

# Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - October 2020 -

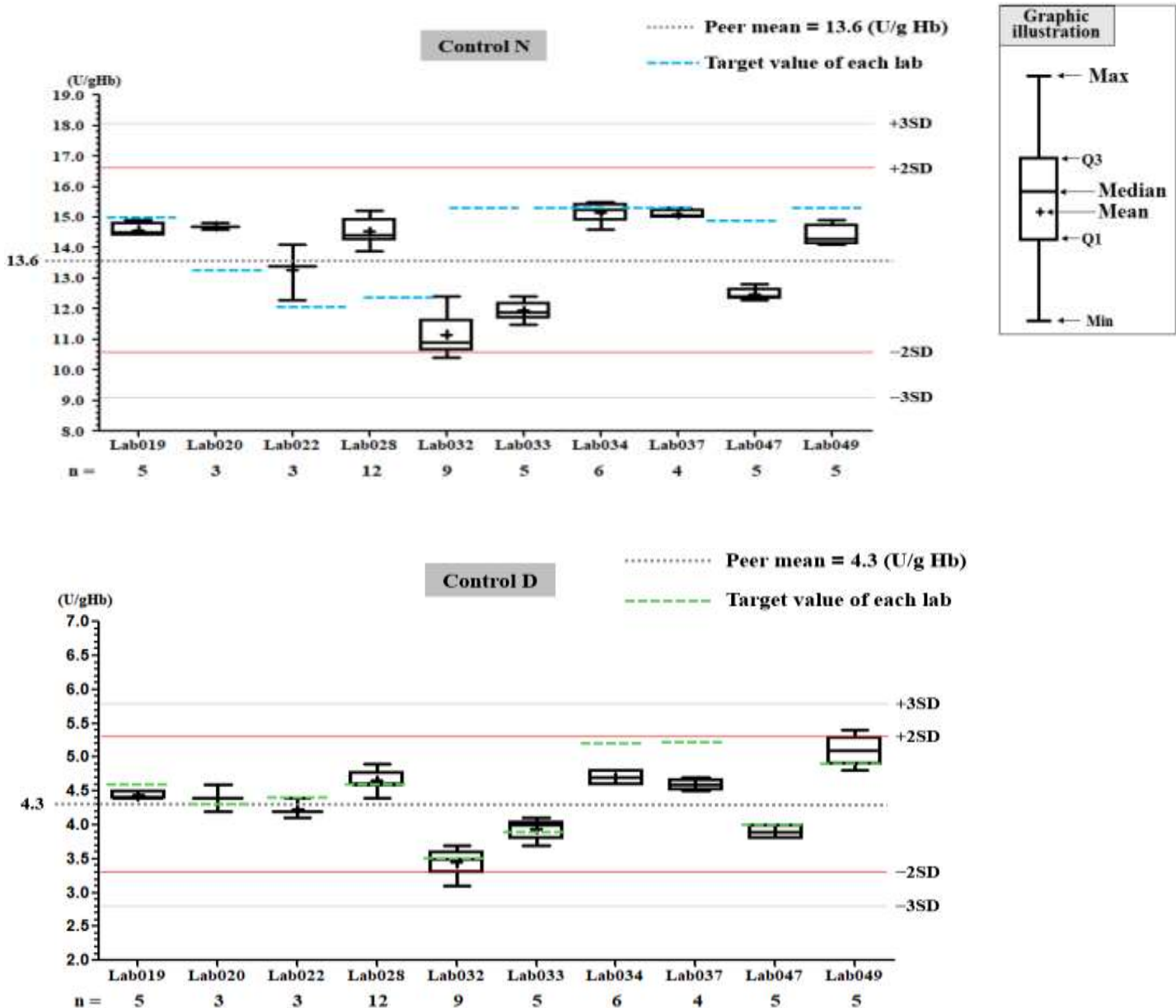
## I. The statistic results of all laboratories in this month

| G6PD                        | Control N<br>(Lot No.:AH1220N) | Control D<br>(Lot No.:AH1220D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs                        | 10                             | 10                             |
| Received results number (n) | 57                             | 57                             |
| Median                      | 14.4 (U/gHb)                   | 4.5 (U/gHb)                    |
| Mean                        | 13.6 (U/gHb)                   | 4.3 (U/gHb)                    |
| SD                          | 1.5                            | 0.5                            |
| CV                          | 11.0%                          | 11.6%                          |
| Range of G6PD               | 10.4 ~ 15.5 (U/gHb)            | 3.1 ~ 5.4 (U/gHb)              |
| Range of Hb                 | 1.9 ~ 2.5 (g/dL)               | 2.0 ~ 2.7 (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 : AH1220N (2019-01-28 ~ 2100-12-31)

