

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 (2024/09)	CUM (2024/04/04~2024/09/30)	Month (2024/09)	CUM (2024/04/04~2024/09/30)
Runs (N)	4	26	4	26
Mean (U/gHb)	15.3	15.7	4.7	4.8
SD	0.4	0.3	0.1	0.1
CV (%)	2.6	1.9	2.1	2.1
Target Value (U/gHb)	15.8	15.8	4.7	4.7
Total Error (%)	8.4	4.5	4.3	6.3
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

Bias (%) = $[(| \text{Mean} - \text{Target} |) / \text{Target}] \times 100\%$

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

σ (Sigma) = $[\text{TEa}\% - \text{Bias}\%] / \text{CV}\%$

Month : 2024 09 Change ; Cumulative : from 2024 04 04 to 2024 09 30 Change

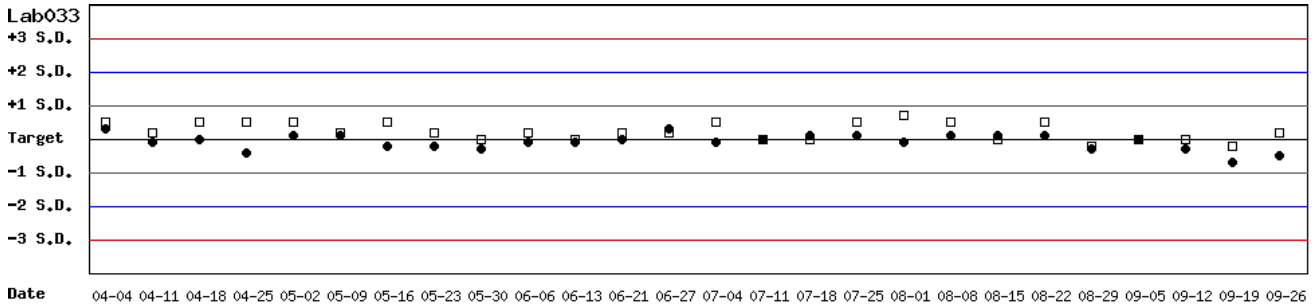
[TOP](#)

Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2024-04-04 to 2024-09-30 ; Target : 15.8 ; SD : 1.48 (●)

Lot No.: BA1116D ; Duration : 2024-04-04 to 2024-09-30 ; Target : 4.7 ; SD : 0.42 (□)

Lab033



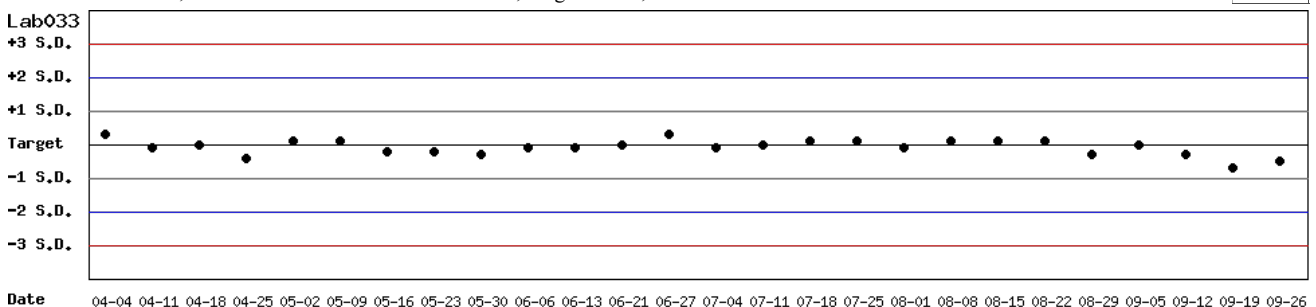
Month : 2024 09 Change ; Cumulative : from 2024 04 04 to 2024 09 30 Change

[TOP](#)

Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2024-04-04 to 2024-09-30 ; Target : 15.8 ; SD : 1.48

