

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

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

Print Table

Lab052

	Control N		Control D	
QC Control Lot No.	BA1116N		BA1116D	
Duration of the Analyzing	Month (2025/03)	CUM (2024/10/01~2025/03/31)	Month (2025/03)	CUM (2024/10/01~2025/03/31)
Runs (N)	1	19	1	19
Mean (U/gHb)	14.8	15.3	4.4	4.7
SD	-	0.4	-	0.2
CV (%)	-	2.6	-	4.3
Target Value (U/gHb)	15.3	15.3	4.6	4.6
Total Error (%)	-	5.2	-	10.7
TEa (%)	20	20	20	20
σ	-	>6	-	4.1

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

Month : 2025 03 Change ; Cumulative : from 2024 10 01 to 2025 03 31 Change

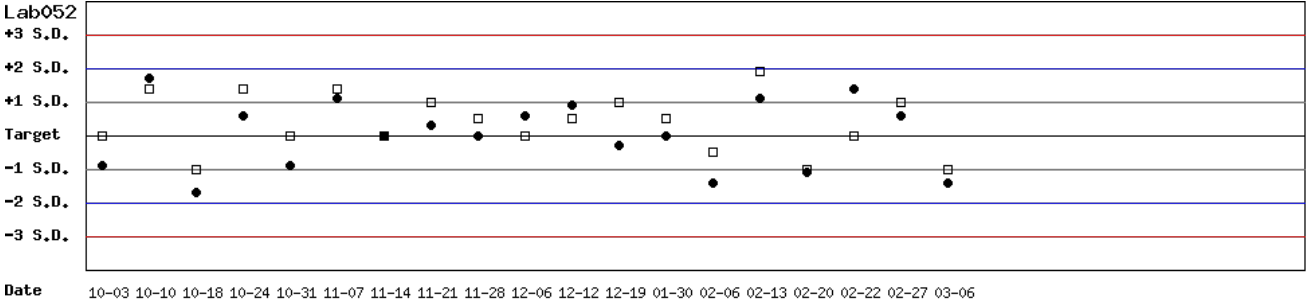
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Control N and Control D SDI
QC Chart

Lot No.: BA1116N ; Duration : 2024-10-01 to 2025-03-31 ; Target : 15.3 ; SD : 0.35 (●)

Lot No.: BA1116D ; Duration : 2024-10-01 to 2025-03-31 ; Target : 4.6 ; SD : 0.21 (□)

Lab052



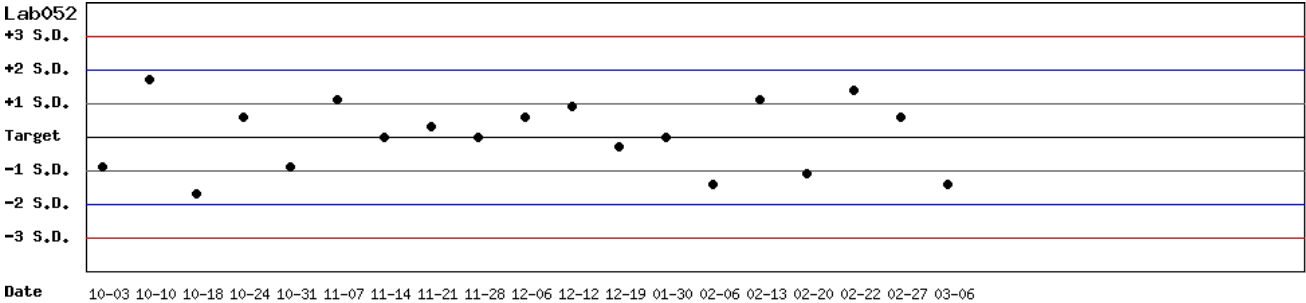
Month : 2025 03 Change ; Cumulative : from 2024 10 01 to 2025 03 31 Change

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2024-10-01 to 2025-03-31 ; Target : 15.3 ; SD : 0.35

