

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

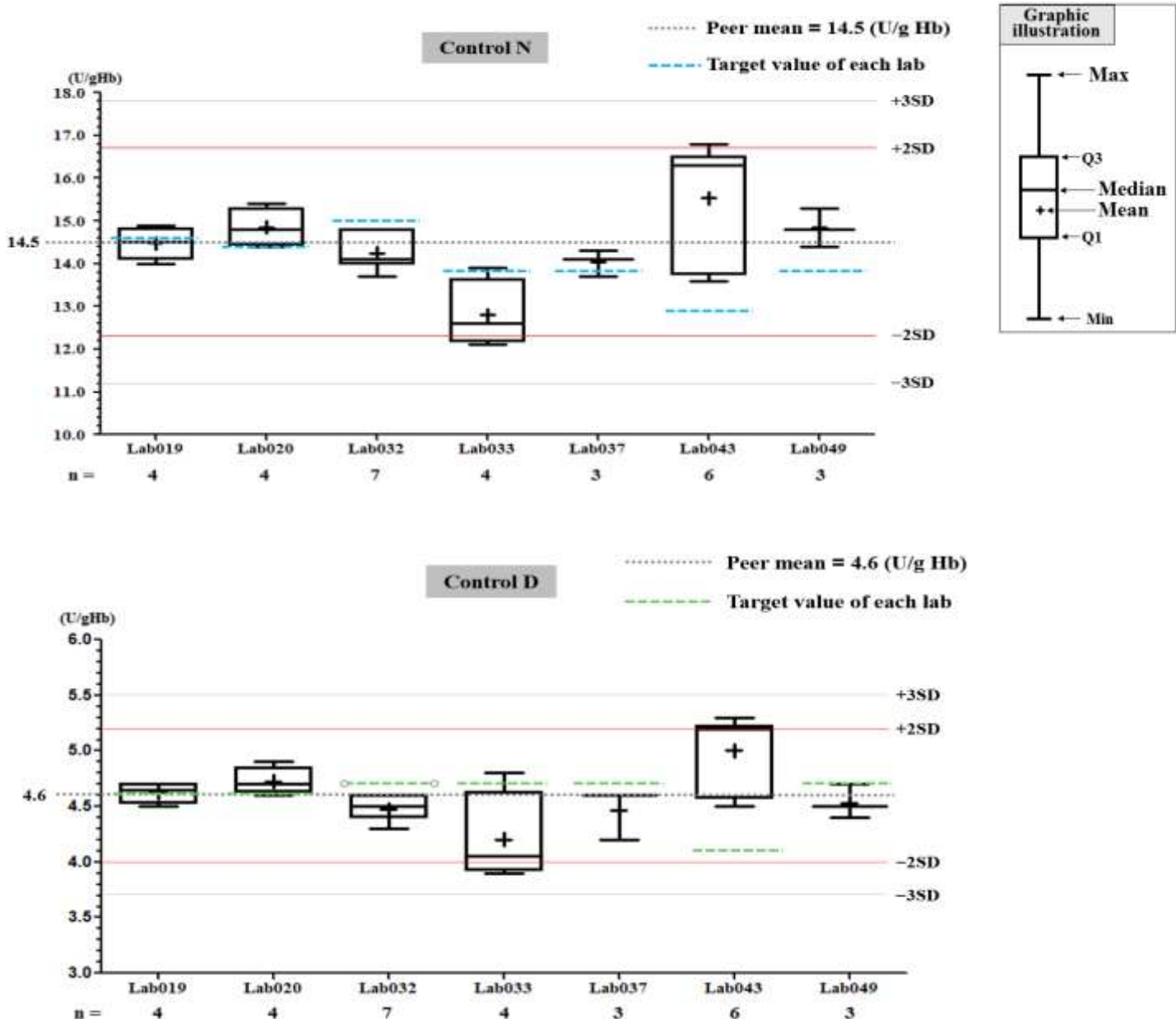
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	7	7
Received results number (n)	31	31
Median	14.4 (U/g Hb)	4.6 (U/g Hb)
Mean	14.5 (U/g Hb)	4.6 (U/g Hb)
SD	1.1	0.3
CV	7.6%	6.5%
Range of G6PD	12.1 ~ 16.8 (U/g Hb)	3.9 ~ 5.3 (U/g Hb)
Range of Hb	2.2 ~ 2.8 (g/dL)	1.9 ~ 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 : BJ0922N (2021-01-01 ~ 2100-12-31) ▼ Change

