

# Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - October 2022 -

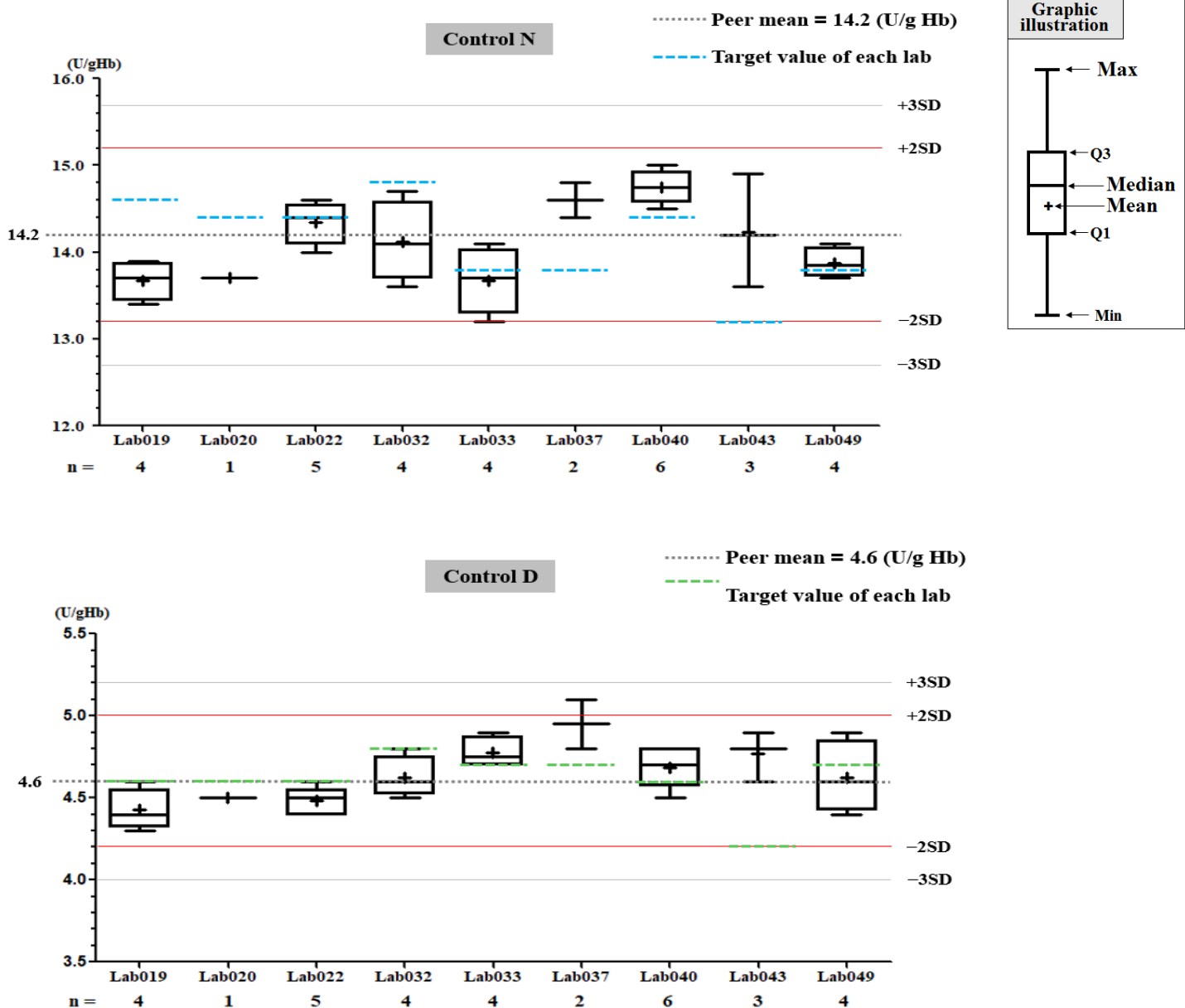
## I. The statistic results of all laboratories in this month

