

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

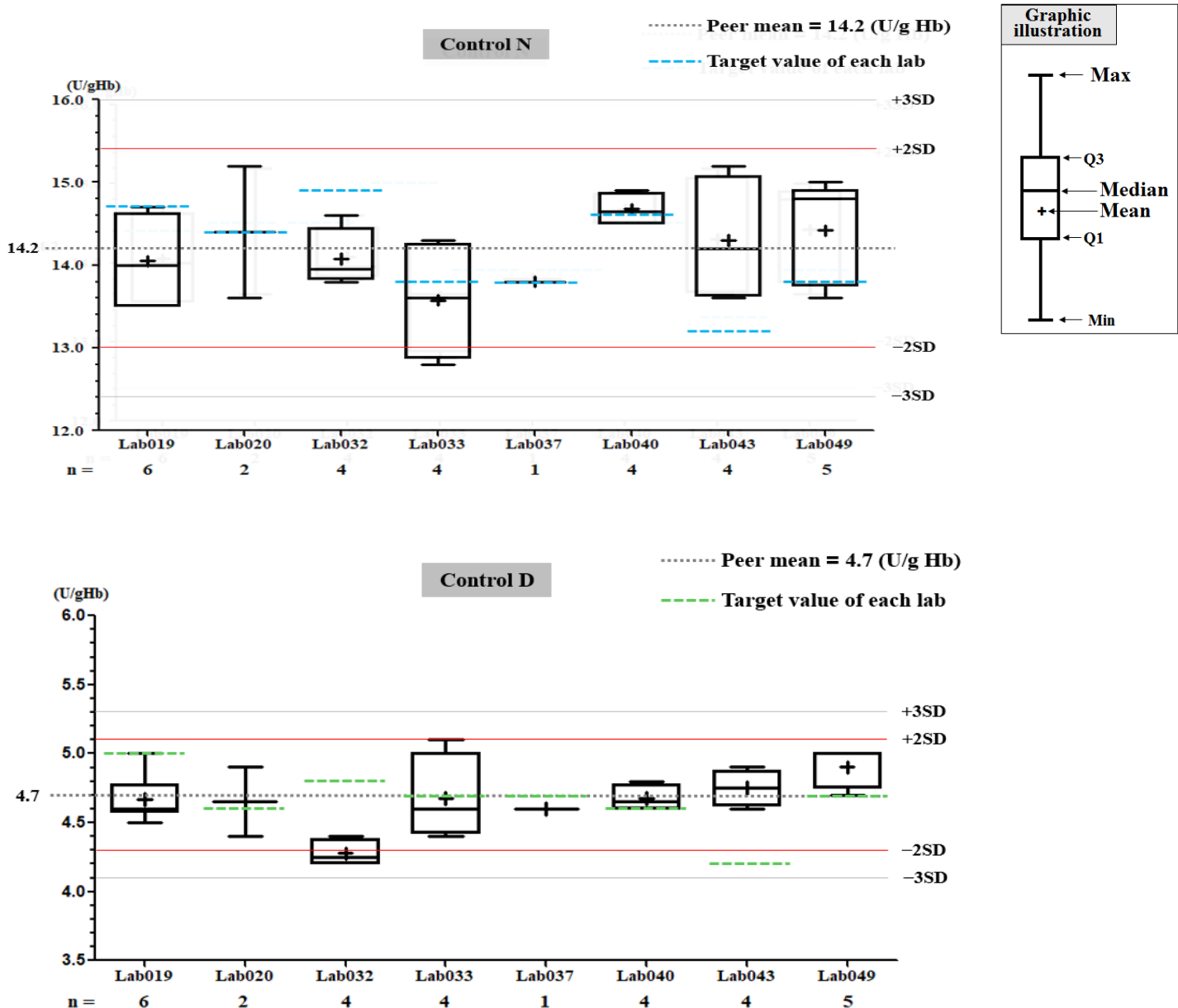
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	8	8
Received results number (n)	30	30
Median	14.1 (U/g Hb)	4.7 (U/g Hb)
Mean	14.2 (U/g Hb)	4.7 (U/g Hb)
SD	0.6	0.2
CV	4.2%	4.3%
Range of G6PD	12.8 ~ 15.2 (U/g Hb)	4.2 ~ 5.1 (U/g Hb)
Range of Hb	2.1 ~ 2.9 (g/dL)	1.7 ~ 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](#)

Lab020

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2023/05)	CUM (2022/08/02~2023/05/31)	Month (2023/05)	CUM (2022/08/02~2023/05/31)
Runs (N)	2	26	2	26
Mean (U/gHb)	14.4	14.4	4.7	4.7
SD	-	0.5	-	0.1
CV (%)	-	3.5	-	2.1
Target Value (U/gHb)	14.4	14.4	4.6	4.6
Total Error (%)	-	6.9	-	6.4
TEa (%)	20	20	20	20
σ	-	5.7	-	>6

