

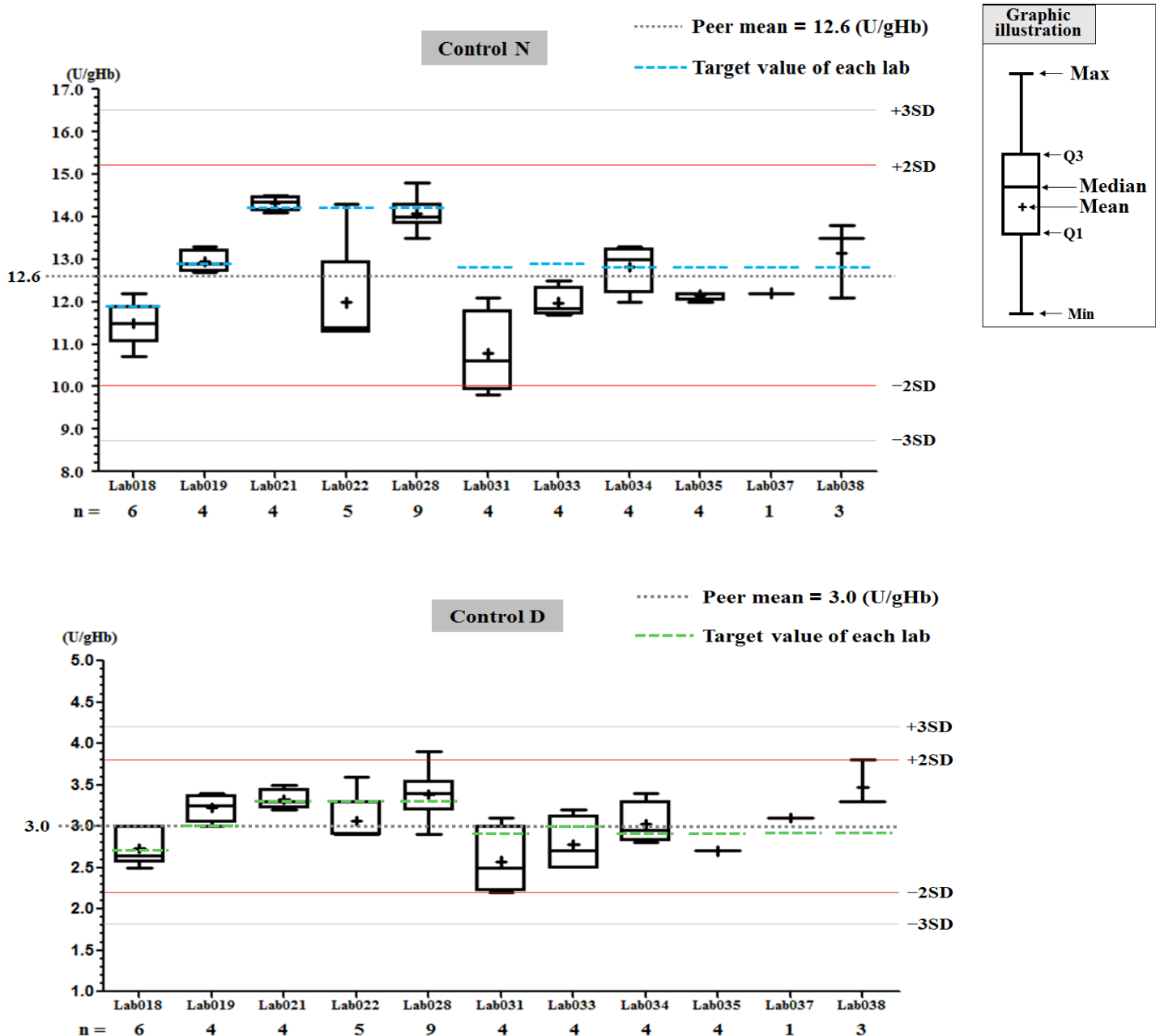
Summary Report of IQC program for G6PD Quantitative Test - AMP Group - January 2016 -

I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:AC1203N) | Control D (Lot No.:AC1203D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs | 11 | 11 |
| Received results number (n) | 48 | 48 |
| Median | 12.4 (U/gHb) | 3.0 (U/gHb) |
| Mean | 12.6 (U/gHb) | 3.0 (U/gHb) |
| SD | 1.3 | 0.4 |
| CV | 10.3% | 13.3% |
| Range of G6PD | 9.8 ~ 14.8 (U/gHb) | 2.2 ~ 3.9 (U/gHb) |
| Range of Hb | 2.1 ~ 2.6 (g/dL) | 2.2 ~ 3.1 (g/dL) |

