

# 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 (2024/02)	CUM (2023/09/07~2024/02/29)	Month (2024/02)	CUM (2023/09/07~2024/02/29)
Runs (N)	5	26	5	26
Mean (U/gHb)	16.0	15.7	4.9	4.8
SD	0.3	0.5	0.2	0.3
CV (%)	1.9	3.2	4.1	6.3
Target Value (U/gHb)	15.8	15.8	4.2	4.2
Total Error (%)	5.0	7.0	24.8	26.8
TEa (%)	20	20	20	20
$\sigma$	>6	>6	0.8	0.9

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

Month : 2024 02 Change ; Cumulative : from 2023 09 07 to 2024 02 29 Change

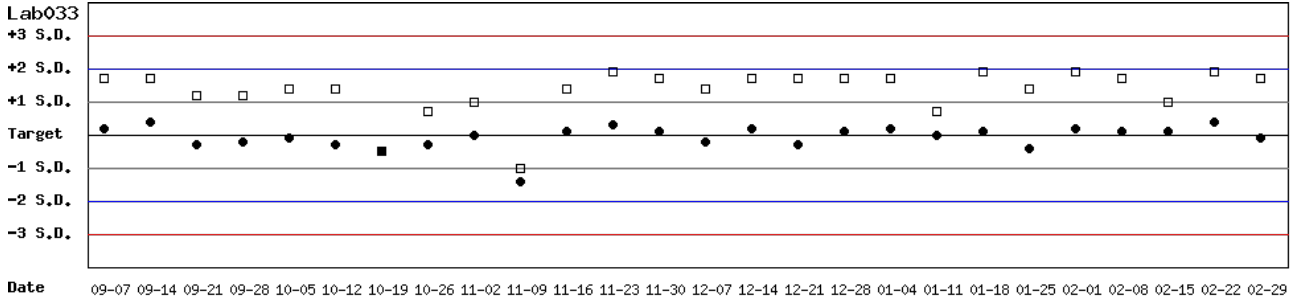
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## Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-09-07 to 2024-02-29 ; Target : 15.8 ; SD : 1.48 (●)

Lot No.: BA1116D ; Duration : 2023-09-07 to 2024-02-29 ; Target : 4.2 ; SD : 0.42 (□)

Lab033



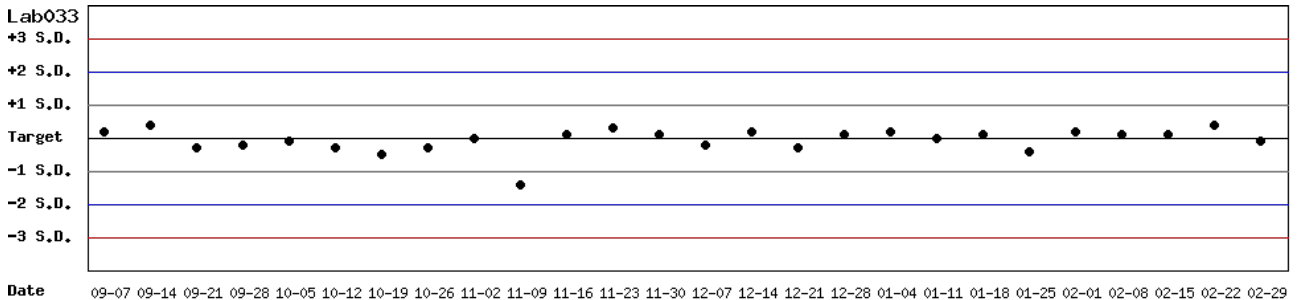
Month : 2024 02 Change ; Cumulative : from 2023 09 07 to 2024 02 29 Change

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## Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-09-07 to 2024-02-29 ; Target : 15.8 ; SD : 1.48

