

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - September 2021 -

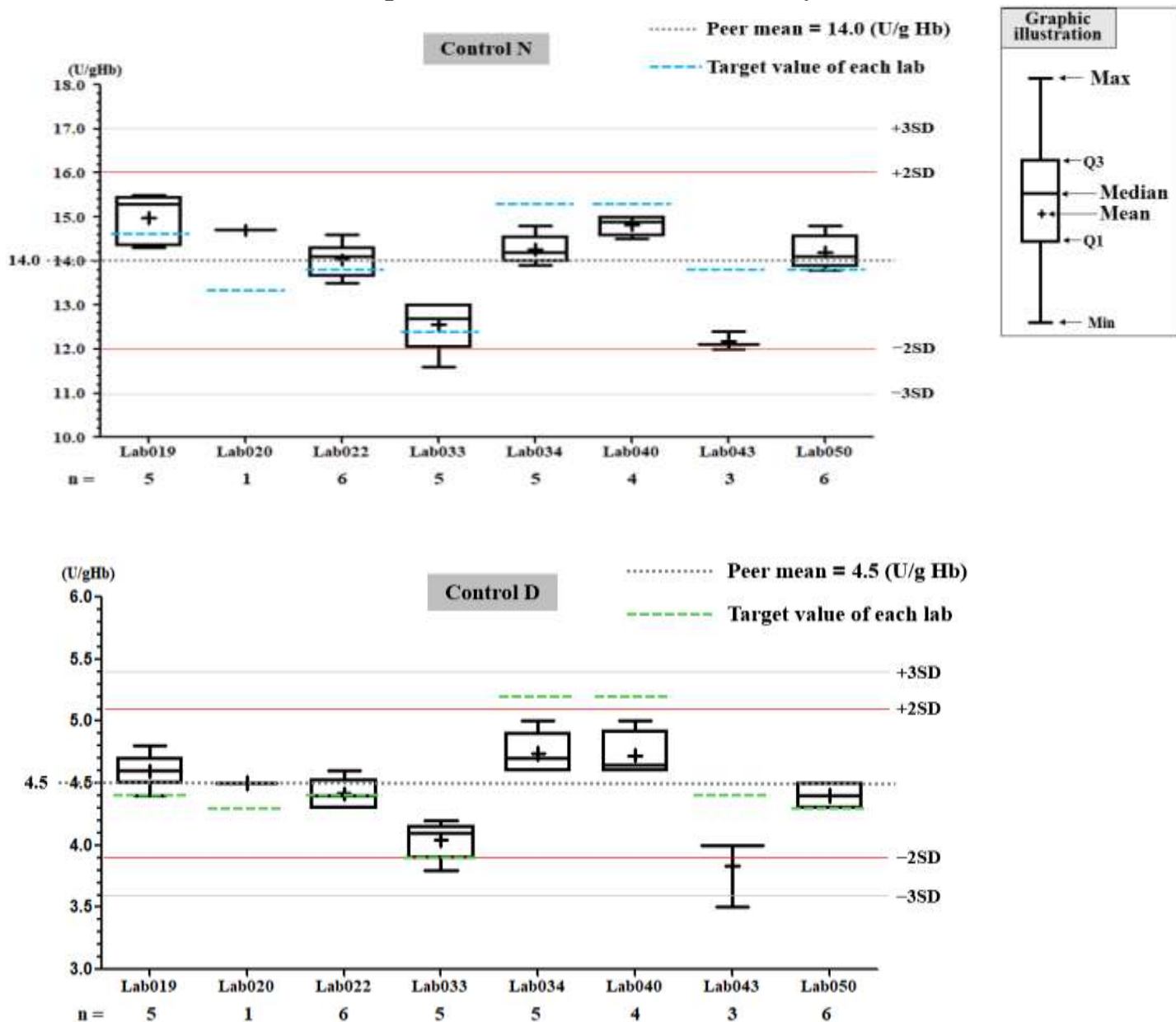
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:AH1220N) | Control D (Lot No.:AH1220D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs | 8 | 8 |
| Received results number (n) | 35 | 35 |
| Median | 14.2 (U/g Hb) | 4.5 (U/g Hb) |
| Mean | 14.0 (U/g Hb) | 4.4 (U/g Hb) |
| SD | 1.0 | 0.3 |
| CV | 7.1% | 6.8% |
| Range of G6PD | 11.6 ~ 15.5 (U/g Hb) | 3.5 ~ 5.0 (U/g Hb) |
| Range of Hb | 2.0 ~ 2.5 (g/dL) | 2.0 ~ 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 : AH1220N (2019-01-28 ~ 2100-12-31)

