

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

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

Lab028

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2021/10)	CUM (2021/08/13~2021/10/30)	Month (2021/10)	CUM (2021/08/13~2021/10/30)
Runs (N)	13	14	13	14
Mean (U/gHb)	15.3	15.3	5.0	4.9
SD	0.6	0.6	0.2	0.2
CV (%)	3.9	3.9	4.0	4.1
Target Value (U/gHb)	13.8	13.8	4.7	4.7
Total Error (%)	18.7	18.7	14.4	12.4
TEa (%)	20	20	20	20
σ	2.3	2.3	3.4	3.8

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

Month : ; Cumulative : from to

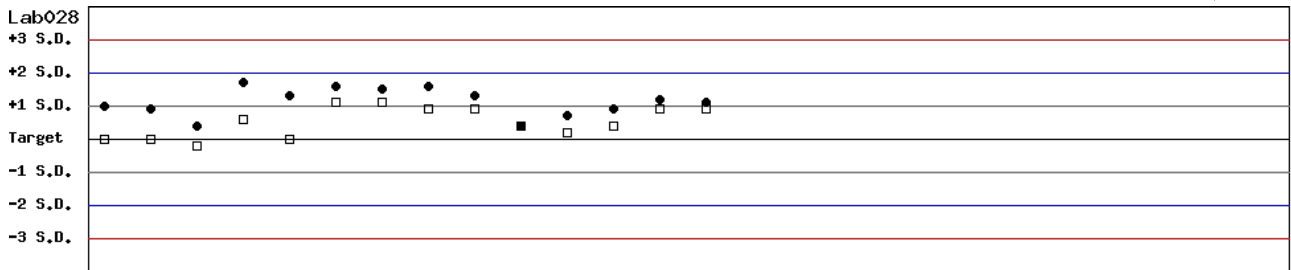
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Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-08-13 to 2021-10-30 ; Target : 13.8 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2021-08-13 to 2021-10-30 ; Target : 4.7 ; SD : 0.47 (□)

Lab028



Date 08-13 10-02 10-05 10-07 10-09 10-12 10-14 10-16 10-19 10-21 10-23 10-26 10-28 10-30

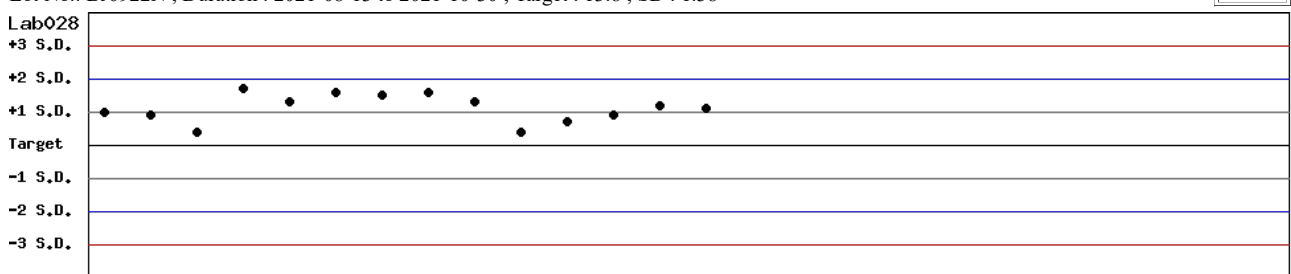
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-08-13 to 2021-10-30 ; Target : 13.8 ; SD : 1.38

Lab028



Date 08-13 10-02 10-05 10-07 10-09 10-12 10-14 10-16 10-19 10-21 10-23 10-26 10-28 10-30

Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2021-08-13 to 2021-10-30 ; Target : 4.7 ; SD : 0.47

Lab028



Date 08-13 10-02 10-05 10-07 10-09 10-12 10-14 10-16 10-19 10-21 10-23 10-26 10-28 10-30