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

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](#)

Lab018

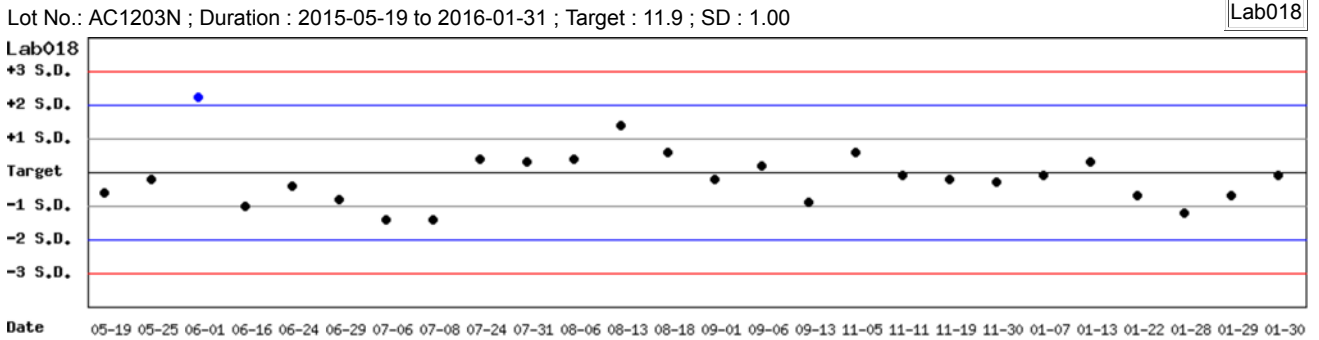
| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | AC1203N | | AC1203D | |
| Duration of the Analyzing | Month (2016/01) | CUM (2015/05/19~2016/01/31) | Month (2016/01) | CUM (2015/05/19~2016/01/31) |
| Runs (N) | 6 | 26 | 6 | 26 |
| Mean (U/gHb) | 11.5 | 11.8 | 2.7 | 2.9 |
| SD | 0.5 | 0.8 | 0.2 | 0.4 |
| CV (%) | 4.3 | 6.8 | 7.4 | 13.8 |
| Target Value (U/gHb) | 11.9 | 11.9 | 2.7 | 2.7 |
| Total Error (%) | 12.1 | 14.4 | 14.8 | 35.0 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | 3.9 | 2.8 | 2.7 | 0.9 |

Bias (%) = [(| Mean - Target |) / Target] x 100%
 TE : Total Error(%) = Bias (%) + 2 x CV (%)
 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2016 01 [Change](#) ; Cumulative : from 2015 05 19 to 2016 01 31 [Change](#)

[TOP](#)

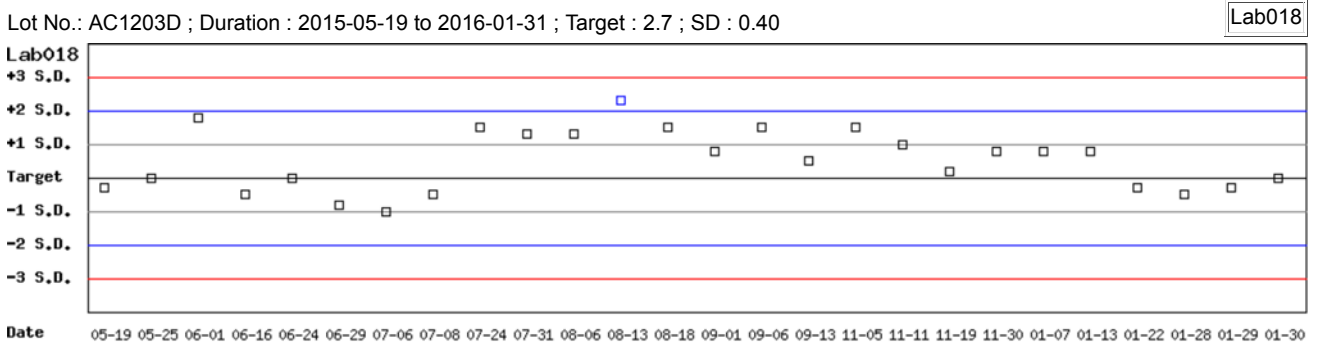
Control N SDI QC Chart



Month : 2016 01 [Change](#) ; Cumulative : from 2015 05 19 to 2016 01 31 [Change](#)

