

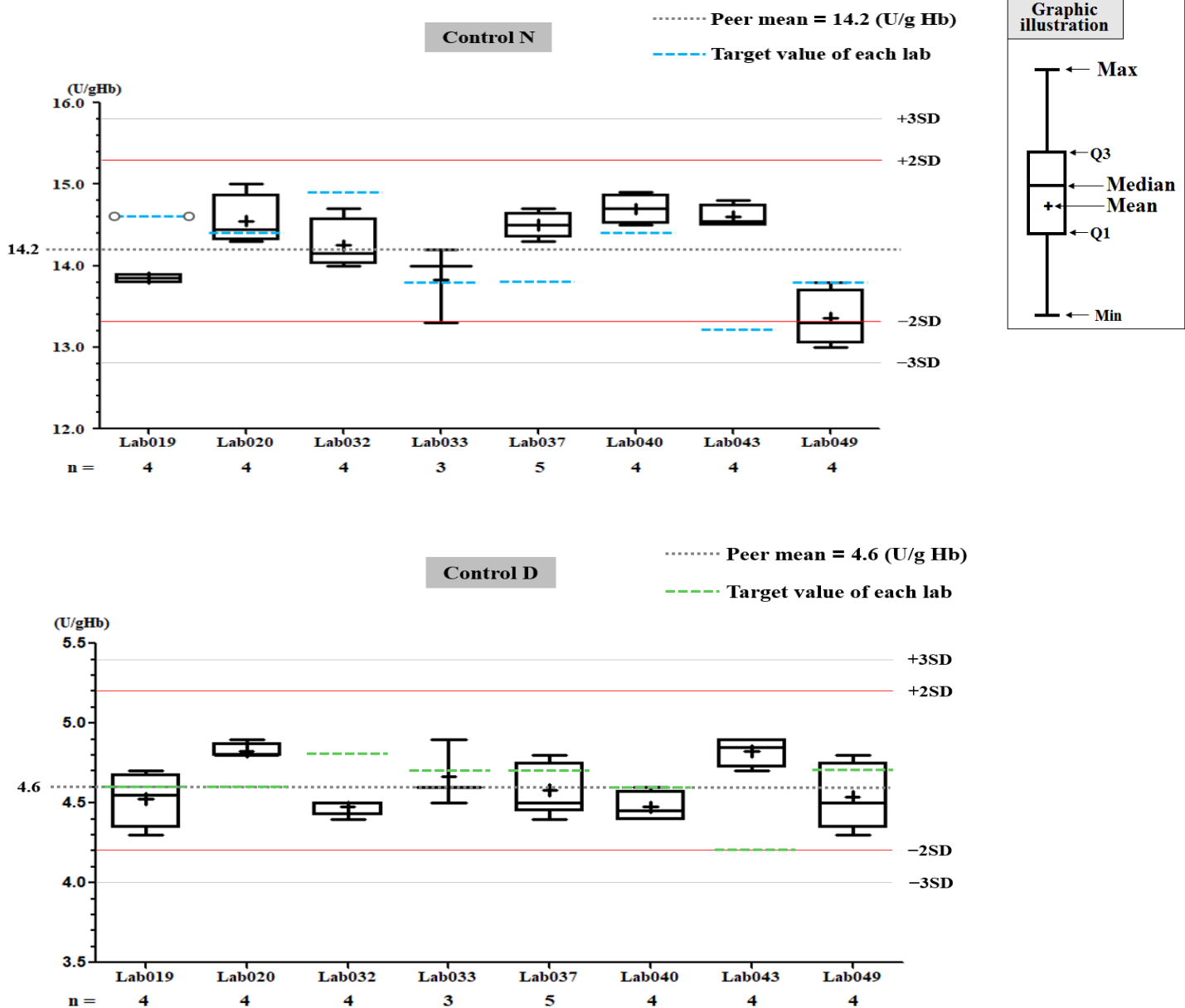
Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - August 2022 -

