

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

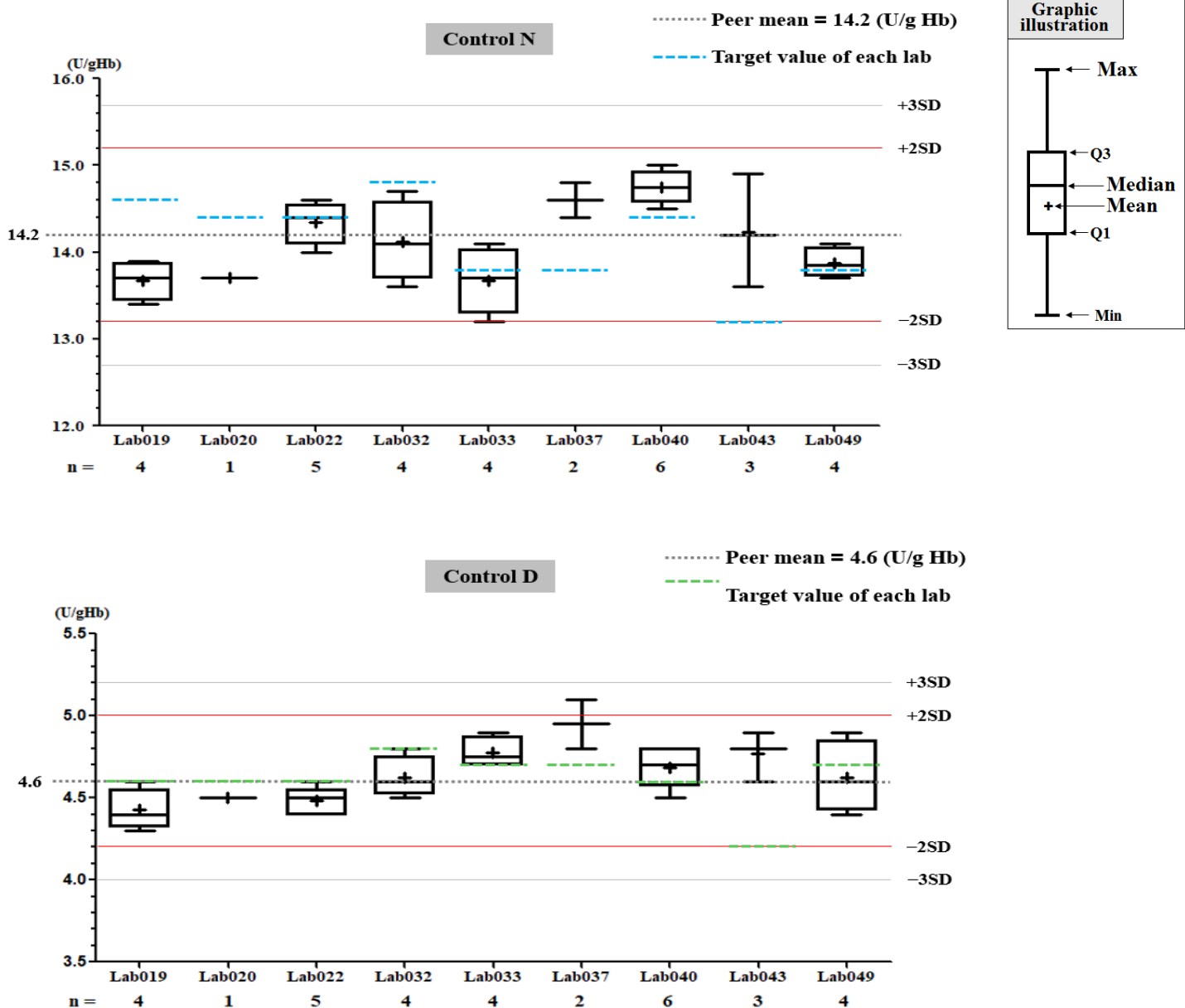
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	9	9
Received results number (n)	33	33
Median	14.1 (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	305%	4.3%
Range of G6PD	13.2 ~ 15.0 (U/g Hb)	4.3 ~ 5.1 (U/g Hb)
Range of Hb	2.0 ~ 2.8 (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 (2022/10)	CUM (2022/03/03~2022/10/31)	Month (2022/10)	CUM (2022/03/03~2022/10/31)
Runs (N)	1	26	1	26
Mean (U/gHb)	13.7	14.3	4.5	4.7
SD	-	0.5	-	0.1
CV (%)	-	3.5	-	2.1
Target Value (U/gHb)	14.4	14.4	4.6	4.6
Total Error (%)	-	7.7	-	6.4
TEa (%)	20	20	20	20
σ	-	5.5	-	>6

