

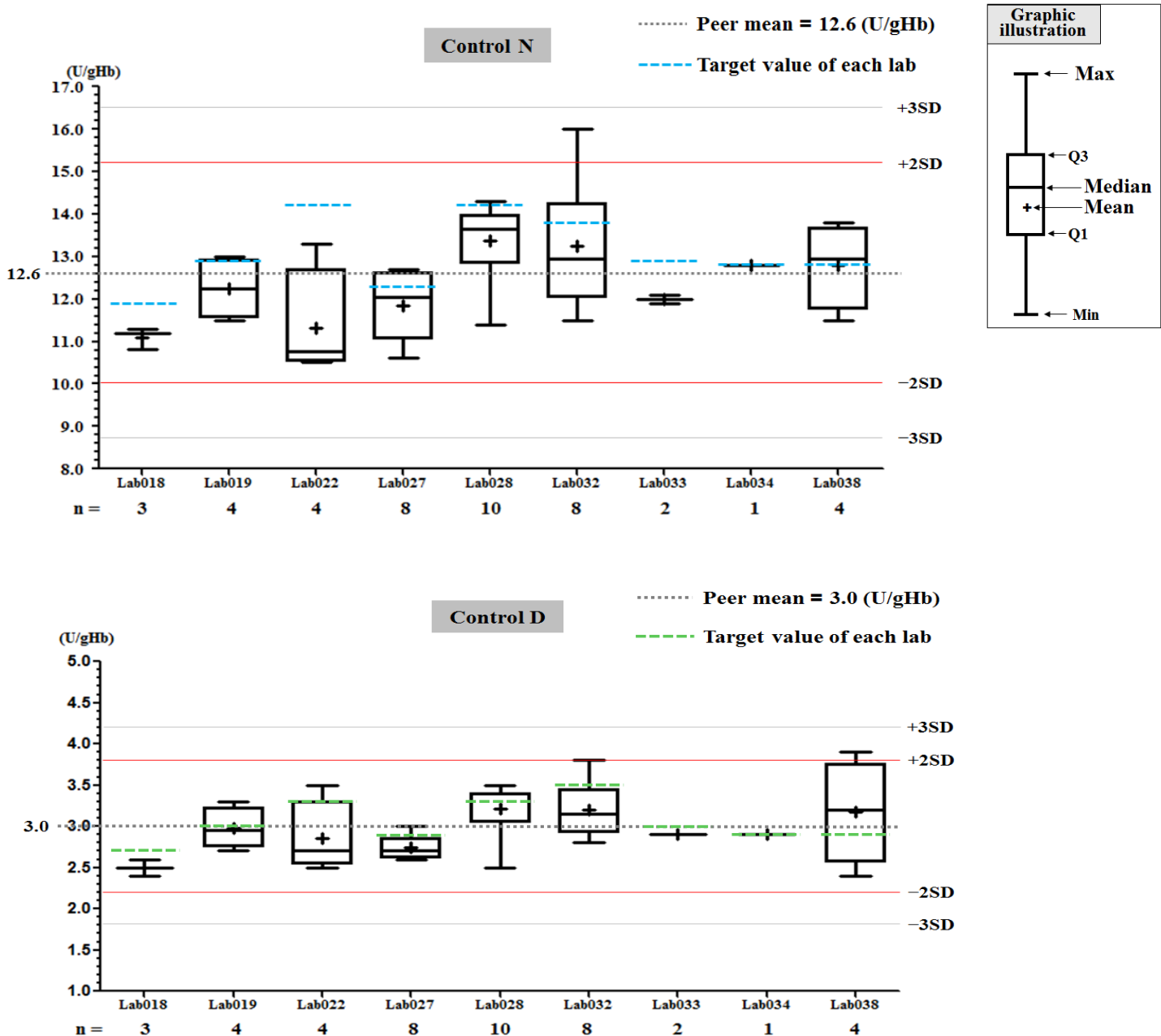
Summary Report of IQC program for G6PD Quantitative Test - AMP Group - February 2016 -

I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AC1203N)	Control D (Lot No.:AC1203D)
Labs	9	9
Received results number (n)	44	44
Median	12.7 (U/gHb)	2.9 (U/gHb)
Mean	12.5 (U/gHb)	3.0 (U/gHb)
SD	1.2	0.4
CV	9.6%	13.3%
Range of G6PD	10.5 ~ 16.0 (U/gHb)	2.4 ~ 3.9 (U/gHb)
Range of Hb	2.3 ~ 2.9 (g/dL)	2.5 ~ 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)

