

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

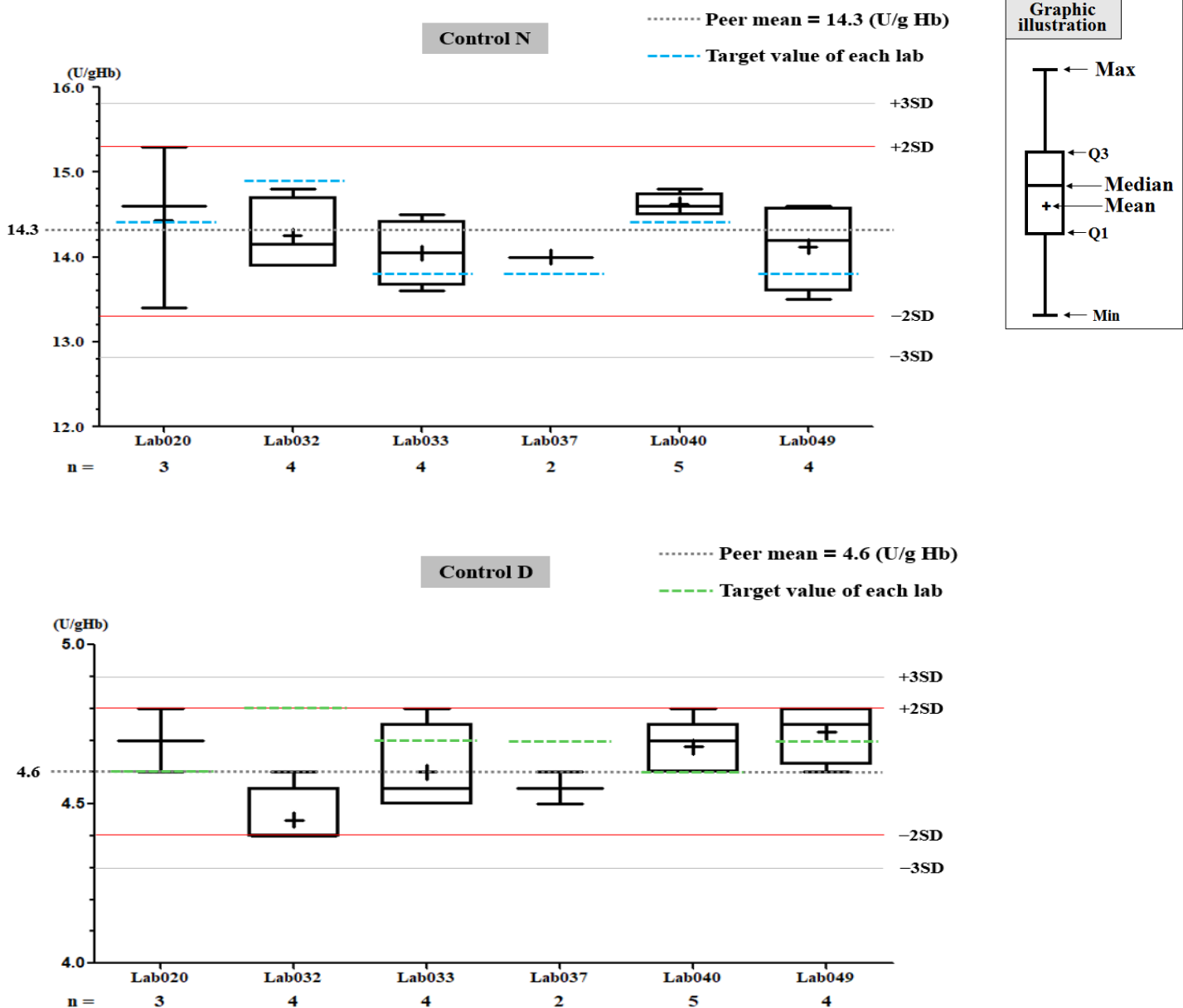
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	6	6
Received results number (n)	22	22
Median	14.5 (U/g Hb)	4.6 (U/g Hb)
Mean	14.3 (U/g Hb)	4.6 (U/g Hb)
SD	0.5	0.1
CV	3.5%	2.2%
Range of G6PD	13.4 ~ 15.3 (U/g Hb)	4.4 ~ 4.8 (U/g Hb)
Range of Hb	2.0 ~ 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 (IQ)for G6PD Quantitative Test

Select LotNo :

Lab020

	Control N		Control D	
QC Control Lot No.	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2022/11)	CUM (2022/03/22~2022/11/30)	Month (2022/11)	CUM (2022/03/22~2022/11/30)
Runs (N)	3	26	3	26
Mean (U/gHb)	14.4	14.3	4.7	4.7
SD	1.0	0.6	0.1	0.1
CV (%)	6.9	4.2	2.1	2.1
Target Value (U/gHb)	14.4	14.4	4.6	4.6
Total Error (%)	13.9	9.1	6.4	6.4
TEa (%)	20	20	20	20
σ	2.9	4.6	>6	>6

