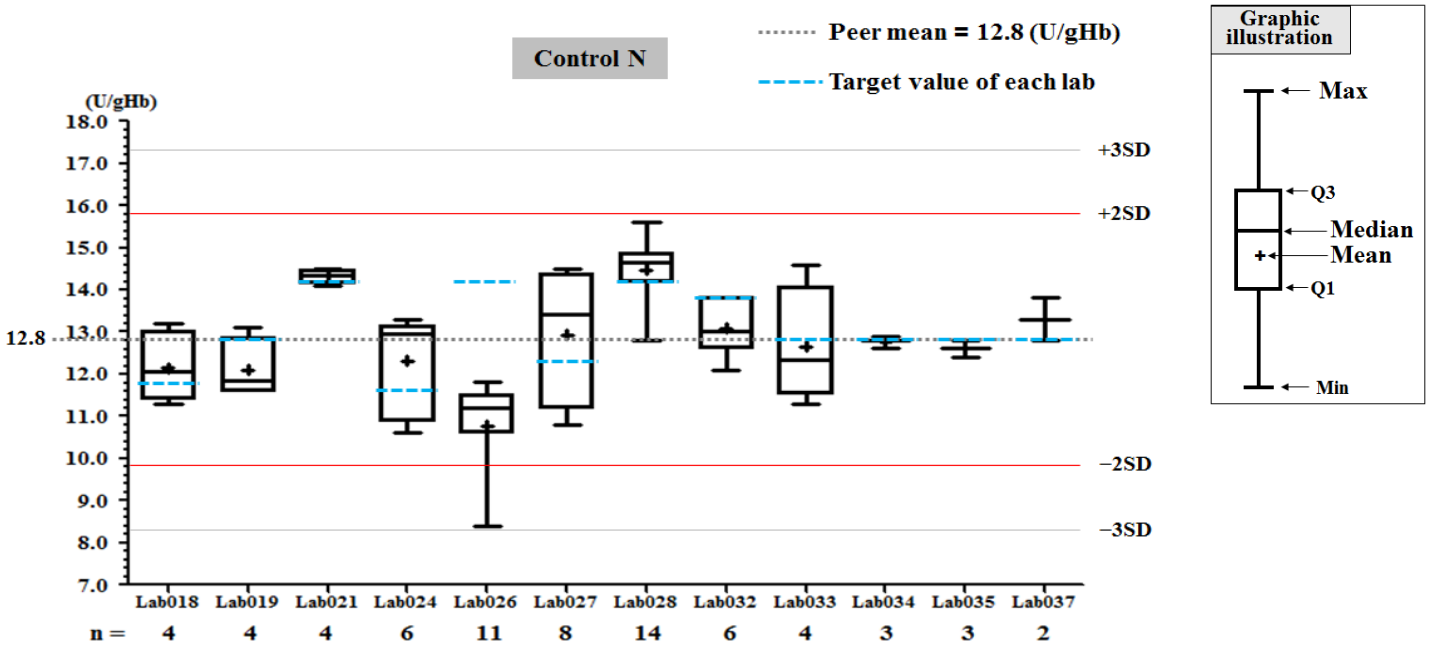
Summary Report of IQC program for G6PD Quantitative Test - AMP Group - May 2015 -

