

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - March 2023 -

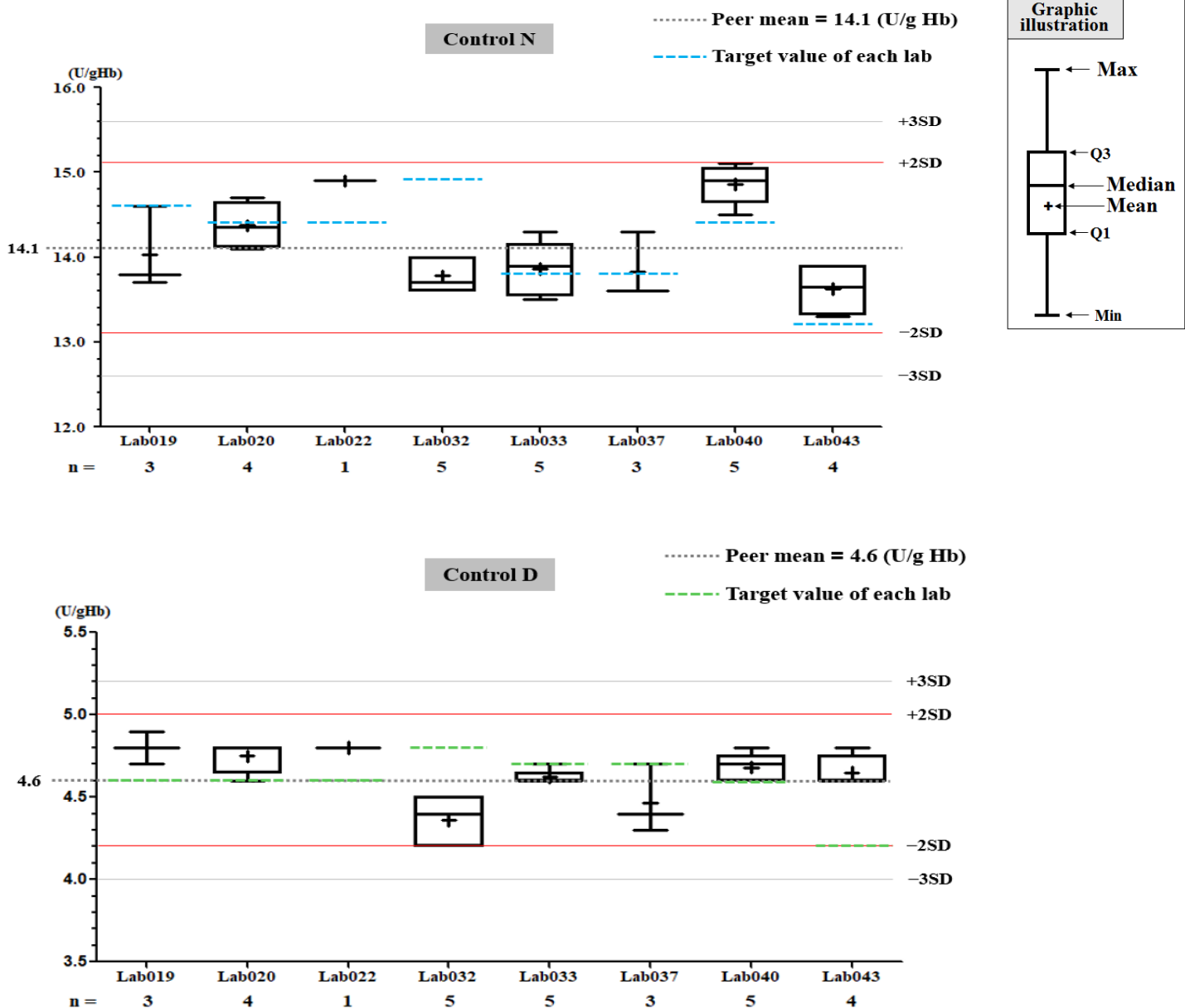
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	8	8
Received results number (n)	30	30
Median	14.0 (U/g Hb)	4.6 (U/g Hb)
Mean	14.1 (U/g Hb)	4.6 (U/g Hb)
SD	0.5	0.2
CV	3.5%	4.3%
Range of G6PD	13.3 ~ 15.1 (U/g Hb)	4.2 ~ 4.9 (U/g Hb)
Range of Hb	2.1 ~ 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