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

Month : 2022 10 Change ; Cumulative : from 2022 03 03 to 2022 10 31 Change

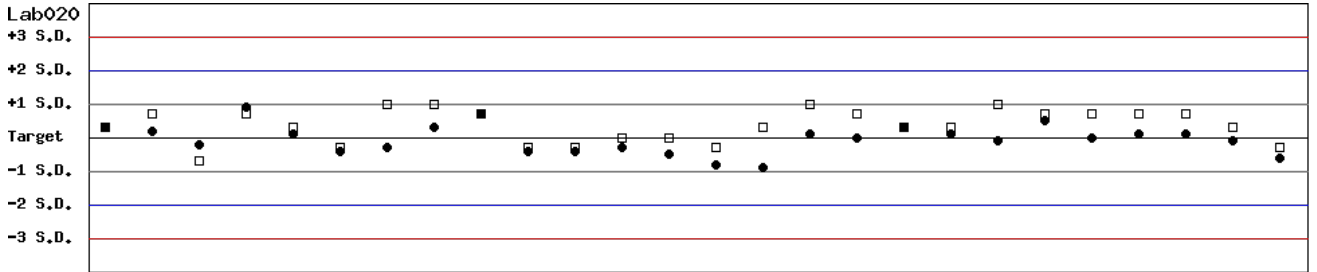
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-03-03 to 2022-10-31 ; Target : 14.4 ; SD : 1.16 (●)

Lot No.: BJ0922D ; Duration : 2022-03-03 to 2022-10-31 ; Target : 4.6 ; SD : 0.30 (□)

Lab020



Date 03-03 03-09 03-15 03-22 03-29 04-07 04-14 04-21 05-03 05-19 05-19 05-24 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

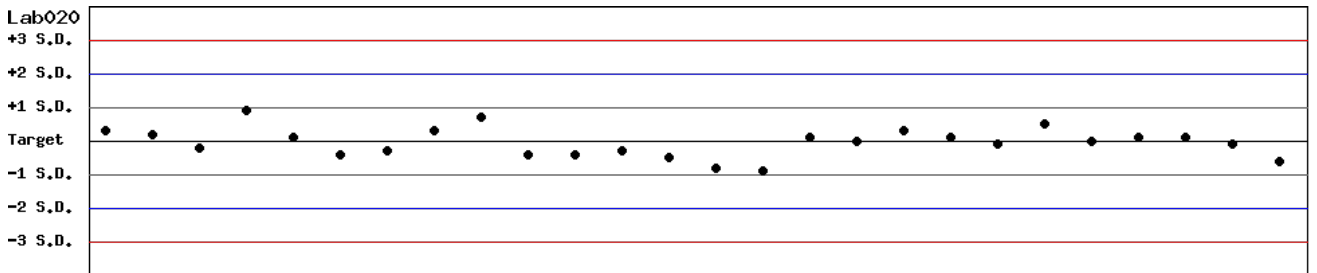
Month : 2022 10 Change ; Cumulative : from 2022 03 03 to 2022 10 31 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-03-03 to 2022-10-31 ; Target : 14.4 ; SD : 1.16

Lab020



Date 03-03 03-09 03-15 03-22 03-29 04-07 04-14 04-21 05-03 05-19 05-19 05-24 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

