

# 2023 年 12 月 G6PD 定量檢驗 實驗室內部品管計畫報告

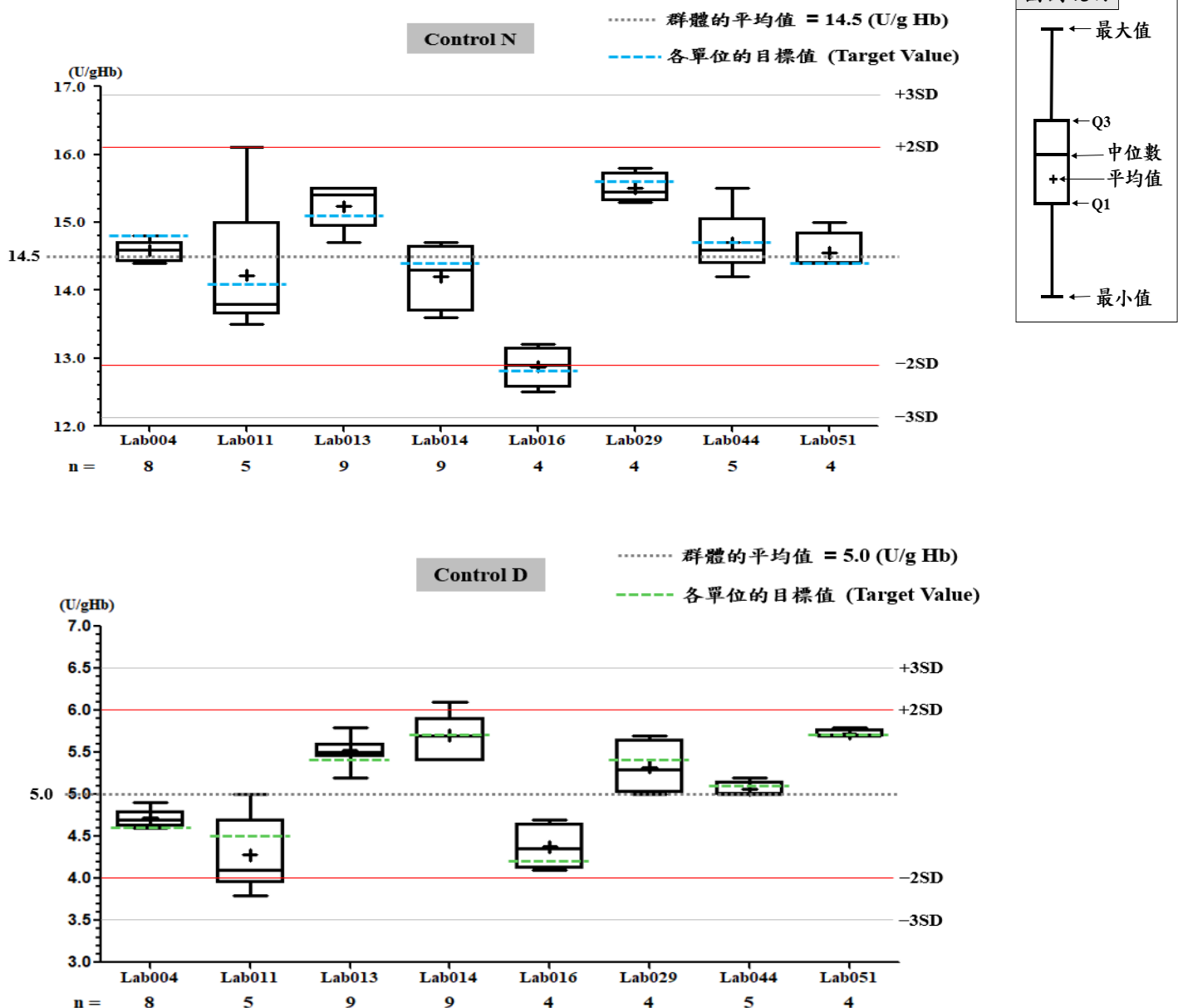
## 一、所有參加單位本月實驗室內部品管結果之彙整

| G6PD         | Control N<br>(Lot No.:BA1116N) | Control D<br>(Lot No.: BA1116D) |
|--------------|--------------------------------|---------------------------------|
| 參加單位         | 8                              | 8                               |
| 總回報數 (n)     | 48                             | 48                              |
| 中位數 (Median) | 14.6 (U/g Hb)                  | 5.2 (U/g Hb)                    |
| 平均值 (Mean)   | 14.5 (U/g Hb)                  | 5.2 (U/g Hb)                    |
| 標準差 (SD)     | 0.8                            | 0.6                             |
| 變異係數 (CV)    | 5.5%                           | 11.5%                           |
| G6PD 檢驗值範圍   | 12.5 ~ 16.1 (U/g Hb)           | 3.8 ~ 6.1 (U/g Hb)              |
| Hb 檢驗值範圍     | 2.1 ~ 2.7 (g/dL)               | 2.0 ~ 2.5 (g/dL)                |

