

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

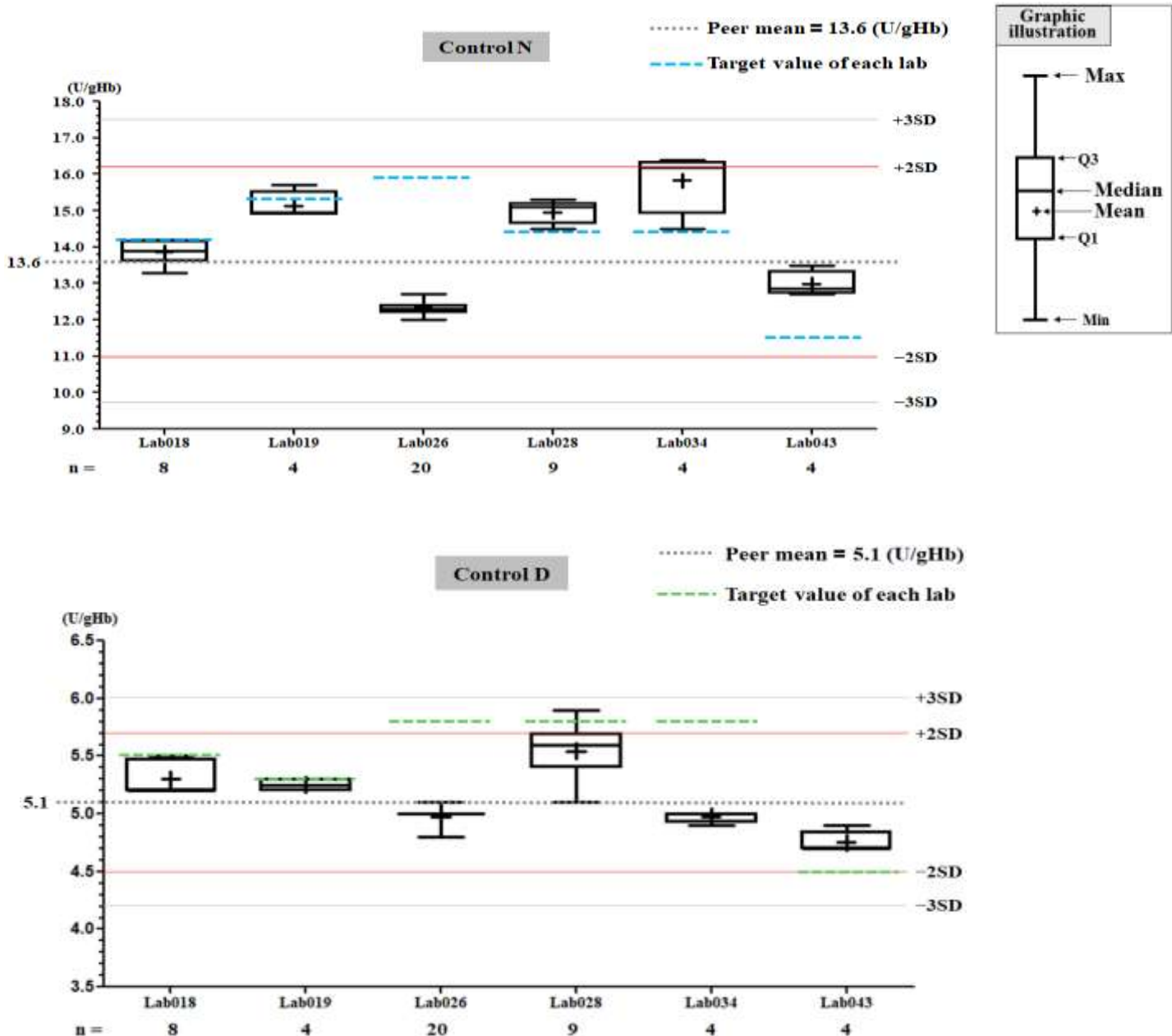
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	6	6
Received results number (n)	49	49
Median	13.5 (U/gHb)	5.0 (U/gHb)
Mean	13.6 (U/gHb)	5.1 (U/gHb)
SD	1.3	0.3
CV	9.6%	5.9%
Range of G6PD	12.0 ~ 16.4 (U/gHb)	4.7 ~ 5.9 (U/gHb)
Range of Hb	1.8 ~ 2.1 (g/dL)	1.5 ~ 2.4 (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](#)

