

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

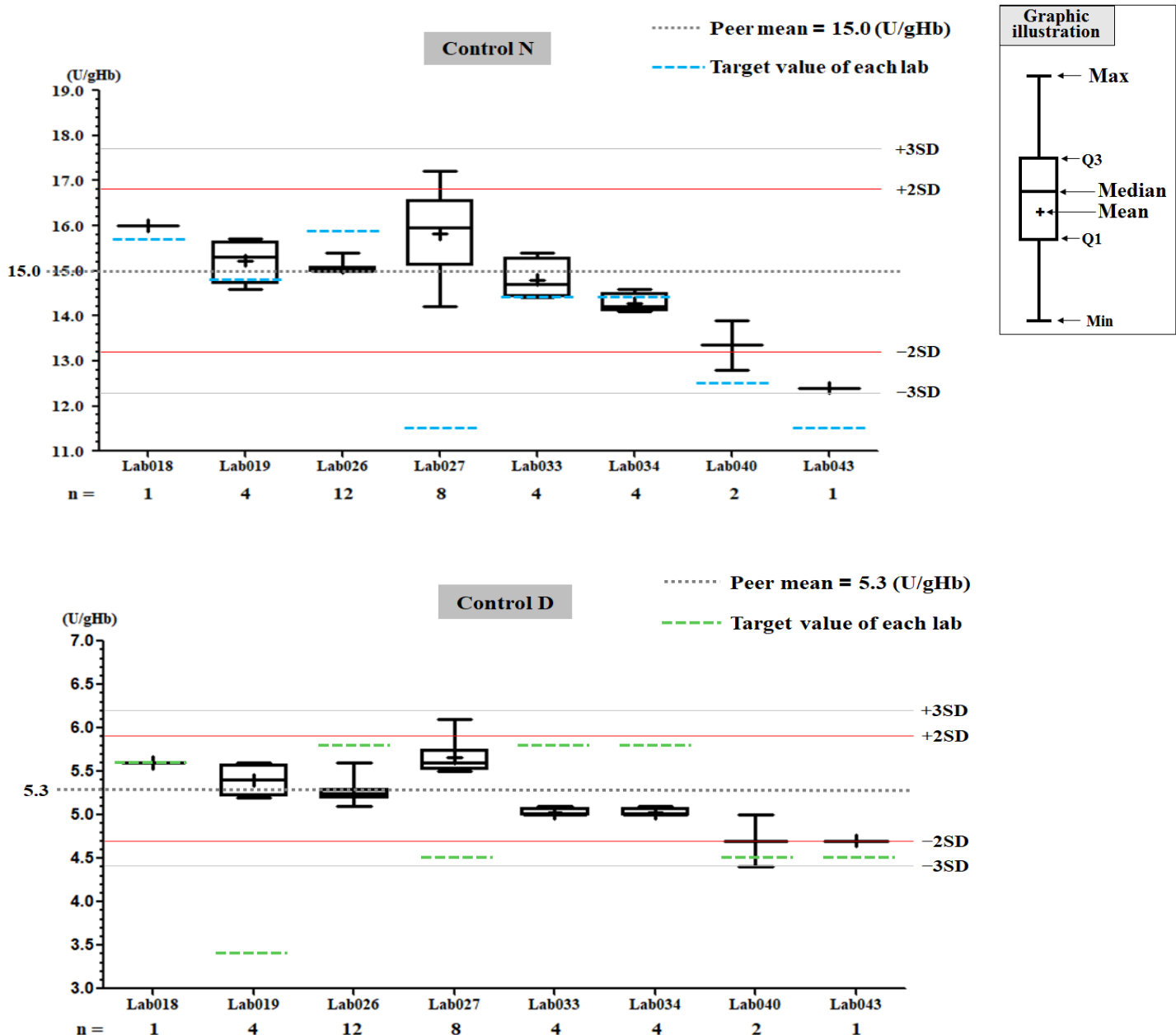
## I. The statistic results of all laboratories in this month

| G6PD                        | Control N<br>(Lot No.:AE0909N) | Control D<br>(Lot No.:AE0909D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs                        | 8                              | 8                              |
| Received results number (n) | 36                             | 36                             |
| Median                      | 15.0 (U/gHb)                   | 5.3 (U/gHb)                    |
| Mean                        | 15.0 (U/gHb)                   | 5.3 (U/gHb)                    |
| SD                          | 0.9                            | 0.3                            |
| CV                          | 6.0%                           | 5.7%                           |
| Range of G6PD               | 12.4 ~ 17.2 (U/gHb)            | 4.4 ~ 6.1 (U/gHb)              |
| Range of Hb                 | 1.4 ~ 2.4 (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](#)

