

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - May 2024 -

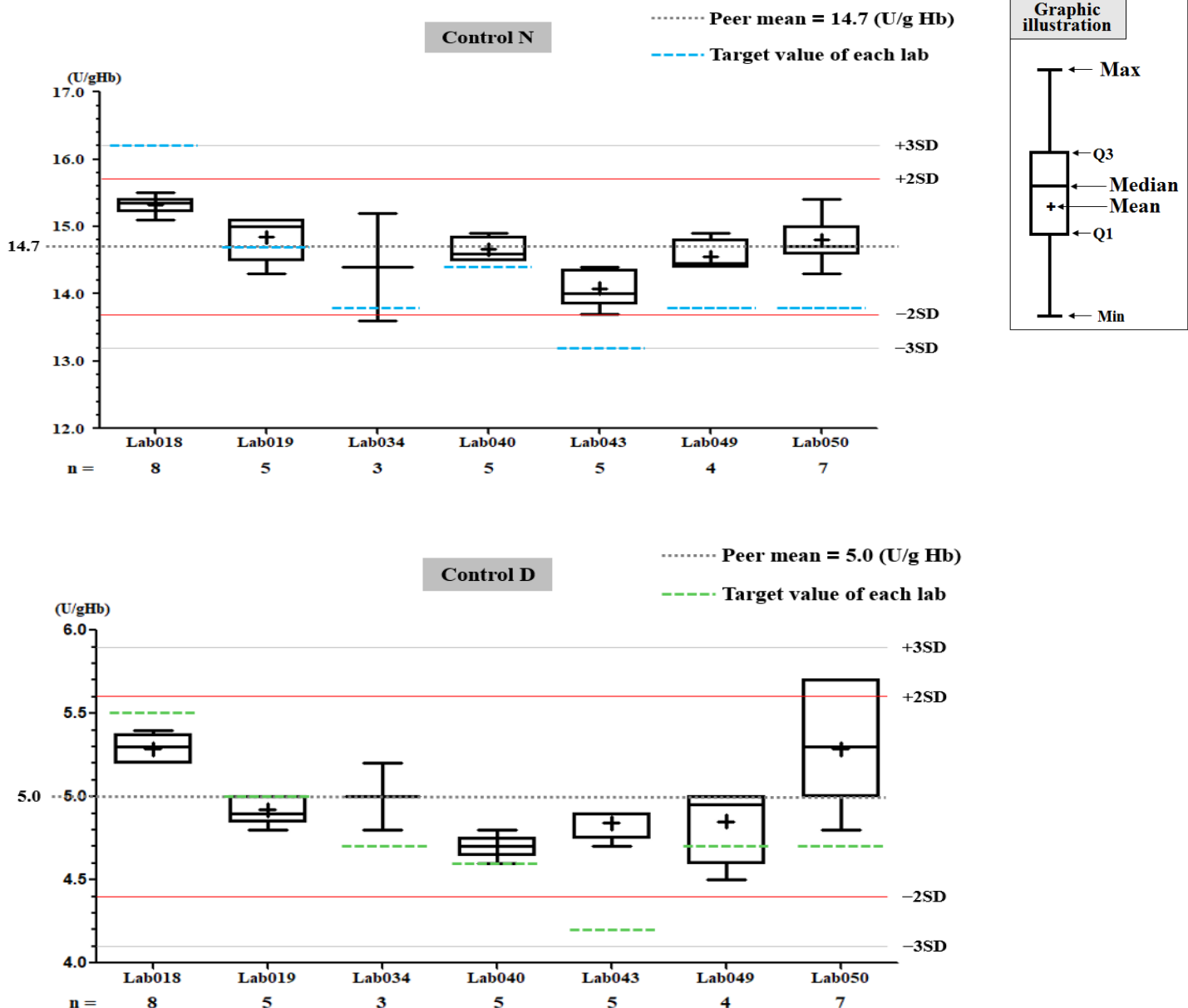
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	7	7
Received results number (n)	37	37
Median	14.7 (U/g Hb)	5.0 (U/g Hb)
Mean	14.7 (U/g Hb)	5.0 (U/g Hb)
SD	0.5	0.3
CV	3.4%	6.0%
Range of G6PD	13.6 ~ 15.5 (U/g Hb)	4.5 ~ 5.7 (U/g Hb)
Range of Hb	2.0 ~ 2.8 (g/dL)	1.8 ~ 2.2 (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](#)

Lab043

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2024/05)	CUM (2023/12/07~2024/05/31)	Month (2024/05)	CUM (2023/12/07~2024/05/31)
Runs (N)	5	26	5	26
Mean (U/gHb)	14.1	14.2	4.8	4.8
SD	0.3	0.4	0.1	0.1
CV (%)	2.1	2.8	2.1	2.1
Target Value (U/gHb)	13.2	13.2	4.2	4.2
Total Error (%)	11.1	13.2	18.5	18.5
TEa (%)	20	20	20	20
σ	>6	4.4	2.7	2.7

