

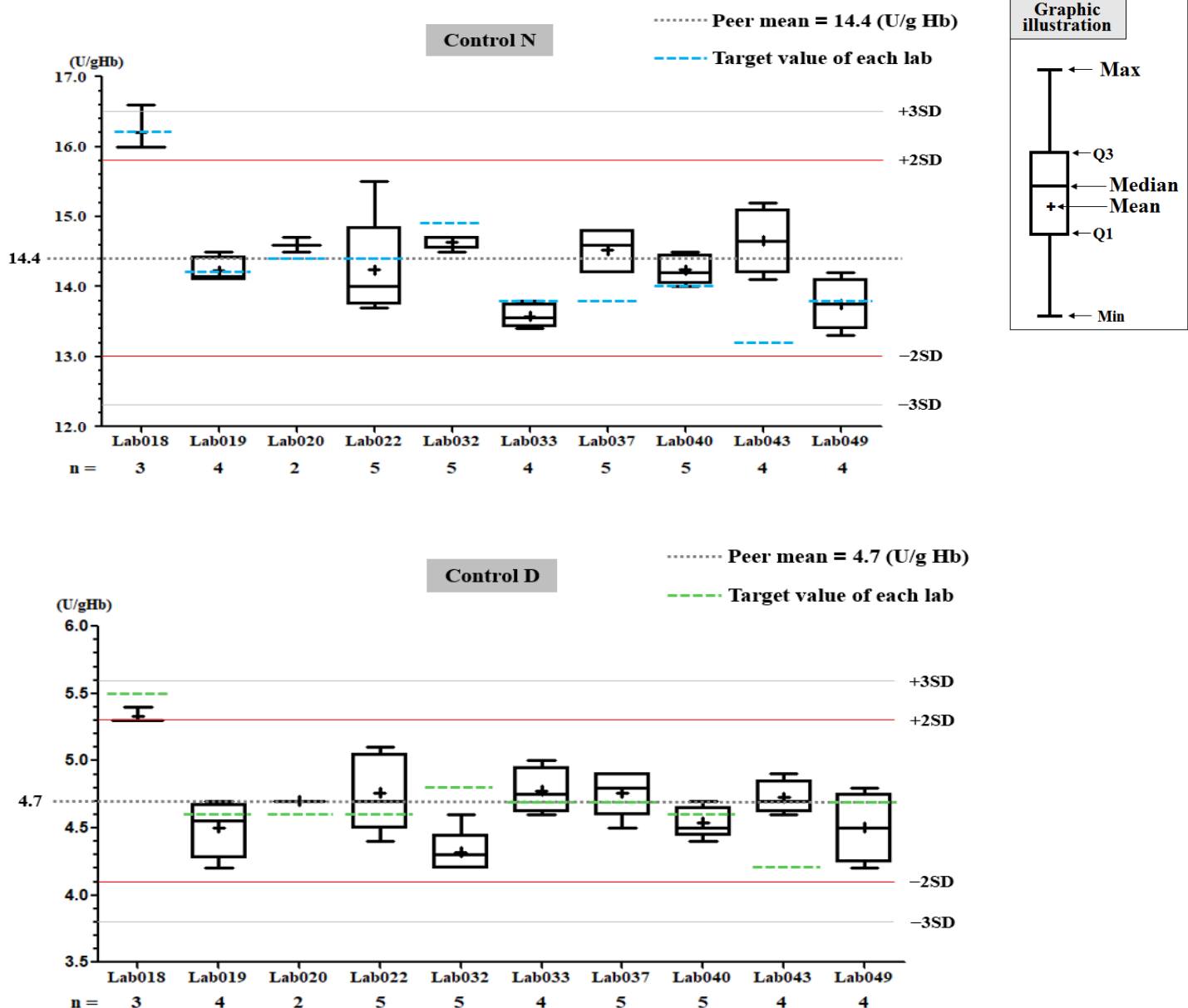
Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - July 2022 -

