

# Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - July 2021 -

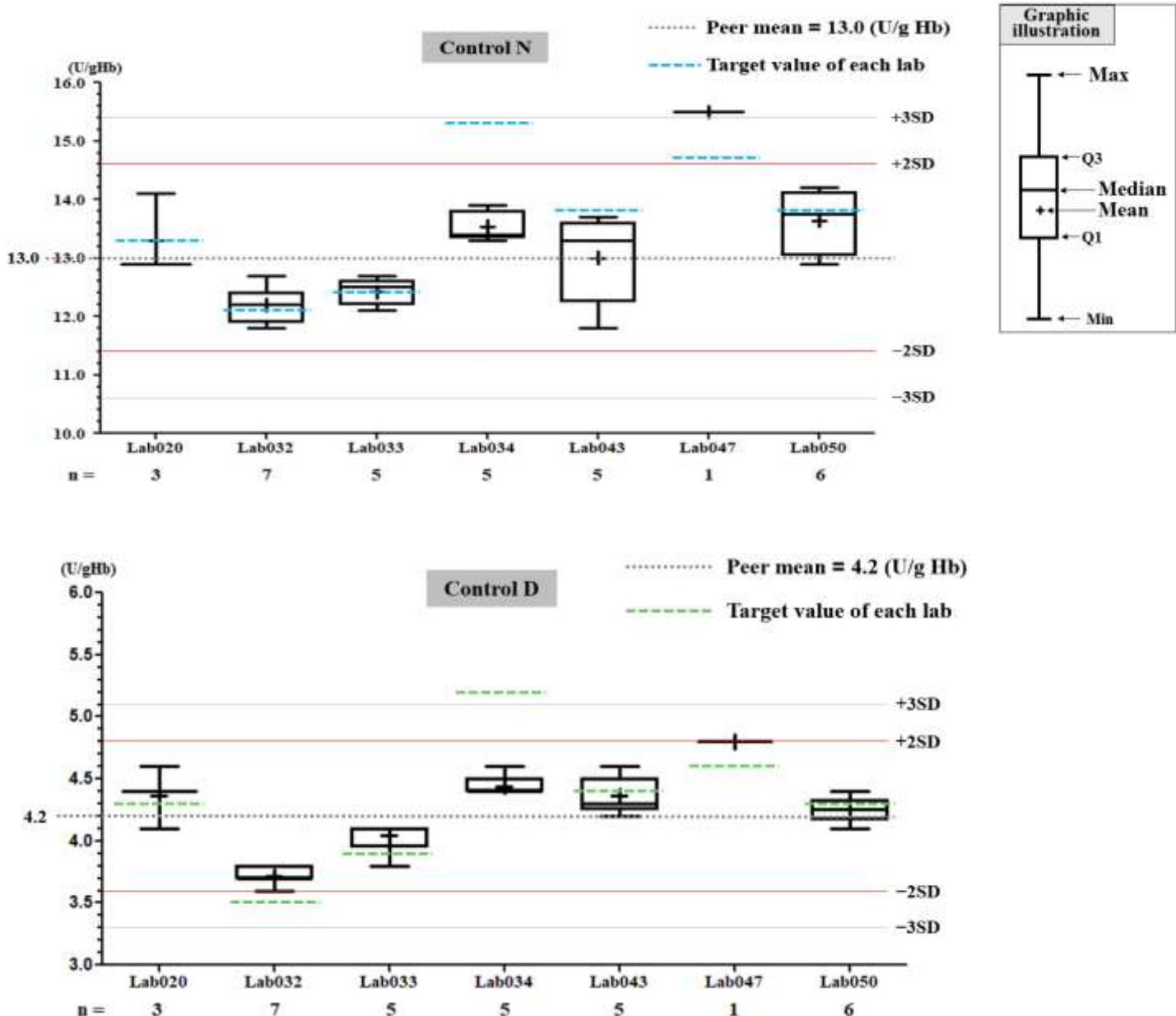
## I. The statistic results of all laboratories in this month

| G6PD                        | Control N<br>(Lot No.:AH1220N) | Control D<br>(Lot No.:AH1220D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs                        | 7                              | 7                              |
| Received results number (n) | 32                             | 32                             |
| Median                      | 12.9 (U/g Hb)                  | 4.2 (U/g Hb)                   |
| Mean                        | 13.0 (U/g Hb)                  | 4.2 (U/g Hb)                   |
| SD                          | 0.8                            | 0.3                            |
| CV                          | 6.2%                           | 7.1%                           |
| Range of G6PD               | 11.8 ~ 15.5 (U/g Hb)           | 3.6 ~ 4.8 (U/g Hb)             |
| Range of Hb                 | 1.9 ~ 2.8 (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) Change

