

Summary Report of IQC program for G6PD Quantitative Test - AMP Group - November 2016 -

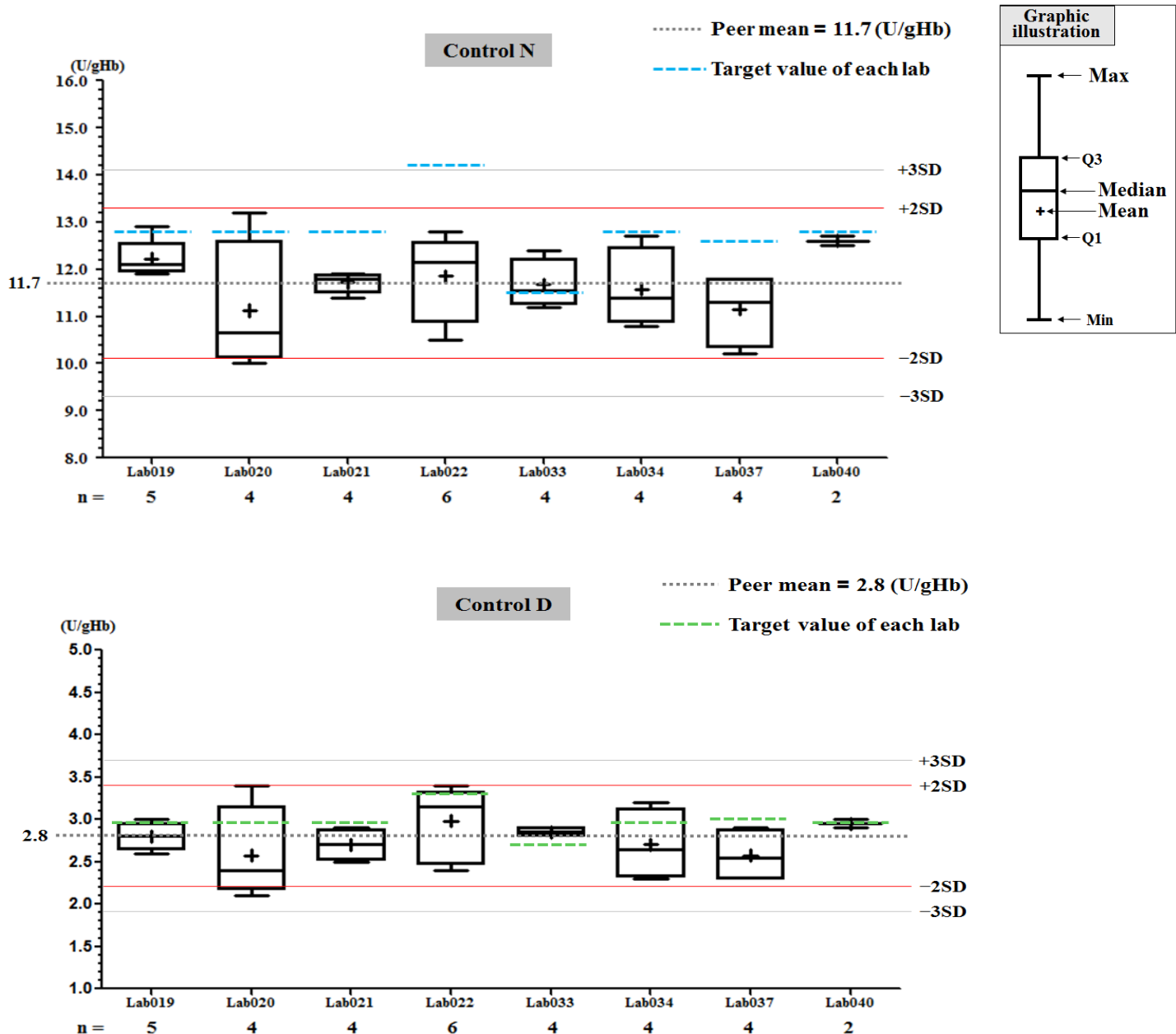
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:AC1203N) | Control D (Lot No.:AC1203D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs | 8 | 8 |
| Received results number (n) | 33 | 33 |
| Median | 11.8 (U/gHb) | 2.8 (U/gHb) |
| Mean | 11.7 (U/gHb) | 2.8 (U/gHb) |
| SD | 0.8 | 0.3 |
| CV | 6.8% | 10.7% |
| Range of G6PD | 10.0 ~ 13.2 (U/gHb) | 2.1 ~ 3.4 (U/gHb) |
| Range of Hb | 2.1 ~ 2.9 (g/dL) | 2.6 ~ 3.2 (g/dL) |

