

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

Select LotNo :

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

Change

Print Table

Lab033

QC Control Lot No.	Control N		Control D	
	BD0728N		BD0728D	
	Month (2025/12)	CUM (2025/06/26~2025/12/31)	Month (2025/12)	CUM (2025/06/26~2025/12/31)
Runs (N)	3	26	3	26
Mean (U/gHb)	15.2	15.0	4.9	4.7
SD	0.3	0.5	0.1	0.2
CV (%)	2.0	3.3	2.0	4.3
Target Value (U/gHb)	15.1	15.1	4.6	4.6
Total Error (%)	4.6	7.3	10.6	10.7
TEa (%)	20	20	20	20
σ	>6	5.9	>6	4.1

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

Month :

2025

12

Change

 ; Cumulative : from

2025

06

26

 to

2025

12

31

Change

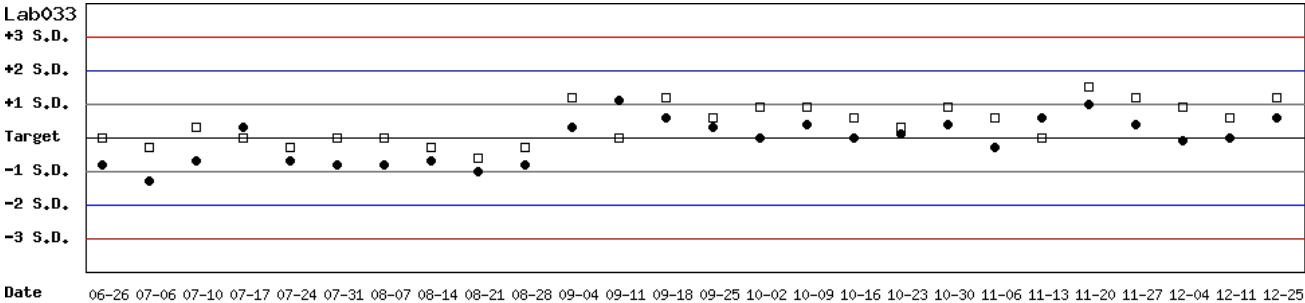
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Control N and Control D SDI
QC Chart

Lot No.: BD0728N ; Duration : 2025-06-26 to 2025-12-31 ; Target : 15.1 ; SD : 0.71 (●)

Lot No.: BD0728D ; Duration : 2025-06-26 to 2025-12-31 ; Target : 4.6 ; SD : 0.33 (□)

Lab033

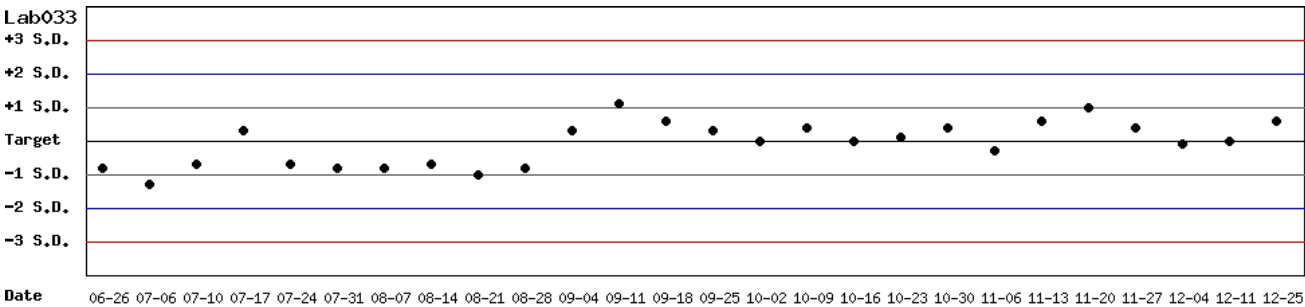


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Control N SDI QC Chart

Lot No.: BD0728N ; Duration : 2025-06-26 to 2025-12-31 ; Target : 15.1 ; SD : 0.71

