

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

Select LotNo : AH1220N (2019-01-28 ~ 2100-12-31) Change

Print Table

Lab033

| | Control N | | Control D | |
|---------------------------|--------------------|--------------------------------|--------------------|--------------------------------|
| QC Control Lot No. | AH1220N | | AH1220D | |
| Duration of the Analyzing | Month (2020/05) | CUM (2019/11/07~2020/05/30) | Month (2020/05) | CUM (2019/11/07~2020/05/30) |
| Runs (N) | 3 | 26 | 3 | 26 |
| Mean (U/gHb) | 12.3 | 12.4 | 3.9 | 3.9 |
| SD | 0.2 | 0.4 | 0.1 | 0.1 |
| CV (%) | 1.6 | 3.2 | 2.6 | 2.6 |
| Target Value (U/gHb) | 12.4 | 12.4 | 3.9 | 3.9 |
| Total Error (%) | 4.1 | 6.5 | 5.1 | 5.1 |
| 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 : 2020 05 Change ; Cumulative : from 2019 11 07 to 2020 05 30 Change

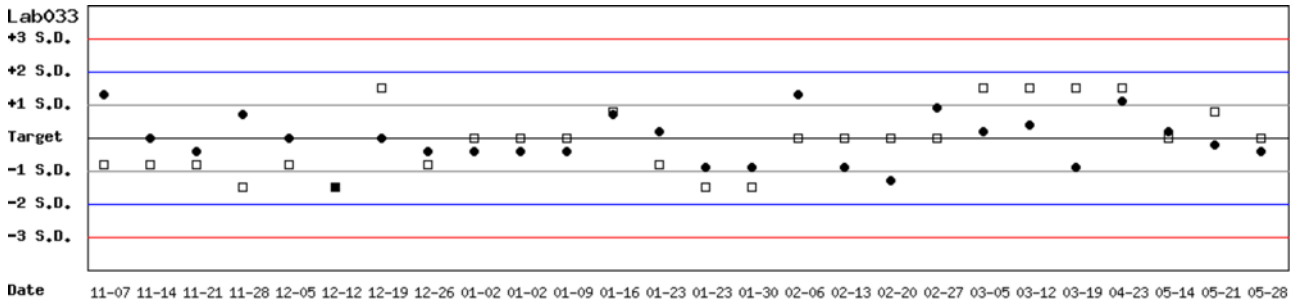
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-11-07 to 2020-05-30 ; Target : 12.4 ; SD : 0.46 (●)

Lot No.: AH1220D ; Duration : 2019-11-07 to 2020-05-30 ; Target : 3.9 ; SD : 0.13 (□)

Lab033



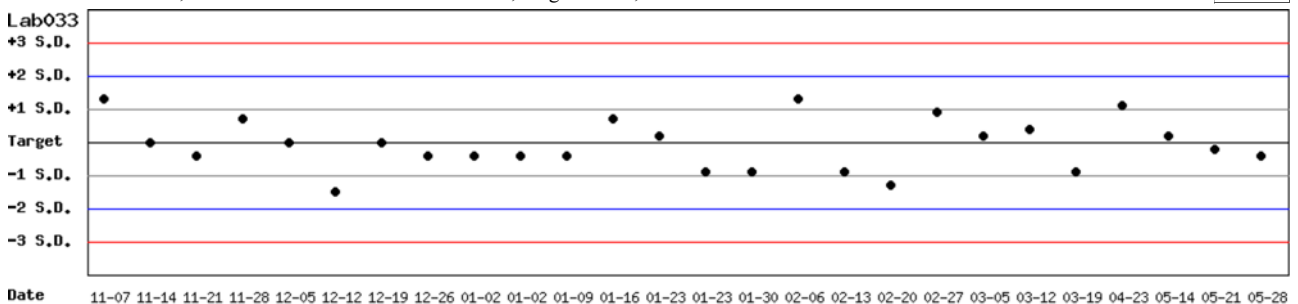
Month : 2020 05 Change ; Cumulative : from 2019 11 07 to 2020 05 30 Change

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-11-07 to 2020-05-30 ; Target : 12.4 ; SD : 0.46

