

Summary Report of IQC program for G6PD Quantitative Test - AMP Group - April 2017 -

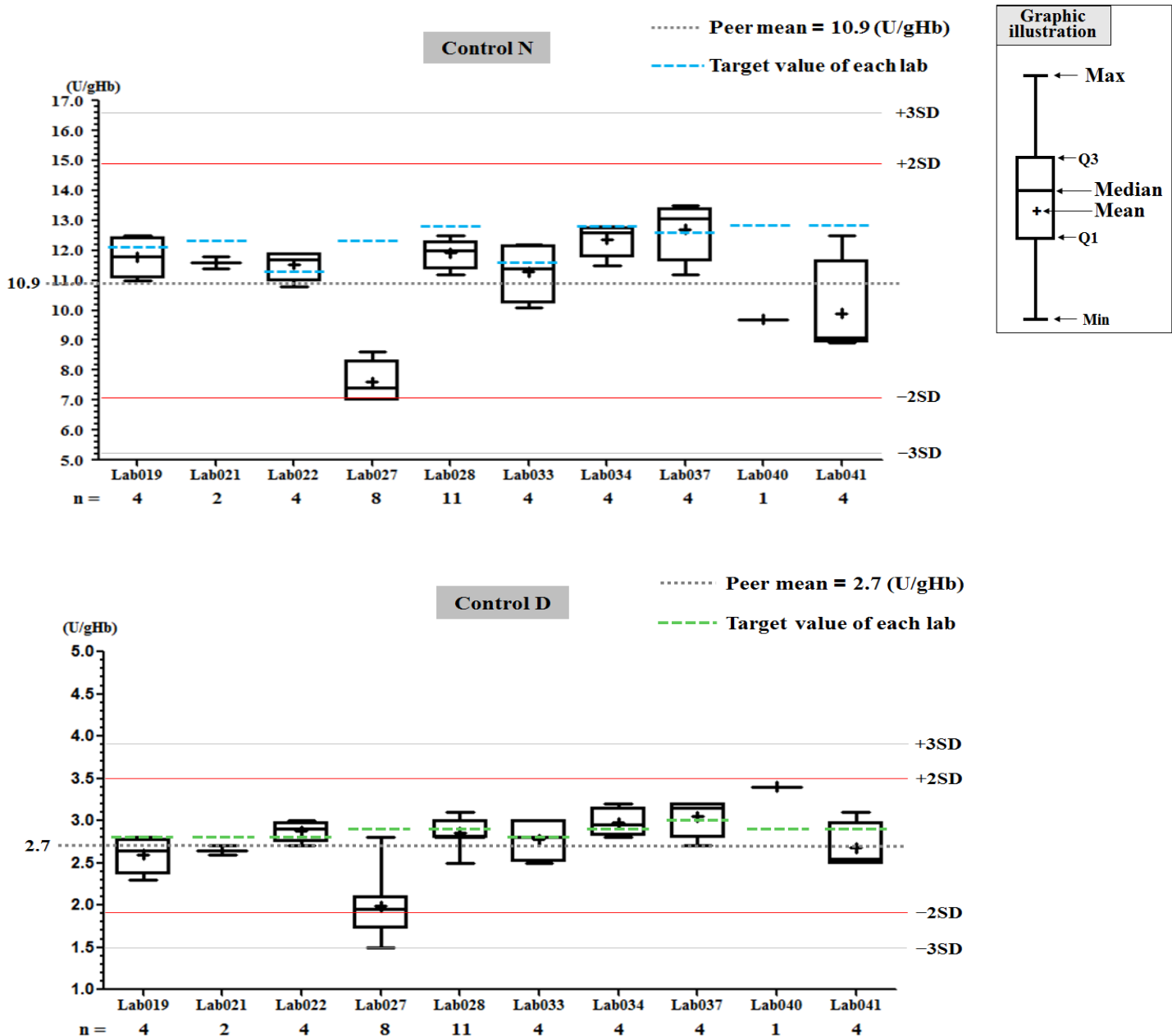
I. The statistic results of all laboratories in this month

