

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

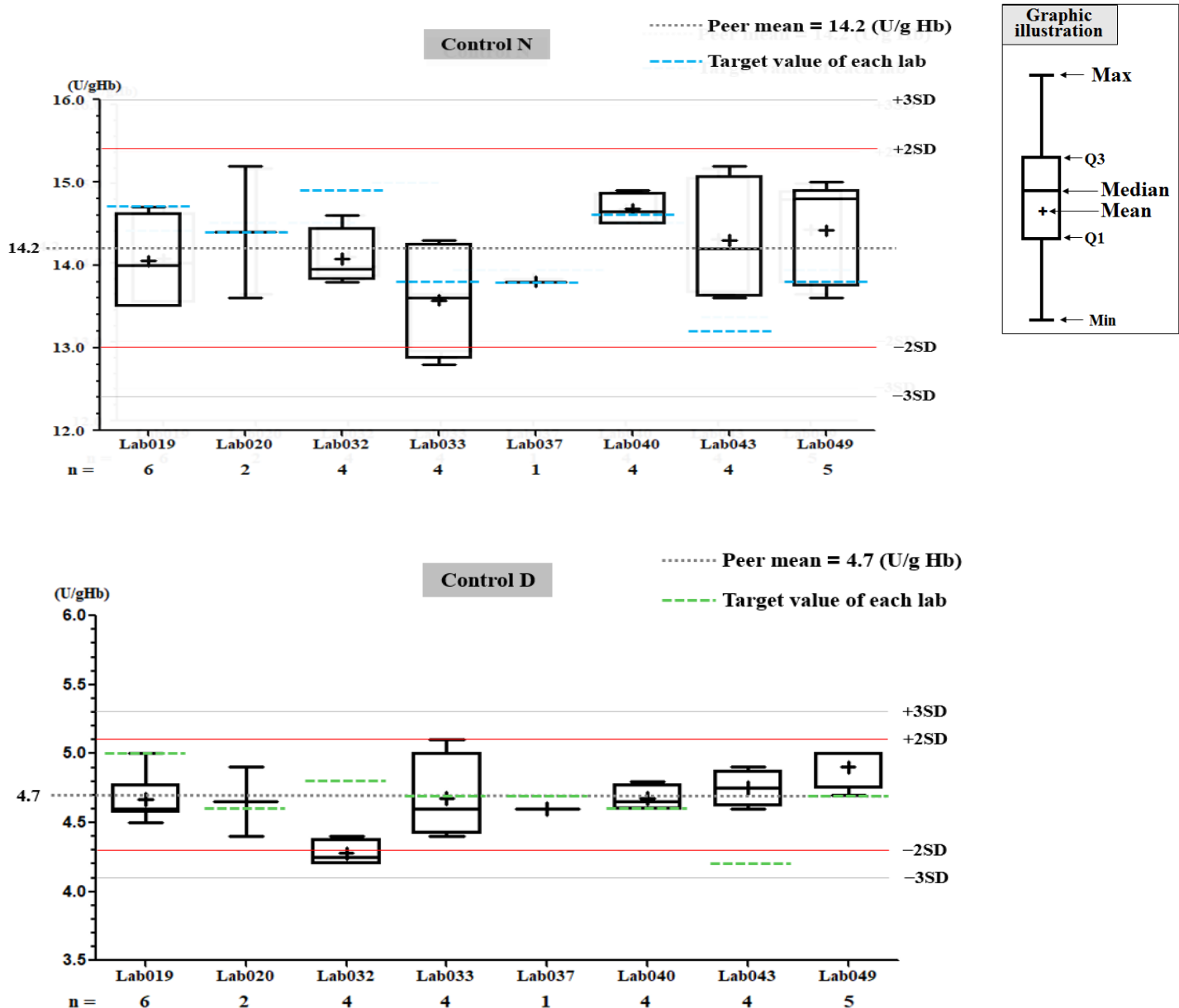
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:BJ0922N) | Control D (Lot No.: BJ0922D) |
|-----------------------------|--------------------------------|---------------------------------|
| Labs | 8 | 8 |
| Received results number (n) | 30 | 30 |
| Median | 14.1 (U/g Hb) | 4.7 (U/g Hb) |
| Mean | 14.2 (U/g Hb) | 4.7 (U/g Hb) |
| SD | 0.6 | 0.2 |
| CV | 4.2% | 4.3% |
| Range of G6PD | 12.8 ~ 15.2 (U/g Hb) | 4.2 ~ 5.1 (U/g Hb) |
| Range of Hb | 2.1 ~ 2.9 (g/dL) | 1.7 ~ 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 :

