

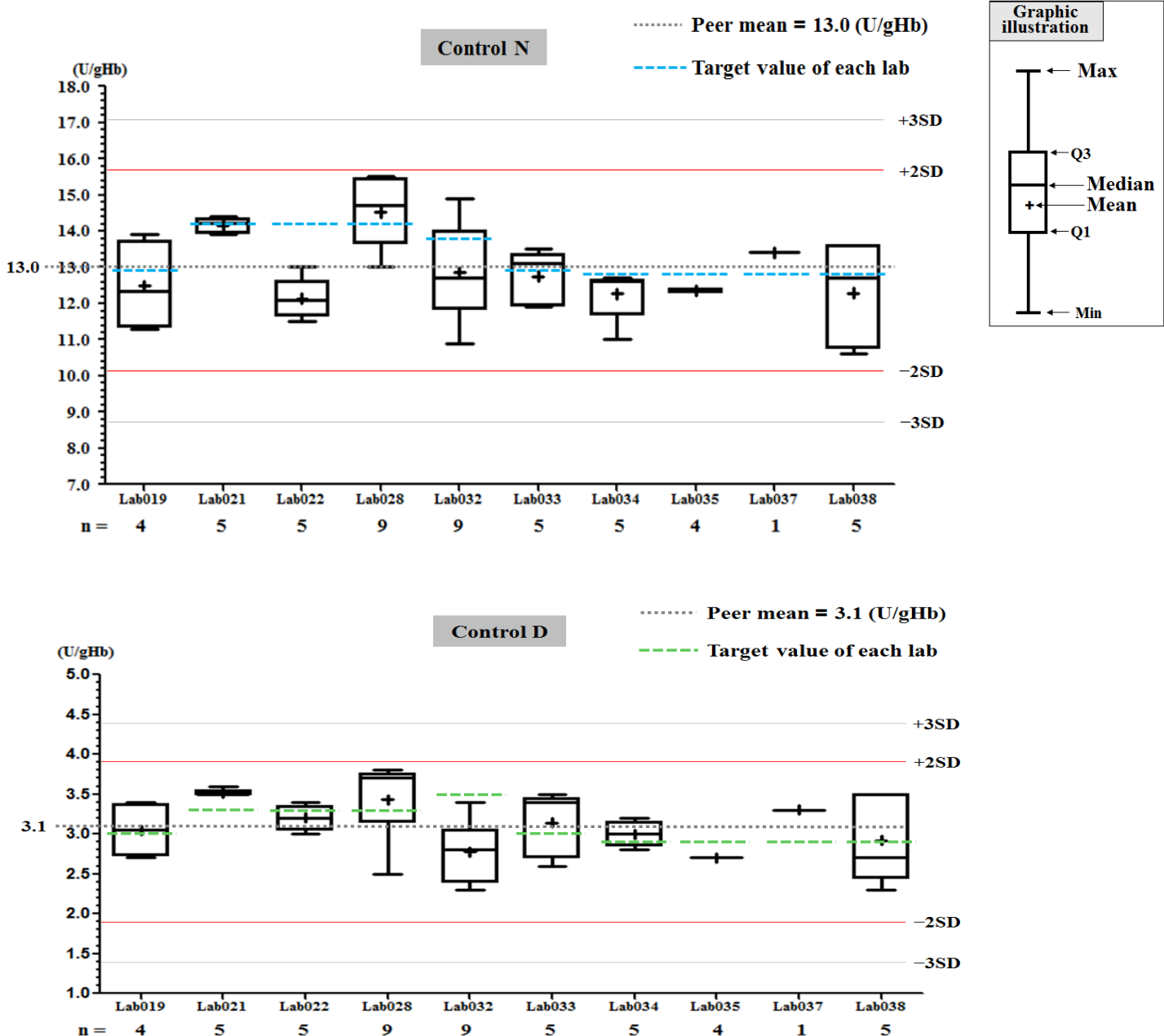
Summary Report of IQC program for G6PD Quantitative Test - AMP Group - October 2015 -

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)	52	52
Median	13.0 (U/gHb)	3.1 (U/gHb)
Mean	13.0 (U/gHb)	3.1 (U/gHb)
SD	1.3	0.4
CV	10.0%	12.9%
Range of G6PD	10.6 ~ 15.5 (U/gHb)	2.3 ~ 3.8 (U/gHb)
Range of Hb	1.1 ~ 2.8 (g/dL)	1.3 ~ 3.2 (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)