Lab040

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | AH1220N | | AH1220D | |
| Duration of the Analyzing | Month (2021/09) | CUM (2020/08/04~2021/09/30) | Month (2021/09) | CUM (2020/08/04~2021/09/30) |
| Runs (N) | 4 | 19 | 4 | 19 |
| Mean (U/gHb) | 14.8 | 15.0 | 4.7 | 5.3 |
| SD | 0.2 | 0.4 | 0.2 | 0.5 |
| CV (%) | 1.4 | 2.7 | 4.3 | 9.4 |
| Target Value (U/gHb) | 15.3 | 15.3 | 5.2 | 5.2 |
| Total Error (%) | 6.0 | 7.3 | 18.1 | 20.8 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | >6 | >6 | 2.4 | 1.9 |

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

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

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

Month : ; Cumulative : from to

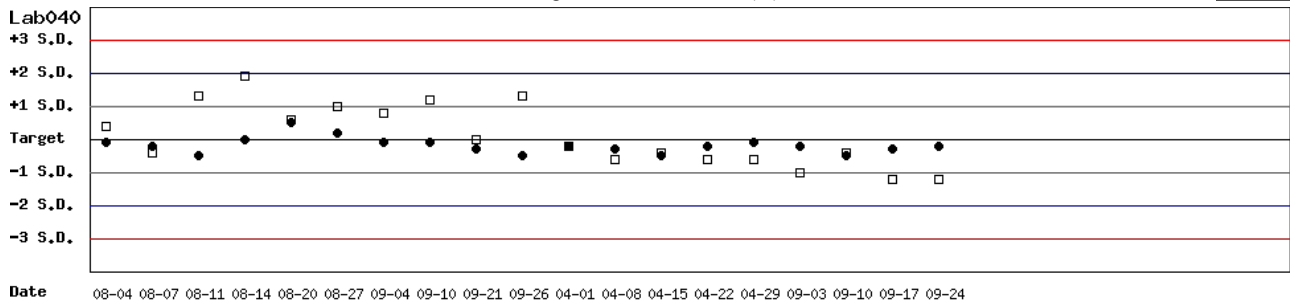
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-08-04 to 2021-09-30 ; Target : 15.3 ; SD : 1.53 (●)

Lot No.: AH1220D ; Duration : 2020-08-04 to 2021-09-30 ; Target : 5.2 ; SD : 0.52 (□)

Lab040



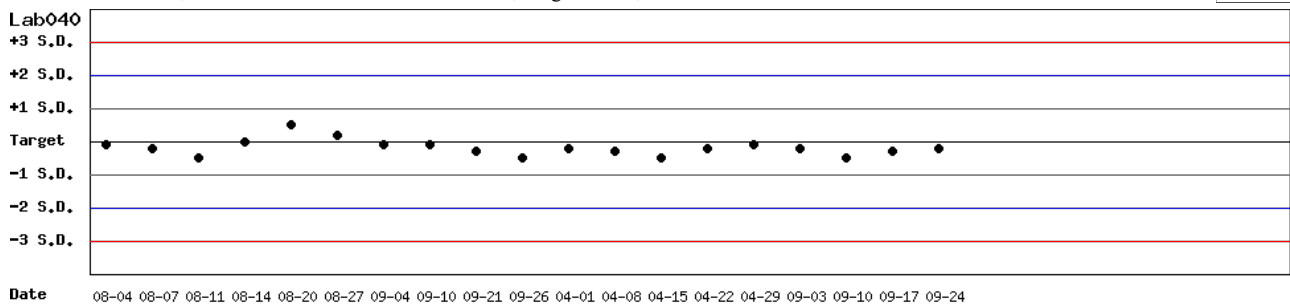
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-08-04 to 2021-09-30 ; Target : 15.3 ; SD : 1.53

Lab040



Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-08-04 to 2021-09-30 ; Target : 5.2 ; SD : 0.52

Lab040



Date 08-04 08-07 08-11 08-14 08-20 08-27 09-04 09-10 09-21 09-26 04-01 04-08 04-15 04-22 04-29 09-03 09-10 09-17 09-24

Month : ; Cumulative : from to

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Peer Group Statistics (Table 1)

