

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

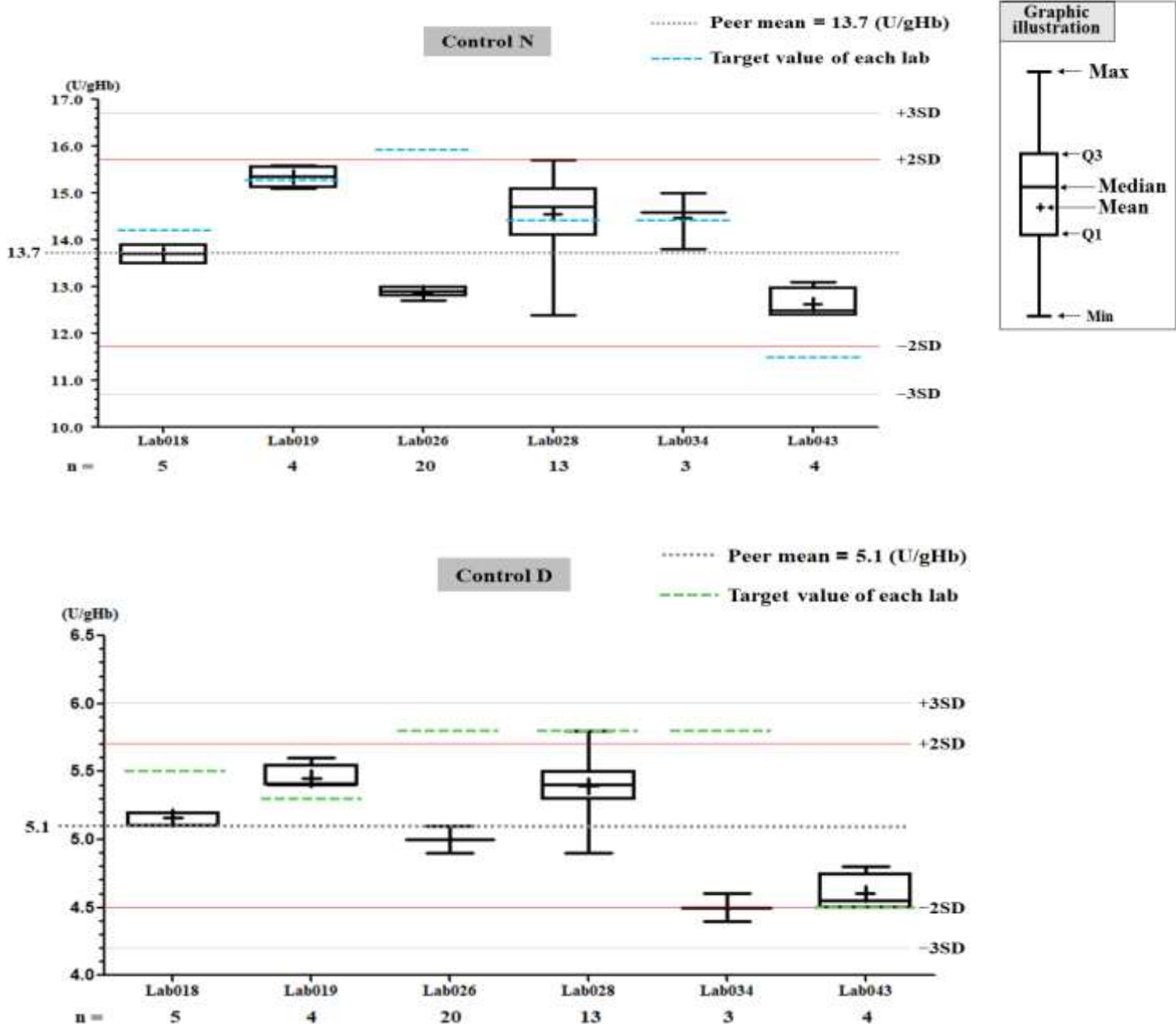
## I. The statistic results of all laboratories in this month

| G6PD                        | Control N<br>(Lot No.:AE0909N) | Control D<br>(Lot No.:AE0909D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs                        | 6                              | 6                              |
| Received results number (n) | 49                             | 49                             |
| Median                      | 13.1 (U/gHb)                   | 5.0 (U/gHb)                    |
| Mean                        | 13.7 (U/gHb)                   | 5.1 (U/gHb)                    |
| SD                          | 1.0                            | 0.3                            |
| CV                          | 7.3%                           | 5.9%                           |
| Range of G6PD               | 12.4 ~ 15.7 (U/gHb)            | 4.4 ~ 5.8 (U/gHb)              |
| Range of Hb                 | 1.0 ~ 2.8 (g/dL)               | 1.1 ~ 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](#)