Lab019

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2023/03)	CUM (2022/07/06~2023/03/31)	Month (2023/03)	CUM (2022/07/06~2023/03/31)
Runs (N)	3	26	3	26
Mean (U/gHb)	14.0	14.0	4.8	4.6
SD	0.5	0.3	0.1	0.2
CV (%)	3.6	2.1	2.1	4.3
Target Value (U/gHb)	14.6	14.6	4.6	4.6
Total Error (%)	11.3	8.4	8.5	8.7
TEa (%)	20	20	20	20
σ	4.4	>6	>6	4.7

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

Month : 2023 ▾ 03 ▾ Change ; Cumulative : from 2022 ▾ 07 ▾ 06 ▾ to 2023 ▾ 03 ▾ 31 ▾ Change

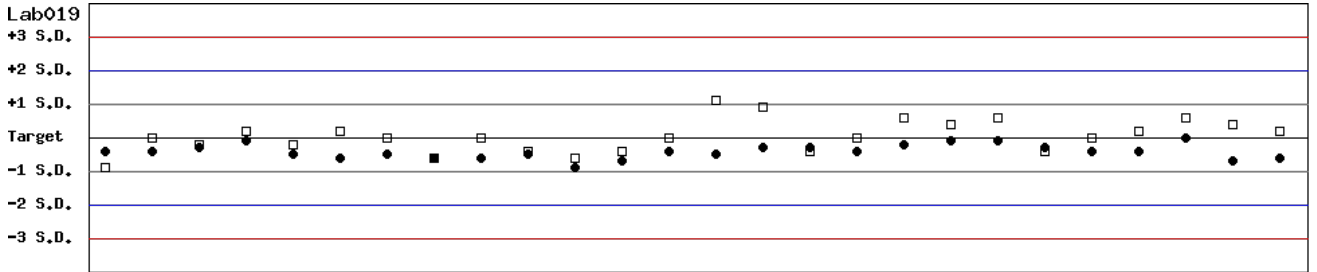
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-07-06 to 2023-03-31 ; Target : 14.6 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2022-07-06 to 2023-03-31 ; Target : 4.6 ; SD : 0.47 (□)

Lab019



Date 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 01-04 01-11 01-18 01-25 02-01 02-08 02-15 03-01 03-08 03-15

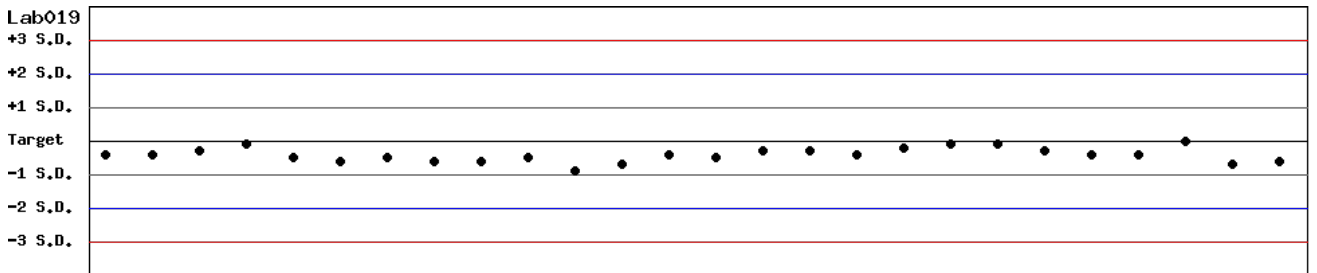
Month : 2023 ▾ 03 ▾ Change ; Cumulative : from 2022 ▾ 07 ▾ 06 ▾ to 2023 ▾ 03 ▾ 31 ▾ Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-07-06 to 2023-03-31 ; Target : 14.6 ; SD : 1.38

