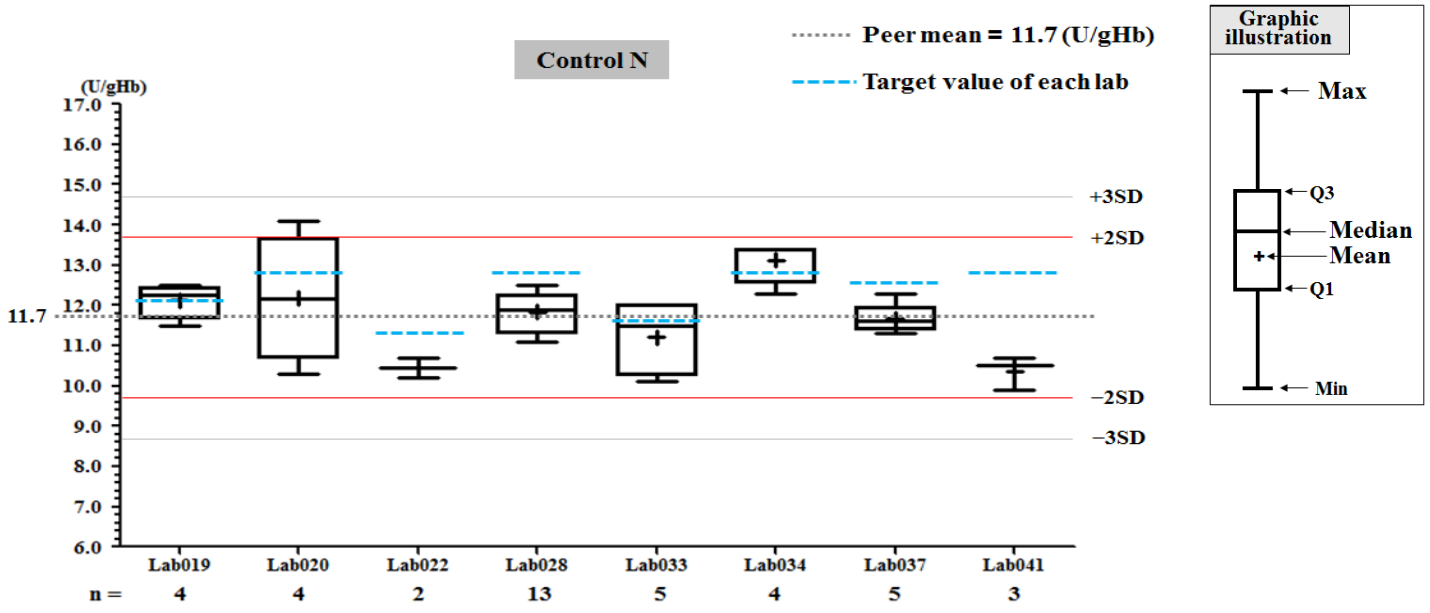
Summary Report of IQC program for G6PD Quantitative Test - AMP Group - March 2017 -

