

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

Select LotNo :

Lab027

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2022/12)	CUM (2022/07/08~2022/12/30)	Month (2022/12)	CUM (2022/07/08~2022/12/30)
Runs (N)	5	26	5	26
Mean (U/gHb)	15.1	15.2	4.8	4.9
SD	0.5	0.6	0.2	0.3
CV (%)	3.3	3.9	4.2	6.1
Target Value (U/gHb)	12.8	12.8	4.2	4.2
Total Error (%)	24.6	26.6	22.6	28.9
TEa (%)	20	20	20	20
σ	0.6	0.3	1.4	0.5

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

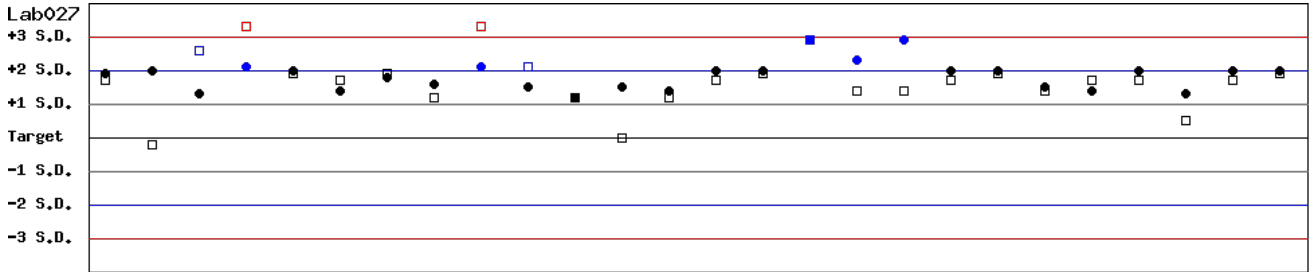
Month : ; Cumulative : from to

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Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-07-08 to 2022-12-30 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: BA1116D ; Duration : 2022-07-08 to 2022-12-30 ; Target : 4.2 ; SD : 0.42 (□)



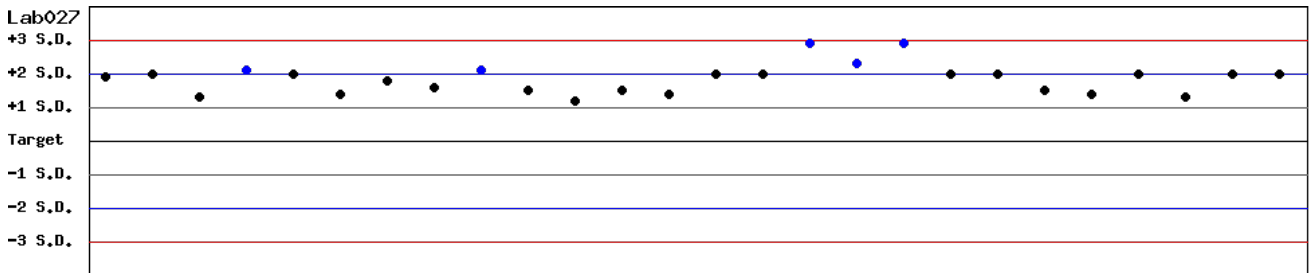
Date 07-08 07-17 07-23 07-31 08-05 08-12 08-19 08-29 09-02 09-09 09-16 09-23 09-30 10-06 10-13 10-20 10-27 11-03 11-10 11-17 11-24 12-01 12-08 12-15 12-22 12-29

Month : ; Cumulative : from to

[\[TOP\]](#)

Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-07-08 to 2022-12-30 ; Target : 12.8 ; SD : 1.28



Date 07-08 07-17 07-23 07-31 08-05 08-12 08-19 08-29 09-02 09-09 09-16 09-23 09-30 10-06 10-13 10-20 10-27 11-03 11-10 11-17 11-24 12-01 12-08 12-15 12-22 12-29

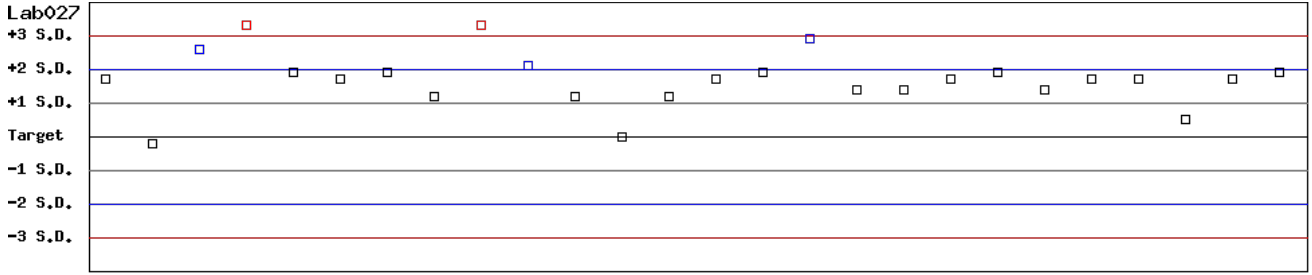
Month : ; Cumulative : from to

[\[TOP\]](#)

Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2022-07-08 to 2022-12-30 ; Target : 4.2 ; SD : 0.42

Lab027



Date 07-08 07-17 07-23 07-31 08-05 08-12 08-19 08-29 09-02 09-09 09-16 09-23 09-30 10-06 10-13 10-20 10-27 11-03 11-10 11-17 11-24 12-01 12-08 12-15 12-22 12-29

Month : ; Cumulative : from to

[TOP](#)

Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon

Monthly

Month : 2022 12

		Control N (Lot No.: BA1116N)								Control D (Lot No.: BA1116D)							
UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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
Lab027	5	12.8	15.1	5	0.5	3.3	24.6	20	0.6	4.2	4.8	5	0.2	4.2	22.6	20	1.4
Total	-	-	15.1	5	0.5	3.3	-	-	-	-	4.8	5	0.2	4.2	-	-	-

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 2022 12 31

		Control N (Lot No.: BA1116N)								Control D (Lot No.: BA1116D)							
UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	48	0.3	2.2	4.4	20	>6	4.3	4.3	48	0.1	2.3	4.7	20	>6
Lab027	5	12.8	15.0	31	0.7	4.7	26.5	20	0.6	4.2	4.8	31	0.4	8.3	31.0	20	0.7
Total	-	-	14.1	79	0.9	6.4	-	-	-	-	4.5	79	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 (2022/12)								CUM (2022/06/01~2022/12/31)							
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	-	0	-	-	-	20	-	13.6	13.6	48	0.3	2.2	4.4	20	>6
Lab027	5	12.8	15.1	5	0.5	3.3	24.6	20	0.6	12.8	15.0	31	0.7	4.7	26.5	20	0.6
Total	-	-	15.1	5	0.5	3.3	-	-	-	-	14.1	79	0.9	6.4	-	-	-

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

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

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

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

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2022/12)								CUM (2022/06/01~2022/12/31)							
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	-	0	-	-	-	20	-	4.3	4.3	48	0.1	2.3	4.7	20	>6
Lab027	5	4.2	4.8	5	0.2	4.2	22.6	20	1.4	4.2	4.8	31	0.4	8.3	31.0	20	0.7
Total	-	-	4.8	5	0.2	4.2	-	-	-	-	4.5	79	0.3	6.7	-	-	-

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

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

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

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

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5