\*統計值為該月全體單位回報的所有數據總合計算所得

\*\* G6PD Method = Innovation kit, 37°C

## 二、各檢驗單位本月實驗室內部品管結果分佈圖



# G6PD 定量檢驗內部品管統計結果及 SDI 分佈圖

選擇 LotNo : BA1116N (2022-04-26 ~ 2100-12-31) Change

列印圖表

檢驗單位 : **Lab011**

| QC Control Lot No. | Control N       |                             | Control D       |                             |
|--------------------|-----------------|-----------------------------|-----------------|-----------------------------|
|                    | BA1116N         |                             | BA1116D         |                             |
| 檢驗期間               | Month (2023/12) | CUM (2023/07/07~2023/12/30) | Month (2023/12) | CUM (2023/07/07~2023/12/30) |
| 累計點數 (N)           | 5               | 26                          | 5               | 26                          |
| 累計平均值 (Mean) U/gHb | 14.2            | 13.7                        | 4.3             | 4.6                         |
| 累計標準差 (SD)         | 1.1             | 1.1                         | 0.5             | 0.3                         |
| 累計變異係數 (CV) %      | 7.7             | 8.0                         | 11.6            | 6.5                         |
| 目標值 (Target) U/gHb | 14.1            | 14.1                        | 4.5             | 4.5                         |
| 總誤差 (TE) %         | 16.2            | 18.9                        | 27.7            | 15.3                        |
| 可容許總誤差 (TEa) %     | 20              | 20                          | 20              | 20                          |
| $\sigma$           | 2.5             | 2.1                         | 1.3             | 2.7                         |

誤差 (Bias)% =  $\{ [ | \text{累計平均值 (Mean)} - \text{目標值 (Target)} | ] / \text{目標值 (Target)} \} \times 100\%$   
 總誤差 (TE, Total Error)% = 誤差 (Bias)% + 2 × 累計變異係數 (CV)  
 $\sigma$  (Sigma) = (TEa% - 誤差 (Bias)% ) / 累計變異係數 (CV)

月統計 : 2023 12 Change ; 累計期間 (CUM) : 自 2023 07 07 至 2023 12 30 Change

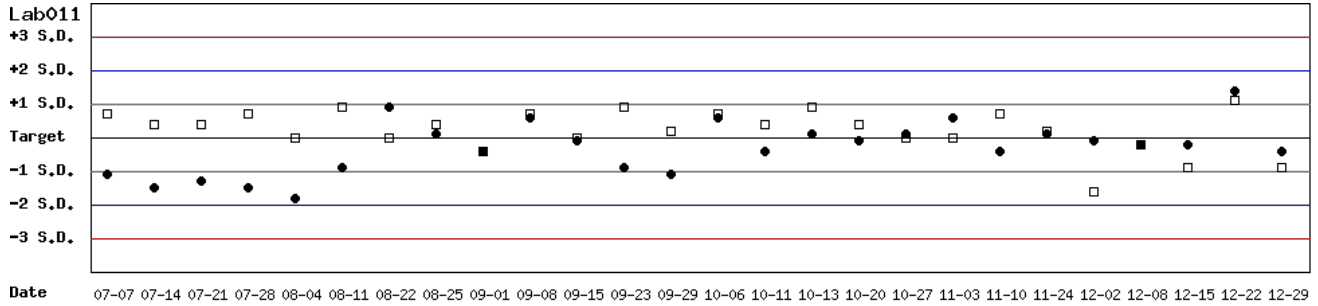
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## Control N 及 Control D SDI 分佈圖

Lot No.: BA1116N ; 檢驗期間 : 2023-07-07 至 2023-12-30 ; 目標值 (Target) : 14.1 ; 參考標準差 (SD) : 1.41 (●)

Lot No.: BA1116D ; 檢驗期間 : 2023-07-07 至 2023-12-30 ; 目標值 (Target) : 4.5 ; 參考標準差 (SD) : 0.45 (□)