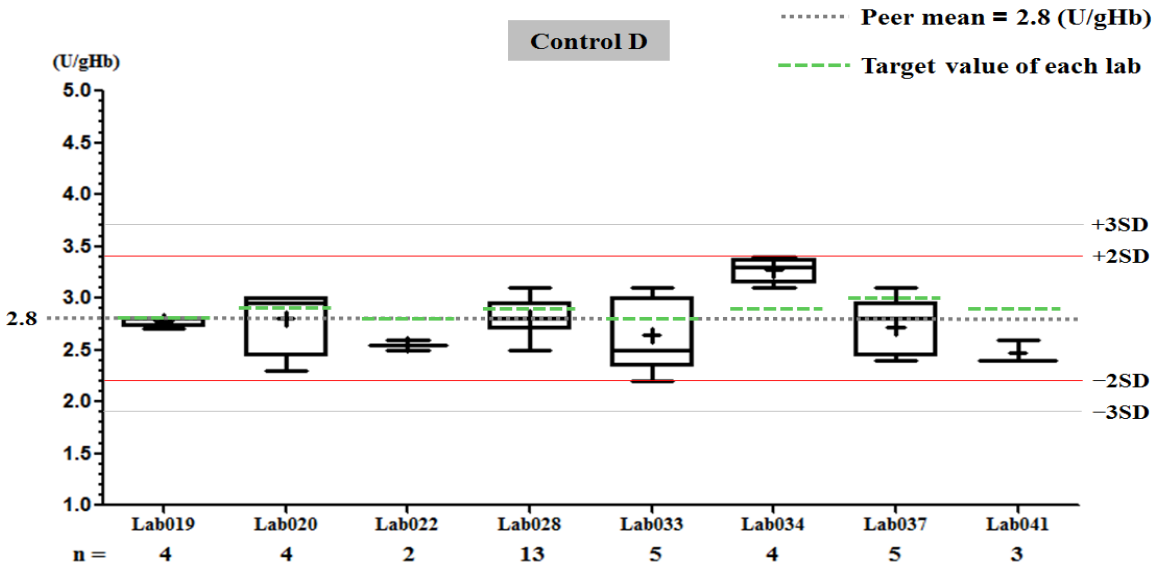
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AC1203N)	Control D (Lot No.:AC1203D)
Labs	8	8
Received results number (n)	40	40
Median	11.9 (U/gHb)	2.8 (U/gHb)
Mean	11.7 (U/gHb)	2.8 (U/gHb)
SD	1.0	0.3
CV	8.5%	10.7%
Range of G6PD	9.9 ~ 14.1 (U/gHb)	2.2 ~ 3.4 (U/gHb)
Range of Hb	2.0 ~ 2.9 (g/dL)	2.3 ~ 3.6 (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





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QC Chart of Internal Quality Control (IQC)for G6PD Quantitative Test

Select LotNo : AC1203N (2014-01-01 ~ 2100-12-31) Change

Print Table

Lab028

	Control N		Control D	
QC Control Lot No.	AC1203N		AC1203D	
Duration of the Analyzing	Month (2017/03)	CUM (2017/01/31~2017/03/31)	Month (2017/03)	CUM (2017/01/31~2017/03/31)
Runs (N)	13	26	13	26
Mean (U/gHb)	11.8	12.2	2.8	2.9
SD	0.5	1.0	0.2	0.3
CV (%)	4.2	8.2	7.1	10.3
Target Value (U/gHb)	12.8	12.8	2.9	2.9
Total Error (%)	16.3	21.1	17.7	20.7
TEa (%)	20	20	20	20
σ	2.9	1.9	2.3	1.9

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

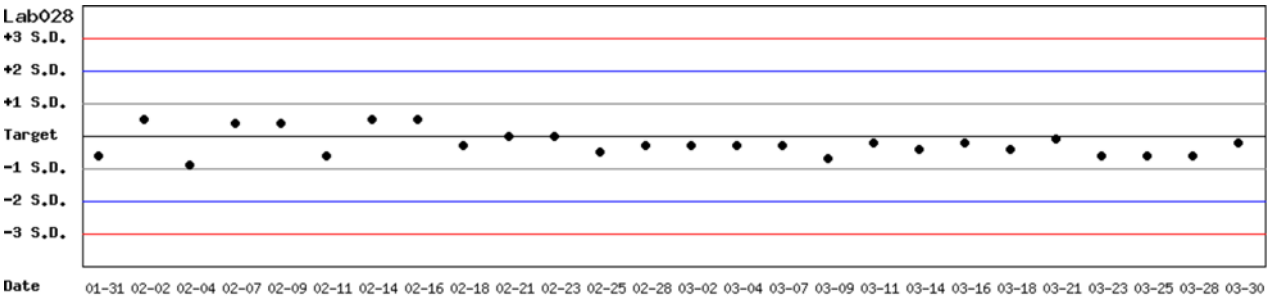
Month : 2017 03 Change ; Cumulative : from 2017 01 31 to 2017 03 31 Change

[TOP]

Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2017-01-31 to 2017-03-31 ; Target : 12.8 ; SD : 2.6

