

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - January 2022 -

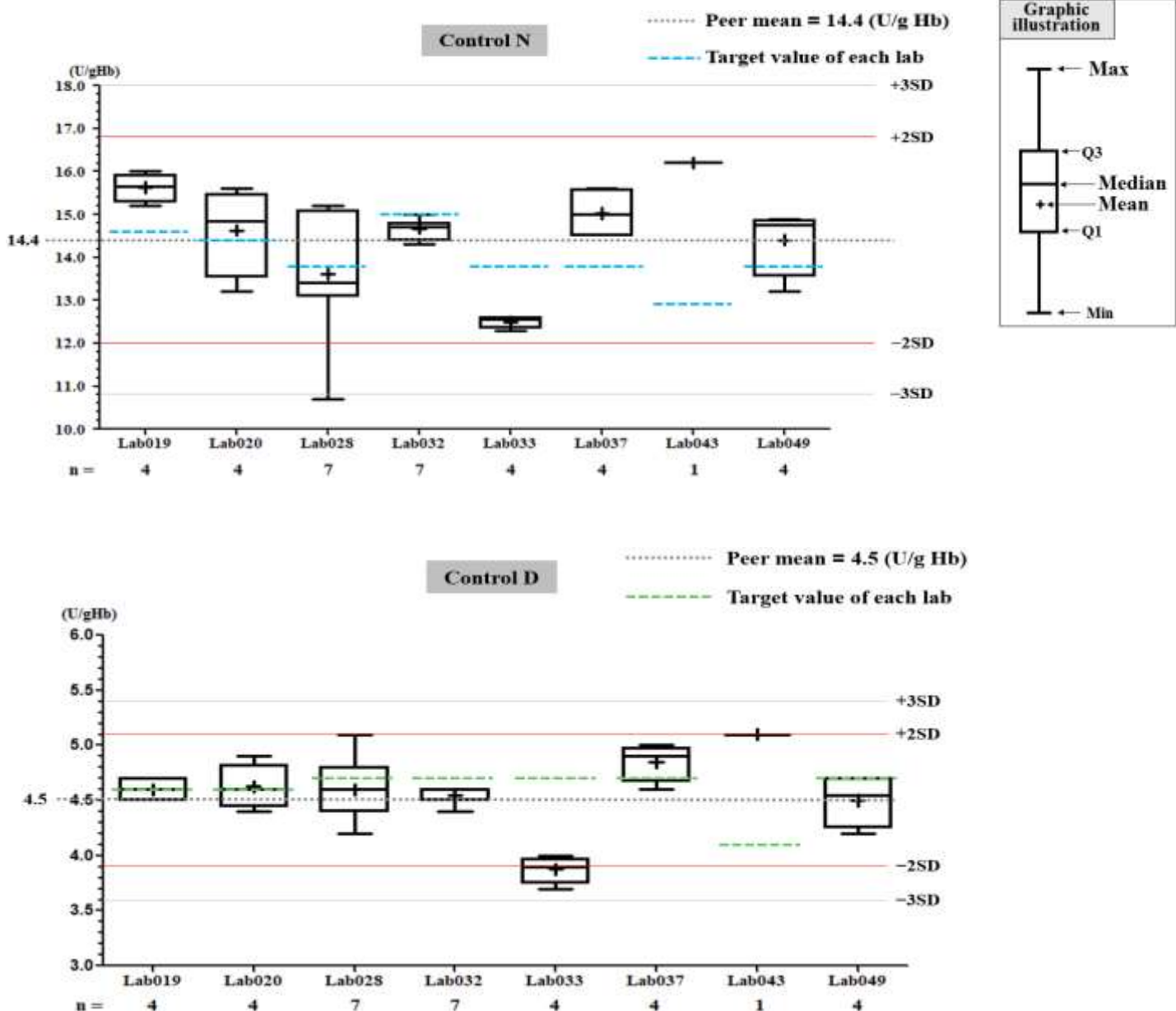
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	8	8
Received results number (n)	35	35
Median	14.7 (U/g Hb)	4.6 (U/g Hb)
Mean	14.4 (U/g Hb)	4.5 (U/g Hb)
SD	1.2	0.3
CV	8.3%	6.7%
Range of G6PD	10.7 ~ 16.2 (U/g Hb)	3.7 ~ 5.1 (U/g Hb)
Range of Hb	2.2 ~ 2.7 (g/dL)	1.9 ~ 2.7 (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 :

Lab037

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2022/01)	CUM (2021/07/02~2022/01/29)	Month (2022/01)	CUM (2021/07/02~2022/01/29)
Runs (N)	4	11	4	11
Mean (U/gHb)	15.0	14.9	4.9	4.8
SD	0.6	0.5	0.2	0.2
CV (%)	4.0	3.4	4.1	4.2
Target Value (U/gHb)	13.8	13.8	4.7	4.7
Total Error (%)	16.7	14.7	12.4	10.5
TEa (%)	20	20	20	20
σ	2.8	3.5	3.8	4.3