Lab019



Date 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 01-04 01-11 01-18 01-25 02-01 02-08 02-15 03-01 03-08 03-15

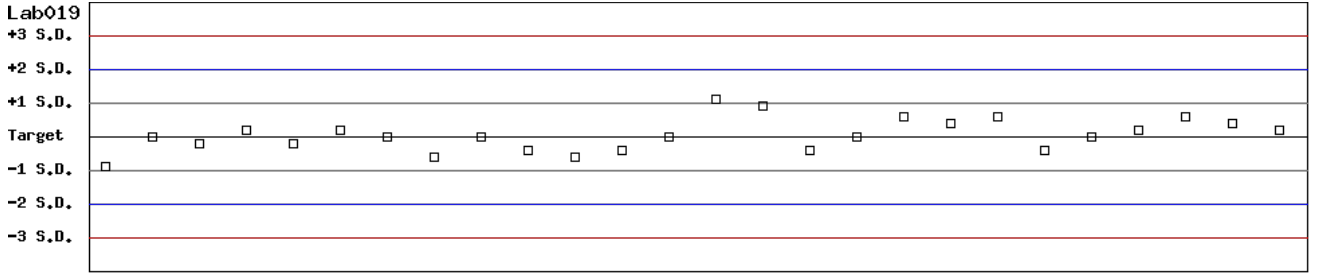
Month : 2023 ▾ 03 ▾ Change ; Cumulative : from 2022 ▾ 07 ▾ 06 ▾ to 2023 ▾ 03 ▾ 31 ▾ Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2022-07-06 to 2023-03-31 ; Target : 4.6 ; SD : 0.47

Lab019



Date 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 01-05 01-12 01-19 01-26 02-02 02-09 02-16 02-23 03-01 03-08 03-15

