

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

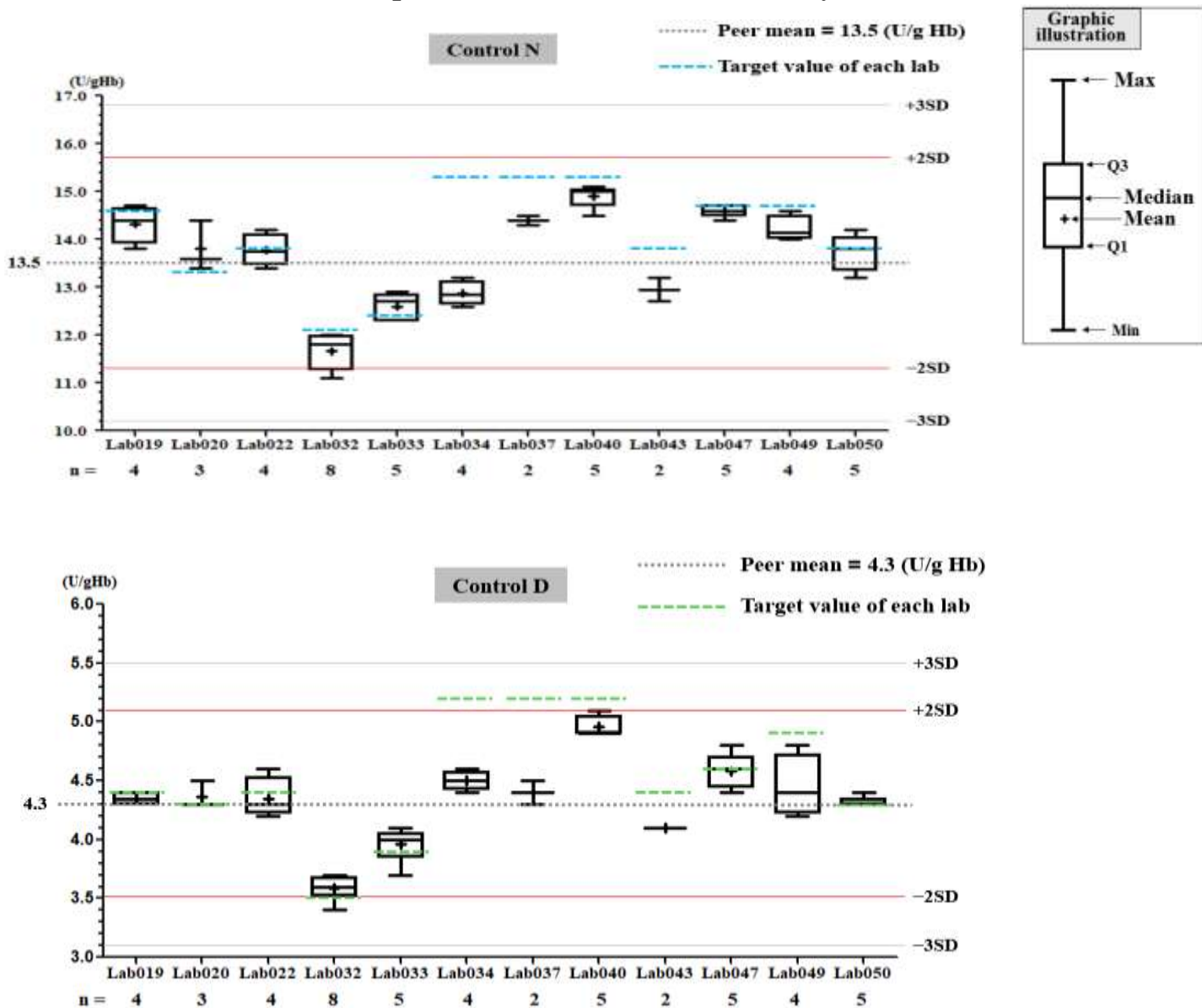
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:AH1220N) | Control D (Lot No.:AH1220D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs | 12 | 12 |
| Received results number (n) | 51 | 51 |
| Median | 13.8 (U/gHb) | 4.3 (U/gHb) |
| Mean | 13.5 (U/gHb) | 4.3 (U/gHb) |
| SD | 1.1 | 0.4 |
| CV | 8.1% | 9.3% |
| Range of G6PD | 11.1 ~ 15.1 (U/gHb) | 3.4 ~ 5.1 (U/gHb) |
| Range of Hb | 1.9 ~ 2.5 (g/dL) | 2.0 ~ 2.9 (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 :

