

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

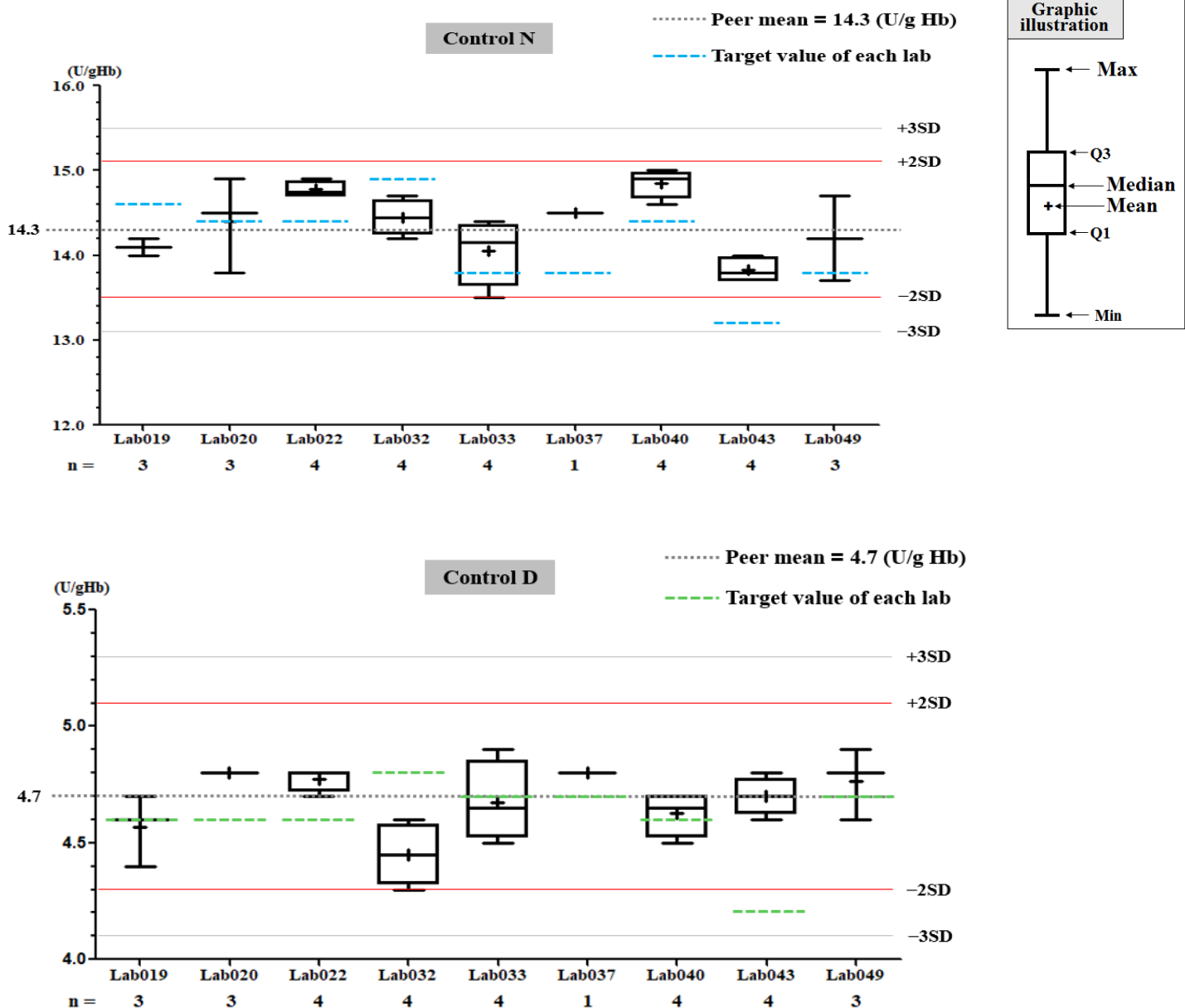
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	9	9
Received results number (n)	30	30
Median	14.4 (U/g Hb)	4.7 (U/g Hb)
Mean	14.3 (U/g Hb)	4.7 (U/g Hb)
SD	0.4	0.2
CV	2.8%	4.3%
Range of G6PD	13.5 ~ 15.0 (U/g Hb)	4.3 ~ 4.9 (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) Change

