

QC Chart of Internal Quality Control (IQC) for G6PD Quantitative Test

Select LotNo : BJ0922N (2021-01-01 ~ 2100-12-31) Change

[Print Table](#)

Lab040

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2023/01)	CUM (2022/09/02~2023/01/31)	Month (2023/01)	CUM (2022/09/02~2023/01/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.7	14.7	4.6	4.7
SD	0.2	0.2	0.1	0.1
CV (%)	1.4	1.4	2.2	2.1
Target Value (U/gHb)	14.4	14.4	4.6	4.6
Total Error (%)	4.8	4.8	4.3	6.4
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

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

Month : 2023 01 Change ; Cumulative : from 2022 09 02 to 2023 01 31 Change

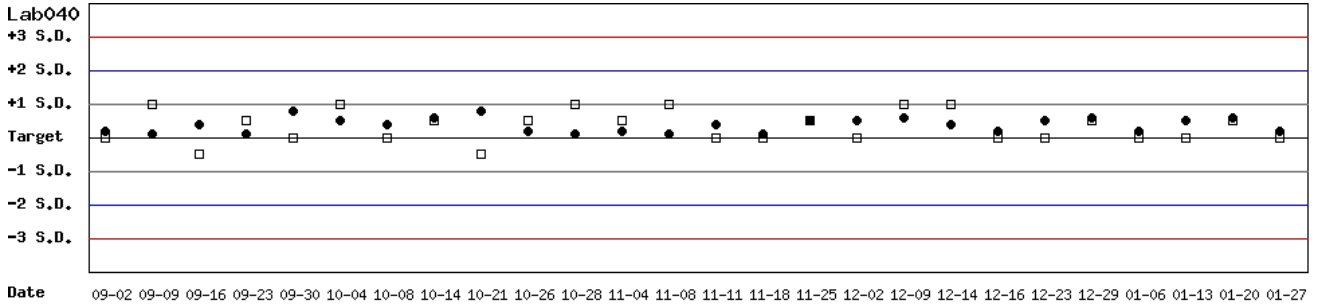
[\[TOP\]](#)

Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-09-02 to 2023-01-31 ; Target : 14.4 ; SD : 0.80 (●)

Lot No.: BJ0922D ; Duration : 2022-09-02 to 2023-01-31 ; Target : 4.6 ; SD : 0.20 (□)

Lab040



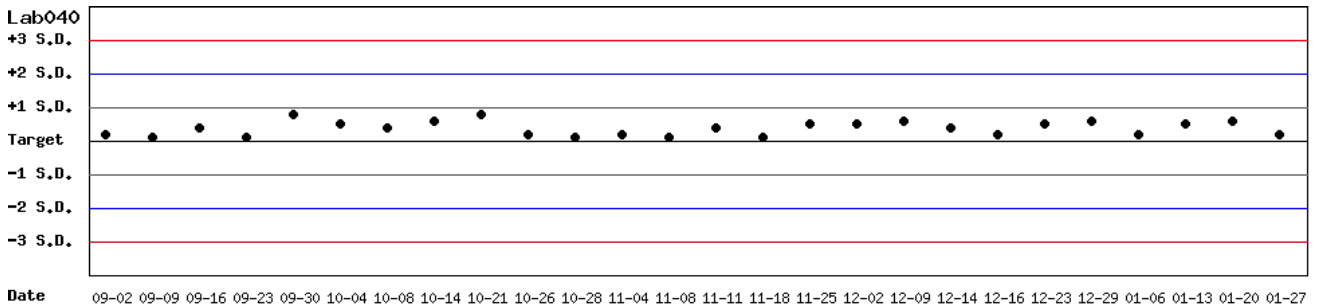
Month : 2023 01 Change ; Cumulative : from 2022 09 02 to 2023 01 31 Change

[\[TOP\]](#)

Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-09-02 to 2023-01-31 ; Target : 14.4 ; SD : 0.80