I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	8	8
Received results number (n)	33	33
Median	14.3 (U/g Hb)	4.6 (U/g Hb)
Mean	14.2 (U/g Hb)	4.6 (U/g Hb)
SD	0.5	0.2
CV	3.5%	4.3%
Range of G6PD	13.0 ~ 15.0 (U/g Hb)	4.3 ~ 4.9 (U/g Hb)
Range of Hb	2.0 ~ 3.1 (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 :

Lab032

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2022/08)	CUM (2022/03/17~2022/08/31)	Month (2022/08)	CUM (2022/03/17~2022/08/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.3	14.6	4.5	4.5
SD	0.3	0.3	0.1	0.2
CV (%)	2.1	2.1	2.2	4.4
Target Value (U/gHb)	14.9	14.9	4.8	4.8
Total Error (%)	8.2	6.1	10.7	15.1
TEa (%)	20	20	20	20
σ	>6	>6	>6	3.1

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

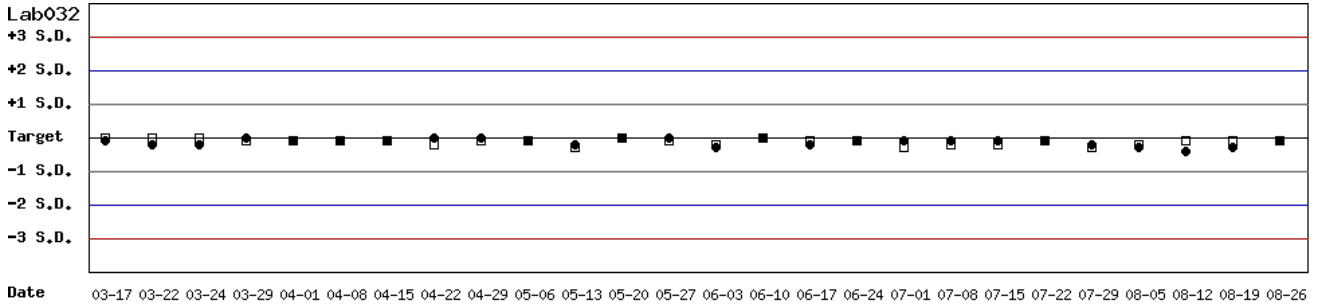
Month : ; Cumulative : from to

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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-03-17 to 2022-08-31 ; Target : 14.9 ; SD : 2.30 (●)

Lot No.: BJ0922D ; Duration : 2022-03-17 to 2022-08-31 ; Target : 4.8 ; SD : 2.10 (□)

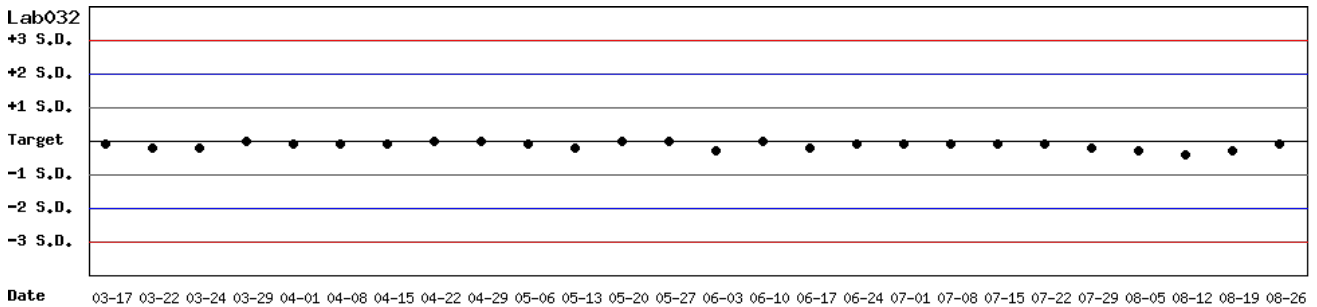


Month : ; Cumulative : from to

[\[TOP\]](#)

Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-03-17 to 2022-08-31 ; Target : 14.9 ; SD : 2.30



