

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

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

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Lab033

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2024/08)	CUM (2024/03/07~2024/08/31)	Month (2024/08)	CUM (2024/03/07~2024/08/31)
Runs (N)	5	26	5	26
Mean (U/gHb)	15.8	15.8	4.8	4.8
SD	0.3	0.3	0.2	0.1
CV (%)	1.9	1.9	4.2	2.1
Target Value (U/gHb)	15.8	15.8	4.7	4.7
Total Error (%)	3.8	3.8	10.5	6.3
TEa (%)	20	20	20	20
σ	>6	>6	4.3	>6

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

Month : 2024 08 Change ; Cumulative : from 2024 03 07 to 2024 08 31 Change

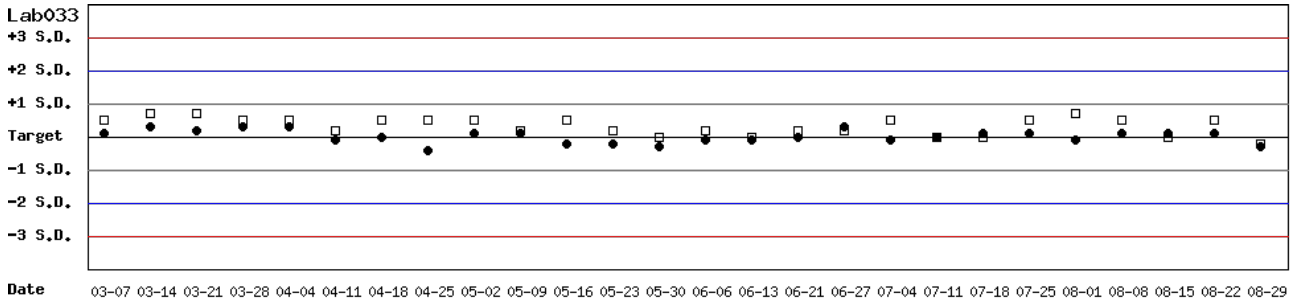
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Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2024-03-07 to 2024-08-31 ; Target : 15.8 ; SD : 1.48 (●)

Lot No.: BA1116D ; Duration : 2024-03-07 to 2024-08-31 ; Target : 4.7 ; SD : 0.42 (□)

Lab033



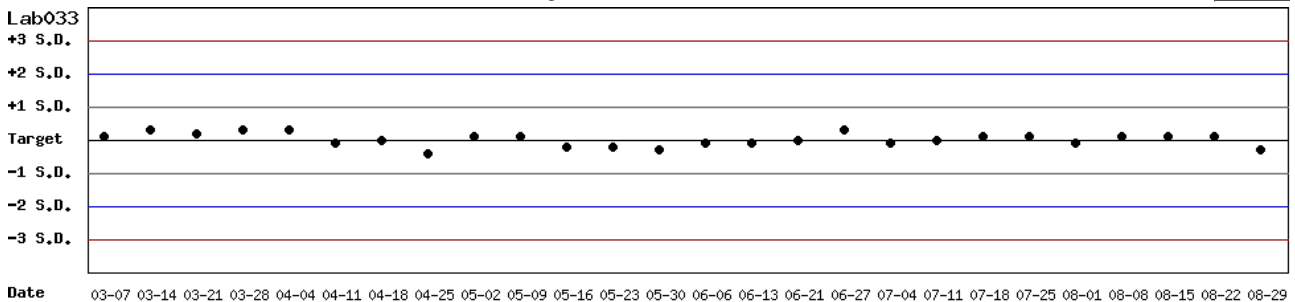
Month : 2024 08 Change ; Cumulative : from 2024 03 07 to 2024 08 31 Change

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2024-03-07 to 2024-08-31 ; Target : 15.8 ; SD : 1.48

