

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

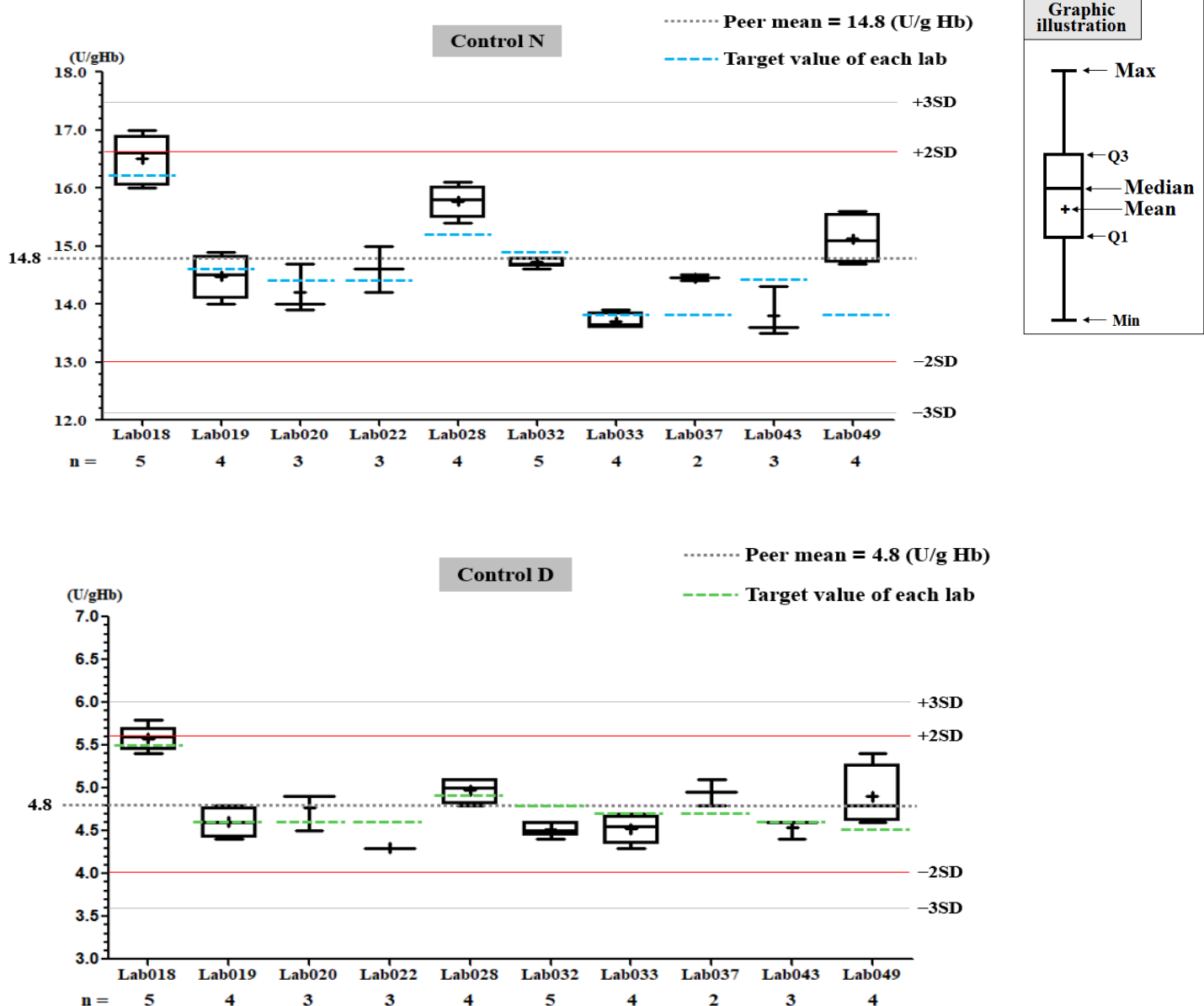
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	10	10
Received results number (n)	37	37
Median	14.7 (U/g Hb)	4.7 (U/g Hb)
Mean	14.8 (U/g Hb)	4.8 (U/g Hb)
SD	0.9	0.4
CV	3.4%	1.3%
Range of G6PD	13.5 ~ 17.0 (U/g Hb)	4.3 ~ 5.8 (U/g Hb)
Range of Hb	2.2 ~ 2.8 (g/dL)	1.9 ~ 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](#)

