

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

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

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Lab032

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2024/03)	CUM (2024/03/08~2024/03/30)	Month (2024/03)	CUM (2024/03/08~2024/03/30)
Runs (N)	4	4	4	4
Mean (U/gHb)	13.9	13.9	4.3	4.3
SD	0.1	0.1	0.2	0.2
CV (%)	0.7	0.7	4.7	4.7
Target Value (U/gHb)	14.9	14.9	5.1	5.1
Total Error (%)	8.2	8.2	25.0	25.0
TEa (%)	20	20	20	20
σ	>6	>6	0.9	0.9

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

Month : 2024 v 03 v Change ; Cumulative : from 2024 v 03 v 08 v to 2024 v 03 v 30 v Change

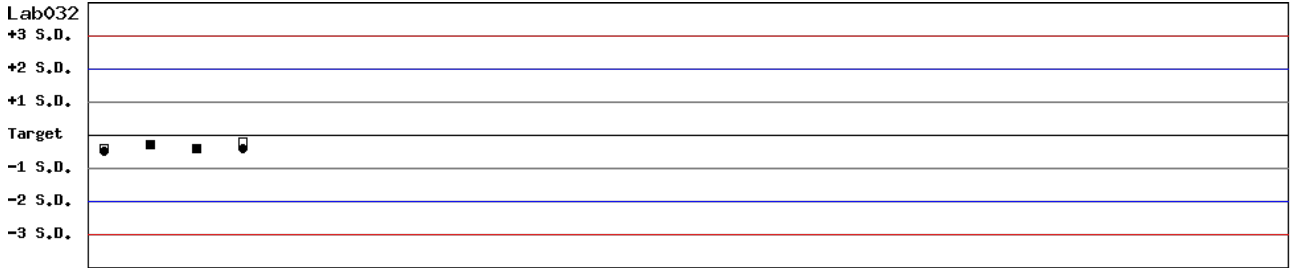
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Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2024-03-08 to 2024-03-30 ; Target : 14.9 ; SD : 2.30 (●)

Lot No.: BA1116D ; Duration : 2024-03-08 to 2024-03-30 ; Target : 5.1 ; SD : 2.50 (□)

Lab032



Date 03-08 03-15 03-22 03-29

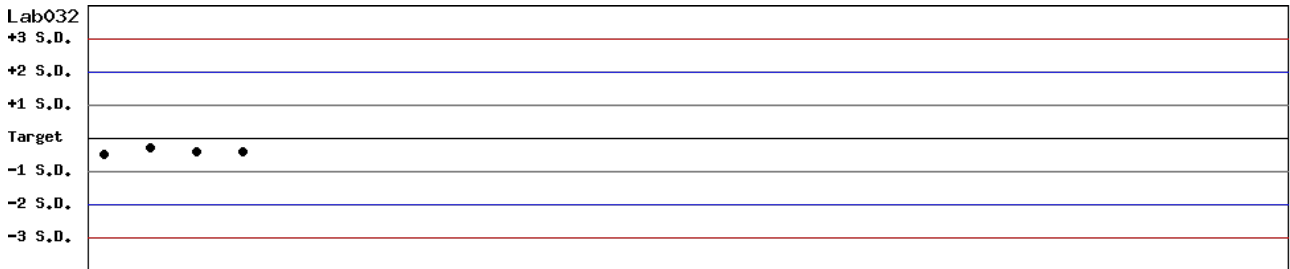
Month : 2024 v 03 v Change ; Cumulative : from 2024 v 03 v 08 v to 2024 v 03 v 30 v Change

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2024-03-08 to 2024-03-30 ; Target : 14.9 ; SD : 2.30

Lab032



Date 03-08 03-15 03-22 03-29

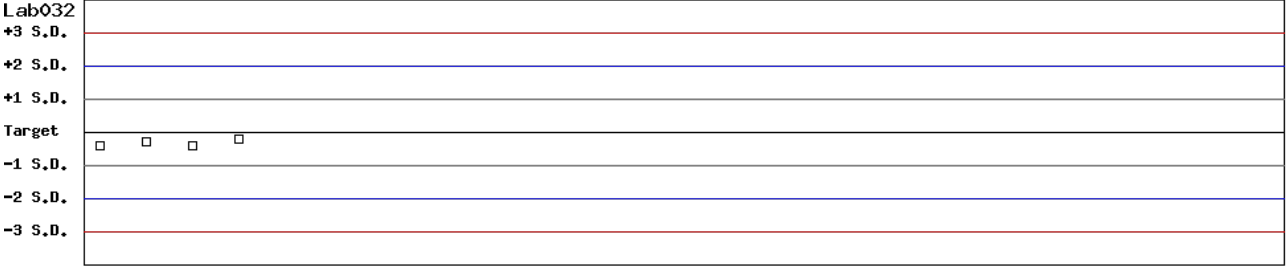
Month : 2024 v 03 v Change ; Cumulative : from 2024 v 03 v 08 v to 2024 v 03 v 30 v Change

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2024-03-08 to 2024-03-30 ; Target : 5.1 ; SD : 2.50

Lab032



Date 03-08 03-15 03-22 03-29

Month : 2024 v 03 v Change ; Cumulative : from 2024 v 03 v 08 v to 2024 v 03 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 03 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	13.9	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	16.2	4	0.1	0.6	3.8	20	>6	4.2	5.0	4	0.1	2.0	23.0	20	0.5
Lab037	5	12.8	13.9	2	-	-	-	20	-	4.2	4.6	2	-	-	-	20	-
Total	-	-	14.8	10	1.2	8.1	-	-	-	-	4.6	10	0.3	6.5	-	-	-

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 03 31 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	35	0.6	3.8	8.2	20	5.1	4.2	4.8	35	0.3	6.3	26.8	20	0.9
Lab037	5	12.8	14.0	14	0.3	2.1	13.7	20	5.1	4.2	4.5	14	0.1	2.2	11.6	20	5.8
Total	-	-	14.5	240	1.0	6.9	-	-	-	-	4.6	240	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 (2024/03)								CUM (2022/06/01~2024/03/31)							
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	13.9	4	0.1	0.7	8.2	20	>6	14.9	13.9	4	0.1	0.7	8.2	20	>6
Lab033	5	15.8	16.2	4	0.1	0.6	3.8	20	>6	15.8	15.9	35	0.6	3.8	8.2	20	5.1
Lab037	5	12.8	13.9	2	-	-	-	20	-	12.8	14.0	14	0.3	2.1	13.7	20	5.1
Total	-	-	14.8	10	1.2	8.1	-	-	-	-	14.5	240	1.0	6.9	-	-	-

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

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

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

Month : 2024 ▼ 03 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2024 ▼ 03 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2024/03)								CUM (2022/06/01~2024/03/31)							
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	4.3	4	0.2	4.7	25.0	20	0.9	5.1	4.3	4	0.2	4.7	25.0	20	0.9
Lab033	5	4.2	5.0	4	0.1	2.0	23.0	20	0.5	4.2	4.8	35	0.3	6.3	26.8	20	0.9
Lab037	5	4.2	4.6	2	-	-	-	20	-	4.2	4.5	14	0.1	2.2	11.6	20	5.8
Total	-	-	4.6	10	0.3	6.5	-	-	-	-	4.6	240	0.3	6.5	-	-	-

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

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

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

Month : 2024 ▼ 03 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2024 ▼ 03 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5