

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 (2025/07)	CUM (2025/03/20~2025/07/31)	Month (2025/07)	CUM (2025/03/20~2025/07/31)
Runs (N)	5	19	5	19
Mean (U/gHb)	14.6	14.9	4.6	4.7
SD	0.4	0.5	0.1	0.2
CV (%)	2.7	3.4	2.2	4.3
Target Value (U/gHb)	15.1	15.1	4.6	4.6
Total Error (%)	8.8	8.0	4.3	10.7
TEa (%)	20	20	20	20
σ	>6	5.5	>6	4.1

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

Month : 2025 07 Change ; Cumulative : from 2025 03 20 to 2025 07 31 Change

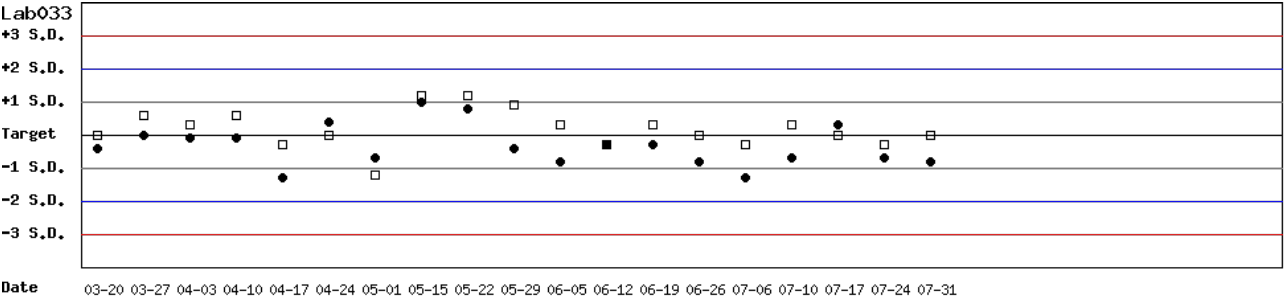
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Control N and Control D SDI
QC Chart

Lot No.: BD0728N ; Duration : 2025-03-20 to 2025-07-31 ; Target : 15.1 ; SD : 0.71 (●)

Lot No.: BD0728D ; Duration : 2025-03-20 to 2025-07-31 ; Target : 4.6 ; SD : 0.33 (□)

Lab033



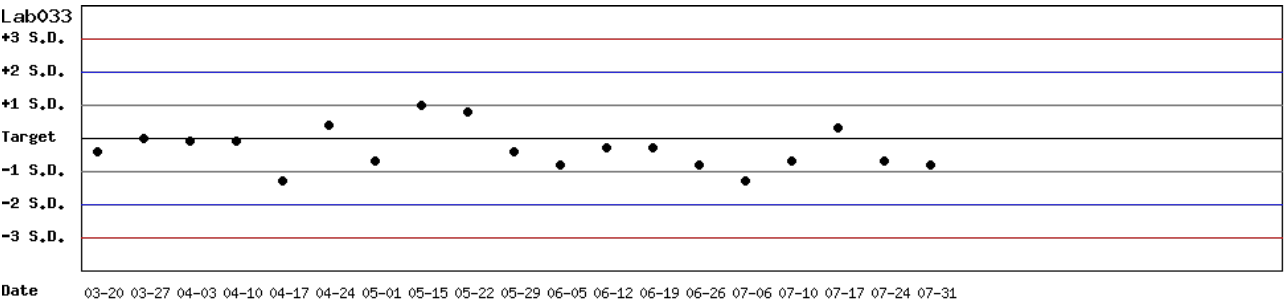
Month : 2025 07 Change ; Cumulative : from 2025 03 20 to 2025 07 31 Change

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Control N SDI QC Chart

Lot No.: BD0728N ; Duration : 2025-03-20 to 2025-07-31 ; Target : 15.1 ; SD : 0.71

