

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

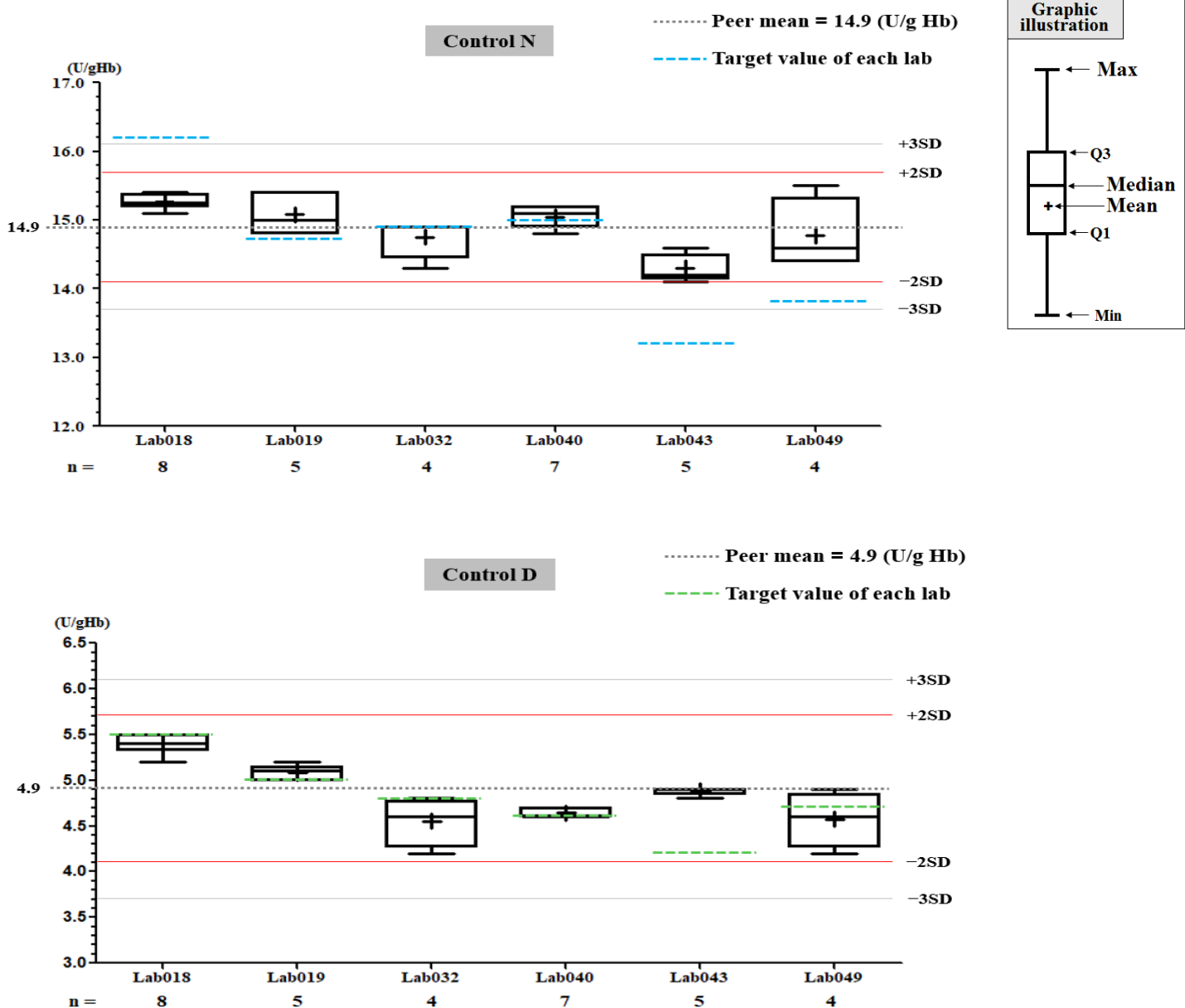
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	6	6
Received results number (n)	33	33
Median	15.0 (U/g Hb)	4.9 (U/g Hb)
Mean	14.9 (U/g Hb)	4.9 (U/g Hb)
SD	0.4	0.4
CV	2.7%	8.2%
Range of G6PD	14.1 ~ 15.5 (U/g Hb)	4.2 ~ 5.5 (U/g Hb)
Range of Hb	2.1 ~ 2.5 (g/dL)	1.9 ~ 2.2 (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

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2023/11)	CUM (2023/07/21~2023/11/30)	Month (2023/11)	CUM (2023/07/21~2023/11/30)
Runs (N)	7	26	7	26
Mean (U/gHb)	15.0	14.9	4.6	4.7
SD	0.2	0.2	0.1	0.1
CV (%)	1.3	1.3	2.2	2.1
Target Value (U/gHb)	14.4	14.4	4.6	4.6
Total Error (%)	6.8	6.2	4.3	6.4
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

