

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

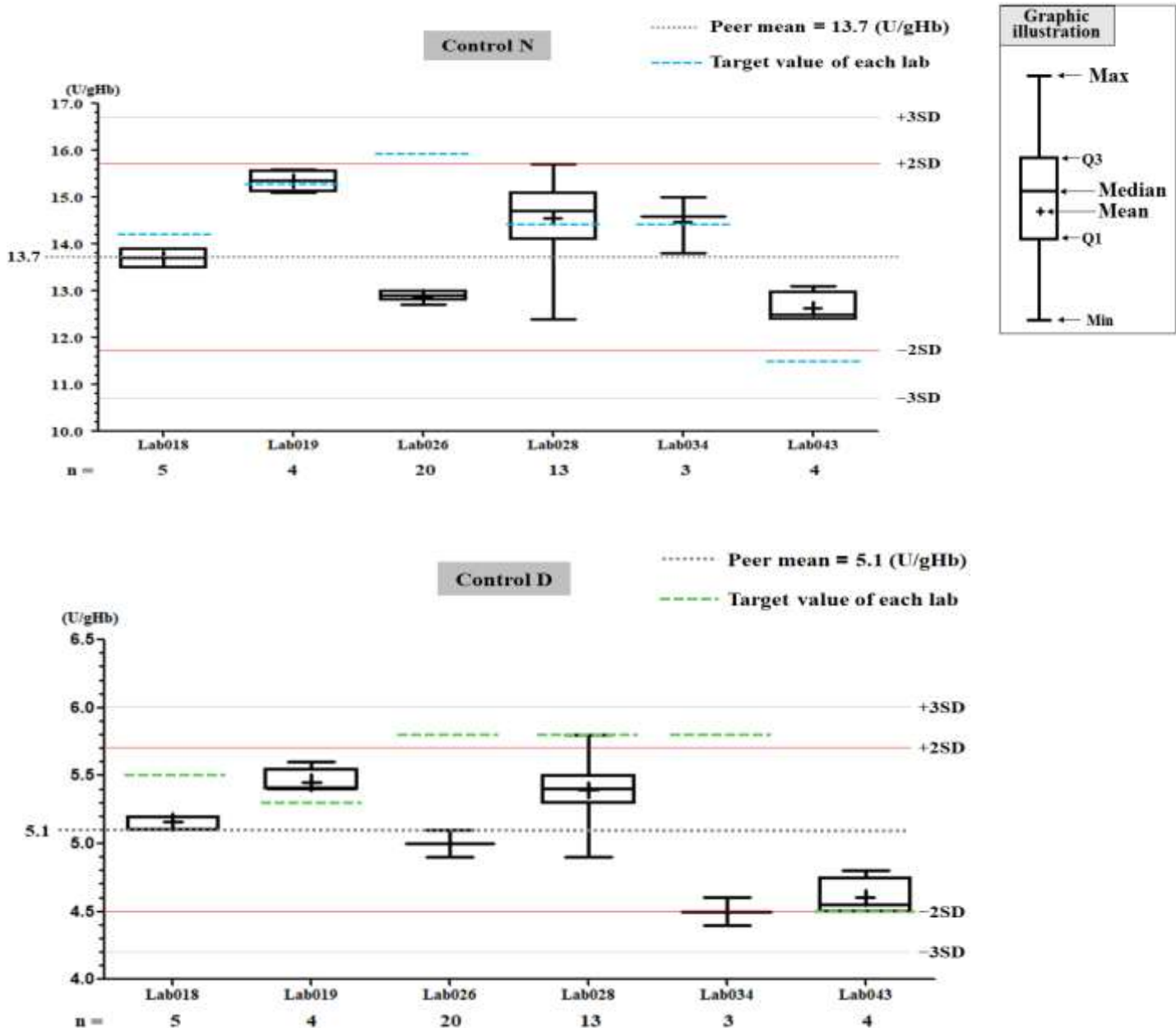
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	6	6
Received results number (n)	49	49
Median	13.1 (U/gHb)	5.0 (U/gHb)
Mean	13.7 (U/gHb)	5.1 (U/gHb)
SD	1.0	0.3
CV	7.3%	5.9%
Range of G6PD	12.4 ~ 15.7 (U/gHb)	4.4 ~ 5.8 (U/gHb)
Range of Hb	1.0 ~ 2.8 (g/dL)	1.1 ~ 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](#)

