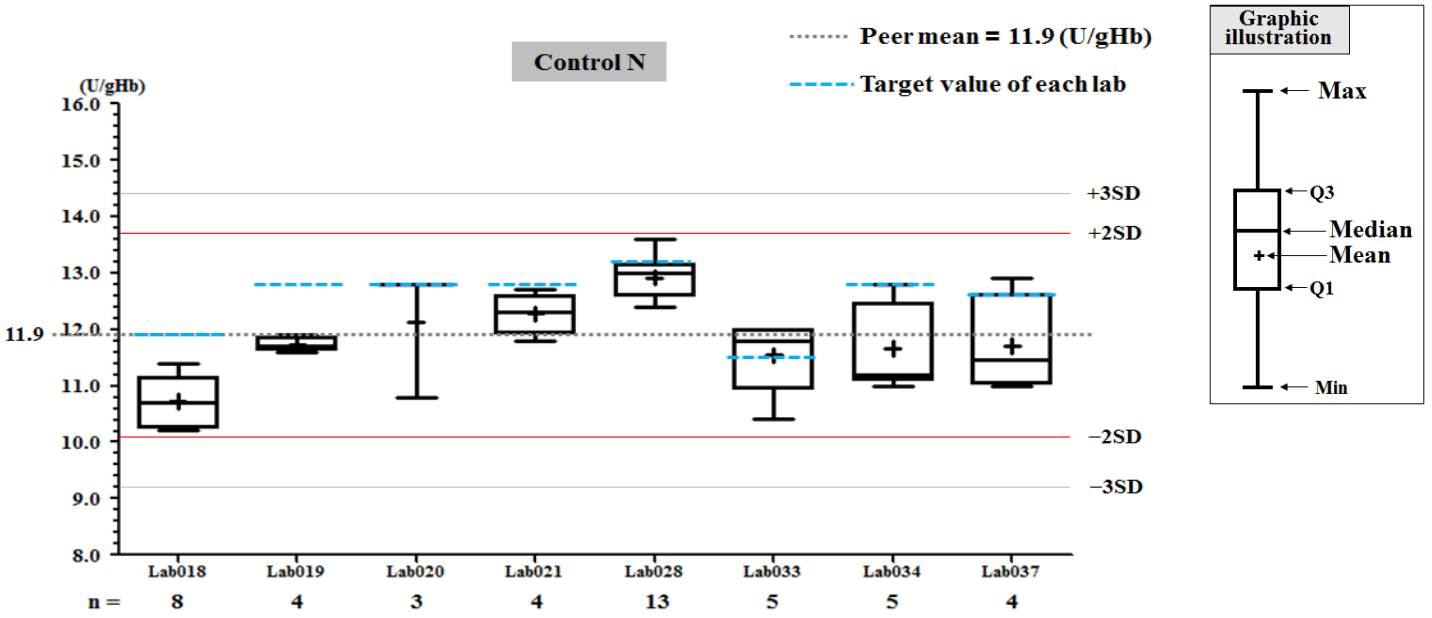
Summary Report of IQC program for G6PD Quantitative Test - AMP Group - October 2016 -