Lab033



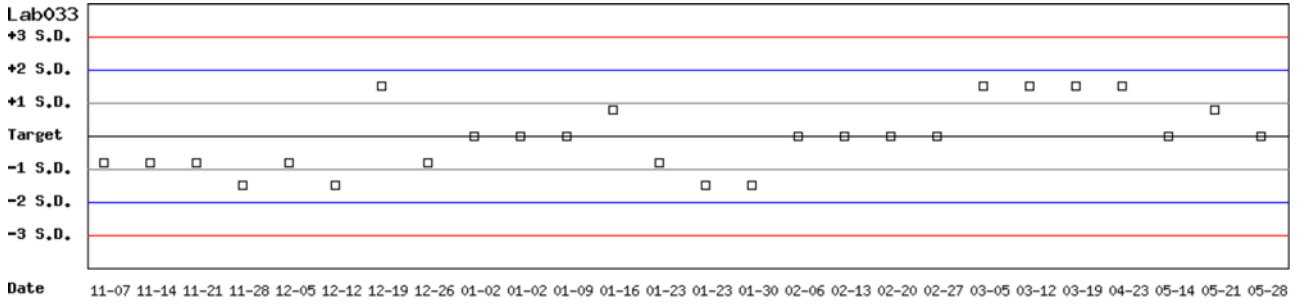
Month : 2020 05 Change ; Cumulative : from 2019 11 07 to 2020 05 30 Change

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2019-11-07 to 2020-05-30 ; Target : 3.9 ; SD : 0.13

Lab033



Month : 2020 05 ; Cumulative : from 2019 11 07 to 2020 05 30

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Peer Group Statistics (Table 1)

Select LotNo : AH1220N (2019-01-28 ~ 2100-12-31)

Select Reagent Kit : 5 - Medicon

Monthly

Month : 2020 05

| UnitID <input type="button" value="↑"/> | Reagent Kit (Code) <input type="button" value="↑"/> | Control N (Lot No.: AH1220N) | | | | | | | | Control D (Lot No.: AH1220D) | | | | | | | |
|---|---|------------------------------|--------------|------------|-----|--------|--------|---------|-----|------------------------------|--------------|------------|-----|--------|--------|---------|------|
| | | 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 |
| Lab020 | 5 | 15.9 | 13.3 | 1 | - | - | - | 20 | - | 5.2 | 4.4 | 1 | - | - | - | 20 | - |
| Lab032 | 5 | 15.3 | 13.0 | 6 | 0.5 | 3.8 | 22.7 | 20 | 1.3 | 5.2 | 4.0 | 6 | 0.1 | 2.5 | 28.1 | 20 | -1.2 |
| Lab033 | 5 | 12.4 | 12.3 | 3 | 0.2 | 1.6 | 4.1 | 20 | >6 | 3.9 | 3.9 | 3 | 0.1 | 2.6 | 5.1 | 20 | >6 |
| Lab037 | 5 | 15.3 | 15.2 | 3 | 0.2 | 1.3 | 3.3 | 20 | >6 | 5.2 | 4.7 | 3 | 0.2 | 4.3 | 18.1 | 20 | 2.4 |
| Total | - | - | 13.4 | 13 | 1.1 | 8.2 | - | - | - | - | 4.2 | 13 | 0.3 | 7.1 | - | - | - |

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

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

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

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Cumulative

Cumulative : from 2019 02 01 to 2020 05 31

| UnitID <input type="button" value="↑"/> | Reagent Kit (Code) <input type="button" value="↑"/> | Control N (Lot No.: AH1220N) | | | | | | | | Control D (Lot No.: AH1220D) | | | | | | | |
|---|---|------------------------------|--------------|------------|-----|--------|--------|---------|-----|------------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | 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 |
| Lab020 | 5 | 15.9 | 15.2 | 17 | 0.8 | 5.3 | 14.9 | 20 | 2.9 | 5.2 | 4.7 | 17 | 0.2 | 4.3 | 18.1 | 20 | 2.4 |
| Lab022 | 5 | 12.4 | 12.3 | 41 | 0.4 | 3.3 | 7.3 | 20 | 5.8 | 4.1 | 4.0 | 41 | 0.1 | 2.5 | 7.4 | 20 | >6 |
| Lab032 | 5 | 15.3 | 14.2 | 68 | 0.6 | 4.2 | 15.6 | 20 | 3.1 | 5.2 | 4.4 | 68 | 0.4 | 9.1 | 33.6 | 20 | 0.5 |
| Lab033 | 5 | 12.4 | 12.5 | 56 | 0.4 | 3.2 | 7.2 | 20 | 6.0 | 3.9 | 3.9 | 56 | 0.1 | 2.6 | 5.1 | 20 | >6 |
| Lab037 | 5 | 15.3 | 15.3 | 16 | 0.4 | 2.6 | 5.2 | 20 | >6 | 5.2 | 4.7 | 16 | 0.2 | 4.3 | 18.1 | 20 | 2.4 |
| Total | - | - | 13.5 | 198 | 1.2 | 8.9 | - | - | - | - | 4.2 | 198 | 0.4 | 9.5 | - | - | - |

