

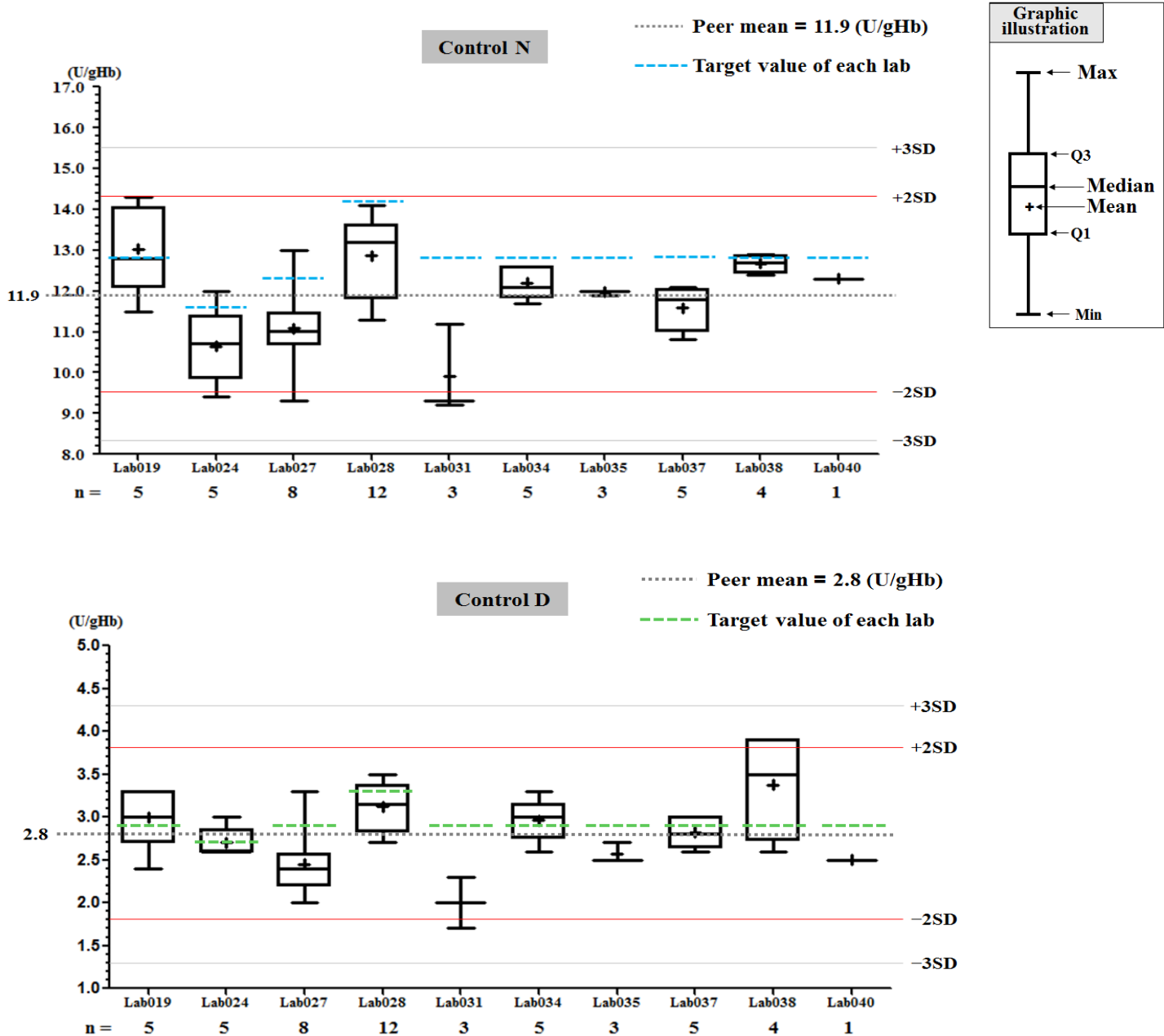
Summary Report of IQC program for G6PD Quantitative Test - AMP Group - April 2016 -