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

Month : 2023 05 Change ; Cumulative : from 2022 08 02 to 2023 05 31 Change

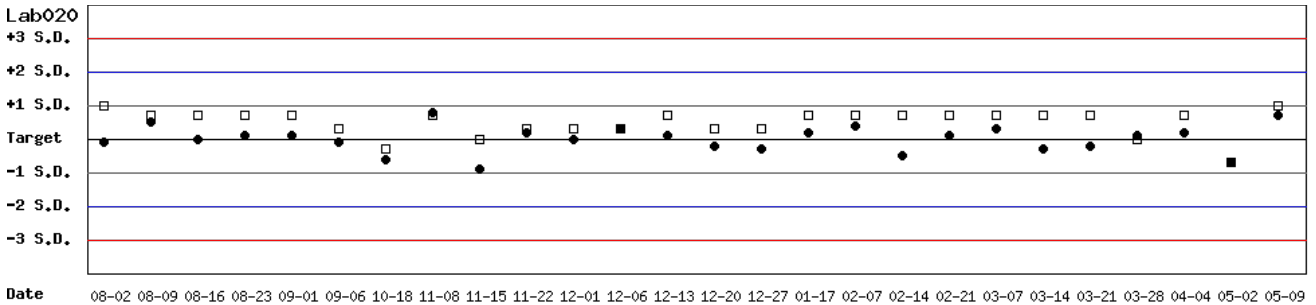
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-08-02 to 2023-05-31 ; Target : 14.4 ; SD : 1.16 (●)

Lot No.: BJ0922D ; Duration : 2022-08-02 to 2023-05-31 ; Target : 4.6 ; SD : 0.30 (□)

Lab020



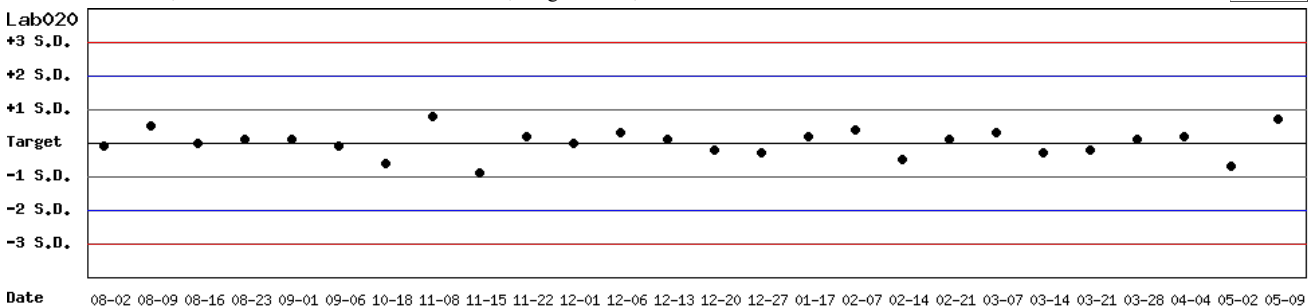
Month : 2023 05 Change ; Cumulative : from 2022 08 02 to 2023 05 31 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-08-02 to 2023-05-31 ; Target : 14.4 ; SD : 1.16

Lab020



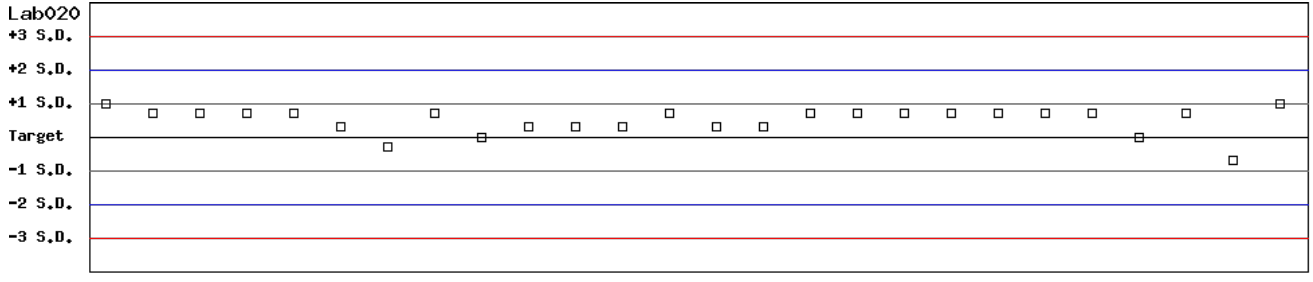
Month : 2023 05 Change ; Cumulative : from 2022 08 02 to 2023 05 31 Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2022-08-02 to 2023-05-31 ; Target : 4.6 ; SD : 0.30

Lab020



Date 08-02 08-09 08-16 08-23 09-01 09-06 10-18 11-08 11-15 11-22 12-01 12-06 12-13 12-20 12-27 01-17 02-07 02-14 02-21 03-07 03-14 03-21 03-28 04-04 05-02 05-09

