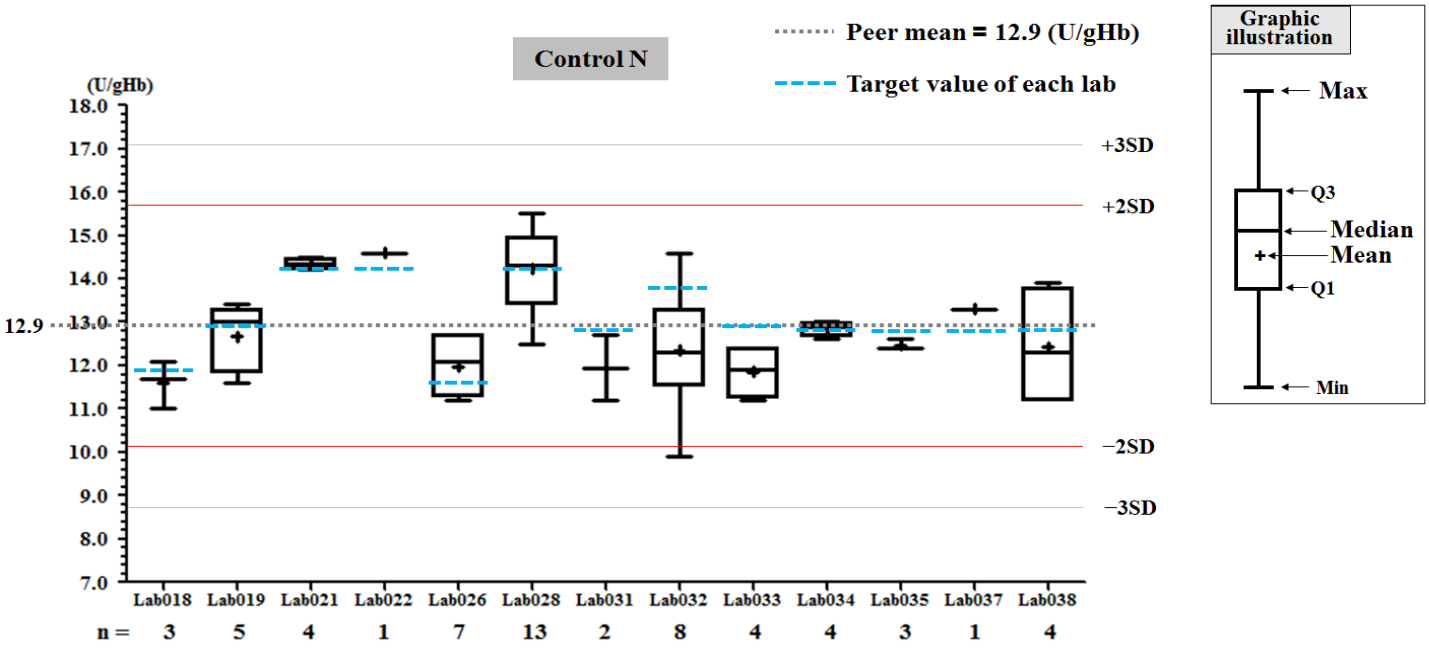
Summary Report of IQC program for G6PD Quantitative Test - AMP Group - September 2015 -

