

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - October 2020 -

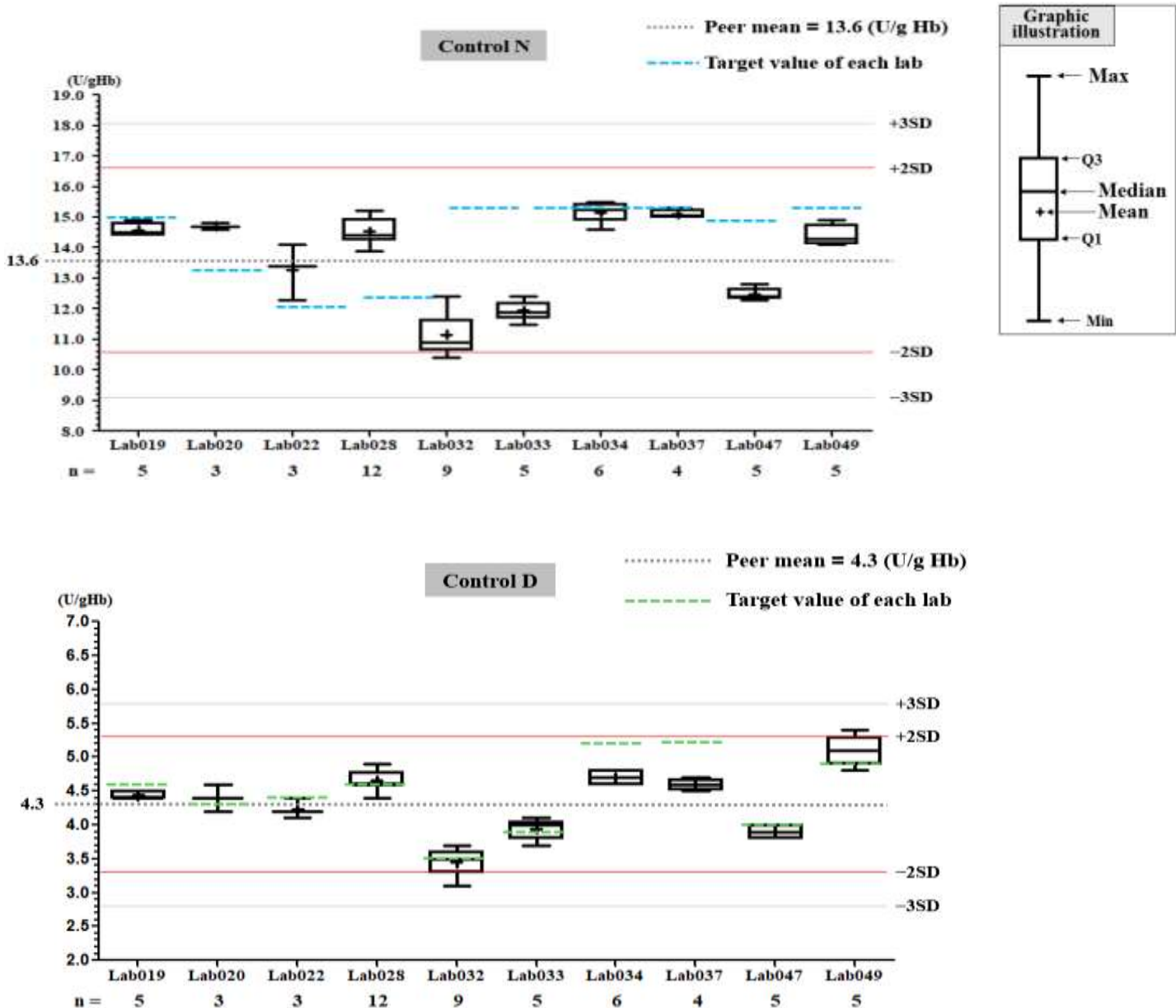
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:AH1220N) | Control D (Lot No.:AH1220D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs | 10 | 10 |
| Received results number (n) | 57 | 57 |
| Median | 14.4 (U/gHb) | 4.5 (U/gHb) |
| Mean | 13.6 (U/gHb) | 4.3 (U/gHb) |
| SD | 1.5 | 0.5 |
| CV | 11.0% | 11.6% |
| Range of G6PD | 10.4 ~ 15.5 (U/gHb) | 3.1 ~ 5.4 (U/gHb) |
| Range of Hb | 1.9 ~ 2.5 (g/dL) | 2.0 ~ 2.7 (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)

