

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

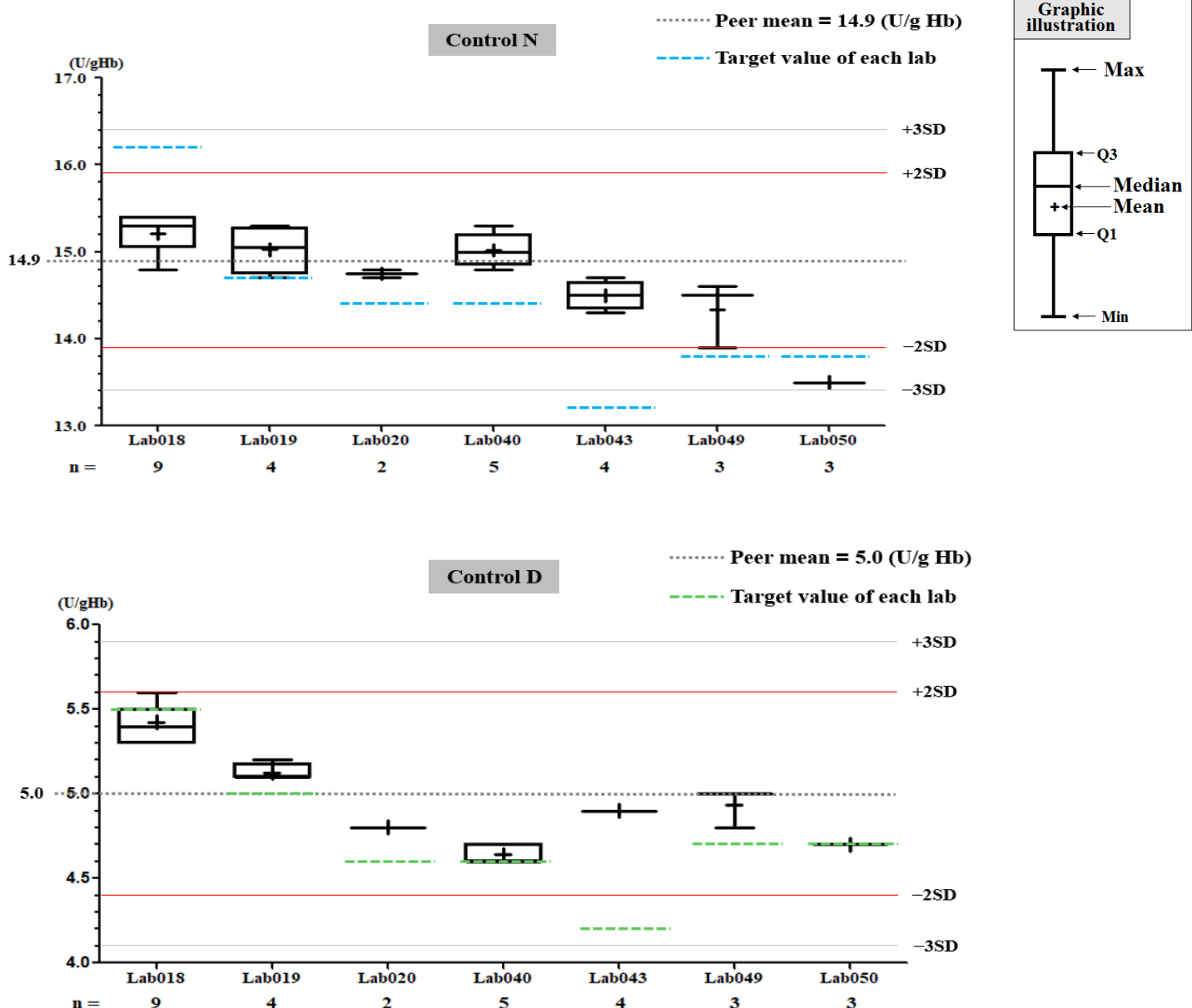
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	7	7
Received results number (n)	28	28
Median	14.9 (U/g Hb)	5.0 (U/g Hb)
Mean	14.9 (U/g Hb)	5.0 (U/g Hb)
SD	0.5	0.3
CV	3.4%	6.0%
Range of G6PD	13.5 ~ 15.4 (U/g Hb)	4.6 ~ 5.6 (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](#)

Lab020

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2023/12)	CUM (2023/02/07~2023/12/29)	Month (2023/12)	CUM (2023/02/07~2023/12/29)
Runs (N)	2	26	2	26
Mean (U/gHb)	14.8	14.5	4.8	4.8
SD	-	0.5	-	0.2
CV (%)	-	3.4	-	4.2
Target Value (U/gHb)	14.4	14.4	4.6	4.6
Total Error (%)	-	7.6	-	12.7
TEa (%)	20	20	20	20
σ	-	5.7	-	3.7