[Print Table](#)

Lab020

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2023/02)	CUM (2022/05/31~2023/02/28)	Month (2023/02)	CUM (2022/05/31~2023/02/28)
Runs (N)	3	26	3	26
Mean (U/gHb)	14.4	14.3	4.8	4.7
SD	0.6	0.5	0.0	0.1
CV (%)	4.2	3.5	0.0	2.1
Target Value (U/gHb)	14.4	14.4	4.6	4.6
Total Error (%)	8.3	7.7	4.3	6.4
TEa (%)	20	20	20	20
σ	4.8	5.5	>6	>6

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

Month : 2023 02 Change ; Cumulative : from 2022 05 31 to 2023 02 28 Change

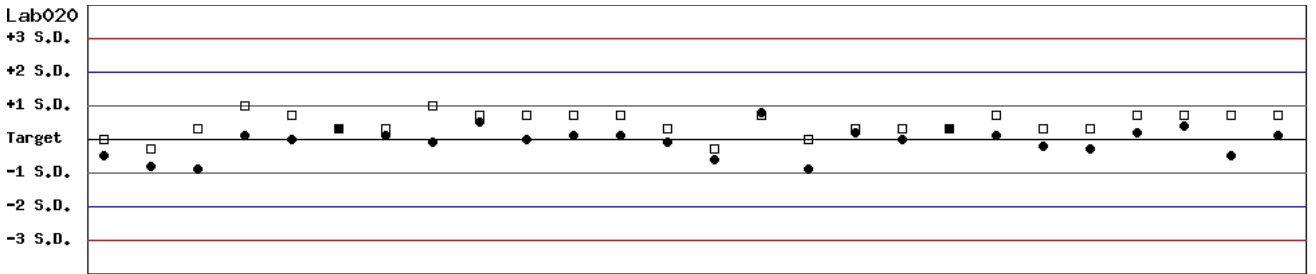
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-05-31 to 2023-02-28 ; Target : 14.4 ; SD : 1.16 (●)

Lot No.: BJ0922D ; Duration : 2022-05-31 to 2023-02-28 ; Target : 4.6 ; SD : 0.30 (□)

Lab020



Date 05-31 06-07 06-14 06-21 06-28 07-21 07-26 08-02 08-09 08-16 08-23 09-01 09-06 10-18 11-08 11-15 11-22 12-01 12-06 12-13 12-20 12-27 01-17 02-07 02-14 02-21

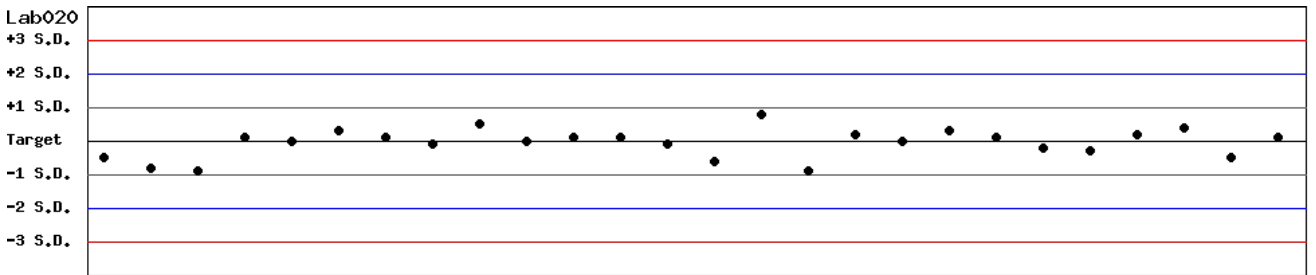
Month : 2023 02 Change ; Cumulative : from 2022 05 31 to 2023 02 28 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-05-31 to 2023-02-28 ; Target : 14.4 ; SD : 1.16

