

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

Select LotNo : BA1116N (2022-04-26 ~ 2100-12-31) Change

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## Lab033

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2024/03)	CUM (2023/10/05~2024/03/30)	Month (2024/03)	CUM (2023/10/05~2024/03/30)
Runs (N)	4	26	4	26
Mean (U/gHb)	16.2	15.8	5.0	4.8
SD	0.1	0.5	0.1	0.3
CV (%)	0.6	3.2	2.0	6.3
Target Value (U/gHb)	15.8	15.8	4.2	4.2
Total Error (%)	3.8	6.3	23.0	26.8
TEa (%)	20	20	20	20
$\sigma$	>6	>6	0.5	0.9

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

Month : 2024 03 Change ; Cumulative : from 2023 10 05 to 2024 03 30 Change

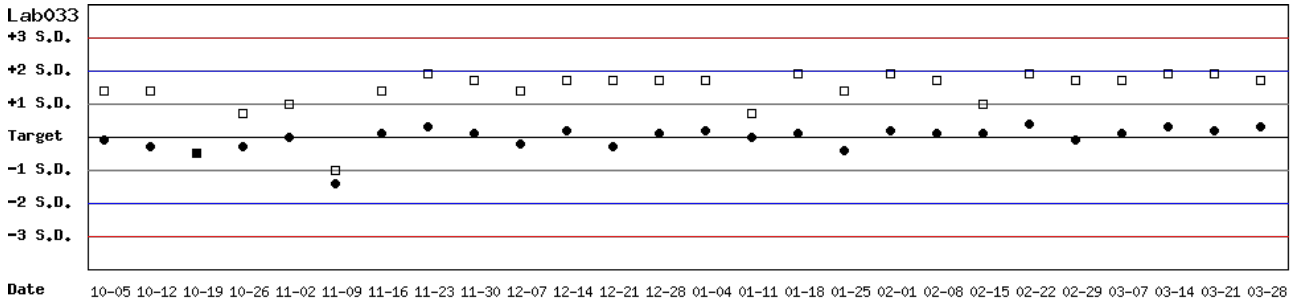
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## Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-10-05 to 2024-03-30 ; Target : 15.8 ; SD : 1.48 (●)

Lot No.: BA1116D ; Duration : 2023-10-05 to 2024-03-30 ; Target : 4.2 ; SD : 0.42 (□)

Lab033



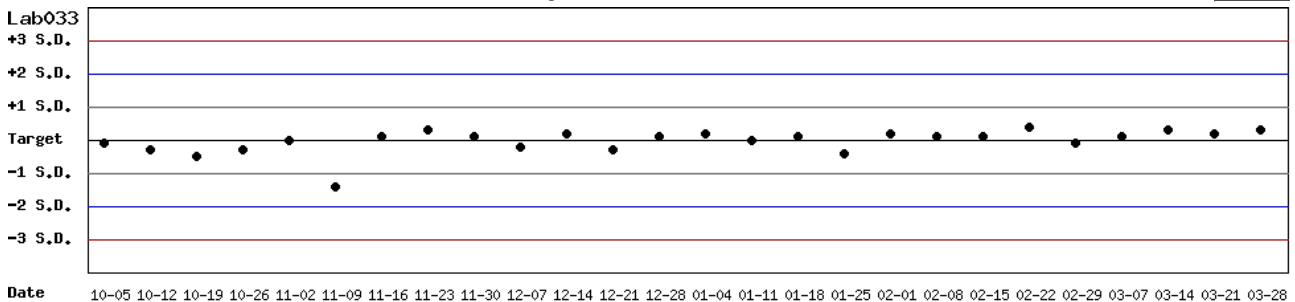
Month : 2024 03 Change ; Cumulative : from 2023 10 05 to 2024 03 30 Change

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## Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-10-05 to 2024-03-30 ; Target : 15.8 ; SD : 1.48

Lab033



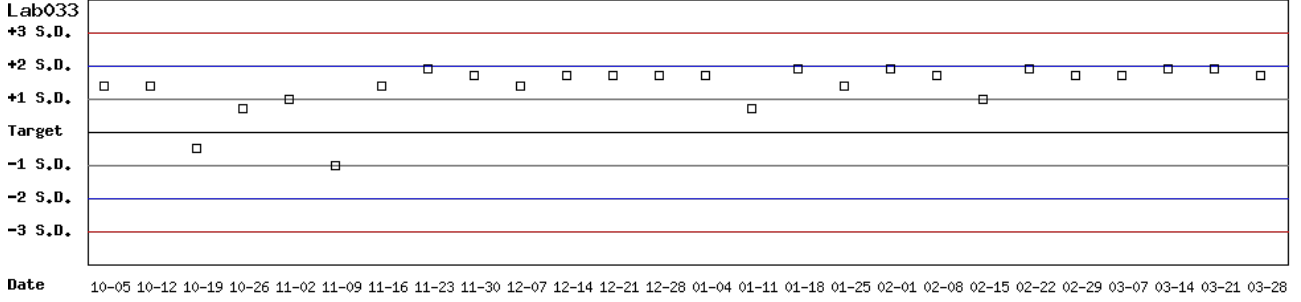
Month : 2024 03 Change ; Cumulative : from 2023 10 05 to 2024 03 30 Change

