

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - April 2023 -

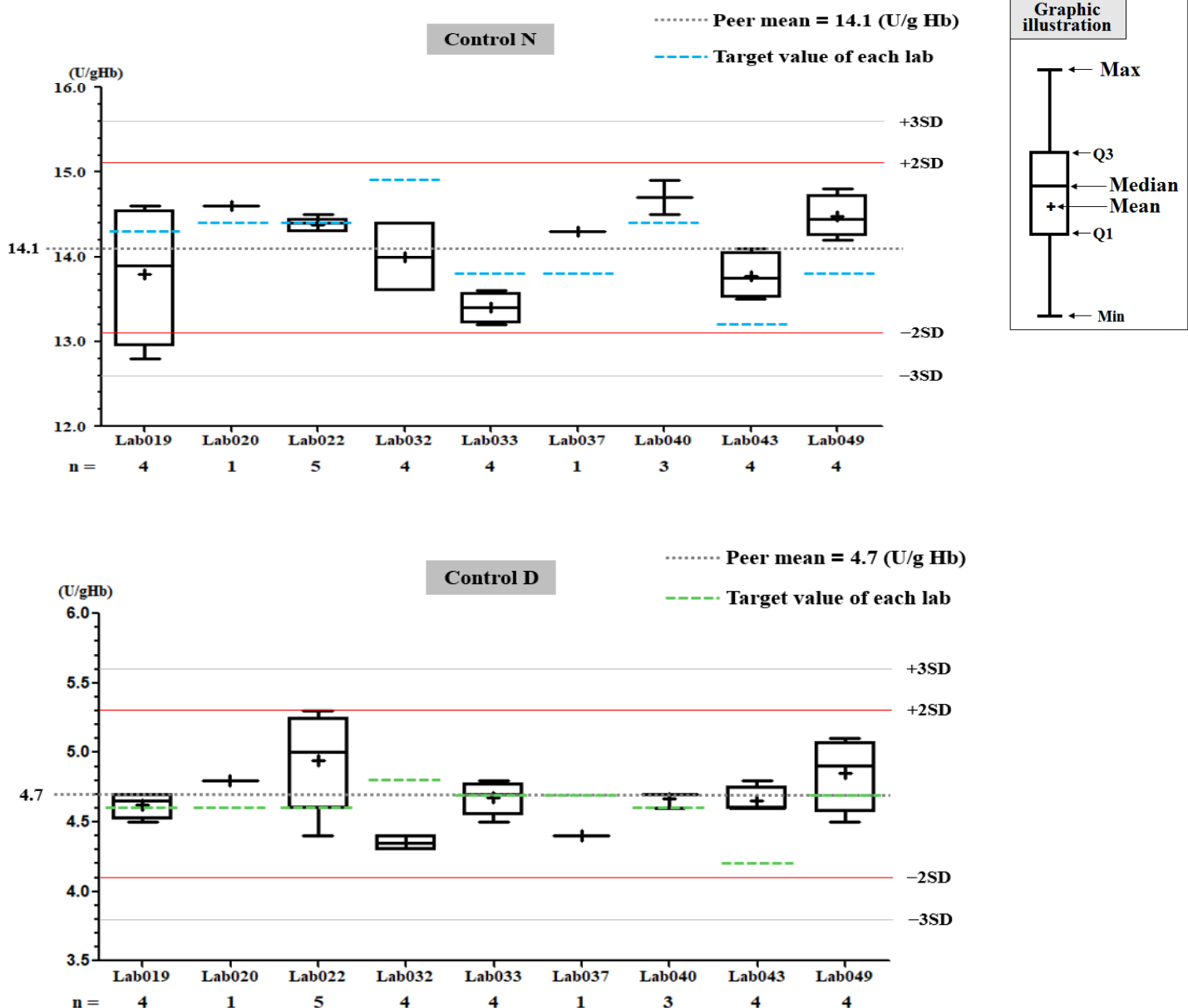
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:BJ0922N) | Control D (Lot No.: BJ0922D) |
|-----------------------------|--------------------------------|---------------------------------|
| Labs | 9 | 9 |
| Received results number (n) | 30 | 30 |
| Median | 14.3 (U/g Hb) | 4.7 (U/g Hb) |
| Mean | 14.1 (U/g Hb) | 4.7 (U/g Hb) |
| SD | 0.5 | 0.3 |
| CV | 3.5% | 4.3% |
| Range of G6PD | 12.8 ~ 14.9 (U/g Hb) | 4.3 ~ 5.3 (U/g Hb) |
| Range of Hb | 2.1 ~ 2.8 (g/dL) | 1.9 ~ 2.4 (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](#)

