

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - April 2018 -

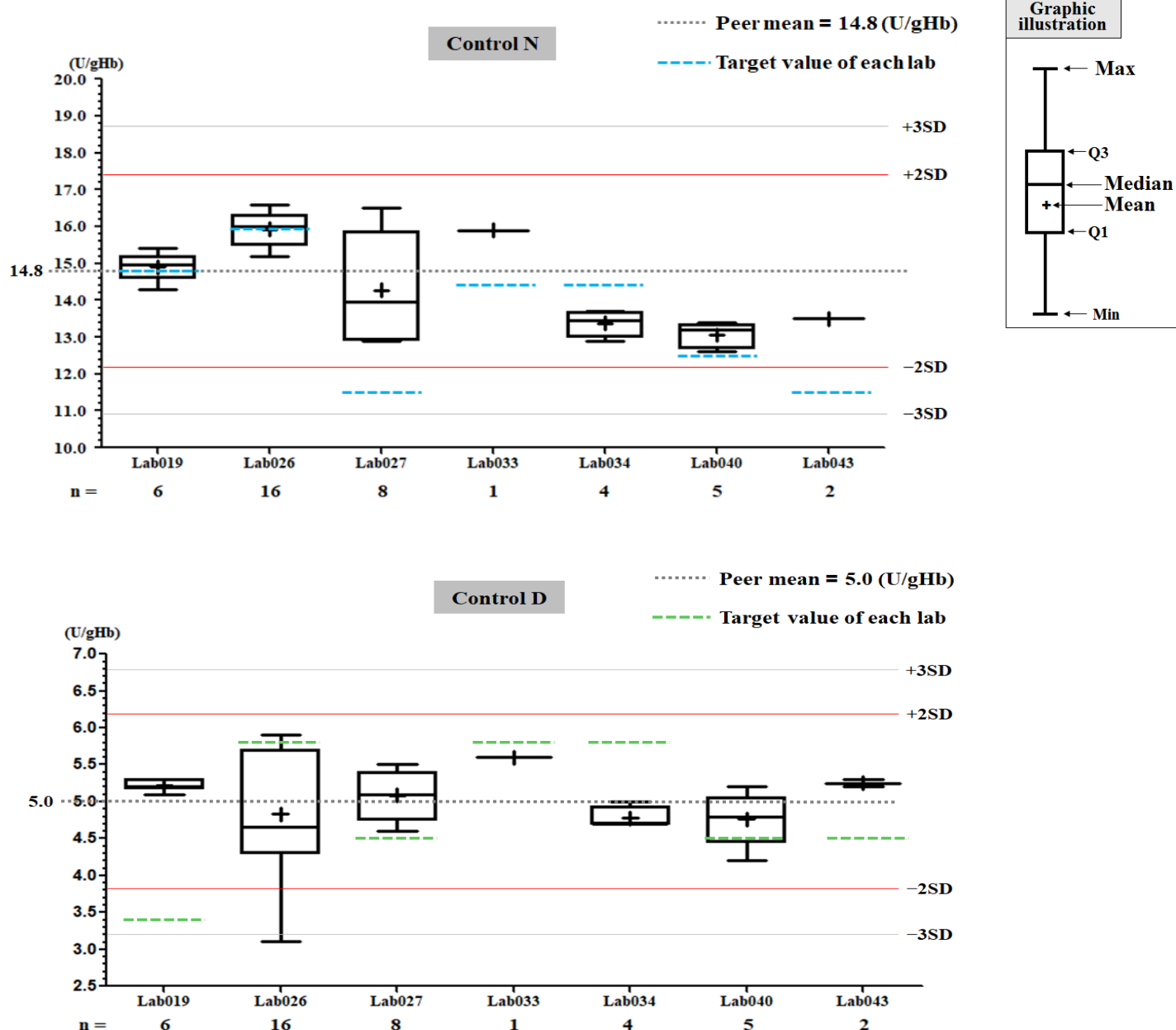
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	7	7
Received results number (n)	42	42
Median	15.1 (U/gHb)	5.1 (U/gHb)
Mean	14.8 (U/gHb)	5.0 (U/gHb)
SD	1.3	0.6
CV	8.8%	12.0%
Range of G6PD	12.6 ~ 16.6 (U/gHb)	3.1 ~ 5.9 (U/gHb)
Range of Hb	1.4 ~ 2.5 (g/dL)	1.7 ~ 2.5 (g/dL)

