

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

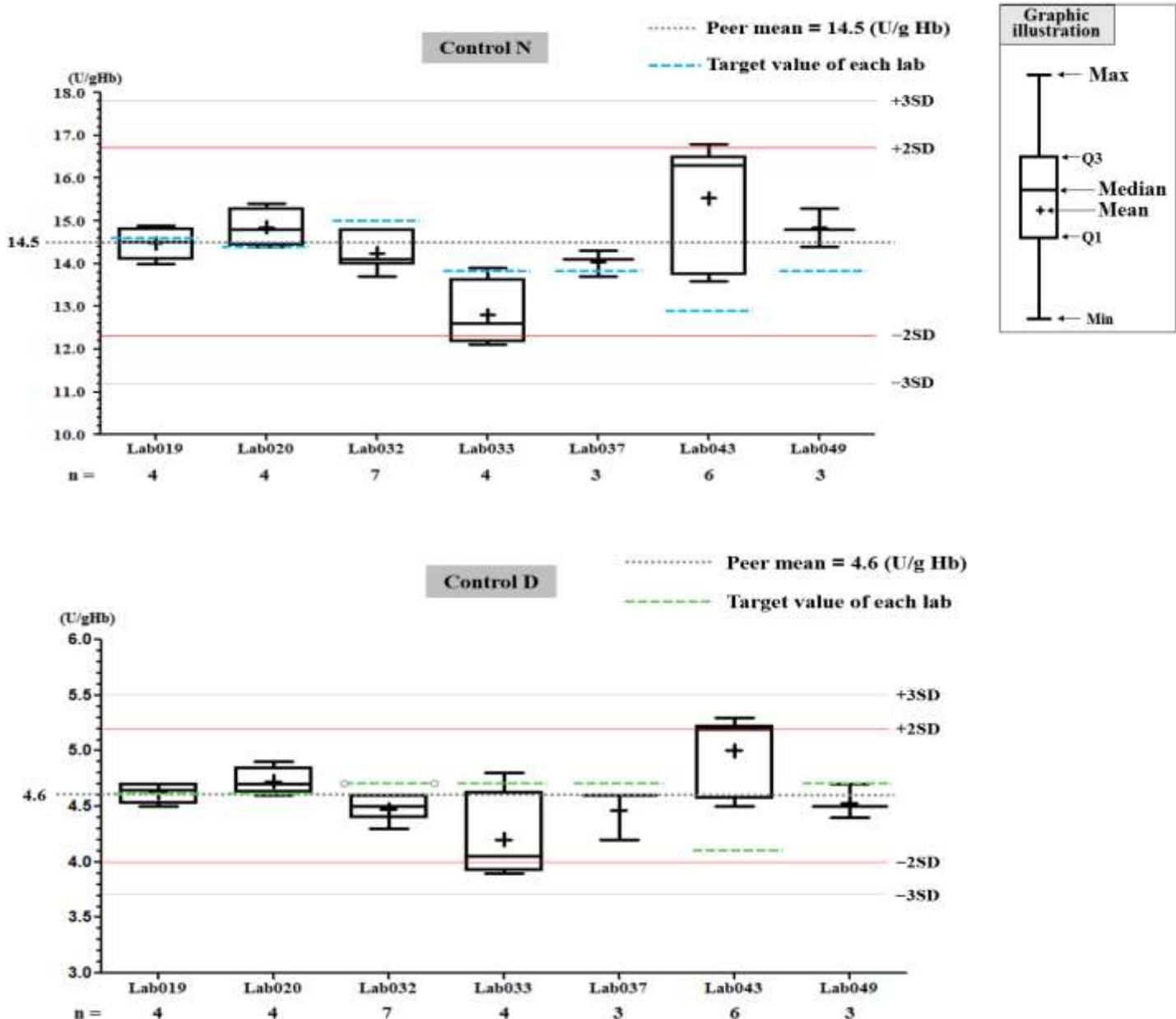
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:BJ0922N) | Control D (Lot No.: BJ0922D) |
|-----------------------------|--------------------------------|---------------------------------|
| Labs | 7 | 7 |
| Received results number (n) | 31 | 31 |
| Median | 14.4 (U/g Hb) | 4.6 (U/g Hb) |
| Mean | 14.5 (U/g Hb) | 4.6 (U/g Hb) |
| SD | 1.1 | 0.3 |
| CV | 7.6% | 6.5% |
| Range of G6PD | 12.1 ~ 16.8 (U/g Hb) | 3.9 ~ 5.3 (U/g Hb) |
| Range of Hb | 2.2 ~ 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 :