Lab028



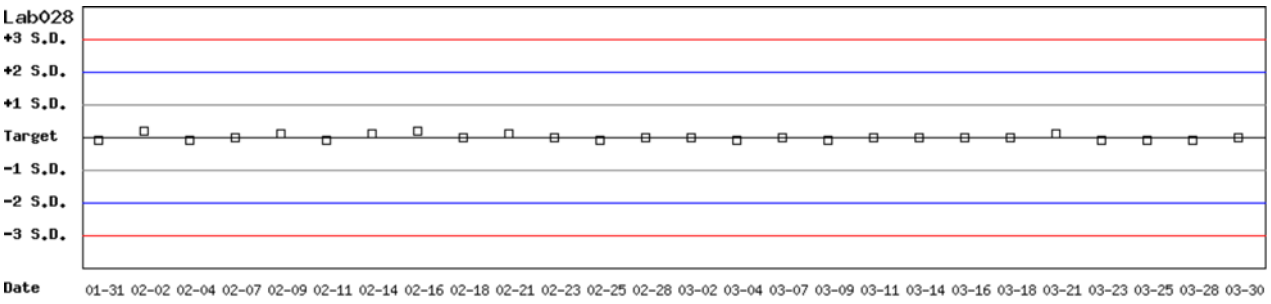
Month : 2017 03 Change ; Cumulative : from 2017 01 31 to 2017 03 31 Change

[TOP]

Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2017-01-31 to 2017-03-31 ; Target : 2.9 ; SD : 3.1

Lab028



Month : 2017 03 Change ; Cumulative : from 2017 01 31 to 2017 03 31 Change

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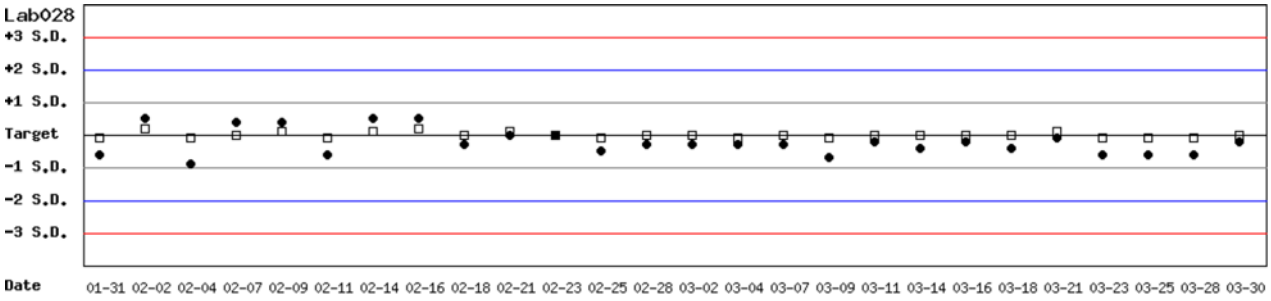
Control N and **Control D SDI**
QC Chart

Lot No.: AC1203N ; Duration : 2017-01-31 to 2017-03-31 ; Target : 12.8 ; SD : 2.6 (●)

Lot No.: AC1203D ; Duration : 2017-01-31 to 2017-03-31 ; Target : 2.9 ; SD : 3.1 (□)

Lab028



Month : 2017 | 03 Change ; Cumulative : from 2017 | 01 | 31 to 2017 | 03 | 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 03 Change

		Control N (Lot No.: AC1203N)								Control D (Lot No.: AC1203D)							
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
Lab019	2	12.1	12.1	4	0.4	3.3	6.6	20	>6	2.8	2.8	4	0.1	3.6	7.1	20	5.6
Lab020	2	12.8	12.2	4	1.6	13.1	30.9	20	1.2	2.9	2.8	4	0.3	10.7	24.9	20	1.5
Lab022	2	11.3	10.5	2	-	-	-	20	-	2.8	2.6	2	-	-	-	20	-
Lab028	2	12.8	11.8	13	0.5	4.2	16.3	20	2.9	2.9	2.8	13	0.2	7.1	17.7	20	2.3
Lab033	2	11.6	11.2	5	0.9	8.0	19.5	20	2.1	2.8	2.6	5	0.4	15.4	37.9	20	0.8
Lab034	2	12.8	13.1	4	0.6	4.6	11.5	20	3.8	2.9	3.3	4	0.1	3.0	19.9	20	2.1
Lab037	2	12.6	11.7	5	0.4	3.4	14.0	20	3.8	3.0	2.7	5	0.3	11.1	32.2	20	0.9
Lab041	2	12.8	10.4	3	0.4	3.8	26.4	20	0.3	2.9	2.5	3	0.1	4.0	21.8	20	1.6
Total	-	-	11.7	40	1.0	8.5	-	-	-	-	2.8	40	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 2017 03 31 Change

