

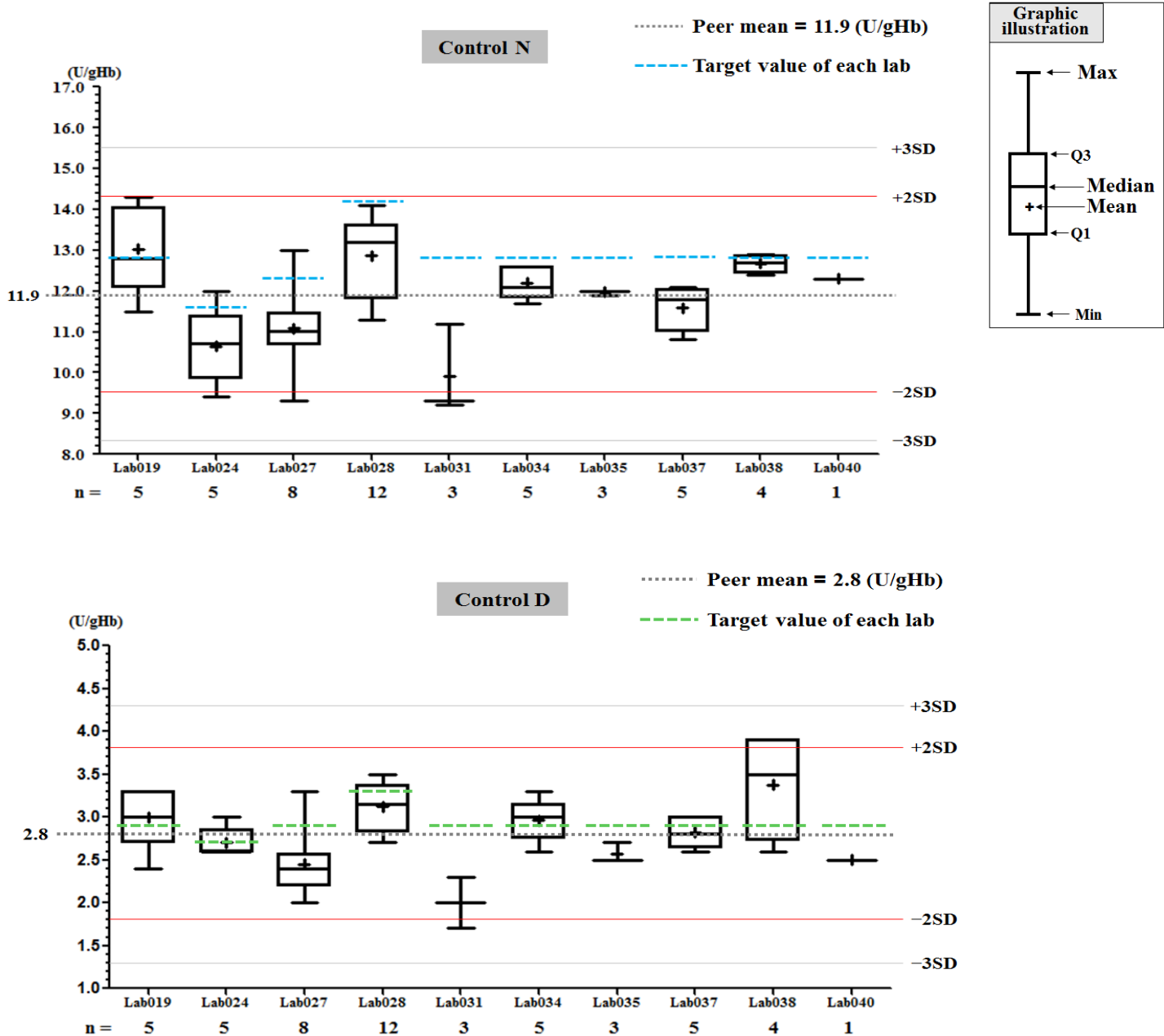
Summary Report of IQC program for G6PD Quantitative Test - AMP Group - April 2016 -

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](#)

Lab028

QC Control Lot No.	Control N		Control D	
	AC1203N		AC1203D	
Duration of the Analyzing	Month (2016/04)	CUM (2016/03/01~2016/04/30)	Month (2016/04)	CUM (2016/03/01~2016/04/30)
Runs (N)	12	26	12	26
Mean (U/gHb)	12.9	13.0	3.1	3.2
SD	0.9	0.8	0.3	0.3
CV (%)	7.0	6.2	9.7	9.4
Target Value (U/gHb)	14.2	14.2	3.3	3.3
Total Error (%)	23.1	20.8	25.4	21.8
TEa (%)	20	20	20	20
σ	1.5	1.9	1.4	1.8

