

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

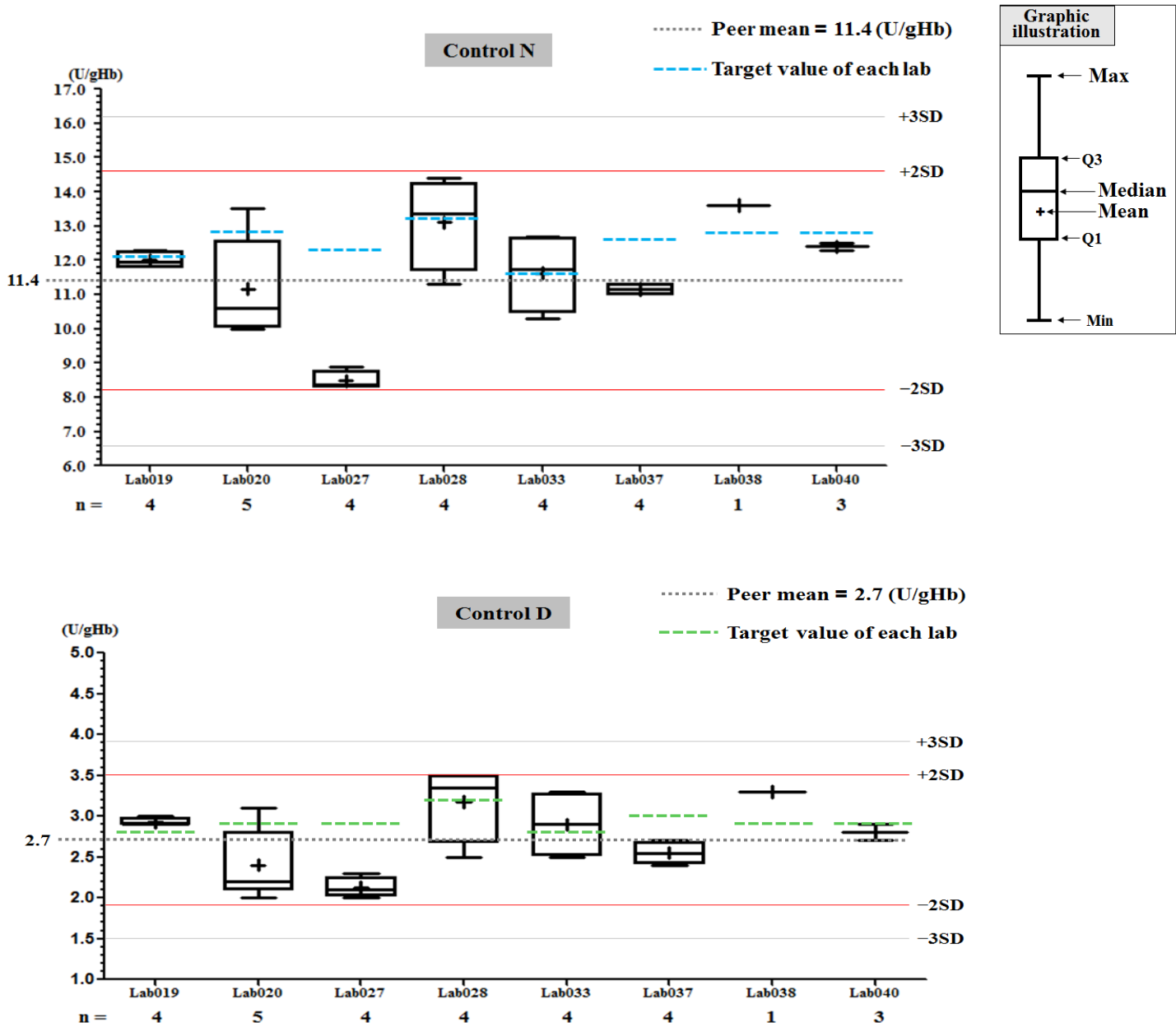
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AC1203N)	Control D (Lot No.:AC1203D)
Labs	8	8
Received results number (n)	29	29
Median	11.6 (U/gHb)	2.7 (U/gHb)
Mean	11.4 (U/gHb)	2.7 (U/gHb)
SD	1.6	0.4
CV	14.0%	14.8%
Range of G6PD	8.3 ~ 14.4 (U/gHb)	2.0 ~ 3.5 (U/gHb)
Range of Hb	2.3 ~ 3.6 (g/dL)	2.8 ~ 4.3 (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