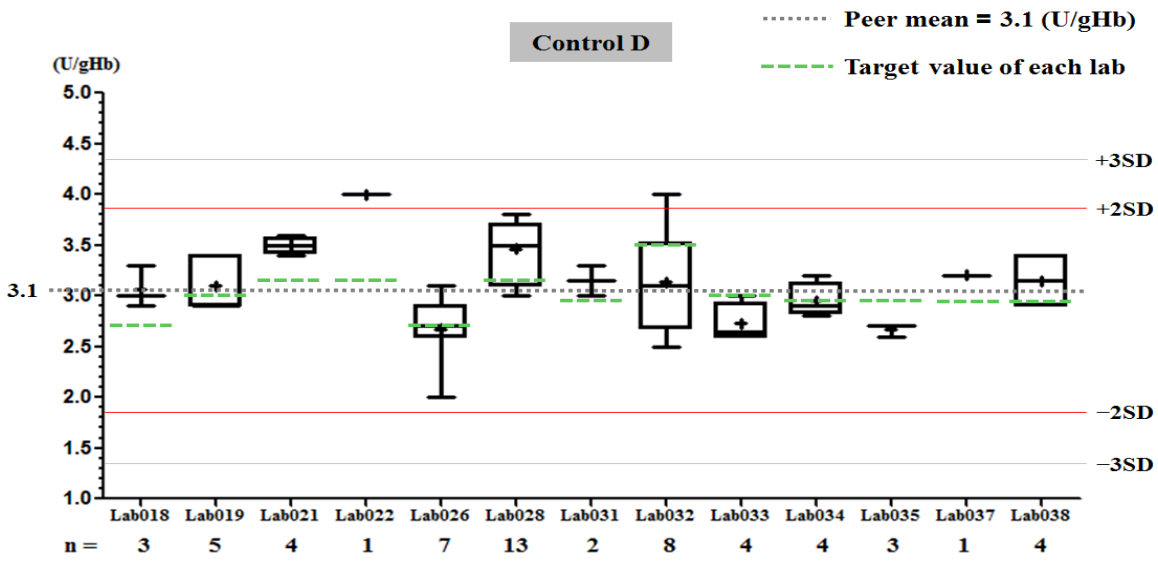
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AC1203N)	Control D (Lot No.:AC1203D)
Labs	13	13
Received results number (n)	59	59
Median	12.7 (U/gHb)	3.1 (U/gHb)
Mean	12.9 (U/gHb)	3.1 (U/gHb)
SD	1.3	0.4
CV	10.1%	12.9%
Range of G6PD	9.9 ~ 15.5 (U/gHb)	2.0 ~ 4.0 (U/gHb)
Range of Hb	1.6 ~ 2.8 (g/dL)	2.4 ~ 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





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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

Lab026

	Control N		Control D	
QC Control Lot No.	AC1203N		AC1203D	
Duration of the Analyzing	Month (2015/09)	CUM (2015/07/22~2015/09/30)	Month (2015/09)	CUM (2015/07/22~2015/09/30)
Runs (N)	7	26	7	26
Mean (U/gHb)	12.0	12.0	2.7	2.8
SD	0.6	0.7	0.3	0.3
CV (%)	5.0	5.8	11.1	10.7
Target Value (U/gHb)	11.6	11.6	2.7	2.7
Total Error (%)	13.4	15.1	22.2	25.1
TEa (%)	36	36	36	36
σ	>6	5.6	3.2	3.0

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

Month : 2015 09 Change ; Cumulative : from 2015 07 22 to 2015 09 30 Change

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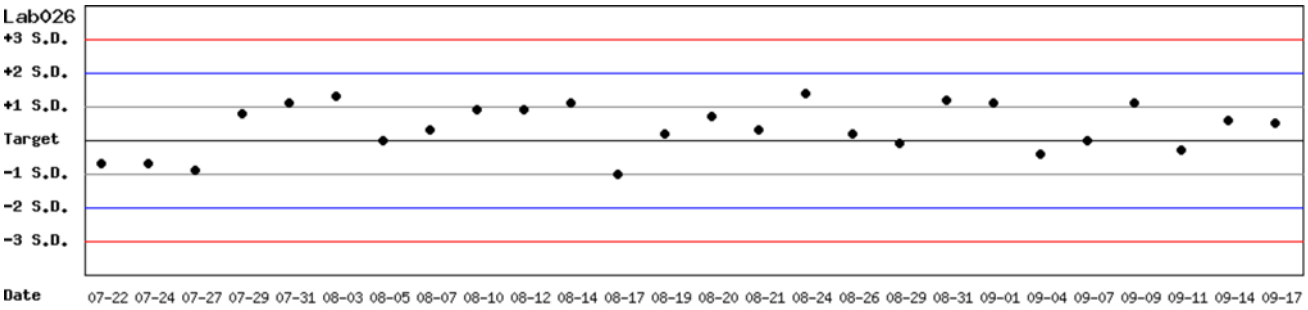
Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2015-07-22 to 2015-09-30 ; Target : 11.6 ; SD : 1.00

