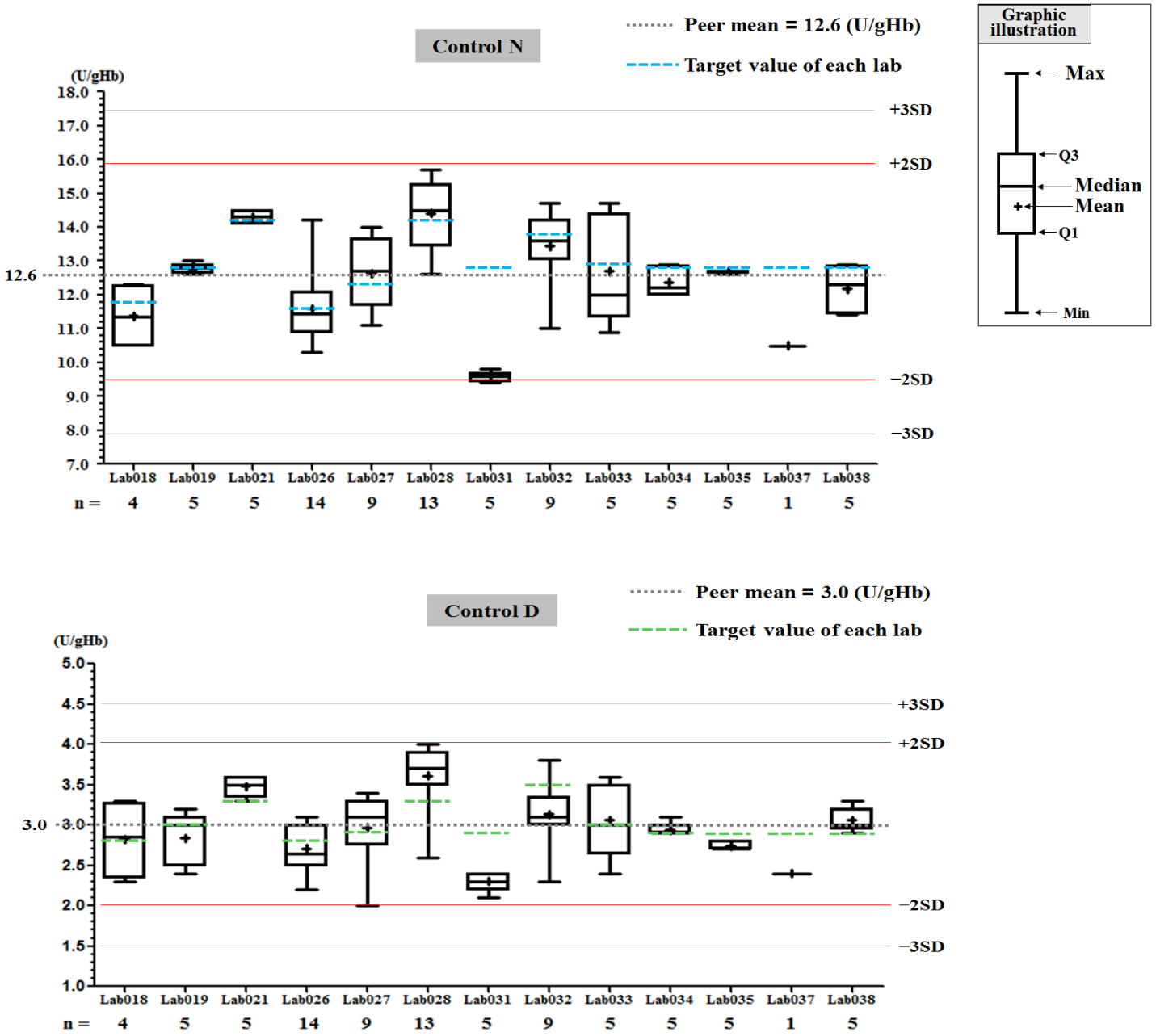
Summary Report of IQC program for G6PD Quantitative Test - AMP Group - July 2015 -

