

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

Select LotNo : BA1116N (2022-04-26 ~ 2100-12-31) Change

Print Table

Lab037

	Control N		Control D	
QC Control Lot No.	BA1116N		BA1116D	
Duration of the Analyzing	Month (2025/11)	CUM (2024/09/27~2025/11/28)	Month (2025/11)	CUM (2024/09/27~2025/11/28)
Runs (N)	4	26	4	26
Mean (U/gHb)	13.5	13.7	4.6	4.4
SD	0.3	0.3	0.2	0.2
CV (%)	2.2	2.2	4.3	4.5
Target Value (U/gHb)	12.8	12.8	4.2	4.2
Total Error (%)	9.9	11.4	18.2	13.9
TEa (%)	20	20	20	20
σ	>6	5.9	2.4	3.4

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

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

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

Month : 2025 11 Change ; Cumulative : from 2024 09 27 to 2025 11 28 Change

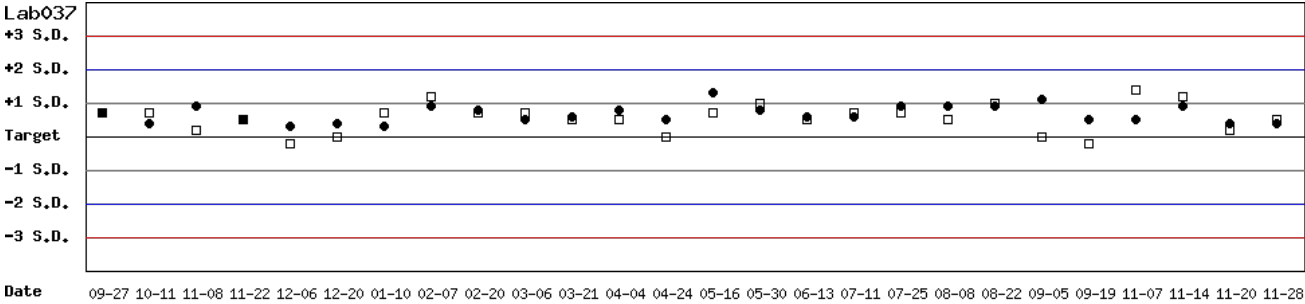
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Control N and Control D SDI
QC Chart

Lot No.: BA1116N ; Duration : 2024-09-27 to 2025-11-28 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: BA1116D ; Duration : 2024-09-27 to 2025-11-28 ; Target : 4.2 ; SD : 0.42 (□)

Lab037

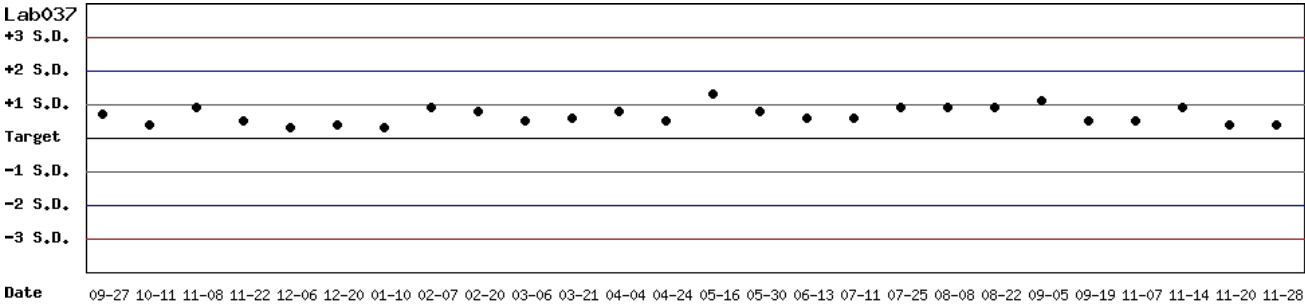


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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2024-09-27 to 2025-11-28 ; Target : 12.8 ; SD : 1.28

Lab037



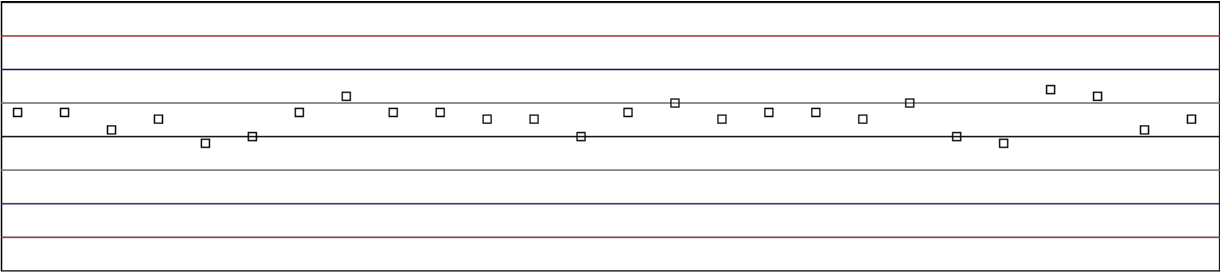
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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2024-09-27 to 2025-11-28 ; Target : 4.2 ; SD : 0.42

Lab037

Lab037
+3 S.D.
+2 S.D.
+1 S.D.
Target
-1 S.D.
-2 S.D.
-3 S.D.