*The statistic results are calculated from all labs reported in this month

** G6PD Method = AMP reagent kit, 37°C

II. The distribution of G6PD reported for each lab in this survey



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

Select LotNo : AC1203N (2014-01-01 ~ 2100-12-31) [Change](#)

[Print Table](#)

Lab033

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | AC1203N | | AC1203D | |
| Duration of the Analyzing | Month (2016/11) | CUM (2016/06/09~2016/11/30) | Month (2016/11) | CUM (2016/06/09~2016/11/30) |
| Runs (N) | 4 | 26 | 4 | 26 |
| Mean (U/gHb) | 11.7 | 11.5 | 2.9 | 2.8 |
| SD | 0.5 | 0.7 | 0.1 | 0.3 |
| CV (%) | 4.3 | 6.1 | 3.4 | 10.7 |
| Target Value (U/gHb) | 11.5 | 11.5 | 2.7 | 2.7 |
| Total Error (%) | 10.3 | 12.2 | 14.3 | 25.1 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | 4.2 | 3.3 | 3.7 | 1.5 |

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

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

σ (Sigma) = $[\text{TEa}\% - \text{Bias}(\%)] / \text{CV}(\%)$

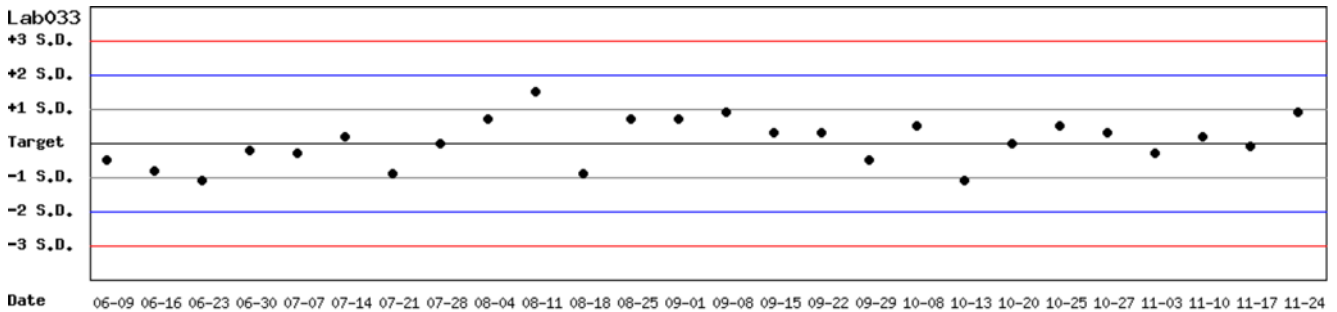
Month : 2016 11 [Change](#) ; Cumulative : from 2016 06 09 to 2016 11 30 [Change](#)

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Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2016-06-09 to 2016-11-30 ; Target : 11.5 ; SD : 1.00