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

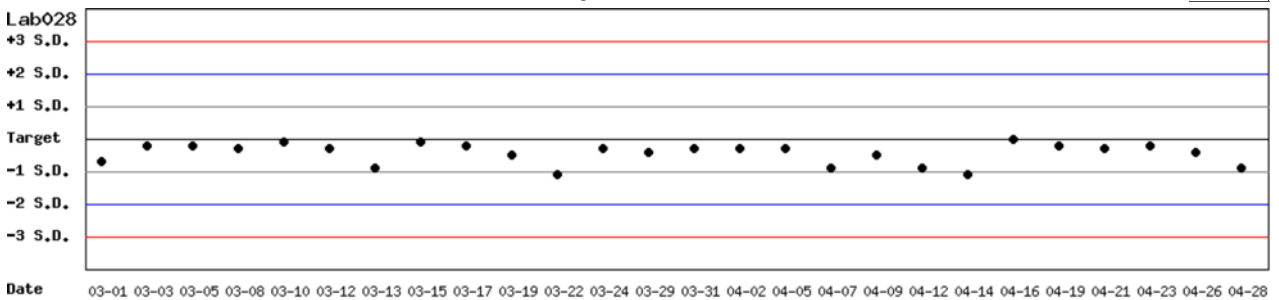
Month : 2016 04 [Change](#) ; Cumulative : from 2016 03 01 to 2016 04 30 [Change](#)

[TOP](#)

Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2016-03-01 to 2016-04-30 ; Target : 14.2 ; SD : 2.6

Lab028



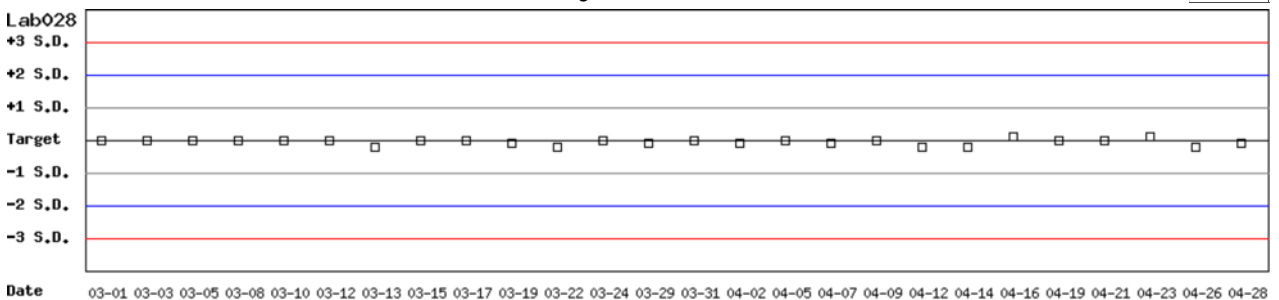
Month : 2016 04 [Change](#) ; Cumulative : from 2016 03 01 to 2016 04 30 [Change](#)

[TOP](#)

Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2016-03-01 to 2016-04-30 ; Target : 3.3 ; SD : 3.1

Lab028



Month : 2016 04 [Change](#) ; Cumulative : from 2016 03 01 to 2016 04 30 [Change](#)

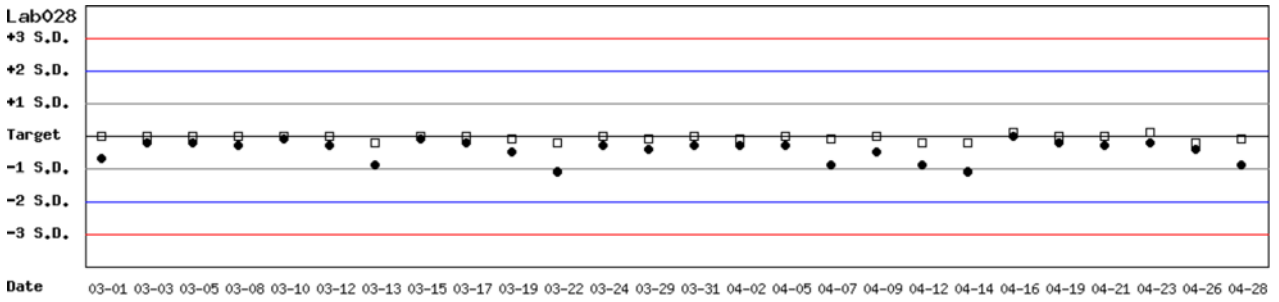
[TOP](#)

Control N and Control D SDI QC Chart

Lot No.: AC1203N ; Duration : 2016-03-01 to 2016-04-30 ; Target : 14.2 ; SD : 2.6 (●)

Lot No.: AC1203D ; Duration : 2016-03-01 to 2016-04-30 ; Target : 3.3 ; SD : 3.1 (□)

Lab028



Month : 2016 04 ; Cumulative : from 2016 03 01 to 2016 04 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 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 (%)

[TOP](#)

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 (%)

[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 (2016/04)								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

[TOP](#)

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

[TOP](#)

Reagent Kit	Reagent Code
AMP	2