Lab033



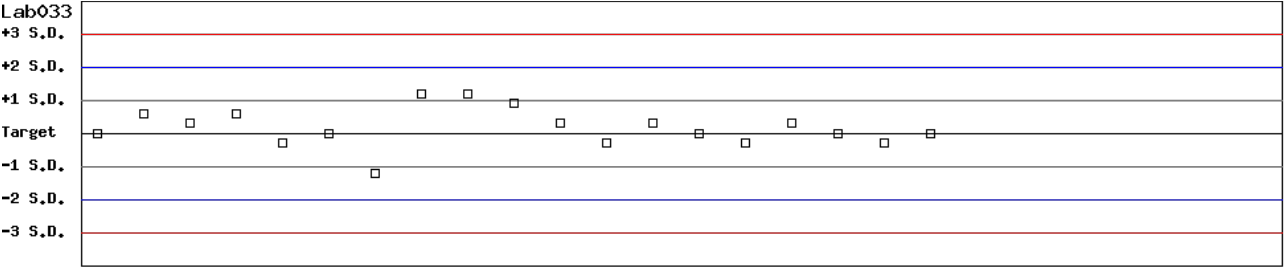
Month : 2025 07 Change ; Cumulative : from 2025 03 20 to 2025 07 31 Change

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Control D SDI QC Chart

Lot No.: BD0728D ; Duration : 2025-03-20 to 2025-07-31 ; Target : 4.6 ; SD : 0.33

Lab033



Date 03-20 03-27 04-03 04-10 04-17 04-24 05-01 05-15 05-22 05-29 06-05 06-12 06-19 06-26 07-06 07-10 07-17 07-24 07-31

Month : 2025 07 Change ; Cumulative : from 2025 03 20 to 2025 07 31 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 07 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	14.6	5	0.4	2.7	8.8	20	>6		4.6	4.6	5	0.1	2.2	4.3	20	>6
Lab052	5	14.9	14.6	5	0.2	1.4	4.8	20	>6		4.6	4.6	5	0.1	2.2	4.3	20	>6
Total	-	-	14.6	10	0.3	2.1	-	-	-		-	4.6	10	0.1	2.2	-	-	-

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 07 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	14.9	19	0.5	3.4	8.0	20	5.5		4.6	4.7	19	0.2	4.3	10.7	20	4.1
Lab052	5	14.9	14.8	16	0.3	2.0	4.7	20	>6		4.6	4.6	16	0.1	2.2	4.3	20	>6
Total	-	-	14.8	35	0.4	2.7	-	-	-		-	4.6	35	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 (2025/07)										CUM (2024/09/01~2025/07/31)							
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	14.6	5	0.4	2.7	8.8	20	>6	15.1	14.9	19	0.5	3.4	8.0	20	5.5
Lab052	5	14.9	14.6	5	0.2	1.4	4.8	20	>6	14.9	14.8	16	0.3	2.0	4.7	20	>6
Total	-	-	14.6	10	0.3	2.1	-	-	-	-	14.8	35	0.4	2.7	-	-	-

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

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

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

Month : 2025 07 Change Cumulative : from 2024 09 01 to 2025 07 31 Change

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Control D Month vs.
Cumulative

Control D (Lot No.: BD0728D)																	
Month (2025/07)										CUM (2024/09/01~2025/07/31)							
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	4.6	5	0.1	2.2	4.3	20	>6	4.6	4.7	19	0.2	4.3	10.7	20	4.1
Lab052	5	4.6	4.6	5	0.1	2.2	4.3	20	>6	4.6	4.6	16	0.1	2.2	4.3	20	>6
Total	-	-	4.6	10	0.1	2.2	-	-	-	-	4.6	35	0.2	4.3	-	-	-

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

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

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

Month : 2025 07 Change Cumulative : from 2024 09 01 to 2025 07 31 Change

[TOP]

Reagent Kit	Reagent Code
Medicon	5