| G6PD | Control N (Lot No.:AC1203N) | Control D (Lot No.:AC1203D) |
|-----------------------------|--------------------------------|--------------------------------|
| Labs | 10 | 10 |
| Received results number (n) | 46 | 46 |
| Median | 11.5 (U/gHb) | 2.8 (U/gHb) |
| Mean | 10.9 (U/gHb) | 2.7 (U/gHb) |
| SD | 1.9 | 0.4 |
| CV | 17.4% | 14.8% |
| Range of G6PD | 7.0 ~ 13.5 (U/gHb) | 1.5 ~ 3.4 (U/gHb) |
| Range of Hb | 2.0 ~ 3.8 (g/dL) | 1.9 ~ 4.5 (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](#)

Lab040

| QC Control Lot No. | Control N | | Control D | |
|---------------------------|-----------------|-----------------------------|-----------------|-----------------------------|
| | AC1203N | | AC1203D | |
| Duration of the Analyzing | Month (2017/04) | CUM (2014/02/01~2017/04/30) | Month (2017/04) | CUM (2014/02/01~2017/04/30) |
| Runs (N) | 1 | 22 | 1 | 22 |
| Mean (U/gHb) | 9.7 | 12.0 | 3.4 | 2.7 |
| SD | - | 0.7 | - | 0.4 |
| CV (%) | - | 5.8 | - | 14.8 |
| Target Value (U/gHb) | 12.8 | 12.8 | 2.9 | 2.9 |
| Total Error (%) | - | 17.9 | - | 36.5 |
| TEa (%) | 20 | 20 | 20 | 20 |
| σ | - | 2.4 | - | 0.9 |

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

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

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

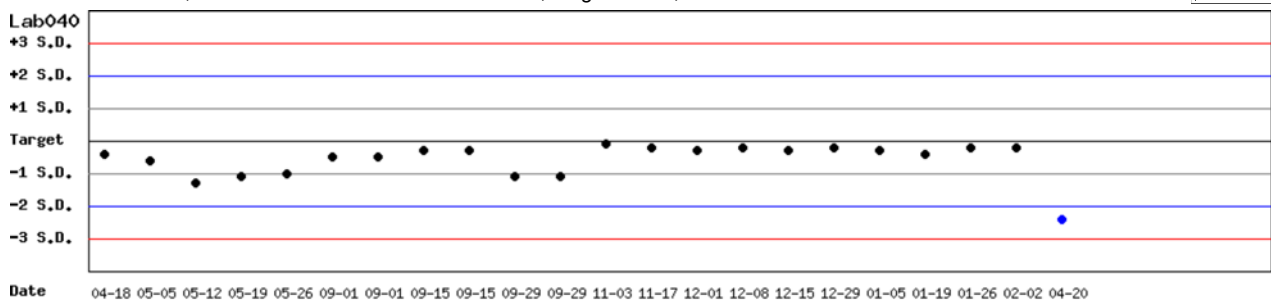
Month : 2017 04 [Change](#) ; Cumulative : from 2014 02 01 to 2017 04 30 [Change](#)

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Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2014-02-01 to 2017-04-30 ; Target : 12.8 ; SD : 1.28

Lab040



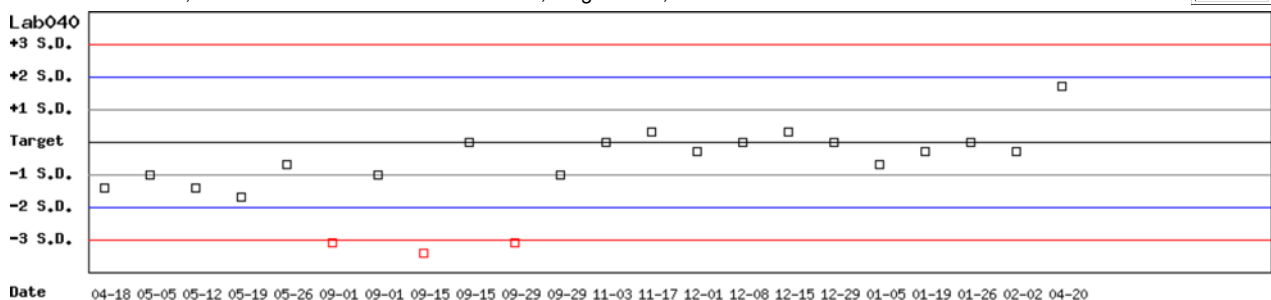
Month : 2017 04 [Change](#) ; Cumulative : from 2014 02 01 to 2017 04 30 [Change](#)