I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AC1203N)	Control D (Lot No.:AC1203D)
Labs	13	14
Received results number (n)	85	85
Median	12.7 (U/gHb)	3.0 (U/gHb)
Mean	12.6 (U/gHb)	3.0 (U/gHb)
SD	1.5	0.5
CV	11.9%	16.7%
Range of G6PD	9.4 ~ 15.7 (U/gHb)	2.0 ~ 4.0 (U/gHb)
Range of Hb	2.0 ~ 2.8 (g/dL)	2.1 ~ 3.3 (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

Lab035

	Control N		Control D	
QC Control Lot No.	AC1203N		AC1203D	
Duration of the Analyzing	Month (2015/07)	CUM (2014/02/01~2015/07/31)	Month (2015/07)	CUM (2014/02/01~2015/07/31)
Runs (N)	5	20	5	20
Mean (U/gHb)	12.7	12.9	2.7	3.0
SD	0.0	0.9	0.1	0.4
CV (%)	0.0	7.0	3.7	13.3
Target Value (U/gHb)	12.8	12.8	2.9	2.9
Total Error (%)	0.8	14.7	14.3	30.1
TEa (%)	20	20	20	20
σ	>6	2.7	3.5	1.2

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

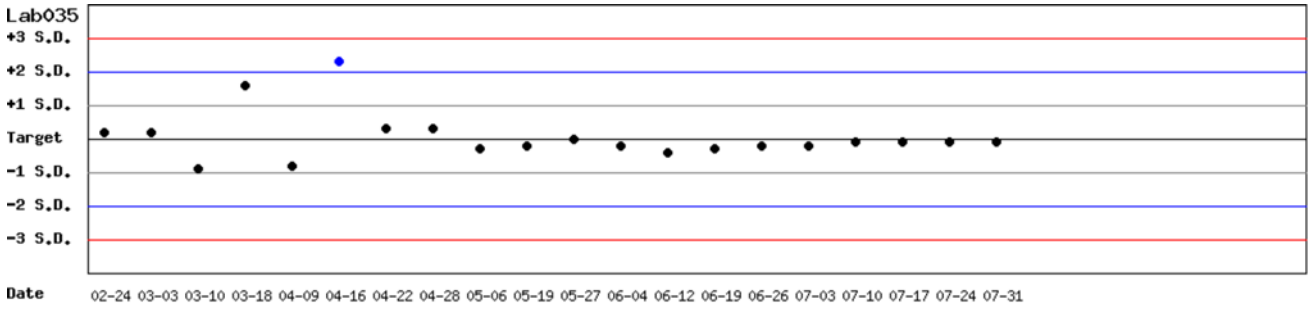
Month : 2015 07 Change ; Cumulative : from 2014 02 01 to 2015 07 31 Change

[TOP]

Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2014-02-01 to 2015-07-31 ; Target : 12.8 ; SD : 1.28