Lab037

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2022/04)	CUM (2021/07/02~2022/04/29)	Month (2022/04)	CUM (2021/07/02~2022/04/29)
Runs (N)	2	21	2	21
Mean (U/gHb)	14.5	14.8	5.0	4.7
SD	-	0.5	-	0.2
CV (%)	-	3.4	-	4.3
Target Value (U/gHb)	13.8	13.8	4.7	4.7
Total Error (%)	-	14.0	-	8.5
TEa (%)	20	20	20	20
σ	-	3.8	-	4.7

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

Month : 2022 04 Change ; Cumulative : from 2021 07 02 to 2022 04 29 Change

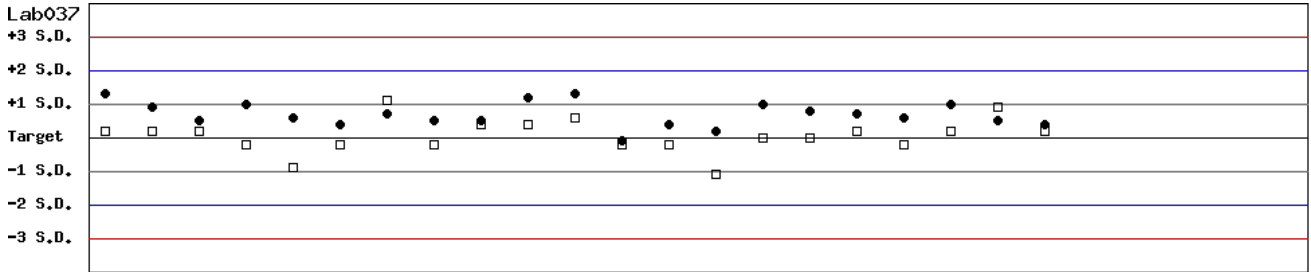
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-07-02 to 2022-04-29 ; Target : 13.8 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2021-07-02 to 2022-04-29 ; Target : 4.7 ; SD : 0.47 (□)

Lab037



Date 07-02 07-14 07-30 08-12 12-01 12-16 12-22 01-06 01-13 01-21 01-27 02-10 02-17 02-24 03-03 03-11 03-16 03-25 03-31 04-07 04-21

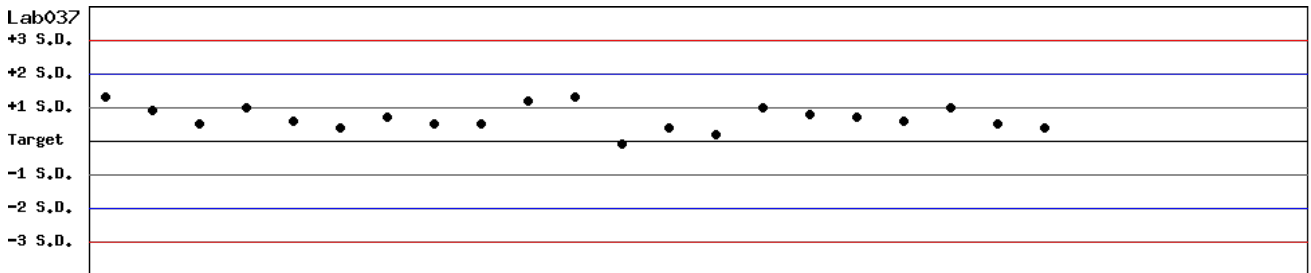
Month : 2022 04 Change ; Cumulative : from 2021 07 02 to 2022 04 29 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-07-02 to 2022-04-29 ; Target : 13.8 ; SD : 1.38

Lab037



Date 07-02 07-14 07-30 08-12 12-01 12-16 12-22 01-06 01-13 01-21 01-27 02-10 02-17 02-24 03-03 03-11 03-16 03-25 03-31 04-07 04-21