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## Control D SDI QC Chart

Lab033

Lot No.: BA1116D ; Duration : 2023-10-05 to 2024-03-30 ; Target : 4.2 ; SD : 0.42



Month :    ; Cumulative : from    to

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# Peer Group Statistics (Table 1)

Select LotNo : BA1116N (2022-04-26 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

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## Monthly

Month : 2024 03 Change

UnitID <sup>↑</sup>	Reagent Kit (Code) <sup>↑</sup>	Control N (Lot No.: BA1116N)								Control D (Lot No.: BA1116D)							
		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	14.9	13.9	4	0.1	0.7	8.2	20	>6	5.1	4.3	4	0.2	4.7	25.0	20	0.9
<a href="#">Lab033</a>	5	15.8	16.2	4	0.1	0.6	3.8	20	>6	4.2	5.0	4	0.1	2.0	23.0	20	0.5
<a href="#">Lab037</a>	5	12.8	13.9	2	-	-	-	20	-	4.2	4.6	2	-	-	-	20	-
Total	-	-	14.8	10	1.2	8.1	-	-	-	-	4.6	10	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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## Cumulative

Cumulative : from 2022 06 01 to 2024 03 31 Change

UnitID <sup>↑</sup>	Reagent Kit (Code) <sup>↑</sup>	Control N (Lot No.: BA1116N)								Control D (Lot No.: BA1116D)							
		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="#">Lab018</a>	5	13.6	13.8	113	0.4	2.9	7.3	20	>6	4.3	4.4	113	0.1	2.3	6.9	20	>6
<a href="#">Lab027</a>	5	12.8	14.9	74	0.9	6.0	28.5	20	0.6	4.2	4.9	74	0.4	8.2	33.0	20	0.4
<a href="#">Lab032</a>	5	14.9	13.9	4	0.1	0.7	8.2	20	>6	5.1	4.3	4	0.2	4.7	25.0	20	0.9
<a href="#">Lab033</a>	5	15.8	15.9	35	0.6	3.8	8.2	20	5.1	4.2	4.8	35	0.3	6.3	26.8	20	0.9
<a href="#">Lab037</a>	5	12.8	14.0	14	0.3	2.1	13.7	20	5.1	4.2	4.5	14	0.1	2.2	11.6	20	5.8
Total	-	-	14.5	240	1.0	6.9	-	-	-	-	4.6	240	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 : BA1116N (2022-04-26 ~ 2100-12-31) ▼ Change

Select Reagent Kit : 5 - Medicon ▼ Change

Print Table 2

### Control N Month vs. Cumulative

		Control N (Lot No.: BA1116N)															
		Month (2024/03)								CUM (2022/06/01~2024/03/31)							
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="#">Lab018</a>	5	13.6	-	0	-	-	-	20	-	13.6	13.8	113	0.4	2.9	7.3	20	>6
<a href="#">Lab027</a>	5	12.8	-	0	-	-	-	20	-	12.8	14.9	74	0.9	6.0	28.5	20	0.6
<a href="#">Lab032</a>	5	14.9	13.9	4	0.1	0.7	8.2	20	>6	14.9	13.9	4	0.1	0.7	8.2	20	>6
<a href="#">Lab033</a>	5	15.8	16.2	4	0.1	0.6	3.8	20	>6	15.8	15.9	35	0.6	3.8	8.2	20	5.1
<a href="#">Lab037</a>	5	12.8	13.9	2	-	-	-	20	-	12.8	14.0	14	0.3	2.1	13.7	20	5.1
<b>Total</b>	-	-	14.8	10	1.2	8.1	-	-	-	-	14.5	240	1.0	6.9	-	-	-

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

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

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

Month : 2024 ▼ 03 ▼ Change      Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2024 ▼ 03 ▼ 31 ▼ Change

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### Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2024/03)								CUM (2022/06/01~2024/03/31)							
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="#">Lab018</a>	5	4.3	-	0	-	-	-	20	-	4.3	4.4	113	0.1	2.3	6.9	20	>6
<a href="#">Lab027</a>	5	4.2	-	0	-	-	-	20	-	4.2	4.9	74	0.4	8.2	33.0	20	0.4
<a href="#">Lab032</a>	5	5.1	4.3	4	0.2	4.7	25.0	20	0.9	5.1	4.3	4	0.2	4.7	25.0	20	0.9
<a href="#">Lab033</a>	5	4.2	5.0	4	0.1	2.0	23.0	20	0.5	4.2	4.8	35	0.3	6.3	26.8	20	0.9
<a href="#">Lab037</a>	5	4.2	4.6	2	-	-	-	20	-	4.2	4.5	14	0.1	2.2	11.6	20	5.8
<b>Total</b>	-	-	4.6	10	0.3	6.5	-	-	-	-	4.6	240	0.3	6.5	-	-	-

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

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

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

Month : 2024 ▼ 03 ▼ Change      Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2024 ▼ 03 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5