

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - June 2023 -

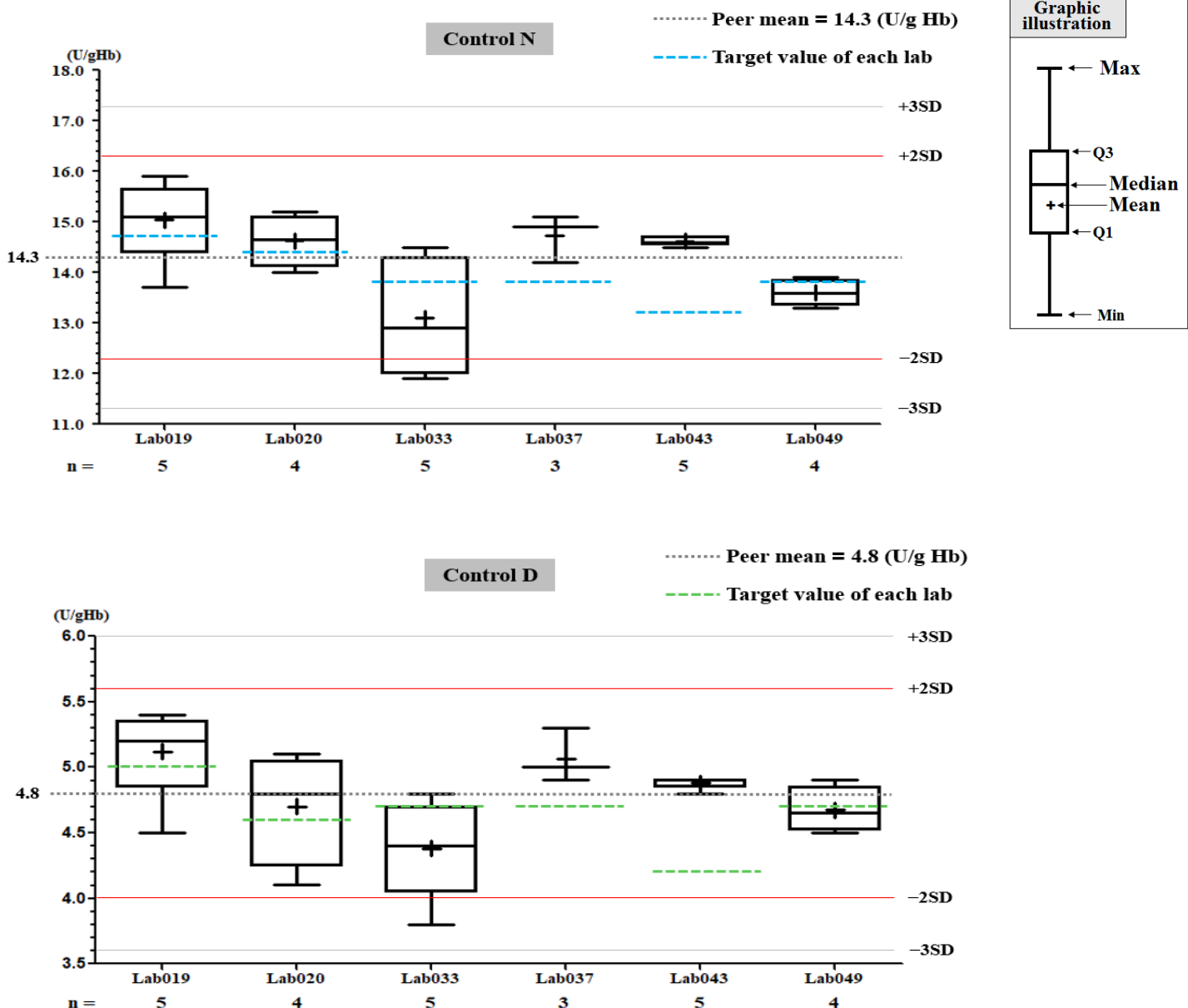
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	6	6
Received results number (n)	26	26
Median	14.5 (U/g Hb)	4.9 (U/g Hb)
Mean	14.3 (U/g Hb)	4.8 (U/g Hb)
SD	1.0	0.4
CV	7.0%	8.3%
Range of G6PD	11.9 ~ 15.2 (U/g Hb)	3.8 ~ 5.4 (U/g Hb)
Range of Hb	2.2 ~ 2.9 (g/dL)	1.9 ~ 2.6 (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](#)

