

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - February 2019 -

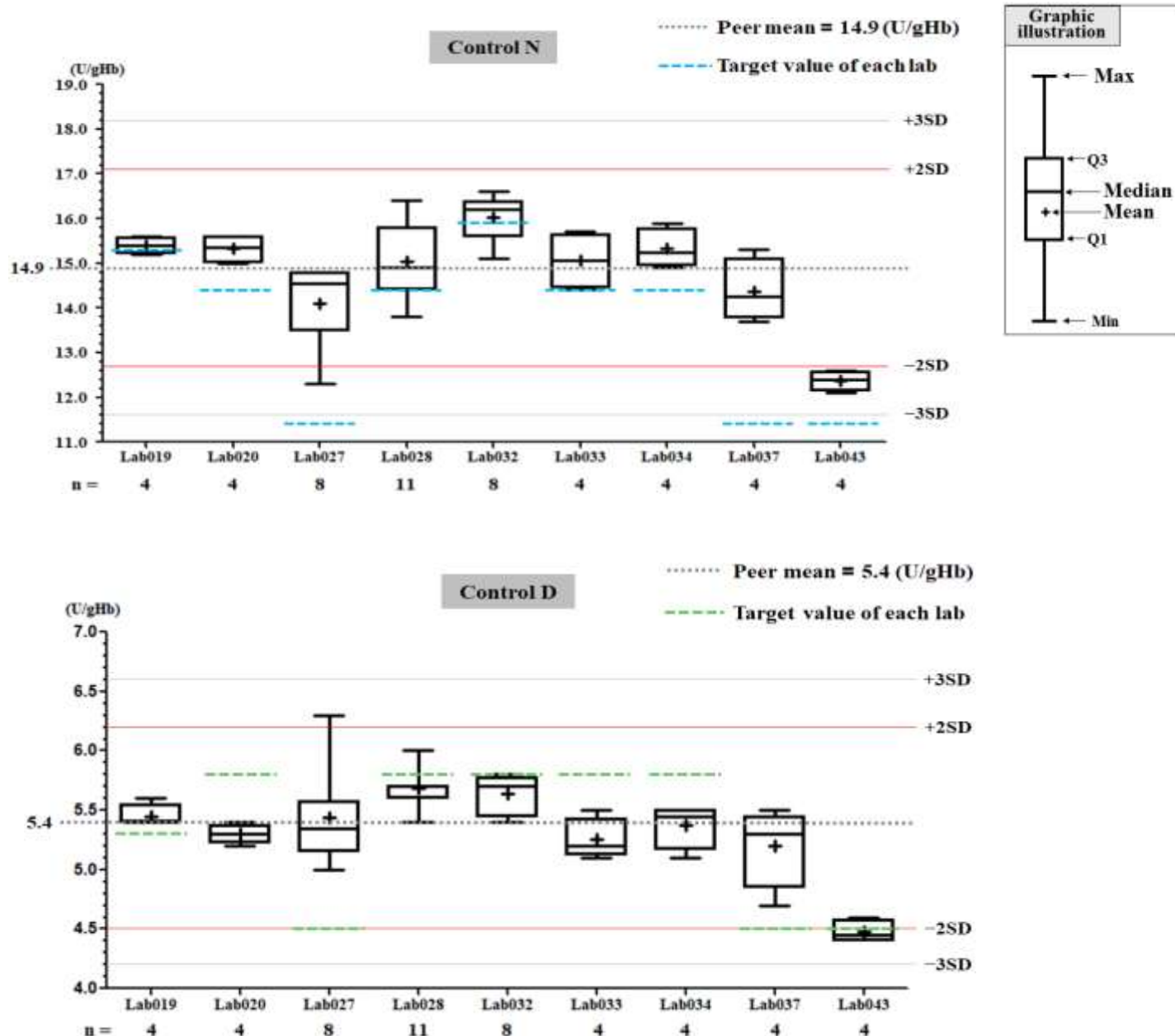
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	9	9
Received results number (n)	51	51
Median	15.0 (U/gHb)	5.4 (U/gHb)
Mean	14.9 (U/gHb)	5.4 (U/gHb)
SD	1.1	0.4
CV	7.4%	7.4%
Range of G6PD	12.1 ~ 16.6 (U/gHb)	4.4 ~ 6.3 (U/gHb)
Range of Hb	1.7 ~ 2.3 (g/dL)	1.8 ~ 2.6 (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](#)

