

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

Select LotNo :

Lab018

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2023/04)	CUM (2022/09/30~2023/04/28)	Month (2023/04)	CUM (2022/09/30~2023/04/28)
Runs (N)	4	26	4	26
Mean (U/gHb)	13.9	13.7	4.5	4.4
SD	0.3	0.4	0.1	0.1
CV (%)	2.2	2.9	2.2	2.3
Target Value (U/gHb)	13.6	13.6	4.3	4.3
Total Error (%)	6.5	6.6	9.1	6.9
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

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

Month : ; Cumulative : from to

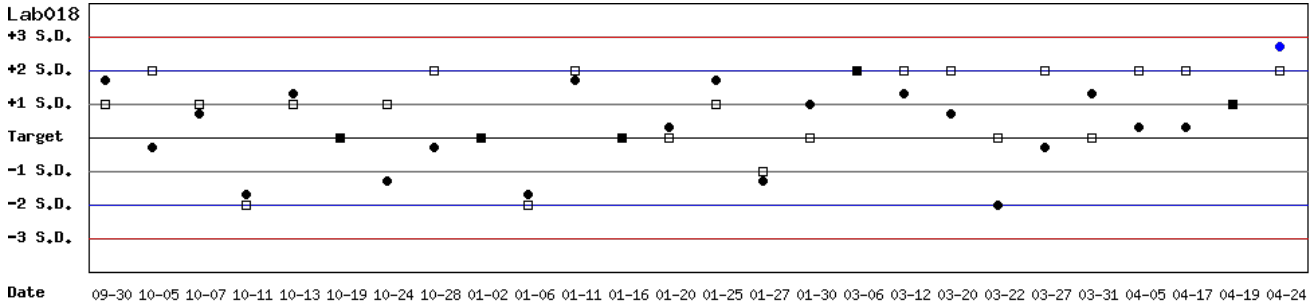
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Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-09-30 to 2023-04-28 ; Target : 13.6 ; SD : 0.30 (●)

Lot No.: BA1116D ; Duration : 2022-09-30 to 2023-04-28 ; Target : 4.3 ; SD : 0.10 (□)

Lab018



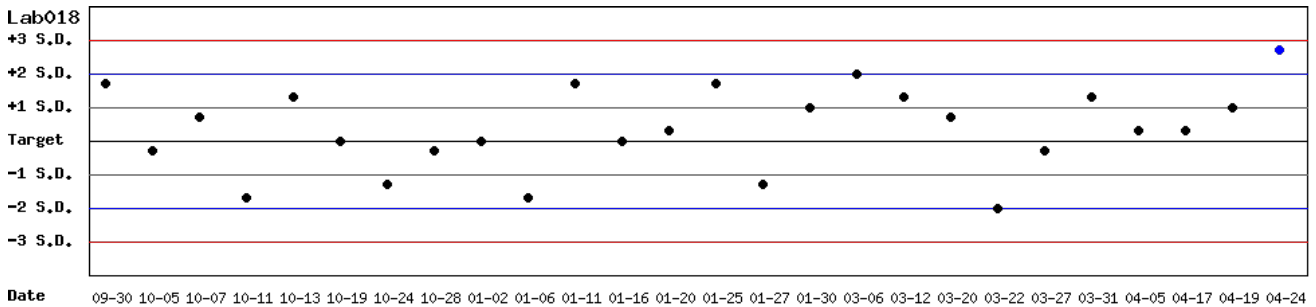
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-09-30 to 2023-04-28 ; Target : 13.6 ; SD : 0.30

Lab018



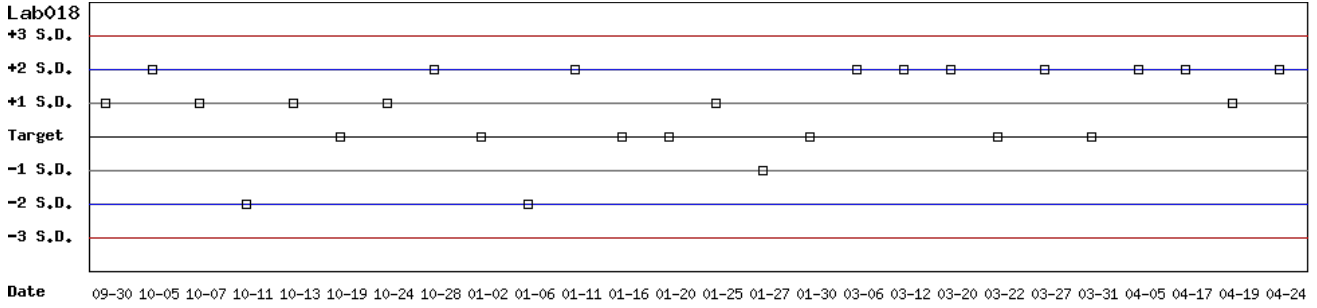
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2022-09-30 to 2023-04-28 ; Target : 4.3 ; SD : 0.10

Lab018



Month : ; Cumulative : from to

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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 04 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	13.9	4	0.3	2.2	6.5	20	>6	4.3	4.5	4	0.1	2.2	9.1	20	>6
Lab027	5	12.8	14.2	4	0.8	5.6	22.2	20	1.6	4.2	4.7	4	0.2	4.3	20.4	20	1.9
Total	-	-	14.1	8	0.6	4.3	-	-	-	-	4.6	8	0.2	4.3	-	-	-

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

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

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

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Cumulative

Cumulative : from 2022 06 01 to 2023 04 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	13.6	66	0.3	2.2	4.4	20	>6	4.3	4.4	66	0.1	2.3	6.9	20	>6
Lab027	5	12.8	14.9	47	0.7	4.7	25.8	20	0.8	4.2	4.8	47	0.3	6.3	26.8	20	0.9
Total	-	-	14.1	113	0.8	5.7	-	-	-	-	4.5	113	0.3	6.7	-	-	-

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

TE : Total Error(%) = Bias (%) + 2 x 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 (2023/04)								CUM (2022/06/01~2023/04/30)							
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	13.9	4	0.3	2.2	6.5	20	>6	13.6	13.6	66	0.3	2.2	4.4	20	>6
Lab027	5	12.8	14.2	4	0.8	5.6	22.2	20	1.6	12.8	14.9	47	0.7	4.7	25.8	20	0.8
Total	-	-	14.1	8	0.6	4.3	-	-	-	-	14.1	113	0.8	5.7	-	-	-

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

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

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

Month : 2023 ▼ 04 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 04 ▼ 30 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2023/04)								CUM (2022/06/01~2023/04/30)							
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	4	0.1	2.2	9.1	20	>6	4.3	4.4	66	0.1	2.3	6.9	20	>6
Lab027	5	4.2	4.7	4	0.2	4.3	20.4	20	1.9	4.2	4.8	47	0.3	6.3	26.8	20	0.9
Total	-	-	4.6	8	0.2	4.3	-	-	-	-	4.5	113	0.3	6.7	-	-	-

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

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

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

Month : 2023 ▼ 04 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 04 ▼ 30 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5