

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

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

[Print Table](#)

Lab027

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2022/07)	CUM (2022/06/03~2022/07/31)	Month (2022/07)	CUM (2022/06/03~2022/07/31)
Runs (N)	5	9	5	9
Mean (U/gHb)	15.0	14.6	4.9	4.7
SD	0.5	0.8	0.6	0.5
CV (%)	3.3	5.5	12.2	10.6
Target Value (U/gHb)	12.8	12.8	4.2	4.2
Total Error (%)	23.9	25.0	41.2	33.2
TEa (%)	20	20	20	20
σ	0.9	1.1	0.3	0.8

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

Month : 2022 07 Change ; Cumulative : from 2022 06 03 to 2022 07 31 Change

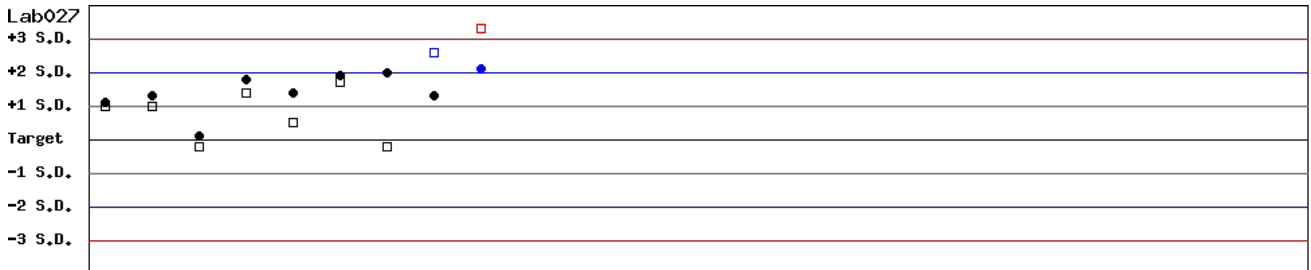
[\[TOP\]](#)

Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-06-03 to 2022-07-31 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: BA1116D ; Duration : 2022-06-03 to 2022-07-31 ; Target : 4.2 ; SD : 0.42 (□)

Lab027



Date 06-03 06-10 06-17 06-24 07-01 07-08 07-17 07-23 07-31

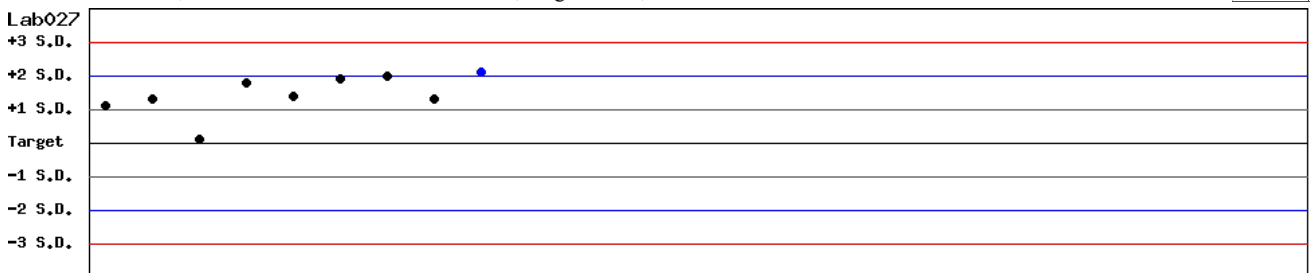
Month : 2022 07 Change ; Cumulative : from 2022 06 03 to 2022 07 31 Change

[\[TOP\]](#)

Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-06-03 to 2022-07-31 ; Target : 12.8 ; SD : 1.28

Lab027



Date 06-03 06-10 06-17 06-24 07-01 07-08 07-17 07-23 07-31

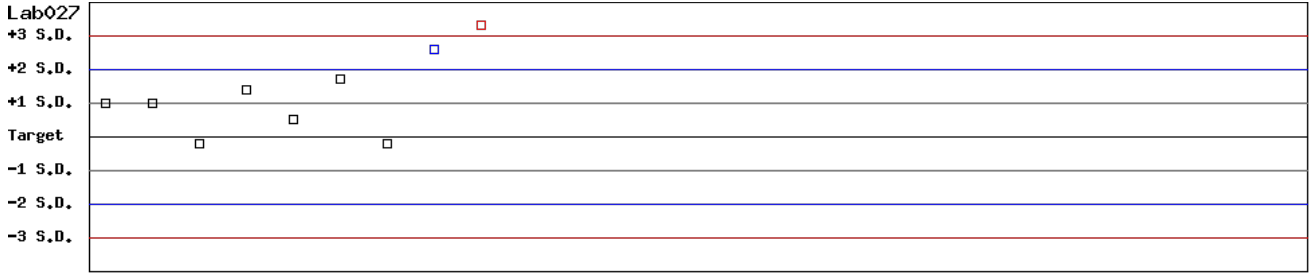
Month : 2022 07 Change ; Cumulative : from 2022 06 03 to 2022 07 31 Change

[\[TOP\]](#)

Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2022-06-03 to 2022-07-31 ; Target : 4.2 ; SD : 0.42

Lab027



Date 06-03 06-10 06-17 06-24 07-01 07-08 07-15 07-22 07-29 07-31

Month : 2022 07 Change ; Cumulative : from 2022 06 03 to 2022 07 31 Change

[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 : 2022 07 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	5	0.3	2.2	5.1	20	>6	4.3	4.4	5	0.0	0.0	2.3	20	>6
Lab027	5	12.8	15.0	5	0.5	3.3	23.9	20	0.9	4.2	4.9	5	0.6	12.2	41.2	20	0.3
Total	-	-	14.4	10	0.8	5.6	-	-	-	-	4.6	10	0.5	10.9	-	-	-

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 2022 07 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	24	0.3	2.2	4.4	20	>6	4.3	4.3	24	0.1	2.3	4.7	20	>6
Lab027	5	12.8	14.6	9	0.8	5.5	25.0	20	1.1	4.2	4.7	9	0.5	10.6	33.2	20	0.8
Total	-	-	13.8	33	0.7	5.1	-	-	-	-	4.4	33	0.3	6.8	-	-	-

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 (2022/07)								CUM (2022/06/01~2022/07/31)							
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	13.7	5	0.3	2.2	5.1	20	>6	13.6	13.6	24	0.3	2.2	4.4	20	>6
Lab027	5	12.8	15.0	5	0.5	3.3	23.9	20	0.9	12.8	14.6	9	0.8	5.5	25.0	20	1.1
Total	-	-	14.4	10	0.8	5.6	-	-	-	-	13.8	33	0.7	5.1	-	-	-

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

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

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

Month : 2022 ▾ 07 ▾ Change Cumulative : from 2022 ▾ 06 ▾ 01 ▾ to 2022 ▾ 07 ▾ 31 ▾ Change

[\[TOP\]](#)

Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2022/07)								CUM (2022/06/01~2022/07/31)							
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	4.4	5	0.0	0.0	2.3	20	>6	4.3	4.3	24	0.1	2.3	4.7	20	>6
Lab027	5	4.2	4.9	5	0.6	12.2	41.2	20	0.3	4.2	4.7	9	0.5	10.6	33.2	20	0.8
Total	-	-	4.6	10	0.5	10.9	-	-	-	-	4.4	33	0.3	6.8	-	-	-

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

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

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

Month : 2022 ▾ 07 ▾ Change Cumulative : from 2022 ▾ 06 ▾ 01 ▾ to 2022 ▾ 07 ▾ 31 ▾ Change

[\[TOP\]](#)

Reagent Kit	Reagent Code
Medicon	5