# Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - March 2019 -

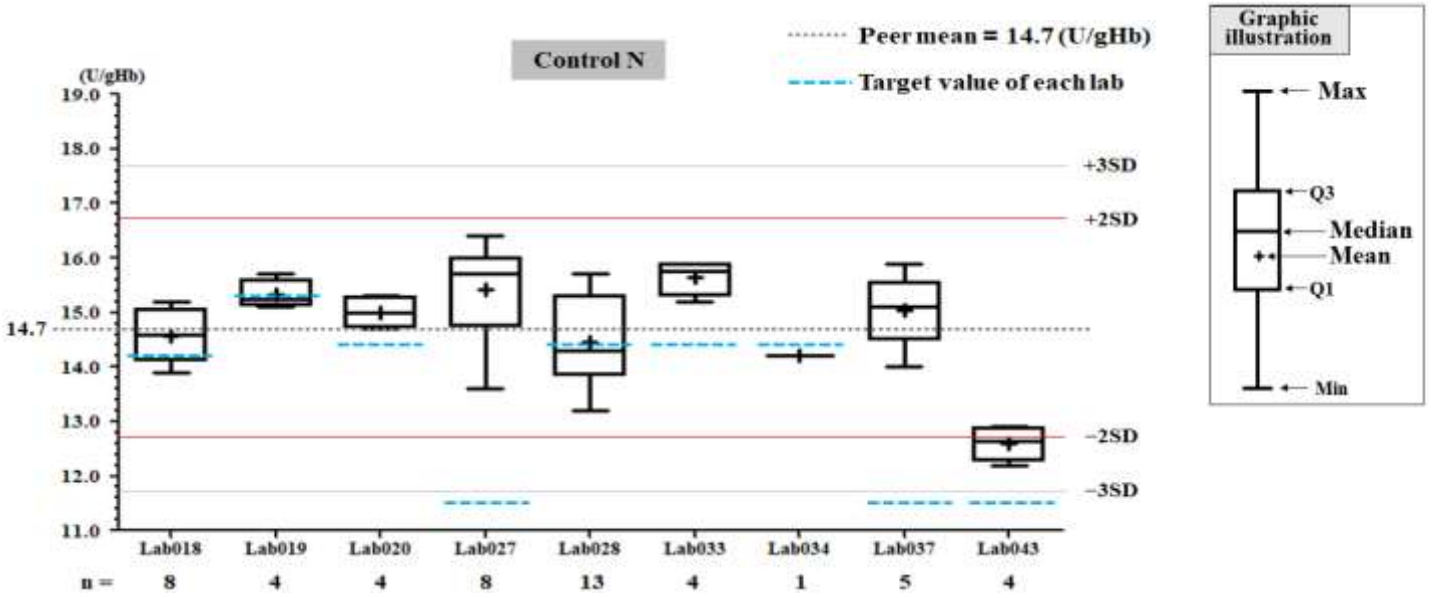
## I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:AE0909N) | Control D (Lot No.:AE0909D) |
|---|---|---|
| Labs | 9 | 9 |
| Received results number (n) | 51 | 51 |
| Median | 15.0 (U/gHb) | 5.6 (U/gHb) |
| Mean | 14.7 (U/gHb) | 5.5 (U/gHb) |
| SD | 1.0 | 0.5 |
| CV | 6.8% | 9.1% |
| Range of G6PD | 12.2 ~ 16.4 (U/gHb) | 4.5 ~ 6.8 (U/gHb) |
| Range of Hb | 1.6 ~ 2.2 (g/dL) | 1.7 ~ 2.4 (g/dL) |