Select LotNo : AH1220N (2019-01-28 ~ 2100-12-31)

Select Reagent Kit : 5 - Medicon

Monthly

Month : 2021

| UnitID <input type="button" value="↑"/> | Reagent Kit (Code) <input type="button" value="↑"/> | Control N (Lot No.: AH1220N) | | | | | | | | Control D (Lot No.: AH1220D) | | | | | | | |
|-----------------------------------------|-----------------------------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|------------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | 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 | 15.0 | 5 | 0.6 | 4.0 | 10.7 | 20 | 4.3 | 4.4 | 4.6 | 5 | 0.1 | 2.2 | 8.9 | 20 | >6 |
| Lab020 | 5 | 13.3 | 14.7 | 1 | - | - | - | 20 | - | 4.3 | 4.5 | 1 | - | - | - | 20 | - |
| Lab022 | 5 | 13.8 | 14.0 | 6 | 0.4 | 2.9 | 7.2 | 20 | >6 | 4.4 | 4.4 | 6 | 0.1 | 2.3 | 4.5 | 20 | >6 |
| Lab033 | 5 | 12.4 | 12.6 | 5 | 0.6 | 4.8 | 11.1 | 20 | 3.8 | 3.9 | 4.0 | 5 | 0.2 | 5.0 | 12.6 | 20 | 3.5 |
| Lab034 | 5 | 15.3 | 14.3 | 5 | 0.3 | 2.1 | 10.7 | 20 | >6 | 5.2 | 4.7 | 5 | 0.2 | 4.3 | 18.1 | 20 | 2.4 |
| Lab040 | 5 | 15.3 | 14.8 | 4 | 0.2 | 1.4 | 6.0 | 20 | >6 | 5.2 | 4.7 | 4 | 0.2 | 4.3 | 18.1 | 20 | 2.4 |
| Lab043 | 5 | 13.8 | 12.2 | 3 | 0.2 | 1.6 | 14.9 | 20 | 5.3 | 4.4 | 3.8 | 3 | 0.3 | 7.9 | 29.4 | 20 | 0.8 |
| Lab050 | 5 | 13.8 | 14.2 | 6 | 0.4 | 2.8 | 8.5 | 20 | >6 | 4.3 | 4.4 | 6 | 0.1 | 2.3 | 6.9 | 20 | >6 |
| Total | - | - | 14.0 | 35 | 1.0 | 7.1 | - | - | - | - | 4.4 | 35 | 0.3 | 6.8 | - | - | - |

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from 2019 to 2021

| UnitID <input type="button" value="↑"/> | Reagent Kit (Code) <input type="button" value="↑"/> | Control N (Lot No.: AH1220N) | | | | | | | | Control D (Lot No.: AH1220D) | | | | | | | |
|-----------------------------------------|-----------------------------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|------------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | 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 | 14.7 | 58 | 0.4 | 2.7 | 6.1 | 20 | >6 | 4.4 | 4.5 | 58 | 0.1 | 2.2 | 6.7 | 20 | >6 |
| Lab020 | 5 | 13.3 | 14.3 | 65 | 1.0 | 7.0 | 21.5 | 20 | 1.8 | 4.3 | 4.5 | 65 | 0.2 | 4.4 | 13.5 | 20 | 3.5 |
| Lab022 | 5 | 13.8 | 12.8 | 76 | 0.9 | 7.0 | 21.3 | 20 | 1.8 | 4.4 | 4.1 | 76 | 0.2 | 4.9 | 16.6 | 20 | 2.7 |
| Lab028 | 5 | 14.6 | 14.6 | 53 | 0.4 | 2.7 | 5.5 | 20 | >6 | 4.6 | 4.6 | 53 | 0.2 | 4.3 | 8.7 | 20 | 4.7 |
| Lab032 | 5 | 12.1 | 12.9 | 136 | 1.4 | 10.9 | 28.3 | 20 | 1.2 | 3.5 | 4.0 | 136 | 0.5 | 12.5 | 39.3 | 20 | 0.5 |
| Lab033 | 5 | 12.4 | 12.5 | 126 | 0.4 | 3.2 | 7.2 | 20 | 6.0 | 3.9 | 3.9 | 126 | 0.2 | 5.1 | 10.3 | 20 | 3.9 |
| Lab034 | 5 | 15.3 | 14.5 | 65 | 1.0 | 6.9 | 19.0 | 20 | 2.1 | 5.2 | 4.6 | 65 | 0.2 | 4.3 | 20.2 | 20 | 2.0 |
| Lab037 | 5 | 15.3 | 15.2 | 55 | 0.4 | 2.6 | 5.9 | 20 | >6 | 5.2 | 4.7 | 55 | 0.2 | 4.3 | 18.1 | 20 | 2.4 |
| Lab040 | 5 | 15.3 | 15.0 | 19 | 0.4 | 2.7 | 7.3 | 20 | >6 | 5.2 | 5.3 | 19 | 0.5 | 9.4 | 20.8 | 20 | 1.9 |
| Lab043 | 5 | 13.8 | 12.7 | 19 | 0.7 | 5.5 | 19.0 | 20 | 2.2 | 4.4 | 4.1 | 19 | 0.3 | 7.3 | 21.5 | 20 | 1.8 |
| Lab047 | 5 | 14.7 | 13.7 | 26 | 1.2 | 8.8 | 24.3 | 20 | 1.5 | 4.6 | 4.3 | 26 | 0.3 | 7.0 | 20.5 | 20 | 1.9 |
| Lab049 | 5 | 14.7 | 14.3 | 42 | 0.5 | 3.5 | 9.7 | 20 | 4.9 | 4.9 | 4.7 | 42 | 0.3 | 6.4 | 16.8 | 20 | 2.5 |
| Lab050 | 5 | 13.8 | 14.0 | 51 | 0.5 | 3.6 | 8.6 | 20 | 5.2 | 4.3 | 4.4 | 51 | 0.2 | 4.5 | 11.4 | 20 | 3.9 |
| Total | - | - | 13.7 | 791 | 1.3 | 9.5 | - | - | - | - | 4.3 | 791 | 0.4 | 9.3 | - | - | - |