Lab049

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | BJ0922N | | BJ0922D | |
| Duration of the Analyzing | Month (2022/02) | CUM (2021/08/25~2022/02/28) | Month (2022/02) | CUM (2021/08/25~2022/02/28) |
| Runs (N) | 3 | 26 | 3 | 26 |
| Mean (U/gHb) | 14.8 | 14.9 | 4.5 | 4.6 |
| SD | 0.5 | 0.6 | 0.2 | 0.2 |
| CV (%) | 3.4 | 4.0 | 4.4 | 4.3 |
| Target Value (U/gHb) | 13.8 | 13.8 | 4.7 | 4.7 |
| Total Error (%) | 14.0 | 16.0 | 13.1 | 10.8 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | 3.8 | 3.0 | 3.6 | 4.2 |

Bias (%) = $(| \text{Mean} - \text{Target} |) / \text{Target} \times 100\%$

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

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

Month : ; Cumulative : from to

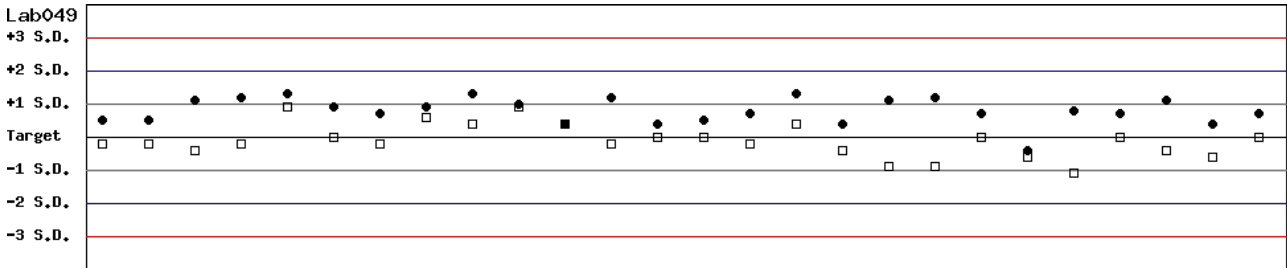
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-08-25 to 2022-02-28 ; Target : 13.8 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2021-08-25 to 2022-02-28 ; Target : 4.7 ; SD : 0.47 (□)

Lab049



Date 08-25 08-25 09-01 09-08 09-15 09-22 09-29 10-06 10-13 10-20 10-27 11-03 11-10 11-17 11-24 12-07 12-15 12-22 12-29 01-05 01-12 01-19 01-26 02-02 02-09 02-23

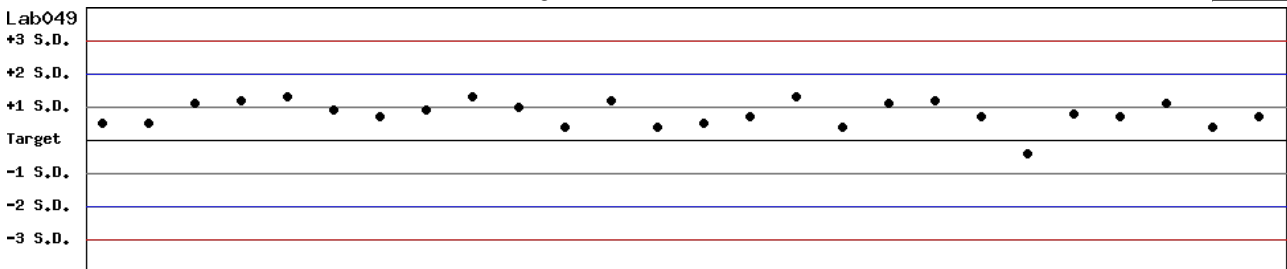
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-08-25 to 2022-02-28 ; Target : 13.8 ; SD : 1.38

Lab049



Date 08-25 08-25 09-01 09-08 09-15 09-22 09-29 10-06 10-13 10-20 10-27 11-03 11-10 11-17 11-24 12-07 12-15 12-22 12-29 01-05 01-12 01-19 01-26 02-02 02-09 02-23

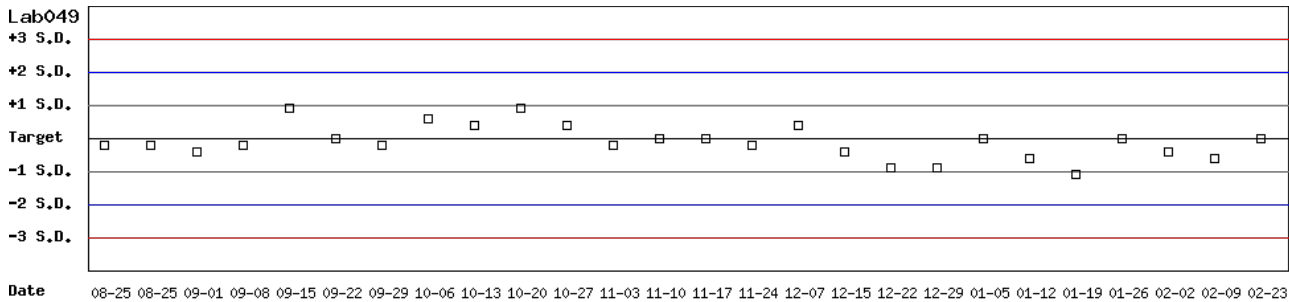
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2021-08-25 to 2022-02-28 ; Target : 4.7 ; SD : 0.47

