

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

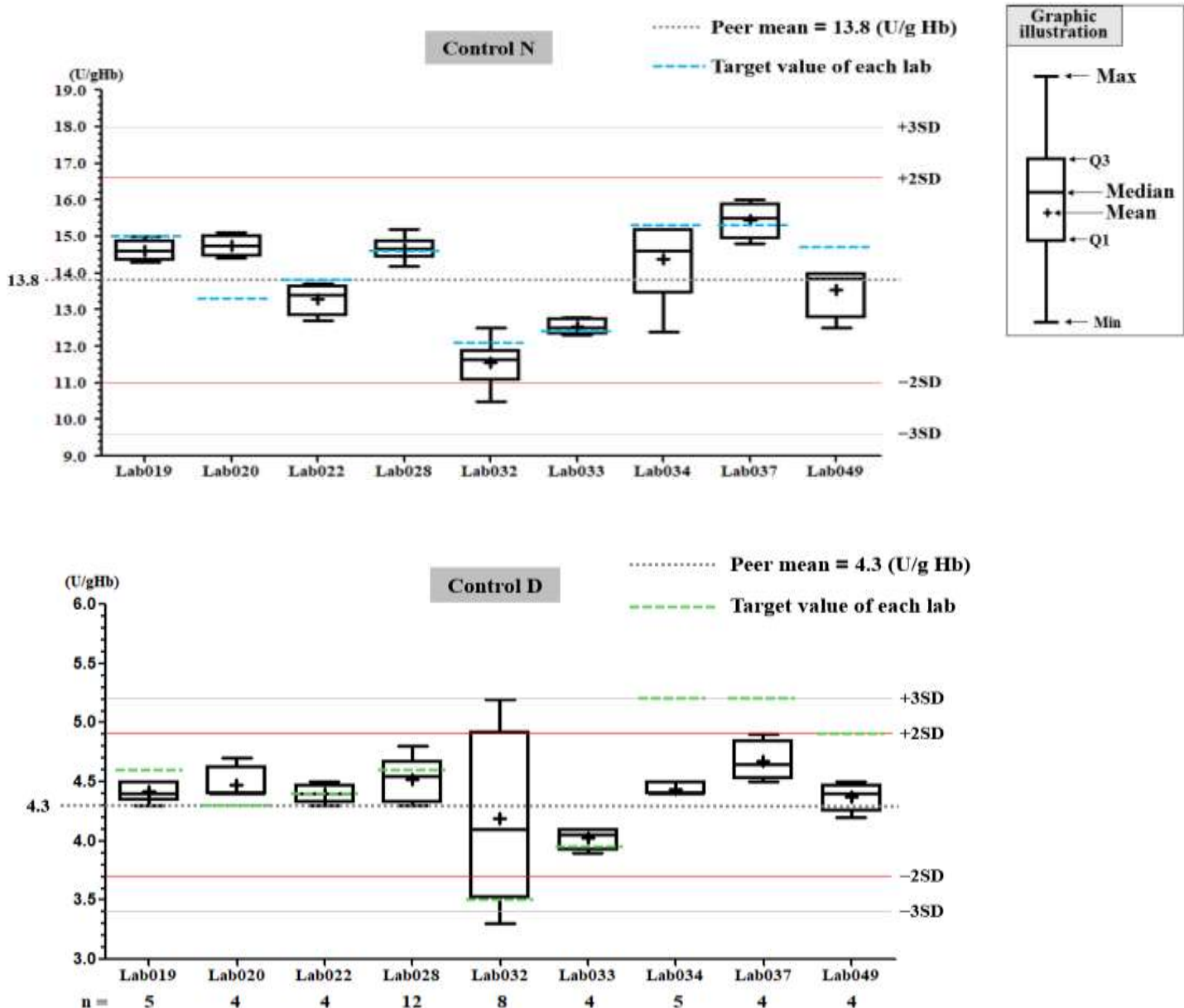
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:AH1220N) | Control D (Lot No.:AH1220D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs | 9 | 9 |
| Received results number (n) | 50 | 50 |
| Median | 14.4 (U/gHb) | 4.4 (U/gHb) |
| Mean | 13.8 (U/gHb) | 4.4 (U/gHb) |
| SD | 1.4 | 0.3 |
| CV | 10.1% | 6.8% |
| Range of G6PD | 10.5 ~ 16.0 (U/gHb) | 3.3 ~ 5.2 (U/gHb) |
| Range of Hb | 2.0 ~ 2.5 (g/dL) | 2.0 ~ 2.8 (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)

