

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

Select LotNo : BD0728N (2024-08-20 ~ 2100-12-31) Change

Print Table

Lab033

	Control N		Control D	
QC Control Lot No.	BD0728N		BD0728D	
Duration of the Analyzing	Month (2025/11)	CUM (2025/06/05~2025/11/27)	Month (2025/11)	CUM (2025/06/05~2025/11/27)
Runs (N)	4	26	4	26
Mean (U/gHb)	15.4	15.0	4.9	4.7
SD	0.4	0.5	0.2	0.2
CV (%)	2.6	3.3	4.1	4.3
Target Value (U/gHb)	15.1	15.1	4.6	4.6
Total Error (%)	7.2	7.3	14.7	10.7
TEa (%)	20	20	20	20
σ	>6	5.9	3.3	4.1

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

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

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

Month : 2025 11 Change ; Cumulative : from 2025 06 05 to 2025 11 27 Change

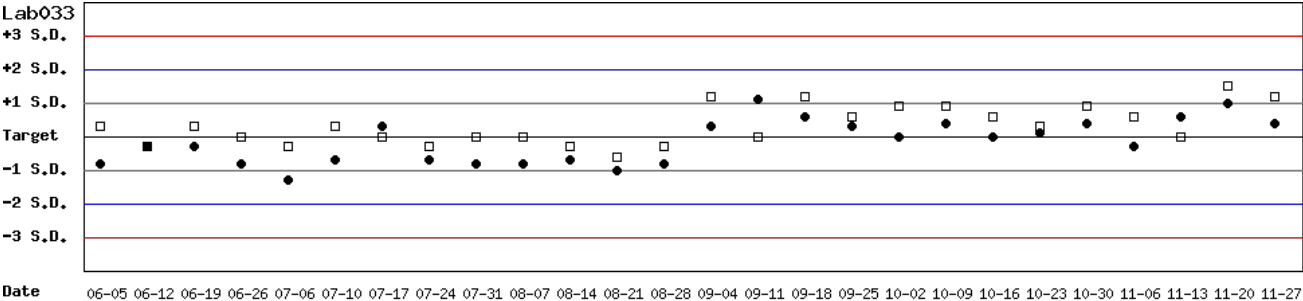
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Control N and Control D SDI
QC Chart

Lot No.: BD0728N ; Duration : 2025-06-05 to 2025-11-27 ; Target : 15.1 ; SD : 0.71 (●)

Lot No.: BD0728D ; Duration : 2025-06-05 to 2025-11-27 ; Target : 4.6 ; SD : 0.33 (□)

