

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

Select LotNo : BE0116N (2025-02-12 ~ 2100-12-31) Change

Print Table

Lab019

|                           | Control N          |                                | Control D          |                                |
|---------------------------|--------------------|--------------------------------|--------------------|--------------------------------|
| QC Control Lot No.        | BE0116N            |                                | BE0116D            |                                |
| Duration of the Analyzing | Month<br>(2025/11) | CUM<br>(2025/08/20~2025/11/29) | Month<br>(2025/11) | CUM<br>(2025/08/20~2025/11/29) |
| Runs (N)                  | 4                  | 14                             | 4                  | 14                             |
| Mean (U/gHb)              | 13.6               | 13.6                           | 4.8                | 4.9                            |
| SD                        | 0.1                | 0.3                            | 0.0                | 0.1                            |
| CV (%)                    | 0.7                | 2.2                            | 0.0                | 2.0                            |
| Target Value (U/gHb)      | 13.5               | 13.5                           | 4.9                | 4.9                            |
| Total Error (%)           | 2.2                | 5.2                            | 2.0                | 4.1                            |
| TEa (%)                   | 20                 | 20                             | 20                 | 20                             |
| σ                         | >6                 | >6                             | >6                 | >6                             |

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

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

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

Month : 2025 11 Change ; Cumulative : from 2025 08 20 to 2025 11 29 Change

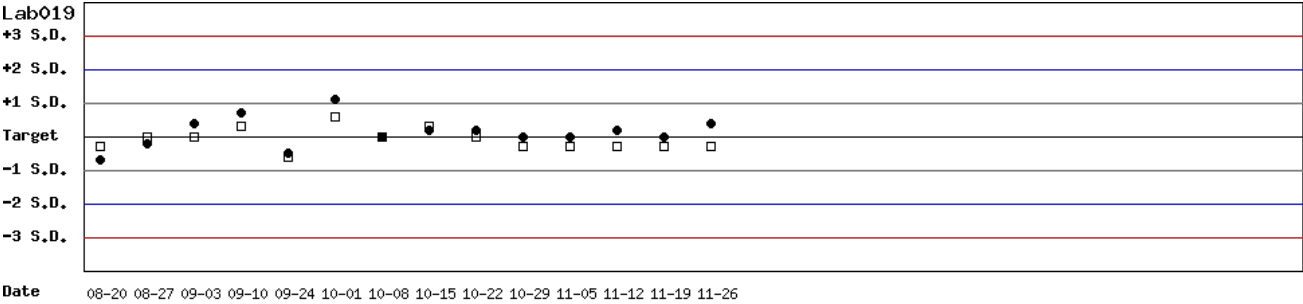
TOP

Control N and Control D SDI  
QC Chart

Lot No.: BE0116N ; Duration : 2025-08-20 to 2025-11-29 ; Target : 13.5 ; SD : 0.56 ( ● )

Lot No.: BE0116D ; Duration : 2025-08-20 to 2025-11-29 ; Target : 4.9 ; SD : 0.32 ( □ )

Lab019

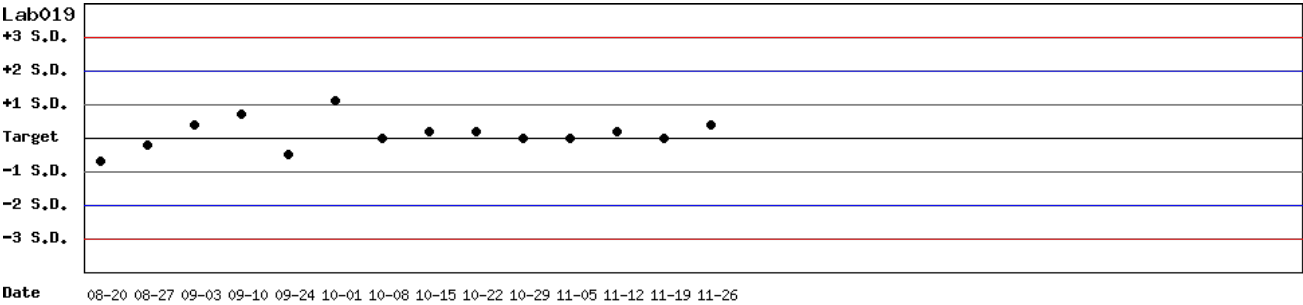


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Control N SDI QC Chart

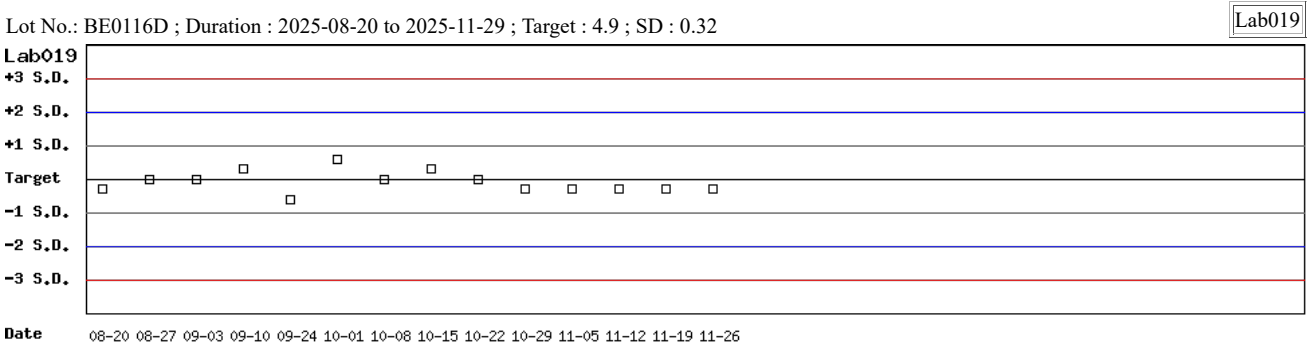
Lot No.: BE0116N ; Duration : 2025-08-20 to 2025-11-29 ; Target : 13.5 ; SD : 0.56

