

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - March 2024 -

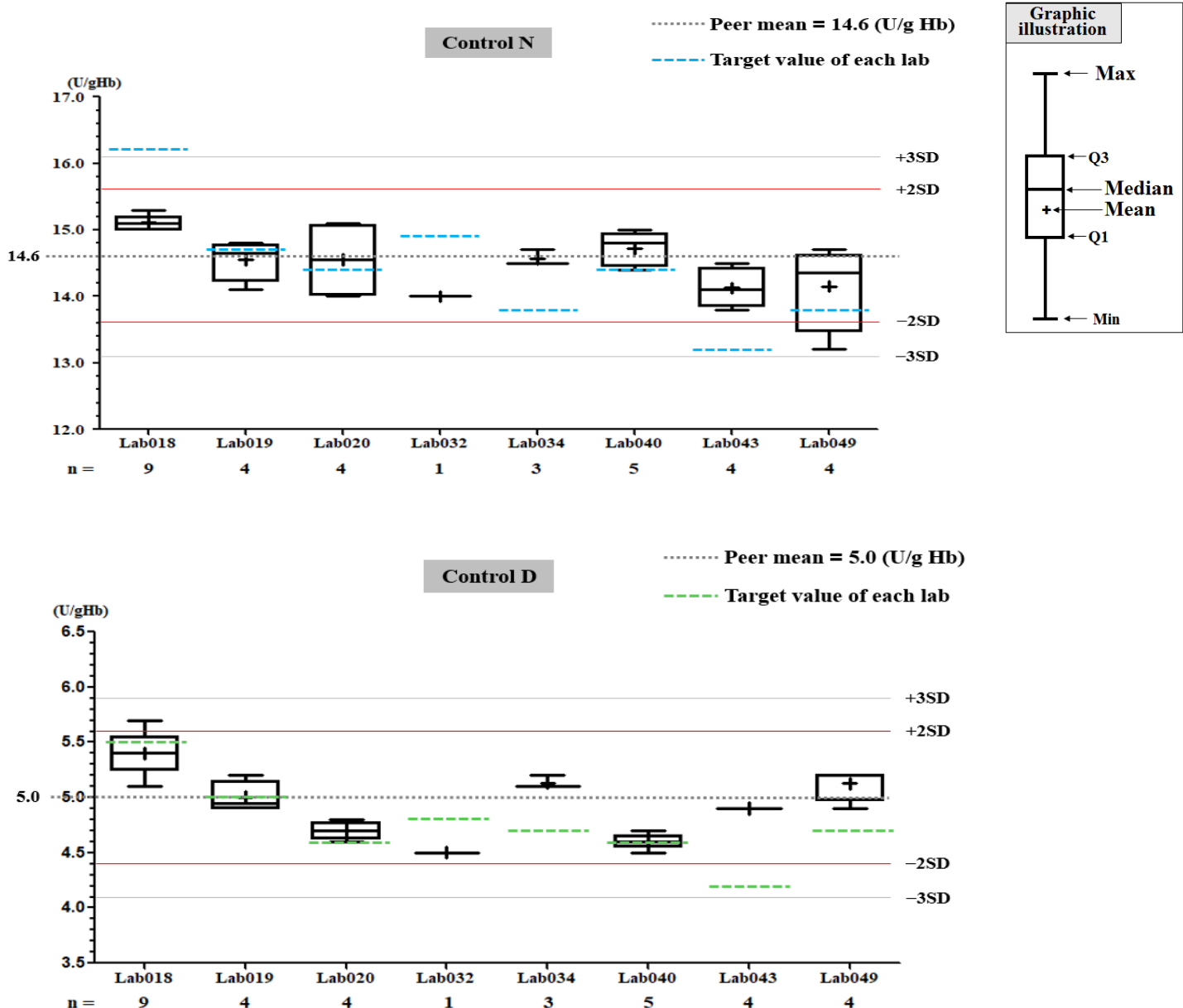
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	8	8
Received results number (n)	34	34
Median	14.7 (U/g Hb)	5.0 (U/g Hb)
Mean	14.6 (U/g Hb)	5.0 (U/g Hb)
SD	0.5	0.3
CV	3.4%	6.0%
Range of G6PD	13.2 ~ 15.3 (U/g Hb)	4.5 ~ 5.7 (U/g Hb)
Range of Hb	2.0 ~ 2.8 (g/dL)	1.8 ~ 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 : BJ0922N (2021-01-01 ~ 2100-12-31) v Change