Lab019

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|--------------------|--------------------------------|--------------------|--------------------------------|
| | BJ0922N | | BJ0922D | |
| Duration of the Analyzing | Month (2023/05) | CUM (2022/10/26~2023/05/31) | Month (2023/05) | CUM (2022/10/26~2023/05/31) |
| Runs (N) | 6 | 26 | 6 | 26 |
| Mean (U/gHb) | 14.1 | 14.0 | 4.7 | 4.7 |
| SD | 0.5 | 0.4 | 0.2 | 0.2 |
| CV (%) | 3.5 | 2.9 | 4.3 | 4.3 |
| Target Value (U/gHb) | 14.7 | 14.7 | 5.0 | 5.0 |
| Total Error (%) | 11.2 | 10.5 | 14.5 | 14.5 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | 4.5 | 5.3 | 3.3 | 3.3 |

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

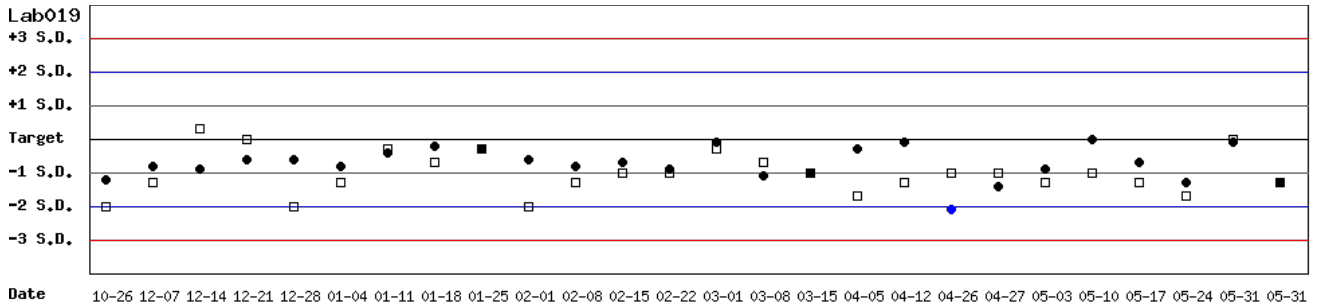
Month : ; Cumulative : from to

[TOP](#)

Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-10-26 to 2023-05-31 ; Target : 14.7 ; SD : 0.90 (●)

Lot No.: BJ0922D ; Duration : 2022-10-26 to 2023-05-31 ; Target : 5.0 ; SD : 0.30 (□)

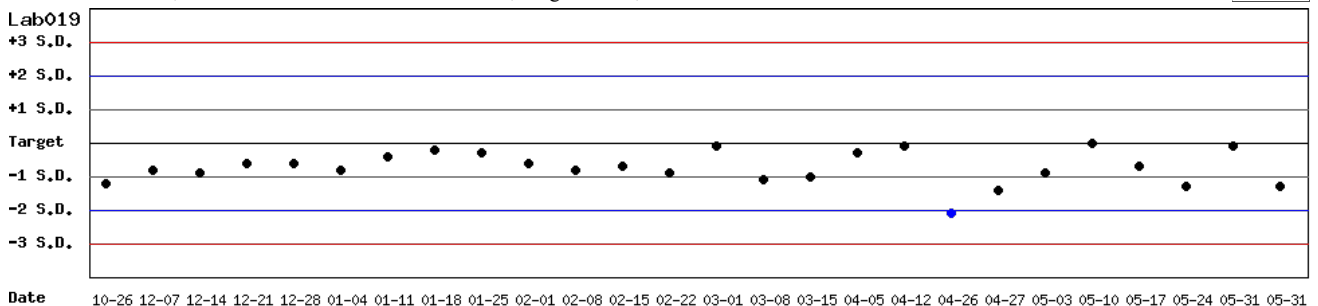


Month : ; Cumulative : from to

[TOP](#)

Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-10-26 to 2023-05-31 ; Target : 14.7 ; SD : 0.90