Lab037

QC Control Lot No.	Control N		Control D	
	AC1203N		AC1203D	
Duration of the Analyzing	Month (2015/10)	CUM (2014/02/01~2015/10/31)	Month (2015/10)	CUM (2014/02/01~2015/10/31)
Runs (N)	1	7	1	7
Mean (U/gHb)	13.4	12.6	3.3	3.1
SD	-	1.1	-	0.3
CV (%)	-	8.7	-	9.7
Target Value (U/gHb)	12.8	12.8	2.9	2.9
Total Error (%)	-	19.0	-	26.3
TEa (%)	20	20	20	20
σ	-	2.1	-	1.4

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

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

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

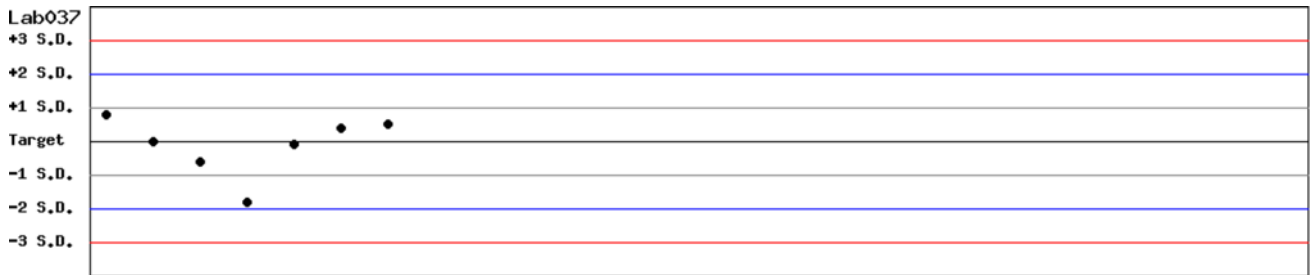
Month : 2015 10 ; Cumulative : from 2014 02 01 to 2015 10 31

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Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2014-02-01 to 2015-10-31 ; Target : 12.8 ; SD : 1.28

Lab037



Date 05-01 05-22 06-19 07-10 08-14 09-11 10-16

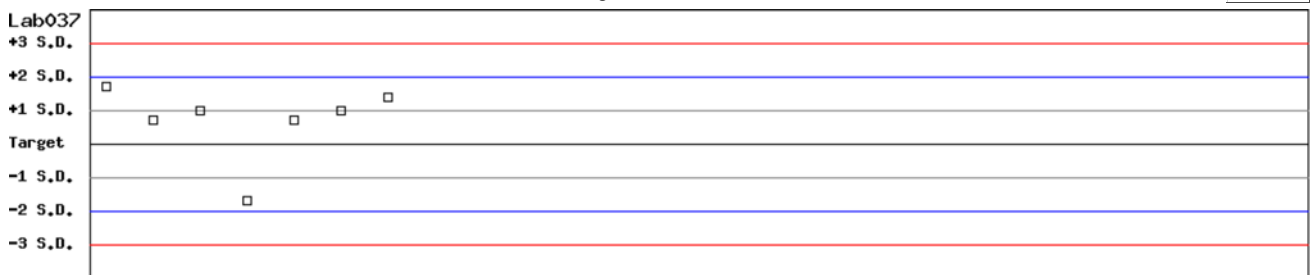
Month : 2015 10 ; Cumulative : from 2014 02 01 to 2015 10 31

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Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2014-02-01 to 2015-10-31 ; Target : 2.9 ; SD : 0.29

Lab037



Date 05-01 05-22 06-19 07-10 08-14 09-11 10-16

Month : 2015 10 ; Cumulative : from 2014 02 01 to 2015 10 31

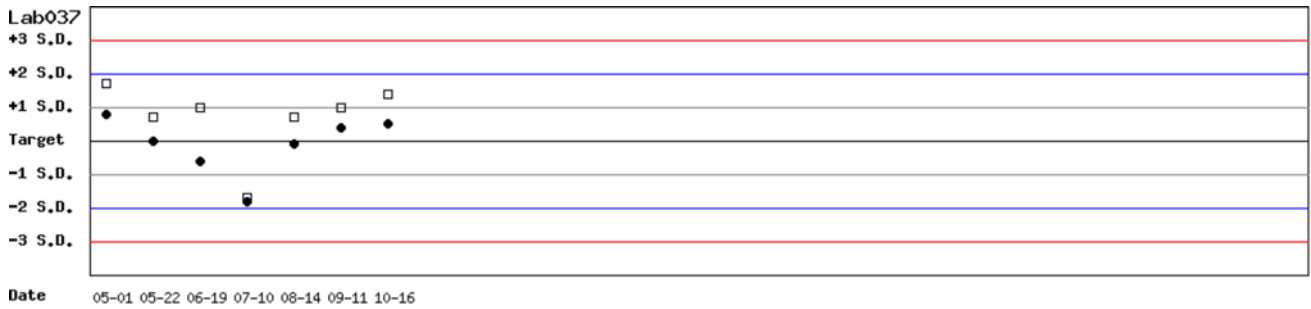
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Control N and Control D SDI QC Chart