Lab020



Date 05-31 06-07 06-14 06-21 06-28 07-21 07-26 08-02 08-09 08-16 08-23 09-01 09-06 10-18 11-08 11-15 11-22 12-01 12-06 12-13 12-20 12-27 01-17 02-07 02-14 02-21

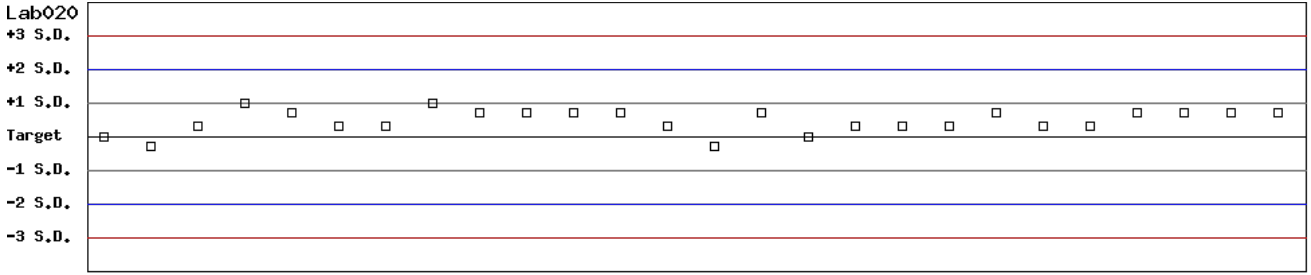
Month : 2023 02 Change ; Cumulative : from 2022 05 31 to 2023 02 28 Change

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Control D SDI QC Chart

Lab020

Lot No.: BJ0922D ; Duration : 2022-05-31 to 2023-02-28 ; Target : 4.6 ; SD : 0.30



Date 05-31 06-07 06-14 06-21 06-28 07-05 07-12 07-19 07-26 08-02 08-09 08-16 08-23 08-30 09-06 09-13 09-20 09-27 10-04 10-11 10-18 10-25 11-01 11-08 11-15 11-22 11-29 12-06 12-13 12-20 12-27 01-03 01-10 01-17 01-24 01-31 02-07 02-14 02-21

Month : 2023 ▾ 02 ▾ Change ; Cumulative : from 2022 ▾ 05 ▾ 31 ▾ to 2023 ▾ 02 ▾ 28 ▾ 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 : 2023 02 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	14.1	3	0.1	0.7	4.8	20	>6	4.6	4.6	3	0.2	4.3	8.7	20	4.7
Lab020	5	14.4	14.4	3	0.6	4.2	8.3	20	4.8	4.6	4.8	3	0.0	0.0	4.3	20	>6
Lab022	5	14.4	14.8	4	0.1	0.7	4.1	20	>6	4.6	4.8	4	0.1	2.1	8.5	20	>6
Lab032	5	14.9	14.5	4	0.2	1.4	5.4	20	>6	4.8	4.5	4	0.1	2.2	10.7	20	>6
Lab033	5	13.8	14.1	4	0.4	2.8	7.8	20	>6	4.7	4.7	4	0.2	4.3	8.5	20	4.7
Lab037	5	13.8	14.5	1	-	-	-	20	-	4.7	4.8	1	-	-	-	20	-
Lab040	5	14.4	14.9	4	0.2	1.3	6.2	20	>6	4.6	4.6	4	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.8	4	0.2	1.4	7.4	20	>6	4.2	4.7	4	0.1	2.1	16.2	20	3.9
Lab049	5	13.8	14.2	3	0.5	3.5	9.9	20	4.9	4.7	4.8	3	0.2	4.2	10.5	20	4.3
Total	-	-	14.3	30	0.4	2.8	-	-	-	-	4.7	30	0.2	4.3	-	-	-