*The statistic results are calculated from all labs reported in this month

** G6PD Method = Medicon 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 : AE0909N (2016-01-01 ~ 2100-12-31) [Change](#)

[Print Table](#)

Lab040

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2018/04)	CUM (2016/02/01~2018/04/30)	Month (2018/04)	CUM (2016/02/01~2018/04/30)
Runs (N)	5	15	5	15
Mean (U/gHb)	13.1	12.6	4.8	4.6
SD	0.3	0.4	0.4	0.3
CV (%)	2.3	3.2	8.3	6.5
Target Value (U/gHb)	12.5	12.5	4.5	4.5
Total Error (%)	9.4	7.1	23.3	15.3
TEa (%)	20	20	20	20
σ	>6	>6	1.6	2.7

Bias (%) = $\left[\frac{(\text{Mean} - \text{Target})}{\text{Target}} \right] \times 100\%$

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

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

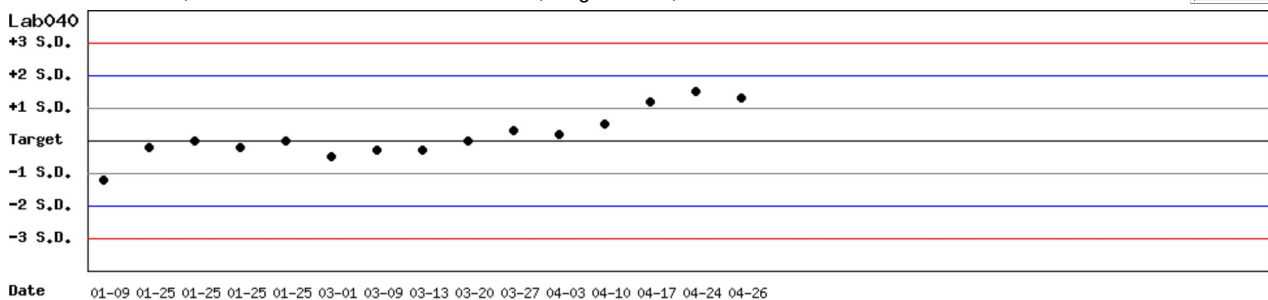
Month : 2018 04 [Change](#) ; Cumulative : from 2016 02 01 to 2018 04 30 [Change](#)

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Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2018-04-30 ; Target : 12.5 ; SD : 0.6

Lab040



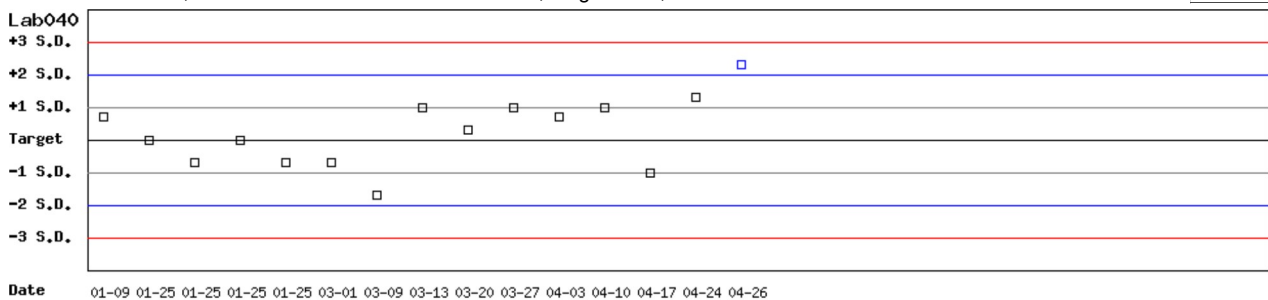
Month : 2018 04 [Change](#) ; Cumulative : from 2016 02 01 to 2018 04 30 [Change](#)

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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2016-02-01 to 2018-04-30 ; Target : 4.5 ; SD : 0.3

Lab040



Month : 2018 04 [Change](#) ; Cumulative : from 2016 02 01 to 2018 04 30 [Change](#)