I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:AC1203N) | Control D (Lot No.:AC1203D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs | 10 | 10 |
| Received results number (n) | 51 | 51 |
| Median | 12.0 (U/gHb) | 2.8 (U/gHb) |
| Mean | 11.9 (U/gHb) | 2.8 (U/gHb) |
| SD | 1.2 | 0.2 |
| CV | 10.1% | 17.9% |
| Range of G6PD | 9.2 ~ 14.3 (U/gHb) | 1.7 ~ 3.9 (U/gHb) |
| Range of Hb | 2.2 ~ 3.9 (g/dL) | 1.3 ~ 3.5 (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

Lab040

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|--------------------|--------------------------------|--------------------|--------------------------------|
| | AC1203N | | AC1203D | |
| Duration of the Analyzing | Month (2016/04) | CUM (2014/02/01~2016/04/30) | Month (2016/04) | CUM (2014/02/01~2016/04/30) |
| Runs (N) | 1 | 1 | 1 | 1 |
| Mean (U/gHb) | 12.3 | 12.3 | 2.5 | 2.5 |
| SD | - | - | - | - |
| CV (%) | - | - | - | - |
| Target Value (U/gHb) | 12.8 | 12.8 | 2.9 | 2.9 |
| Total Error (%) | - | - | - | - |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | - | - | - | - |

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

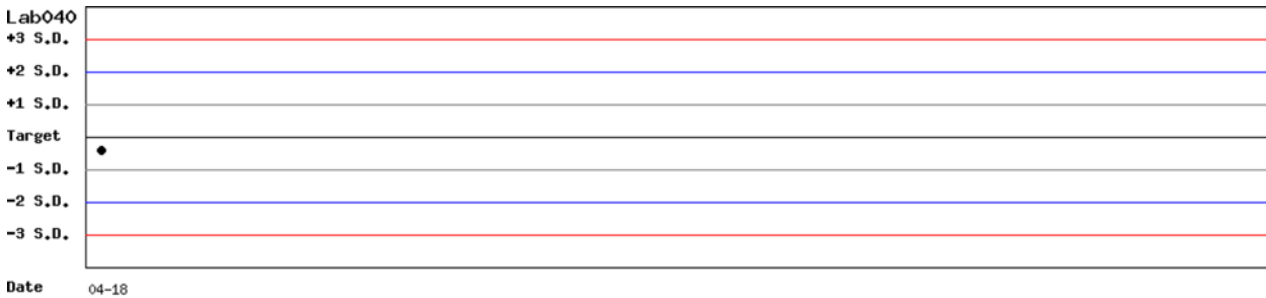
Month : 2016 04 Change ; Cumulative : from 2014 02 01 to 2016 04 30 Change

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Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2014-02-01 to 2016-04-30 ; Target : 12.8 ; SD : 1.28

Lab040



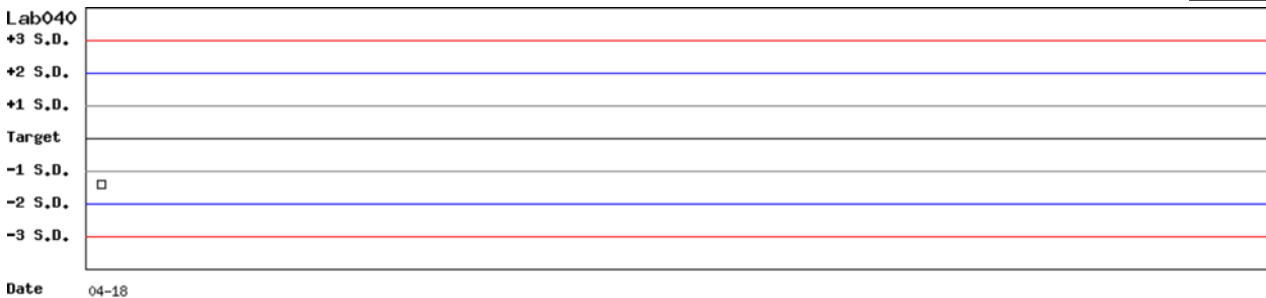
Month : 2016 04 Change ; Cumulative : from 2014 02 01 to 2016 04 30 Change