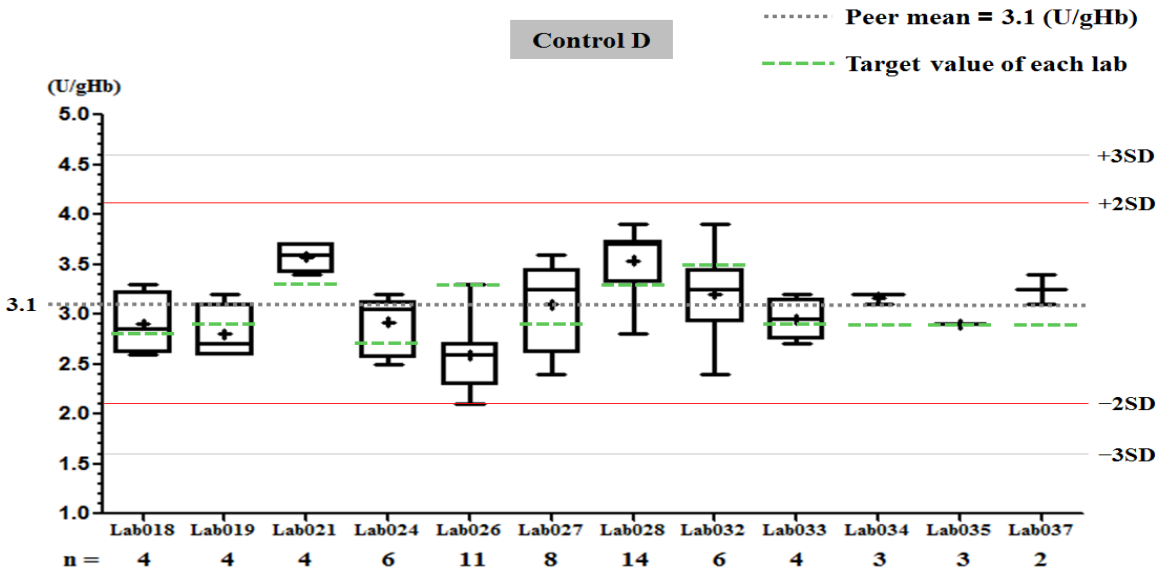
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AC1203N)	Control D (Lot No.:AC1203D)
Labs	12	12
Received results number (n)	69	69
Median	12.8 (U/gHb)	3.1 (U/gHb)
Mean	12.8 (U/gHb)	3.1 (U/gHb)
SD	1.5	0.5
CV	11.7%	16.1%
Range of G6PD	8.4 ~ 15.6 (U/gHb)	2.1 ~ 3.9 (U/gHb)
Range of Hb	1.9 ~ 2.9 (g/dL)	2.2 ~ 3.4 (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

Lab034

	Control N		Control D	
QC Control Lot No.	AC1203N		AC1203D	
Duration of the Analyzing	Month (2015/05)	CUM (2014/02/01~2015/05/31)	Month (2015/05)	CUM (2014/02/01~2015/05/31)
Runs (N)	3	14	3	14
Mean (U/gHb)	12.8	12.7	3.2	3.0
SD	0.2	0.4	0.1	0.1
CV (%)	1.6	3.1	3.1	3.3
Target Value (U/gHb)	12.8	12.8	2.9	2.9
Total Error (%)	3.1	7.1	16.6	10.1
TEa (%)	20	20	20	20
σ	>6	>6	3.1	5.0

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

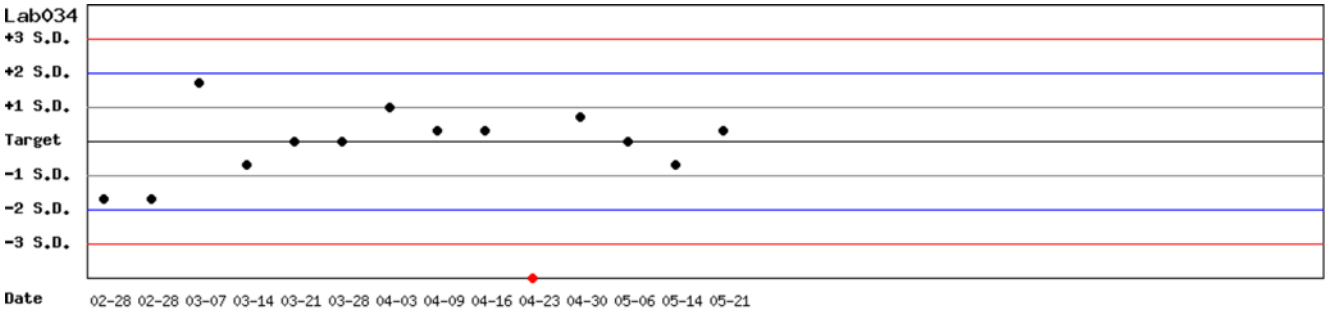
Month： 2015 05 Change ； Cumulative : from 2014 02 01 to 2015 05 31 Change

[TOP]

Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2014-02-01 to 2015-05-31 ; Target : 12.8 ; SD : 0.30

Lab034



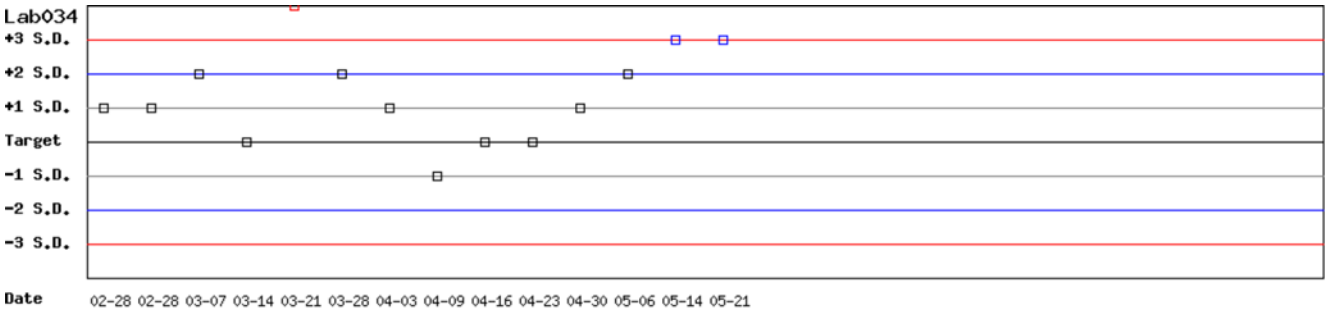
Month： 2015 05 Change ； Cumulative : from 2014 02 01 to 2015 05 31 Change

[TOP]

Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2014-02-01 to 2015-05-31 ; Target : 2.9 ; SD : 0.10

Lab034



Month： 2015 05 Change ； Cumulative : from 2014 02 01 to 2015 05 31 Change

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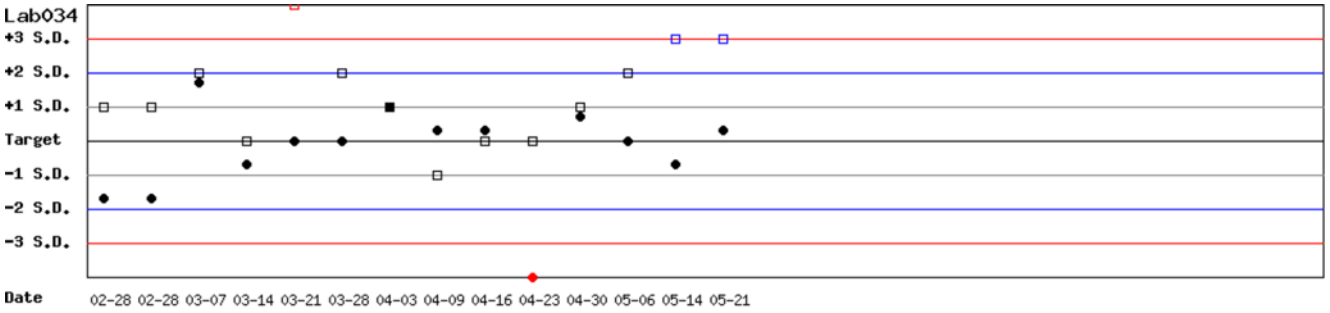
Control N and **Control D SDI**
QC Chart

Lot No.: AC1203N ; Duration : 2014-02-01 to 2015-05-31 ; Target : 12.8 ; SD : 0.30 (●)

Lot No.: AC1203D ; Duration : 2014-02-01 to 2015-05-31 ; Target : 2.9 ; SD : 0.10 (□)

