

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

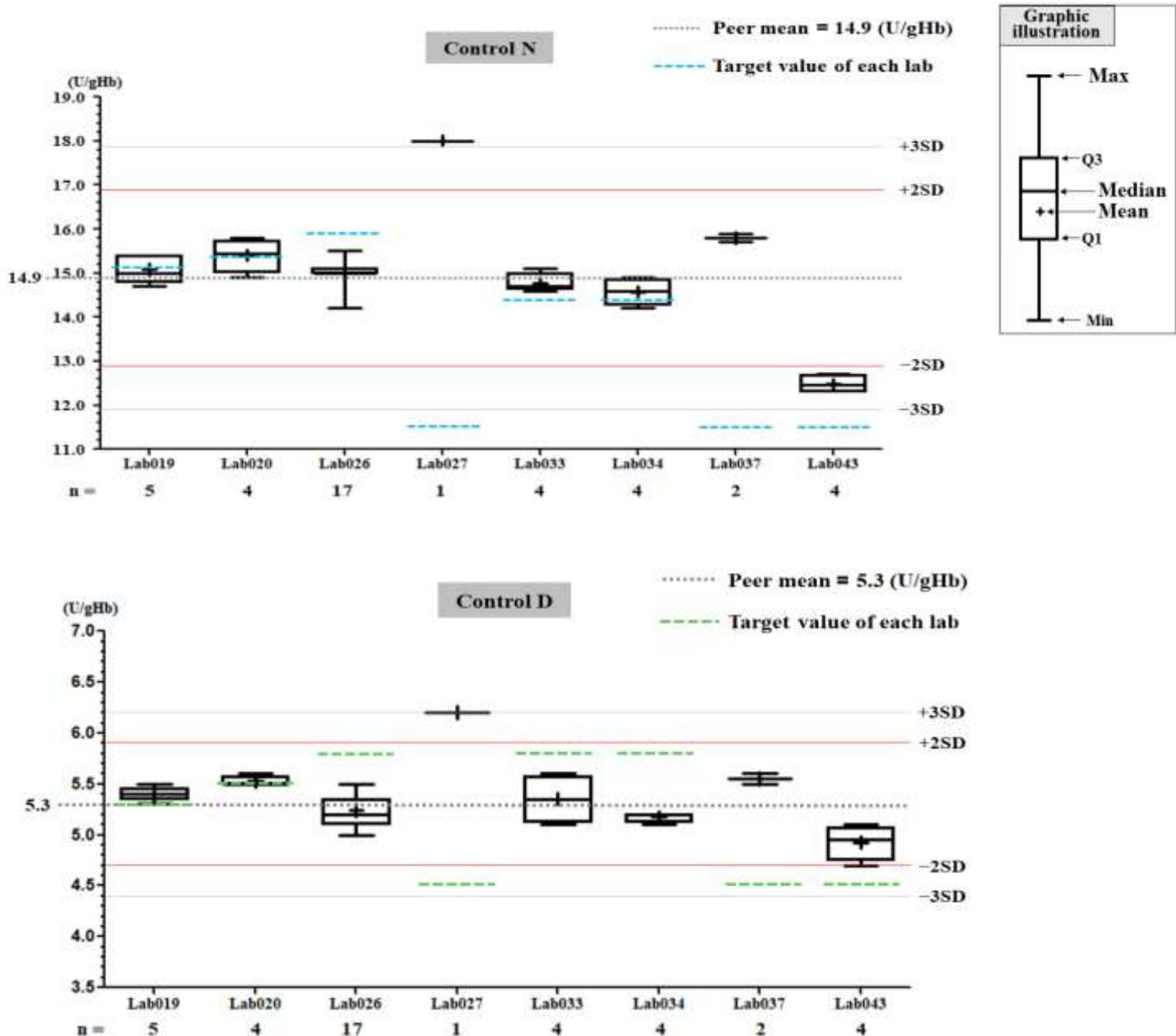
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	8	8
Received results number (n)	41	41
Median	15.0 (U/gHb)	5.3 (U/gHb)
Mean	14.9 (U/gHb)	5.3 (U/gHb)
SD	1.0	0.3
CV	6.7%	5.7%
Range of G6PD	12.3 ~ 18.0 (U/gHb)	4.7 ~ 6.2 (U/gHb)
Range of Hb	1.7 ~ 2.1 (g/dL)	2.0 ~ 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](#)

Lab027

QC Control Lot No.	Control N		Control D	
	AE0909N		AE0909D	
Duration of the Analyzing	Month (2018/10)	CUM (2018/07/05~2018/10/31)	Month (2018/10)	CUM (2018/07/05~2018/10/31)
Runs (N)	1	26	1	26
Mean (U/gHb)	18.0	16.8	6.2	5.8
SD	-	0.9	-	0.2
CV (%)	-	5.4	-	3.4
Target Value (U/gHb)	11.5	11.5	4.5	4.5
Total Error (%)	-	56.8	-	35.8
TEa (%)	20	20	20	20
σ	-	-4.8	-	-2.6