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Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2014-02-01 to 2016-04-30 ; Target : 2.9 ; SD : 0.29

Lab040



Month : 2016 04 Change ; Cumulative : from 2014 02 01 to 2016 04 30 Change

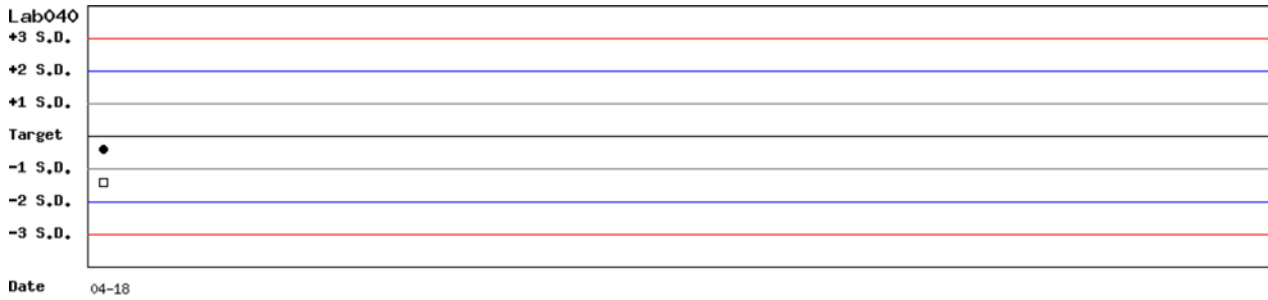
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Control N and Control D SDI QC Chart

Lot No.: AC1203N ; Duration : 2014-02-01 to 2016-04-30 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: AC1203D ; Duration : 2014-02-01 to 2016-04-30 ; Target : 2.9 ; SD : 0.29 (□)

Lab040



Month : 2016 04 Change ; Cumulative : from 2014 02 01 to 2016 04 30 Change

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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 04 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 | 13.0 | 5 | 1.1 | 8.5 | 18.5 | 20 | 2.2 | 2.9 | 3.0 | 5 | 0.4 | 13.3 | 30.1 | 20 | 1.2 |
| Lab024 | 2 | 11.6 | 10.6 | 5 | 0.9 | 8.5 | 25.6 | 20 | 1.3 | 2.7 | 2.7 | 5 | 0.2 | 7.4 | 14.8 | 20 | 2.7 |
| Lab027 | 2 | 12.3 | 11.1 | 8 | 1.0 | 9.0 | 27.8 | 20 | 1.1 | 2.9 | 2.5 | 8 | 0.4 | 16.0 | 45.8 | 20 | 0.4 |
| Lab028 | 2 | 14.2 | 12.9 | 12 | 0.9 | 7.0 | 23.1 | 20 | 1.5 | 3.3 | 3.1 | 12 | 0.3 | 9.7 | 25.4 | 20 | 1.4 |
| Lab031 | 2 | 12.8 | 9.9 | 3 | 1.1 | 11.1 | 44.9 | 20 | -0.2 | 2.9 | 2.0 | 3 | 0.3 | 15.0 | 61.0 | 20 | -0.7 |
| Lab034 | 2 | 12.8 | 12.2 | 5 | 0.4 | 3.3 | 11.2 | 20 | 4.6 | 2.9 | 3.0 | 5 | 0.3 | 10.0 | 23.4 | 20 | 1.7 |
| Lab035 | 2 | 12.8 | 12.0 | 3 | 0.1 | 0.8 | 7.9 | 20 | >6 | 2.9 | 2.6 | 3 | 0.1 | 3.8 | 18.0 | 20 | 2.5 |
| Lab037 | 2 | 12.8 | 11.6 | 5 | 0.6 | 5.2 | 19.7 | 20 | 2.0 | 2.9 | 2.8 | 5 | 0.2 | 7.1 | 17.7 | 20 | 2.3 |
| Lab038 | 2 | 12.8 | 12.7 | 4 | 0.2 | 1.6 | 3.9 | 20 | >6 | 2.9 | 3.4 | 4 | 0.6 | 17.6 | 52.5 | 20 | 0.2 |
| Lab040 | 2 | 12.8 | 12.3 | 1 | - | - | - | 20 | - | 2.9 | 2.5 | 1 | - | - | - | 20 | - |
| Total | - | - | 11.9 | 51 | 1.2 | 10.1 | - | - | - | - | 2.8 | 51 | 0.5 | 17.9 | - | - | - |