Lab052



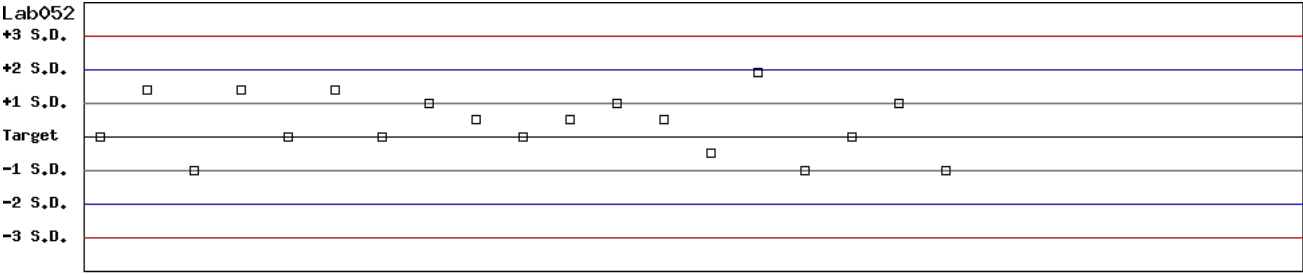
Month : 2025 03 Change ; Cumulative : from 2024 10 01 to 2025 03 31 Change

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2024-10-01 to 2025-03-31 ; Target : 4.6 ; SD : 0.21

Lab052



Date 10-03 10-10 10-18 10-24 10-31 11-07 11-14 11-21 11-28 12-06 12-12 12-19 01-30 02-06 02-13 02-20 02-22 02-27 03-06

Month : 2025 03 Change ; Cumulative : from 2024 10 01 to 2025 03 31 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 03 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	8	0.2	1.4	5.1	20	>6		4.3	4.4	8	0.1	2.3	6.9	20	>6
Lab032	5	14.9	13.7	4	0.4	2.9	13.9	20	4.1		5.1	4.2	4	0.1	2.4	22.4	20	1.0
Lab033	5	15.8	15.4	2	-	-	-	20	-		4.7	4.7	2	-	-	-	20	-
Lab037	5	12.8	13.5	2	-	-	-	20	-		4.2	4.5	2	-	-	-	20	-
Lab052	5	15.3	14.8	1	-	-	-	20	-		4.6	4.4	1	-	-	-	20	-
Total	-	-	14.0	17	0.6	4.3	-	-	-		-	4.4	17	0.2	4.5	-	-	-

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 03 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	30	0.4	2.9	13.2	20	4.4		5.1	4.2	30	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	37	0.4	2.9	13.6	20	4.2		4.2	4.4	37	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	392	0.9	6.2	-	-	-		-	4.6	392	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 (2025/03)										CUM (2022/06/01~2025/03/31)							
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	13.9	8	0.2	1.4	5.1	20	>6	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	13.7	4	0.4	2.9	13.9	20	4.1	14.9	13.8	30	0.4	2.9	13.2	20	4.4
Lab033	5	15.8	15.4	2	-	-	-	20	-	15.8	15.7	85	0.6	3.8	8.3	20	5.1
Lab037	5	12.8	13.5	2	-	-	-	20	-	12.8	13.8	37	0.4	2.9	13.6	20	4.2
Lab052	5	15.3	14.8	1	-	-	-	20	-	15.3	15.3	15	0.3	2.0	3.9	20	>6
Total	-	-	14.0	17	0.6	4.3	-	-	-	-	14.5	392	0.9	6.2	-	-	-

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

Month : 2025 03 Change Cumulative : from 2022 06 01 to 2025 03 31 Change

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Control D Month vs. Cumulative

Control D (Lot No.: BA1116D)																	
Month (2025/03)										CUM (2022/06/01~2025/03/31)							
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	4.4	8	0.1	2.3	6.9	20	>6	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	4.2	4	0.1	2.4	22.4	20	1.0	5.1	4.2	30	0.2	4.8	27.2	20	0.5
Lab033	5	4.7	4.7	2	-	-	-	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	37	0.2	4.5	13.9	20	3.4
Lab052	5	4.6	4.4	1	-	-	-	20	-	4.6	4.7	15	0.2	4.3	10.7	20	4.1
Total	-	-	4.4	17	0.2	4.5	-	-	-	-	4.6	392	0.3	6.5	-	-	-

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

Month : 2025 03 Change Cumulative : from 2022 06 01 to 2025 03 31 Change

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Reagent Kit	Reagent Code
Medicon	5