

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

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

Lab018

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | BA1116N | | BA1116D | |
| Duration of the Analyzing | Month (2023/09) | CUM (2023/07/05~2023/09/29) | Month (2023/09) | CUM (2023/07/05~2023/09/29) |
| Runs (N) | 9 | 26 | 9 | 26 |
| Mean (U/gHb) | 14.1 | 14.1 | 4.4 | 4.4 |
| SD | 0.1 | 0.2 | 0.1 | 0.1 |
| CV (%) | 0.7 | 1.4 | 2.3 | 2.3 |
| Target Value (U/gHb) | 13.6 | 13.6 | 4.3 | 4.3 |
| Total Error (%) | 5.1 | 6.5 | 6.9 | 6.9 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | >6 | >6 | >6 | >6 |

Bias (%) = $((| \text{Mean} - \text{Target} |) / \text{Target}) \times 100\%$

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

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

Month : ; Cumulative : from to

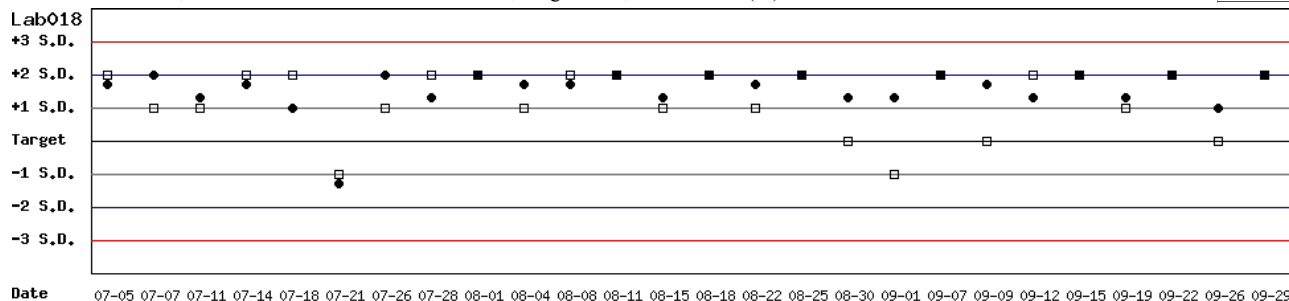
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Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-07-05 to 2023-09-29 ; Target : 13.6 ; SD : 0.30 (●)

Lot No.: BA1116D ; Duration : 2023-07-05 to 2023-09-29 ; Target : 4.3 ; SD : 0.10 (□)

Lab018



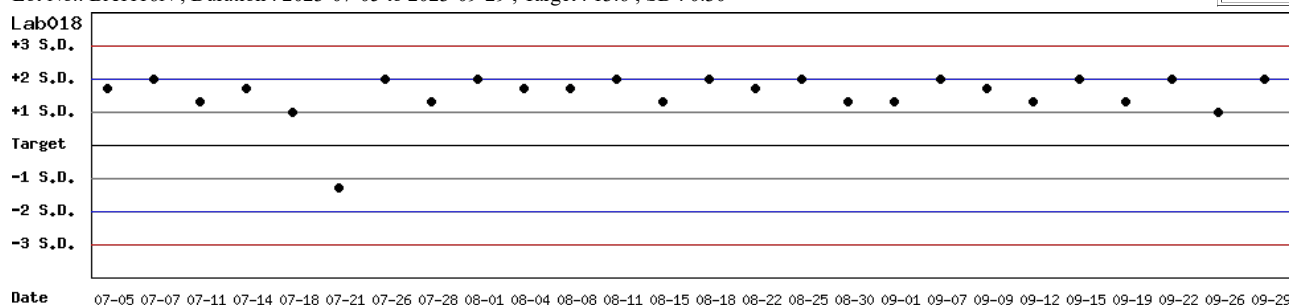
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-07-05 to 2023-09-29 ; Target : 13.6 ; SD : 0.30

Lab018



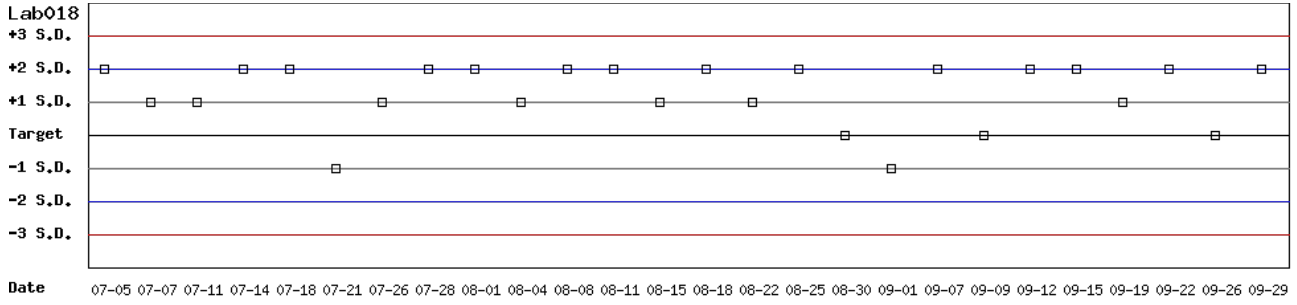
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2023-07-05 to 2023-09-29 ; Target : 4.3 ; SD : 0.10