## Lab034

| QC Control Lot No.        | Control N       |                             | Control D       |                             |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
|                           | AE0909N         |                             | AE0909D         |                             |
| Duration of the Analyzing | Month (2018/06) | CUM (2016/02/01~2018/06/30) | Month (2018/06) | CUM (2016/02/01~2018/06/30) |
| Runs (N)                  | 4               | 15                          | 4               | 15                          |
| Mean (U/gHb)              | 14.3            | 13.9                        | 5.0             | 4.9                         |
| SD                        | 0.2             | 0.6                         | 0.1             | 0.2                         |
| CV (%)                    | 1.4             | 4.3                         | 2.0             | 4.1                         |
| Target Value (U/gHb)      | 14.4            | 14.4                        | 5.8             | 5.8                         |
| Total Error (%)           | 3.5             | 12.1                        | 17.8            | 23.7                        |
| TEa (%)                   | 20              | 20                          | 20              | 20                          |
| $\sigma$                  | >6              | 3.8                         | 3.1             | 1.1                         |

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

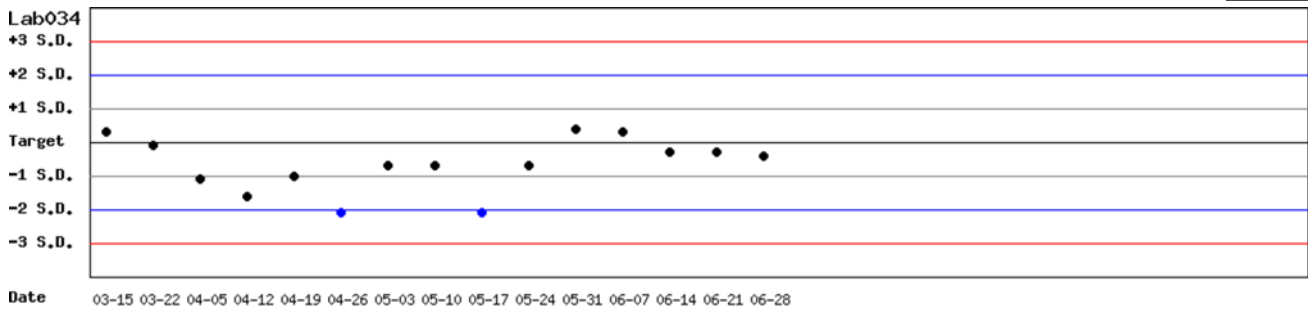
Month : 2018 06 [Change](#) ; Cumulative : from 2016 02 01 to 2018 06 30 [Change](#)

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## Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2018-06-30 ; Target : 14.4 ; SD : 0.70

Lab034



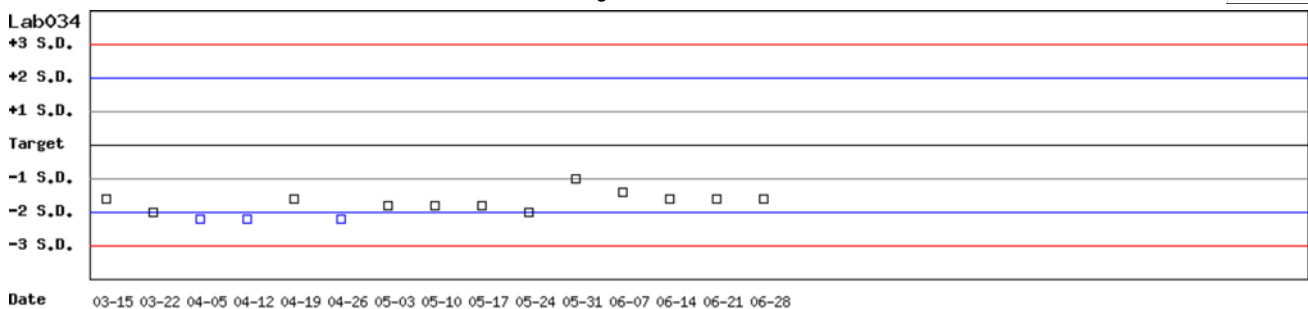
Month : 2018 06 [Change](#) ; Cumulative : from 2016 02 01 to 2018 06 30 [Change](#)