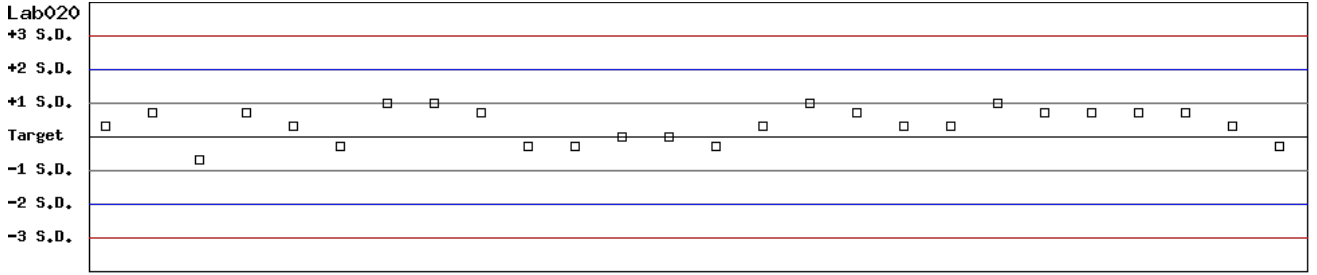
Month : 2022 10 Change ; Cumulative : from 2022 03 03 to 2022 10 31 Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2022-03-03 to 2022-10-31 ; Target : 4.6 ; SD : 0.30

Lab020



Date 03-03 03-09 03-15 03-22 03-29 04-07 04-14 04-21 05-03 05-19 05-24 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

Month : 2022 ▾ 10 ▾ Change ; Cumulative : from 2022 ▾ 03 ▾ 03 ▾ to 2022 ▾ 10 ▾ 31 ▾ 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 : 2022 10 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	13.7	4	0.2	1.5	9.1	20	>6	4.6	4.4	4	0.1	2.3	8.9	20	>6
Lab020	5	14.4	13.7	1	-	-	-	20	-	4.6	4.5	1	-	-	-	20	-
Lab022	5	14.4	14.3	5	0.2	1.4	3.5	20	>6	4.6	4.5	5	0.1	2.2	6.6	20	>6
Lab032	5	14.9	14.1	4	0.5	3.5	12.5	20	4.2	4.8	4.6	4	0.1	2.2	8.5	20	>6
Lab033	5	13.8	13.7	4	0.4	2.9	6.6	20	>6	4.7	4.8	4	0.1	2.1	6.3	20	>6
Lab037	5	13.8	14.6	2	-	-	-	20	-	4.7	5.0	2	-	-	-	20	-
Lab040	5	14.4	14.8	6	0.2	1.4	5.5	20	>6	4.6	4.7	6	0.1	2.1	6.4	20	>6
Lab043	5	13.2	14.2	3	0.7	4.9	17.4	20	2.5	4.2	4.8	3	0.2	4.2	22.6	20	1.4
Lab049	5	13.8	13.9	4	0.2	1.4	3.6	20	>6	4.7	4.6	4	0.2	4.3	10.8	20	4.2
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 (%)

