

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

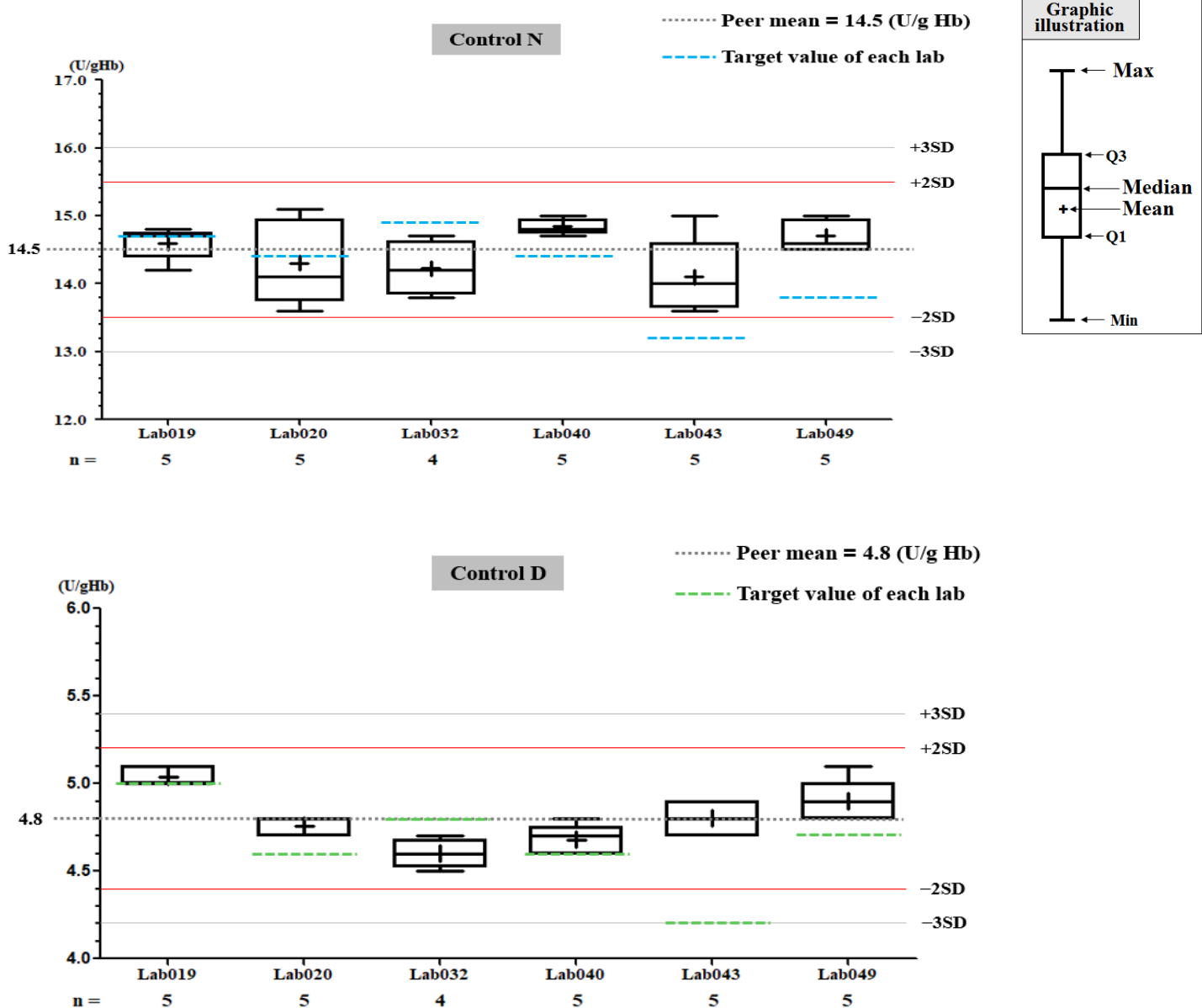
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	6	6
Received results number (n)	29	29
Median	14.6 (U/g Hb)	4.8 (U/g Hb)
Mean	14.5 (U/g Hb)	4.8 (U/g Hb)
SD	0.5	0.2
CV	3.4%	4.2%
Range of G6PD	13.6 ~ 15.1 (U/g Hb)	4.5 ~ 5.1 (U/g Hb)
Range of Hb	1.7 ~ 3.2 (g/dL)	1.6 ~ 2.7 (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)