Lab033



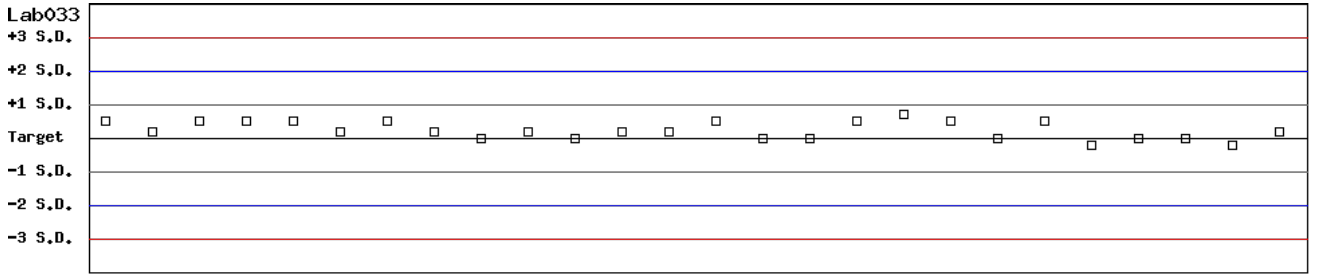
Month : 2024 09 Change ; Cumulative : from 2024 04 04 to 2024 09 30 Change

[TOP](#)

Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2024-04-04 to 2024-09-30 ; Target : 4.7 ; SD : 0.42

Lab033



Date 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 07-04 07-11 07-18 07-25 08-01 08-08 08-15 08-22 08-29 09-05 09-12 09-19 09-26

Month : ; Cumulative : from to

[\[TOP\]](#)

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 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
Lab032	5	14.9	13.3	4	0.2	1.5	13.7	20	>6	5.1	4.1	4	0.2	4.9	29.4	20	0.1
Lab033	5	15.8	15.3	4	0.4	2.6	8.4	20	>6	4.7	4.7	4	0.1	2.1	4.3	20	>6
Lab037	5	12.8	14.0	2	-	-	-	20	-	4.2	4.6	2	-	-	-	20	-
Total	-	-	14.2	10	1.0	7.0	-	-	-	-	4.5	10	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 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	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	13.7	17	0.4	2.9	13.9	20	4.1	5.1	4.3	17	0.2	4.7	25.0	20	0.9
Lab033	5	15.8	15.8	61	0.5	3.2	6.3	20	>6	4.7	4.8	61	0.2	4.2	10.5	20	4.3
Lab037	5	12.8	13.9	27	0.4	2.9	14.3	20	3.9	4.2	4.4	27	0.2	4.5	13.9	20	3.4
Total	-	-	14.5	292	1.0	6.9	-	-	-	-	4.6	292	0.3	6.5	-	-	-

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

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

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

[\[TOP\]](#)

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 (2024/09)								CUM (2022/06/01~2024/09/30)							
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	13.3	4	0.2	1.5	13.7	20	>6	14.9	13.7	17	0.4	2.9	13.9	20	4.1
Lab033	5	15.8	15.3	4	0.4	2.6	8.4	20	>6	15.8	15.8	61	0.5	3.2	6.3	20	>6
Lab037	5	12.8	14.0	2	-	-	-	20	-	12.8	13.9	27	0.4	2.9	14.3	20	3.9
Total	-	-	14.2	10	1.0	7.0	-	-	-	-	14.5	292	1.0	6.9	-	-	-

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

Month : 2024 09 Change Cumulative : from 2022 06 01 to 2024 09 30 Change

[\[TOP\]](#)

Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2024/09)								CUM (2022/06/01~2024/09/30)							
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	4.1	4	0.2	4.9	29.4	20	0.1	5.1	4.3	17	0.2	4.7	25.0	20	0.9
Lab033	5	4.7	4.7	4	0.1	2.1	4.3	20	>6	4.7	4.8	61	0.2	4.2	10.5	20	4.3
Lab037	5	4.2	4.6	2	-	-	-	20	-	4.2	4.4	27	0.2	4.5	13.9	20	3.4
Total	-	-	4.5	10	0.3	6.7	-	-	-	-	4.6	292	0.3	6.5	-	-	-

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

Month : 2024 09 Change Cumulative : from 2022 06 01 to 2024 09 30 Change

[\[TOP\]](#)

Reagent Kit	Reagent Code
Medicon	5