

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

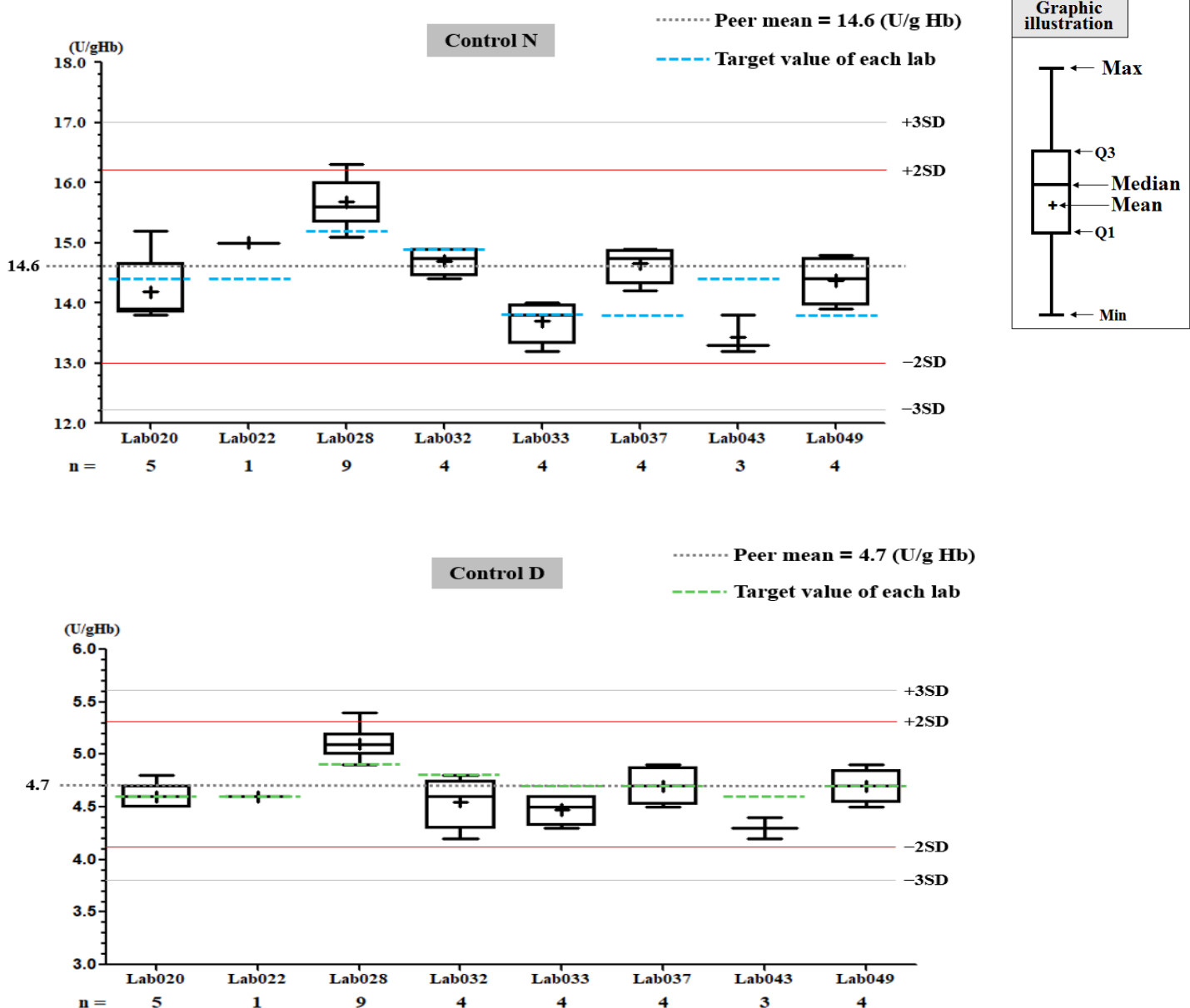
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	8	8
Received results number (n)	34	34
Median	14.7 (U/g Hb)	4.6 (U/g Hb)
Mean	14.6 (U/g Hb)	4.7 (U/g Hb)
SD	0.8	0.3
CV	5.5%	6.4%
Range of G6PD	13.2 ~ 16.3 (U/g Hb)	4.2 ~ 5.4 (U/g Hb)
Range of Hb	2.1 ~ 2.7 (g/dL)	1.8 ~ 2.4 (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](#)