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Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2014-02-01 to 2017-04-30 ; Target : 2.9 ; SD : 0.29

Lab040



Month : 2017 04 [Change](#) ; Cumulative : from 2014 02 01 to 2017 04 30 [Change](#)

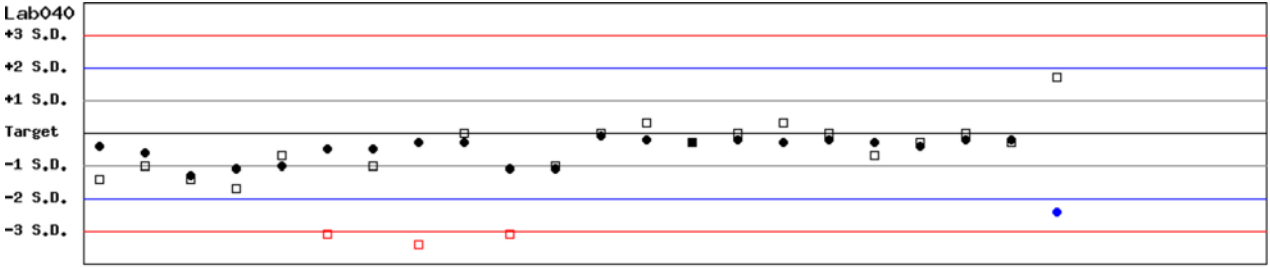
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Control N and Control D SDI QC Chart

Lot No.: AC1203N ; Duration : 2014-02-01 to 2017-04-30 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: AC1203D ; Duration : 2014-02-01 to 2017-04-30 ; Target : 2.9 ; SD : 0.29 (◻)

Lab040



Date 04-18 05-05 05-12 05-19 05-26 09-01 09-01 09-15 09-15 09-29 09-29 11-03 11-17 12-01 12-08 12-15 12-29 01-05 01-19 01-26 02-02 04-20

Month : 2017 | 04 ; Cumulative : from 2014 | 02 | 01 to 2017 | 04 | 30

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Peer Group Statistics (Table 1)

Select LotNo :

Select Reagent Kit :

Monthly

Month :

| 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 | 12.1 | 11.8 | 4 | 0.7 | 5.9 | 14.3 | 20 | 3.0 | 2.8 | 2.6 | 4 | 0.2 | 7.7 | 22.5 | 20 | 1.7 |
| Lab021 | 2 | 12.3 | 11.6 | 2 | - | - | - | 20 | - | 2.8 | 2.7 | 2 | - | - | - | 20 | - |
| Lab022 | 2 | 11.3 | 11.5 | 4 | 0.5 | 4.3 | 10.5 | 20 | 4.2 | 2.8 | 2.9 | 4 | 0.1 | 3.4 | 10.5 | 20 | 4.8 |
| Lab027 | 2 | 12.3 | 7.6 | 8 | 0.7 | 9.2 | 56.6 | 20 | -2.0 | 2.9 | 2.0 | 8 | 0.4 | 20.0 | 71.0 | 20 | -0.6 |
| Lab028 | 2 | 12.8 | 11.9 | 11 | 0.5 | 4.2 | 15.4 | 20 | 3.1 | 2.9 | 2.9 | 11 | 0.2 | 6.9 | 13.8 | 20 | 2.9 |
| Lab033 | 2 | 11.6 | 11.3 | 4 | 1.0 | 8.8 | 20.3 | 20 | 2.0 | 2.8 | 2.8 | 4 | 0.3 | 10.7 | 21.4 | 20 | 1.9 |
| Lab034 | 2 | 12.8 | 12.4 | 4 | 0.6 | 4.8 | 12.8 | 20 | 3.5 | 2.9 | 3.0 | 4 | 0.2 | 6.7 | 16.8 | 20 | 2.5 |
| Lab037 | 2 | 12.6 | 12.7 | 4 | 1.0 | 7.9 | 16.5 | 20 | 2.4 | 3.0 | 3.1 | 4 | 0.2 | 6.5 | 16.2 | 20 | 2.6 |
| Lab040 | 2 | 12.8 | 9.7 | 1 | - | - | - | 20 | - | 2.9 | 3.4 | 1 | - | - | - | 20 | - |
| Lab041 | 2 | 12.8 | 9.9 | 4 | 1.7 | 17.2 | 57.0 | 20 | -0.2 | 2.9 | 2.7 | 4 | 0.3 | 11.1 | 29.1 | 20 | 1.2 |
| Total | - | - | 10.9 | 46 | 1.9 | 17.4 | - | - | - | - | 2.7 | 46 | 0.4 | 14.8 | - | - | - |