## Lab028

| QC Control Lot No.        | Control N       |                             | Control D       |                             |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
|                           | AE0909N         |                             | AE0909D         |                             |
| Duration of the Analyzing | Month (2019/12) | CUM (2019/10/31~2019/12/31) | Month (2019/12) | CUM (2019/10/31~2019/12/31) |
| Runs (N)                  | 13              | 26                          | 13              | 26                          |
| Mean (U/gHb)              | 14.6            | 14.6                        | 5.4             | 5.4                         |
| SD                        | 0.9             | 0.7                         | 0.2             | 0.2                         |
| CV (%)                    | 6.2             | 4.8                         | 3.7             | 3.7                         |
| Target Value (U/gHb)      | 14.4            | 14.4                        | 5.8             | 5.8                         |
| Total Error (%)           | 13.7            | 11.0                        | 14.3            | 14.3                        |
| TEa (%)                   | 20              | 20                          | 20              | 20                          |
| $\sigma$                  | 3.0             | 3.9                         | 3.5             | 3.5                         |

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

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

$\sigma$  (Sigma) = [TEa% - Bias (%) ] / CV (%)

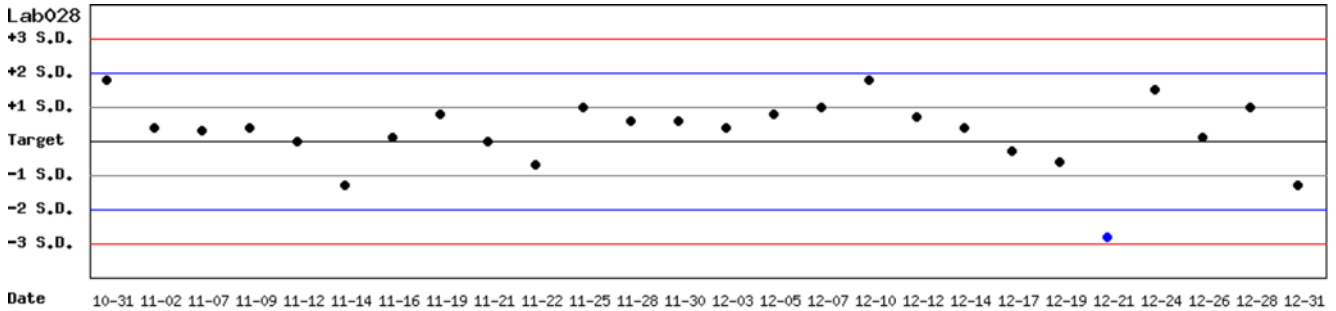
Month : 2019 12 [Change](#) ; Cumulative : from 2019 10 31 to 2019 12 31 [Change](#)

[\[TOP\]](#)

## Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-10-31 to 2019-12-31 ; Target : 14.4 ; SD : 0.72

Lab028



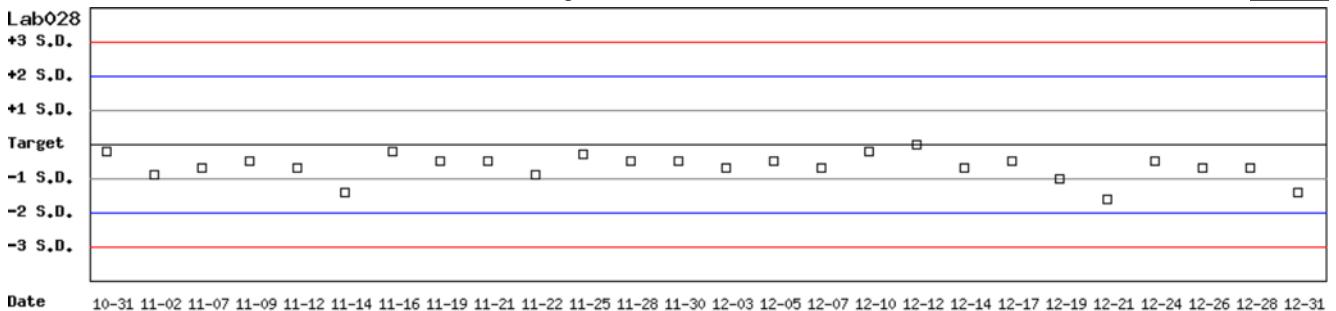
Month : 2019 12 [Change](#) ; Cumulative : from 2019 10 31 to 2019 12 31 [Change](#)