[Print Table](#)

Lab018

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2024/03)	CUM (2024/01/09~2024/03/29)	Month (2024/03)	CUM (2024/01/09~2024/03/29)
Runs (N)	9	26	9	26
Mean (U/gHb)	15.1	15.1	5.4	5.4
SD	0.1	0.1	0.2	0.2
CV (%)	0.7	0.7	3.7	3.7
Target Value (U/gHb)	16.2	16.2	5.5	5.5
Total Error (%)	8.1	8.1	9.2	9.2
TEa (%)	20	20	20	20
σ	>6	>6	4.9	4.9

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

Month : 2024 v 03 v Change ; Cumulative : from 2024 v 01 v 09 v to 2024 v 03 v 29 v Change

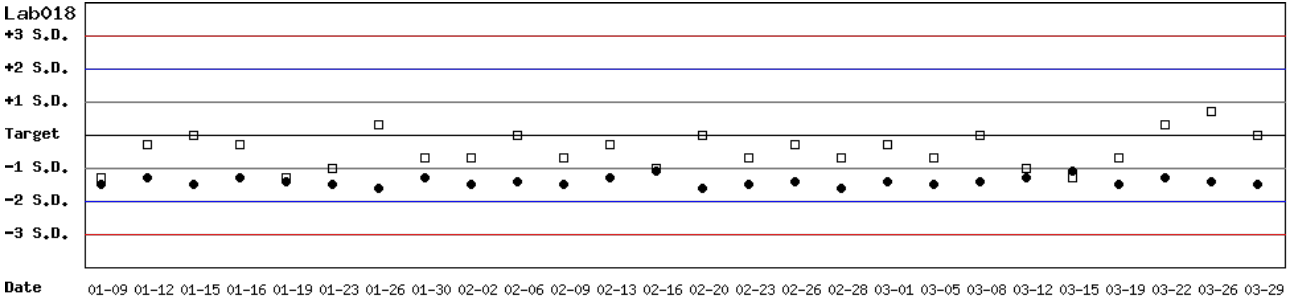
[TOP](#)

Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-01-09 to 2024-03-29 ; Target : 16.2 ; SD : 0.80 (●)

Lot No.: BJ0922D ; Duration : 2024-01-09 to 2024-03-29 ; Target : 5.5 ; SD : 0.30 (□)

Lab018



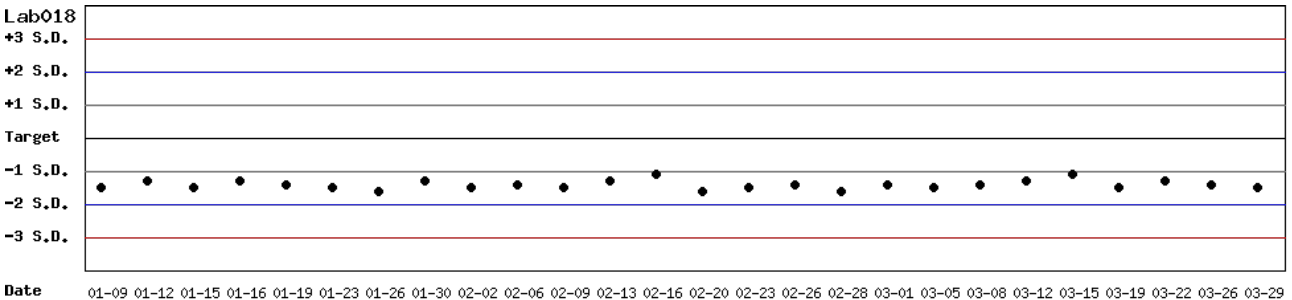
Month : 2024 v 03 v Change ; Cumulative : from 2024 v 01 v 09 v to 2024 v 03 v 29 v Change

[TOP](#)

Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-01-09 to 2024-03-29 ; Target : 16.2 ; SD : 0.80

