

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - February 2021 -

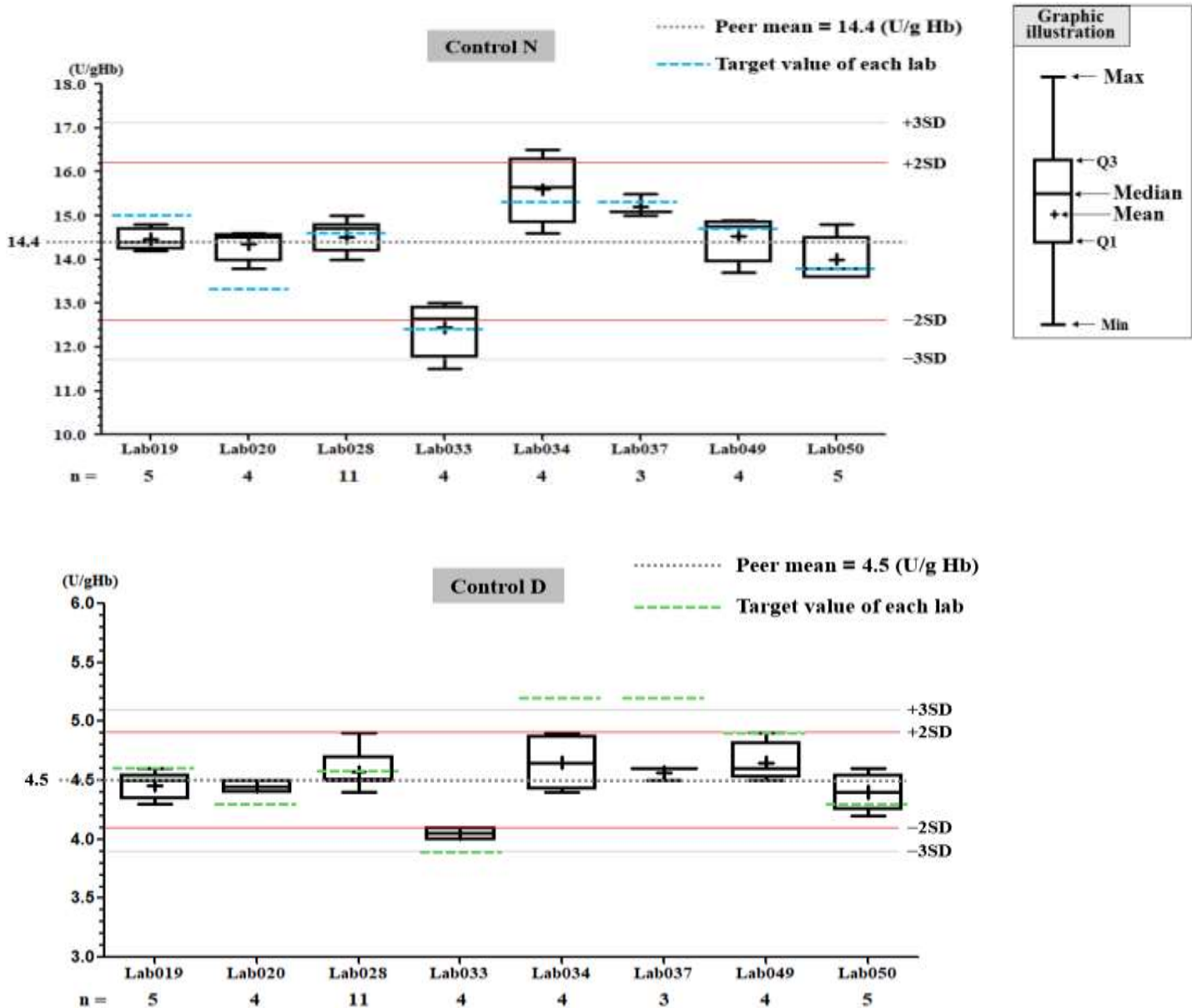
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	8	8
Received results number (n)	40	40
Median	14.6 (U/gHb)	4.5 (U/gHb)
Mean	14.4 (U/gHb)	4.5 (U/gHb)
SD	0.9	0.2
CV	6.3%	4.4%
Range of G6PD	11.5 ~ 16.5 (U/gHb)	4.0 ~ 4.9 (U/gHb)
Range of Hb	1.9 ~ 2.3 (g/dL)	2.0 ~ 2.5 (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 :

