

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - October 2023 -

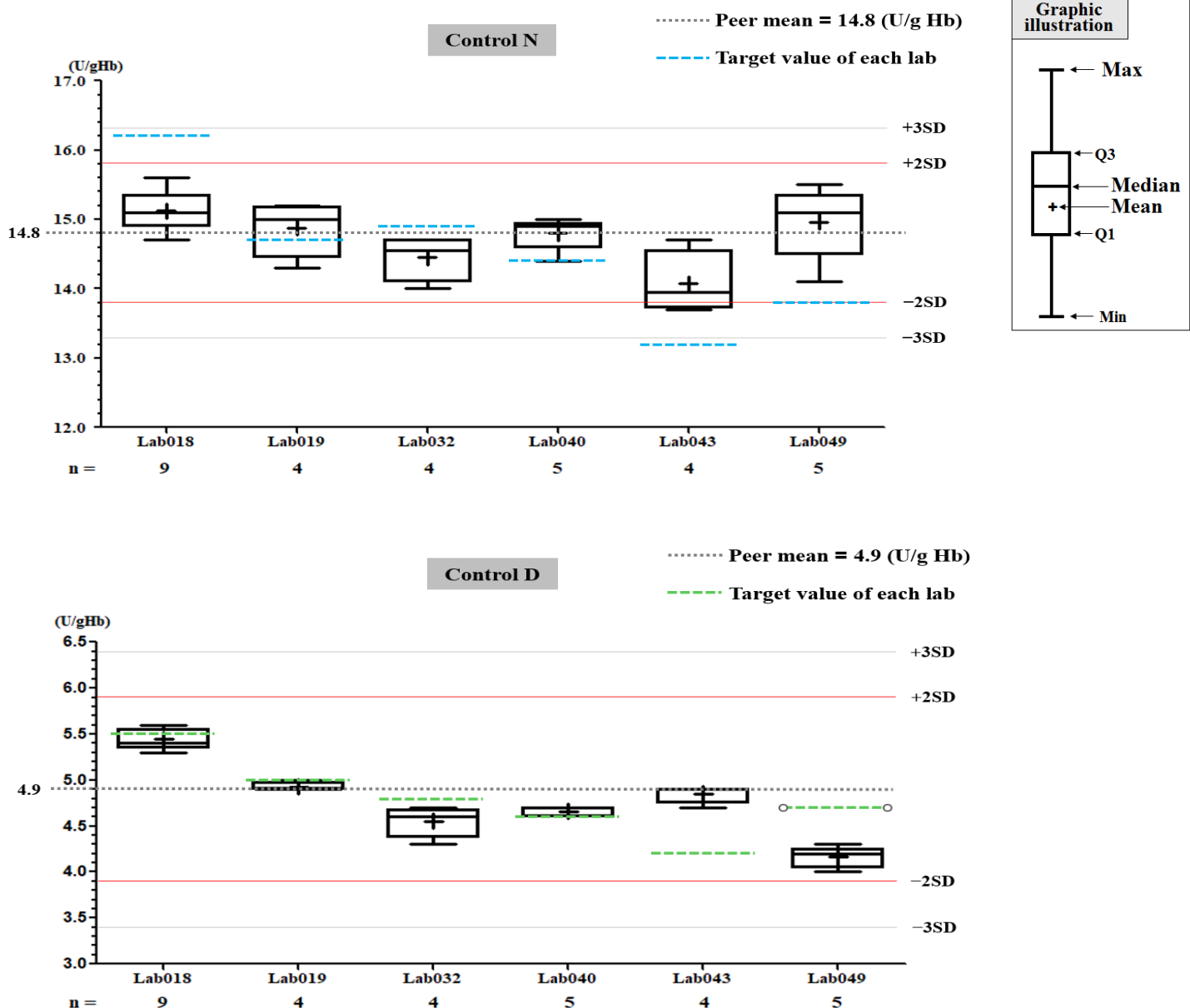
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	6	6
Received results number (n)	31	31
Median	14.9 (U/g Hb)	4.9 (U/g Hb)
Mean	14.8 (U/g Hb)	4.9 (U/g Hb)
SD	0.5	0.5
CV	3.4%	10.2%
Range of G6PD	13.7 ~ 15.6 (U/g Hb)	4.0 ~ 5.6 (U/g Hb)
Range of Hb	2.1 ~ 2.6 (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)

Lab043

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2023/10)	CUM (2023/04/27~2023/10/31)	Month (2023/10)	CUM (2023/04/27~2023/10/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.1	14.3	4.9	4.8
SD	0.5	0.5	0.1	0.1
CV (%)	3.5	3.5	2.0	2.1
Target Value (U/gHb)	13.2	13.2	4.2	4.2
Total Error (%)	13.9	15.3	20.7	18.5
TEa (%)	20	20	20	20
σ	3.8	3.3	1.7	2.7