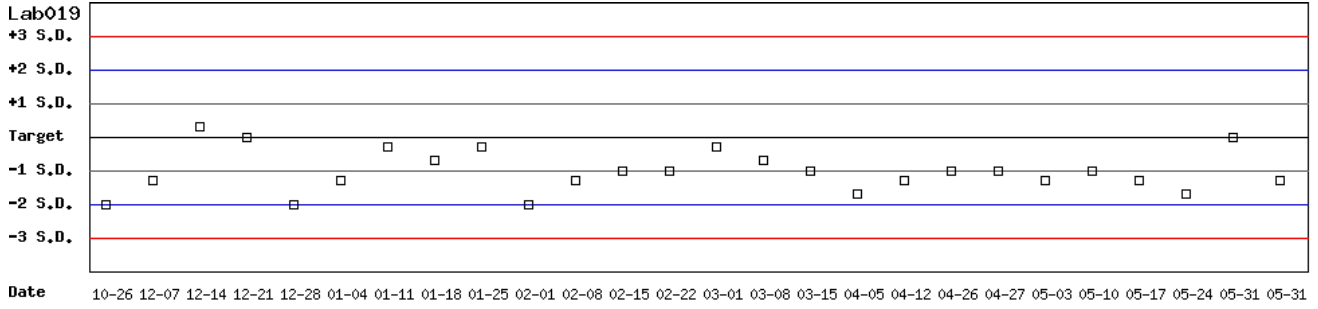
Month : ; Cumulative : from to

[TOP](#)

Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2022-10-26 to 2023-05-31 ; Target : 5.0 ; SD : 0.30

Lab019



Month : ; Cumulative : from to

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Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon

Monthly

Month : 2023 05

| UnitID <input type="button" value="↑"/> | Reagent Kit (Code) <input type="button" value="↑"/> | 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 | 14.7 | 14.1 | 6 | 0.5 | 3.5 | 11.2 | 20 | 4.5 | 5.0 | 4.7 | 6 | 0.2 | 4.3 | 14.5 | 20 | 3.3 |
| Lab020 | 5 | 14.4 | 14.4 | 2 | - | - | - | 20 | - | 4.6 | 4.7 | 2 | - | - | - | 20 | - |
| Lab032 | 5 | 14.9 | 14.1 | 4 | 0.4 | 2.8 | 11.0 | 20 | 5.2 | 4.8 | 4.3 | 4 | 0.1 | 2.3 | 15.1 | 20 | 4.2 |
| Lab033 | 5 | 13.8 | 13.6 | 4 | 0.7 | 5.1 | 11.7 | 20 | 3.6 | 4.7 | 4.7 | 4 | 0.3 | 6.4 | 12.8 | 20 | 3.1 |
| Lab037 | 5 | 13.8 | 13.8 | 1 | - | - | - | 20 | - | 4.7 | 4.6 | 1 | - | - | - | 20 | - |
| Lab040 | 5 | 14.4 | 14.7 | 4 | 0.2 | 1.4 | 4.8 | 20 | >6 | 4.6 | 4.7 | 4 | 0.1 | 2.1 | 6.4 | 20 | >6 |
| Lab043 | 5 | 13.2 | 14.3 | 4 | 0.8 | 5.6 | 19.5 | 20 | 2.1 | 4.2 | 4.8 | 4 | 0.1 | 2.1 | 18.5 | 20 | 2.7 |
| Lab049 | 5 | 13.8 | 14.4 | 5 | 0.6 | 4.2 | 12.7 | 20 | 3.7 | 4.7 | 4.9 | 5 | 0.1 | 2.0 | 8.3 | 20 | >6 |
| Total | - | - | 14.2 | 30 | 0.6 | 4.2 | - | - | - | - | 4.7 | 30 | 0.2 | 4.3 | - | - | - |