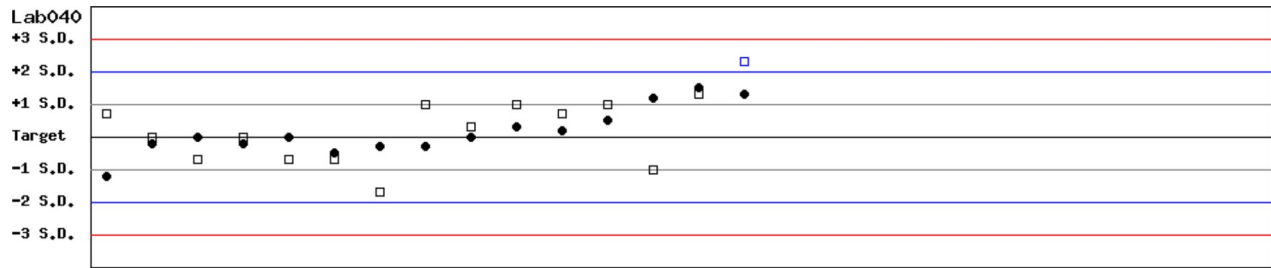
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Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2018-04-30 ; Target : 12.5 ; SD : 0.6 (●)

Lot No.: AE0909D ; Duration : 2016-02-01 to 2018-04-30 ; Target : 4.5 ; SD : 0.3 (□)

Lab040



Date 01-09 01-25 01-25 01-25 01-25 03-01 03-09 03-13 03-20 03-27 04-03 04-10 04-17 04-24 04-26

Month : 2018 04 Change ; Cumulative : from 2016 02 01 to 2018 04 30 Change

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Peer Group Statistics (Table 1)

Select LotNo : AE0909N (2016-01-01 ~ 2100-12-31) ▼ Change

Select Reagent Kit : 5 - Medicon ▼ Change

[Print Table 1](#)

Monthly

Month : 2018 ▼ 04 ▼ Change

UnitID 	Reagent Kit (Code) 	Control N (Lot No.: AE0909N)								Control D (Lot No.: AE0909D)							
		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
Lab019	5	14.8	14.9	6	0.4	2.7	6.0	20	>6	3.4	5.2	6	0.1	1.9	56.8	20	-17.3
Lab026	5	15.9	15.9	16	0.4	2.5	5.0	20	>6	5.8	4.8	16	0.9	18.8	54.7	20	0.1
Lab027	5	11.5	14.3	8	1.5	10.5	45.3	20	-0.4	4.5	5.1	8	0.4	7.8	29.0	20	0.9
Lab033	5	14.4	15.9	1	-	-	-	20	-	5.8	5.6	1	-	-	-	20	-
Lab034	5	14.4	13.4	4	0.4	3.0	12.9	20	4.4	5.8	4.8	4	0.2	4.2	25.6	20	0.7
Lab040	5	12.5	13.1	5	0.3	2.3	9.4	20	>6	4.5	4.8	5	0.4	8.3	23.3	20	1.6
Lab043	5	11.5	13.5	2	-	-	-	20	-	4.5	5.3	2	-	-	-	20	-
Total	-	-	14.8	42	1.3	8.8	-	-	-	-	5.0	42	0.6	12.0	-	-	-

Bias (%) = $\left[\left(\left| \text{Mean} - \text{Target} \right| \right) / \text{Target} \right] \times 100\%$

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

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

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Cumulative

Cumulative : from 2016 ▼ 02 ▼ 01 ▼ to 2018 ▼ 04 ▼ 30 ▼ Change

UnitID 	Reagent Kit (Code) 	Control N (Lot No.: AE0909N)								Control D (Lot No.: AE0909D)							
		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	5	15.7	16.2	29	0.8	4.9	13.1	20	3.4	5.6	5.8	29	0.3	5.2	13.9	20	3.2
Lab019	5	14.8	15.0	11	0.4	2.7	6.7	20	>6	3.4	5.2	11	0.1	1.9	56.8	20	-17.3
Lab026	5	15.9	15.9	16	0.4	2.5	5.0	20	>6	5.8	4.8	16	0.9	18.8	54.7	20	0.1
Lab027	5	11.5	14.3	8	1.5	10.5	45.3	20	-0.4	4.5	5.1	8	0.4	7.8	29.0	20	0.9
Lab032	5	15.9	15.8	22	1.0	6.3	13.3	20	3.1	5.8	5.7	22	0.4	7.0	15.8	20	2.6
Lab033	5	14.4	15.9	1	-	-	-	20	-	5.8	5.6	1	-	-	-	20	-
Lab034	5	14.4	13.7	6	0.6	4.4	13.6	20	3.4	5.8	4.8	6	0.1	2.1	21.4	20	1.3
Lab040	5	12.5	12.6	15	0.4	3.2	7.1	20	>6	4.5	4.6	15	0.3	6.5	15.3	20	2.7
Lab043	5	11.5	14.5	14	0.9	6.2	38.5	20	-1.0	4.5	5.3	14	0.3	5.7	29.1	20	0.4
Total	-	-	15.1	122	1.4	9.3	-	-	-	-	5.3	122	0.6	11.3	-	-	-