Lab033

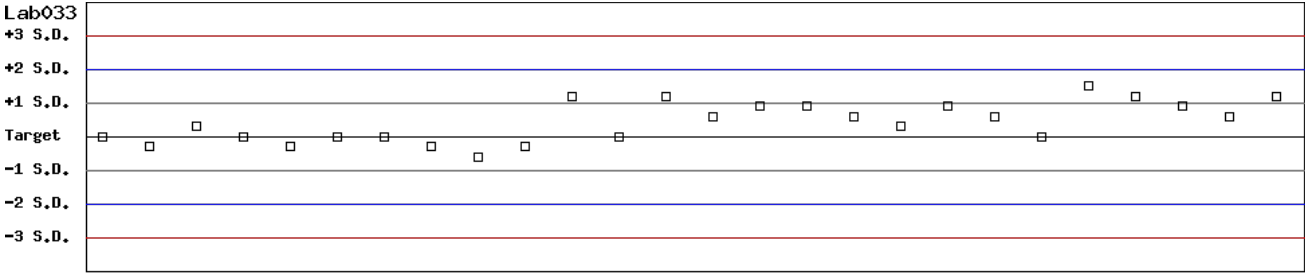


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Control D SDI QC Chart

Lot No.: BD0728D ; Duration : 2025-06-26 to 2025-12-31 ; Target : 4.6 ; SD : 0.33

Lab033



Date 06-26 07-06 07-10 07-17 07-24 07-31 08-07 08-14 08-21 08-28 09-04 09-11 09-18 09-25 10-02 10-09 10-16 10-23 10-30 11-06 11-13 11-20 11-27 12-04 12-11 12-25

Month : 2025 12 Change ; Cumulative : from 2025 06 26 to 2025 12 31 Change

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 12 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	15.2	3	0.3	2.0	4.6	20	>6	4.6	4.9	3	0.1	2.0	10.6	20	>6
Lab040	5	14.9	14.8	5	0.2	1.4	3.4	20	>6	4.8	4.7	5	0.1	2.1	6.3	20	>6
Total	-	-	15.0	8	0.3	2.0	-	-	-	-	4.8	8	0.1	2.1	-	-	-

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

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Cumulative

Cumulative : from 2024 09 01 to 2025 12 31 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	39	0.5	3.3	7.3	20	5.9	4.6	4.7	39	0.2	4.3	10.7	20	4.1
Lab040	5	14.9	15.0	20	0.3	2.0	4.7	20	>6	4.8	4.8	20	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	88	0.4	2.7	-	-	-	-	4.7	88	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 (2025/12)								CUM (2024/09/01~2025/12/31)							
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	15.2	3	0.3	2.0	4.6	20	>6	15.1	15.0	39	0.5	3.3	7.3	20	5.9
Lab040	5	14.9	14.8	5	0.2	1.4	3.4	20	>6	14.9	15.0	20	0.3	2.0	4.7	20	>6
Lab052	5	14.9	-	0	-	-	-	20	-	14.9	15.0	29	0.4	2.7	6.0	20	>6
Total	-	-	15.0	8	0.3	2.0	-	-	-	-	15.0	88	0.4	2.7	-	-	-

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

Month : 2025 12 Change Cumulative : from 2024 09 01 to 2025 12 31 Change

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Control D Month vs.
Cumulative

		Control D (Lot No.: BD0728D)															
		Month (2025/12)								CUM (2024/09/01~2025/12/31)							
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	3	0.1	2.0	10.6	20	>6	4.6	4.7	39	0.2	4.3	10.7	20	4.1
Lab040	5	4.8	4.7	5	0.1	2.1	6.3	20	>6	4.8	4.8	20	0.1	2.1	4.2	20	>6
Lab052	5	4.6	-	0	-	-	-	20	-	4.6	4.6	29	0.1	2.2	4.3	20	>6
Total	-	-	4.8	8	0.1	2.1	-	-	-	-	4.7	88	0.2	4.3	-	-	-

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

Month : 2025 12 Change Cumulative : from 2024 09 01 to 2025 12 31 Change

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Reagent Kit	Reagent Code
Medicon	5