

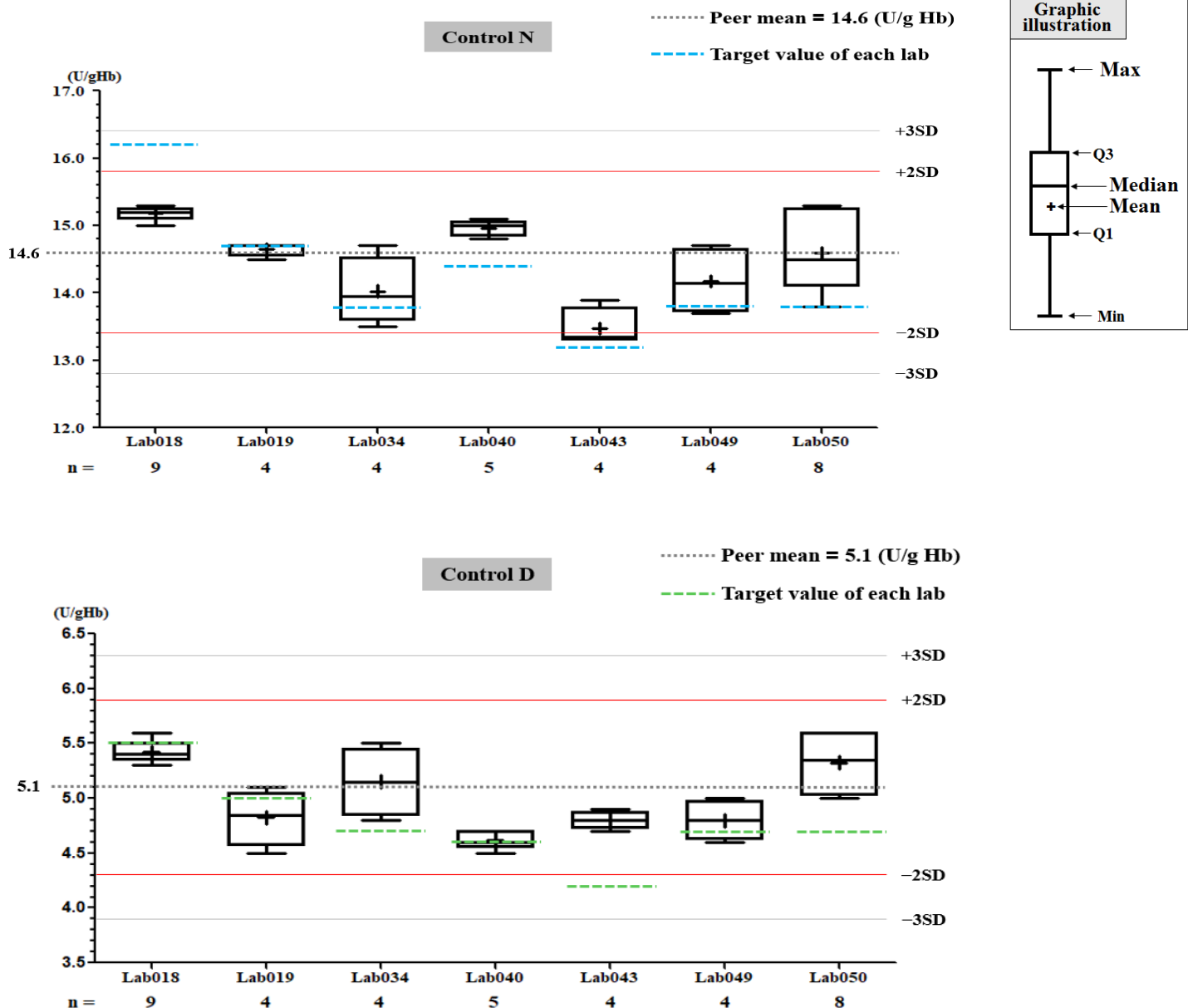
Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - August 2024 -

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)	38	38
Median	14.7 (U/g Hb)	5.0 (U/g Hb)
Mean	14.6 (U/g Hb)	5.1 (U/g Hb)
SD	0.6	0.4
CV	4.1%	7.8%
Range of G6PD	13.3 ~ 15.3 (U/g Hb)	4.5 ~ 5.6 (U/g Hb)
Range of Hb	1.9 ~ 2.6 (g/dL)	1.7 ~ 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](#)

Lab018

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2024/08)	CUM (2024/06/04~2024/08/30)	Month (2024/08)	CUM (2024/06/04~2024/08/30)
Runs (N)	9	26	9	26
Mean (U/gHb)	15.2	15.3	5.4	5.4
SD	0.1	0.1	0.1	0.1
CV (%)	0.7	0.7	1.9	1.9
Target Value (U/gHb)	16.2	16.2	5.5	5.5
Total Error (%)	7.5	6.9	5.5	5.5
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

