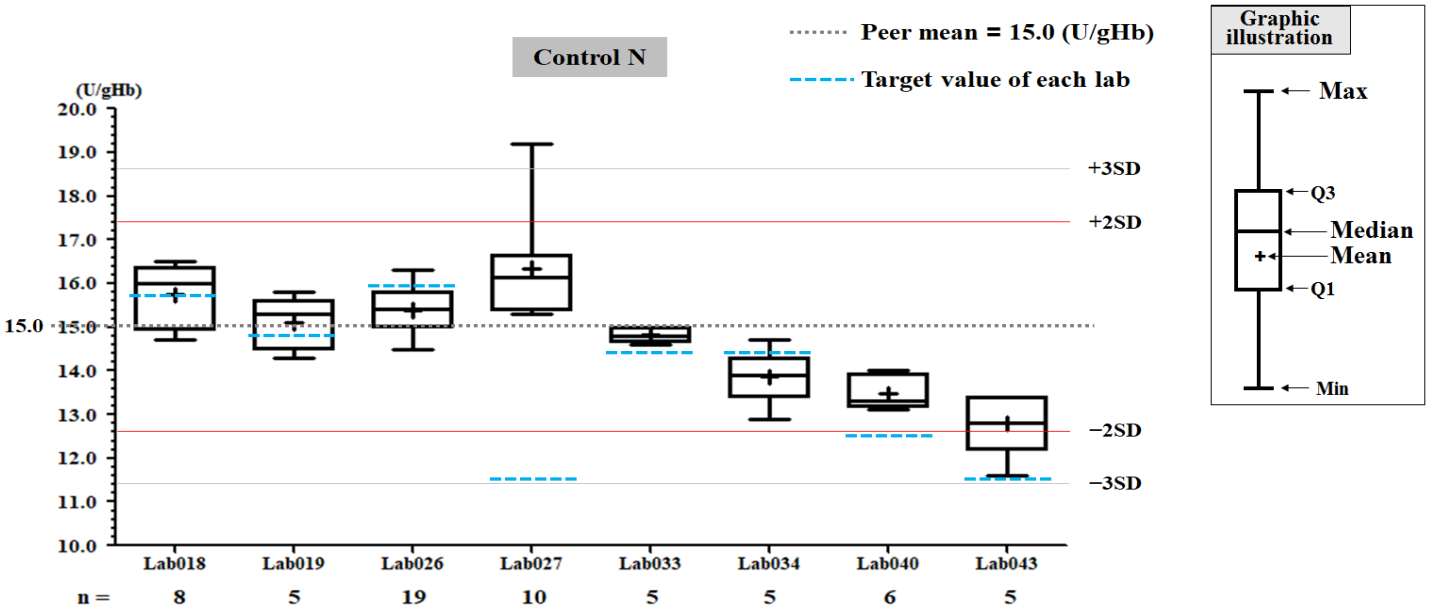
# Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - May 2018 -