Lab018



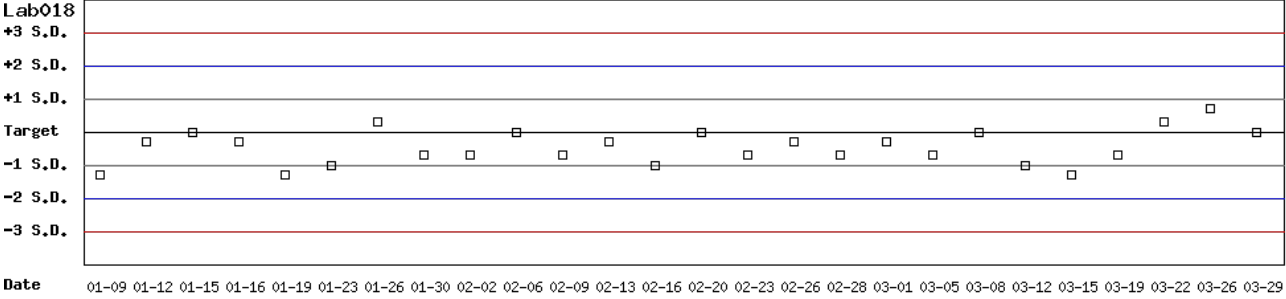
Month : 2024 v 03 v Change ; Cumulative : from 2024 v 01 v 09 v to 2024 v 03 v 29 v Change

[TOP](#)

Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2024-01-09 to 2024-03-29 ; Target : 5.5 ; SD : 0.30

Lab018



Month : 2024 v 03 v Change ; Cumulative : from 2024 v 01 v 09 v to 2024 v 03 v 29 v Change

[TOP](#)

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 : 2024 03 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
Lab018	5	16.2	15.1	9	0.1	0.7	8.1	20	>6	5.5	5.4	9	0.2	3.7	9.2	20	4.9
Lab019	5	14.7	14.6	4	0.3	2.1	4.8	20	>6	5.0	5.0	4	0.1	2.0	4.0	20	>6
Lab020	5	14.4	14.6	4	0.6	4.1	9.6	20	4.5	4.6	4.7	4	0.1	2.1	6.4	20	>6
Lab032	5	14.9	14.0	1	-	-	-	20	-	4.8	4.5	1	-	-	-	20	-
Lab034	5	13.8	14.6	3	0.1	0.7	7.2	20	>6	4.7	5.1	3	0.1	2.0	12.4	20	5.7
Lab040	5	14.4	14.7	5	0.3	2.0	6.2	20	>6	4.6	4.6	5	0.1	2.2	4.3	20	>6
Lab043	5	13.2	14.1	4	0.3	2.1	11.1	20	>6	4.2	4.9	4	0.0	0.0	16.7	20	>6
Lab049	5	13.8	14.2	4	0.7	4.9	12.8	20	3.5	4.7	5.1	4	0.2	3.9	16.4	20	2.9
Total	-	-	14.6	34	0.5	3.4	-	-	-	-	5.0	34	0.3	6.0	-	-	-

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 2024 03 31 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
Lab018	5	16.2	15.3	62	0.5	3.3	12.1	20	4.4	5.5	5.4	62	0.1	1.9	5.5	20	>6
Lab019	5	14.7	14.5	105	0.6	4.1	9.6	20	4.5	5.0	4.8	105	0.3	6.3	16.5	20	2.5
Lab020	5	14.4	14.4	85	0.5	3.5	6.9	20	5.7	4.6	4.7	85	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	153	0.4	2.8	9.6	20	5.7	4.8	4.5	153	0.2	4.4	15.1	20	3.1
Lab033	5	13.8	13.6	81	0.7	5.1	11.7	20	3.6	4.7	4.6	81	0.3	6.5	15.2	20	2.7
Lab034	5	13.8	14.6	3	0.1	0.7	7.2	20	>6	4.7	5.1	3	0.1	2.0	12.4	20	5.7
Lab037	5	13.8	14.5	59	0.5	3.4	12.0	20	4.4	4.7	4.7	59	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.8	97	0.3	2.0	6.8	20	>6	4.6	4.6	97	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.9	132	1.1	7.9	21.1	20	1.9	4.2	4.6	132	0.4	8.7	26.9	20	1.2
Lab049	5	13.8	14.4	202	0.6	4.2	12.7	20	3.7	4.7	4.7	202	0.3	6.4	12.8	20	3.1
Lab050	5	13.8	14.1	7	0.9	6.4	14.9	20	2.8	4.7	5.4	7	0.4	7.4	29.7	20	0.7
Total	-	-	14.4	1047	0.8	5.6	-	-	-	-	4.7	1047	0.3	6.4	-	-	-