Lab032

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | AH1220N | | AH1220D | |
| Duration of the Analyzing | Month (2021/01) | CUM (2020/09/24~2021/01/30) | Month (2021/01) | CUM (2020/09/24~2021/01/30) |
| Runs (N) | 8 | 26 | 8 | 26 |
| Mean (U/gHb) | 11.6 | 11.4 | 4.2 | 3.7 |
| SD | 0.6 | 0.6 | 0.7 | 0.5 |
| CV (%) | 5.2 | 5.3 | 16.7 | 13.5 |
| Target Value (U/gHb) | 12.1 | 12.1 | 3.5 | 3.5 |
| Total Error (%) | 14.5 | 16.3 | 53.3 | 32.7 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | 3.1 | 2.7 | 0.0 | 1.1 |

Bias (%) = [(| Mean - Target |) / Target] x 100%
 TE : Total Error(%) = Bias (%) + 2 x CV (%)
 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2021 01 ; Cumulative : from 2020 09 24 to 2021 01 30

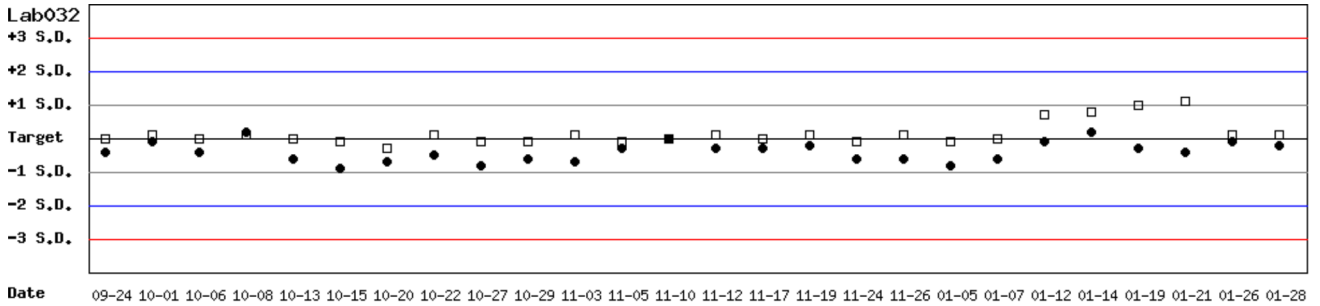
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-09-24 to 2021-01-30 ; Target : 12.1 ; SD : 2.00 (●)

Lot No.: AH1220D ; Duration : 2020-09-24 to 2021-01-30 ; Target : 3.5 ; SD : 1.50 (□)

Lab032



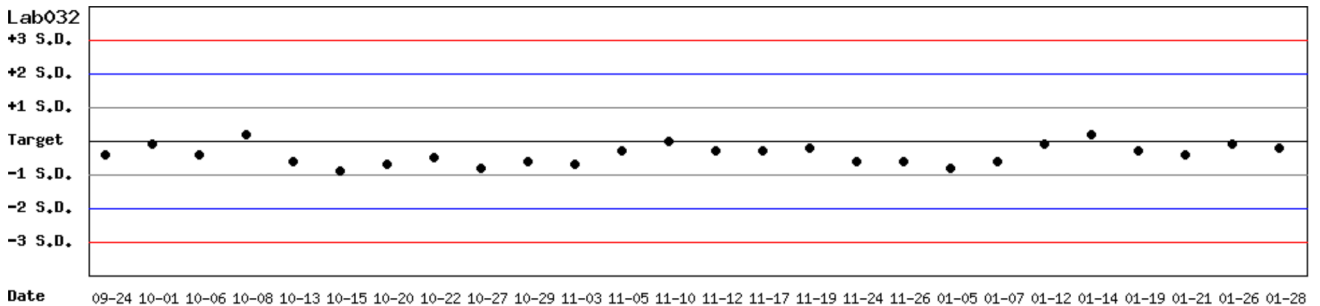
Month : 2021 01 ; Cumulative : from 2020 09 24 to 2021 01 30

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-09-24 to 2021-01-30 ; Target : 12.1 ; SD : 2.00