Lab032

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2022/05)	CUM (2022/01/20~2022/05/31)	Month (2022/05)	CUM (2022/01/20~2022/05/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.7	14.5	4.6	4.5
SD	0.2	0.3	0.3	0.1
CV (%)	1.4	2.1	6.5	2.2
Target Value (U/gHb)	14.9	14.9	4.8	4.8
Total Error (%)	4.1	6.8	17.2	10.7
TEa (%)	20	20	20	20
σ	>6	>6	2.4	>6

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

Month : 2022 05 Change ; Cumulative : from 2022 01 20 to 2022 05 31 Change

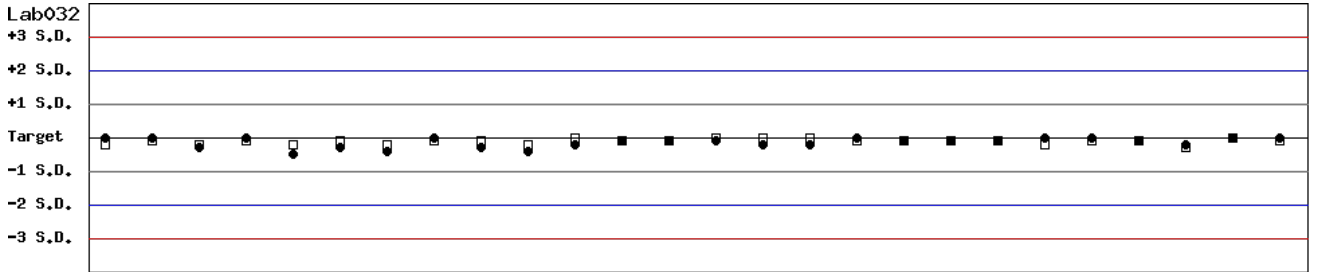
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-01-20 to 2022-05-31 ; Target : 14.9 ; SD : 2.30 (●)

Lot No.: BJ0922D ; Duration : 2022-01-20 to 2022-05-31 ; Target : 4.8 ; SD : 2.10 (□)

Lab032



Date 01-20 01-23 02-08 02-10 02-15 02-17 02-22 02-24 02-28 03-03 03-08 03-10 03-15 03-17 03-22 03-24 03-29 04-01 04-08 04-15 04-22 04-29 05-06 05-13 05-20 05-27

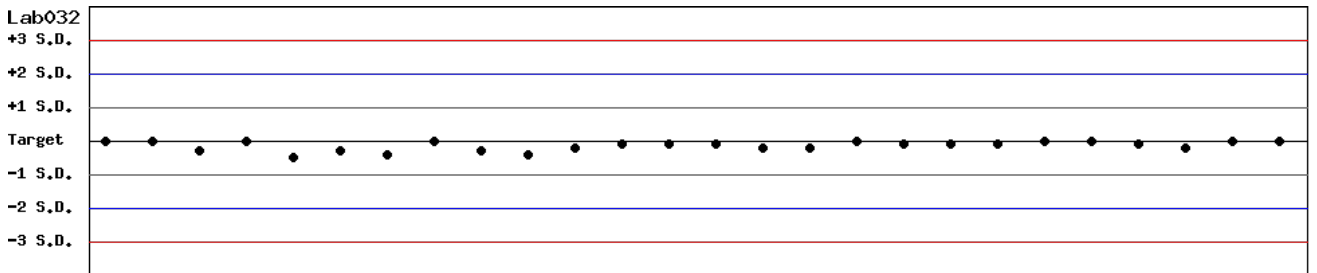
Month : 2022 05 Change ; Cumulative : from 2022 01 20 to 2022 05 31 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-01-20 to 2022-05-31 ; Target : 14.9 ; SD : 2.30

