

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

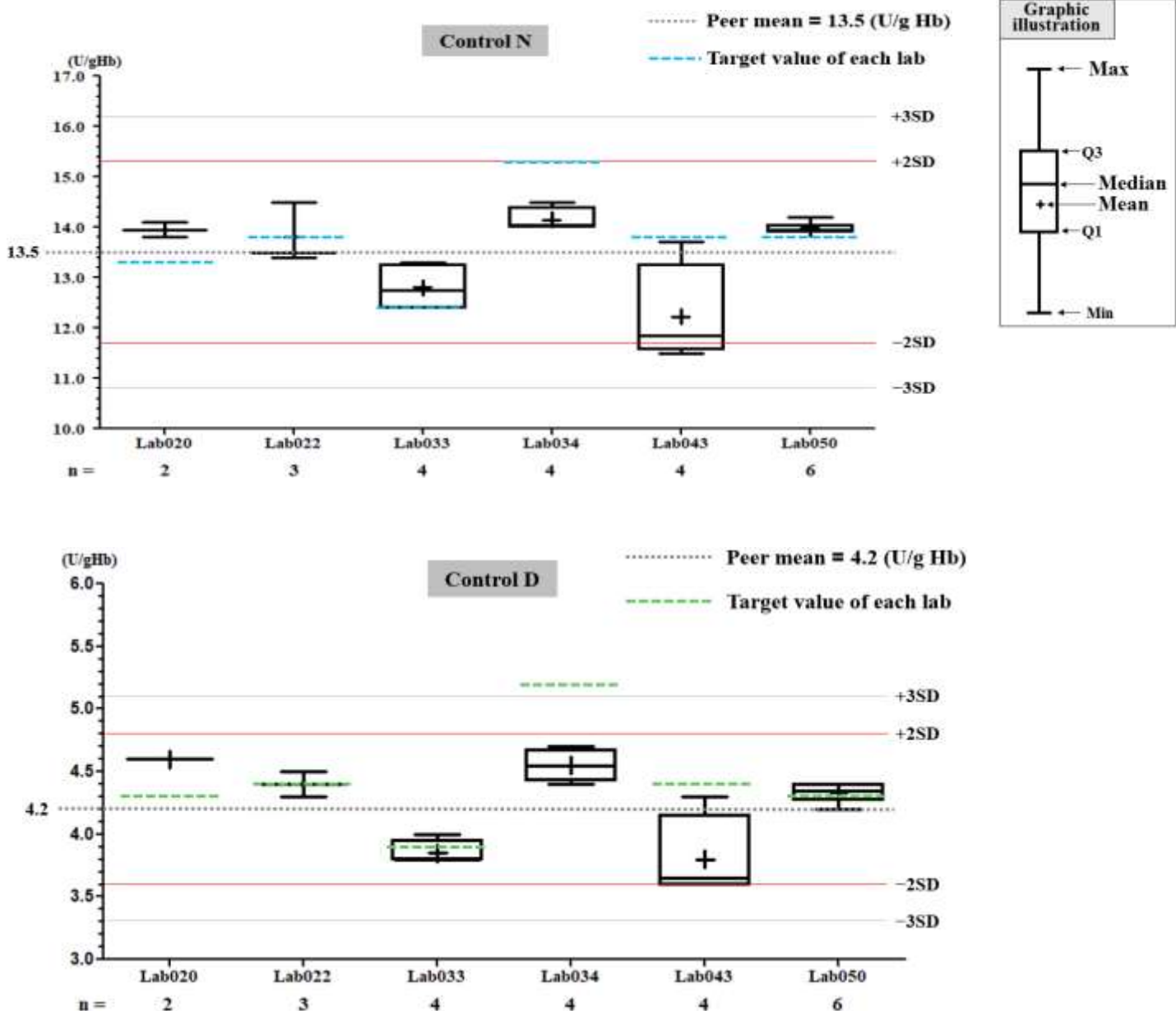
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:AH1220N) | Control D (Lot No.:AH1220D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs | 6 | 6 |
| Received results number (n) | 23 | 23 |
| Median | 13.9 (U/g Hb) | 4.3 (U/g Hb) |
| Mean | 13.5 (U/g Hb) | 4.2 (U/g Hb) |
| SD | 0.9 | 0.3 |
| CV | 6.7% | 7.1% |
| Range of G6PD | 11.5 ~ 14.5 (U/g Hb) | 3.6 ~ 4.7 (U/g Hb) |
| Range of Hb | 2.0 ~ 2.5 (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 : AH1220N (2019-01-28 ~ 2100-12-31)

