

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

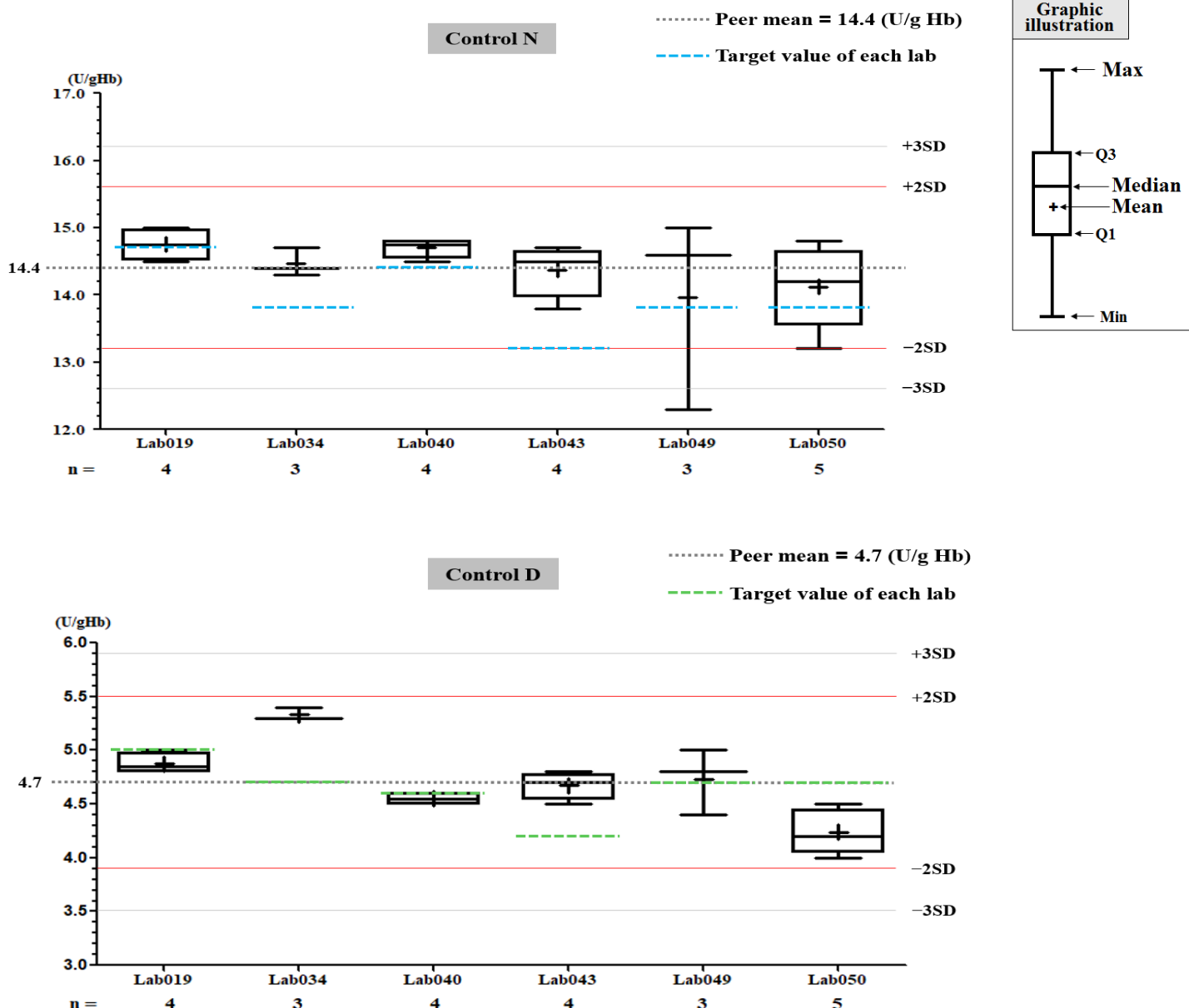
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	6	6
Received results number (n)	23	23
Median	14.5 (U/g Hb)	4.7 (U/g Hb)
Mean	14.4 (U/g Hb)	4.7 (U/g Hb)
SD	0.6	0.4
CV	4.2%	8.5%
Range of G6PD	12.3 ~ 15.0 (U/g Hb)	4.0 ~ 5.4 (U/g Hb)
Range of Hb	2.0 ~ 2.5 (g/dL)	1.9 ~ 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

