

QC Chart of Internal Quality Control (IQC)for G6PD Quantitative Test

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

Print Table

Lab037

|                           | Control N          |                                | Control D          |                                |
|---------------------------|--------------------|--------------------------------|--------------------|--------------------------------|
| QC Control Lot No.        | BA1116N            |                                | BA1116D            |                                |
| Duration of the Analyzing | Month<br>(2025/07) | CUM<br>(2024/06/06~2025/07/30) | Month<br>(2025/07) | CUM<br>(2024/06/06~2025/07/30) |
| Runs (N)                  | 2                  | 26                             | 2                  | 26                             |
| Mean (U/gHb)              | 13.8               | 13.7                           | 4.5                | 4.4                            |
| SD                        | -                  | 0.4                            | -                  | 0.2                            |
| CV (%)                    | -                  | 2.9                            | -                  | 4.5                            |
| Target Value (U/gHb)      | 12.8               | 12.8                           | 4.2                | 4.2                            |
| Total Error (%)           | -                  | 12.9                           | -                  | 13.9                           |
| TEa (%)                   | 20                 | 20                             | 20                 | 20                             |
| σ                         | -                  | 4.5                            | -                  | 3.4                            |

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

Month : 2025 07 Change ; Cumulative : from 2024 06 06 to 2025 07 30 Change

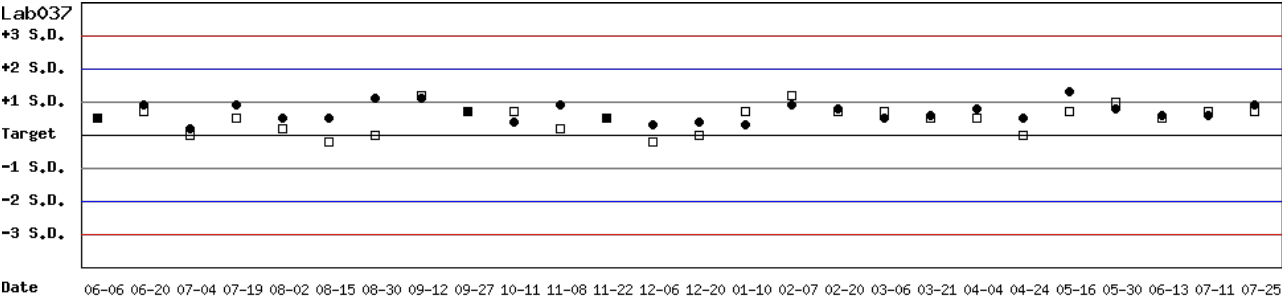
TOP

Control N and Control D SDI  
QC Chart

Lot No.: BA1116N ; Duration : 2024-06-06 to 2025-07-30 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: BA1116D ; Duration : 2024-06-06 to 2025-07-30 ; Target : 4.2 ; SD : 0.42 (□)