Lab020

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | AH1220N | | AH1220D | |
| Duration of the Analyzing | Month (2021/08) | CUM (2021/01/07~2021/08/31) | Month (2021/08) | CUM (2021/01/07~2021/08/31) |
| Runs (N) | 2 | 26 | 2 | 26 |
| Mean (U/gHb) | 14.0 | 14.3 | 4.6 | 4.5 |
| SD | - | 0.7 | - | 0.1 |
| CV (%) | - | 4.9 | - | 2.2 |
| Target Value (U/gHb) | 13.3 | 13.3 | 4.3 | 4.3 |
| Total Error (%) | - | 17.3 | - | 9.1 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | - | 2.5 | - | >6 |

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

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

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

Month : ; Cumulative : from to

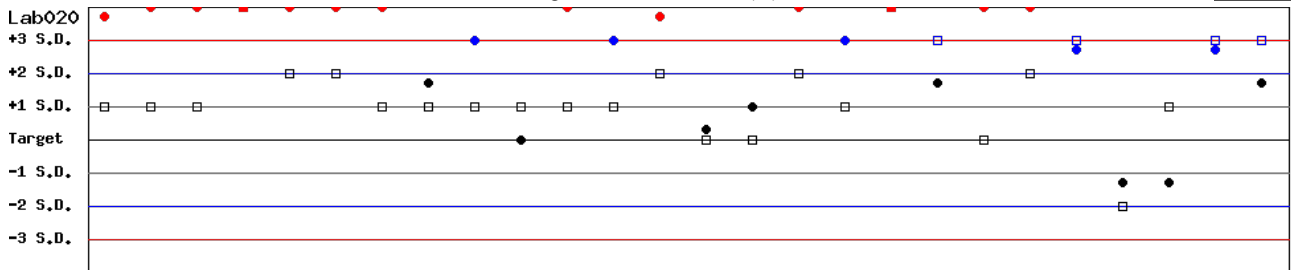
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-01-07 to 2021-08-31 ; Target : 13.3 ; SD : 0.30 (●)

Lot No.: AH1220D ; Duration : 2021-01-07 to 2021-08-31 ; Target : 4.3 ; SD : 0.10 (□)

Lab020



Date 01-07 01-14 01-21 01-28 02-04 02-11 02-18 02-25 03-04 03-11 03-18 03-25 04-01 04-15 04-29 05-13 05-20 06-03 06-10 06-17 06-24 07-01 07-08 07-15 08-19 08-26

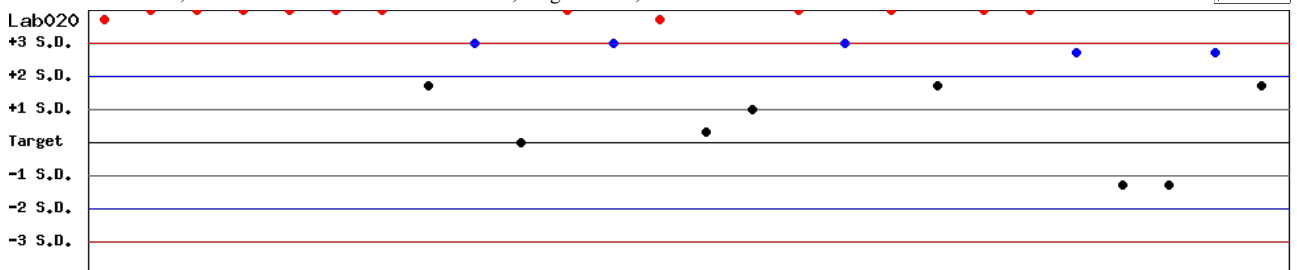
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-01-07 to 2021-08-31 ; Target : 13.3 ; SD : 0.30

Lab020



Date 01-07 01-14 01-21 01-28 02-04 02-11 02-18 02-25 03-04 03-11 03-18 03-25 04-01 04-15 04-29 05-13 05-20 06-03 06-10 06-17 06-24 07-01 07-08 07-15 08-19 08-26