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Control D SDI QC Chart



Month : 2025 11 Change ; Cumulative : from 2025 08 20 to 2025 11 29 Change

# Peer Group Statistics (Table 1)

Select LotNo : BE0116N (2025-02-12 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

[Print Table 1](#)

## Monthly

Month : 2025 11 Change

|                        |                                   | Control N (Lot No.: BE0116N) |              |            |     |        |        |         |    |  | Control D (Lot No.: BE0116D) |              |            |     |        |        |         |    |
|------------------------|-----------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|----|--|------------------------------|--------------|------------|-----|--------|--------|---------|----|
| 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                                 | 14.8                         | 14.3         | 8          | 0.2 | 1.4    | 6.2    | 20      | >6 |  | 5.2                          | 5.2          | 8          | 0.1 | 1.9    | 3.8    | 20      | >6 |
| <a href="#">Lab019</a> | 5                                 | 13.5                         | 13.6         | 4          | 0.1 | 0.7    | 2.2    | 20      | >6 |  | 4.9                          | 4.8          | 4          | 0.0 | 0.0    | 2.0    | 20      | >6 |
| Total                  | -                                 | -                            | 14.0         | 12         | 0.4 | 2.9    | -      | -       | -  |  | -                            | 5.0          | 12         | 0.2 | 4.0    | -      | -       | -  |

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

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

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

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## Cumulative

Cumulative : from 2025 04 01 to 2025 11 30 Change

|                        |                                   | Control N (Lot No.: BE0116N) |              |            |     |        |        |         |    |  | Control D (Lot No.: BE0116D) |              |            |     |        |        |         |    |
|------------------------|-----------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|----|--|------------------------------|--------------|------------|-----|--------|--------|---------|----|
| 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                                 | 14.8                         | 14.3         | 8          | 0.2 | 1.4    | 6.2    | 20      | >6 |  | 5.2                          | 5.2          | 8          | 0.1 | 1.9    | 3.8    | 20      | >6 |
| <a href="#">Lab019</a> | 5                                 | 13.5                         | 13.6         | 14         | 0.3 | 2.2    | 5.2    | 20      | >6 |  | 4.9                          | 4.9          | 14         | 0.1 | 2.0    | 4.1    | 20      | >6 |
| Total                  | -                                 | -                            | 13.8         | 22         | 0.4 | 2.9    | -      | -       | -  |  | -                            | 5.0          | 22         | 0.2 | 4.0    | -      | -       | -  |

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 : BE0116N (2025-02-12 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 2

Control N Month vs.  
Cumulative

|                                                                                          |                                                                                                         | Control N (Lot No.: BE0116N) |                 |               |     |           |           |            |    |                             |                 |               |     |           |           |            |    |
|------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|----|-----------------------------|-----------------|---------------|-----|-----------|-----------|------------|----|
|                                                                                          |                                                                                                         | Month (2025/11)              |                 |               |     |           |           |            |    | CUM (2025/04/01~2025/11/30) |                 |               |     |           |           |            |    |
| UnitID  | Reagent Kit<br>(Code)  | 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="#">Lab018</a>                                                                   | 5                                                                                                       | 14.8                         | 14.3            | 8             | 0.2 | 1.4       | 6.2       | 20         | >6 | 14.8                        | 14.3            | 8             | 0.2 | 1.4       | 6.2       | 20         | >6 |
| <a href="#">Lab019</a>                                                                   | 5                                                                                                       | 13.5                         | 13.6            | 4             | 0.1 | 0.7       | 2.2       | 20         | >6 | 13.5                        | 13.6            | 14            | 0.3 | 2.2       | 5.2       | 20         | >6 |
| Total                                                                                    | -                                                                                                       | -                            | 14.0            | 12            | 0.4 | 2.9       | -         | -          | -  | -                           | 13.8            | 22            | 0.4 | 2.9       | -         | -          | -  |

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

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

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

Month : 2025 11 Change Cumulative : from 2025 04 01 to 2025 11 30 Change

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Control D Month vs.  
Cumulative

|                                                                                            |                                                                                                           | Control D (Lot No.: BE0116D) |                 |               |     |           |           |            |    |                             |                 |               |     |           |           |            |    |
|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|----|-----------------------------|-----------------|---------------|-----|-----------|-----------|------------|----|
|                                                                                            |                                                                                                           | Month (2025/11)              |                 |               |     |           |           |            |    | CUM (2025/04/01~2025/11/30) |                 |               |     |           |           |            |    |
| UnitID  | Reagent Kit<br>(Code)  | 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="#">Lab018</a>                                                                     | 5                                                                                                         | 5.2                          | 5.2             | 8             | 0.1 | 1.9       | 3.8       | 20         | >6 | 5.2                         | 5.2             | 8             | 0.1 | 1.9       | 3.8       | 20         | >6 |
| <a href="#">Lab019</a>                                                                     | 5                                                                                                         | 4.9                          | 4.8             | 4             | 0.0 | 0.0       | 2.0       | 20         | >6 | 4.9                         | 4.9             | 14            | 0.1 | 2.0       | 4.1       | 20         | >6 |
| Total                                                                                      | -                                                                                                         | -                            | 5.0             | 12            | 0.2 | 4.0       | -         | -          | -  | -                           | 5.0             | 22            | 0.2 | 4.0       | -         | -          | -  |

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

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

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

Month : 2025 11 Change Cumulative : from 2025 04 01 to 2025 11 30 Change

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