| G6PD                        | Control N<br>(Lot No.:BJ0922N) | Control D<br>(Lot No.: BJ0922D) |
|-----------------------------|--------------------------------|---------------------------------|
| Labs                        | 9                              | 9                               |
| Received results number (n) | 33                             | 33                              |
| Median                      | 14.1 (U/g Hb)                  | 4.6 (U/g Hb)                    |
| Mean                        | 14.2 (U/g Hb)                  | 4.6 (U/g Hb)                    |
| SD                          | 0.5                            | 0.2                             |
| CV                          | 305%                           | 4.3%                            |
| Range of G6PD               | 13.2 ~ 15.0 (U/g Hb)           | 4.3 ~ 5.1 (U/g Hb)              |
| Range of Hb                 | 2.0 ~ 2.8 (g/dL)               | 1.9 ~ 2.3 (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 : BJ0922N (2021-01-01 ~ 2100-12-31) Change

[Print Table](#)

## Lab037

| QC Control Lot No.        | Control N       |                             | Control D       |                             |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
|                           | BJ0922N         |                             | BJ0922D         |                             |
| Duration of the Analyzing | Month (2022/10) | CUM (2022/03/16~2022/10/31) | Month (2022/10) | CUM (2022/03/16~2022/10/31) |
| Runs (N)                  | 2               | 26                          | 2               | 26                          |
| Mean (U/gHb)              | 14.6            | 14.6                        | 5.0             | 4.7                         |
| SD                        | -               | 0.3                         | -               | 0.2                         |
| CV (%)                    | -               | 2.1                         | -               | 4.3                         |
| Target Value (U/gHb)      | 13.8            | 13.8                        | 4.7             | 4.7                         |
| Total Error (%)           | -               | 9.9                         | -               | 8.5                         |
| TEa (%)                   | 20              | 20                          | 20              | 20                          |
| $\sigma$                  | -               | >6                          | -               | 4.7                         |

Bias (%) =  $\left[ \frac{(\text{Mean} - \text{Target})}{\text{Target}} \right] \times 100\%$   
 TE : Total Error(%) = Bias (%) + 2 × CV (%)  
 $\sigma$  (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2022 10 Change ; Cumulative : from 2022 03 16 to 2022 10 31 Change

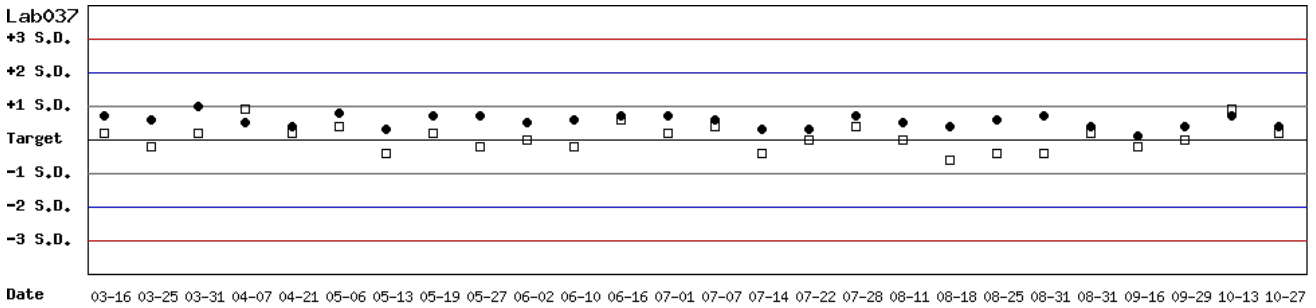
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## Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-03-16 to 2022-10-31 ; Target : 13.8 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2022-03-16 to 2022-10-31 ; Target : 4.7 ; SD : 0.47 (□)

