

2023 年 10 月 G6PD 定量檢驗 實驗室內部品管計畫報告

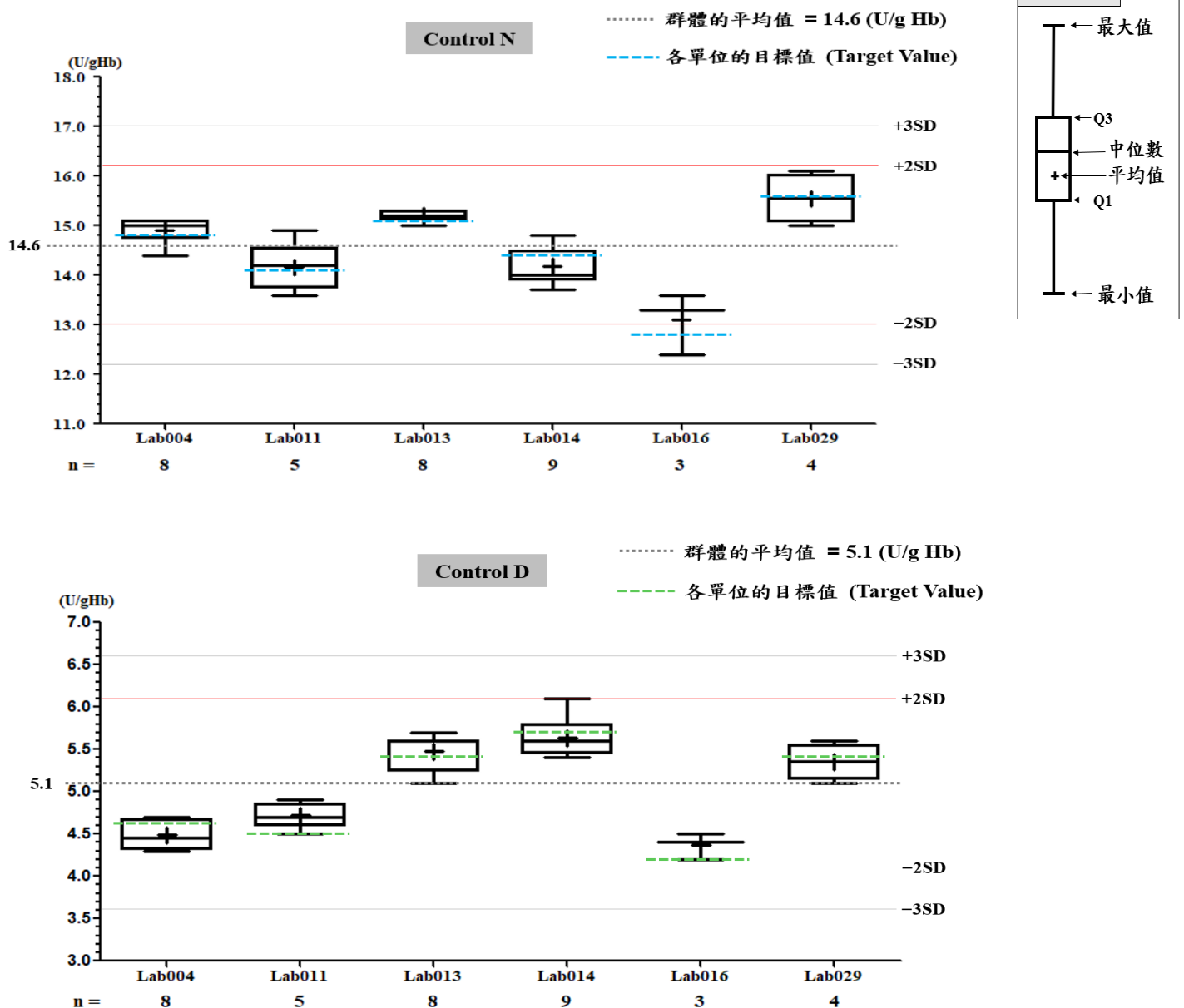
一、所有參加單位本月實驗室內部品管結果之彙整

| G6PD | Control N (Lot No.:BA1116N) | Control D (Lot No.: BA1116D) |
|--------------|--------------------------------|---------------------------------|
| 參加單位 | 6 | 6 |
| 總回報數 (n) | 37 | 37 |
| 中位數 (Median) | 14.9 (U/g Hb) | 5.2 (U/g Hb) |
| 平均值 (Mean) | 14.6 (U/g Hb) | 5.1 (U/g Hb) |
| 標準差 (SD) | 0.8 | 0.5 |
| 變異係數 (CV) | 5.5% | 9.8% |
| G6PD 檢驗值範圍 | 12.4 ~ 16.1 (U/g Hb) | 4.2 ~ 6.1 (U/g Hb) |
| Hb 檢驗值範圍 | 2.2 ~ 2.5 (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 : Lab029