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)	41	41
Median	14.2 (U/g Hb)	4.7 (U/g Hb)
Mean	14.4 (U/g Hb)	4.7 (U/g Hb)
SD	0.7	0.3
CV	4.9%	6.4%
Range of G6PD	13.3 ~ 16.6 (U/g Hb)	4.2 ~ 5.4 (U/g Hb)
Range of Hb	1.9 ~ 3.0 (g/dL)	1.9 ~ 2.6 (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 (2022/07)	CUM (2022/01/19~2022/07/30)	Month (2022/07)	CUM (2022/01/19~2022/07/30)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.2	14.5	4.5	4.6
SD	0.2	0.5	0.2	0.1
CV (%)	1.4	3.4	4.4	2.2
Target Value (U/gHb)	14.6	14.6	4.6	4.6
Total Error (%)	5.6	7.6	11.1	4.3
TEa (%)	20	20	20	20
σ	>6	5.7	4.1	>6

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

Month : 2022 07 Change ; Cumulative : from 2022 01 19 to 2022 07 30 Change

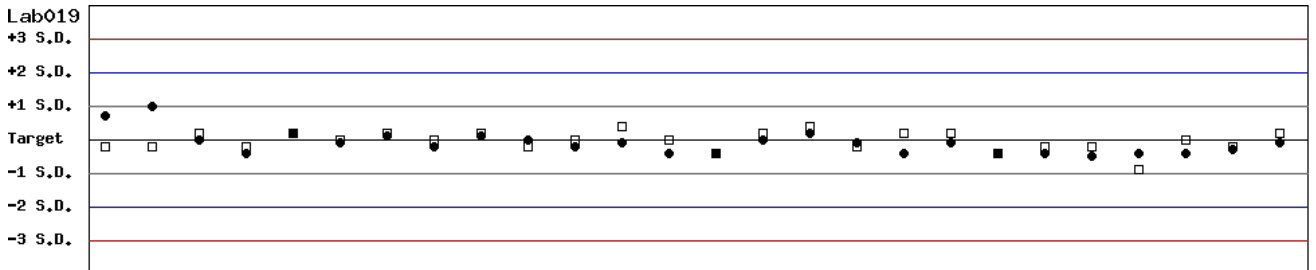
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-01-19 to 2022-07-30 ; Target : 14.6 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2022-01-19 to 2022-07-30 ; Target : 4.6 ; SD : 0.47 (□)

Lab019



Date 01-19 01-26 02-02 02-09 02-16 02-23 03-02 03-06 03-09 03-09 03-16 03-23 03-30 04-06 04-13 04-20 04-27 05-01 05-08 05-15 05-22 05-29 07-06 07-13 07-20 07-27

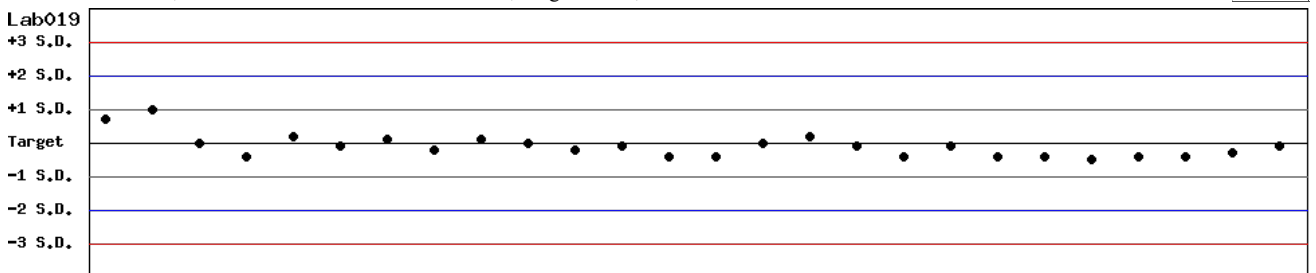
Month : 2022 07 Change ; Cumulative : from 2022 01 19 to 2022 07 30 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-01-19 to 2022-07-30 ; Target : 14.6 ; SD : 1.38

Lab019



Date 01-19 01-26 02-02 02-09 02-16 02-23 03-02 03-06 03-09 03-09 03-16 03-23 03-30 04-06 04-13 04-20 04-27 05-01 05-08 05-15 05-22 05-29 07-06 07-13 07-20 07-27

