

# 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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## Lab032

QC Control Lot No.	Control N		Control D	
	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2021/09)	CUM (2021/08/03~2021/09/30)	Month (2021/09)	CUM (2021/08/03~2021/09/30)
Runs (N)	9	18	9	18
Mean (U/gHb)	14.0	14.1	4.4	4.4
SD	0.5	0.4	0.2	0.2
CV (%)	3.6	2.8	4.5	4.5
Target Value (U/gHb)	15.0	15.0	4.7	4.7
Total Error (%)	13.8	11.7	15.5	15.5
TEa (%)	20	20	20	20
$\sigma$	3.7	5.0	3.0	3.0

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

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

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

Month : 2021 09 Change ; Cumulative : from 2021 08 03 to 2021 09 30 Change

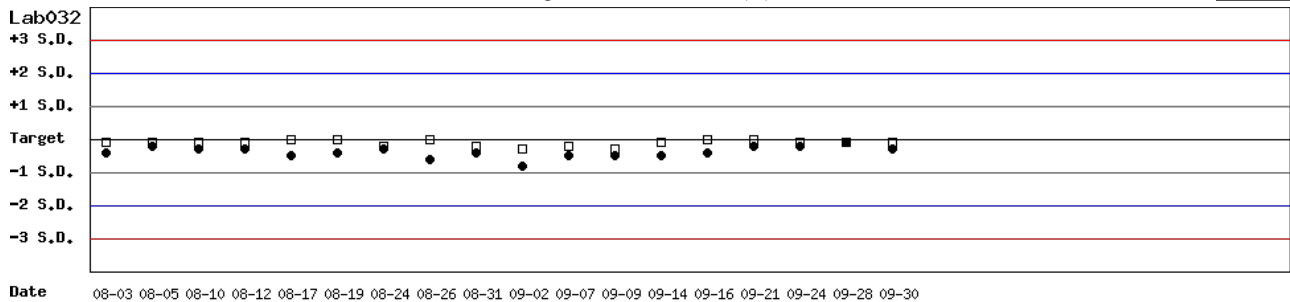
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## Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-08-03 to 2021-09-30 ; Target : 15.0 ; SD : 2.40 (●)

Lot No.: BJ0922D ; Duration : 2021-08-03 to 2021-09-30 ; Target : 4.7 ; SD : 2.30 (□)

Lab032



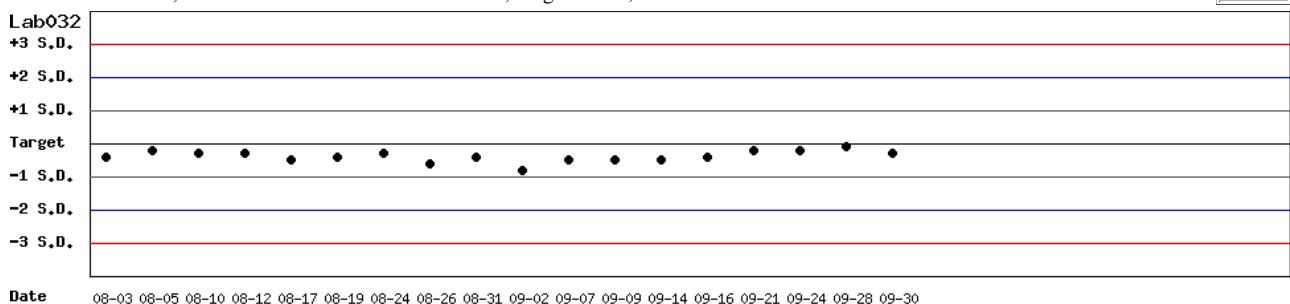
Month : 2021 09 Change ; Cumulative : from 2021 08 03 to 2021 09 30 Change

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## Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2021-08-03 to 2021-09-30 ; Target : 15.0 ; SD : 2.40

Lab032



Month : 2021 09 Change ; Cumulative : from 2021 08 03 to 2021 09 30 Change

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# Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2021-08-03 to 2021-09-30 ; Target : 4.7 ; SD : 2.30

