7.4 | 20 | >6 | 13.8 | 14.7 | 65 | 0.7 | 4.8 | 16.0 | 20 | 2.8 |
| Total | - | - | 14.2 | 33 | 0.5 | 3.5 | - | - | - | - | 14.4 | 414 | 1.0 | 6.9 | - | - | - |

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

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

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

Month : 2022 ▼ 08 ▼ Change

Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2022 ▼ 08 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

| Control D (Lot No.: BJ0922D) | | | | | | | | | | | | | | | | | |
|------------------------------|----------------------|-----------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2022/08) | | | | | | | | CUM (2021/01/01~2022/08/31) | | | | | | | |
| UnitID ↑ | Reagent Kit (Code) ↑ | 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 | - | 0 | - | - | - | 20 | - | 5.5 | 5.5 | 8 | 0.2 | 3.6 | 7.3 | 20 | 5.6 |
| Lab019 | 5 | 4.6 | 4.5 | 4 | 0.2 | 4.4 | 11.1 | 20 | 4.1 | 4.6 | 4.6 | 32 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab020 | 5 | 4.6 | 4.8 | 4 | 0.1 | 2.1 | 8.5 | 20 | >6 | 4.6 | 4.7 | 40 | 0.2 | 4.3 | 10.7 | 20 | 4.1 |
| Lab022 | 5 | 4.6 | - | 0 | - | - | - | 20 | - | 4.6 | 4.6 | 12 | 0.3 | 6.5 | 13.0 | 20 | 3.1 |
| Lab028 | 5 | 4.9 | - | 0 | - | - | - | 20 | - | 4.9 | 4.9 | 34 | 0.3 | 6.1 | 12.2 | 20 | 3.3 |
| Lab032 | 5 | 4.8 | 4.5 | 4 | 0.1 | 2.2 | 10.7 | 20 | >6 | 4.8 | 4.5 | 88 | 0.1 | 2.2 | 10.7 | 20 | >6 |
| Lab033 | 5 | 4.7 | 4.7 | 3 | 0.2 | 4.3 | 8.5 | 20 | 4.7 | 4.7 | 4.5 | 33 | 0.3 | 6.7 | 17.6 | 20 | 2.3 |
| Lab037 | 5 | 4.7 | 4.6 | 5 | 0.2 | 4.3 | 10.8 | 20 | 4.2 | 4.7 | 4.7 | 38 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Lab040 | 5 | 4.6 | 4.5 | 4 | 0.1 | 2.2 | 6.6 | 20 | >6 | 4.6 | 4.5 | 9 | 0.1 | 2.2 | 6.6 | 20 | >6 |
| Lab043 | 5 | 4.2 | 4.8 | 4 | 0.1 | 2.1 | 18.5 | 20 | 2.7 | 4.2 | 4.3 | 55 | 0.5 | 11.6 | 25.6 | 20 | 1.5 |
| Lab049 | 5 | 4.7 | 4.5 | 5 | 0.2 | 4.4 | 13.1 | 20 | 3.6 | 4.7 | 4.7 | 65 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Total | - | - | 4.6 | 33 | 0.2 | 4.3 | - | - | - | - | 4.6 | 414 | 0.3 | 6.5 | - | - | - |

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

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

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

Month : 2022 ▼ 08 ▼ Change

Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2022 ▼ 08 ▼ 31 ▼ Change

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