

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

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

Print Table

Lab040

	Control N		Control D	
QC Control Lot No.	BD0728N		BD0728D	
Duration of the Analyzing	Month (2025/10)	CUM (2025/08/01~2025/10/30)	Month (2025/10)	CUM (2025/08/01~2025/10/30)
Runs (N)	5	15	5	15
Mean (U/gHb)	14.8	15.1	4.7	4.8
SD	0.1	0.3	0.1	0.1
CV (%)	0.7	2.0	2.1	2.1
Target Value (U/gHb)	14.9	14.9	4.8	4.8
Total Error (%)	2.0	5.3	6.3	4.2
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

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

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

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

Month : 2025 10 Change ; Cumulative : from 2025 08 01 to 2025 10 30 Change

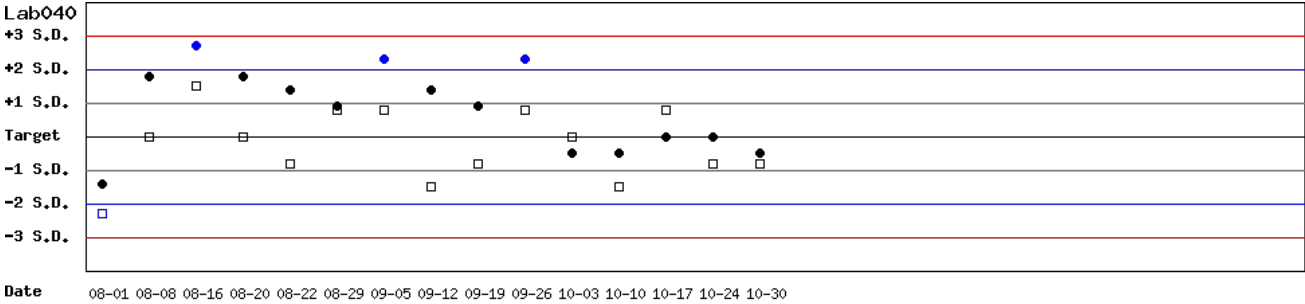
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Control N and Control D SDI
QC Chart

Lot No.: BD0728N ; Duration : 2025-08-01 to 2025-10-30 ; Target : 14.9 ; SD : 0.22 (●)

Lot No.: BD0728D ; Duration : 2025-08-01 to 2025-10-30 ; Target : 4.8 ; SD : 0.13 (□)

Lab040



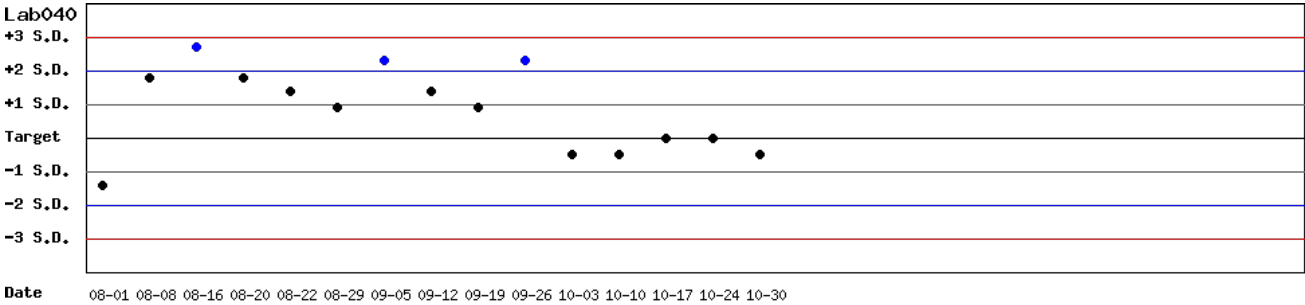
Month : 2025 10 Change ; Cumulative : from 2025 08 01 to 2025 10 30 Change

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Control N SDI QC Chart

Lot No.: BD0728N ; Duration : 2025-08-01 to 2025-10-30 ; Target : 14.9 ; SD : 0.22