Lab049

| | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| QC Control Lot No. | AH1220N | | AH1220D | |
| Duration of the Analyzing | Month (2020/10) | CUM (2020/07/01~2020/10/31) | Month (2020/10) | CUM (2020/07/01~2020/10/31) |
| Runs (N) | 5 | 13 | 5 | 13 |
| Mean (U/gHb) | 14.4 | 14.5 | 5.1 | 5.1 |
| SD | 0.3 | 0.3 | 0.2 | 0.3 |
| CV (%) | 2.1 | 2.1 | 3.9 | 5.9 |
| Target Value (U/gHb) | 14.7 | 14.7 | 4.9 | 4.9 |
| Total Error (%) | 6.2 | 5.5 | 11.9 | 15.8 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | >6 | >6 | 4.1 | 2.7 |

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

Month : 2020 / 10 / ; Cumulative : from 2020 / 07 / 01 / to 2020 / 10 / 31 /

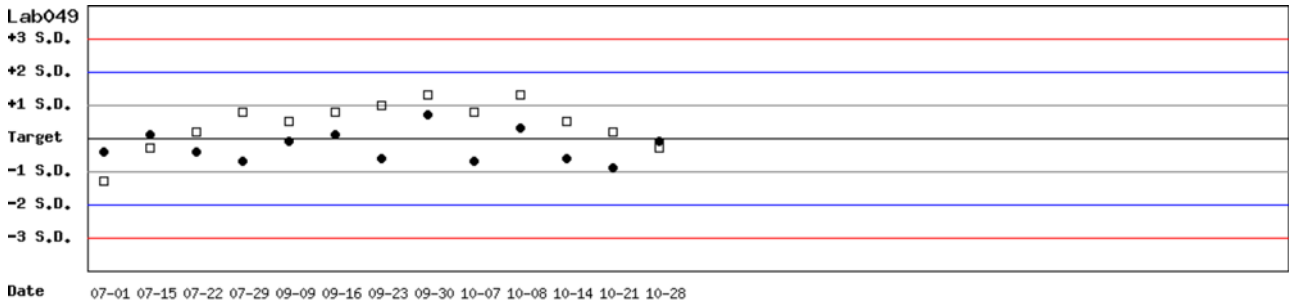
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-07-01 to 2020-10-31 ; Target : 14.7 ; SD : 0.67 (●)

Lot No.: AH1220D ; Duration : 2020-07-01 to 2020-10-31 ; Target : 4.9 ; SD : 0.40 (□)

Lab049



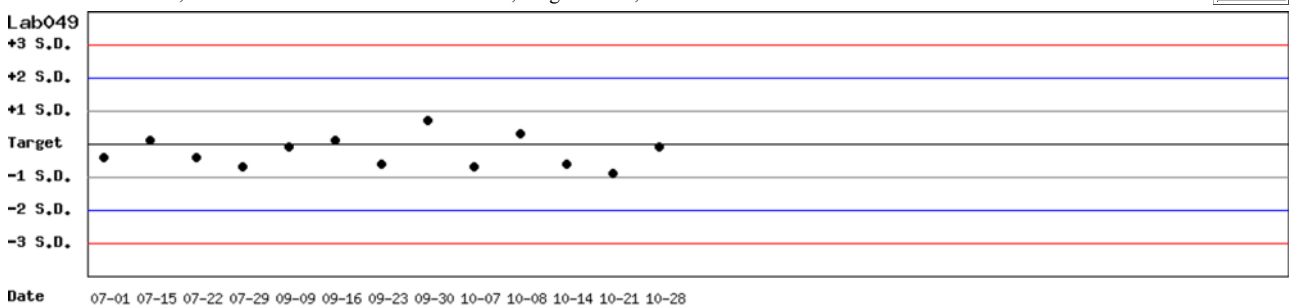
Month : 2020 / 10 / ; Cumulative : from 2020 / 07 / 01 / to 2020 / 10 / 31 /