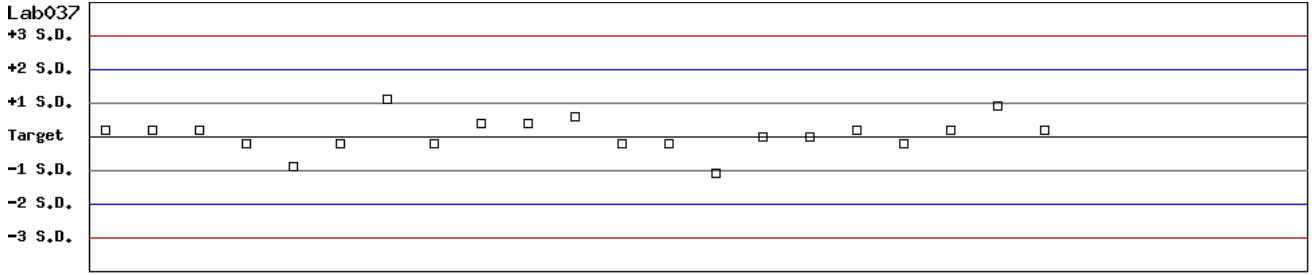
Month : 2022 04 Change ; Cumulative : from 2021 07 02 to 2022 04 29 Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2021-07-02 to 2022-04-29 ; Target : 4.7 ; SD : 0.47

Lab037



Date 07-02 07-14 07-30 08-12 12-01 12-16 12-22 01-06 01-13 01-21 01-27 02-10 02-17 02-24 03-03 03-11 03-16 03-25 03-31 04-07 04-21

Month : 2022 04 Change ; Cumulative : from 2021 07 02 to 2022 04 29 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 04 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	16.5	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	14.5	4	0.4	2.8	6.2	20	>6	4.6	4.6	4	0.2	4.3	8.7	20	4.7
Lab020	5	14.4	14.2	3	0.4	2.8	7.0	20	>6	4.6	4.8	3	0.2	4.2	12.7	20	3.7
Lab022	5	14.4	14.6	3	0.4	2.7	6.9	20	>6	4.6	4.3	3	0.0	0.0	6.5	20	>6
Lab028	5	15.2	15.8	4	0.3	1.9	7.7	20	>6	4.9	5.0	4	0.2	4.0	10.0	20	4.5
Lab032	5	14.9	14.7	5	0.1	0.7	2.7	20	>6	4.8	4.5	5	0.1	2.2	10.7	20	>6
Lab033	5	13.8	13.7	4	0.1	0.7	2.2	20	>6	4.7	4.5	4	0.2	4.4	13.1	20	3.6
Lab037	5	13.8	14.5	2	-	-	-	20	-	4.7	5.0	2	-	-	-	20	-
Lab043	5	14.4	13.8	3	0.4	2.9	10.0	20	5.5	4.6	4.5	3	0.1	2.2	6.6	20	>6
Lab049	5	13.8	15.1	4	0.4	2.6	14.7	20	4.1	4.7	4.9	4	0.4	8.2	20.6	20	1.9
Total	-	-	14.8	37	0.9	6.1	-	-	-	-	4.8	37	0.4	8.3	-	-	-