Lab033



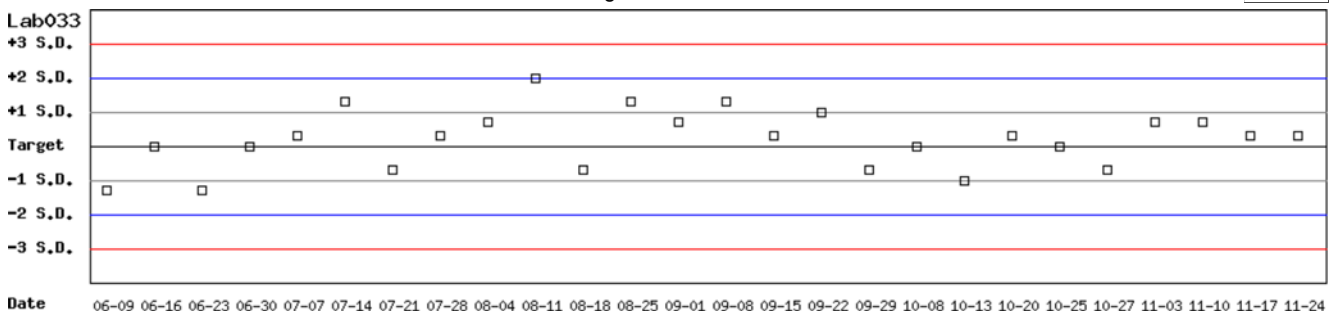
Month : 2016 11 [Change](#) ; Cumulative : from 2016 06 09 to 2016 11 30 [Change](#)

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Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2016-06-09 to 2016-11-30 ; Target : 2.7 ; SD : 0.30

Lab033



Month : 2016 11 [Change](#) ; Cumulative : from 2016 06 09 to 2016 11 30 [Change](#)

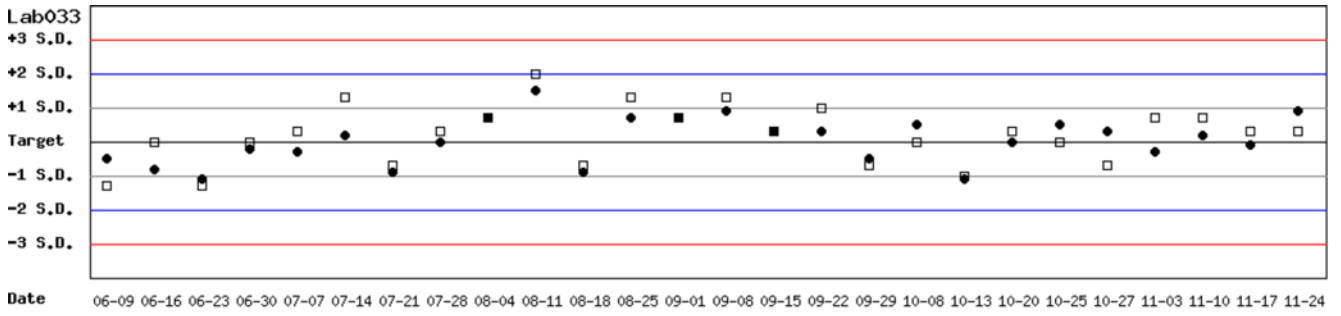
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Control N and Control D SDI QC Chart

Lot No.: AC1203N ; Duration : 2016-06-09 to 2016-11-30 ; Target : 11.5 ; SD : 1.00 (●)

Lot No.: AC1203D ; Duration : 2016-06-09 to 2016-11-30 ; Target : 2.7 ; SD : 0.30 (□)

Lab033



Month : 2016 11 ; Cumulative : from 2016 06 09 to 2016 11 30

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Peer Group Statistics (Table 1)