Lab020

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2023/06)	CUM (2022/09/01~2023/06/30)	Month (2023/06)	CUM (2022/09/01~2023/06/30)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.6	14.4	4.7	4.7
SD	0.5	0.5	0.4	0.2
CV (%)	3.4	3.5	8.5	4.3
Target Value (U/gHb)	14.4	14.4	4.6	4.6
Total Error (%)	8.2	6.9	19.2	10.7
TEa (%)	20	20	20	20
σ	5.5	5.7	2.1	4.1

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

Month : 2023 06 Change ; Cumulative : from 2022 09 01 to 2023 06 30 Change

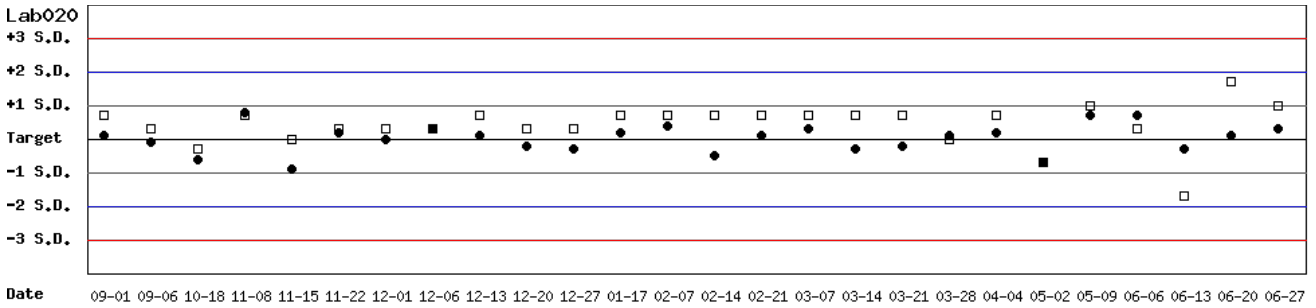
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-09-01 to 2023-06-30 ; Target : 14.4 ; SD : 1.16 (●)

Lot No.: BJ0922D ; Duration : 2022-09-01 to 2023-06-30 ; Target : 4.6 ; SD : 0.30 (□)

Lab020



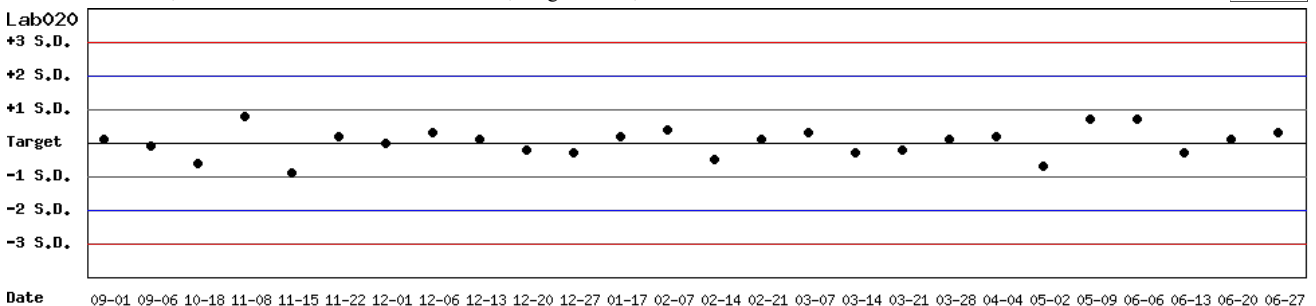
Month : 2023 06 Change ; Cumulative : from 2022 09 01 to 2023 06 30 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-09-01 to 2023-06-30 ; Target : 14.4 ; SD : 1.16