Lab049



Month : 2022 ▾ 02 ▾ Change ; Cumulative : from 2021 ▾ 08 ▾ 25 ▾ to 2022 ▾ 02 ▾ 28 ▾ 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 02 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 | 14.6 | 14.5 | 4 | 0.4 | 2.8 | 6.2 | 20 | >6 | 4.6 | 4.6 | 4 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab020 | 5 | 14.4 | 14.9 | 4 | 0.4 | 2.7 | 8.8 | 20 | >6 | 4.6 | 4.7 | 4 | 0.1 | 2.1 | 6.4 | 20 | >6 |
| Lab032 | 5 | 15.0 | 14.2 | 7 | 0.4 | 2.8 | 11.0 | 20 | 5.2 | 4.7 | 4.5 | 7 | 0.1 | 2.2 | 8.7 | 20 | >6 |
| Lab033 | 5 | 13.8 | 12.8 | 4 | 0.8 | 6.3 | 19.7 | 20 | 2.0 | 4.7 | 4.2 | 4 | 0.4 | 9.5 | 29.7 | 20 | 1.0 |
| Lab037 | 5 | 13.8 | 14.0 | 3 | 0.3 | 2.1 | 5.7 | 20 | >6 | 4.7 | 4.5 | 3 | 0.2 | 4.4 | 13.1 | 20 | 3.6 |
| Lab043 | 5 | 12.9 | 15.5 | 6 | 1.4 | 9.0 | 38.2 | 20 | 0.0 | 4.1 | 5.0 | 6 | 0.4 | 8.0 | 38.0 | 20 | -0.2 |
| Lab049 | 5 | 13.8 | 14.8 | 3 | 0.5 | 3.4 | 14.0 | 20 | 3.8 | 4.7 | 4.5 | 3 | 0.2 | 4.4 | 13.1 | 20 | 3.6 |
| Total | - | - | 14.5 | 31 | 1.1 | 7.6 | - | - | - | - | 4.6 | 31 | 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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Cumulative

Cumulative : from 2021 01 01 to 2022 02 28 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 | 14.6 | 15.1 | 8 | 0.7 | 4.6 | 12.7 | 20 | 3.6 | 4.6 | 4.6 | 8 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab020 | 5 | 14.4 | 14.6 | 17 | 0.6 | 4.1 | 9.6 | 20 | 4.5 | 4.6 | 4.7 | 17 | 0.2 | 4.3 | 10.7 | 20 | 4.1 |
| Lab028 | 5 | 13.8 | 14.8 | 21 | 1.3 | 8.8 | 24.8 | 20 | 1.4 | 4.7 | 4.8 | 21 | 0.3 | 6.3 | 14.6 | 20 | 2.8 |
| Lab032 | 5 | 15.0 | 14.3 | 58 | 0.4 | 2.8 | 10.3 | 20 | 5.5 | 4.7 | 4.5 | 58 | 0.1 | 2.2 | 8.7 | 20 | >6 |
| Lab033 | 5 | 13.8 | 12.7 | 8 | 0.6 | 4.7 | 17.4 | 20 | 2.6 | 4.7 | 4.0 | 8 | 0.3 | 7.5 | 29.9 | 20 | 0.7 |
| Lab037 | 5 | 13.8 | 14.7 | 14 | 0.6 | 4.1 | 14.7 | 20 | 3.3 | 4.7 | 4.7 | 14 | 0.3 | 6.4 | 12.8 | 20 | 3.1 |
| Lab043 | 5 | 12.9 | 13.0 | 35 | 1.7 | 13.1 | 26.9 | 20 | 1.5 | 4.1 | 4.1 | 35 | 0.5 | 12.2 | 24.4 | 20 | 1.6 |
| Lab049 | 5 | 13.8 | 15.0 | 38 | 0.6 | 4.0 | 16.7 | 20 | 2.8 | 4.7 | 4.7 | 38 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Total | - | - | 14.3 | 199 | 1.2 | 8.4 | - | - | - | - | 4.5 | 199 | 0.4 | 8.9 | - | - | - |