Lab032



Date 01-20 01-23 02-08 02-10 02-15 02-17 02-22 02-24 02-28 03-03 03-08 03-10 03-15 03-17 03-22 03-24 03-29 04-01 04-08 04-15 04-22 04-29 05-06 05-13 05-20 05-27

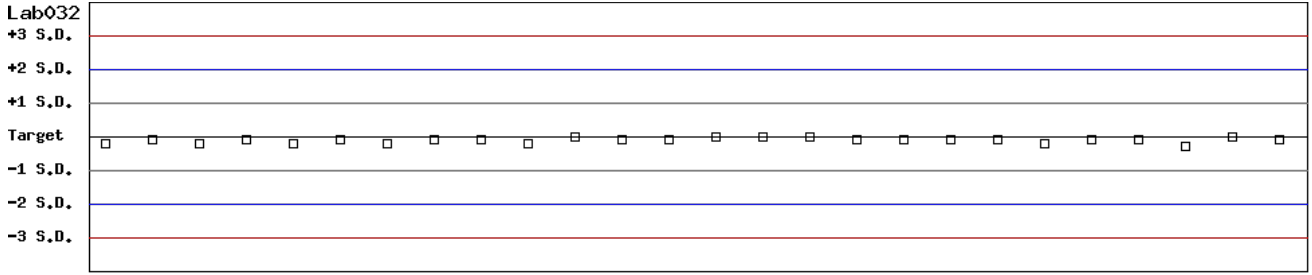
Month : 2022 05 Change ; Cumulative : from 2022 01 20 to 2022 05 31 Change

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Control D SDI QC Chart

Lab032

Lot No.: BJ0922D ; Duration : 2022-01-20 to 2022-05-31 ; Target : 4.8 ; SD : 2.10



Date 01-20 01-23 02-08 02-10 02-15 02-17 02-22 02-24 02-28 03-03 03-08 03-10 03-15 03-17 03-22 03-24 03-29 04-01 04-08 04-15 04-22 04-29 05-06 05-13 05-20 05-27

Month : 2022 05 Change ; Cumulative : from 2022 01 20 to 2022 05 31 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 : 2022 05

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
Lab020	5	14.4	14.2	5	0.6	4.2	9.8	20	4.4	4.6	4.6	5	0.1	2.2	4.3	20	>6
Lab022	5	14.4	15.0	1	-	-	-	20	-	4.6	4.6	1	-	-	-	20	-
Lab028	5	15.2	15.7	9	0.4	2.5	8.4	20	>6	4.9	5.1	9	0.2	3.9	11.9	20	4.1
Lab032	5	14.9	14.7	4	0.2	1.4	4.1	20	>6	4.8	4.6	4	0.3	6.5	17.2	20	2.4
Lab033	5	13.8	13.7	4	0.4	2.9	6.6	20	>6	4.7	4.5	4	0.2	4.4	13.1	20	3.6
Lab037	5	13.8	14.7	4	0.3	2.0	10.6	20	>6	4.7	4.7	4	0.2	4.3	8.5	20	4.7
Lab043	5	14.4	13.4	3	0.3	2.2	11.4	20	5.9	4.6	4.3	3	0.1	2.3	11.2	20	5.9
Lab049	5	13.8	14.4	4	0.4	2.8	9.9	20	5.6	4.7	4.7	4	0.2	4.3	8.5	20	4.7
Total	-	-	14.6	34	0.8	5.5	-	-	-	-	4.7	34	0.3	6.4	-	-	-