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

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

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

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

Peer Group Statistics (Table 2)

Select LotNo : AH1220N (2019-01-28 ~ 2100-12-31) ▼ Change

Select Reagent Kit : 5 - Medicon ▼ Change

Print Table 2

Control N Month vs. Cumulative

| | | Control N (Lot No.: AH1220N) | | | | | | | | | | | | | | | |
|------------------------|--------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2020/05) | | | | | | | | CUM (2019/02/01~2020/05/31) | | | | | | | |
| 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 |
| Lab020 | 5 | 15.9 | 13.3 | 1 | - | - | - | 20 | - | 15.9 | 15.2 | 17 | 0.8 | 5.3 | 14.9 | 20 | 2.9 |
| Lab022 | 5 | 12.4 | - | 0 | - | - | - | 20 | - | 12.4 | 12.3 | 41 | 0.4 | 3.3 | 7.3 | 20 | 5.8 |
| Lab032 | 5 | 15.3 | 13.0 | 6 | 0.5 | 3.8 | 22.7 | 20 | 1.3 | 15.3 | 14.2 | 68 | 0.6 | 4.2 | 15.6 | 20 | 3.1 |
| Lab033 | 5 | 12.4 | 12.3 | 3 | 0.2 | 1.6 | 4.1 | 20 | >6 | 12.4 | 12.5 | 56 | 0.4 | 3.2 | 7.2 | 20 | 6.0 |
| Lab037 | 5 | 15.3 | 15.2 | 3 | 0.2 | 1.3 | 3.3 | 20 | >6 | 15.3 | 15.3 | 16 | 0.4 | 2.6 | 5.2 | 20 | >6 |
| Total | - | - | 13.4 | 13 | 1.1 | 8.2 | - | - | - | - | 13.5 | 198 | 1.2 | 8.9 | - | - | - |

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

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

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

Month : 2020 ▼ 05 ▼ Change Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2020 ▼ 05 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: AH1220D) | | | | | | | | | | | | | | | |
|------------------------|--------------------|------------------------------|--------------|------------|-----|--------|--------|---------|------|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2020/05) | | | | | | | | CUM (2019/02/01~2020/05/31) | | | | | | | |
| 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 |
| Lab020 | 5 | 5.2 | 4.4 | 1 | - | - | - | 20 | - | 5.2 | 4.7 | 17 | 0.2 | 4.3 | 18.1 | 20 | 2.4 |
| Lab022 | 5 | 4.1 | - | 0 | - | - | - | 20 | - | 4.1 | 4.0 | 41 | 0.1 | 2.5 | 7.4 | 20 | >6 |
| Lab032 | 5 | 5.2 | 4.0 | 6 | 0.1 | 2.5 | 28.1 | 20 | -1.2 | 5.2 | 4.4 | 68 | 0.4 | 9.1 | 33.6 | 20 | 0.5 |
| Lab033 | 5 | 3.9 | 3.9 | 3 | 0.1 | 2.6 | 5.1 | 20 | >6 | 3.9 | 3.9 | 56 | 0.1 | 2.6 | 5.1 | 20 | >6 |
| Lab037 | 5 | 5.2 | 4.7 | 3 | 0.2 | 4.3 | 18.1 | 20 | 2.4 | 5.2 | 4.7 | 16 | 0.2 | 4.3 | 18.1 | 20 | 2.4 |
| Total | - | - | 4.2 | 13 | 0.3 | 7.1 | - | - | - | - | 4.2 | 198 | 0.4 | 9.5 | - | - | - |

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

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

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

Month : 2020 ▼ 05 ▼ Change Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2020 ▼ 05 ▼ 31 ▼ Change

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