

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 (2022/08)	CUM (2022/06/03~2022/08/30)	Month (2022/08)	CUM (2022/06/03~2022/08/30)
Runs (N)	4	13	4	13
Mean (U/gHb)	15.0	14.7	4.9	4.8
SD	0.4	0.7	0.1	0.4
CV (%)	2.7	4.8	2.0	8.3
Target Value (U/gHb)	12.8	12.8	4.2	4.2
Total Error (%)	22.5	24.4	20.7	31.0
TEa (%)	20	20	20	20
σ	1.0	1.1	1.7	0.7

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

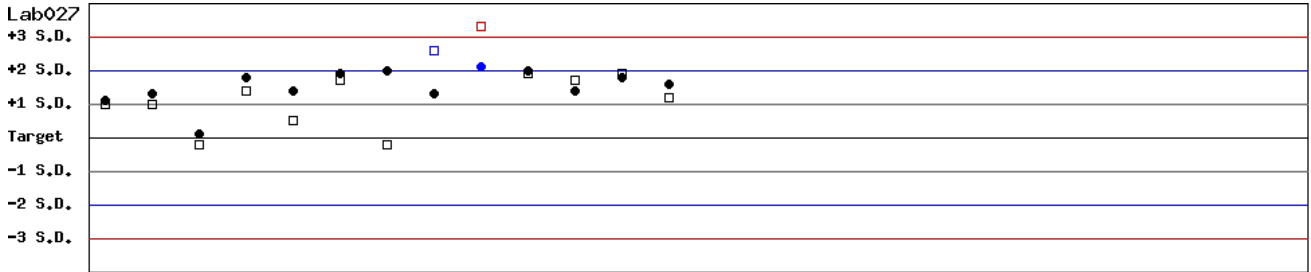
Month : ; Cumulative : from to

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Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-06-03 to 2022-08-30 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: BA1116D ; Duration : 2022-06-03 to 2022-08-30 ; Target : 4.2 ; SD : 0.42 (□)



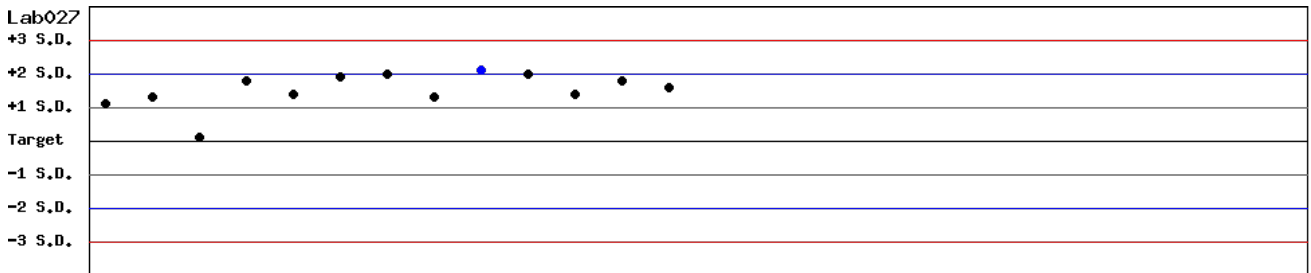
Date 06-03 06-10 06-17 06-24 07-01 07-08 07-17 07-23 07-31 08-05 08-12 08-19 08-29

Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-06-03 to 2022-08-30 ; Target : 12.8 ; SD : 1.28



Date 06-03 06-10 06-17 06-24 07-01 07-08 07-17 07-23 07-31 08-05 08-12 08-19 08-29

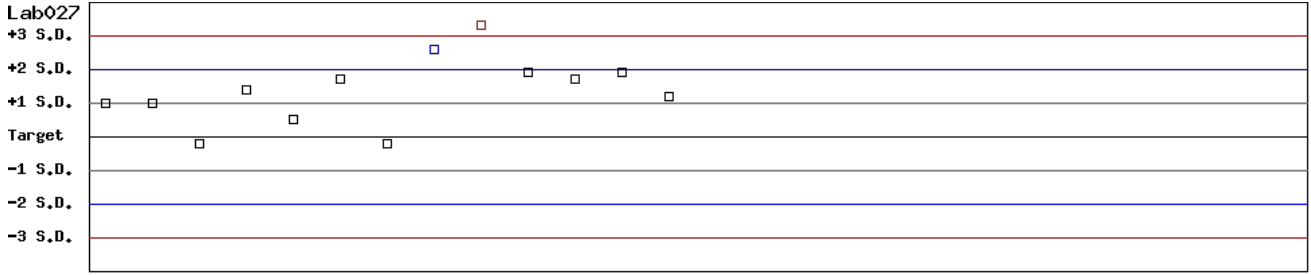
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2022-06-03 to 2022-08-30 ; 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 08-05 08-12 08-19 08-26

Month : ; Cumulative : from to

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Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon

Monthly

Month : 2022 08

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	8	0.3	2.2	4.4	20	>6	4.3	4.5	8	0.1	2.2	9.1	20	>6
Lab027	5	12.8	15.0	4	0.4	2.7	22.5	20	1.0	4.2	4.9	4	0.1	2.0	20.7	20	1.7
Total	-	-	14.0	12	0.8	5.7	-	-	-	-	4.6	12	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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Cumulative

Cumulative : from 2022 06 01 to 2022 08 31

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	32	0.3	2.2	4.4	20	>6	4.3	4.3	32	0.1	2.3	4.7	20	>6
Lab027	5	12.8	14.7	13	0.7	4.8	24.4	20	1.1	4.2	4.8	13	0.4	8.3	31.0	20	0.7
Total	-	-	13.9	45	0.7	5.0	-	-	-	-	4.5	45	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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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 (2022/08)								CUM (2022/06/01~2022/08/31)							
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	13.6	8	0.3	2.2	4.4	20	>6	13.6	13.6	32	0.3	2.2	4.4	20	>6
Lab027	5	12.8	15.0	4	0.4	2.7	22.5	20	1.0	12.8	14.7	13	0.7	4.8	24.4	20	1.1
Total	-	-	14.0	12	0.8	5.7	-	-	-	-	13.9	45	0.7	5.0	-	-	-

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

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

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

Month : 2022 ▼ 08 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2022 ▼ 08 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2022/08)								CUM (2022/06/01~2022/08/31)							
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	4.5	8	0.1	2.2	9.1	20	>6	4.3	4.3	32	0.1	2.3	4.7	20	>6
Lab027	5	4.2	4.9	4	0.1	2.0	20.7	20	1.7	4.2	4.8	13	0.4	8.3	31.0	20	0.7
Total	-	-	4.6	12	0.3	6.5	-	-	-	-	4.5	45	0.3	6.7	-	-	-

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

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

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

Month : 2022 ▼ 08 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2022 ▼ 08 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5