Print Table

## Lab033

| QC Control Lot No.        | Control N       |                             | Control D       |                             |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
|                           | AH1220N         |                             | AH1220D         |                             |
| Duration of the Analyzing | Month (2021/07) | CUM (2021/02/04~2021/07/31) | Month (2021/07) | CUM (2021/02/04~2021/07/31) |
| Runs (N)                  | 5               | 26                          | 5               | 26                          |
| Mean (U/gHb)              | 12.4            | 12.4                        | 4.0             | 4.0                         |
| SD                        | 0.2             | 0.5                         | 0.1             | 0.1                         |
| CV (%)                    | 1.6             | 4.0                         | 2.5             | 2.5                         |
| Target Value (U/gHb)      | 12.4            | 12.4                        | 3.9             | 3.9                         |
| Total Error (%)           | 3.2             | 8.1                         | 7.6             | 7.6                         |
| TEa (%)                   | 20              | 20                          | 20              | 20                          |
| $\sigma$                  | >6              | 5.0                         | >6              | >6                          |

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

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

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

Month : 2021 07 Change ; Cumulative : from 2021 02 04 to 2021 07 31 Change

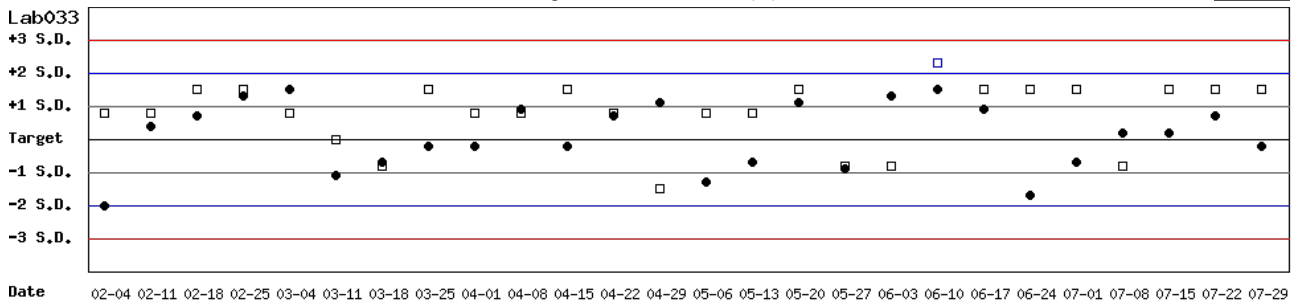
[\[TOP\]](#)

## Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-02-04 to 2021-07-31 ; Target : 12.4 ; SD : 0.46 ( ● )

Lot No.: AH1220D ; Duration : 2021-02-04 to 2021-07-31 ; Target : 3.9 ; SD : 0.13 ( □ )

Lab033



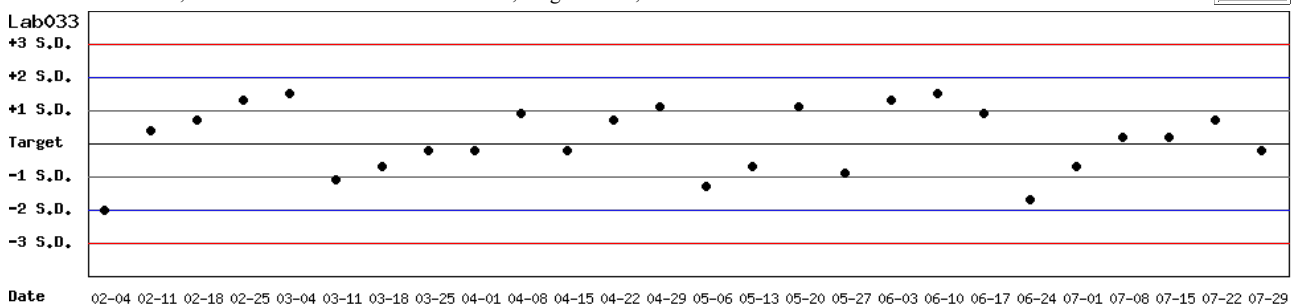
Month : 2021 07 Change ; Cumulative : from 2021 02 04 to 2021 07 31 Change