Select LotNo : AC1203N (2014-01-01 ~ 2100-12-31) Change

Select Reagent Kit : 2 - AMP Change

Print Table 1

Monthly

Month : 2016 11 Change

| UnitID [↑] | Reagent Kit (Code) [↑] | Control N (Lot No.: AC1203N) | | | | | | | | Control D (Lot No.: AC1203D) | | | | | | | |
|------------------------|------------------------------------|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|
| | | 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 |
| Lab019 | 2 | 12.8 | 12.2 | 5 | 0.4 | 3.3 | 11.2 | 20 | 4.6 | 2.9 | 2.8 | 5 | 0.2 | 7.1 | 17.7 | 20 | 2.3 |
| Lab020 | 2 | 12.8 | 11.1 | 4 | 1.4 | 12.6 | 38.5 | 20 | 0.5 | 2.9 | 2.6 | 4 | 0.6 | 23.1 | 56.5 | 20 | 0.4 |
| Lab021 | 2 | 12.8 | 11.7 | 4 | 0.2 | 1.7 | 12.0 | 20 | >6 | 2.9 | 2.7 | 4 | 0.2 | 7.4 | 21.7 | 20 | 1.8 |
| Lab022 | 2 | 14.2 | 11.9 | 6 | 0.9 | 7.6 | 31.3 | 20 | 0.5 | 3.3 | 3.0 | 6 | 0.4 | 13.3 | 35.8 | 20 | 0.8 |
| Lab033 | 2 | 11.5 | 11.7 | 4 | 0.5 | 4.3 | 10.3 | 20 | 4.2 | 2.7 | 2.9 | 4 | 0.1 | 3.4 | 14.3 | 20 | 3.7 |
| Lab034 | 2 | 12.8 | 11.6 | 4 | 0.8 | 6.9 | 23.2 | 20 | 1.5 | 2.9 | 2.7 | 4 | 0.4 | 14.8 | 36.5 | 20 | 0.9 |
| Lab037 | 2 | 12.6 | 11.2 | 4 | 0.8 | 7.1 | 25.4 | 20 | 1.3 | 3.0 | 2.6 | 4 | 0.3 | 11.5 | 36.4 | 20 | 0.6 |
| Lab040 | 2 | 12.8 | 12.6 | 2 | - | - | - | 20 | - | 2.9 | 3.0 | 2 | - | - | - | 20 | - |
| Total | - | - | 11.7 | 33 | 0.8 | 6.8 | - | - | - | - | 2.8 | 33 | 0.3 | 10.7 | - | - | - |

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

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

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

[TOP](#)

