

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

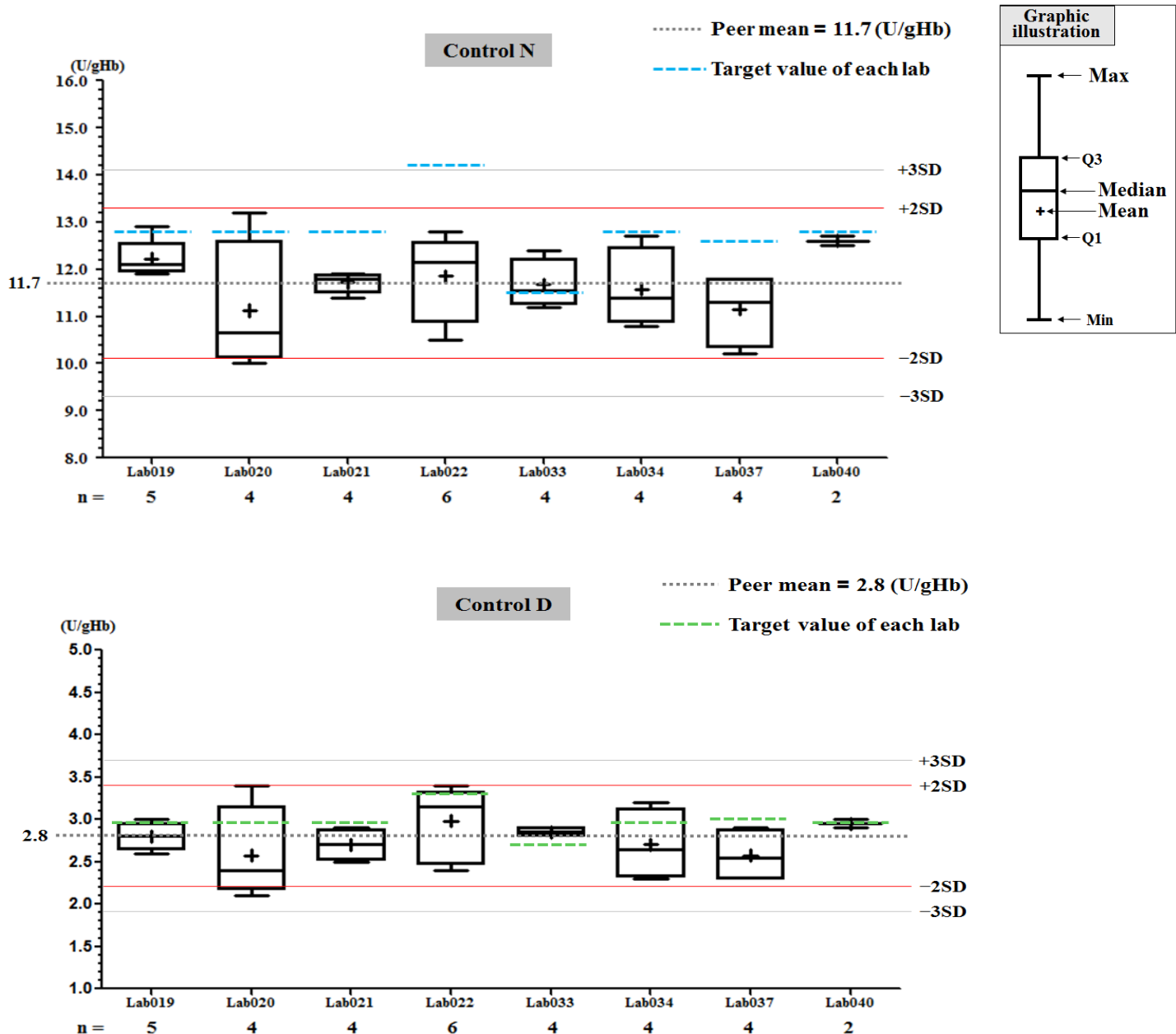
I. The statistic results of all laboratories in this month

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](#)

Lab034

QC Control Lot No.	Control N		Control D	
	AC1203N		AC1203D	
Duration of the Analyzing	Month (2016/11)	CUM (2016/05/20~2016/11/30)	Month (2016/11)	CUM (2016/05/20~2016/11/30)
Runs (N)	4	26	4	26
Mean (U/gHb)	11.6	11.9	2.7	2.8
SD	0.8	0.9	0.4	0.4
CV (%)	6.9	7.6	14.8	14.3
Target Value (U/gHb)	12.8	12.8	2.9	2.9
Total Error (%)	23.2	22.2	36.5	32.0
TEa (%)	20	20	20	20
σ	1.5	1.7	0.9	1.2