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 (2022/02) | | | | | | | | CUM (2021/01/01~2022/02/28) | | | | | | | |
| 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 |
| Lab019 | 5 | 14.6 | 14.5 | 4 | 0.4 | 2.8 | 6.2 | 20 | >6 | 14.6 | 15.1 | 8 | 0.7 | 4.6 | 12.7 | 20 | 3.6 |
| Lab020 | 5 | 14.4 | 14.9 | 4 | 0.4 | 2.7 | 8.8 | 20 | >6 | 14.4 | 14.6 | 17 | 0.6 | 4.1 | 9.6 | 20 | 4.5 |
| Lab028 | 5 | 13.8 | - | 0 | - | - | - | 20 | - | 13.8 | 14.8 | 21 | 1.3 | 8.8 | 24.8 | 20 | 1.4 |
| Lab032 | 5 | 15.0 | 14.2 | 7 | 0.4 | 2.8 | 11.0 | 20 | 5.2 | 15.0 | 14.3 | 58 | 0.4 | 2.8 | 10.3 | 20 | 5.5 |
| Lab033 | 5 | 13.8 | 12.8 | 4 | 0.8 | 6.3 | 19.7 | 20 | 2.0 | 13.8 | 12.7 | 8 | 0.6 | 4.7 | 17.4 | 20 | 2.6 |
| Lab037 | 5 | 13.8 | 14.0 | 3 | 0.3 | 2.1 | 5.7 | 20 | >6 | 13.8 | 14.7 | 14 | 0.6 | 4.1 | 14.7 | 20 | 3.3 |
| Lab043 | 5 | 12.9 | 15.5 | 6 | 1.4 | 9.0 | 38.2 | 20 | 0.0 | 12.9 | 13.0 | 35 | 1.7 | 13.1 | 26.9 | 20 | 1.5 |
| Lab049 | 5 | 13.8 | 14.8 | 3 | 0.5 | 3.4 | 14.0 | 20 | 3.8 | 13.8 | 15.0 | 38 | 0.6 | 4.0 | 16.7 | 20 | 2.8 |
| Total | - | - | 14.5 | 31 | 1.1 | 7.6 | - | - | - | - | 14.3 | 199 | 1.2 | 8.4 | - | - | - |

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

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

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

Month : 2022 02 Change Cumulative : from 2021 01 01 to 2022 02 28 Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: BJ0922D) | | | | | | | | | | | | | | | |
|---|---|------------------------------|--------------|------------|-----|--------|--------|---------|------|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2022/02) | | | | | | | | CUM (2021/01/01~2022/02/28) | | | | | | | |
| 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 |
| Lab019 | 5 | 4.6 | 4.6 | 4 | 0.1 | 2.2 | 4.3 | 20 | >6 | 4.6 | 4.6 | 8 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab020 | 5 | 4.6 | 4.7 | 4 | 0.1 | 2.1 | 6.4 | 20 | >6 | 4.6 | 4.7 | 17 | 0.2 | 4.3 | 10.7 | 20 | 4.1 |
| Lab028 | 5 | 4.7 | - | 0 | - | - | - | 20 | - | 4.7 | 4.8 | 21 | 0.3 | 6.3 | 14.6 | 20 | 2.8 |
| Lab032 | 5 | 4.7 | 4.5 | 7 | 0.1 | 2.2 | 8.7 | 20 | >6 | 4.7 | 4.5 | 58 | 0.1 | 2.2 | 8.7 | 20 | >6 |
| Lab033 | 5 | 4.7 | 4.2 | 4 | 0.4 | 9.5 | 29.7 | 20 | 1.0 | 4.7 | 4.0 | 8 | 0.3 | 7.5 | 29.9 | 20 | 0.7 |
| Lab037 | 5 | 4.7 | 4.5 | 3 | 0.2 | 4.4 | 13.1 | 20 | 3.6 | 4.7 | 4.7 | 14 | 0.3 | 6.4 | 12.8 | 20 | 3.1 |
| Lab043 | 5 | 4.1 | 5.0 | 6 | 0.4 | 8.0 | 38.0 | 20 | -0.2 | 4.1 | 4.1 | 35 | 0.5 | 12.2 | 24.4 | 20 | 1.6 |
| Lab049 | 5 | 4.7 | 4.5 | 3 | 0.2 | 4.4 | 13.1 | 20 | 3.6 | 4.7 | 4.7 | 38 | 0.2 | 4.3 | 8.5 | 20 | 4.7 |
| Total | - | - | 4.6 | 31 | 0.3 | 6.5 | - | - | - | - | 4.5 | 199 | 0.4 | 8.9 | - | - | - |

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

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

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

Month : 2022 02 Change Cumulative : from 2021 01 01 to 2022 02 28 Change

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