

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

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

[Print Table](#)

Lab033

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2024/06)	CUM (2024/01/04~2024/06/30)	Month (2024/06)	CUM (2024/01/04~2024/06/30)
Runs (N)	4	26	4	26
Mean (U/gHb)	15.8	15.8	4.8	4.9
SD	0.3	0.3	0.1	0.1
CV (%)	1.9	1.9	2.1	2.0
Target Value (U/gHb)	15.8	15.8	4.7	4.7
Total Error (%)	3.8	3.8	6.3	8.3
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 : 2024 06 Change ; Cumulative : from 2024 01 04 to 2024 06 30 Change

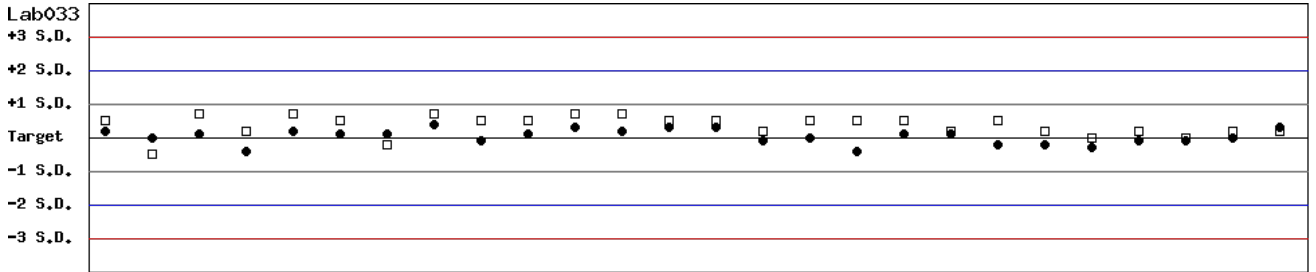
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Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2024-01-04 to 2024-06-30 ; Target : 15.8 ; SD : 1.48 (●)

Lot No.: BA1116D ; Duration : 2024-01-04 to 2024-06-30 ; Target : 4.7 ; SD : 0.42 (□)

Lab033



Date 01-04 01-11 01-18 01-25 02-01 02-08 02-15 02-22 02-29 03-07 03-14 03-21 03-28 04-04 04-11 04-18 04-25 05-02 05-09 05-16 05-23 05-30 06-06 06-13 06-21 06-27

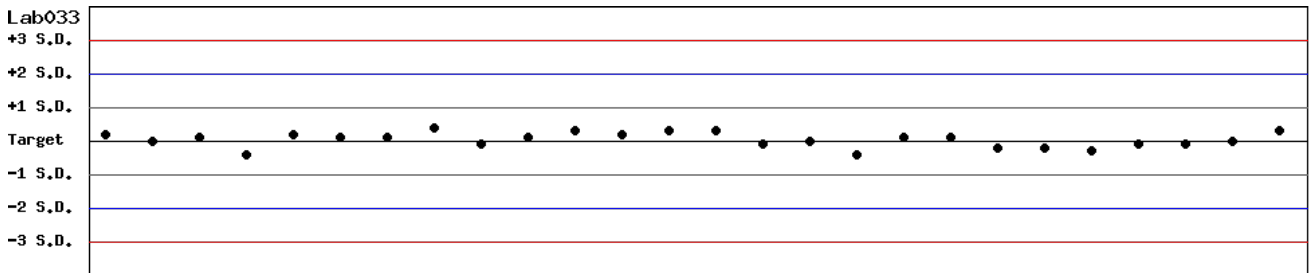
Month : 2024 06 Change ; Cumulative : from 2024 01 04 to 2024 06 30 Change

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2024-01-04 to 2024-06-30 ; Target : 15.8 ; SD : 1.48

Lab033



Date 01-04 01-11 01-18 01-25 02-01 02-08 02-15 02-22 02-29 03-07 03-14 03-21 03-28 04-04 04-11 04-18 04-25 05-02 05-09 05-16 05-23 05-30 06-06 06-13 06-21 06-27