Lab019

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2023/08)	CUM (2023/03/08~2023/08/31)	Month (2023/08)	CUM (2023/03/08~2023/08/31)
Runs (N)	5	26	5	26
Mean (U/gHb)	14.6	14.5	5.0	4.9
SD	0.2	0.8	0.1	0.3
CV (%)	1.4	5.5	2.0	6.1
Target Value (U/gHb)	14.7	14.7	5.0	5.0
Total Error (%)	3.4	12.4	4.0	14.2
TEa (%)	20	20	20	20
σ	>6	3.4	>6	3.0

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

Month : ; Cumulative : from to

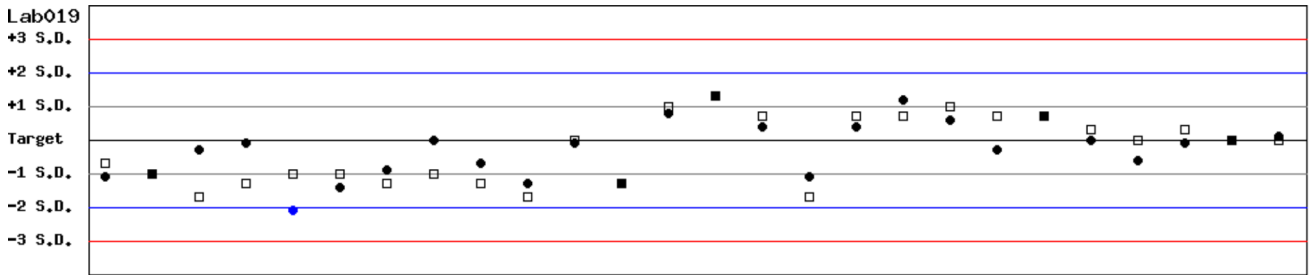
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-03-08 to 2023-08-31 ; Target : 14.7 ; SD : 0.90 (●)

Lot No.: BJ0922D ; Duration : 2023-03-08 to 2023-08-31 ; Target : 5.0 ; SD : 0.30 (□)

Lab019



Date 03-08 03-15 04-05 04-12 04-26 04-27 05-03 05-10 05-17 05-24 05-31 05-31 06-02 06-07 06-14 06-21 06-28 07-04 07-12 07-19 07-26 08-02 08-09 08-16 08-23 08-30

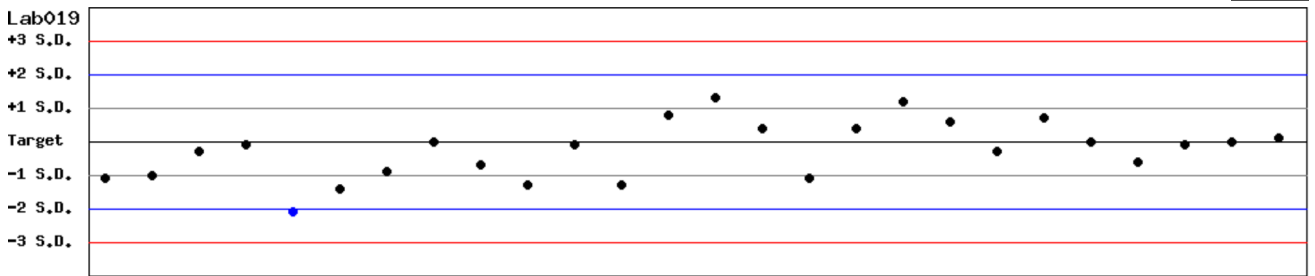
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-03-08 to 2023-08-31 ; Target : 14.7 ; SD : 0.90

