

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

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

Print Table

Lab033

	Control N		Control D	
QC Control Lot No.	BA1116N		BA1116D	
Duration of the Analyzing	Month (2025/02)	CUM (2024/09/01~2025/02/28)	Month (2025/02)	CUM (2024/09/01~2025/02/28)
Runs (N)	4	26	4	26
Mean (U/gHb)	15.0	15.4	4.6	4.7
SD	0.4	0.5	0.1	0.2
CV (%)	2.7	3.2	2.2	4.3
Target Value (U/gHb)	15.8	15.8	4.7	4.7
Total Error (%)	10.4	9.0	6.5	8.5
TEa (%)	20	20	20	20
σ	5.5	5.5	>6	4.7

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

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

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

Month : 2025 02 Change ; Cumulative : from 2024 09 01 to 2025 02 28 Change

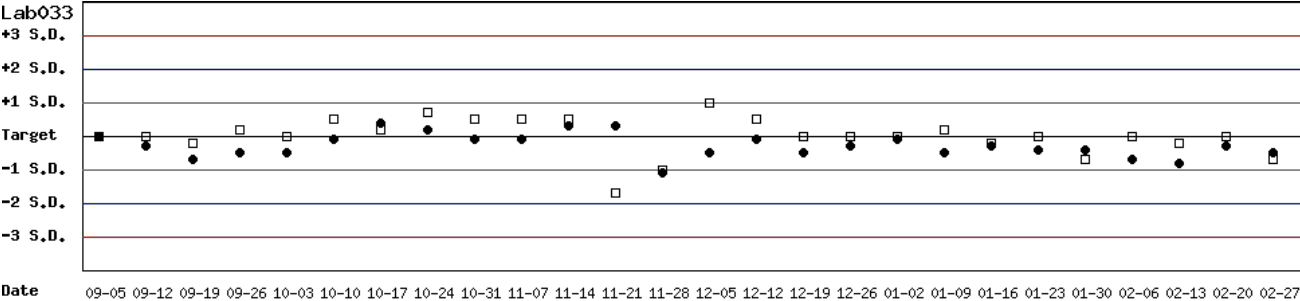
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Control N and Control D SDI
QC Chart

Lot No.: BA1116N ; Duration : 2024-09-01 to 2025-02-28 ; Target : 15.8 ; SD : 1.48 (●)

Lot No.: BA1116D ; Duration : 2024-09-01 to 2025-02-28 ; Target : 4.7 ; SD : 0.42 (□)

Lab033



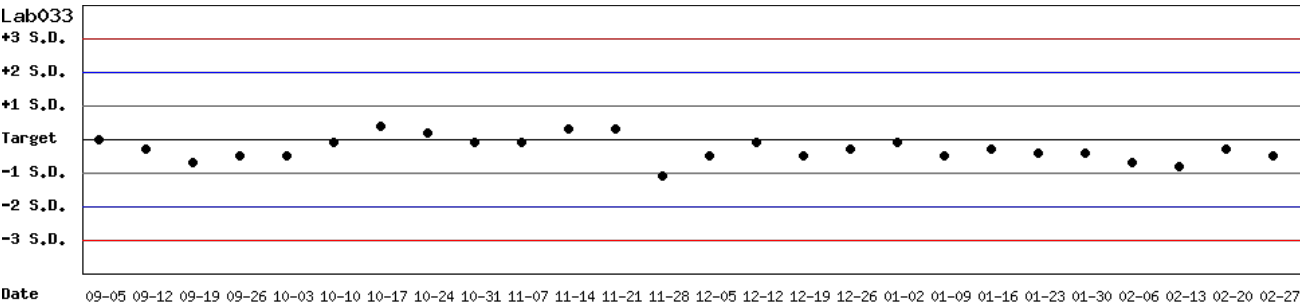
Month : 2025 02 Change ; Cumulative : from 2024 09 01 to 2025 02 28 Change

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2024-09-01 to 2025-02-28 ; Target : 15.8 ; SD : 1.48

Lab033



Month : 2025 02 Change ; Cumulative : from 2024 09 01 to 2025 02 28 Change

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Control D SDI QC Chart

Lab033

Lot No.: BA1116D ; Duration : 2024-09-01 to 2025-02-28 ; Target : 4.7 ; SD : 0.42

Lab033

+3 S.D.

