

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

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

Print Table

Lab043

	Control N		Control D	
QC Control Lot No.	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2025/08)	CUM (2025/03/06~2025/08/28)	Month (2025/08)	CUM (2025/03/06~2025/08/28)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.9	14.7	4.8	4.8
SD	0.5	0.3	0.0	0.0
CV (%)	3.4	2.0	0.0	0.0
Target Value (U/gHb)	13.2	13.2	4.2	4.2
Total Error (%)	19.6	15.4	14.3	14.3
TEa (%)	20	20	20	20
σ	2.1	4.3	>6	>6

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

Month : 2025 08 Change ; Cumulative : from 2025 03 06 to 2025 08 28 Change

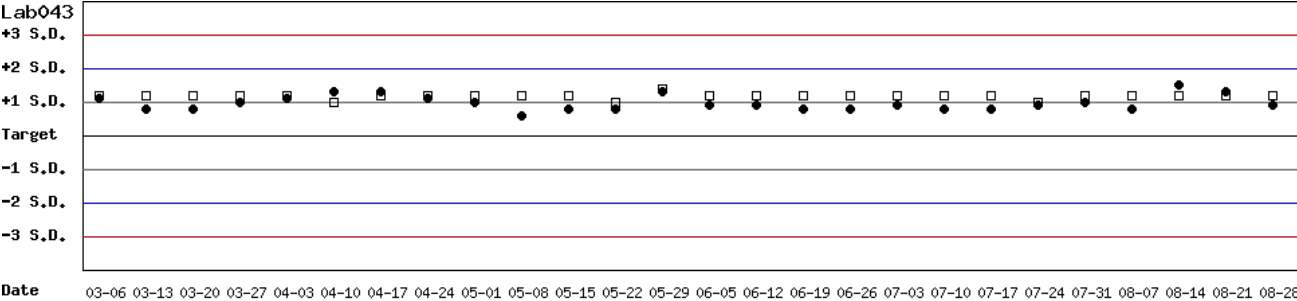
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Control N and Control D SDI
QC Chart

Lot No.: BJ0922N ; Duration : 2025-03-06 to 2025-08-28 ; Target : 13.2 ; SD : 1.50 (●)

Lot No.: BJ0922D ; Duration : 2025-03-06 to 2025-08-28 ; Target : 4.2 ; SD : 0.50 (□)

Lab043



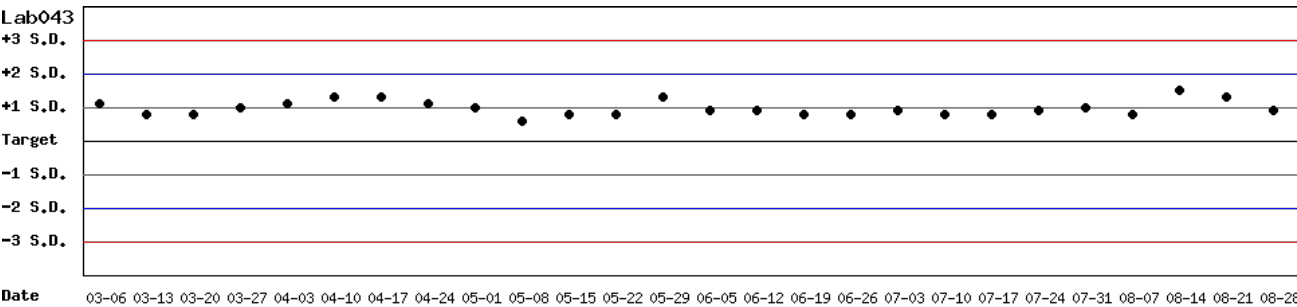
Month : 2025 08 Change ; Cumulative : from 2025 03 06 to 2025 08 28 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2025-03-06 to 2025-08-28 ; Target : 13.2 ; SD : 1.50

Lab043



Month : 2025 08 Change ; Cumulative : from 2025 03 06 to 2025 08 28 Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2025-03-06 to 2025-08-28 ; Target : 4.2 ; SD : 0.50

Lab043

Lab043

+3 S.D.

+2 S.D.

+1 S.D.

Target

-1 S.D.

-2 S.D.

-3 S.D.

Date _____

03-06 03-13 03-20 03-27 04-03 04-10 04-17 04-24 05-01 05-08 05-15 05-22 05-29 06-05 06-12 06-19 06-26 07-03 07-10 07-17 07-24 07-31 08-07 08-14 08-21 08-28

Month : 2025 ▾ 08 ▾ Change ; Cumulative : from 2025 ▾ 03 ▾ 06 ▾ to 2025 ▾ 08 ▾ 28 ▾ 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 : 2025 08 Change

		Control N (Lot No.: BJ0922N)									Control D (Lot No.: BJ0922D)							
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
Lab019	5	14.7	14.0	2	-	-	-	20	-		5.0	4.5	2	-	-	-	20	-
Lab034	5	13.8	15.0	2	-	-	-	20	-		4.7	4.6	2	-	-	-	20	-
Lab043	5	13.2	14.9	4	0.5	3.4	19.6	20	2.1		4.2	4.8	4	0.0	0.0	14.3	20	>6
Lab049	5	13.8	14.7	4	0.3	2.0	10.6	20	>6		4.7	4.4	4	0.1	2.3	10.9	20	5.9
Lab050	5	13.8	13.8	6	0.4	2.9	5.8	20	>6		4.7	5.4	6	0.2	3.7	22.3	20	1.4
Total	-	-	14.4	18	0.6	4.2	-	-	-		-	4.9	18	0.5	10.2	-	-	-