Print Table

Lab043

	Control N		Control D	
QC Control Lot No.	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2022/02)	CUM (2021/10/25~2022/02/28)	Month (2022/02)	CUM (2021/10/25~2022/02/28)
Runs (N)	6	24	6	24
Mean (U/gHb)	15.5	13.3	5.0	4.2
SD	1.4	1.9	0.4	0.6
CV (%)	9.0	14.3	8.0	14.3
Target Value (U/gHb)	12.9	12.9	4.1	4.1
Total Error (%)	38.2	31.7	38.0	31.0
TEa (%)	20	20	20	20
σ	0.0	1.2	-0.2	1.2

Bias (%) = $(| \text{Mean} - \text{Target} |) / \text{Target} \times 100\%$

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

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

Month : 2022 ▼ 02 ▼ Change ; Cumulative : from 2021 ▼ 10 ▼ 25 ▼ to 2022 ▼ 02 ▼ 28 ▼ Change

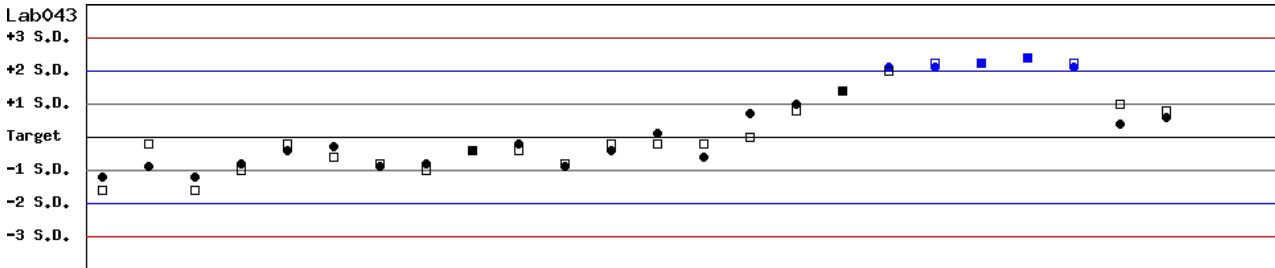
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-10-25 to 2022-02-28 ; Target : 12.9 ; SD : 1.60 (●)

Lot No.: BJ0922D ; Duration : 2021-10-25 to 2022-02-28 ; Target : 4.1 ; SD : 0.50 (□)

Lab043



Date 10-25 10-25 10-25 10-29 10-29 10-29 10-29 10-29 10-29 10-29 10-29 11-04 11-09 11-09 11-16 11-16 12-15 01-06 02-10 02-12 02-15 02-17 02-19 02-24

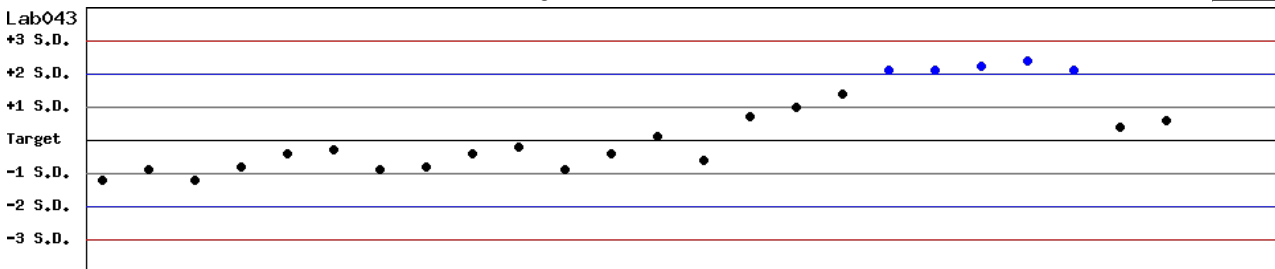
Month : 2022 ▼ 02 ▼ Change ; Cumulative : from 2021 ▼ 10 ▼ 25 ▼ to 2022 ▼ 02 ▼ 28 ▼ Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-10-25 to 2022-02-28 ; Target : 12.9 ; SD : 1.60