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Control D SDI QC Chart



Month : 2016 01 [Change](#) ; Cumulative : from 2015 05 19 to 2016 01 31 [Change](#)

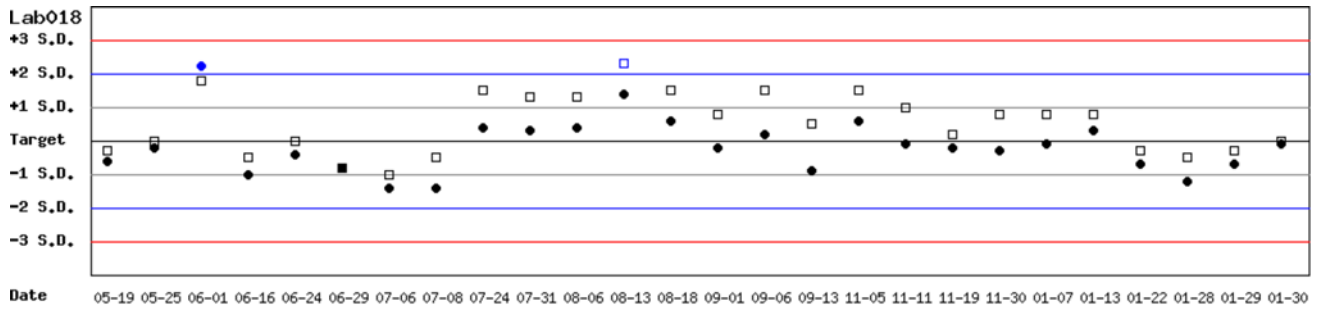
[TOP](#)

Control N and Control D SDI QC Chart

Lot No.: AC1203N ; Duration : 2015-05-19 to 2016-01-31 ; Target : 11.9 ; SD : 1.00 (●)

Lot No.: AC1203D ; Duration : 2015-05-19 to 2016-01-31 ; Target : 2.7 ; SD : 0.40 (□)

Lab018



Month : 2016 01 ; Cumulative : from 2015 05 19 to 2016 01 31

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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 01 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 |
| Lab018 | 2 | 11.9 | 11.5 | 6 | 0.5 | 4.3 | 12.1 | 20 | 3.9 | 2.7 | 2.7 | 6 | 0.2 | 7.4 | 14.8 | 20 | 2.7 |
| Lab019 | 2 | 12.9 | 13.0 | 4 | 0.3 | 2.3 | 5.4 | 20 | >6 | 3.0 | 3.2 | 4 | 0.2 | 6.3 | 19.2 | 20 | 2.1 |
| Lab021 | 2 | 14.2 | 14.3 | 4 | 0.2 | 1.4 | 3.5 | 20 | >6 | 3.3 | 3.3 | 4 | 0.1 | 3.0 | 6.1 | 20 | >6 |
| Lab022 | 2 | 14.2 | 12.0 | 5 | 1.3 | 10.8 | 37.2 | 20 | 0.4 | 3.3 | 3.1 | 5 | 0.3 | 9.7 | 25.4 | 20 | 1.4 |
| Lab028 | 2 | 14.2 | 14.1 | 9 | 0.4 | 2.8 | 6.4 | 20 | >6 | 3.3 | 3.4 | 9 | 0.3 | 8.8 | 20.7 | 20 | 1.9 |
| Lab031 | 2 | 12.8 | 10.8 | 4 | 1.0 | 9.3 | 34.1 | 20 | 0.5 | 2.9 | 2.6 | 4 | 0.4 | 15.4 | 41.1 | 20 | 0.6 |
| Lab033 | 2 | 12.9 | 12.0 | 4 | 0.4 | 3.3 | 13.6 | 20 | 3.9 | 3.0 | 2.8 | 4 | 0.3 | 10.7 | 28.1 | 20 | 1.2 |
| Lab034 | 2 | 12.8 | 12.8 | 4 | 0.6 | 4.7 | 9.4 | 20 | 4.3 | 2.9 | 3.0 | 4 | 0.3 | 10.0 | 23.4 | 20 | 1.7 |
| Lab035 | 2 | 12.8 | 12.2 | 4 | 0.1 | 0.8 | 6.3 | 20 | >6 | 2.9 | 2.7 | 4 | 0.0 | 0.0 | 6.9 | 20 | >6 |
| Lab037 | 2 | 12.8 | 12.2 | 1 | - | - | - | 20 | - | 2.9 | 3.1 | 1 | - | - | - | 20 | - |
| Lab038 | 2 | 12.8 | 13.1 | 3 | 0.9 | 6.9 | 16.1 | 20 | 2.6 | 2.9 | 3.5 | 3 | 0.3 | 8.6 | 37.8 | 20 | -0.1 |
| Total | - | - | 12.6 | 48 | 1.3 | 10.3 | - | - | - | - | 3.0 | 48 | 0.4 | 13.3 | - | - | - |