## Lab034

|                           | Control N       |                             | Control D       |                             |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| QC Control Lot No.        | AH1220N         |                             | AH1220D         |                             |
| Duration of the Analyzing | Month (2020/10) | CUM (2020/07/30~2020/10/31) | Month (2020/10) | CUM (2020/07/30~2020/10/31) |
| Runs (N)                  | 6               | 17                          | 6               | 17                          |
| Mean (U/gHb)              | 15.2            | 15.4                        | 4.7             | 4.7                         |
| SD                        | 0.3             | 0.4                         | 0.1             | 0.1                         |
| CV (%)                    | 2.0             | 2.6                         | 2.1             | 2.1                         |
| Target Value (U/gHb)      | 15.3            | 15.3                        | 5.2             | 5.2                         |
| Total Error (%)           | 4.6             | 5.8                         | 13.9            | 13.9                        |
| TEa (%)                   | 20              | 20                          | 20              | 20                          |
| $\sigma$                  | >6              | >6                          | 4.9             | 4.9                         |

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

Month : 2020  10  ; Cumulative : from 2020  07  30  to 2020  10  31

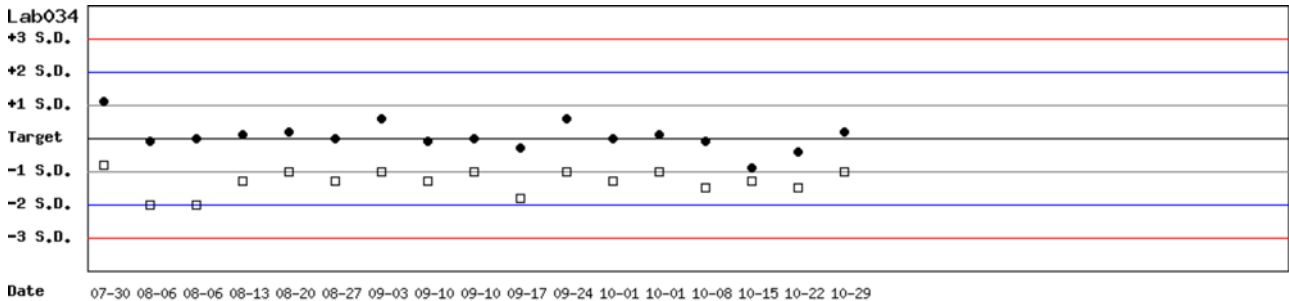
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## Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-07-30 to 2020-10-31 ; Target : 15.3 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2020-07-30 to 2020-10-31 ; Target : 5.2 ; SD : 0.4 (□)

Lab034



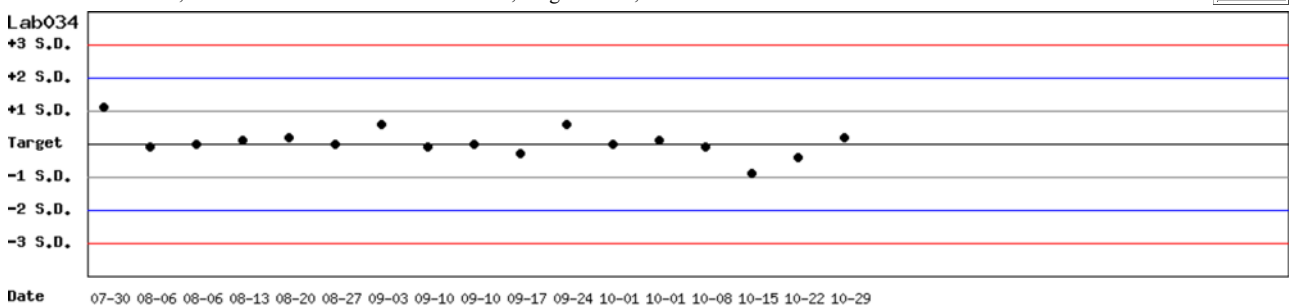
Month : 2020  10  ; Cumulative : from 2020  07  30  to 2020  10  31