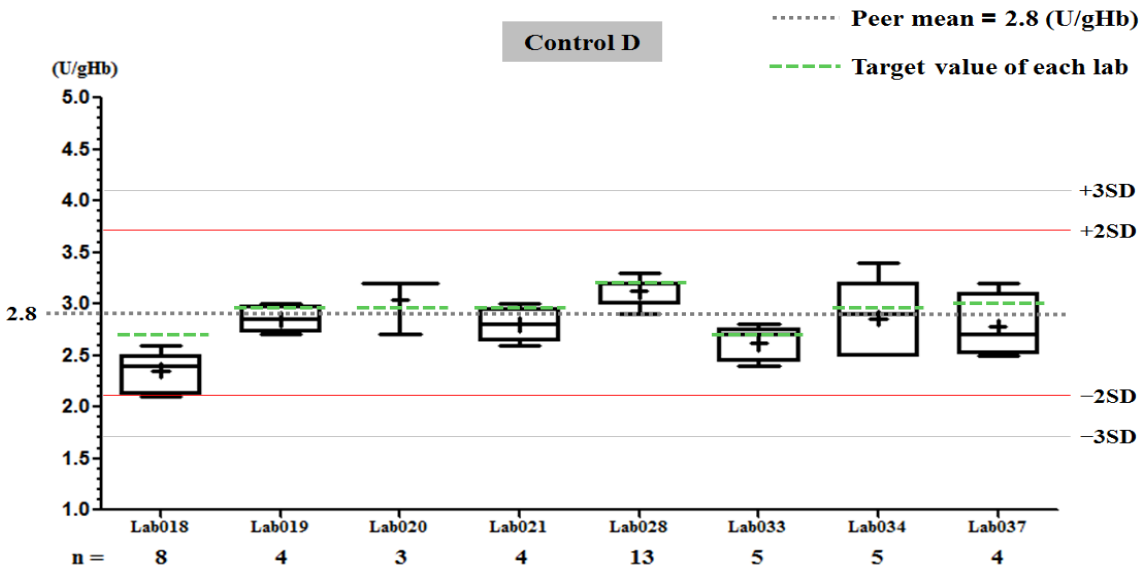
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AC1203N)	Control D (Lot No.:AC1203D)
Labs	8	8
Received results number (n)	46	46
Median	12.0 (U/gHb)	2.8 (U/gHb)
Mean	11.9 (U/gHb)	2.8 (U/gHb)
SD	0.9	0.3
CV	7.5%	10.7%
Range of G6PD	10.2 ~ 13.6 (U/gHb)	2.1 ~ 3.4 (U/gHb)
Range of Hb	2.3 ~ 2.6 (g/dL)	2.5 ~ 3.1 (g/dL)

*The statistic results are calculated from all labs reported in this month
** G6PD Method = AMP reagent kit, 37°C

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) Change

Print Table

Lab033

	Control N		Control D	
QC Control Lot No.	AC1203N		AC1203D	
Duration of the Analyzing	Month (2016/10)	CUM (2016/05/12~2016/10/31)	Month (2016/10)	CUM (2016/05/12~2016/10/31)
Runs (N)	5	26	5	26
Mean (U/gHb)	11.5	11.4	2.6	2.7
SD	0.7	0.8	0.2	0.3
CV (%)	6.1	7.0	7.7	11.1
Target Value (U/gHb)	11.5	11.5	2.7	2.7
Total Error (%)	12.2	14.9	19.1	22.2
TEa (%)	20	20	20	20
σ	3.3	2.7	2.1	1.8

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

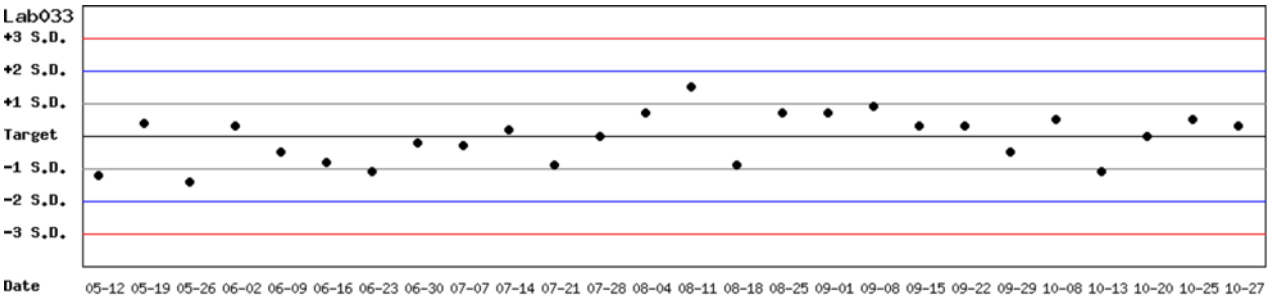
Month : 2016 10 Change ; Cumulative : from 2016 05 12 to 2016 10 31 Change

[TOP]

Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2016-05-12 to 2016-10-31 ; Target : 11.5 ; SD : 1.00