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 04 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	16.5	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	14.6	25	0.6	4.1	9.6	20	4.5	4.6	4.7	25	0.2	4.3	10.7	20	4.1
Lab022	5	14.4	14.6	3	0.4	2.7	6.9	20	>6	4.6	4.3	3	0.0	0.0	6.5	20	>6
Lab028	5	15.2	14.9	25	1.2	8.1	18.1	20	2.2	4.9	4.8	25	0.3	6.3	14.5	20	2.9
Lab032	5	14.9	14.4	71	0.4	2.8	8.9	20	5.9	4.8	4.5	71	0.1	2.2	10.7	20	>6
Lab033	5	13.8	13.2	17	0.7	5.3	15.0	20	3.0	4.7	4.3	17	0.4	9.3	27.1	20	1.2
Lab037	5	13.8	14.8	21	0.5	3.4	14.0	20	3.8	4.7	4.7	21	0.2	4.3	8.5	20	4.7
Lab043	5	14.4	13.0	38	1.6	12.3	34.3	20	0.8	4.6	4.2	38	0.5	11.9	32.5	20	0.9
Lab049	5	13.8	15.0	47	0.6	4.0	16.7	20	2.8	4.7	4.7	47	0.3	6.4	12.8	20	3.1
Total	-	-	14.4	271	1.1	7.6	-	-	-	-	4.6	271	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 (2022/04)										CUM (2021/01/01~2022/04/30)							
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	16.5	5	0.4	2.4	6.7	20	>6	16.2	16.5	5	0.4	2.4	6.7	20	>6
Lab019	5	14.6	14.5	4	0.4	2.8	6.2	20	>6	14.6	14.7	19	0.6	4.1	8.8	20	4.7
Lab020	5	14.4	14.2	3	0.4	2.8	7.0	20	>6	14.4	14.6	25	0.6	4.1	9.6	20	4.5
Lab022	5	14.4	14.6	3	0.4	2.7	6.9	20	>6	14.4	14.6	3	0.4	2.7	6.9	20	>6
Lab028	5	15.2	15.8	4	0.3	1.9	7.7	20	>6	15.2	14.9	25	1.2	8.1	18.1	20	2.2
Lab032	5	14.9	14.7	5	0.1	0.7	2.7	20	>6	14.9	14.4	71	0.4	2.8	8.9	20	5.9
Lab033	5	13.8	13.7	4	0.1	0.7	2.2	20	>6	13.8	13.2	17	0.7	5.3	15.0	20	3.0
Lab037	5	13.8	14.5	2	-	-	-	20	-	13.8	14.8	21	0.5	3.4	14.0	20	3.8
Lab043	5	14.4	13.8	3	0.4	2.9	10.0	20	5.5	14.4	13.0	38	1.6	12.3	34.3	20	0.8
Lab049	5	13.8	15.1	4	0.4	2.6	14.7	20	4.1	13.8	15.0	47	0.6	4.0	16.7	20	2.8
Total	-	-	14.8	37	0.9	6.1	-	-	-	-	14.4	271	1.1	7.6	-	-	-

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

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

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

Month : 2022 04 Change

Cumulative : from 2021 01 01 to 2022 04 30 Change

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Control D Month vs. Cumulative

Control D (Lot No.: BJ0922D)																	
Month (2022/04)										CUM (2021/01/01~2022/04/30)							
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	5.6	5	0.2	3.6	9.0	20	5.1	5.5	5.6	5	0.2	3.6	9.0	20	5.1
Lab019	5	4.6	4.6	4	0.2	4.3	8.7	20	4.7	4.6	4.6	19	0.1	2.2	4.3	20	>6
Lab020	5	4.6	4.8	3	0.2	4.2	12.7	20	3.7	4.6	4.7	25	0.2	4.3	10.7	20	4.1
Lab022	5	4.6	4.3	3	0.0	0.0	6.5	20	>6	4.6	4.3	3	0.0	0.0	6.5	20	>6
Lab028	5	4.9	5.0	4	0.2	4.0	10.0	20	4.5	4.9	4.8	25	0.3	6.3	14.5	20	2.9
Lab032	5	4.8	4.5	5	0.1	2.2	10.7	20	>6	4.8	4.5	71	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	4.3	17	0.4	9.3	27.1	20	1.2
Lab037	5	4.7	5.0	2	-	-	-	20	-	4.7	4.7	21	0.2	4.3	8.5	20	4.7
Lab043	5	4.6	4.5	3	0.1	2.2	6.6	20	>6	4.6	4.2	38	0.5	11.9	32.5	20	0.9
Lab049	5	4.7	4.9	4	0.4	8.2	20.6	20	1.9	4.7	4.7	47	0.3	6.4	12.8	20	3.1
Total	-	-	4.8	37	0.4	8.3	-	-	-	-	4.6	271	0.4	8.7	-	-	-

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

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

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

Month : 2022 04 Change

Cumulative : from 2021 01 01 to 2022 04 30 Change

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Reagent Kit	Reagent Code
Medicon	5