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

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Cumulative

Cumulative : from 2014 02 01 to 2016 04 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 | 11.9 | 10.8 | 76 | 1.6 | 14.8 | 38.9 | 20 | 0.7 | 2.7 | 2.6 | 76 | 1.1 | 42.3 | 88.3 | 20 | 0.4 |
| Lab019 | 2 | 12.8 | 12.2 | 114 | 1.2 | 9.8 | 24.4 | 20 | 1.6 | 2.9 | 2.8 | 114 | 0.4 | 14.3 | 32.0 | 20 | 1.2 |
| 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 | 11.9 | 23 | 1.1 | 9.2 | 34.7 | 20 | 0.4 | 3.3 | 3.1 | 23 | 0.3 | 9.7 | 25.4 | 20 | 1.4 |
| Lab024 | 2 | 11.6 | 11.1 | 54 | 1.2 | 10.8 | 25.9 | 20 | 1.5 | 2.7 | 2.7 | 54 | 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 | 138 | 1.6 | 13.6 | 31.2 | 20 | 1.2 | 2.9 | 2.7 | 138 | 0.5 | 18.5 | 43.9 | 20 | 0.7 |
| Lab028 | 2 | 14.2 | 13.8 | 227 | 1.2 | 8.7 | 20.2 | 20 | 2.0 | 3.3 | 3.4 | 227 | 0.6 | 17.6 | 38.3 | 20 | 1.0 |
| Lab031 | 2 | 12.8 | 10.1 | 66 | 1.3 | 12.9 | 46.8 | 20 | -0.1 | 2.9 | 2.4 | 66 | 0.4 | 16.7 | 50.6 | 20 | 0.2 |
| Lab032 | 2 | 13.8 | 11.3 | 177 | 2.0 | 17.7 | 53.5 | 20 | 0.1 | 3.5 | 2.6 | 177 | 0.5 | 19.2 | 64.2 | 20 | -0.3 |
| Lab033 | 2 | 12.9 | 12.2 | 100 | 1.0 | 8.2 | 21.8 | 20 | 1.8 | 3.0 | 2.9 | 100 | 0.3 | 10.3 | 24.0 | 20 | 1.6 |
| Lab034 | 2 | 12.8 | 12.5 | 53 | 0.6 | 4.8 | 11.9 | 20 | 3.7 | 2.9 | 3.0 | 53 | 0.2 | 6.7 | 16.8 | 20 | 2.5 |
| Lab035 | 2 | 12.8 | 12.5 | 43 | 0.7 | 5.6 | 13.5 | 20 | 3.2 | 2.9 | 2.8 | 43 | 0.3 | 10.7 | 24.9 | 20 | 1.5 |
| Lab037 | 2 | 12.8 | 12.1 | 18 | 0.9 | 7.4 | 20.3 | 20 | 2.0 | 2.9 | 3.0 | 18 | 0.3 | 10.0 | 23.4 | 20 | 1.7 |
| Lab038 | 2 | 12.8 | 12.6 | 46 | 1.1 | 8.7 | 19.0 | 20 | 2.1 | 2.9 | 3.2 | 46 | 0.5 | 15.6 | 41.6 | 20 | 0.6 |
| Lab040 | 2 | 12.8 | 12.3 | 1 | - | - | - | 20 | - | 2.9 | 2.5 | 1 | - | - | - | 20 | - |