Lab043



Date 10-25 10-25 10-25 10-29 10-29 10-29 10-29 10-29 10-29 10-29 10-29 11-04 11-09 11-09 11-16 11-16 12-15 01-06 02-10 02-12 02-15 02-17 02-19 02-24

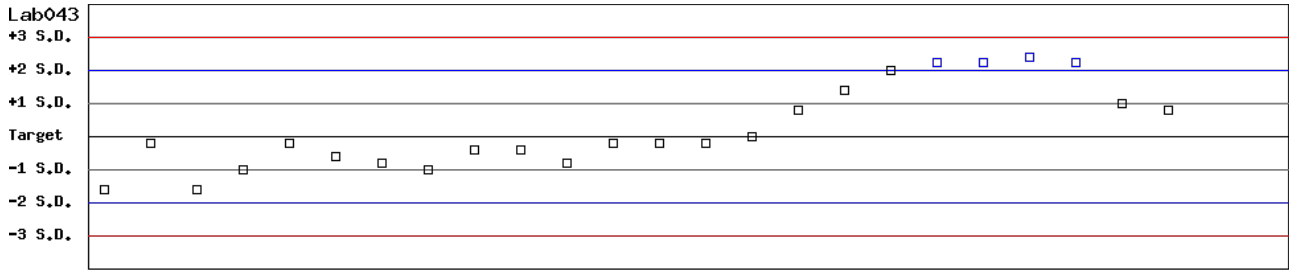
Month : 2022 ▼ 02 ▼ Change ; Cumulative : from 2021 ▼ 10 ▼ 25 ▼ to 2022 ▼ 02 ▼ 28 ▼ Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2021-10-25 to 2022-02-28 ; Target : 4.1 ; SD : 0.50

Lab043



Date 10-25 10-25 10-25 10-29 10-29 10-29 10-29 10-29 10-29 10-29 10-29 10-29 10-29 11-04 11-09 11-09 11-16 11-16 12-15 01-06 02-10 02-12 02-15 02-17 02-19 02-24

Month : ; Cumulative : from to

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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 02 Change

UnitID ↑	Reagent Kit (Code) ↑	Control N (Lot No.: BJ0922N)								Control D (Lot No.: BJ0922D)							
		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	14.5	4	0.4	2.8	6.2	20	>6	4.6	4.6	4	0.1	2.2	4.3	20	>6
Lab020	5	14.4	14.9	4	0.4	2.7	8.8	20	>6	4.6	4.7	4	0.1	2.1	6.4	20	>6
Lab032	5	15.0	14.2	7	0.4	2.8	11.0	20	5.2	4.7	4.5	7	0.1	2.2	8.7	20	>6
Lab033	5	13.8	12.8	4	0.8	6.3	19.7	20	2.0	4.7	4.2	4	0.4	9.5	29.7	20	1.0
Lab037	5	13.8	14.0	3	0.3	2.1	5.7	20	>6	4.7	4.5	3	0.2	4.4	13.1	20	3.6
Lab043	5	12.9	15.5	6	1.4	9.0	38.2	20	0.0	4.1	5.0	6	0.4	8.0	38.0	20	-0.2
Lab049	5	13.8	14.8	3	0.5	3.4	14.0	20	3.8	4.7	4.5	3	0.2	4.4	13.1	20	3.6
Total	-	-	14.5	31	1.1	7.6	-	-	-	-	4.6	31	0.3	6.5	-	-	-

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from 2021 01 01 to 2022 02 28 Change