Lab022

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | AH1220N | | AH1220D | |
| Duration of the Analyzing | Month (2021/04) | CUM (2020/01/08~2021/04/30) | Month (2021/04) | CUM (2020/01/08~2021/04/30) |
| Runs (N) | 4 | 26 | 4 | 26 |
| Mean (U/gHb) | 13.8 | 12.6 | 4.4 | 4.1 |
| SD | 0.3 | 1.0 | 0.2 | 0.3 |
| CV (%) | 2.2 | 7.9 | 4.5 | 7.3 |
| Target Value (U/gHb) | 13.8 | 13.8 | 4.4 | 4.4 |
| Total Error (%) | 4.3 | 24.6 | 9.1 | 21.5 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | >6 | 1.4 | 4.4 | 1.8 |

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

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

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

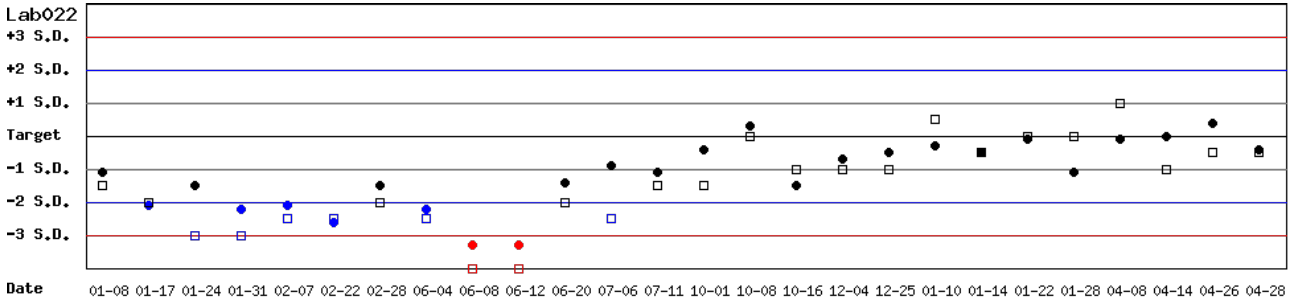
Month : ; Cumulative : from to

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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-01-08 to 2021-04-30 ; Target : 13.8 ; SD : 1.00 (●)

Lot No.: AH1220D ; Duration : 2020-01-08 to 2021-04-30 ; Target : 4.4 ; SD : 0.20 (□)

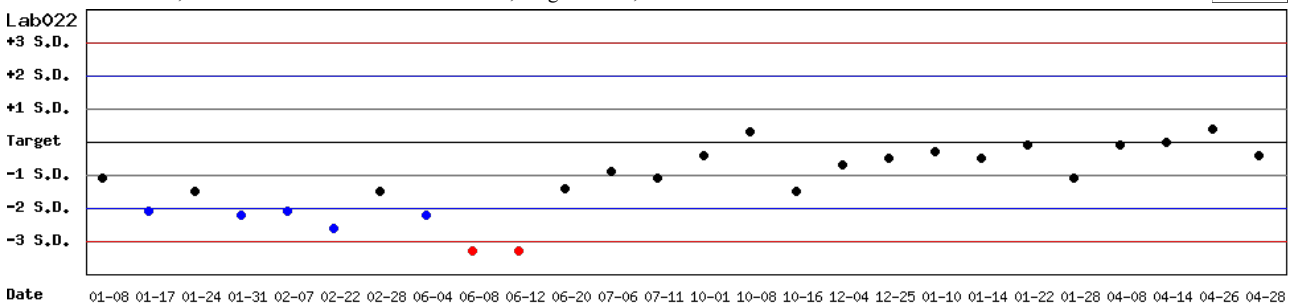


Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-01-08 to 2021-04-30 ; Target : 13.8 ; SD : 1.00