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

Month : 2023 12 Change ; Cumulative : from 2023 02 07 to 2023 12 29 Change

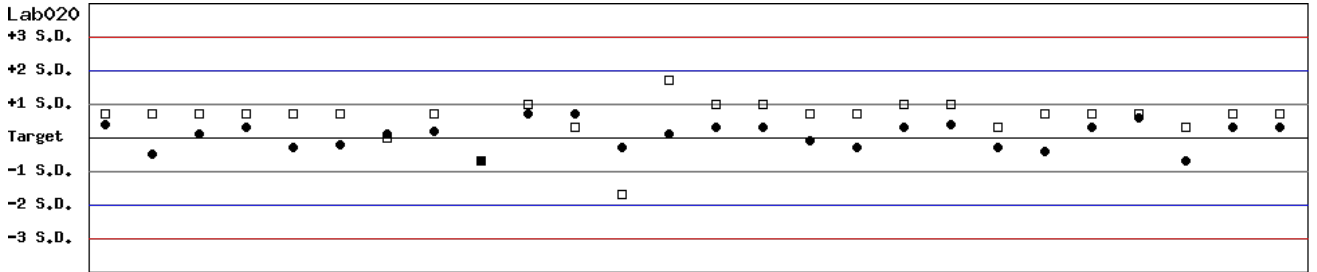
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-02-07 to 2023-12-29 ; Target : 14.4 ; SD : 1.16 (●)

Lot No.: BJ0922D ; Duration : 2023-02-07 to 2023-12-29 ; Target : 4.6 ; SD : 0.30 (□)

Lab020



Date 02-07 02-14 02-21 03-07 03-14 03-21 03-28 04-04 05-02 05-09 06-06 06-13 06-20 06-27 07-04 07-04 07-11 07-18 07-25 08-01 08-08 08-15 08-21 08-29 12-05 12-12

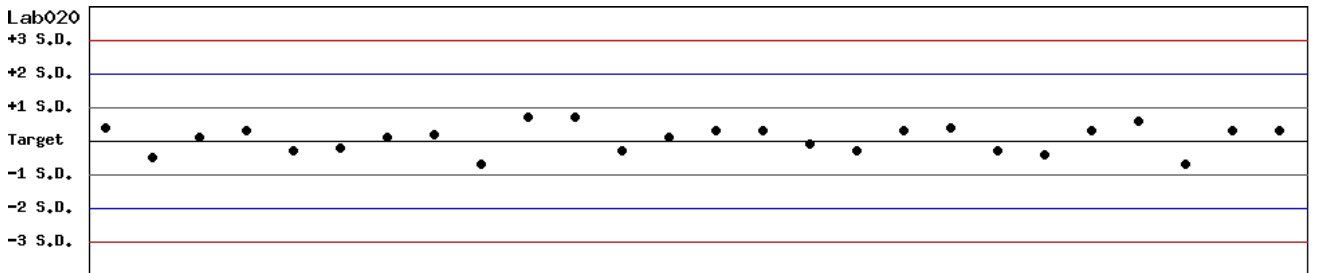
Month : 2023 12 Change ; Cumulative : from 2023 02 07 to 2023 12 29 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-02-07 to 2023-12-29 ; Target : 14.4 ; SD : 1.16

Lab020



Date 02-07 02-14 02-21 03-07 03-14 03-21 03-28 04-04 05-02 05-09 06-06 06-13 06-20 06-27 07-04 07-04 07-11 07-18 07-25 08-01 08-08 08-15 08-21 08-29 12-05 12-12

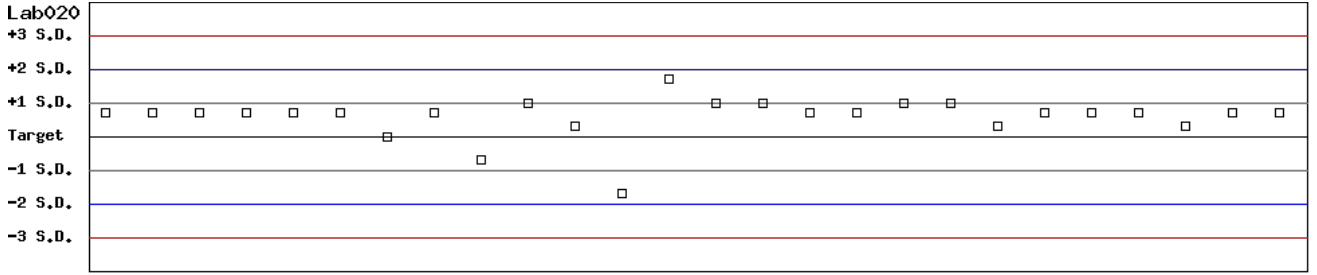
Month : 2023 12 Change ; Cumulative : from 2023 02 07 to 2023 12 29 Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2023-02-07 to 2023-12-29 ; Target : 4.6 ; SD : 0.30