[\[TOP\]](#)

## Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2019-10-31 to 2019-12-31 ; Target : 5.8 ; SD : 0.58

Lab028



Month : 2019 12 [Change](#) ; Cumulative : from 2019 10 31 to 2019 12 31 [Change](#)

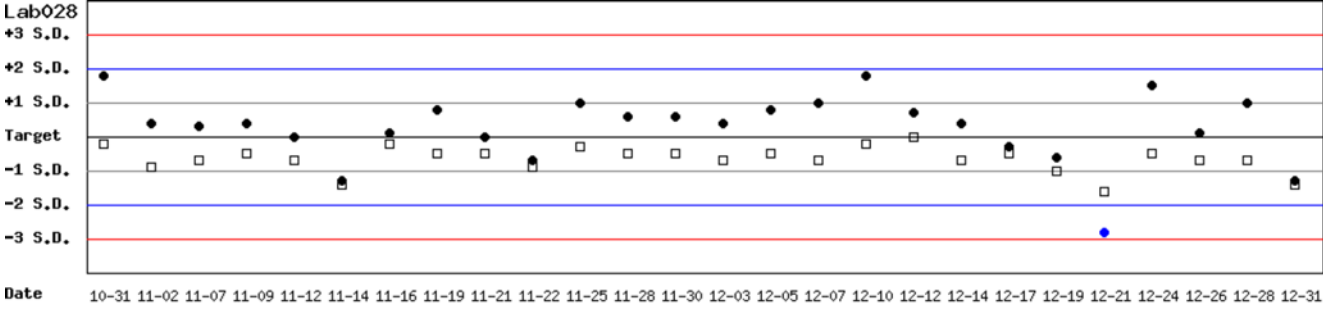
[\[TOP\]](#)

## Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-10-31 to 2019-12-31 ; Target : 14.4 ; SD : 0.72 (●)

Lot No.: AE0909D ; Duration : 2019-10-31 to 2019-12-31 ; Target : 5.8 ; SD : 0.58 (□)

Lab028



Month : 2019 | 12 |  ; Cumulative : from 2019 | 10 | 31 to 2019 | 12 | 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 : 2019 ▼ 12 ▼ Change

| UnitID                 | Reagent Kit<br>(Code) | Control N (Lot No.: AE0909N) |                 |               |     |           |           |            |     |                   | Control D (Lot No.: AE0909D) |               |     |           |           |            |      |  |
|------------------------|-----------------------|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|-------------------|------------------------------|---------------|-----|-----------|-----------|------------|------|--|
|                        |                       | Target<br>(U/gHb)            | Mean<br>(U/gHb) | n for<br>Mean | SD  | CV<br>(%) | TE<br>(%) | TEa<br>(%) | σ   | Target<br>(U/gHb) | Mean<br>(U/gHb)              | n for<br>Mean | SD  | CV<br>(%) | TE<br>(%) | TEa<br>(%) | σ    |  |
| <a href="#">Lab018</a> | 5                     | 14.2                         | 13.7            | 5             | 0.2 | 1.5       | 6.4       | 20         | >6  | 5.5               | 5.2                          | 5             | 0.1 | 1.9       | 9.3       | 20         | >6   |  |
| <a href="#">Lab019</a> | 5                     | 15.3                         | 15.4            | 4             | 0.2 | 1.3       | 3.3       | 20         | >6  | 5.3               | 5.5                          | 4             | 0.1 | 1.8       | 7.4       | 20         | >6   |  |
| <a href="#">Lab026</a> | 5                     | 15.9                         | 12.9            | 20            | 0.1 | 0.8       | 20.4      | 20         | 1.4 | 5.8               | 5.0                          | 20            | 0.0 | 0.0       | 13.8      | 20         | >6   |  |
| <a href="#">Lab028</a> | 5                     | 14.4                         | 14.6            | 13            | 0.9 | 6.2       | 13.7      | 20         | 3.0 | 5.8               | 5.4                          | 13            | 0.2 | 3.7       | 14.3      | 20         | 3.5  |  |
| <a href="#">Lab034</a> | 5                     | 14.4                         | 14.5            | 3             | 0.6 | 4.1       | 9.0       | 20         | 4.7 | 5.8               | 4.5                          | 3             | 0.1 | 2.2       | 26.9      | 20         | -1.1 |  |
| <a href="#">Lab043</a> | 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                  | -                     | -                            | 13.7            | 49            | 1.0 | 7.3       | -         | -          | -   | -                 | 5.1                          | 49            | 0.3 | 5.9       | -         | -          | -    |  |

