

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

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

Lab027

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2023/10)	CUM (2023/01/19~2023/10/31)	Month (2023/10)	CUM (2023/01/19~2023/10/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	15.5	14.9	5.1	4.8
SD	0.7	0.9	0.4	0.4
CV (%)	4.5	6.0	7.8	8.3
Target Value (U/gHb)	12.8	12.8	4.2	4.2
Total Error (%)	30.1	28.5	37.1	31.0
TEa (%)	20	20	20	20
σ	-0.2	0.6	-0.2	0.7

Bias (%) = $(\frac{| \text{Mean} - \text{Target} |}{\text{Target}}) \times 100\%$
 TE : Total Error(%) = Bias (%) + 2 × CV (%)
 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : ; Cumulative : from to

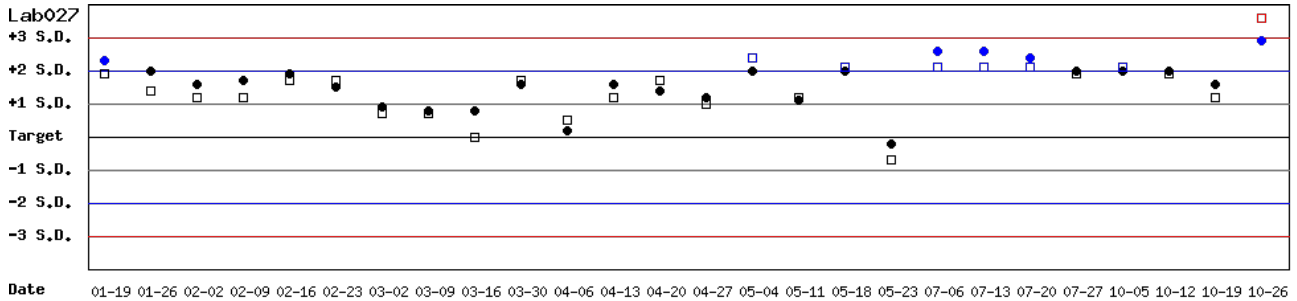
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Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-01-19 to 2023-10-31 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: BA1116D ; Duration : 2023-01-19 to 2023-10-31 ; Target : 4.2 ; SD : 0.42 (□)

Lab027



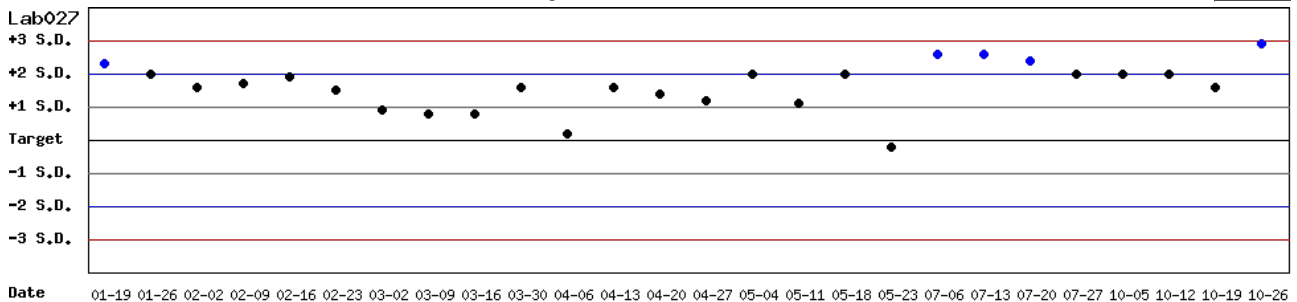
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-01-19 to 2023-10-31 ; Target : 12.8 ; SD : 1.28