Lab033



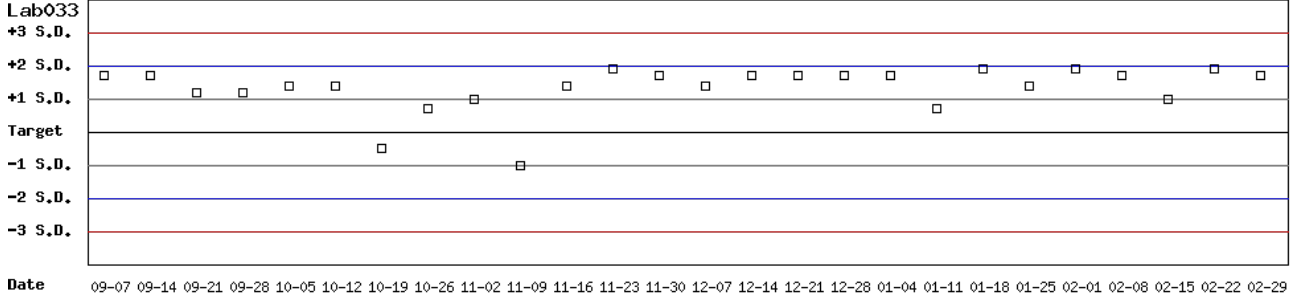
Month : 2024 02 Change ; Cumulative : from 2023 09 07 to 2024 02 29 Change

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## Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2023-09-07 to 2024-02-29 ; Target : 4.2 ; SD : 0.42

Lab033



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 02 Change

UnitID <span>↑</span>	Reagent Kit (Code) <span>↑</span>	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="#">Lab027</a>	5	12.8	14.9	2	-	-	-	20	-	4.2	5.7	2	-	-	-	20	-
<a href="#">Lab033</a>	5	15.8	16.0	5	0.3	1.9	5.0	20	>6	4.2	4.9	5	0.2	4.1	24.8	20	0.8
<a href="#">Lab037</a>	5	12.8	14.1	2	-	-	-	20	-	4.2	4.5	2	-	-	-	20	-
Total	-	-	15.3	9	1.0	6.5	-	-	-	-	5.0	9	0.5	10.0	-	-	-

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 02 29 Change

UnitID <span>↑</span>	Reagent Kit (Code) <span>↑</span>	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="#">Lab033</a>	5	15.8	15.9	31	0.6	3.8	8.2	20	5.1	4.2	4.8	31	0.3	6.3	26.8	20	0.9
<a href="#">Lab037</a>	5	12.8	14.0	12	0.4	2.9	15.1	20	3.7	4.2	4.5	12	0.1	2.2	11.6	20	5.8
Total	-	-	14.4	230	1.0	6.9	-	-	-	-	4.6	230	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 (2024/02)								CUM (2022/06/01~2024/02/29)							
UnitID <span>↑</span>	Reagent Kit (Code) <span>↑</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	14.9	2	-	-	-	20	-	12.8	14.9	74	0.9	6.0	28.5	20	0.6
<a href="#">Lab033</a>	5	15.8	16.0	5	0.3	1.9	5.0	20	>6	15.8	15.9	31	0.6	3.8	8.2	20	5.1
<a href="#">Lab037</a>	5	12.8	14.1	2	-	-	-	20	-	12.8	14.0	12	0.4	2.9	15.1	20	3.7
<b>Total</b>	-	-	15.3	9	1.0	6.5	-	-	-	-	14.4	230	1.0	6.9	-	-	-

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

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

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

Month : 2024 02 Change Cumulative : from 2022 06 01 to 2024 02 29 Change

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### Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2024/02)								CUM (2022/06/01~2024/02/29)							
UnitID <span>↑</span>	Reagent Kit (Code) <span>↑</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	5.7	2	-	-	-	20	-	4.2	4.9	74	0.4	8.2	33.0	20	0.4
<a href="#">Lab033</a>	5	4.2	4.9	5	0.2	4.1	24.8	20	0.8	4.2	4.8	31	0.3	6.3	26.8	20	0.9
<a href="#">Lab037</a>	5	4.2	4.5	2	-	-	-	20	-	4.2	4.5	12	0.1	2.2	11.6	20	5.8
<b>Total</b>	-	-	5.0	9	0.5	10.0	-	-	-	-	4.6	230	0.3	6.5	-	-	-

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

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

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

Month : 2024 02 Change Cumulative : from 2022 06 01 to 2024 02 29 Change

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Reagent Kit	Reagent Code
Medicon	5