

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

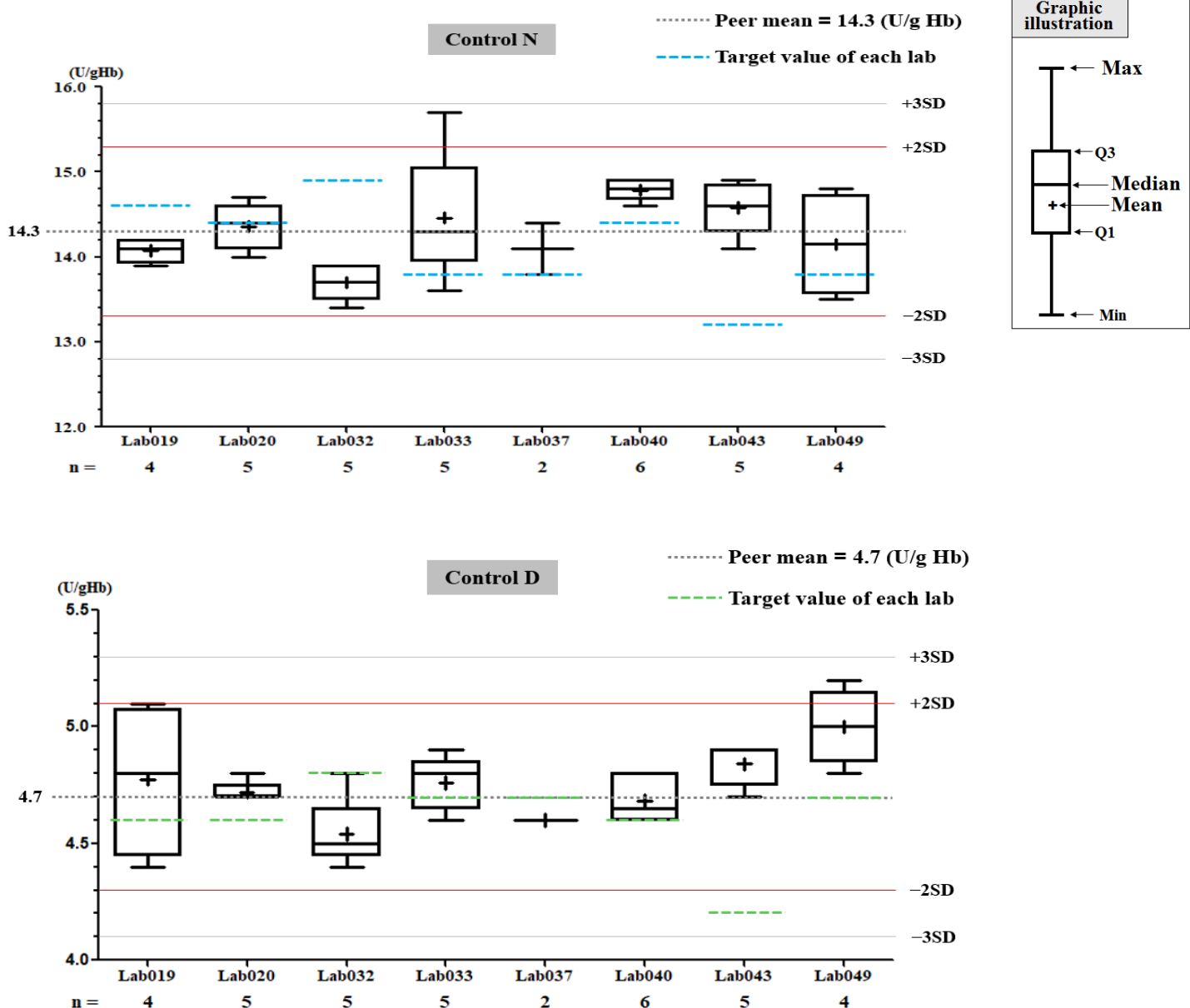
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	8	8
Received results number (n)	36	36
Median	14.4 (U/g Hb)	4.7 (U/g Hb)
Mean	14.3 (U/g Hb)	4.7 (U/g Hb)
SD	0.5	0.2
CV	3.5%	4.3%
Range of G6PD	13.4 ~ 15.7 (U/g Hb)	4.4 ~ 5.2 (U/g Hb)
Range of Hb	2.0 ~ 2.6 (g/dL)	1.8 ~ 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](#)