Lab037

QC Control Lot No.	Control N		Control D	
	AC1203N		AC1203D	
Duration of the Analyzing	Month (2017/01)	CUM (2016/08/01~2017/01/31)	Month (2017/01)	CUM (2016/08/01~2017/01/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	11.2	11.9	2.6	2.8
SD	0.2	1.2	0.1	0.4
CV (%)	1.8	10.1	3.8	14.3
Target Value (U/gHb)	12.6	12.6	3.0	3.0
Total Error (%)	14.7	25.7	21.0	35.2
TEa (%)	20	20	20	20
σ	4.9	1.4	1.8	0.9

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

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

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

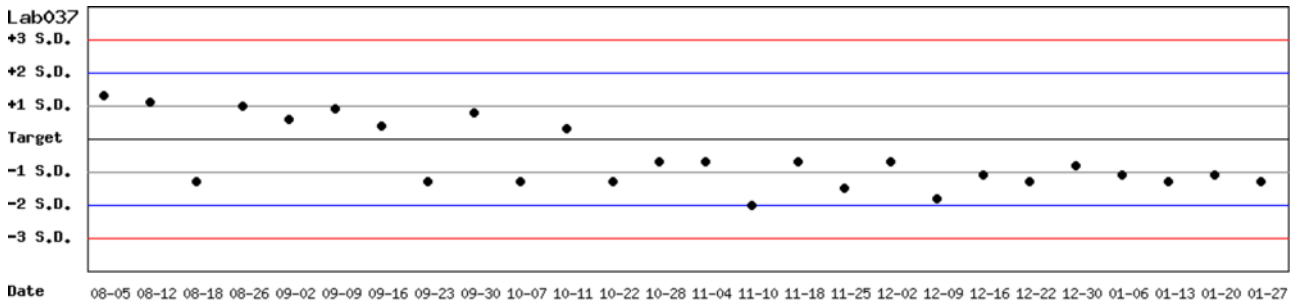
Month : 2017 01 Change ; Cumulative : from 2016 08 01 to 2017 01 31 Change

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Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2016-08-01 to 2017-01-31 ; Target : 12.6 ; SD : 1.20

Lab037



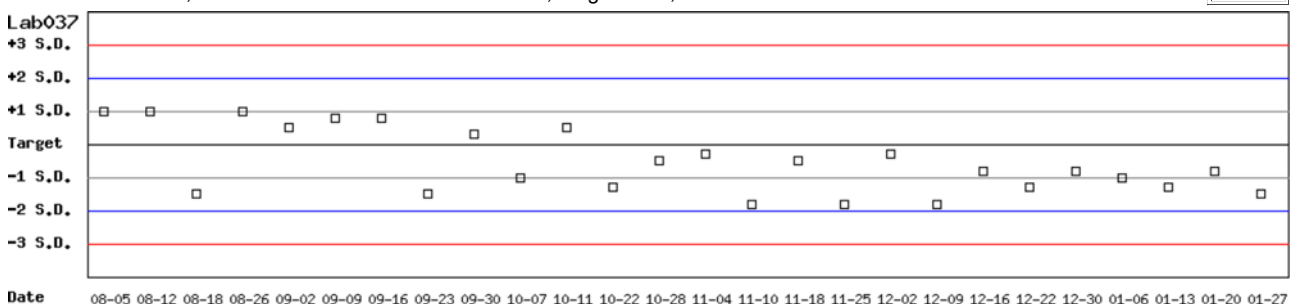
Month : 2017 01 Change ; Cumulative : from 2016 08 01 to 2017 01 31 Change

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Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2016-08-01 to 2017-01-31 ; Target : 3.0 ; SD : 0.40

