

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

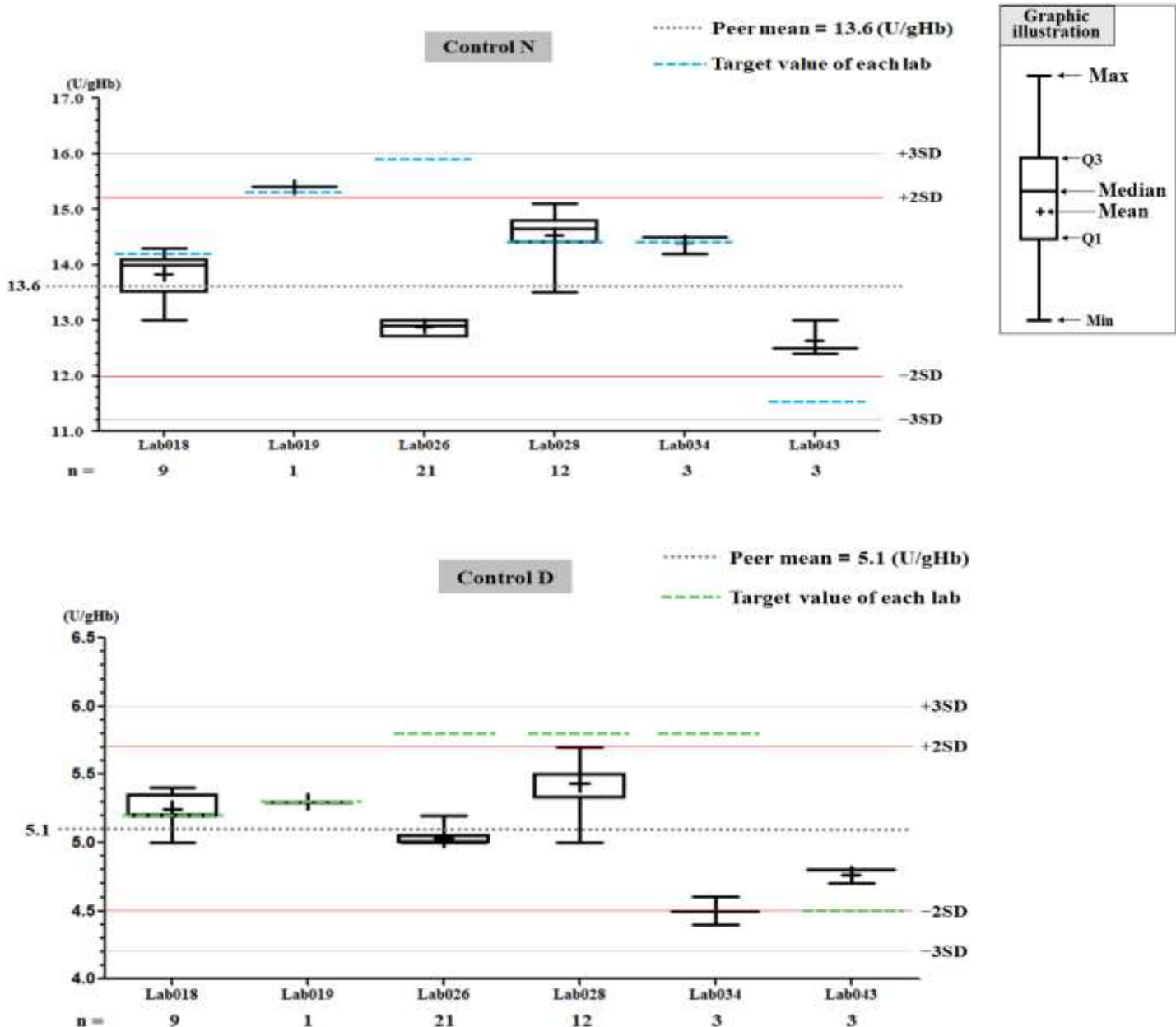
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	6	6
Received results number (n)	49	49
Median	13.0 (U/gHb)	5.1 (U/gHb)
Mean	13.6 (U/gHb)	5.1 (U/gHb)
SD	0.8	0.3
CV	5.9%	5.7%
Range of G6PD	12.4 ~ 15.4 (U/gHb)	4.4 ~ 5.7 (U/gHb)
Range of Hb	1.8 ~ 2.1 (g/dL)	2.0 ~ 2.3 (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

