

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

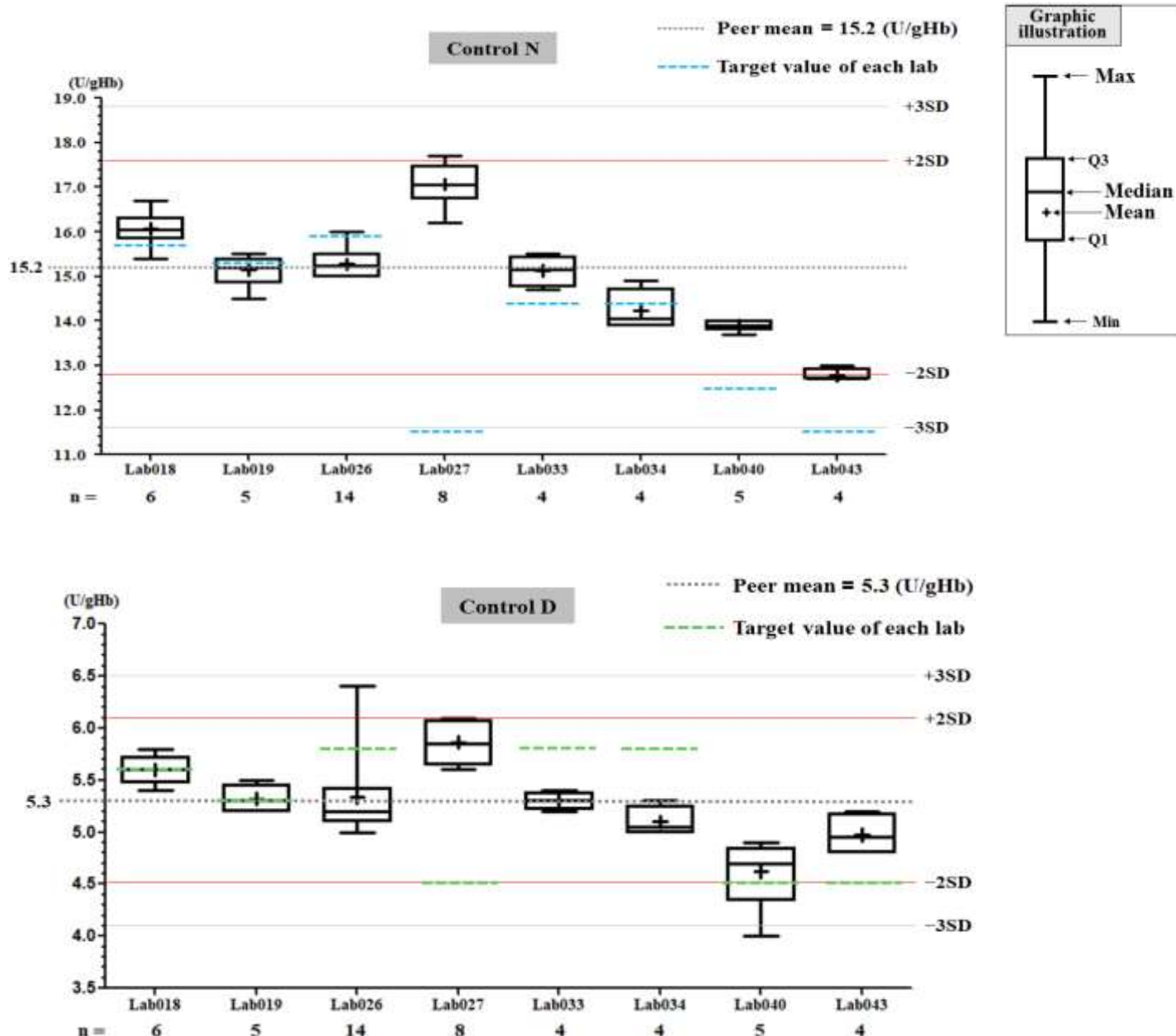
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	8	8
Received results number (n)	50	50
Median	15.3 (U/gHb)	5.3 (U/gHb)
Mean	15.2 (U/gHb)	5.3 (U/gHb)
SD	1.2	0.4
CV	7.9%	7.5%
Range of G6PD	12.7 ~ 17.7 (U/gHb)	4.0 ~ 6.4 (U/gHb)
Range of Hb	1.5 ~ 2.3 (g/dL)	1.7 ~ 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](#)