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 01 31 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 | 11.9 | 10.8 | 72 | 1.6 | 14.8 | 38.9 | 20 | 0.7 | 2.7 | 2.6 | 72 | 1.1 | 42.3 | 88.3 | 20 | 0.4 |
| Lab019 | 2 | 12.9 | 12.1 | 100 | 1.2 | 9.9 | 26.0 | 20 | 1.4 | 3.0 | 2.8 | 100 | 0.4 | 14.3 | 35.2 | 20 | 0.9 |
| Lab021 | 2 | 14.2 | 14.2 | 54 | 0.2 | 1.4 | 2.8 | 20 | >6 | 3.3 | 3.4 | 54 | 0.1 | 2.9 | 8.9 | 20 | 5.9 |
| Lab022 | 2 | 14.2 | 12.0 | 18 | 1.0 | 8.3 | 32.2 | 20 | 0.5 | 3.3 | 3.1 | 18 | 0.3 | 9.7 | 25.4 | 20 | 1.4 |
| Lab024 | 2 | 11.6 | 11.1 | 49 | 1.2 | 10.8 | 25.9 | 20 | 1.5 | 2.7 | 2.7 | 49 | 0.4 | 14.8 | 29.6 | 20 | 1.4 |
| Lab026 | 2 | 11.6 | 11.5 | 211 | 1.6 | 13.9 | 28.7 | 36 | 2.5 | 2.7 | 2.8 | 211 | 0.5 | 17.9 | 39.4 | 36 | 1.8 |
| Lab027 | 2 | 12.3 | 11.8 | 113 | 1.7 | 14.4 | 32.9 | 20 | 1.1 | 2.9 | 2.7 | 113 | 0.5 | 18.5 | 43.9 | 20 | 0.7 |
| Lab028 | 2 | 14.2 | 13.9 | 191 | 1.3 | 9.4 | 20.8 | 20 | 1.9 | 3.3 | 3.4 | 191 | 0.6 | 17.6 | 38.3 | 20 | 1.0 |
| Lab031 | 2 | 12.8 | 10.1 | 63 | 1.4 | 13.9 | 48.8 | 20 | -0.1 | 2.9 | 2.4 | 63 | 0.4 | 16.7 | 50.6 | 20 | 0.2 |
| Lab032 | 2 | 13.8 | 11.2 | 167 | 1.9 | 17.0 | 52.8 | 20 | 0.1 | 3.5 | 2.6 | 167 | 0.5 | 19.2 | 64.2 | 20 | -0.3 |
| Lab033 | 2 | 12.9 | 12.2 | 98 | 1.0 | 8.2 | 21.8 | 20 | 1.8 | 3.0 | 2.9 | 98 | 0.3 | 10.3 | 24.0 | 20 | 1.6 |
| Lab034 | 2 | 12.8 | 12.6 | 46 | 0.5 | 4.0 | 9.5 | 20 | 4.6 | 2.9 | 3.0 | 46 | 0.1 | 3.3 | 10.1 | 20 | 5.0 |
| Lab035 | 2 | 12.8 | 12.6 | 37 | 0.7 | 5.6 | 12.7 | 20 | 3.3 | 2.9 | 2.9 | 37 | 0.3 | 10.3 | 20.7 | 20 | 1.9 |
| Lab037 | 2 | 12.8 | 12.5 | 9 | 1.0 | 8.0 | 18.3 | 20 | 2.2 | 2.9 | 3.1 | 9 | 0.3 | 9.7 | 26.3 | 20 | 1.4 |
| Lab038 | 2 | 12.8 | 12.7 | 33 | 1.2 | 9.4 | 19.7 | 20 | 2.0 | 2.9 | 3.2 | 33 | 0.5 | 15.6 | 41.6 | 20 | 0.6 |
| Total | - | - | 12.1 | 1297 | 1.8 | 14.9 | - | - | - | - | 2.9 | 1297 | 0.7 | 24.1 | - | - | - |