*The statistic results are calculated from all labs reported in this month

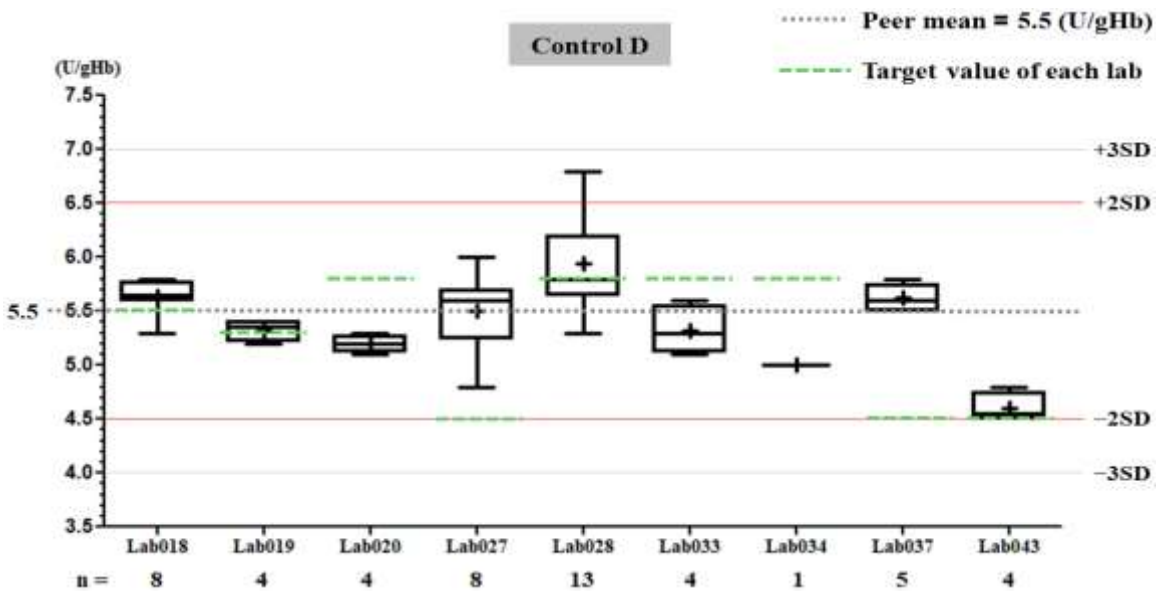
** G6PD Method = Medicon reagent kit, 37°C

## 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

| | Control N | | Control D | |
|---|---|---|---|---|
| QC Control Lot No. | AE0909N | | AE0909D | |
| Duration of the Analyzing | Month (2019/03) | CUM (2018/10/10~2019/03/31) | Month (2019/03) | CUM (2018/10/10~2019/03/31) |
| Runs (N) | 4 | 26 | 4 | 26 |
| Mean (U/gHb) | 15.3 | 15.2 | 5.3 | 5.3 |
| 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 (%) | 3.9 | 4.6 | 3.8 | 3.8 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | >6 | >6 | >6 | >6 |

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

Month : 2019 03 Change ; Cumulative : from 2018 10 10 to 2019 03 31 Change

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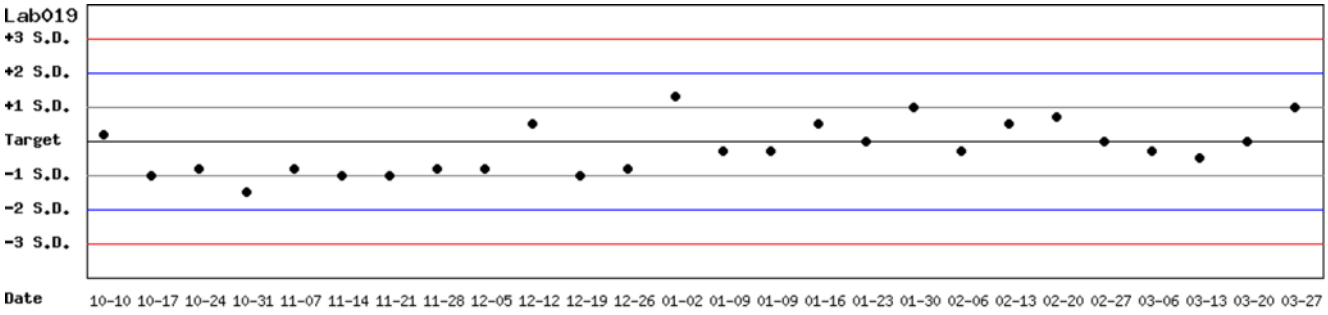
## Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-10-10 to 2019-03-31 ; Target : 15.3 ; SD : 0.40