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## Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-02-04 to 2021-07-31 ; Target : 12.4 ; SD : 0.46

Lab033



Month : 2021 07 Change ; Cumulative : from 2021 02 04 to 2021 07 31 Change

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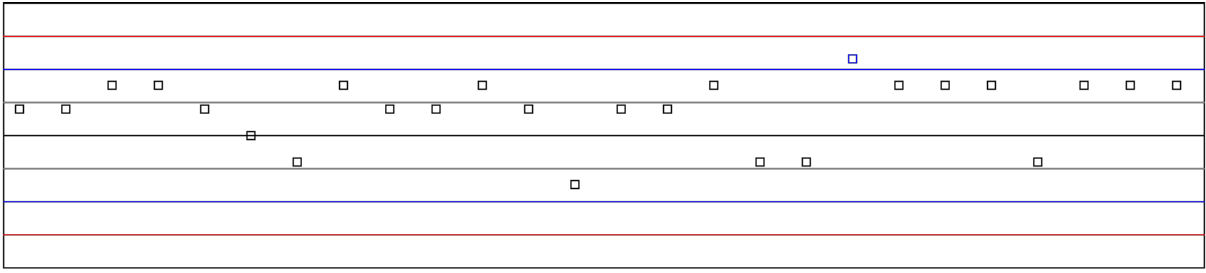
# Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2021-02-04 to 2021-07-31 ; Target : 3.9 ; SD : 0.13

Lab033

Lab033

+3 S.D.  
+2 S.D.  
+1 S.D.  
Target  
-1 S.D.  
-2 S.D.  
-3 S.D.



Date 02-04 02-11 02-18 02-25 03-04 03-11 03-18 03-25 04-01 04-08 04-15 04-22 04-29 05-06 05-13 05-20 05-27 06-03 06-10 06-17 06-24 07-01 07-08 07-15 07-22 07-29

Month : 2021 07 Change ; Cumulative : from 2021 02 04 to 2021 07 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 : 2021 07 Change

| UnitID <small>↑</small> | Reagent Kit<br>(Code) <small>↑</small> | 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="#">Lab020</a>  | 5                                      | 13.3                         | 13.3            | 3             | 0.7 | 5.3       | 10.5      | 20         | 3.8 | 4.3                          | 4.4             | 3             | 0.3 | 6.8       | 16.0      | 20         | 2.6 |
| <a href="#">Lab032</a>  | 5                                      | 12.1                         | 12.2            | 7             | 0.3 | 2.5       | 5.7       | 20         | >6  | 3.5                          | 3.7             | 7             | 0.1 | 2.7       | 11.1      | 20         | 5.3 |
| <a href="#">Lab033</a>  | 5                                      | 12.4                         | 12.4            | 5             | 0.2 | 1.6       | 3.2       | 20         | >6  | 3.9                          | 4.0             | 5             | 0.1 | 2.5       | 7.6       | 20         | >6  |
| <a href="#">Lab034</a>  | 5                                      | 15.3                         | 13.5            | 5             | 0.3 | 2.2       | 16.2      | 20         | 3.7 | 5.2                          | 4.4             | 5             | 0.1 | 2.3       | 19.9      | 20         | 2.0 |
| <a href="#">Lab043</a>  | 5                                      | 13.8                         | 13.0            | 5             | 0.8 | 6.2       | 18.1      | 20         | 2.3 | 4.4                          | 4.4             | 5             | 0.2 | 4.5       | 9.1       | 20         | 4.4 |
| <a href="#">Lab047</a>  | 5                                      | 14.7                         | 15.5            | 1             | -   | -         | -         | 20         | -   | 4.6                          | 4.8             | 1             | -   | -         | -         | 20         | -   |
| <a href="#">Lab050</a>  | 5                                      | 13.8                         | 13.6            | 6             | 0.5 | 3.7       | 8.8       | 20         | 5.0 | 4.3                          | 4.3             | 6             | 0.1 | 2.3       | 4.7       | 20         | >6  |
| Total                   | -                                      | -                            | 13.0            | 32            | 0.8 | 6.2       | -         | -          | -   | -                            | 4.2             | 32            | 0.3 | 7.1       | -         | -          | -   |