Lab037



Month : 2017 01 Change ; Cumulative : from 2016 08 01 to 2017 01 31 Change

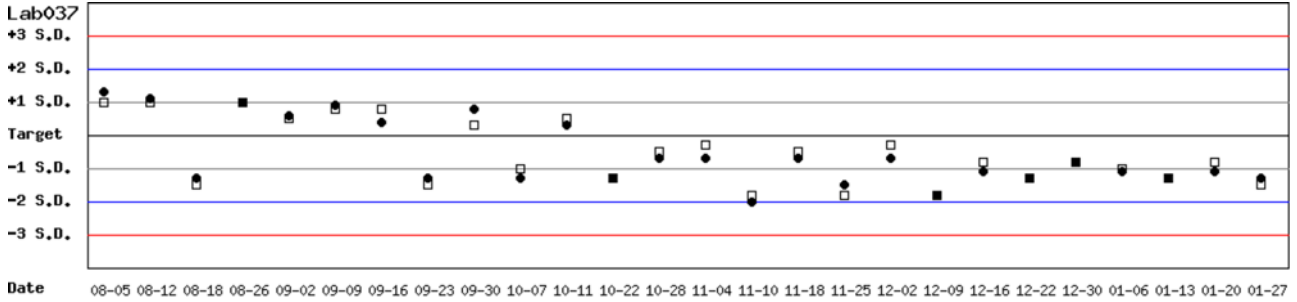
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Control N and Control D SDI QC Chart

Lot No.: AC1203N ; Duration : 2016-08-01 to 2017-01-31 ; Target : 12.6 ; SD : 1.20 (●)

Lot No.: AC1203D ; Duration : 2016-08-01 to 2017-01-31 ; Target : 3.0 ; SD : 0.40 (◻)

Lab037



Month : 2017 01 Change ; Cumulative : from 2016 08 01 to 2017 01 31 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 : 2017 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
Lab019	2	12.1	12.0	4	0.2	1.7	4.2	20	>6	2.8	2.9	4	0.1	3.4	10.5	20	4.8
Lab020	2	12.8	11.2	5	1.5	13.4	39.3	20	0.6	2.9	2.4	5	0.4	16.7	50.6	20	0.2
Lab027	2	12.3	8.5	4	0.3	3.5	38.0	20	-3.1	2.9	2.1	4	0.1	4.8	37.1	20	-1.6
Lab028	2	13.2	13.1	4	1.3	9.9	20.6	20	1.9	3.2	3.2	4	0.5	15.6	31.3	20	1.3
Lab033	2	11.6	11.6	4	1.2	10.3	20.7	20	1.9	2.8	2.9	4	0.4	13.8	31.2	20	1.2
Lab037	2	12.6	11.2	4	0.2	1.8	14.7	20	4.9	3.0	2.6	4	0.1	3.8	21.0	20	1.8
Lab038	2	12.8	13.6	1	-	-	-	20	-	2.9	3.3	1	-	-	-	20	-
Lab040	2	12.8	12.4	3	0.1	0.8	4.7	20	>6	2.9	2.8	3	0.1	3.6	10.6	20	4.6
Total	-	-	11.4	29	1.6	14.0	-	-	-	-	2.7	29	0.4	14.8	-	-	-