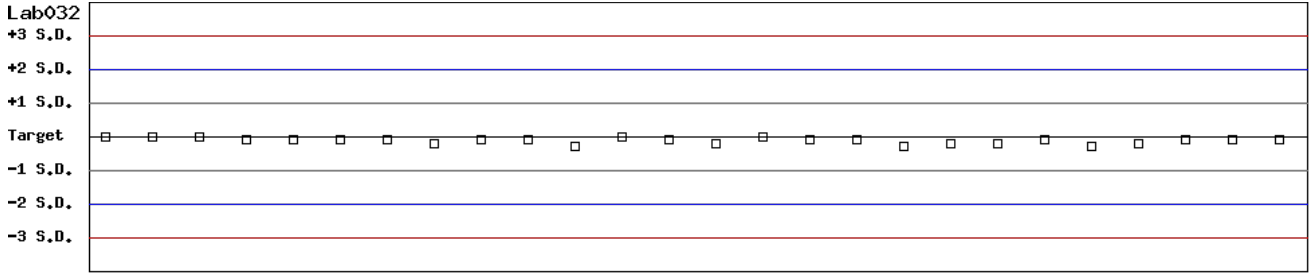
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lab032

Lot No.: BJ0922D ; Duration : 2022-03-17 to 2022-08-31 ; Target : 4.8 ; SD : 2.10



Date 03-17 03-22 03-24 03-29 04-01 04-08 04-15 04-22 04-29 05-06 05-13 05-20 05-27 06-03 06-10 06-17 06-24 07-01 07-08 07-15 07-22 07-29 08-05 08-12 08-19 08-26

Month : ; Cumulative : from to

[TOP](#)

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 : 2022 08 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
Lab019	5	14.6	13.9	4	0.1	0.7	6.2	20	>6	4.6	4.5	4	0.2	4.4	11.1	20	4.1
Lab020	5	14.4	14.6	4	0.3	2.1	5.5	20	>6	4.6	4.8	4	0.1	2.1	8.5	20	>6
Lab032	5	14.9	14.3	4	0.3	2.1	8.2	20	>6	4.8	4.5	4	0.1	2.2	10.7	20	>6
Lab033	5	13.8	13.8	3	0.5	3.6	7.2	20	5.6	4.7	4.7	3	0.2	4.3	8.5	20	4.7
Lab037	5	13.8	14.5	5	0.2	1.4	7.8	20	>6	4.7	4.6	5	0.2	4.3	10.8	20	4.2
Lab040	5	14.4	14.7	4	0.2	1.4	4.8	20	>6	4.6	4.5	4	0.1	2.2	6.6	20	>6
Lab043	5	13.2	14.6	4	0.1	0.7	12.0	20	>6	4.2	4.8	4	0.1	2.1	18.5	20	2.7
Lab049	5	13.8	13.4	5	0.3	2.2	7.4	20	>6	4.7	4.5	5	0.2	4.4	13.1	20	3.6
Total	-	-	14.2	33	0.5	3.5	-	-	-	-	4.6	33	0.2	4.3	-	-	-

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 2022 08 31 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	16.4	8	0.4	2.4	6.1	20	>6	5.5	5.5	8	0.2	3.6	7.3	20	5.6
Lab019	5	14.6	14.4	32	0.6	4.2	9.7	20	4.4	4.6	4.6	32	0.1	2.2	4.3	20	>6
Lab020	5	14.4	14.5	40	0.6	4.1	9.0	20	4.7	4.6	4.7	40	0.2	4.3	10.7	20	4.1
Lab022	5	14.4	14.3	12	0.6	4.2	9.1	20	4.6	4.6	4.6	12	0.3	6.5	13.0	20	3.1
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	14.4	88	0.4	2.8	8.9	20	5.9	4.8	4.5	88	0.1	2.2	10.7	20	>6
Lab033	5	13.8	13.5	33	0.6	4.4	11.1	20	4.1	4.7	4.5	33	0.3	6.7	17.6	20	2.3
Lab037	5	13.8	14.7	38	0.4	2.7	12.0	20	5.0	4.7	4.7	38	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.4	9	0.3	2.1	4.2	20	>6	4.6	4.5	9	0.1	2.2	6.6	20	>6
Lab043	5	13.2	13.4	55	1.5	11.2	23.9	20	1.7	4.2	4.3	55	0.5	11.6	25.6	20	1.5
Lab049	5	13.8	14.7	65	0.7	4.8	16.0	20	2.8	4.7	4.7	65	0.2	4.3	8.5	20	4.7
Total	-	-	14.4	414	1.0	6.9	-	-	-	-	4.6	414	0.3	6.5	-	-	-

