

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

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

Print Table

Lab032

	Control N		Control D	
QC Control Lot No.	BA1116N		BA1116D	
Duration of the Analyzing	Month (2025/07)	CUM (2024/08/02~2025/07/30)	Month (2025/07)	CUM (2024/08/02~2025/07/30)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.3	13.8	4.3	4.2
SD	0.3	0.5	0.1	0.2
CV (%)	2.1	3.6	2.3	4.8
Target Value (U/gHb)	14.9	14.9	5.1	5.1
Total Error (%)	8.2	14.6	20.3	27.2
TEa (%)	20	20	20	20
σ	>6	3.5	1.9	0.5

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

Month : 2025 07 Change ; Cumulative : from 2024 08 02 to 2025 07 30 Change

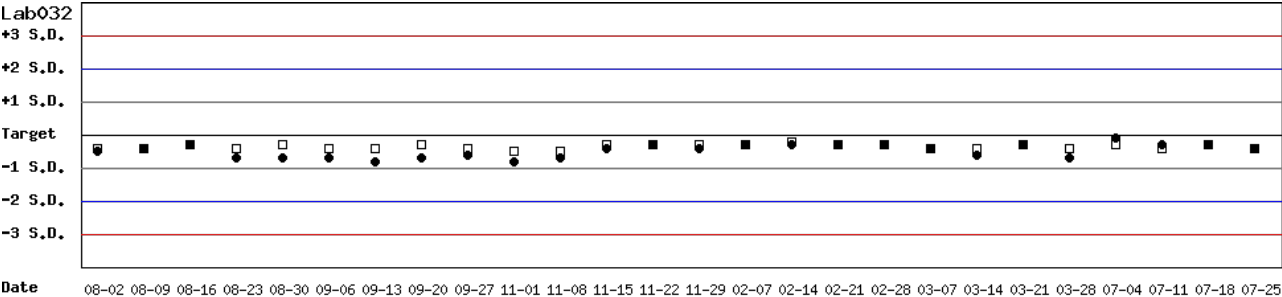
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Control N and Control D SDI
QC Chart

Lot No.: BA1116N ; Duration : 2024-08-02 to 2025-07-30 ; Target : 14.9 ; SD : 2.30 (●)

Lot No.: BA1116D ; Duration : 2024-08-02 to 2025-07-30 ; Target : 5.1 ; SD : 2.50 (□)

Lab032



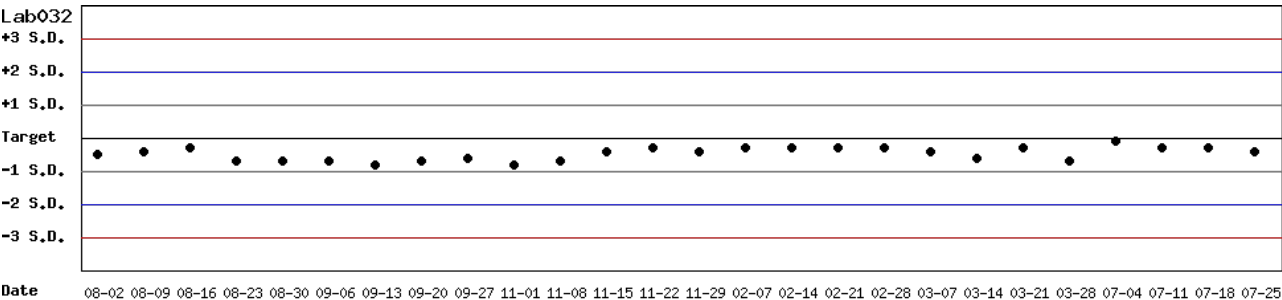
Month : 2025 07 Change ; Cumulative : from 2024 08 02 to 2025 07 30 Change

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2024-08-02 to 2025-07-30 ; Target : 14.9 ; SD : 2.30

Lab032



Month : 2025 07 Change ; Cumulative : from 2024 08 02 to 2025 07 30 Change

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2024-08-02 to 2025-07-30 ; Target : 5.1 ; SD : 2.50

Lab032

Lab032

+3 S.D.

+2 S.D.

+1 S.D.

Target

-1 S.D.

-2 S.D.

-3 S.D.

Date _____

[illegible]

08-02 08-09 08-16 08-23 08-30 09-06 09-13 09-20 09-27 11-01 11-08 11-15 11-22 11-29 02-07 02-14 02-21 02-28 03-07 03-14 03-21 03-28 07-04 07-11 07-18 07-25

Month : 2025 07 Change ; Cumulative : from 2024 08 02 to 2025 07 30 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 07 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	0.3	2.1	8.2	20	>6	5.1	4.3	4	0.1	2.3	20.3	20	1.9
Lab037	5	12.8	13.8	2	-	-	-	20	-	4.2	4.5	2	-	-	-	20	-
Total	-	-	14.1	6	0.4	2.8	-	-	-	-	4.4	6	0.1	2.3	-	-	-

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 07 31 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	34	0.4	2.9	13.2	20	4.4	5.1	4.2	34	0.2	4.8	27.2	20	0.5
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	44	0.4	2.9	13.6	20	4.2	4.2	4.4	44	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	403	0.9	6.2	-	-	-	-	4.6	403	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 (2025/07)								CUM (2022/06/01~2025/07/31)							
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	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	14.3	4	0.3	2.1	8.2	20	>6	14.9	13.8	34	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	13.8	2	-	-	-	20	-	12.8	13.8	44	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	-	-	14.1	6	0.4	2.8	-	-	-	-	14.5	403	0.9	6.2	-	-	-

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

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

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

Month : 2025 ▼ 07 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2025 ▼ 07 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2025/07)								CUM (2022/06/01~2025/07/31)							
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	4.3	-	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	4.3	4	0.1	2.3	20.3	20	1.9	5.1	4.2	34	0.2	4.8	27.2	20	0.5
Lab033	5	4.7	-	0	-	-	-	20	-	4.7	4.8	85	0.2	4.2	10.5	20	4.3
Lab037	5	4.2	4.5	2	-	-	-	20	-	4.2	4.4	44	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	-	-	4.4	6	0.1	2.3	-	-	-	-	4.6	403	0.3	6.5	-	-	-

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

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

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

Month : 2025 ▼ 07 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2025 ▼ 07 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5