Lab019



Date 03-08 03-15 04-05 04-12 04-26 04-27 05-03 05-10 05-17 05-24 05-31 05-31 06-02 06-07 06-14 06-21 06-28 07-04 07-12 07-19 07-26 08-02 08-09 08-16 08-23 08-30

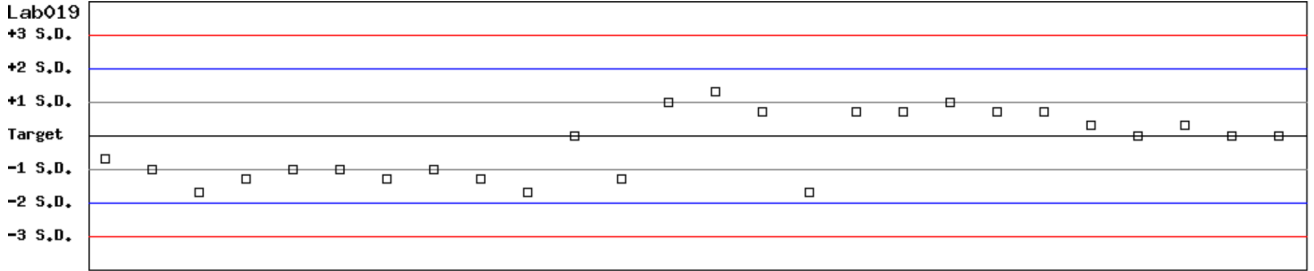
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2023-03-08 to 2023-08-31 ; Target : 5.0 ; SD : 0.30

Lab019



Date 03-08 03-15 04-05 04-12 04-26 04-27 05-03 05-10 05-17 05-24 05-31 06-02 06-07 06-14 06-21 06-28 07-04 07-12 07-19 07-26 08-02 08-09 08-16 08-23 08-30

Month : 2023 08 Change ; Cumulative : from 2023 03 08 to 2023 08 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 : 2023 08

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
Lab019	5	14.7	14.6	5	0.2	1.4	3.4	20	>6	5.0	5.0	5	0.1	2.0	4.0	20	>6
Lab020	5	14.4	14.3	5	0.6	4.2	9.1	20	4.6	4.6	4.8	5	0.1	2.1	8.5	20	>6
Lab032	5	14.9	14.2	4	0.4	2.8	10.3	20	5.5	4.8	4.6	4	0.1	2.2	8.5	20	>6
Lab040	5	14.4	14.8	5	0.1	0.7	4.1	20	>6	4.6	4.7	5	0.1	2.1	6.4	20	>6
Lab043	5	13.2	14.1	5	0.6	4.3	15.3	20	3.1	4.2	4.8	5	0.1	2.1	18.5	20	2.7
Lab049	5	13.8	14.7	5	0.2	1.4	9.2	20	>6	4.7	4.9	5	0.1	2.0	8.3	20	>6
Total	-	-	14.5	29	0.5	3.4	-	-	-	-	4.8	29	0.2	4.2	-	-	-

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

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

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

[TOP](#)