Month : 2023 ▾ 05 ▾ Change ; Cumulative : from 2022 ▾ 08 ▾ 02 ▾ to 2023 ▾ 05 ▾ 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 : 2023 05 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	14.7	14.1	6	0.5	3.5	11.2	20	4.5	5.0	4.7	6	0.2	4.3	14.5	20	3.3
Lab020	5	14.4	14.4	2	-	-	-	20	-	4.6	4.7	2	-	-	-	20	-
Lab032	5	14.9	14.1	4	0.4	2.8	11.0	20	5.2	4.8	4.3	4	0.1	2.3	15.1	20	4.2
Lab033	5	13.8	13.6	4	0.7	5.1	11.7	20	3.6	4.7	4.7	4	0.3	6.4	12.8	20	3.1
Lab037	5	13.8	13.8	1	-	-	-	20	-	4.7	4.6	1	-	-	-	20	-
Lab040	5	14.4	14.7	4	0.2	1.4	4.8	20	>6	4.6	4.7	4	0.1	2.1	6.4	20	>6
Lab043	5	13.2	14.3	4	0.8	5.6	19.5	20	2.1	4.2	4.8	4	0.1	2.1	18.5	20	2.7
Lab049	5	13.8	14.4	5	0.6	4.2	12.7	20	3.7	4.7	4.9	5	0.1	2.0	8.3	20	>6
Total	-	-	14.2	30	0.6	4.2	-	-	-	-	4.7	30	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 2023 05 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	14.7	14.2	61	0.5	3.5	10.4	20	4.7	5.0	4.6	61	0.2	4.3	16.7	20	2.8
Lab020	5	14.4	14.4	62	0.5	3.5	6.9	20	5.7	4.6	4.7	62	0.1	2.1	6.4	20	>6
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	127	0.4	2.8	9.6	20	5.7	4.8	4.5	127	0.2	4.4	15.1	20	3.1
Lab033	5	13.8	13.7	72	0.6	4.4	9.5	20	4.4	4.7	4.6	72	0.3	6.5	15.2	20	2.7
Lab037	5	13.8	14.5	55	0.5	3.4	12.0	20	4.4	4.7	4.7	55	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.7	51	0.2	1.4	4.8	20	>6	4.6	4.6	51	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.7	89	1.3	9.5	22.8	20	1.7	4.2	4.5	89	0.5	11.1	29.4	20	1.2
Lab049	5	13.8	14.4	136	0.6	4.2	12.7	20	3.7	4.7	4.7	136	0.2	4.3	8.5	20	4.7
Total	-	-	14.3	722	0.8	5.6	-	-	-	-	4.6	722	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 (2023/05)								CUM (2021/01/01~2023/05/31)							
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	14.1	6	0.5	3.5	11.2	20	4.5	14.7	14.2	61	0.5	3.5	10.4	20	4.7
Lab020	5	14.4	14.4	2	-	-	-	20	-	14.4	14.4	62	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	14.1	4	0.4	2.8	11.0	20	5.2	14.9	14.3	127	0.4	2.8	9.6	20	5.7
Lab033	5	13.8	13.6	4	0.7	5.1	11.7	20	3.6	13.8	13.7	72	0.6	4.4	9.5	20	4.4
Lab037	5	13.8	13.8	1	-	-	-	20	-	13.8	14.5	55	0.5	3.4	12.0	20	4.4
Lab040	5	14.4	14.7	4	0.2	1.4	4.8	20	>6	14.4	14.7	51	0.2	1.4	4.8	20	>6
Lab043	5	13.2	14.3	4	0.8	5.6	19.5	20	2.1	13.2	13.7	89	1.3	9.5	22.8	20	1.7
Lab049	5	13.8	14.4	5	0.6	4.2	12.7	20	3.7	13.8	14.4	136	0.6	4.2	12.7	20	3.7
Total	-	-	14.2	30	0.6	4.2	-	-	-	-	14.3	722	0.8	5.6	-	-	-

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

Month : 2023 ▼ 05 ▼ Change

Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2023 ▼ 05 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2023/05)								CUM (2021/01/01~2023/05/31)							
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	4.7	6	0.2	4.3	14.5	20	3.3	5.0	4.6	61	0.2	4.3	16.7	20	2.8
Lab020	5	4.6	4.7	2	-	-	-	20	-	4.6	4.7	62	0.1	2.1	6.4	20	>6
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	4.3	4	0.1	2.3	15.1	20	4.2	4.8	4.5	127	0.2	4.4	15.1	20	3.1
Lab033	5	4.7	4.7	4	0.3	6.4	12.8	20	3.1	4.7	4.6	72	0.3	6.5	15.2	20	2.7
Lab037	5	4.7	4.6	1	-	-	-	20	-	4.7	4.7	55	0.2	4.3	8.5	20	4.7
Lab040	5	4.6	4.7	4	0.1	2.1	6.4	20	>6	4.6	4.6	51	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.8	4	0.1	2.1	18.5	20	2.7	4.2	4.5	89	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	136	0.2	4.3	8.5	20	4.7
Total	-	-	4.7	30	0.2	4.3	-	-	-	-	4.6	722	0.3	6.5	-	-	-

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

Month : 2023 ▼ 05 ▼ Change

Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2023 ▼ 05 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5