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-07-01 to 2020-10-31 ; Target : 14.7 ; SD : 0.67

Lab049



Month : 2020 / 10 / ; Cumulative : from 2020 / 07 / 01 / to 2020 / 10 / 31 /

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-07-01 to 2020-10-31 ; Target : 4.9 ; SD : 0.40

Lab049



Date 07-01 07-15 07-22 07-29 09-09 09-16 09-23 09-30 10-07 10-08 10-14 10-21 10-28

Month : 2020 ▾ 10 ▾ Change ; Cumulative : from 2020 ▾ 07 ▾ 01 ▾ to 2020 ▾ 10 ▾ 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 : 2020 10 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 | 0.2 | 1.4 | 5.4 | 20 | >6 | 4.6 | 4.4 | 5 | 0.1 | 2.3 | 8.9 | 20 | >6 |
| Lab020 | 5 | 13.3 | 14.7 | 3 | 0.1 | 0.7 | 11.9 | 20 | >6 | 4.3 | 4.4 | 3 | 0.2 | 4.5 | 11.4 | 20 | 3.9 |
| Lab022 | 5 | 13.8 | 13.3 | 3 | 0.9 | 6.8 | 17.2 | 20 | 2.4 | 4.4 | 4.2 | 3 | 0.2 | 4.8 | 14.1 | 20 | 3.2 |
| Lab028 | 5 | 14.6 | 14.5 | 12 | 0.4 | 2.8 | 6.2 | 20 | >6 | 4.6 | 4.7 | 12 | 0.1 | 2.1 | 6.4 | 20 | >6 |
| Lab032 | 5 | 12.1 | 11.2 | 9 | 0.7 | 6.3 | 19.9 | 20 | 2.0 | 3.5 | 3.4 | 9 | 0.2 | 5.9 | 14.6 | 20 | 2.9 |
| Lab033 | 5 | 12.4 | 11.9 | 5 | 0.3 | 2.5 | 9.1 | 20 | >6 | 3.9 | 3.9 | 5 | 0.2 | 5.1 | 10.3 | 20 | 3.9 |
| Lab034 | 5 | 15.3 | 15.2 | 6 | 0.3 | 2.0 | 4.6 | 20 | >6 | 5.2 | 4.7 | 6 | 0.1 | 2.1 | 13.9 | 20 | 4.9 |
| Lab037 | 5 | 15.3 | 15.1 | 4 | 0.1 | 0.7 | 2.6 | 20 | >6 | 5.2 | 4.6 | 4 | 0.1 | 2.2 | 15.9 | 20 | 3.8 |
| Lab047 | 5 | 12.7 | 12.5 | 5 | 0.2 | 1.6 | 4.8 | 20 | >6 | 4.0 | 3.9 | 5 | 0.1 | 2.6 | 7.6 | 20 | >6 |
| Lab049 | 5 | 14.7 | 14.4 | 5 | 0.3 | 2.1 | 6.2 | 20 | >6 | 4.9 | 5.1 | 5 | 0.2 | 3.9 | 11.9 | 20 | 4.1 |
| Total | - | - | 13.6 | 57 | 1.5 | 11.0 | - | - | - | - | 4.3 | 57 | 0.5 | 11.6 | - | - | - |