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 05 31

| UnitID <input type="button" value="↑"/> | Reagent Kit (Code) <input type="button" value="↑"/> | 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 | 14.7 | 14.2 | 61 | 0.5 | 3.5 | 10.4 | 20 | 4.7 | 5.0 | 4.6 | 61 | 0.2 | 4.3 | 16.7 | 20 | 2.8 |
| Lab020 | 5 | 14.4 | 14.4 | 62 | 0.5 | 3.5 | 6.9 | 20 | 5.7 | 4.6 | 4.7 | 62 | 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 | 127 | 0.4 | 2.8 | 9.6 | 20 | 5.7 | 4.8 | 4.5 | 127 | 0.2 | 4.4 | 15.1 | 20 | 3.1 |
| Lab033 | 5 | 13.8 | 13.7 | 72 | 0.6 | 4.4 | 9.5 | 20 | 4.4 | 4.7 | 4.6 | 72 | 0.3 | 6.5 | 15.2 | 20 | 2.7 |
| Lab037 | 5 | 13.8 | 14.5 | 55 | 0.5 | 3.4 | 12.0 | 20 | 4.4 | 4.7 | 4.7 | 55 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Lab040 | 5 | 14.4 | 14.7 | 51 | 0.2 | 1.4 | 4.8 | 20 | >6 | 4.6 | 4.6 | 51 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab043 | 5 | 13.2 | 13.7 | 89 | 1.3 | 9.5 | 22.8 | 20 | 1.7 | 4.2 | 4.5 | 89 | 0.5 | 11.1 | 29.4 | 20 | 1.2 |
| Lab049 | 5 | 13.8 | 14.4 | 136 | 0.6 | 4.2 | 12.7 | 20 | 3.7 | 4.7 | 4.7 | 136 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Total | - | - | 14.3 | 722 | 0.8 | 5.6 | - | - | - | - | 4.6 | 722 | 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 (2023/05) | | | | | | | | CUM (2021/01/01~2023/05/31) | | | | | | | |
| 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 | 14.7 | 14.1 | 6 | 0.5 | 3.5 | 11.2 | 20 | 4.5 | 14.7 | 14.2 | 61 | 0.5 | 3.5 | 10.4 | 20 | 4.7 |
| Lab020 | 5 | 14.4 | 14.4 | 2 | - | - | - | 20 | - | 14.4 | 14.4 | 62 | 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 | 14.1 | 4 | 0.4 | 2.8 | 11.0 | 20 | 5.2 | 14.9 | 14.3 | 127 | 0.4 | 2.8 | 9.6 | 20 | 5.7 |
| Lab033 | 5 | 13.8 | 13.6 | 4 | 0.7 | 5.1 | 11.7 | 20 | 3.6 | 13.8 | 13.7 | 72 | 0.6 | 4.4 | 9.5 | 20 | 4.4 |
| Lab037 | 5 | 13.8 | 13.8 | 1 | - | - | - | 20 | - | 13.8 | 14.5 | 55 | 0.5 | 3.4 | 12.0 | 20 | 4.4 |
| Lab040 | 5 | 14.4 | 14.7 | 4 | 0.2 | 1.4 | 4.8 | 20 | >6 | 14.4 | 14.7 | 51 | 0.2 | 1.4 | 4.8 | 20 | >6 |
| Lab043 | 5 | 13.2 | 14.3 | 4 | 0.8 | 5.6 | 19.5 | 20 | 2.1 | 13.2 | 13.7 | 89 | 1.3 | 9.5 | 22.8 | 20 | 1.7 |
| Lab049 | 5 | 13.8 | 14.4 | 5 | 0.6 | 4.2 | 12.7 | 20 | 3.7 | 13.8 | 14.4 | 136 | 0.6 | 4.2 | 12.7 | 20 | 3.7 |
| Total | - | - | 14.2 | 30 | 0.6 | 4.2 | - | - | - | - | 14.3 | 722 | 0.8 | 5.6 | - | - | - |

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

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

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

Month : 2023 05 Change

Cumulative : from 2021 01 01 to 2023 05 31 Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: BJ0922D) | | | | | | | | | | | | | | | |
|------------------------|-----------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2023/05) | | | | | | | | CUM (2021/01/01~2023/05/31) | | | | | | | |
| 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 | 5.0 | 4.7 | 6 | 0.2 | 4.3 | 14.5 | 20 | 3.3 | 5.0 | 4.6 | 61 | 0.2 | 4.3 | 16.7 | 20 | 2.8 |
| Lab020 | 5 | 4.6 | 4.7 | 2 | - | - | - | 20 | - | 4.6 | 4.7 | 62 | 0.1 | 2.1 | 6.4 | 20 | >6 |
| 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 | 4.3 | 4 | 0.1 | 2.3 | 15.1 | 20 | 4.2 | 4.8 | 4.5 | 127 | 0.2 | 4.4 | 15.1 | 20 | 3.1 |
| Lab033 | 5 | 4.7 | 4.7 | 4 | 0.3 | 6.4 | 12.8 | 20 | 3.1 | 4.7 | 4.6 | 72 | 0.3 | 6.5 | 15.2 | 20 | 2.7 |
| Lab037 | 5 | 4.7 | 4.6 | 1 | - | - | - | 20 | - | 4.7 | 4.7 | 55 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Lab040 | 5 | 4.6 | 4.7 | 4 | 0.1 | 2.1 | 6.4 | 20 | >6 | 4.6 | 4.6 | 51 | 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 | 4.5 | 89 | 0.5 | 11.1 | 29.4 | 20 | 1.2 |
| Lab049 | 5 | 4.7 | 4.9 | 5 | 0.1 | 2.0 | 8.3 | 20 | >6 | 4.7 | 4.7 | 136 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Total | - | - | 4.7 | 30 | 0.2 | 4.3 | - | - | - | - | 4.6 | 722 | 0.3 | 6.5 | - | - | - |

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

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

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

Month : 2023 05 Change

Cumulative : from 2021 01 01 to 2023 05 31 Change

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