| Total | - | - | 12.1 | 1437 | 1.8 | 14.9 | - | - | - | - | 2.9 | 1437 | 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 (2016/04) | | | | | | | | CUM (2014/02/01~2016/04/30) | | | | | | | |
| 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 | 11.9 | - | 0 | - | - | - | 20 | - | 11.9 | 10.8 | 76 | 1.6 | 14.8 | 38.9 | 20 | 0.7 |
| Lab019 | 2 | 12.8 | 13.0 | 5 | 1.1 | 8.5 | 18.5 | 20 | 2.2 | 12.8 | 12.2 | 114 | 1.2 | 9.8 | 24.4 | 20 | 1.6 |
| Lab021 | 2 | 14.2 | - | 0 | - | - | - | 20 | - | 14.2 | 14.2 | 54 | 0.2 | 1.4 | 2.8 | 20 | >6 |
| Lab022 | 2 | 14.2 | - | 0 | - | - | - | 20 | - | 14.2 | 11.9 | 23 | 1.1 | 9.2 | 34.7 | 20 | 0.4 |
| Lab024 | 2 | 11.6 | 10.6 | 5 | 0.9 | 8.5 | 25.6 | 20 | 1.3 | 11.6 | 11.1 | 54 | 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 | 11.1 | 8 | 1.0 | 9.0 | 27.8 | 20 | 1.1 | 12.3 | 11.8 | 138 | 1.6 | 13.6 | 31.2 | 20 | 1.2 |
| Lab028 | 2 | 14.2 | 12.9 | 12 | 0.9 | 7.0 | 23.1 | 20 | 1.5 | 14.2 | 13.8 | 227 | 1.2 | 8.7 | 20.2 | 20 | 2.0 |
| Lab031 | 2 | 12.8 | 9.9 | 3 | 1.1 | 11.1 | 44.9 | 20 | -0.2 | 12.8 | 10.1 | 66 | 1.3 | 12.9 | 46.8 | 20 | -0.1 |
| Lab032 | 2 | 13.8 | - | 0 | - | - | - | 20 | - | 13.8 | 11.3 | 177 | 2.0 | 17.7 | 53.5 | 20 | 0.1 |
| Lab033 | 2 | 12.9 | - | 0 | - | - | - | 20 | - | 12.9 | 12.2 | 100 | 1.0 | 8.2 | 21.8 | 20 | 1.8 |
| Lab034 | 2 | 12.8 | 12.2 | 5 | 0.4 | 3.3 | 11.2 | 20 | 4.6 | 12.8 | 12.5 | 53 | 0.6 | 4.8 | 11.9 | 20 | 3.7 |
| Lab035 | 2 | 12.8 | 12.0 | 3 | 0.1 | 0.8 | 7.9 | 20 | >6 | 12.8 | 12.5 | 43 | 0.7 | 5.6 | 13.5 | 20 | 3.2 |
| Lab037 | 2 | 12.8 | 11.6 | 5 | 0.6 | 5.2 | 19.7 | 20 | 2.0 | 12.8 | 12.1 | 18 | 0.9 | 7.4 | 20.3 | 20 | 2.0 |
| Lab038 | 2 | 12.8 | 12.7 | 4 | 0.2 | 1.6 | 3.9 | 20 | >6 | 12.8 | 12.6 | 46 | 1.1 | 8.7 | 19.0 | 20 | 2.1 |
| Lab040 | 2 | 12.8 | 12.3 | 1 | - | - | - | 20 | - | 12.8 | 12.3 | 1 | - | - | - | 20 | - |
| Total | - | - | 11.9 | 51 | 1.2 | 10.1 | - | - | - | - | 12.1 | 1437 | 1.8 | 14.9 | - | - | - |