QC Control Lot No.	Control N		Control D	
	AE0909N		AE0909D	
Duration of the Analyzing	Month (2019/11)	CUM (2019/01/24~2019/11/30)	Month (2019/11)	CUM (2019/01/24~2019/11/30)
Runs (N)	3	26	3	26
Mean (U/gHb)	14.4	14.9	4.5	5.1
SD	0.2	0.9	0.1	0.5
CV (%)	1.4	6.0	2.2	9.8
Target Value (U/gHb)	14.4	14.4	5.8	5.8
Total Error (%)	2.8	15.6	26.9	31.7
TEa (%)	20	20	20	20
σ	>6	2.8	-1.1	0.8

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

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

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

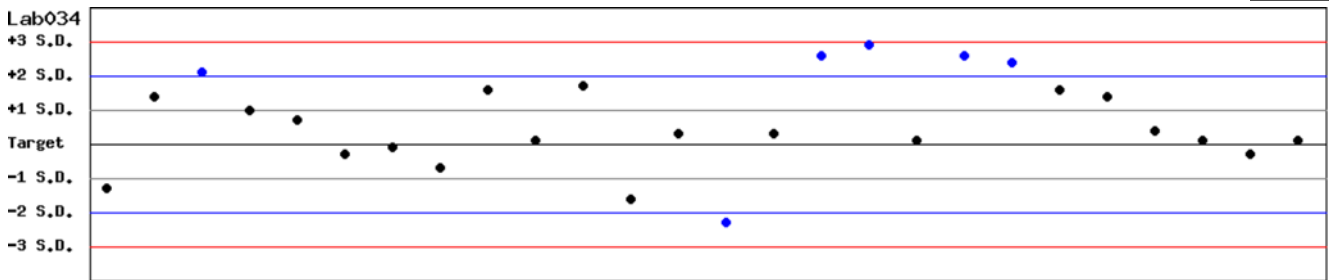
Month : 2019 11 [Change](#) ; Cumulative : from 2019 01 24 to 2019 11 30 [Change](#)

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Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-01-24 to 2019-11-30 ; Target : 14.4 ; SD : 0.70

Lab034



Date 01-24 02-07 02-14 02-21 02-28 03-07 07-04 07-11 07-18 07-25 08-01 08-08 08-15 08-23 08-30 09-05 09-12 09-19 09-26 10-03 10-17 10-24 10-31 11-07 11-14 11-21

Month : 2019 11 [Change](#) ; Cumulative : from 2019 01 24 to 2019 11 30 [Change](#)

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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2019-01-24 to 2019-11-30 ; Target : 5.8 ; SD : 0.50

Lab034



Date 01-24 02-07 02-14 02-21 02-28 03-07 07-04 07-11 07-18 07-25 08-01 08-08 08-15 08-23 08-30 09-05 09-12 09-19 09-26 10-03 10-17 10-24 10-31 11-07 11-14 11-21

Month : 2019 11 [Change](#) ; Cumulative : from 2019 01 24 to 2019 11 30 [Change](#)

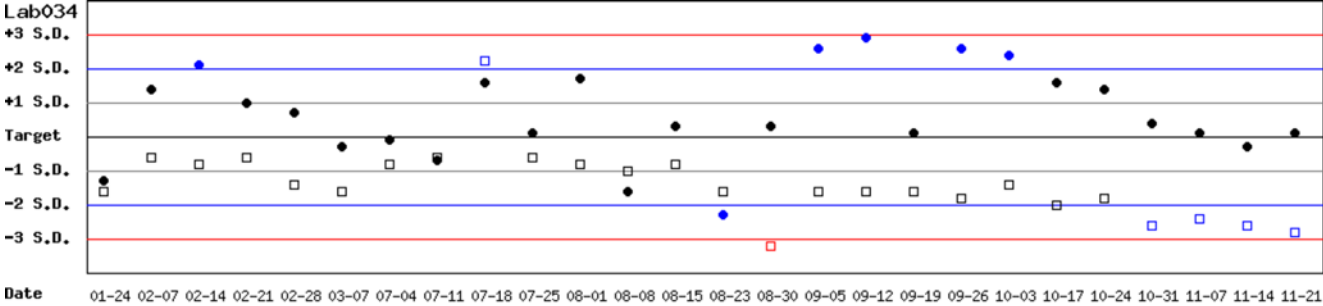
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Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-01-24 to 2019-11-30 ; Target : 14.4 ; SD : 0.70 (●)

Lot No.: AE0909D ; Duration : 2019-01-24 to 2019-11-30 ; Target : 5.8 ; SD : 0.50 (□)