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

Month : 2024 05 Change ; Cumulative : from 2023 12 07 to 2024 05 31 Change

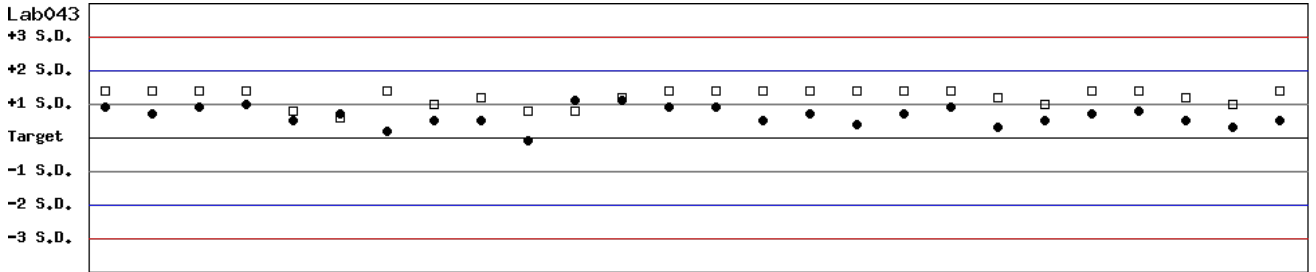
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-12-07 to 2024-05-31 ; Target : 13.2 ; SD : 1.50 (●)

Lot No.: BJ0922D ; Duration : 2023-12-07 to 2024-05-31 ; Target : 4.2 ; SD : 0.50 (□)

Lab043



Date 12-07 12-14 12-21 12-28 01-04 01-11 01-18 01-25 02-01 02-08 02-15 02-22 02-29 03-07 03-14 03-21 03-28 04-04 04-11 04-18 04-25 05-02 05-09 05-16 05-23 05-30

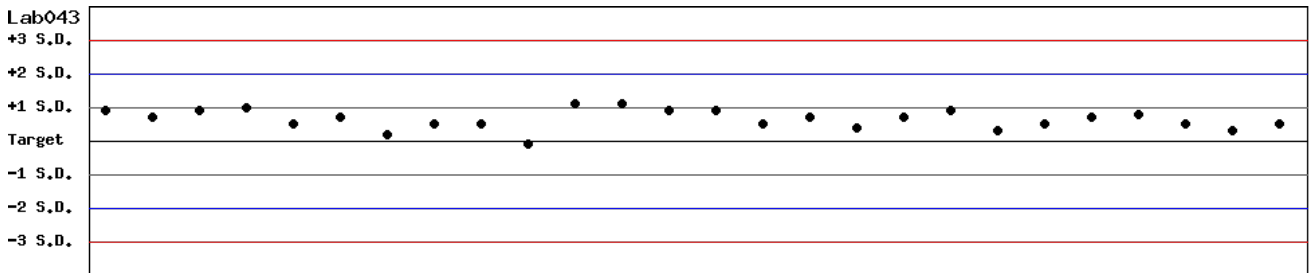
Month : 2024 05 Change ; Cumulative : from 2023 12 07 to 2024 05 31 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-12-07 to 2024-05-31 ; Target : 13.2 ; SD : 1.50

Lab043



Date 12-07 12-14 12-21 12-28 01-04 01-11 01-18 01-25 02-01 02-08 02-15 02-22 02-29 03-07 03-14 03-21 03-28 04-04 04-11 04-18 04-25 05-02 05-09 05-16 05-23 05-30

Month : 2024 05 Change ; Cumulative : from 2023 12 07 to 2024 05 31 Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2023-12-07 to 2024-05-31 ; Target : 4.2 ; SD : 0.50

Lab043



Date 12-07 12-14 12-21 12-28 01-04 01-11 01-18 01-25 02-01 02-08 02-15 02-22 02-29 03-07 03-14 03-21 03-28 04-04 04-11 04-18 04-25 05-02 05-09 05-16 05-23 05-30

Month : 2024 05 Change ; Cumulative : from 2023 12 07 to 2024 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 : 2024 05 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	15.3	8	0.1	0.7	6.9	20	>6	5.5	5.3	8	0.1	1.9	7.4	20	>6
Lab019	5	14.7	14.8	5	0.3	2.0	4.7	20	>6	5.0	4.9	5	0.1	2.0	6.1	20	>6
Lab034	5	13.8	14.4	3	0.8	5.6	15.5	20	2.8	4.7	5.0	3	0.2	4.0	14.4	20	3.4
Lab040	5	14.4	14.7	5	0.2	1.4	4.8	20	>6	4.6	4.7	5	0.1	2.1	6.4	20	>6
Lab043	5	13.2	14.1	5	0.3	2.1	11.1	20	>6	4.2	4.8	5	0.1	2.1	18.5	20	2.7
Lab049	5	13.8	14.6	4	0.2	1.4	8.5	20	>6	4.7	4.9	4	0.2	4.1	12.4	20	3.8
Lab050	5	13.8	14.8	7	0.3	2.0	11.3	20	>6	4.7	5.3	7	0.3	5.7	24.1	20	1.3
Total	-	-	14.7	37	0.5	3.4	-	-	-	-	5.0	37	0.3	6.0	-	-	-

