

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

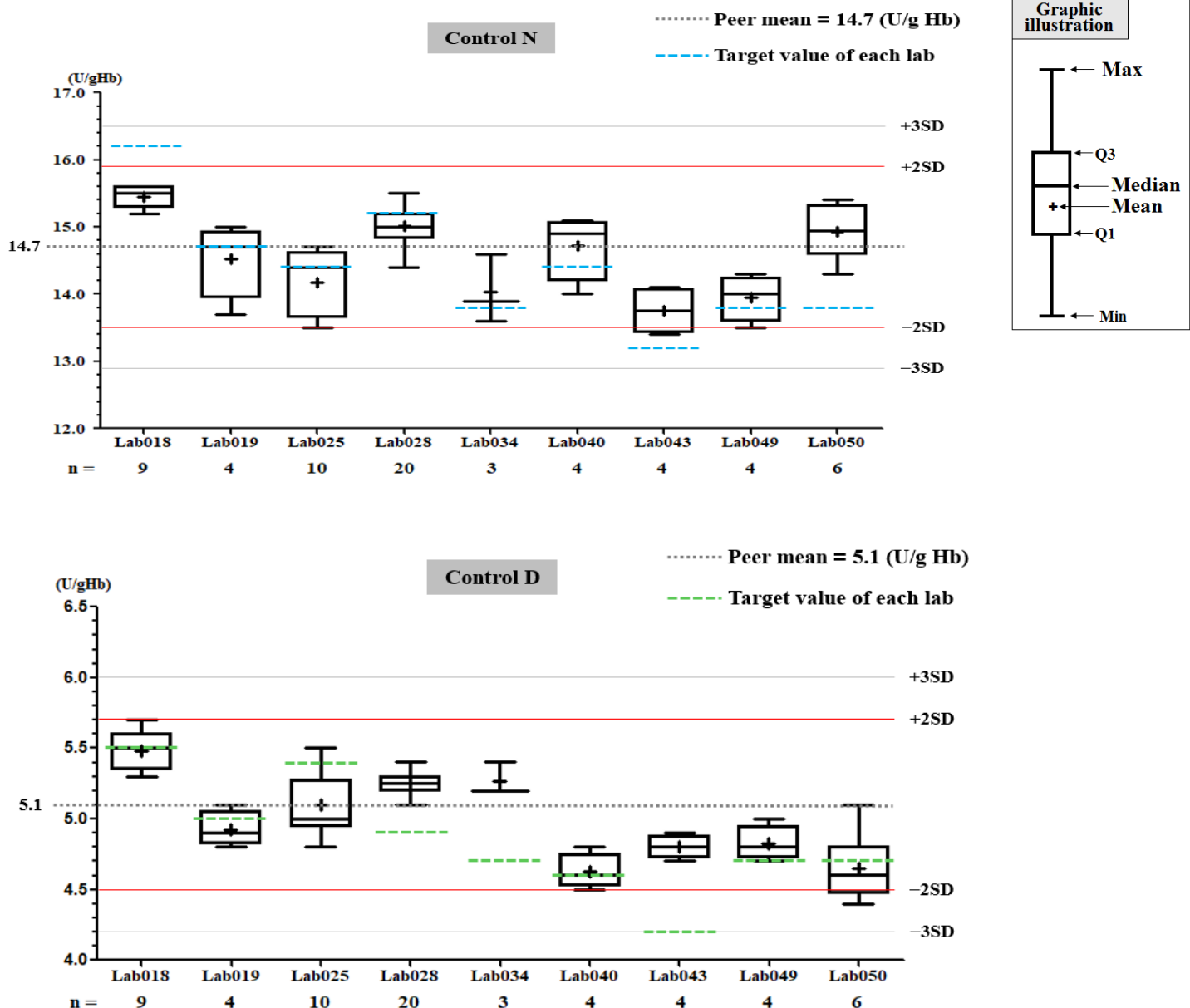
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	9	9
Received results number (n)	64	64
Median	14.8 (U/g Hb)	5.2 (U/g Hb)
Mean	14.7 (U/g Hb)	5.1 (U/g Hb)
SD	0.6	0.3
CV	4.1%	5.9%
Range of G6PD	13.4 ~ 15.6 (U/g Hb)	4.4 ~ 5.7 (U/g Hb)
Range of Hb	1.9 ~ 2.7 (g/dL)	1.9 ~ 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) Change

[Print Table](#)

Lab019

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2024/09)	CUM (2024/04/03~2024/09/30)	Month (2024/09)	CUM (2024/04/03~2024/09/30)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.5	14.8	4.9	4.9
SD	0.6	0.4	0.1	0.1
CV (%)	4.1	2.7	2.0	2.0
Target Value (U/gHb)	14.7	14.7	5.0	5.0
Total Error (%)	9.6	6.1	6.1	6.1
TEa (%)	20	20	20	20
σ	4.5	>6	>6	>6