Lab034



Month : 2015 05 Change ; Cumulative : from 2014 02 01 to 2015 05 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 05 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	12.2	4	0.8	6.6	16.5	20	2.5	2.8	2.9	4	0.3	10.3	24.3	20	1.6
Lab019	2	12.8	12.1	4	0.7	5.8	17.0	20	2.5	2.9	2.8	4	0.3	10.7	24.9	20	1.5
Lab021	2	14.2	14.3	4	0.2	1.4	3.5	20	>6	3.3	3.6	4	0.2	5.6	20.2	20	1.9
Lab024	2	11.6	12.3	6	1.2	9.8	25.5	20	1.4	2.7	2.9	6	0.3	10.3	28.1	20	1.2
Lab026	2	14.2	10.8	11	1.1	10.2	44.3	20	-0.4	3.3	2.6	11	0.3	11.5	44.3	20	-0.1
Lab027	2	12.3	12.9	8	1.5	11.6	28.1	20	1.3	2.9	3.1	8	0.4	12.9	32.7	20	1.0
Lab028	2	14.2	14.5	14	0.8	5.5	13.1	20	3.3	3.3	3.5	14	0.4	11.4	28.9	20	1.2
Lab032	2	13.8	13.1	6	0.7	5.3	15.8	20	2.8	3.5	3.2	6	0.5	15.6	39.8	20	0.7
Lab033	2	12.8	12.7	4	1.4	11.0	22.8	20	1.7	2.9	3.0	4	0.2	6.7	16.8	20	2.5
Lab034	2	12.8	12.8	3	0.2	1.6	3.1	20	>6	2.9	3.2	3	0.1	3.1	16.6	20	3.1
Lab035	2	12.8	12.6	3	0.2	1.6	4.7	20	>6	2.9	2.9	3	0.0	0.0	0.0	20	>6
Lab037	2	12.8	13.3	2	-	-	-	20	-	2.9	3.3	2	-	-	-	20	-
Total	-	-	12.8	69	1.5	11.7	-	-	-	-	3.1	69	0.5	16.1	-	-	-

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 05 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	10.4	45	1.7	16.3	44.6	20	0.5	2.8	2.4	45	1.3	54.2	122.6	20	0.1
Lab019	2	12.8	11.8	64	1.2	10.2	28.2	20	1.2	2.9	2.7	64	0.4	14.8	36.5	20	0.9
Lab021	2	14.2	14.2	9	0.2	1.4	2.8	20	>6	3.3	3.5	9	0.2	5.7	17.5	20	2.4
Lab024	2	11.6	11.2	31	1.5	13.4	30.2	20	1.2	2.7	2.7	31	0.4	14.8	29.6	20	1.4
Lab026	2	14.2	11.5	162	1.8	15.7	50.3	20	0.1	3.3	2.8	162	0.5	17.9	50.9	20	0.3
Lab027	2	12.3	11.6	95	1.7	14.7	35.0	20	1.0	2.9	2.7	95	0.5	18.5	43.9	20	0.7
Lab028	2	14.2	13.4	87	1.5	11.2	28.0	20	1.3	3.3	3.3	87	0.8	24.2	48.5	20	0.8
Lab031	2	12.8	9.9	41	1.5	15.2	53.0	20	-0.2	2.9	2.3	41	0.4	17.4	55.5	20	0.0
Lab032	2	13.8	10.4	124	1.6	15.4	55.4	20	-0.3	3.5	2.4	124	0.4	16.7	64.8	20	-0.7
Lab033	2	12.8	12.0	62	1.0	8.3	22.9	20	1.7	2.9	2.9	62	0.3	10.3	20.7	20	1.9
Lab034	2	12.8	12.7	14	0.4	3.1	7.1	20	>6	2.9	3.0	14	0.1	3.3	10.1	20	5.0
Lab035	2	12.8	13.1	11	1.2	9.2	20.7	20	1.9	2.9	3.2	11	0.4	12.5	35.3	20	0.8
Lab037	2	12.8	13.3	2	-	-	-	20	-	2.9	3.3	2	-	-	-	20	-
Total	-	-	11.6	783	1.9	16.4	-	-	-	-	2.8	783	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 (2015/05)								CUM (2014/02/01~2015/05/31)							
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	12.2	4	0.8	6.6	16.5	20	2.5	11.8	10.4	45	1.7	16.3	44.6	20	0.5
Lab019	2	12.8	12.1	4	0.7	5.8	17.0	20	2.5	12.8	11.8	64	1.2	10.2	28.2	20	1.2
Lab021	2	14.2	14.3	4	0.2	1.4	3.5	20	>6	14.2	14.2	9	0.2	1.4	2.8	20	>6
Lab024	2	11.6	12.3	6	1.2	9.8	25.5	20	1.4	11.6	11.2	31	1.5	13.4	30.2	20	1.2
Lab026	2	14.2	10.8	11	1.1	10.2	44.3	20	-0.4	14.2	11.5	162	1.8	15.7	50.3	20	0.1
Lab027	2	12.3	12.9	8	1.5	11.6	28.1	20	1.3	12.3	11.6	95	1.7	14.7	35.0	20	1.0
Lab028	2	14.2	14.5	14	0.8	5.5	13.1	20	3.3	14.2	13.4	87	1.5	11.2	28.0	20	1.3
Lab031	2	12.8	-	0	-	-	-	20	-	12.8	9.9	41	1.5	15.2	53.0	20	-0.2
Lab032	2	13.8	13.1	6	0.7	5.3	15.8	20	2.8	13.8	10.4	124	1.6	15.4	55.4	20	-0.3
Lab033	2	12.8	12.7	4	1.4	11.0	22.8	20	1.7	12.8	12.0	62	1.0	8.3	22.9	20	1.7
Lab034	2	12.8	12.8	3	0.2	1.6	3.1	20	>6	12.8	12.7	14	0.4	3.1	7.1	20	>6
Lab035	2	12.8	12.6	3	0.2	1.6	4.7	20	>6	12.8	13.1	11	1.2	9.2	20.7	20	1.9
Lab037	2	12.8	13.3	2	-	-	-	20	-	12.8	13.3	2	-	-	-	20	-
Total	-	-	12.8	69	1.5	11.7	-	-	-	-	11.6	783	1.9	16.4	-	-	-