Bias (%) = $(| \text{Mean} - \text{Target} |) / \text{Target} \times 100\%$
 TE : Total Error(%) = Bias (%) + 2 × CV (%)
 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : ; Cumulative : from to

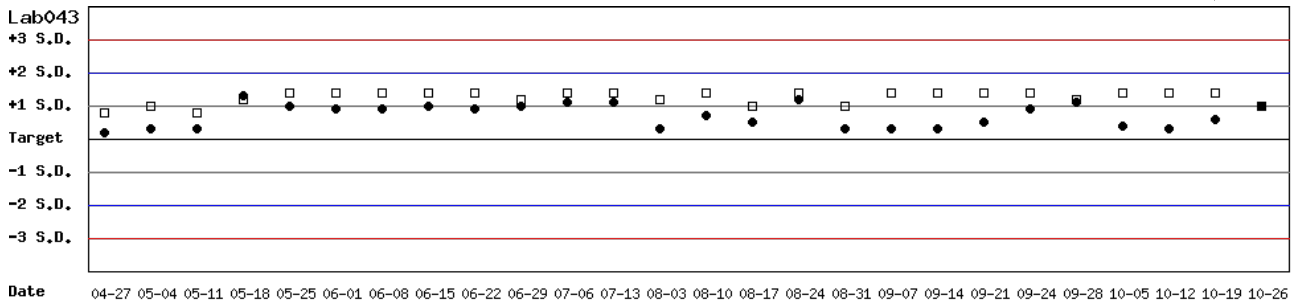
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-04-27 to 2023-10-31 ; Target : 13.2 ; SD : 1.50 (●)

Lot No.: BJ0922D ; Duration : 2023-04-27 to 2023-10-31 ; Target : 4.2 ; SD : 0.50 (□)

Lab043



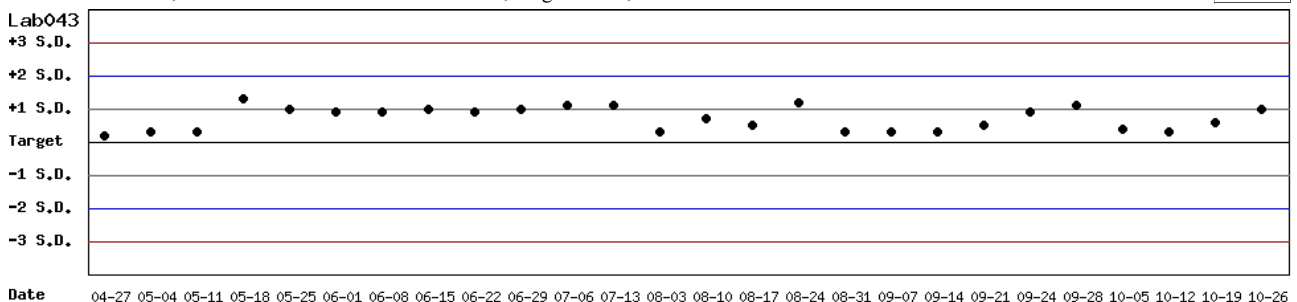
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-04-27 to 2023-10-31 ; Target : 13.2 ; SD : 1.50

Lab043



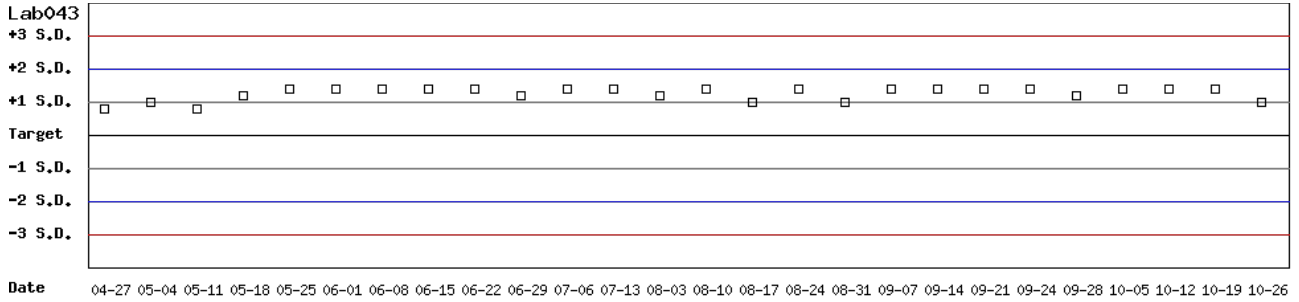
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2023-04-27 to 2023-10-31 ; Target : 4.2 ; SD : 0.50

Lab043



Month : 2023 10 Change ; Cumulative : from 2023 04 27 to 2023 10 31 Change

[\[TOP\]](#)