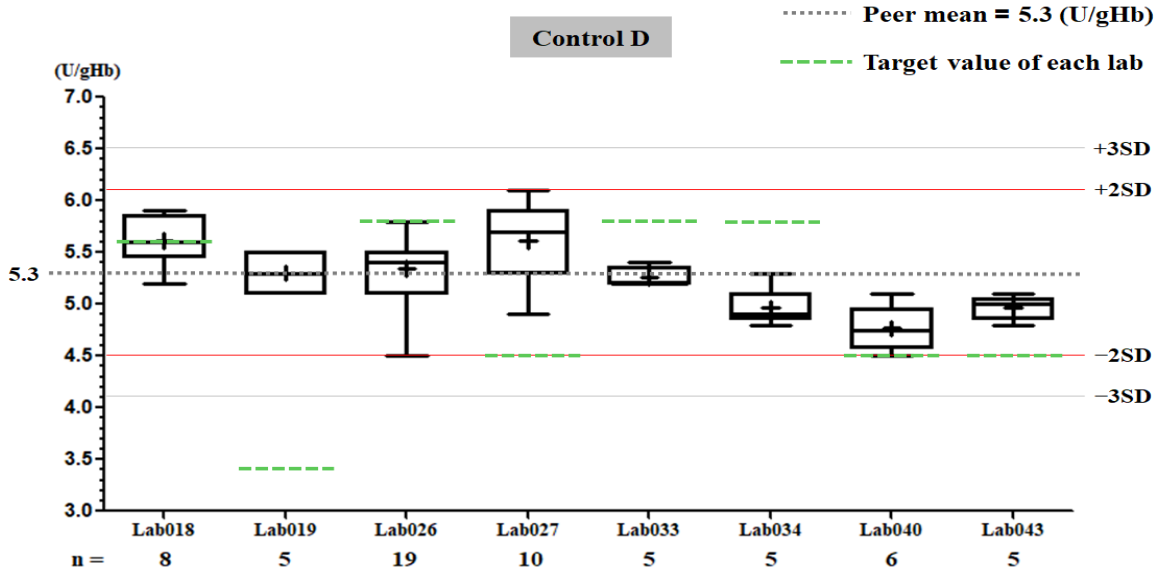
## I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:AE0909N) | Control D (Lot No.:AE0909D) |
|---|---|---|
| Labs | 8 | 8 |
| Received results number (n) | 63 | 63 |
| Median | 15.2 (U/gHb) | 5.3 (U/gHb) |
| Mean | 15.0 (U/gHb) | 5.3 (U/gHb) |
| SD | 1.2 | 0.4 |
| CV | 8.0% | 7.5% |
| Range of G6PD | 11.6 ~ 19.2 (U/gHb) | 4.5 ~ 6.1 (U/gHb) |
| Range of Hb | 1.0 ~ 2.3 (g/dL) | 1.8 ~ 2.5 (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

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# 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 (2018/05) | CUM (2016/02/01~2018/05/31) | Month (2018/05) | CUM (2016/02/01~2018/05/31) |
| Runs (N) | 5 | 16 | 5 | 16 |
| Mean (U/gHb) | 15.1 | 15.0 | 5.3 | 5.2 |
| SD | 0.6 | 0.4 | 0.2 | 0.2 |
| CV (%) | 4.0 | 2.7 | 3.8 | 3.8 |
| Target Value (U/gHb) | 14.8 | 14.8 | 3.4 | 3.4 |
| Total Error (%) | 10.0 | 6.7 | 63.4 | 60.6 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | 4.5 | >6 | -9.4 | -8.7 |

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

Month： 2018 05 Change ； Cumulative : from 2016 02 01 to 2018 05 31 Change

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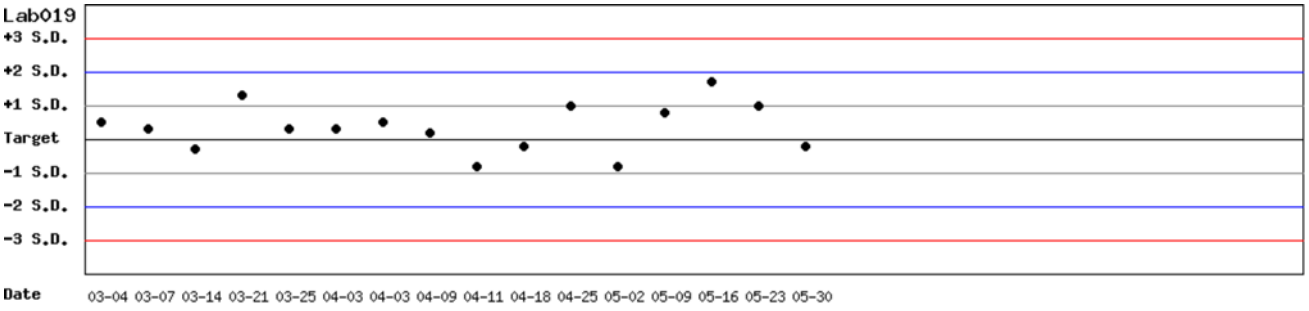
## Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2018-05-31 ; Target : 14.8 ; SD : 0.6