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## Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2016-02-01 to 2018-06-30 ; Target : 5.8 ; SD : 0.50

Lab034



Month : 2018 06 [Change](#) ; Cumulative : from 2016 02 01 to 2018 06 30 [Change](#)

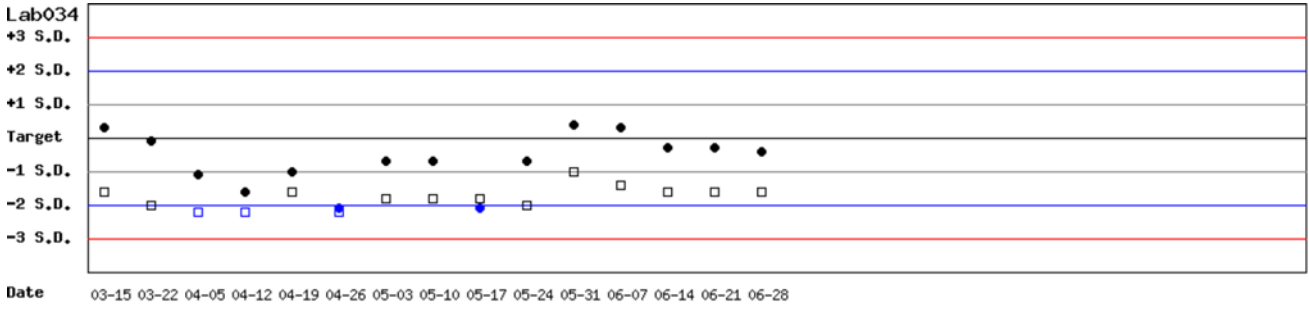
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## Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2018-06-30 ; Target : 14.4 ; SD : 0.70 (●)

Lot No.: AE0909D ; Duration : 2016-02-01 to 2018-06-30 ; Target : 5.8 ; SD : 0.50 (□)

Lab034



Month : 2018 06  ; Cumulative : from 2016 02 01 to 2018 06 30

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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 ▼ 06 ▼ Change

| UnitID <sup>†</sup>    | Reagent Kit<br>(Code) <sup>†</sup> | 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                                  | 15.7                         | 16.0            | 1             | -   | -         | -         | 20         | -    | 5.6                          | 5.6             | 1             | -   | -         | -         | 20         | -     |
| <a href="#">Lab019</a> | 5                                  | 14.8                         | 15.2            | 4             | 0.5 | 3.3       | 9.3       | 20         | 5.2  | 3.4                          | 5.4             | 4             | 0.2 | 3.7       | 66.2      | 20         | -10.5 |
| <a href="#">Lab026</a> | 5                                  | 15.9                         | 15.1            | 12            | 0.1 | 0.7       | 6.4       | 20         | >6   | 5.8                          | 5.3             | 12            | 0.2 | 3.8       | 16.2      | 20         | 3.0   |
| <a href="#">Lab027</a> | 5                                  | 11.5                         | 15.8            | 8             | 0.9 | 5.7       | 48.8      | 20         | -3.1 | 4.5                          | 5.7             | 8             | 0.2 | 3.5       | 33.7      | 20         | -1.9  |
| <a href="#">Lab033</a> | 5                                  | 14.4                         | 14.8            | 4             | 0.5 | 3.4       | 9.5       | 20         | 5.1  | 5.8                          | 5.0             | 4             | 0.1 | 2.0       | 17.8      | 20         | 3.1   |
| <a href="#">Lab034</a> | 5                                  | 14.4                         | 14.3            | 4             | 0.2 | 1.4       | 3.5       | 20         | >6   | 5.8                          | 5.0             | 4             | 0.1 | 2.0       | 17.8      | 20         | 3.1   |
| <a href="#">Lab040</a> | 5                                  | 12.5                         | 13.4            | 2             | -   | -         | -         | 20         | -    | 4.5                          | 4.7             | 2             | -   | -         | -         | 20         | -     |
| <a href="#">Lab043</a> | 5                                  | 11.5                         | 12.4            | 1             | -   | -         | -         | 20         | -    | 4.5                          | 4.7             | 1             | -   | -         | -         | 20         | -     |
| Total                  | -                                  | -                            | 15.0            | 36            | 0.9 | 6.0       | -         | -          | -    | -                            | 5.3             | 36            | 0.3 | 5.7       | -         | -          | -     |