Lab026



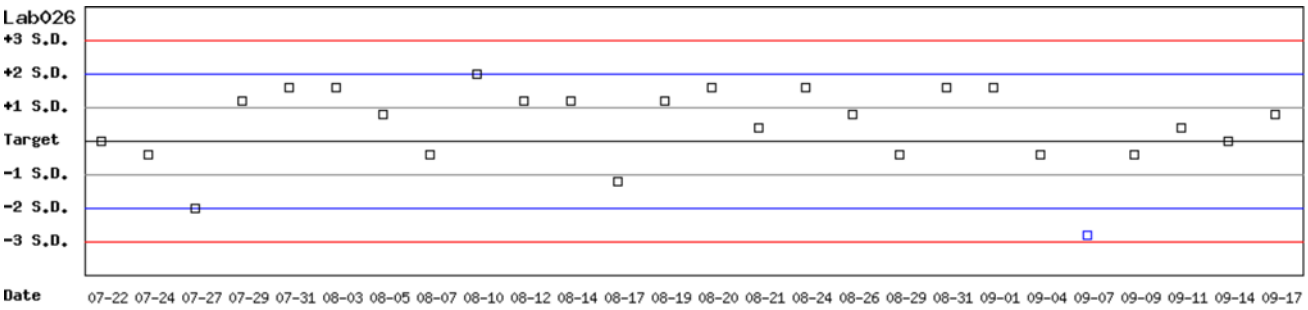
Month : 2015 09 Change ; Cumulative : from 2015 07 22 to 2015 09 30 Change

[TOP]

Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2015-07-22 to 2015-09-30 ; Target : 2.7 ; SD : 0.25

Lab026



Month : 2015 09 Change ; Cumulative : from 2015 07 22 to 2015 09 30 Change

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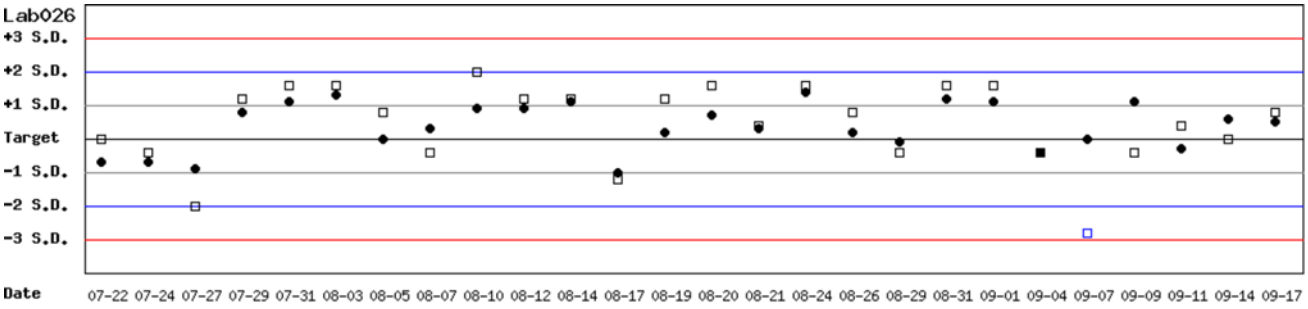
Control N and **Control D SDI**
QC Chart

Lot No.: AC1203N ; Duration : 2015-07-22 to 2015-09-30 ; Target : 11.6 ; SD : 1.00 (●)

Lot No.: AC1203D ; Duration : 2015-07-22 to 2015-09-30 ; Target : 2.7 ; SD : 0.25 (□)