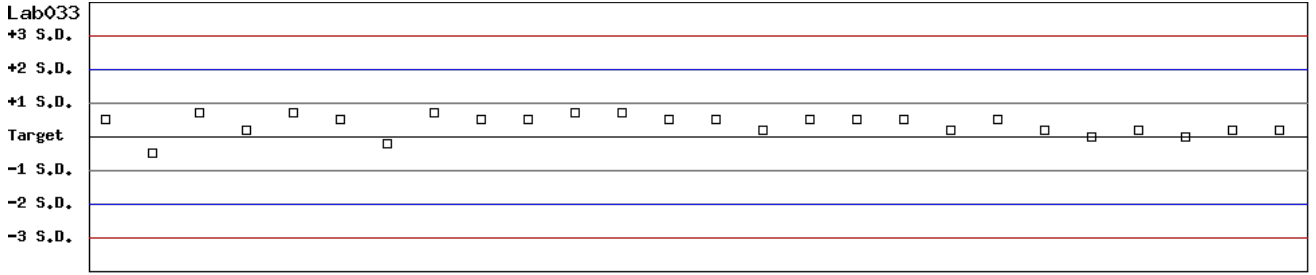
Month : 2024 06 Change ; Cumulative : from 2024 01 04 to 2024 06 30 Change

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2024-01-04 to 2024-06-30 ; Target : 4.7 ; SD : 0.42

Lab033



Date: 01-04 01-11 01-18 01-25 02-01 02-08 02-15 02-22 02-29 03-07 03-14 03-21 03-28 04-04 04-11 04-18 04-25 05-02 05-09 05-16 05-23 05-30 06-06 06-13 06-21 06-27

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 : 2024 06 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
Lab033	5	15.8	15.8	4	0.3	1.9	3.8	20	>6	4.7	4.8	4	0.1	2.1	6.3	20	>6
Lab037	5	12.8	13.7	2	-	-	-	20	-	4.2	4.5	2	-	-	-	20	-
Total	-	-	15.1	6	1.1	7.3	-	-	-	-	4.7	6	0.2	4.3	-	-	-

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 2024 06 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	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	13.9	4	0.1	0.7	8.2	20	>6	5.1	4.3	4	0.2	4.7	25.0	20	0.9
Lab033	5	15.8	15.9	48	0.5	3.1	6.9	20	>6	4.7	4.8	48	0.2	4.2	10.5	20	4.3
Lab037	5	12.8	13.9	20	0.3	2.2	12.9	20	5.2	4.2	4.5	20	0.1	2.2	11.6	20	5.8
Total	-	-	14.5	259	1.0	6.9	-	-	-	-	4.6	259	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 (2024/06)								CUM (2022/06/01~2024/06/30)							
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	-	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	-	0	-	-	-	20	-	14.9	13.9	4	0.1	0.7	8.2	20	>6
Lab033	5	15.8	15.8	4	0.3	1.9	3.8	20	>6	15.8	15.9	48	0.5	3.1	6.9	20	>6
Lab037	5	12.8	13.7	2	-	-	-	20	-	12.8	13.9	20	0.3	2.2	12.9	20	5.2
Total	-	-	15.1	6	1.1	7.3	-	-	-	-	14.5	259	1.0	6.9	-	-	-

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

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

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

Month : 2024 06 Change Cumulative : from 2022 06 01 to 2024 06 30 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2024/06)								CUM (2022/06/01~2024/06/30)							
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	-	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	-	0	-	-	-	20	-	5.1	4.3	4	0.2	4.7	25.0	20	0.9
Lab033	5	4.7	4.8	4	0.1	2.1	6.3	20	>6	4.7	4.8	48	0.2	4.2	10.5	20	4.3
Lab037	5	4.2	4.5	2	-	-	-	20	-	4.2	4.5	20	0.1	2.2	11.6	20	5.8
Total	-	-	4.7	6	0.2	4.3	-	-	-	-	4.6	259	0.3	6.5	-	-	-

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

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

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

Month : 2024 06 Change Cumulative : from 2022 06 01 to 2024 06 30 Change

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Reagent Kit	Reagent Code
Medicon	5