Cumulative

Cumulative : from 2014 02 01 to 2016 11 30 Change

| UnitID [↑] | Reagent Kit (Code) [↑] | Control N (Lot No.: AC1203N) | | | | | | | | Control D (Lot No.: AC1203D) | | | | | | | |
|------------------------|------------------------------------|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|------------------------------|-----------------|---------------|-----|-----------|-----------|------------|-----|
| | | 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 |
| Lab017 | 2 | 14.2 | 13.8 | 36 | 1.6 | 11.6 | 26.0 | 20 | 1.5 | 3.3 | 3.9 | 36 | 1.4 | 35.9 | 90.0 | 20 | 0.1 |
| Lab018 | 2 | 10.9 | 10.9 | 113 | 1.3 | 11.9 | 23.9 | 20 | 1.7 | 2.5 | 2.6 | 113 | 0.9 | 34.6 | 73.2 | 20 | 0.5 |
| Lab019 | 2 | 12.8 | 12.2 | 145 | 1.2 | 9.8 | 24.4 | 20 | 1.6 | 2.9 | 2.8 | 145 | 0.4 | 14.3 | 32.0 | 20 | 1.2 |
| Lab020 | 2 | 12.8 | 11.6 | 7 | 1.3 | 11.2 | 31.8 | 20 | 0.9 | 2.9 | 2.8 | 7 | 0.5 | 17.9 | 39.2 | 20 | 0.9 |
| Lab021 | 2 | 12.8 | 13.6 | 84 | 1.0 | 7.4 | 21.0 | 20 | 1.9 | 2.9 | 3.2 | 84 | 0.3 | 9.4 | 29.1 | 20 | 1.0 |
| Lab022 | 2 | 14.2 | 11.5 | 63 | 1.2 | 10.4 | 39.9 | 20 | 0.1 | 3.3 | 2.9 | 63 | 0.3 | 10.3 | 32.8 | 20 | 0.8 |
| Lab024 | 2 | 11.6 | 11.1 | 58 | 1.2 | 10.8 | 25.9 | 20 | 1.5 | 2.7 | 2.7 | 58 | 0.3 | 11.1 | 22.2 | 20 | 1.8 |
| Lab026 | 2 | 11.6 | 11.5 | 212 | 1.6 | 13.9 | 28.7 | 36 | 2.5 | 2.7 | 2.8 | 212 | 0.5 | 17.9 | 39.4 | 36 | 1.8 |
| Lab027 | 2 | 12.3 | 11.8 | 147 | 1.6 | 13.6 | 31.2 | 20 | 1.2 | 2.9 | 2.7 | 147 | 0.5 | 18.5 | 43.9 | 20 | 0.7 |
| Lab028 | 2 | 13.2 | 13.6 | 309 | 1.2 | 8.8 | 20.7 | 20 | 1.9 | 3.2 | 3.3 | 309 | 0.5 | 15.2 | 33.4 | 20 | 1.1 |
| Lab031 | 2 | 12.8 | 10.4 | 89 | 1.5 | 14.4 | 47.6 | 20 | 0.1 | 2.9 | 2.5 | 89 | 0.5 | 20.0 | 53.8 | 20 | 0.3 |
| Lab032 | 2 | 12.3 | 11.5 | 222 | 1.9 | 16.5 | 39.5 | 20 | 0.8 | 2.9 | 2.7 | 222 | 0.5 | 18.5 | 43.9 | 20 | 0.7 |
| Lab033 | 2 | 11.5 | 12.0 | 134 | 1.0 | 8.3 | 21.0 | 20 | 1.9 | 2.7 | 2.9 | 134 | 0.3 | 10.3 | 28.1 | 20 | 1.2 |
| Lab034 | 2 | 12.8 | 12.3 | 82 | 0.7 | 5.7 | 15.3 | 20 | 2.8 | 2.9 | 3.0 | 82 | 0.3 | 10.0 | 23.4 | 20 | 1.7 |
| Lab035 | 2 | 12.8 | 12.4 | 55 | 0.7 | 5.6 | 14.4 | 20 | 3.0 | 2.9 | 2.8 | 55 | 0.3 | 10.7 | 24.9 | 20 | 1.5 |
| Lab037 | 2 | 12.6 | 12.5 | 48 | 1.2 | 9.6 | 20.0 | 20 | 2.0 | 3.0 | 3.0 | 48 | 0.4 | 13.3 | 26.7 | 20 | 1.5 |
| Lab038 | 2 | 12.8 | 12.7 | 55 | 1.0 | 7.9 | 16.5 | 20 | 2.4 | 2.9 | 3.1 | 55 | 0.5 | 16.1 | 39.2 | 20 | 0.8 |
| Lab040 | 2 | 12.8 | 12.0 | 13 | 0.5 | 4.2 | 14.6 | 20 | 3.3 | 2.9 | 2.5 | 13 | 0.4 | 16.0 | 45.8 | 20 | 0.4 |
| Total | - | - | 12.1 | 1872 | 1.7 | 14.0 | - | - | - | - | 2.9 | 1872 | 0.6 | 20.7 | - | - | - |

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 |
|-------------|--------------|
| AMP | 2 |

Peer Group Statistics (Table 2)

Select LotNo : AC1203N (2014-01-01 ~ 2100-12-31) Change

Select Reagent Kit : 2 - AMP Change

[Print Table 2](#)

