

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - January 2025 -

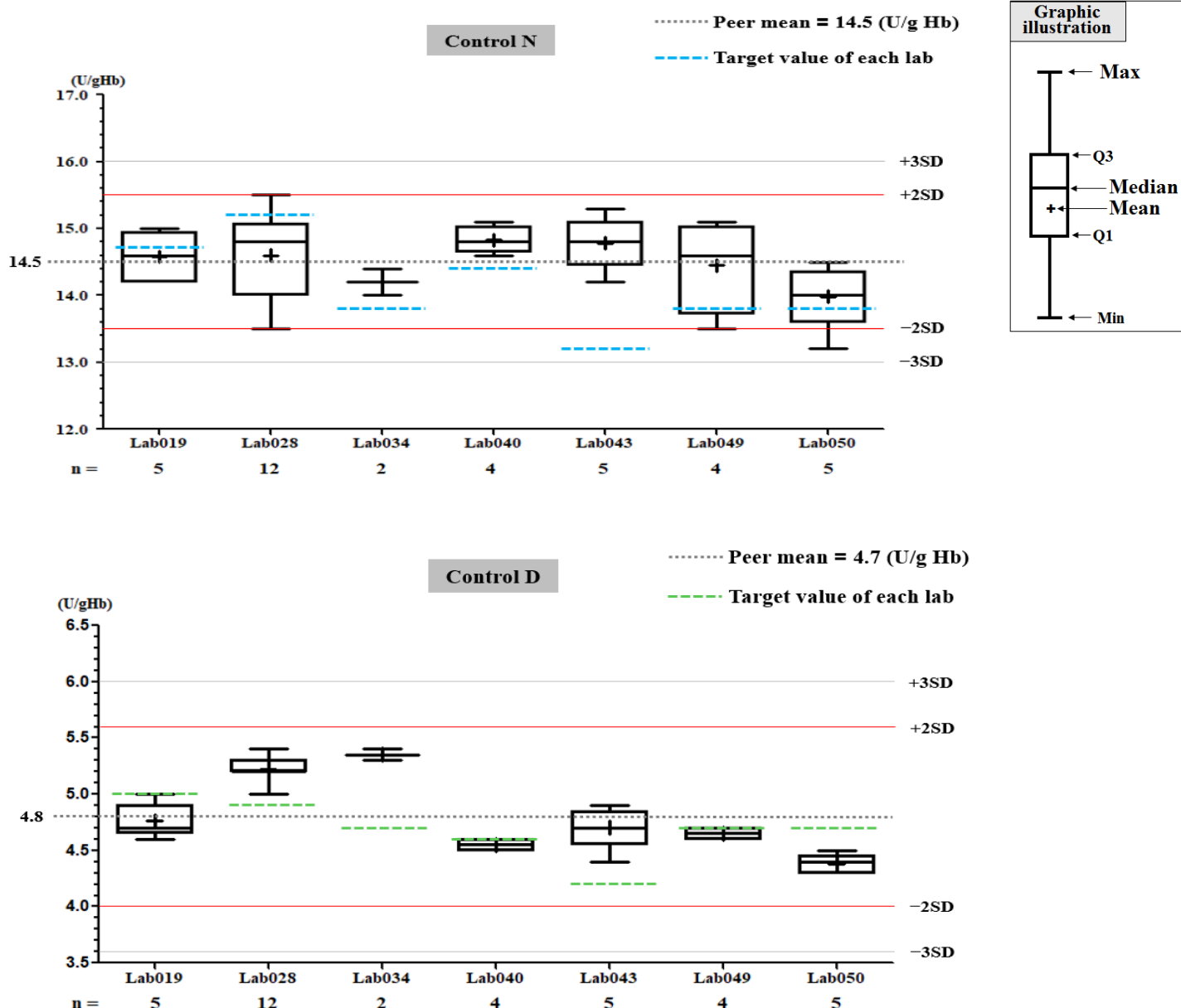
I. The statistic results of all laboratories in this month

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)	4.7 (U/g Hb)
Mean	14.5 (U/g Hb)	4.8 (U/g Hb)
SD	0.5	0.4
CV	3.4%	8.3%
Range of G6PD	13.2 ~ 15.5 (U/g Hb)	4.3 ~ 5.4 (U/g Hb)
Range of Hb	1.9 ~ 2.6 (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

Lab040

	Control N		Control D	
QC Control Lot No.	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2025/01)	CUM (2024/08/01~2025/01/31)	Month (2025/01)	CUM (2024/08/01~2025/01/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.8	14.8	4.6	4.6
SD	0.2	0.2	0.1	0.1
CV (%)	1.4	1.4	2.2	2.2
Target Value (U/gHb)	14.4	14.4	4.6	4.6
Total Error (%)	5.5	5.5	4.3	4.3
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

