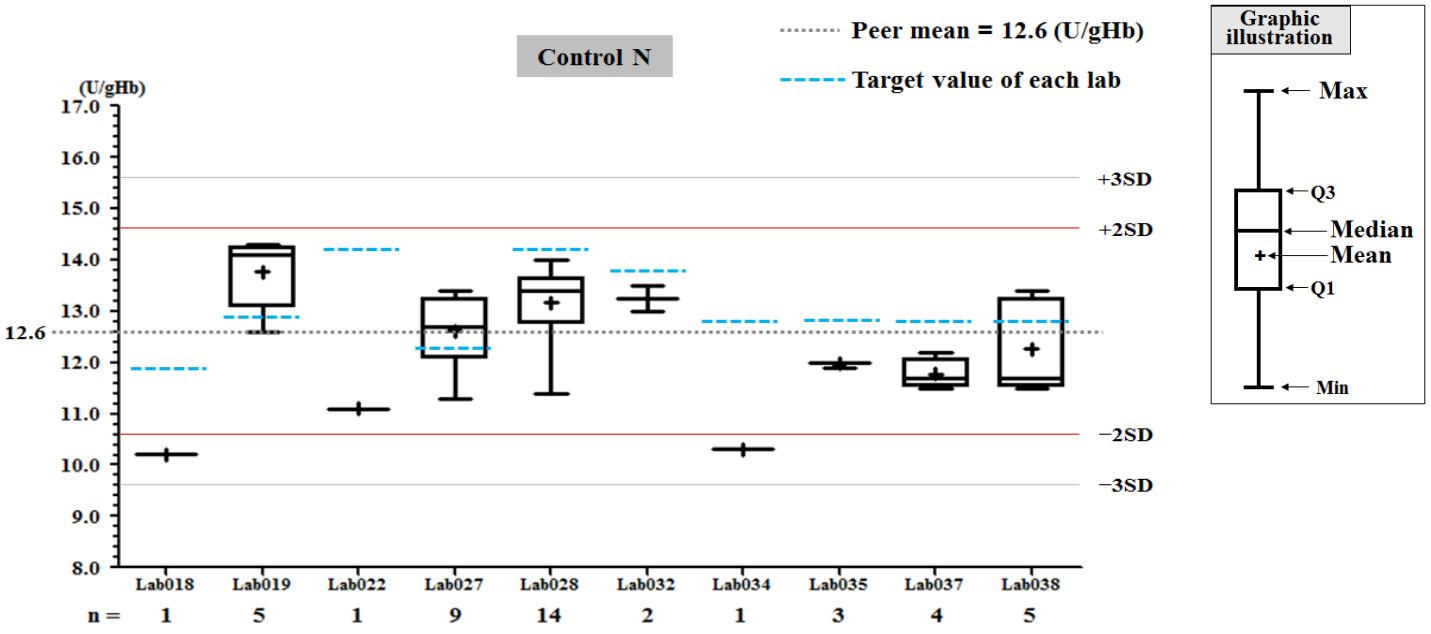
Summary Report of IQC program for G6PD Quantitative Test - AMP Group - March 2016 -

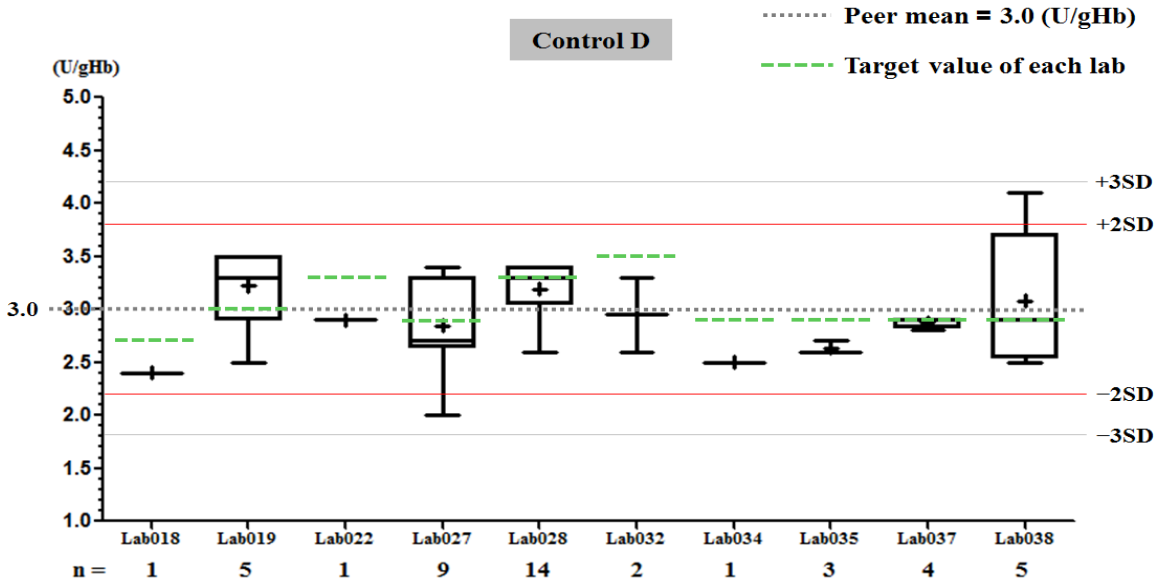
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AC1203N)	Control D (Lot No.:AC1203D)
Labs	10	10
Received results number (n)	45	45
Median	12.7 (U/gHb)	2.9 (U/gHb)
Mean	12.5 (U/gHb)	3.0 (U/gHb)
SD	1.0	0.4
CV	7.9%	13.3%
Range of G6PD	10.2 ~ 14.3 (U/gHb)	2.0 ~ 4.1 (U/gHb)
Range of Hb	1.8 ~ 2.7 (g/dL)	2.4 ~ 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