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

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

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

[TOP](#)

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 (2024/03)								CUM (2021/01/01~2024/03/31)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	15.1	9	0.1	0.7	8.1	20	>6	16.2	15.3	62	0.5	3.3	12.1	20	4.4
Lab019	5	14.7	14.6	4	0.3	2.1	4.8	20	>6	14.7	14.5	105	0.6	4.1	9.6	20	4.5
Lab020	5	14.4	14.6	4	0.6	4.1	9.6	20	4.5	14.4	14.4	85	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	14.0	1	-	-	-	20	-	14.9	14.3	153	0.4	2.8	9.6	20	5.7
Lab033	5	13.8	-	0	-	-	-	20	-	13.8	13.6	81	0.7	5.1	11.7	20	3.6
Lab034	5	13.8	14.6	3	0.1	0.7	7.2	20	>6	13.8	14.6	3	0.1	0.7	7.2	20	>6
Lab037	5	13.8	-	0	-	-	-	20	-	13.8	14.5	59	0.5	3.4	12.0	20	4.4
Lab040	5	14.4	14.7	5	0.3	2.0	6.2	20	>6	14.4	14.8	97	0.3	2.0	6.8	20	>6
Lab043	5	13.2	14.1	4	0.3	2.1	11.1	20	>6	13.2	13.9	132	1.1	7.9	21.1	20	1.9
Lab049	5	13.8	14.2	4	0.7	4.9	12.8	20	3.5	13.8	14.4	202	0.6	4.2	12.7	20	3.7
Lab050	5	13.8	-	0	-	-	-	20	-	13.8	14.1	7	0.9	6.4	14.9	20	2.8
Total	-	-	14.6	34	0.5	3.4	-	-	-	-	14.4	1047	0.8	5.6	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%
 TE : Total Error(%) = Bias (%) + 2 × CV (%)
 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2024 03 Change

Cumulative : from 2021 01 01 to 2024 03 31 Change

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2024/03)								CUM (2021/01/01~2024/03/31)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	5.4	9	0.2	3.7	9.2	20	4.9	5.5	5.4	62	0.1	1.9	5.5	20	>6
Lab019	5	5.0	5.0	4	0.1	2.0	4.0	20	>6	5.0	4.8	105	0.3	6.3	16.5	20	2.5
Lab020	5	4.6	4.7	4	0.1	2.1	6.4	20	>6	4.6	4.7	85	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	4.5	1	-	-	-	20	-	4.8	4.5	153	0.2	4.4	15.1	20	3.1
Lab033	5	4.7	-	0	-	-	-	20	-	4.7	4.6	81	0.3	6.5	15.2	20	2.7
Lab034	5	4.7	5.1	3	0.1	2.0	12.4	20	5.7	4.7	5.1	3	0.1	2.0	12.4	20	5.7
Lab037	5	4.7	-	0	-	-	-	20	-	4.7	4.7	59	0.2	4.3	8.5	20	4.7
Lab040	5	4.6	4.6	5	0.1	2.2	4.3	20	>6	4.6	4.6	97	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.9	4	0.0	0.0	16.7	20	>6	4.2	4.6	132	0.4	8.7	26.9	20	1.2
Lab049	5	4.7	5.1	4	0.2	3.9	16.4	20	2.9	4.7	4.7	202	0.3	6.4	12.8	20	3.1
Lab050	5	4.7	-	0	-	-	-	20	-	4.7	5.4	7	0.4	7.4	29.7	20	0.7
Total	-	-	5.0	34	0.3	6.0	-	-	-	-	4.7	1047	0.3	6.4	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%
 TE : Total Error(%) = Bias (%) + 2 × CV (%)
 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2024 03 Change

Cumulative : from 2021 01 01 to 2024 03 31 Change

[TOP](#)

Reagent Kit	Reagent Code
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