Lab034

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2019/09)	CUM (2018/12/01~2019/09/30)	Month (2019/09)	CUM (2018/12/01~2019/09/30)
Runs (N)	4	26	4	26
Mean (U/gHb)	15.8	14.6	5.0	5.2
SD	0.9	1.0	0.1	0.4
CV (%)	5.7	6.8	2.0	7.7
Target Value (U/gHb)	14.4	14.4	5.8	5.8
Total Error (%)	21.1	15.1	17.8	25.7
TEa (%)	20	20	20	20
σ	1.8	2.7	3.1	1.3

Bias (%) = [(| Mean - Target |) / Target] x 100%

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

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

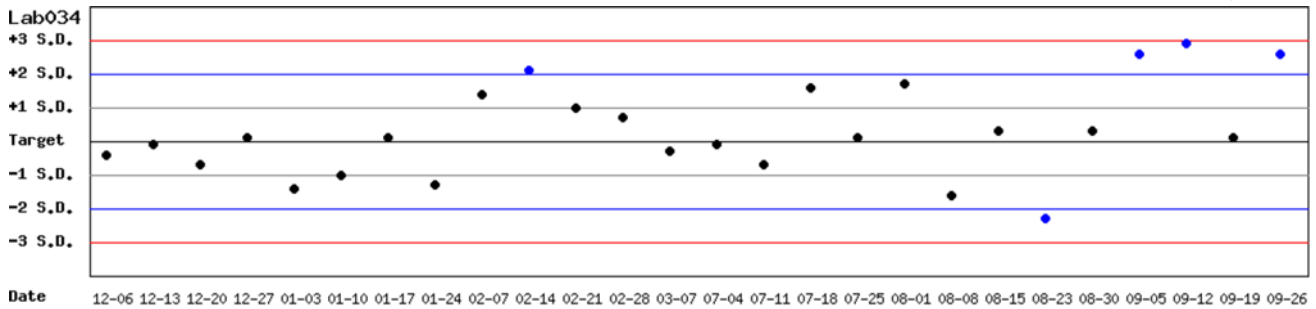
Month : 2019 09 [Change](#) ; Cumulative : from 2018 12 01 to 2019 09 30 [Change](#)

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Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-12-01 to 2019-09-30 ; Target : 14.4 ; SD : 0.70

Lab034



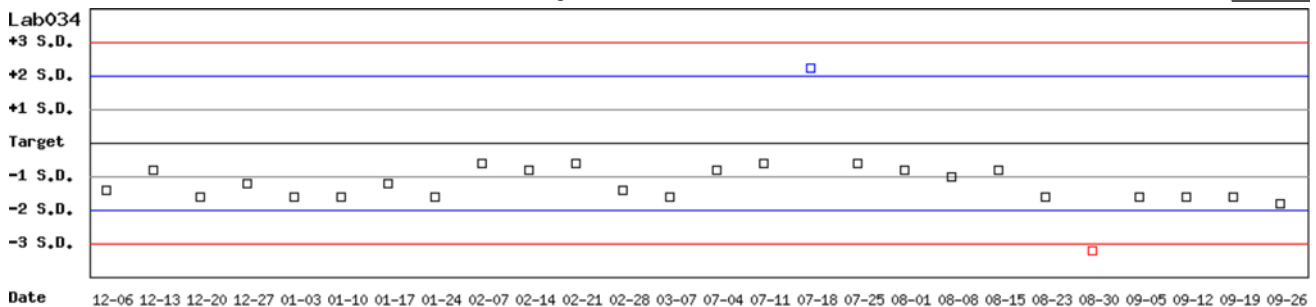
Month : 2019 09 [Change](#) ; Cumulative : from 2018 12 01 to 2019 09 30 [Change](#)

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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2018-12-01 to 2019-09-30 ; Target : 5.8 ; SD : 0.50

Lab034



Month : 2019 09 [Change](#) ; Cumulative : from 2018 12 01 to 2019 09 30 [Change](#)

