

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

Select LotNo : BE0116N (2025-02-12 ~ 2100-12-31) Change

Print Table

Lab019

QC Control Lot No.	Control N		Control D	
	BE0116N		BE0116D	
	Month (2025/12)	CUM (2025/08/20~2025/12/31)	Month (2025/12)	CUM (2025/08/20~2025/12/31)
Runs (N)	4	18	4	18
Mean (U/gHb)	13.5	13.5	4.8	4.9
SD	0.1	0.2	0.1	0.1
CV (%)	0.7	1.5	2.1	2.0
Target Value (U/gHb)	13.5	13.5	4.9	4.9
Total Error (%)	1.5	3.0	6.2	4.1
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 12 Change ; Cumulative : from 2025 08 20 to 2025 12 31 Change

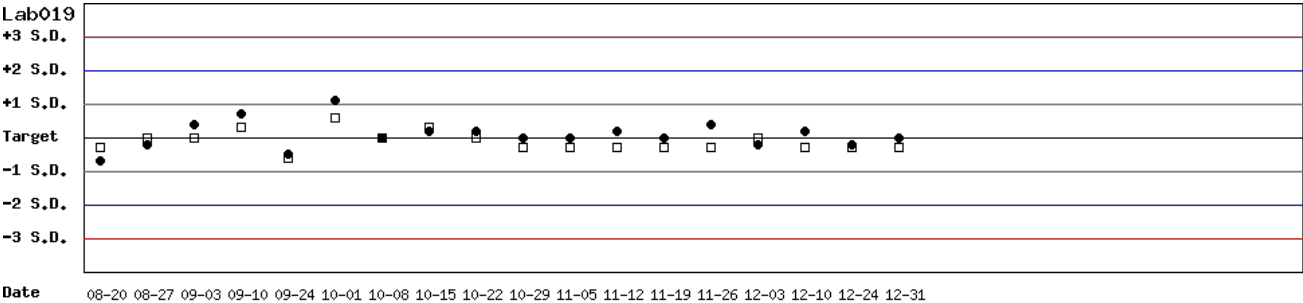
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Control N and Control D SDI
QC Chart

Lot No.: BE0116N ; Duration : 2025-08-20 to 2025-12-31 ; Target : 13.5 ; SD : 0.56 (●)

Lot No.: BE0116D ; Duration : 2025-08-20 to 2025-12-31 ; Target : 4.9 ; SD : 0.32 (□)

Lab019

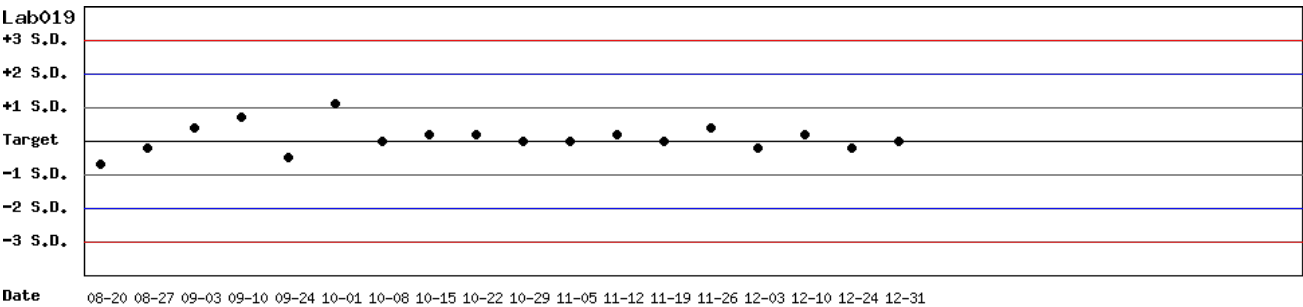


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Control N SDI QC Chart

Lot No.: BE0116N ; Duration : 2025-08-20 to 2025-12-31 ; Target : 13.5 ; SD : 0.56