Lab033



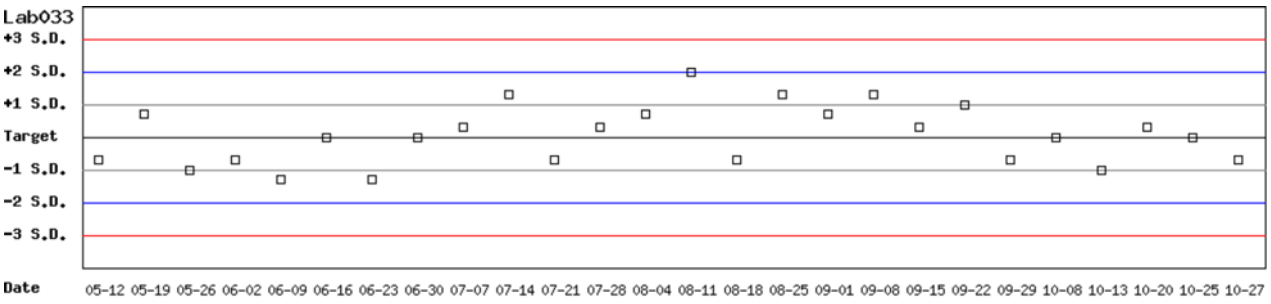
Month : 2016 10 Change ; Cumulative : from 2016 05 12 to 2016 10 31 Change

[TOP]

Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2016-05-12 to 2016-10-31 ; Target : 2.7 ; SD : 0.30

Lab033



Month : 2016 10 Change ; Cumulative : from 2016 05 12 to 2016 10 31 Change

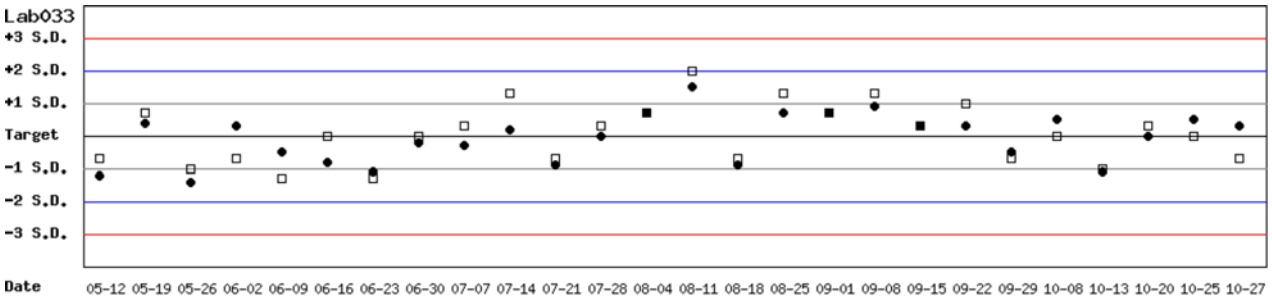
[TOP]

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

Lot No.: AC1203N ; Duration : 2016-05-12 to 2016-10-31 ; Target : 11.5 ; SD : 1.00 (●)

Lot No.: AC1203D ; Duration : 2016-05-12 to 2016-10-31 ; Target : 2.7 ; SD : 0.30 (□)

Lab033



Month : 2016 | 10 Change ; Cumulative : from 2016 | 05 12 to 2016 | 10 31 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 : 2016 10 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	10.7	8	0.5	4.7	19.4	20	2.1	2.7	2.4	8	0.2	8.3	27.8	20	1.1
Lab019	2	12.8	11.7	4	0.1	0.9	10.3	20	>6	2.9	2.9	4	0.1	3.4	6.9	20	5.9
Lab020	2	12.8	12.1	3	1.2	9.9	25.3	20	1.5	2.9	3.0	3	0.3	10.0	23.4	20	1.7
Lab021	2	12.8	12.3	4	0.4	3.3	10.4	20	4.9	2.9	2.8	4	0.2	7.1	17.7	20	2.3
Lab028	2	13.2	12.9	13	0.3	2.3	6.9	20	>6	3.2	3.1	13	0.1	3.2	9.6	20	5.3
Lab033	2	11.5	11.5	5	0.7	6.1	12.2	20	3.3	2.7	2.6	5	0.2	7.7	19.1	20	2.1
Lab034	2	12.8	11.7	5	0.8	6.8	22.3	20	1.7	2.9	2.9	5	0.4	13.8	27.6	20	1.4
Lab037	2	12.6	11.7	4	0.9	7.7	22.5	20	1.7	3.0	2.8	4	0.3	10.7	28.1	20	1.2
Total	-	-	11.9	46	0.9	7.6	-	-	-	-	2.8	46	0.3	10.7	-	-	-

