

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

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

Print Table

Lab052

	Control N		Control D	
QC Control Lot No.	BD0728N		BD0728D	
Duration of the Analyzing	Month (2025/06)	CUM (2025/03/13~2025/06/30)	Month (2025/06)	CUM (2025/03/13~2025/06/30)
Runs (N)	4	11	4	11
Mean (U/gHb)	15.0	14.9	4.7	4.6
SD	0.2	0.3	0.1	0.1
CV (%)	1.3	2.0	2.1	2.2
Target Value (U/gHb)	14.9	14.9	4.6	4.6
Total Error (%)	3.3	4.0	6.4	4.3
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 06 Change ; Cumulative : from 2025 03 13 to 2025 06 30 Change

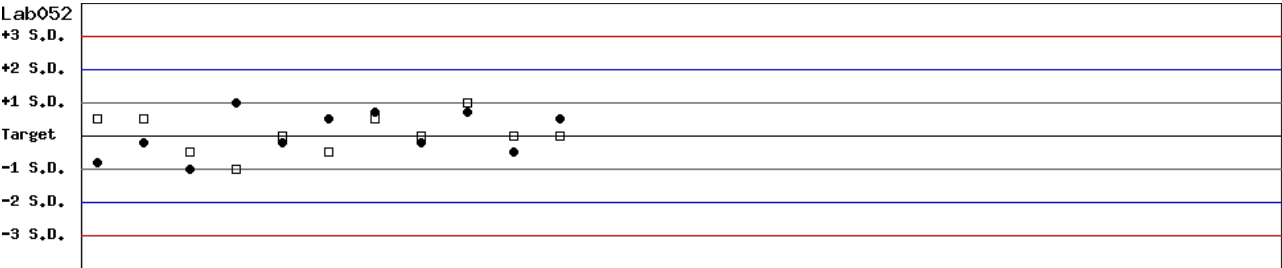
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Control N and Control D SDI
QC Chart

Lot No.: BD0728N ; Duration : 2025-03-13 to 2025-06-30 ; Target : 14.9 ; SD : 0.40 (●)

Lot No.: BD0728D ; Duration : 2025-03-13 to 2025-06-30 ; Target : 4.6 ; SD : 0.20 (□)

Lab052



Date 03-13 05-06 05-15 05-19 05-20 05-21 05-29 06-05 06-07 06-19 06-26

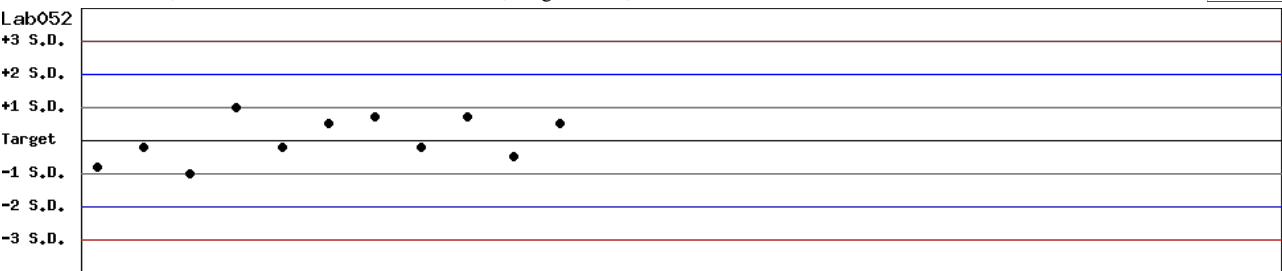
Month : 2025 06 Change ; Cumulative : from 2025 03 13 to 2025 06 30 Change

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Control N SDI QC Chart

Lot No.: BD0728N ; Duration : 2025-03-13 to 2025-06-30 ; Target : 14.9 ; SD : 0.40