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 : AH1220N (2019-01-28 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

[Print Table 2](#)

Control N Month vs. Cumulative

| | | Control N (Lot No.: AH1220N) | | | | | | | | | | | | | | | |
|-------------------------|-------------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2021/09) | | | | | | | | CUM (2019/02/01~2021/09/30) | | | | | | | |
| 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 |
| Lab019 | 5 | 14.6 | 15.0 | 5 | 0.6 | 4.0 | 10.7 | 20 | 4.3 | 14.6 | 14.7 | 58 | 0.4 | 2.7 | 6.1 | 20 | >6 |
| Lab020 | 5 | 13.3 | 14.7 | 1 | - | - | - | 20 | - | 13.3 | 14.3 | 65 | 1.0 | 7.0 | 21.5 | 20 | 1.8 |
| Lab022 | 5 | 13.8 | 14.0 | 6 | 0.4 | 2.9 | 7.2 | 20 | >6 | 13.8 | 12.8 | 76 | 0.9 | 7.0 | 21.3 | 20 | 1.8 |
| Lab028 | 5 | 14.6 | - | 0 | - | - | - | 20 | - | 14.6 | 14.6 | 53 | 0.4 | 2.7 | 5.5 | 20 | >6 |
| Lab032 | 5 | 12.1 | - | 0 | - | - | - | 20 | - | 12.1 | 12.9 | 136 | 1.4 | 10.9 | 28.3 | 20 | 1.2 |
| Lab033 | 5 | 12.4 | 12.6 | 5 | 0.6 | 4.8 | 11.1 | 20 | 3.8 | 12.4 | 12.5 | 126 | 0.4 | 3.2 | 7.2 | 20 | 6.0 |
| Lab034 | 5 | 15.3 | 14.3 | 5 | 0.3 | 2.1 | 10.7 | 20 | >6 | 15.3 | 14.5 | 65 | 1.0 | 6.9 | 19.0 | 20 | 2.1 |
| Lab037 | 5 | 15.3 | - | 0 | - | - | - | 20 | - | 15.3 | 15.2 | 55 | 0.4 | 2.6 | 5.9 | 20 | >6 |
| Lab040 | 5 | 15.3 | 14.8 | 4 | 0.2 | 1.4 | 6.0 | 20 | >6 | 15.3 | 15.0 | 19 | 0.4 | 2.7 | 7.3 | 20 | >6 |
| Lab043 | 5 | 13.8 | 12.2 | 3 | 0.2 | 1.6 | 14.9 | 20 | 5.3 | 13.8 | 12.7 | 19 | 0.7 | 5.5 | 19.0 | 20 | 2.2 |
| Lab047 | 5 | 14.7 | - | 0 | - | - | - | 20 | - | 14.7 | 13.7 | 26 | 1.2 | 8.8 | 24.3 | 20 | 1.5 |
| Lab049 | 5 | 14.7 | - | 0 | - | - | - | 20 | - | 14.7 | 14.3 | 42 | 0.5 | 3.5 | 9.7 | 20 | 4.9 |
| Lab050 | 5 | 13.8 | 14.2 | 6 | 0.4 | 2.8 | 8.5 | 20 | >6 | 13.8 | 14.0 | 51 | 0.5 | 3.6 | 8.6 | 20 | 5.2 |
| Total | - | - | 14.0 | 35 | 1.0 | 7.1 | - | - | - | - | 13.7 | 791 | 1.3 | 9.5 | - | - | - |