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

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

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

[TOP](#)

### Cumulative

Cumulative : from 2016 ▼ 02 ▼ 01 ▼ to 2019 ▼ 12 ▼ 31 ▼ Change

| UnitID                 | Reagent Kit<br>(Code) | Control N (Lot No.: AE0909N) |                 |               |     |           |           |            |     |                   | Control D (Lot No.: AE0909D) |               |     |           |           |            |     |  |
|------------------------|-----------------------|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|-------------------|------------------------------|---------------|-----|-----------|-----------|------------|-----|--|
|                        |                       | Target<br>(U/gHb)            | Mean<br>(U/gHb) | n for<br>Mean | SD  | CV<br>(%) | TE<br>(%) | TEa<br>(%) | σ   | Target<br>(U/gHb) | Mean<br>(U/gHb)              | n for<br>Mean | SD  | CV<br>(%) | TE<br>(%) | TEa<br>(%) | σ   |  |
| <a href="#">Lab018</a> | 5                     | 14.2                         | 14.9            | 142           | 1.2 | 8.1       | 21.0      | 20         | 1.9 | 5.5               | 5.5                          | 142           | 0.3 | 5.5       | 10.9      | 20         | 3.6 |  |
| <a href="#">Lab019</a> | 5                     | 15.3                         | 15.2            | 94            | 0.3 | 2.0       | 4.6       | 20         | >6  | 5.3               | 5.3                          | 94            | 0.1 | 1.9       | 3.8       | 20         | >6  |  |
| <a href="#">Lab020</a> | 5                     | 14.4                         | 15.2            | 28            | 0.5 | 3.3       | 12.1      | 20         | 4.4 | 5.8               | 5.3                          | 28            | 0.3 | 5.7       | 19.9      | 20         | 2.0 |  |
| <a href="#">Lab026</a> | 5                     | 15.9                         | 13.7            | 295           | 1.4 | 10.2      | 34.3      | 20         | 0.6 | 5.8               | 5.1                          | 295           | 0.4 | 7.8       | 27.8      | 20         | 1.0 |  |
| <a href="#">Lab027</a> | 5                     | 15.5                         | 15.5            | 107           | 1.3 | 8.4       | 16.8      | 20         | 2.4 | 5.4               | 5.6                          | 107           | 0.5 | 8.9       | 21.6      | 20         | 1.8 |  |
| <a href="#">Lab028</a> | 5                     | 14.4                         | 14.6            | 121           | 0.7 | 4.8       | 11.0      | 20         | 3.9 | 5.8               | 5.6                          | 121           | 0.3 | 5.4       | 14.2      | 20         | 3.1 |  |
| <a href="#">Lab032</a> | 5                     | 15.3                         | 15.9            | 38            | 0.9 | 5.7       | 15.2      | 20         | 2.8 | 5.2               | 5.7                          | 38            | 0.3 | 5.3       | 20.1      | 20         | 2.0 |  |
| <a href="#">Lab033</a> | 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 |  |
| <a href="#">Lab034</a> | 5                     | 14.4                         | 14.4            | 73            | 0.8 | 5.6       | 11.1      | 20         | 3.6 | 5.8               | 5.1                          | 73            | 0.4 | 7.8       | 27.8      | 20         | 1.0 |  |
| <a href="#">Lab037</a> | 5                     | 14.9                         | 15.2            | 30            | 0.8 | 5.3       | 12.5      | 20         | 3.4 | 5.4               | 5.5                          | 30            | 0.3 | 5.5       | 12.8      | 20         | 3.3 |  |
| <a href="#">Lab040</a> | 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 |  |
| <a href="#">Lab043</a> | 5                     | 11.5                         | 13.1            | 84            | 0.9 | 6.9       | 27.7      | 20         | 0.9 | 4.5               | 4.9                          | 84            | 0.3 | 6.1       | 21.1      | 20         | 1.8 |  |
| Total                  | -                     | -                            | 14.5            | 1100          | 1.3 | 9.0       | -         | -          | -   | -                 | 5.3                          | 1100          | 0.4 | 7.5       | -         | -          | -   |  |