Lab034

	Control N		Control D	
QC Control Lot No.	AC1203N		AC1203D	
Duration of the Analyzing	Month (2016/02)	CUM (2015/07/23~2016/02/29)	Month (2016/02)	CUM (2015/07/23~2016/02/29)
Runs (N)	1	26	1	26
Mean (U/gHb)	12.8	12.6	2.9	3.0
SD	-	0.5	-	0.1
CV (%)	-	4.0	-	3.3
Target Value (U/gHb)	12.8	12.8	2.9	2.9
Total Error (%)	-	9.5	-	10.1
TEa (%)	20	20	20	20
σ	-	4.6	-	5.0

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

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

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

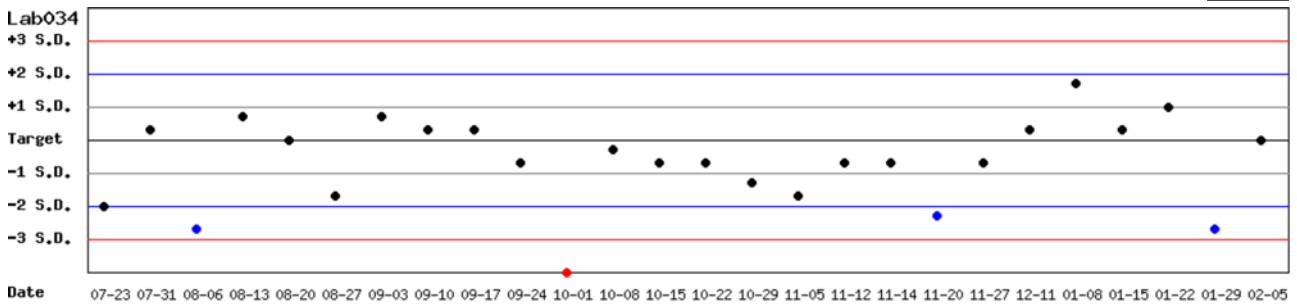
Month : 2016 02 ; Cumulative : from 2015 07 23 to 2016 02 29

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Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2015-07-23 to 2016-02-29 ; Target : 12.8 ; SD : 0.30

Lab034



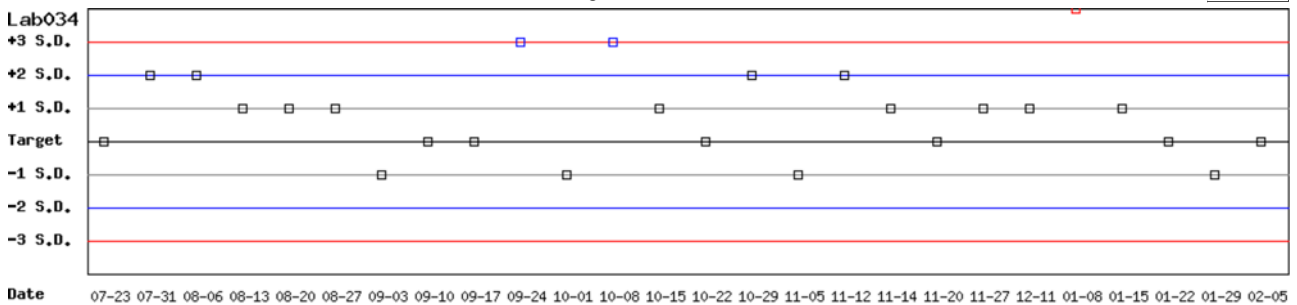
Month : 2016 02 ; Cumulative : from 2015 07 23 to 2016 02 29

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Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2015-07-23 to 2016-02-29 ; Target : 2.9 ; SD : 0.10