Lab037



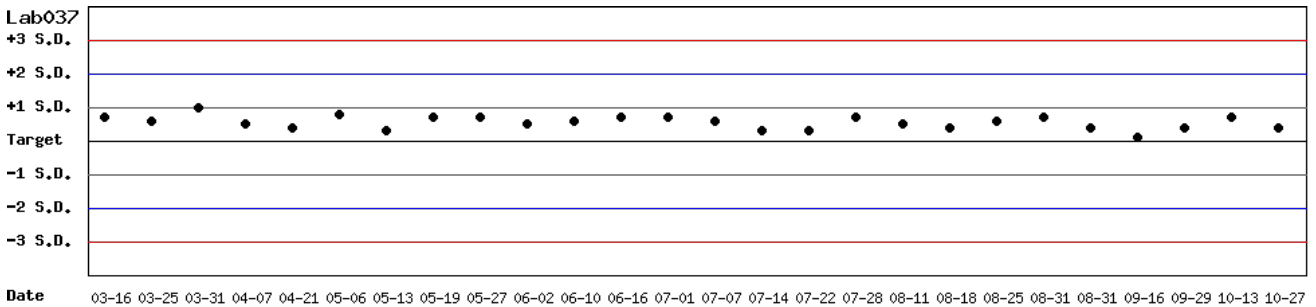
Month : 2022 10 Change ; Cumulative : from 2022 03 16 to 2022 10 31 Change

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## Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-03-16 to 2022-10-31 ; Target : 13.8 ; SD : 1.38

Lab037



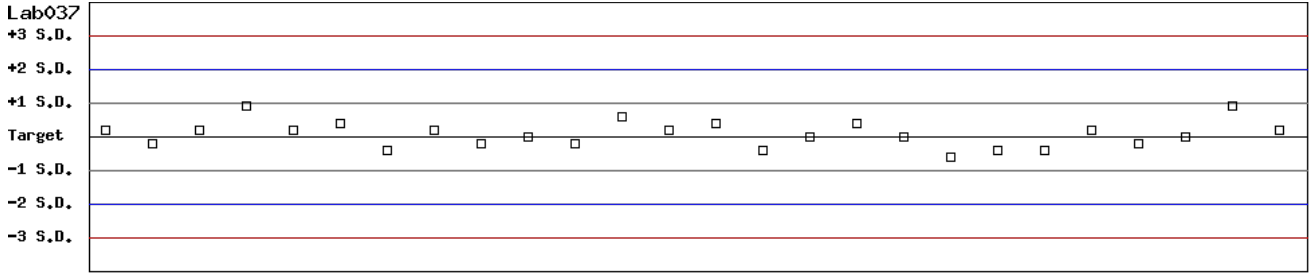
Month : 2022 10 Change ; Cumulative : from 2022 03 16 to 2022 10 31 Change

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## Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2022-03-16 to 2022-10-31 ; Target : 4.7 ; SD : 0.47

Lab037



**Date**    03-16   03-25   03-31   04-07   04-21   05-06   05-13   05-19   05-27   06-02   06-10   06-16   07-01   07-07   07-14   07-22   07-28   08-11   08-18   08-25   08-31   08-31   09-16   09-29   10-13   10-27

Month :    ; Cumulative : from    to

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# Peer Group Statistics (Table 1)

Select LotNo : BJ0922N (2021-01-01 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

[Print Table 1](#)

## Monthly

Month : 2022 10 Change

| UnitID <span>↑</span>  | Reagent Kit (Code) <span>↑</span> | Control N (Lot No.: BJ0922N) |              |            |     |        |        |         |     | Control D (Lot No.: BJ0922D) |              |            |     |        |        |         |     |
|------------------------|-----------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|------------------------------|--------------|------------|-----|--------|--------|---------|-----|
|                        |                                   | 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                         | 13.7         | 4          | 0.2 | 1.5    | 9.1    | 20      | >6  | 4.6                          | 4.4          | 4          | 0.1 | 2.3    | 8.9    | 20      | >6  |
| <a href="#">Lab020</a> | 5                                 | 14.4                         | 13.7         | 1          | -   | -      | -      | 20      | -   | 4.6                          | 4.5          | 1          | -   | -      | -      | 20      | -   |
| <a href="#">Lab022</a> | 5                                 | 14.4                         | 14.3         | 5          | 0.2 | 1.4    | 3.5    | 20      | >6  | 4.6                          | 4.5          | 5          | 0.1 | 2.2    | 6.6    | 20      | >6  |
| <a href="#">Lab032</a> | 5                                 | 14.9                         | 14.1         | 4          | 0.5 | 3.5    | 12.5   | 20      | 4.2 | 4.8                          | 4.6          | 4          | 0.1 | 2.2    | 8.5    | 20      | >6  |
| <a href="#">Lab033</a> | 5                                 | 13.8                         | 13.7         | 4          | 0.4 | 2.9    | 6.6    | 20      | >6  | 4.7                          | 4.8          | 4          | 0.1 | 2.1    | 6.3    | 20      | >6  |
| <a href="#">Lab037</a> | 5                                 | 13.8                         | 14.6         | 2          | -   | -      | -      | 20      | -   | 4.7                          | 5.0          | 2          | -   | -      | -      | 20      | -   |
| <a href="#">Lab040</a> | 5                                 | 14.4                         | 14.8         | 6          | 0.2 | 1.4    | 5.5    | 20      | >6  | 4.6                          | 4.7          | 6          | 0.1 | 2.1    | 6.4    | 20      | >6  |
| <a href="#">Lab043</a> | 5                                 | 13.2                         | 14.2         | 3          | 0.7 | 4.9    | 17.4   | 20      | 2.5 | 4.2                          | 4.8          | 3          | 0.2 | 4.2    | 22.6   | 20      | 1.4 |
| <a href="#">Lab049</a> | 5                                 | 13.8                         | 13.9         | 4          | 0.2 | 1.4    | 3.6    | 20      | >6  | 4.7                          | 4.6          | 4          | 0.2 | 4.3    | 10.8   | 20      | 4.2 |
| Total                  | -                                 | -                            | 14.2         | 33         | 0.5 | 3.5    | -      | -       | -   | -                            | 4.6          | 33         | 0.2 | 4.3    | -      | -       | -   |