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

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

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

[TOP](#)

Cumulative

Cumulative : from to

| 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 | 12.1 | 12.2 | 161 | 1.1 | 9.0 | 18.9 | 20 | 2.1 | 2.8 | 2.8 | 161 | 0.4 | 14.3 | 28.6 | 20 | 1.4 |
| Lab020 | 2 | 12.8 | 11.8 | 19 | 1.4 | 11.9 | 31.5 | 20 | 1.0 | 2.9 | 2.7 | 19 | 0.5 | 18.5 | 43.9 | 20 | 0.7 |
| Lab021 | 2 | 12.3 | 13.5 | 90 | 1.1 | 8.1 | 26.1 | 20 | 1.3 | 2.8 | 3.2 | 90 | 0.3 | 9.4 | 33.0 | 20 | 0.6 |
| Lab022 | 2 | 11.3 | 11.5 | 69 | 1.1 | 9.6 | 20.9 | 20 | 1.9 | 2.8 | 2.9 | 69 | 0.3 | 10.3 | 24.3 | 20 | 1.6 |
| 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 | 11.4 | 167 | 1.9 | 16.7 | 40.7 | 20 | 0.8 | 2.9 | 2.7 | 167 | 0.5 | 18.5 | 43.9 | 20 | 0.7 |
| Lab028 | 2 | 12.8 | 13.5 | 349 | 1.2 | 8.9 | 23.2 | 20 | 1.6 | 2.9 | 3.3 | 349 | 0.5 | 15.2 | 44.1 | 20 | 0.4 |
| 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 | 13.2 | 11.5 | 222 | 1.9 | 16.5 | 45.9 | 20 | 0.4 | 5.4 | 2.7 | 222 | 0.5 | 18.5 | 87.0 | 20 | -1.6 |
| Lab033 | 2 | 11.6 | 11.9 | 156 | 1.0 | 8.4 | 19.4 | 20 | 2.1 | 2.8 | 2.9 | 156 | 0.3 | 10.3 | 24.3 | 20 | 1.6 |
| Lab034 | 2 | 12.8 | 12.3 | 94 | 0.7 | 5.7 | 15.3 | 20 | 2.8 | 2.9 | 3.0 | 94 | 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 | 12.2 | 70 | 1.2 | 9.8 | 22.8 | 20 | 1.7 | 3.0 | 2.9 | 70 | 0.4 | 13.8 | 30.9 | 20 | 1.2 |
| Lab038 | 2 | 12.8 | 12.7 | 60 | 1.0 | 7.9 | 16.5 | 20 | 2.4 | 2.9 | 3.2 | 60 | 0.5 | 15.6 | 41.6 | 20 | 0.6 |
| Lab040 | 2 | 12.8 | 12.0 | 22 | 0.7 | 5.8 | 17.9 | 20 | 2.4 | 2.9 | 2.7 | 22 | 0.4 | 14.8 | 36.5 | 20 | 0.9 |
| Lab041 | 2 | 12.8 | 10.2 | 8 | 1.2 | 11.8 | 43.8 | 20 | 0.0 | 2.9 | 2.6 | 8 | 0.2 | 7.7 | 25.7 | 20 | 1.3 |
| Total | - | - | 12.1 | 2050 | 1.7 | 14.0 | - | - | - | - | 2.9 | 2050 | 0.6 | 20.7 | - | - | - |