Lab052

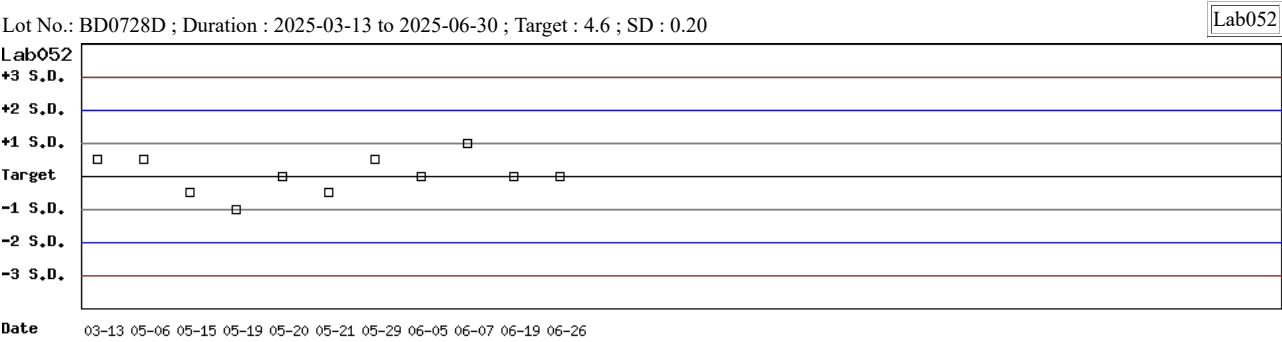


Date 03-13 05-06 05-15 05-19 05-20 05-21 05-29 06-05 06-07 06-19 06-26

Month : 2025 06 Change ; Cumulative : from 2025 03 13 to 2025 06 30 Change

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Control D SDI QC Chart



Month : 2025 06 Change ; Cumulative : from 2025 03 13 to 2025 06 30 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 06 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	14.7	4	0.2	1.4	5.4	20	>6		4.6	4.6	4	0.1	2.2	4.3	20	>6
Lab052	5	14.9	15.0	4	0.2	1.3	3.3	20	>6		4.6	4.7	4	0.1	2.1	6.4	20	>6
Total	-	-	14.8	8	0.3	2.0	-	-	-		-	4.6	8	0.1	2.2	-	-	-

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 06 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	14.9	14	0.5	3.4	8.0	20	5.5		4.6	4.7	14	0.2	4.3	10.7	20	4.1
Lab052	5	14.9	14.9	11	0.3	2.0	4.0	20	>6		4.6	4.6	11	0.1	2.2	4.3	20	>6
Total	-	-	14.9	25	0.4	2.7	-	-	-		-	4.7	25	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 (2025/06)										CUM (2024/09/01~2025/06/30)							
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	14.7	4	0.2	1.4	5.4	20	>6	15.1	14.9	14	0.5	3.4	8.0	20	5.5
Lab052	5	14.9	15.0	4	0.2	1.3	3.3	20	>6	14.9	14.9	11	0.3	2.0	4.0	20	>6
Total	-	-	14.8	8	0.3	2.0	-	-	-	-	14.9	25	0.4	2.7	-	-	-

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

Month : 2025 06 Change Cumulative : from 2024 09 01 to 2025 06 30 Change

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Control D Month vs.
Cumulative

Control D (Lot No.: BD0728D)																	
Month (2025/06)										CUM (2024/09/01~2025/06/30)							
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	4.6	4	0.1	2.2	4.3	20	>6	4.6	4.7	14	0.2	4.3	10.7	20	4.1
Lab052	5	4.6	4.7	4	0.1	2.1	6.4	20	>6	4.6	4.6	11	0.1	2.2	4.3	20	>6
Total	-	-	4.6	8	0.1	2.2	-	-	-	-	4.7	25	0.2	4.3	-	-	-

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

Month : 2025 06 Change Cumulative : from 2024 09 01 to 2025 06 30 Change

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Reagent Kit	Reagent Code
Medicon	5