

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 (2025/08)	CUM (2025/03/20~2025/08/29)	Month (2025/08)	CUM (2025/03/20~2025/08/29)
Runs (N)	4	23	4	23
Mean (U/gHb)	14.5	14.8	4.5	4.6
SD	0.1	0.4	0.1	0.2
CV (%)	0.7	2.7	2.2	4.3
Target Value (U/gHb)	15.1	15.1	4.6	4.6
Total Error (%)	5.4	7.4	6.6	8.7
TEa (%)	20	20	20	20
σ	>6	>6	>6	4.7

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

Month : 2025 08 Change ; Cumulative : from 2025 03 20 to 2025 08 29 Change

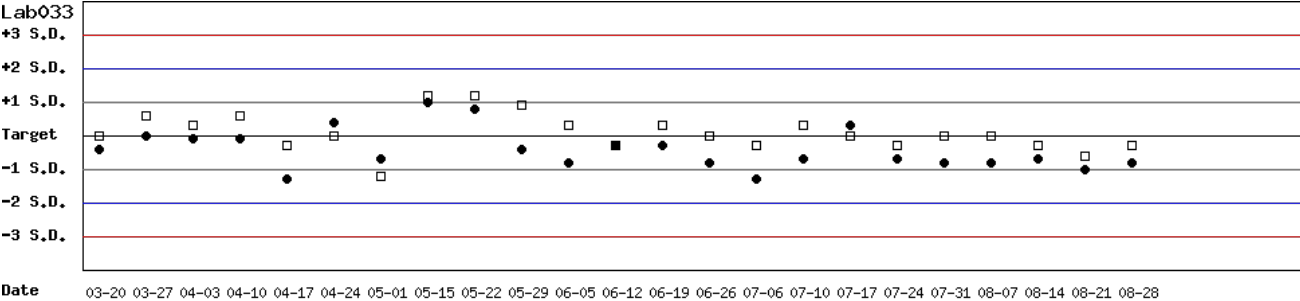
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Control N and Control D SDI
QC Chart

Lot No.: BD0728N ; Duration : 2025-03-20 to 2025-08-29 ; Target : 15.1 ; SD : 0.71 (●)

Lot No.: BD0728D ; Duration : 2025-03-20 to 2025-08-29 ; Target : 4.6 ; SD : 0.33 (□)

Lab033



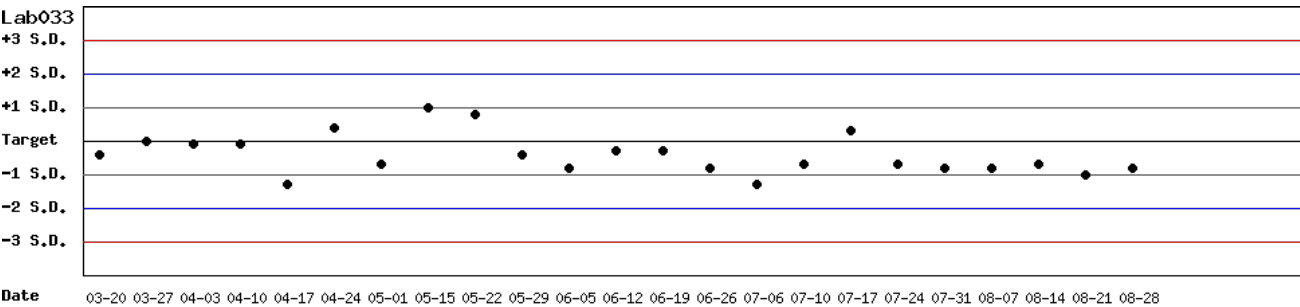
Month : 2025 08 Change ; Cumulative : from 2025 03 20 to 2025 08 29 Change

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Control N SDI QC Chart

Lot No.: BD0728N ; Duration : 2025-03-20 to 2025-08-29 ; Target : 15.1 ; SD : 0.71