Lab032



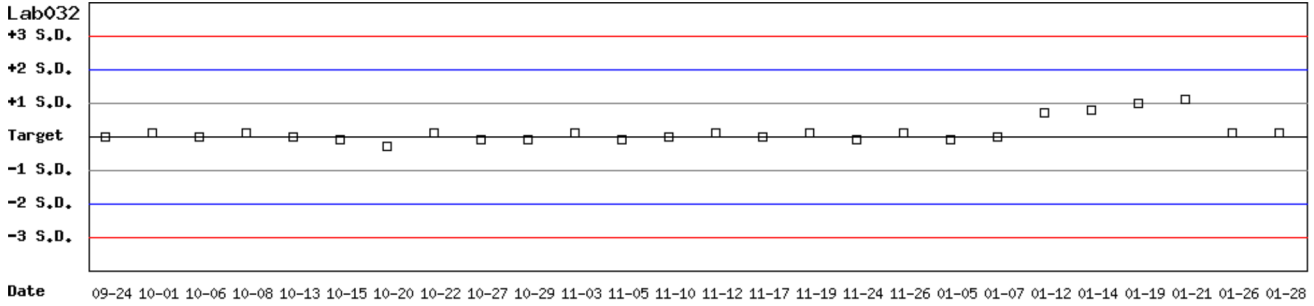
Month : 2021 01 ; Cumulative : from 2020 09 24 to 2021 01 30

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-09-24 to 2021-01-30 ; Target : 3.5 ; SD : 1.50