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

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

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

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Cumulative

Cumulative : from 2021 01 01 to 2024 05 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	15.3	78	0.4	2.6	10.8	20	5.6	5.5	5.4	78	0.1	1.9	5.5	20	>6
Lab019	5	14.7	14.5	114	0.6	4.1	9.6	20	4.5	5.0	4.8	114	0.3	6.3	16.5	20	2.5
Lab020	5	14.4	14.4	85	0.5	3.5	6.9	20	5.7	4.6	4.7	85	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	153	0.4	2.8	9.6	20	5.7	4.8	4.5	153	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
Lab034	5	13.8	14.4	9	0.5	3.5	11.3	20	4.5	4.7	5.2	9	0.2	3.8	18.3	20	2.5
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	14.8	109	0.2	1.4	5.5	20	>6	4.6	4.6	109	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.9	141	1.1	7.9	21.1	20	1.9	4.2	4.6	141	0.4	8.7	26.9	20	1.2
Lab049	5	13.8	14.4	211	0.6	4.2	12.7	20	3.7	4.7	4.7	211	0.3	6.4	12.8	20	3.1
Lab050	5	13.8	14.4	20	0.7	4.9	14.1	20	3.2	4.7	5.3	20	0.3	5.7	24.1	20	1.3
Total	-	-	14.4	1121	0.8	5.6	-	-	-	-	4.7	1121	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 (2024/05)								CUM (2021/01/01~2024/05/31)							
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	15.3	8	0.1	0.7	6.9	20	>6	16.2	15.3	78	0.4	2.6	10.8	20	5.6
Lab019	5	14.7	14.8	5	0.3	2.0	4.7	20	>6	14.7	14.5	114	0.6	4.1	9.6	20	4.5
Lab020	5	14.4	-	0	-	-	-	20	-	14.4	14.4	85	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	-	0	-	-	-	20	-	14.9	14.3	153	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
Lab034	5	13.8	14.4	3	0.8	5.6	15.5	20	2.8	13.8	14.4	9	0.5	3.5	11.3	20	4.5
Lab037	5	13.8	-	0	-	-	-	20	-	13.8	14.5	59	0.5	3.4	12.0	20	4.4
Lab040	5	14.4	14.7	5	0.2	1.4	4.8	20	>6	14.4	14.8	109	0.2	1.4	5.5	20	>6
Lab043	5	13.2	14.1	5	0.3	2.1	11.1	20	>6	13.2	13.9	141	1.1	7.9	21.1	20	1.9
Lab049	5	13.8	14.6	4	0.2	1.4	8.5	20	>6	13.8	14.4	211	0.6	4.2	12.7	20	3.7
Lab050	5	13.8	14.8	7	0.3	2.0	11.3	20	>6	13.8	14.4	20	0.7	4.9	14.1	20	3.2
Total	-	-	14.7	37	0.5	3.4	-	-	-	-	14.4	1121	0.8	5.6	-	-	-

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

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

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

Month : 2024 05 Change

Cumulative : from 2021 01 01 to 2024 05 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2024/05)								CUM (2021/01/01~2024/05/31)							
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	5.3	8	0.1	1.9	7.4	20	>6	5.5	5.4	78	0.1	1.9	5.5	20	>6
Lab019	5	5.0	4.9	5	0.1	2.0	6.1	20	>6	5.0	4.8	114	0.3	6.3	16.5	20	2.5
Lab020	5	4.6	-	0	-	-	-	20	-	4.6	4.7	85	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	-	0	-	-	-	20	-	4.8	4.5	153	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
Lab034	5	4.7	5.0	3	0.2	4.0	14.4	20	3.4	4.7	5.2	9	0.2	3.8	18.3	20	2.5
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	109	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	4.6	141	0.4	8.7	26.9	20	1.2
Lab049	5	4.7	4.9	4	0.2	4.1	12.4	20	3.8	4.7	4.7	211	0.3	6.4	12.8	20	3.1
Lab050	5	4.7	5.3	7	0.3	5.7	24.1	20	1.3	4.7	5.3	20	0.3	5.7	24.1	20	1.3
Total	-	-	5.0	37	0.3	6.0	-	-	-	-	4.7	1121	0.3	6.4	-	-	-

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

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

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

Month : 2024 05 Change

Cumulative : from 2021 01 01 to 2024 05 31 Change

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Reagent Kit	Reagent Code
Medicon	5