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

Month : 2015 05 Change Cumulative : from 2014 02 01 to 2015 05 31 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: AC1203D)															
		Month (2015/05)								CUM (2014/02/01~2015/05/31)							
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	2.9	4	0.3	10.3	24.3	20	1.6	2.8	2.4	45	1.3	54.2	122.6	20	0.1
Lab019	2	2.9	2.8	4	0.3	10.7	24.9	20	1.5	2.9	2.7	64	0.4	14.8	36.5	20	0.9
Lab021	2	3.3	3.6	4	0.2	5.6	20.2	20	1.9	3.3	3.5	9	0.2	5.7	17.5	20	2.4
Lab024	2	2.7	2.9	6	0.3	10.3	28.1	20	1.2	2.7	2.7	31	0.4	14.8	29.6	20	1.4
Lab026	2	3.3	2.6	11	0.3	11.5	44.3	20	-0.1	3.3	2.8	162	0.5	17.9	50.9	20	0.3
Lab027	2	2.9	3.1	8	0.4	12.9	32.7	20	1.0	2.9	2.7	95	0.5	18.5	43.9	20	0.7
Lab028	2	3.3	3.5	14	0.4	11.4	28.9	20	1.2	3.3	3.3	87	0.8	24.2	48.5	20	0.8
Lab031	2	2.9	-	0	-	-	-	20	-	2.9	2.3	41	0.4	17.4	55.5	20	0.0
Lab032	2	3.5	3.2	6	0.5	15.6	39.8	20	0.7	3.5	2.4	124	0.4	16.7	64.8	20	-0.7
Lab033	2	2.9	3.0	4	0.2	6.7	16.8	20	2.5	2.9	2.9	62	0.3	10.3	20.7	20	1.9
Lab034	2	2.9	3.2	3	0.1	3.1	16.6	20	3.1	2.9	3.0	14	0.1	3.3	10.1	20	5.0
Lab035	2	2.9	2.9	3	0.0	0.0	0.0	20	>6	2.9	3.2	11	0.4	12.5	35.3	20	0.8
Lab037	2	2.9	3.3	2	-	-	-	20	-	2.9	3.3	2	-	-	-	20	-
Total	-	-	3.1	69	0.5	16.1	-	-	-	-	2.8	783	0.7	25.0	-	-	-

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

Month : 2015 05 Change Cumulative : from 2014 02 01 to 2015 05 31 Change

[TOP]

Reagent Kit	Reagent Code
AMP	2