

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

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

Lab037

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2023/09)	CUM (2023/07/28~2023/09/29)	Month (2023/09)	CUM (2023/07/28~2023/09/29)
Runs (N)	2	4	2	4
Mean (U/gHb)	14.3	14.0	4.5	4.5
SD	-	0.3	-	0.1
CV (%)	-	2.1	-	2.2
Target Value (U/gHb)	12.8	12.8	4.2	4.2
Total Error (%)	-	13.7	-	11.6
TEa (%)	20	20	20	20
σ	-	5.1	-	5.8

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

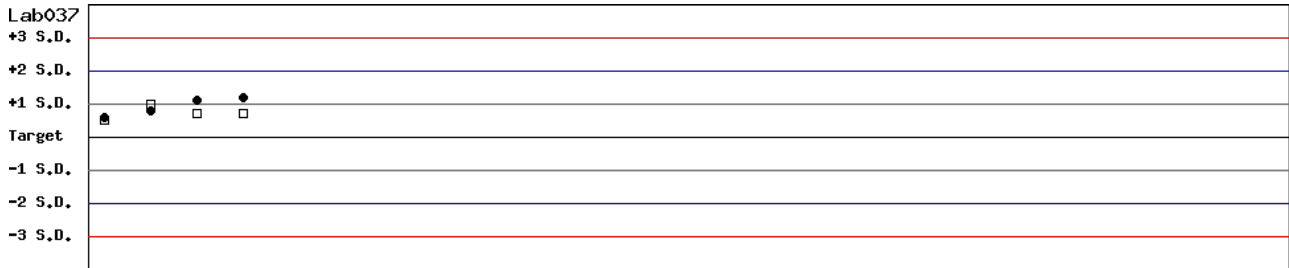
Month : ; Cumulative : from to

[TOP](#)

Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-07-28 to 2023-09-29 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: BA1116D ; Duration : 2023-07-28 to 2023-09-29 ; Target : 4.2 ; SD : 0.42 (□)



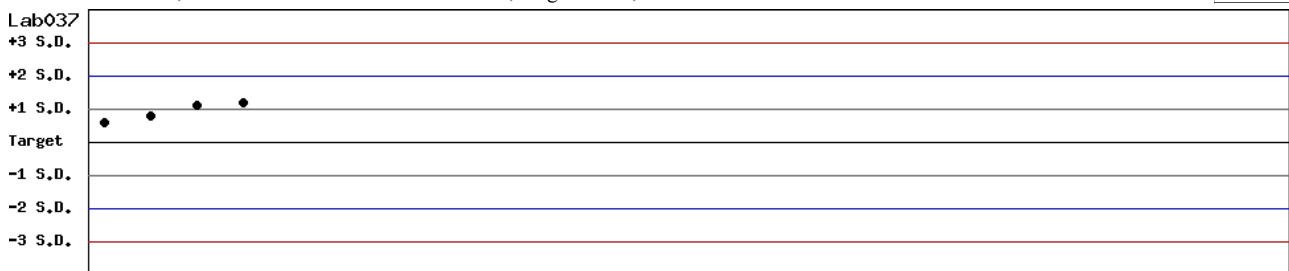
Date 07-28 08-24 09-08 09-29

Month : ; Cumulative : from to

[TOP](#)

Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-07-28 to 2023-09-29 ; Target : 12.8 ; SD : 1.28