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

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

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

Month : 2025 01 Change ; Cumulative : from 2024 08 01 to 2025 01 31 Change

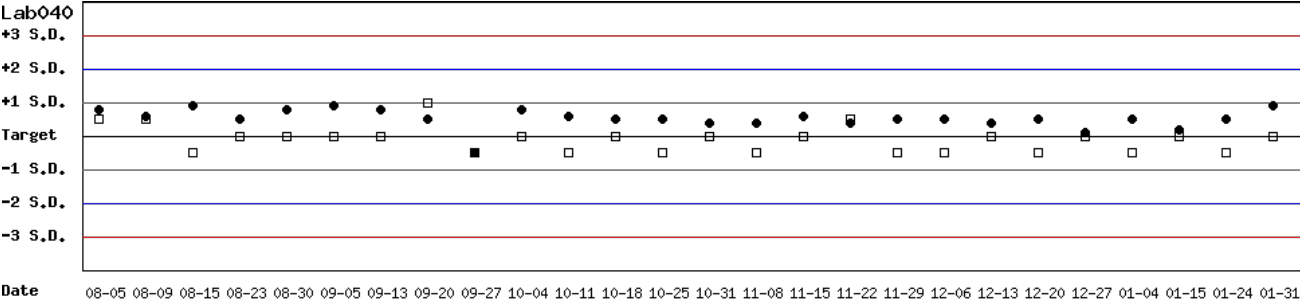
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Control N and Control D SDI
QC Chart

Lot No.: BJ0922N ; Duration : 2024-08-01 to 2025-01-31 ; Target : 14.4 ; SD : 0.80 (●)

Lot No.: BJ0922D ; Duration : 2024-08-01 to 2025-01-31 ; Target : 4.6 ; SD : 0.20 (□)

Lab040

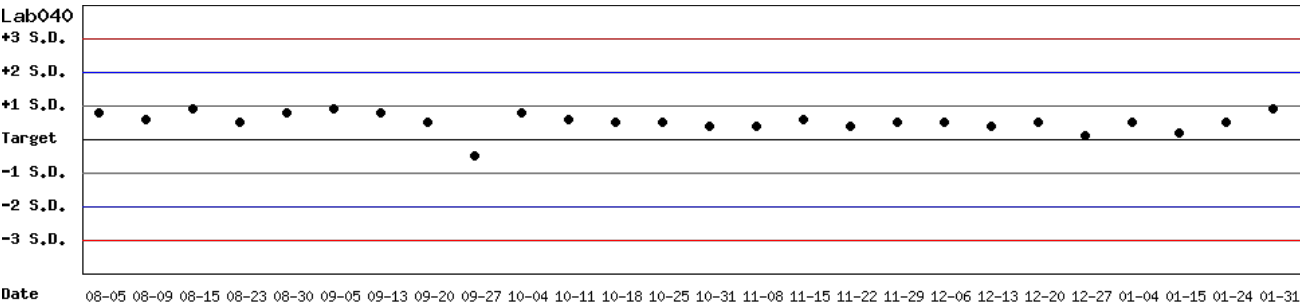


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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-08-01 to 2025-01-31 ; Target : 14.4 ; SD : 0.80

Lab040



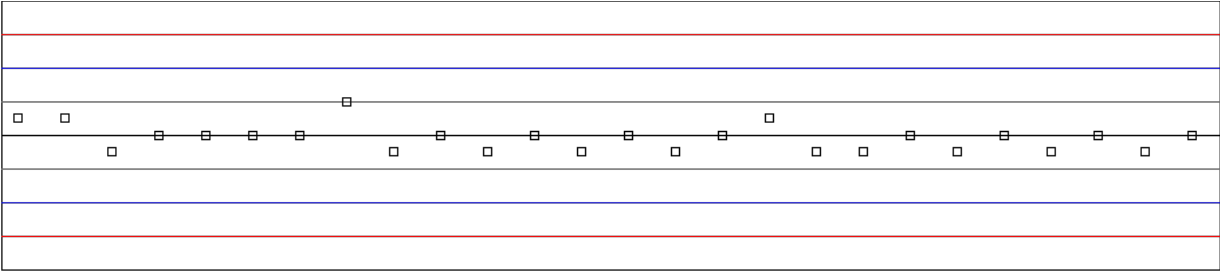
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Control D SDI QC Chart

Lab040

Lot No.: BJ0922D ; Duration : 2024-08-01 to 2025-01-31 ; Target : 4.6 ; SD : 0.20

Lab040
+3 S.D.
+2 S.D.
+1 S.D.
Target
-1 S.D.
-2 S.D.
-3 S.D.