Control N Month vs. Cumulative

| | | Control N (Lot No.: AC1203N) | | | | | | | | | | | | | | | |
|------------------------|----------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2016/11) | | | | | | | | CUM (2014/02/01~2016/11/30) | | | | | | | |
| 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 |
| Lab017 | 2 | 14.2 | - | 0 | - | - | - | 20 | - | 14.2 | 13.8 | 36 | 1.6 | 11.6 | 26.0 | 20 | 1.5 |
| Lab018 | 2 | 10.9 | - | 0 | - | - | - | 20 | - | 10.9 | 10.9 | 113 | 1.3 | 11.9 | 23.9 | 20 | 1.7 |
| Lab019 | 2 | 12.8 | 12.2 | 5 | 0.4 | 3.3 | 11.2 | 20 | 4.6 | 12.8 | 12.2 | 145 | 1.2 | 9.8 | 24.4 | 20 | 1.6 |
| Lab020 | 2 | 12.8 | 11.1 | 4 | 1.4 | 12.6 | 38.5 | 20 | 0.5 | 12.8 | 11.6 | 7 | 1.3 | 11.2 | 31.8 | 20 | 0.9 |
| Lab021 | 2 | 12.8 | 11.7 | 4 | 0.2 | 1.7 | 12.0 | 20 | >6 | 12.8 | 13.6 | 84 | 1.0 | 7.4 | 21.0 | 20 | 1.9 |
| Lab022 | 2 | 14.2 | 11.9 | 6 | 0.9 | 7.6 | 31.3 | 20 | 0.5 | 14.2 | 11.5 | 63 | 1.2 | 10.4 | 39.9 | 20 | 0.1 |
| Lab024 | 2 | 11.6 | - | 0 | - | - | - | 20 | - | 11.6 | 11.1 | 58 | 1.2 | 10.8 | 25.9 | 20 | 1.5 |
| Lab026 | 2 | 11.6 | - | 0 | - | - | - | 36 | - | 11.6 | 11.5 | 212 | 1.6 | 13.9 | 28.7 | 36 | 2.5 |
| Lab027 | 2 | 12.3 | - | 0 | - | - | - | 20 | - | 12.3 | 11.8 | 147 | 1.6 | 13.6 | 31.2 | 20 | 1.2 |
| Lab028 | 2 | 13.2 | - | 0 | - | - | - | 20 | - | 13.2 | 13.6 | 309 | 1.2 | 8.8 | 20.7 | 20 | 1.9 |
| Lab031 | 2 | 12.8 | - | 0 | - | - | - | 20 | - | 12.8 | 10.4 | 89 | 1.5 | 14.4 | 47.6 | 20 | 0.1 |
| Lab032 | 2 | 12.3 | - | 0 | - | - | - | 20 | - | 12.3 | 11.5 | 222 | 1.9 | 16.5 | 39.5 | 20 | 0.8 |
| Lab033 | 2 | 11.5 | 11.7 | 4 | 0.5 | 4.3 | 10.3 | 20 | 4.2 | 11.5 | 12.0 | 134 | 1.0 | 8.3 | 21.0 | 20 | 1.9 |
| Lab034 | 2 | 12.8 | 11.6 | 4 | 0.8 | 6.9 | 23.2 | 20 | 1.5 | 12.8 | 12.3 | 82 | 0.7 | 5.7 | 15.3 | 20 | 2.8 |
| Lab035 | 2 | 12.8 | - | 0 | - | - | - | 20 | - | 12.8 | 12.4 | 55 | 0.7 | 5.6 | 14.4 | 20 | 3.0 |
| Lab037 | 2 | 12.6 | 11.2 | 4 | 0.8 | 7.1 | 25.4 | 20 | 1.3 | 12.6 | 12.5 | 48 | 1.2 | 9.6 | 20.0 | 20 | 2.0 |
| Lab038 | 2 | 12.8 | - | 0 | - | - | - | 20 | - | 12.8 | 12.7 | 55 | 1.0 | 7.9 | 16.5 | 20 | 2.4 |
| Lab040 | 2 | 12.8 | 12.6 | 2 | - | - | - | 20 | - | 12.8 | 12.0 | 13 | 0.5 | 4.2 | 14.6 | 20 | 3.3 |
| Total | - | - | 11.7 | 33 | 0.8 | 6.8 | - | - | - | - | 12.1 | 1872 | 1.7 | 14.0 | - | - | - |