Lab019




Month : 2019 03 Change ; Cumulative : from 2018 10 10 to 2019 03 31 Change

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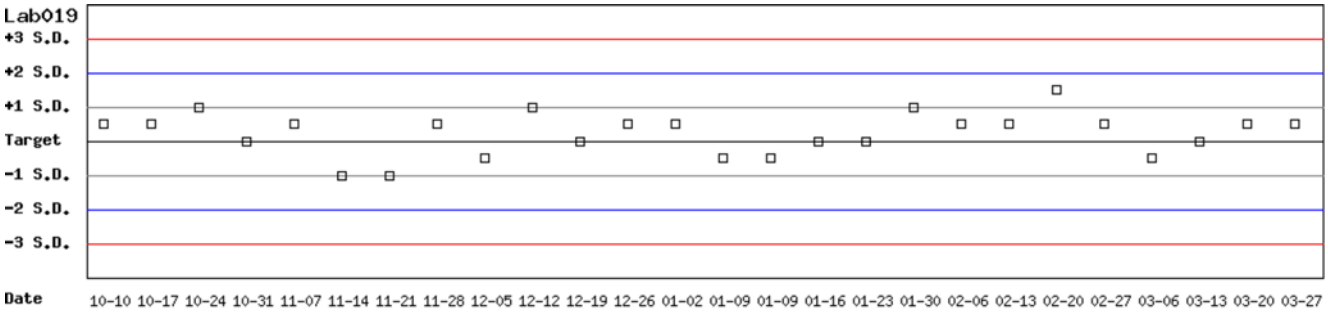
## Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2018-10-10 to 2019-03-31 ; Target : 5.3 ; SD : 0.20

Lab019




Month : 2019 03 Change ; Cumulative : from 2018 10 10 to 2019 03 31 Change

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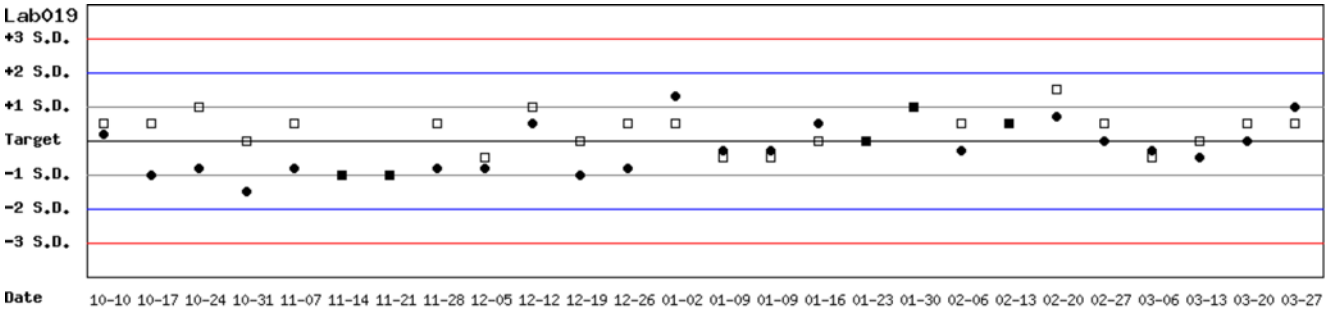
# **Control N** and **Control D SDI**
QC Chart

Lot No.: AE0909N ; Duration : 2018-10-10 to 2019-03-31 ; Target : 15.3 ; SD : 0.40 ( ●)

Lot No.: AE0909D ; Duration : 2018-10-10 to 2019-03-31 ; Target : 5.3 ; SD : 0.20 ( □)