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 ▼ 06 ▼ 30 ▼ Change

| UnitID <sup>†</sup>    | Reagent Kit<br>(Code) <sup>†</sup> | 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                                  | 15.7                         | 16.1            | 38            | 0.8 | 5.0       | 12.5      | 20         | 3.5  | 5.6                          | 5.7             | 38            | 0.3 | 5.3       | 12.3      | 20         | 3.4  |
| <a href="#">Lab019</a> | 5                                  | 14.8                         | 15.1            | 20            | 0.4 | 2.6       | 7.3       | 20         | >6   | 3.4                          | 5.3             | 20            | 0.2 | 3.8       | 63.4      | 20         | -9.4 |
| <a href="#">Lab026</a> | 5                                  | 15.9                         | 15.5            | 47            | 0.5 | 3.2       | 9.0       | 20         | 5.5  | 5.8                          | 5.2             | 47            | 0.6 | 11.5      | 33.4      | 20         | 0.8  |
| <a href="#">Lab027</a> | 5                                  | 11.5                         | 15.5            | 26            | 1.5 | 9.7       | 54.1      | 20         | -1.5 | 4.5                          | 5.5             | 26            | 0.4 | 7.3       | 36.8      | 20         | -0.3 |
| <a href="#">Lab032</a> | 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  |
| <a href="#">Lab033</a> | 5                                  | 14.4                         | 14.9            | 10            | 0.4 | 2.7       | 8.8       | 20         | >6   | 5.8                          | 5.2             | 10            | 0.2 | 3.8       | 18.0      | 20         | 2.5  |
| <a href="#">Lab034</a> | 5                                  | 14.4                         | 13.9            | 15            | 0.6 | 4.3       | 12.1      | 20         | 3.8  | 5.8                          | 4.9             | 15            | 0.2 | 4.1       | 23.7      | 20         | 1.1  |
| <a href="#">Lab040</a> | 5                                  | 12.5                         | 12.9            | 23            | 0.6 | 4.7       | 12.5      | 20         | 3.6  | 4.5                          | 4.6             | 23            | 0.3 | 6.5       | 15.3      | 20         | 2.7  |
| <a href="#">Lab043</a> | 5                                  | 11.5                         | 13.9            | 20            | 1.2 | 8.6       | 38.1      | 20         | -0.1 | 4.5                          | 5.2             | 20            | 0.3 | 5.8       | 27.1      | 20         | 0.8  |
| Total                  | -                                  | -                            | 15.0            | 221           | 1.3 | 8.7       | -         | -          | -    | -                            | 5.3             | 221           | 0.5 | 9.4       | -         | -          | -    |

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 :

Select Reagent Kit :