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

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

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

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## Cumulative

Cumulative : from 2021 01 01 to 2022 10 31 Change

| UnitID <span>↑</span>  | Reagent Kit (Code) <span>↑</span> | Control N (Lot No.: BJ0922N) |              |            |     |        |        |         |     | Control D (Lot No.: BJ0922D) |              |            |     |        |        |         |     |
|------------------------|-----------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|------------------------------|--------------|------------|-----|--------|--------|---------|-----|
|                        |                                   | 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                                 | 16.2                         | 16.4         | 8          | 0.4 | 2.4    | 6.1    | 20      | >6  | 5.5                          | 5.5          | 8          | 0.2 | 3.6    | 7.3    | 20      | 5.6 |
| <a href="#">Lab019</a> | 5                                 | 14.6                         | 14.4         | 36         | 0.6 | 4.2    | 9.7    | 20      | 4.4 | 4.6                          | 4.6          | 36         | 0.1 | 2.2    | 4.3    | 20      | >6  |
| <a href="#">Lab020</a> | 5                                 | 14.4                         | 14.4         | 43         | 0.6 | 4.2    | 8.3    | 20      | 4.8 | 4.6                          | 4.7          | 43         | 0.2 | 4.3    | 10.7   | 20      | 4.1 |
| <a href="#">Lab022</a> | 5                                 | 14.4                         | 14.3         | 17         | 0.5 | 3.5    | 7.7    | 20      | 5.5 | 4.6                          | 4.5          | 17         | 0.2 | 4.4    | 11.1   | 20      | 4.1 |
| <a href="#">Lab028</a> | 5                                 | 15.2                         | 15.1         | 34         | 1.1 | 7.3    | 15.2   | 20      | 2.6 | 4.9                          | 4.9          | 34         | 0.3 | 6.1    | 12.2   | 20      | 3.3 |
| <a href="#">Lab032</a> | 5                                 | 14.9                         | 14.4         | 97         | 0.4 | 2.8    | 8.9    | 20      | 5.9 | 4.8                          | 4.5          | 97         | 0.1 | 2.2    | 10.7   | 20      | >6  |
| <a href="#">Lab033</a> | 5                                 | 13.8                         | 13.5         | 42         | 0.5 | 3.7    | 9.6    | 20      | 4.8 | 4.7                          | 4.5          | 42         | 0.3 | 6.7    | 17.6   | 20      | 2.3 |
| <a href="#">Lab037</a> | 5                                 | 13.8                         | 14.6         | 42         | 0.4 | 2.7    | 11.3   | 20      | 5.3 | 4.7                          | 4.7          | 42         | 0.2 | 4.3    | 8.5    | 20      | 4.7 |
| <a href="#">Lab040</a> | 5                                 | 14.4                         | 14.6         | 20         | 0.3 | 2.1    | 5.5    | 20      | >6  | 4.6                          | 4.6          | 20         | 0.1 | 2.2    | 4.3    | 20      | >6  |
| <a href="#">Lab043</a> | 5                                 | 13.2                         | 13.6         | 64         | 1.4 | 10.3   | 23.6   | 20      | 1.6 | 4.2                          | 4.4          | 64         | 0.5 | 11.4   | 27.5   | 20      | 1.3 |
| <a href="#">Lab049</a> | 5                                 | 13.8                         | 14.6         | 73         | 0.7 | 4.8    | 15.4   | 20      | 3.0 | 4.7                          | 4.7          | 73         | 0.2 | 4.3    | 8.5    | 20      | 4.7 |
| Total                  | -                                 | -                            | 14.4         | 476        | 0.9 | 6.3    | -      | -       | -   | -                            | 4.6          | 476        | 0.3 | 6.5    | -      | -       | -   |