Lab026



Month : 2015 09 Change ; Cumulative : from 2015 07 22 to 2015 09 30 Change

[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 : 2015 09 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
Lab018	2	11.9	11.6	3	0.6	5.2	12.9	20	3.4	2.7	3.1	3	0.2	6.5	27.7	20	0.8
Lab019	2	12.9	12.7	5	0.8	6.3	14.1	20	2.9	3.0	3.1	5	0.3	9.7	22.7	20	1.7
Lab021	2	14.2	14.4	4	0.1	0.7	2.8	20	>6	3.3	3.5	4	0.1	2.9	11.8	20	4.8
Lab022	2	14.2	14.6	1	-	-	-	20	-	3.3	4.0	1	-	-	-	20	-
Lab026	2	11.6	12.0	7	0.6	5.0	13.4	36	>6	2.7	2.7	7	0.3	11.1	22.2	36	3.2
Lab028	2	14.2	14.2	13	0.9	6.3	12.7	20	3.2	3.3	3.5	13	0.3	8.6	23.2	20	1.6
Lab031	2	12.8	12.0	2	-	-	-	20	-	2.9	3.2	2	-	-	-	20	-
Lab032	2	13.8	12.4	8	1.4	11.3	32.7	20	0.9	3.5	3.1	8	0.5	16.1	43.7	20	0.5
Lab033	2	12.9	11.9	4	0.6	5.0	17.8	20	2.4	3.0	2.7	4	0.2	7.4	24.8	20	1.4
Lab034	2	12.8	12.9	4	0.2	1.6	3.9	20	>6	2.9	3.0	4	0.2	6.7	16.8	20	2.5
Lab035	2	12.8	12.5	3	0.1	0.8	3.9	20	>6	2.9	2.7	3	0.1	3.7	14.3	20	3.5
Lab037	2	12.8	13.3	1	-	-	-	20	-	2.9	3.2	1	-	-	-	20	-
Lab038	2	12.8	12.4	4	1.4	11.3	25.7	20	1.5	2.9	3.2	4	0.3	9.4	29.1	20	1.0
Total	-	-	12.9	59	1.3	10.1	-	-	-	-	3.1	59	0.4	12.9	-	-	-

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 2015 09 30 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	11.9	10.7	62	1.7	15.9	41.9	20	0.6	2.7	2.5	62	1.2	48.0	103.4	20	0.3
Lab019	2	12.9	12.0	83	1.3	10.8	28.6	20	1.2	3.0	2.8	83	0.4	14.3	35.2	20	0.9
Lab021	2	14.2	14.3	37	0.2	1.4	3.5	20	>6	3.3	3.4	37	0.1	2.9	8.9	20	5.9
Lab022	2	14.2	14.6	1	-	-	-	20	-	3.3	4.0	1	-	-	-	20	-
Lab024	2	11.6	11.1	39	1.3	11.7	27.7	20	1.3	2.7	2.7	39	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	113	1.7	14.4	32.9	20	1.1	2.9	2.7	113	0.5	18.5	43.9	20	0.7
Lab028	2	14.2	13.8	147	1.4	10.1	23.1	20	1.7	3.3	3.4	147	0.7	20.6	44.2	20	0.8
Lab031	2	12.8	10.0	59	1.4	14.0	49.9	20	-0.1	2.9	2.4	59	0.4	16.7	50.6	20	0.2
Lab032	2	13.8	11.1	158	1.9	17.1	53.8	20	0.0	3.5	2.6	158	0.6	23.1	71.9	20	-0.2
Lab033	2	12.9	12.1	79	1.1	9.1	24.4	20	1.5	3.0	2.9	79	0.3	10.3	24.0	20	1.6
Lab034	2	12.8	12.6	31	0.4	3.2	7.9	20	5.8	2.9	3.0	31	0.1	3.3	10.1	20	5.0
Lab035	2	12.8	12.8	26	0.8	6.3	12.5	20	3.2	2.9	2.9	26	0.4	13.8	27.6	20	1.4
Lab037	2	12.8	12.5	6	1.2	9.6	21.5	20	1.8	2.9	3.1	6	0.3	9.7	26.3	20	1.4
Lab038	2	12.8	12.8	17	1.2	9.4	18.8	20	2.1	2.9	3.3	17	0.5	15.2	44.1	20	0.4
Total	-	-	12.0	1105	1.9	15.8	-	-	-	-	2.9	1105	0.7	24.1	-	-	-

