

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 (2024/12)	CUM (2024/10/03~2024/12/31)	Month (2024/12)	CUM (2024/10/03~2024/12/31)
Runs (N)	3	12	3	12
Mean (U/gHb)	15.4	15.3	4.7	4.7
SD	0.2	0.3	0.1	0.2
CV (%)	1.3	2.0	2.1	4.3
Target Value (U/gHb)	15.3	15.3	4.6	4.6
Total Error (%)	3.3	3.9	6.4	10.7
TEa (%)	20	20	20	20
σ	>6	>6	>6	4.1

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

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

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

Month : 2024 12 Change ; Cumulative : from 2024 10 03 to 2024 12 31 Change

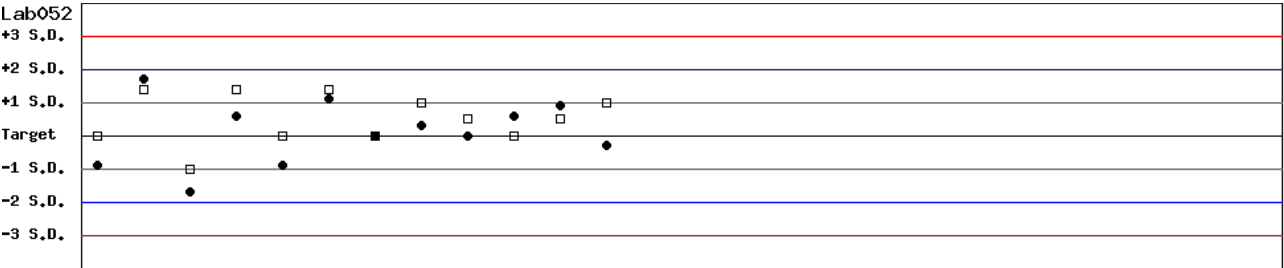
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Control N and Control D SDI
QC Chart

Lot No.: BA1116N ; Duration : 2024-10-03 to 2024-12-31 ; Target : 15.3 ; SD : 0.35 (●)

Lot No.: BA1116D ; Duration : 2024-10-03 to 2024-12-31 ; 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

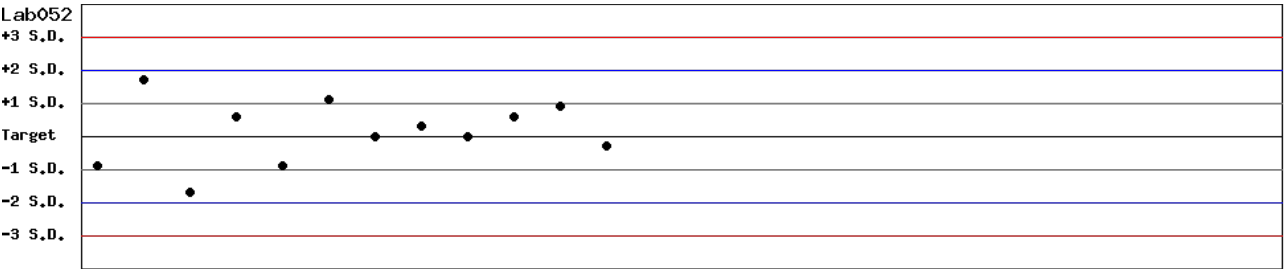
Month : 2024 12 Change ; Cumulative : from 2024 10 03 to 2024 12 31 Change

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2024-10-03 to 2024-12-31 ; Target : 15.3 ; SD : 0.35