Cumulative

Cumulative : from 2021 01 01 to 2023 08 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	16.4	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	14.7	14.4	75	0.6	4.2	10.4	20	4.3	5.0	4.7	75	0.3	6.4	18.8	20	2.2
Lab020	5	14.4	14.4	76	0.5	3.5	6.9	20	5.7	4.6	4.7	76	0.2	4.3	10.7	20	4.1
Lab022	5	14.4	14.4	27	0.5	3.5	6.9	20	5.7	4.6	4.7	27	0.3	6.4	14.9	20	2.8
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	131	0.4	2.8	9.6	20	5.7	4.8	4.5	131	0.2	4.4	15.1	20	3.1
Lab033	5	13.8	13.6	81	0.7	5.1	11.7	20	3.6	4.7	4.6	81	0.3	6.5	15.2	20	2.7
Lab037	5	13.8	14.5	59	0.5	3.4	12.0	20	4.4	4.7	4.7	59	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.7	60	0.2	1.4	4.8	20	>6	4.6	4.6	60	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.8	101	1.2	8.7	21.9	20	1.8	4.2	4.5	101	0.5	11.1	29.4	20	1.2
Lab049	5	13.8	14.4	149	0.6	4.2	12.7	20	3.7	4.7	4.7	149	0.2	4.3	8.5	20	4.7
Total	-	-	14.3	801	0.8	5.6	-	-	-	-	4.7	801	0.3	6.4	-	-	-

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

TE : Total Error(%) = Bias (%) + 2 x 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 (2023/08)								CUM (2021/01/01~2023/08/31)							
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	14.7	14.6	5	0.2	1.4	3.4	20	>6	14.7	14.4	75	0.6	4.2	10.4	20	4.3
Lab020	5	14.4	14.3	5	0.6	4.2	9.1	20	4.6	14.4	14.4	76	0.5	3.5	6.9	20	5.7
Lab022	5	14.4	-	0	-	-	-	20	-	14.4	14.4	27	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	14.2	4	0.4	2.8	10.3	20	5.5	14.9	14.3	131	0.4	2.8	9.6	20	5.7
Lab033	5	13.8	-	0	-	-	-	20	-	13.8	13.6	81	0.7	5.1	11.7	20	3.6
Lab037	5	13.8	-	0	-	-	-	20	-	13.8	14.5	59	0.5	3.4	12.0	20	4.4
Lab040	5	14.4	14.8	5	0.1	0.7	4.1	20	>6	14.4	14.7	60	0.2	1.4	4.8	20	>6
Lab043	5	13.2	14.1	5	0.6	4.3	15.3	20	3.1	13.2	13.8	101	1.2	8.7	21.9	20	1.8
Lab049	5	13.8	14.7	5	0.2	1.4	9.2	20	>6	13.8	14.4	149	0.6	4.2	12.7	20	3.7
Total	-	-	14.5	29	0.5	3.4	-	-	-	-	14.3	801	0.8	5.6	-	-	-

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

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

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

Month : 2023 08 Change

Cumulative : from 2021 01 01 to 2023 08 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2023/08)								CUM (2021/01/01~2023/08/31)							
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	5.0	5.0	5	0.1	2.0	4.0	20	>6	5.0	4.7	75	0.3	6.4	18.8	20	2.2
Lab020	5	4.6	4.8	5	0.1	2.1	8.5	20	>6	4.6	4.7	76	0.2	4.3	10.7	20	4.1
Lab022	5	4.6	-	0	-	-	-	20	-	4.6	4.7	27	0.3	6.4	14.9	20	2.8
Lab028	5	4.9	-	0	-	-	-	20	-	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	4.8	4.6	4	0.1	2.2	8.5	20	>6	4.8	4.5	131	0.2	4.4	15.1	20	3.1
Lab033	5	4.7	-	0	-	-	-	20	-	4.7	4.6	81	0.3	6.5	15.2	20	2.7
Lab037	5	4.7	-	0	-	-	-	20	-	4.7	4.7	59	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	60	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	4.5	101	0.5	11.1	29.4	20	1.2
Lab049	5	4.7	4.9	5	0.1	2.0	8.3	20	>6	4.7	4.7	149	0.2	4.3	8.5	20	4.7
Total	-	-	4.8	29	0.2	4.2	-	-	-	-	4.7	801	0.3	6.4	-	-	-

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

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

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

Month : 2023 08 Change

Cumulative : from 2021 01 01 to 2023 08 31 Change

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Reagent Kit	Reagent Code
Medicon	5