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## Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-07-30 to 2020-10-31 ; Target : 15.3 ; SD : 0.8

Lab034



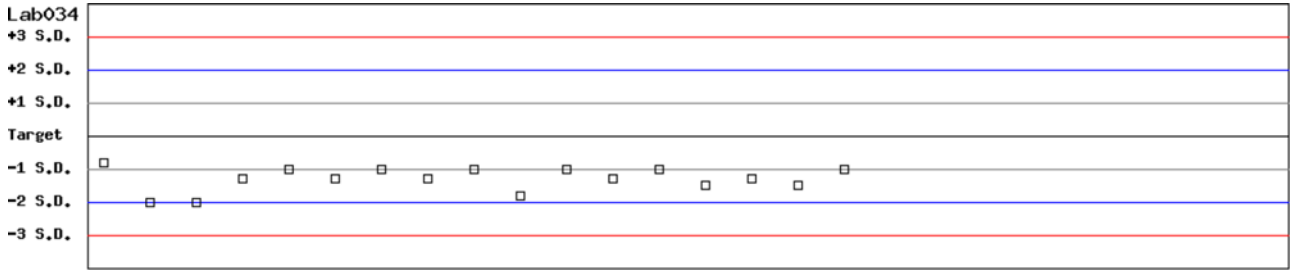
Month : 2020  10  ; Cumulative : from 2020  07  30  to 2020  10  31

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## Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-07-30 to 2020-10-31 ; Target : 5.2 ; SD : 0.4

Lab034



Date: 07-30 08-06 08-06 08-13 08-20 08-27 09-03 09-10 09-10 09-17 09-24 10-01 10-01 10-08 10-15 10-22 10-29

Month : 2020 ▾ 10 ▾ Change ; Cumulative : from 2020 ▾ 07 ▾ 30 ▾ to 2020 ▾ 10 ▾ 31 ▾ Change

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## Peer Group Statistics (Table 1)

Select LotNo : AH1220N (2019-01-28 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 1

### Monthly

Month : 2020 10 Change

| UnitID                 | Reagent Kit<br>(Code) | Control N (Lot No.: AH1220N) |                 |               |     |           |           |            |     | Control D (Lot No.: AH1220D) |                 |               |     |           |           |            |     |
|------------------------|-----------------------|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|
|                        |                       | 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="#">Lab019</a> | 5                     | 15.0                         | 14.6            | 5             | 0.2 | 1.4       | 5.4       | 20         | >6  | 4.6                          | 4.4             | 5             | 0.1 | 2.3       | 8.9       | 20         | >6  |
| <a href="#">Lab020</a> | 5                     | 13.3                         | 14.7            | 3             | 0.1 | 0.7       | 11.9      | 20         | >6  | 4.3                          | 4.4             | 3             | 0.2 | 4.5       | 11.4      | 20         | 3.9 |
| <a href="#">Lab022</a> | 5                     | 13.8                         | 13.3            | 3             | 0.9 | 6.8       | 17.2      | 20         | 2.4 | 4.4                          | 4.2             | 3             | 0.2 | 4.8       | 14.1      | 20         | 3.2 |
| <a href="#">Lab028</a> | 5                     | 14.6                         | 14.5            | 12            | 0.4 | 2.8       | 6.2       | 20         | >6  | 4.6                          | 4.7             | 12            | 0.1 | 2.1       | 6.4       | 20         | >6  |
| <a href="#">Lab032</a> | 5                     | 12.1                         | 11.2            | 9             | 0.7 | 6.3       | 19.9      | 20         | 2.0 | 3.5                          | 3.4             | 9             | 0.2 | 5.9       | 14.6      | 20         | 2.9 |
| <a href="#">Lab033</a> | 5                     | 12.4                         | 11.9            | 5             | 0.3 | 2.5       | 9.1       | 20         | >6  | 3.9                          | 3.9             | 5             | 0.2 | 5.1       | 10.3      | 20         | 3.9 |
| <a href="#">Lab034</a> | 5                     | 15.3                         | 15.2            | 6             | 0.3 | 2.0       | 4.6       | 20         | >6  | 5.2                          | 4.7             | 6             | 0.1 | 2.1       | 13.9      | 20         | 4.9 |
| <a href="#">Lab037</a> | 5                     | 15.3                         | 15.1            | 4             | 0.1 | 0.7       | 2.6       | 20         | >6  | 5.2                          | 4.6             | 4             | 0.1 | 2.2       | 15.9      | 20         | 3.8 |
| <a href="#">Lab047</a> | 5                     | 12.7                         | 12.5            | 5             | 0.2 | 1.6       | 4.8       | 20         | >6  | 4.0                          | 3.9             | 5             | 0.1 | 2.6       | 7.6       | 20         | >6  |
| <a href="#">Lab049</a> | 5                     | 14.7                         | 14.4            | 5             | 0.3 | 2.1       | 6.2       | 20         | >6  | 4.9                          | 5.1             | 5             | 0.2 | 3.9       | 11.9      | 20         | 4.1 |
| Total                  | -                     | -                            | 13.6            | 57            | 1.5 | 11.0      | -         | -          | -   | -                            | 4.3             | 57            | 0.5 | 11.6      | -         | -          | -   |

