

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

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

Lab033

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2023/09)	CUM (2023/08/03~2023/09/29)	Month (2023/09)	CUM (2023/08/03~2023/09/29)
Runs (N)	4	9	4	9
Mean (U/gHb)	15.9	16.3	4.8	5.0
SD	0.5	0.6	0.1	0.2
CV (%)	3.1	3.7	2.1	4.0
Target Value (U/gHb)	12.8	12.8	4.2	4.2
Total Error (%)	30.5	34.7	18.5	27.0
TEa (%)	20	20	20	20
σ	-1.4	-2.0	2.7	0.2

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

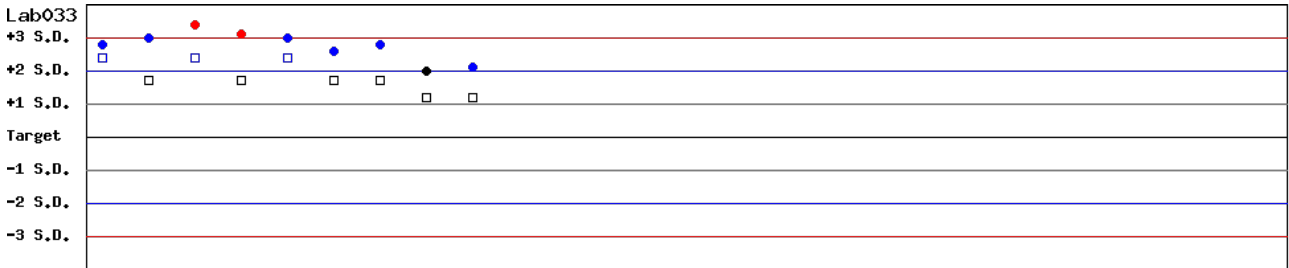
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Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-08-03 to 2023-09-29 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: BA1116D ; Duration : 2023-08-03 to 2023-09-29 ; Target : 4.2 ; SD : 0.42 (□)

Lab033



Date 08-03 08-10 08-17 08-24 08-31 09-07 09-14 09-21 09-28

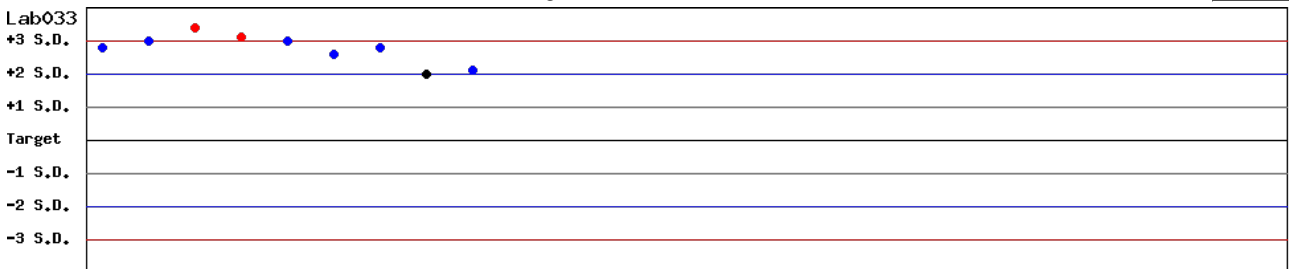
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-08-03 to 2023-09-29 ; Target : 12.8 ; SD : 1.28