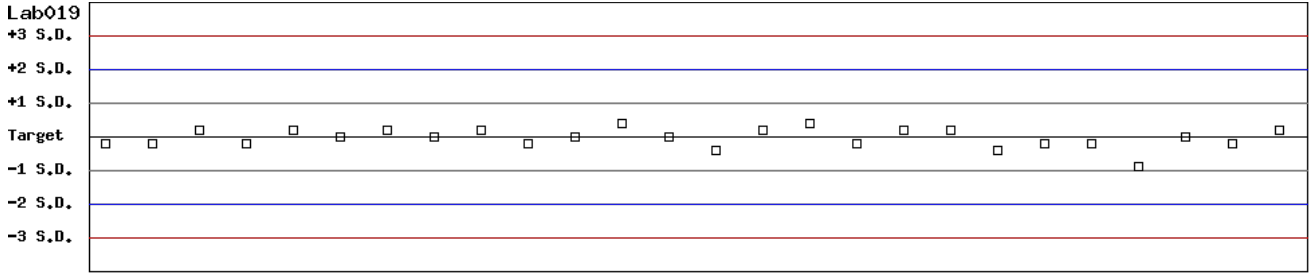
Month : 2022 07 Change ; Cumulative : from 2022 01 19 to 2022 07 30 Change

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Control D SDI QC Chart

Lab019

Lot No.: BJ0922D ; Duration : 2022-01-19 to 2022-07-30 ; Target : 4.6 ; SD : 0.47



Date 01-19 01-26 02-02 02-09 02-16 02-23 03-02 03-06 03-09 03-09 03-16 03-23 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

Month : ; Cumulative : from to

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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 07

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	16.2	3	0.3	1.9	3.7	20	>6	5.5	5.3	3	0.1	1.9	7.4	20	>6
Lab019	5	14.6	14.2	4	0.2	1.4	5.6	20	>6	4.6	4.5	4	0.2	4.4	11.1	20	4.1
Lab020	5	14.4	14.6	2	-	-	-	20	-	4.6	4.7	2	-	-	-	20	-
Lab022	5	14.4	14.2	5	0.7	4.9	11.2	20	3.8	4.6	4.8	5	0.3	6.3	16.8	20	2.5
Lab032	5	14.9	14.6	5	0.1	0.7	3.4	20	>6	4.8	4.3	5	0.2	4.7	19.7	20	2.0
Lab033	5	13.8	13.6	4	0.2	1.5	4.4	20	>6	4.7	4.8	4	0.2	4.2	10.5	20	4.3
Lab037	5	13.8	14.5	5	0.3	2.1	9.2	20	>6	4.7	4.8	5	0.2	4.2	10.5	20	4.3
Lab040	5	14.4	14.2	5	0.2	1.4	4.2	20	>6	4.6	4.5	5	0.1	2.2	6.6	20	>6
Lab043	5	13.2	14.7	4	0.5	3.4	18.2	20	2.5	4.2	4.7	4	0.1	2.1	16.2	20	3.9
Lab049	5	13.8	13.8	4	0.4	2.9	5.8	20	>6	4.7	4.5	4	0.3	6.7	17.6	20	2.3
Total	-	-	14.4	41	0.7	4.9	-	-	-	-	4.7	41	0.3	6.4	-	-	-

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 2022 07 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	14.6	14.5	28	0.5	3.4	7.6	20	5.7	4.6	4.6	28	0.1	2.2	4.3	20	>6
Lab020	5	14.4	14.4	36	0.6	4.2	8.3	20	4.8	4.6	4.7	36	0.2	4.3	10.7	20	4.1
Lab022	5	14.4	14.3	12	0.6	4.2	9.1	20	4.6	4.6	4.6	12	0.3	6.5	13.0	20	3.1
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	84	0.4	2.8	8.9	20	5.9	4.8	4.5	84	0.2	4.4	15.1	20	3.1
Lab033	5	13.8	13.4	30	0.6	4.5	11.9	20	3.8	4.7	4.5	30	0.4	8.9	22.0	20	1.8
Lab037	5	13.8	14.7	33	0.4	2.7	12.0	20	5.0	4.7	4.7	33	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.2	5	0.2	1.4	4.2	20	>6	4.6	4.5	5	0.1	2.2	6.6	20	>6
Lab043	5	13.2	13.3	51	1.5	11.3	23.3	20	1.7	4.2	4.3	51	0.5	11.6	25.6	20	1.5
Lab049	5	13.8	14.8	60	0.6	4.1	15.4	20	3.1	4.7	4.7	60	0.2	4.3	8.5	20	4.7
Total	-	-	14.4	381	1.0	6.9	-	-	-	-	4.6	381	0.3	6.5	-	-	-