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

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

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

[TOP](#)

### Cumulative

Cumulative : from 2019 02 01 to 2020 10 31 Change

| UnitID                 | Reagent Kit<br>(Code) | Control N (Lot No.: AH1220N) |                 |               |     |           |           |            |     | Control D (Lot No.: AH1220D) |                 |               |     |           |           |            |     |
|------------------------|-----------------------|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|
|                        |                       | 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="#">Lab019</a> | 5                     | 15.0                         | 14.8            | 19            | 0.4 | 2.7       | 6.7       | 20         | >6  | 4.6                          | 4.5             | 19            | 0.1 | 2.2       | 6.6       | 20         | >6  |
| <a href="#">Lab020</a> | 5                     | 13.3                         | 14.5            | 29            | 1.2 | 8.3       | 25.6      | 20         | 1.3 | 4.3                          | 4.5             | 29            | 0.3 | 6.7       | 18.0      | 20         | 2.3 |
| <a href="#">Lab022</a> | 5                     | 13.8                         | 12.3            | 50            | 0.6 | 4.9       | 20.6      | 20         | 1.9 | 4.4                          | 4.0             | 50            | 0.2 | 5.0       | 19.1      | 20         | 2.2 |
| <a href="#">Lab028</a> | 5                     | 14.6                         | 14.6            | 22            | 0.4 | 2.7       | 5.5       | 20         | >6  | 4.6                          | 4.6             | 22            | 0.1 | 2.2       | 4.3       | 20         | >6  |
| <a href="#">Lab032</a> | 5                     | 12.1                         | 13.4            | 96            | 1.4 | 10.4      | 31.6      | 20         | 0.9 | 3.5                          | 4.2             | 96            | 0.6 | 14.3      | 48.6      | 20         | 0.0 |
| <a href="#">Lab033</a> | 5                     | 12.4                         | 12.5            | 78            | 0.4 | 3.2       | 7.2       | 20         | 6.0 | 3.9                          | 3.9             | 78            | 0.1 | 2.6       | 5.1       | 20         | >6  |
| <a href="#">Lab034</a> | 5                     | 15.3                         | 15.4            | 17            | 0.4 | 2.6       | 5.8       | 20         | >6  | 5.2                          | 4.7             | 17            | 0.1 | 2.1       | 13.9      | 20         | 4.9 |
| <a href="#">Lab037</a> | 5                     | 15.3                         | 15.2            | 34            | 0.3 | 2.0       | 4.6       | 20         | >6  | 5.2                          | 4.7             | 34            | 0.2 | 4.3       | 18.1      | 20         | 2.4 |
| <a href="#">Lab040</a> | 5                     | 15.3                         | 15.1            | 10            | 0.5 | 3.3       | 7.9       | 20         | 5.7 | 5.2                          | 5.6             | 10            | 0.4 | 7.1       | 22.0      | 20         | 1.7 |
| <a href="#">Lab047</a> | 5                     | 12.7                         | 12.5            | 5             | 0.2 | 1.6       | 4.8       | 20         | >6  | 4.0                          | 3.9             | 5             | 0.1 | 2.6       | 7.6       | 20         | >6  |
| <a href="#">Lab049</a> | 5                     | 14.7                         | 14.5            | 13            | 0.3 | 2.1       | 5.5       | 20         | >6  | 4.9                          | 5.1             | 13            | 0.3 | 5.9       | 15.8      | 20         | 2.7 |
| <a href="#">Lab050</a> | 5                     | 15.3                         | 14.6            | 6             | 0.8 | 5.5       | 15.5      | 20         | 2.8 | 5.2                          | 4.4             | 6             | 0.5 | 11.4      | 38.1      | 20         | 0.4 |
| Total                  | -                     | -                            | 13.6            | 379           | 1.4 | 10.3      | -         | -          | -   | -                            | 4.3             | 379           | 0.5 | 11.6      | -         | -          | -   |