Lab020



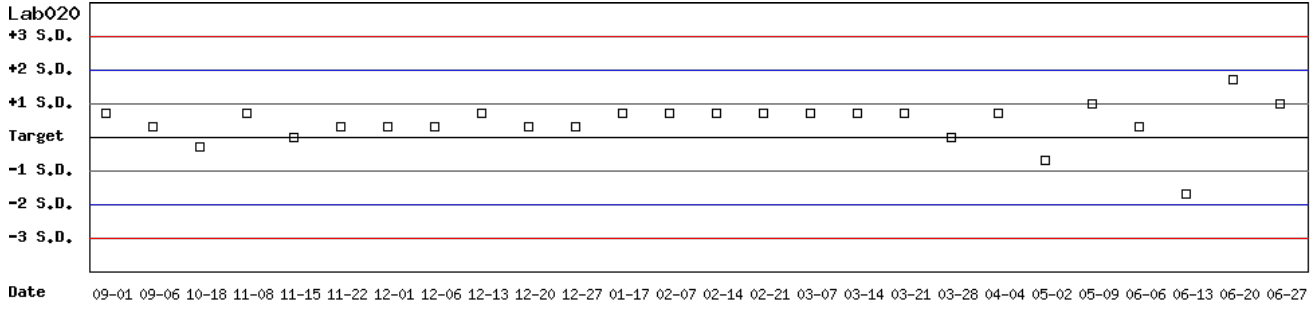
Month : 2023 06 Change ; Cumulative : from 2022 09 01 to 2023 06 30 Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2022-09-01 to 2023-06-30 ; Target : 4.6 ; SD : 0.30

Lab020



Month : ; Cumulative : from to

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Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon

Monthly

Month : 2023

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	14.7	15.0	5	0.8	5.3	12.7	20	3.4	5.0	5.1	5	0.4	7.8	17.7	20	2.3
Lab020	5	14.4	14.6	4	0.5	3.4	8.2	20	5.5	4.6	4.7	4	0.4	8.5	19.2	20	2.1
Lab033	5	13.8	13.1	5	1.2	9.2	23.4	20	1.6	4.7	4.4	5	0.4	9.1	24.6	20	1.5
Lab037	5	13.8	14.7	3	0.5	3.4	13.3	20	4.0	4.7	5.1	3	0.2	3.9	16.4	20	2.9
Lab043	5	13.2	14.6	5	0.1	0.7	12.0	20	>6	4.2	4.9	5	0.1	2.0	20.7	20	1.7
Lab049	5	13.8	13.6	4	0.3	2.2	5.9	20	>6	4.7	4.7	4	0.2	4.3	8.5	20	4.7
Total	-	-	14.3	26	1.0	7.0	-	-	-	-	4.8	26	0.4	8.3	-	-	-

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

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

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

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Cumulative

Cumulative : from 2021 to 2023

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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
Lab018	5	16.2	16.4	8	0.4	2.4	6.1	20	>6	5.5	5.5	8	0.2	3.6	7.3	20	5.6
Lab019	5	14.7	14.3	66	0.6	4.2	11.1	20	4.1	5.0	4.7	66	0.2	4.3	14.5	20	3.3
Lab020	5	14.4	14.4	66	0.5	3.5	6.9	20	5.7	4.6	4.7	66	0.2	4.3	10.7	20	4.1
Lab022	5	14.4	14.4	27	0.5	3.5	6.9	20	5.7	4.6	4.7	27	0.3	6.4	14.9	20	2.8
Lab028	5	15.2	15.1	34	1.1	7.3	15.2	20	2.6	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	14.9	14.3	127	0.4	2.8	9.6	20	5.7	4.8	4.5	127	0.2	4.4	15.1	20	3.1
Lab033	5	13.8	13.6	77	0.6	4.4	10.3	20	4.2	4.7	4.6	77	0.3	6.5	15.2	20	2.7
Lab037	5	13.8	14.5	58	0.5	3.4	12.0	20	4.4	4.7	4.7	58	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.7	51	0.2	1.4	4.8	20	>6	4.6	4.6	51	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.8	94	1.3	9.4	23.4	20	1.6	4.2	4.5	94	0.5	11.1	29.4	20	1.2
Lab049	5	13.8	14.4	140	0.7	4.9	14.1	20	3.2	4.7	4.7	140	0.2	4.3	8.5	20	4.7
Total	-	-	14.3	748	0.8	5.6	-	-	-	-	4.6	748	0.3	6.5	-	-	-