Lab020

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | BJ0922N | | BJ0922D | |
| Duration of the Analyzing | Month (2023/04) | CUM (2022/07/21~2023/04/30) | Month (2023/04) | CUM (2022/07/21~2023/04/30) |
| Runs (N) | 1 | 26 | 1 | 26 |
| Mean (U/gHb) | 14.6 | 14.4 | 4.8 | 4.7 |
| SD | - | 0.4 | - | 0.1 |
| CV (%) | - | 2.8 | - | 2.1 |
| Target Value (U/gHb) | 14.4 | 14.4 | 4.6 | 4.6 |
| Total Error (%) | - | 5.6 | - | 6.4 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | - | >6 | - | >6 |

Bias (%) = $\left[\frac{(\text{Mean} - \text{Target})}{\text{Target}} \right] \times 100\%$
 TE : Total Error(%) = Bias (%) + 2 × CV (%)
 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2023 04 Change ; Cumulative : from 2022 07 21 to 2023 04 30 Change

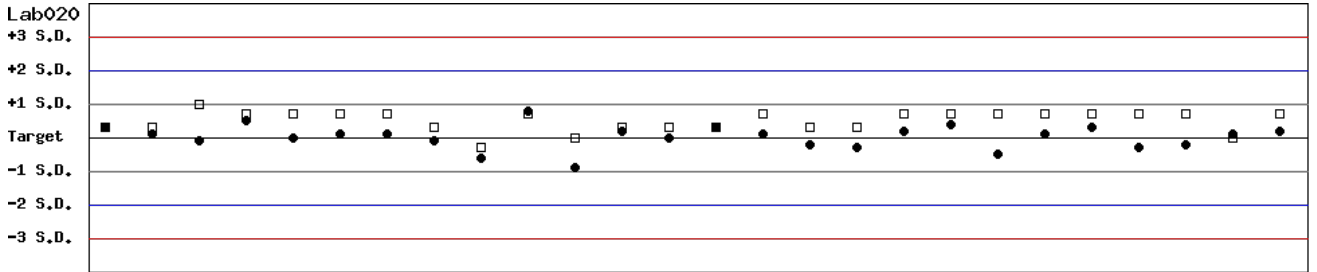
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-07-21 to 2023-04-30 ; Target : 14.4 ; SD : 1.16 (●)

Lot No.: BJ0922D ; Duration : 2022-07-21 to 2023-04-30 ; Target : 4.6 ; SD : 0.30 (□)

Lab020



Date 07-21 07-26 08-02 08-09 08-16 08-23 09-01 09-06 10-18 11-08 11-15 11-22 12-01 12-06 12-13 12-20 12-27 01-17 02-07 02-14 02-21 03-07 03-14 03-21 03-28 04-04