Lab028

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2019/02)	CUM (2016/02/01~2019/02/28)	Month (2019/02)	CUM (2016/02/01~2019/02/28)
Runs (N)	11	23	11	23
Mean (U/gHb)	15.0	14.6	5.7	5.5
SD	0.8	0.8	0.1	0.4
CV (%)	5.3	5.5	1.8	7.3
Target Value (U/gHb)	14.4	14.4	5.8	5.8
Total Error (%)	14.8	12.3	5.2	19.7
TEa (%)	20	20	20	20
σ	3.0	3.4	>6	2.0

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

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

σ (Sigma) = $[\text{TEa\%} - \text{Bias (\%)}] / \text{CV (\%)}$

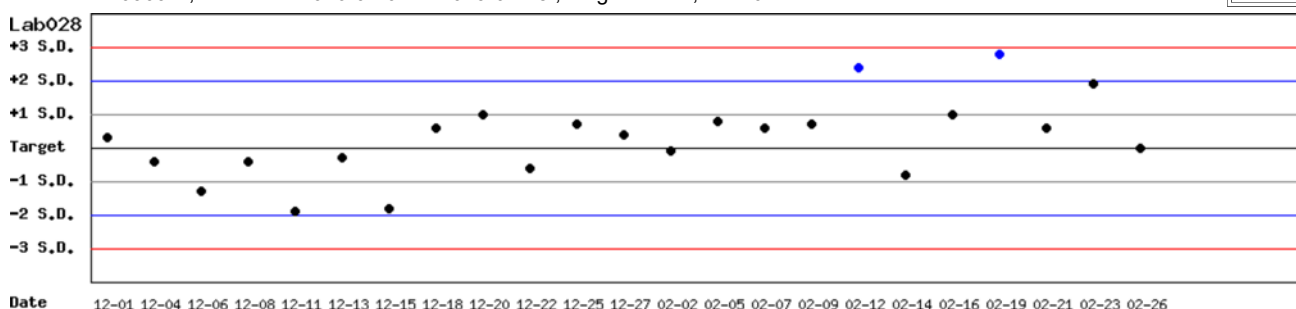
Month : 2019 02 [Change](#) ; Cumulative : from 2016 02 01 to 2019 02 28 [Change](#)

[\[TOP\]](#)

Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2019-02-28 ; Target : 14.4 ; SD : 0.72

Lab028



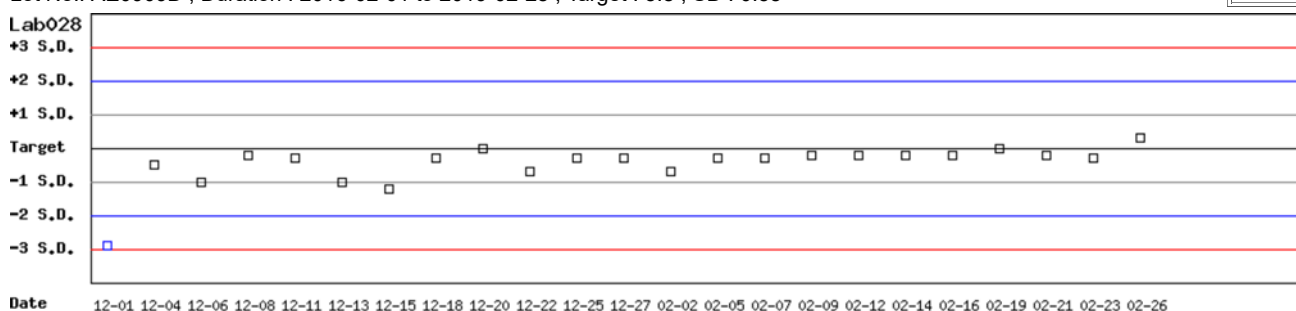
Month : 2019 02 [Change](#) ; Cumulative : from 2016 02 01 to 2019 02 28 [Change](#)

[\[TOP\]](#)

Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2016-02-01 to 2019-02-28 ; Target : 5.8 ; SD : 0.58

Lab028



Month : 2019 02 [Change](#) ; Cumulative : from 2016 02 01 to 2019 02 28 [Change](#)