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

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

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

Month : 2016 04 Change

Cumulative : from 2014 02 01 to 2016 04 30 Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: AC1203D) | | | | | | | | | | | | | | | |
|---|---|------------------------------|--------------|------------|-----|--------|--------|---------|------|-----------------------------|--------------|------------|-----|--------|--------|---------|------|
| | | Month (2016/04) | | | | | | | | CUM (2014/02/01~2016/04/30) | | | | | | | |
| 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 | 2.7 | - | 0 | - | - | - | 20 | - | 2.7 | 2.6 | 76 | 1.1 | 42.3 | 88.3 | 20 | 0.4 |
| Lab019 | 2 | 2.9 | 3.0 | 5 | 0.4 | 13.3 | 30.1 | 20 | 1.2 | 2.9 | 2.8 | 114 | 0.4 | 14.3 | 32.0 | 20 | 1.2 |
| Lab021 | 2 | 3.3 | - | 0 | - | - | - | 20 | - | 3.3 | 3.4 | 54 | 0.1 | 2.9 | 8.9 | 20 | 5.9 |
| Lab022 | 2 | 3.3 | - | 0 | - | - | - | 20 | - | 3.3 | 3.1 | 23 | 0.3 | 9.7 | 25.4 | 20 | 1.4 |
| Lab024 | 2 | 2.7 | 2.7 | 5 | 0.2 | 7.4 | 14.8 | 20 | 2.7 | 2.7 | 2.7 | 54 | 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 | 2.5 | 8 | 0.4 | 16.0 | 45.8 | 20 | 0.4 | 2.9 | 2.7 | 138 | 0.5 | 18.5 | 43.9 | 20 | 0.7 |
| Lab028 | 2 | 3.3 | 3.1 | 12 | 0.3 | 9.7 | 25.4 | 20 | 1.4 | 3.3 | 3.4 | 227 | 0.6 | 17.6 | 38.3 | 20 | 1.0 |
| Lab031 | 2 | 2.9 | 2.0 | 3 | 0.3 | 15.0 | 61.0 | 20 | -0.7 | 2.9 | 2.4 | 66 | 0.4 | 16.7 | 50.6 | 20 | 0.2 |
| Lab032 | 2 | 3.5 | - | 0 | - | - | - | 20 | - | 3.5 | 2.6 | 177 | 0.5 | 19.2 | 64.2 | 20 | -0.3 |
| Lab033 | 2 | 3.0 | - | 0 | - | - | - | 20 | - | 3.0 | 2.9 | 100 | 0.3 | 10.3 | 24.0 | 20 | 1.6 |
| Lab034 | 2 | 2.9 | 3.0 | 5 | 0.3 | 10.0 | 23.4 | 20 | 1.7 | 2.9 | 3.0 | 53 | 0.2 | 6.7 | 16.8 | 20 | 2.5 |
| Lab035 | 2 | 2.9 | 2.6 | 3 | 0.1 | 3.8 | 18.0 | 20 | 2.5 | 2.9 | 2.8 | 43 | 0.3 | 10.7 | 24.9 | 20 | 1.5 |
| Lab037 | 2 | 2.9 | 2.8 | 5 | 0.2 | 7.1 | 17.7 | 20 | 2.3 | 2.9 | 3.0 | 18 | 0.3 | 10.0 | 23.4 | 20 | 1.7 |
| Lab038 | 2 | 2.9 | 3.4 | 4 | 0.6 | 17.6 | 52.5 | 20 | 0.2 | 2.9 | 3.2 | 46 | 0.5 | 15.6 | 41.6 | 20 | 0.6 |
| Lab040 | 2 | 2.9 | 2.5 | 1 | - | - | - | 20 | - | 2.9 | 2.5 | 1 | - | - | - | 20 | - |
| Total | - | - | 2.8 | 51 | 0.5 | 17.9 | - | - | - | - | 2.9 | 1437 | 0.6 | 20.7 | - | - | - |

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

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

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

Month : 2016 04 Change

Cumulative : from 2014 02 01 to 2016 04 30 Change

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