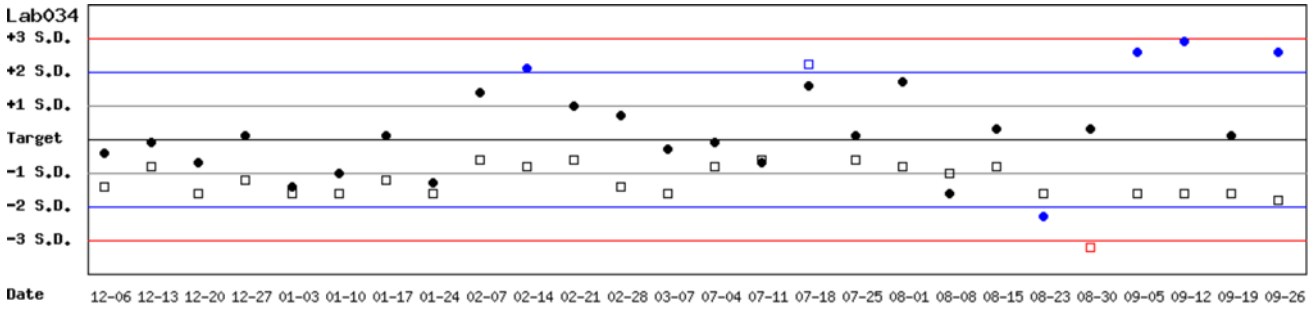
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Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-12-01 to 2019-09-30 ; Target : 14.4 ; SD : 0.70 (●)

Lot No.: AE0909D ; Duration : 2018-12-01 to 2019-09-30 ; Target : 5.8 ; SD : 0.50 (□)

Lab034



Month : 2019 09 ; Cumulative : from 2018 12 01 to 2019 09 30

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Peer Group Statistics (Table 1)

Select LotNo :

Select Reagent Kit :

Monthly

Month :

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	14.2	13.9	8	0.3	2.2	6.4	20	>6	5.5	5.3	8	0.1	1.9	7.4	20	>6
Lab019	5	15.3	15.1	4	0.4	2.6	6.6	20	>6	5.3	5.3	4	0.1	1.9	3.8	20	>6
Lab026	5	15.9	12.3	20	0.2	1.6	25.9	20	-1.7	5.8	5.0	20	0.1	2.0	17.8	20	3.1
Lab028	5	14.4	15.0	9	0.3	2.0	8.2	20	>6	5.8	5.5	9	0.2	3.6	12.4	20	4.1
Lab034	5	14.4	15.8	4	0.9	5.7	21.1	20	1.8	5.8	5.0	4	0.1	2.0	17.8	20	3.1
Lab043	5	11.5	13.0	4	0.4	3.1	19.2	20	2.2	4.5	4.8	4	0.1	2.1	10.8	20	>6
Total	-	-	13.6	49	1.3	9.6	-	-	-	-	5.1	49	0.3	5.9	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%

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

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

[TOP](#)

Cumulative

Cumulative : from to

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	14.2	15.1	119	1.2	7.9	22.2	20	1.7	5.5	5.6	119	0.3	5.4	12.5	20	3.4
Lab019	5	15.3	15.2	85	0.3	2.0	4.6	20	>6	5.3	5.3	85	0.1	1.9	3.8	20	>6
Lab020	5	14.4	15.2	28	0.5	3.3	12.1	20	4.4	5.8	5.3	28	0.3	5.7	19.9	20	2.0
Lab026	5	15.9	14.0	229	1.4	10.0	31.9	20	0.8	5.8	5.1	229	0.4	7.8	27.8	20	1.0
Lab027	5	15.5	15.5	107	1.3	8.4	16.8	20	2.4	5.4	5.6	107	0.5	8.9	21.6	20	1.8
Lab028	5	14.4	14.6	83	0.7	4.8	11.0	20	3.9	5.8	5.6	83	0.3	5.4	14.2	20	3.1
Lab032	5	15.3	15.9	38	0.9	5.7	15.2	20	2.8	5.2	5.7	38	0.3	5.3	20.1	20	2.0
Lab033	5	14.4	14.9	49	0.6	4.0	11.5	20	4.1	5.8	5.2	49	0.2	3.8	18.0	20	2.5
Lab034	5	14.4	14.3	63	0.8	5.6	11.9	20	3.4	5.8	5.1	63	0.3	5.9	23.8	20	1.3
Lab037	5	14.9	15.2	30	0.8	5.3	12.5	20	3.4	5.4	5.5	30	0.3	5.5	12.8	20	3.3
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	13.1	77	0.9	6.9	27.7	20	0.9	4.5	4.9	77	0.3	6.1	21.1	20	1.8
Total	-	-	14.6	947	1.3	8.9	-	-	-	-	5.3	947	0.4	7.5	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 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 :