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

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

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

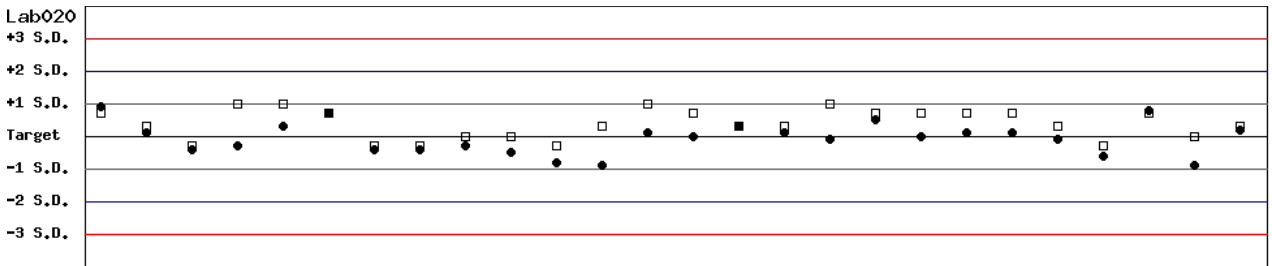
Month : ; Cumulative : from to

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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-03-22 to 2022-11-30 ; Target : 14.4 ; SD : 1.16 (●)

Lot No.: BJ0922D ; Duration : 2022-03-22 to 2022-11-30 ; Target : 4.6 ; SD : 0.30 (□)



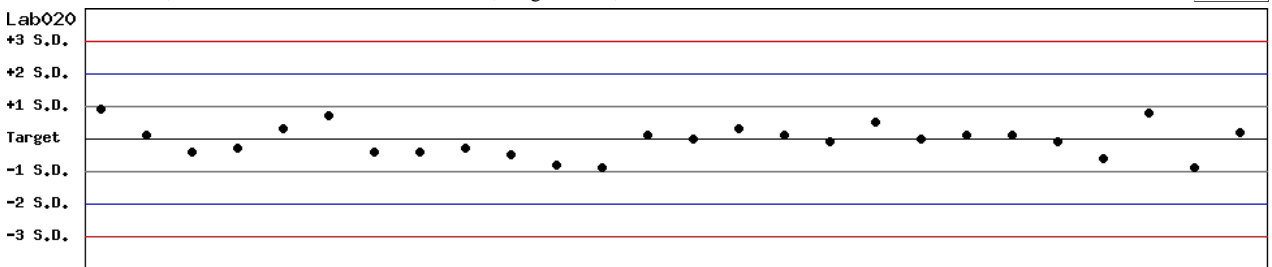
Date 03-22 03-29 04-07 04-14 04-21 05-03 05-19 05-19 05-24 05-31 06-07 06-14 06-21 06-28 07-21 07-26 08-02 08-09 08-16 08-23 09-01 09-06 10-18 11-08 11-15 11-22

Month : ; Cumulative : from to

[\[TOP\]](#)

Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-03-22 to 2022-11-30 ; Target : 14.4 ; SD : 1.16



Date 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 11-08 11-15 11-22

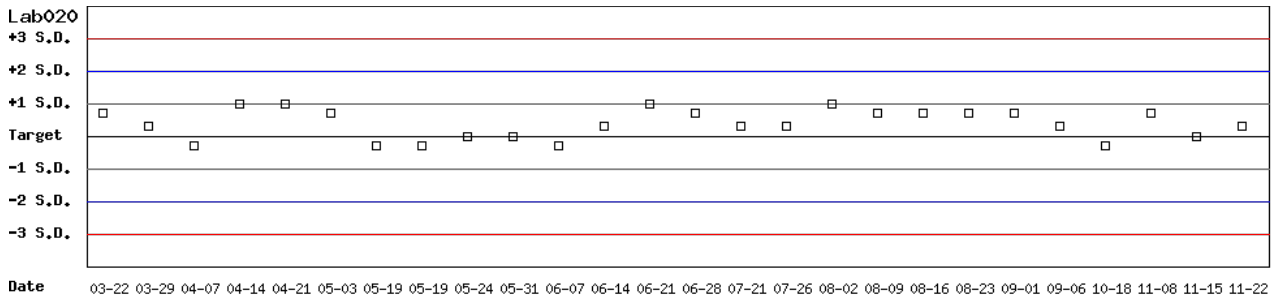
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2022-03-22 to 2022-11-30 ; Target : 4.6 ; SD : 0.30