Lab032



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 01 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 | 15.0 | 14.6 | 5 | 0.3 | 2.1 | 6.8 | 20 | >6 | 4.6 | 4.4 | 5 | 0.1 | 2.3 | 8.9 | 20 | >6 |
| Lab020 | 5 | 13.3 | 14.8 | 4 | 0.3 | 2.0 | 15.3 | 20 | 4.4 | 4.3 | 4.5 | 4 | 0.2 | 4.4 | 13.5 | 20 | 3.5 |
| Lab022 | 5 | 13.8 | 13.3 | 4 | 0.4 | 3.0 | 9.6 | 20 | 5.5 | 4.4 | 4.4 | 4 | 0.1 | 2.3 | 4.5 | 20 | >6 |
| Lab028 | 5 | 14.6 | 14.7 | 12 | 0.3 | 2.0 | 4.8 | 20 | >6 | 4.6 | 4.5 | 12 | 0.2 | 4.4 | 11.1 | 20 | 4.1 |
| Lab032 | 5 | 12.1 | 11.6 | 8 | 0.6 | 5.2 | 14.5 | 20 | 3.1 | 3.5 | 4.2 | 8 | 0.7 | 16.7 | 53.3 | 20 | 0.0 |
| Lab033 | 5 | 12.4 | 12.5 | 4 | 0.2 | 1.6 | 4.0 | 20 | >6 | 3.9 | 4.0 | 4 | 0.1 | 2.5 | 7.6 | 20 | >6 |
| Lab034 | 5 | 15.3 | 14.4 | 5 | 1.2 | 8.3 | 22.5 | 20 | 1.7 | 5.2 | 4.4 | 5 | 0.1 | 2.3 | 19.9 | 20 | 2.0 |
| Lab037 | 5 | 15.3 | 15.5 | 4 | 0.5 | 3.2 | 7.8 | 20 | 5.8 | 5.2 | 4.7 | 4 | 0.2 | 4.3 | 18.1 | 20 | 2.4 |
| Lab049 | 5 | 14.7 | 13.6 | 4 | 0.7 | 5.1 | 17.8 | 20 | 2.5 | 4.9 | 4.4 | 4 | 0.1 | 2.3 | 14.7 | 20 | 4.3 |
| Total | - | - | 13.8 | 50 | 1.4 | 10.1 | - | - | - | - | 4.4 | 50 | 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 02 01 to 2021 01 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 | 15.0 | 14.7 | 30 | 0.3 | 2.0 | 6.1 | 20 | >6 | 4.6 | 4.5 | 30 | 0.1 | 2.2 | 6.6 | 20 | >6 |
| Lab020 | 5 | 13.3 | 14.4 | 42 | 1.1 | 7.6 | 23.5 | 20 | 1.5 | 4.3 | 4.5 | 42 | 0.3 | 6.7 | 18.0 | 20 | 2.3 |
| Lab022 | 5 | 13.8 | 12.4 | 56 | 0.7 | 5.6 | 21.4 | 20 | 1.8 | 4.4 | 4.0 | 56 | 0.2 | 5.0 | 19.1 | 20 | 2.2 |
| Lab028 | 5 | 14.6 | 14.6 | 34 | 0.4 | 2.7 | 5.5 | 20 | >6 | 4.6 | 4.6 | 34 | 0.2 | 4.3 | 8.7 | 20 | 4.7 |
| Lab032 | 5 | 12.1 | 13.1 | 112 | 1.5 | 11.5 | 31.2 | 20 | 1.0 | 3.5 | 4.1 | 112 | 0.6 | 14.6 | 46.4 | 20 | 0.2 |
| Lab033 | 5 | 12.4 | 12.5 | 91 | 0.4 | 3.2 | 7.2 | 20 | 6.0 | 3.9 | 3.9 | 91 | 0.2 | 5.1 | 10.3 | 20 | 3.9 |
| Lab034 | 5 | 15.3 | 15.1 | 29 | 0.7 | 4.6 | 10.6 | 20 | 4.1 | 5.2 | 4.6 | 29 | 0.2 | 4.3 | 20.2 | 20 | 2.0 |
| Lab037 | 5 | 15.3 | 15.2 | 44 | 0.4 | 2.6 | 5.9 | 20 | >6 | 5.2 | 4.7 | 44 | 0.2 | 4.3 | 18.1 | 20 | 2.4 |
| Lab040 | 5 | 15.3 | 15.1 | 10 | 0.5 | 3.3 | 7.9 | 20 | 5.7 | 5.2 | 5.6 | 10 | 0.4 | 7.1 | 22.0 | 20 | 1.7 |
| Lab047 | 5 | 12.7 | 12.6 | 13 | 0.2 | 1.6 | 4.0 | 20 | >6 | 4.0 | 4.0 | 13 | 0.1 | 2.5 | 5.0 | 20 | >6 |
| Lab049 | 5 | 14.7 | 14.2 | 25 | 0.6 | 4.2 | 11.9 | 20 | 4.0 | 4.9 | 4.8 | 25 | 0.4 | 8.3 | 18.7 | 20 | 2.2 |
| Lab050 | 5 | 15.3 | 14.6 | 6 | 0.8 | 5.5 | 15.5 | 20 | 2.8 | 5.2 | 4.4 | 6 | 0.5 | 11.4 | 38.1 | 20 | 0.4 |
| Total | - | - | 13.6 | 492 | 1.4 | 10.3 | - | - | - | - | 4.3 | 492 | 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 (2021/01) | | | | | | | | CUM (2019/02/01~2021/01/31) | | | | | | | |
| 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 | 15.0 | 14.6 | 5 | 0.3 | 2.1 | 6.8 | 20 | >6 | 15.0 | 14.7 | 30 | 0.3 | 2.0 | 6.1 | 20 | >6 |
| Lab020 | 5 | 13.3 | 14.8 | 4 | 0.3 | 2.0 | 15.3 | 20 | 4.4 | 13.3 | 14.4 | 42 | 1.1 | 7.6 | 23.5 | 20 | 1.5 |
| Lab022 | 5 | 13.8 | 13.3 | 4 | 0.4 | 3.0 | 9.6 | 20 | 5.5 | 13.8 | 12.4 | 56 | 0.7 | 5.6 | 21.4 | 20 | 1.8 |
| Lab028 | 5 | 14.6 | 14.7 | 12 | 0.3 | 2.0 | 4.8 | 20 | >6 | 14.6 | 14.6 | 34 | 0.4 | 2.7 | 5.5 | 20 | >6 |
| Lab032 | 5 | 12.1 | 11.6 | 8 | 0.6 | 5.2 | 14.5 | 20 | 3.1 | 12.1 | 13.1 | 112 | 1.5 | 11.5 | 31.2 | 20 | 1.0 |
| Lab033 | 5 | 12.4 | 12.5 | 4 | 0.2 | 1.6 | 4.0 | 20 | >6 | 12.4 | 12.5 | 91 | 0.4 | 3.2 | 7.2 | 20 | 6.0 |
| Lab034 | 5 | 15.3 | 14.4 | 5 | 1.2 | 8.3 | 22.5 | 20 | 1.7 | 15.3 | 15.1 | 29 | 0.7 | 4.6 | 10.6 | 20 | 4.1 |
| Lab037 | 5 | 15.3 | 15.5 | 4 | 0.5 | 3.2 | 7.8 | 20 | 5.8 | 15.3 | 15.2 | 44 | 0.4 | 2.6 | 5.9 | 20 | >6 |
| Lab040 | 5 | 15.3 | - | 0 | - | - | - | 20 | - | 15.3 | 15.1 | 10 | 0.5 | 3.3 | 7.9 | 20 | 5.7 |
| Lab047 | 5 | 12.7 | - | 0 | - | - | - | 20 | - | 12.7 | 12.6 | 13 | 0.2 | 1.6 | 4.0 | 20 | >6 |
| Lab049 | 5 | 14.7 | 13.6 | 4 | 0.7 | 5.1 | 17.8 | 20 | 2.5 | 14.7 | 14.2 | 25 | 0.6 | 4.2 | 11.9 | 20 | 4.0 |
| Lab050 | 5 | 15.3 | - | 0 | - | - | - | 20 | - | 15.3 | 14.6 | 6 | 0.8 | 5.5 | 15.5 | 20 | 2.8 |
| Total | - | - | 13.8 | 50 | 1.4 | 10.1 | - | - | - | - | 13.6 | 492 | 1.4 | 10.3 | - | - | - |