Lab018



Month : 2023 09 Change ; Cumulative : from 2023 07 05 to 2023 09 29 Change

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Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon Change

[Print Table 1](#)

Monthly

Month : 2023 09 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 |
| Lab018 | 5 | 13.6 | 14.1 | 9 | 0.1 | 0.7 | 5.1 | 20 | >6 | 4.3 | 4.4 | 9 | 0.1 | 2.3 | 6.9 | 20 | >6 |
| Lab033 | 5 | 12.8 | 15.9 | 4 | 0.5 | 3.1 | 30.5 | 20 | -1.4 | 4.2 | 4.8 | 4 | 0.1 | 2.1 | 18.5 | 20 | 2.7 |
| Lab037 | 5 | 12.8 | 14.3 | 2 | - | - | - | 20 | - | 4.2 | 4.5 | 2 | - | - | - | 20 | - |
| Total | - | - | 14.6 | 15 | 0.8 | 5.5 | - | - | - | - | 4.5 | 15 | 0.2 | 4.4 | - | - | - |

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

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

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

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Cumulative

Cumulative : from 2022 06 01 to 2023 09 30 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 |
| Lab018 | 5 | 13.6 | 13.8 | 113 | 0.4 | 2.9 | 7.3 | 20 | >6 | 4.3 | 4.4 | 113 | 0.1 | 2.3 | 6.9 | 20 | >6 |
| Lab027 | 5 | 12.8 | 14.9 | 55 | 0.8 | 5.4 | 27.1 | 20 | 0.7 | 4.2 | 4.8 | 55 | 0.3 | 6.3 | 26.8 | 20 | 0.9 |
| Lab033 | 5 | 12.8 | 16.3 | 9 | 0.6 | 3.7 | 34.7 | 20 | -2.0 | 4.2 | 5.0 | 9 | 0.2 | 4.0 | 27.0 | 20 | 0.2 |
| Lab037 | 5 | 12.8 | 14.0 | 4 | 0.3 | 2.1 | 13.7 | 20 | 5.1 | 4.2 | 4.5 | 4 | 0.1 | 2.2 | 11.6 | 20 | 5.8 |
| Total | - | - | 14.3 | 181 | 0.9 | 6.3 | - | - | - | - | 4.5 | 181 | 0.3 | 6.7 | - | - | - |

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 (2023/09) | | | | | | | | CUM (2022/06/01~2023/09/30) | | | | | | | |
| 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 |
| Lab018 | 5 | 13.6 | 14.1 | 9 | 0.1 | 0.7 | 5.1 | 20 | >6 | 13.6 | 13.8 | 113 | 0.4 | 2.9 | 7.3 | 20 | >6 |
| Lab027 | 5 | 12.8 | - | 0 | - | - | - | 20 | - | 12.8 | 14.9 | 55 | 0.8 | 5.4 | 27.1 | 20 | 0.7 |
| Lab033 | 5 | 12.8 | 15.9 | 4 | 0.5 | 3.1 | 30.5 | 20 | -1.4 | 12.8 | 16.3 | 9 | 0.6 | 3.7 | 34.7 | 20 | -2.0 |
| Lab037 | 5 | 12.8 | 14.3 | 2 | - | - | - | 20 | - | 12.8 | 14.0 | 4 | 0.3 | 2.1 | 13.7 | 20 | 5.1 |
| Total | - | - | 14.6 | 15 | 0.8 | 5.5 | - | - | - | - | 14.3 | 181 | 0.9 | 6.3 | - | - | - |

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

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

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

Month : 2023 ▼ 09 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 09 ▼ 30 ▼ Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: BA1116D) | | | | | | | | | | | | | | | |
|---|---|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2023/09) | | | | | | | | CUM (2022/06/01~2023/09/30) | | | | | | | |
| 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 |
| Lab018 | 5 | 4.3 | 4.4 | 9 | 0.1 | 2.3 | 6.9 | 20 | >6 | 4.3 | 4.4 | 113 | 0.1 | 2.3 | 6.9 | 20 | >6 |
| Lab027 | 5 | 4.2 | - | 0 | - | - | - | 20 | - | 4.2 | 4.8 | 55 | 0.3 | 6.3 | 26.8 | 20 | 0.9 |
| Lab033 | 5 | 4.2 | 4.8 | 4 | 0.1 | 2.1 | 18.5 | 20 | 2.7 | 4.2 | 5.0 | 9 | 0.2 | 4.0 | 27.0 | 20 | 0.2 |
| Lab037 | 5 | 4.2 | 4.5 | 2 | - | - | - | 20 | - | 4.2 | 4.5 | 4 | 0.1 | 2.2 | 11.6 | 20 | 5.8 |
| Total | - | - | 4.5 | 15 | 0.2 | 4.4 | - | - | - | - | 4.5 | 181 | 0.3 | 6.7 | - | - | - |

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

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

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

Month : 2023 ▼ 09 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 09 ▼ 30 ▼ Change

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