Lab052

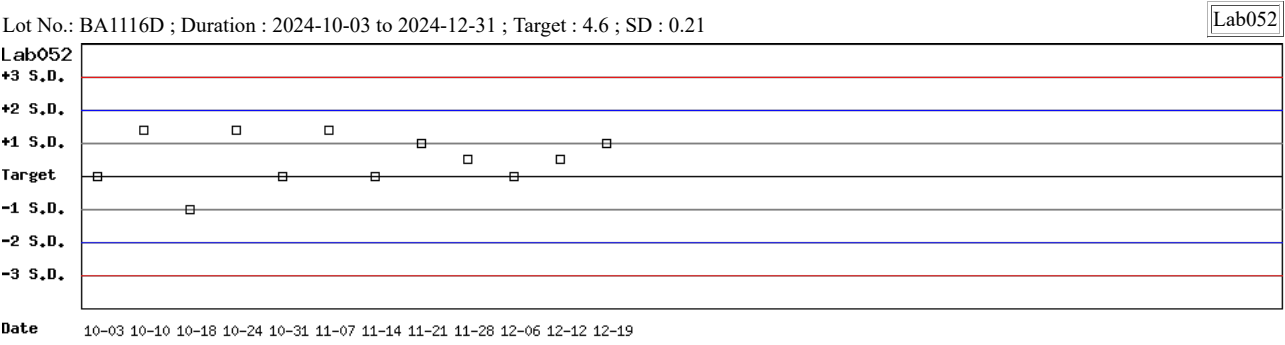


Date 10-03 10-10 10-18 10-24 10-31 11-07 11-14 11-21 11-28 12-06 12-12 12-19

Month : 2024 12 Change ; Cumulative : from 2024 10 03 to 2024 12 31 Change

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Control D SDI QC Chart



Month : 2024 12 Change ; Cumulative : from 2024 10 03 to 2024 12 31 Change

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 : 2024 12 Change

UnitID 	Reagent Kit (Code) 	Control N (Lot No.: BA1116N)									Control D (Lot No.: BA1116D)							
		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	14.1	8	0.1	0.7	5.1	20	>6		4.3	4.4	8	0.1	2.3	6.9	20	>6
Lab033	5	15.8	15.3	4	0.3	2.0	7.1	20	>6		4.7	4.9	4	0.2	4.1	12.4	20	3.8
Lab037	5	12.8	13.3	2	-	-	-	20	-		4.2	4.2	2	-	-	-	20	-
Lab052	5	15.3	15.4	3	0.2	1.3	3.3	20	>6		4.6	4.7	3	0.1	2.1	6.4	20	>6
Total	-	-	14.5	17	0.8	5.5	-	-	-		-	4.5	17	0.3	6.7	-	-	-

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 2024 12 31 Change

UnitID 	Reagent Kit (Code) 	Control N (Lot No.: BA1116N)									Control D (Lot No.: BA1116D)							
		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	130	0.4	2.9	7.3	20	>6		4.3	4.4	130	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	13.7	22	0.4	2.9	13.9	20	4.1		5.1	4.2	22	0.2	4.8	27.2	20	0.5
Lab033	5	15.8	15.8	74	0.5	3.2	6.3	20	>6		4.7	4.8	74	0.2	4.2	10.5	20	4.3
Lab037	5	12.8	13.8	32	0.4	2.9	13.6	20	4.2		4.2	4.4	32	0.2	4.5	13.9	20	3.4
Lab052	5	15.3	15.4	8	0.2	1.3	3.3	20	>6		4.6	4.7	8	0.1	2.1	6.4	20	>6
Total	-	-	14.5	344	1.0	6.9	-	-	-		-	4.6	344	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 (2024/12)								CUM (2022/06/01~2024/12/31)							
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	13.6	14.1	8	0.1	0.7	5.1	20	>6	13.6	13.8	130	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	-	0	-	-	-	20	-	14.9	13.7	22	0.4	2.9	13.9	20	4.1
Lab033	5	15.8	15.3	4	0.3	2.0	7.1	20	>6	15.8	15.8	74	0.5	3.2	6.3	20	>6
Lab037	5	12.8	13.3	2	-	-	-	20	-	12.8	13.8	32	0.4	2.9	13.6	20	4.2
Lab052	5	15.3	15.4	3	0.2	1.3	3.3	20	>6	15.3	15.4	8	0.2	1.3	3.3	20	>6
Total	-	-	14.5	17	0.8	5.5	-	-	-	-	14.5	344	1.0	6.9	-	-	-

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

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

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

Month : 2024 12 Change Cumulative : from 2022 06 01 to 2024 12 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2024/12)								CUM (2022/06/01~2024/12/31)							
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	4.3	4.4	8	0.1	2.3	6.9	20	>6	4.3	4.4	130	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	4.2	22	0.2	4.8	27.2	20	0.5
Lab033	5	4.7	4.9	4	0.2	4.1	12.4	20	3.8	4.7	4.8	74	0.2	4.2	10.5	20	4.3
Lab037	5	4.2	4.2	2	-	-	-	20	-	4.2	4.4	32	0.2	4.5	13.9	20	3.4
Lab052	5	4.6	4.7	3	0.1	2.1	6.4	20	>6	4.6	4.7	8	0.1	2.1	6.4	20	>6
Total	-	-	4.5	17	0.3	6.7	-	-	-	-	4.6	344	0.3	6.5	-	-	-

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

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

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

Month : 2024 12 Change Cumulative : from 2022 06 01 to 2024 12 31 Change

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Reagent Kit	Reagent Code
Medicon	5