Lab019




Month： 2018 05 Change ； Cumulative : from 2016 02 01 to 2018 05 31 Change

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## Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2016-02-01 to 2018-05-31 ; Target : 3.4 ; SD : 0.3

Lab019

Month： 2018 05 Change ； Cumulative : from 2016 02 01 to 2018 05 31 Change

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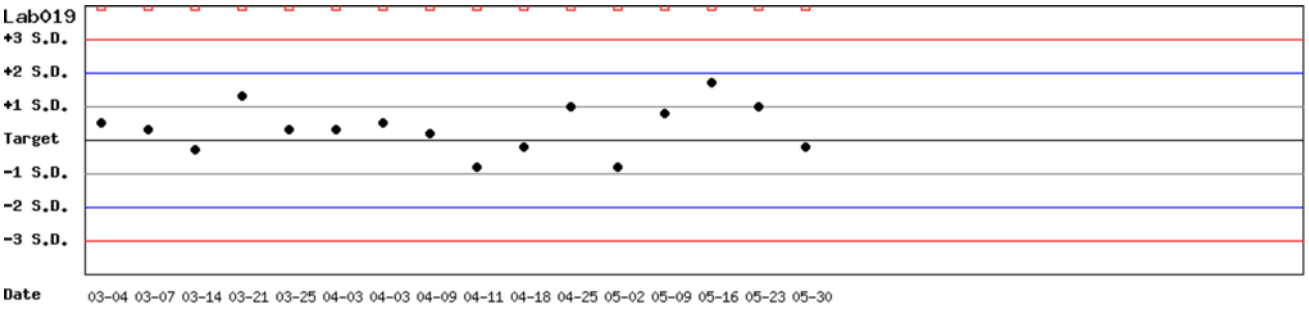
# **Control N** and **Control D SDI**
QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2018-05-31 ; Target : 14.8 ; SD : 0.6 ( ●)

Lot No.: AE0909D ; Duration : 2016-02-01 to 2018-05-31 ; Target : 3.4 ; SD : 0.3 ( □)

Lab019




Month : 2018 05 Change ; Cumulative : from 2016 02 01 to 2018 05 31 Change

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# 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 05 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 | 15.7 | 15.7 | 8 | 0.7 | 4.5 | 8.9 | 20 | 4.4 | 5.6 | 5.6 | 8 | 0.2 | 3.6 | 7.1 | 20 | 5.6 |
| Lab019 | 5 | 14.8 | 15.1 | 5 | 0.6 | 4.0 | 10.0 | 20 | 4.5 | 3.4 | 5.3 | 5 | 0.2 | 3.8 | 63.4 | 20 | -9.4 |
| Lab026 | 5 | 15.9 | 15.4 | 19 | 0.4 | 2.6 | 8.3 | 20 | >6 | 5.8 | 5.3 | 19 | 0.3 | 5.7 | 19.9 | 20 | 2.0 |
| Lab027 | 5 | 11.5 | 16.3 | 10 | 1.2 | 7.4 | 56.5 | 20 | -2.9 | 4.5 | 5.6 | 10 | 0.4 | 7.1 | 38.7 | 20 | -0.6 |
| Lab033 | 5 | 14.4 | 14.8 | 5 | 0.2 | 1.4 | 5.5 | 20 | >6 | 5.8 | 5.3 | 5 | 0.1 | 1.9 | 12.4 | 20 | 6.0 |
| Lab034 | 5 | 14.4 | 13.9 | 5 | 0.6 | 4.3 | 12.1 | 20 | 3.8 | 5.8 | 5.0 | 5 | 0.2 | 4.0 | 21.8 | 20 | 1.6 |
| Lab040 | 5 | 12.5 | 13.5 | 6 | 0.4 | 3.0 | 13.9 | 20 | 4.0 | 4.5 | 4.8 | 6 | 0.2 | 4.2 | 15.0 | 20 | 3.2 |
| Lab043 | 5 | 11.5 | 12.8 | 5 | 0.7 | 5.5 | 22.2 | 20 | 1.6 | 4.5 | 5.0 | 5 | 0.1 | 2.0 | 15.1 | 20 | 4.4 |
| Total | - | - | 15.0 | 63 | 1.2 | 8.0 | - | - | - | - | 5.3 | 63 | 0.4 | 7.5 | - | - | - |

