

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

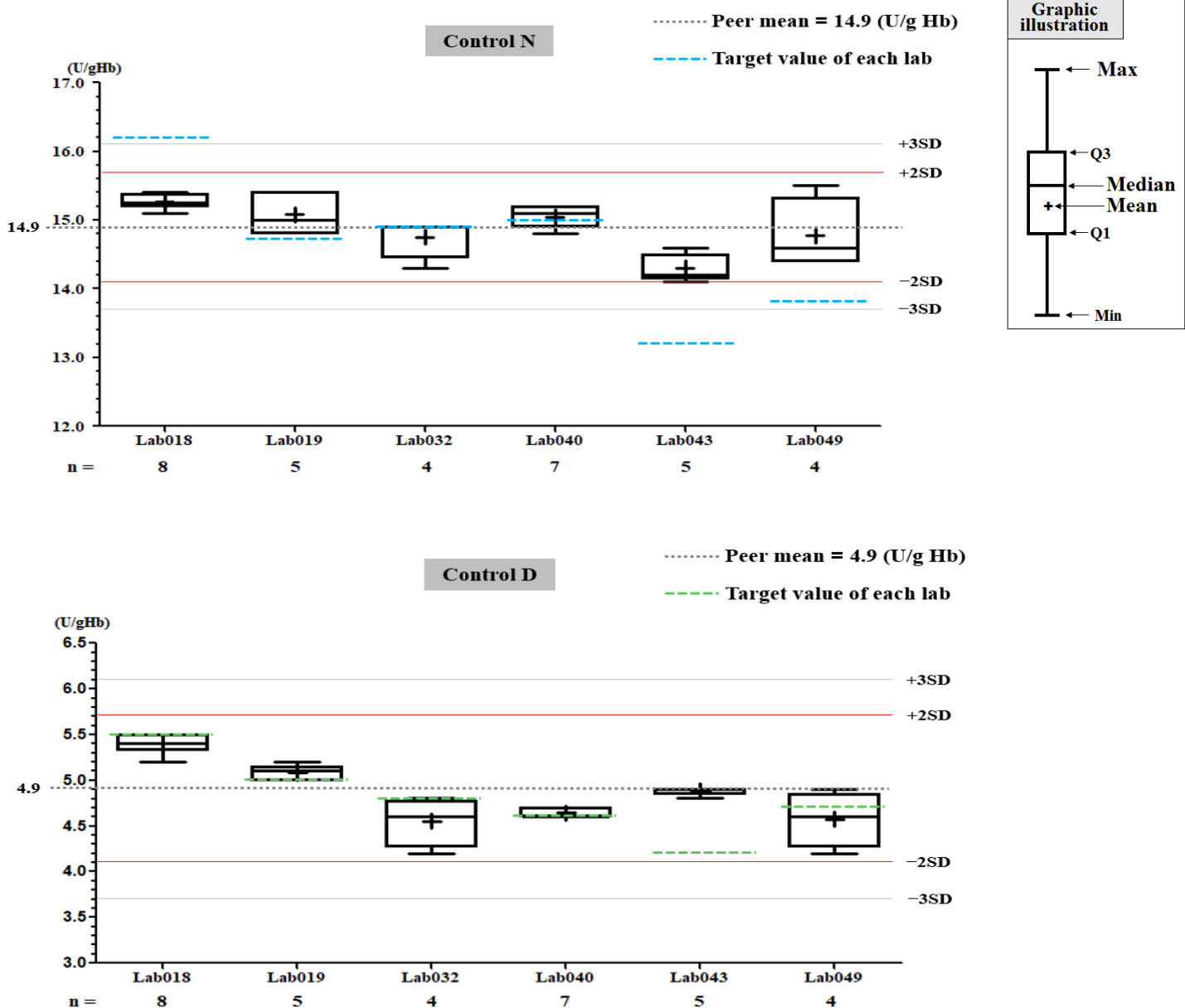
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:BJ0922N) | Control D (Lot No.: BJ0922D) |
|-----------------------------|--------------------------------|---------------------------------|
| Labs | 6 | 6 |
| Received results number (n) | 33 | 33 |
| Median | 15.0 (U/g Hb) | 4.9 (U/g Hb) |
| Mean | 14.9 (U/g Hb) | 4.9 (U/g Hb) |
| SD | 0.4 | 0.4 |
| CV | 2.7% | 8.2% |
| Range of G6PD | 14.1 ~ 15.5 (U/g Hb) | 4.2 ~ 5.5 (U/g Hb) |
| Range of Hb | 2.1 ~ 2.5 (g/dL) | 1.9 ~ 2.2 (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](#)

