

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

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

## Lab037

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2021/12)	CUM (2021/07/02~2021/12/31)	Month (2021/12)	CUM (2021/07/02~2021/12/31)
Runs (N)	3	7	3	7
Mean (U/gHb)	14.5	14.9	4.7	4.7
SD	0.2	0.5	0.5	0.3
CV (%)	1.4	3.4	10.6	6.4
Target Value (U/gHb)	13.8	13.8	4.7	4.7
Total Error (%)	7.8	14.7	21.3	12.8
TEa (%)	20	20	20	20
$\sigma$	>6	3.5	1.9	3.1

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

Month :    ; Cumulative : from    to

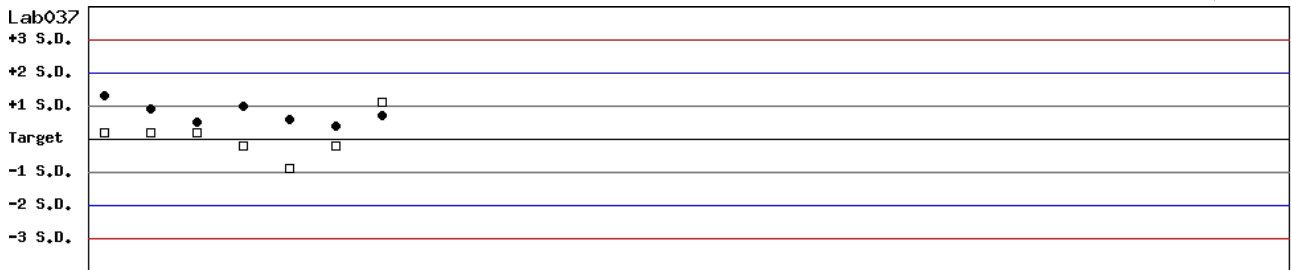
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## Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-07-02 to 2021-12-31 ; Target : 13.8 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2021-07-02 to 2021-12-31 ; Target : 4.7 ; SD : 0.47 (□)

Lab037



Date 07-02 07-14 07-30 08-12 12-01 12-16 12-22

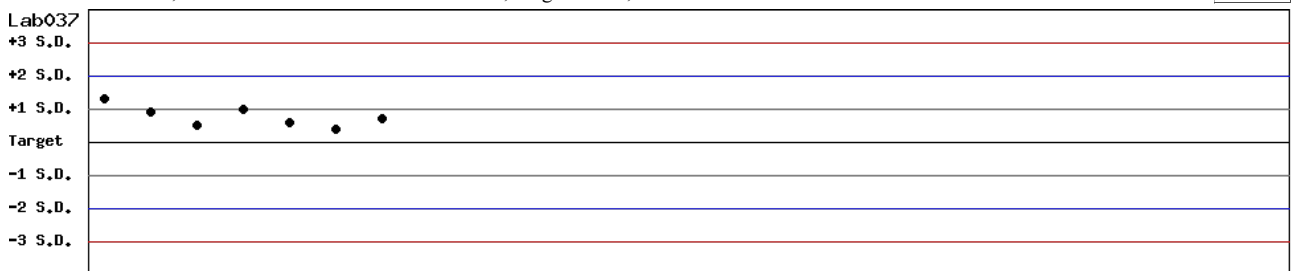
Month :    ; Cumulative : from    to

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## Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-07-02 to 2021-12-31 ; Target : 13.8 ; SD : 1.38

Lab037



Date 07-02 07-14 07-30 08-12 12-01 12-16 12-22

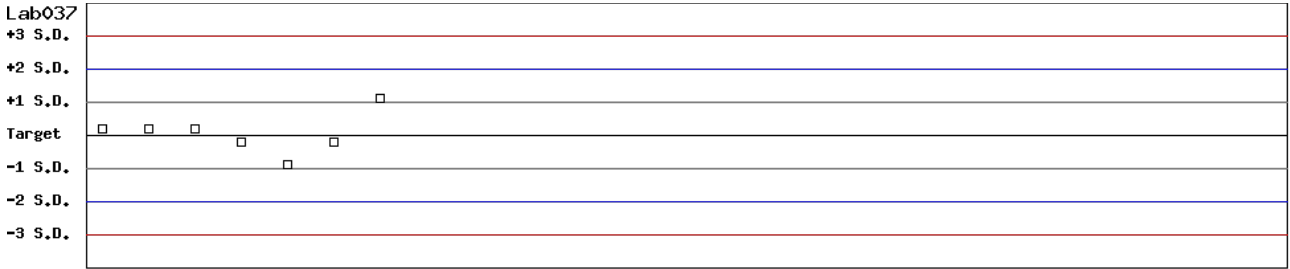
Month :    ; Cumulative : from    to

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### Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2021-07-02 to 2021-12-31 ; Target : 4.7 ; SD : 0.47