Lab020



Month : 2022 ▾ 11 ▾ Change ; Cumulative : from 2022 ▾ 03 ▾ 22 ▾ to 2022 ▾ 11 ▾ 30 ▾ 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 ▼ 11 ▼ 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
Lab020	5	14.4	14.4	3	1.0	6.9	13.9	20	2.9	4.6	4.7	3	0.1	2.1	6.4	20	>6
Lab032	5	14.9	14.3	4	0.4	2.8	9.6	20	5.7	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	4.6	4	0.1	2.2	6.5	20	>6
Lab037	5	13.8	14.0	2	-	-	-	20	-	4.7	4.6	2	-	-	-	20	-
Lab040	5	14.4	14.6	5	0.1	0.7	2.8	20	>6	4.6	4.7	5	0.1	2.1	6.4	20	>6
Lab049	5	13.8	14.1	4	0.5	3.5	9.3	20	5.1	4.7	4.7	4	0.1	2.1	4.3	20	>6
Total	-	-	14.3	22	0.5	3.5	-	-	-	-	4.6	22	0.1	2.2	-	-	-

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 ▼ 11 ▼ 30 ▼ 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	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	46	0.6	4.2	8.3	20	4.8	4.6	4.7	46	0.1	2.1	6.4	20	>6
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	101	0.4	2.8	8.9	20	5.9	4.8	4.5	101	0.1	2.2	10.7	20	>6
Lab033	5	13.8	13.6	46	0.6	4.4	10.3	20	4.2	4.7	4.6	46	0.3	6.5	15.2	20	2.7
Lab037	5	13.8	14.6	44	0.4	2.7	11.3	20	5.3	4.7	4.7	44	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.6	25	0.3	2.1	5.5	20	>6	4.6	4.6	25	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	77	0.7	4.8	15.4	20	3.0	4.7	4.7	77	0.2	4.3	8.5	20	4.7
Total	-	-	14.4	498	0.9	6.3	-	-	-	-	4.6	498	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 (2022/11)								CUM (2021/01/01~2022/11/30)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	-	0	-	-	-	20	-	14.6	14.4	36	0.6	4.2	9.7	20	4.4
Lab020	5	14.4	14.4	3	1.0	6.9	13.9	20	2.9	14.4	14.4	46	0.6	4.2	8.3	20	4.8
Lab022	5	14.4	-	0	-	-	-	20	-	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	14.3	4	0.4	2.8	9.6	20	5.7	14.9	14.4	101	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	13.6	46	0.6	4.4	10.3	20	4.2
Lab037	5	13.8	14.0	2	-	-	-	20	-	13.8	14.6	44	0.4	2.7	11.3	20	5.3
Lab040	5	14.4	14.6	5	0.1	0.7	2.8	20	>6	14.4	14.6	25	0.3	2.1	5.5	20	>6
Lab043	5	13.2	-	0	-	-	-	20	-	13.2	13.6	64	1.4	10.3	23.6	20	1.6
Lab049	5	13.8	14.1	4	0.5	3.5	9.3	20	5.1	13.8	14.6	77	0.7	4.8	15.4	20	3.0
Total	-	-	14.3	22	0.5	3.5	-	-	-	-	14.4	498	0.9	6.3	-	-	-

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

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

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

Month : 2022 11 Change

Cumulative : from 2021 01 01 to 2022 11 30 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2022/11)								CUM (2021/01/01~2022/11/30)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	-	0	-	-	-	20	-	4.6	4.6	36	0.1	2.2	4.3	20	>6
Lab020	5	4.6	4.7	3	0.1	2.1	6.4	20	>6	4.6	4.7	46	0.1	2.1	6.4	20	>6
Lab022	5	4.6	-	0	-	-	-	20	-	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	4.5	4	0.1	2.2	10.7	20	>6	4.8	4.5	101	0.1	2.2	10.7	20	>6
Lab033	5	4.7	4.6	4	0.1	2.2	6.5	20	>6	4.7	4.6	46	0.3	6.5	15.2	20	2.7
Lab037	5	4.7	4.6	2	-	-	-	20	-	4.7	4.7	44	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	25	0.1	2.2	4.3	20	>6
Lab043	5	4.2	-	0	-	-	-	20	-	4.2	4.4	64	0.5	11.4	27.5	20	1.3
Lab049	5	4.7	4.7	4	0.1	2.1	4.3	20	>6	4.7	4.7	77	0.2	4.3	8.5	20	4.7
Total	-	-	4.6	22	0.1	2.2	-	-	-	-	4.6	498	0.3	6.5	-	-	-

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

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

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

Month : 2022 11 Change

Cumulative : from 2021 01 01 to 2022 11 30 Change

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Reagent Kit	Reagent Code
Medicon	5