Lab037

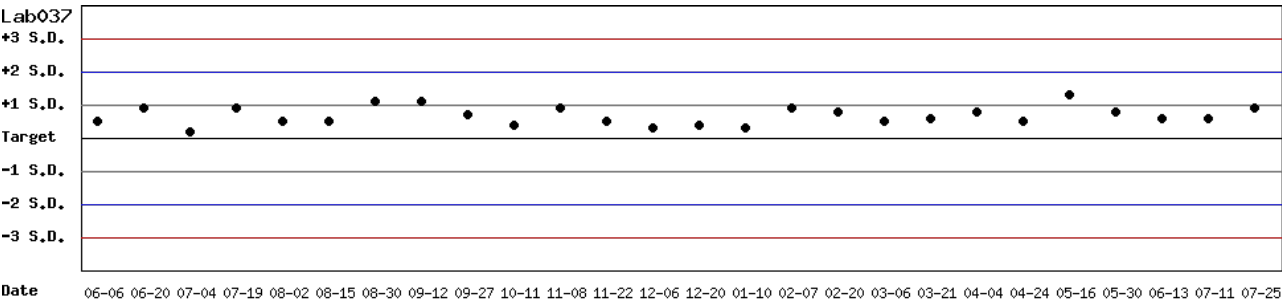


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Control N SDI QC Chart

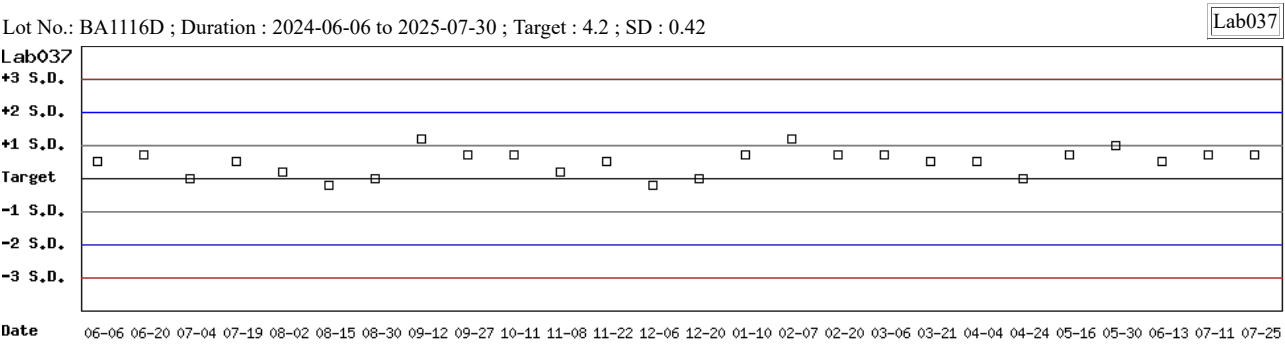
Lot No.: BA1116N ; Duration : 2024-06-06 to 2025-07-30 ; Target : 12.8 ; SD : 1.28

Lab037



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Control D SDI QC Chart



# Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon Change

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Monthly

Month : 2025 07 Change

|                        |                                   | Control N (Lot No.: BA1116N) |              |            |     |        |        |         |    | Control D (Lot No.: BA1116D) |              |            |     |        |        |         |     |
|------------------------|-----------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|----|------------------------------|--------------|------------|-----|--------|--------|---------|-----|
| UnitID <span>↑</span>  | Reagent Kit (Code) <span>↑</span> | 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="#">Lab032</a> | 5                                 | 14.9                         | 14.3         | 4          | 0.3 | 2.1    | 8.2    | 20      | >6 | 5.1                          | 4.3          | 4          | 0.1 | 2.3    | 20.3   | 20      | 1.9 |
| <a href="#">Lab037</a> | 5                                 | 12.8                         | 13.8         | 2          | -   | -      | -      | 20      | -  | 4.2                          | 4.5          | 2          | -   | -      | -      | 20      | -   |
| Total                  | -                                 | -                            | 14.1         | 6          | 0.4 | 2.8    | -      | -       | -  | -                            | 4.4          | 6          | 0.1 | 2.3    | -      | -       | -   |

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from 2022 06 01 to 2025 07 31 Change

|                        |                                   | Control N (Lot No.: BA1116N) |              |            |     |        |        |         |     | Control D (Lot No.: BA1116D) |              |            |     |        |        |         |     |
|------------------------|-----------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|------------------------------|--------------|------------|-----|--------|--------|---------|-----|
| UnitID <span>↑</span>  | Reagent Kit (Code) <span>↑</span> | 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                                 | 13.6                         | 13.9         | 147        | 0.3 | 2.2    | 6.5    | 20      | >6  | 4.3                          | 4.4          | 147        | 0.1 | 2.3    | 6.9    | 20      | >6  |
| <a href="#">Lab027</a> | 5                                 | 12.8                         | 14.9         | 74         | 0.9 | 6.0    | 28.5   | 20      | 0.6 | 4.2                          | 4.9          | 74         | 0.4 | 8.2    | 33.0   | 20      | 0.4 |
| <a href="#">Lab032</a> | 5                                 | 14.9                         | 13.8         | 34         | 0.4 | 2.9    | 13.2   | 20      | 4.4 | 5.1                          | 4.2          | 34         | 0.2 | 4.8    | 27.2   | 20      | 0.5 |
| <a href="#">Lab033</a> | 5                                 | 15.8                         | 15.7         | 85         | 0.6 | 3.8    | 8.3    | 20      | 5.1 | 4.7                          | 4.8          | 85         | 0.2 | 4.2    | 10.5   | 20      | 4.3 |
| <a href="#">Lab037</a> | 5                                 | 12.8                         | 13.8         | 44         | 0.4 | 2.9    | 13.6   | 20      | 4.2 | 4.2                          | 4.4          | 44         | 0.2 | 4.5    | 13.9   | 20      | 3.4 |
| <a href="#">Lab052</a> | 5                                 | 15.3                         | 15.3         | 15         | 0.3 | 2.0    | 3.9    | 20      | >6  | 4.6                          | 4.7          | 15         | 0.2 | 4.3    | 10.7   | 20      | 4.1 |
| Total                  | -                                 | -                            | 14.5         | 403        | 0.9 | 6.2    | -      | -       | -   | -                            | 4.6          | 403        | 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 : BA1116N (2022-04-26 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

[Print Table 2](#)