Select Reagent Kit :

Control N Month vs. Cumulative

		Control N (Lot No.: AE0909N)															
		Month (2019/09)								CUM (2016/02/01~2019/09/30)							
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	14.2	13.9	8	0.3	2.2	6.4	20	>6	14.2	15.1	119	1.2	7.9	22.2	20	1.7
Lab019	5	15.3	15.1	4	0.4	2.6	6.6	20	>6	15.3	15.2	85	0.3	2.0	4.6	20	>6
Lab020	5	14.4	-	0	-	-	-	20	-	14.4	15.2	28	0.5	3.3	12.1	20	4.4
Lab026	5	15.9	12.3	20	0.2	1.6	25.9	20	-1.7	15.9	14.0	229	1.4	10.0	31.9	20	0.8
Lab027	5	15.5	-	0	-	-	-	20	-	15.5	15.5	107	1.3	8.4	16.8	20	2.4
Lab028	5	14.4	15.0	9	0.3	2.0	8.2	20	>6	14.4	14.6	83	0.7	4.8	11.0	20	3.9
Lab032	5	15.3	-	0	-	-	-	20	-	15.3	15.9	38	0.9	5.7	15.2	20	2.8
Lab033	5	14.4	-	0	-	-	-	20	-	14.4	14.9	49	0.6	4.0	11.5	20	4.1
Lab034	5	14.4	15.8	4	0.9	5.7	21.1	20	1.8	14.4	14.3	63	0.8	5.6	11.9	20	3.4
Lab037	5	14.9	-	0	-	-	-	20	-	14.9	15.2	30	0.8	5.3	12.5	20	3.4
Lab040	5	14.4	-	0	-	-	-	20	-	14.4	13.3	39	0.7	5.3	18.2	20	2.3
Lab043	5	11.5	13.0	4	0.4	3.1	19.2	20	2.2	11.5	13.1	77	0.9	6.9	27.7	20	0.9
Total	-	-	13.6	49	1.3	9.6	-	-	-	-	14.6	947	1.3	8.9	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%

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

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

Month :

Cumulative : from to

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Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2019/09)								CUM (2016/02/01~2019/09/30)							
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	5.5	5.3	8	0.1	1.9	7.4	20	>6	5.5	5.6	119	0.3	5.4	12.5	20	3.4
Lab019	5	5.3	5.3	4	0.1	1.9	3.8	20	>6	5.3	5.3	85	0.1	1.9	3.8	20	>6
Lab020	5	5.8	-	0	-	-	-	20	-	5.8	5.3	28	0.3	5.7	19.9	20	2.0
Lab026	5	5.8	5.0	20	0.1	2.0	17.8	20	3.1	5.8	5.1	229	0.4	7.8	27.8	20	1.0
Lab027	5	5.4	-	0	-	-	-	20	-	5.4	5.6	107	0.5	8.9	21.6	20	1.8
Lab028	5	5.8	5.5	9	0.2	3.6	12.4	20	4.1	5.8	5.6	83	0.3	5.4	14.2	20	3.1
Lab032	5	5.2	-	0	-	-	-	20	-	5.2	5.7	38	0.3	5.3	20.1	20	2.0
Lab033	5	5.8	-	0	-	-	-	20	-	5.8	5.2	49	0.2	3.8	18.0	20	2.5
Lab034	5	5.8	5.0	4	0.1	2.0	17.8	20	3.1	5.8	5.1	63	0.3	5.9	23.8	20	1.3
Lab037	5	5.4	-	0	-	-	-	20	-	5.4	5.5	30	0.3	5.5	12.8	20	3.3
Lab040	5	5.8	-	0	-	-	-	20	-	5.8	4.7	39	0.3	6.4	31.7	20	0.2
Lab043	5	4.5	4.8	4	0.1	2.1	10.8	20	>6	4.5	4.9	77	0.3	6.1	21.1	20	1.8
Total	-	-	5.1	49	0.3	5.9	-	-	-	-	5.3	947	0.4	7.5	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%

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

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

Month :

Cumulative : from to

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5