

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

Select LotNo :

Lab033

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2023/12)	CUM (2023/08/03~2023/12/30)	Month (2023/12)	CUM (2023/08/03~2023/12/30)
Runs (N)	4	22	4	22
Mean (U/gHb)	15.7	15.9	4.9	4.8
SD	0.4	0.7	0.1	0.3
CV (%)	2.5	4.4	2.0	6.3
Target Value (U/gHb)	15.8	15.8	4.2	4.2
Total Error (%)	5.7	9.4	20.7	26.8
TEa (%)	20	20	20	20
σ	>6	4.4	1.7	0.9

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

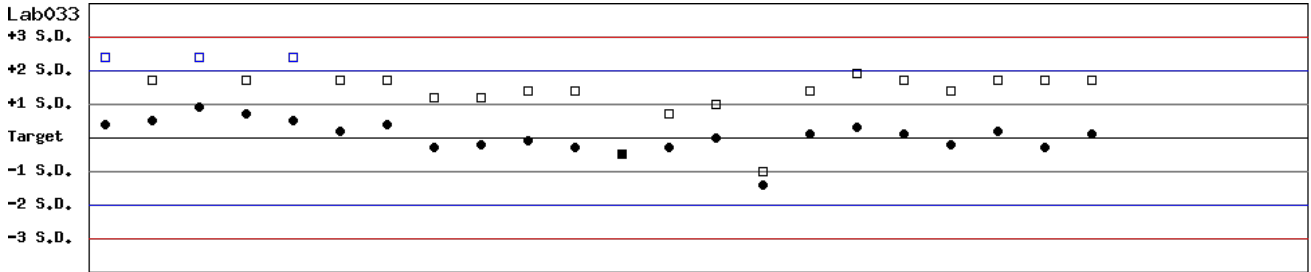
Month : ; Cumulative : from to

[\[TOP\]](#)

Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-08-03 to 2023-12-30 ; Target : 15.8 ; SD : 1.48 (●)

Lot No.: BA1116D ; Duration : 2023-08-03 to 2023-12-30 ; Target : 4.2 ; SD : 0.42 (□)



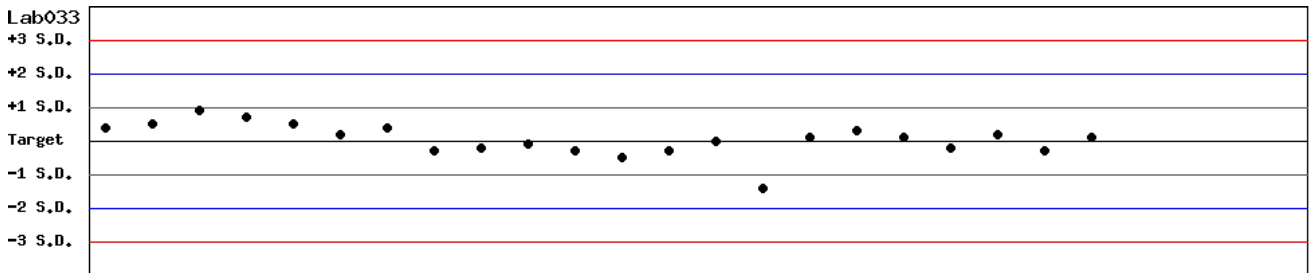
Date 08-03 08-10 08-17 08-24 08-31 09-07 09-14 09-21 09-28 10-05 10-12 10-19 10-26 11-02 11-09 11-16 11-23 11-30 12-07 12-14 12-21 12-28

Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-08-03 to 2023-12-30 ; Target : 15.8 ; SD : 1.48



Date 08-03 08-10 08-17 08-24 08-31 09-07 09-14 09-21 09-28 10-05 10-12 10-19 10-26 11-02 11-09 11-16 11-23 11-30 12-07 12-14 12-21 12-28