單位 : Lab011



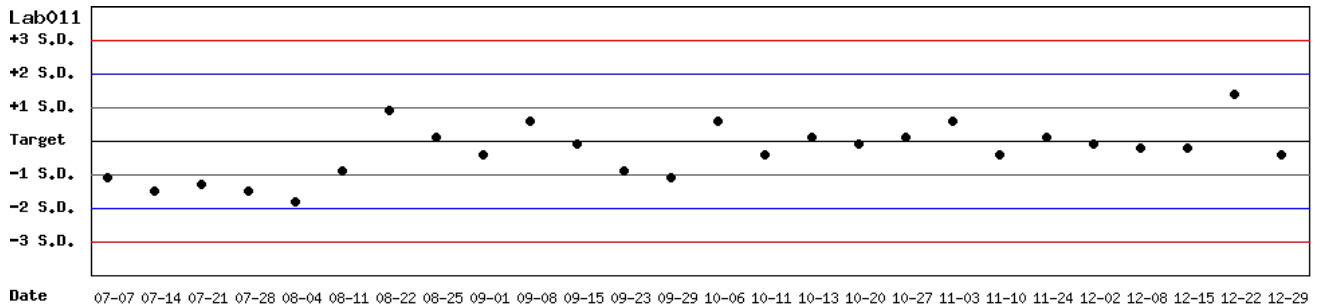
月統計 : 2023 12 Change ; 累計期間 (CUM) : 自 2023 07 07 至 2023 12 30 Change

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## Control N SDI 分佈圖

Lot No.: BA1116N ; 檢驗期間 : 2023-07-07 至 2023-12-30 ; 目標值 (Target) : 14.1 ; 參考標準差 (SD) : 1.41

單位 : Lab011



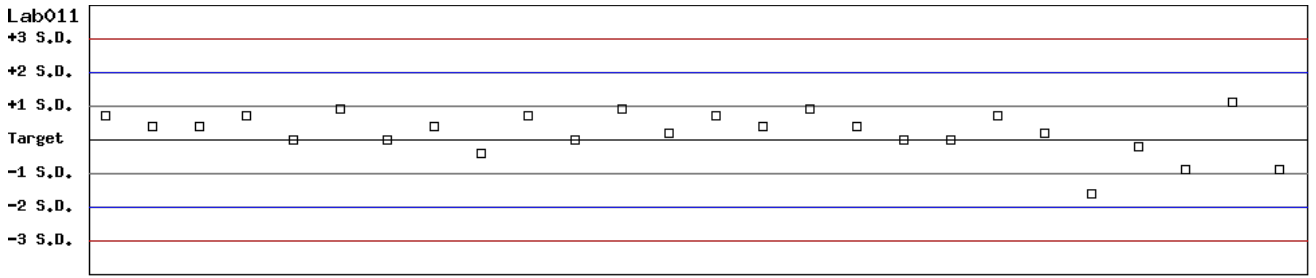
月統計 : 2023 12 Change ; 累計期間 (CUM) : 自 2023 07 07 至 2023 12 30 Change

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# Control D SDI 分佈圖

Lot No.: BA1116D ; 檢驗期間 : 2023-07-07 至 2023-12-30 ; 目標值 (Target) : 4.5 ; 參考標準差 (SD) : 0.45

單位 : Lab011



Date 07-07 07-14 07-21 07-28 08-04 08-11 08-22 08-25 09-01 09-08 09-15 09-23 09-29 10-06 10-11 10-13 10-20 10-27 11-03 11-10 11-24 12-02 12-08 12-15 12-22 12-29

月統計 : 2023 v 12 v Change ; 累計期間 (CUM) : 自 2023 v 07 v 07 v 至 2023 v 12 v 30 v Change

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# 各檢驗單位 G6PD 定量檢驗 內部品管統計結果 (總表一)

選擇 LotNo : BA1116N (2022-04-26 ~ 2100-12-31) Change

選擇 Reagent Kit : 3 - Innovation Change

[列印總表一](#)