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 : AH1220N (2019-01-28 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 2

### Control N Month vs. Cumulative

|                        |                    | Control N (Lot No.: AH1220N) |              |            |     |        |        |         |     |                             |              |            |     |        |        |         |     |
|------------------------|--------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
|                        |                    | Month (2020/10)              |              |            |     |        |        |         |     | CUM (2019/02/01~2020/10/31) |              |            |     |        |        |         |     |
| 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   |
| <a href="#">Lab019</a> | 5                  | 15.0                         | 14.6         | 5          | 0.2 | 1.4    | 5.4    | 20      | >6  | 15.0                        | 14.8         | 19         | 0.4 | 2.7    | 6.7    | 20      | >6  |
| <a href="#">Lab020</a> | 5                  | 13.3                         | 14.7         | 3          | 0.1 | 0.7    | 11.9   | 20      | >6  | 13.3                        | 14.5         | 29         | 1.2 | 8.3    | 25.6   | 20      | 1.3 |
| <a href="#">Lab022</a> | 5                  | 13.8                         | 13.3         | 3          | 0.9 | 6.8    | 17.2   | 20      | 2.4 | 13.8                        | 12.3         | 50         | 0.6 | 4.9    | 20.6   | 20      | 1.9 |
| <a href="#">Lab028</a> | 5                  | 14.6                         | 14.5         | 12         | 0.4 | 2.8    | 6.2    | 20      | >6  | 14.6                        | 14.6         | 22         | 0.4 | 2.7    | 5.5    | 20      | >6  |
| <a href="#">Lab032</a> | 5                  | 12.1                         | 11.2         | 9          | 0.7 | 6.3    | 19.9   | 20      | 2.0 | 12.1                        | 13.4         | 96         | 1.4 | 10.4   | 31.6   | 20      | 0.9 |
| <a href="#">Lab033</a> | 5                  | 12.4                         | 11.9         | 5          | 0.3 | 2.5    | 9.1    | 20      | >6  | 12.4                        | 12.5         | 78         | 0.4 | 3.2    | 7.2    | 20      | 6.0 |
| <a href="#">Lab034</a> | 5                  | 15.3                         | 15.2         | 6          | 0.3 | 2.0    | 4.6    | 20      | >6  | 15.3                        | 15.4         | 17         | 0.4 | 2.6    | 5.8    | 20      | >6  |
| <a href="#">Lab037</a> | 5                  | 15.3                         | 15.1         | 4          | 0.1 | 0.7    | 2.6    | 20      | >6  | 15.3                        | 15.2         | 34         | 0.3 | 2.0    | 4.6    | 20      | >6  |
| <a href="#">Lab040</a> | 5                  | 15.3                         | -            | 0          | -   | -      | -      | 20      | -   | 15.3                        | 15.1         | 10         | 0.5 | 3.3    | 7.9    | 20      | 5.7 |
| <a href="#">Lab047</a> | 5                  | 12.7                         | 12.5         | 5          | 0.2 | 1.6    | 4.8    | 20      | >6  | 12.7                        | 12.5         | 5          | 0.2 | 1.6    | 4.8    | 20      | >6  |
| <a href="#">Lab049</a> | 5                  | 14.7                         | 14.4         | 5          | 0.3 | 2.1    | 6.2    | 20      | >6  | 14.7                        | 14.5         | 13         | 0.3 | 2.1    | 5.5    | 20      | >6  |
| <a href="#">Lab050</a> | 5                  | 15.3                         | -            | 0          | -   | -      | -      | 20      | -   | 15.3                        | 14.6         | 6          | 0.8 | 5.5    | 15.5   | 20      | 2.8 |
| Total                  | -                  | -                            | 13.6         | 57         | 1.5 | 11.0   | -      | -       | -   | -                           | 13.6         | 379        | 1.4 | 10.3   | -      | -       | -   |