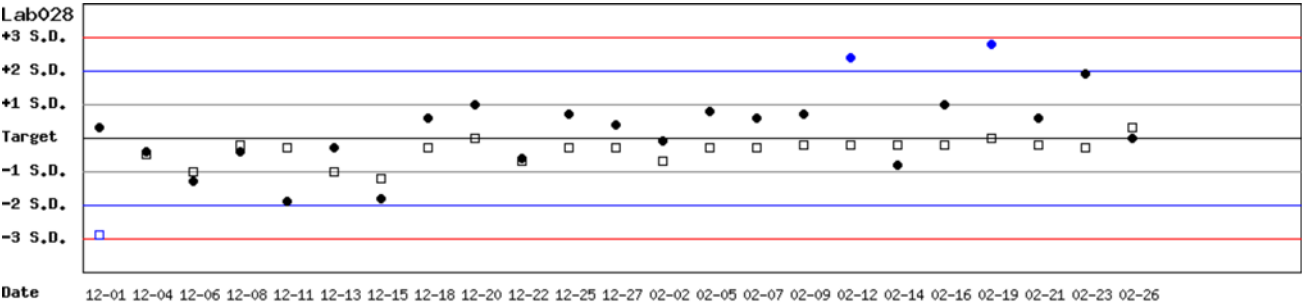
[\[TOP\]](#)

Control N and Control D SDI
QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2019-02-28 ; Target : 14.4 ; SD : 0.72 (●)

Lot No.: AE0909D ; Duration : 2016-02-01 to 2019-02-28 ; Target : 5.8 ; SD : 0.58 (□)

Lab028



Month : 2019 02 Change ; Cumulative : from 2016 02 01 to 2019 02 28 Change

[\[TOP\]](#)

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 : 2019 02 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	15.3	15.4	4	0.2	1.3	3.3	20	>6	5.3	5.5	4	0.1	1.8	7.4	20	>6
Lab020	5	14.4	15.3	4	0.3	2.0	10.2	20	>6	5.8	5.3	4	0.1	1.9	12.4	20	6.0
Lab027	5	11.5	14.1	8	0.9	6.4	35.4	20	-0.4	4.5	5.4	8	0.4	7.4	34.8	20	0.0
Lab028	5	14.4	15.0	11	0.8	5.3	14.8	20	3.0	5.8	5.7	11	0.1	1.8	5.2	20	>6
Lab032	5	15.9	16.0	8	0.5	3.1	6.9	20	>6	5.8	5.6	8	0.2	3.6	10.6	20	4.6
Lab033	5	14.4	15.1	4	0.6	4.0	12.8	20	3.8	5.8	5.3	4	0.2	3.8	16.2	20	3.0
Lab034	5	14.4	15.3	4	0.4	2.6	11.5	20	5.3	5.8	5.4	4	0.2	3.7	14.3	20	3.5
Lab037	5	11.5	14.4	4	0.7	4.9	34.9	20	-1.1	4.5	5.2	4	0.3	5.8	27.1	20	0.8
Lab043	5	11.5	12.4	4	0.2	1.6	11.1	20	>6	4.5	4.5	4	0.1	2.2	4.4	20	>6
Total	-	-	14.9	51	1.1	7.4	-	-	-	-	5.4	51	0.4	7.4	-	-	-

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 (%)

[TOP](#)

Cumulative

Cumulative : from 2016 02 01 to 2019 02 28 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	16.1	60	0.7	4.3	11.2	20	4.1	5.6	5.7	60	0.3	5.3	12.3	20	3.4
Lab019	5	15.3	15.2	57	0.4	2.6	5.9	20	>6	5.3	5.3	57	0.1	1.9	3.8	20	>6
Lab020	5	14.4	15.2	15	0.4	2.6	10.8	20	5.6	5.8	5.4	15	0.1	1.9	10.6	20	>6
Lab026	5	15.9	15.3	125	0.5	3.3	10.3	20	4.9	5.8	5.2	125	0.4	7.7	25.7	20	1.3
Lab027	5	11.5	15.9	61	1.5	9.4	57.1	20	-1.9	4.5	5.6	61	0.4	7.1	38.7	20	-0.6
Lab028	5	14.4	14.6	23	0.8	5.5	12.3	20	3.4	5.8	5.5	23	0.4	7.3	19.7	20	2.0
Lab032	5	15.9	15.9	38	0.9	5.7	11.3	20	3.5	5.8	5.7	38	0.3	5.3	12.3	20	3.4
Lab033	5	14.4	14.9	45	0.5	3.4	10.2	20	4.9	5.8	5.2	45	0.2	3.8	18.0	20	2.5
Lab034	5	14.4	14.2	49	0.6	4.2	9.8	20	4.4	5.8	5.1	49	0.2	3.9	19.9	20	2.0
Lab037	5	11.5	14.8	15	0.7	4.7	38.2	20	-1.9	4.5	5.3	15	0.3	5.7	29.1	20	0.4
Lab040	5	14.4	13.3	39	0.7	5.3	18.2	20	2.3	5.8	4.7	39	0.3	6.4	31.7	20	0.2
Lab043	5	11.5	13.2	55	1.0	7.6	29.9	20	0.7	4.5	5.0	55	0.3	6.0	23.1	20	1.5
Total	-	-	15.0	582	1.2	8.0	-	-	-	-	5.3	582	0.4	7.5	-	-	-