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

Month : 2024 08 Change ; Cumulative : from 2024 06 04 to 2024 08 30 Change

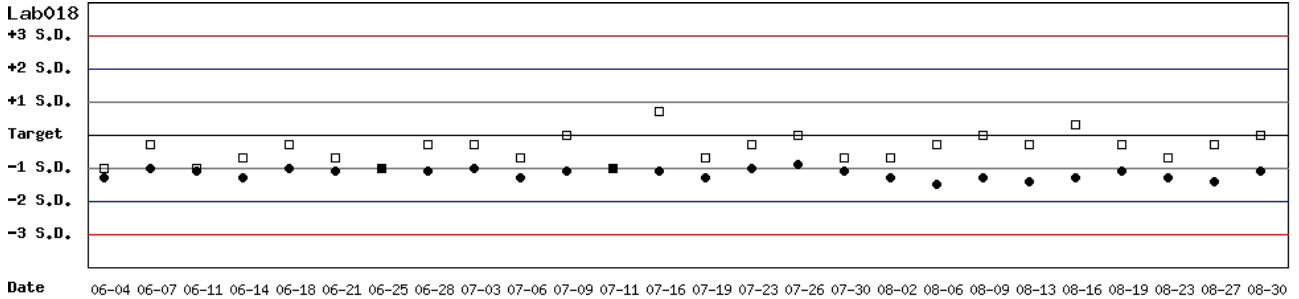
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-06-04 to 2024-08-30 ; Target : 16.2 ; SD : 0.80 (●)

Lot No.: BJ0922D ; Duration : 2024-06-04 to 2024-08-30 ; Target : 5.5 ; SD : 0.30 (□)

Lab018



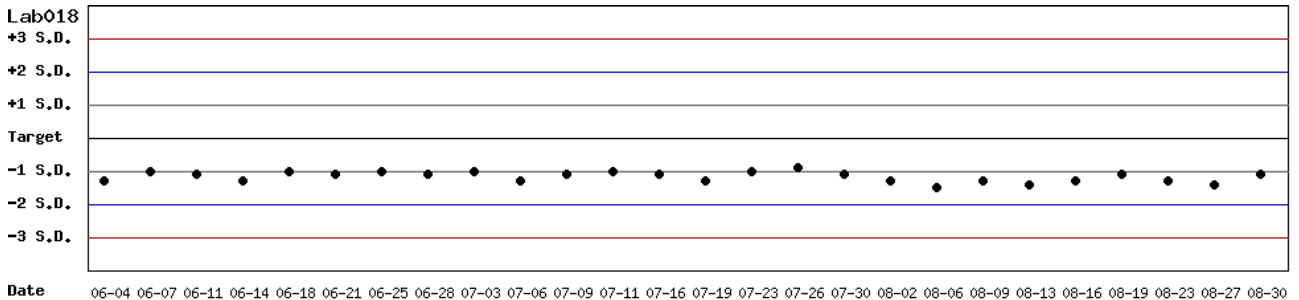
Month : 2024 08 Change ; Cumulative : from 2024 06 04 to 2024 08 30 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-06-04 to 2024-08-30 ; Target : 16.2 ; SD : 0.80

Lab018



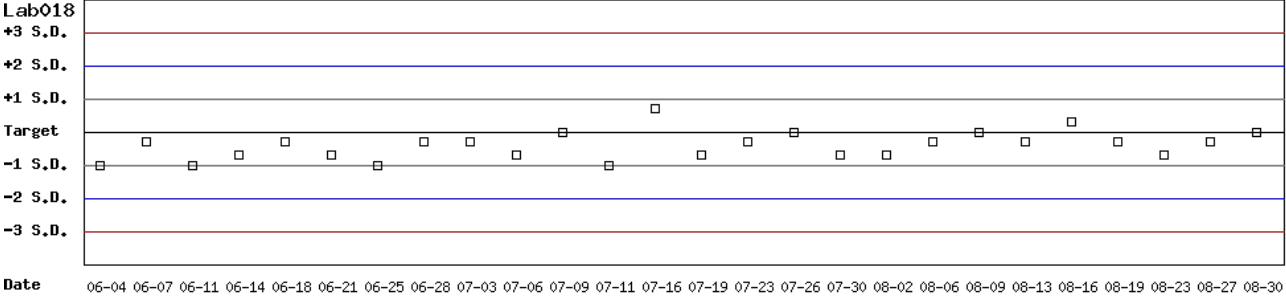
Month : 2024 08 Change ; Cumulative : from 2024 06 04 to 2024 08 30 Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2024-06-04 to 2024-08-30 ; Target : 5.5 ; SD : 0.30