Date 07-28 08-24 09-08 09-29

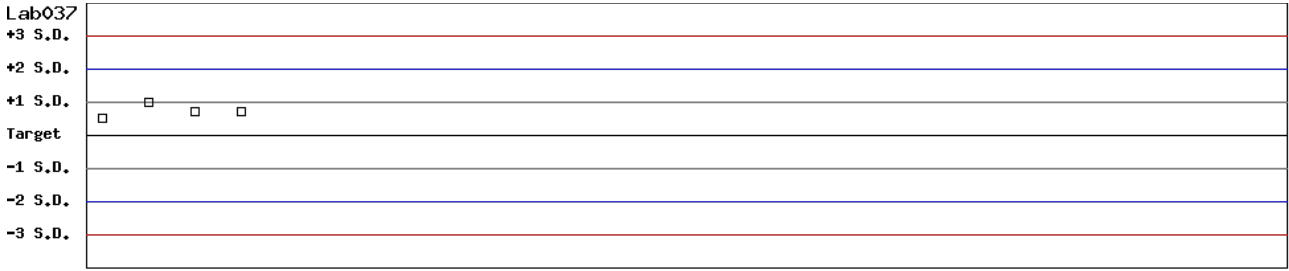
Month : ; Cumulative : from to

[TOP](#)

Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2023-07-28 to 2023-09-29 ; Target : 4.2 ; SD : 0.42

Lab037



Date 07-28 08-24 09-08 09-29

Month : ; Cumulative : from to

[TOP](#)

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 : 2023 09 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	9	0.1	0.7	5.1	20	>6	4.3	4.4	9	0.1	2.3	6.9	20	>6
Lab033	5	12.8	15.9	4	0.5	3.1	30.5	20	-1.4	4.2	4.8	4	0.1	2.1	18.5	20	2.7
Lab037	5	12.8	14.3	2	-	-	-	20	-	4.2	4.5	2	-	-	-	20	-
Total	-	-	14.6	15	0.8	5.5	-	-	-	-	4.5	15	0.2	4.4	-	-	-

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from 2022 06 01 to 2023 09 30 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	113	0.4	2.9	7.3	20	>6	4.3	4.4	113	0.1	2.3	6.9	20	>6
Lab027	5	12.8	14.9	55	0.8	5.4	27.1	20	0.7	4.2	4.8	55	0.3	6.3	26.8	20	0.9
Lab033	5	12.8	16.3	9	0.6	3.7	34.7	20	-2.0	4.2	5.0	9	0.2	4.0	27.0	20	0.2
Lab037	5	12.8	14.0	4	0.3	2.1	13.7	20	5.1	4.2	4.5	4	0.1	2.2	11.6	20	5.8
Total	-	-	14.3	181	0.9	6.3	-	-	-	-	4.5	181	0.3	6.7	-	-	-

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

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

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

[\[TOP\]](#)

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 (2023/09)								CUM (2022/06/01~2023/09/30)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	9	0.1	0.7	5.1	20	>6	13.6	13.8	113	0.4	2.9	7.3	20	>6
Lab027	5	12.8	-	0	-	-	-	20	-	12.8	14.9	55	0.8	5.4	27.1	20	0.7
Lab033	5	12.8	15.9	4	0.5	3.1	30.5	20	-1.4	12.8	16.3	9	0.6	3.7	34.7	20	-2.0
Lab037	5	12.8	14.3	2	-	-	-	20	-	12.8	14.0	4	0.3	2.1	13.7	20	5.1
Total	-	-	14.6	15	0.8	5.5	-	-	-	-	14.3	181	0.9	6.3	-	-	-

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

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

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

Month : 2023 ▼ 09 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 09 ▼ 30 ▼ Change

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2023/09)								CUM (2022/06/01~2023/09/30)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	9	0.1	2.3	6.9	20	>6	4.3	4.4	113	0.1	2.3	6.9	20	>6
Lab027	5	4.2	-	0	-	-	-	20	-	4.2	4.8	55	0.3	6.3	26.8	20	0.9
Lab033	5	4.2	4.8	4	0.1	2.1	18.5	20	2.7	4.2	5.0	9	0.2	4.0	27.0	20	0.2
Lab037	5	4.2	4.5	2	-	-	-	20	-	4.2	4.5	4	0.1	2.2	11.6	20	5.8
Total	-	-	4.5	15	0.2	4.4	-	-	-	-	4.5	181	0.3	6.7	-	-	-

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

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

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

Month : 2023 ▼ 09 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 09 ▼ 30 ▼ Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5