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 :

Select Reagent Kit :

Control N Month vs. Cumulative

| | | Control N (Lot No.: AC1203N) | | | | | | | | | | | | | | | |
|------------------------|---------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|-----|-----------------------------|--------------|------------|-----|--------|--------|---------|------|
| | | Month (2016/01) | | | | | | | | CUM (2014/02/01~2016/01/31) | | | | | | | |
| 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 |
| Lab017 | 2 | 14.2 | - | 0 | - | - | - | 20 | - | 14.2 | 13.8 | 36 | 1.6 | 11.6 | 26.0 | 20 | 1.5 |
| Lab018 | 2 | 11.9 | 11.5 | 6 | 0.5 | 4.3 | 12.1 | 20 | 3.9 | 11.9 | 10.8 | 72 | 1.6 | 14.8 | 38.9 | 20 | 0.7 |
| Lab019 | 2 | 12.9 | 13.0 | 4 | 0.3 | 2.3 | 5.4 | 20 | >6 | 12.9 | 12.1 | 100 | 1.2 | 9.9 | 26.0 | 20 | 1.4 |
| Lab021 | 2 | 14.2 | 14.3 | 4 | 0.2 | 1.4 | 3.5 | 20 | >6 | 14.2 | 14.2 | 54 | 0.2 | 1.4 | 2.8 | 20 | >6 |
| Lab022 | 2 | 14.2 | 12.0 | 5 | 1.3 | 10.8 | 37.2 | 20 | 0.4 | 14.2 | 12.0 | 18 | 1.0 | 8.3 | 32.2 | 20 | 0.5 |
| Lab024 | 2 | 11.6 | - | 0 | - | - | - | 20 | - | 11.6 | 11.1 | 49 | 1.2 | 10.8 | 25.9 | 20 | 1.5 |
| Lab026 | 2 | 11.6 | - | 0 | - | - | - | 36 | - | 11.6 | 11.5 | 211 | 1.6 | 13.9 | 28.7 | 36 | 2.5 |
| Lab027 | 2 | 12.3 | - | 0 | - | - | - | 20 | - | 12.3 | 11.8 | 113 | 1.7 | 14.4 | 32.9 | 20 | 1.1 |
| Lab028 | 2 | 14.2 | 14.1 | 9 | 0.4 | 2.8 | 6.4 | 20 | >6 | 14.2 | 13.9 | 191 | 1.3 | 9.4 | 20.8 | 20 | 1.9 |
| Lab031 | 2 | 12.8 | 10.8 | 4 | 1.0 | 9.3 | 34.1 | 20 | 0.5 | 12.8 | 10.1 | 63 | 1.4 | 13.9 | 48.8 | 20 | -0.1 |
| Lab032 | 2 | 13.8 | - | 0 | - | - | - | 20 | - | 13.8 | 11.2 | 167 | 1.9 | 17.0 | 52.8 | 20 | 0.1 |
| Lab033 | 2 | 12.9 | 12.0 | 4 | 0.4 | 3.3 | 13.6 | 20 | 3.9 | 12.9 | 12.2 | 98 | 1.0 | 8.2 | 21.8 | 20 | 1.8 |
| Lab034 | 2 | 12.8 | 12.8 | 4 | 0.6 | 4.7 | 9.4 | 20 | 4.3 | 12.8 | 12.6 | 46 | 0.5 | 4.0 | 9.5 | 20 | 4.6 |
| Lab035 | 2 | 12.8 | 12.2 | 4 | 0.1 | 0.8 | 6.3 | 20 | >6 | 12.8 | 12.6 | 37 | 0.7 | 5.6 | 12.7 | 20 | 3.3 |
| Lab037 | 2 | 12.8 | 12.2 | 1 | - | - | - | 20 | - | 12.8 | 12.5 | 9 | 1.0 | 8.0 | 18.3 | 20 | 2.2 |
| Lab038 | 2 | 12.8 | 13.1 | 3 | 0.9 | 6.9 | 16.1 | 20 | 2.6 | 12.8 | 12.7 | 33 | 1.2 | 9.4 | 19.7 | 20 | 2.0 |
| Total | - | - | 12.6 | 48 | 1.3 | 10.3 | - | - | - | - | 12.1 | 1297 | 1.8 | 14.9 | - | - | - |