Lab049

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/02)	CUM (2020/07/29~2021/02/27)	Month (2021/02)	CUM (2020/07/29~2021/02/27)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.5	14.2	4.7	4.8
SD	0.6	0.6	0.2	0.4
CV (%)	4.1	4.2	4.3	8.3
Target Value (U/gHb)	14.7	14.7	4.9	4.9
Total Error (%)	9.6	11.9	12.6	18.7
TEa (%)	20	20	20	20
σ	4.5	4.0	3.7	2.2

Bias (%) = $\left[\frac{(\text{Mean} - \text{Target})}{\text{Target}} \right] \times 100\%$
 TE : Total Error(%) = Bias (%) + 2 × CV (%)
 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

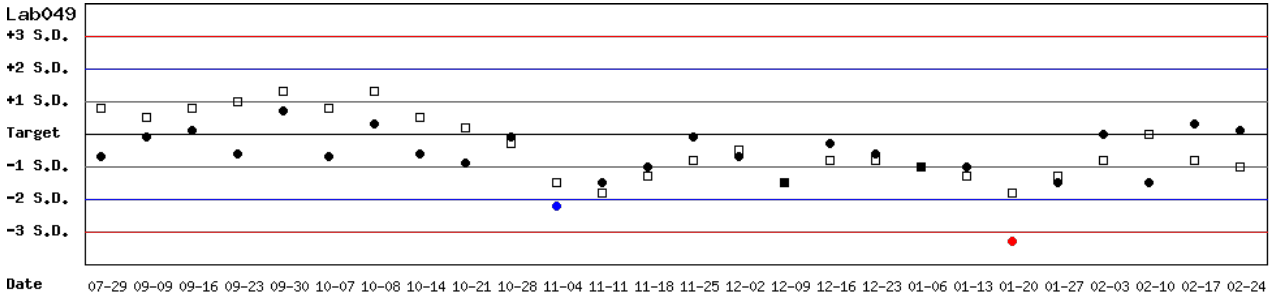
Month : ; Cumulative : from to

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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-07-29 to 2021-02-27 ; Target : 14.7 ; SD : 0.67 (●)

Lot No.: AH1220D ; Duration : 2020-07-29 to 2021-02-27 ; Target : 4.9 ; SD : 0.40 (□)

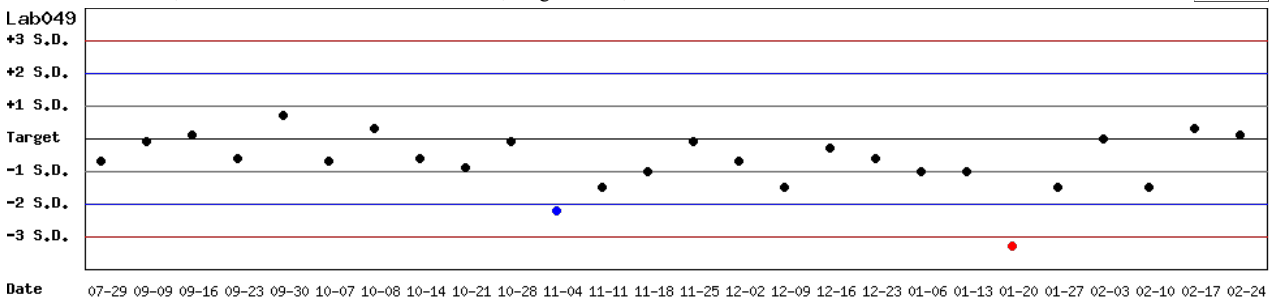


Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-07-29 to 2021-02-27 ; Target : 14.7 ; SD : 0.67



Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-07-29 to 2021-02-27 ; Target : 4.9 ; SD : 0.40

Lab049

Lab049

+3 S.D.

+2 S.D.

+1 S.D.

Target

-1 S.D.

-2 S.D.

-3 S.D.

