

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - October 2018 -

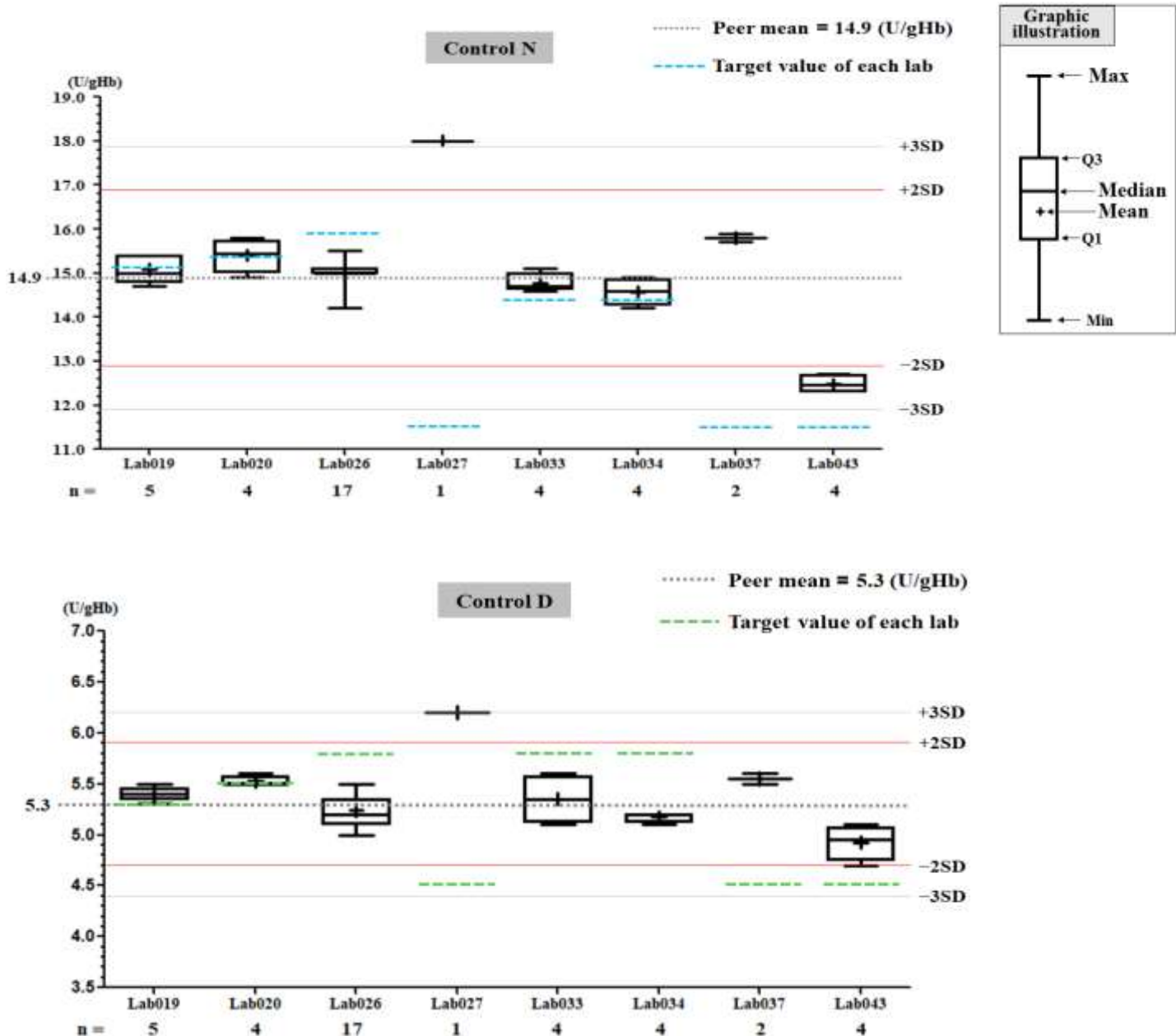
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:AE0909N) | Control D (Lot No.:AE0909D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs | 8 | 8 |
| Received results number (n) | 41 | 41 |
| Median | 15.0 (U/gHb) | 5.3 (U/gHb) |
| Mean | 14.9 (U/gHb) | 5.3 (U/gHb) |
| SD | 1.0 | 0.3 |
| CV | 6.7% | 5.7% |
| Range of G6PD | 12.3 ~ 18.0 (U/gHb) | 4.7 ~ 6.2 (U/gHb) |
| Range of Hb | 1.7 ~ 2.1 (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 : AE0909N (2016-01-01 ~ 2100-12-31) [Change](#)