Lab035



Month : 2015 07 Change ; Cumulative : from 2014 02 01 to 2015 07 31 Change

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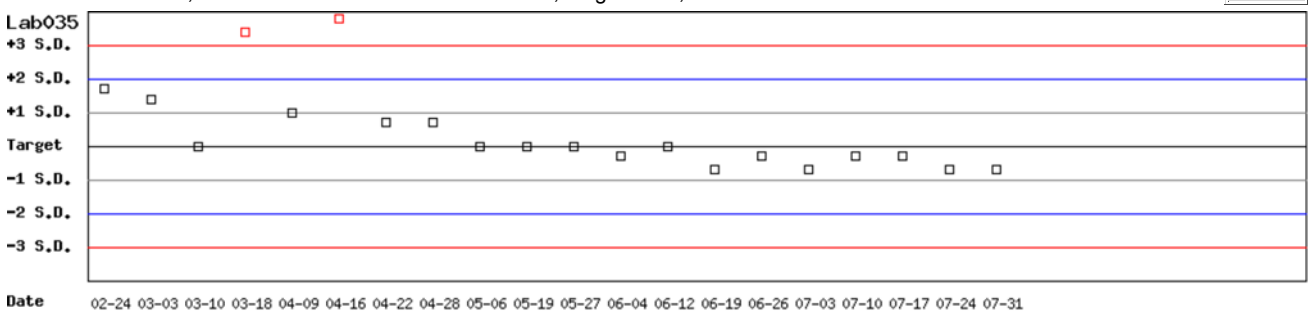
Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2014-02-01 to 2015-07-31 ; Target : 2.9 ; SD : 0.29

Lab035



Month : 2015 07 Change ; Cumulative : from 2014 02 01 to 2015 07 31 Change

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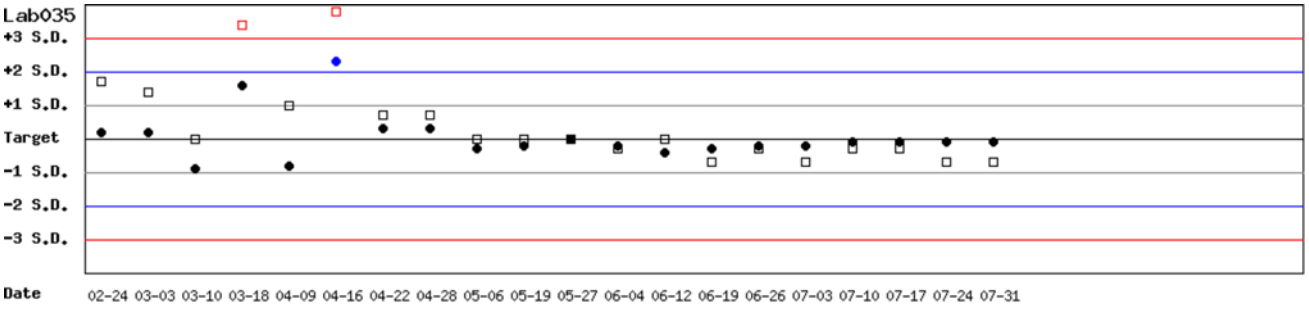
Control N and **Control D SDI**
QC Chart

Lot No.: AC1203N ; Duration : 2014-02-01 to 2015-07-31 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: AC1203D ; Duration : 2014-02-01 to 2015-07-31 ; Target : 2.9 ; SD : 0.29 (□)

Lab035



Month : 2015 07 Change ; Cumulative : from 2014 02 01 to 2015 07 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 : 2015 07 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	11.8	11.4	4	1.0	8.8	20.9	20	1.9	2.8	2.8	4	0.5	17.9	35.7	20	1.1
Lab019	2	12.9	12.8	5	0.2	1.6	3.9	20	>6	3.0	2.8	5	0.3	10.7	28.1	20	1.2
Lab021	2	14.2	14.3	5	0.2	1.4	3.5	20	>6	3.3	3.5	5	0.1	2.9	11.8	20	4.8
Lab026	2	11.6	11.6	14	1.0	8.6	17.2	36	4.2	2.7	2.7	14	0.3	11.1	22.2	36	3.2
Lab027	2	12.3	12.6	9	1.0	7.9	18.3	20	2.2	2.9	3.0	9	0.4	13.3	30.1	20	1.2
Lab028	2	14.2	14.4	13	1.0	6.9	15.3	20	2.7	3.3	3.6	13	0.4	11.1	31.3	20	1.0
Lab031	2	12.8	9.6	5	0.2	2.1	29.2	20	-2.4	2.9	2.3	5	0.1	4.3	29.4	20	-0.2
Lab032	2	13.8	13.4	9	1.1	8.2	19.3	20	2.1	3.5	3.1	9	0.4	12.9	37.2	20	0.7
Lab033	2	12.9	12.7	5	1.6	12.6	26.7	20	1.5	3.0	3.1	5	0.5	16.1	35.6	20	1.0
Lab034	2	12.8	12.4	5	0.4	3.2	9.6	20	5.3	2.9	2.9	5	0.1	3.4	6.9	20	5.9
Lab035	2	12.8	12.7	5	0.0	0.0	0.8	20	>6	2.9	2.7	5	0.1	3.7	14.3	20	3.5
Lab037	2	12.8	10.5	1	-	-	-	20	-	2.9	2.4	1	-	-	-	20	-
Lab038	2	12.8	12.2	5	0.7	5.7	16.2	20	2.7	2.9	3.1	5	0.2	6.5	19.8	20	2.0
Total	-	-	12.6	85	1.5	11.9	-	-	-	-	3.0	85	0.5	16.7	-	-	-