Lab040



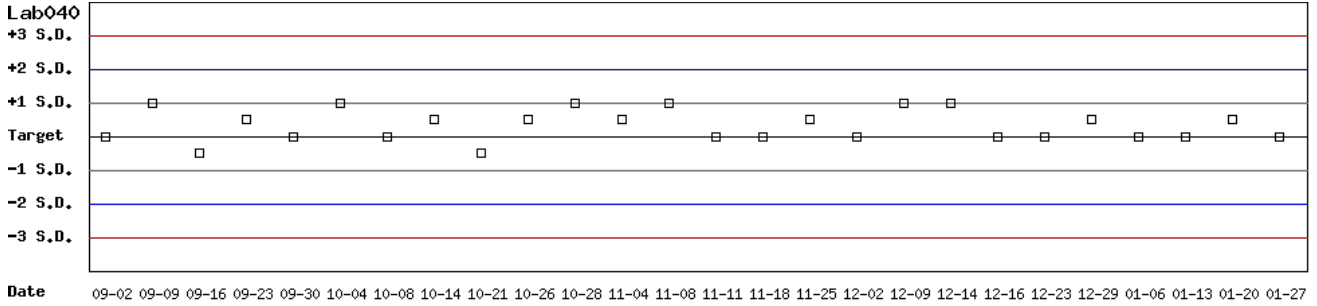
Month : 2023 01 Change ; Cumulative : from 2022 09 02 to 2023 01 31 Change

[\[TOP\]](#)

Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2022-09-02 to 2023-01-31 ; Target : 4.6 ; SD : 0.20

Lab040



Month : 2023 01 Change ; Cumulative : from 2022 09 02 to 2023 01 31 Change

[TOP](#)

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 01 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
Lab019	5	14.6	14.3	4	0.2	1.4	4.9	20	>6	4.6	4.8	4	0.1	2.1	8.5	20	>6
Lab020	5	14.4	14.6	1	-	-	-	20	-	4.6	4.8	1	-	-	-	20	-
Lab032	5	14.9	14.5	4	0.2	1.4	5.4	20	>6	4.8	4.4	4	0.3	6.8	22.0	20	1.7
Lab033	5	13.8	13.9	4	0.3	2.2	5.0	20	>6	4.7	4.7	4	0.1	2.1	4.3	20	>6
Lab037	5	13.8	14.0	2	-	-	-	20	-	4.7	4.6	2	-	-	-	20	-
Lab040	5	14.4	14.7	4	0.2	1.4	4.8	20	>6	4.6	4.6	4	0.1	2.2	4.3	20	>6
Lab043	5	13.2	14.7	4	0.4	2.7	16.8	20	3.2	4.2	4.9	4	0.1	2.0	20.7	20	1.7
Lab049	5	13.8	14.1	3	0.2	1.4	5.0	20	>6	4.7	4.7	3	0.1	2.1	4.3	20	>6
Total	-	-	14.3	26	0.4	2.8	-	-	-	-	4.7	26	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 01 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	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	14.3	44	0.5	3.5	9.0	20	5.1	4.6	4.6	44	0.2	4.3	8.7	20	4.7
Lab020	5	14.4	14.4	52	0.6	4.2	8.3	20	4.8	4.6	4.7	52	0.1	2.1	6.4	20	>6
Lab022	5	14.4	14.3	17	0.5	3.5	7.7	20	5.5	4.6	4.5	17	0.2	4.4	11.1	20	4.1
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	110	0.4	2.8	8.9	20	5.9	4.8	4.5	110	0.2	4.4	15.1	20	3.1
Lab033	5	13.8	13.7	55	0.6	4.4	9.5	20	4.4	4.7	4.6	55	0.3	6.5	15.2	20	2.7
Lab037	5	13.8	14.6	48	0.4	2.7	11.3	20	5.3	4.7	4.7	48	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.6	35	0.2	1.4	4.1	20	>6	4.6	4.6	35	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.7	73	1.4	10.2	24.2	20	1.6	4.2	4.4	73	0.5	11.4	27.5	20	1.3
Lab049	5	13.8	14.6	84	0.7	4.8	15.4	20	3.0	4.7	4.7	84	0.2	4.3	8.5	20	4.7
Total	-	-	14.3	560	0.9	6.3	-	-	-	-	4.6	560	0.3	6.5	-	-	-