Lot No.: AC1203N ; Duration : 2014-02-01 to 2015-10-31 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: AC1203D ; Duration : 2014-02-01 to 2015-10-31 ; Target : 2.9 ; SD : 0.29 (◻)

Lab037



Month : 2015 10 ; Cumulative : from 2014 02 01 to 2015 10 31

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Peer Group Statistics (Table 1)

Select LotNo :

Select Reagent Kit :

Monthly

Month :

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	12.9	12.5	4	1.3	10.4	23.9	20	1.6	3.0	3.1	4	0.4	12.9	29.1	20	1.3
Lab021	2	14.2	14.2	5	0.2	1.4	2.8	20	>6	3.3	3.5	5	0.1	2.9	11.8	20	4.8
Lab022	2	14.2	12.1	5	0.6	5.0	24.7	20	1.0	3.3	3.2	5	0.2	6.3	15.5	20	2.7
Lab028	2	14.2	14.5	9	1.0	6.9	15.9	20	2.6	3.3	3.4	9	0.5	14.7	32.4	20	1.2
Lab032	2	13.8	12.8	9	1.4	10.9	29.1	20	1.2	3.5	2.8	9	0.4	14.3	48.6	20	0.0
Lab033	2	12.9	12.7	5	0.7	5.5	12.6	20	3.4	3.0	3.1	5	0.4	12.9	29.1	20	1.3
Lab034	2	12.8	12.3	5	0.7	5.7	15.3	20	2.8	2.9	3.0	5	0.2	6.7	16.8	20	2.5
Lab035	2	12.8	12.4	4	0.1	0.8	4.7	20	>6	2.9	2.7	4	0.0	0.0	6.9	20	>6
Lab037	2	12.8	13.4	1	-	-	-	20	-	2.9	3.3	1	-	-	-	20	-
Lab038	2	12.8	12.3	5	1.4	11.4	26.7	20	1.4	2.9	2.9	5	0.6	20.7	41.4	20	1.0
Total	-	-	13.0	52	1.3	10.0	-	-	-	-	3.1	52	0.4	12.9	-	-	-

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

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Cumulative

Cumulative : from to

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	10.7	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	12.1	87	1.3	10.7	27.7	20	1.3	3.0	2.8	87	0.4	14.3	35.2	20	0.9
Lab021	2	14.2	14.2	42	0.2	1.4	2.8	20	>6	3.3	3.5	42	0.1	2.9	11.8	20	4.8
Lab022	2	14.2	12.5	6	1.1	8.8	29.6	20	0.9	3.3	3.3	6	0.4	12.1	24.2	20	1.7
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	13.9	156	1.3	9.4	20.8	20	1.9	3.3	3.4	156	0.6	17.6	38.3	20	1.0
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	11.2	167	1.9	17.0	52.8	20	0.1	3.5	2.6	167	0.5	19.2	64.2	20	-0.3
Lab033	2	12.9	12.1	84	1.1	9.1	24.4	20	1.5	3.0	2.9	84	0.3	10.3	24.0	20	1.6
Lab034	2	12.8	12.5	36	0.5	4.0	10.3	20	4.4	2.9	3.0	36	0.1	3.3	10.1	20	5.0
Lab035	2	12.8	12.7	30	0.8	6.3	13.4	20	3.1	2.9	2.9	30	0.3	10.3	20.7	20	1.9
Lab037	2	12.8	12.6	7	1.1	8.7	19.0	20	2.1	2.9	3.1	7	0.3	9.7	26.3	20	1.4
Lab038	2	12.8	12.7	22	1.3	10.2	21.3	20	1.9	2.9	3.2	22	0.5	15.6	41.6	20	0.6
Total	-	-	12.0	1157	1.9	15.8	-	-	-	-	2.9	1157	0.7	24.1	-	-	-

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 :

Select Reagent Kit :

