

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

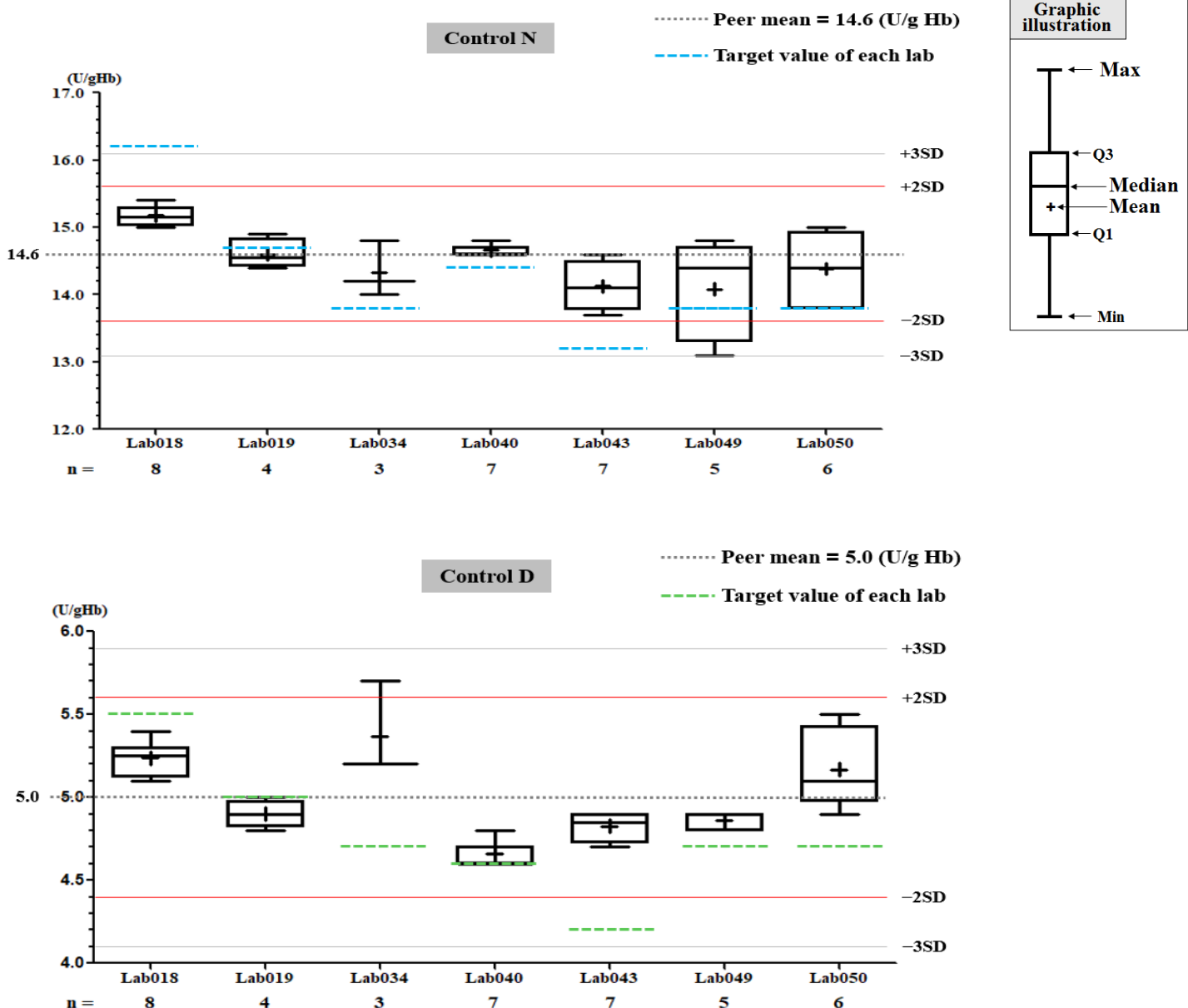
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	7	7
Received results number (n)	37	37
Median	14.6 (U/g Hb)	4.9 (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	13.1 ~ 15.4 (U/g Hb)	4.6 ~ 5.7 (U/g Hb)
Range of Hb	2.0 ~ 2.7 (g/dL)	1.8 ~ 2.3 (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](#)

Lab049

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2024/04)	CUM (2024/01/24~2024/04/30)	Month (2024/04)	CUM (2024/01/24~2024/04/30)
Runs (N)	5	25	5	25
Mean (U/gHb)	14.1	14.2	4.9	4.8
SD	0.7	0.6	0.1	0.3
CV (%)	5.0	4.2	2.0	6.3
Target Value (U/gHb)	13.8	13.8	4.7	4.7
Total Error (%)	12.1	11.3	8.3	14.6
TEa (%)	20	20	20	20
σ	3.6	4.1	>6	2.8