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

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

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

Month : 2024 09 Change ; Cumulative : from 2024 04 03 to 2024 09 30 Change

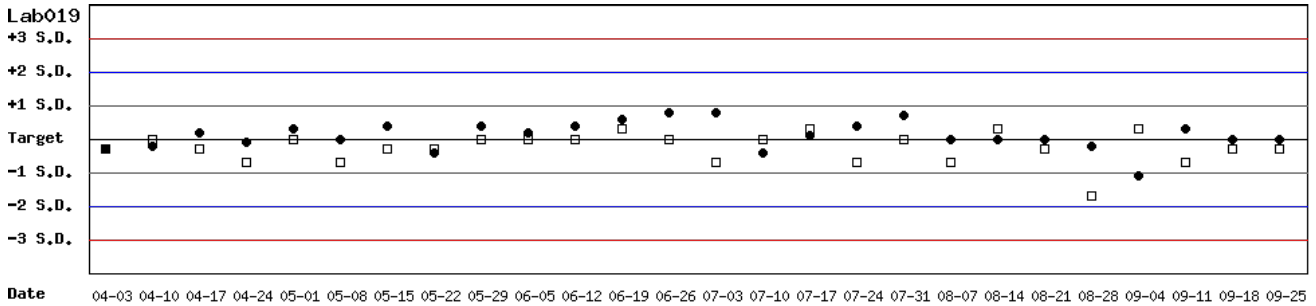
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-04-03 to 2024-09-30 ; Target : 14.7 ; SD : 0.90 (●)

Lot No.: BJ0922D ; Duration : 2024-04-03 to 2024-09-30 ; Target : 5.0 ; SD : 0.30 (□)

Lab019



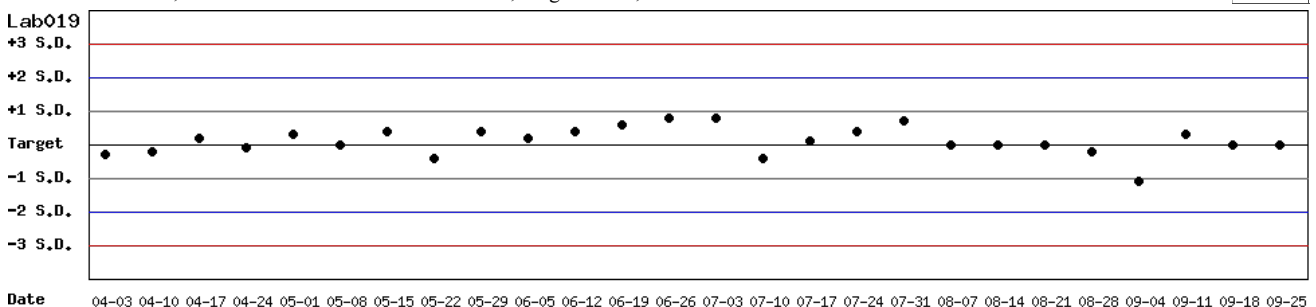
Month : 2024 09 Change ; Cumulative : from 2024 04 03 to 2024 09 30 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-04-03 to 2024-09-30 ; Target : 14.7 ; SD : 0.90

Lab019



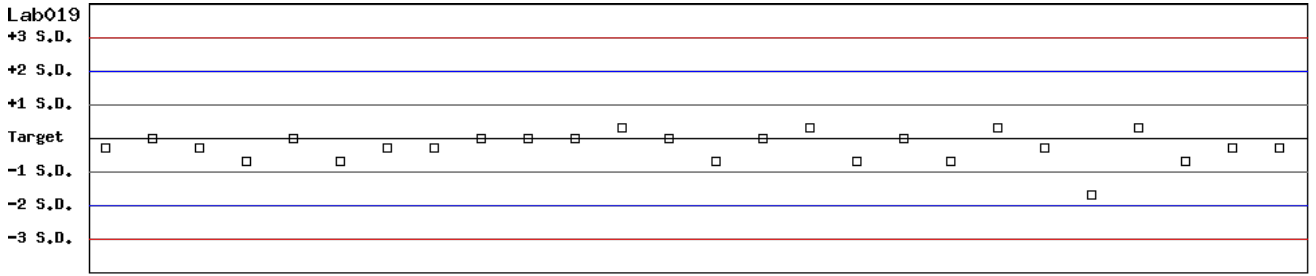
Month : 2024 09 Change ; Cumulative : from 2024 04 03 to 2024 09 30 Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2024-04-03 to 2024-09-30 ; Target : 5.0 ; SD : 0.30

Lab019



Date 04-03 04-10 04-17 04-24 05-01 05-08 05-15 05-22 05-29 06-05 06-12 06-19 06-26 07-03 07-10 07-17 07-24 07-31 08-07 08-14 08-21 08-28 09-04 09-11 09-18 09-25