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 (2022/08)								CUM (2021/01/01~2022/08/31)							
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	16.4	8	0.4	2.4	6.1	20	>6
Lab019	5	14.6	13.9	4	0.1	0.7	6.2	20	>6	14.6	14.4	32	0.6	4.2	9.7	20	4.4
Lab020	5	14.4	14.6	4	0.3	2.1	5.5	20	>6	14.4	14.5	40	0.6	4.1	9.0	20	4.7
Lab022	5	14.4	-	0	-	-	-	20	-	14.4	14.3	12	0.6	4.2	9.1	20	4.6
Lab028	5	15.2	-	0	-	-	-	20	-	15.2	15.1	34	1.1	7.3	15.2	20	2.6
Lab032	5	14.9	14.3	4	0.3	2.1	8.2	20	>6	14.9	14.4	88	0.4	2.8	8.9	20	5.9
Lab033	5	13.8	13.8	3	0.5	3.6	7.2	20	5.6	13.8	13.5	33	0.6	4.4	11.1	20	4.1
Lab037	5	13.8	14.5	5	0.2	1.4	7.8	20	>6	13.8	14.7	38	0.4	2.7	12.0	20	5.0
Lab040	5	14.4	14.7	4	0.2	1.4	4.8	20	>6	14.4	14.4	9	0.3	2.1	4.2	20	>6
Lab043	5	13.2	14.6	4	0.1	0.7	12.0	20	>6	13.2	13.4	55	1.5	11.2	23.9	20	1.7
Lab049	5	13.8	13.4	5	0.3	2.2	7.4	20	>6	13.8	14.7	65	0.7	4.8	16.0	20	2.8
Total	-	-	14.2	33	0.5	3.5	-	-	-	-	14.4	414	1.0	6.9	-	-	-

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

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

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

Month : 2022 08 Change

Cumulative : from 2021 01 01 to 2022 08 31 Change

[TOP](#)

Control D Month vs. Cumulative

Control D (Lot No.: BJ0922D)																	
		Month (2022/08)								CUM (2021/01/01~2022/08/31)							
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	5.5	8	0.2	3.6	7.3	20	5.6
Lab019	5	4.6	4.5	4	0.2	4.4	11.1	20	4.1	4.6	4.6	32	0.1	2.2	4.3	20	>6
Lab020	5	4.6	4.8	4	0.1	2.1	8.5	20	>6	4.6	4.7	40	0.2	4.3	10.7	20	4.1
Lab022	5	4.6	-	0	-	-	-	20	-	4.6	4.6	12	0.3	6.5	13.0	20	3.1
Lab028	5	4.9	-	0	-	-	-	20	-	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	4.8	4.5	4	0.1	2.2	10.7	20	>6	4.8	4.5	88	0.1	2.2	10.7	20	>6
Lab033	5	4.7	4.7	3	0.2	4.3	8.5	20	4.7	4.7	4.5	33	0.3	6.7	17.6	20	2.3
Lab037	5	4.7	4.6	5	0.2	4.3	10.8	20	4.2	4.7	4.7	38	0.2	4.3	8.5	20	4.7
Lab040	5	4.6	4.5	4	0.1	2.2	6.6	20	>6	4.6	4.5	9	0.1	2.2	6.6	20	>6
Lab043	5	4.2	4.8	4	0.1	2.1	18.5	20	2.7	4.2	4.3	55	0.5	11.6	25.6	20	1.5
Lab049	5	4.7	4.5	5	0.2	4.4	13.1	20	3.6	4.7	4.7	65	0.2	4.3	8.5	20	4.7
Total	-	-	4.6	33	0.2	4.3	-	-	-	-	4.6	414	0.3	6.5	-	-	-

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

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

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

Month : 2022 08 Change

Cumulative : from 2021 01 01 to 2022 08 31 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5