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

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

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

Month : 2018 10 [Change](#) ; Cumulative : from 2018 07 05 to 2018 10 31 [Change](#)

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Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-07-05 to 2018-10-31 ; Target : 11.5 ; SD : 0.6

Lab027



Date 07-05 07-10 07-12 07-17 07-19 07-24 07-26 07-31 08-02 08-07 08-09 08-14 08-16 08-21 08-23 08-28 08-30 09-04 09-06 09-11 09-13 09-18 09-20 09-25 09-27 10-02

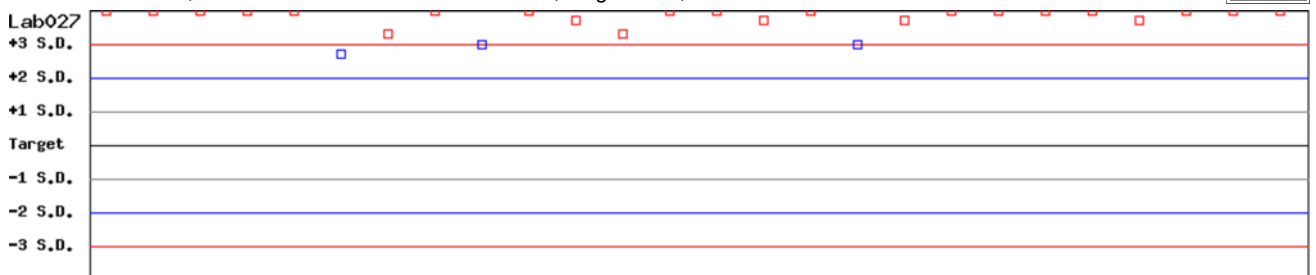
Month : 2018 10 [Change](#) ; Cumulative : from 2018 07 05 to 2018 10 31 [Change](#)

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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2018-07-05 to 2018-10-31 ; Target : 4.5 ; SD : 0.3

Lab027



Date 07-05 07-10 07-12 07-17 07-19 07-24 07-26 07-31 08-02 08-07 08-09 08-14 08-16 08-21 08-23 08-28 08-30 09-04 09-06 09-11 09-13 09-18 09-20 09-25 09-27 10-02

Month : 2018 10 [Change](#) ; Cumulative : from 2018 07 05 to 2018 10 31 [Change](#)

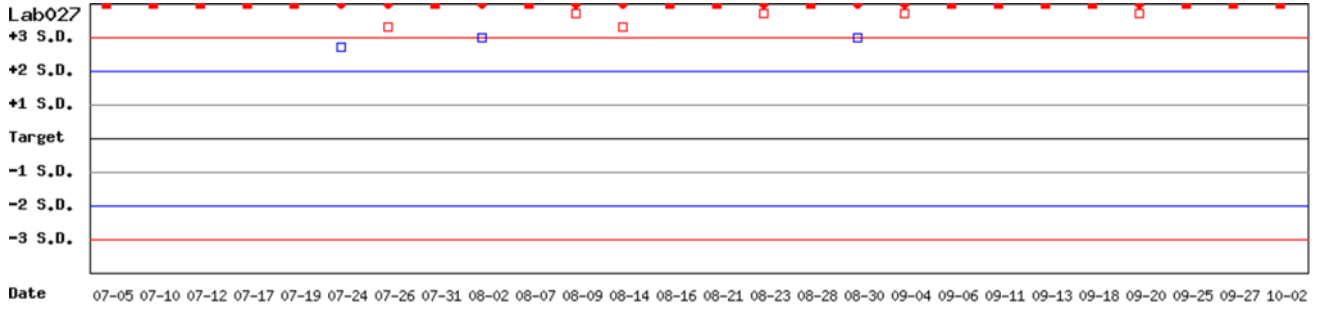
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Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-07-05 to 2018-10-31 ; Target : 11.5 ; SD : 0.6 (●)

Lot No.: AE0909D ; Duration : 2018-07-05 to 2018-10-31 ; Target : 4.5 ; SD : 0.3 (□)

Lab027



Month : 2018 10 ; Cumulative : from 2018 07 05 to 2018 10 31

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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 ▼ 10 ▼ 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	15.1	5	0.3	2.0	5.3	20	>6	5.3	5.4	5	0.1	1.9	5.6	20	>6
Lab020	5	15.4	15.4	4	0.4	2.6	5.2	20	>6	5.5	5.5	4	0.1	1.8	3.6	20	>6
Lab026	5	15.9	15.0	17	0.3	2.0	9.7	20	>6	5.8	5.2	17	0.2	3.8	18.0	20	2.5
Lab027	5	11.5	18.0	1	-	-	-	20	-	4.5	6.2	1	-	-	-	20	-
Lab033	5	14.4	14.8	4	0.2	1.4	5.5	20	>6	5.8	5.4	4	0.2	3.7	14.3	20	3.5
Lab034	5	14.4	14.6	4	0.3	2.1	5.5	20	>6	5.8	5.2	4	0.1	1.9	14.2	20	5.1
Lab037	5	11.5	15.8	2	-	-	-	20	-	4.5	5.6	2	-	-	-	20	-
Lab043	5	11.5	12.5	4	0.2	1.6	11.9	20	>6	4.5	4.9	4	0.2	4.1	17.1	20	2.7
Total	-	-	14.9	41	1.0	6.7	-	-	-	-	5.3	41	0.3	5.7	-	-	-