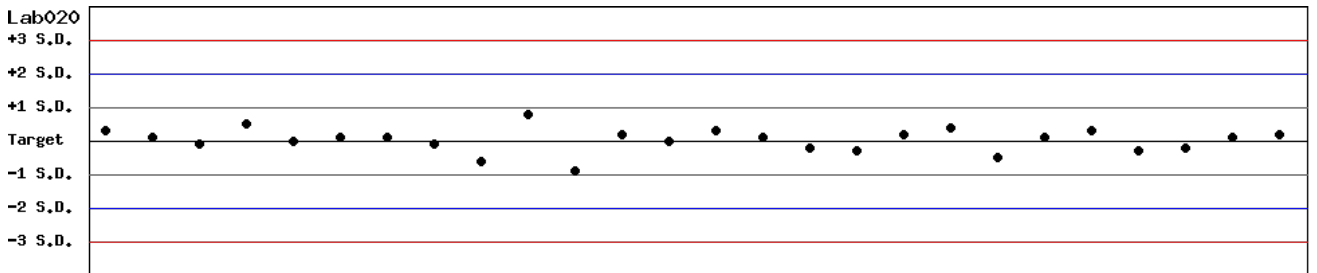
Month : 2023 04 Change ; Cumulative : from 2022 07 21 to 2023 04 30 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-07-21 to 2023-04-30 ; Target : 14.4 ; SD : 1.16

Lab020



Date 07-21 07-26 08-02 08-09 08-16 08-23 09-01 09-06 10-18 11-08 11-15 11-22 12-01 12-06 12-13 12-20 12-27 01-17 02-07 02-14 02-21 03-07 03-14 03-21 03-28 04-04

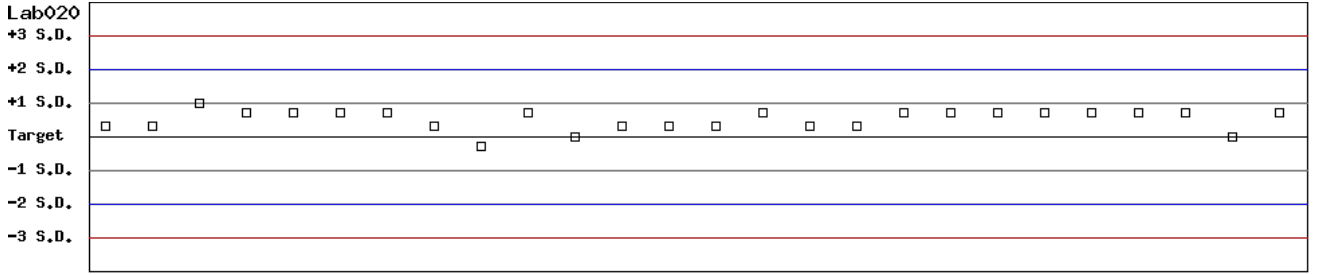
Month : 2023 04 Change ; Cumulative : from 2022 07 21 to 2023 04 30 Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2022-07-21 to 2023-04-30 ; Target : 4.6 ; SD : 0.30

Lab020



Date 07-21 07-26 08-02 08-09 08-16 08-23 09-01 09-06 10-18 11-08 11-15 11-22 12-01 12-06 12-13 12-20 12-27 01-17 02-07 02-14 02-21 03-07 03-14 03-21 03-28 04-04