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

Month : 2024 04 Change ; Cumulative : from 2024 01 24 to 2024 04 30 Change

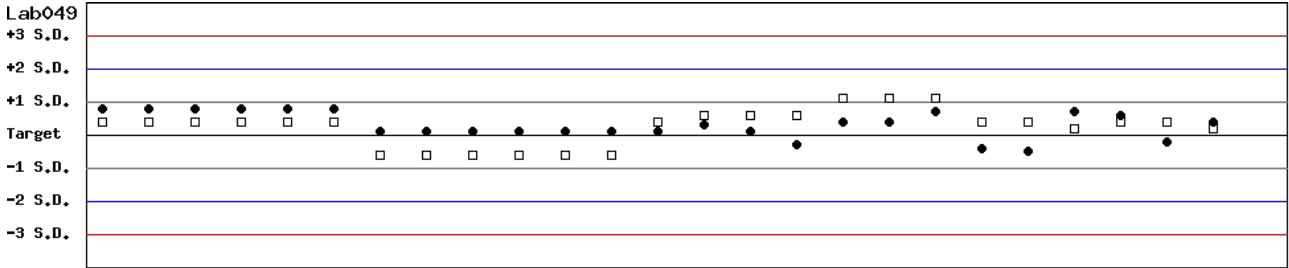
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-01-24 to 2024-04-30 ; Target : 13.8 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2024-01-24 to 2024-04-30 ; Target : 4.7 ; SD : 0.47 (□)

Lab049



Date 01-24 01-24 01-24 01-24 01-24 01-24 01-31 01-31 01-31 01-31 01-31 01-31 01-31 02-07 02-14 02-21 02-28 03-06 03-13 03-20 03-26 04-03 04-11 04-17 04-24 04-30

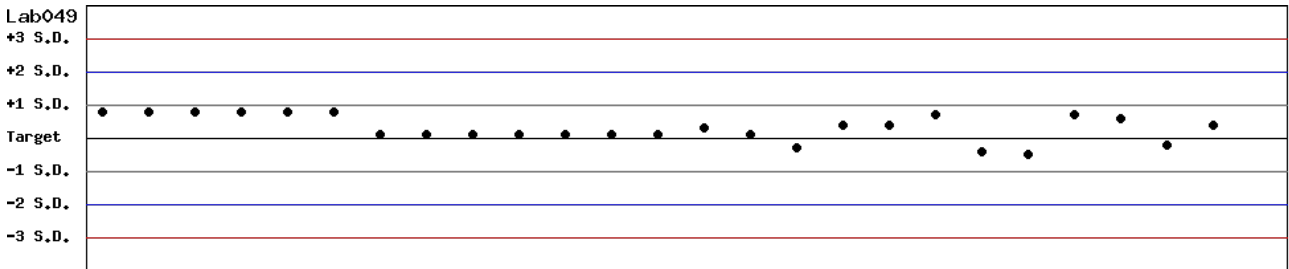
Month : 2024 04 Change ; Cumulative : from 2024 01 24 to 2024 04 30 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-01-24 to 2024-04-30 ; Target : 13.8 ; SD : 1.38

Lab049



Date 01-24 01-24 01-24 01-24 01-24 01-24 01-31 01-31 01-31 01-31 01-31 01-31 01-31 02-07 02-14 02-21 02-28 03-06 03-13 03-20 03-26 04-03 04-11 04-17 04-24 04-30

Month : 2024 04 Change ; Cumulative : from 2024 01 24 to 2024 04 30 Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2024-01-24 to 2024-04-30 ; Target : 4.7 ; SD : 0.47

Lab049



Date 01-24 01-24 01-24 01-24 01-24 01-24 01-31 01-31 01-31 01-31 01-31 01-31 02-07 02-14 02-21 02-28 03-06 03-13 03-20 03-26 04-03 04-11 04-17 04-24 04-30