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

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

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

Month : 2023 11 Change ; Cumulative : from 2023 07 21 to 2023 11 30 Change

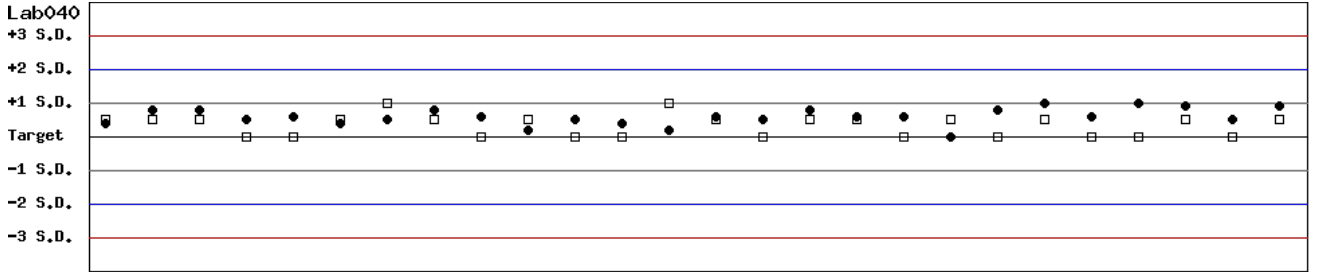
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-07-21 to 2023-11-30 ; Target : 14.4 ; SD : 0.80 (●)

Lot No.: BJ0922D ; Duration : 2023-07-21 to 2023-11-30 ; Target : 4.6 ; SD : 0.20 (□)

Lab040



Date 07-21 07-28 08-04 08-10 08-14 08-18 08-25 09-01 09-05 09-08 09-11 09-15 09-22 09-28 10-06 10-10 10-14 10-20 10-27 11-01 11-06 11-09 11-14 11-17 11-24 11-29

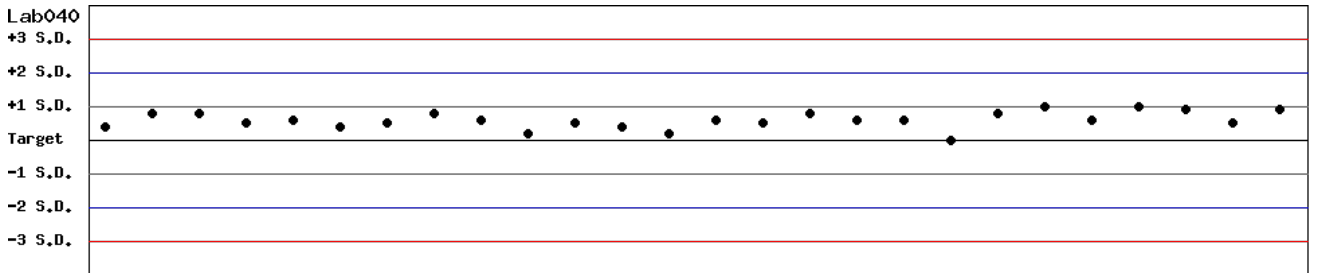
Month : 2023 11 Change ; Cumulative : from 2023 07 21 to 2023 11 30 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-07-21 to 2023-11-30 ; Target : 14.4 ; SD : 0.80

Lab040



Date 07-21 07-28 08-04 08-10 08-14 08-18 08-25 09-01 09-05 09-08 09-11 09-15 09-22 09-28 10-06 10-10 10-14 10-20 10-27 11-01 11-06 11-09 11-14 11-17 11-24 11-29

Month : 2023 11 Change ; Cumulative : from 2023 07 21 to 2023 11 30 Change

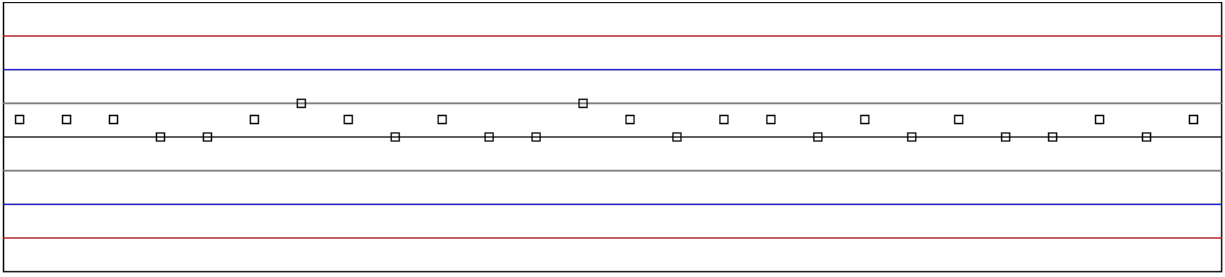
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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2023-07-21 to 2023-11-30 ; Target : 4.6 ; SD : 0.20

