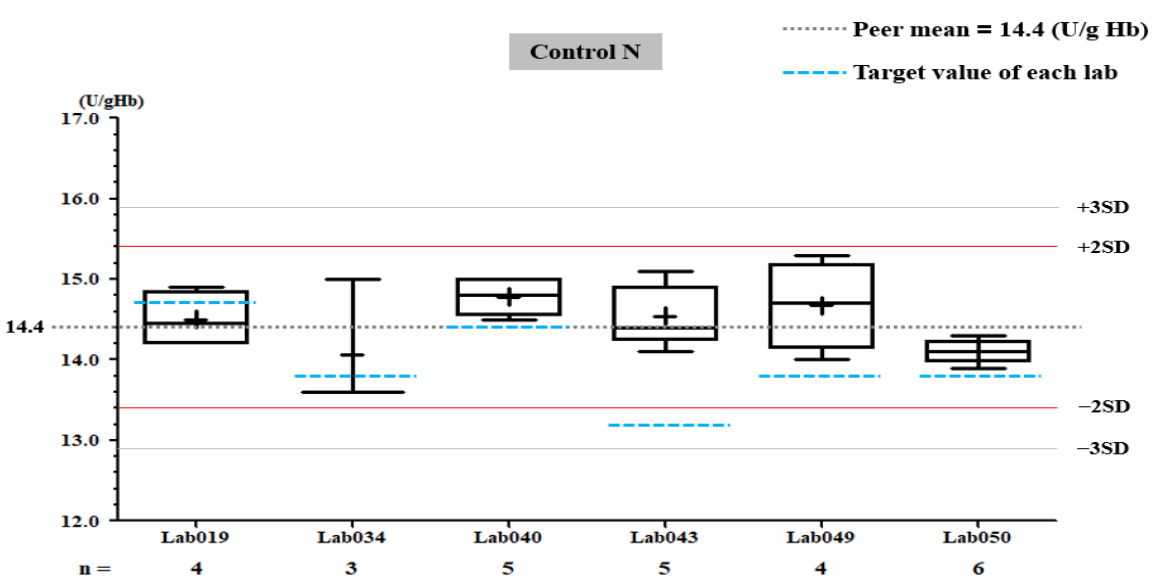
Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - May 2025 -

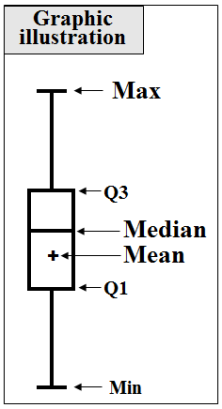
I. The statistic results of all laboratories in this month

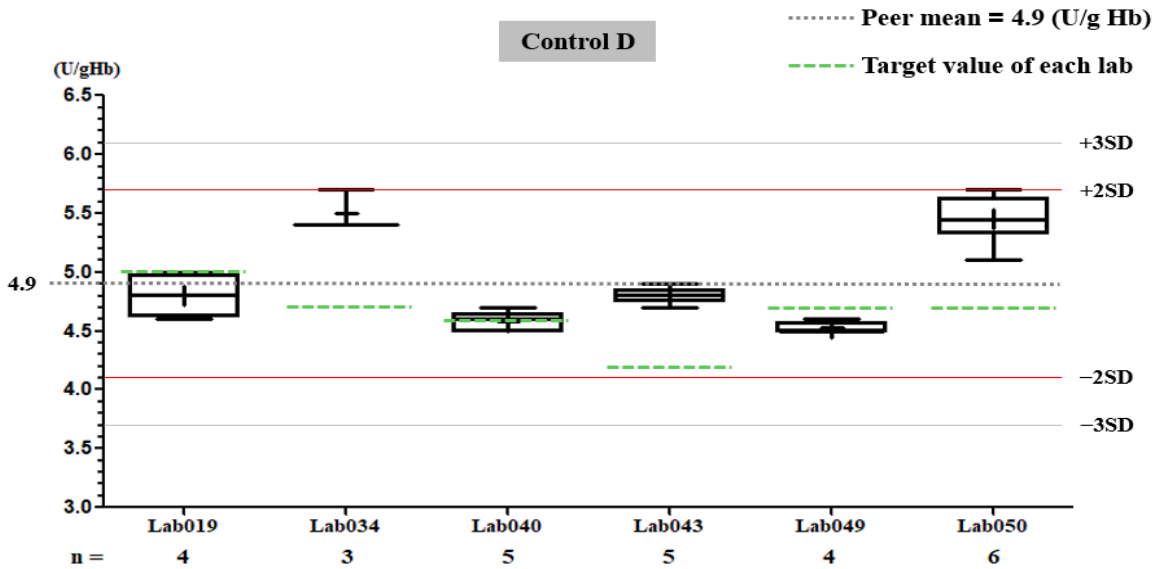
G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	6	6
Received results number (n)	27	27
Median	14.4 (U/g Hb)	4.8 (U/g Hb)
Mean	14.4 (U/g Hb)	4.9 (U/g Hb)
SD	0.5	0.4
CV	3.5%	8.2%
Range of G6PD	13.6 ~ 15.3 (U/g Hb)	4.5 ~ 5.7 (U/g Hb)
Range of Hb	1.9 ~ 2.6 (g/dL)	1.8 ~ 2.3 (g/dL)

