

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

Select LotNo :

Lab018

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | BA1116N | | BA1116D | |
| Duration of the Analyzing | Month (2022/07) | CUM (2022/06/02~2022/07/31) | Month (2022/07) | CUM (2022/06/02~2022/07/31) |
| Runs (N) | 5 | 24 | 5 | 24 |
| Mean (U/gHb) | 13.7 | 13.6 | 4.4 | 4.3 |
| SD | 0.3 | 0.3 | 0.0 | 0.1 |
| CV (%) | 2.2 | 2.2 | 0.0 | 2.3 |
| Target Value (U/gHb) | 13.6 | 13.6 | 4.3 | 4.3 |
| Total Error (%) | 5.1 | 4.4 | 2.3 | 4.7 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | >6 | >6 | >6 | >6 |

Bias (%) = $(\frac{| \text{Mean} - \text{Target} |}{\text{Target}}) \times 100\%$
 TE : Total Error(%) = Bias (%) + 2 × CV (%)
 σ (Sigma) = $(\text{TEa}\% - \text{Bias}(\%)) / \text{CV}(\%)$

Month : ; Cumulative : from to

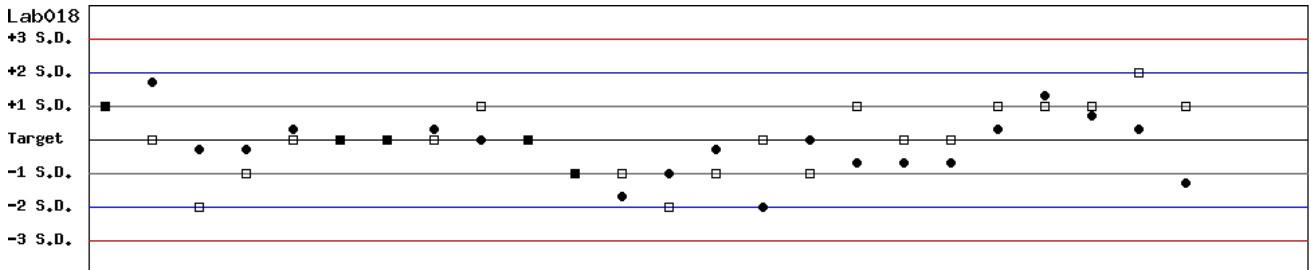
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Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-06-02 to 2022-07-31 ; Target : 13.6 ; SD : 0.30 (●)

Lot No.: BA1116D ; Duration : 2022-06-02 to 2022-07-31 ; Target : 4.3 ; SD : 0.10 (□)

Lab018



Date 06-02 06-06 06-07 06-10 06-10 06-14 06-14 06-17 06-17 06-17 06-21 06-21 06-21 06-24 06-24 06-24 06-24 06-24 06-24 06-24 06-24 06-24 06-24 07-08 07-12 07-14 07-20 07-26

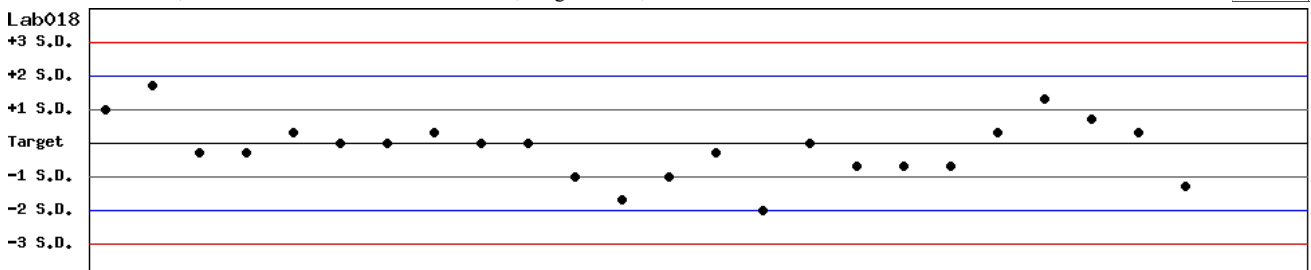
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-06-02 to 2022-07-31 ; Target : 13.6 ; SD : 0.30

Lab018



Date 06-02 06-06 06-07 06-10 06-10 06-14 06-14 06-17 06-17 06-17 06-21 06-21 06-21 06-24 06-24 06-24 06-24 06-24 06-24 06-24 06-24 06-24 06-24 06-24 07-08 07-12 07-14 07-20 07-26