Lab019

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2018/09)	CUM (2018/04/11~2018/09/30)	Month (2018/09)	CUM (2018/04/11~2018/09/30)
Runs (N)	5	26	5	26
Mean (U/gHb)	15.1	15.1	5.3	5.3
SD	0.4	0.4	0.1	0.2
CV (%)	2.6	2.6	1.9	3.8
Target Value (U/gHb)	15.3	15.3	5.3	5.3
Total Error (%)	6.6	6.6	3.8	7.5
TEa (%)	20	20	20	20
σ	>6	>6	>6	5.3

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

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

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

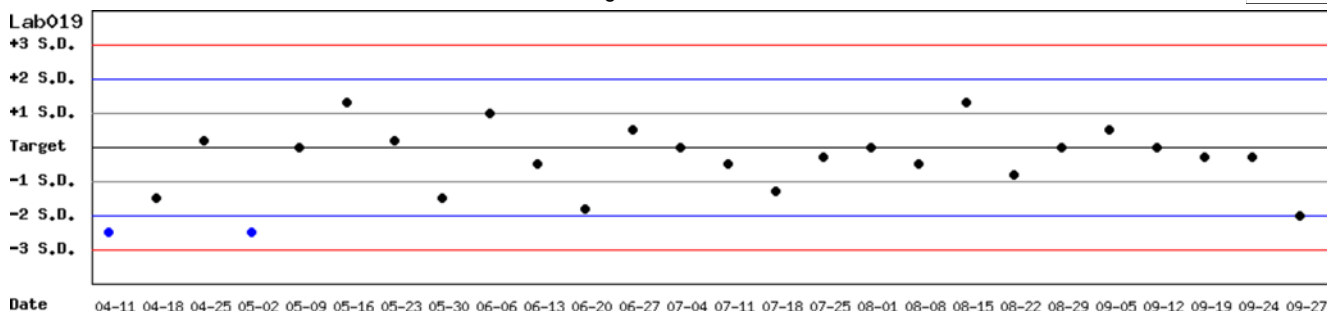
Month : 2018 09 [Change](#) ; Cumulative : from 2018 04 11 to 2018 09 30 [Change](#)

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Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-04-11 to 2018-09-30 ; Target : 15.3 ; SD : 0.40

Lab019



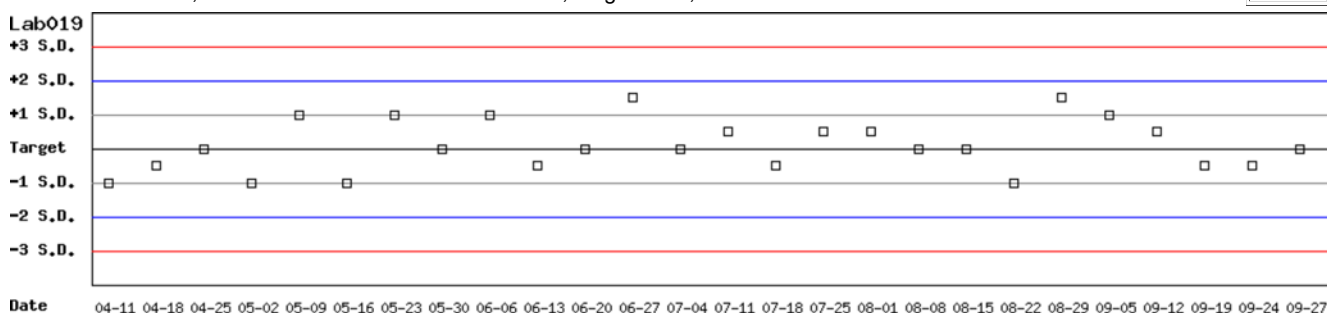
Month : 2018 09 [Change](#) ; Cumulative : from 2018 04 11 to 2018 09 30 [Change](#)

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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2018-04-11 to 2018-09-30 ; Target : 5.3 ; SD : 0.20