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

Month : ; Cumulative : from to

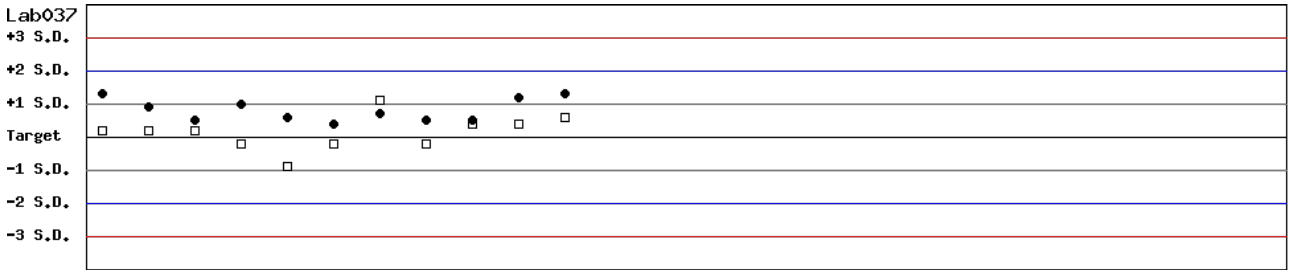
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-07-02 to 2022-01-29 ; Target : 13.8 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2021-07-02 to 2022-01-29 ; Target : 4.7 ; SD : 0.47 (□)

Lab037



Date 07-02 07-14 07-30 08-12 12-01 12-16 12-22 01-06 01-13 01-21 01-27

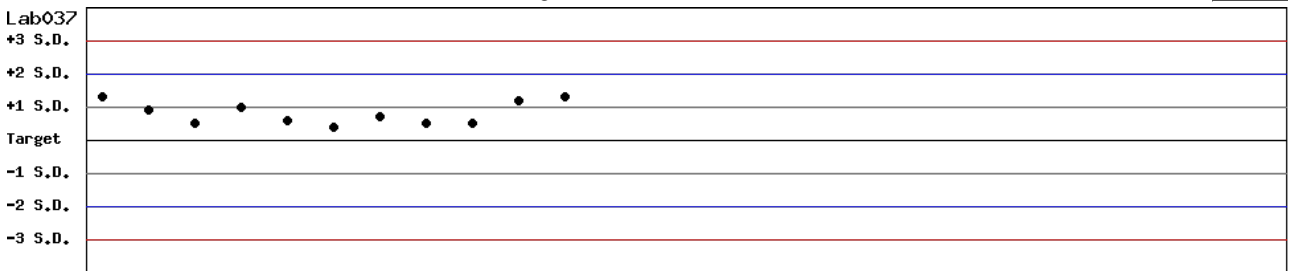
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-07-02 to 2022-01-29 ; Target : 13.8 ; SD : 1.38

Lab037



Date 07-02 07-14 07-30 08-12 12-01 12-16 12-22 01-06 01-13 01-21 01-27

Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2021-07-02 to 2022-01-29 ; Target : 4.7 ; SD : 0.47

Lab037



Date 07-02 07-14 07-30 08-12 12-01 12-16 12-22 01-06 01-13 01-21 01-27

Month : 2022 ▼ 01 ▼ Change ; Cumulative : from 2021 ▼ 07 ▼ 02 ▼ to 2022 ▼ 01 ▼ 29 ▼ Change

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Peer Group Statistics (Table 1)

Select LotNo : BJ0922N (2021-01-01 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 1

Monthly

Month : 2022 01 Change

		Control N (Lot No.: BJ0922N)								Control D (Lot No.: BJ0922D)							
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	14.6	15.6	4	0.3	1.9	10.7	20	>6	4.6	4.6	4	0.1	2.2	4.3	20	>6
Lab020	5	14.4	14.6	4	1.0	6.8	15.1	20	2.7	4.6	4.6	4	0.2	4.3	8.7	20	4.7
Lab028	5	13.8	13.6	7	1.5	11.0	23.5	20	1.7	4.7	4.6	7	0.3	6.5	15.2	20	2.7
Lab032	5	15.0	14.7	7	0.2	1.4	4.7	20	>6	4.7	4.5	7	0.1	2.2	8.7	20	>6
Lab033	5	13.8	12.5	4	0.1	0.8	11.0	20	>6	4.7	3.9	4	0.1	2.6	22.1	20	1.1
Lab037	5	13.8	15.0	4	0.6	4.0	16.7	20	2.8	4.7	4.9	4	0.2	4.1	12.4	20	3.8
Lab043	5	12.9	16.2	1	-	-	-	20	-	4.1	5.1	1	-	-	-	20	-
Lab049	5	13.8	14.4	4	0.8	5.6	15.5	20	2.8	4.7	4.5	4	0.2	4.4	13.1	20	3.6
Total	-	-	14.4	35	1.2	8.3	-	-	-	-	4.5	35	0.3	6.7	-	-	-