Month : ; Cumulative : from to

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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 : 2023 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 |
| Lab019 | 5 | 14.3 | 13.8 | 4 | 0.8 | 5.8 | 15.1 | 20 | 2.8 | 4.6 | 4.6 | 4 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab020 | 5 | 14.4 | 14.6 | 1 | - | - | - | 20 | - | 4.6 | 4.8 | 1 | - | - | - | 20 | - |
| Lab022 | 5 | 14.4 | 14.4 | 5 | 0.1 | 0.7 | 1.4 | 20 | >6 | 4.6 | 4.9 | 5 | 0.4 | 8.2 | 22.8 | 20 | 1.6 |
| Lab032 | 5 | 14.9 | 14.0 | 4 | 0.5 | 3.6 | 13.2 | 20 | 3.9 | 4.8 | 4.4 | 4 | 0.1 | 2.3 | 12.9 | 20 | 5.1 |
| Lab033 | 5 | 13.8 | 13.4 | 4 | 0.2 | 1.5 | 5.9 | 20 | >6 | 4.7 | 4.7 | 4 | 0.1 | 2.1 | 4.3 | 20 | >6 |
| Lab037 | 5 | 13.8 | 14.3 | 1 | - | - | - | 20 | - | 4.7 | 4.4 | 1 | - | - | - | 20 | - |
| Lab040 | 5 | 14.4 | 14.7 | 3 | 0.2 | 1.4 | 4.8 | 20 | >6 | 4.6 | 4.7 | 3 | 0.1 | 2.1 | 6.4 | 20 | >6 |
| Lab043 | 5 | 13.2 | 13.8 | 4 | 0.3 | 2.2 | 8.9 | 20 | >6 | 4.2 | 4.7 | 4 | 0.1 | 2.1 | 16.2 | 20 | 3.9 |
| Lab049 | 5 | 13.8 | 14.5 | 4 | 0.3 | 2.1 | 9.2 | 20 | >6 | 4.7 | 4.9 | 4 | 0.3 | 6.1 | 16.5 | 20 | 2.6 |
| Total | - | - | 14.1 | 30 | 0.5 | 3.5 | - | - | - | - | 4.7 | 30 | 0.3 | 6.4 | - | - | - |

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from 2021 01 01 to 2023 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 | 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 | 14.3 | 14.3 | 54 | 0.6 | 4.2 | 8.4 | 20 | 4.8 | 4.6 | 4.6 | 54 | 0.2 | 4.3 | 8.7 | 20 | 4.7 |
| Lab020 | 5 | 14.4 | 14.4 | 60 | 0.5 | 3.5 | 6.9 | 20 | 5.7 | 4.6 | 4.7 | 60 | 0.1 | 2.1 | 6.4 | 20 | >6 |
| 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 | 123 | 0.4 | 2.8 | 9.6 | 20 | 5.7 | 4.8 | 4.5 | 123 | 0.2 | 4.4 | 15.1 | 20 | 3.1 |
| Lab033 | 5 | 13.8 | 13.7 | 68 | 0.6 | 4.4 | 9.5 | 20 | 4.4 | 4.7 | 4.6 | 68 | 0.3 | 6.5 | 15.2 | 20 | 2.7 |
| Lab037 | 5 | 13.8 | 14.5 | 53 | 0.5 | 3.4 | 12.0 | 20 | 4.4 | 4.7 | 4.7 | 53 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Lab040 | 5 | 14.4 | 14.7 | 47 | 0.2 | 1.4 | 4.8 | 20 | >6 | 4.6 | 4.6 | 47 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab043 | 5 | 13.2 | 13.7 | 85 | 1.3 | 9.5 | 22.8 | 20 | 1.7 | 4.2 | 4.5 | 85 | 0.5 | 11.1 | 29.4 | 20 | 1.2 |
| Lab049 | 5 | 13.8 | 14.5 | 91 | 0.7 | 4.8 | 14.7 | 20 | 3.1 | 4.7 | 4.7 | 91 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Total | - | - | 14.3 | 650 | 0.8 | 5.6 | - | - | - | - | 4.6 | 650 | 0.3 | 6.5 | - | - | - |

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

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

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

[\[TOP\]](#)