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 2016 10 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	11.9	10.9	113	1.3	11.9	32.3	20	1.0	2.7	2.6	113	0.9	34.6	72.9	20	0.5
Lab019	2	12.8	12.2	140	1.2	9.8	24.4	20	1.6	2.9	2.8	140	0.4	14.3	32.0	20	1.2
Lab020	2	12.8	12.1	3	1.2	9.9	25.3	20	1.5	2.9	3.0	3	0.3	10.0	23.4	20	1.7
Lab021	2	12.8	13.7	80	0.9	6.6	20.2	20	2.0	2.9	3.3	80	0.3	9.1	32.0	20	0.7
Lab022	2	14.2	11.5	57	1.2	10.4	39.9	20	0.1	3.3	2.9	57	0.3	10.3	32.8	20	0.8
Lab024	2	11.6	11.1	58	1.2	10.8	25.9	20	1.5	2.7	2.7	58	0.3	11.1	22.2	20	1.8
Lab026	2	11.6	11.5	212	1.6	13.9	28.7	36	2.5	2.7	2.8	212	0.5	17.9	39.4	36	1.8
Lab027	2	12.3	11.8	147	1.6	13.6	31.2	20	1.2	2.9	2.7	147	0.5	18.5	43.9	20	0.7
Lab028	2	13.2	13.6	309	1.2	8.8	20.7	20	1.9	3.2	3.3	309	0.5	15.2	33.4	20	1.1
Lab031	2	12.8	10.4	89	1.5	14.4	47.6	20	0.1	2.9	2.5	89	0.5	20.0	53.8	20	0.3
Lab032	2	12.3	11.5	222	1.9	16.5	39.5	20	0.8	2.9	2.7	222	0.5	18.5	43.9	20	0.7
Lab033	2	11.5	12.0	130	1.0	8.3	21.0	20	1.9	2.7	2.9	130	0.3	10.3	28.1	20	1.2
Lab034	2	12.8	12.3	78	0.7	5.7	15.3	20	2.8	2.9	3.0	78	0.2	6.7	16.8	20	2.5
Lab035	2	12.8	12.4	55	0.7	5.6	14.4	20	3.0	2.9	2.8	55	0.3	10.7	24.9	20	1.5
Lab037	2	12.6	12.6	44	1.2	9.5	19.0	20	2.1	3.0	3.0	44	0.4	13.3	26.7	20	1.5
Lab038	2	12.8	12.7	55	1.0	7.9	16.5	20	2.4	2.9	3.1	55	0.5	16.1	39.2	20	0.8
Lab040	2	12.8	11.8	11	0.5	4.2	16.3	20	2.9	2.9	2.4	11	0.3	12.5	42.2	20	0.2
Total	-	-	12.1	1839	1.7	14.0	-	-	-	-	2.9	1839	0.6	20.7	-	-	-

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 (2016/10)								CUM (2014/02/01~2016/10/31)							
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	11.9	10.7	8	0.5	4.7	19.4	20	2.1	11.9	10.9	113	1.3	11.9	32.3	20	1.0
Lab019	2	12.8	11.7	4	0.1	0.9	10.3	20	>6	12.8	12.2	140	1.2	9.8	24.4	20	1.6
Lab020	2	12.8	12.1	3	1.2	9.9	25.3	20	1.5	12.8	12.1	3	1.2	9.9	25.3	20	1.5
Lab021	2	12.8	12.3	4	0.4	3.3	10.4	20	4.9	12.8	13.7	80	0.9	6.6	20.2	20	2.0
Lab022	2	14.2	-	0	-	-	-	20	-	14.2	11.5	57	1.2	10.4	39.9	20	0.1
Lab024	2	11.6	-	0	-	-	-	20	-	11.6	11.1	58	1.2	10.8	25.9	20	1.5
Lab026	2	11.6	-	0	-	-	-	36	-	11.6	11.5	212	1.6	13.9	28.7	36	2.5
Lab027	2	12.3	-	0	-	-	-	20	-	12.3	11.8	147	1.6	13.6	31.2	20	1.2
Lab028	2	13.2	12.9	13	0.3	2.3	6.9	20	>6	13.2	13.6	309	1.2	8.8	20.7	20	1.9
Lab031	2	12.8	-	0	-	-	-	20	-	12.8	10.4	89	1.5	14.4	47.6	20	0.1
Lab032	2	12.3	-	0	-	-	-	20	-	12.3	11.5	222	1.9	16.5	39.5	20	0.8
Lab033	2	11.5	11.5	5	0.7	6.1	12.2	20	3.3	11.5	12.0	130	1.0	8.3	21.0	20	1.9
Lab034	2	12.8	11.7	5	0.8	6.8	22.3	20	1.7	12.8	12.3	78	0.7	5.7	15.3	20	2.8
Lab035	2	12.8	-	0	-	-	-	20	-	12.8	12.4	55	0.7	5.6	14.4	20	3.0
Lab037	2	12.6	11.7	4	0.9	7.7	22.5	20	1.7	12.6	12.6	44	1.2	9.5	19.0	20	2.1
Lab038	2	12.8	-	0	-	-	-	20	-	12.8	12.7	55	1.0	7.9	16.5	20	2.4
Lab040	2	12.8	-	0	-	-	-	20	-	12.8	11.8	11	0.5	4.2	16.3	20	2.9
Total	-	-	11.9	46	0.9	7.6	-	-	-	-	12.1	1839	1.7	14.0	-	-	-