Month : 2021 ▾ 10 ▾ Change ; Cumulative : from 2021 ▾ 08 ▾ 13 ▾ to 2021 ▾ 10 ▾ 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 : 2021 10 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
Lab020	5	14.4	14.6	2	-	-	-	20	-	4.6	4.5	2	-	-	-	20	-
Lab028	5	13.8	15.3	13	0.6	3.9	18.7	20	2.3	4.7	5.0	13	0.2	4.0	14.4	20	3.4
Lab032	5	15.0	14.5	8	0.5	3.4	10.2	20	4.9	4.7	4.5	8	0.2	4.4	13.1	20	3.6
Lab043	5	14.4	12.0	20	0.5	4.2	25.0	20	0.8	4.6	3.8	20	0.2	5.3	27.9	20	0.5
Lab049	5	13.8	15.1	4	0.5	3.3	16.0	20	3.2	4.7	5.0	4	0.1	2.0	10.4	20	>6
Total	-	-	13.7	47	1.6	11.7	-	-	-	-	4.4	47	0.6	13.6	-	-	-

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 2021 11 30 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
Lab020	5	14.4	14.6	6	0.3	2.1	5.5	20	>6	4.6	4.7	6	0.2	4.3	10.7	20	4.1
Lab028	5	13.8	15.3	14	0.6	3.9	18.7	20	2.3	4.7	4.9	14	0.2	4.1	12.4	20	3.8
Lab032	5	15.0	14.3	35	0.5	3.5	11.7	20	4.4	4.7	4.5	35	0.2	4.4	13.1	20	3.6
Lab037	5	13.8	15.1	4	0.5	3.3	16.0	20	3.2	4.7	4.8	4	0.1	2.1	6.3	20	>6
Lab043	5	14.4	12.2	28	0.8	6.6	28.4	20	0.7	4.6	3.9	28	0.2	5.1	25.5	20	0.9
Lab049	5	13.8	15.0	41	0.5	3.3	15.4	20	3.4	4.7	4.7	41	0.2	4.3	8.5	20	4.7
Total	-	-	14.2	128	1.2	8.5	-	-	-	-	4.5	128	0.4	8.9	-	-	-

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 (2021/10)								CUM (2021/01/01~2021/11/30)							
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
Lab020	5	14.4	14.6	2	-	-	-	20	-	14.4	14.6	6	0.3	2.1	5.5	20	>6
Lab028	5	13.8	15.3	13	0.6	3.9	18.7	20	2.3	13.8	15.3	14	0.6	3.9	18.7	20	2.3
Lab032	5	15.0	14.5	8	0.5	3.4	10.2	20	4.9	15.0	14.3	35	0.5	3.5	11.7	20	4.4
Lab037	5	13.8	-	0	-	-	-	20	-	13.8	15.1	4	0.5	3.3	16.0	20	3.2
Lab043	5	14.4	12.0	20	0.5	4.2	25.0	20	0.8	14.4	12.2	28	0.8	6.6	28.4	20	0.7
Lab049	5	13.8	15.1	4	0.5	3.3	16.0	20	3.2	13.8	15.0	41	0.5	3.3	15.4	20	3.4
Total	-	-	13.7	47	1.6	11.7	-	-	-	-	14.2	128	1.2	8.5	-	-	-

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

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

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

Month : 2021 ▼ 10 ▼ Change

Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2021 ▼ 11 ▼ 30 ▼ Change

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Control D Month vs. Cumulative

Control D (Lot No.: BJ0922D)																	
		Month (2021/10)								CUM (2021/01/01~2021/11/30)							
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
Lab020	5	4.6	4.5	2	-	-	-	20	-	4.6	4.7	6	0.2	4.3	10.7	20	4.1
Lab028	5	4.7	5.0	13	0.2	4.0	14.4	20	3.4	4.7	4.9	14	0.2	4.1	12.4	20	3.8
Lab032	5	4.7	4.5	8	0.2	4.4	13.1	20	3.6	4.7	4.5	35	0.2	4.4	13.1	20	3.6
Lab037	5	4.7	-	0	-	-	-	20	-	4.7	4.8	4	0.1	2.1	6.3	20	>6
Lab043	5	4.6	3.8	20	0.2	5.3	27.9	20	0.5	4.6	3.9	28	0.2	5.1	25.5	20	0.9
Lab049	5	4.7	5.0	4	0.1	2.0	10.4	20	>6	4.7	4.7	41	0.2	4.3	8.5	20	4.7
Total	-	-	4.4	47	0.6	13.6	-	-	-	-	4.5	128	0.4	8.9	-	-	-

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

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

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

Month : 2021 ▼ 10 ▼ Change

Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2021 ▼ 11 ▼ 30 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5