

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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Lab018

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2023/05)	CUM (2023/01/20~2023/05/31)	Month (2023/05)	CUM (2023/01/20~2023/05/31)
Runs (N)	12	26	12	26
Mean (U/gHb)	13.9	13.9	4.5	4.5
SD	0.2	0.3	0.0	0.1
CV (%)	1.4	2.2	0.0	2.2
Target Value (U/gHb)	13.6	13.6	4.3	4.3
Total Error (%)	5.1	6.5	4.7	9.1
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

Bias (%) = $\left[\frac{|\text{Mean} - \text{Target}|}{\text{Target}} \right] \times 100\%$
 TE : Total Error(%) = Bias (%) + 2 × CV (%)
 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2023 v 05 v Change ; Cumulative : from 2023 v 01 v 20 v to 2023 v 05 v 31 v Change

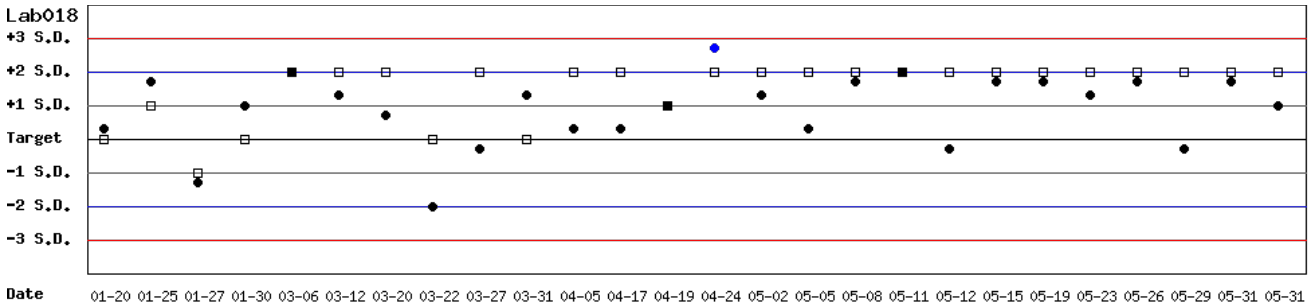
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Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-01-20 to 2023-05-31 ; Target : 13.6 ; SD : 0.30 (●)

Lot No.: BA1116D ; Duration : 2023-01-20 to 2023-05-31 ; Target : 4.3 ; SD : 0.10 (□)

Lab018



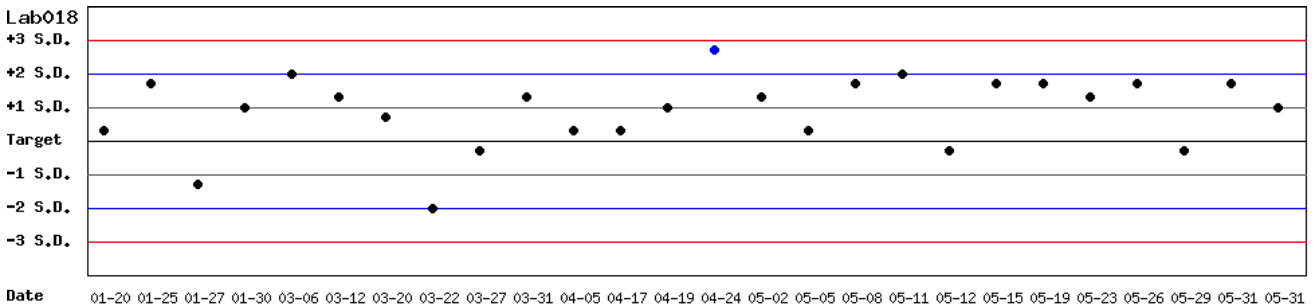
Month : 2023 v 05 v Change ; Cumulative : from 2023 v 01 v 20 v to 2023 v 05 v 31 v Change

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2023-01-20 to 2023-05-31 ; Target : 13.6 ; SD : 0.30