Lab043

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | BJ0922N | | BJ0922D | |
| Duration of the Analyzing | Month (2023/11) | CUM (2023/06/01~2023/11/30) | Month (2023/11) | CUM (2023/06/01~2023/11/30) |
| Runs (N) | 5 | 26 | 5 | 26 |
| Mean (U/gHb) | 14.3 | 14.3 | 4.9 | 4.9 |
| SD | 0.2 | 0.4 | 0.1 | 0.1 |
| CV (%) | 1.4 | 2.8 | 2.0 | 2.0 |
| Target Value (U/gHb) | 13.2 | 13.2 | 4.2 | 4.2 |
| Total Error (%) | 11.1 | 13.9 | 20.7 | 20.7 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | >6 | 4.2 | 1.7 | 1.7 |

Bias (%) = $\left[\frac{(\text{Mean} - \text{Target})}{\text{Target}} \right] \times 100\%$

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

σ (Sigma) = $[\text{TEa}\% - \text{Bias}\%] / \text{CV}\%$

Month : 2023 11 Change ; Cumulative : from 2023 06 01 to 2023 11 30 Change

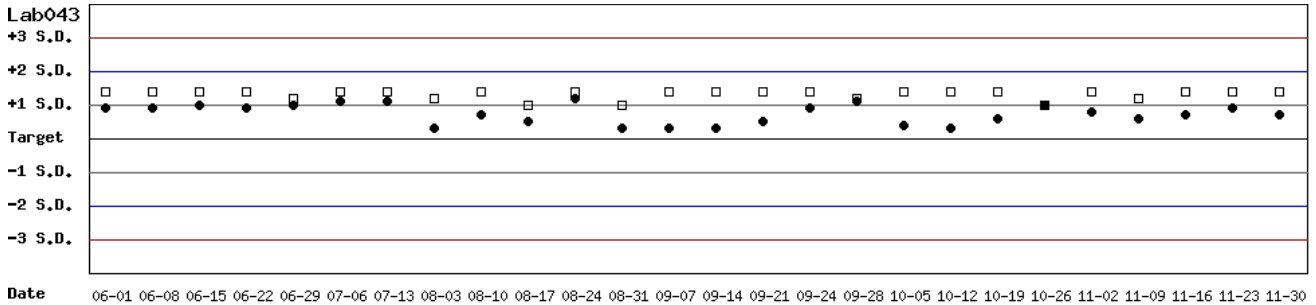
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-06-01 to 2023-11-30 ; Target : 13.2 ; SD : 1.50 (●)

Lot No.: BJ0922D ; Duration : 2023-06-01 to 2023-11-30 ; Target : 4.2 ; SD : 0.50 (□)

Lab043



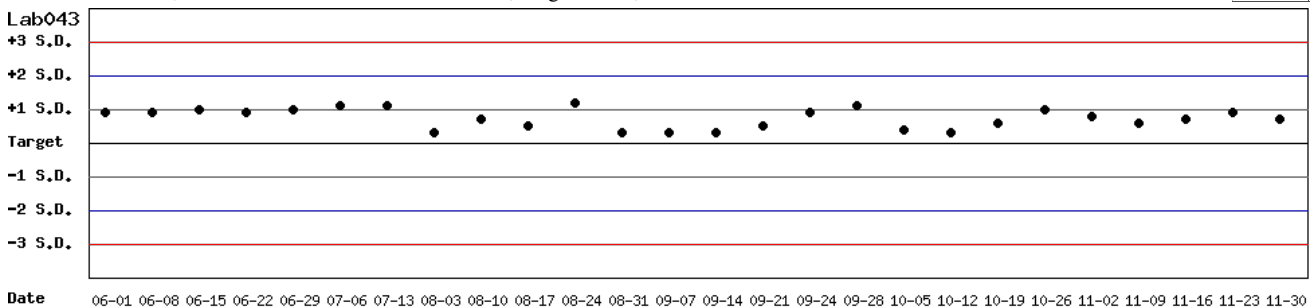
Month : 2023 11 Change ; Cumulative : from 2023 06 01 to 2023 11 30 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-06-01 to 2023-11-30 ; Target : 13.2 ; SD : 1.50

Lab043



Month : 2023 11 Change ; Cumulative : from 2023 06 01 to 2023 11 30 Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2023-06-01 to 2023-11-30 ; Target : 4.2 ; SD : 0.50

Lab043

Lab043

+3 S.D.