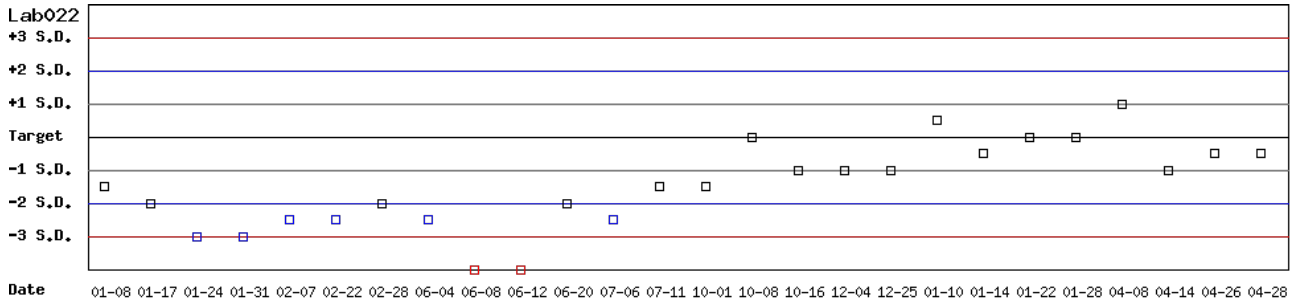
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-01-08 to 2021-04-30 ; Target : 4.4 ; SD : 0.20

Lab022



Month : ; Cumulative : from to

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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 04 Change

| UnitID <small>↑</small> | Reagent Kit (Code) <small>↑</small> | 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 | 14.3 | 4 | 0.4 | 2.8 | 7.6 | 20 | >6 | 4.4 | 4.4 | 4 | 0.1 | 2.3 | 4.5 | 20 | >6 |
| Lab020 | 5 | 13.3 | 13.8 | 3 | 0.5 | 3.6 | 11.0 | 20 | 4.5 | 4.3 | 4.4 | 3 | 0.1 | 2.3 | 6.9 | 20 | >6 |
| Lab022 | 5 | 13.8 | 13.8 | 4 | 0.3 | 2.2 | 4.3 | 20 | >6 | 4.4 | 4.4 | 4 | 0.2 | 4.5 | 9.1 | 20 | 4.4 |
| Lab032 | 5 | 12.1 | 11.7 | 8 | 0.4 | 3.4 | 10.1 | 20 | 4.9 | 3.5 | 3.6 | 8 | 0.1 | 2.8 | 8.4 | 20 | >6 |
| Lab033 | 5 | 12.4 | 12.6 | 5 | 0.3 | 2.4 | 6.4 | 20 | >6 | 3.9 | 4.0 | 5 | 0.2 | 5.0 | 12.6 | 20 | 3.5 |
| Lab034 | 5 | 15.3 | 12.9 | 4 | 0.3 | 2.3 | 20.3 | 20 | 1.9 | 5.2 | 4.5 | 4 | 0.1 | 2.2 | 17.9 | 20 | 3.0 |
| Lab037 | 5 | 15.3 | 14.4 | 2 | - | - | - | 20 | - | 5.2 | 4.4 | 2 | - | - | - | 20 | - |
| Lab040 | 5 | 15.3 | 14.9 | 5 | 0.2 | 1.3 | 5.3 | 20 | >6 | 5.2 | 5.0 | 5 | 0.1 | 2.0 | 7.8 | 20 | >6 |
| Lab043 | 5 | 13.8 | 13.0 | 2 | - | - | - | 20 | - | 4.4 | 4.1 | 2 | - | - | - | 20 | - |
| Lab047 | 5 | 14.7 | 14.6 | 5 | 0.1 | 0.7 | 2.1 | 20 | >6 | 4.6 | 4.6 | 5 | 0.2 | 4.3 | 8.7 | 20 | 4.7 |
| Lab049 | 5 | 14.7 | 14.2 | 4 | 0.3 | 2.1 | 7.6 | 20 | >6 | 4.9 | 4.5 | 4 | 0.3 | 6.7 | 21.5 | 20 | 1.8 |
| Lab050 | 5 | 13.8 | 13.7 | 5 | 0.4 | 2.9 | 6.6 | 20 | >6 | 4.3 | 4.3 | 5 | 0.1 | 2.3 | 4.7 | 20 | >6 |
| Total | - | - | 13.5 | 51 | 1.1 | 8.1 | - | - | - | - | 4.3 | 51 | 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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Cumulative