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 (%)

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5

Peer Group Statistics (Table 2)

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

Select Reagent Kit : 5 - Medicon Change

[Print Table 2](#)

Control N Month vs. Cumulative

Control N (Lot No.: AE0909N)																	
Month (2019/02)										CUM (2016/02/01~2019/02/28)							
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	16.1	60	0.7	4.3	11.2	20	4.1
Lab019	5	15.3	15.4	4	0.2	1.3	3.3	20	>6	15.3	15.2	57	0.4	2.6	5.9	20	>6
Lab020	5	14.4	15.3	4	0.3	2.0	10.2	20	>6	14.4	15.2	15	0.4	2.6	10.8	20	5.6
Lab026	5	15.9	-	0	-	-	-	20	-	15.9	15.3	125	0.5	3.3	10.3	20	4.9
Lab027	5	11.5	14.1	8	0.9	6.4	35.4	20	-0.4	11.5	15.9	61	1.5	9.4	57.1	20	-1.9
Lab028	5	14.4	15.0	11	0.8	5.3	14.8	20	3.0	14.4	14.6	23	0.8	5.5	12.3	20	3.4
Lab032	5	15.9	16.0	8	0.5	3.1	6.9	20	>6	15.9	15.9	38	0.9	5.7	11.3	20	3.5
Lab033	5	14.4	15.1	4	0.6	4.0	12.8	20	3.8	14.4	14.9	45	0.5	3.4	10.2	20	4.9
Lab034	5	14.4	15.3	4	0.4	2.6	11.5	20	5.3	14.4	14.2	49	0.6	4.2	9.8	20	4.4
Lab037	5	11.5	14.4	4	0.7	4.9	34.9	20	-1.1	11.5	14.8	15	0.7	4.7	38.2	20	-1.9
Lab040	5	14.4	-	0	-	-	-	20	-	14.4	13.3	39	0.7	5.3	18.2	20	2.3
Lab043	5	11.5	12.4	4	0.2	1.6	11.1	20	>6	11.5	13.2	55	1.0	7.6	29.9	20	0.7
Total	-	-	14.9	51	1.1	7.4	-	-	-	-	15.0	582	1.2	8.0	-	-	-

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

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

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

Month : 2019 02 Change

Cumulative : from 2016 02 01 to 2019 02 28 Change

[TOP](#)

Control D Month vs. Cumulative

Control D (Lot No.: AE0909D)																	
Month (2019/02)										CUM (2016/02/01~2019/02/28)							
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	5.7	60	0.3	5.3	12.3	20	3.4
Lab019	5	5.3	5.5	4	0.1	1.8	7.4	20	>6	5.3	5.3	57	0.1	1.9	3.8	20	>6
Lab020	5	5.8	5.3	4	0.1	1.9	12.4	20	6.0	5.8	5.4	15	0.1	1.9	10.6	20	>6
Lab026	5	5.8	-	0	-	-	-	20	-	5.8	5.2	125	0.4	7.7	25.7	20	1.3
Lab027	5	4.5	5.4	8	0.4	7.4	34.8	20	0.0	4.5	5.6	61	0.4	7.1	38.7	20	-0.6
Lab028	5	5.8	5.7	11	0.1	1.8	5.2	20	>6	5.8	5.5	23	0.4	7.3	19.7	20	2.0
Lab032	5	5.8	5.6	8	0.2	3.6	10.6	20	4.6	5.8	5.7	38	0.3	5.3	12.3	20	3.4
Lab033	5	5.8	5.3	4	0.2	3.8	16.2	20	3.0	5.8	5.2	45	0.2	3.8	18.0	20	2.5
Lab034	5	5.8	5.4	4	0.2	3.7	14.3	20	3.5	5.8	5.1	49	0.2	3.9	19.9	20	2.0
Lab037	5	4.5	5.2	4	0.3	5.8	27.1	20	0.8	4.5	5.3	15	0.3	5.7	29.1	20	0.4
Lab040	5	5.8	-	0	-	-	-	20	-	5.8	4.7	39	0.3	6.4	31.7	20	0.2
Lab043	5	4.5	4.5	4	0.1	2.2	4.4	20	>6	4.5	5.0	55	0.3	6.0	23.1	20	1.5
Total	-	-	5.4	51	0.4	7.4	-	-	-	-	5.3	582	0.4	7.5	-	-	-

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

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

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

Month : 2019 02 Change

Cumulative : from 2016 02 01 to 2019 02 28 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5