+2 S.D.

+1 S.D.

Target

-1 S.D.

-2 S.D.

-3 S.D.



Date 06-01 06-08 06-15 06-22 06-29 07-06 07-13 08-03 08-10 08-17 08-24 08-31 09-07 09-14 09-21 09-24 09-28 10-05 10-12 10-19 10-26 11-02 11-09 11-16 11-23 11-30

Month : 2023 11 Change ; Cumulative : from 2023 06 01 to 2023 11 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 : 2023 11 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 | 8 | 0.1 | 0.7 | 6.9 | 20 | >6 | 5.5 | 5.4 | 8 | 0.1 | 1.9 | 5.5 | 20 | >6 |
| Lab019 | 5 | 14.7 | 15.1 | 5 | 0.3 | 2.0 | 6.7 | 20 | >6 | 5.0 | 5.1 | 5 | 0.1 | 2.0 | 5.9 | 20 | >6 |
| Lab032 | 5 | 14.9 | 14.8 | 4 | 0.3 | 2.0 | 4.7 | 20 | >6 | 4.8 | 4.6 | 4 | 0.3 | 6.5 | 17.2 | 20 | 2.4 |
| Lab040 | 5 | 14.4 | 15.0 | 7 | 0.2 | 1.3 | 6.8 | 20 | >6 | 4.6 | 4.6 | 7 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab043 | 5 | 13.2 | 14.3 | 5 | 0.2 | 1.4 | 11.1 | 20 | >6 | 4.2 | 4.9 | 5 | 0.1 | 2.0 | 20.7 | 20 | 1.7 |
| Lab049 | 5 | 13.8 | 14.8 | 4 | 0.5 | 3.4 | 14.0 | 20 | 3.8 | 4.7 | 4.6 | 4 | 0.3 | 6.5 | 15.2 | 20 | 2.7 |
| Total | - | - | 14.9 | 33 | 0.4 | 2.7 | - | - | - | - | 4.9 | 33 | 0.4 | 8.2 | - | - | - |

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

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

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

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Cumulative

Cumulative : from 2021 01 01 to 2023 11 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 | 15.6 | 25 | 0.6 | 3.8 | 11.4 | 20 | 4.3 | 5.5 | 5.4 | 25 | 0.1 | 1.9 | 5.5 | 20 | >6 |
| Lab019 | 5 | 14.7 | 14.4 | 88 | 0.6 | 4.2 | 10.4 | 20 | 4.3 | 5.0 | 4.8 | 88 | 0.3 | 6.3 | 16.5 | 20 | 2.5 |
| Lab020 | 5 | 14.4 | 14.4 | 76 | 0.5 | 3.5 | 6.9 | 20 | 5.7 | 4.6 | 4.7 | 76 | 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 | 144 | 0.4 | 2.8 | 9.6 | 20 | 5.7 | 4.8 | 4.5 | 144 | 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 |
| 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 | 79 | 0.2 | 1.4 | 5.5 | 20 | >6 | 4.6 | 4.6 | 79 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab043 | 5 | 13.2 | 13.9 | 115 | 1.2 | 8.6 | 22.6 | 20 | 1.7 | 4.2 | 4.6 | 115 | 0.4 | 8.7 | 26.9 | 20 | 1.2 |
| Lab049 | 5 | 13.8 | 14.4 | 167 | 0.6 | 4.2 | 12.7 | 20 | 3.7 | 4.7 | 4.7 | 167 | 0.3 | 6.4 | 12.8 | 20 | 3.1 |
| Total | - | - | 14.4 | 895 | 0.8 | 5.6 | - | - | - | - | 4.7 | 895 | 0.3 | 6.4 | - | - | - |