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 (2015/09)									CUM (2014/02/01~2015/09/30)						
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	11.6	3	0.6	5.2	12.9	20	3.4		11.9	10.7	62	1.7	15.9	41.9	20	0.6
Lab019	2	12.9	12.7	5	0.8	6.3	14.1	20	2.9		12.9	12.0	83	1.3	10.8	28.6	20	1.2
Lab021	2	14.2	14.4	4	0.1	0.7	2.8	20	>6		14.2	14.3	37	0.2	1.4	3.5	20	>6
Lab022	2	14.2	14.6	1	-	-	-	20	-		14.2	14.6	1	-	-	-	20	-
Lab024	2	11.6	-	0	-	-	-	20	-		11.6	11.1	39	1.3	11.7	27.7	20	1.3
Lab026	2	11.6	12.0	7	0.6	5.0	13.4	36	>6		11.6	11.5	211	1.6	13.9	28.7	36	2.5
Lab027	2	12.3	-	0	-	-	-	20	-		12.3	11.8	113	1.7	14.4	32.9	20	1.1
Lab028	2	14.2	14.2	13	0.9	6.3	12.7	20	3.2		14.2	13.8	147	1.4	10.1	23.1	20	1.7
Lab031	2	12.8	12.0	2	-	-	-	20	-		12.8	10.0	59	1.4	14.0	49.9	20	-0.1
Lab032	2	13.8	12.4	8	1.4	11.3	32.7	20	0.9		13.8	11.1	158	1.9	17.1	53.8	20	0.0
Lab033	2	12.9	11.9	4	0.6	5.0	17.8	20	2.4		12.9	12.1	79	1.1	9.1	24.4	20	1.5
Lab034	2	12.8	12.9	4	0.2	1.6	3.9	20	>6		12.8	12.6	31	0.4	3.2	7.9	20	5.8
Lab035	2	12.8	12.5	3	0.1	0.8	3.9	20	>6		12.8	12.8	26	0.8	6.3	12.5	20	3.2
Lab037	2	12.8	13.3	1	-	-	-	20	-		12.8	12.5	6	1.2	9.6	21.5	20	1.8
Lab038	2	12.8	12.4	4	1.4	11.3	25.7	20	1.5		12.8	12.8	17	1.2	9.4	18.8	20	2.1
Total	-	-	12.9	59	1.3	10.1	-	-	-		-	12.0	1105	1.9	15.8	-	-	-

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

Month : 2015 09 Change Cumulative : from 2014 02 01 to 2015 09 30 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: AC1203D)															
		Month (2015/09)									CUM (2014/02/01~2015/09/30)						
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	3.1	3	0.2	6.5	27.7	20	0.8		2.7	2.5	62	1.2	48.0	103.4	20	0.3
Lab019	2	3.0	3.1	5	0.3	9.7	22.7	20	1.7		3.0	2.8	83	0.4	14.3	35.2	20	0.9
Lab021	2	3.3	3.5	4	0.1	2.9	11.8	20	4.8		3.3	3.4	37	0.1	2.9	8.9	20	5.9
Lab022	2	3.3	4.0	1	-	-	-	20	-		3.3	4.0	1	-	-	-	20	-
Lab024	2	2.7	-	0	-	-	-	20	-		2.7	2.7	39	0.4	14.8	29.6	20	1.4
Lab026	2	2.7	2.7	7	0.3	11.1	22.2	36	3.2		2.7	2.8	211	0.5	17.9	39.4	36	1.8
Lab027	2	2.9	-	0	-	-	-	20	-		2.9	2.7	113	0.5	18.5	43.9	20	0.7
Lab028	2	3.3	3.5	13	0.3	8.6	23.2	20	1.6		3.3	3.4	147	0.7	20.6	44.2	20	0.8
Lab031	2	2.9	3.2	2	-	-	-	20	-		2.9	2.4	59	0.4	16.7	50.6	20	0.2
Lab032	2	3.5	3.1	8	0.5	16.1	43.7	20	0.5		3.5	2.6	158	0.6	23.1	71.9	20	-0.2
Lab033	2	3.0	2.7	4	0.2	7.4	24.8	20	1.4		3.0	2.9	79	0.3	10.3	24.0	20	1.6
Lab034	2	2.9	3.0	4	0.2	6.7	16.8	20	2.5		2.9	3.0	31	0.1	3.3	10.1	20	5.0
Lab035	2	2.9	2.7	3	0.1	3.7	14.3	20	3.5		2.9	2.9	26	0.4	13.8	27.6	20	1.4
Lab037	2	2.9	3.2	1	-	-	-	20	-		2.9	3.1	6	0.3	9.7	26.3	20	1.4
Lab038	2	2.9	3.2	4	0.3	9.4	29.1	20	1.0		2.9	3.3	17	0.5	15.2	44.1	20	0.4
Total	-	-	3.1	59	0.4	12.9	-	-	-		-	2.9	1105	0.7	24.1	-	-	-

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

Month : 2015 09 Change Cumulative : from 2014 02 01 to 2015 09 30 Change

[TOP]

Reagent Kit	Reagent Code
AMP	2