[Print Table](#)

Lab019

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | AE0909N | | AE0909D | |
| Duration of the Analyzing | Month (2018/10) | CUM (2018/05/16~2018/10/31) | Month (2018/10) | CUM (2018/05/16~2018/10/31) |
| Runs (N) | 5 | 26 | 5 | 26 |
| Mean (U/gHb) | 15.1 | 15.2 | 5.4 | 5.4 |
| SD | 0.3 | 0.3 | 0.1 | 0.1 |
| CV (%) | 2.0 | 2.0 | 1.9 | 1.9 |
| Target Value (U/gHb) | 15.3 | 15.3 | 5.3 | 5.3 |
| Total Error (%) | 5.3 | 4.6 | 5.6 | 5.6 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | >6 | >6 | >6 | >6 |

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

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

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

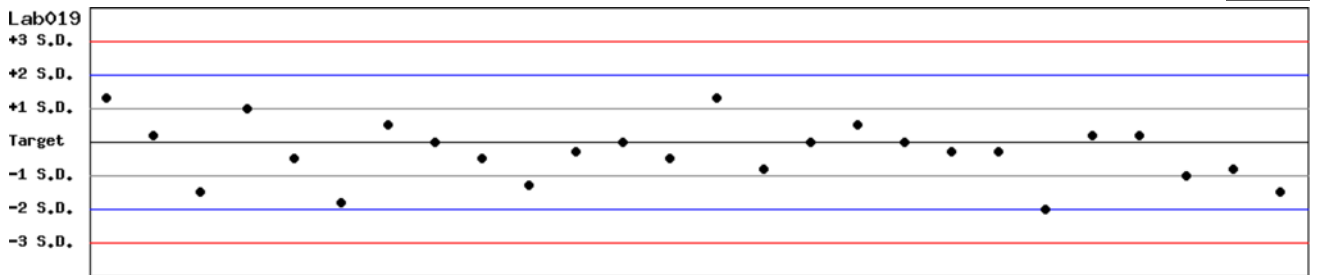
Month : 2018 10 [Change](#) ; Cumulative : from 2018 05 16 to 2018 10 31 [Change](#)

[TOP](#)

Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-05-16 to 2018-10-31 ; Target : 15.3 ; SD : 0.40

Lab019



Date 05-16 05-23 05-30 06-06 06-13 06-20 06-27 07-04 07-11 07-18 07-25 08-01 08-08 08-15 08-22 08-29 09-05 09-12 09-19 09-24 09-27 10-03 10-10 10-17 10-24 10-31

Month : 2018 10 [Change](#) ; Cumulative : from 2018 05 16 to 2018 10 31 [Change](#)

[TOP](#)

Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2018-05-16 to 2018-10-31 ; Target : 5.3 ; SD : 0.20

Lab019



Date 05-16 05-23 05-30 06-06 06-13 06-20 06-27 07-04 07-11 07-18 07-25 08-01 08-08 08-15 08-22 08-29 09-05 09-12 09-19 09-24 09-27 10-03 10-10 10-17 10-24 10-31

Month : 2018 10 [Change](#) ; Cumulative : from 2018 05 16 to 2018 10 31 [Change](#)

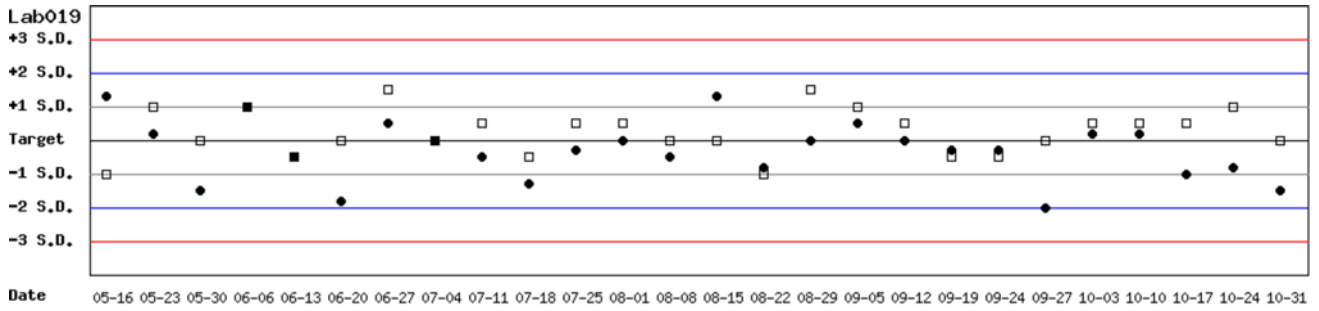
[TOP](#)

Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-05-16 to 2018-10-31 ; Target : 15.3 ; SD : 0.40 (●)

Lot No.: AE0909D ; Duration : 2018-05-16 to 2018-10-31 ; Target : 5.3 ; SD : 0.20 (□)

Lab019



Month : 2018 10 ; Cumulative : from 2018 05 16 to 2018 10 31

[TOP](#)

Peer Group Statistics (Table 1)

Select LotNo : AE0909N (2016-01-01 ~ 2100-12-31) ▼ Change

Select Reagent Kit : 5 - Medicon ▼ Change

Print Table 1

Monthly

Month : 2018 ▼ 10 ▼ Change

| UnitID † | Reagent Kit (Code) † | Control N (Lot No.: AE0909N) | | | | | | | | | Control D (Lot No.: AE0909D) | | | | | | |
|------------------------|-------------------------|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|----|-------------------|------------------------------|---------------|-----|-----------|-----------|------------|-----|
| | | 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 | 15.3 | 15.1 | 5 | 0.3 | 2.0 | 5.3 | 20 | >6 | 5.3 | 5.4 | 5 | 0.1 | 1.9 | 5.6 | 20 | >6 |
| Lab020 | 5 | 15.4 | 15.4 | 4 | 0.4 | 2.6 | 5.2 | 20 | >6 | 5.5 | 5.5 | 4 | 0.1 | 1.8 | 3.6 | 20 | >6 |
| Lab026 | 5 | 15.9 | 15.0 | 17 | 0.3 | 2.0 | 9.7 | 20 | >6 | 5.8 | 5.2 | 17 | 0.2 | 3.8 | 18.0 | 20 | 2.5 |
| Lab027 | 5 | 11.5 | 18.0 | 1 | - | - | - | 20 | - | 4.5 | 6.2 | 1 | - | - | - | 20 | - |
| Lab033 | 5 | 14.4 | 14.8 | 4 | 0.2 | 1.4 | 5.5 | 20 | >6 | 5.8 | 5.4 | 4 | 0.2 | 3.7 | 14.3 | 20 | 3.5 |
| Lab034 | 5 | 14.4 | 14.6 | 4 | 0.3 | 2.1 | 5.5 | 20 | >6 | 5.8 | 5.2 | 4 | 0.1 | 1.9 | 14.2 | 20 | 5.1 |
| Lab037 | 5 | 11.5 | 15.8 | 2 | - | - | - | 20 | - | 4.5 | 5.6 | 2 | - | - | - | 20 | - |
| Lab043 | 5 | 11.5 | 12.5 | 4 | 0.2 | 1.6 | 11.9 | 20 | >6 | 4.5 | 4.9 | 4 | 0.2 | 4.1 | 17.1 | 20 | 2.7 |
| Total | - | - | 14.9 | 41 | 1.0 | 6.7 | - | - | - | - | 5.3 | 41 | 0.3 | 5.7 | - | - | - |

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from 2016 ▼ 02 ▼ 01 ▼ to 2018 ▼ 10 ▼ 31 ▼ Change