	Control N		Control D	
QC Control Lot No.	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2024/12)	CUM (2024/06/26~2024/12/27)	Month (2024/12)	CUM (2024/06/26~2024/12/27)
Runs (N)	3	26	3	26
Mean (U/gHb)	14.0	14.0	4.7	4.8
SD	1.5	0.6	0.3	0.2
CV (%)	10.7	4.3	6.4	4.2
Target Value (U/gHb)	13.8	13.8	4.7	4.7
Total Error (%)	22.9	10.0	12.8	10.5
TEa (%)	20	20	20	20
σ	1.7	4.3	3.1	4.3

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

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

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

Month : 2024 12 Change ; Cumulative : from 2024 06 26 to 2024 12 27 Change

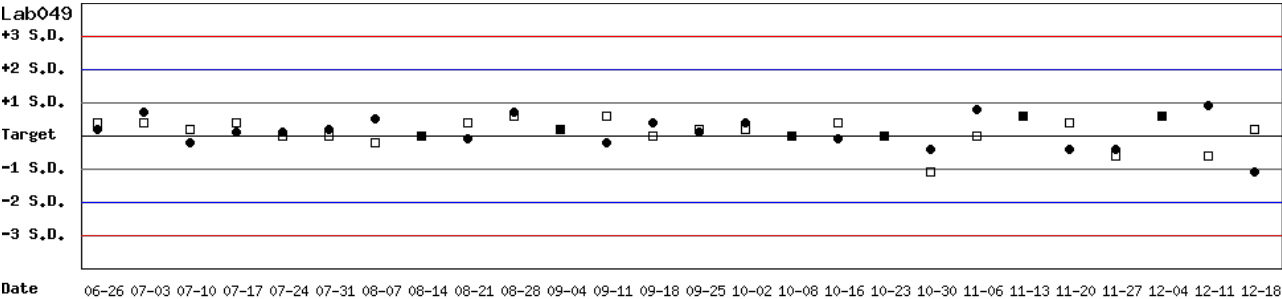
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Control N and Control D SDI
QC Chart

Lot No.: BJ0922N ; Duration : 2024-06-26 to 2024-12-27 ; Target : 13.8 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2024-06-26 to 2024-12-27 ; Target : 4.7 ; SD : 0.47 (□)

Lab049



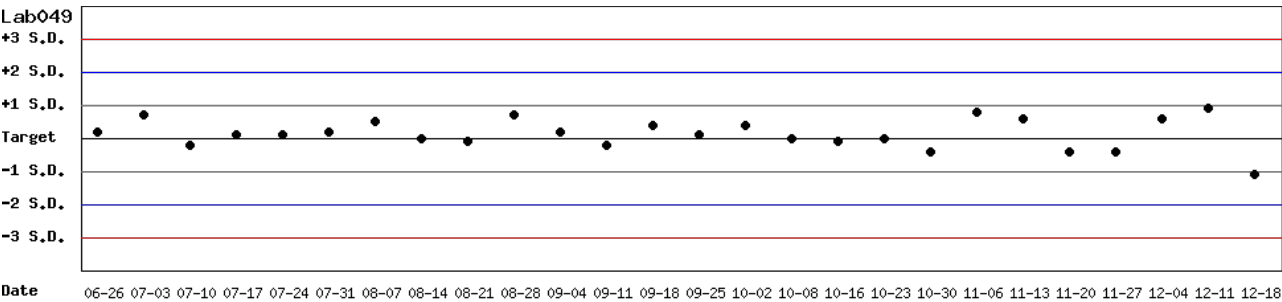
Month : 2024 12 Change ; Cumulative : from 2024 06 26 to 2024 12 27 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-06-26 to 2024-12-27 ; Target : 13.8 ; SD : 1.38