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 : 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 (2023/06)								CUM (2021/01/01~2023/06/30)							
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	16.2	-	0	-	-	-	20	-	16.2	16.4	8	0.4	2.4	6.1	20	>6
Lab019	5	14.7	15.0	5	0.8	5.3	12.7	20	3.4	14.7	14.3	66	0.6	4.2	11.1	20	4.1
Lab020	5	14.4	14.6	4	0.5	3.4	8.2	20	5.5	14.4	14.4	66	0.5	3.5	6.9	20	5.7
Lab022	5	14.4	-	0	-	-	-	20	-	14.4	14.4	27	0.5	3.5	6.9	20	5.7
Lab028	5	15.2	-	0	-	-	-	20	-	15.2	15.1	34	1.1	7.3	15.2	20	2.6
Lab032	5	14.9	-	0	-	-	-	20	-	14.9	14.3	127	0.4	2.8	9.6	20	5.7
Lab033	5	13.8	13.1	5	1.2	9.2	23.4	20	1.6	13.8	13.6	77	0.6	4.4	10.3	20	4.2
Lab037	5	13.8	14.7	3	0.5	3.4	13.3	20	4.0	13.8	14.5	58	0.5	3.4	12.0	20	4.4
Lab040	5	14.4	-	0	-	-	-	20	-	14.4	14.7	51	0.2	1.4	4.8	20	>6
Lab043	5	13.2	14.6	5	0.1	0.7	12.0	20	>6	13.2	13.8	94	1.3	9.4	23.4	20	1.6
Lab049	5	13.8	13.6	4	0.3	2.2	5.9	20	>6	13.8	14.4	140	0.7	4.9	14.1	20	3.2
Total	-	-	14.3	26	1.0	7.0	-	-	-	-	14.3	748	0.8	5.6	-	-	-

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

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

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

Month : 2023 ▼ 06 ▼ Change

Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2023 ▼ 06 ▼ 30 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2023/06)								CUM (2021/01/01~2023/06/30)							
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	-	0	-	-	-	20	-	5.5	5.5	8	0.2	3.6	7.3	20	5.6
Lab019	5	5.0	5.1	5	0.4	7.8	17.7	20	2.3	5.0	4.7	66	0.2	4.3	14.5	20	3.3
Lab020	5	4.6	4.7	4	0.4	8.5	19.2	20	2.1	4.6	4.7	66	0.2	4.3	10.7	20	4.1
Lab022	5	4.6	-	0	-	-	-	20	-	4.6	4.7	27	0.3	6.4	14.9	20	2.8
Lab028	5	4.9	-	0	-	-	-	20	-	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	4.8	-	0	-	-	-	20	-	4.8	4.5	127	0.2	4.4	15.1	20	3.1
Lab033	5	4.7	4.4	5	0.4	9.1	24.6	20	1.5	4.7	4.6	77	0.3	6.5	15.2	20	2.7
Lab037	5	4.7	5.1	3	0.2	3.9	16.4	20	2.9	4.7	4.7	58	0.2	4.3	8.5	20	4.7
Lab040	5	4.6	-	0	-	-	-	20	-	4.6	4.6	51	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.9	5	0.1	2.0	20.7	20	1.7	4.2	4.5	94	0.5	11.1	29.4	20	1.2
Lab049	5	4.7	4.7	4	0.2	4.3	8.5	20	4.7	4.7	4.7	140	0.2	4.3	8.5	20	4.7
Total	-	-	4.8	26	0.4	8.3	-	-	-	-	4.6	748	0.3	6.5	-	-	-

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

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

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

Month : 2023 ▼ 06 ▼ Change

Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2023 ▼ 06 ▼ 30 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5