Lab033



Date 08-03 08-10 08-17 08-24 08-31 09-07 09-14 09-21 09-28

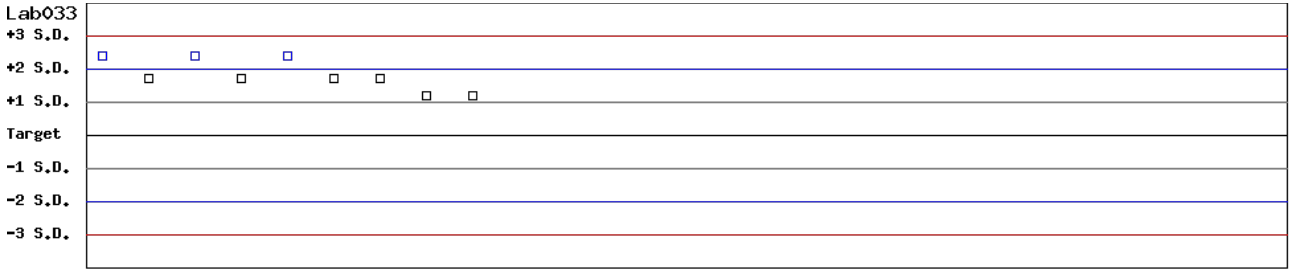
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2023-08-03 to 2023-09-29 ; Target : 4.2 ; SD : 0.42

Lab033



Date 08-03 08-10 08-17 08-24 08-31 09-07 09-14 09-21 09-28

Month : 2023 ▾ 09 ▾ Change ; Cumulative : from 2023 ▾ 08 ▾ 03 ▾ to 2023 ▾ 09 ▾ 29 ▾ Change

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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 09 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	14.1	9	0.1	0.7	5.1	20	>6	4.3	4.4	9	0.1	2.3	6.9	20	>6
Lab033	5	12.8	15.9	4	0.5	3.1	30.5	20	-1.4	4.2	4.8	4	0.1	2.1	18.5	20	2.7
Lab037	5	12.8	14.3	2	-	-	-	20	-	4.2	4.5	2	-	-	-	20	-
Total	-	-	14.6	15	0.8	5.5	-	-	-	-	4.5	15	0.2	4.4	-	-	-

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 09 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	13.8	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	55	0.8	5.4	27.1	20	0.7	4.2	4.8	55	0.3	6.3	26.8	20	0.9
Lab033	5	12.8	16.3	9	0.6	3.7	34.7	20	-2.0	4.2	5.0	9	0.2	4.0	27.0	20	0.2
Lab037	5	12.8	14.0	4	0.3	2.1	13.7	20	5.1	4.2	4.5	4	0.1	2.2	11.6	20	5.8
Total	-	-	14.3	181	0.9	6.3	-	-	-	-	4.5	181	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 (2023/09)								CUM (2022/06/01~2023/09/30)							
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	14.1	9	0.1	0.7	5.1	20	>6	13.6	13.8	113	0.4	2.9	7.3	20	>6
Lab027	5	12.8	-	0	-	-	-	20	-	12.8	14.9	55	0.8	5.4	27.1	20	0.7
Lab033	5	12.8	15.9	4	0.5	3.1	30.5	20	-1.4	12.8	16.3	9	0.6	3.7	34.7	20	-2.0
Lab037	5	12.8	14.3	2	-	-	-	20	-	12.8	14.0	4	0.3	2.1	13.7	20	5.1
Total	-	-	14.6	15	0.8	5.5	-	-	-	-	14.3	181	0.9	6.3	-	-	-

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

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

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

Month : 2023 ▼ 09 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 09 ▼ 30 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2023/09)								CUM (2022/06/01~2023/09/30)							
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	4.4	9	0.1	2.3	6.9	20	>6	4.3	4.4	113	0.1	2.3	6.9	20	>6
Lab027	5	4.2	-	0	-	-	-	20	-	4.2	4.8	55	0.3	6.3	26.8	20	0.9
Lab033	5	4.2	4.8	4	0.1	2.1	18.5	20	2.7	4.2	5.0	9	0.2	4.0	27.0	20	0.2
Lab037	5	4.2	4.5	2	-	-	-	20	-	4.2	4.5	4	0.1	2.2	11.6	20	5.8
Total	-	-	4.5	15	0.2	4.4	-	-	-	-	4.5	181	0.3	6.7	-	-	-

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

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

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

Month : 2023 ▼ 09 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 09 ▼ 30 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5