Cumulative : from 2019 02 01 to 2021 04 30 Change

| UnitID <small>↑</small> | Reagent Kit (Code) <small>↑</small> | 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 | 44 | 0.3 | 2.1 | 4.1 | 20 | >6 | 4.4 | 4.4 | 44 | 0.1 | 2.3 | 4.5 | 20 | >6 |
| Lab020 | 5 | 13.3 | 14.4 | 53 | 1.0 | 6.9 | 22.2 | 20 | 1.7 | 4.3 | 4.5 | 53 | 0.2 | 4.4 | 13.5 | 20 | 3.5 |
| Lab022 | 5 | 13.8 | 12.5 | 60 | 0.7 | 5.6 | 20.6 | 20 | 1.9 | 4.4 | 4.1 | 60 | 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 | 13.0 | 129 | 1.4 | 10.8 | 29.0 | 20 | 1.2 | 3.5 | 4.0 | 129 | 0.6 | 15.0 | 44.3 | 20 | 0.4 |
| Lab033 | 5 | 12.4 | 12.5 | 104 | 0.4 | 3.2 | 7.2 | 20 | 6.0 | 3.9 | 3.9 | 104 | 0.2 | 5.1 | 10.3 | 20 | 3.9 |
| Lab034 | 5 | 15.3 | 14.9 | 41 | 1.0 | 6.7 | 16.0 | 20 | 2.6 | 5.2 | 4.6 | 41 | 0.2 | 4.3 | 20.2 | 20 | 2.0 |
| Lab037 | 5 | 15.3 | 15.2 | 51 | 0.4 | 2.6 | 5.9 | 20 | >6 | 5.2 | 4.7 | 51 | 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 | 12.9 | 6 | 0.4 | 3.1 | 12.7 | 20 | 4.3 | 4.4 | 4.2 | 6 | 0.2 | 4.8 | 14.1 | 20 | 3.2 |
| Lab047 | 5 | 14.7 | 13.2 | 18 | 0.9 | 6.8 | 23.8 | 20 | 1.4 | 4.6 | 4.2 | 18 | 0.3 | 7.1 | 23.0 | 20 | 1.6 |
| Lab049 | 5 | 14.7 | 14.3 | 38 | 0.5 | 3.5 | 9.7 | 20 | 4.9 | 4.9 | 4.7 | 38 | 0.4 | 8.5 | 21.1 | 20 | 1.9 |
| Lab050 | 5 | 13.8 | 14.1 | 21 | 0.6 | 4.3 | 10.7 | 20 | 4.1 | 4.3 | 4.4 | 21 | 0.3 | 6.8 | 16.0 | 20 | 2.6 |
| Total | - | - | 13.7 | 633 | 1.3 | 9.5 | - | - | - | - | 4.3 | 633 | 0.5 | 11.6 | - | - | - |

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 (2021/04) | | | | | | | | CUM (2019/02/01~2021/04/30) | | | | | | | |
| 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 | 14.3 | 4 | 0.4 | 2.8 | 7.6 | 20 | >6 | 14.6 | 14.6 | 44 | 0.3 | 2.1 | 4.1 | 20 | >6 |
| Lab020 | 5 | 13.3 | 13.8 | 3 | 0.5 | 3.6 | 11.0 | 20 | 4.5 | 13.3 | 14.4 | 53 | 1.0 | 6.9 | 22.2 | 20 | 1.7 |
| Lab022 | 5 | 13.8 | 13.8 | 4 | 0.3 | 2.2 | 4.3 | 20 | >6 | 13.8 | 12.5 | 60 | 0.7 | 5.6 | 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 | 11.7 | 8 | 0.4 | 3.4 | 10.1 | 20 | 4.9 | 12.1 | 13.0 | 129 | 1.4 | 10.8 | 29.0 | 20 | 1.2 |
| Lab033 | 5 | 12.4 | 12.6 | 5 | 0.3 | 2.4 | 6.4 | 20 | >6 | 12.4 | 12.5 | 104 | 0.4 | 3.2 | 7.2 | 20 | 6.0 |
| Lab034 | 5 | 15.3 | 12.9 | 4 | 0.3 | 2.3 | 20.3 | 20 | 1.9 | 15.3 | 14.9 | 41 | 1.0 | 6.7 | 16.0 | 20 | 2.6 |
| Lab037 | 5 | 15.3 | 14.4 | 2 | - | - | - | 20 | - | 15.3 | 15.2 | 51 | 0.4 | 2.6 | 5.9 | 20 | >6 |
| Lab040 | 5 | 15.3 | 14.9 | 5 | 0.2 | 1.3 | 5.3 | 20 | >6 | 15.3 | 15.0 | 15 | 0.4 | 2.7 | 7.3 | 20 | >6 |
| Lab043 | 5 | 13.8 | 13.0 | 2 | - | - | - | 20 | - | 13.8 | 12.9 | 6 | 0.4 | 3.1 | 12.7 | 20 | 4.3 |
| Lab047 | 5 | 14.7 | 14.6 | 5 | 0.1 | 0.7 | 2.1 | 20 | >6 | 14.7 | 13.2 | 18 | 0.9 | 6.8 | 23.8 | 20 | 1.4 |
| Lab049 | 5 | 14.7 | 14.2 | 4 | 0.3 | 2.1 | 7.6 | 20 | >6 | 14.7 | 14.3 | 38 | 0.5 | 3.5 | 9.7 | 20 | 4.9 |
| Lab050 | 5 | 13.8 | 13.7 | 5 | 0.4 | 2.9 | 6.6 | 20 | >6 | 13.8 | 14.1 | 21 | 0.6 | 4.3 | 10.7 | 20 | 4.1 |
| Total | - | - | 13.5 | 51 | 1.1 | 8.1 | - | - | - | - | 13.7 | 633 | 1.3 | 9.5 | - | - | - |