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 (2022/07)										CUM (2021/01/01~2022/07/31)							
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	16.2	3	0.3	1.9	3.7	20	>6	16.2	16.4	8	0.4	2.4	6.1	20	>6
Lab019	5	14.6	14.2	4	0.2	1.4	5.6	20	>6	14.6	14.5	28	0.5	3.4	7.6	20	5.7
Lab020	5	14.4	14.6	2	-	-	-	20	-	14.4	14.4	36	0.6	4.2	8.3	20	4.8
Lab022	5	14.4	14.2	5	0.7	4.9	11.2	20	3.8	14.4	14.3	12	0.6	4.2	9.1	20	4.6
Lab028	5	15.2	-	0	-	-	-	20	-	15.2	15.1	34	1.1	7.3	15.2	20	2.6
Lab032	5	14.9	14.6	5	0.1	0.7	3.4	20	>6	14.9	14.4	84	0.4	2.8	8.9	20	5.9
Lab033	5	13.8	13.6	4	0.2	1.5	4.4	20	>6	13.8	13.4	30	0.6	4.5	11.9	20	3.8
Lab037	5	13.8	14.5	5	0.3	2.1	9.2	20	>6	13.8	14.7	33	0.4	2.7	12.0	20	5.0
Lab040	5	14.4	14.2	5	0.2	1.4	4.2	20	>6	14.4	14.2	5	0.2	1.4	4.2	20	>6
Lab043	5	13.2	14.7	4	0.5	3.4	18.2	20	2.5	13.2	13.3	51	1.5	11.3	23.3	20	1.7
Lab049	5	13.8	13.8	4	0.4	2.9	5.8	20	>6	13.8	14.8	60	0.6	4.1	15.4	20	3.1
Total	-	-	14.4	41	0.7	4.9	-	-	-	-	14.4	381	1.0	6.9	-	-	-

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

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

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

Month : 2022 07 Change

Cumulative : from 2021 01 01 to 2022 07 31 Change

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Control D Month vs. Cumulative

Control D (Lot No.: BJ0922D)																	
Month (2022/07)										CUM (2021/01/01~2022/07/31)							
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	5.3	3	0.1	1.9	7.4	20	>6	5.5	5.5	8	0.2	3.6	7.3	20	5.6
Lab019	5	4.6	4.5	4	0.2	4.4	11.1	20	4.1	4.6	4.6	28	0.1	2.2	4.3	20	>6
Lab020	5	4.6	4.7	2	-	-	-	20	-	4.6	4.7	36	0.2	4.3	10.7	20	4.1
Lab022	5	4.6	4.8	5	0.3	6.3	16.8	20	2.5	4.6	4.6	12	0.3	6.5	13.0	20	3.1
Lab028	5	4.9	-	0	-	-	-	20	-	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	4.8	4.3	5	0.2	4.7	19.7	20	2.0	4.8	4.5	84	0.2	4.4	15.1	20	3.1
Lab033	5	4.7	4.8	4	0.2	4.2	10.5	20	4.3	4.7	4.5	30	0.4	8.9	22.0	20	1.8
Lab037	5	4.7	4.8	5	0.2	4.2	10.5	20	4.3	4.7	4.7	33	0.2	4.3	8.5	20	4.7
Lab040	5	4.6	4.5	5	0.1	2.2	6.6	20	>6	4.6	4.5	5	0.1	2.2	6.6	20	>6
Lab043	5	4.2	4.7	4	0.1	2.1	16.2	20	3.9	4.2	4.3	51	0.5	11.6	25.6	20	1.5
Lab049	5	4.7	4.5	4	0.3	6.7	17.6	20	2.3	4.7	4.7	60	0.2	4.3	8.5	20	4.7
Total	-	-	4.7	41	0.3	6.4	-	-	-	-	4.6	381	0.3	6.5	-	-	-

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

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

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

Month : 2022 07 Change

Cumulative : from 2021 01 01 to 2022 07 31 Change

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Reagent Kit	Reagent Code
Medicon	5