

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 (2023/09)	CUM (2023/03/17~2023/09/30)	Month (2023/09)	CUM (2023/03/17~2023/09/30)
Runs (N)	7	26	7	26
Mean (U/gHb)	14.8	14.8	4.7	4.7
SD	0.2	0.2	0.1	0.1
CV (%)	1.4	1.4	2.1	2.1
Target Value (U/gHb)	14.4	14.4	4.6	4.6
Total Error (%)	5.5	5.5	6.4	6.4
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

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

Month : 2023 09 Change ; Cumulative : from 2023 03 17 to 2023 09 30 Change

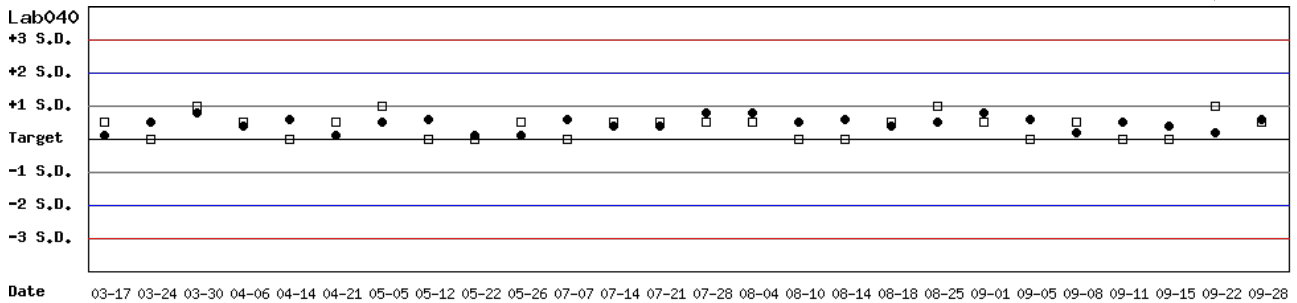
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-03-17 to 2023-09-30 ; Target : 14.4 ; SD : 0.80 (●)

Lot No.: BJ0922D ; Duration : 2023-03-17 to 2023-09-30 ; Target : 4.6 ; SD : 0.20 (□)

Lab040



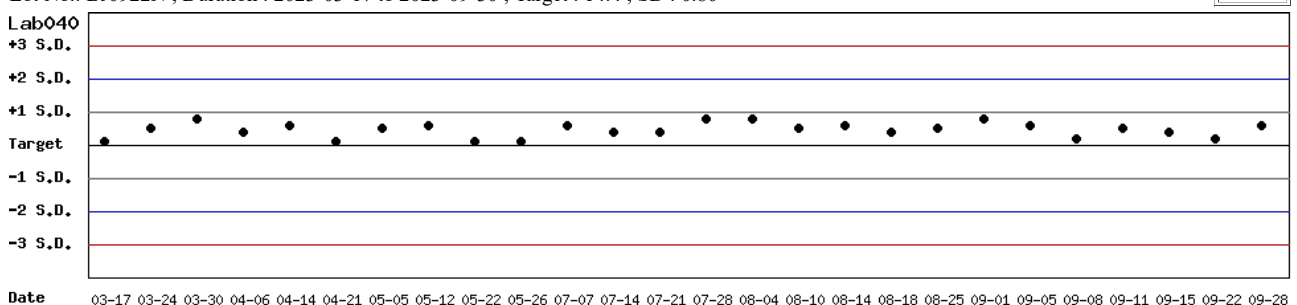
Month : 2023 09 Change ; Cumulative : from 2023 03 17 to 2023 09 30 Change

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2023-03-17 to 2023-09-30 ; Target : 14.4 ; SD : 0.80

Lab040



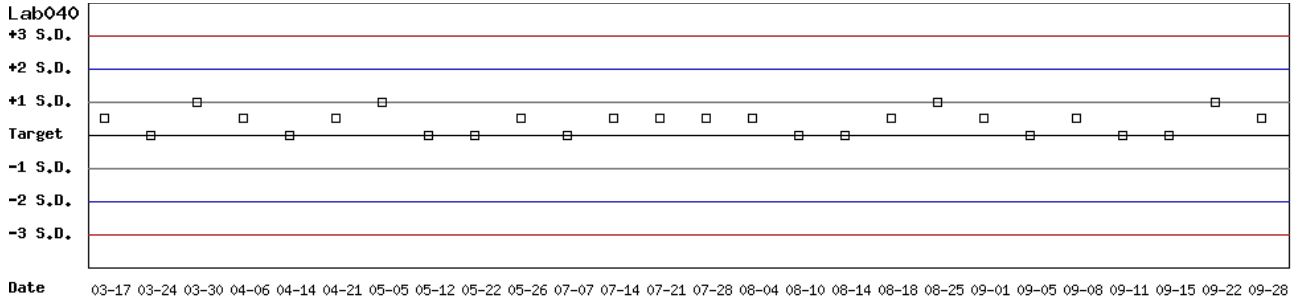
Month : 2023 09 Change ; Cumulative : from 2023 03 17 to 2023 09 30 Change