## 月統計表

統計月份 : 2023 12 Change

| UnitID <span>↑</span>  | Reagent Kit (Code) <span>↑</span> | Control N (Lot No.: BA1116N) |              |            |     |        |        |         |          |                | Control D (Lot No.: BA1116D) |            |     |        |        |         |          |
|------------------------|-----------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|----------|----------------|------------------------------|------------|-----|--------|--------|---------|----------|
|                        |                                   | Target (U/gHb)               | Mean (U/gHb) | n for Mean | SD  | CV (%) | TE (%) | TEa (%) | $\sigma$ | Target (U/gHb) | Mean (U/gHb)                 | n for Mean | SD  | CV (%) | TE (%) | TEa (%) | $\sigma$ |
| <a href="#">Lab004</a> | 3                                 | 14.8                         | 14.6         | 8          | 0.2 | 1.4    | 4.1    | 30      | >6       | 4.6            | 4.7                          | 8          | 0.1 | 2.1    | 6.4    | 30      | >6       |
| <a href="#">Lab011</a> | 3                                 | 14.1                         | 14.2         | 5          | 1.1 | 7.7    | 16.2   | 20      | 2.5      | 4.5            | 4.3                          | 5          | 0.5 | 11.6   | 27.7   | 20      | 1.3      |
| <a href="#">Lab013</a> | 3                                 | 15.1                         | 15.2         | 9          | 0.3 | 2.0    | 4.6    | 20      | >6       | 5.4            | 5.5                          | 9          | 0.2 | 3.6    | 9.1    | 20      | 5.0      |
| <a href="#">Lab014</a> | 3                                 | 14.4                         | 14.2         | 9          | 0.4 | 2.8    | 7.0    | 20      | >6       | 5.7            | 5.7                          | 9          | 0.3 | 5.3    | 10.5   | 20      | 3.8      |
| <a href="#">Lab016</a> | 3                                 | 12.8                         | 12.9         | 4          | 0.3 | 2.3    | 5.4    | 20      | >6       | 4.2            | 4.4                          | 4          | 0.3 | 6.8    | 18.4   | 20      | 2.2      |
| <a href="#">Lab029</a> | 3                                 | 15.6                         | 15.5         | 4          | 0.2 | 1.3    | 3.2    | 20      | >6       | 5.4            | 5.3                          | 4          | 0.3 | 5.7    | 13.2   | 20      | 3.2      |
| <a href="#">Lab044</a> | 3                                 | 14.7                         | 14.7         | 5          | 0.5 | 3.4    | 6.8    | 20      | 5.9      | 5.1            | 5.1                          | 5          | 0.1 | 2.0    | 3.9    | 20      | >6       |
| <a href="#">Lab051</a> | 3                                 | 14.4                         | 14.6         | 4          | 0.3 | 2.1    | 5.5    | 20      | >6       | 5.7            | 5.7                          | 4          | 0.1 | 1.8    | 3.5    | 20      | >6       |
| Total                  | -                                 | -                            | 14.5         | 48         | 0.8 | 5.5    | -      | -       | -        | -              | 5.2                          | 48         | 0.6 | 11.5   | -      | -       | -        |

誤差 (Bias)% = { [ | 累計平均值 (Mean) - 目標值 (Target) | ] / 目標值 (Target) } x 100%

總誤差 (TE, Total Error)% = 誤差 (Bias)% + 2 x 累計變異係數 (CV)

$\sigma$  (Sigma) = (TEa% - 誤差 (Bias)% ) / 累計變異係數 (CV)