Lab034



Month : 2019 | 11 | ; Cumulative : from 2019 | 01 | 24 to 2019 | 11 | 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 : 2019 ▼ 11 ▼ 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	14.2	13.8	9	0.5	3.6	10.1	20	4.8	5.5	5.2	9	0.1	1.9	9.3	20	>6
Lab019	5	15.3	15.4	1	-	-	-	20	-	5.3	5.3	1	-	-	-	20	-
Lab026	5	15.9	12.9	21	0.1	0.8	20.4	20	1.4	5.8	5.0	21	0.1	2.0	17.8	20	3.1
Lab028	5	14.4	14.5	12	0.5	3.4	7.6	20	5.7	5.8	5.4	12	0.2	3.7	14.3	20	3.5
Lab034	5	14.4	14.4	3	0.2	1.4	2.8	20	>6	5.8	4.5	3	0.1	2.2	26.9	20	-1.1
Lab043	5	11.5	12.6	3	0.3	2.4	14.3	20	4.3	4.5	4.8	3	0.1	2.1	10.8	20	>6
Total	-	-	13.6	49	0.8	5.9	-	-	-	-	5.1	49	0.3	5.9	-	-	-

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

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

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

[TOP](#)

Cumulative

Cumulative : from 2016 ▼ 02 ▼ 01 ▼ to 2019 ▼ 11 ▼ 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	14.2	14.9	137	1.2	8.1	21.0	20	1.9	5.5	5.5	137	0.3	5.5	10.9	20	3.6
Lab019	5	15.3	15.2	90	0.3	2.0	4.6	20	>6	5.3	5.3	90	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	13.8	275	1.4	10.1	33.5	20	0.7	5.8	5.1	275	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	108	0.7	4.8	11.0	20	3.9	5.8	5.6	108	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	14.4	70	0.8	5.6	11.1	20	3.6	5.8	5.1	70	0.4	7.8	27.8	20	1.0
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	80	0.9	6.9	27.7	20	0.9	4.5	4.9	80	0.3	6.1	21.1	20	1.8
Total	-	-	14.5	1051	1.3	9.0	-	-	-	-	5.3	1051	0.4	7.5	-	-	-

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

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

Select Reagent Kit : 5 - Medicon Change

Print Table 2

Control N Month vs. Cumulative

		Control N (Lot No.: AE0909N)															
		Month (2019/11)								CUM (2016/02/01~2019/11/30)							
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	13.8	9	0.5	3.6	10.1	20	4.8	14.2	14.9	137	1.2	8.1	21.0	20	1.9
Lab019	5	15.3	15.4	1	-	-	-	20	-	15.3	15.2	90	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	12.9	21	0.1	0.8	20.4	20	1.4	15.9	13.8	275	1.4	10.1	33.5	20	0.7
Lab027	5	15.5	-	0	-	-	-	20	-	15.5	15.5	107	1.3	8.4	16.8	20	2.4
Lab028	5	14.4	14.5	12	0.5	3.4	7.6	20	5.7	14.4	14.6	108	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	14.4	3	0.2	1.4	2.8	20	>6	14.4	14.4	70	0.8	5.6	11.1	20	3.6
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	12.6	3	0.3	2.4	14.3	20	4.3	11.5	13.1	80	0.9	6.9	27.7	20	0.9
Total	-	-	13.6	49	0.8	5.9	-	-	-	-	14.5	1051	1.3	9.0	-	-	-

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

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

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

Month : 2019 11 Change

Cumulative : from 2016 02 01 to 2019 11 30 Change

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2019/11)								CUM (2016/02/01~2019/11/30)							
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	5.2	9	0.1	1.9	9.3	20	>6	5.5	5.5	137	0.3	5.5	10.9	20	3.6
Lab019	5	5.3	5.3	1	-	-	-	20	-	5.3	5.3	90	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	21	0.1	2.0	17.8	20	3.1	5.8	5.1	275	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	5.4	12	0.2	3.7	14.3	20	3.5	5.8	5.6	108	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	4.5	3	0.1	2.2	26.9	20	-1.1	5.8	5.1	70	0.4	7.8	27.8	20	1.0
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	3	0.1	2.1	10.8	20	>6	4.5	4.9	80	0.3	6.1	21.1	20	1.8
Total	-	-	5.1	49	0.3	5.9	-	-	-	-	5.3	1051	0.4	7.5	-	-	-

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

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

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

Month : 2019 11 Change

Cumulative : from 2016 02 01 to 2019 11 30 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5