Month : 2024 04 Change ; Cumulative : from 2024 01 24 to 2024 04 30 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 : 2024 04 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	15.2	8	0.2	1.3	8.8	20	>6	5.5	5.2	8	0.1	1.9	9.3	20	>6
Lab019	5	14.7	14.6	4	0.2	1.4	3.4	20	>6	5.0	4.9	4	0.1	2.0	6.1	20	>6
Lab034	5	13.8	14.3	3	0.4	2.8	9.2	20	5.8	4.7	5.4	3	0.3	5.6	26.0	20	0.9
Lab040	5	14.4	14.7	7	0.1	0.7	3.4	20	>6	4.6	4.7	7	0.1	2.1	6.4	20	>6
Lab043	5	13.2	14.1	4	0.4	2.8	12.5	20	4.7	4.2	4.8	4	0.1	2.1	18.5	20	2.7
Lab049	5	13.8	14.1	5	0.7	5.0	12.1	20	3.6	4.7	4.9	5	0.1	2.0	8.3	20	>6
Lab050	5	13.8	14.4	6	0.5	3.5	11.3	20	4.5	4.7	5.2	6	0.2	3.8	18.3	20	2.5
Total	-	-	14.6	37	0.5	3.4	-	-	-	-	5.0	37	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 04 30 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	70	0.5	3.3	12.1	20	4.4	5.5	5.4	70	0.1	1.9	5.5	20	>6
Lab019	5	14.7	14.5	109	0.6	4.1	9.6	20	4.5	5.0	4.8	109	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	14.5	6	0.3	2.1	9.2	20	>6	4.7	5.3	6	0.2	3.8	20.3	20	1.9
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	104	0.2	1.4	5.5	20	>6	4.6	4.6	104	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.9	136	1.1	7.9	21.1	20	1.9	4.2	4.6	136	0.4	8.7	26.9	20	1.2
Lab049	5	13.8	14.4	207	0.6	4.2	12.7	20	3.7	4.7	4.7	207	0.3	6.4	12.8	20	3.1
Lab050	5	13.8	14.2	13	0.7	4.9	12.8	20	3.5	4.7	5.3	13	0.3	5.7	24.1	20	1.3
Total	-	-	14.4	1084	0.8	5.6	-	-	-	-	4.7	1084	0.3	6.4	-	-	-

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 (2024/04)									CUM (2021/01/01-2024/04/30)						
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	15.2	8	0.2	1.3	8.8	20	>6	16.2	15.3	70	0.5	3.3	12.1	20	4.4
Lab019	5	14.7	14.6	4	0.2	1.4	3.4	20	>6	14.7	14.5	109	0.6	4.1	9.6	20	4.5
Lab020	5	14.4	-	0	-	-	-	20	-	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	-	0	-	-	-	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	14.3	3	0.4	2.8	9.2	20	5.8	13.8	14.5	6	0.3	2.1	9.2	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	7	0.1	0.7	3.4	20	>6	14.4	14.8	104	0.2	1.4	5.5	20	>6
Lab043	5	13.2	14.1	4	0.4	2.8	12.5	20	4.7	13.2	13.9	136	1.1	7.9	21.1	20	1.9
Lab049	5	13.8	14.1	5	0.7	5.0	12.1	20	3.6	13.8	14.4	207	0.6	4.2	12.7	20	3.7
Lab050	5	13.8	14.4	6	0.5	3.5	11.3	20	4.5	13.8	14.2	13	0.7	4.9	12.8	20	3.5
Total	-	-	14.6	37	0.5	3.4	-	-	-	-	14.4	1084	0.8	5.6	-	-	-

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

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

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

Month : 2024 04 Change

Cumulative : from 2021 01 01 to 2024 04 30 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2024/04)									CUM (2021/01/01-2024/04/30)						
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	5.2	8	0.1	1.9	9.3	20	>6	5.5	5.4	70	0.1	1.9	5.5	20	>6
Lab019	5	5.0	4.9	4	0.1	2.0	6.1	20	>6	5.0	4.8	109	0.3	6.3	16.5	20	2.5
Lab020	5	4.6	-	0	-	-	-	20	-	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	-	0	-	-	-	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	5.4	3	0.3	5.6	26.0	20	0.9	4.7	5.3	6	0.2	3.8	20.3	20	1.9
Lab037	5	4.7	-	0	-	-	-	20	-	4.7	4.7	59	0.2	4.3	8.5	20	4.7
Lab040	5	4.6	4.7	7	0.1	2.1	6.4	20	>6	4.6	4.6	104	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.8	4	0.1	2.1	18.5	20	2.7	4.2	4.6	136	0.4	8.7	26.9	20	1.2
Lab049	5	4.7	4.9	5	0.1	2.0	8.3	20	>6	4.7	4.7	207	0.3	6.4	12.8	20	3.1
Lab050	5	4.7	5.2	6	0.2	3.8	18.3	20	2.5	4.7	5.3	13	0.3	5.7	24.1	20	1.3
Total	-	-	5.0	37	0.3	6.0	-	-	-	-	4.7	1084	0.3	6.4	-	-	-

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

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

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

Month : 2024 04 Change

Cumulative : from 2021 01 01 to 2024 04 30 Change

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Reagent Kit	Reagent Code
Medicon	5