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 2022 05 31

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	16.5	5	0.4	2.4	6.7	20	>6	5.5	5.6	5	0.2	3.6	9.0	20	5.1
Lab019	5	14.6	14.7	19	0.6	4.1	8.8	20	4.7	4.6	4.6	19	0.1	2.2	4.3	20	>6
Lab020	5	14.4	14.5	30	0.6	4.1	9.0	20	4.7	4.6	4.7	30	0.2	4.3	10.7	20	4.1
Lab022	5	14.4	14.7	4	0.4	2.7	7.5	20	>6	4.6	4.4	4	0.2	4.5	13.4	20	3.5
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	75	0.4	2.8	8.9	20	5.9	4.8	4.5	75	0.1	2.2	10.7	20	>6
Lab033	5	13.8	13.3	21	0.6	4.5	12.6	20	3.6	4.7	4.4	21	0.4	9.1	24.6	20	1.5
Lab037	5	13.8	14.7	25	0.5	3.4	13.3	20	4.0	4.7	4.7	25	0.2	4.3	8.5	20	4.7
Lab043	5	14.4	13.1	41	1.6	12.2	33.5	20	0.9	4.6	4.2	41	0.5	11.9	32.5	20	0.9
Lab049	5	13.8	14.9	51	0.6	4.0	16.0	20	3.0	4.7	4.7	51	0.3	6.4	12.8	20	3.1
Total	-	-	14.4	305	1.1	7.6	-	-	-	-	4.6	305	0.4	8.7	-	-	-

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 (2022/05)								CUM (2021/01/01~2022/05/31)							
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	16.5	5	0.4	2.4	6.7	20	>6
Lab019	5	14.6	-	0	-	-	-	20	-	14.6	14.7	19	0.6	4.1	8.8	20	4.7
Lab020	5	14.4	14.2	5	0.6	4.2	9.8	20	4.4	14.4	14.5	30	0.6	4.1	9.0	20	4.7
Lab022	5	14.4	15.0	1	-	-	-	20	-	14.4	14.7	4	0.4	2.7	7.5	20	>6
Lab028	5	15.2	15.7	9	0.4	2.5	8.4	20	>6	15.2	15.1	34	1.1	7.3	15.2	20	2.6
Lab032	5	14.9	14.7	4	0.2	1.4	4.1	20	>6	14.9	14.4	75	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	13.3	21	0.6	4.5	12.6	20	3.6
Lab037	5	13.8	14.7	4	0.3	2.0	10.6	20	>6	13.8	14.7	25	0.5	3.4	13.3	20	4.0
Lab043	5	14.4	13.4	3	0.3	2.2	11.4	20	5.9	14.4	13.1	41	1.6	12.2	33.5	20	0.9
Lab049	5	13.8	14.4	4	0.4	2.8	9.9	20	5.6	13.8	14.9	51	0.6	4.0	16.0	20	3.0
Total	-	-	14.6	34	0.8	5.5	-	-	-	-	14.4	305	1.1	7.6	-	-	-

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

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

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

Month : 2022 ▼ 05 ▼ Change

Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2022 ▼ 05 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2022/05)								CUM (2021/01/01~2022/05/31)							
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	5.6	5	0.2	3.6	9.0	20	5.1
Lab019	5	4.6	-	0	-	-	-	20	-	4.6	4.6	19	0.1	2.2	4.3	20	>6
Lab020	5	4.6	4.6	5	0.1	2.2	4.3	20	>6	4.6	4.7	30	0.2	4.3	10.7	20	4.1
Lab022	5	4.6	4.6	1	-	-	-	20	-	4.6	4.4	4	0.2	4.5	13.4	20	3.5
Lab028	5	4.9	5.1	9	0.2	3.9	11.9	20	4.1	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	75	0.1	2.2	10.7	20	>6
Lab033	5	4.7	4.5	4	0.2	4.4	13.1	20	3.6	4.7	4.4	21	0.4	9.1	24.6	20	1.5
Lab037	5	4.7	4.7	4	0.2	4.3	8.5	20	4.7	4.7	4.7	25	0.2	4.3	8.5	20	4.7
Lab043	5	4.6	4.3	3	0.1	2.3	11.2	20	5.9	4.6	4.2	41	0.5	11.9	32.5	20	0.9
Lab049	5	4.7	4.7	4	0.2	4.3	8.5	20	4.7	4.7	4.7	51	0.3	6.4	12.8	20	3.1
Total	-	-	4.7	34	0.3	6.4	-	-	-	-	4.6	305	0.4	8.7	-	-	-

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

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

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

Month : 2022 ▼ 05 ▼ Change

Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2022 ▼ 05 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5