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 2021 07 31 Change

| UnitID <small>↑</small> | Reagent Kit<br>(Code) <small>↑</small> | 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                                      | 14.6                         | 14.6            | 53            | 0.3 | 2.1       | 4.1       | 20         | >6  | 4.4                          | 4.4             | 53            | 0.1 | 2.3       | 4.5       | 20         | >6  |
| <a href="#">Lab020</a>  | 5                                      | 13.3                         | 14.3            | 62            | 1.0 | 7.0       | 21.5      | 20         | 1.8 | 4.3                          | 4.5             | 62            | 0.2 | 4.4       | 13.5      | 20         | 3.5 |
| <a href="#">Lab022</a>  | 5                                      | 13.8                         | 12.6            | 67            | 0.8 | 6.3       | 21.4      | 20         | 1.8 | 4.4                          | 4.1             | 67            | 0.2 | 4.9       | 16.6      | 20         | 2.7 |
| <a href="#">Lab028</a>  | 5                                      | 14.6                         | 14.6            | 53            | 0.4 | 2.7       | 5.5       | 20         | >6  | 4.6                          | 4.6             | 53            | 0.2 | 4.3       | 8.7       | 20         | 4.7 |
| <a href="#">Lab032</a>  | 5                                      | 12.1                         | 12.9            | 136           | 1.4 | 10.9      | 28.3      | 20         | 1.2 | 3.5                          | 4.0             | 136           | 0.5 | 12.5      | 39.3      | 20         | 0.5 |
| <a href="#">Lab033</a>  | 5                                      | 12.4                         | 12.5            | 117           | 0.4 | 3.2       | 7.2       | 20         | 6.0 | 3.9                          | 3.9             | 117           | 0.2 | 5.1       | 10.3      | 20         | 3.9 |
| <a href="#">Lab034</a>  | 5                                      | 15.3                         | 14.6            | 56            | 1.1 | 7.5       | 19.6      | 20         | 2.1 | 5.2                          | 4.6             | 56            | 0.2 | 4.3       | 20.2      | 20         | 2.0 |
| <a href="#">Lab037</a>  | 5                                      | 15.3                         | 15.2            | 55            | 0.4 | 2.6       | 5.9       | 20         | >6  | 5.2                          | 4.7             | 55            | 0.2 | 4.3       | 18.1      | 20         | 2.4 |
| <a href="#">Lab040</a>  | 5                                      | 15.3                         | 15.0            | 15            | 0.4 | 2.7       | 7.3       | 20         | >6  | 5.2                          | 5.4             | 15            | 0.4 | 7.4       | 18.7      | 20         | 2.2 |
| <a href="#">Lab043</a>  | 5                                      | 13.8                         | 13.0            | 12            | 0.5 | 3.8       | 13.5      | 20         | 3.7 | 4.4                          | 4.3             | 12            | 0.2 | 4.7       | 11.6      | 20         | 3.8 |
| <a href="#">Lab047</a>  | 5                                      | 14.7                         | 13.7            | 26            | 1.2 | 8.8       | 24.3      | 20         | 1.5 | 4.6                          | 4.3             | 26            | 0.3 | 7.0       | 20.5      | 20         | 1.9 |
| <a href="#">Lab049</a>  | 5                                      | 14.7                         | 14.3            | 42            | 0.5 | 3.5       | 9.7       | 20         | 4.9 | 4.9                          | 4.7             | 42            | 0.3 | 6.4       | 16.8      | 20         | 2.5 |
| <a href="#">Lab050</a>  | 5                                      | 13.8                         | 14.0            | 39            | 0.6 | 4.3       | 10.0      | 20         | 4.3 | 4.3                          | 4.4             | 39            | 0.2 | 4.5       | 11.4      | 20         | 3.9 |
| Total                   | -                                      | -                            | 13.7            | 733           | 1.3 | 9.5       | -         | -          | -   | -                            | 4.3             | 733           | 0.4 | 9.3       | -         | -          | -   |