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

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

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

Month : 2021 ▼ 01 ▼ Change

Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2021 ▼ 01 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: AH1220D) | | | | | | | | | | | | | | | |
|---|---|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2021/01) | | | | | | | | CUM (2019/02/01~2021/01/31) | | | | | | | |
| 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 | 4.6 | 4.4 | 5 | 0.1 | 2.3 | 8.9 | 20 | >6 | 4.6 | 4.5 | 30 | 0.1 | 2.2 | 6.6 | 20 | >6 |
| Lab020 | 5 | 4.3 | 4.5 | 4 | 0.2 | 4.4 | 13.5 | 20 | 3.5 | 4.3 | 4.5 | 42 | 0.3 | 6.7 | 18.0 | 20 | 2.3 |
| Lab022 | 5 | 4.4 | 4.4 | 4 | 0.1 | 2.3 | 4.5 | 20 | >6 | 4.4 | 4.0 | 56 | 0.2 | 5.0 | 19.1 | 20 | 2.2 |
| Lab028 | 5 | 4.6 | 4.5 | 12 | 0.2 | 4.4 | 11.1 | 20 | 4.1 | 4.6 | 4.6 | 34 | 0.2 | 4.3 | 8.7 | 20 | 4.7 |
| Lab032 | 5 | 3.5 | 4.2 | 8 | 0.7 | 16.7 | 53.3 | 20 | 0.0 | 3.5 | 4.1 | 112 | 0.6 | 14.6 | 46.4 | 20 | 0.2 |
| Lab033 | 5 | 3.9 | 4.0 | 4 | 0.1 | 2.5 | 7.6 | 20 | >6 | 3.9 | 3.9 | 91 | 0.2 | 5.1 | 10.3 | 20 | 3.9 |
| Lab034 | 5 | 5.2 | 4.4 | 5 | 0.1 | 2.3 | 19.9 | 20 | 2.0 | 5.2 | 4.6 | 29 | 0.2 | 4.3 | 20.2 | 20 | 2.0 |
| Lab037 | 5 | 5.2 | 4.7 | 4 | 0.2 | 4.3 | 18.1 | 20 | 2.4 | 5.2 | 4.7 | 44 | 0.2 | 4.3 | 18.1 | 20 | 2.4 |
| Lab040 | 5 | 5.2 | - | 0 | - | - | - | 20 | - | 5.2 | 5.6 | 10 | 0.4 | 7.1 | 22.0 | 20 | 1.7 |
| Lab047 | 5 | 4.0 | - | 0 | - | - | - | 20 | - | 4.0 | 4.0 | 13 | 0.1 | 2.5 | 5.0 | 20 | >6 |
| Lab049 | 5 | 4.9 | 4.4 | 4 | 0.1 | 2.3 | 14.7 | 20 | 4.3 | 4.9 | 4.8 | 25 | 0.4 | 8.3 | 18.7 | 20 | 2.2 |
| Lab050 | 5 | 5.2 | - | 0 | - | - | - | 20 | - | 5.2 | 4.4 | 6 | 0.5 | 11.4 | 38.1 | 20 | 0.4 |
| Total | - | - | 4.4 | 50 | 0.3 | 6.8 | - | - | - | - | 4.3 | 492 | 0.5 | 11.6 | - | - | - |

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

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

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

Month : 2021 ▼ 01 ▼ Change

Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2021 ▼ 01 ▼ 31 ▼ Change

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