| QC Control Lot No. | Control N | | Control D | |
|--------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | BA1116N | | BA1116D | |
| 檢驗期間 | Month (2023/10) | CUM (2023/05/09~2023/10/31) | Month (2023/10) | CUM (2023/05/09~2023/10/31) |
| 累計點數 (N) | 4 | 26 | 4 | 26 |
| 累計平均值 (Mean) U/gHb | 15.6 | 15.5 | 5.4 | 5.5 |
| 累計標準差 (SD) | 0.5 | 0.4 | 0.2 | 0.2 |
| 累計變異係數 (CV) % | 3.2 | 2.6 | 3.7 | 3.6 |
| 目標值 (Target) U/gHb | 15.6 | 15.6 | 5.4 | 5.4 |
| 總誤差 (TE) % | 6.4 | 5.8 | 7.4 | 9.1 |
| 可容許總誤差 (TEa) % | 20 | 20 | 20 | 20 |
| σ | >6 | >6 | 5.4 | 5.0 |

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 10 Change ; 累計期間 (CUM) : 自 2023 05 09 至 2023 10 31 Change

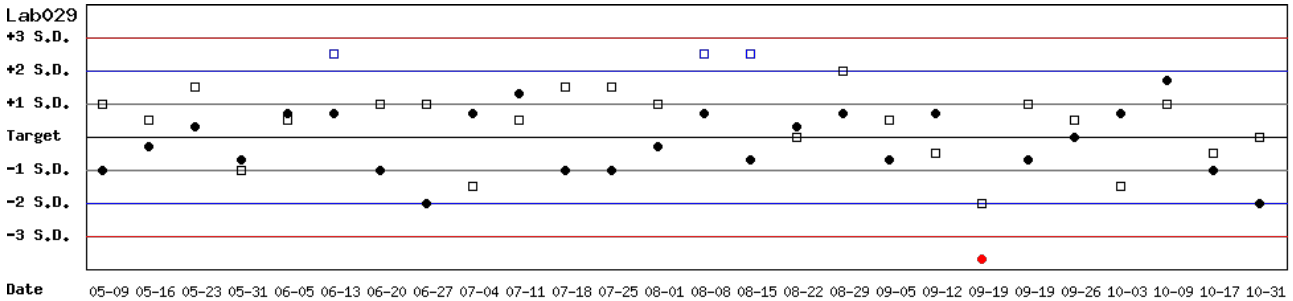
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Control N 及 Control D SDI 分佈圖

Lot No.: BA1116N; 檢驗期間: 2023-05-09 至 2023-10-31; 目標值 (Target): 15.6; 參考標準差 (SD): 0.30 (●)

Lot No.: BA1116D; 檢驗期間: 2023-05-09 至 2023-10-31; 目標值 (Target): 5.4; 參考標準差 (SD): 0.20 (□)

單位: Lab029



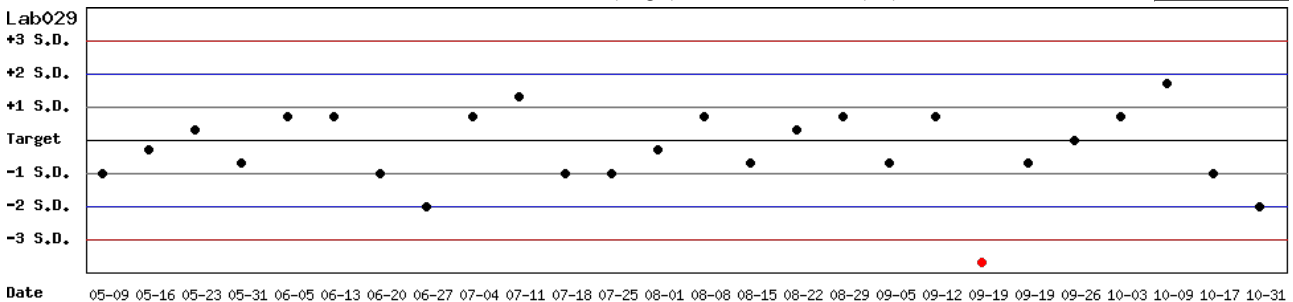
月統計 : 2023 10 Change ; 累計期間 (CUM) : 自 2023 05 09 至 2023 10 31 Change

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Control N SDI 分佈圖

Lot No.: BA1116N; 檢驗期間: 2023-05-09 至 2023-10-31; 目標值 (Target): 15.6; 參考標準差 (SD): 0.30