Lab019



Month : 2018 09 [Change](#) ; Cumulative : from 2018 04 11 to 2018 09 30 [Change](#)

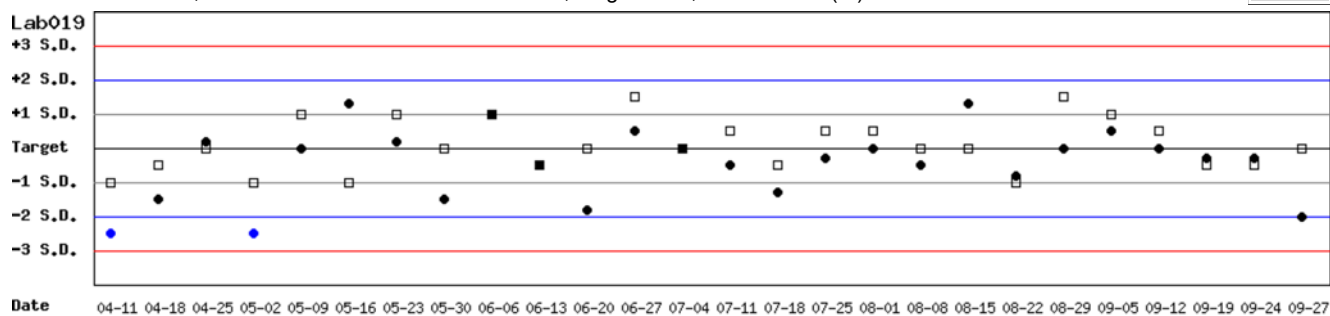
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Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-04-11 to 2018-09-30 ; Target : 15.3 ; SD : 0.40 (●)

Lot No.: AE0909D ; Duration : 2018-04-11 to 2018-09-30 ; Target : 5.3 ; SD : 0.20 (□)

Lab019



Month : 2018 09 ; Cumulative : from 2018 04 11 to 2018 09 30

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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 09 Change

		Control N (Lot No.: AE0909N)									Control D (Lot No.: AE0909D)							
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	16.1	6	0.4	2.5	7.5	20	>6		5.6	5.6	6	0.1	1.8	3.6	20	>6
Lab019	5	15.3	15.1	5	0.4	2.6	6.6	20	>6		5.3	5.3	5	0.1	1.9	3.8	20	>6
Lab026	5	15.9	15.3	14	0.3	2.0	7.7	20	>6		5.8	5.3	14	0.4	7.5	23.7	20	1.5
Lab027	5	11.5	17.1	8	0.5	2.9	54.5	20	-9.9		4.5	5.9	8	0.2	3.4	37.9	20	-3.3
Lab033	5	14.4	15.1	4	0.4	2.6	10.2	20	5.8		5.8	5.3	4	0.1	1.9	12.4	20	6.0
Lab034	5	14.4	14.2	4	0.5	3.5	8.4	20	5.3		5.8	5.1	4	0.1	2.0	16.0	20	4.0
Lab040	5	12.5	13.9	5	0.1	0.7	12.6	20	>6		4.5	4.6	5	0.4	8.7	19.6	20	2.0
Lab043	5	11.5	12.8	4	0.2	1.6	14.4	20	5.4		4.5	5.0	4	0.2	4.0	19.1	20	2.2
Total	-	-	15.2	50	1.2	7.9	-	-	-		-	5.3	50	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 (%)

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Cumulative

Cumulative : from 2016 02 01 to 2018 09 30 Change

		Control N (Lot No.: AE0909N)									Control D (Lot No.: AE0909D)							
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	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	15.1	34	0.4	2.6	6.6	20	>6		5.3	5.3	34	0.2	3.8	7.5	20	5.3
Lab026	5	15.9	15.3	100	0.4	2.6	9.0	20	>6		5.8	5.2	100	0.5	9.6	29.6	20	1.0
Lab027	5	11.5	16.1	52	1.4	8.7	57.4	20	-2.3		4.5	5.6	52	0.4	7.1	38.7	20	-0.6
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	14.8	23	0.7	4.7	12.2	20	3.7		5.8	5.2	23	0.2	3.8	18.0	20	2.5
Lab034	5	14.4	14.1	28	0.5	3.5	9.2	20	5.1		5.8	5.0	28	0.3	6.0	25.8	20	1.0
Lab040	5	12.5	13.2	38	0.6	4.5	14.7	20	3.2		4.5	4.7	38	0.3	6.4	17.2	20	2.4
Lab043	5	11.5	13.4	33	1.2	9.0	34.4	20	0.4		4.5	5.1	33	0.3	5.9	25.1	20	1.1
Total	-	-	15.1	390	1.3	8.6	-	-	-		-	5.3	390	0.5	9.4	-	-	-