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

TE : Total Error(%) = Bias (%) + 2 x 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 (2019/12)              |              |            |     |        |        |         |     | CUM (2016/02/01~2019/12/31) |              |            |     |        |        |         |     |
| UnitID <input type="text"/> | Reagent Kit (Code) <input type="text"/> | 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   |
| <a href="#">Lab018</a>      | 5                                       | 14.2                         | 13.7         | 5          | 0.2 | 1.5    | 6.4    | 20      | >6  | 14.2                        | 14.9         | 142        | 1.2 | 8.1    | 21.0   | 20      | 1.9 |
| <a href="#">Lab019</a>      | 5                                       | 15.3                         | 15.4         | 4          | 0.2 | 1.3    | 3.3    | 20      | >6  | 15.3                        | 15.2         | 94         | 0.3 | 2.0    | 4.6    | 20      | >6  |
| <a href="#">Lab020</a>      | 5                                       | 14.4                         | -            | 0          | -   | -      | -      | 20      | -   | 14.4                        | 15.2         | 28         | 0.5 | 3.3    | 12.1   | 20      | 4.4 |
| <a href="#">Lab026</a>      | 5                                       | 15.9                         | 12.9         | 20         | 0.1 | 0.8    | 20.4   | 20      | 1.4 | 15.9                        | 13.7         | 295        | 1.4 | 10.2   | 34.3   | 20      | 0.6 |
| <a href="#">Lab027</a>      | 5                                       | 15.5                         | -            | 0          | -   | -      | -      | 20      | -   | 15.5                        | 15.5         | 107        | 1.3 | 8.4    | 16.8   | 20      | 2.4 |
| <a href="#">Lab028</a>      | 5                                       | 14.4                         | 14.6         | 13         | 0.9 | 6.2    | 13.7   | 20      | 3.0 | 14.4                        | 14.6         | 121        | 0.7 | 4.8    | 11.0   | 20      | 3.9 |
| <a href="#">Lab032</a>      | 5                                       | 15.3                         | -            | 0          | -   | -      | -      | 20      | -   | 15.3                        | 15.9         | 38         | 0.9 | 5.7    | 15.2   | 20      | 2.8 |
| <a href="#">Lab033</a>      | 5                                       | 14.4                         | -            | 0          | -   | -      | -      | 20      | -   | 14.4                        | 14.9         | 49         | 0.6 | 4.0    | 11.5   | 20      | 4.1 |
| <a href="#">Lab034</a>      | 5                                       | 14.4                         | 14.5         | 3          | 0.6 | 4.1    | 9.0    | 20      | 4.7 | 14.4                        | 14.4         | 73         | 0.8 | 5.6    | 11.1   | 20      | 3.6 |
| <a href="#">Lab037</a>      | 5                                       | 14.9                         | -            | 0          | -   | -      | -      | 20      | -   | 14.9                        | 15.2         | 30         | 0.8 | 5.3    | 12.5   | 20      | 3.4 |
| <a href="#">Lab040</a>      | 5                                       | 14.4                         | -            | 0          | -   | -      | -      | 20      | -   | 14.4                        | 13.3         | 39         | 0.7 | 5.3    | 18.2   | 20      | 2.3 |
| <a href="#">Lab043</a>      | 5                                       | 11.5                         | 12.6         | 4          | 0.3 | 2.4    | 14.3   | 20      | 4.3 | 11.5                        | 13.1         | 84         | 0.9 | 6.9    | 27.7   | 20      | 0.9 |
| Total                       | -                                       | -                            | 13.7         | 49         | 1.0 | 7.3    | -      | -       | -   | -                           | 14.5         | 1100       | 1.3 | 9.0    | -      | -       | -   |