Month : 2024 09 Change ; Cumulative : from 2024 04 03 to 2024 09 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 09 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	15.4	9	0.2	1.3	7.5	20	>6	5.5	5.5	9	0.1	1.8	3.6	20	>6
Lab019	5	14.7	14.5	4	0.6	4.1	9.6	20	4.5	5.0	4.9	4	0.1	2.0	6.1	20	>6
Lab025	5	14.4	14.2	10	0.5	3.5	8.4	20	5.3	5.4	5.1	10	0.2	3.9	13.4	20	3.7
Lab028	5	15.2	15.0	20	0.3	2.0	5.3	20	>6	4.9	5.3	20	0.1	1.9	11.9	20	>6
Lab034	5	13.8	14.0	3	0.5	3.6	8.6	20	5.2	4.7	5.3	3	0.1	1.9	16.5	20	3.8
Lab040	5	14.4	14.7	4	0.5	3.4	8.9	20	5.3	4.6	4.6	4	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.8	4	0.4	2.9	10.3	20	5.3	4.2	4.8	4	0.1	2.1	18.5	20	2.7
Lab049	5	13.8	14.0	4	0.3	2.1	5.7	20	>6	4.7	4.8	4	0.1	2.1	6.3	20	>6
Lab050	5	13.8	14.9	6	0.4	2.7	13.3	20	4.5	4.7	4.7	6	0.3	6.4	12.8	20	3.1
Total	-	-	14.7	64	0.6	4.1	-	-	-	-	5.1	64	0.3	5.9	-	-	-

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

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

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

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Cumulative

Cumulative : from 2021 01 01 to 2024 09 30 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	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	131	0.6	4.1	8.9	20	4.7	5.0	4.8	131	0.3	6.3	16.5	20	2.5
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	14.1	12	0.5	3.5	9.2	20	5.1	5.4	5.1	12	0.2	3.9	13.4	20	3.7
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	14.4	20	0.5	3.5	11.3	20	4.5	4.7	5.2	20	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	127	0.2	1.4	5.5	20	>6	4.6	4.6	127	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.9	157	1.0	7.2	19.7	20	2.0	4.2	4.6	157	0.4	8.7	26.9	20	1.2
Lab049	5	13.8	14.4	228	0.6	4.2	12.7	20	3.7	4.7	4.7	228	0.3	6.4	12.8	20	3.1
Lab050	5	13.8	14.6	52	0.6	4.1	14.0	20	3.5	4.7	5.2	52	0.4	7.7	26.0	20	1.2
Total	-	-	14.5	1304	0.7	4.8	-	-	-	-	4.8	1304	0.4	8.3	-	-	-

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 (2024/09)								CUM (2021/01/01~2024/09/30)							
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	15.4	9	0.2	1.3	7.5	20	>6	16.2	15.3	113	0.4	2.6	10.8	20	5.6
Lab019	5	14.7	14.5	4	0.6	4.1	9.6	20	4.5	14.7	14.6	131	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	14.2	10	0.5	3.5	8.4	20	5.3	14.4	14.1	12	0.5	3.5	9.2	20	5.1
Lab028	5	15.2	15.0	20	0.3	2.0	5.3	20	>6	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	14.0	3	0.5	3.6	8.6	20	5.2	13.8	14.4	20	0.5	3.5	11.3	20	4.5
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	0.5	3.4	8.9	20	5.3	14.4	14.8	127	0.2	1.4	5.5	20	>6
Lab043	5	13.2	13.8	4	0.4	2.9	10.3	20	5.3	13.2	13.9	157	1.0	7.2	19.7	20	2.0
Lab049	5	13.8	14.0	4	0.3	2.1	5.7	20	>6	13.8	14.4	228	0.6	4.2	12.7	20	3.7
Lab050	5	13.8	14.9	6	0.4	2.7	13.3	20	4.5	13.8	14.6	52	0.6	4.1	14.0	20	3.5
Total	-	-	14.7	64	0.6	4.1	-	-	-	-	14.5	1304	0.7	4.8	-	-	-

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

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

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

Month : 2024 09 Change

Cumulative : from 2021 01 01 to 2024 09 30 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2024/09)								CUM (2021/01/01~2024/09/30)							
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	5.5	9	0.1	1.8	3.6	20	>6	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	131	0.3	6.3	16.5	20	2.5
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	5.1	10	0.2	3.9	13.4	20	3.7	5.4	5.1	12	0.2	3.9	13.4	20	3.7
Lab028	5	4.9	5.3	20	0.1	1.9	11.9	20	>6	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	20	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	127	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	157	0.4	8.7	26.9	20	1.2
Lab049	5	4.7	4.8	4	0.1	2.1	6.3	20	>6	4.7	4.7	228	0.3	6.4	12.8	20	3.1
Lab050	5	4.7	4.7	6	0.3	6.4	12.8	20	3.1	4.7	5.2	52	0.4	7.7	26.0	20	1.2
Total	-	-	5.1	64	0.3	5.9	-	-	-	-	4.8	1304	0.4	8.3	-	-	-

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

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

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

Month : 2024 09 Change

Cumulative : from 2021 01 01 to 2024 09 30 Change

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Reagent Kit	Reagent Code
Medicon	5