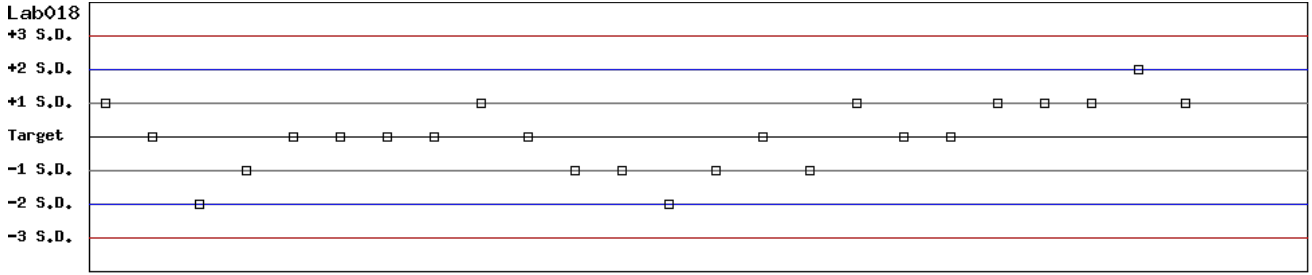
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2022-06-02 to 2022-07-31 ; Target : 4.3 ; SD : 0.10

Lab018



Date 06-02 06-06 06-07 06-10 06-10 06-14 06-14 06-17 06-17 06-17 06-21 06-21 06-21 06-24 06-24 06-24 06-24 06-24 06-24 06-24 07-08 07-12 07-14 07-14 07-20 07-26

Month : ; Cumulative : from to

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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 : 2022 07 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 | 13.7 | 5 | 0.3 | 2.2 | 5.1 | 20 | >6 | 4.3 | 4.4 | 5 | 0.0 | 0.0 | 2.3 | 20 | >6 |
| Lab027 | 5 | 12.8 | 15.0 | 5 | 0.5 | 3.3 | 23.9 | 20 | 0.9 | 4.2 | 4.9 | 5 | 0.6 | 12.2 | 41.2 | 20 | 0.3 |
| Total | - | - | 14.4 | 10 | 0.8 | 5.6 | - | - | - | - | 4.6 | 10 | 0.5 | 10.9 | - | - | - |

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from 2022 06 01 to 2022 07 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 |
| Lab018 | 5 | 13.6 | 13.6 | 24 | 0.3 | 2.2 | 4.4 | 20 | >6 | 4.3 | 4.3 | 24 | 0.1 | 2.3 | 4.7 | 20 | >6 |
| Lab027 | 5 | 12.8 | 14.6 | 9 | 0.8 | 5.5 | 25.0 | 20 | 1.1 | 4.2 | 4.7 | 9 | 0.5 | 10.6 | 33.2 | 20 | 0.8 |
| Total | - | - | 13.8 | 33 | 0.7 | 5.1 | - | - | - | - | 4.4 | 33 | 0.3 | 6.8 | - | - | - |

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

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

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

[\[TOP\]](#)

| 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 (2022/07) | | | | | | | | CUM (2022/06/01~2022/07/31) | | | | | | | |
| 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 |
| Lab018 | 5 | 13.6 | 13.7 | 5 | 0.3 | 2.2 | 5.1 | 20 | >6 | 13.6 | 13.6 | 24 | 0.3 | 2.2 | 4.4 | 20 | >6 |
| Lab027 | 5 | 12.8 | 15.0 | 5 | 0.5 | 3.3 | 23.9 | 20 | 0.9 | 12.8 | 14.6 | 9 | 0.8 | 5.5 | 25.0 | 20 | 1.1 |
| Total | - | - | 14.4 | 10 | 0.8 | 5.6 | - | - | - | - | 13.8 | 33 | 0.7 | 5.1 | - | - | - |

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

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

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

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

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Control D Month vs. Cumulative

| | | Control D (Lot No.: BA1116D) | | | | | | | | | | | | | | | |
|------------------------|----------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2022/07) | | | | | | | | CUM (2022/06/01~2022/07/31) | | | | | | | |
| 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 |
| Lab018 | 5 | 4.3 | 4.4 | 5 | 0.0 | 0.0 | 2.3 | 20 | >6 | 4.3 | 4.3 | 24 | 0.1 | 2.3 | 4.7 | 20 | >6 |
| Lab027 | 5 | 4.2 | 4.9 | 5 | 0.6 | 12.2 | 41.2 | 20 | 0.3 | 4.2 | 4.7 | 9 | 0.5 | 10.6 | 33.2 | 20 | 0.8 |
| Total | - | - | 4.6 | 10 | 0.5 | 10.9 | - | - | - | - | 4.4 | 33 | 0.3 | 6.8 | - | - | - |

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

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

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

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

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