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

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

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

[TOP](#)

| 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 (2017/04) | | | | | | | | CUM (2014/02/01~2017/04/30) | | | | | | | |
| 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 | 10.9 | - | 0 | - | - | - | 20 | - | 10.9 | 10.9 | 113 | 1.3 | 11.9 | 23.9 | 20 | 1.7 |
| Lab019 | 2 | 12.1 | 11.8 | 4 | 0.7 | 5.9 | 14.3 | 20 | 3.0 | 12.1 | 12.2 | 161 | 1.1 | 9.0 | 18.9 | 20 | 2.1 |
| Lab020 | 2 | 12.8 | - | 0 | - | - | - | 20 | - | 12.8 | 11.8 | 19 | 1.4 | 11.9 | 31.5 | 20 | 1.0 |
| Lab021 | 2 | 12.3 | 11.6 | 2 | - | - | - | 20 | - | 12.3 | 13.5 | 90 | 1.1 | 8.1 | 26.1 | 20 | 1.3 |
| Lab022 | 2 | 11.3 | 11.5 | 4 | 0.5 | 4.3 | 10.5 | 20 | 4.2 | 11.3 | 11.5 | 69 | 1.1 | 9.6 | 20.9 | 20 | 1.9 |
| 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 | 7.6 | 8 | 0.7 | 9.2 | 56.6 | 20 | -2.0 | 12.3 | 11.4 | 167 | 1.9 | 16.7 | 40.7 | 20 | 0.8 |
| Lab028 | 2 | 12.8 | 11.9 | 11 | 0.5 | 4.2 | 15.4 | 20 | 3.1 | 12.8 | 13.5 | 349 | 1.2 | 8.9 | 23.2 | 20 | 1.6 |
| Lab031 | 2 | 12.8 | - | 0 | - | - | - | 20 | - | 12.8 | 10.4 | 89 | 1.5 | 14.4 | 47.6 | 20 | 0.1 |
| Lab032 | 2 | 13.2 | - | 0 | - | - | - | 20 | - | 13.2 | 11.5 | 222 | 1.9 | 16.5 | 45.9 | 20 | 0.4 |
| Lab033 | 2 | 11.6 | 11.3 | 4 | 1.0 | 8.8 | 20.3 | 20 | 2.0 | 11.6 | 11.9 | 156 | 1.0 | 8.4 | 19.4 | 20 | 2.1 |
| Lab034 | 2 | 12.8 | 12.4 | 4 | 0.6 | 4.8 | 12.8 | 20 | 3.5 | 12.8 | 12.3 | 94 | 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 | 12.7 | 4 | 1.0 | 7.9 | 16.5 | 20 | 2.4 | 12.6 | 12.2 | 70 | 1.2 | 9.8 | 22.8 | 20 | 1.7 |
| Lab038 | 2 | 12.8 | - | 0 | - | - | - | 20 | - | 12.8 | 12.7 | 60 | 1.0 | 7.9 | 16.5 | 20 | 2.4 |
| Lab040 | 2 | 12.8 | 9.7 | 1 | - | - | - | 20 | - | 12.8 | 12.0 | 22 | 0.7 | 5.8 | 17.9 | 20 | 2.4 |
| Lab041 | 2 | 12.8 | 9.9 | 4 | 1.7 | 17.2 | 57.0 | 20 | -0.2 | 12.8 | 10.2 | 8 | 1.2 | 11.8 | 43.8 | 20 | 0.0 |
| Total | - | - | 10.9 | 46 | 1.9 | 17.4 | - | - | - | - | 12.1 | 2050 | 1.7 | 14.0 | - | - | - |