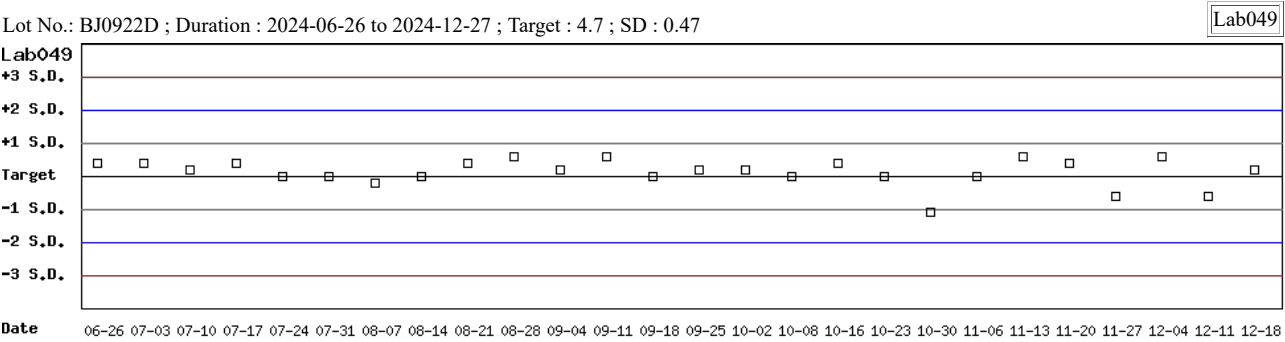
Lab049



Month : 2024 12 Change ; Cumulative : from 2024 06 26 to 2024 12 27 Change

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Control D SDI QC Chart



Month : 2024 12 Change ; Cumulative : from 2024 06 26 to 2024 12 27 Change

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 12 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	14.7	14.8	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	14.5	3	0.2	1.4	7.8	20	>6		4.7	5.3	3	0.1	1.9	16.5	20	3.8
Lab040	5	14.4	14.7	4	0.1	0.7	3.4	20	>6		4.6	4.6	4	0.1	2.2	4.3	20	>6
Lab043	5	13.2	14.4	4	0.4	2.8	14.6	20	3.9		4.2	4.7	4	0.1	2.1	16.2	20	3.9
Lab049	5	13.8	14.0	3	1.5	10.7	22.9	20	1.7		4.7	4.7	3	0.3	6.4	12.8	20	3.1
Lab050	5	13.8	14.1	5	0.6	4.3	10.7	20	4.1		4.7	4.2	5	0.2	4.8	20.2	20	2.0
Total	-	-	14.4	23	0.6	4.2	-	-	-		-	4.7	23	0.4	8.5	-	-	-

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 2024 12 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
Lab018	5	16.2	15.3	113	0.4	2.6	10.8	20	5.6		5.5	5.4	113	0.1	1.9	5.5	20	>6
Lab019	5	14.7	14.6	144	0.6	4.1	8.9	20	4.7		5.0	4.8	144	0.2	4.2	12.3	20	3.8
Lab020	5	14.4	14.4	90	0.5	3.5	6.9	20	5.7		4.6	4.7	90	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
Lab025	5	14.4	14.2	13	0.5	3.5	8.4	20	5.3		5.4	5.1	13	0.3	5.9	17.3	20	2.4
Lab028	5	15.2	15.1	54	0.9	6.0	12.6	20	3.2		4.9	5.0	54	0.3	6.0	14.0	20	3.0
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	14.3	27	0.5	3.5	10.6	20	4.7		4.7	5.2	27	0.2	3.8	18.3	20	2.5
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	140	0.2	1.4	5.5	20	>6		4.6	4.6	140	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.9	170	1.0	7.2	19.7	20	2.0		4.2	4.6	170	0.4	8.7	26.9	20	1.2
Lab049	5	13.8	14.4	240	0.6	4.2	12.7	20	3.7		4.7	4.7	240	0.3	6.4	12.8	20	3.1
Lab050	5	13.8	14.6	64	0.6	4.1	14.0	20	3.5		4.7	5.1	64	0.5	9.8	28.1	20	1.2
Total	-	-	14.5	1375	0.7	4.8	-	-	-		-	4.8	1375	0.4	8.3	-	-	-