### Control N Month vs. Cumulative

|                         |                                     | Control N (Lot No.: AE0909N) |              |            |     |        |        |         |      |                             |              |            |     |        |        |         |      |
|-------------------------|-------------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|------|-----------------------------|--------------|------------|-----|--------|--------|---------|------|
|                         |                                     | Month (2018/06)              |              |            |     |        |        |         |      | CUM (2016/02/01~2018/06/30) |              |            |     |        |        |         |      |
| UnitID <small>↑</small> | Reagent Kit (Code) <small>↑</small> | 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                                   | 15.7                         | 16.0         | 1          | -   | -      | -      | 20      | -    | 15.7                        | 16.1         | 38         | 0.8 | 5.0    | 12.5   | 20      | 3.5  |
| <a href="#">Lab019</a>  | 5                                   | 14.8                         | 15.2         | 4          | 0.5 | 3.3    | 9.3    | 20      | 5.2  | 14.8                        | 15.1         | 20         | 0.4 | 2.6    | 7.3    | 20      | >6   |
| <a href="#">Lab026</a>  | 5                                   | 15.9                         | 15.1         | 12         | 0.1 | 0.7    | 6.4    | 20      | >6   | 15.9                        | 15.5         | 47         | 0.5 | 3.2    | 9.0    | 20      | 5.5  |
| <a href="#">Lab027</a>  | 5                                   | 11.5                         | 15.8         | 8          | 0.9 | 5.7    | 48.8   | 20      | -3.1 | 11.5                        | 15.5         | 26         | 1.5 | 9.7    | 54.1   | 20      | -1.5 |
| <a href="#">Lab032</a>  | 5                                   | 15.9                         | -            | 0          | -   | -      | -      | 20      | -    | 15.9                        | 15.8         | 22         | 1.0 | 6.3    | 13.3   | 20      | 3.1  |
| <a href="#">Lab033</a>  | 5                                   | 14.4                         | 14.8         | 4          | 0.5 | 3.4    | 9.5    | 20      | 5.1  | 14.4                        | 14.9         | 10         | 0.4 | 2.7    | 8.8    | 20      | >6   |
| <a href="#">Lab034</a>  | 5                                   | 14.4                         | 14.3         | 4          | 0.2 | 1.4    | 3.5    | 20      | >6   | 14.4                        | 13.9         | 15         | 0.6 | 4.3    | 12.1   | 20      | 3.8  |
| <a href="#">Lab040</a>  | 5                                   | 12.5                         | 13.4         | 2          | -   | -      | -      | 20      | -    | 12.5                        | 12.9         | 23         | 0.6 | 4.7    | 12.5   | 20      | 3.6  |
| <a href="#">Lab043</a>  | 5                                   | 11.5                         | 12.4         | 1          | -   | -      | -      | 20      | -    | 11.5                        | 13.9         | 20         | 1.2 | 8.6    | 38.1   | 20      | -0.1 |
| Total                   | -                                   | -                            | 15.0         | 36         | 0.9 | 6.0    | -      | -       | -    | -                           | 15.0         | 221        | 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 (2018/06)              |              |            |     |        |        |         |       | CUM (2016/02/01~2018/06/30) |              |            |     |        |        |         |      |
| UnitID <small>↑</small> | Reagent Kit (Code) <small>↑</small> | 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                                   | 5.6                          | 5.6          | 1          | -   | -      | -      | 20      | -     | 5.6                         | 5.7          | 38         | 0.3 | 5.3    | 12.3   | 20      | 3.4  |
| <a href="#">Lab019</a>  | 5                                   | 3.4                          | 5.4          | 4          | 0.2 | 3.7    | 66.2   | 20      | -10.5 | 3.4                         | 5.3          | 20         | 0.2 | 3.8    | 63.4   | 20      | -9.4 |
| <a href="#">Lab026</a>  | 5                                   | 5.8                          | 5.3          | 12         | 0.2 | 3.8    | 16.2   | 20      | 3.0   | 5.8                         | 5.2          | 47         | 0.6 | 11.5   | 33.4   | 20      | 0.8  |
| <a href="#">Lab027</a>  | 5                                   | 4.5                          | 5.7          | 8          | 0.2 | 3.5    | 33.7   | 20      | -1.9  | 4.5                         | 5.5          | 26         | 0.4 | 7.3    | 36.8   | 20      | -0.3 |
| <a href="#">Lab032</a>  | 5                                   | 5.8                          | -            | 0          | -   | -      | -      | 20      | -     | 5.8                         | 5.7          | 22         | 0.4 | 7.0    | 15.8   | 20      | 2.6  |
| <a href="#">Lab033</a>  | 5                                   | 5.8                          | 5.0          | 4          | 0.1 | 2.0    | 17.8   | 20      | 3.1   | 5.8                         | 5.2          | 10         | 0.2 | 3.8    | 18.0   | 20      | 2.5  |
| <a href="#">Lab034</a>  | 5                                   | 5.8                          | 5.0          | 4          | 0.1 | 2.0    | 17.8   | 20      | 3.1   | 5.8                         | 4.9          | 15         | 0.2 | 4.1    | 23.7   | 20      | 1.1  |
| <a href="#">Lab040</a>  | 5                                   | 4.5                          | 4.7          | 2          | -   | -      | -      | 20      | -     | 4.5                         | 4.6          | 23         | 0.3 | 6.5    | 15.3   | 20      | 2.7  |
| <a href="#">Lab043</a>  | 5                                   | 4.5                          | 4.7          | 1          | -   | -      | -      | 20      | -     | 4.5                         | 5.2          | 20         | 0.3 | 5.8    | 27.1   | 20      | 0.8  |
| Total                   | -                                   | -                            | 5.3          | 36         | 0.3 | 5.7    | -      | -       | -     | -                           | 5.3          | 221        | 0.5 | 9.4    | -      | -       | -    |

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            |