Lab040



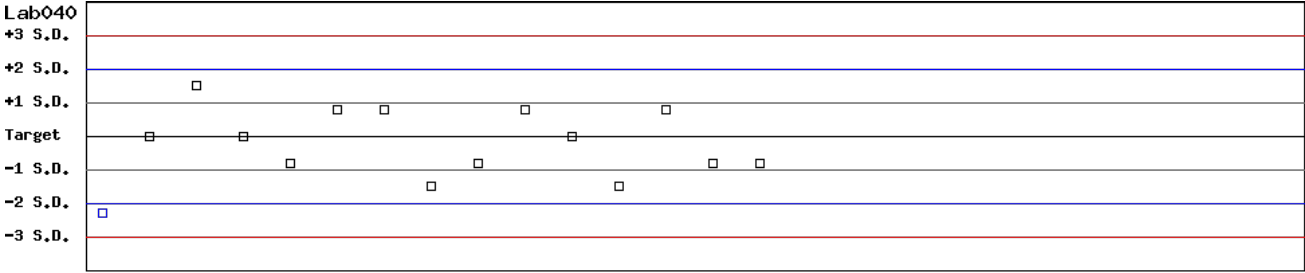
Month : 2025 10 Change ; Cumulative : from 2025 08 01 to 2025 10 30 Change

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Control D SDI QC Chart

Lot No.: BD0728D ; Duration : 2025-08-01 to 2025-10-30 ; Target : 4.8 ; SD : 0.13

Lab040



Date 08-01 08-08 08-16 08-20 08-22 08-29 09-05 09-12 09-19 09-26 10-03 10-10 10-17 10-24 10-30

Month : 2025 10 Change ; Cumulative : from 2025 08 01 to 2025 10 30 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 10 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	5	0.2	1.3	3.3	20	>6		4.6	4.8	5	0.1	2.1	8.5	20	>6
Lab040	5	14.9	14.8	5	0.1	0.7	2.0	20	>6		4.8	4.7	5	0.1	2.1	6.3	20	>6
Lab052	5	14.9	15.2	4	0.2	1.3	4.6	20	>6		4.6	4.5	4	0.1	2.2	6.6	20	>6
Total	-	-	15.1	14	0.2	1.3	-	-	-		-	4.7	14	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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Cumulative

Cumulative : from 2024 09 01 to 2025 10 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	32	0.5	3.3	7.3	20	5.9		4.6	4.7	32	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	28	0.4	2.7	6.0	20	>6		4.6	4.6	28	0.1	2.2	4.3	20	>6
Total	-	-	15.0	75	0.4	2.7	-	-	-		-	4.7	75	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 (2025/10)								CUM (2024/09/01~2025/10/31)							
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	5	0.2	1.3	3.3	20	>6	15.1	15.0	32	0.5	3.3	7.3	20	5.9
Lab040	5	14.9	14.8	5	0.1	0.7	2.0	20	>6	14.9	15.1	15	0.3	2.0	5.3	20	>6
Lab052	5	14.9	15.2	4	0.2	1.3	4.6	20	>6	14.9	15.0	28	0.4	2.7	6.0	20	>6
Total	-	-	15.1	14	0.2	1.3	-	-	-	-	15.0	75	0.4	2.7	-	-	-

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

Month : 2025 10 Change Cumulative : from 2024 09 01 to 2025 10 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BD0728D)															
		Month (2025/10)								CUM (2024/09/01~2025/10/31)							
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	4.8	5	0.1	2.1	8.5	20	>6	4.6	4.7	32	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	15	0.1	2.1	4.2	20	>6
Lab052	5	4.6	4.5	4	0.1	2.2	6.6	20	>6	4.6	4.6	28	0.1	2.2	4.3	20	>6
Total	-	-	4.7	14	0.2	4.3	-	-	-	-	4.7	75	0.2	4.3	-	-	-

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

Month : 2025 10 Change Cumulative : from 2024 09 01 to 2025 10 31 Change

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Reagent Kit	Reagent Code
Medicon	5