

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

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

Lab037

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2024/04)	CUM (2023/07/28~2024/04/30)	Month (2024/04)	CUM (2023/07/28~2024/04/30)
Runs (N)	2	16	2	16
Mean (U/gHb)	13.9	14.0	4.4	4.5
SD	-	0.3	-	0.1
CV (%)	-	2.1	-	2.2
Target Value (U/gHb)	12.8	12.8	4.2	4.2
Total Error (%)	-	13.7	-	11.6
TEa (%)	20	20	20	20
σ	-	5.1	-	5.8

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

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

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

Month : ; Cumulative : from to

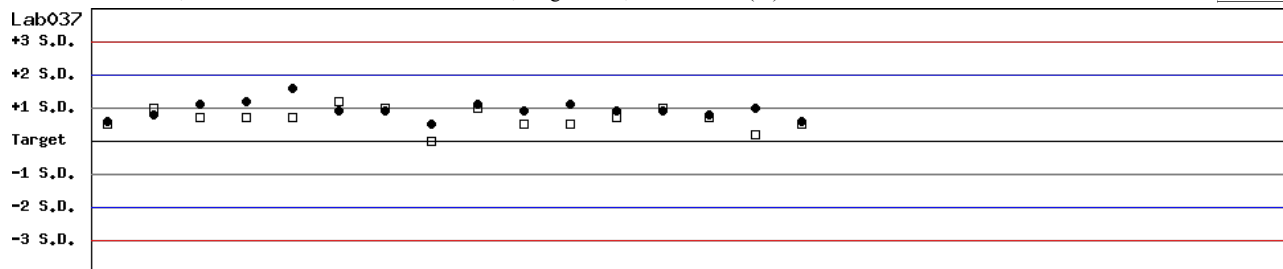
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Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-07-28 to 2024-04-30 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: BA1116D ; Duration : 2023-07-28 to 2024-04-30 ; Target : 4.2 ; SD : 0.42 (□)

Lab037



Date 07-28 08-24 09-08 09-29 10-12 10-26 11-09 11-24 01-10 01-25 02-08 02-23 03-08 03-21 04-05 04-26

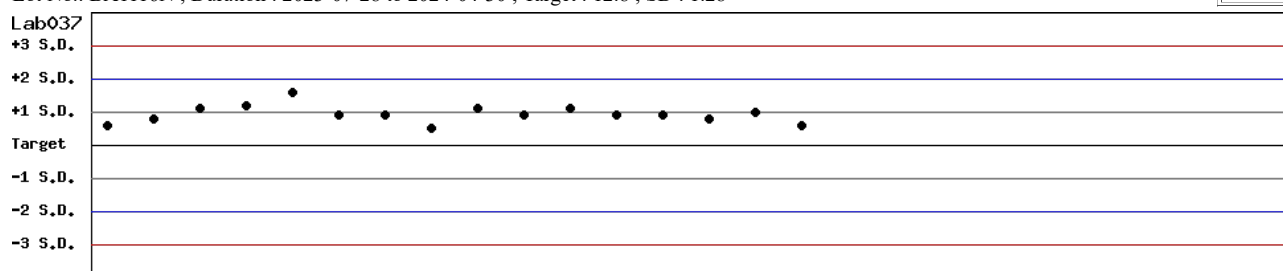
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-07-28 to 2024-04-30 ; Target : 12.8 ; SD : 1.28

Lab037



Date 07-28 08-24 09-08 09-29 10-12 10-26 11-09 11-24 01-10 01-25 02-08 02-23 03-08 03-21 04-05 04-26

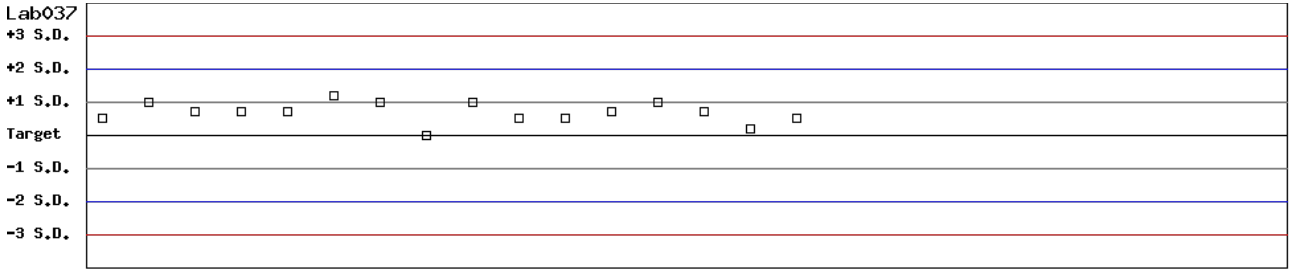
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2023-07-28 to 2024-04-30 ; Target : 4.2 ; SD : 0.42

Lab037



Date 07-28 08-24 09-08 09-29 10-12 10-26 11-09 11-24 01-10 01-25 02-08 02-23 03-08 03-21 04-05 04-26

Month : 2024 v 04 v Change ; Cumulative : from 2023 v 07 v 28 v to 2024 v 04 v 30 v 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 : 2024 04 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	15.7	4	0.4	2.5	5.7	20	>6	4.2	4.9	4	0.1	2.0	20.7	20	1.7
Lab037	5	12.8	13.9	2	-	-	-	20	-	4.2	4.4	2	-	-	-	20	-
Total	-	-	15.1	6	1.0	6.6	-	-	-	-	4.7	6	0.3	6.4	-	-	-

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 2024 04 30 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	39	0.6	3.8	8.2	20	5.1	4.2	4.8	39	0.3	6.3	26.8	20	0.9
Lab037	5	12.8	14.0	16	0.3	2.1	13.7	20	5.1	4.2	4.5	16	0.1	2.2	11.6	20	5.8
Total	-	-	14.5	246	1.0	6.9	-	-	-	-	4.6	246	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 (2024/04)								CUM (2022/06/01~2024/04/30)							
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	15.7	4	0.4	2.5	5.7	20	>6	15.8	15.9	39	0.6	3.8	8.2	20	5.1
Lab037	5	12.8	13.9	2	-	-	-	20	-	12.8	14.0	16	0.3	2.1	13.7	20	5.1
Total	-	-	15.1	6	1.0	6.6	-	-	-	-	14.5	246	1.0	6.9	-	-	-

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

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

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

Month : 2024 ▼ 04 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2024 ▼ 04 ▼ 30 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2024/04)								CUM (2022/06/01~2024/04/30)							
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	4.2	4.9	4	0.1	2.0	20.7	20	1.7	4.2	4.8	39	0.3	6.3	26.8	20	0.9
Lab037	5	4.2	4.4	2	-	-	-	20	-	4.2	4.5	16	0.1	2.2	11.6	20	5.8
Total	-	-	4.7	6	0.3	6.4	-	-	-	-	4.6	246	0.3	6.5	-	-	-

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

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

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

Month : 2024 ▼ 04 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2024 ▼ 04 ▼ 30 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5