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 : BJ0922N (2021-01-01 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

[Print Table 2](#)

### Control N Month vs. Cumulative

|                        |                      | Control N (Lot No.: BJ0922N) |              |            |     |        |        |         |     |                             |              |            |     |        |        |         |     |
|------------------------|----------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
|                        |                      | Month (2022/10)              |              |            |     |        |        |         |     | CUM (2021/01/01~2022/10/31) |              |            |     |        |        |         |     |
| 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="#">Lab018</a> | 5                    | 16.2                         | -            | 0          | -   | -      | -      | 20      | -   | 16.2                        | 16.4         | 8          | 0.4 | 2.4    | 6.1    | 20      | >6  |
| <a href="#">Lab019</a> | 5                    | 14.6                         | 13.7         | 4          | 0.2 | 1.5    | 9.1    | 20      | >6  | 14.6                        | 14.4         | 36         | 0.6 | 4.2    | 9.7    | 20      | 4.4 |
| <a href="#">Lab020</a> | 5                    | 14.4                         | 13.7         | 1          | -   | -      | -      | 20      | -   | 14.4                        | 14.4         | 43         | 0.6 | 4.2    | 8.3    | 20      | 4.8 |
| <a href="#">Lab022</a> | 5                    | 14.4                         | 14.3         | 5          | 0.2 | 1.4    | 3.5    | 20      | >6  | 14.4                        | 14.3         | 17         | 0.5 | 3.5    | 7.7    | 20      | 5.5 |
| <a href="#">Lab028</a> | 5                    | 15.2                         | -            | 0          | -   | -      | -      | 20      | -   | 15.2                        | 15.1         | 34         | 1.1 | 7.3    | 15.2   | 20      | 2.6 |
| <a href="#">Lab032</a> | 5                    | 14.9                         | 14.1         | 4          | 0.5 | 3.5    | 12.5   | 20      | 4.2 | 14.9                        | 14.4         | 97         | 0.4 | 2.8    | 8.9    | 20      | 5.9 |
| <a href="#">Lab033</a> | 5                    | 13.8                         | 13.7         | 4          | 0.4 | 2.9    | 6.6    | 20      | >6  | 13.8                        | 13.5         | 42         | 0.5 | 3.7    | 9.6    | 20      | 4.8 |
| <a href="#">Lab037</a> | 5                    | 13.8                         | 14.6         | 2          | -   | -      | -      | 20      | -   | 13.8                        | 14.6         | 42         | 0.4 | 2.7    | 11.3   | 20      | 5.3 |
| <a href="#">Lab040</a> | 5                    | 14.4                         | 14.8         | 6          | 0.2 | 1.4    | 5.5    | 20      | >6  | 14.4                        | 14.6         | 20         | 0.3 | 2.1    | 5.5    | 20      | >6  |
| <a href="#">Lab043</a> | 5                    | 13.2                         | 14.2         | 3          | 0.7 | 4.9    | 17.4   | 20      | 2.5 | 13.2                        | 13.6         | 64         | 1.4 | 10.3   | 23.6   | 20      | 1.6 |
| <a href="#">Lab049</a> | 5                    | 13.8                         | 13.9         | 4          | 0.2 | 1.4    | 3.6    | 20      | >6  | 13.8                        | 14.6         | 73         | 0.7 | 4.8    | 15.4   | 20      | 3.0 |
| Total                  | -                    | -                            | 14.2         | 33         | 0.5 | 3.5    | -      | -       | -   | -                           | 14.4         | 476        | 0.9 | 6.3    | -      | -       | -   |