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 2023 02 28 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	14.3	47	0.5	3.5	9.0	20	5.1	4.6	4.6	47	0.2	4.3	8.7	20	4.7
Lab020	5	14.4	14.4	55	0.5	3.5	6.9	20	5.7	4.6	4.7	55	0.1	2.1	6.4	20	>6
Lab022	5	14.4	14.4	21	0.5	3.5	6.9	20	5.7	4.6	4.6	21	0.2	4.3	8.7	20	4.7
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	114	0.4	2.8	8.9	20	5.9	4.8	4.5	114	0.1	2.2	10.7	20	>6
Lab033	5	13.8	13.7	59	0.6	4.4	9.5	20	4.4	4.7	4.6	59	0.3	6.5	15.2	20	2.7
Lab037	5	13.8	14.6	49	0.4	2.7	11.3	20	5.3	4.7	4.7	49	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.7	39	0.2	1.4	4.8	20	>6	4.6	4.6	39	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.7	77	1.4	10.2	24.2	20	1.6	4.2	4.4	77	0.5	11.4	27.5	20	1.3
Lab049	5	13.8	14.6	87	0.7	4.8	15.4	20	3.0	4.7	4.7	87	0.2	4.3	8.5	20	4.7
Total	-	-	14.3	590	0.9	6.3	-	-	-	-	4.6	590	0.3	6.5	-	-	-

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 (2023/02)								CUM (2021/01/01~2023/02/28)							
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	14.1	3	0.1	0.7	4.8	20	>6	14.6	14.3	47	0.5	3.5	9.0	20	5.1
Lab020	5	14.4	14.4	3	0.6	4.2	8.3	20	4.8	14.4	14.4	55	0.5	3.5	6.9	20	5.7
Lab022	5	14.4	14.8	4	0.1	0.7	4.1	20	>6	14.4	14.4	21	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	0.2	1.4	5.4	20	>6	14.9	14.4	114	0.4	2.8	8.9	20	5.9
Lab033	5	13.8	14.1	4	0.4	2.8	7.8	20	>6	13.8	13.7	59	0.6	4.4	9.5	20	4.4
Lab037	5	13.8	14.5	1	-	-	-	20	-	13.8	14.6	49	0.4	2.7	11.3	20	5.3
Lab040	5	14.4	14.9	4	0.2	1.3	6.2	20	>6	14.4	14.7	39	0.2	1.4	4.8	20	>6
Lab043	5	13.2	13.8	4	0.2	1.4	7.4	20	>6	13.2	13.7	77	1.4	10.2	24.2	20	1.6
Lab049	5	13.8	14.2	3	0.5	3.5	9.9	20	4.9	13.8	14.6	87	0.7	4.8	15.4	20	3.0
Total	-	-	14.3	30	0.4	2.8	-	-	-	-	14.3	590	0.9	6.3	-	-	-

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

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

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

Month : 2023 02 Change

Cumulative : from 2021 01 01 to 2023 02 28 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2023/02)								CUM (2021/01/01~2023/02/28)							
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	4.6	3	0.2	4.3	8.7	20	4.7	4.6	4.6	47	0.2	4.3	8.7	20	4.7
Lab020	5	4.6	4.8	3	0.0	0.0	4.3	20	>6	4.6	4.7	55	0.1	2.1	6.4	20	>6
Lab022	5	4.6	4.8	4	0.1	2.1	8.5	20	>6	4.6	4.6	21	0.2	4.3	8.7	20	4.7
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	114	0.1	2.2	10.7	20	>6
Lab033	5	4.7	4.7	4	0.2	4.3	8.5	20	4.7	4.7	4.6	59	0.3	6.5	15.2	20	2.7
Lab037	5	4.7	4.8	1	-	-	-	20	-	4.7	4.7	49	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	39	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.7	4	0.1	2.1	16.2	20	3.9	4.2	4.4	77	0.5	11.4	27.5	20	1.3
Lab049	5	4.7	4.8	3	0.2	4.2	10.5	20	4.3	4.7	4.7	87	0.2	4.3	8.5	20	4.7
Total	-	-	4.7	30	0.2	4.3	-	-	-	-	4.6	590	0.3	6.5	-	-	-

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

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

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

Month : 2023 02 Change

Cumulative : from 2021 01 01 to 2023 02 28 Change

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Reagent Kit	Reagent Code
Medicon	5