Lab019

	Control N		Control D	
QC Control Lot No.	AC1203N		AC1203D	
Duration of the Analyzing	Month (2016/03)	CUM (2015/10/07~2016/03/31)	Month (2016/03)	CUM (2015/10/07~2016/03/31)
Runs (N)	5	26	5	26
Mean (U/gHb)	13.8	12.8	3.2	3.0
SD	0.7	0.8	0.4	0.3
CV (%)	5.1	6.3	12.5	10.0
Target Value (U/gHb)	12.9	12.9	3.0	3.0
Total Error (%)	17.1	13.3	31.7	20.0
TEa (%)	20	20	20	20
σ	2.6	3.1	1.1	2.0

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

Month : 2016 03 Change ; Cumulative : from 2015 10 07 to 2016 03 31 Change

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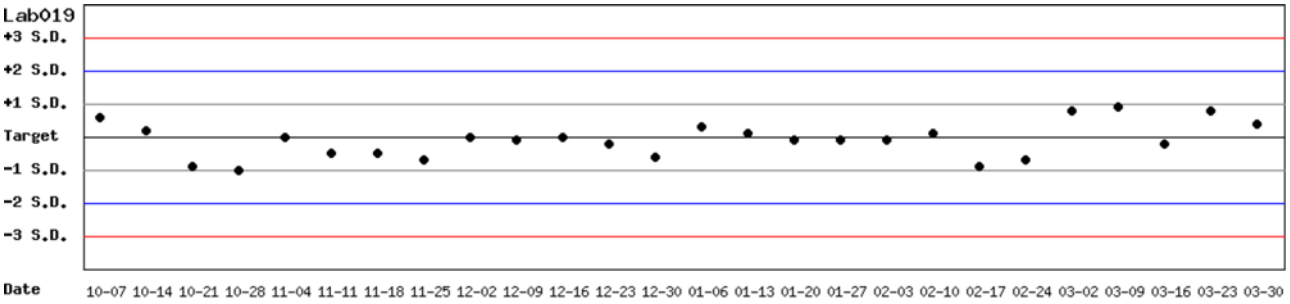
Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2015-10-07 to 2016-03-31 ; Target : 12.9 ; SD : 1.60

Lab019



Month : 2016 03 Change ; Cumulative : from 2015 10 07 to 2016 03 31 Change

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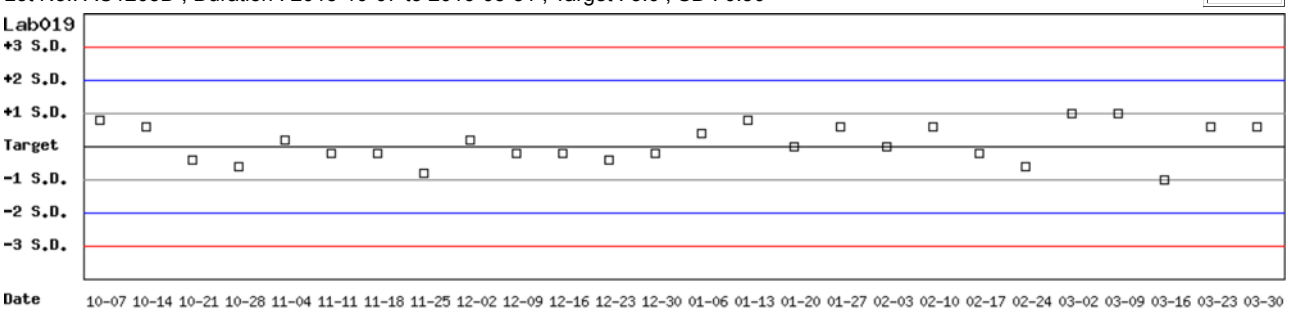
Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2015-10-07 to 2016-03-31 ; Target : 3.0 ; SD : 0.50