| 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 (2023/04) | | | | | | | | CUM (2021/01/01~2023/04/30) | | | | | | | |
| 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 | 14.3 | 13.8 | 4 | 0.8 | 5.8 | 15.1 | 20 | 2.8 | 14.3 | 14.3 | 54 | 0.6 | 4.2 | 8.4 | 20 | 4.8 |
| Lab020 | 5 | 14.4 | 14.6 | 1 | - | - | - | 20 | - | 14.4 | 14.4 | 60 | 0.5 | 3.5 | 6.9 | 20 | 5.7 |
| Lab022 | 5 | 14.4 | 14.4 | 5 | 0.1 | 0.7 | 1.4 | 20 | >6 | 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 | 14.0 | 4 | 0.5 | 3.6 | 13.2 | 20 | 3.9 | 14.9 | 14.3 | 123 | 0.4 | 2.8 | 9.6 | 20 | 5.7 |
| Lab033 | 5 | 13.8 | 13.4 | 4 | 0.2 | 1.5 | 5.9 | 20 | >6 | 13.8 | 13.7 | 68 | 0.6 | 4.4 | 9.5 | 20 | 4.4 |
| Lab037 | 5 | 13.8 | 14.3 | 1 | - | - | - | 20 | - | 13.8 | 14.5 | 53 | 0.5 | 3.4 | 12.0 | 20 | 4.4 |
| Lab040 | 5 | 14.4 | 14.7 | 3 | 0.2 | 1.4 | 4.8 | 20 | >6 | 14.4 | 14.7 | 47 | 0.2 | 1.4 | 4.8 | 20 | >6 |
| Lab043 | 5 | 13.2 | 13.8 | 4 | 0.3 | 2.2 | 8.9 | 20 | >6 | 13.2 | 13.7 | 85 | 1.3 | 9.5 | 22.8 | 20 | 1.7 |
| Lab049 | 5 | 13.8 | 14.5 | 4 | 0.3 | 2.1 | 9.2 | 20 | >6 | 13.8 | 14.5 | 91 | 0.7 | 4.8 | 14.7 | 20 | 3.1 |
| Total | - | - | 14.1 | 30 | 0.5 | 3.5 | - | - | - | - | 14.3 | 650 | 0.8 | 5.6 | - | - | - |

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

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

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

Month : 2023 04 Change

Cumulative : from 2021 01 01 to 2023 04 30 Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: BJ0922D) | | | | | | | | | | | | | | | |
|------------------------|----------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2023/04) | | | | | | | | CUM (2021/01/01~2023/04/30) | | | | | | | |
| 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 | 4.6 | 4 | 0.1 | 2.2 | 4.3 | 20 | >6 | 4.6 | 4.6 | 54 | 0.2 | 4.3 | 8.7 | 20 | 4.7 |
| Lab020 | 5 | 4.6 | 4.8 | 1 | - | - | - | 20 | - | 4.6 | 4.7 | 60 | 0.1 | 2.1 | 6.4 | 20 | >6 |
| Lab022 | 5 | 4.6 | 4.9 | 5 | 0.4 | 8.2 | 22.8 | 20 | 1.6 | 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 | 4.4 | 4 | 0.1 | 2.3 | 12.9 | 20 | 5.1 | 4.8 | 4.5 | 123 | 0.2 | 4.4 | 15.1 | 20 | 3.1 |
| Lab033 | 5 | 4.7 | 4.7 | 4 | 0.1 | 2.1 | 4.3 | 20 | >6 | 4.7 | 4.6 | 68 | 0.3 | 6.5 | 15.2 | 20 | 2.7 |
| Lab037 | 5 | 4.7 | 4.4 | 1 | - | - | - | 20 | - | 4.7 | 4.7 | 53 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Lab040 | 5 | 4.6 | 4.7 | 3 | 0.1 | 2.1 | 6.4 | 20 | >6 | 4.6 | 4.6 | 47 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab043 | 5 | 4.2 | 4.7 | 4 | 0.1 | 2.1 | 16.2 | 20 | 3.9 | 4.2 | 4.5 | 85 | 0.5 | 11.1 | 29.4 | 20 | 1.2 |
| Lab049 | 5 | 4.7 | 4.9 | 4 | 0.3 | 6.1 | 16.5 | 20 | 2.6 | 4.7 | 4.7 | 91 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Total | - | - | 4.7 | 30 | 0.3 | 6.4 | - | - | - | - | 4.6 | 650 | 0.3 | 6.5 | - | - | - |

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

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

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

Month : 2023 04 Change

Cumulative : from 2021 01 01 to 2023 04 30 Change

[TOP](#)

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