

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

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

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## Lab049

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2021/07)	CUM (2021/06/09~2021/07/31)	Month (2021/07)	CUM (2021/06/09~2021/07/31)
Runs (N)	4	8	4	8
Mean (U/gHb)	15.5	15.3	5.0	4.9
SD	0.3	0.5	0.3	0.3
CV (%)	1.9	3.3	6.0	6.1
Target Value (U/gHb)	13.8	13.8	4.7	4.7
Total Error (%)	16.2	17.4	18.4	16.5
TEa (%)	20	20	20	20
$\sigma$	4.0	2.8	2.3	2.6

Bias (%) =  $[(| \text{Mean} - \text{Target} |) / \text{Target}] \times 100\%$

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

$\sigma$  (Sigma) =  $[\text{TEa}\% - \text{Bias}(\%)] / \text{CV}(\%)$

Month : 2021 07 Change ; Cumulative : from 2021 06 09 to 2021 07 31 Change

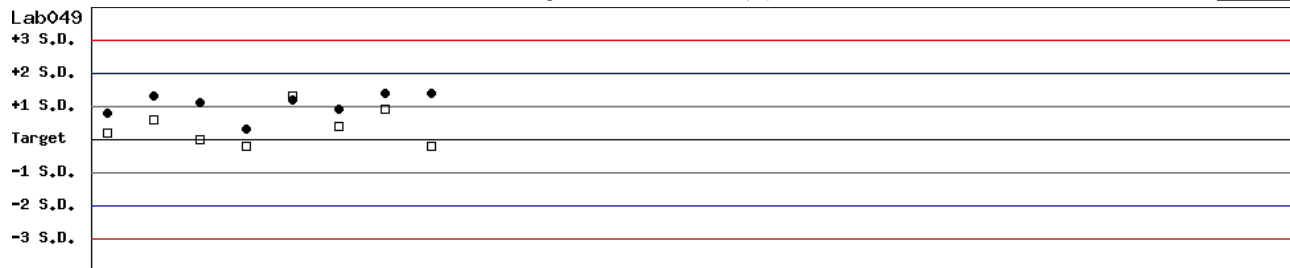
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## Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-06-09 to 2021-07-31 ; Target : 13.8 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2021-06-09 to 2021-07-31 ; Target : 4.7 ; SD : 0.47 (□)

Lab049



Date 06-09 06-16 06-23 06-30 07-07 07-14 07-21 07-28

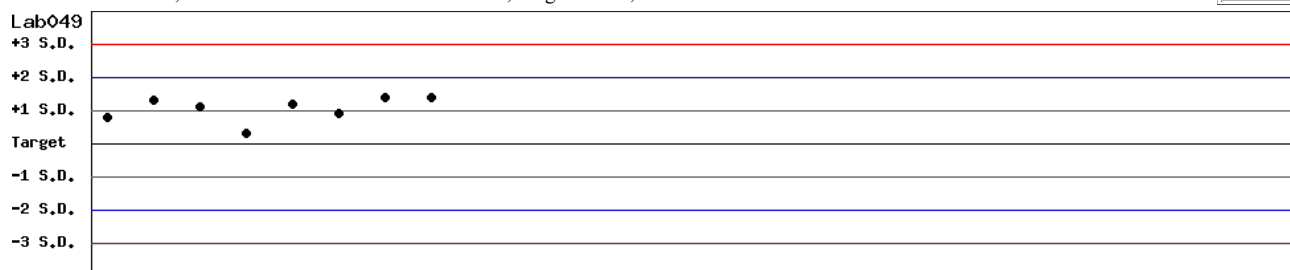
Month : 2021 07 Change ; Cumulative : from 2021 06 09 to 2021 07 31 Change

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## Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-06-09 to 2021-07-31 ; Target : 13.8 ; SD : 1.38

Lab049



Date 06-09 06-16 06-23 06-30 07-07 07-14 07-21 07-28

Month : 2021 07 Change ; Cumulative : from 2021 06 09 to 2021 07 31 Change

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# Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2021-06-09 to 2021-07-31 ; Target : 4.7 ; SD : 0.47

Lab049

Lab049

+3 S.D.