Lab026

QC Control Lot No.	Control N		Control D	
	AE0909N		AE0909D	
Duration of the Analyzing	Month (2019/12)	CUM (2019/11/22~2019/12/31)	Month (2019/12)	CUM (2019/11/22~2019/12/31)
Runs (N)	20	26	20	26
Mean (U/gHb)	12.9	12.9	5.0	5.0
SD	0.1	0.1	0.0	0.0
CV (%)	0.8	0.8	0.0	0.0
Target Value (U/gHb)	15.9	15.9	5.8	5.8
Total Error (%)	20.4	20.4	13.8	13.8
TEa (%)	20	20	20	20
σ	1.4	1.4	>6	>6

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

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

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

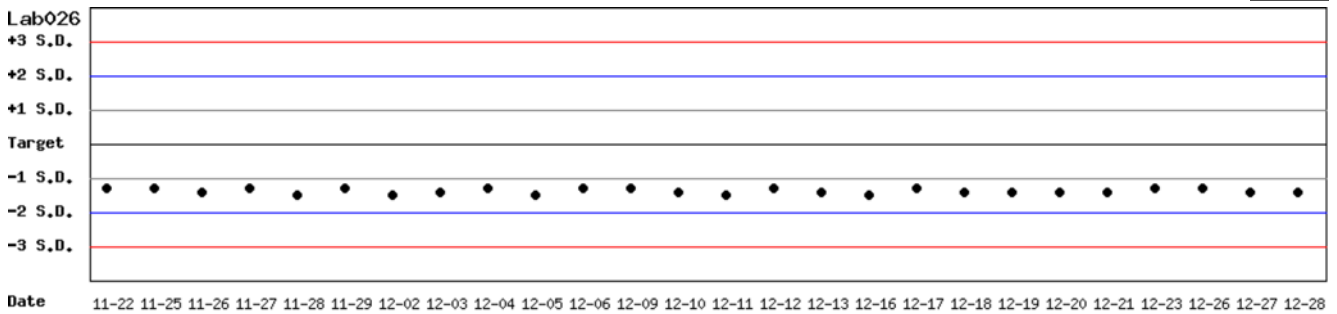
Month : 2019 12 [Change](#) ; Cumulative : from 2019 11 22 to 2019 12 31 [Change](#)

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Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-11-22 to 2019-12-31 ; Target : 15.9 ; SD : 2.20

Lab026



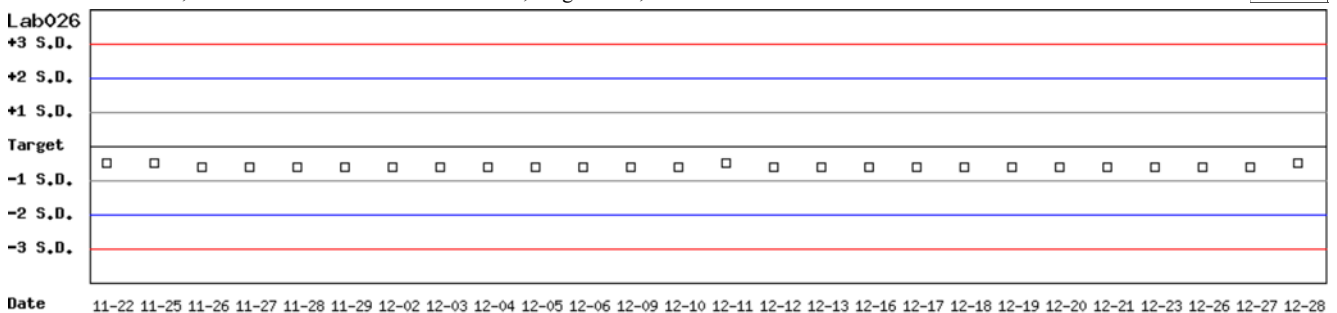
Month : 2019 12 [Change](#) ; Cumulative : from 2019 11 22 to 2019 12 31 [Change](#)

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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2019-11-22 to 2019-12-31 ; Target : 5.8 ; SD : 1.40

Lab026



Month : 2019 12 [Change](#) ; Cumulative : from 2019 11 22 to 2019 12 31 [Change](#)