Date

07-29 09-09 09-16 09-23 09-30 10-07 10-08 10-14 10-21 10-28 11-04 11-11 11-18 11-25 12-02 12-09 12-16 12-23 01-06 01-13 01-20 01-27 02-03 02-10 02-17 02-24

Month : ; Cumulative : from to

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Peer Group Statistics (Table 1)

Select LotNo : AH1220N (2019-01-28 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 1

Monthly

Month : 2021 02 Change

UnitID ↑	Reagent Kit (Code) ↑	Control N (Lot No.: AH1220N)									Control D (Lot No.: AH1220D)						
		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	15.0	14.5	5	0.2	1.4	6.1	20	>6	4.6	4.5	5	0.1	2.2	6.6	20	>6
Lab020	5	13.3	14.4	4	0.4	2.8	13.8	20	4.2	4.3	4.5	4	0.1	2.2	9.1	20	>6
Lab028	5	14.6	14.5	11	0.4	2.8	6.2	20	>6	4.6	4.6	11	0.2	4.3	8.7	20	4.7
Lab033	5	12.4	12.5	4	0.7	5.6	12.0	20	3.4	3.9	4.1	4	0.1	2.4	10.0	20	>6
Lab034	5	15.3	15.6	4	0.8	5.1	12.2	20	3.5	5.2	4.7	4	0.2	4.3	18.1	20	2.4
Lab037	5	15.3	15.2	3	0.3	2.0	4.6	20	>6	5.2	4.6	3	0.1	2.2	15.9	20	3.8
Lab049	5	14.7	14.5	4	0.6	4.1	9.6	20	4.5	4.9	4.7	4	0.2	4.3	12.6	20	3.7
Lab050	5	13.8	14.0	5	0.5	3.6	8.6	20	5.2	4.3	4.4	5	0.2	4.5	11.4	20	3.9
Total	-	-	14.4	40	0.9	6.3	-	-	-	-	4.5	40	0.2	4.4	-	-	-

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

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

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

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Cumulative

Cumulative : from 2019 02 01 to 2021 02 28 Change

UnitID ↑	Reagent Kit (Code) ↑	Control N (Lot No.: AH1220N)									Control D (Lot No.: AH1220D)						
		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	15.0	14.7	35	0.3	2.0	6.1	20	>6	4.6	4.5	35	0.1	2.2	6.6	20	>6
Lab020	5	13.3	14.4	46	1.0	6.9	22.2	20	1.7	4.3	4.5	46	0.3	6.7	18.0	20	2.3
Lab022	5	13.8	12.4	56	0.7	5.6	21.4	20	1.8	4.4	4.0	56	0.2	5.0	19.1	20	2.2
Lab028	5	14.6	14.6	45	0.4	2.7	5.5	20	>6	4.6	4.6	45	0.2	4.3	8.7	20	4.7
Lab032	5	12.1	13.1	112	1.5	11.5	31.2	20	1.0	3.5	4.1	112	0.6	14.6	46.4	20	0.2
Lab033	5	12.4	12.5	95	0.4	3.2	7.2	20	6.0	3.9	3.9	95	0.2	5.1	10.3	20	3.9
Lab034	5	15.3	15.2	33	0.7	4.6	9.9	20	4.2	5.2	4.6	33	0.2	4.3	20.2	20	2.0
Lab037	5	15.3	15.2	47	0.4	2.6	5.9	20	>6	5.2	4.7	47	0.1	2.1	13.9	20	4.9
Lab040	5	15.3	15.1	10	0.5	3.3	7.9	20	5.7	5.2	5.6	10	0.4	7.1	22.0	20	1.7
Lab047	5	12.7	12.6	13	0.2	1.6	4.0	20	>6	4.0	4.0	13	0.1	2.5	5.0	20	>6
Lab049	5	14.7	14.3	29	0.6	4.2	11.1	20	4.1	4.9	4.7	29	0.4	8.5	21.1	20	1.9
Lab050	5	13.8	14.3	11	0.7	4.9	13.4	20	3.3	4.3	4.4	11	0.4	9.1	20.5	20	1.9
Total	-	-	13.7	532	1.4	10.2	-	-	-	-	4.3	532	0.5	11.6	-	-	-

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 : AH1220N (2019-01-28 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 2