| UnitID † | Reagent Kit (Code) † | Control N (Lot No.: AE0909N) | | | | | | | | | Control D (Lot No.: AE0909D) | | | | | | |
|------------------------|-------------------------|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|------|-------------------|------------------------------|---------------|-----|-----------|-----------|------------|------|
| | | 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 |
| Lab018 | 5 | 15.7 | 16.1 | 60 | 0.7 | 4.3 | 11.2 | 20 | 4.1 | 5.6 | 5.7 | 60 | 0.3 | 5.3 | 12.3 | 20 | 3.4 |
| Lab019 | 5 | 15.3 | 15.1 | 39 | 0.4 | 2.6 | 6.6 | 20 | >6 | 5.3 | 5.3 | 39 | 0.2 | 3.8 | 7.5 | 20 | 5.3 |
| Lab020 | 5 | 15.4 | 15.4 | 4 | 0.4 | 2.6 | 5.2 | 20 | >6 | 5.5 | 5.5 | 4 | 0.1 | 1.8 | 3.6 | 20 | >6 |
| Lab026 | 5 | 15.9 | 15.3 | 117 | 0.4 | 2.6 | 9.0 | 20 | >6 | 5.8 | 5.2 | 117 | 0.4 | 7.7 | 25.7 | 20 | 1.3 |
| Lab027 | 5 | 11.5 | 16.2 | 53 | 1.4 | 8.6 | 58.2 | 20 | -2.4 | 4.5 | 5.6 | 53 | 0.4 | 7.1 | 38.7 | 20 | -0.6 |
| Lab032 | 5 | 15.9 | 15.8 | 22 | 1.0 | 6.3 | 13.3 | 20 | 3.1 | 5.8 | 5.7 | 22 | 0.4 | 7.0 | 15.8 | 20 | 2.6 |
| Lab033 | 5 | 14.4 | 14.8 | 27 | 0.6 | 4.1 | 10.9 | 20 | 4.2 | 5.8 | 5.3 | 27 | 0.2 | 3.8 | 16.2 | 20 | 3.0 |
| Lab034 | 5 | 14.4 | 14.1 | 32 | 0.5 | 3.5 | 9.2 | 20 | 5.1 | 5.8 | 5.0 | 32 | 0.3 | 6.0 | 25.8 | 20 | 1.0 |
| Lab037 | 5 | 11.5 | 15.8 | 2 | - | - | - | 20 | - | 4.5 | 5.6 | 2 | - | - | - | 20 | - |
| Lab040 | 5 | 12.5 | 13.2 | 38 | 0.6 | 4.5 | 14.7 | 20 | 3.2 | 4.5 | 4.7 | 38 | 0.3 | 6.4 | 17.2 | 20 | 2.4 |
| Lab043 | 5 | 11.5 | 13.3 | 37 | 1.1 | 8.3 | 32.2 | 20 | 0.5 | 4.5 | 5.1 | 37 | 0.3 | 5.9 | 25.1 | 20 | 1.1 |
| Total | - | - | 15.0 | 431 | 1.3 | 8.7 | - | - | - | - | 5.3 | 431 | 0.4 | 7.5 | - | - | - |

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

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

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

[\[TOP\]](#)

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

Peer Group Statistics (Table 2)

Select LotNo :

Select Reagent Kit :

Control N Month vs. Cumulative

| | | Control N (Lot No.: AE0909N) | | | | | | | | | | | | | | | |
|------------------------|---------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|----|-----------------------------|--------------|------------|-----|--------|--------|---------|------|
| | | Month (2018/10) | | | | | | | | CUM (2016/02/01~2018/10/31) | | | | | | | |
| 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 |
| Lab018 | 5 | 15.7 | - | 0 | - | - | - | 20 | - | 15.7 | 16.1 | 60 | 0.7 | 4.3 | 11.2 | 20 | 4.1 |
| Lab019 | 5 | 15.3 | 15.1 | 5 | 0.3 | 2.0 | 5.3 | 20 | >6 | 15.3 | 15.1 | 39 | 0.4 | 2.6 | 6.6 | 20 | >6 |
| Lab020 | 5 | 15.4 | 15.4 | 4 | 0.4 | 2.6 | 5.2 | 20 | >6 | 15.4 | 15.4 | 4 | 0.4 | 2.6 | 5.2 | 20 | >6 |
| Lab026 | 5 | 15.9 | 15.0 | 17 | 0.3 | 2.0 | 9.7 | 20 | >6 | 15.9 | 15.3 | 117 | 0.4 | 2.6 | 9.0 | 20 | >6 |
| Lab027 | 5 | 11.5 | 18.0 | 1 | - | - | - | 20 | - | 11.5 | 16.2 | 53 | 1.4 | 8.6 | 58.2 | 20 | -2.4 |
| Lab032 | 5 | 15.9 | - | 0 | - | - | - | 20 | - | 15.9 | 15.8 | 22 | 1.0 | 6.3 | 13.3 | 20 | 3.1 |
| Lab033 | 5 | 14.4 | 14.8 | 4 | 0.2 | 1.4 | 5.5 | 20 | >6 | 14.4 | 14.8 | 27 | 0.6 | 4.1 | 10.9 | 20 | 4.2 |
| Lab034 | 5 | 14.4 | 14.6 | 4 | 0.3 | 2.1 | 5.5 | 20 | >6 | 14.4 | 14.1 | 32 | 0.5 | 3.5 | 9.2 | 20 | 5.1 |
| Lab037 | 5 | 11.5 | 15.8 | 2 | - | - | - | 20 | - | 11.5 | 15.8 | 2 | - | - | - | 20 | - |
| Lab040 | 5 | 12.5 | - | 0 | - | - | - | 20 | - | 12.5 | 13.2 | 38 | 0.6 | 4.5 | 14.7 | 20 | 3.2 |
| Lab043 | 5 | 11.5 | 12.5 | 4 | 0.2 | 1.6 | 11.9 | 20 | >6 | 11.5 | 13.3 | 37 | 1.1 | 8.3 | 32.2 | 20 | 0.5 |
| Total | - | - | 14.9 | 41 | 1.0 | 6.7 | - | - | - | - | 15.0 | 431 | 1.3 | 8.7 | - | - | - |