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from 2016 ▼ 02 ▼ 01 ▼ to 2018 ▼ 10 ▼ 31 ▼ 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	15.1	39	0.4	2.6	6.6	20	>6	5.3	5.3	39	0.2	3.8	7.5	20	5.3
Lab020	5	15.4	15.4	4	0.4	2.6	5.2	20	>6	5.5	5.5	4	0.1	1.8	3.6	20	>6
Lab026	5	15.9	15.3	117	0.4	2.6	9.0	20	>6	5.8	5.2	117	0.4	7.7	25.7	20	1.3
Lab027	5	11.5	16.2	53	1.4	8.6	58.2	20	-2.4	4.5	5.6	53	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	27	0.6	4.1	10.9	20	4.2	5.8	5.3	27	0.2	3.8	16.2	20	3.0
Lab034	5	14.4	14.1	32	0.5	3.5	9.2	20	5.1	5.8	5.0	32	0.3	6.0	25.8	20	1.0
Lab037	5	11.5	15.8	2	-	-	-	20	-	4.5	5.6	2	-	-	-	20	-
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	13.3	37	1.1	8.3	32.2	20	0.5	4.5	5.1	37	0.3	5.9	25.1	20	1.1
Total	-	-	15.0	431	1.3	8.7	-	-	-	-	5.3	431	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 (2018/10)								CUM (2016/02/01~2018/10/31)							
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
Lab018	5	15.7	-	0	-	-	-	20	-	15.7	16.1	60	0.7	4.3	11.2	20	4.1
Lab019	5	15.3	15.1	5	0.3	2.0	5.3	20	>6	15.3	15.1	39	0.4	2.6	6.6	20	>6
Lab020	5	15.4	15.4	4	0.4	2.6	5.2	20	>6	15.4	15.4	4	0.4	2.6	5.2	20	>6
Lab026	5	15.9	15.0	17	0.3	2.0	9.7	20	>6	15.9	15.3	117	0.4	2.6	9.0	20	>6
Lab027	5	11.5	18.0	1	-	-	-	20	-	11.5	16.2	53	1.4	8.6	58.2	20	-2.4
Lab032	5	15.9	-	0	-	-	-	20	-	15.9	15.8	22	1.0	6.3	13.3	20	3.1
Lab033	5	14.4	14.8	4	0.2	1.4	5.5	20	>6	14.4	14.8	27	0.6	4.1	10.9	20	4.2
Lab034	5	14.4	14.6	4	0.3	2.1	5.5	20	>6	14.4	14.1	32	0.5	3.5	9.2	20	5.1
Lab037	5	11.5	15.8	2	-	-	-	20	-	11.5	15.8	2	-	-	-	20	-
Lab040	5	12.5	-	0	-	-	-	20	-	12.5	13.2	38	0.6	4.5	14.7	20	3.2
Lab043	5	11.5	12.5	4	0.2	1.6	11.9	20	>6	11.5	13.3	37	1.1	8.3	32.2	20	0.5
Total	-	-	14.9	41	1.0	6.7	-	-	-	-	15.0	431	1.3	8.7	-	-	-

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

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

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

Month :

Cumulative : from to

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2018/10)								CUM (2016/02/01~2018/10/31)							
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
Lab018	5	5.6	-	0	-	-	-	20	-	5.6	5.7	60	0.3	5.3	12.3	20	3.4
Lab019	5	5.3	5.4	5	0.1	1.9	5.6	20	>6	5.3	5.3	39	0.2	3.8	7.5	20	5.3
Lab020	5	5.5	5.5	4	0.1	1.8	3.6	20	>6	5.5	5.5	4	0.1	1.8	3.6	20	>6
Lab026	5	5.8	5.2	17	0.2	3.8	18.0	20	2.5	5.8	5.2	117	0.4	7.7	25.7	20	1.3
Lab027	5	4.5	6.2	1	-	-	-	20	-	4.5	5.6	53	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	5.4	4	0.2	3.7	14.3	20	3.5	5.8	5.3	27	0.2	3.8	16.2	20	3.0
Lab034	5	5.8	5.2	4	0.1	1.9	14.2	20	5.1	5.8	5.0	32	0.3	6.0	25.8	20	1.0
Lab037	5	4.5	5.6	2	-	-	-	20	-	4.5	5.6	2	-	-	-	20	-
Lab040	5	4.5	-	0	-	-	-	20	-	4.5	4.7	38	0.3	6.4	17.2	20	2.4
Lab043	5	4.5	4.9	4	0.2	4.1	17.1	20	2.7	4.5	5.1	37	0.3	5.9	25.1	20	1.1
Total	-	-	5.3	41	0.3	5.7	-	-	-	-	5.3	431	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