Control N Month vs. Cumulative

		Control N (Lot No.: AH1220N)															
		Month (2021/02)								CUM (2019/02/01~2021/02/28)							
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
Lab019	5	15.0	14.5	5	0.2	1.4	6.1	20	>6	15.0	14.7	35	0.3	2.0	6.1	20	>6
Lab020	5	13.3	14.4	4	0.4	2.8	13.8	20	4.2	13.3	14.4	46	1.0	6.9	22.2	20	1.7
Lab022	5	13.8	-	0	-	-	-	20	-	13.8	12.4	56	0.7	5.6	21.4	20	1.8
Lab028	5	14.6	14.5	11	0.4	2.8	6.2	20	>6	14.6	14.6	45	0.4	2.7	5.5	20	>6
Lab032	5	12.1	-	0	-	-	-	20	-	12.1	13.1	112	1.5	11.5	31.2	20	1.0
Lab033	5	12.4	12.5	4	0.7	5.6	12.0	20	3.4	12.4	12.5	95	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	15.6	4	0.8	5.1	12.2	20	3.5	15.3	15.2	33	0.7	4.6	9.9	20	4.2
Lab037	5	15.3	15.2	3	0.3	2.0	4.6	20	>6	15.3	15.2	47	0.4	2.6	5.9	20	>6
Lab040	5	15.3	-	0	-	-	-	20	-	15.3	15.1	10	0.5	3.3	7.9	20	5.7
Lab047	5	12.7	-	0	-	-	-	20	-	12.7	12.6	13	0.2	1.6	4.0	20	>6
Lab049	5	14.7	14.5	4	0.6	4.1	9.6	20	4.5	14.7	14.3	29	0.6	4.2	11.1	20	4.1
Lab050	5	13.8	14.0	5	0.5	3.6	8.6	20	5.2	13.8	14.3	11	0.7	4.9	13.4	20	3.3
Total	-	-	14.4	40	0.9	6.3	-	-	-	-	13.7	532	1.4	10.2	-	-	-

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

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

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

Month : 2021 02 Change

Cumulative : from 2019 02 01 to 2021 02 28 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2021/02)								CUM (2019/02/01~2021/02/28)							
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
Lab019	5	4.6	4.5	5	0.1	2.2	6.6	20	>6	4.6	4.5	35	0.1	2.2	6.6	20	>6
Lab020	5	4.3	4.5	4	0.1	2.2	9.1	20	>6	4.3	4.5	46	0.3	6.7	18.0	20	2.3
Lab022	5	4.4	-	0	-	-	-	20	-	4.4	4.0	56	0.2	5.0	19.1	20	2.2
Lab028	5	4.6	4.6	11	0.2	4.3	8.7	20	4.7	4.6	4.6	45	0.2	4.3	8.7	20	4.7
Lab032	5	3.5	-	0	-	-	-	20	-	3.5	4.1	112	0.6	14.6	46.4	20	0.2
Lab033	5	3.9	4.1	4	0.1	2.4	10.0	20	>6	3.9	3.9	95	0.2	5.1	10.3	20	3.9
Lab034	5	5.2	4.7	4	0.2	4.3	18.1	20	2.4	5.2	4.6	33	0.2	4.3	20.2	20	2.0
Lab037	5	5.2	4.6	3	0.1	2.2	15.9	20	3.8	5.2	4.7	47	0.1	2.1	13.9	20	4.9
Lab040	5	5.2	-	0	-	-	-	20	-	5.2	5.6	10	0.4	7.1	22.0	20	1.7
Lab047	5	4.0	-	0	-	-	-	20	-	4.0	4.0	13	0.1	2.5	5.0	20	>6
Lab049	5	4.9	4.7	4	0.2	4.3	12.6	20	3.7	4.9	4.7	29	0.4	8.5	21.1	20	1.9
Lab050	5	4.3	4.4	5	0.2	4.5	11.4	20	3.9	4.3	4.4	11	0.4	9.1	20.5	20	1.9
Total	-	-	4.5	40	0.2	4.4	-	-	-	-	4.3	532	0.5	11.6	-	-	-

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

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

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

Month : 2021 02 Change

Cumulative : from 2019 02 01 to 2021 02 28 Change

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Reagent Kit	Reagent Code
Medicon	5