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

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

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

Month : 2021 09 Change

Cumulative : from 2019 02 01 to 2021 09 30 Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: AH1220D) | | | | | | | | | | | | | | | |
|-------------------------|-------------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2021/09) | | | | | | | | CUM (2019/02/01~2021/09/30) | | | | | | | |
| 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 |
| Lab019 | 5 | 4.4 | 4.6 | 5 | 0.1 | 2.2 | 8.9 | 20 | >6 | 4.4 | 4.5 | 58 | 0.1 | 2.2 | 6.7 | 20 | >6 |
| Lab020 | 5 | 4.3 | 4.5 | 1 | - | - | - | 20 | - | 4.3 | 4.5 | 65 | 0.2 | 4.4 | 13.5 | 20 | 3.5 |
| Lab022 | 5 | 4.4 | 4.4 | 6 | 0.1 | 2.3 | 4.5 | 20 | >6 | 4.4 | 4.1 | 76 | 0.2 | 4.9 | 16.6 | 20 | 2.7 |
| Lab028 | 5 | 4.6 | - | 0 | - | - | - | 20 | - | 4.6 | 4.6 | 53 | 0.2 | 4.3 | 8.7 | 20 | 4.7 |
| Lab032 | 5 | 3.5 | - | 0 | - | - | - | 20 | - | 3.5 | 4.0 | 136 | 0.5 | 12.5 | 39.3 | 20 | 0.5 |
| Lab033 | 5 | 3.9 | 4.0 | 5 | 0.2 | 5.0 | 12.6 | 20 | 3.5 | 3.9 | 3.9 | 126 | 0.2 | 5.1 | 10.3 | 20 | 3.9 |
| Lab034 | 5 | 5.2 | 4.7 | 5 | 0.2 | 4.3 | 18.1 | 20 | 2.4 | 5.2 | 4.6 | 65 | 0.2 | 4.3 | 20.2 | 20 | 2.0 |
| Lab037 | 5 | 5.2 | - | 0 | - | - | - | 20 | - | 5.2 | 4.7 | 55 | 0.2 | 4.3 | 18.1 | 20 | 2.4 |
| Lab040 | 5 | 5.2 | 4.7 | 4 | 0.2 | 4.3 | 18.1 | 20 | 2.4 | 5.2 | 5.3 | 19 | 0.5 | 9.4 | 20.8 | 20 | 1.9 |
| Lab043 | 5 | 4.4 | 3.8 | 3 | 0.3 | 7.9 | 29.4 | 20 | 0.8 | 4.4 | 4.1 | 19 | 0.3 | 7.3 | 21.5 | 20 | 1.8 |
| Lab047 | 5 | 4.6 | - | 0 | - | - | - | 20 | - | 4.6 | 4.3 | 26 | 0.3 | 7.0 | 20.5 | 20 | 1.9 |
| Lab049 | 5 | 4.9 | - | 0 | - | - | - | 20 | - | 4.9 | 4.7 | 42 | 0.3 | 6.4 | 16.8 | 20 | 2.5 |
| Lab050 | 5 | 4.3 | 4.4 | 6 | 0.1 | 2.3 | 6.9 | 20 | >6 | 4.3 | 4.4 | 51 | 0.2 | 4.5 | 11.4 | 20 | 3.9 |
| Total | - | - | 4.4 | 35 | 0.3 | 6.8 | - | - | - | - | 4.3 | 791 | 0.4 | 9.3 | - | - | - |

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

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

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

Month : 2021 09 Change

Cumulative : from 2019 02 01 to 2021 09 30 Change

[TOP](#)

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