Lab037



Date 07-02 07-14 07-30 08-12 12-01 12-16 12-22

Month : 2021 v 12 v Change ; Cumulative : from 2021 v 07 v 02 v to 2021 v 12 v 31 v 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 12 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
<a href="#">Lab020</a>	5	14.4	14.2	3	0.9	6.3	14.1	20	3.0	4.6	4.7	3	0.1	2.1	6.4	20	>6
<a href="#">Lab032</a>	5	15.0	14.5	9	0.3	2.1	7.5	20	>6	4.7	4.5	9	0.1	2.2	8.7	20	>6
<a href="#">Lab037</a>	5	13.8	14.5	3	0.2	1.4	7.8	20	>6	4.7	4.7	3	0.5	10.6	21.3	20	1.9
<a href="#">Lab043</a>	5	14.4	15.1	1	-	-	-	20	-	4.6	4.8	1	-	-	-	20	-
<a href="#">Lab049</a>	5	13.8	15.2	4	0.6	3.9	18.0	20	2.5	4.7	4.5	4	0.3	6.7	17.6	20	2.3
Total	-	-	14.6	20	0.5	3.4	-	-	-	-	4.6	20	0.2	4.3	-	-	-

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 12 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
<a href="#">Lab020</a>	5	14.4	14.4	9	0.5	3.5	6.9	20	5.7	4.6	4.7	9	0.2	4.3	10.7	20	4.1
<a href="#">Lab028</a>	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
<a href="#">Lab032</a>	5	15.0	14.3	44	0.4	2.8	10.3	20	5.5	4.7	4.5	44	0.2	4.4	13.1	20	3.6
<a href="#">Lab037</a>	5	13.8	14.9	7	0.5	3.4	14.7	20	3.5	4.7	4.7	7	0.3	6.4	12.8	20	3.1
<a href="#">Lab043</a>	5	14.4	12.3	28	0.9	7.3	29.2	20	0.7	4.6	3.9	28	0.3	7.7	30.6	20	0.6
<a href="#">Lab049</a>	5	13.8	15.1	31	0.5	3.3	16.0	20	3.2	4.7	4.8	31	0.2	4.2	10.5	20	4.3
Total	-	-	14.2	133	1.2	8.5	-	-	-	-	4.5	133	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 (2021/12)								CUM (2021/01/01~2021/12/31)							
UnitID <span style="font-size: small;">↑</span>	Reagent Kit (Code) <span style="font-size: small;">↑</span>	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
<a href="#">Lab020</a>	5	14.4	14.2	3	0.9	6.3	14.1	20	3.0	14.4	14.4	9	0.5	3.5	6.9	20	5.7
<a href="#">Lab028</a>	5	13.8	-	0	-	-	-	20	-	13.8	15.3	14	0.6	3.9	18.7	20	2.3
<a href="#">Lab032</a>	5	15.0	14.5	9	0.3	2.1	7.5	20	>6	15.0	14.3	44	0.4	2.8	10.3	20	5.5
<a href="#">Lab037</a>	5	13.8	14.5	3	0.2	1.4	7.8	20	>6	13.8	14.9	7	0.5	3.4	14.7	20	3.5
<a href="#">Lab043</a>	5	14.4	15.1	1	-	-	-	20	-	14.4	12.3	28	0.9	7.3	29.2	20	0.7
<a href="#">Lab049</a>	5	13.8	15.2	4	0.6	3.9	18.0	20	2.5	13.8	15.1	31	0.5	3.3	16.0	20	3.2
Total	-	-	14.6	20	0.5	3.4	-	-	-	-	14.2	133	1.2	8.5	-	-	-

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

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

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

Month : 2021 12 Change

Cumulative : from 2021 01 01 to 2021 12 31 Change

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### Control D Month vs. Cumulative

Control D (Lot No.: BJ0922D)																	
		Month (2021/12)								CUM (2021/01/01~2021/12/31)							
UnitID <span style="font-size: small;">↑</span>	Reagent Kit (Code) <span style="font-size: small;">↑</span>	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
<a href="#">Lab020</a>	5	4.6	4.7	3	0.1	2.1	6.4	20	>6	4.6	4.7	9	0.2	4.3	10.7	20	4.1
<a href="#">Lab028</a>	5	4.7	-	0	-	-	-	20	-	4.7	4.9	14	0.2	4.1	12.4	20	3.8
<a href="#">Lab032</a>	5	4.7	4.5	9	0.1	2.2	8.7	20	>6	4.7	4.5	44	0.2	4.4	13.1	20	3.6
<a href="#">Lab037</a>	5	4.7	4.7	3	0.5	10.6	21.3	20	1.9	4.7	4.7	7	0.3	6.4	12.8	20	3.1
<a href="#">Lab043</a>	5	4.6	4.8	1	-	-	-	20	-	4.6	3.9	28	0.3	7.7	30.6	20	0.6
<a href="#">Lab049</a>	5	4.7	4.5	4	0.3	6.7	17.6	20	2.3	4.7	4.8	31	0.2	4.2	10.5	20	4.3
Total	-	-	4.6	20	0.2	4.3	-	-	-	-	4.5	133	0.4	8.9	-	-	-

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

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

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

Month : 2021 12 Change

Cumulative : from 2021 01 01 to 2021 12 31 Change

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Reagent Kit	Reagent Code
Medicon	5