Lab033



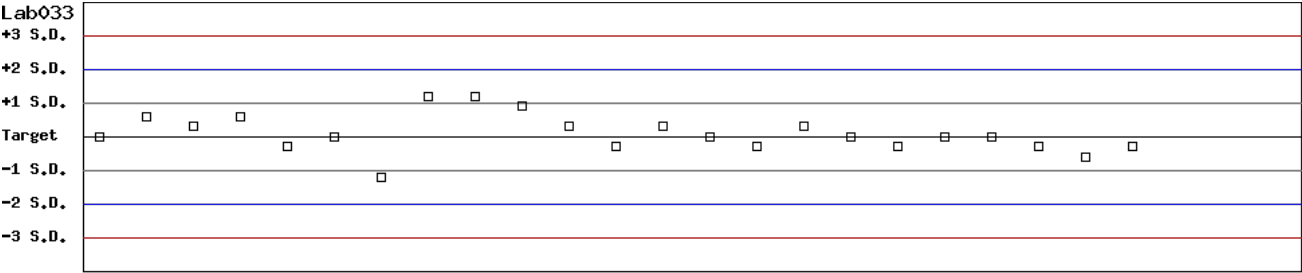
Month : 2025 08 Change ; Cumulative : from 2025 03 20 to 2025 08 29 Change

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Control D SDI QC Chart

Lot No.: BD0728D ; Duration : 2025-03-20 to 2025-08-29 ; Target : 4.6 ; SD : 0.33

Lab033



Date

03-2003-2704-0304-1004-1704-2405-0105-1505-2205-2906-0506-1206-1906-2607-0607-1007-1707-2407-3108-0708-1408-2108-28

Month :

2025

08

Change

;

Cumulative : from

2025

03

20

to

2025

08

29

Change

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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 08 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	14.5	4	0.1	0.7	5.4	20	>6	4.6	4.5	4	0.1	2.2	6.6	20	>6
Lab040	5	14.9	15.2	6	0.3	2.0	6.0	20	>6	4.8	4.8	6	0.2	4.2	8.3	20	4.8
Lab052	5	14.9	15.3	4	0.3	2.0	6.6	20	>6	4.6	4.6	4	0.1	2.2	4.3	20	>6
Total	-	-	15.0	14	0.4	2.7	-	-	-	-	4.7	14	0.2	4.3	-	-	-

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

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Cumulative

Cumulative : from 2024 09 01 to 2025 08 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	14.8	23	0.4	2.7	7.4	20	>6	4.6	4.6	23	0.2	4.3	8.7	20	4.7
Lab040	5	14.9	15.2	6	0.3	2.0	6.0	20	>6	4.8	4.8	6	0.2	4.2	8.3	20	4.8
Lab052	5	14.9	14.9	20	0.4	2.7	5.4	20	>6	4.6	4.6	20	0.1	2.2	4.3	20	>6
Total	-	-	14.9	49	0.4	2.7	-	-	-	-	4.6	49	0.2	4.3	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%
TE : Total Error(%) = Bias (%) + 2 x 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 (2025/08)								CUM (2024/09/01~2025/08/31)							
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	14.5	4	0.1	0.7	5.4	20	>6	15.1	14.8	23	0.4	2.7	7.4	20	>6
Lab040	5	14.9	15.2	6	0.3	2.0	6.0	20	>6	14.9	15.2	6	0.3	2.0	6.0	20	>6
Lab052	5	14.9	15.3	4	0.3	2.0	6.6	20	>6	14.9	14.9	20	0.4	2.7	5.4	20	>6
Total	-	-	15.0	14	0.4	2.7	-	-	-	-	14.9	49	0.4	2.7	-	-	-

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

Month : 2025 08 Change Cumulative : from 2024 09 01 to 2025 08 31 Change

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Control D Month vs.
Cumulative

		Control D (Lot No.: BD0728D)															
		Month (2025/08)								CUM (2024/09/01~2025/08/31)							
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	4.5	4	0.1	2.2	6.6	20	>6	4.6	4.6	23	0.2	4.3	8.7	20	4.7
Lab040	5	4.8	4.8	6	0.2	4.2	8.3	20	4.8	4.8	4.8	6	0.2	4.2	8.3	20	4.8
Lab052	5	4.6	4.6	4	0.1	2.2	4.3	20	>6	4.6	4.6	20	0.1	2.2	4.3	20	>6
Total	-	-	4.7	14	0.2	4.3	-	-	-	-	4.6	49	0.2	4.3	-	-	-

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

Month : 2025 08 Change Cumulative : from 2024 09 01 to 2025 08 31 Change

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Reagent Kit	Reagent Code
Medicon	5