Lab034



Month : 2016 02 ; Cumulative : from 2015 07 23 to 2016 02 29

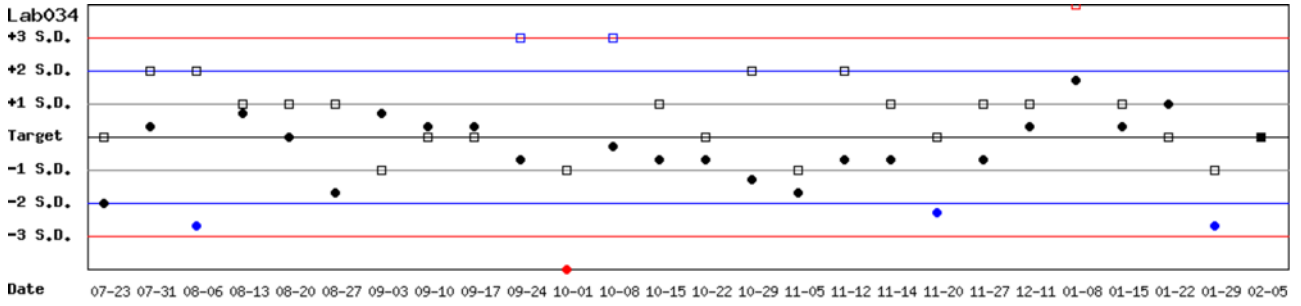
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Control N and Control D SDI QC Chart

Lot No.: AC1203N ; Duration : 2015-07-23 to 2016-02-29 ; Target : 12.8 ; SD : 0.30 (●)

Lot No.: AC1203D ; Duration : 2015-07-23 to 2016-02-29 ; Target : 2.9 ; SD : 0.10 (□)

Lab034



Month : 2016 02 ; Cumulative : from 2015 07 23 to 2016 02 29

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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 : 2016 02 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
Lab018	2	11.9	11.1	3	0.3	2.7	12.1	20	4.9	2.7	2.5	3	0.1	4.0	15.4	20	3.1
Lab019	2	12.9	12.3	4	0.7	5.7	16.0	20	2.7	3.0	3.0	4	0.3	10.0	20.0	20	2.0
Lab022	2	14.2	11.3	4	1.3	11.5	43.4	20	0.0	3.3	2.9	4	0.4	13.8	39.7	20	0.6
Lab027	2	12.3	11.9	8	0.8	6.7	16.7	20	2.5	2.9	2.7	8	0.1	3.7	14.3	20	3.5
Lab028	2	14.2	13.4	10	0.9	6.7	19.1	20	2.1	3.3	3.2	10	0.4	12.5	28.0	20	1.4
Lab032	2	13.8	13.3	8	1.5	11.3	26.2	20	1.4	3.5	3.2	8	0.3	9.4	27.3	20	1.2
Lab033	2	12.9	12.0	2	-	-	-	20	-	3.0	2.9	2	-	-	-	20	-
Lab034	2	12.8	12.8	1	-	-	-	20	-	2.9	2.9	1	-	-	-	20	-
Lab038	2	12.8	12.8	4	1.0	7.8	15.6	20	2.6	2.9	3.2	4	0.6	18.8	47.8	20	0.5
Total	-	-	12.5	44	1.2	9.6	-	-	-	-	3.0	44	0.4	13.3	-	-	-

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

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

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

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Cumulative

Cumulative : from 2014 02 01 to 2016 02 29 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	75	1.6	14.8	38.9	20	0.7	2.7	2.6	75	1.1	42.3	88.3	20	0.4
Lab019	2	12.9	12.1	104	1.2	9.9	26.0	20	1.4	3.0	2.8	104	0.4	14.3	35.2	20	0.9
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	22	1.1	9.2	34.7	20	0.4	3.3	3.1	22	0.4	12.9	31.9	20	1.1
Lab024	2	11.6	11.1	49	1.2	10.8	25.9	20	1.5	2.7	2.7	49	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	121	1.6	13.6	31.2	20	1.2	2.9	2.7	121	0.5	18.5	43.9	20	0.7
Lab028	2	14.2	13.9	201	1.2	8.6	19.4	20	2.1	3.3	3.4	201	0.6	17.6	38.3	20	1.0
Lab031	2	12.8	10.1	63	1.4	13.9	48.8	20	-0.1	2.9	2.4	63	0.4	16.7	50.6	20	0.2
Lab032	2	13.8	11.3	175	2.0	17.7	53.5	20	0.1	3.5	2.6	175	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	12.6	47	0.5	4.0	9.5	20	4.6	2.9	3.0	47	0.1	3.3	10.1	20	5.0
Lab035	2	12.8	12.6	37	0.7	5.6	12.7	20	3.3	2.9	2.9	37	0.3	10.3	20.7	20	1.9
Lab037	2	12.8	12.5	9	1.0	8.0	18.3	20	2.2	2.9	3.1	9	0.3	9.7	26.3	20	1.4
Lab038	2	12.8	12.7	37	1.2	9.4	19.7	20	2.0	2.9	3.2	37	0.5	15.6	41.6	20	0.6
Total	-	-	12.1	1341	1.8	14.9	-	-	-	-	2.9	1341	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 :