Lab019




Month : 2019 | 03 Change ; Cumulative : from 2018 | 10 10 to 2019 | 03 31 Change

[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 : 2019 03 Change

| | | Control N (Lot No.: AE0909N) | | | | | | | | Control D (Lot No.: AE0909D) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 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 | 14.2 | 14.6 | 8 | 0.5 | 3.4 | 9.7 | 20 | 5.1 | 5.5 | 5.6 | 8 | 0.2 | 3.6 | 9.0 | 20 | 5.1 |
| Lab019 | 5 | 15.3 | 15.3 | 4 | 0.3 | 2.0 | 3.9 | 20 | >6 | 5.3 | 5.3 | 4 | 0.1 | 1.9 | 3.8 | 20 | >6 |
| Lab020 | 5 | 14.4 | 15.0 | 4 | 0.3 | 2.0 | 8.2 | 20 | >6 | 5.8 | 5.2 | 4 | 0.1 | 1.9 | 14.2 | 20 | 5.1 |
| Lab027 | 5 | 11.5 | 15.4 | 8 | 0.9 | 5.8 | 45.6 | 20 | -2.4 | 4.5 | 5.5 | 8 | 0.4 | 7.3 | 36.8 | 20 | -0.3 |
| Lab028 | 5 | 14.4 | 14.5 | 13 | 0.8 | 5.5 | 11.7 | 20 | 3.5 | 5.8 | 5.9 | 13 | 0.5 | 8.5 | 18.7 | 20 | 2.2 |
| Lab033 | 5 | 14.4 | 15.7 | 4 | 0.3 | 1.9 | 12.8 | 20 | 5.8 | 5.8 | 5.3 | 4 | 0.2 | 3.8 | 16.2 | 20 | 3.0 |
| Lab034 | 5 | 14.4 | 14.2 | 1 | - | - | - | 20 | - | 5.8 | 5.0 | 1 | - | - | - | 20 | - |
| Lab037 | 5 | 11.5 | 15.0 | 5 | 0.7 | 4.7 | 39.8 | 20 | -2.2 | 4.5 | 5.6 | 5 | 0.1 | 1.8 | 28.0 | 20 | -2.5 |
| Lab043 | 5 | 11.5 | 12.6 | 4 | 0.3 | 2.4 | 14.3 | 20 | 4.3 | 4.5 | 4.6 | 4 | 0.1 | 2.2 | 6.6 | 20 | >6 |
| Total | - | - | 14.7 | 51 | 1.0 | 6.8 | - | - | - | - | 5.5 | 51 | 0.5 | 9.1 | - | - | - |

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 2019 03 31 Change

| | | Control N (Lot No.: AE0909N) | | | | | | | | Control D (Lot No.: AE0909D) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 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 | 14.2 | 15.9 | 68 | 0.9 | 5.7 | 23.3 | 20 | 1.4 | 5.5 | 5.7 | 68 | 0.2 | 3.5 | 10.7 | 20 | 4.7 |
| Lab019 | 5 | 15.3 | 15.2 | 61 | 0.4 | 2.6 | 5.9 | 20 | >6 | 5.3 | 5.3 | 61 | 0.1 | 1.9 | 3.8 | 20 | >6 |
| Lab020 | 5 | 14.4 | 15.2 | 19 | 0.4 | 2.6 | 10.8 | 20 | 5.6 | 5.8 | 5.4 | 19 | 0.2 | 3.7 | 14.3 | 20 | 3.5 |
| Lab026 | 5 | 15.9 | 15.3 | 125 | 0.5 | 3.3 | 10.3 | 20 | 4.9 | 5.8 | 5.2 | 125 | 0.4 | 7.7 | 25.7 | 20 | 1.3 |
| Lab027 | 5 | 11.5 | 15.8 | 69 | 1.4 | 8.9 | 55.1 | 20 | -2.0 | 4.5 | 5.6 | 69 | 0.4 | 7.1 | 38.7 | 20 | -0.6 |
| Lab028 | 5 | 14.4 | 14.5 | 36 | 0.8 | 5.5 | 11.7 | 20 | 3.5 | 5.8 | 5.7 | 36 | 0.5 | 8.8 | 19.3 | 20 | 2.1 |
| Lab032 | 5 | 15.9 | 15.9 | 38 | 0.9 | 5.7 | 11.3 | 20 | 3.5 | 5.8 | 5.7 | 38 | 0.3 | 5.3 | 12.3 | 20 | 3.4 |
| Lab033 | 5 | 14.4 | 14.9 | 49 | 0.6 | 4.0 | 11.5 | 20 | 4.1 | 5.8 | 5.2 | 49 | 0.2 | 3.8 | 18.0 | 20 | 2.5 |
| Lab034 | 5 | 14.4 | 14.2 | 50 | 0.6 | 4.2 | 9.8 | 20 | 4.4 | 5.8 | 5.1 | 50 | 0.2 | 3.9 | 19.9 | 20 | 2.0 |
| Lab037 | 5 | 11.5 | 14.9 | 20 | 0.7 | 4.7 | 39.0 | 20 | -2.0 | 4.5 | 5.4 | 20 | 0.3 | 5.6 | 31.1 | 20 | 0.0 |
| Lab040 | 5 | 14.4 | 13.3 | 39 | 0.7 | 5.3 | 18.2 | 20 | 2.3 | 5.8 | 4.7 | 39 | 0.3 | 6.4 | 31.7 | 20 | 0.2 |
| Lab043 | 5 | 11.5 | 13.1 | 59 | 1.0 | 7.6 | 29.2 | 20 | 0.8 | 4.5 | 4.9 | 59 | 0.3 | 6.1 | 21.1 | 20 | 1.8 |
| Total | - | - | 14.9 | 633 | 1.2 | 8.1 | - | - | - | - | 5.3 | 633 | 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：AE0909N (2016-01-01 ~ 2100-12-31) Change