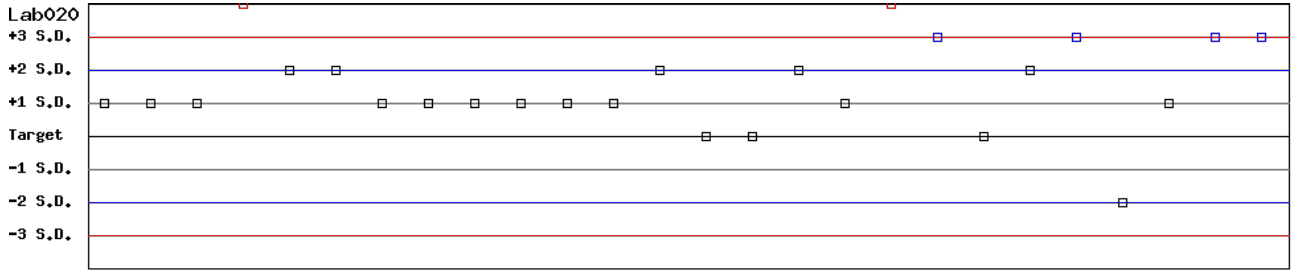
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2021-01-07 to 2021-08-31 ; Target : 4.3 ; SD : 0.10

Lab020



Date 01-07 01-14 01-21 01-28 02-04 02-11 02-18 02-25 03-04 03-11 03-18 03-25 04-01 04-15 04-29 05-13 05-20 06-03 06-10 06-17 06-24 07-01 07-08 07-15 08-19 08-26

Month : 2021 08 Change ; Cumulative : from 2021 01 07 to 2021 08 31 Change

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Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon Change

Print Table 1

Monthly

Month : 2021 08 Change

| UnitID ↑ | Reagent Kit (Code) ↑ | 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 |
| Lab020 | 5 | 13.3 | 14.0 | 2 | - | - | - | 20 | - | 4.3 | 4.6 | 2 | - | - | - | 20 | - |
| Lab022 | 5 | 13.8 | 13.8 | 3 | 0.6 | 4.3 | 8.7 | 20 | 4.7 | 4.4 | 4.4 | 3 | 0.1 | 2.3 | 4.5 | 20 | >6 |
| Lab033 | 5 | 12.4 | 12.8 | 4 | 0.5 | 3.9 | 11.0 | 20 | 4.3 | 3.9 | 3.9 | 4 | 0.1 | 2.6 | 5.1 | 20 | >6 |
| Lab034 | 5 | 15.3 | 14.2 | 4 | 0.2 | 1.4 | 10.0 | 20 | >6 | 5.2 | 4.6 | 4 | 0.1 | 2.2 | 15.9 | 20 | 3.8 |
| Lab043 | 5 | 13.8 | 12.2 | 4 | 1.0 | 8.2 | 28.0 | 20 | 1.0 | 4.4 | 3.8 | 4 | 0.3 | 7.9 | 29.4 | 20 | 0.8 |
| Lab050 | 5 | 13.8 | 14.0 | 6 | 0.1 | 0.7 | 2.9 | 20 | >6 | 4.3 | 4.3 | 6 | 0.1 | 2.3 | 4.7 | 20 | >6 |
| Total | - | - | 13.5 | 23 | 0.9 | 6.7 | - | - | - | - | 4.2 | 23 | 0.3 | 7.1 | - | - | - |

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

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

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

[TOP](#)