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 : 2023 10 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	15.1	9	0.3	2.0	10.8	20	>6	5.5	5.4	9	0.1	1.9	5.5	20	>6
Lab019	5	14.7	14.9	4	0.4	2.7	6.7	20	>6	5.0	4.9	4	0.1	2.0	6.1	20	>6
Lab032	5	14.9	14.5	4	0.3	2.1	6.8	20	>6	4.8	4.6	4	0.2	4.3	12.9	20	3.7
Lab040	5	14.4	14.8	5	0.2	1.4	5.5	20	>6	4.6	4.7	5	0.1	2.1	6.4	20	>6
Lab043	5	13.2	14.1	4	0.5	3.5	13.9	20	3.8	4.2	4.9	4	0.1	2.0	20.7	20	1.7
Lab049	5	13.8	15.0	5	0.5	3.3	15.4	20	3.4	4.7	4.2	5	0.1	2.4	15.4	20	3.9
Total	-	-	14.8	31	0.5	3.4	-	-	-	-	4.9	31	0.5	10.2	-	-	-

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 2023 10 31 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	15.7	17	0.7	4.5	12.0	20	3.8	5.5	5.5	17	0.1	1.8	3.6	20	>6
Lab019	5	14.7	14.4	83	0.6	4.2	10.4	20	4.3	5.0	4.7	83	0.3	6.4	18.8	20	2.2
Lab020	5	14.4	14.4	76	0.5	3.5	6.9	20	5.7	4.6	4.7	76	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
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	14.3	140	0.4	2.8	9.6	20	5.7	4.8	4.5	140	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
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	14.7	72	0.2	1.4	4.8	20	>6	4.6	4.6	72	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.8	110	1.2	8.7	21.9	20	1.8	4.2	4.6	110	0.4	8.7	26.9	20	1.2
Lab049	5	13.8	14.4	163	0.6	4.2	12.7	20	3.7	4.7	4.7	163	0.3	6.4	12.8	20	3.1
Total	-	-	14.3	862	0.8	5.6	-	-	-	-	4.7	862	0.3	6.4	-	-	-

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 (2023/10)								CUM (2021/01/01~2023/10/31)							
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	15.1	9	0.3	2.0	10.8	20	>6	16.2	15.7	17	0.7	4.5	12.0	20	3.8
Lab019	5	14.7	14.9	4	0.4	2.7	6.7	20	>6	14.7	14.4	83	0.6	4.2	10.4	20	4.3
Lab020	5	14.4	-	0	-	-	-	20	-	14.4	14.4	76	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
Lab028	5	15.2	-	0	-	-	-	20	-	15.2	15.1	34	1.1	7.3	15.2	20	2.6
Lab032	5	14.9	14.5	4	0.3	2.1	6.8	20	>6	14.9	14.3	140	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
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	14.7	72	0.2	1.4	4.8	20	>6
Lab043	5	13.2	14.1	4	0.5	3.5	13.9	20	3.8	13.2	13.8	110	1.2	8.7	21.9	20	1.8
Lab049	5	13.8	15.0	5	0.5	3.3	15.4	20	3.4	13.8	14.4	163	0.6	4.2	12.7	20	3.7
Total	-	-	14.8	31	0.5	3.4	-	-	-	-	14.3	862	0.8	5.6	-	-	-

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

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

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

Month : 2023 10 Change

Cumulative : from 2021 01 01 to 2023 10 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2023/10)								CUM (2021/01/01~2023/10/31)							
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	5.4	9	0.1	1.9	5.5	20	>6	5.5	5.5	17	0.1	1.8	3.6	20	>6
Lab019	5	5.0	4.9	4	0.1	2.0	6.1	20	>6	5.0	4.7	83	0.3	6.4	18.8	20	2.2
Lab020	5	4.6	-	0	-	-	-	20	-	4.6	4.7	76	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
Lab028	5	4.9	-	0	-	-	-	20	-	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	4.8	4.6	4	0.2	4.3	12.9	20	3.7	4.8	4.5	140	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
Lab037	5	4.7	-	0	-	-	-	20	-	4.7	4.7	59	0.2	4.3	8.5	20	4.7
Lab040	5	4.6	4.7	5	0.1	2.1	6.4	20	>6	4.6	4.6	72	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.9	4	0.1	2.0	20.7	20	1.7	4.2	4.6	110	0.4	8.7	26.9	20	1.2
Lab049	5	4.7	4.2	5	0.1	2.4	15.4	20	3.9	4.7	4.7	163	0.3	6.4	12.8	20	3.1
Total	-	-	4.9	31	0.5	10.2	-	-	-	-	4.7	862	0.3	6.4	-	-	-

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

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

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

Month : 2023 10 Change

Cumulative : from 2021 01 01 to 2023 10 31 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5