Control N Month vs. Cumulative

		Control N (Lot No.: AC1203N)															
		Month (2015/10)								CUM (2014/02/01~2015/10/31)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	10.7	62	1.7	15.9	41.9	20	0.6
Lab019	2	12.9	12.5	4	1.3	10.4	23.9	20	1.6	12.9	12.1	87	1.3	10.7	27.7	20	1.3
Lab021	2	14.2	14.2	5	0.2	1.4	2.8	20	>6	14.2	14.2	42	0.2	1.4	2.8	20	>6
Lab022	2	14.2	12.1	5	0.6	5.0	24.7	20	1.0	14.2	12.5	6	1.1	8.8	29.6	20	0.9
Lab024	2	11.6	-	0	-	-	-	20	-	11.6	11.1	39	1.3	11.7	27.7	20	1.3
Lab026	2	11.6	-	0	-	-	-	36	-	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	14.5	9	1.0	6.9	15.9	20	2.6	14.2	13.9	156	1.3	9.4	20.8	20	1.9
Lab031	2	12.8	-	0	-	-	-	20	-	12.8	10.0	59	1.4	14.0	49.9	20	-0.1
Lab032	2	13.8	12.8	9	1.4	10.9	29.1	20	1.2	13.8	11.2	167	1.9	17.0	52.8	20	0.1
Lab033	2	12.9	12.7	5	0.7	5.5	12.6	20	3.4	12.9	12.1	84	1.1	9.1	24.4	20	1.5
Lab034	2	12.8	12.3	5	0.7	5.7	15.3	20	2.8	12.8	12.5	36	0.5	4.0	10.3	20	4.4
Lab035	2	12.8	12.4	4	0.1	0.8	4.7	20	>6	12.8	12.7	30	0.8	6.3	13.4	20	3.1
Lab037	2	12.8	13.4	1	-	-	-	20	-	12.8	12.6	7	1.1	8.7	19.0	20	2.1
Lab038	2	12.8	12.3	5	1.4	11.4	26.7	20	1.4	12.8	12.7	22	1.3	10.2	21.3	20	1.9
Total	-	-	13.0	52	1.3	10.0	-	-	-	-	12.0	1157	1.9	15.8	-	-	-

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

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

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

Month :

Cumulative : from to

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Control D Month vs. Cumulative

		Control D (Lot No.: AC1203D)															
		Month (2015/10)								CUM (2014/02/01~2015/10/31)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	2.5	62	1.2	48.0	103.4	20	0.3
Lab019	2	3.0	3.1	4	0.4	12.9	29.1	20	1.3	3.0	2.8	87	0.4	14.3	35.2	20	0.9
Lab021	2	3.3	3.5	5	0.1	2.9	11.8	20	4.8	3.3	3.5	42	0.1	2.9	11.8	20	4.8
Lab022	2	3.3	3.2	5	0.2	6.3	15.5	20	2.7	3.3	3.3	6	0.4	12.1	24.2	20	1.7
Lab024	2	2.7	-	0	-	-	-	20	-	2.7	2.7	39	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	-	0	-	-	-	20	-	2.9	2.7	113	0.5	18.5	43.9	20	0.7
Lab028	2	3.3	3.4	9	0.5	14.7	32.4	20	1.2	3.3	3.4	156	0.6	17.6	38.3	20	1.0
Lab031	2	2.9	-	0	-	-	-	20	-	2.9	2.4	59	0.4	16.7	50.6	20	0.2
Lab032	2	3.5	2.8	9	0.4	14.3	48.6	20	0.0	3.5	2.6	167	0.5	19.2	64.2	20	-0.3
Lab033	2	3.0	3.1	5	0.4	12.9	29.1	20	1.3	3.0	2.9	84	0.3	10.3	24.0	20	1.6
Lab034	2	2.9	3.0	5	0.2	6.7	16.8	20	2.5	2.9	3.0	36	0.1	3.3	10.1	20	5.0
Lab035	2	2.9	2.7	4	0.0	0.0	6.9	20	>6	2.9	2.9	30	0.3	10.3	20.7	20	1.9
Lab037	2	2.9	3.3	1	-	-	-	20	-	2.9	3.1	7	0.3	9.7	26.3	20	1.4
Lab038	2	2.9	2.9	5	0.6	20.7	41.4	20	1.0	2.9	3.2	22	0.5	15.6	41.6	20	0.6
Total	-	-	3.1	52	0.4	12.9	-	-	-	-	2.9	1157	0.7	24.1	-	-	-

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

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

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

Month :

Cumulative : from to

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Reagent Kit	Reagent Code
AMP	2