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

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

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

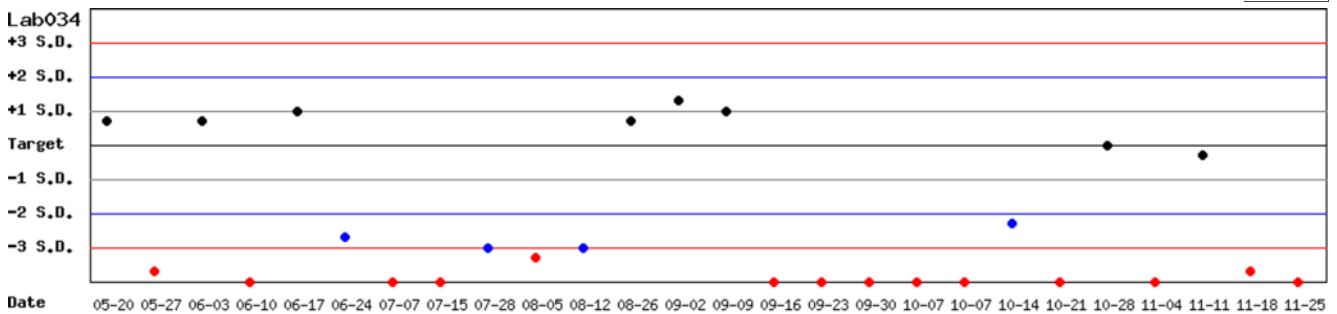
Month : 2016 11 [Change](#) ; Cumulative : from 2016 05 20 to 2016 11 30 [Change](#)

[TOP](#)

Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2016-05-20 to 2016-11-30 ; Target : 12.8 ; SD : 0.30

Lab034



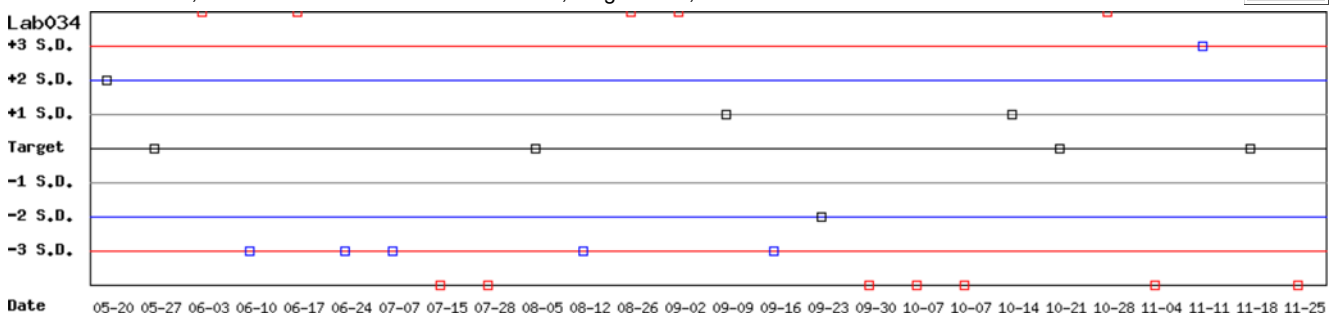
Month : 2016 11 [Change](#) ; Cumulative : from 2016 05 20 to 2016 11 30 [Change](#)

[TOP](#)

Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2016-05-20 to 2016-11-30 ; Target : 2.9 ; SD : 0.10

Lab034



Month : 2016 11 [Change](#) ; Cumulative : from 2016 05 20 to 2016 11 30 [Change](#)

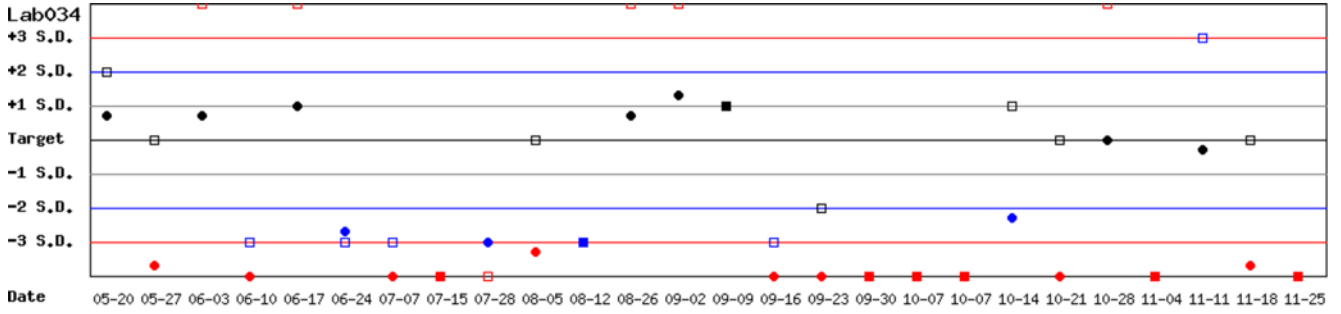
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Control N and Control D SDI QC Chart

Lot No.: AC1203N ; Duration : 2016-05-20 to 2016-11-30 ; Target : 12.8 ; SD : 0.30 (●)

Lot No.: AC1203D ; Duration : 2016-05-20 to 2016-11-30 ; Target : 2.9 ; SD : 0.10 (□)

Lab034



Month : 2016 11 ; Cumulative : from 2016 05 20 to 2016 11 30

[TOP](#)

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 (%)

[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 (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

[TOP](#)

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

[TOP](#)

Reagent Kit	Reagent Code
AMP	2