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2023-03-17 to 2023-09-30 ; Target : 4.6 ; SD : 0.20

Lab040



Month : 2023 09 Change ; Cumulative : from 2023 03 17 to 2023 09 30 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 09 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	14.8	4	0.3	2.0	4.7	20	>6	5.0	5.0	4	0.1	2.0	4.0	20	>6
Lab032	5	14.9	14.6	5	0.3	2.1	6.1	20	>6	4.8	4.4	5	0.2	4.5	17.4	20	2.6
Lab040	5	14.4	14.8	7	0.2	1.4	5.5	20	>6	4.6	4.7	7	0.1	2.1	6.4	20	>6
Lab043	5	13.2	14.1	5	0.5	3.5	13.9	20	3.8	4.2	4.9	5	0.1	2.0	20.7	20	1.7
Lab049	5	13.8	14.5	9	0.2	1.4	7.8	20	>6	4.7	4.5	9	0.6	13.3	30.9	20	1.2
Total	-	-	14.6	30	0.4	2.7	-	-	-	-	4.7	30	0.4	8.5	-	-	-

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 2023 09 30 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	14.4	79	0.6	4.2	10.4	20	4.3	5.0	4.7	79	0.3	6.4	18.8	20	2.2
Lab020	5	14.4	14.4	76	0.5	3.5	6.9	20	5.7	4.6	4.7	76	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	136	0.4	2.8	9.6	20	5.7	4.8	4.5	136	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
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	14.7	67	0.2	1.4	4.8	20	>6	4.6	4.6	67	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.8	106	1.2	8.7	21.9	20	1.8	4.2	4.5	106	0.5	11.1	29.4	20	1.2
Lab049	5	13.8	14.4	158	0.6	4.2	12.7	20	3.7	4.7	4.7	158	0.2	4.3	8.5	20	4.7
Total	-	-	14.3	831	0.8	5.6	-	-	-	-	4.7	831	0.3	6.4	-	-	-

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 (2023/09)									CUM (2021/01/01~2023/09/30)						
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	14.8	4	0.3	2.0	4.7	20	>6	14.7	14.4	79	0.6	4.2	10.4	20	4.3
Lab020	5	14.4	-	0	-	-	-	20	-	14.4	14.4	76	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	14.6	5	0.3	2.1	6.1	20	>6	14.9	14.3	136	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
Lab037	5	13.8	-	0	-	-	-	20	-	13.8	14.5	59	0.5	3.4	12.0	20	4.4
Lab040	5	14.4	14.8	7	0.2	1.4	5.5	20	>6	14.4	14.7	67	0.2	1.4	4.8	20	>6
Lab043	5	13.2	14.1	5	0.5	3.5	13.9	20	3.8	13.2	13.8	106	1.2	8.7	21.9	20	1.8
Lab049	5	13.8	14.5	9	0.2	1.4	7.8	20	>6	13.8	14.4	158	0.6	4.2	12.7	20	3.7
Total	-	-	14.6	30	0.4	2.7	-	-	-	-	14.3	831	0.8	5.6	-	-	-

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

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

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

Month : 2023 09 Change

Cumulative : from 2021 01 01 to 2023 09 30 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2023/09)									CUM (2021/01/01~2023/09/30)						
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	5.0	4	0.1	2.0	4.0	20	>6	5.0	4.7	79	0.3	6.4	18.8	20	2.2
Lab020	5	4.6	-	0	-	-	-	20	-	4.6	4.7	76	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	4.4	5	0.2	4.5	17.4	20	2.6	4.8	4.5	136	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
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	7	0.1	2.1	6.4	20	>6	4.6	4.6	67	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.9	5	0.1	2.0	20.7	20	1.7	4.2	4.5	106	0.5	11.1	29.4	20	1.2
Lab049	5	4.7	4.5	9	0.6	13.3	30.9	20	1.2	4.7	4.7	158	0.2	4.3	8.5	20	4.7
Total	-	-	4.7	30	0.4	8.5	-	-	-	-	4.7	831	0.3	6.4	-	-	-

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

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

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

Month : 2023 09 Change

Cumulative : from 2021 01 01 to 2023 09 30 Change

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Reagent Kit	Reagent Code
Medicon	5