Lab018



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 : 2024 08 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	15.2	9	0.1	0.7	7.5	20	>6	5.5	5.4	9	0.1	1.9	5.5	20	>6
Lab019	5	14.7	14.7	4	0.1	0.7	1.4	20	>6	5.0	4.8	4	0.3	6.3	16.5	20	2.5
Lab034	5	13.8	14.0	4	0.5	3.6	8.6	20	5.2	4.7	5.2	4	0.3	5.8	22.2	20	1.6
Lab040	5	14.4	15.0	5	0.1	0.7	5.5	20	>6	4.6	4.6	5	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.5	4	0.3	2.2	6.7	20	>6	4.2	4.8	4	0.1	2.1	18.5	20	2.7
Lab049	5	13.8	14.2	4	0.5	3.5	9.9	20	4.9	4.7	4.8	4	0.2	4.2	10.5	20	4.3
Lab050	5	13.8	14.6	8	0.6	4.1	14.0	20	3.5	4.7	5.3	8	0.3	5.7	24.1	20	1.3
Total	-	-	14.6	38	0.6	4.1	-	-	-	-	5.1	38	0.4	7.8	-	-	-

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 2024 08 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	15.3	104	0.4	2.6	10.8	20	5.6	5.5	5.4	104	0.1	1.9	5.5	20	>6
Lab019	5	14.7	14.6	127	0.6	4.1	8.9	20	4.7	5.0	4.8	127	0.3	6.3	16.5	20	2.5
Lab020	5	14.4	14.4	90	0.5	3.5	6.9	20	5.7	4.6	4.7	90	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
Lab025	5	13.6	13.9	2	-	-	-	20	-	4.9	5.2	2	-	-	-	20	-
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	17	0.5	3.5	11.3	20	4.5	4.7	5.1	17	0.2	3.9	16.4	20	2.9
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	123	0.2	1.4	5.5	20	>6	4.6	4.6	123	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.9	153	1.0	7.2	19.7	20	2.0	4.2	4.6	153	0.4	8.7	26.9	20	1.2
Lab049	5	13.8	14.4	224	0.6	4.2	12.7	20	3.7	4.7	4.7	224	0.3	6.4	12.8	20	3.1
Lab050	5	13.8	14.6	46	0.6	4.1	14.0	20	3.5	4.7	5.3	46	0.3	5.7	24.1	20	1.3
Total	-	-	14.4	1240	0.7	4.9	-	-	-	-	4.8	1240	0.4	8.3	-	-	-

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 (2024/08)								CUM (2021/01/01~2024/08/31)							
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	15.2	9	0.1	0.7	7.5	20	>6	16.2	15.3	104	0.4	2.6	10.8	20	5.6
Lab019	5	14.7	14.7	4	0.1	0.7	1.4	20	>6	14.7	14.6	127	0.6	4.1	8.9	20	4.7
Lab020	5	14.4	-	0	-	-	-	20	-	14.4	14.4	90	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
Lab025	5	13.6	-	0	-	-	-	20	-	13.6	13.9	2	-	-	-	20	-
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	14.0	4	0.5	3.6	8.6	20	5.2	13.8	14.4	17	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	15.0	5	0.1	0.7	5.5	20	>6	14.4	14.8	123	0.2	1.4	5.5	20	>6
Lab043	5	13.2	13.5	4	0.3	2.2	6.7	20	>6	13.2	13.9	153	1.0	7.2	19.7	20	2.0
Lab049	5	13.8	14.2	4	0.5	3.5	9.9	20	4.9	13.8	14.4	224	0.6	4.2	12.7	20	3.7
Lab050	5	13.8	14.6	8	0.6	4.1	14.0	20	3.5	13.8	14.6	46	0.6	4.1	14.0	20	3.5
Total	-	-	14.6	38	0.6	4.1	-	-	-	-	14.4	1240	0.7	4.9	-	-	-

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

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

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

Month : 2024 08 Change

Cumulative : from 2021 01 01 to 2024 08 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2024/08)								CUM (2021/01/01~2024/08/31)							
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	5.4	9	0.1	1.9	5.5	20	>6	5.5	5.4	104	0.1	1.9	5.5	20	>6
Lab019	5	5.0	4.8	4	0.3	6.3	16.5	20	2.5	5.0	4.8	127	0.3	6.3	16.5	20	2.5
Lab020	5	4.6	-	0	-	-	-	20	-	4.6	4.7	90	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
Lab025	5	4.9	-	0	-	-	-	20	-	4.9	5.2	2	-	-	-	20	-
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	5.2	4	0.3	5.8	22.2	20	1.6	4.7	5.1	17	0.2	3.9	16.4	20	2.9
Lab037	5	4.7	-	0	-	-	-	20	-	4.7	4.7	59	0.2	4.3	8.5	20	4.7
Lab040	5	4.6	4.6	5	0.1	2.2	4.3	20	>6	4.6	4.6	123	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	4.6	153	0.4	8.7	26.9	20	1.2
Lab049	5	4.7	4.8	4	0.2	4.2	10.5	20	4.3	4.7	4.7	224	0.3	6.4	12.8	20	3.1
Lab050	5	4.7	5.3	8	0.3	5.7	24.1	20	1.3	4.7	5.3	46	0.3	5.7	24.1	20	1.3
Total	-	-	5.1	38	0.4	7.8	-	-	-	-	4.8	1240	0.4	8.3	-	-	-

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

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

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

Month : 2024 08 Change

Cumulative : from 2021 01 01 to 2024 08 31 Change

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Reagent Kit	Reagent Code
Medicon	5