		Control N (Lot No.: AC1203N)								Control D (Lot No.: AC1203D)							
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	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	157	1.1	9.0	18.9	20	2.1	2.8	2.8	157	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	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	11.3	11.5	65	1.2	10.4	22.6	20	1.8	2.8	2.9	65	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	11.8	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	12.8	13.5	338	1.2	8.9	23.2	20	1.6	2.9	3.3	338	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	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	11.9	152	1.0	8.4	19.4	20	2.1	2.8	2.9	152	0.3	10.3	24.3	20	1.6
Lab034	2	12.8	12.3	90	0.7	5.7	15.3	20	2.8	2.9	3.0	90	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	66	1.2	9.8	22.8	20	1.7	3.0	2.9	66	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	21	0.5	4.1	13.7	20	3.5	2.9	2.6	21	0.3	11.5	33.4	20	0.8
Lab041	2	12.8	10.4	4	0.4	3.8	26.4	20	0.3	2.9	2.5	4	0.1	4.0	21.8	20	1.6
Total	-	-	12.1	1996	1.6	13.2	-	-	-	-	2.9	1996	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 (2017/03)								CUM (2014/02/01~2017/03/31)							
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	12.1	4	0.4	3.3	6.6	20	>6	12.1	12.2	157	1.1	9.0	18.9	20	2.1
Lab020	2	12.8	12.2	4	1.6	13.1	30.9	20	1.2	12.8	11.8	19	1.4	11.9	31.5	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	11.3	10.5	2	-	-	-	20	-	11.3	11.5	65	1.2	10.4	22.6	20	1.8
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	151	1.6	13.6	31.2	20	1.2
Lab028	2	12.8	11.8	13	0.5	4.2	16.3	20	2.9	12.8	13.5	338	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	12.3	-	0	-	-	-	20	-	12.3	11.5	222	1.9	16.5	39.5	20	0.8
Lab033	2	11.6	11.2	5	0.9	8.0	19.5	20	2.1	11.6	11.9	152	1.0	8.4	19.4	20	2.1
Lab034	2	12.8	13.1	4	0.6	4.6	11.5	20	3.8	12.8	12.3	90	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	11.7	5	0.4	3.4	14.0	20	3.8	12.6	12.2	66	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	-	0	-	-	-	20	-	12.8	12.1	21	0.5	4.1	13.7	20	3.5
Lab041	2	12.8	10.4	3	0.4	3.8	26.4	20	0.3	12.8	10.4	4	0.4	3.8	26.4	20	0.3
Total	-	-	11.7	40	1.0	8.5	-	-	-	-	12.1	1996	1.6	13.2	-	-	-

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

Month : 2017 03 Change

Cumulative : from 2014 02 01 to 2017 03 31 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: AC1203D)															
		Month (2017/03)								CUM (2014/02/01~2017/03/31)							
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	2.8	4	0.1	3.6	7.1	20	5.6	2.8	2.8	157	0.4	14.3	28.6	20	1.4
Lab020	2	2.9	2.8	4	0.3	10.7	24.9	20	1.5	2.9	2.7	19	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	2.8	2.6	2	-	-	-	20	-	2.8	2.9	65	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	-	0	-	-	-	20	-	2.9	2.7	151	0.5	18.5	43.9	20	0.7
Lab028	2	2.9	2.8	13	0.2	7.1	17.7	20	2.3	2.9	3.3	338	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	2.9	-	0	-	-	-	20	-	2.9	2.7	222	0.5	18.5	43.9	20	0.7
Lab033	2	2.8	2.6	5	0.4	15.4	37.9	20	0.8	2.8	2.9	152	0.3	10.3	24.3	20	1.6
Lab034	2	2.9	3.3	4	0.1	3.0	19.9	20	2.1	2.9	3.0	90	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	2.7	5	0.3	11.1	32.2	20	0.9	3.0	2.9	66	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	-	0	-	-	-	20	-	2.9	2.6	21	0.3	11.5	33.4	20	0.8
Lab041	2	2.9	2.5	3	0.1	4.0	21.8	20	1.6	2.9	2.5	4	0.1	4.0	21.8	20	1.6
Total	-	-	2.8	40	0.3	10.7	-	-	-	-	2.9	1996	0.6	20.7	-	-	-

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

Month : 2017 03 Change

Cumulative : from 2014 02 01 to 2017 03 31 Change

[TOP]

Reagent Kit	Reagent Code
AMP	2