Lab020



Date 02-07 02-14 02-21 03-07 03-14 03-21 03-28 04-04 05-02 05-09 06-06 06-13 06-20 06-27 07-04 07-11 07-18 07-25 08-01 08-08 08-15 08-21 08-29 12-05 12-12

Month : 2023 12 Change ; Cumulative : from 2023 02 07 to 2023 12 29 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 12 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	15.2	9	0.2	1.3	8.8	20	>6	5.5	5.4	9	0.1	1.9	5.5	20	>6
Lab019	5	14.7	15.0	4	0.3	2.0	6.0	20	>6	5.0	5.1	4	0.1	2.0	5.9	20	>6
Lab020	5	14.4	14.8	2	-	-	-	20	-	4.6	4.8	2	-	-	-	20	-
Lab040	5	14.4	15.0	5	0.2	1.3	6.8	20	>6	4.6	4.6	5	0.1	2.2	4.3	20	>6
Lab043	5	13.2	14.5	4	0.2	1.4	12.6	20	>6	4.2	4.9	4	0.0	0.0	16.7	20	>6
Lab049	5	13.8	14.3	3	0.4	2.8	9.2	20	5.8	4.7	4.9	3	0.1	2.0	8.3	20	>6
Lab050	5	13.8	13.5	1	-	-	-	20	-	4.7	4.7	1	-	-	-	20	-
Total	-	-	14.9	28	0.5	3.4	-	-	-	-	5.0	28	0.3	6.0	-	-	-

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 12 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	15.5	34	0.6	3.9	12.1	20	4.0	5.5	5.4	34	0.1	1.9	5.5	20	>6
Lab019	5	14.7	14.5	92	0.6	4.1	9.6	20	4.5	5.0	4.8	92	0.3	6.3	16.5	20	2.5
Lab020	5	14.4	14.4	78	0.5	3.5	6.9	20	5.7	4.6	4.7	78	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	84	0.2	1.4	5.5	20	>6	4.6	4.6	84	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.9	119	1.2	8.6	22.6	20	1.7	4.2	4.6	119	0.4	8.7	26.9	20	1.2
Lab049	5	13.8	14.4	170	0.6	4.2	12.7	20	3.7	4.7	4.7	170	0.3	6.4	12.8	20	3.1
Lab050	5	13.8	13.5	1	-	-	-	20	-	4.7	4.7	1	-	-	-	20	-
Total	-	-	14.4	923	0.8	5.6	-	-	-	-	4.7	923	0.3	6.4	-	-	-

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 (2023/12)									CUM (2021/01/01~2023/12/31)						
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	15.2	9	0.2	1.3	8.8	20	>6	16.2	15.5	34	0.6	3.9	12.1	20	4.0
Lab019	5	14.7	15.0	4	0.3	2.0	6.0	20	>6	14.7	14.5	92	0.6	4.1	9.6	20	4.5
Lab020	5	14.4	14.8	2	-	-	-	20	-	14.4	14.4	78	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	-	0	-	-	-	20	-	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	5	0.2	1.3	6.8	20	>6	14.4	14.8	84	0.2	1.4	5.5	20	>6
Lab043	5	13.2	14.5	4	0.2	1.4	12.6	20	>6	13.2	13.9	119	1.2	8.6	22.6	20	1.7
Lab049	5	13.8	14.3	3	0.4	2.8	9.2	20	5.8	13.8	14.4	170	0.6	4.2	12.7	20	3.7
Lab050	5	13.8	13.5	1	-	-	-	20	-	13.8	13.5	1	-	-	-	20	-
Total	-	-	14.9	28	0.5	3.4	-	-	-	-	14.4	923	0.8	5.6	-	-	-

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

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

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

Month : 2023 12 Change

Cumulative : from 2021 01 01 to 2023 12 31 Change

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2023/12)									CUM (2021/01/01~2023/12/31)						
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	5.4	34	0.1	1.9	5.5	20	>6
Lab019	5	5.0	5.1	4	0.1	2.0	5.9	20	>6	5.0	4.8	92	0.3	6.3	16.5	20	2.5
Lab020	5	4.6	4.8	2	-	-	-	20	-	4.6	4.7	78	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	-	0	-	-	-	20	-	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	5	0.1	2.2	4.3	20	>6	4.6	4.6	84	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.9	4	0.0	0.0	16.7	20	>6	4.2	4.6	119	0.4	8.7	26.9	20	1.2
Lab049	5	4.7	4.9	3	0.1	2.0	8.3	20	>6	4.7	4.7	170	0.3	6.4	12.8	20	3.1
Lab050	5	4.7	4.7	1	-	-	-	20	-	4.7	4.7	1	-	-	-	20	-
Total	-	-	5.0	28	0.3	6.0	-	-	-	-	4.7	923	0.3	6.4	-	-	-

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

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

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

Month : 2023 12 Change

Cumulative : from 2021 01 01 to 2023 12 31 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5