單位: Lab029



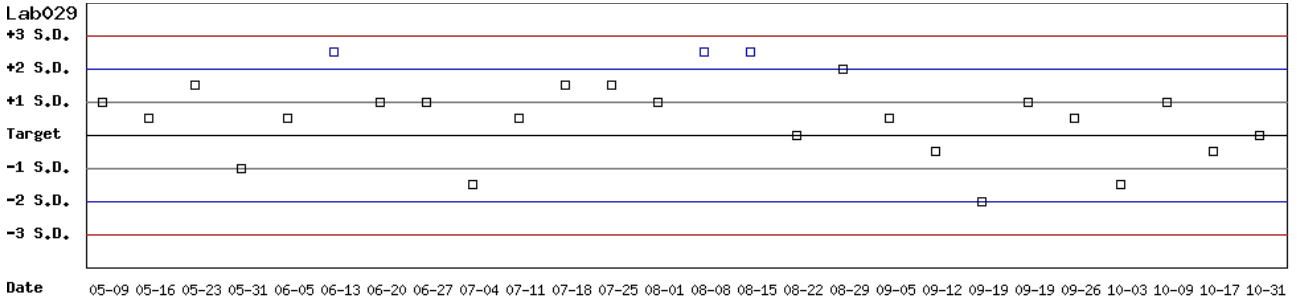
月統計 : 2023 10 Change ; 累計期間 (CUM) : 自 2023 05 09 至 2023 10 31 Change

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Control D SDI 分佈圖

Lot No.: BA1116D ; 檢驗期間 : 2023-05-09 至 2023-10-31 ; 目標值 (Target) : 5.4 ; 參考標準差 (SD) : 0.20

單位 : Lab029



月統計 : 2023 ▾ 10 ▾ Change ; 累計期間 (CUM) : 自 2023 ▾ 05 ▾ 09 ▾ 至 2023 ▾ 10 ▾ 31 ▾ 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 10 Change

| UnitID ↑ | Reagent Kit (Code) ↑ | Control N (Lot No.: BA1116N) | | | | | | | | | Control D (Lot No.: BA1116D) | | | | | | |
|------------------------|-----------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|----------|----------------|------------------------------|------------|-----|--------|--------|---------|----------|
| | | 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 | 14.9 | 8 | 0.2 | 1.3 | 3.4 | 30 | >6 | 4.6 | 4.5 | 8 | 0.2 | 4.4 | 11.1 | 30 | >6 |
| Lab011 | 3 | 14.1 | 14.2 | 5 | 0.5 | 3.5 | 7.8 | 20 | 5.5 | 4.5 | 4.7 | 5 | 0.2 | 4.3 | 13.0 | 20 | 3.6 |
| Lab013 | 3 | 15.1 | 15.2 | 8 | 0.1 | 0.7 | 2.0 | 20 | >6 | 5.4 | 5.5 | 8 | 0.2 | 3.6 | 9.1 | 20 | 5.0 |
| Lab014 | 3 | 14.4 | 14.2 | 9 | 0.4 | 2.8 | 7.0 | 20 | >6 | 5.7 | 5.6 | 9 | 0.3 | 5.4 | 12.5 | 20 | 3.4 |
| Lab016 | 3 | 12.8 | 13.1 | 3 | 0.6 | 4.6 | 11.5 | 20 | 3.8 | 4.2 | 4.4 | 3 | 0.2 | 4.5 | 13.9 | 20 | 3.4 |
| Lab029 | 3 | 15.6 | 15.6 | 4 | 0.5 | 3.2 | 6.4 | 20 | >6 | 5.4 | 5.4 | 4 | 0.2 | 3.7 | 7.4 | 20 | 5.4 |
| Total | - | - | 14.6 | 37 | 0.8 | 5.5 | - | - | - | - | 5.1 | 37 | 0.5 | 9.8 | - | - | - |

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)