Lab033



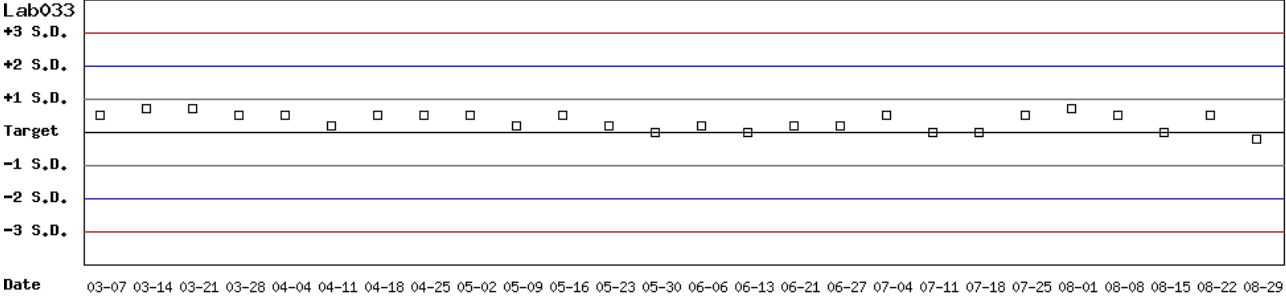
Month : 2024 08 Change ; Cumulative : from 2024 03 07 to 2024 08 31 Change

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2024-03-07 to 2024-08-31 ; Target : 4.7 ; SD : 0.42

Lab033



Month : 2024 v 08 v Change ; Cumulative : from 2024 v 03 v 07 v to 2024 v 08 v 31 v 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 : 2024 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
Lab032	5	14.9	13.7	5	0.5	3.6	15.4	20	3.3	5.1	4.2	5	0.2	4.8	27.2	20	0.5
Lab033	5	15.8	15.8	5	0.3	1.9	3.8	20	>6	4.7	4.8	5	0.2	4.2	10.5	20	4.3
Lab037	5	12.8	13.7	3	0.5	3.6	14.3	20	3.6	4.2	4.2	3	0.1	2.4	4.8	20	>6
Total	-	-	14.5	13	1.1	7.6	-	-	-	-	4.5	13	0.3	6.7	-	-	-

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 2024 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	13.8	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	74	0.9	6.0	28.5	20	0.6	4.2	4.9	74	0.4	8.2	33.0	20	0.4
Lab032	5	14.9	13.8	13	0.3	2.2	11.7	20	5.7	5.1	4.3	13	0.2	4.7	25.0	20	0.9
Lab033	5	15.8	15.8	57	0.5	3.2	6.3	20	>6	4.7	4.8	57	0.2	4.2	10.5	20	4.3
Lab037	5	12.8	13.9	25	0.4	2.9	14.3	20	3.9	4.2	4.4	25	0.2	4.5	13.9	20	3.4
Total	-	-	14.5	282	1.0	6.9	-	-	-	-	4.6	282	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 (2024/08)								CUM (2022/06/01~2024/08/31)							
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	-	0	-	-	-	20	-	13.6	13.8	113	0.4	2.9	7.3	20	>6
Lab027	5	12.8	-	0	-	-	-	20	-	12.8	14.9	74	0.9	6.0	28.5	20	0.6
Lab032	5	14.9	13.7	5	0.5	3.6	15.4	20	3.3	14.9	13.8	13	0.3	2.2	11.7	20	5.7
Lab033	5	15.8	15.8	5	0.3	1.9	3.8	20	>6	15.8	15.8	57	0.5	3.2	6.3	20	>6
Lab037	5	12.8	13.7	3	0.5	3.6	14.3	20	3.6	12.8	13.9	25	0.4	2.9	14.3	20	3.9
Total	-	-	14.5	13	1.1	7.6	-	-	-	-	14.5	282	1.0	6.9	-	-	-

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

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

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

Month : 2024 ▼ 08 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2024 ▼ 08 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2024/08)								CUM (2022/06/01~2024/08/31)							
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	-	0	-	-	-	20	-	4.3	4.4	113	0.1	2.3	6.9	20	>6
Lab027	5	4.2	-	0	-	-	-	20	-	4.2	4.9	74	0.4	8.2	33.0	20	0.4
Lab032	5	5.1	4.2	5	0.2	4.8	27.2	20	0.5	5.1	4.3	13	0.2	4.7	25.0	20	0.9
Lab033	5	4.7	4.8	5	0.2	4.2	10.5	20	4.3	4.7	4.8	57	0.2	4.2	10.5	20	4.3
Lab037	5	4.2	4.2	3	0.1	2.4	4.8	20	>6	4.2	4.4	25	0.2	4.5	13.9	20	3.4
Total	-	-	4.5	13	0.3	6.7	-	-	-	-	4.6	282	0.3	6.5	-	-	-

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

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

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

Month : 2024 ▼ 08 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2024 ▼ 08 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5