

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

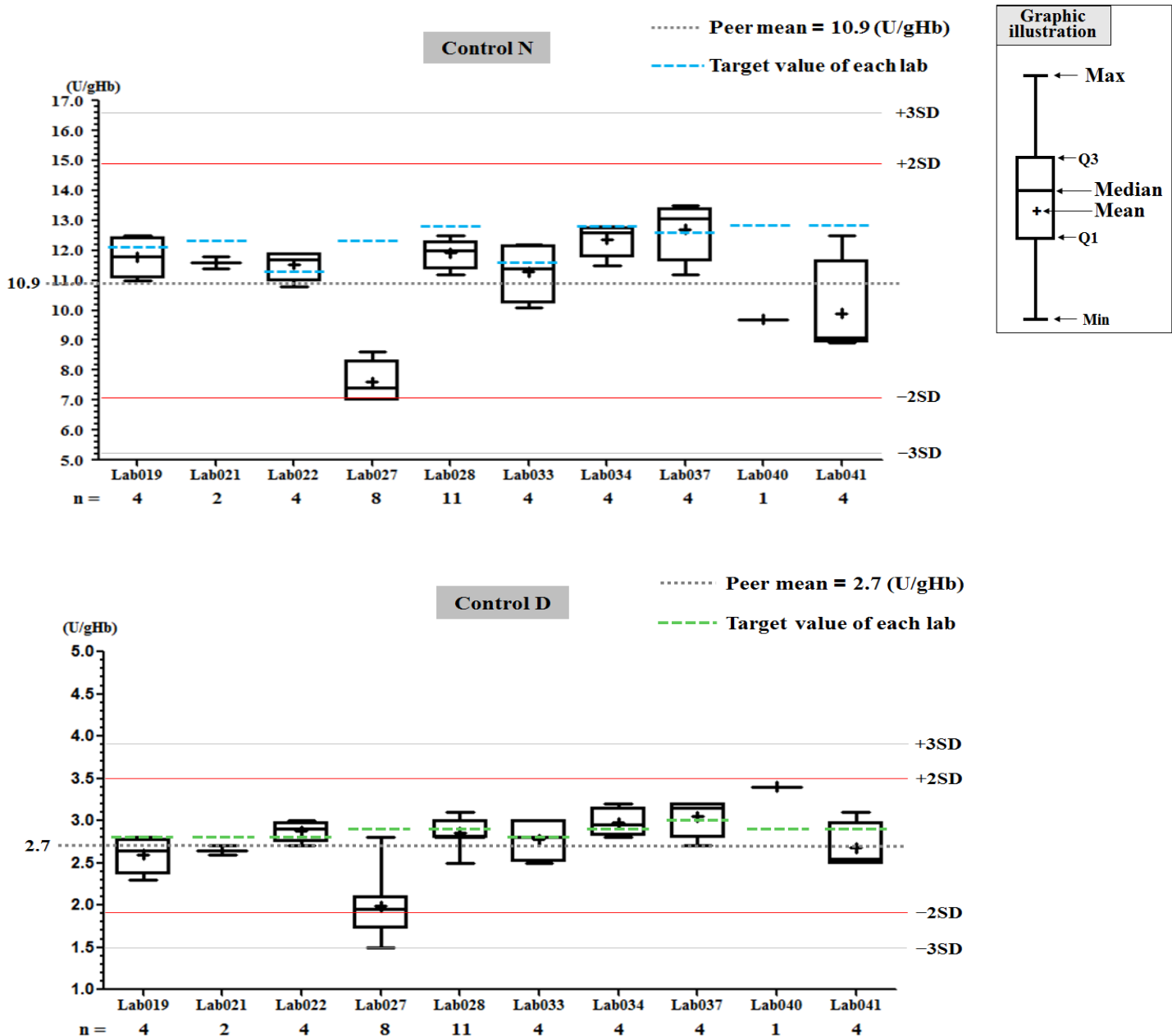
I. The statistic results of all laboratories in this month

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](#)

Lab022

QC Control Lot No.	Control N		Control D	
	AC1203N		AC1203D	
Duration of the Analyzing	Month (2017/04)	CUM (2016/06/14~2017/04/30)	Month (2017/04)	CUM (2016/06/14~2017/04/30)
Runs (N)	4	26	4	26
Mean (U/gHb)	11.5	11.3	2.9	2.8
SD	0.5	0.9	0.1	0.3
CV (%)	4.3	8.0	3.4	10.7
Target Value (U/gHb)	11.3	11.3	2.8	2.8
Total Error (%)	10.5	15.9	10.5	21.4
TEa (%)	20	20	20	20
σ	4.2	2.5	4.8	1.9