Lab019

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2022/12)	CUM (2022/03/30~2022/12/31)	Month (2022/12)	CUM (2022/03/30~2022/12/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.1	14.1	4.8	4.6
SD	0.2	0.3	0.3	0.2
CV (%)	1.4	2.1	6.3	4.3
Target Value (U/gHb)	14.6	14.6	4.6	4.6
Total Error (%)	6.3	7.7	16.8	8.7
TEa (%)	20	20	20	20
σ	>6	>6	2.5	4.7

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

Month : 2022 12 Change ; Cumulative : from 2022 03 30 to 2022 12 31 Change

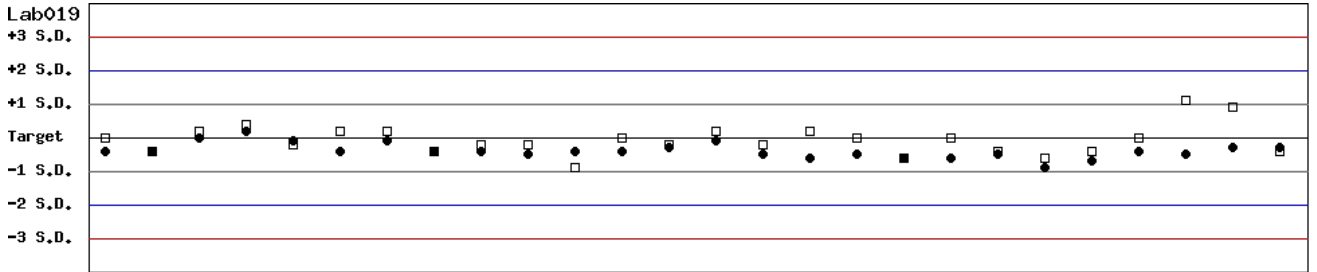
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-03-30 to 2022-12-31 ; Target : 14.6 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2022-03-30 to 2022-12-31 ; Target : 4.6 ; SD : 0.47 (□)

Lab019



Date 03-30 04-06 04-13 04-20 04-27 06-01 06-08 06-15 06-22 06-29 07-06 07-13 07-20 07-27 08-03 08-03 08-17 08-24 10-05 10-12 10-19 10-26 12-07 12-14 12-21 12-28

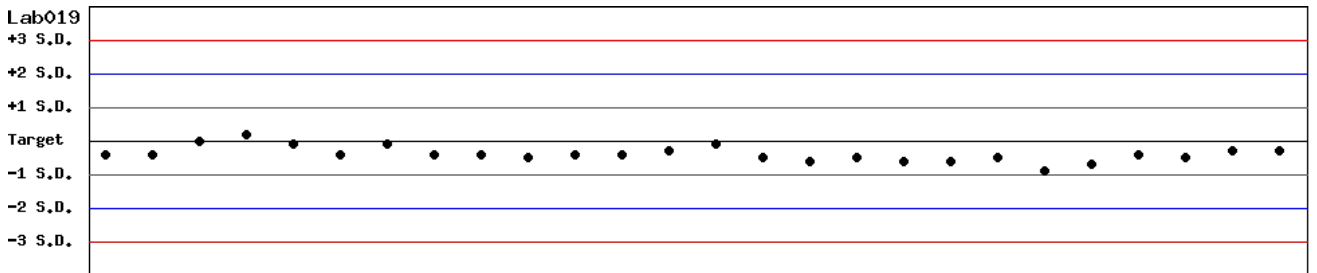
Month : 2022 12 Change ; Cumulative : from 2022 03 30 to 2022 12 31 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-03-30 to 2022-12-31 ; Target : 14.6 ; SD : 1.38