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累計統計表

累計期間 : 自 2022 06 01 至 2023 10 31 Change

| UnitID ↑ | Reagent Kit (Code) ↑ | Control N (Lot No.: BA1116N) | | | | | | | | | Control D (Lot No.: BA1116D) | | | | | | |
|------------------------|-----------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|----------|----------------|------------------------------|------------|-----|--------|--------|---------|----------|
| | | 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 | 14.8 | 20 | 0.4 | 2.7 | 5.4 | 30 | >6 | 4.6 | 4.6 | 20 | 0.2 | 4.3 | 8.7 | 30 | >6 |
| Lab011 | 3 | 14.1 | 13.3 | 22 | 1.1 | 8.3 | 22.2 | 20 | 1.7 | 4.5 | 4.7 | 22 | 0.2 | 4.3 | 13.0 | 20 | 3.6 |
| Lab013 | 3 | 15.1 | 15.3 | 81 | 0.2 | 1.3 | 3.9 | 20 | >6 | 5.4 | 5.5 | 81 | 0.2 | 3.6 | 9.1 | 20 | 5.0 |
| Lab014 | 3 | 14.4 | 14.2 | 102 | 0.3 | 2.1 | 5.6 | 20 | >6 | 5.7 | 5.6 | 102 | 0.2 | 3.6 | 8.9 | 20 | 5.1 |
| Lab016 | 3 | 12.8 | 12.7 | 50 | 0.4 | 3.1 | 7.1 | 20 | >6 | 4.2 | 4.2 | 50 | 0.2 | 4.8 | 9.5 | 20 | 4.2 |
| Lab029 | 3 | 15.6 | 15.3 | 42 | 0.5 | 3.3 | 8.5 | 20 | 5.5 | 5.4 | 5.4 | 42 | 0.3 | 5.6 | 11.1 | 20 | 3.6 |
| Total | - | - | 14.4 | 317 | 1.0 | 6.9 | - | - | - | - | 5.2 | 317 | 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)

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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 (2023/10) | | | | | | | | CUM (2022/06/01~2023/10/31) | | | | | | | |
| 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 |
| Lab004 | 3 | 14.8 | 14.9 | 8 | 0.2 | 1.3 | 3.4 | 30 | >6 | 14.8 | 14.8 | 20 | 0.4 | 2.7 | 5.4 | 30 | >6 |
| Lab011 | 3 | 14.1 | 14.2 | 5 | 0.5 | 3.5 | 7.8 | 20 | 5.5 | 14.1 | 13.3 | 22 | 1.1 | 8.3 | 22.2 | 20 | 1.7 |
| Lab013 | 3 | 15.1 | 15.2 | 8 | 0.1 | 0.7 | 2.0 | 20 | >6 | 15.1 | 15.3 | 81 | 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 | 102 | 0.3 | 2.1 | 5.6 | 20 | >6 |
| Lab016 | 3 | 12.8 | 13.1 | 3 | 0.6 | 4.6 | 11.5 | 20 | 3.8 | 12.8 | 12.7 | 50 | 0.4 | 3.1 | 7.1 | 20 | >6 |
| Lab029 | 3 | 15.6 | 15.6 | 4 | 0.5 | 3.2 | 6.4 | 20 | >6 | 15.6 | 15.3 | 42 | 0.5 | 3.3 | 8.5 | 20 | 5.5 |
| Total | - | - | 14.6 | 37 | 0.8 | 5.5 | - | - | - | - | 14.4 | 317 | 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 10 Change

累計期間 (CUM) : 自 2022 06 01 至 2023 10 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 (2023/10) | | | | | | | | CUM (2022/06/01~2023/10/31) | | | | | | | |
| 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 |
| Lab004 | 3 | 4.6 | 4.5 | 8 | 0.2 | 4.4 | 11.1 | 30 | >6 | 4.6 | 4.6 | 20 | 0.2 | 4.3 | 8.7 | 30 | >6 |
| Lab011 | 3 | 4.5 | 4.7 | 5 | 0.2 | 4.3 | 13.0 | 20 | 3.6 | 4.5 | 4.7 | 22 | 0.2 | 4.3 | 13.0 | 20 | 3.6 |
| Lab013 | 3 | 5.4 | 5.5 | 8 | 0.2 | 3.6 | 9.1 | 20 | 5.0 | 5.4 | 5.5 | 81 | 0.2 | 3.6 | 9.1 | 20 | 5.0 |
| Lab014 | 3 | 5.7 | 5.6 | 9 | 0.3 | 5.4 | 12.5 | 20 | 3.4 | 5.7 | 5.6 | 102 | 0.2 | 3.6 | 8.9 | 20 | 5.1 |
| Lab016 | 3 | 4.2 | 4.4 | 3 | 0.2 | 4.5 | 13.9 | 20 | 3.4 | 4.2 | 4.2 | 50 | 0.2 | 4.8 | 9.5 | 20 | 4.2 |
| Lab029 | 3 | 5.4 | 5.4 | 4 | 0.2 | 3.7 | 7.4 | 20 | 5.4 | 5.4 | 5.4 | 42 | 0.3 | 5.6 | 11.1 | 20 | 3.6 |
| Total | - | - | 5.1 | 37 | 0.5 | 9.8 | - | - | - | - | 5.2 | 317 | 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 10 Change

累計期間 (CUM) : 自 2022 06 01 至 2023 10 31 Change

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