Select Reagent Kit :

Control N Month vs. Cumulative

		Control N (Lot No.: AC1203N)															
		Month (2016/02)								CUM (2014/02/01~2016/02/29)							
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	11.1	3	0.3	2.7	12.1	20	4.9	11.9	10.8	75	1.6	14.8	38.9	20	0.7
Lab019	2	12.9	12.3	4	0.7	5.7	16.0	20	2.7	12.9	12.1	104	1.2	9.9	26.0	20	1.4
Lab021	2	14.2	-	0	-	-	-	20	-	14.2	14.2	54	0.2	1.4	2.8	20	>6
Lab022	2	14.2	11.3	4	1.3	11.5	43.4	20	0.0	14.2	11.9	22	1.1	9.2	34.7	20	0.4
Lab024	2	11.6	-	0	-	-	-	20	-	11.6	11.1	49	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	11.9	8	0.8	6.7	16.7	20	2.5	12.3	11.8	121	1.6	13.6	31.2	20	1.2
Lab028	2	14.2	13.4	10	0.9	6.7	19.1	20	2.1	14.2	13.9	201	1.2	8.6	19.4	20	2.1
Lab031	2	12.8	-	0	-	-	-	20	-	12.8	10.1	63	1.4	13.9	48.8	20	-0.1
Lab032	2	13.8	13.3	8	1.5	11.3	26.2	20	1.4	13.8	11.3	175	2.0	17.7	53.5	20	0.1
Lab033	2	12.9	12.0	2	-	-	-	20	-	12.9	12.2	100	1.0	8.2	21.8	20	1.8
Lab034	2	12.8	12.8	1	-	-	-	20	-	12.8	12.6	47	0.5	4.0	9.5	20	4.6
Lab035	2	12.8	-	0	-	-	-	20	-	12.8	12.6	37	0.7	5.6	12.7	20	3.3
Lab037	2	12.8	-	0	-	-	-	20	-	12.8	12.5	9	1.0	8.0	18.3	20	2.2
Lab038	2	12.8	12.8	4	1.0	7.8	15.6	20	2.6	12.8	12.7	37	1.2	9.4	19.7	20	2.0
Total	-	-	12.5	44	1.2	9.6	-	-	-	-	12.1	1341	1.8	14.9	-	-	-

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 (2016/02)								CUM (2014/02/01~2016/02/29)							
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	2.5	3	0.1	4.0	15.4	20	3.1	2.7	2.6	75	1.1	42.3	88.3	20	0.4
Lab019	2	3.0	3.0	4	0.3	10.0	20.0	20	2.0	3.0	2.8	104	0.4	14.3	35.2	20	0.9
Lab021	2	3.3	-	0	-	-	-	20	-	3.3	3.4	54	0.1	2.9	8.9	20	5.9
Lab022	2	3.3	2.9	4	0.4	13.8	39.7	20	0.6	3.3	3.1	22	0.4	12.9	31.9	20	1.1
Lab024	2	2.7	-	0	-	-	-	20	-	2.7	2.7	49	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	2.7	8	0.1	3.7	14.3	20	3.5	2.9	2.7	121	0.5	18.5	43.9	20	0.7
Lab028	2	3.3	3.2	10	0.4	12.5	28.0	20	1.4	3.3	3.4	201	0.6	17.6	38.3	20	1.0
Lab031	2	2.9	-	0	-	-	-	20	-	2.9	2.4	63	0.4	16.7	50.6	20	0.2
Lab032	2	3.5	3.2	8	0.3	9.4	27.3	20	1.2	3.5	2.6	175	0.5	19.2	64.2	20	-0.3
Lab033	2	3.0	2.9	2	-	-	-	20	-	3.0	2.9	100	0.3	10.3	24.0	20	1.6
Lab034	2	2.9	2.9	1	-	-	-	20	-	2.9	3.0	47	0.1	3.3	10.1	20	5.0
Lab035	2	2.9	-	0	-	-	-	20	-	2.9	2.9	37	0.3	10.3	20.7	20	1.9
Lab037	2	2.9	-	0	-	-	-	20	-	2.9	3.1	9	0.3	9.7	26.3	20	1.4
Lab038	2	2.9	3.2	4	0.6	18.8	47.8	20	0.5	2.9	3.2	37	0.5	15.6	41.6	20	0.6
Total	-	-	3.0	44	0.4	13.3	-	-	-	-	2.9	1341	0.6	20.7	-	-	-

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