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

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## Cumulative

Cumulative : from 2016 02 01 to 2018 05 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 | 15.7 | 16.1 | 37 | 0.8 | 5.0 | 12.5 | 20 | 3.5 | 5.6 | 5.7 | 37 | 0.3 | 5.3 | 12.3 | 20 | 3.4 |
| Lab019 | 5 | 14.8 | 15.0 | 16 | 0.4 | 2.7 | 6.7 | 20 | >6 | 3.4 | 5.2 | 16 | 0.2 | 3.8 | 60.6 | 20 | -8.7 |
| Lab026 | 5 | 15.9 | 15.6 | 35 | 0.5 | 3.2 | 8.3 | 20 | 5.7 | 5.8 | 5.1 | 35 | 0.7 | 13.7 | 39.5 | 20 | 0.6 |
| Lab027 | 5 | 11.5 | 15.4 | 18 | 1.7 | 11.0 | 56.0 | 20 | -1.3 | 4.5 | 5.4 | 18 | 0.4 | 7.4 | 34.8 | 20 | 0.0 |
| 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 | 15.0 | 6 | 0.5 | 3.3 | 10.8 | 20 | 4.8 | 5.8 | 5.3 | 6 | 0.2 | 3.8 | 16.2 | 20 | 3.0 |
| Lab034 | 5 | 14.4 | 13.8 | 11 | 0.6 | 4.3 | 12.9 | 20 | 3.7 | 5.8 | 4.9 | 11 | 0.2 | 4.1 | 23.7 | 20 | 1.1 |
| Lab040 | 5 | 12.5 | 12.8 | 21 | 0.6 | 4.7 | 11.8 | 20 | 3.7 | 4.5 | 4.6 | 21 | 0.3 | 6.5 | 15.3 | 20 | 2.7 |
| Lab043 | 5 | 11.5 | 14.0 | 19 | 1.1 | 7.9 | 37.5 | 20 | -0.2 | 4.5 | 5.2 | 19 | 0.3 | 5.8 | 27.1 | 20 | 0.8 |
| Total | - | - | 15.1 | 185 | 1.4 | 9.3 | - | - | - | - | 5.3 | 185 | 0.5 | 9.4 | - | - | - |