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 2020 10 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 | 14.8 | 19 | 0.4 | 2.7 | 6.7 | 20 | >6 | 4.6 | 4.5 | 19 | 0.1 | 2.2 | 6.6 | 20 | >6 |
| Lab020 | 5 | 13.3 | 14.5 | 29 | 1.2 | 8.3 | 25.6 | 20 | 1.3 | 4.3 | 4.5 | 29 | 0.3 | 6.7 | 18.0 | 20 | 2.3 |
| Lab022 | 5 | 13.8 | 12.3 | 50 | 0.6 | 4.9 | 20.6 | 20 | 1.9 | 4.4 | 4.0 | 50 | 0.2 | 5.0 | 19.1 | 20 | 2.2 |
| Lab028 | 5 | 14.6 | 14.6 | 22 | 0.4 | 2.7 | 5.5 | 20 | >6 | 4.6 | 4.6 | 22 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab032 | 5 | 12.1 | 13.4 | 96 | 1.4 | 10.4 | 31.6 | 20 | 0.9 | 3.5 | 4.2 | 96 | 0.6 | 14.3 | 48.6 | 20 | 0.0 |
| Lab033 | 5 | 12.4 | 12.5 | 78 | 0.4 | 3.2 | 7.2 | 20 | 6.0 | 3.9 | 3.9 | 78 | 0.1 | 2.6 | 5.1 | 20 | >6 |
| Lab034 | 5 | 15.3 | 15.4 | 17 | 0.4 | 2.6 | 5.8 | 20 | >6 | 5.2 | 4.7 | 17 | 0.1 | 2.1 | 13.9 | 20 | 4.9 |
| Lab037 | 5 | 15.3 | 15.2 | 34 | 0.3 | 2.0 | 4.6 | 20 | >6 | 5.2 | 4.7 | 34 | 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 | 12.5 | 5 | 0.2 | 1.6 | 4.8 | 20 | >6 | 4.0 | 3.9 | 5 | 0.1 | 2.6 | 7.6 | 20 | >6 |
| Lab049 | 5 | 14.7 | 14.5 | 13 | 0.3 | 2.1 | 5.5 | 20 | >6 | 4.9 | 5.1 | 13 | 0.3 | 5.9 | 15.8 | 20 | 2.7 |
| 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 | 379 | 1.4 | 10.3 | - | - | - | - | 4.3 | 379 | 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 (2020/10) | | | | | | | | CUM (2019/02/01~2020/10/31) | | | | | | | |
| 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 | 0.2 | 1.4 | 5.4 | 20 | >6 | 15.0 | 14.8 | 19 | 0.4 | 2.7 | 6.7 | 20 | >6 |
| Lab020 | 5 | 13.3 | 14.7 | 3 | 0.1 | 0.7 | 11.9 | 20 | >6 | 13.3 | 14.5 | 29 | 1.2 | 8.3 | 25.6 | 20 | 1.3 |
| Lab022 | 5 | 13.8 | 13.3 | 3 | 0.9 | 6.8 | 17.2 | 20 | 2.4 | 13.8 | 12.3 | 50 | 0.6 | 4.9 | 20.6 | 20 | 1.9 |
| Lab028 | 5 | 14.6 | 14.5 | 12 | 0.4 | 2.8 | 6.2 | 20 | >6 | 14.6 | 14.6 | 22 | 0.4 | 2.7 | 5.5 | 20 | >6 |
| Lab032 | 5 | 12.1 | 11.2 | 9 | 0.7 | 6.3 | 19.9 | 20 | 2.0 | 12.1 | 13.4 | 96 | 1.4 | 10.4 | 31.6 | 20 | 0.9 |
| Lab033 | 5 | 12.4 | 11.9 | 5 | 0.3 | 2.5 | 9.1 | 20 | >6 | 12.4 | 12.5 | 78 | 0.4 | 3.2 | 7.2 | 20 | 6.0 |
| Lab034 | 5 | 15.3 | 15.2 | 6 | 0.3 | 2.0 | 4.6 | 20 | >6 | 15.3 | 15.4 | 17 | 0.4 | 2.6 | 5.8 | 20 | >6 |
| Lab037 | 5 | 15.3 | 15.1 | 4 | 0.1 | 0.7 | 2.6 | 20 | >6 | 15.3 | 15.2 | 34 | 0.3 | 2.0 | 4.6 | 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 | 12.5 | 5 | 0.2 | 1.6 | 4.8 | 20 | >6 | 12.7 | 12.5 | 5 | 0.2 | 1.6 | 4.8 | 20 | >6 |
| Lab049 | 5 | 14.7 | 14.4 | 5 | 0.3 | 2.1 | 6.2 | 20 | >6 | 14.7 | 14.5 | 13 | 0.3 | 2.1 | 5.5 | 20 | >6 |
| Lab050 | 5 | 15.3 | - | 0 | - | - | - | 20 | - | 15.3 | 14.6 | 6 | 0.8 | 5.5 | 15.5 | 20 | 2.8 |
| Total | - | - | 13.6 | 57 | 1.5 | 11.0 | - | - | - | - | 13.6 | 379 | 1.4 | 10.3 | - | - | - |