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 2017 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	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	153	1.1	9.0	18.9	20	2.1	2.8	2.8	153	0.4	14.3	28.6	20	1.4
Lab020	2	12.8	11.7	15	1.4	12.0	32.5	20	1.0	2.9	2.7	15	0.5	18.5	43.9	20	0.7
Lab021	2	12.3	13.5	88	1.0	7.4	24.6	20	1.4	2.8	3.2	88	0.3	9.4	33.0	20	0.6
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	151	1.6	13.6	31.2	20	1.2	2.9	2.7	151	0.5	18.5	43.9	20	0.7
Lab028	2	13.2	13.6	313	1.2	8.8	20.7	20	1.9	3.2	3.3	313	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	11.6	12.0	143	1.0	8.3	20.1	20	2.0	2.8	2.9	143	0.3	10.3	24.3	20	1.6
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	12.3	57	1.2	9.8	21.9	20	1.8	3.0	2.9	57	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	12.1	20	0.5	4.1	13.7	20	3.5	2.9	2.6	20	0.3	11.5	33.4	20	0.8
Total	-	-	12.1	1930	1.6	13.2	-	-	-	-	2.9	1930	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 (2017/01)								CUM (2014/02/01~2017/01/31)							
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	10.9	-	0	-	-	-	20	-	10.9	10.9	113	1.3	11.9	23.9	20	1.7
Lab019	2	12.1	12.0	4	0.2	1.7	4.2	20	>6	12.1	12.2	153	1.1	9.0	18.9	20	2.1
Lab020	2	12.8	11.2	5	1.5	13.4	39.3	20	0.6	12.8	11.7	15	1.4	12.0	32.5	20	1.0
Lab021	2	12.3	-	0	-	-	-	20	-	12.3	13.5	88	1.0	7.4	24.6	20	1.4
Lab022	2	14.2	-	0	-	-	-	20	-	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	8.5	4	0.3	3.5	38.0	20	-3.1	12.3	11.8	151	1.6	13.6	31.2	20	1.2
Lab028	2	13.2	13.1	4	1.3	9.9	20.6	20	1.9	13.2	13.6	313	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	11.6	11.6	4	1.2	10.3	20.7	20	1.9	11.6	12.0	143	1.0	8.3	20.1	20	2.0
Lab034	2	12.8	-	0	-	-	-	20	-	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	0.2	1.8	14.7	20	4.9	12.6	12.3	57	1.2	9.8	21.9	20	1.8
Lab038	2	12.8	13.6	1	-	-	-	20	-	12.8	12.7	60	1.0	7.9	16.5	20	2.4
Lab040	2	12.8	12.4	3	0.1	0.8	4.7	20	>6	12.8	12.1	20	0.5	4.1	13.7	20	3.5
Total	-	-	11.4	29	1.6	14.0	-	-	-	-	12.1	1930	1.6	13.2	-	-	-

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

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

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

Month : 2017 01 Change

Cumulative : from 2014 02 01 to 2017 01 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AC1203D)															
		Month (2017/01)								CUM (2014/02/01~2017/01/31)							
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	2.5	-	0	-	-	-	20	-	2.5	2.6	113	0.9	34.6	73.2	20	0.5
Lab019	2	2.8	2.9	4	0.1	3.4	10.5	20	4.8	2.8	2.8	153	0.4	14.3	28.6	20	1.4
Lab020	2	2.9	2.4	5	0.4	16.7	50.6	20	0.2	2.9	2.7	15	0.5	18.5	43.9	20	0.7
Lab021	2	2.8	-	0	-	-	-	20	-	2.8	3.2	88	0.3	9.4	33.0	20	0.6
Lab022	2	3.3	-	0	-	-	-	20	-	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	2.1	4	0.1	4.8	37.1	20	-1.6	2.9	2.7	151	0.5	18.5	43.9	20	0.7
Lab028	2	3.2	3.2	4	0.5	15.6	31.3	20	1.3	3.2	3.3	313	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	2.8	2.9	4	0.4	13.8	31.2	20	1.2	2.8	2.9	143	0.3	10.3	24.3	20	1.6
Lab034	2	2.9	-	0	-	-	-	20	-	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	0.1	3.8	21.0	20	1.8	3.0	2.9	57	0.4	13.8	30.9	20	1.2
Lab038	2	2.9	3.3	1	-	-	-	20	-	2.9	3.2	60	0.5	15.6	41.6	20	0.6
Lab040	2	2.9	2.8	3	0.1	3.6	10.6	20	4.6	2.9	2.6	20	0.3	11.5	33.4	20	0.8
Total	-	-	2.7	29	0.4	14.8	-	-	-	-	2.9	1930	0.6	20.7	-	-	-

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

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

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

Month : 2017 01 Change

Cumulative : from 2014 02 01 to 2017 01 31 Change

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Reagent Kit	Reagent Code
AMP	2