UnitID ↑	Reagent Kit (Code) ↑	Control N (Lot No.: BJ0922N)								Control D (Lot No.: BJ0922D)							
		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	15.1	8	0.7	4.6	12.7	20	3.6	4.6	4.6	8	0.1	2.2	4.3	20	>6
Lab020	5	14.4	14.6	17	0.6	4.1	9.6	20	4.5	4.6	4.7	17	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	14.3	58	0.4	2.8	10.3	20	5.5	4.7	4.5	58	0.1	2.2	8.7	20	>6
Lab033	5	13.8	12.7	8	0.6	4.7	17.4	20	2.6	4.7	4.0	8	0.3	7.5	29.9	20	0.7
Lab037	5	13.8	14.7	14	0.6	4.1	14.7	20	3.3	4.7	4.7	14	0.3	6.4	12.8	20	3.1
Lab043	5	12.9	13.0	35	1.7	13.1	26.9	20	1.5	4.1	4.1	35	0.5	12.2	24.4	20	1.6
Lab049	5	13.8	15.0	38	0.6	4.0	16.7	20	2.8	4.7	4.7	38	0.2	4.3	8.5	20	4.7
Total	-	-	14.3	199	1.2	8.4	-	-	-	-	4.5	199	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 (2022/02)								CUM (2021/01/01~2022/02/28)							
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	14.6	14.5	4	0.4	2.8	6.2	20	>6	14.6	15.1	8	0.7	4.6	12.7	20	3.6
Lab020	5	14.4	14.9	4	0.4	2.7	8.8	20	>6	14.4	14.6	17	0.6	4.1	9.6	20	4.5
Lab028	5	13.8	-	0	-	-	-	20	-	13.8	14.8	21	1.3	8.8	24.8	20	1.4
Lab032	5	15.0	14.2	7	0.4	2.8	11.0	20	5.2	15.0	14.3	58	0.4	2.8	10.3	20	5.5
Lab033	5	13.8	12.8	4	0.8	6.3	19.7	20	2.0	13.8	12.7	8	0.6	4.7	17.4	20	2.6
Lab037	5	13.8	14.0	3	0.3	2.1	5.7	20	>6	13.8	14.7	14	0.6	4.1	14.7	20	3.3
Lab043	5	12.9	15.5	6	1.4	9.0	38.2	20	0.0	12.9	13.0	35	1.7	13.1	26.9	20	1.5
Lab049	5	13.8	14.8	3	0.5	3.4	14.0	20	3.8	13.8	15.0	38	0.6	4.0	16.7	20	2.8
Total	-	-	14.5	31	1.1	7.6	-	-	-	-	14.3	199	1.2	8.4	-	-	-

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

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

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

Month : 2022 02 Change Cumulative : from 2021 01 01 to 2022 02 28 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2022/02)								CUM (2021/01/01~2022/02/28)							
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	4.6	4	0.1	2.2	4.3	20	>6	4.6	4.6	8	0.1	2.2	4.3	20	>6
Lab020	5	4.6	4.7	4	0.1	2.1	6.4	20	>6	4.6	4.7	17	0.2	4.3	10.7	20	4.1
Lab028	5	4.7	-	0	-	-	-	20	-	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	58	0.1	2.2	8.7	20	>6
Lab033	5	4.7	4.2	4	0.4	9.5	29.7	20	1.0	4.7	4.0	8	0.3	7.5	29.9	20	0.7
Lab037	5	4.7	4.5	3	0.2	4.4	13.1	20	3.6	4.7	4.7	14	0.3	6.4	12.8	20	3.1
Lab043	5	4.1	5.0	6	0.4	8.0	38.0	20	-0.2	4.1	4.1	35	0.5	12.2	24.4	20	1.6
Lab049	5	4.7	4.5	3	0.2	4.4	13.1	20	3.6	4.7	4.7	38	0.2	4.3	8.5	20	4.7
Total	-	-	4.6	31	0.3	6.5	-	-	-	-	4.5	199	0.4	8.9	-	-	-

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

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

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

Month : 2022 02 Change Cumulative : from 2021 01 01 to 2022 02 28 Change

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Reagent Kit	Reagent Code
Medicon	5