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 2025 08 31 Change

		Control N (Lot No.: BJ0922N)									Control D (Lot No.: BJ0922D)							
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	15.3	113	0.4	2.6	10.8	20	5.6		5.5	5.4	113	0.1	1.9	5.5	20	>6
Lab019	5	14.7	14.6	177	0.5	3.4	7.5	20	5.7		5.0	4.8	177	0.2	4.2	12.3	20	3.8
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	14.4	14.2	13	0.5	3.5	8.4	20	5.3		5.4	5.1	13	0.3	5.9	17.3	20	2.4
Lab028	5	15.2	15.0	66	0.9	6.0	13.3	20	3.1		4.9	5.1	66	0.3	5.9	15.8	20	2.7
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	44	0.6	4.2	12.7	20	3.7		4.7	5.2	44	0.4	7.7	26.0	20	1.2
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	169	0.2	1.4	5.5	20	>6		4.6	4.6	169	0.1	2.2	4.3	20	>6
Lab043	5	13.2	14.1	205	1.0	7.1	21.0	20	1.9		4.2	4.7	205	0.4	8.5	28.9	20	1.0
Lab049	5	13.8	14.4	273	0.6	4.2	12.7	20	3.7		4.7	4.7	273	0.3	6.4	12.8	20	3.1
Lab050	5	13.8	14.4	109	0.6	4.2	12.7	20	3.7		4.7	5.1	109	0.5	9.8	28.1	20	1.2
Total	-	-	14.5	1579	0.7	4.8	-	-	-		-	4.8	1579	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 (2025/08)									CUM (2021/01/01~2025/08/31)						
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	-	0	-	-	-	20	-	16.2	15.3	113	0.4	2.6	10.8	20	5.6
Lab019	5	14.7	14.0	2	-	-	-	20	-	14.7	14.6	177	0.5	3.4	7.5	20	5.7
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	14.4	-	0	-	-	-	20	-	14.4	14.2	13	0.5	3.5	8.4	20	5.3
Lab028	5	15.2	-	0	-	-	-	20	-	15.2	15.0	66	0.9	6.0	13.3	20	3.1
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	15.0	2	-	-	-	20	-	13.8	14.4	44	0.6	4.2	12.7	20	3.7
Lab037	5	13.8	-	0	-	-	-	20	-	13.8	14.5	59	0.5	3.4	12.0	20	4.4
Lab040	5	14.4	-	0	-	-	-	20	-	14.4	14.8	169	0.2	1.4	5.5	20	>6
Lab043	5	13.2	14.9	4	0.5	3.4	19.6	20	2.1	13.2	14.1	205	1.0	7.1	21.0	20	1.9
Lab049	5	13.8	14.7	4	0.3	2.0	10.6	20	>6	13.8	14.4	273	0.6	4.2	12.7	20	3.7
Lab050	5	13.8	13.8	6	0.4	2.9	5.8	20	>6	13.8	14.4	109	0.6	4.2	12.7	20	3.7
Total	-	-	14.4	18	0.6	4.2	-	-	-	-	14.5	1579	0.7	4.8	-	-	-

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

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

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

Month : 2025 08 Change

Cumulative : from 2021 01 01 to 2025 08 31 Change

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Control D Month vs. Cumulative

Control D (Lot No.: BJ0922D)																	
		Month (2025/08)									CUM (2021/01/01~2025/08/31)						
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	-	0	-	-	-	20	-	5.5	5.4	113	0.1	1.9	5.5	20	>6
Lab019	5	5.0	4.5	2	-	-	-	20	-	5.0	4.8	177	0.2	4.2	12.3	20	3.8
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	5.4	-	0	-	-	-	20	-	5.4	5.1	13	0.3	5.9	17.3	20	2.4
Lab028	5	4.9	-	0	-	-	-	20	-	4.9	5.1	66	0.3	5.9	15.8	20	2.7
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	4.6	2	-	-	-	20	-	4.7	5.2	44	0.4	7.7	26.0	20	1.2
Lab037	5	4.7	-	0	-	-	-	20	-	4.7	4.7	59	0.2	4.3	8.5	20	4.7
Lab040	5	4.6	-	0	-	-	-	20	-	4.6	4.6	169	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.8	4	0.0	0.0	14.3	20	>6	4.2	4.7	205	0.4	8.5	28.9	20	1.0
Lab049	5	4.7	4.4	4	0.1	2.3	10.9	20	5.9	4.7	4.7	273	0.3	6.4	12.8	20	3.1
Lab050	5	4.7	5.4	6	0.2	3.7	22.3	20	1.4	4.7	5.1	109	0.5	9.8	28.1	20	1.2
Total	-	-	4.9	18	0.5	10.2	-	-	-	-	4.8	1579	0.4	8.3	-	-	-

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

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

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

Month : 2025 08 Change

Cumulative : from 2021 01 01 to 2025 08 31 Change

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Reagent Kit	Reagent Code
Medicon	5