Lab019



Month : 2016 03 Change ; Cumulative : from 2015 10 07 to 2016 03 31 Change

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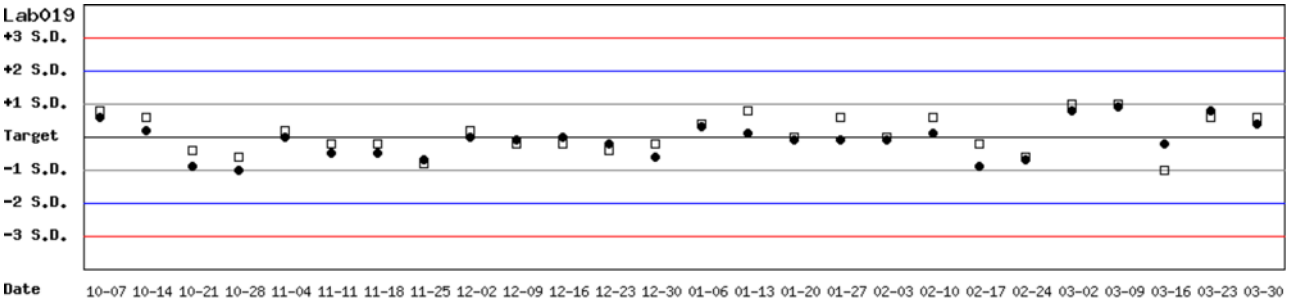
Control N and **Control D SDI**
QC Chart

Lot No.: AC1203N ; Duration : 2015-10-07 to 2016-03-31 ; Target : 12.9 ; SD : 1.60 (●)

Lot No.: AC1203D ; Duration : 2015-10-07 to 2016-03-31 ; Target : 3.0 ; SD : 0.50 (□)

Lab019



Month : 2016 03 Change ; Cumulative : from 2015 10 07 to 2016 03 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 : 2016 03 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	10.2	1	-	-	-	20	-	2.7	2.4	1	-	-	-	20	-
Lab019	2	12.9	13.8	5	0.7	5.1	17.1	20	2.6	3.0	3.2	5	0.4	12.5	31.7	20	1.1
Lab022	2	14.2	11.1	1	-	-	-	20	-	3.3	2.9	1	-	-	-	20	-
Lab027	2	12.3	12.6	9	0.7	5.6	13.6	20	3.1	2.9	2.8	9	0.4	14.3	32.0	20	1.2
Lab028	2	14.2	13.2	14	0.8	6.1	19.2	20	2.1	3.3	3.2	14	0.3	9.4	21.8	20	1.8
Lab032	2	13.8	13.3	2	-	-	-	20	-	3.5	3.0	2	-	-	-	20	-
Lab034	2	12.8	10.3	1	-	-	-	20	-	2.9	2.5	1	-	-	-	20	-
Lab035	2	12.8	12.0	3	0.1	0.8	7.9	20	>6	2.9	2.6	3	0.1	3.8	18.0	20	2.5
Lab037	2	12.8	11.8	4	0.3	2.5	12.9	20	4.9	2.9	2.9	4	0.1	3.4	6.9	20	5.9
Lab038	2	12.8	12.3	5	0.9	7.3	18.5	20	2.2	2.9	3.1	5	0.7	22.6	52.1	20	0.6
Total	-	-	12.6	45	1.0	7.9	-	-	-	-	3.0	45	0.4	13.3	-	-	-