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

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

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

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Cumulative

Cumulative : from 2021 01 01 to 2022 01 31 Change

		Control N (Lot No.: BJ0922N)								Control D (Lot No.: BJ0922D)							
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	14.6	15.6	4	0.3	1.9	10.7	20	>6	4.6	4.6	4	0.1	2.2	4.3	20	>6
Lab020	5	14.4	14.5	13	0.7	4.8	10.3	20	4.0	4.6	4.7	13	0.2	4.3	10.7	20	4.1
Lab028	5	13.8	14.8	21	1.3	8.8	24.8	20	1.4	4.7	4.8	21	0.3	6.3	14.6	20	2.8
Lab032	5	15.0	14.4	51	0.4	2.8	9.6	20	5.7	4.7	4.5	51	0.1	2.2	8.7	20	>6
Lab033	5	13.8	12.5	4	0.1	0.8	11.0	20	>6	4.7	3.9	4	0.1	2.6	22.1	20	1.1
Lab037	5	13.8	14.9	11	0.5	3.4	14.7	20	3.5	4.7	4.8	11	0.2	4.2	10.5	20	4.3
Lab043	5	12.9	12.5	29	1.2	9.6	22.3	20	1.8	4.1	3.9	29	0.4	10.3	25.4	20	1.5
Lab049	5	13.8	15.0	35	0.6	4.0	16.7	20	2.8	4.7	4.7	35	0.2	4.3	8.5	20	4.7
Total	-	-	14.2	168	1.2	8.5	-	-	-	-	4.5	168	0.4	8.9	-	-	-

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 : BJ0922N (2021-01-01 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

[Print Table 2](#)

Control N Month vs. Cumulative

		Control N (Lot No.: BJ0922N)															
		Month (2022/01)								CUM (2021/01/01~2022/01/31)							
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
Lab019	5	14.6	15.6	4	0.3	1.9	10.7	20	>6	14.6	15.6	4	0.3	1.9	10.7	20	>6
Lab020	5	14.4	14.6	4	1.0	6.8	15.1	20	2.7	14.4	14.5	13	0.7	4.8	10.3	20	4.0
Lab028	5	13.8	13.6	7	1.5	11.0	23.5	20	1.7	13.8	14.8	21	1.3	8.8	24.8	20	1.4
Lab032	5	15.0	14.7	7	0.2	1.4	4.7	20	>6	15.0	14.4	51	0.4	2.8	9.6	20	5.7
Lab033	5	13.8	12.5	4	0.1	0.8	11.0	20	>6	13.8	12.5	4	0.1	0.8	11.0	20	>6
Lab037	5	13.8	15.0	4	0.6	4.0	16.7	20	2.8	13.8	14.9	11	0.5	3.4	14.7	20	3.5
Lab043	5	12.9	16.2	1	-	-	-	20	-	12.9	12.5	29	1.2	9.6	22.3	20	1.8
Lab049	5	13.8	14.4	4	0.8	5.6	15.5	20	2.8	13.8	15.0	35	0.6	4.0	16.7	20	2.8
Total	-	-	14.4	35	1.2	8.3	-	-	-	-	14.2	168	1.2	8.5	-	-	-

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

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

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

Month : 2022 ▼ 01 ▼ Change Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2022 ▼ 01 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2022/01)								CUM (2021/01/01~2022/01/31)							
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
Lab019	5	4.6	4.6	4	0.1	2.2	4.3	20	>6	4.6	4.6	4	0.1	2.2	4.3	20	>6
Lab020	5	4.6	4.6	4	0.2	4.3	8.7	20	4.7	4.6	4.7	13	0.2	4.3	10.7	20	4.1
Lab028	5	4.7	4.6	7	0.3	6.5	15.2	20	2.7	4.7	4.8	21	0.3	6.3	14.6	20	2.8
Lab032	5	4.7	4.5	7	0.1	2.2	8.7	20	>6	4.7	4.5	51	0.1	2.2	8.7	20	>6
Lab033	5	4.7	3.9	4	0.1	2.6	22.1	20	1.1	4.7	3.9	4	0.1	2.6	22.1	20	1.1
Lab037	5	4.7	4.9	4	0.2	4.1	12.4	20	3.8	4.7	4.8	11	0.2	4.2	10.5	20	4.3
Lab043	5	4.1	5.1	1	-	-	-	20	-	4.1	3.9	29	0.4	10.3	25.4	20	1.5
Lab049	5	4.7	4.5	4	0.2	4.4	13.1	20	3.6	4.7	4.7	35	0.2	4.3	8.5	20	4.7
Total	-	-	4.5	35	0.3	6.7	-	-	-	-	4.5	168	0.4	8.9	-	-	-

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

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

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

Month : 2022 ▼ 01 ▼ Change Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2022 ▼ 01 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5