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 (2018/05) | | | | | | | | CUM (2016/02/01~2018/05/31) | | | | | | | |
| 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 | 15.7 | 8 | 0.7 | 4.5 | 8.9 | 20 | 4.4 | 15.7 | 16.1 | 37 | 0.8 | 5.0 | 12.5 | 20 | 3.5 |
| Lab019 | 5 | 14.8 | 15.1 | 5 | 0.6 | 4.0 | 10.0 | 20 | 4.5 | 14.8 | 15.0 | 16 | 0.4 | 2.7 | 6.7 | 20 | >6 |
| Lab026 | 5 | 15.9 | 15.4 | 19 | 0.4 | 2.6 | 8.3 | 20 | >6 | 15.9 | 15.6 | 35 | 0.5 | 3.2 | 8.3 | 20 | 5.7 |
| Lab027 | 5 | 11.5 | 16.3 | 10 | 1.2 | 7.4 | 56.5 | 20 | -2.9 | 11.5 | 15.4 | 18 | 1.7 | 11.0 | 56.0 | 20 | -1.3 |
| 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 | 5 | 0.2 | 1.4 | 5.5 | 20 | >6 | 14.4 | 15.0 | 6 | 0.5 | 3.3 | 10.8 | 20 | 4.8 |
| Lab034 | 5 | 14.4 | 13.9 | 5 | 0.6 | 4.3 | 12.1 | 20 | 3.8 | 14.4 | 13.8 | 11 | 0.6 | 4.3 | 12.9 | 20 | 3.7 |
| Lab040 | 5 | 12.5 | 13.5 | 6 | 0.4 | 3.0 | 13.9 | 20 | 4.0 | 12.5 | 12.8 | 21 | 0.6 | 4.7 | 11.8 | 20 | 3.7 |
| Lab043 | 5 | 11.5 | 12.8 | 5 | 0.7 | 5.5 | 22.2 | 20 | 1.6 | 11.5 | 14.0 | 19 | 1.1 | 7.9 | 37.5 | 20 | -0.2 |
| Total | - | - | 15.0 | 63 | 1.2 | 8.0 | - | - | - | - | 15.1 | 185 | 1.4 | 9.3 | - | - | - |

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

Month : 2018 05 Change  Cumulative : from 2016 02 01 to 2018 05 31 Change

[TOP]

## Control D Month vs. Cumulative

| | | Control D (Lot No.: AE0909D) | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Month (2018/05) | | | | | | | | CUM (2016/02/01~2018/05/31) | | | | | | | |
| 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 | 5.6 | 8 | 0.2 | 3.6 | 7.1 | 20 | 5.6 | 5.6 | 5.7 | 37 | 0.3 | 5.3 | 12.3 | 20 | 3.4 |
| Lab019 | 5 | 3.4 | 5.3 | 5 | 0.2 | 3.8 | 63.4 | 20 | -9.4 | 3.4 | 5.2 | 16 | 0.2 | 3.8 | 60.6 | 20 | -8.7 |
| Lab026 | 5 | 5.8 | 5.3 | 19 | 0.3 | 5.7 | 19.9 | 20 | 2.0 | 5.8 | 5.1 | 35 | 0.7 | 13.7 | 39.5 | 20 | 0.6 |
| Lab027 | 5 | 4.5 | 5.6 | 10 | 0.4 | 7.1 | 38.7 | 20 | -0.6 | 4.5 | 5.4 | 18 | 0.4 | 7.4 | 34.8 | 20 | 0.0 |
| Lab032 | 5 | 5.8 | - | 0 | - | - | - | 20 | - | 5.8 | 5.7 | 22 | 0.4 | 7.0 | 15.8 | 20 | 2.6 |
| Lab033 | 5 | 5.8 | 5.3 | 5 | 0.1 | 1.9 | 12.4 | 20 | 6.0 | 5.8 | 5.3 | 6 | 0.2 | 3.8 | 16.2 | 20 | 3.0 |
| Lab034 | 5 | 5.8 | 5.0 | 5 | 0.2 | 4.0 | 21.8 | 20 | 1.6 | 5.8 | 4.9 | 11 | 0.2 | 4.1 | 23.7 | 20 | 1.1 |
| Lab040 | 5 | 4.5 | 4.8 | 6 | 0.2 | 4.2 | 15.0 | 20 | 3.2 | 4.5 | 4.6 | 21 | 0.3 | 6.5 | 15.3 | 20 | 2.7 |
| Lab043 | 5 | 4.5 | 5.0 | 5 | 0.1 | 2.0 | 15.1 | 20 | 4.4 | 4.5 | 5.2 | 19 | 0.3 | 5.8 | 27.1 | 20 | 0.8 |
| Total | - | - | 5.3 | 63 | 0.4 | 7.5 | - | - | - | - | 5.3 | 185 | 0.5 | 9.4 | - | - | - |

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

Month : 2018 05 Change  Cumulative : from 2016 02 01 to 2018 05 31 Change

[TOP]

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