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

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

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

Month : 2021 ▼ 04 ▼ Change

Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2021 ▼ 04 ▼ 30 ▼ Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: AH1220D) | | | | | | | | | | | | | | | |
|---|---|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2021/04) | | | | | | | | CUM (2019/02/01~2021/04/30) | | | | | | | |
| 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 | 4.4 | 4 | 0.1 | 2.3 | 4.5 | 20 | >6 | 4.4 | 4.4 | 44 | 0.1 | 2.3 | 4.5 | 20 | >6 |
| Lab020 | 5 | 4.3 | 4.4 | 3 | 0.1 | 2.3 | 6.9 | 20 | >6 | 4.3 | 4.5 | 53 | 0.2 | 4.4 | 13.5 | 20 | 3.5 |
| Lab022 | 5 | 4.4 | 4.4 | 4 | 0.2 | 4.5 | 9.1 | 20 | 4.4 | 4.4 | 4.1 | 60 | 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 | 3.6 | 8 | 0.1 | 2.8 | 8.4 | 20 | >6 | 3.5 | 4.0 | 129 | 0.6 | 15.0 | 44.3 | 20 | 0.4 |
| Lab033 | 5 | 3.9 | 4.0 | 5 | 0.2 | 5.0 | 12.6 | 20 | 3.5 | 3.9 | 3.9 | 104 | 0.2 | 5.1 | 10.3 | 20 | 3.9 |
| Lab034 | 5 | 5.2 | 4.5 | 4 | 0.1 | 2.2 | 17.9 | 20 | 3.0 | 5.2 | 4.6 | 41 | 0.2 | 4.3 | 20.2 | 20 | 2.0 |
| Lab037 | 5 | 5.2 | 4.4 | 2 | - | - | - | 20 | - | 5.2 | 4.7 | 51 | 0.2 | 4.3 | 18.1 | 20 | 2.4 |
| Lab040 | 5 | 5.2 | 5.0 | 5 | 0.1 | 2.0 | 7.8 | 20 | >6 | 5.2 | 5.4 | 15 | 0.4 | 7.4 | 18.7 | 20 | 2.2 |
| Lab043 | 5 | 4.4 | 4.1 | 2 | - | - | - | 20 | - | 4.4 | 4.2 | 6 | 0.2 | 4.8 | 14.1 | 20 | 3.2 |
| Lab047 | 5 | 4.6 | 4.6 | 5 | 0.2 | 4.3 | 8.7 | 20 | 4.7 | 4.6 | 4.2 | 18 | 0.3 | 7.1 | 23.0 | 20 | 1.6 |
| Lab049 | 5 | 4.9 | 4.5 | 4 | 0.3 | 6.7 | 21.5 | 20 | 1.8 | 4.9 | 4.7 | 38 | 0.4 | 8.5 | 21.1 | 20 | 1.9 |
| Lab050 | 5 | 4.3 | 4.3 | 5 | 0.1 | 2.3 | 4.7 | 20 | >6 | 4.3 | 4.4 | 21 | 0.3 | 6.8 | 16.0 | 20 | 2.6 |
| Total | - | - | 4.3 | 51 | 0.4 | 9.3 | - | - | - | - | 4.3 | 633 | 0.5 | 11.6 | - | - | - |

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

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

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

Month : 2021 ▼ 04 ▼ Change

Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2021 ▼ 04 ▼ 30 ▼ Change

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