Cumulative

Cumulative : from 2019 02 01 to 2021 08 31 Change

| UnitID ↑ | Reagent Kit (Code) ↑ | 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 | 14.6 | 53 | 0.3 | 2.1 | 4.1 | 20 | >6 | 4.4 | 4.4 | 53 | 0.1 | 2.3 | 4.5 | 20 | >6 |
| Lab020 | 5 | 13.3 | 14.3 | 64 | 1.0 | 7.0 | 21.5 | 20 | 1.8 | 4.3 | 4.5 | 64 | 0.2 | 4.4 | 13.5 | 20 | 3.5 |
| Lab022 | 5 | 13.8 | 12.7 | 70 | 0.8 | 6.3 | 20.6 | 20 | 1.9 | 4.4 | 4.1 | 70 | 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 | 121 | 0.4 | 3.2 | 7.2 | 20 | 6.0 | 3.9 | 3.9 | 121 | 0.2 | 5.1 | 10.3 | 20 | 3.9 |
| Lab034 | 5 | 15.3 | 14.5 | 60 | 1.0 | 6.9 | 19.0 | 20 | 2.1 | 5.2 | 4.6 | 60 | 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 | 15 | 0.4 | 2.7 | 7.3 | 20 | >6 | 5.2 | 5.4 | 15 | 0.4 | 7.4 | 18.7 | 20 | 2.2 |
| Lab043 | 5 | 13.8 | 12.8 | 16 | 0.7 | 5.5 | 18.2 | 20 | 2.3 | 4.4 | 4.1 | 16 | 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 | 45 | 0.5 | 3.6 | 8.6 | 20 | 5.2 | 4.3 | 4.4 | 45 | 0.2 | 4.5 | 11.4 | 20 | 3.9 |
| Total | - | - | 13.7 | 756 | 1.3 | 9.5 | - | - | - | - | 4.3 | 756 | 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 (2021/08) | | | | | | | | CUM (2019/02/01~2021/08/31) | | | | | | | |
| 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 |
| Lab019 | 5 | 14.6 | - | 0 | - | - | - | 20 | - | 14.6 | 14.6 | 53 | 0.3 | 2.1 | 4.1 | 20 | >6 |
| Lab020 | 5 | 13.3 | 14.0 | 2 | - | - | - | 20 | - | 13.3 | 14.3 | 64 | 1.0 | 7.0 | 21.5 | 20 | 1.8 |
| Lab022 | 5 | 13.8 | 13.8 | 3 | 0.6 | 4.3 | 8.7 | 20 | 4.7 | 13.8 | 12.7 | 70 | 0.8 | 6.3 | 20.6 | 20 | 1.9 |
| 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 | 12.8 | 4 | 0.5 | 3.9 | 11.0 | 20 | 4.3 | 12.4 | 12.5 | 121 | 0.4 | 3.2 | 7.2 | 20 | 6.0 |
| Lab034 | 5 | 15.3 | 14.2 | 4 | 0.2 | 1.4 | 10.0 | 20 | >6 | 15.3 | 14.5 | 60 | 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 | - | 0 | - | - | - | 20 | - | 15.3 | 15.0 | 15 | 0.4 | 2.7 | 7.3 | 20 | >6 |
| Lab043 | 5 | 13.8 | 12.2 | 4 | 1.0 | 8.2 | 28.0 | 20 | 1.0 | 13.8 | 12.8 | 16 | 0.7 | 5.5 | 18.2 | 20 | 2.3 |
| 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 | 14.0 | 6 | 0.1 | 0.7 | 2.9 | 20 | >6 | 13.8 | 14.0 | 45 | 0.5 | 3.6 | 8.6 | 20 | 5.2 |
| Total | - | - | 13.5 | 23 | 0.9 | 6.7 | - | - | - | - | 13.7 | 756 | 1.3 | 9.5 | - | - | - |

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

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

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

Month : 2021 08 Change

Cumulative : from 2019 02 01 to 2021 08 31 Change

[TOP](#)

Control D Month vs. Cumulative

| | | Control D (Lot No.: AH1220D) | | | | | | | | | | | | | | | |
|---|---|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2021/08) | | | | | | | | CUM (2019/02/01~2021/08/31) | | | | | | | |
| 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 |
| Lab019 | 5 | 4.4 | - | 0 | - | - | - | 20 | - | 4.4 | 4.4 | 53 | 0.1 | 2.3 | 4.5 | 20 | >6 |
| Lab020 | 5 | 4.3 | 4.6 | 2 | - | - | - | 20 | - | 4.3 | 4.5 | 64 | 0.2 | 4.4 | 13.5 | 20 | 3.5 |
| Lab022 | 5 | 4.4 | 4.4 | 3 | 0.1 | 2.3 | 4.5 | 20 | >6 | 4.4 | 4.1 | 70 | 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 | 3.9 | 4 | 0.1 | 2.6 | 5.1 | 20 | >6 | 3.9 | 3.9 | 121 | 0.2 | 5.1 | 10.3 | 20 | 3.9 |
| Lab034 | 5 | 5.2 | 4.6 | 4 | 0.1 | 2.2 | 15.9 | 20 | 3.8 | 5.2 | 4.6 | 60 | 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 | - | 0 | - | - | - | 20 | - | 5.2 | 5.4 | 15 | 0.4 | 7.4 | 18.7 | 20 | 2.2 |
| Lab043 | 5 | 4.4 | 3.8 | 4 | 0.3 | 7.9 | 29.4 | 20 | 0.8 | 4.4 | 4.1 | 16 | 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 | 4.3 | 6 | 0.1 | 2.3 | 4.7 | 20 | >6 | 4.3 | 4.4 | 45 | 0.2 | 4.5 | 11.4 | 20 | 3.9 |
| Total | - | - | 4.2 | 23 | 0.3 | 7.1 | - | - | - | - | 4.3 | 756 | 0.4 | 9.3 | - | - | - |

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

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

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

Month : 2021 08 Change

Cumulative : from 2019 02 01 to 2021 08 31 Change

[TOP](#)

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