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

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

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

[TOP](#)

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 (2023/01)								CUM (2021/01/01~2023/01/31)							
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	14.6	14.3	4	0.2	1.4	4.9	20	>6	14.6	14.3	44	0.5	3.5	9.0	20	5.1
Lab020	5	14.4	14.6	1	-	-	-	20	-	14.4	14.4	52	0.6	4.2	8.3	20	4.8
Lab022	5	14.4	-	0	-	-	-	20	-	14.4	14.3	17	0.5	3.5	7.7	20	5.5
Lab028	5	15.2	-	0	-	-	-	20	-	15.2	15.1	34	1.1	7.3	15.2	20	2.6
Lab032	5	14.9	14.5	4	0.2	1.4	5.4	20	>6	14.9	14.4	110	0.4	2.8	8.9	20	5.9
Lab033	5	13.8	13.9	4	0.3	2.2	5.0	20	>6	13.8	13.7	55	0.6	4.4	9.5	20	4.4
Lab037	5	13.8	14.0	2	-	-	-	20	-	13.8	14.6	48	0.4	2.7	11.3	20	5.3
Lab040	5	14.4	14.7	4	0.2	1.4	4.8	20	>6	14.4	14.6	35	0.2	1.4	4.1	20	>6
Lab043	5	13.2	14.7	4	0.4	2.7	16.8	20	3.2	13.2	13.7	73	1.4	10.2	24.2	20	1.6
Lab049	5	13.8	14.1	3	0.2	1.4	5.0	20	>6	13.8	14.6	84	0.7	4.8	15.4	20	3.0
Total	-	-	14.3	26	0.4	2.8	-	-	-	-	14.3	560	0.9	6.3	-	-	-

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

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

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

Month : 2023 01 Change

Cumulative : from 2021 01 01 to 2023 01 31 Change

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2023/01)								CUM (2021/01/01~2023/01/31)							
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	4.6	4.8	4	0.1	2.1	8.5	20	>6	4.6	4.6	44	0.2	4.3	8.7	20	4.7
Lab020	5	4.6	4.8	1	-	-	-	20	-	4.6	4.7	52	0.1	2.1	6.4	20	>6
Lab022	5	4.6	-	0	-	-	-	20	-	4.6	4.5	17	0.2	4.4	11.1	20	4.1
Lab028	5	4.9	-	0	-	-	-	20	-	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	4.8	4.4	4	0.3	6.8	22.0	20	1.7	4.8	4.5	110	0.2	4.4	15.1	20	3.1
Lab033	5	4.7	4.7	4	0.1	2.1	4.3	20	>6	4.7	4.6	55	0.3	6.5	15.2	20	2.7
Lab037	5	4.7	4.6	2	-	-	-	20	-	4.7	4.7	48	0.2	4.3	8.5	20	4.7
Lab040	5	4.6	4.6	4	0.1	2.2	4.3	20	>6	4.6	4.6	35	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.9	4	0.1	2.0	20.7	20	1.7	4.2	4.4	73	0.5	11.4	27.5	20	1.3
Lab049	5	4.7	4.7	3	0.1	2.1	4.3	20	>6	4.7	4.7	84	0.2	4.3	8.5	20	4.7
Total	-	-	4.7	26	0.2	4.3	-	-	-	-	4.6	560	0.3	6.5	-	-	-

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

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

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

Month : 2023 01 Change

Cumulative : from 2021 01 01 to 2023 01 31 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5