Lab019



Date 03-30 04-06 04-13 04-20 04-27 06-01 06-08 06-15 06-22 06-29 07-06 07-13 07-20 07-27 08-03 08-03 08-17 08-24 10-05 10-12 10-19 10-26 12-07 12-14 12-21 12-28

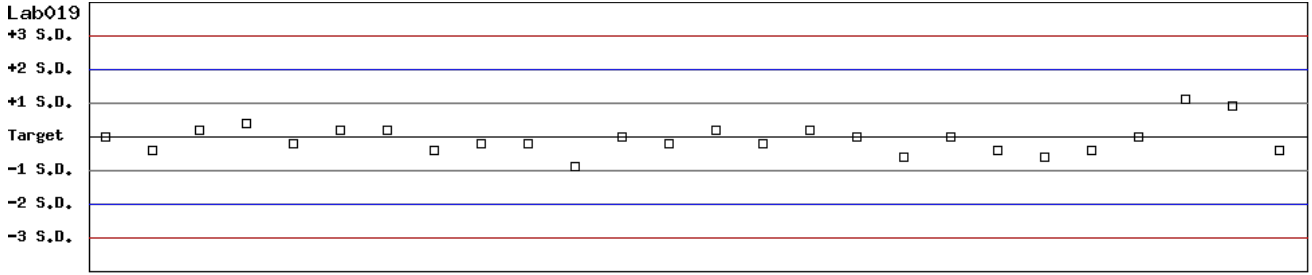
Month : 2022 12 Change ; Cumulative : from 2022 03 30 to 2022 12 31 Change

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Control D SDI QC Chart

Lab019

Lot No.: BJ0922D ; Duration : 2022-03-30 to 2022-12-31 ; Target : 4.6 ; SD : 0.47



Date 03-30 04-06 04-13 04-20 04-27 05-04 05-11 05-18 05-25 06-01 06-08 06-15 06-22 06-29 07-06 07-13 07-20 07-27 08-03 08-10 08-17 08-24 09-01 09-08 09-15 09-22 09-29 10-06 10-13 10-20 10-27 11-03 11-10 11-17 11-24 12-01 12-08 12-15 12-22 12-29

Month : 2022 12 Change ; Cumulative : from 2022 03 30 to 2022 12 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 12 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
Lab019	5	14.6	14.1	4	0.2	1.4	6.3	20	>6	4.6	4.8	4	0.3	6.3	16.8	20	2.5
Lab020	5	14.4	14.4	5	0.3	2.1	4.2	20	>6	4.6	4.7	5	0.0	0.0	2.2	20	>6
Lab032	5	14.9	13.7	5	0.2	1.5	11.0	20	>6	4.8	4.5	5	0.2	4.4	15.1	20	3.1
Lab033	5	13.8	14.5	5	0.8	5.5	16.1	20	2.7	4.7	4.8	5	0.1	2.1	6.3	20	>6
Lab037	5	13.8	14.1	2	-	-	-	20	-	4.7	4.6	2	-	-	-	20	-
Lab040	5	14.4	14.8	6	0.1	0.7	4.1	20	>6	4.6	4.7	6	0.1	2.1	6.4	20	>6
Lab043	5	13.2	14.6	5	0.3	2.1	14.7	20	4.5	4.2	4.8	5	0.1	2.1	18.5	20	2.7
Lab049	5	13.8	14.2	4	0.6	4.2	11.3	20	4.1	4.7	5.0	4	0.2	4.0	14.4	20	3.4
Total	-	-	14.3	36	0.5	3.5	-	-	-	-	4.7	36	0.2	4.3	-	-	-