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 03 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	10.8	76	1.6	14.8	38.9	20	0.7	2.7	2.6	76	1.1	42.3	88.3	20	0.4
Lab019	2	12.9	12.2	109	1.2	9.8	25.1	20	1.5	3.0	2.8	109	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	23	1.1	9.2	34.7	20	0.4	3.3	3.1	23	0.3	9.7	25.4	20	1.4
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	11.9	130	1.6	13.4	30.1	20	1.2	2.9	2.7	130	0.5	18.5	43.9	20	0.7
Lab028	2	14.2	13.8	215	1.2	8.7	20.2	20	2.0	3.3	3.4	215	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	177	2.0	17.7	53.5	20	0.1	3.5	2.6	177	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	12.5	48	0.6	4.8	11.9	20	3.7	2.9	3.0	48	0.2	6.7	16.8	20	2.5
Lab035	2	12.8	12.6	40	0.7	5.6	12.7	20	3.3	2.9	2.9	40	0.3	10.3	20.7	20	1.9
Lab037	2	12.8	12.3	13	0.9	7.3	18.5	20	2.2	2.9	3.0	13	0.3	10.0	23.4	20	1.7
Lab038	2	12.8	12.6	42	1.1	8.7	19.0	20	2.1	2.9	3.2	42	0.5	15.6	41.6	20	0.6
Total	-	-	12.1	1386	1.8	14.9	-	-	-	-	2.9	1386	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 (2016/03)								CUM (2014/02/01~2016/03/31)							
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	10.2	1	-	-	-	20	-	11.9	10.8	76	1.6	14.8	38.9	20	0.7
Lab019	2	12.9	13.8	5	0.7	5.1	17.1	20	2.6	12.9	12.2	109	1.2	9.8	25.1	20	1.5
Lab021	2	14.2	-	0	-	-	-	20	-	14.2	14.2	54	0.2	1.4	2.8	20	>6
Lab022	2	14.2	11.1	1	-	-	-	20	-	14.2	11.9	23	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	12.6	9	0.7	5.6	13.6	20	3.1	12.3	11.9	130	1.6	13.4	30.1	20	1.2
Lab028	2	14.2	13.2	14	0.8	6.1	19.2	20	2.1	14.2	13.8	215	1.2	8.7	20.2	20	2.0
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	2	-	-	-	20	-	13.8	11.3	177	2.0	17.7	53.5	20	0.1
Lab033	2	12.9	-	0	-	-	-	20	-	12.9	12.2	100	1.0	8.2	21.8	20	1.8
Lab034	2	12.8	10.3	1	-	-	-	20	-	12.8	12.5	48	0.6	4.8	11.9	20	3.7
Lab035	2	12.8	12.0	3	0.1	0.8	7.9	20	>6	12.8	12.6	40	0.7	5.6	12.7	20	3.3
Lab037	2	12.8	11.8	4	0.3	2.5	12.9	20	4.9	12.8	12.3	13	0.9	7.3	18.5	20	2.2
Lab038	2	12.8	12.3	5	0.9	7.3	18.5	20	2.2	12.8	12.6	42	1.1	8.7	19.0	20	2.1
Total	-	-	12.6	45	1.0	7.9	-	-	-	-	12.1	1386	1.8	14.9	-	-	-

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

Month : 2016 03 Change Cumulative : from 2014 02 01 to 2016 03 31 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: AC1203D)																
		Month (2016/03)								CUM (2014/02/01~2016/03/31)							
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	1	-	-	-	20	-	2.7	2.6	76	1.1	42.3	88.3	20	0.4
Lab019	2	3.0	3.2	5	0.4	12.5	31.7	20	1.1	3.0	2.8	109	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	1	-	-	-	20	-	3.3	3.1	23	0.3	9.7	25.4	20	1.4
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	2.8	9	0.4	14.3	32.0	20	1.2	2.9	2.7	130	0.5	18.5	43.9	20	0.7
Lab028	2	3.3	3.2	14	0.3	9.4	21.8	20	1.8	3.3	3.4	215	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	3.0	2	-	-	-	20	-	3.5	2.6	177	0.5	19.2	64.2	20	-0.3
Lab033	2	3.0	-	0	-	-	-	20	-	3.0	2.9	100	0.3	10.3	24.0	20	1.6
Lab034	2	2.9	2.5	1	-	-	-	20	-	2.9	3.0	48	0.2	6.7	16.8	20	2.5
Lab035	2	2.9	2.6	3	0.1	3.8	18.0	20	2.5	2.9	2.9	40	0.3	10.3	20.7	20	1.9
Lab037	2	2.9	2.9	4	0.1	3.4	6.9	20	5.9	2.9	3.0	13	0.3	10.0	23.4	20	1.7
Lab038	2	2.9	3.1	5	0.7	22.6	52.1	20	0.6	2.9	3.2	42	0.5	15.6	41.6	20	0.6
Total	-	-	3.0	45	0.4	13.3	-	-	-	-	2.9	1386	0.6	20.7	-	-	-

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

Month : 2016 03 Change Cumulative : from 2014 02 01 to 2016 03 31 Change

[TOP]

Reagent Kit	Reagent Code
AMP	2