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## 累計統計表

累計期間 : 自 2022 06 01 至 2023 12 31 Change

| UnitID <span>↑</span>  | Reagent Kit (Code) <span>↑</span> | Control N (Lot No.: BA1116N) |              |            |     |        |        |         |          |                | Control D (Lot No.: BA1116D) |            |     |        |        |         |          |
|------------------------|-----------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|----------|----------------|------------------------------|------------|-----|--------|--------|---------|----------|
|                        |                                   | Target (U/gHb)               | Mean (U/gHb) | n for Mean | SD  | CV (%) | TE (%) | TEa (%) | $\sigma$ | Target (U/gHb) | Mean (U/gHb)                 | n for Mean | SD  | CV (%) | TE (%) | TEa (%) | $\sigma$ |
| <a href="#">Lab004</a> | 3                                 | 14.8                         | 14.7         | 38         | 0.4 | 2.7    | 6.1    | 30      | >6       | 4.6            | 4.6                          | 38         | 0.2 | 4.3    | 8.7    | 30      | >6       |
| <a href="#">Lab011</a> | 3                                 | 14.1                         | 13.6         | 30         | 1.1 | 8.1    | 19.7   | 20      | 2.0      | 4.5            | 4.6                          | 30         | 0.3 | 6.5    | 15.3   | 20      | 2.7      |
| <a href="#">Lab013</a> | 3                                 | 15.1                         | 15.3         | 98         | 0.2 | 1.3    | 3.9    | 20      | >6       | 5.4            | 5.5                          | 98         | 0.2 | 3.6    | 9.1    | 20      | 5.0      |
| <a href="#">Lab014</a> | 3                                 | 14.4                         | 14.2         | 119        | 0.3 | 2.1    | 5.6    | 20      | >6       | 5.7            | 5.6                          | 119        | 0.2 | 3.6    | 8.9    | 20      | 5.1      |
| <a href="#">Lab016</a> | 3                                 | 12.8                         | 12.7         | 59         | 0.4 | 3.1    | 7.1    | 20      | >6       | 4.2            | 4.2                          | 59         | 0.2 | 4.8    | 9.5    | 20      | 4.2      |
| <a href="#">Lab029</a> | 3                                 | 15.6                         | 15.4         | 50         | 0.5 | 3.2    | 7.8    | 20      | 5.8      | 5.4            | 5.4                          | 50         | 0.3 | 5.6    | 11.1   | 20      | 3.6      |
| <a href="#">Lab044</a> | 3                                 | 14.7                         | 14.2         | 9          | 0.8 | 5.6    | 14.7   | 20      | 3.0      | 5.1            | 5.1                          | 9          | 0.1 | 2.0    | 3.9    | 20      | >6       |
| <a href="#">Lab051</a> | 3                                 | 14.4                         | 14.6         | 4          | 0.3 | 2.1    | 5.5    | 20      | >6       | 5.7            | 5.7                          | 4          | 0.1 | 1.8    | 3.5    | 20      | >6       |
| Total                  | -                                 | -                            | 14.4         | 407        | 1.0 | 6.9    | -      | -       | -        | -              | 5.2                          | 407        | 0.6 | 11.5   | -      | -       | -        |

誤差 (Bias)% = { [ | 累計平均值 (Mean) - 目標值 (Target) | ] / 目標值 (Target) } x 100%

總誤差 (TE, Total Error)% = 誤差 (Bias)% + 2 x 累計變異係數 (CV)

$\sigma$  (Sigma) = (TEa% - 誤差 (Bias)% ) / 累計變異係數 (CV)

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| Reagent Kit | Reagent Code |
|-------------|--------------|
| Innovation  | 3            |

各檢驗單位 G6PD 定量檢驗 內部品管統計結果 (總表二)

選擇 LotNo : BA1116N (2022-04-26 ~ 2100-12-31) Change

選擇 Reagent Kit : 3 - Innovation Change

列印總表二

Control N 月統計與累計統計之比較表

|        |                    | Control N (Lot No.: BA1116N) |              |            |     |        |        |         |     |                             |              |            |     |        |        |         |     |
|--------|--------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
|        |                    | Month (2023/12)              |              |            |     |        |        |         |     | CUM (2022/06/01~2023/12/31) |              |            |     |        |        |         |     |
| 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   |
| Lab004 | 3                  | 14.8                         | 14.6         | 8          | 0.2 | 1.4    | 4.1    | 30      | >6  | 14.8                        | 14.7         | 38         | 0.4 | 2.7    | 6.1    | 30      | >6  |
| Lab011 | 3                  | 14.1                         | 14.2         | 5          | 1.1 | 7.7    | 16.2   | 20      | 2.5 | 14.1                        | 13.6         | 30         | 1.1 | 8.1    | 19.7   | 20      | 2.0 |
| Lab013 | 3                  | 15.1                         | 15.2         | 9          | 0.3 | 2.0    | 4.6    | 20      | >6  | 15.1                        | 15.3         | 98         | 0.2 | 1.3    | 3.9    | 20      | >6  |
| Lab014 | 3                  | 14.4                         | 14.2         | 9          | 0.4 | 2.8    | 7.0    | 20      | >6  | 14.4                        | 14.2         | 119        | 0.3 | 2.1    | 5.6    | 20      | >6  |
| Lab016 | 3                  | 12.8                         | 12.9         | 4          | 0.3 | 2.3    | 5.4    | 20      | >6  | 12.8                        | 12.7         | 59         | 0.4 | 3.1    | 7.1    | 20      | >6  |
| Lab029 | 3                  | 15.6                         | 15.5         | 4          | 0.2 | 1.3    | 3.2    | 20      | >6  | 15.6                        | 15.4         | 50         | 0.5 | 3.2    | 7.8    | 20      | 5.8 |
| Lab044 | 3                  | 14.7                         | 14.7         | 5          | 0.5 | 3.4    | 6.8    | 20      | 5.9 | 14.7                        | 14.2         | 9          | 0.8 | 5.6    | 14.7   | 20      | 3.0 |
| Lab051 | 3                  | 14.4                         | 14.6         | 4          | 0.3 | 2.1    | 5.5    | 20      | >6  | 14.4                        | 14.6         | 4          | 0.3 | 2.1    | 5.5    | 20      | >6  |
| Total  | -                  | -                            | 14.5         | 48         | 0.8 | 5.5    | -      | -       | -   | -                           | 14.4         | 407        | 1.0 | 6.9    | -      | -       | -   |