Lab040

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



Date 07-21 07-28 08-04 08-10 08-14 08-18 08-25 09-01 09-05 09-08 09-11 09-15 09-22 09-28 10-06 10-10 10-14 10-20 10-27 11-01 11-06 11-09 11-14 11-17 11-24 11-29

Month : 2023 11 Change ; Cumulative : from 2023 07 21 to 2023 11 30 Change

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Peer Group Statistics (Table 1)

Select LotNo : BJ0922N (2021-01-01 ~ 2100-12-31)

Select Reagent Kit : 5 - Medicon

Monthly

Month : 2023 11

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	8	0.1	0.7	6.9	20	>6	5.5	5.4	8	0.1	1.9	5.5	20	>6
Lab019	5	14.7	15.1	5	0.3	2.0	6.7	20	>6	5.0	5.1	5	0.1	2.0	5.9	20	>6
Lab032	5	14.9	14.8	4	0.3	2.0	4.7	20	>6	4.8	4.6	4	0.3	6.5	17.2	20	2.4
Lab040	5	14.4	15.0	7	0.2	1.3	6.8	20	>6	4.6	4.6	7	0.1	2.2	4.3	20	>6
Lab043	5	13.2	14.3	5	0.2	1.4	11.1	20	>6	4.2	4.9	5	0.1	2.0	20.7	20	1.7
Lab049	5	13.8	14.8	4	0.5	3.4	14.0	20	3.8	4.7	4.6	4	0.3	6.5	15.2	20	2.7
Total	-	-	14.9	33	0.4	2.7	-	-	-	-	4.9	33	0.4	8.2	-	-	-

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from 2021 01 01 to 2023 11 30

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	15.6	25	0.6	3.8	11.4	20	4.3	5.5	5.4	25	0.1	1.9	5.5	20	>6
Lab019	5	14.7	14.4	88	0.6	4.2	10.4	20	4.3	5.0	4.8	88	0.3	6.3	16.5	20	2.5
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	144	0.4	2.8	9.6	20	5.7	4.8	4.5	144	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	14.8	79	0.2	1.4	5.5	20	>6	4.6	4.6	79	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.9	115	1.2	8.6	22.6	20	1.7	4.2	4.6	115	0.4	8.7	26.9	20	1.2
Lab049	5	13.8	14.4	167	0.6	4.2	12.7	20	3.7	4.7	4.7	167	0.3	6.4	12.8	20	3.1
Total	-	-	14.4	895	0.8	5.6	-	-	-	-	4.7	895	0.3	6.4	-	-	-

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

TE : Total Error(%) = Bias (%) + 2 x 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 (2023/11)								CUM (2021/01/01~2023/11/30)							
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	8	0.1	0.7	6.9	20	>6	16.2	15.6	25	0.6	3.8	11.4	20	4.3
Lab019	5	14.7	15.1	5	0.3	2.0	6.7	20	>6	14.7	14.4	88	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	14.8	4	0.3	2.0	4.7	20	>6	14.9	14.3	144	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	15.0	7	0.2	1.3	6.8	20	>6	14.4	14.8	79	0.2	1.4	5.5	20	>6
Lab043	5	13.2	14.3	5	0.2	1.4	11.1	20	>6	13.2	13.9	115	1.2	8.6	22.6	20	1.7
Lab049	5	13.8	14.8	4	0.5	3.4	14.0	20	3.8	13.8	14.4	167	0.6	4.2	12.7	20	3.7
Total	-	-	14.9	33	0.4	2.7	-	-	-	-	14.4	895	0.8	5.6	-	-	-

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

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

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

Month : 2023 11 Change

Cumulative : from 2021 01 01 to 2023 11 30 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2023/11)								CUM (2021/01/01~2023/11/30)							
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	8	0.1	1.9	5.5	20	>6	5.5	5.4	25	0.1	1.9	5.5	20	>6
Lab019	5	5.0	5.1	5	0.1	2.0	5.9	20	>6	5.0	4.8	88	0.3	6.3	16.5	20	2.5
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	0.3	6.5	17.2	20	2.4	4.8	4.5	144	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	4.6	7	0.1	2.2	4.3	20	>6	4.6	4.6	79	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.9	5	0.1	2.0	20.7	20	1.7	4.2	4.6	115	0.4	8.7	26.9	20	1.2
Lab049	5	4.7	4.6	4	0.3	6.5	15.2	20	2.7	4.7	4.7	167	0.3	6.4	12.8	20	3.1
Total	-	-	4.9	33	0.4	8.2	-	-	-	-	4.7	895	0.3	6.4	-	-	-

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

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

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

Month : 2023 11 Change

Cumulative : from 2021 01 01 to 2023 11 30 Change

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Reagent Kit	Reagent Code
Medicon	5