*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







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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 (2025/05)	CUM (2024/11/13~2025/05/30)	Month (2025/05)	CUM (2024/11/13~2025/05/30)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.7	14.3	4.5	4.5
SD	0.5	0.7	0.1	0.3
CV (%)	3.4	4.9	2.2	6.7
Target Value (U/gHb)	13.8	13.8	4.7	4.7
Total Error (%)	13.3	13.4	8.7	17.6
TEa (%)	20	20	20	20
σ	4.0	3.3	>6	2.3

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

Month : 2025 05 Change ; Cumulative : from 2024 11 13 to 2025 05 30 Change

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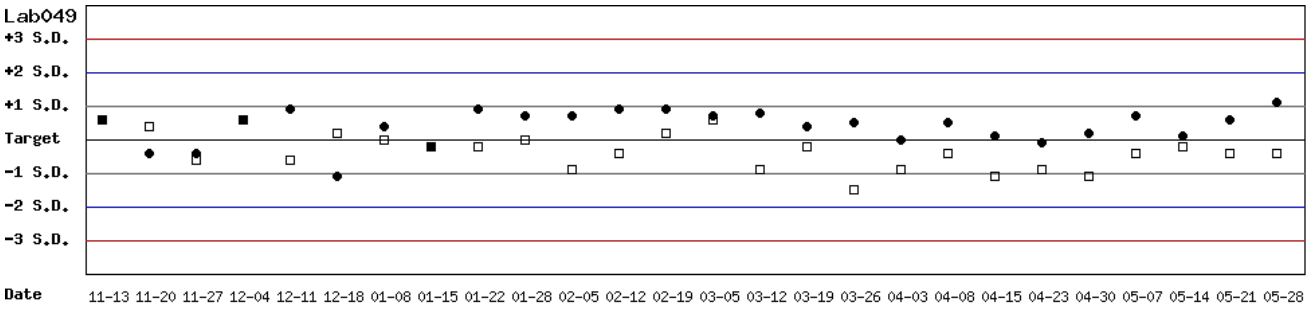
Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-11-13 to 2025-05-30 ; Target : 13.8 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2024-11-13 to 2025-05-30 ; Target : 4.7 ; SD : 0.47 (□)

Lab049



Month : 2025 05 Change ; Cumulative : from 2024 11 13 to 2025 05 30 Change

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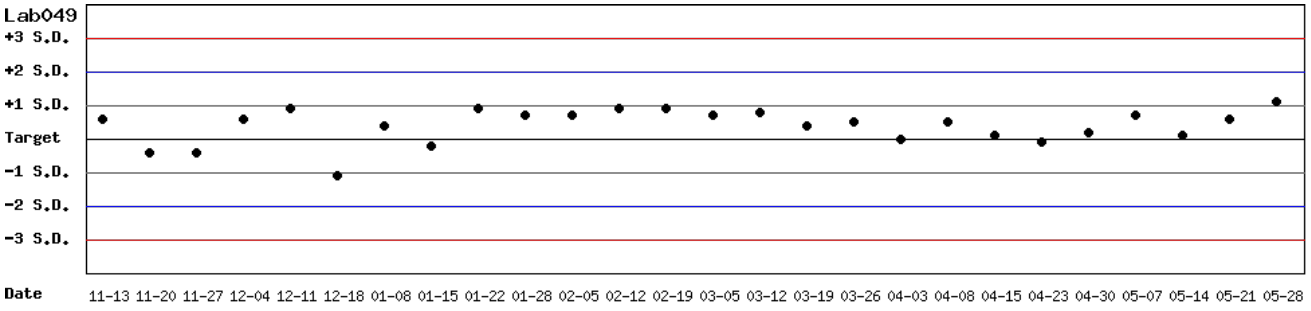
Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-11-13 to 2025-05-30 ; Target : 13.8 ; SD : 1.38

Lab049



Month : 2025 05 Change ; Cumulative : from 2024 11 13 to 2025 05 30 Change

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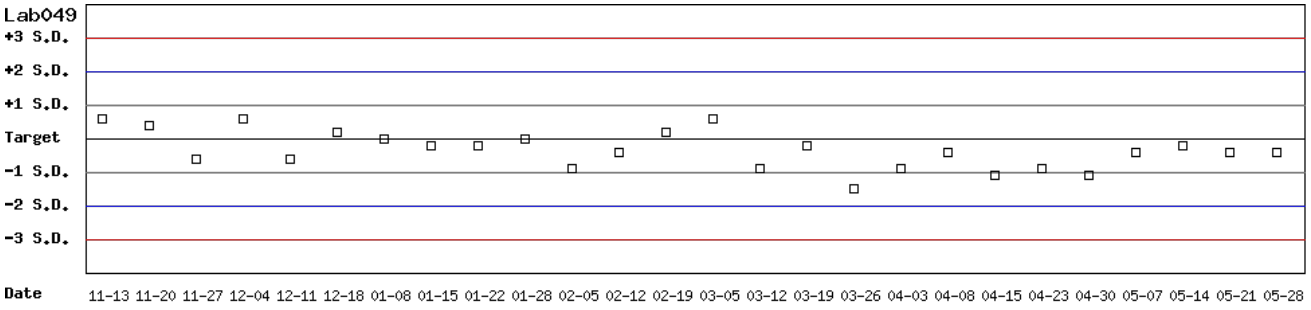
Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2024-11-13 to 2025-05-30 ; Target : 4.7 ; SD : 0.47