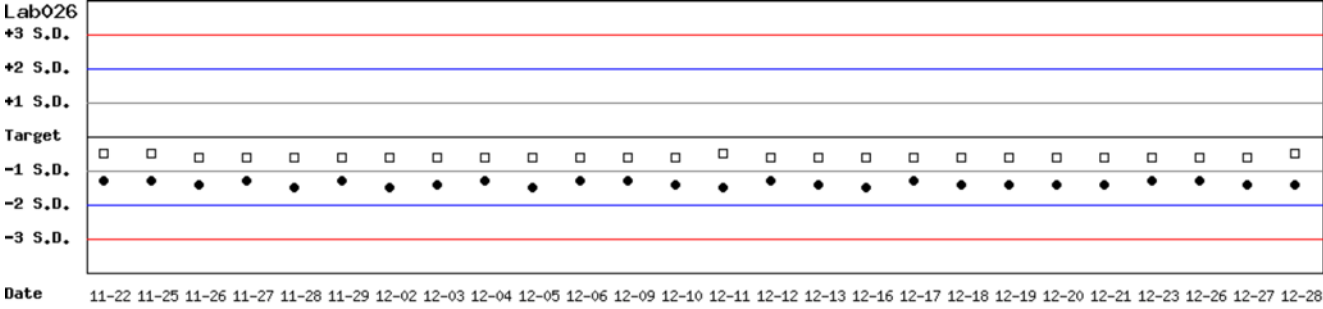
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Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-11-22 to 2019-12-31 ; Target : 15.9 ; SD : 2.20 (●)

Lot No.: AE0909D ; Duration : 2019-11-22 to 2019-12-31 ; Target : 5.8 ; SD : 1.40 (□)

Lab026



Month : 2019 | 12 | ; Cumulative : from 2019 | 11 | 22 to 2019 | 12 | 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 : 2019 12 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	13.7	5	0.2	1.5	6.4	20	>6	5.5	5.2	5	0.1	1.9	9.3	20	>6
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
Lab026	5	15.9	12.9	20	0.1	0.8	20.4	20	1.4	5.8	5.0	20	0.0	0.0	13.8	20	>6
Lab028	5	14.4	14.6	13	0.9	6.2	13.7	20	3.0	5.8	5.4	13	0.2	3.7	14.3	20	3.5
Lab034	5	14.4	14.5	3	0.6	4.1	9.0	20	4.7	5.8	4.5	3	0.1	2.2	26.9	20	-1.1
Lab043	5	11.5	12.6	4	0.3	2.4	14.3	20	4.3	4.5	4.6	4	0.1	2.2	6.6	20	>6
Total	-	-	13.7	49	1.0	7.3	-	-	-	-	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 12 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	14.2	14.9	142	1.2	8.1	21.0	20	1.9	5.5	5.5	142	0.3	5.5	10.9	20	3.6
Lab019	5	15.3	15.2	94	0.3	2.0	4.6	20	>6	5.3	5.3	94	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	13.7	295	1.4	10.2	34.3	20	0.6	5.8	5.1	295	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	121	0.7	4.8	11.0	20	3.9	5.8	5.6	121	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	73	0.8	5.6	11.1	20	3.6	5.8	5.1	73	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	84	0.9	6.9	27.7	20	0.9	4.5	4.9	84	0.3	6.1	21.1	20	1.8
Total	-	-	14.5	1100	1.3	9.0	-	-	-	-	5.3	1100	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 (2019/12)								CUM (2016/02/01~2019/12/31)							
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	14.2	13.7	5	0.2	1.5	6.4	20	>6	14.2	14.9	142	1.2	8.1	21.0	20	1.9
Lab019	5	15.3	15.4	4	0.2	1.3	3.3	20	>6	15.3	15.2	94	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	20	0.1	0.8	20.4	20	1.4	15.9	13.7	295	1.4	10.2	34.3	20	0.6
Lab027	5	15.5	-	0	-	-	-	20	-	15.5	15.5	107	1.3	8.4	16.8	20	2.4
Lab028	5	14.4	14.6	13	0.9	6.2	13.7	20	3.0	14.4	14.6	121	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	14.5	3	0.6	4.1	9.0	20	4.7	14.4	14.4	73	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	4	0.3	2.4	14.3	20	4.3	11.5	13.1	84	0.9	6.9	27.7	20	0.9
Total	-	-	13.7	49	1.0	7.3	-	-	-	-	14.5	1100	1.3	9.0	-	-	-

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

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

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

Month : 2019 12 Change

Cumulative : from 2016 02 01 to 2019 12 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2019/12)								CUM (2016/02/01~2019/12/31)							
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	5.5	5.2	5	0.1	1.9	9.3	20	>6	5.5	5.5	142	0.3	5.5	10.9	20	3.6
Lab019	5	5.3	5.5	4	0.1	1.8	7.4	20	>6	5.3	5.3	94	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	0.0	0.0	13.8	20	>6	5.8	5.1	295	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	13	0.2	3.7	14.3	20	3.5	5.8	5.6	121	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	73	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	4.6	4	0.1	2.2	6.6	20	>6	4.5	4.9	84	0.3	6.1	21.1	20	1.8
Total	-	-	5.1	49	0.3	5.9	-	-	-	-	5.3	1100	0.4	7.5	-	-	-

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

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

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

Month : 2019 12 Change

Cumulative : from 2016 02 01 to 2019 12 31 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5