Month : ; Cumulative : from to

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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 : 2023 03 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	14.0	3	0.5	3.6	11.3	20	4.4	4.6	4.8	3	0.1	2.1	8.5	20	>6
Lab020	5	14.4	14.4	4	0.3	2.1	4.2	20	>6	4.6	4.8	4	0.1	2.1	8.5	20	>6
Lab022	5	14.4	14.9	1	-	-	-	20	-	4.6	4.8	1	-	-	-	20	-
Lab032	5	14.9	13.8	5	0.2	1.4	10.3	20	>6	4.8	4.4	5	0.2	4.5	17.4	20	2.6
Lab033	5	13.8	13.9	5	0.3	2.2	5.0	20	>6	4.7	4.6	5	0.1	2.2	6.5	20	>6
Lab037	5	13.8	13.8	3	0.4	2.9	5.8	20	>6	4.7	4.5	3	0.2	4.4	13.1	20	3.6
Lab040	5	14.4	14.9	5	0.2	1.3	6.2	20	>6	4.6	4.7	5	0.1	2.1	6.4	20	>6
Lab043	5	13.2	13.6	4	0.3	2.2	7.4	20	>6	4.2	4.7	4	0.1	2.1	16.2	20	3.9
Total	-	-	14.1	30	0.5	3.5	-	-	-	-	4.6	30	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 2023 03 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	14.3	50	0.5	3.5	9.0	20	5.1	4.6	4.6	50	0.2	4.3	8.7	20	4.7
Lab020	5	14.4	14.4	59	0.5	3.5	6.9	20	5.7	4.6	4.7	59	0.1	2.1	6.4	20	>6
Lab022	5	14.4	14.4	22	0.5	3.5	6.9	20	5.7	4.6	4.6	22	0.2	4.3	8.7	20	4.7
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	14.3	119	0.4	2.8	9.6	20	5.7	4.8	4.5	119	0.2	4.4	15.1	20	3.1
Lab033	5	13.8	13.7	64	0.6	4.4	9.5	20	4.4	4.7	4.6	64	0.3	6.5	15.2	20	2.7
Lab037	5	13.8	14.5	52	0.5	3.4	12.0	20	4.4	4.7	4.7	52	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.7	44	0.2	1.4	4.8	20	>6	4.6	4.6	44	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.7	81	1.3	9.5	22.8	20	1.7	4.2	4.5	81	0.5	11.1	29.4	20	1.2
Lab049	5	13.8	14.6	87	0.7	4.8	15.4	20	3.0	4.7	4.7	87	0.2	4.3	8.5	20	4.7
Total	-	-	14.3	620	0.8	5.6	-	-	-	-	4.6	620	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 (2023/03)								CUM (2021/01/01~2023/03/31)							
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	14.0	3	0.5	3.6	11.3	20	4.4	14.6	14.3	50	0.5	3.5	9.0	20	5.1
Lab020	5	14.4	14.4	4	0.3	2.1	4.2	20	>6	14.4	14.4	59	0.5	3.5	6.9	20	5.7
Lab022	5	14.4	14.9	1	-	-	-	20	-	14.4	14.4	22	0.5	3.5	6.9	20	5.7
Lab028	5	15.2	-	0	-	-	-	20	-	15.2	15.1	34	1.1	7.3	15.2	20	2.6
Lab032	5	14.9	13.8	5	0.2	1.4	10.3	20	>6	14.9	14.3	119	0.4	2.8	9.6	20	5.7
Lab033	5	13.8	13.9	5	0.3	2.2	5.0	20	>6	13.8	13.7	64	0.6	4.4	9.5	20	4.4
Lab037	5	13.8	13.8	3	0.4	2.9	5.8	20	>6	13.8	14.5	52	0.5	3.4	12.0	20	4.4
Lab040	5	14.4	14.9	5	0.2	1.3	6.2	20	>6	14.4	14.7	44	0.2	1.4	4.8	20	>6
Lab043	5	13.2	13.6	4	0.3	2.2	7.4	20	>6	13.2	13.7	81	1.3	9.5	22.8	20	1.7
Lab049	5	13.8	-	0	-	-	-	20	-	13.8	14.6	87	0.7	4.8	15.4	20	3.0
Total	-	-	14.1	30	0.5	3.5	-	-	-	-	14.3	620	0.8	5.6	-	-	-

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

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

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

Month : 2023 03 Change

Cumulative : from 2021 01 01 to 2023 03 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2023/03)								CUM (2021/01/01~2023/03/31)							
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	4.8	3	0.1	2.1	8.5	20	>6	4.6	4.6	50	0.2	4.3	8.7	20	4.7
Lab020	5	4.6	4.8	4	0.1	2.1	8.5	20	>6	4.6	4.7	59	0.1	2.1	6.4	20	>6
Lab022	5	4.6	4.8	1	-	-	-	20	-	4.6	4.6	22	0.2	4.3	8.7	20	4.7
Lab028	5	4.9	-	0	-	-	-	20	-	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	4.8	4.4	5	0.2	4.5	17.4	20	2.6	4.8	4.5	119	0.2	4.4	15.1	20	3.1
Lab033	5	4.7	4.6	5	0.1	2.2	6.5	20	>6	4.7	4.6	64	0.3	6.5	15.2	20	2.7
Lab037	5	4.7	4.5	3	0.2	4.4	13.1	20	3.6	4.7	4.7	52	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	44	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.7	4	0.1	2.1	16.2	20	3.9	4.2	4.5	81	0.5	11.1	29.4	20	1.2
Lab049	5	4.7	-	0	-	-	-	20	-	4.7	4.7	87	0.2	4.3	8.5	20	4.7
Total	-	-	4.6	30	0.2	4.3	-	-	-	-	4.6	620	0.3	6.5	-	-	-

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

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

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

Month : 2023 03 Change

Cumulative : from 2021 01 01 to 2023 03 31 Change

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Reagent Kit	Reagent Code
Medicon	5