Lab032



Date 08-03 08-05 08-10 08-12 08-17 08-19 08-24 08-26 08-31 09-02 09-07 09-09 09-14 09-16 09-21 09-24 09-28 09-30

Month : 2021 09 Change ; Cumulative : from 2021 08 03 to 2021 09 30 Change

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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  09

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="#">Lab032</a>	5	15.0	14.0	9	0.5	3.6	13.8	20	3.7	4.7	4.4	9	0.2	4.5	15.5	20	3.0
<a href="#">Lab043</a>	5	14.4	12.2	2	-	-	-	20	-	4.6	3.9	2	-	-	-	20	-
<a href="#">Lab049</a>	5	13.8	15.3	5	0.3	2.0	14.8	20	4.6	4.7	4.7	5	0.2	4.3	8.5	20	4.7
Total	-	-	14.2	16	1.1	7.7	-	-	-	-	4.4	16	0.3	6.8	-	-	-

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  09  30

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="#">Lab028</a>	5	13.8	15.2	1	-	-	-	20	-	4.7	4.7	1	-	-	-	20	-
<a href="#">Lab032</a>	5	15.0	14.1	18	0.4	2.8	11.7	20	5.0	4.7	4.4	18	0.2	4.5	15.5	20	3.0
<a href="#">Lab037</a>	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
<a href="#">Lab043</a>	5	14.4	12.2	2	-	-	-	20	-	4.6	3.9	2	-	-	-	20	-
<a href="#">Lab049</a>	5	13.8	15.1	19	0.5	3.3	16.0	20	3.2	4.7	4.8	19	0.2	4.2	10.5	20	4.3
Total	-	-	14.6	44	0.9	6.2	-	-	-	-	4.6	44	0.3	6.5	-	-	-

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

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### Control N Month vs. Cumulative

		Control N (Lot No.: BJ0922N)															
		Month (2021/09)								CUM (2021/01/01~2021/09/30)							
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="#">Lab028</a>	5	13.8	-	0	-	-	-	20	-	13.8	15.2	1	-	-	-	20	-
<a href="#">Lab032</a>	5	15.0	14.0	9	0.5	3.6	13.8	20	3.7	15.0	14.1	18	0.4	2.8	11.7	20	5.0
<a href="#">Lab037</a>	5	13.8	-	0	-	-	-	20	-	13.8	15.1	4	0.5	3.3	16.0	20	3.2
<a href="#">Lab043</a>	5	14.4	12.2	2	-	-	-	20	-	14.4	12.2	2	-	-	-	20	-
<a href="#">Lab049</a>	5	13.8	15.3	5	0.3	2.0	14.8	20	4.6	13.8	15.1	19	0.5	3.3	16.0	20	3.2
<b>Total</b>	-	-	14.2	16	1.1	7.7	-	-	-	-	14.6	44	0.9	6.2	-	-	-

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

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

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

Month : 2021 ▼ 09 ▼ Change      Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2021 ▼ 09 ▼ 30 ▼ Change

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### Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2021/09)								CUM (2021/01/01~2021/09/30)							
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="#">Lab028</a>	5	4.7	-	0	-	-	-	20	-	4.7	4.7	1	-	-	-	20	-
<a href="#">Lab032</a>	5	4.7	4.4	9	0.2	4.5	15.5	20	3.0	4.7	4.4	18	0.2	4.5	15.5	20	3.0
<a href="#">Lab037</a>	5	4.7	-	0	-	-	-	20	-	4.7	4.8	4	0.1	2.1	6.3	20	>6
<a href="#">Lab043</a>	5	4.6	3.9	2	-	-	-	20	-	4.6	3.9	2	-	-	-	20	-
<a href="#">Lab049</a>	5	4.7	4.7	5	0.2	4.3	8.5	20	4.7	4.7	4.8	19	0.2	4.2	10.5	20	4.3
<b>Total</b>	-	-	4.4	16	0.3	6.8	-	-	-	-	4.6	44	0.3	6.5	-	-	-

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

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

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

Month : 2021 ▼ 09 ▼ Change      Cumulative : from 2021 ▼ 01 ▼ 01 ▼ to 2021 ▼ 09 ▼ 30 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5