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 : 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 (2021/07)              |              |            |     |        |        |         |     | CUM (2019/02/01~2021/07/31) |              |            |     |        |        |         |     |
| 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="#">Lab019</a>  | 5                                   | 14.6                         | -            | 0          | -   | -      | -      | 20      | -   | 14.6                        | 14.6         | 53         | 0.3 | 2.1    | 4.1    | 20      | >6  |
| <a href="#">Lab020</a>  | 5                                   | 13.3                         | 13.3         | 3          | 0.7 | 5.3    | 10.5   | 20      | 3.8 | 13.3                        | 14.3         | 62         | 1.0 | 7.0    | 21.5   | 20      | 1.8 |
| <a href="#">Lab022</a>  | 5                                   | 13.8                         | -            | 0          | -   | -      | -      | 20      | -   | 13.8                        | 12.6         | 67         | 0.8 | 6.3    | 21.4   | 20      | 1.8 |
| <a href="#">Lab028</a>  | 5                                   | 14.6                         | -            | 0          | -   | -      | -      | 20      | -   | 14.6                        | 14.6         | 53         | 0.4 | 2.7    | 5.5    | 20      | >6  |
| <a href="#">Lab032</a>  | 5                                   | 12.1                         | 12.2         | 7          | 0.3 | 2.5    | 5.7    | 20      | >6  | 12.1                        | 12.9         | 136        | 1.4 | 10.9   | 28.3   | 20      | 1.2 |
| <a href="#">Lab033</a>  | 5                                   | 12.4                         | 12.4         | 5          | 0.2 | 1.6    | 3.2    | 20      | >6  | 12.4                        | 12.5         | 117        | 0.4 | 3.2    | 7.2    | 20      | 6.0 |
| <a href="#">Lab034</a>  | 5                                   | 15.3                         | 13.5         | 5          | 0.3 | 2.2    | 16.2   | 20      | 3.7 | 15.3                        | 14.6         | 56         | 1.1 | 7.5    | 19.6   | 20      | 2.1 |
| <a href="#">Lab037</a>  | 5                                   | 15.3                         | -            | 0          | -   | -      | -      | 20      | -   | 15.3                        | 15.2         | 55         | 0.4 | 2.6    | 5.9    | 20      | >6  |
| <a href="#">Lab040</a>  | 5                                   | 15.3                         | -            | 0          | -   | -      | -      | 20      | -   | 15.3                        | 15.0         | 15         | 0.4 | 2.7    | 7.3    | 20      | >6  |
| <a href="#">Lab043</a>  | 5                                   | 13.8                         | 13.0         | 5          | 0.8 | 6.2    | 18.1   | 20      | 2.3 | 13.8                        | 13.0         | 12         | 0.5 | 3.8    | 13.5   | 20      | 3.7 |
| <a href="#">Lab047</a>  | 5                                   | 14.7                         | 15.5         | 1          | -   | -      | -      | 20      | -   | 14.7                        | 13.7         | 26         | 1.2 | 8.8    | 24.3   | 20      | 1.5 |
| <a href="#">Lab049</a>  | 5                                   | 14.7                         | -            | 0          | -   | -      | -      | 20      | -   | 14.7                        | 14.3         | 42         | 0.5 | 3.5    | 9.7    | 20      | 4.9 |
| <a href="#">Lab050</a>  | 5                                   | 13.8                         | 13.6         | 6          | 0.5 | 3.7    | 8.8    | 20      | 5.0 | 13.8                        | 14.0         | 39         | 0.6 | 4.3    | 10.0   | 20      | 4.3 |
| Total                   | -                                   | -                            | 13.0         | 32         | 0.8 | 6.2    | -      | -       | -   | -                           | 13.7         | 733        | 1.3 | 9.5    | -      | -       | -   |