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

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

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

Month : 2019 12 Change

Cumulative : from 2016 02 01 to 2019 12 31 Change

[TOP](#)

### Control D Month vs. Cumulative

|                             |   | Control D (Lot No.: AE0909D) |              |            |     |        |        |         |      |                             |              |            |     |        |        |         |     |
|-----------------------------|---|------------------------------|--------------|------------|-----|--------|--------|---------|------|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
|                             |   | Month (2019/12)              |              |            |     |        |        |         |      | CUM (2016/02/01~2019/12/31) |              |            |     |        |        |         |     |
| UnitID <input type="text"/> | Reagent Kit (Code) <input type="text"/> | 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   |
| <a href="#">Lab018</a>      | 5                                       | 5.5                          | 5.2          | 5          | 0.1 | 1.9    | 9.3    | 20      | >6   | 5.5                         | 5.5          | 142        | 0.3 | 5.5    | 10.9   | 20      | 3.6 |
| <a href="#">Lab019</a>      | 5                                       | 5.3                          | 5.5          | 4          | 0.1 | 1.8    | 7.4    | 20      | >6   | 5.3                         | 5.3          | 94         | 0.1 | 1.9    | 3.8    | 20      | >6  |
| <a href="#">Lab020</a>      | 5                                       | 5.8                          | -            | 0          | -   | -      | -      | 20      | -    | 5.8                         | 5.3          | 28         | 0.3 | 5.7    | 19.9   | 20      | 2.0 |
| <a href="#">Lab026</a>      | 5                                       | 5.8                          | 5.0          | 20         | 0.0 | 0.0    | 13.8   | 20      | >6   | 5.8                         | 5.1          | 295        | 0.4 | 7.8    | 27.8   | 20      | 1.0 |
| <a href="#">Lab027</a>      | 5                                       | 5.4                          | -            | 0          | -   | -      | -      | 20      | -    | 5.4                         | 5.6          | 107        | 0.5 | 8.9    | 21.6   | 20      | 1.8 |
| <a href="#">Lab028</a>      | 5                                       | 5.8                          | 5.4          | 13         | 0.2 | 3.7    | 14.3   | 20      | 3.5  | 5.8                         | 5.6          | 121        | 0.3 | 5.4    | 14.2   | 20      | 3.1 |
| <a href="#">Lab032</a>      | 5                                       | 5.2                          | -            | 0          | -   | -      | -      | 20      | -    | 5.2                         | 5.7          | 38         | 0.3 | 5.3    | 20.1   | 20      | 2.0 |
| <a href="#">Lab033</a>      | 5                                       | 5.8                          | -            | 0          | -   | -      | -      | 20      | -    | 5.8                         | 5.2          | 49         | 0.2 | 3.8    | 18.0   | 20      | 2.5 |
| <a href="#">Lab034</a>      | 5                                       | 5.8                          | 4.5          | 3          | 0.1 | 2.2    | 26.9   | 20      | -1.1 | 5.8                         | 5.1          | 73         | 0.4 | 7.8    | 27.8   | 20      | 1.0 |
| <a href="#">Lab037</a>      | 5                                       | 5.4                          | -            | 0          | -   | -      | -      | 20      | -    | 5.4                         | 5.5          | 30         | 0.3 | 5.5    | 12.8   | 20      | 3.3 |
| <a href="#">Lab040</a>      | 5                                       | 5.8                          | -            | 0          | -   | -      | -      | 20      | -    | 5.8                         | 4.7          | 39         | 0.3 | 6.4    | 31.7   | 20      | 0.2 |
| <a href="#">Lab043</a>      | 5                                       | 4.5                          | 4.6          | 4          | 0.1 | 2.2    | 6.6    | 20      | >6   | 4.5                         | 4.9          | 84         | 0.3 | 6.1    | 21.1   | 20      | 1.8 |
| Total                       | -                                       | -                            | 5.1          | 49         | 0.3 | 5.9    | -      | -       | -    | -                           | 5.3          | 1100       | 0.4 | 7.5    | -      | -       | -   |

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

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

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

Month : 2019 12 Change

Cumulative : from 2016 02 01 to 2019 12 31 Change

[TOP](#)

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