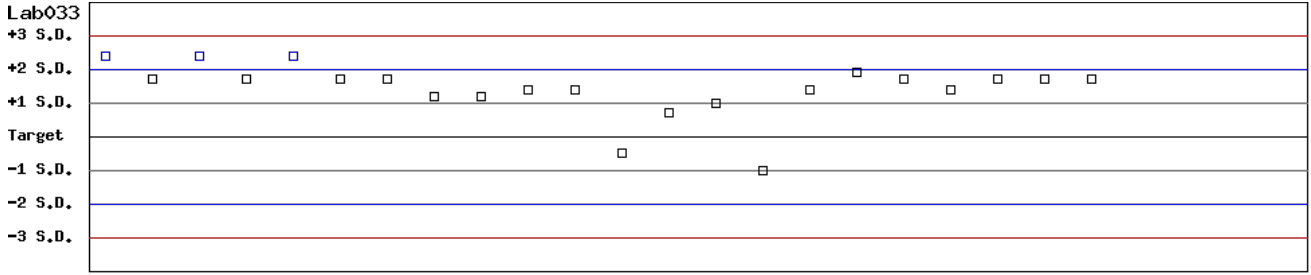
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2023-08-03 to 2023-12-30 ; 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 10-05 10-12 10-19 10-26 11-02 11-09 11-16 11-23 11-30 12-07 12-14 12-21 12-28

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 : 2023

		Control N (Lot No.: BA1116N)								Control D (Lot No.: BA1116D)							
UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	13.9	4	1.3	9.4	27.3	20	1.2	4.2	4.8	4	0.5	10.4	35.1	20	0.5
Lab033	5	15.8	15.7	4	0.4	2.5	5.7	20	>6	4.2	4.9	4	0.1	2.0	20.7	20	1.7
Total	-	-	14.8	8	1.3	8.8	-	-	-	-	4.8	8	0.3	6.3	-	-	-

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 to 2023

		Control N (Lot No.: BA1116N)								Control D (Lot No.: BA1116D)							
UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	68	0.9	6.0	28.5	20	0.6	4.2	4.8	68	0.4	8.3	31.0	20	0.7
Lab033	5	15.8	15.9	22	0.7	4.4	9.4	20	4.4	4.2	4.8	22	0.3	6.3	26.8	20	0.9
Lab037	5	12.8	14.0	8	0.4	2.9	15.1	20	3.7	4.2	4.5	8	0.2	4.4	16.0	20	2.9
Total	-	-	14.4	211	0.9	6.3	-	-	-	-	4.6	211	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 (2023/12)								CUM (2022/06/01~2023/12/31)							
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	13.9	4	1.3	9.4	27.3	20	1.2	12.8	14.9	68	0.9	6.0	28.5	20	0.6
Lab033	5	15.8	15.7	4	0.4	2.5	5.7	20	>6	15.8	15.9	22	0.7	4.4	9.4	20	4.4
Lab037	5	12.8	-	0	-	-	-	20	-	12.8	14.0	8	0.4	2.9	15.1	20	3.7
Total	-	-	14.8	8	1.3	8.8	-	-	-	-	14.4	211	0.9	6.3	-	-	-

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

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

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

Month : 2023 ▼ 12 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 12 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2023/12)								CUM (2022/06/01~2023/12/31)							
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	4.8	4	0.5	10.4	35.1	20	0.5	4.2	4.8	68	0.4	8.3	31.0	20	0.7
Lab033	5	4.2	4.9	4	0.1	2.0	20.7	20	1.7	4.2	4.8	22	0.3	6.3	26.8	20	0.9
Lab037	5	4.2	-	0	-	-	-	20	-	4.2	4.5	8	0.2	4.4	16.0	20	2.9
Total	-	-	4.8	8	0.3	6.3	-	-	-	-	4.6	211	0.3	6.5	-	-	-

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

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

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

Month : 2023 ▼ 12 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 12 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5