Select Reagent Kit：5 - Medicon Change

Print Table 2

## Control N Month vs. Cumulative

| | | Control N (Lot No.: AE0909N) | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Month (2019/03) | | | | | | | | CUM (2016/02/01~2019/03/31) | | | | | | | |
| 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 | 14.2 | 14.6 | 8 | 0.5 | 3.4 | 9.7 | 20 | 5.1 | 14.2 | 15.9 | 68 | 0.9 | 5.7 | 23.3 | 20 | 1.4 |
| Lab019 | 5 | 15.3 | 15.3 | 4 | 0.3 | 2.0 | 3.9 | 20 | >6 | 15.3 | 15.2 | 61 | 0.4 | 2.6 | 5.9 | 20 | >6 |
| Lab020 | 5 | 14.4 | 15.0 | 4 | 0.3 | 2.0 | 8.2 | 20 | >6 | 14.4 | 15.2 | 19 | 0.4 | 2.6 | 10.8 | 20 | 5.6 |
| Lab026 | 5 | 15.9 | - | 0 | - | - | - | 20 | - | 15.9 | 15.3 | 125 | 0.5 | 3.3 | 10.3 | 20 | 4.9 |
| Lab027 | 5 | 11.5 | 15.4 | 8 | 0.9 | 5.8 | 45.6 | 20 | -2.4 | 11.5 | 15.8 | 69 | 1.4 | 8.9 | 55.1 | 20 | -2.0 |
| Lab028 | 5 | 14.4 | 14.5 | 13 | 0.8 | 5.5 | 11.7 | 20 | 3.5 | 14.4 | 14.5 | 36 | 0.8 | 5.5 | 11.7 | 20 | 3.5 |
| Lab032 | 5 | 15.9 | - | 0 | - | - | - | 20 | - | 15.9 | 15.9 | 38 | 0.9 | 5.7 | 11.3 | 20 | 3.5 |
| Lab033 | 5 | 14.4 | 15.7 | 4 | 0.3 | 1.9 | 12.8 | 20 | 5.8 | 14.4 | 14.9 | 49 | 0.6 | 4.0 | 11.5 | 20 | 4.1 |
| Lab034 | 5 | 14.4 | 14.2 | 1 | - | - | - | 20 | - | 14.4 | 14.2 | 50 | 0.6 | 4.2 | 9.8 | 20 | 4.4 |
| Lab037 | 5 | 11.5 | 15.0 | 5 | 0.7 | 4.7 | 39.8 | 20 | -2.2 | 11.5 | 14.9 | 20 | 0.7 | 4.7 | 39.0 | 20 | -2.0 |
| Lab040 | 5 | 14.4 | - | 0 | - | - | - | 20 | - | 14.4 | 13.3 | 39 | 0.7 | 5.3 | 18.2 | 20 | 2.3 |
| Lab043 | 5 | 11.5 | 12.6 | 4 | 0.3 | 2.4 | 14.3 | 20 | 4.3 | 11.5 | 13.1 | 59 | 1.0 | 7.6 | 29.2 | 20 | 0.8 |
| Total | - | - | 14.7 | 51 | 1.0 | 6.8 | - | - | - | - | 14.9 | 633 | 1.2 | 8.1 | - | - | - |