Lab019

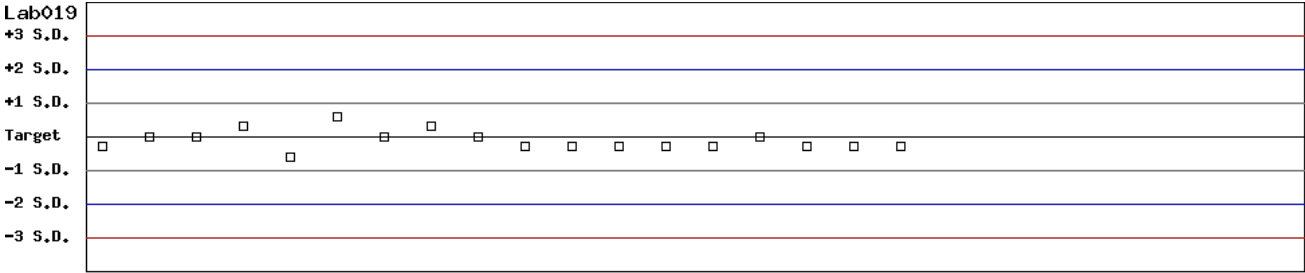


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Control D SDI QC Chart

Lot No.: BE0116D ; Duration : 2025-08-20 to 2025-12-31 ; Target : 4.9 ; SD : 0.32

Lab019



Date

08-2008-2709-0309-1009-2410-0110-0810-1510-2210-2911-0511-1211-1911-2612-0312-1012-2412-31

Month :

2025

12

Change

;

Cumulative : from

2025

08

20

to

2025

12

31

Change

Peer Group Statistics (Table 1)

Select LotNo : BE0116N (2025-02-12 ~ 2100-12-31) ▼ Change

Select Reagent Kit : 5 - Medicon ▼ Change

[Print Table 1](#)

Monthly

Month : 2025 ▼ 12 ▼ Change

		Control N (Lot No.: BE0116N)									Control D (Lot No.: BE0116D)							
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
Lab018	5	15.3	14.4	8	0.1	0.7	7.3	20	>6		4.7	5.0	8	0.1	2.0	10.4	20	>6
Lab019	5	13.5	13.5	4	0.1	0.7	1.5	20	>6		4.9	4.8	4	0.1	2.1	6.2	20	>6
Lab052	5	13.5	13.4	4	0.3	2.2	5.2	20	>6		4.9	4.7	4	0.2	4.3	12.6	20	3.7
Total	-	-	13.9	16	0.5	3.6	-	-	-		-	4.9	16	0.2	4.1	-	-	-

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from 2025 ▼ 04 ▼ 01 ▼ to 2025 ▼ 12 ▼ 31 ▼ Change

		Control N (Lot No.: BE0116N)									Control D (Lot No.: BE0116D)							
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
Lab018	5	15.3	14.3	16	0.2	1.4	9.3	20	>6		4.7	5.1	16	0.1	2.0	12.4	20	5.7
Lab019	5	13.5	13.5	18	0.2	1.5	3.0	20	>6		4.9	4.9	18	0.1	2.0	4.1	20	>6
Lab052	5	13.5	13.4	4	0.3	2.2	5.2	20	>6		4.9	4.7	4	0.2	4.3	12.6	20	3.7
Total	-	-	13.9	38	0.5	3.6	-	-	-		-	4.9	38	0.2	4.1	-	-	-

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 : BE0116N (2025-02-12 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 2

Control N Month vs.
Cumulative

Control N (Lot No.: BE0116N)																	
Month (2025/12)										CUM (2025/04/01~2025/12/31)							
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
Lab018	5	15.3	14.4	8	0.1	0.7	7.3	20	>6	15.3	14.3	16	0.2	1.4	9.3	20	>6
Lab019	5	13.5	13.5	4	0.1	0.7	1.5	20	>6	13.5	13.5	18	0.2	1.5	3.0	20	>6
Lab052	5	13.5	13.4	4	0.3	2.2	5.2	20	>6	13.5	13.4	4	0.3	2.2	5.2	20	>6
Total	-	-	13.9	16	0.5	3.6	-	-	-	-	13.9	38	0.5	3.6	-	-	-

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

Month : 2025 12 Change Cumulative : from 2025 04 01 to 2025 12 31 Change

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Control D Month vs.
Cumulative

Control D (Lot No.: BE0116D)																	
Month (2025/12)										CUM (2025/04/01~2025/12/31)							
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
Lab018	5	4.7	5.0	8	0.1	2.0	10.4	20	>6	4.7	5.1	16	0.1	2.0	12.4	20	5.7
Lab019	5	4.9	4.8	4	0.1	2.1	6.2	20	>6	4.9	4.9	18	0.1	2.0	4.1	20	>6
Lab052	5	4.9	4.7	4	0.2	4.3	12.6	20	3.7	4.9	4.7	4	0.2	4.3	12.6	20	3.7
Total	-	-	4.9	16	0.2	4.1	-	-	-	-	4.9	38	0.2	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 04 01 to 2025 12 31 Change

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Reagent Kit	Reagent Code
Medicon	5