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Cumulative

Cumulative : from 2021 01 01 to 2022 10 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	36	0.6	4.2	9.7	20	4.4	4.6	4.6	36	0.1	2.2	4.3	20	>6
Lab020	5	14.4	14.4	43	0.6	4.2	8.3	20	4.8	4.6	4.7	43	0.2	4.3	10.7	20	4.1
Lab022	5	14.4	14.3	17	0.5	3.5	7.7	20	5.5	4.6	4.5	17	0.2	4.4	11.1	20	4.1
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	97	0.4	2.8	8.9	20	5.9	4.8	4.5	97	0.1	2.2	10.7	20	>6
Lab033	5	13.8	13.5	42	0.5	3.7	9.6	20	4.8	4.7	4.5	42	0.3	6.7	17.6	20	2.3
Lab037	5	13.8	14.6	42	0.4	2.7	11.3	20	5.3	4.7	4.7	42	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.6	20	0.3	2.1	5.5	20	>6	4.6	4.6	20	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.6	64	1.4	10.3	23.6	20	1.6	4.2	4.4	64	0.5	11.4	27.5	20	1.3
Lab049	5	13.8	14.6	73	0.7	4.8	15.4	20	3.0	4.7	4.7	73	0.2	4.3	8.5	20	4.7
Total	-	-	14.4	476	0.9	6.3	-	-	-	-	4.6	476	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 (2022/10)								CUM (2021/01/01~2022/10/31)							
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	-	0	-	-	-	20	-	16.2	16.4	8	0.4	2.4	6.1	20	>6
Lab019	5	14.6	13.7	4	0.2	1.5	9.1	20	>6	14.6	14.4	36	0.6	4.2	9.7	20	4.4
Lab020	5	14.4	13.7	1	-	-	-	20	-	14.4	14.4	43	0.6	4.2	8.3	20	4.8
Lab022	5	14.4	14.3	5	0.2	1.4	3.5	20	>6	14.4	14.3	17	0.5	3.5	7.7	20	5.5
Lab028	5	15.2	-	0	-	-	-	20	-	15.2	15.1	34	1.1	7.3	15.2	20	2.6
Lab032	5	14.9	14.1	4	0.5	3.5	12.5	20	4.2	14.9	14.4	97	0.4	2.8	8.9	20	5.9
Lab033	5	13.8	13.7	4	0.4	2.9	6.6	20	>6	13.8	13.5	42	0.5	3.7	9.6	20	4.8
Lab037	5	13.8	14.6	2	-	-	-	20	-	13.8	14.6	42	0.4	2.7	11.3	20	5.3
Lab040	5	14.4	14.8	6	0.2	1.4	5.5	20	>6	14.4	14.6	20	0.3	2.1	5.5	20	>6
Lab043	5	13.2	14.2	3	0.7	4.9	17.4	20	2.5	13.2	13.6	64	1.4	10.3	23.6	20	1.6
Lab049	5	13.8	13.9	4	0.2	1.4	3.6	20	>6	13.8	14.6	73	0.7	4.8	15.4	20	3.0
Total	-	-	14.2	33	0.5	3.5	-	-	-	-	14.4	476	0.9	6.3	-	-	-

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

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

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

Month : 2022 ↓ 10 ↓ Change

Cumulative : from 2021 ↓ 01 ↓ 01 ↓ to 2022 ↓ 10 ↓ 31 ↓ Change

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Control D Month vs. Cumulative

Control D (Lot No.: BJ0922D)																	
		Month (2022/10)								CUM (2021/01/01~2022/10/31)							
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	-	0	-	-	-	20	-	5.5	5.5	8	0.2	3.6	7.3	20	5.6
Lab019	5	4.6	4.4	4	0.1	2.3	8.9	20	>6	4.6	4.6	36	0.1	2.2	4.3	20	>6
Lab020	5	4.6	4.5	1	-	-	-	20	-	4.6	4.7	43	0.2	4.3	10.7	20	4.1
Lab022	5	4.6	4.5	5	0.1	2.2	6.6	20	>6	4.6	4.5	17	0.2	4.4	11.1	20	4.1
Lab028	5	4.9	-	0	-	-	-	20	-	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	4.8	4.6	4	0.1	2.2	8.5	20	>6	4.8	4.5	97	0.1	2.2	10.7	20	>6
Lab033	5	4.7	4.8	4	0.1	2.1	6.3	20	>6	4.7	4.5	42	0.3	6.7	17.6	20	2.3
Lab037	5	4.7	5.0	2	-	-	-	20	-	4.7	4.7	42	0.2	4.3	8.5	20	4.7
Lab040	5	4.6	4.7	6	0.1	2.1	6.4	20	>6	4.6	4.6	20	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.8	3	0.2	4.2	22.6	20	1.4	4.2	4.4	64	0.5	11.4	27.5	20	1.3
Lab049	5	4.7	4.6	4	0.2	4.3	10.8	20	4.2	4.7	4.7	73	0.2	4.3	8.5	20	4.7
Total	-	-	4.6	33	0.2	4.3	-	-	-	-	4.6	476	0.3	6.5	-	-	-

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

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

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

Month : 2022 ↓ 10 ↓ Change

Cumulative : from 2021 ↓ 01 ↓ 01 ↓ to 2022 ↓ 10 ↓ 31 ↓ Change

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Reagent Kit	Reagent Code
Medicon	5