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

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

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

Month : 2020 10 Change

Cumulative : from 2019 02 01 to 2020 10 31 Change

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### Control D Month vs. Cumulative

|                        |                    | Control D (Lot No.: AH1220D) |              |            |     |        |        |         |     |                             |              |            |     |        |        |         |     |
|------------------------|--------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
|                        |                    | Month (2020/10)              |              |            |     |        |        |         |     | CUM (2019/02/01~2020/10/31) |              |            |     |        |        |         |     |
| 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   |
| <a href="#">Lab019</a> | 5                  | 4.6                          | 4.4          | 5          | 0.1 | 2.3    | 8.9    | 20      | >6  | 4.6                         | 4.5          | 19         | 0.1 | 2.2    | 6.6    | 20      | >6  |
| <a href="#">Lab020</a> | 5                  | 4.3                          | 4.4          | 3          | 0.2 | 4.5    | 11.4   | 20      | 3.9 | 4.3                         | 4.5          | 29         | 0.3 | 6.7    | 18.0   | 20      | 2.3 |
| <a href="#">Lab022</a> | 5                  | 4.4                          | 4.2          | 3          | 0.2 | 4.8    | 14.1   | 20      | 3.2 | 4.4                         | 4.0          | 50         | 0.2 | 5.0    | 19.1   | 20      | 2.2 |
| <a href="#">Lab028</a> | 5                  | 4.6                          | 4.7          | 12         | 0.1 | 2.1    | 6.4    | 20      | >6  | 4.6                         | 4.6          | 22         | 0.1 | 2.2    | 4.3    | 20      | >6  |
| <a href="#">Lab032</a> | 5                  | 3.5                          | 3.4          | 9          | 0.2 | 5.9    | 14.6   | 20      | 2.9 | 3.5                         | 4.2          | 96         | 0.6 | 14.3   | 48.6   | 20      | 0.0 |
| <a href="#">Lab033</a> | 5                  | 3.9                          | 3.9          | 5          | 0.2 | 5.1    | 10.3   | 20      | 3.9 | 3.9                         | 3.9          | 78         | 0.1 | 2.6    | 5.1    | 20      | >6  |
| <a href="#">Lab034</a> | 5                  | 5.2                          | 4.7          | 6          | 0.1 | 2.1    | 13.9   | 20      | 4.9 | 5.2                         | 4.7          | 17         | 0.1 | 2.1    | 13.9   | 20      | 4.9 |
| <a href="#">Lab037</a> | 5                  | 5.2                          | 4.6          | 4          | 0.1 | 2.2    | 15.9   | 20      | 3.8 | 5.2                         | 4.7          | 34         | 0.2 | 4.3    | 18.1   | 20      | 2.4 |
| <a href="#">Lab040</a> | 5                  | 5.2                          | -            | 0          | -   | -      | -      | 20      | -   | 5.2                         | 5.6          | 10         | 0.4 | 7.1    | 22.0   | 20      | 1.7 |
| <a href="#">Lab047</a> | 5                  | 4.0                          | 3.9          | 5          | 0.1 | 2.6    | 7.6    | 20      | >6  | 4.0                         | 3.9          | 5          | 0.1 | 2.6    | 7.6    | 20      | >6  |
| <a href="#">Lab049</a> | 5                  | 4.9                          | 5.1          | 5          | 0.2 | 3.9    | 11.9   | 20      | 4.1 | 4.9                         | 5.1          | 13         | 0.3 | 5.9    | 15.8   | 20      | 2.7 |
| <a href="#">Lab050</a> | 5                  | 5.2                          | -            | 0          | -   | -      | -      | 20      | -   | 5.2                         | 4.4          | 6          | 0.5 | 11.4   | 38.1   | 20      | 0.4 |
| Total                  | -                  | -                            | 4.3          | 57         | 0.5 | 11.6   | -      | -       | -   | -                           | 4.3          | 379        | 0.5 | 11.6   | -      | -       | -   |

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

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

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

Month : 2020 10 Change

Cumulative : from 2019 02 01 to 2020 10 31 Change

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