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

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

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

Month : 2016 11 Change

Cumulative : from 2014 02 01 to 2016 11 30 Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: AC1203D) | | | | | | | | | | | | | | | |
|------------------------|----------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|-----|
| | | Month (2016/11) | | | | | | | | CUM (2014/02/01~2016/11/30) | | | | | | | |
| 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 |
| Lab017 | 2 | 3.3 | - | 0 | - | - | - | 20 | - | 3.3 | 3.9 | 36 | 1.4 | 35.9 | 90.0 | 20 | 0.1 |
| Lab018 | 2 | 2.5 | - | 0 | - | - | - | 20 | - | 2.5 | 2.6 | 113 | 0.9 | 34.6 | 73.2 | 20 | 0.5 |
| Lab019 | 2 | 2.9 | 2.8 | 5 | 0.2 | 7.1 | 17.7 | 20 | 2.3 | 2.9 | 2.8 | 145 | 0.4 | 14.3 | 32.0 | 20 | 1.2 |
| Lab020 | 2 | 2.9 | 2.6 | 4 | 0.6 | 23.1 | 56.5 | 20 | 0.4 | 2.9 | 2.8 | 7 | 0.5 | 17.9 | 39.2 | 20 | 0.9 |
| Lab021 | 2 | 2.9 | 2.7 | 4 | 0.2 | 7.4 | 21.7 | 20 | 1.8 | 2.9 | 3.2 | 84 | 0.3 | 9.4 | 29.1 | 20 | 1.0 |
| Lab022 | 2 | 3.3 | 3.0 | 6 | 0.4 | 13.3 | 35.8 | 20 | 0.8 | 3.3 | 2.9 | 63 | 0.3 | 10.3 | 32.8 | 20 | 0.8 |
| Lab024 | 2 | 2.7 | - | 0 | - | - | - | 20 | - | 2.7 | 2.7 | 58 | 0.3 | 11.1 | 22.2 | 20 | 1.8 |
| Lab026 | 2 | 2.7 | - | 0 | - | - | - | 36 | - | 2.7 | 2.8 | 212 | 0.5 | 17.9 | 39.4 | 36 | 1.8 |
| Lab027 | 2 | 2.9 | - | 0 | - | - | - | 20 | - | 2.9 | 2.7 | 147 | 0.5 | 18.5 | 43.9 | 20 | 0.7 |
| Lab028 | 2 | 3.2 | - | 0 | - | - | - | 20 | - | 3.2 | 3.3 | 309 | 0.5 | 15.2 | 33.4 | 20 | 1.1 |
| Lab031 | 2 | 2.9 | - | 0 | - | - | - | 20 | - | 2.9 | 2.5 | 89 | 0.5 | 20.0 | 53.8 | 20 | 0.3 |
| Lab032 | 2 | 2.9 | - | 0 | - | - | - | 20 | - | 2.9 | 2.7 | 222 | 0.5 | 18.5 | 43.9 | 20 | 0.7 |
| Lab033 | 2 | 2.7 | 2.9 | 4 | 0.1 | 3.4 | 14.3 | 20 | 3.7 | 2.7 | 2.9 | 134 | 0.3 | 10.3 | 28.1 | 20 | 1.2 |
| Lab034 | 2 | 2.9 | 2.7 | 4 | 0.4 | 14.8 | 36.5 | 20 | 0.9 | 2.9 | 3.0 | 82 | 0.3 | 10.0 | 23.4 | 20 | 1.7 |
| Lab035 | 2 | 2.9 | - | 0 | - | - | - | 20 | - | 2.9 | 2.8 | 55 | 0.3 | 10.7 | 24.9 | 20 | 1.5 |
| Lab037 | 2 | 3.0 | 2.6 | 4 | 0.3 | 11.5 | 36.4 | 20 | 0.6 | 3.0 | 3.0 | 48 | 0.4 | 13.3 | 26.7 | 20 | 1.5 |
| Lab038 | 2 | 2.9 | - | 0 | - | - | - | 20 | - | 2.9 | 3.1 | 55 | 0.5 | 16.1 | 39.2 | 20 | 0.8 |
| Lab040 | 2 | 2.9 | 3.0 | 2 | - | - | - | 20 | - | 2.9 | 2.5 | 13 | 0.4 | 16.0 | 45.8 | 20 | 0.4 |
| Total | - | - | 2.8 | 33 | 0.3 | 10.7 | - | - | - | - | 2.9 | 1872 | 0.6 | 20.7 | - | - | - |

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

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

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

Month : 2016 11 Change

Cumulative : from 2014 02 01 to 2016 11 30 Change

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| Reagent Kit | Reagent Code |
|-------------|--------------|
| AMP | 2 |