Lab018



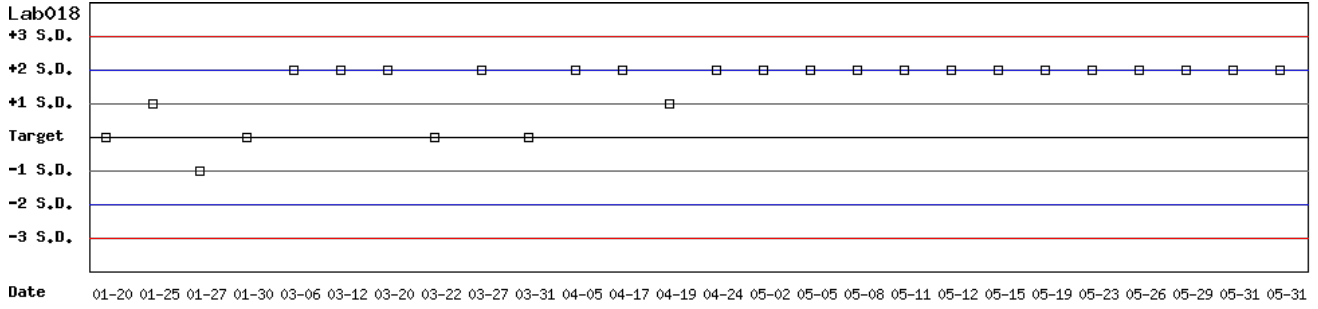
Month : 2023 v 05 v Change ; Cumulative : from 2023 v 01 v 20 v to 2023 v 05 v 31 v Change

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2023-01-20 to 2023-05-31 ; Target : 4.3 ; SD : 0.10

Lab018



Month : 2023 05 Change ; Cumulative : from 2023 01 20 to 2023 05 31 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

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Monthly

Month : 2023 05 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	13.9	12	0.2	1.4	5.1	20	>6	4.3	4.5	12	0.0	0.0	4.7	20	>6
Lab027	5	12.8	14.4	4	1.4	9.7	31.9	20	0.8	4.2	4.7	4	0.6	12.8	37.4	20	0.6
Total	-	-	14.1	16	0.7	5.0	-	-	-	-	4.6	16	0.3	6.5	-	-	-

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

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

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

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Cumulative

Cumulative : from 2022 06 01 to 2023 05 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	13.7	78	0.3	2.2	5.1	20	>6	4.3	4.4	78	0.1	2.3	6.9	20	>6
Lab027	5	12.8	14.8	51	0.8	5.4	26.4	20	0.8	4.2	4.8	51	0.4	8.3	31.0	20	0.7
Total	-	-	14.1	129	0.8	5.7	-	-	-	-	4.5	129	0.3	6.7	-	-	-

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

TE : Total Error(%) = Bias (%) + 2 x 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 (2023/05)								CUM (2022/06/01~2023/05/31)							
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	13.9	12	0.2	1.4	5.1	20	>6	13.6	13.7	78	0.3	2.2	5.1	20	>6
Lab027	5	12.8	14.4	4	1.4	9.7	31.9	20	0.8	12.8	14.8	51	0.8	5.4	26.4	20	0.8
Total	-	-	14.1	16	0.7	5.0	-	-	-	-	14.1	129	0.8	5.7	-	-	-

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

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

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

Month : 2023 ▼ 05 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 05 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2023/05)								CUM (2022/06/01~2023/05/31)							
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	4.5	12	0.0	0.0	4.7	20	>6	4.3	4.4	78	0.1	2.3	6.9	20	>6
Lab027	5	4.2	4.7	4	0.6	12.8	37.4	20	0.6	4.2	4.8	51	0.4	8.3	31.0	20	0.7
Total	-	-	4.6	16	0.3	6.5	-	-	-	-	4.5	129	0.3	6.7	-	-	-

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

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

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

Month : 2023 ▼ 05 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 05 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5