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

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

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

Month : 2020 10 Change

Cumulative : from 2019 02 01 to 2020 10 31 Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: AH1220D) | | | | | | | | | | | | | | | |
|------------------------|--------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2020/10) | | | | | | | | CUM (2019/02/01~2020/10/31) | | | | | | | |
| 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 | 19 | 0.1 | 2.2 | 6.6 | 20 | >6 |
| Lab020 | 5 | 4.3 | 4.4 | 3 | 0.2 | 4.5 | 11.4 | 20 | 3.9 | 4.3 | 4.5 | 29 | 0.3 | 6.7 | 18.0 | 20 | 2.3 |
| Lab022 | 5 | 4.4 | 4.2 | 3 | 0.2 | 4.8 | 14.1 | 20 | 3.2 | 4.4 | 4.0 | 50 | 0.2 | 5.0 | 19.1 | 20 | 2.2 |
| Lab028 | 5 | 4.6 | 4.7 | 12 | 0.1 | 2.1 | 6.4 | 20 | >6 | 4.6 | 4.6 | 22 | 0.1 | 2.2 | 4.3 | 20 | >6 |
| Lab032 | 5 | 3.5 | 3.4 | 9 | 0.2 | 5.9 | 14.6 | 20 | 2.9 | 3.5 | 4.2 | 96 | 0.6 | 14.3 | 48.6 | 20 | 0.0 |
| Lab033 | 5 | 3.9 | 3.9 | 5 | 0.2 | 5.1 | 10.3 | 20 | 3.9 | 3.9 | 3.9 | 78 | 0.1 | 2.6 | 5.1 | 20 | >6 |
| Lab034 | 5 | 5.2 | 4.7 | 6 | 0.1 | 2.1 | 13.9 | 20 | 4.9 | 5.2 | 4.7 | 17 | 0.1 | 2.1 | 13.9 | 20 | 4.9 |
| Lab037 | 5 | 5.2 | 4.6 | 4 | 0.1 | 2.2 | 15.9 | 20 | 3.8 | 5.2 | 4.7 | 34 | 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 | 3.9 | 5 | 0.1 | 2.6 | 7.6 | 20 | >6 | 4.0 | 3.9 | 5 | 0.1 | 2.6 | 7.6 | 20 | >6 |
| Lab049 | 5 | 4.9 | 5.1 | 5 | 0.2 | 3.9 | 11.9 | 20 | 4.1 | 4.9 | 5.1 | 13 | 0.3 | 5.9 | 15.8 | 20 | 2.7 |
| Lab050 | 5 | 5.2 | - | 0 | - | - | - | 20 | - | 5.2 | 4.4 | 6 | 0.5 | 11.4 | 38.1 | 20 | 0.4 |
| Total | - | - | 4.3 | 57 | 0.5 | 11.6 | - | - | - | - | 4.3 | 379 | 0.5 | 11.6 | - | - | - |

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

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

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

Month : 2020 10 Change

Cumulative : from 2019 02 01 to 2020 10 31 Change

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