誤差 (Bias)% = { [ | 累計平均值 (Mean) - 目標值 (Target) | ] / 目標值 (Target) } x 100%

總誤差 (TE, Total Error)% = 誤差 (Bias)% + 2 x 累計變異係數 (CV)

σ (Sigma) = (TEa% - 誤差 (Bias)% ) / 累計變異係數 (CV)

月統計 : 2023 12 Change

累計期間 (CUM) : 自 2022 06 01 至 2023 12 31 Change

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Control D 月統計與累計統計之比較表

|        |                    | Control D (Lot No.: BA1116D) |              |            |     |        |        |         |     |                             |              |            |     |        |        |         |     |
|--------|--------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
|        |                    | Month (2023/12)              |              |            |     |        |        |         |     | CUM (2022/06/01~2023/12/31) |              |            |     |        |        |         |     |
| 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   |
| Lab004 | 3                  | 4.6                          | 4.7          | 8          | 0.1 | 2.1    | 6.4    | 30      | >6  | 4.6                         | 4.6          | 38         | 0.2 | 4.3    | 8.7    | 30      | >6  |
| Lab011 | 3                  | 4.5                          | 4.3          | 5          | 0.5 | 11.6   | 27.7   | 20      | 1.3 | 4.5                         | 4.6          | 30         | 0.3 | 6.5    | 15.3   | 20      | 2.7 |
| Lab013 | 3                  | 5.4                          | 5.5          | 9          | 0.2 | 3.6    | 9.1    | 20      | 5.0 | 5.4                         | 5.5          | 98         | 0.2 | 3.6    | 9.1    | 20      | 5.0 |
| Lab014 | 3                  | 5.7                          | 5.7          | 9          | 0.3 | 5.3    | 10.5   | 20      | 3.8 | 5.7                         | 5.6          | 119        | 0.2 | 3.6    | 8.9    | 20      | 5.1 |
| Lab016 | 3                  | 4.2                          | 4.4          | 4          | 0.3 | 6.8    | 18.4   | 20      | 2.2 | 4.2                         | 4.2          | 59         | 0.2 | 4.8    | 9.5    | 20      | 4.2 |
| Lab029 | 3                  | 5.4                          | 5.3          | 4          | 0.3 | 5.7    | 13.2   | 20      | 3.2 | 5.4                         | 5.4          | 50         | 0.3 | 5.6    | 11.1   | 20      | 3.6 |
| Lab044 | 3                  | 5.1                          | 5.1          | 5          | 0.1 | 2.0    | 3.9    | 20      | >6  | 5.1                         | 5.1          | 9          | 0.1 | 2.0    | 3.9    | 20      | >6  |
| Lab051 | 3                  | 5.7                          | 5.7          | 4          | 0.1 | 1.8    | 3.5    | 20      | >6  | 5.7                         | 5.7          | 4          | 0.1 | 1.8    | 3.5    | 20      | >6  |
| Total  | -                  | -                            | 5.2          | 48         | 0.6 | 11.5   | -      | -       | -   | -                           | 5.2          | 407        | 0.6 | 11.5   | -      | -       | -   |

誤差 (Bias)% = { [ | 累計平均值 (Mean) - 目標值 (Target) | ] / 目標值 (Target) } x 100%

總誤差 (TE, Total Error)% = 誤差 (Bias)% + 2 x 累計變異係數 (CV)

σ (Sigma) = (TEa% - 誤差 (Bias)% ) / 累計變異係數 (CV)

月統計 : 2023 12 Change

累計期間 (CUM) : 自 2022 06 01 至 2023 12 31 Change

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| Reagent Kit | Reagent Code |
|-------------|--------------|
| Innovation  | 3            |