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 2015 07 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	11.8	10.6	53	1.7	16.0	42.2	20	0.6	2.8	2.5	53	1.2	48.0	106.7	20	0.2
Lab019	2	12.9	12.0	73	1.3	10.8	28.6	20	1.2	3.0	2.7	73	0.4	14.8	39.6	20	0.7
Lab021	2	14.2	14.3	19	0.2	1.4	3.5	20	>6	3.3	3.5	19	0.1	2.9	11.8	20	4.8
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	11.4	188	1.7	14.9	31.5	36	2.3	2.7	2.8	188	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	13.6	113	1.4	10.3	24.8	20	1.5	3.3	3.4	113	0.7	20.6	44.2	20	0.8
Lab031	2	12.8	9.9	50	1.3	13.1	48.9	20	-0.2	2.9	2.3	50	0.4	17.4	55.5	20	0.0
Lab032	2	13.8	10.8	142	1.8	16.7	55.1	20	-0.1	3.5	2.5	142	0.5	20.0	68.6	20	-0.4
Lab033	2	12.9	12.1	71	1.1	9.1	24.4	20	1.5	3.0	2.9	71	0.3	10.3	24.0	20	1.6
Lab034	2	12.8	12.6	23	0.4	3.2	7.9	20	5.8	2.9	3.0	23	0.1	3.3	10.1	20	5.0
Lab035	2	12.8	12.9	20	0.9	7.0	14.7	20	2.7	2.9	3.0	20	0.4	13.3	30.1	20	1.2
Lab037	2	12.8	12.3	4	1.4	11.4	26.7	20	1.4	2.9	3.0	4	0.4	13.3	30.1	20	1.2
Lab038	2	12.8	13.0	9	1.3	10.0	21.6	20	1.8	2.9	3.5	9	0.6	17.1	55.0	20	0.0
Total	-	-	11.8	953	1.9	16.1	-	-	-	-	2.8	953	0.7	25.0	-	-	-