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

Month : 2019 03 Change  Cumulative : from 2016 02 01 to 2019 03 31 Change

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## Control D Month vs. Cumulative

| | | Control D (Lot No.: AE0909D) | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Month (2019/03) | | | | | | | | CUM (2016/02/01~2019/03/31) | | | | | | | |
| 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 | 5.5 | 5.6 | 8 | 0.2 | 3.6 | 9.0 | 20 | 5.1 | 5.5 | 5.7 | 68 | 0.2 | 3.5 | 10.7 | 20 | 4.7 |
| Lab019 | 5 | 5.3 | 5.3 | 4 | 0.1 | 1.9 | 3.8 | 20 | >6 | 5.3 | 5.3 | 61 | 0.1 | 1.9 | 3.8 | 20 | >6 |
| Lab020 | 5 | 5.8 | 5.2 | 4 | 0.1 | 1.9 | 14.2 | 20 | 5.1 | 5.8 | 5.4 | 19 | 0.2 | 3.7 | 14.3 | 20 | 3.5 |
| Lab026 | 5 | 5.8 | - | 0 | - | - | - | 20 | - | 5.8 | 5.2 | 125 | 0.4 | 7.7 | 25.7 | 20 | 1.3 |
| Lab027 | 5 | 4.5 | 5.5 | 8 | 0.4 | 7.3 | 36.8 | 20 | -0.3 | 4.5 | 5.6 | 69 | 0.4 | 7.1 | 38.7 | 20 | -0.6 |
| Lab028 | 5 | 5.8 | 5.9 | 13 | 0.5 | 8.5 | 18.7 | 20 | 2.2 | 5.8 | 5.7 | 36 | 0.5 | 8.8 | 19.3 | 20 | 2.1 |
| Lab032 | 5 | 5.8 | - | 0 | - | - | - | 20 | - | 5.8 | 5.7 | 38 | 0.3 | 5.3 | 12.3 | 20 | 3.4 |
| Lab033 | 5 | 5.8 | 5.3 | 4 | 0.2 | 3.8 | 16.2 | 20 | 3.0 | 5.8 | 5.2 | 49 | 0.2 | 3.8 | 18.0 | 20 | 2.5 |
| Lab034 | 5 | 5.8 | 5.0 | 1 | - | - | - | 20 | - | 5.8 | 5.1 | 50 | 0.2 | 3.9 | 19.9 | 20 | 2.0 |
| Lab037 | 5 | 4.5 | 5.6 | 5 | 0.1 | 1.8 | 28.0 | 20 | -2.5 | 4.5 | 5.4 | 20 | 0.3 | 5.6 | 31.1 | 20 | 0.0 |
| Lab040 | 5 | 5.8 | - | 0 | - | - | - | 20 | - | 5.8 | 4.7 | 39 | 0.3 | 6.4 | 31.7 | 20 | 0.2 |
| Lab043 | 5 | 4.5 | 4.6 | 4 | 0.1 | 2.2 | 6.6 | 20 | >6 | 4.5 | 4.9 | 59 | 0.3 | 6.1 | 21.1 | 20 | 1.8 |
| Total | - | - | 5.5 | 51 | 0.5 | 9.1 | - | - | - | - | 5.3 | 633 | 0.4 | 7.5 | - | - | - |

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

Month : 2019 03 Change  Cumulative : from 2016 02 01 to 2019 03 31 Change

[TOP]

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