+2 S.D.

+1 S.D.

Target

-1 S.D.

-2 S.D.

-3 S.D.

Date

09-05 09-12 09-19 09-26 10-03 10-10 10-17 10-24 10-31 11-07 11-14 11-21 11-28 12-05 12-12 12-19 12-26 01-02 01-09 01-16 01-23 01-30 02-06 02-13 02-20 02-27

Month : 2025 02 Change ; Cumulative : from 2024 09 01 to 2025 02 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 02 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
Lab032	5	14.9	14.3	4	0.1	0.7	5.4	20	>6		5.1	4.4	4	0.1	2.3	18.3	20	2.7
Lab033	5	15.8	15.0	4	0.4	2.7	10.4	20	5.5		4.7	4.6	4	0.1	2.2	6.5	20	>6
Lab037	5	12.8	13.9	2	-	-	-	20	-		4.2	4.6	2	-	-	-	20	-
Lab052	5	15.3	15.3	5	0.5	3.3	6.5	20	>6		4.6	4.7	5	0.2	4.3	10.7	20	4.1
Total	-	-	14.7	15	0.6	4.1	-	-	-		-	4.6	15	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 02 28 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	13.8	139	0.4	2.9	7.3	20	>6		4.3	4.4	139	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	26	0.4	2.9	13.2	20	4.4		5.1	4.3	26	0.2	4.7	25.0	20	0.9
Lab033	5	15.8	15.7	83	0.6	3.8	8.3	20	5.1		4.7	4.8	83	0.2	4.2	10.5	20	4.3
Lab037	5	12.8	13.8	35	0.4	2.9	13.6	20	4.2		4.2	4.4	35	0.2	4.5	13.9	20	3.4
Lab052	5	15.3	15.4	14	0.3	1.9	4.5	20	>6		4.6	4.7	14	0.2	4.3	10.7	20	4.1
Total	-	-	14.5	375	1.0	6.9	-	-	-		-	4.6	375	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 (2025/02)										CUM (2022/06/01~2025/02/28)							
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	13.8	139	0.4	2.9	7.3	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	14.3	4	0.1	0.7	5.4	20	>6	14.9	13.8	26	0.4	2.9	13.2	20	4.4
Lab033	5	15.8	15.0	4	0.4	2.7	10.4	20	5.5	15.8	15.7	83	0.6	3.8	8.3	20	5.1
Lab037	5	12.8	13.9	2	-	-	-	20	-	12.8	13.8	35	0.4	2.9	13.6	20	4.2
Lab052	5	15.3	15.3	5	0.5	3.3	6.5	20	>6	15.3	15.4	14	0.3	1.9	4.5	20	>6
Total	-	-	14.7	15	0.6	4.1	-	-	-	-	14.5	375	1.0	6.9	-	-	-

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

Month : 2025 02 Change Cumulative : from 2022 06 01 to 2025 02 28 Change

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Control D Month vs. Cumulative

Control D (Lot No.: BA1116D)																	
Month (2025/02)										CUM (2022/06/01~2025/02/28)							
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	139	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	4.4	4	0.1	2.3	18.3	20	2.7	5.1	4.3	26	0.2	4.7	25.0	20	0.9
Lab033	5	4.7	4.6	4	0.1	2.2	6.5	20	>6	4.7	4.8	83	0.2	4.2	10.5	20	4.3
Lab037	5	4.2	4.6	2	-	-	-	20	-	4.2	4.4	35	0.2	4.5	13.9	20	3.4
Lab052	5	4.6	4.7	5	0.2	4.3	10.7	20	4.1	4.6	4.7	14	0.2	4.3	10.7	20	4.1
Total	-	-	4.6	15	0.2	4.3	-	-	-	-	4.6	375	0.3	6.5	-	-	-

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

Month : 2025 02 Change Cumulative : from 2022 06 01 to 2025 02 28 Change

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Reagent Kit	Reagent Code
Medicon	5