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

Month : 2021 07 Change

Cumulative : from 2019 02 01 to 2021 07 31 Change

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### Control D Month vs. Cumulative

|                         |                                     | Control D (Lot No.: AH1220D) |              |            |     |        |        |         |     |                             |              |            |     |        |        |         |     |
|-------------------------|-------------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
|                         |                                     | Month (2021/07)              |              |            |     |        |        |         |     | CUM (2019/02/01~2021/07/31) |              |            |     |        |        |         |     |
| 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="#">Lab019</a>  | 5                                   | 4.4                          | -            | 0          | -   | -      | -      | 20      | -   | 4.4                         | 4.4          | 53         | 0.1 | 2.3    | 4.5    | 20      | >6  |
| <a href="#">Lab020</a>  | 5                                   | 4.3                          | 4.4          | 3          | 0.3 | 6.8    | 16.0   | 20      | 2.6 | 4.3                         | 4.5          | 62         | 0.2 | 4.4    | 13.5   | 20      | 3.5 |
| <a href="#">Lab022</a>  | 5                                   | 4.4                          | -            | 0          | -   | -      | -      | 20      | -   | 4.4                         | 4.1          | 67         | 0.2 | 4.9    | 16.6   | 20      | 2.7 |
| <a href="#">Lab028</a>  | 5                                   | 4.6                          | -            | 0          | -   | -      | -      | 20      | -   | 4.6                         | 4.6          | 53         | 0.2 | 4.3    | 8.7    | 20      | 4.7 |
| <a href="#">Lab032</a>  | 5                                   | 3.5                          | 3.7          | 7          | 0.1 | 2.7    | 11.1   | 20      | 5.3 | 3.5                         | 4.0          | 136        | 0.5 | 12.5   | 39.3   | 20      | 0.5 |
| <a href="#">Lab033</a>  | 5                                   | 3.9                          | 4.0          | 5          | 0.1 | 2.5    | 7.6    | 20      | >6  | 3.9                         | 3.9          | 117        | 0.2 | 5.1    | 10.3   | 20      | 3.9 |
| <a href="#">Lab034</a>  | 5                                   | 5.2                          | 4.4          | 5          | 0.1 | 2.3    | 19.9   | 20      | 2.0 | 5.2                         | 4.6          | 56         | 0.2 | 4.3    | 20.2   | 20      | 2.0 |
| <a href="#">Lab037</a>  | 5                                   | 5.2                          | -            | 0          | -   | -      | -      | 20      | -   | 5.2                         | 4.7          | 55         | 0.2 | 4.3    | 18.1   | 20      | 2.4 |
| <a href="#">Lab040</a>  | 5                                   | 5.2                          | -            | 0          | -   | -      | -      | 20      | -   | 5.2                         | 5.4          | 15         | 0.4 | 7.4    | 18.7   | 20      | 2.2 |
| <a href="#">Lab043</a>  | 5                                   | 4.4                          | 4.4          | 5          | 0.2 | 4.5    | 9.1    | 20      | 4.4 | 4.4                         | 4.3          | 12         | 0.2 | 4.7    | 11.6   | 20      | 3.8 |
| <a href="#">Lab047</a>  | 5                                   | 4.6                          | 4.8          | 1          | -   | -      | -      | 20      | -   | 4.6                         | 4.3          | 26         | 0.3 | 7.0    | 20.5   | 20      | 1.9 |
| <a href="#">Lab049</a>  | 5                                   | 4.9                          | -            | 0          | -   | -      | -      | 20      | -   | 4.9                         | 4.7          | 42         | 0.3 | 6.4    | 16.8   | 20      | 2.5 |
| <a href="#">Lab050</a>  | 5                                   | 4.3                          | 4.3          | 6          | 0.1 | 2.3    | 4.7    | 20      | >6  | 4.3                         | 4.4          | 39         | 0.2 | 4.5    | 11.4   | 20      | 3.9 |
| Total                   | -                                   | -                            | 4.2          | 32         | 0.3 | 7.1    | -      | -       | -   | -                           | 4.3          | 733        | 0.4 | 9.3    | -      | -       | -   |

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

Month : 2021 07 Change

Cumulative : from 2019 02 01 to 2021 07 31 Change

[TOP](#)

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