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

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

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

Month :

Cumulative : from to

[TOP](#)

Control D Month vs. Cumulative

| | | Control D (Lot No.: AE0909D) | | | | | | | | | | | | | | | |
|------------------------|---------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|------|
| | | Month (2018/10) | | | | | | | | CUM (2016/02/01~2018/10/31) | | | | | | | |
| 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 |
| Lab018 | 5 | 5.6 | - | 0 | - | - | - | 20 | - | 5.6 | 5.7 | 60 | 0.3 | 5.3 | 12.3 | 20 | 3.4 |
| Lab019 | 5 | 5.3 | 5.4 | 5 | 0.1 | 1.9 | 5.6 | 20 | >6 | 5.3 | 5.3 | 39 | 0.2 | 3.8 | 7.5 | 20 | 5.3 |
| Lab020 | 5 | 5.5 | 5.5 | 4 | 0.1 | 1.8 | 3.6 | 20 | >6 | 5.5 | 5.5 | 4 | 0.1 | 1.8 | 3.6 | 20 | >6 |
| Lab026 | 5 | 5.8 | 5.2 | 17 | 0.2 | 3.8 | 18.0 | 20 | 2.5 | 5.8 | 5.2 | 117 | 0.4 | 7.7 | 25.7 | 20 | 1.3 |
| Lab027 | 5 | 4.5 | 6.2 | 1 | - | - | - | 20 | - | 4.5 | 5.6 | 53 | 0.4 | 7.1 | 38.7 | 20 | -0.6 |
| Lab032 | 5 | 5.8 | - | 0 | - | - | - | 20 | - | 5.8 | 5.7 | 22 | 0.4 | 7.0 | 15.8 | 20 | 2.6 |
| Lab033 | 5 | 5.8 | 5.4 | 4 | 0.2 | 3.7 | 14.3 | 20 | 3.5 | 5.8 | 5.3 | 27 | 0.2 | 3.8 | 16.2 | 20 | 3.0 |
| Lab034 | 5 | 5.8 | 5.2 | 4 | 0.1 | 1.9 | 14.2 | 20 | 5.1 | 5.8 | 5.0 | 32 | 0.3 | 6.0 | 25.8 | 20 | 1.0 |
| Lab037 | 5 | 4.5 | 5.6 | 2 | - | - | - | 20 | - | 4.5 | 5.6 | 2 | - | - | - | 20 | - |
| Lab040 | 5 | 4.5 | - | 0 | - | - | - | 20 | - | 4.5 | 4.7 | 38 | 0.3 | 6.4 | 17.2 | 20 | 2.4 |
| Lab043 | 5 | 4.5 | 4.9 | 4 | 0.2 | 4.1 | 17.1 | 20 | 2.7 | 4.5 | 5.1 | 37 | 0.3 | 5.9 | 25.1 | 20 | 1.1 |
| Total | - | - | 5.3 | 41 | 0.3 | 5.7 | - | - | - | - | 5.3 | 431 | 0.4 | 7.5 | - | - | - |

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

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

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

Month :

Cumulative : from to

[TOP](#)

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