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

TE : Total Error(%) = Bias (%) + 2 x 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 (2023/11) | | | | | | | | CUM (2021/01/01~2023/11/30) | | | | | | | |
| 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 | 15.3 | 8 | 0.1 | 0.7 | 6.9 | 20 | >6 | 16.2 | 15.6 | 25 | 0.6 | 3.8 | 11.4 | 20 | 4.3 |
| Lab019 | 5 | 14.7 | 15.1 | 5 | 0.3 | 2.0 | 6.7 | 20 | >6 | 14.7 | 14.4 | 88 | 0.6 | 4.2 | 10.4 | 20 | 4.3 |
| Lab020 | 5 | 14.4 | - | 0 | - | - | - | 20 | - | 14.4 | 14.4 | 76 | 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 | 14.8 | 4 | 0.3 | 2.0 | 4.7 | 20 | >6 | 14.9 | 14.3 | 144 | 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 |
| Lab037 | 5 | 13.8 | - | 0 | - | - | - | 20 | - | 13.8 | 14.5 | 59 | 0.5 | 3.4 | 12.0 | 20 | 4.4 |
| Lab040 | 5 | 14.4 | 15.0 | 7 | 0.2 | 1.3 | 6.8 | 20 | >6 | 14.4 | 14.8 | 79 | 0.2 | 1.4 | 5.5 | 20 | >6 |
| Lab043 | 5 | 13.2 | 14.3 | 5 | 0.2 | 1.4 | 11.1 | 20 | >6 | 13.2 | 13.9 | 115 | 1.2 | 8.6 | 22.6 | 20 | 1.7 |
| Lab049 | 5 | 13.8 | 14.8 | 4 | 0.5 | 3.4 | 14.0 | 20 | 3.8 | 13.8 | 14.4 | 167 | 0.6 | 4.2 | 12.7 | 20 | 3.7 |
| Total | - | - | 14.9 | 33 | 0.4 | 2.7 | - | - | - | - | 14.4 | 895 | 0.8 | 5.6 | - | - | - |

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

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

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

Month : 2023 ↓ 11 ↓ Change

Cumulative : from 2021 ↓ 01 ↓ 01 ↓ to 2023 ↓ 11 ↓ 30 ↓ Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: BJ0922D) | | | | | | | | | | | | | | | |
|-------------------------|-------------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2023/11) | | | | | | | | CUM (2021/01/01~2023/11/30) | | | | | | | |
| 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 | 5.4 | 8 | 0.1 | 1.9 | 5.5 | 20 | >6 | 5.5 | 5.4 | 25 | 0.1 | 1.9 | 5.5 | 20 | >6 |
| Lab019 | 5 | 5.0 | 5.1 | 5 | 0.1 | 2.0 | 5.9 | 20 | >6 | 5.0 | 4.8 | 88 | 0.3 | 6.3 | 16.5 | 20 | 2.5 |
| Lab020 | 5 | 4.6 | - | 0 | - | - | - | 20 | - | 4.6 | 4.7 | 76 | 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 | 4.6 | 4 | 0.3 | 6.5 | 17.2 | 20 | 2.4 | 4.8 | 4.5 | 144 | 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 |
| Lab037 | 5 | 4.7 | - | 0 | - | - | - | 20 | - | 4.7 | 4.7 | 59 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Lab040 | 5 | 4.6 | 4.6 | 7 | 0.1 | 2.2 | 4.3 | 20 | >6 | 4.6 | 4.6 | 79 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab043 | 5 | 4.2 | 4.9 | 5 | 0.1 | 2.0 | 20.7 | 20 | 1.7 | 4.2 | 4.6 | 115 | 0.4 | 8.7 | 26.9 | 20 | 1.2 |
| Lab049 | 5 | 4.7 | 4.6 | 4 | 0.3 | 6.5 | 15.2 | 20 | 2.7 | 4.7 | 4.7 | 167 | 0.3 | 6.4 | 12.8 | 20 | 3.1 |
| Total | - | - | 4.9 | 33 | 0.4 | 8.2 | - | - | - | - | 4.7 | 895 | 0.3 | 6.4 | - | - | - |

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

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

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

Month : 2023 ↓ 11 ↓ Change

Cumulative : from 2021 ↓ 01 ↓ 01 ↓ to 2023 ↓ 11 ↓ 30 ↓ Change

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