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

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

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

Month : 2017 04 Change

Cumulative : from 2014 02 01 to 2017 04 30 Change

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Control D Month vs. Cumulative

| | | Control D (Lot No.: AC1203D) | | | | | | | | | | | | | | | |
|------------------------|---------------------------------|------------------------------|--------------|------------|-----|--------|--------|---------|------|-----------------------------|--------------|------------|-----|--------|--------|---------|------|
| | | Month (2017/04) | | | | | | | | CUM (2014/02/01~2017/04/30) | | | | | | | |
| 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 | 2.5 | - | 0 | - | - | - | 20 | - | 2.5 | 2.6 | 113 | 0.9 | 34.6 | 73.2 | 20 | 0.5 |
| Lab019 | 2 | 2.8 | 2.6 | 4 | 0.2 | 7.7 | 22.5 | 20 | 1.7 | 2.8 | 2.8 | 161 | 0.4 | 14.3 | 28.6 | 20 | 1.4 |
| Lab020 | 2 | 2.9 | - | 0 | - | - | - | 20 | - | 2.9 | 2.7 | 19 | 0.5 | 18.5 | 43.9 | 20 | 0.7 |
| Lab021 | 2 | 2.8 | 2.7 | 2 | - | - | - | 20 | - | 2.8 | 3.2 | 90 | 0.3 | 9.4 | 33.0 | 20 | 0.6 |
| Lab022 | 2 | 2.8 | 2.9 | 4 | 0.1 | 3.4 | 10.5 | 20 | 4.8 | 2.8 | 2.9 | 69 | 0.3 | 10.3 | 24.3 | 20 | 1.6 |
| 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 | 2.0 | 8 | 0.4 | 20.0 | 71.0 | 20 | -0.6 | 2.9 | 2.7 | 167 | 0.5 | 18.5 | 43.9 | 20 | 0.7 |
| Lab028 | 2 | 2.9 | 2.9 | 11 | 0.2 | 6.9 | 13.8 | 20 | 2.9 | 2.9 | 3.3 | 349 | 0.5 | 15.2 | 44.1 | 20 | 0.4 |
| Lab031 | 2 | 2.9 | - | 0 | - | - | - | 20 | - | 2.9 | 2.5 | 89 | 0.5 | 20.0 | 53.8 | 20 | 0.3 |
| Lab032 | 2 | 5.4 | - | 0 | - | - | - | 20 | - | 5.4 | 2.7 | 222 | 0.5 | 18.5 | 87.0 | 20 | -1.6 |
| Lab033 | 2 | 2.8 | 2.8 | 4 | 0.3 | 10.7 | 21.4 | 20 | 1.9 | 2.8 | 2.9 | 156 | 0.3 | 10.3 | 24.3 | 20 | 1.6 |
| Lab034 | 2 | 2.9 | 3.0 | 4 | 0.2 | 6.7 | 16.8 | 20 | 2.5 | 2.9 | 3.0 | 94 | 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 | 3.1 | 4 | 0.2 | 6.5 | 16.2 | 20 | 2.6 | 3.0 | 2.9 | 70 | 0.4 | 13.8 | 30.9 | 20 | 1.2 |
| Lab038 | 2 | 2.9 | - | 0 | - | - | - | 20 | - | 2.9 | 3.2 | 60 | 0.5 | 15.6 | 41.6 | 20 | 0.6 |
| Lab040 | 2 | 2.9 | 3.4 | 1 | - | - | - | 20 | - | 2.9 | 2.7 | 22 | 0.4 | 14.8 | 36.5 | 20 | 0.9 |
| Lab041 | 2 | 2.9 | 2.7 | 4 | 0.3 | 11.1 | 29.1 | 20 | 1.2 | 2.9 | 2.6 | 8 | 0.2 | 7.7 | 25.7 | 20 | 1.3 |
| Total | - | - | 2.7 | 46 | 0.4 | 14.8 | - | - | - | - | 2.9 | 2050 | 0.6 | 20.7 | - | - | - |

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

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

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

Month : 2017 04 Change

Cumulative : from 2014 02 01 to 2017 04 30 Change

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