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 (2015/07)								CUM (2014/02/01~2015/07/31)							
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	11.8	11.4	4	1.0	8.8	20.9	20	1.9	11.8	10.6	53	1.7	16.0	42.2	20	0.6
Lab019	2	12.9	12.8	5	0.2	1.6	3.9	20	>6	12.9	12.0	73	1.3	10.8	28.6	20	1.2
Lab021	2	14.2	14.3	5	0.2	1.4	3.5	20	>6	14.2	14.3	19	0.2	1.4	3.5	20	>6
Lab024	2	11.6	-	0	-	-	-	20	-	11.6	11.1	39	1.3	11.7	27.7	20	1.3
Lab026	2	11.6	11.6	14	1.0	8.6	17.2	36	4.2	11.6	11.4	188	1.7	14.9	31.5	36	2.3
Lab027	2	12.3	12.6	9	1.0	7.9	18.3	20	2.2	12.3	11.8	113	1.7	14.4	32.9	20	1.1
Lab028	2	14.2	14.4	13	1.0	6.9	15.3	20	2.7	14.2	13.6	113	1.4	10.3	24.8	20	1.5
Lab031	2	12.8	9.6	5	0.2	2.1	29.2	20	-2.4	12.8	9.9	50	1.3	13.1	48.9	20	-0.2
Lab032	2	13.8	13.4	9	1.1	8.2	19.3	20	2.1	13.8	10.8	142	1.8	16.7	55.1	20	-0.1
Lab033	2	12.9	12.7	5	1.6	12.6	26.7	20	1.5	12.9	12.1	71	1.1	9.1	24.4	20	1.5
Lab034	2	12.8	12.4	5	0.4	3.2	9.6	20	5.3	12.8	12.6	23	0.4	3.2	7.9	20	5.8
Lab035	2	12.8	12.7	5	0.0	0.0	0.8	20	>6	12.8	12.9	20	0.9	7.0	14.7	20	2.7
Lab037	2	12.8	10.5	1	-	-	-	20	-	12.8	12.3	4	1.4	11.4	26.7	20	1.4
Lab038	2	12.8	12.2	5	0.7	5.7	16.2	20	2.7	12.8	13.0	9	1.3	10.0	21.6	20	1.8
Total	-	-	12.6	85	1.5	11.9	-	-	-	-	11.8	953	1.9	16.1	-	-	-

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

Month : 2015 07 Change Cumulative : from 2014 02 01 to 2015 07 31 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: AC1203D)															
		Month (2015/07)								CUM (2014/02/01~2015/07/31)							
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	2.8	2.8	4	0.5	17.9	35.7	20	1.1	2.8	2.5	53	1.2	48.0	106.7	20	0.2
Lab019	2	3.0	2.8	5	0.3	10.7	28.1	20	1.2	3.0	2.7	73	0.4	14.8	39.6	20	0.7
Lab021	2	3.3	3.5	5	0.1	2.9	11.8	20	4.8	3.3	3.5	19	0.1	2.9	11.8	20	4.8
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	14	0.3	11.1	22.2	36	3.2	2.7	2.8	188	0.5	17.9	39.4	36	1.8
Lab027	2	2.9	3.0	9	0.4	13.3	30.1	20	1.2	2.9	2.7	113	0.5	18.5	43.9	20	0.7
Lab028	2	3.3	3.6	13	0.4	11.1	31.3	20	1.0	3.3	3.4	113	0.7	20.6	44.2	20	0.8
Lab031	2	2.9	2.3	5	0.1	4.3	29.4	20	-0.2	2.9	2.3	50	0.4	17.4	55.5	20	0.0
Lab032	2	3.5	3.1	9	0.4	12.9	37.2	20	0.7	3.5	2.5	142	0.5	20.0	68.6	20	-0.4
Lab033	2	3.0	3.1	5	0.5	16.1	35.6	20	1.0	3.0	2.9	71	0.3	10.3	24.0	20	1.6
Lab034	2	2.9	2.9	5	0.1	3.4	6.9	20	5.9	2.9	3.0	23	0.1	3.3	10.1	20	5.0
Lab035	2	2.9	2.7	5	0.1	3.7	14.3	20	3.5	2.9	3.0	20	0.4	13.3	30.1	20	1.2
Lab037	2	2.9	2.4	1	-	-	-	20	-	2.9	3.0	4	0.4	13.3	30.1	20	1.2
Lab038	2	2.9	3.1	5	0.2	6.5	19.8	20	2.0	2.9	3.5	9	0.6	17.1	55.0	20	0.0
Total	-	-	3.0	85	0.5	16.7	-	-	-	-	2.8	953	0.7	25.0	-	-	-

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

Month : 2015 07 Change Cumulative : from 2014 02 01 to 2015 07 31 Change

[TOP]

Reagent Kit	Reagent Code
AMP	2