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 (2024/12)								CUM (2021/01/01~2024/12/31)							
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
Lab018	5	16.2	-	0	-	-	-	20	-	16.2	15.3	113	0.4	2.6	10.8	20	5.6
Lab019	5	14.7	14.8	4	0.2	1.4	3.4	20	>6	14.7	14.6	144	0.6	4.1	8.9	20	4.7
Lab020	5	14.4	-	0	-	-	-	20	-	14.4	14.4	90	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
Lab025	5	14.4	-	0	-	-	-	20	-	14.4	14.2	13	0.5	3.5	8.4	20	5.3
Lab028	5	15.2	-	0	-	-	-	20	-	15.2	15.1	54	0.9	6.0	12.6	20	3.2
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	14.5	3	0.2	1.4	7.8	20	>6	13.8	14.3	27	0.5	3.5	10.6	20	4.7
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	4	0.1	0.7	3.4	20	>6	14.4	14.8	140	0.2	1.4	5.5	20	>6
Lab043	5	13.2	14.4	4	0.4	2.8	14.6	20	3.9	13.2	13.9	170	1.0	7.2	19.7	20	2.0
Lab049	5	13.8	14.0	3	1.5	10.7	22.9	20	1.7	13.8	14.4	240	0.6	4.2	12.7	20	3.7
Lab050	5	13.8	14.1	5	0.6	4.3	10.7	20	4.1	13.8	14.6	64	0.6	4.1	14.0	20	3.5
Total	-	-	14.4	23	0.6	4.2	-	-	-	-	14.5	1375	0.7	4.8	-	-	-

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

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

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

Month : 2024 12 Change

Cumulative : from 2021 01 01 to 2024 12 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2024/12)								CUM (2021/01/01~2024/12/31)							
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
Lab018	5	5.5	-	0	-	-	-	20	-	5.5	5.4	113	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	144	0.2	4.2	12.3	20	3.8
Lab020	5	4.6	-	0	-	-	-	20	-	4.6	4.7	90	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
Lab025	5	5.4	-	0	-	-	-	20	-	5.4	5.1	13	0.3	5.9	17.3	20	2.4
Lab028	5	4.9	-	0	-	-	-	20	-	4.9	5.0	54	0.3	6.0	14.0	20	3.0
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	5.3	3	0.1	1.9	16.5	20	3.8	4.7	5.2	27	0.2	3.8	18.3	20	2.5
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	4	0.1	2.2	4.3	20	>6	4.6	4.6	140	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.7	4	0.1	2.1	16.2	20	3.9	4.2	4.6	170	0.4	8.7	26.9	20	1.2
Lab049	5	4.7	4.7	3	0.3	6.4	12.8	20	3.1	4.7	4.7	240	0.3	6.4	12.8	20	3.1
Lab050	5	4.7	4.2	5	0.2	4.8	20.2	20	2.0	4.7	5.1	64	0.5	9.8	28.1	20	1.2
Total	-	-	4.7	23	0.4	8.5	-	-	-	-	4.8	1375	0.4	8.3	-	-	-

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

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

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

Month : 2024 12 Change

Cumulative : from 2021 01 01 to 2024 12 31 Change

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Reagent Kit	Reagent Code
Medicon	5