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 12 31 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	14.3	40	0.6	4.2	10.4	20	4.3	4.6	4.6	40	0.2	4.3	8.7	20	4.7
Lab020	5	14.4	14.4	51	0.6	4.2	8.3	20	4.8	4.6	4.7	51	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	106	0.4	2.8	8.9	20	5.9	4.8	4.5	106	0.1	2.2	10.7	20	>6
Lab033	5	13.8	13.6	51	0.6	4.4	10.3	20	4.2	4.7	4.6	51	0.3	6.5	15.2	20	2.7
Lab037	5	13.8	14.6	46	0.4	2.7	11.3	20	5.3	4.7	4.7	46	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.6	31	0.2	1.4	4.1	20	>6	4.6	4.6	31	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.6	69	1.4	10.3	23.6	20	1.6	4.2	4.4	69	0.5	11.4	27.5	20	1.3
Lab049	5	13.8	14.6	81	0.7	4.8	15.4	20	3.0	4.7	4.7	81	0.2	4.3	8.5	20	4.7
Total	-	-	14.3	534	0.9	6.3	-	-	-	-	4.6	534	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 (2022/12)								CUM (2021/01/01~2022/12/31)							
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	14.1	4	0.2	1.4	6.3	20	>6	14.6	14.3	40	0.6	4.2	10.4	20	4.3
Lab020	5	14.4	14.4	5	0.3	2.1	4.2	20	>6	14.4	14.4	51	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	13.7	5	0.2	1.5	11.0	20	>6	14.9	14.4	106	0.4	2.8	8.9	20	5.9
Lab033	5	13.8	14.5	5	0.8	5.5	16.1	20	2.7	13.8	13.6	51	0.6	4.4	10.3	20	4.2
Lab037	5	13.8	14.1	2	-	-	-	20	-	13.8	14.6	46	0.4	2.7	11.3	20	5.3
Lab040	5	14.4	14.8	6	0.1	0.7	4.1	20	>6	14.4	14.6	31	0.2	1.4	4.1	20	>6
Lab043	5	13.2	14.6	5	0.3	2.1	14.7	20	4.5	13.2	13.6	69	1.4	10.3	23.6	20	1.6
Lab049	5	13.8	14.2	4	0.6	4.2	11.3	20	4.1	13.8	14.6	81	0.7	4.8	15.4	20	3.0
Total	-	-	14.3	36	0.5	3.5	-	-	-	-	14.3	534	0.9	6.3	-	-	-

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

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

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

Month : 2022 12 Change

Cumulative : from 2021 01 01 to 2022 12 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2022/12)								CUM (2021/01/01~2022/12/31)							
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	4.8	4	0.3	6.3	16.8	20	2.5	4.6	4.6	40	0.2	4.3	8.7	20	4.7
Lab020	5	4.6	4.7	5	0.0	0.0	2.2	20	>6	4.6	4.7	51	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	5	0.2	4.4	15.1	20	3.1	4.8	4.5	106	0.1	2.2	10.7	20	>6
Lab033	5	4.7	4.8	5	0.1	2.1	6.3	20	>6	4.7	4.6	51	0.3	6.5	15.2	20	2.7
Lab037	5	4.7	4.6	2	-	-	-	20	-	4.7	4.7	46	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	31	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.8	5	0.1	2.1	18.5	20	2.7	4.2	4.4	69	0.5	11.4	27.5	20	1.3
Lab049	5	4.7	5.0	4	0.2	4.0	14.4	20	3.4	4.7	4.7	81	0.2	4.3	8.5	20	4.7
Total	-	-	4.7	36	0.2	4.3	-	-	-	-	4.6	534	0.3	6.5	-	-	-

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

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

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

Month : 2022 12 Change

Cumulative : from 2021 01 01 to 2022 12 31 Change

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Reagent Kit	Reagent Code
Medicon	5