Bias (%) = $\left[\left(\left| \text{Mean} - \text{Target} \right| \right) / \text{Target} \right] \times 100\%$

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

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

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Reagent Kit	Reagent Code
Medicon	5

Peer Group Statistics (Table 2)

Select LotNo : AE0909N (2016-01-01 ~ 2100-12-31)

Select Reagent Kit : 5 - Medicon

[Print Table 2](#)

Control N Month vs. Cumulative

		Control N (Lot No.: AE0909N)															
		Month (2018/04)								CUM (2016/02/01~2018/04/30)							
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	5	15.7	-	0	-	-	-	20	-	15.7	16.2	29	0.8	4.9	13.1	20	3.4
Lab019	5	14.8	14.9	6	0.4	2.7	6.0	20	>6	14.8	15.0	11	0.4	2.7	6.7	20	>6
Lab026	5	15.9	15.9	16	0.4	2.5	5.0	20	>6	15.9	15.9	16	0.4	2.5	5.0	20	>6
Lab027	5	11.5	14.3	8	1.5	10.5	45.3	20	-0.4	11.5	14.3	8	1.5	10.5	45.3	20	-0.4
Lab032	5	15.9	-	0	-	-	-	20	-	15.9	15.8	22	1.0	6.3	13.3	20	3.1
Lab033	5	14.4	15.9	1	-	-	-	20	-	14.4	15.9	1	-	-	-	20	-
Lab034	5	14.4	13.4	4	0.4	3.0	12.9	20	4.4	14.4	13.7	6	0.6	4.4	13.6	20	3.4
Lab040	5	12.5	13.1	5	0.3	2.3	9.4	20	>6	12.5	12.6	15	0.4	3.2	7.1	20	>6
Lab043	5	11.5	13.5	2	-	-	-	20	-	11.5	14.5	14	0.9	6.2	38.5	20	-1.0
Total	-	-	14.8	42	1.3	8.8	-	-	-	-	15.1	122	1.4	9.3	-	-	-

Bias (%) = $\left[\left(\left| \text{Mean} - \text{Target} \right| \right) / \text{Target} \right] \times 100\%$

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

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

Month : 2018 04

Cumulative : from 2016 02 01 to 2018 04 30

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Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2018/04)								CUM (2016/02/01~2018/04/30)							
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	5	5.6	-	0	-	-	-	20	-	5.6	5.8	29	0.3	5.2	13.9	20	3.2
Lab019	5	3.4	5.2	6	0.1	1.9	56.8	20	-17.3	3.4	5.2	11	0.1	1.9	56.8	20	-17.3
Lab026	5	5.8	4.8	16	0.9	18.8	54.7	20	0.1	5.8	4.8	16	0.9	18.8	54.7	20	0.1
Lab027	5	4.5	5.1	8	0.4	7.8	29.0	20	0.9	4.5	5.1	8	0.4	7.8	29.0	20	0.9
Lab032	5	5.8	-	0	-	-	-	20	-	5.8	5.7	22	0.4	7.0	15.8	20	2.6
Lab033	5	5.8	5.6	1	-	-	-	20	-	5.8	5.6	1	-	-	-	20	-
Lab034	5	5.8	4.8	4	0.2	4.2	25.6	20	0.7	5.8	4.8	6	0.1	2.1	21.4	20	1.3
Lab040	5	4.5	4.8	5	0.4	8.3	23.3	20	1.6	4.5	4.6	15	0.3	6.5	15.3	20	2.7
Lab043	5	4.5	5.3	2	-	-	-	20	-	4.5	5.3	14	0.3	5.7	29.1	20	0.4
Total	-	-	5.0	42	0.6	12.0	-	-	-	-	5.3	122	0.6	11.3	-	-	-

Bias (%) = $\left[\left(\left| \text{Mean} - \text{Target} \right| \right) / \text{Target} \right] \times 100\%$

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

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

Month : 2018 04

Cumulative : from 2016 02 01 to 2018 04 30

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Reagent Kit	Reagent Code
Medicon	5