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

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

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

Month :

Cumulative : from to

[TOP](#)

Control D Month vs. Cumulative

| | | Control D (Lot No.: AC1203D) | | | | | | | | | | | | | | | |
|------------------------|---------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|------|-----------------------------|--------------|------------|-----|--------|--------|---------|------|
| | | Month (2016/01) | | | | | | | | CUM (2014/02/01~2016/01/31) | | | | | | | |
| 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 |
| Lab017 | 2 | 3.3 | - | 0 | - | - | - | 20 | - | 3.3 | 3.9 | 36 | 1.4 | 35.9 | 90.0 | 20 | 0.1 |
| Lab018 | 2 | 2.7 | 2.7 | 6 | 0.2 | 7.4 | 14.8 | 20 | 2.7 | 2.7 | 2.6 | 72 | 1.1 | 42.3 | 88.3 | 20 | 0.4 |
| Lab019 | 2 | 3.0 | 3.2 | 4 | 0.2 | 6.3 | 19.2 | 20 | 2.1 | 3.0 | 2.8 | 100 | 0.4 | 14.3 | 35.2 | 20 | 0.9 |
| Lab021 | 2 | 3.3 | 3.3 | 4 | 0.1 | 3.0 | 6.1 | 20 | >6 | 3.3 | 3.4 | 54 | 0.1 | 2.9 | 8.9 | 20 | 5.9 |
| Lab022 | 2 | 3.3 | 3.1 | 5 | 0.3 | 9.7 | 25.4 | 20 | 1.4 | 3.3 | 3.1 | 18 | 0.3 | 9.7 | 25.4 | 20 | 1.4 |
| Lab024 | 2 | 2.7 | - | 0 | - | - | - | 20 | - | 2.7 | 2.7 | 49 | 0.4 | 14.8 | 29.6 | 20 | 1.4 |
| Lab026 | 2 | 2.7 | - | 0 | - | - | - | 36 | - | 2.7 | 2.8 | 211 | 0.5 | 17.9 | 39.4 | 36 | 1.8 |
| Lab027 | 2 | 2.9 | - | 0 | - | - | - | 20 | - | 2.9 | 2.7 | 113 | 0.5 | 18.5 | 43.9 | 20 | 0.7 |
| Lab028 | 2 | 3.3 | 3.4 | 9 | 0.3 | 8.8 | 20.7 | 20 | 1.9 | 3.3 | 3.4 | 191 | 0.6 | 17.6 | 38.3 | 20 | 1.0 |
| Lab031 | 2 | 2.9 | 2.6 | 4 | 0.4 | 15.4 | 41.1 | 20 | 0.6 | 2.9 | 2.4 | 63 | 0.4 | 16.7 | 50.6 | 20 | 0.2 |
| Lab032 | 2 | 3.5 | - | 0 | - | - | - | 20 | - | 3.5 | 2.6 | 167 | 0.5 | 19.2 | 64.2 | 20 | -0.3 |
| Lab033 | 2 | 3.0 | 2.8 | 4 | 0.3 | 10.7 | 28.1 | 20 | 1.2 | 3.0 | 2.9 | 98 | 0.3 | 10.3 | 24.0 | 20 | 1.6 |
| Lab034 | 2 | 2.9 | 3.0 | 4 | 0.3 | 10.0 | 23.4 | 20 | 1.7 | 2.9 | 3.0 | 46 | 0.1 | 3.3 | 10.1 | 20 | 5.0 |
| Lab035 | 2 | 2.9 | 2.7 | 4 | 0.0 | 0.0 | 6.9 | 20 | >6 | 2.9 | 2.9 | 37 | 0.3 | 10.3 | 20.7 | 20 | 1.9 |
| Lab037 | 2 | 2.9 | 3.1 | 1 | - | - | - | 20 | - | 2.9 | 3.1 | 9 | 0.3 | 9.7 | 26.3 | 20 | 1.4 |
| Lab038 | 2 | 2.9 | 3.5 | 3 | 0.3 | 8.6 | 37.8 | 20 | -0.1 | 2.9 | 3.2 | 33 | 0.5 | 15.6 | 41.6 | 20 | 0.6 |
| Total | - | - | 3.0 | 48 | 0.4 | 13.3 | - | - | - | - | 2.9 | 1297 | 0.7 | 24.1 | - | - | - |

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

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

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

Month :

Cumulative : from to

[TOP](#)

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