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

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

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

Month : 2022 ↓ 10 ↓ Change

Cumulative : from 2021 ↓ 01 ↓ 01 ↓ to 2022 ↓ 10 ↓ 31 ↓ Change

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### Control D Month vs. Cumulative

|                        |                      | Control D (Lot No.: BJ0922D) |              |            |     |        |        |         |     |                             |              |            |     |        |        |         |     |
|------------------------|----------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
|                        |                      | Month (2022/10)              |              |            |     |        |        |         |     | CUM (2021/01/01~2022/10/31) |              |            |     |        |        |         |     |
| 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="#">Lab018</a> | 5                    | 5.5                          | -            | 0          | -   | -      | -      | 20      | -   | 5.5                         | 5.5          | 8          | 0.2 | 3.6    | 7.3    | 20      | 5.6 |
| <a href="#">Lab019</a> | 5                    | 4.6                          | 4.4          | 4          | 0.1 | 2.3    | 8.9    | 20      | >6  | 4.6                         | 4.6          | 36         | 0.1 | 2.2    | 4.3    | 20      | >6  |
| <a href="#">Lab020</a> | 5                    | 4.6                          | 4.5          | 1          | -   | -      | -      | 20      | -   | 4.6                         | 4.7          | 43         | 0.2 | 4.3    | 10.7   | 20      | 4.1 |
| <a href="#">Lab022</a> | 5                    | 4.6                          | 4.5          | 5          | 0.1 | 2.2    | 6.6    | 20      | >6  | 4.6                         | 4.5          | 17         | 0.2 | 4.4    | 11.1   | 20      | 4.1 |
| <a href="#">Lab028</a> | 5                    | 4.9                          | -            | 0          | -   | -      | -      | 20      | -   | 4.9                         | 4.9          | 34         | 0.3 | 6.1    | 12.2   | 20      | 3.3 |
| <a href="#">Lab032</a> | 5                    | 4.8                          | 4.6          | 4          | 0.1 | 2.2    | 8.5    | 20      | >6  | 4.8                         | 4.5          | 97         | 0.1 | 2.2    | 10.7   | 20      | >6  |
| <a href="#">Lab033</a> | 5                    | 4.7                          | 4.8          | 4          | 0.1 | 2.1    | 6.3    | 20      | >6  | 4.7                         | 4.5          | 42         | 0.3 | 6.7    | 17.6   | 20      | 2.3 |
| <a href="#">Lab037</a> | 5                    | 4.7                          | 5.0          | 2          | -   | -      | -      | 20      | -   | 4.7                         | 4.7          | 42         | 0.2 | 4.3    | 8.5    | 20      | 4.7 |
| <a href="#">Lab040</a> | 5                    | 4.6                          | 4.7          | 6          | 0.1 | 2.1    | 6.4    | 20      | >6  | 4.6                         | 4.6          | 20         | 0.1 | 2.2    | 4.3    | 20      | >6  |
| <a href="#">Lab043</a> | 5                    | 4.2                          | 4.8          | 3          | 0.2 | 4.2    | 22.6   | 20      | 1.4 | 4.2                         | 4.4          | 64         | 0.5 | 11.4   | 27.5   | 20      | 1.3 |
| <a href="#">Lab049</a> | 5                    | 4.7                          | 4.6          | 4          | 0.2 | 4.3    | 10.8   | 20      | 4.2 | 4.7                         | 4.7          | 73         | 0.2 | 4.3    | 8.5    | 20      | 4.7 |
| Total                  | -                    | -                            | 4.6          | 33         | 0.2 | 4.3    | -      | -       | -   | -                           | 4.6          | 476        | 0.3 | 6.5    | -      | -       | -   |

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

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

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

Month : 2022 ↓ 10 ↓ Change

Cumulative : from 2021 ↓ 01 ↓ 01 ↓ to 2022 ↓ 10 ↓ 31 ↓ Change

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