### Control N Month vs. Cumulative

|                                                                                          |                                                                                                      | Control N (Lot No.: BA1116N) |              |            |     |        |        |         |    |                             |              |            |     |        |        |         |     |
|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
|                                                                                          |                                                                                                      | Month (2025/07)              |              |            |     |        |        |         |    | CUM (2022/06/01~2025/07/31) |              |            |     |        |        |         |     |
| 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                                                                                                    | 13.6                         | -            | 0          | -   | -      | -      | 20      | -  | 13.6                        | 13.9         | 147        | 0.3 | 2.2    | 6.5    | 20      | >6  |
| <a href="#">Lab027</a>                                                                   | 5                                                                                                    | 12.8                         | -            | 0          | -   | -      | -      | 20      | -  | 12.8                        | 14.9         | 74         | 0.9 | 6.0    | 28.5   | 20      | 0.6 |
| <a href="#">Lab032</a>                                                                   | 5                                                                                                    | 14.9                         | 14.3         | 4          | 0.3 | 2.1    | 8.2    | 20      | >6 | 14.9                        | 13.8         | 34         | 0.4 | 2.9    | 13.2   | 20      | 4.4 |
| <a href="#">Lab033</a>                                                                   | 5                                                                                                    | 15.8                         | -            | 0          | -   | -      | -      | 20      | -  | 15.8                        | 15.7         | 85         | 0.6 | 3.8    | 8.3    | 20      | 5.1 |
| <a href="#">Lab037</a>                                                                   | 5                                                                                                    | 12.8                         | 13.8         | 2          | -   | -      | -      | 20      | -  | 12.8                        | 13.8         | 44         | 0.4 | 2.9    | 13.6   | 20      | 4.2 |
| <a href="#">Lab052</a>                                                                   | 5                                                                                                    | 15.3                         | -            | 0          | -   | -      | -      | 20      | -  | 15.3                        | 15.3         | 15         | 0.3 | 2.0    | 3.9    | 20      | >6  |
| Total                                                                                    | -                                                                                                    | -                            | 14.1         | 6          | 0.4 | 2.8    | -      | -       | -  | -                           | 14.5         | 403        | 0.9 | 6.2    | -      | -       | -   |

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

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

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

Month : 2025 ▼ 07 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2025 ▼ 07 ▼ 31 ▼ Change

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### Control D Month vs. Cumulative

|                                                                                            |                                                                                                        | Control D (Lot No.: BA1116D) |              |            |     |        |        |         |     |                             |              |            |     |        |        |         |     |
|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
|                                                                                            |                                                                                                        | Month (2025/07)              |              |            |     |        |        |         |     | CUM (2022/06/01~2025/07/31) |              |            |     |        |        |         |     |
| 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                                                                                                      | 4.3                          | -            | 0          | -   | -      | -      | 20      | -   | 4.3                         | 4.4          | 147        | 0.1 | 2.3    | 6.9    | 20      | >6  |
| <a href="#">Lab027</a>                                                                     | 5                                                                                                      | 4.2                          | -            | 0          | -   | -      | -      | 20      | -   | 4.2                         | 4.9          | 74         | 0.4 | 8.2    | 33.0   | 20      | 0.4 |
| <a href="#">Lab032</a>                                                                     | 5                                                                                                      | 5.1                          | 4.3          | 4          | 0.1 | 2.3    | 20.3   | 20      | 1.9 | 5.1                         | 4.2          | 34         | 0.2 | 4.8    | 27.2   | 20      | 0.5 |
| <a href="#">Lab033</a>                                                                     | 5                                                                                                      | 4.7                          | -            | 0          | -   | -      | -      | 20      | -   | 4.7                         | 4.8          | 85         | 0.2 | 4.2    | 10.5   | 20      | 4.3 |
| <a href="#">Lab037</a>                                                                     | 5                                                                                                      | 4.2                          | 4.5          | 2          | -   | -      | -      | 20      | -   | 4.2                         | 4.4          | 44         | 0.2 | 4.5    | 13.9   | 20      | 3.4 |
| <a href="#">Lab052</a>                                                                     | 5                                                                                                      | 4.6                          | -            | 0          | -   | -      | -      | 20      | -   | 4.6                         | 4.7          | 15         | 0.2 | 4.3    | 10.7   | 20      | 4.1 |
| Total                                                                                      | -                                                                                                      | -                            | 4.4          | 6          | 0.1 | 2.3    | -      | -       | -   | -                           | 4.6          | 403        | 0.3 | 6.5    | -      | -       | -   |

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

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

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

Month : 2025 ▼ 07 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2025 ▼ 07 ▼ 31 ▼ Change

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