+2 S.D.

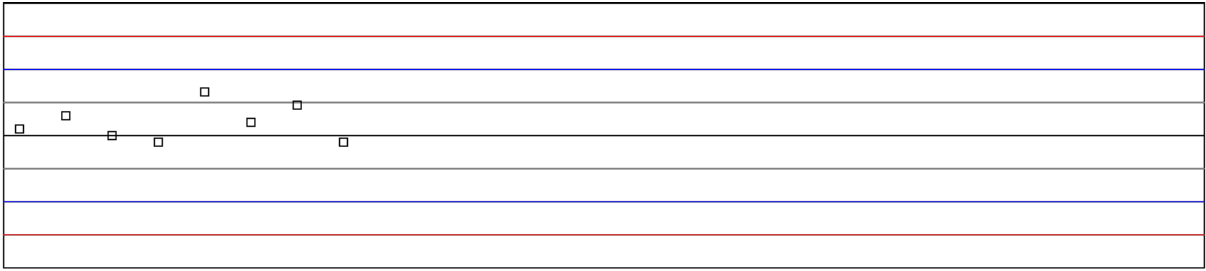
+1 S.D.

Target

-1 S.D.

-2 S.D.

-3 S.D.



Date 06-09 06-16 06-23 06-30 07-07 07-14 07-21 07-28

Month :    ; Cumulative : from    to

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# Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon

## Monthly

Month : 2021  07

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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="#">Lab037</a>	5	13.8	15.1	3	0.6	4.0	17.4	20	2.6	4.7	4.8	3	0.0	0.0	2.1	20	>6
<a href="#">Lab049</a>	5	13.8	15.5	4	0.3	1.9	16.2	20	4.0	4.7	5.0	4	0.3	6.0	18.4	20	2.3
Total	-	-	15.3	7	0.4	2.6	-	-	-	-	4.9	7	0.2	4.1	-	-	-

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  07  31

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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="#">Lab037</a>	5	13.8	15.1	3	0.6	4.0	17.4	20	2.6	4.7	4.8	3	0.0	0.0	2.1	20	>6
<a href="#">Lab049</a>	5	13.8	15.3	8	0.5	3.3	17.4	20	2.8	4.7	4.9	8	0.3	6.1	16.5	20	2.6
Total	-	-	15.2	11	0.5	3.3	-	-	-	-	4.9	11	0.2	4.1	-	-	-

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 (2021/07)								CUM (2021/01/01~2021/07/31)							
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="#">Lab037</a>	5	13.8	15.1	3	0.6	4.0	17.4	20	2.6	13.8	15.1	3	0.6	4.0	17.4	20	2.6
<a href="#">Lab049</a>	5	13.8	15.5	4	0.3	1.9	16.2	20	4.0	13.8	15.3	8	0.5	3.3	17.4	20	2.8
Total	-	-	15.3	7	0.4	2.6	-	-	-	-	15.2	11	0.5	3.3	-	-	-

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

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

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

Month : 2021 07 Change Cumulative : from 2021 01 01 to 2021 07 31 Change

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### Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2021/07)								CUM (2021/01/01~2021/07/31)							
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="#">Lab037</a>	5	4.7	4.8	3	0.0	0.0	2.1	20	>6	4.7	4.8	3	0.0	0.0	2.1	20	>6
<a href="#">Lab049</a>	5	4.7	5.0	4	0.3	6.0	18.4	20	2.3	4.7	4.9	8	0.3	6.1	16.5	20	2.6
Total	-	-	4.9	7	0.2	4.1	-	-	-	-	4.9	11	0.2	4.1	-	-	-

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

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

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

Month : 2021 07 Change Cumulative : from 2021 01 01 to 2021 07 31 Change

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Reagent Kit	Reagent Code
Medicon	5