Lab027



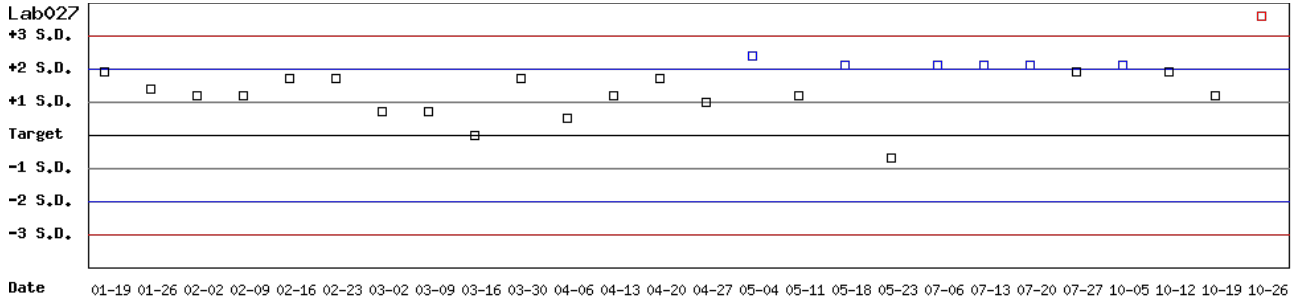
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2023-01-19 to 2023-10-31 ; Target : 4.2 ; SD : 0.42

Lab027



Month : 2023 10 Change ; Cumulative : from 2023 01 19 to 2023 10 31 Change

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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 : 2023 10

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
Lab027	5	12.8	15.5	4	0.7	4.5	30.1	20	-0.2	4.2	5.1	4	0.4	7.8	37.1	20	-0.2
Lab033	5	12.8	15.4	4	0.3	1.9	24.2	20	-0.2	4.2	4.5	4	0.4	8.9	24.9	20	1.4
Lab037	5	12.8	14.5	2	-	-	-	20	-	4.2	4.6	2	-	-	-	20	-
Total	-	-	15.2	10	0.6	3.9	-	-	-	-	4.8	10	0.4	8.3	-	-	-

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 2023 10 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	13.8	113	0.4	2.9	7.3	20	>6	4.3	4.4	113	0.1	2.3	6.9	20	>6
Lab027	5	12.8	14.9	59	0.8	5.4	27.1	20	0.7	4.2	4.8	59	0.4	8.3	31.0	20	0.7
Lab033	5	12.8	16.0	13	0.7	4.4	33.8	20	-1.1	4.2	4.8	13	0.3	6.3	26.8	20	0.9
Lab037	5	12.8	14.1	6	0.5	3.5	17.2	20	2.8	4.2	4.5	6	0.1	2.2	11.6	20	5.8
Total	-	-	14.3	191	0.9	6.3	-	-	-	-	4.6	191	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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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 (2023/10)								CUM (2022/06/01~2023/10/31)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	13.8	113	0.4	2.9	7.3	20	>6
Lab027	5	12.8	15.5	4	0.7	4.5	30.1	20	-0.2	12.8	14.9	59	0.8	5.4	27.1	20	0.7
Lab033	5	12.8	15.4	4	0.3	1.9	24.2	20	-0.2	12.8	16.0	13	0.7	4.4	33.8	20	-1.1
Lab037	5	12.8	14.5	2	-	-	-	20	-	12.8	14.1	6	0.5	3.5	17.2	20	2.8
Total	-	-	15.2	10	0.6	3.9	-	-	-	-	14.3	191	0.9	6.3	-	-	-

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

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

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

Month : 2023 ▼ 10 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 10 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2023/10)								CUM (2022/06/01~2023/10/31)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	4.4	113	0.1	2.3	6.9	20	>6
Lab027	5	4.2	5.1	4	0.4	7.8	37.1	20	-0.2	4.2	4.8	59	0.4	8.3	31.0	20	0.7
Lab033	5	4.2	4.5	4	0.4	8.9	24.9	20	1.4	4.2	4.8	13	0.3	6.3	26.8	20	0.9
Lab037	5	4.2	4.6	2	-	-	-	20	-	4.2	4.5	6	0.1	2.2	11.6	20	5.8
Total	-	-	4.8	10	0.4	8.3	-	-	-	-	4.6	191	0.3	6.5	-	-	-

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

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

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

Month : 2023 ▼ 10 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 10 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5