Date 08-05 08-09 08-15 08-23 08-30 09-05 09-13 09-20 09-27 10-04 10-11 10-18 10-25 10-31 11-08 11-15 11-22 11-29 12-06 12-13 12-20 12-27 01-04 01-15 01-24 01-31

Month : 2025 01 Change ; Cumulative : from 2024 08 01 to 2025 01 31 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 : 2025 01 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	14.6	5	0.4	2.7	6.2	20	>6		5.0	4.8	5	0.2	4.2	12.3	20	3.8
Lab028	5	15.2	14.6	12	0.6	4.1	12.2	20	3.9		4.9	5.2	12	0.1	1.9	10.0	20	>6
Lab034	5	13.8	14.2	2	-	-	-	20	-		4.7	5.4	2	-	-	-	20	-
Lab040	5	14.4	14.8	4	0.2	1.4	5.5	20	>6		4.6	4.6	4	0.1	2.2	4.3	20	>6
Lab043	5	13.2	14.8	5	0.4	2.7	17.5	20	2.9		4.2	4.7	5	0.2	4.3	20.4	20	1.9
Lab049	5	13.8	14.5	4	0.7	4.8	14.7	20	3.1		4.7	4.7	4	0.1	2.1	4.3	20	>6
Lab050	5	13.8	14.0	5	0.5	3.6	8.6	20	5.2		4.7	4.4	5	0.1	2.3	10.9	20	5.9
Total	-	-	14.5	37	0.5	3.4	-	-	-		-	4.8	37	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 01 01 to 2025 01 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	149	0.6	4.1	8.9	20	4.7		5.0	4.8	149	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	15.0	66	0.9	6.0	13.3	20	3.1		4.9	5.1	66	0.3	5.9	15.8	20	2.7
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	29	0.5	3.5	10.6	20	4.7		4.7	5.2	29	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	144	0.2	1.4	5.5	20	>6		4.6	4.6	144	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.9	175	1.0	7.2	19.7	20	2.0		4.2	4.6	175	0.4	8.7	26.9	20	1.2
Lab049	5	13.8	14.4	244	0.6	4.2	12.7	20	3.7		4.7	4.7	244	0.3	6.4	12.8	20	3.1
Lab050	5	13.8	14.5	69	0.6	4.1	13.3	20	3.6		4.7	5.0	69	0.5	10.0	26.4	20	1.4
Total	-	-	14.5	1412	0.7	4.8	-	-	-		-	4.8	1412	0.4	8.3	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%
TE : Total Error(%) = Bias (%) + 2 x 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 - MediconChange

Print Table 2

Control N Month vs. Cumulative

		Control N (Lot No.: BJ0922N)																
		Month (2025/01)									CUM (2021/01/01~2025/01/31)							
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	14.6	5	0.4	2.7	6.2	20	>6		14.7	14.6	149	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	14.6	12	0.6	4.1	12.2	20	3.9		15.2	15.0	66	0.9	6.0	13.3	20	3.1
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	14.2	2	-	-	-	20	-		13.8	14.3	29	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	14.8	4	0.2	1.4	5.5	20	>6		14.4	14.8	144	0.2	1.4	5.5	20	>6
Lab043	5	13.2	14.8	5	0.4	2.7	17.5	20	2.9		13.2	13.9	175	1.0	7.2	19.7	20	2.0
Lab049	5	13.8	14.5	4	0.7	4.8	14.7	20	3.1		13.8	14.4	244	0.6	4.2	12.7	20	3.7
Lab050	5	13.8	14.0	5	0.5	3.6	8.6	20	5.2		13.8	14.5	69	0.6	4.1	13.3	20	3.6
Total	-	-	14.5	37	0.5	3.4	-	-	-		-	14.5	1412	0.7	4.8	-	-	-

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

Month : 202501Change

Cumulative : from 20210101 to 20250131Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)																
		Month (2025/01)									CUM (2021/01/01~2025/01/31)							
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	4.8	5	0.2	4.2	12.3	20	3.8		5.0	4.8	149	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	5.2	12	0.1	1.9	10.0	20	>6		4.9	5.1	66	0.3	5.9	15.8	20	2.7
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	2	-	-	-	20	-		4.7	5.2	29	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	144	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.7	5	0.2	4.3	20.4	20	1.9		4.2	4.6	175	0.4	8.7	26.9	20	1.2
Lab049	5	4.7	4.7	4	0.1	2.1	4.3	20	>6		4.7	4.7	244	0.3	6.4	12.8	20	3.1
Lab050	5	4.7	4.4	5	0.1	2.3	10.9	20	5.9		4.7	5.0	69	0.5	10.0	26.4	20	1.4
Total	-	-	4.8	37	0.4	8.3	-	-	-		-	4.8	1412	0.4	8.3	-	-	-

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

Month : 202501Change

Cumulative : from 20210101 to 20250131Change

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Reagent Kit	Reagent Code
Medicon	5