Lab033

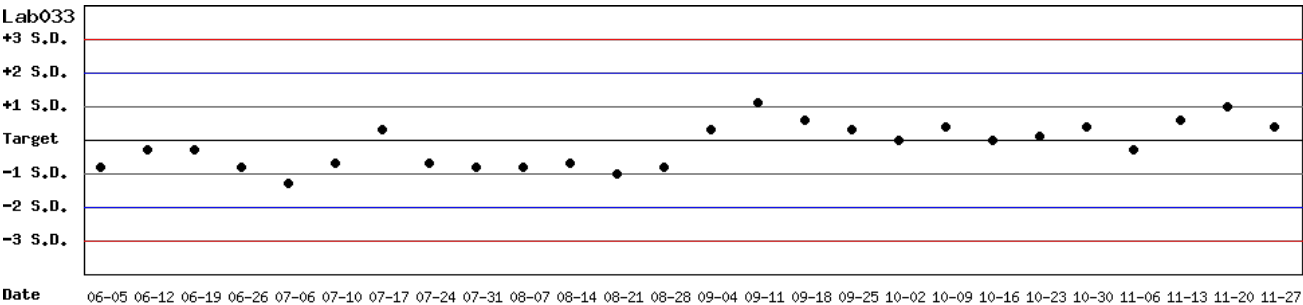


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Control N SDI QC Chart

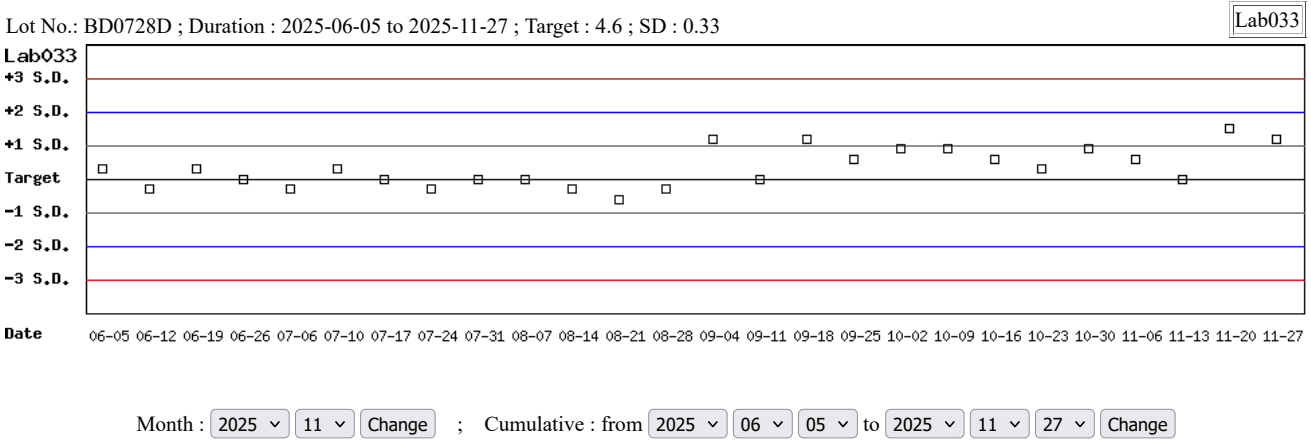
Lot No.: BD0728N ; Duration : 2025-06-05 to 2025-11-27 ; Target : 15.1 ; SD : 0.71

Lab033



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Control D SDI QC Chart



Peer Group Statistics (Table 1)

Select LotNo :

BD0728N (2024-08-20 ~ 2100-12-31)

Change

Select Reagent Kit :

5 - Medicon

Change

Print Table 1

Monthly

Month :

2025

11

Change

		Control N (Lot No.: BD0728N)									Control D (Lot No.: BD0728D)							
UnitID	Reagent Kit (Code)	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
Lab033	5	15.1	15.4	4	0.4	2.6	7.2	20	>6		4.6	4.9	4	0.2	4.1	14.7	20	3.3
Lab052	5	14.9	15.0	1	-	-	-	20	-		4.6	4.5	1	-	-	-	20	-
Total	-	-	15.3	5	0.4	2.6	-	-	-		-	4.8	5	0.3	6.3	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%
TE : Total Error(%) = Bias (%) + 2 × CV (%)
σ (Sigma) = [TEa% - Bias (%)] / CV (%)

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Cumulative

Cumulative : from

2024

09

01

 to

2025

11

30

Change

		Control N (Lot No.: BD0728N)									Control D (Lot No.: BD0728D)							
UnitID	Reagent Kit (Code)	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
Lab033	5	15.1	15.0	36	0.5	3.3	7.3	20	5.9		4.6	4.7	36	0.2	4.3	10.7	20	4.1
Lab040	5	14.9	15.1	15	0.3	2.0	5.3	20	>6		4.8	4.8	15	0.1	2.1	4.2	20	>6
Lab052	5	14.9	15.0	29	0.4	2.7	6.0	20	>6		4.6	4.6	29	0.1	2.2	4.3	20	>6
Total	-	-	15.0	80	0.4	2.7	-	-	-		-	4.7	80	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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Reagent Kit	Reagent Code
Medicon	5

Peer Group Statistics (Table 2)

Select LotNo : BD0728N (2024-08-20 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 2

Control N Month vs. Cumulative

		Control N (Lot No.: BD0728N)															
		Month (2025/11)								CUM (2024/09/01~2025/11/30)							
UnitID	Reagent Kit (Code)	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
Lab033	5	15.1	15.4	4	0.4	2.6	7.2	20	>6	15.1	15.0	36	0.5	3.3	7.3	20	5.9
Lab040	5	14.9	-	0	-	-	-	20	-	14.9	15.1	15	0.3	2.0	5.3	20	>6
Lab052	5	14.9	15.0	1	-	-	-	20	-	14.9	15.0	29	0.4	2.7	6.0	20	>6
Total	-	-	15.3	5	0.4	2.6	-	-	-	-	15.0	80	0.4	2.7	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%
TE : Total Error(%) = Bias (%) + 2 × CV (%)
σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2025 11 Change Cumulative : from 2024 09 01 to 2025 11 30 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BD0728D)															
		Month (2025/11)								CUM (2024/09/01~2025/11/30)							
UnitID	Reagent Kit (Code)	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
Lab033	5	4.6	4.9	4	0.2	4.1	14.7	20	3.3	4.6	4.7	36	0.2	4.3	10.7	20	4.1
Lab040	5	4.8	-	0	-	-	-	20	-	4.8	4.8	15	0.1	2.1	4.2	20	>6
Lab052	5	4.6	4.5	1	-	-	-	20	-	4.6	4.6	29	0.1	2.2	4.3	20	>6
Total	-	-	4.8	5	0.3	6.3	-	-	-	-	4.7	80	0.2	4.3	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%
TE : Total Error(%) = Bias (%) + 2 × CV (%)
σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2025 11 Change Cumulative : from 2024 09 01 to 2025 11 30 Change

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Reagent Kit	Reagent Code
Medicon	5