Date 09-27 10-11 11-08 11-22 12-06 12-20 01-10 02-07 02-20 03-06 03-21 04-04 04-24 05-16 05-30 06-13 07-11 07-25 08-08 08-22 09-05 09-19 11-07 11-14 11-20 11-28

Month : 2025 ▾ 11 ▾ Change ; Cumulative : from 2024 ▾ 09 ▾ 27 ▾ to 2025 ▾ 11 ▾ 28 ▾ Change

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Peer Group Statistics (Table 1)

Select LotNo : BA1116N (2022-04-26 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

[Print Table 1](#)

Monthly

Month : 2025 11 Change

		Control N (Lot No.: BA1116N)									Control D (Lot No.: BA1116D)							
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
Lab037	5	12.8	13.5	4	0.3	2.2	9.9	20	>6		4.2	4.6	4	0.2	4.3	18.2	20	2.4
Total	-	-	13.5	4	0.3	2.2	-	-	-		-	4.6	4	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 2022 06 01 to 2025 11 30 Change

		Control N (Lot No.: BA1116N)									Control D (Lot No.: BA1116D)							
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	13.6	13.9	147	0.3	2.2	6.5	20	>6		4.3	4.4	147	0.1	2.3	6.9	20	>6
Lab027	5	12.8	14.9	74	0.9	6.0	28.5	20	0.6		4.2	4.9	74	0.4	8.2	33.0	20	0.4
Lab032	5	14.9	13.8	39	0.4	2.9	13.2	20	4.4		5.1	4.3	39	0.2	4.7	25.0	20	0.9
Lab033	5	15.8	15.7	85	0.6	3.8	8.3	20	5.1		4.7	4.8	85	0.2	4.2	10.5	20	4.3
Lab037	5	12.8	13.8	52	0.4	2.9	13.6	20	4.2		4.2	4.4	52	0.2	4.5	13.9	20	3.4
Lab052	5	15.3	15.3	15	0.3	2.0	3.9	20	>6		4.6	4.7	15	0.2	4.3	10.7	20	4.1
Total	-	-	14.5	416	0.9	6.2	-	-	-		-	4.6	416	0.3	6.5	-	-	-

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 : BA1116N (2022-04-26 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 2

Control N Month vs. Cumulative

Control N (Lot No.: BA1116N)																	
Month (2025/11)										CUM (2022/06/01~2025/11/30)							
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
Lab018	5	13.6	-	0	-	-	-	20	-	13.6	13.9	147	0.3	2.2	6.5	20	>6
Lab027	5	12.8	-	0	-	-	-	20	-	12.8	14.9	74	0.9	6.0	28.5	20	0.6
Lab032	5	14.9	-	0	-	-	-	20	-	14.9	13.8	39	0.4	2.9	13.2	20	4.4
Lab033	5	15.8	-	0	-	-	-	20	-	15.8	15.7	85	0.6	3.8	8.3	20	5.1
Lab037	5	12.8	13.5	4	0.3	2.2	9.9	20	>6	12.8	13.8	52	0.4	2.9	13.6	20	4.2
Lab052	5	15.3	-	0	-	-	-	20	-	15.3	15.3	15	0.3	2.0	3.9	20	>6
Total	-	-	13.5	4	0.3	2.2	-	-	-	-	14.5	416	0.9	6.2	-	-	-

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

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

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

Month : 2025 11 Change Cumulative : from 2022 06 01 to 2025 11 30 Change

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Control D Month vs. Cumulative

Control D (Lot No.: BA1116D)																	
Month (2025/11)										CUM (2022/06/01~2025/11/30)							
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
Lab018	5	4.3	-	0	-	-	-	20	-	4.3	4.4	147	0.1	2.3	6.9	20	>6
Lab027	5	4.2	-	0	-	-	-	20	-	4.2	4.9	74	0.4	8.2	33.0	20	0.4
Lab032	5	5.1	-	0	-	-	-	20	-	5.1	4.3	39	0.2	4.7	25.0	20	0.9
Lab033	5	4.7	-	0	-	-	-	20	-	4.7	4.8	85	0.2	4.2	10.5	20	4.3
Lab037	5	4.2	4.6	4	0.2	4.3	18.2	20	2.4	4.2	4.4	52	0.2	4.5	13.9	20	3.4
Lab052	5	4.6	-	0	-	-	-	20	-	4.6	4.7	15	0.2	4.3	10.7	20	4.1
Total	-	-	4.6	4	0.2	4.3	-	-	-	-	4.6	416	0.3	6.5	-	-	-

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

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

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

Month : 2025 11 Change Cumulative : from 2022 06 01 to 2025 11 30 Change

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Reagent Kit	Reagent Code
Medicon	5