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

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

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

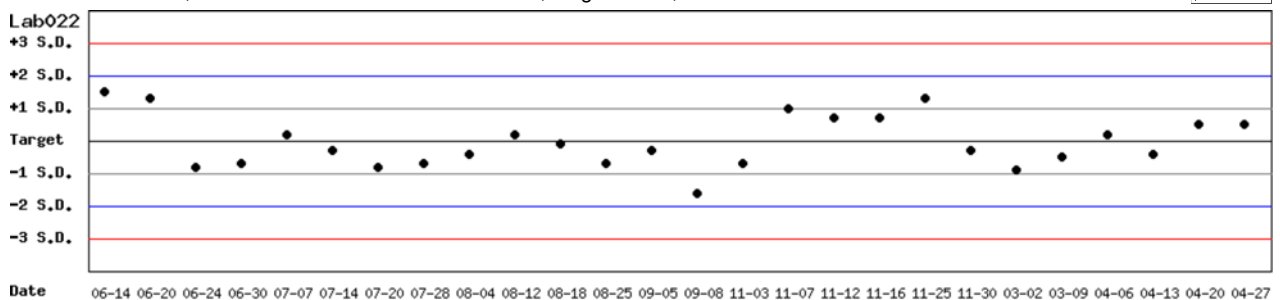
Month : 2017 04 [Change](#) ; Cumulative : from 2016 06 14 to 2017 04 30 [Change](#)

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Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2016-06-14 to 2017-04-30 ; Target : 11.3 ; SD : 1.20

Lab022



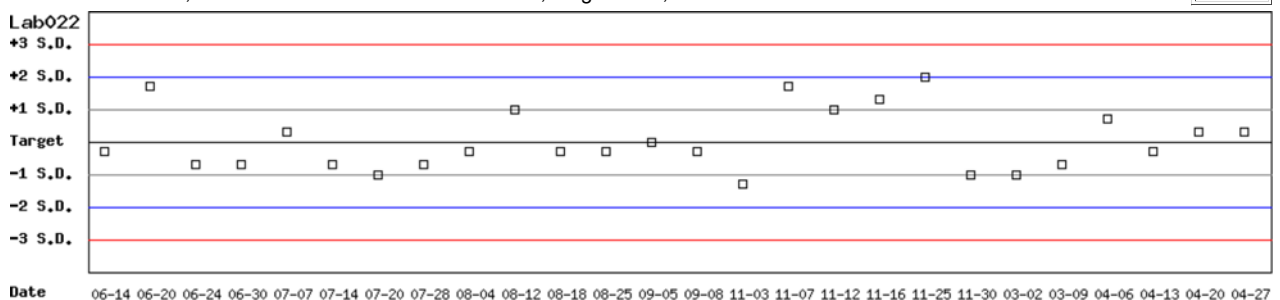
Month : 2017 04 [Change](#) ; Cumulative : from 2016 06 14 to 2017 04 30 [Change](#)

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Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2016-06-14 to 2017-04-30 ; Target : 2.8 ; SD : 0.30

Lab022



Month : 2017 04 [Change](#) ; Cumulative : from 2016 06 14 to 2017 04 30 [Change](#)

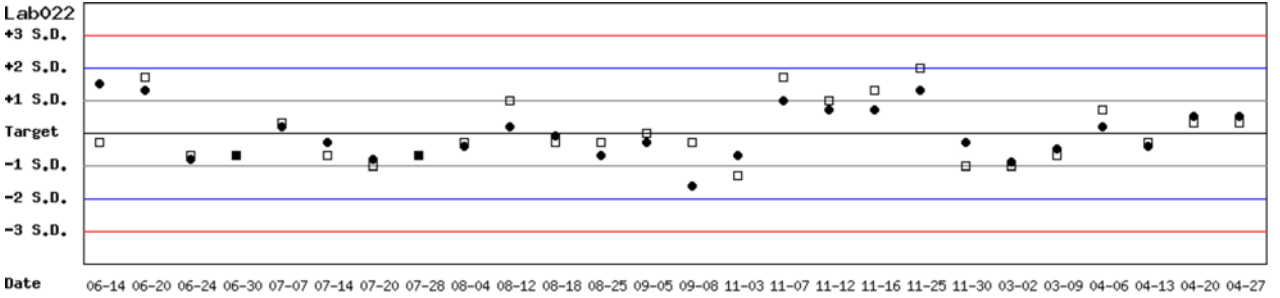
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Control N and Control D SDI QC Chart

Lot No.: AC1203N ; Duration : 2016-06-14 to 2017-04-30 ; Target : 11.3 ; SD : 1.20 (●)

Lot No.: AC1203D ; Duration : 2016-06-14 to 2017-04-30 ; Target : 2.8 ; SD : 0.30 (□)

Lab022



Date 06-14 06-20 06-24 06-30 07-07 07-14 07-20 07-28 08-04 08-12 08-18 08-25 09-05 09-08 11-03 11-07 11-12 11-16 11-25 11-30 03-02 03-09 04-06 04-13 04-20 04-27

Month : 2017 04 Change ; Cumulative : from 2016 06 14 to 2017 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 : 2017 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	12.1	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 2014 02 01 to 2017 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	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 (%)

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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 (2017/04)								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

[TOP](#)

Reagent Kit	Reagent Code
AMP	2