Lab049



Month : 2025 05 Change ; Cumulative : from 2024 11 13 to 2025 05 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 : 2025 05 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	14.5	4	0.4	2.8	6.9	20	>6	5.0	4.8	4	0.2	4.2	12.3	20	3.8
Lab034	5	13.8	14.1	3	0.8	5.7	13.5	20	3.1	4.7	5.5	3	0.2	3.6	24.3	20	0.8
Lab040	5	14.4	14.8	5	0.2	1.4	5.5	20	>6	4.6	4.6	5	0.1	2.2	4.3	20	>6
Lab043	5	13.2	14.5	5	0.4	2.8	15.4	20	3.6	4.2	4.8	5	0.1	2.1	18.5	20	2.7
Lab049	5	13.8	14.7	4	0.5	3.4	13.3	20	4.0	4.7	4.5	4	0.1	2.2	8.7	20	>6
Lab050	5	13.8	14.1	6	0.2	1.4	5.0	20	>6	4.7	5.5	6	0.2	3.6	24.3	20	0.8
Total	-	-	14.4	27	0.5	3.5	-	-	-	-	4.9	27	0.4	8.2	-	-	-

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 2025 05 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	166	0.5	3.4	7.5	20	5.7	5.0	4.8	166	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	14.4	38	0.6	4.2	12.7	20	3.7	4.7	5.3	38	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	161	0.2	1.4	5.5	20	>6	4.6	4.6	161	0.1	2.2	4.3	20	>6
Lab043	5	13.2	14.0	192	1.0	7.1	20.3	20	2.0	4.2	4.7	192	0.4	8.5	28.9	20	1.0
Lab049	5	13.8	14.4	260	0.6	4.2	12.7	20	3.7	4.7	4.7	260	0.3	6.4	12.8	20	3.1
Lab050	5	13.8	14.5	93	0.6	4.1	13.3	20	3.6	4.7	5.1	93	0.5	9.8	28.1	20	1.2
Total	-	-	14.5	1512	0.7	4.8	-	-	-	-	4.8	1512	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 (2025/05)								CUM (2021/01/01~2025/05/31)							
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	14.5	4	0.4	2.8	6.9	20	>6	14.7	14.6	166	0.5	3.4	7.5	20	5.7
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	15.0	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	14.1	3	0.8	5.7	13.5	20	3.1	13.8	14.4	38	0.6	4.2	12.7	20	3.7
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	5	0.2	1.4	5.5	20	>6	14.4	14.8	161	0.2	1.4	5.5	20	>6
Lab043	5	13.2	14.5	5	0.4	2.8	15.4	20	3.6	13.2	14.0	192	1.0	7.1	20.3	20	2.0
Lab049	5	13.8	14.7	4	0.5	3.4	13.3	20	4.0	13.8	14.4	260	0.6	4.2	12.7	20	3.7
Lab050	5	13.8	14.1	6	0.2	1.4	5.0	20	>6	13.8	14.5	93	0.6	4.1	13.3	20	3.6
Total	-	-	14.4	27	0.5	3.5	-	-	-	-	14.5	1512	0.7	4.8	-	-	-

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

Month : 2025 05 Change Cumulative : from 2021 01 01 to 2025 05 31 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2025/05)								CUM (2021/01/01~2025/05/31)							
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	4	0.2	4.2	12.3	20	3.8	5.0	4.8	166	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	5.1	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	5.5	3	0.2	3.6	24.3	20	0.8	4.7	5.3	38	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	4.6	5	0.1	2.2	4.3	20	>6	4.6	4.6	161	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.8	5	0.1	2.1	18.5	20	2.7	4.2	4.7	192	0.4	8.5	28.9	20	1.0
Lab049	5	4.7	4.5	4	0.1	2.2	8.7	20	>6	4.7	4.7	260	0.3	6.4	12.8	20	3.1
Lab050	5	4.7	5.5	6	0.2	3.6	24.3	20	0.8	4.7	5.1	93	0.5	9.8	28.1	20	1.2
Total	-	-	4.9	27	0.4	8.2	-	-	-	-	4.8	1512	0.4	8.3	-	-	-

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

Month : 2025 05 Change Cumulative : from 2021 01 01 to 2025 05 31 Change

[TOP]

Reagent Kit	Reagent Code
Medicon	5