

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

Select LotNo :

Lab027

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2023/01)	CUM (2022/08/05~2023/01/31)	Month (2023/01)	CUM (2022/08/05~2023/01/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	15.0	15.1	4.8	4.9
SD	0.9	0.6	0.3	0.3
CV (%)	6.0	4.0	6.3	6.1
Target Value (U/gHb)	12.8	12.8	4.2	4.2
Total Error (%)	29.2	25.9	26.8	28.9
TEa (%)	20	20	20	20
σ	0.5	0.5	0.9	0.5

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

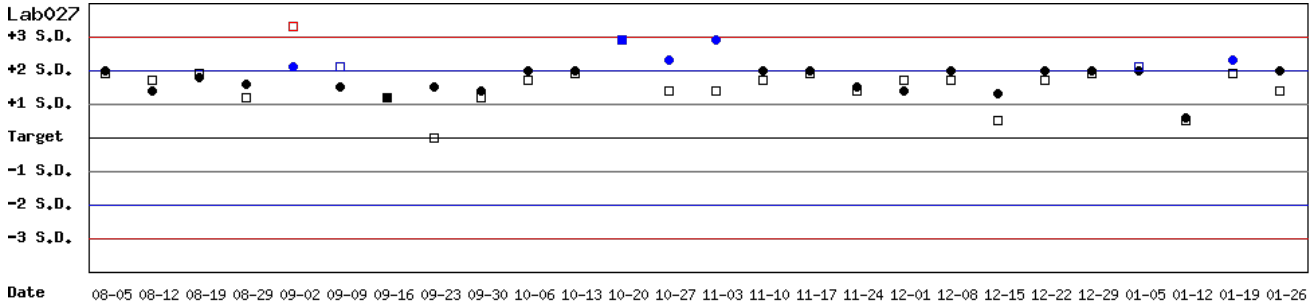
Month : ; Cumulative : from to

[\[TOP\]](#)

Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-08-05 to 2023-01-31 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: BA1116D ; Duration : 2022-08-05 to 2023-01-31 ; Target : 4.2 ; SD : 0.42 (□)

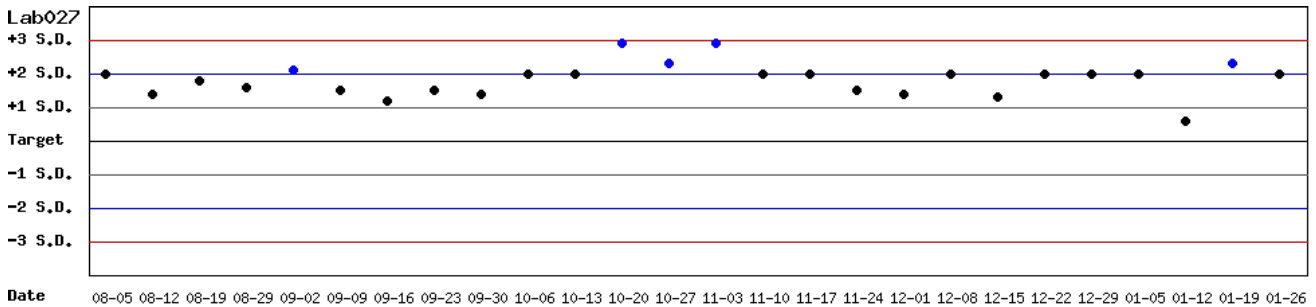


Month : ; Cumulative : from to

[\[TOP\]](#)

Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-08-05 to 2023-01-31 ; Target : 12.8 ; SD : 1.28



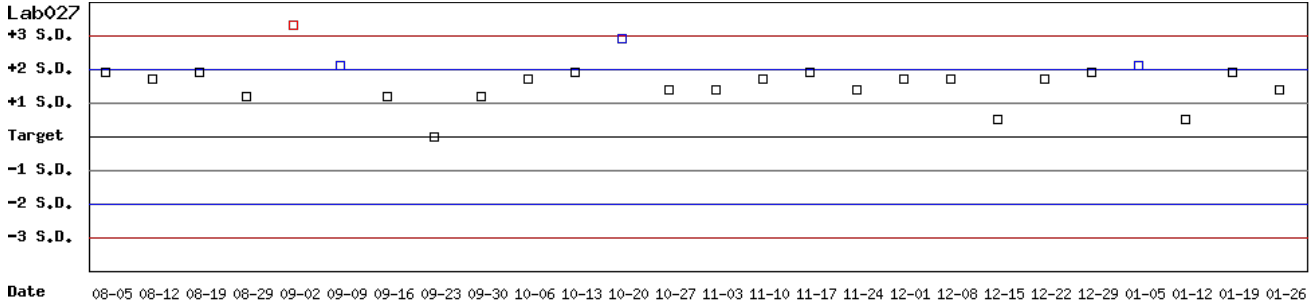
Month : ; Cumulative : from to

[\[TOP\]](#)

Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2022-08-05 to 2023-01-31 ; Target : 4.2 ; SD : 0.42

Lab027



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 01 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	13.7	8	0.4	2.9	6.6	20	>6	4.3	4.3	8	0.1	2.3	4.7	20	>6
Lab027	5	12.8	15.0	4	0.9	6.0	29.2	20	0.5	4.2	4.8	4	0.3	6.3	26.8	20	0.9
Total	-	-	14.1	12	0.9	6.4	-	-	-	-	4.5	12	0.3	6.7	-	-	-

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from 2022 06 01 to 2023 01 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	13.6	56	0.3	2.2	4.4	20	>6	4.3	4.3	56	0.1	2.3	4.7	20	>6
Lab027	5	12.8	15.0	35	0.7	4.7	26.5	20	0.6	4.2	4.8	35	0.4	8.3	31.0	20	0.7
Total	-	-	14.1	91	0.9	6.4	-	-	-	-	4.5	91	0.3	6.7	-	-	-

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

TE : Total Error(%) = Bias (%) + 2 x 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 (2023/01)								CUM (2022/06/01~2023/01/31)							
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	13.7	8	0.4	2.9	6.6	20	>6	13.6	13.6	56	0.3	2.2	4.4	20	>6
Lab027	5	12.8	15.0	4	0.9	6.0	29.2	20	0.5	12.8	15.0	35	0.7	4.7	26.5	20	0.6
Total	-	-	14.1	12	0.9	6.4	-	-	-	-	14.1	91	0.9	6.4	-	-	-

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

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

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

Month : 2023 v 01 v Change Cumulative : from 2022 v 06 v 01 v to 2023 v 01 v 31 v Change

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2023/01)								CUM (2022/06/01~2023/01/31)							
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	4.3	8	0.1	2.3	4.7	20	>6	4.3	4.3	56	0.1	2.3	4.7	20	>6
Lab027	5	4.2	4.8	4	0.3	6.3	26.8	20	0.9	4.2	4.8	35	0.4	8.3	31.0	20	0.7
Total	-	-	4.5	12	0.3	6.7	-	-	-	-	4.5	91	0.3	6.7	-	-	-

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

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

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

Month : 2023 v 01 v Change Cumulative : from 2022 v 06 v 01 v to 2023 v 01 v 31 v Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5