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 (%)

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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 (2018/09)										CUM (2016/02/01~2018/09/30)							
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	15.7	16.1	6	0.4	2.5	7.5	20	>6	15.7	16.1	60	0.7	4.3	11.2	20	4.1
Lab019	5	15.3	15.1	5	0.4	2.6	6.6	20	>6	15.3	15.1	34	0.4	2.6	6.6	20	>6
Lab026	5	15.9	15.3	14	0.3	2.0	7.7	20	>6	15.9	15.3	100	0.4	2.6	9.0	20	>6
Lab027	5	11.5	17.1	8	0.5	2.9	54.5	20	-9.9	11.5	16.1	52	1.4	8.7	57.4	20	-2.3
Lab032	5	15.9	-	0	-	-	-	20	-	15.9	15.8	22	1.0	6.3	13.3	20	3.1
Lab033	5	14.4	15.1	4	0.4	2.6	10.2	20	5.8	14.4	14.8	23	0.7	4.7	12.2	20	3.7
Lab034	5	14.4	14.2	4	0.5	3.5	8.4	20	5.3	14.4	14.1	28	0.5	3.5	9.2	20	5.1
Lab040	5	12.5	13.9	5	0.1	0.7	12.6	20	>6	12.5	13.2	38	0.6	4.5	14.7	20	3.2
Lab043	5	11.5	12.8	4	0.2	1.6	14.4	20	5.4	11.5	13.4	33	1.2	9.0	34.4	20	0.4
Total	-	-	15.2	50	1.2	7.9	-	-	-	-	15.1	390	1.3	8.6	-	-	-

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

TE : Total Error(%) = Bias (%) + $2 \times \text{CV} (%)$

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

Month : 2018 09

Cumulative : from 2016 02 01 to 2018 09 30

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Control D Month vs. Cumulative

Control D (Lot No.: AE0909D)																	
Month (2018/09)										CUM (2016/02/01~2018/09/30)							
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	5.6	5.6	6	0.1	1.8	3.6	20	>6	5.6	5.7	60	0.3	5.3	12.3	20	3.4
Lab019	5	5.3	5.3	5	0.1	1.9	3.8	20	>6	5.3	5.3	34	0.2	3.8	7.5	20	5.3
Lab026	5	5.8	5.3	14	0.4	7.5	23.7	20	1.5	5.8	5.2	100	0.5	9.6	29.6	20	1.0
Lab027	5	4.5	5.9	8	0.2	3.4	37.9	20	-3.3	4.5	5.6	52	0.4	7.1	38.7	20	-0.6
Lab032	5	5.8	-	0	-	-	-	20	-	5.8	5.7	22	0.4	7.0	15.8	20	2.6
Lab033	5	5.8	5.3	4	0.1	1.9	12.4	20	6.0	5.8	5.2	23	0.2	3.8	18.0	20	2.5
Lab034	5	5.8	5.1	4	0.1	2.0	16.0	20	4.0	5.8	5.0	28	0.3	6.0	25.8	20	1.0
Lab040	5	4.5	4.6	5	0.4	8.7	19.6	20	2.0	4.5	4.7	38	0.3	6.4	17.2	20	2.4
Lab043	5	4.5	5.0	4	0.2	4.0	19.1	20	2.2	4.5	5.1	33	0.3	5.9	25.1	20	1.1
Total	-	-	5.3	50	0.4	7.5	-	-	-	-	5.3	390	0.5	9.4	-	-	-

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

TE : Total Error(%) = Bias (%) + $2 \times \text{CV} (%)$

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

Month : 2018 09

Cumulative : from 2016 02 01 to 2018 09 30

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Reagent Kit	Reagent Code
Medicon	5