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

Month : 2016 10 Change Cumulative : from 2014 02 01 to 2016 10 31 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: AC1203D)															
		Month (2016/10)								CUM (2014/02/01~2016/10/31)							
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	2.7	2.4	8	0.2	8.3	27.8	20	1.1	2.7	2.6	113	0.9	34.6	72.9	20	0.5
Lab019	2	2.9	2.9	4	0.1	3.4	6.9	20	5.9	2.9	2.8	140	0.4	14.3	32.0	20	1.2
Lab020	2	2.9	3.0	3	0.3	10.0	23.4	20	1.7	2.9	3.0	3	0.3	10.0	23.4	20	1.7
Lab021	2	2.9	2.8	4	0.2	7.1	17.7	20	2.3	2.9	3.3	80	0.3	9.1	32.0	20	0.7
Lab022	2	3.3	-	0	-	-	-	20	-	3.3	2.9	57	0.3	10.3	32.8	20	0.8
Lab024	2	2.7	-	0	-	-	-	20	-	2.7	2.7	58	0.3	11.1	22.2	20	1.8
Lab026	2	2.7	-	0	-	-	-	36	-	2.7	2.8	212	0.5	17.9	39.4	36	1.8
Lab027	2	2.9	-	0	-	-	-	20	-	2.9	2.7	147	0.5	18.5	43.9	20	0.7
Lab028	2	3.2	3.1	13	0.1	3.2	9.6	20	5.3	3.2	3.3	309	0.5	15.2	33.4	20	1.1
Lab031	2	2.9	-	0	-	-	-	20	-	2.9	2.5	89	0.5	20.0	53.8	20	0.3
Lab032	2	2.9	-	0	-	-	-	20	-	2.9	2.7	222	0.5	18.5	43.9	20	0.7
Lab033	2	2.7	2.6	5	0.2	7.7	19.1	20	2.1	2.7	2.9	130	0.3	10.3	28.1	20	1.2
Lab034	2	2.9	2.9	5	0.4	13.8	27.6	20	1.4	2.9	3.0	78	0.2	6.7	16.8	20	2.5
Lab035	2	2.9	-	0	-	-	-	20	-	2.9	2.8	55	0.3	10.7	24.9	20	1.5
Lab037	2	3.0	2.8	4	0.3	10.7	28.1	20	1.2	3.0	3.0	44	0.4	13.3	26.7	20	1.5
Lab038	2	2.9	-	0	-	-	-	20	-	2.9	3.1	55	0.5	16.1	39.2	20	0.8
Lab040	2	2.9	-	0	-	-	-	20	-	2.9	2.4	11	0.3	12.5	42.2	20	0.2
Total	-	-	2.8	46	0.3	10.7	-	-	-	-	2.9	1839	0.6	20.7	-	-	-

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

Month : 2016 10 Change Cumulative : from 2014 02 01 to 2016 10 31 Change

[TOP]

Reagent Kit	Reagent Code
AMP	2