

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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Lab027

QC Control Lot No.	Control N		Control D	
	BA1116N		BA1116D	
Duration of the Analyzing	Month (2023/02)	CUM (2022/09/02~2023/02/28)	Month (2023/02)	CUM (2022/09/02~2023/02/28)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.9	15.1	4.8	4.9
SD	0.2	0.6	0.1	0.3
CV (%)	1.3	4.0	2.1	6.1
Target Value (U/gHb)	12.8	12.8	4.2	4.2
Total Error (%)	19.1	25.9	18.5	28.9
TEa (%)	20	20	20	20
σ	2.8	0.5	2.7	0.5

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

Month : 2023 02 Change ; Cumulative : from 2022 09 02 to 2023 02 28 Change

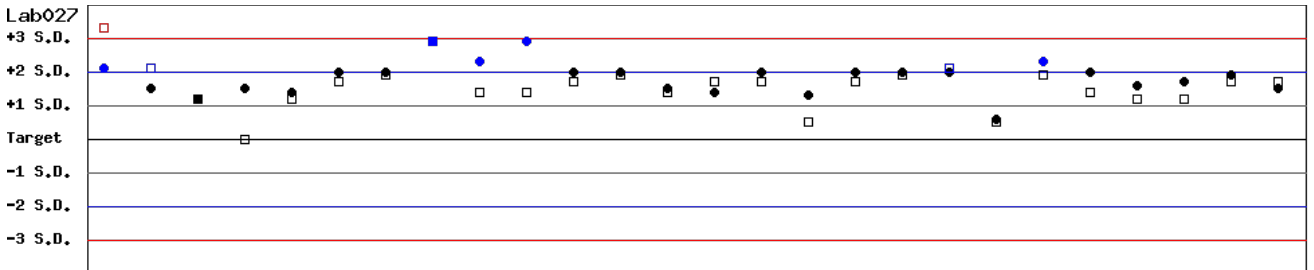
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Control N and Control D SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-09-02 to 2023-02-28 ; Target : 12.8 ; SD : 1.28 (●)

Lot No.: BA1116D ; Duration : 2022-09-02 to 2023-02-28 ; Target : 4.2 ; SD : 0.42 (□)

Lab027



Date 09-02 09-09 09-16 09-23 09-30 10-06 10-13 10-20 10-27 11-03 11-10 11-17 11-24 12-01 12-08 12-15 12-22 12-29 01-05 01-12 01-19 01-26 02-02 02-09 02-16 02-23

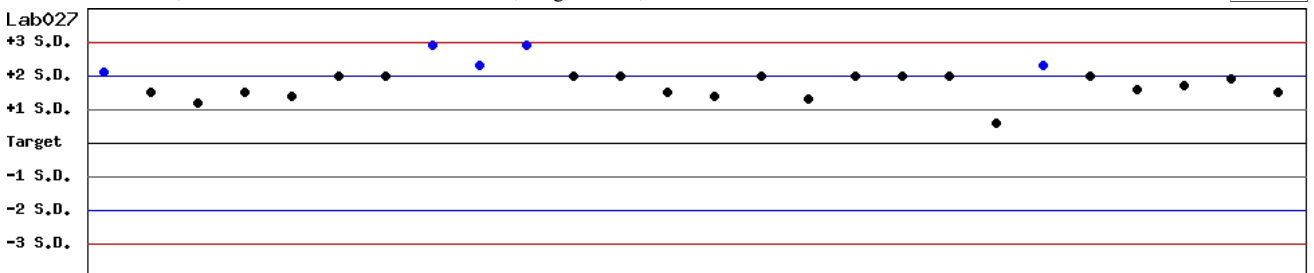
Month : 2023 02 Change ; Cumulative : from 2022 09 02 to 2023 02 28 Change

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Control N SDI QC Chart

Lot No.: BA1116N ; Duration : 2022-09-02 to 2023-02-28 ; Target : 12.8 ; SD : 1.28

Lab027



Date 09-02 09-09 09-16 09-23 09-30 10-06 10-13 10-20 10-27 11-03 11-10 11-17 11-24 12-01 12-08 12-15 12-22 12-29 01-05 01-12 01-19 01-26 02-02 02-09 02-16 02-23

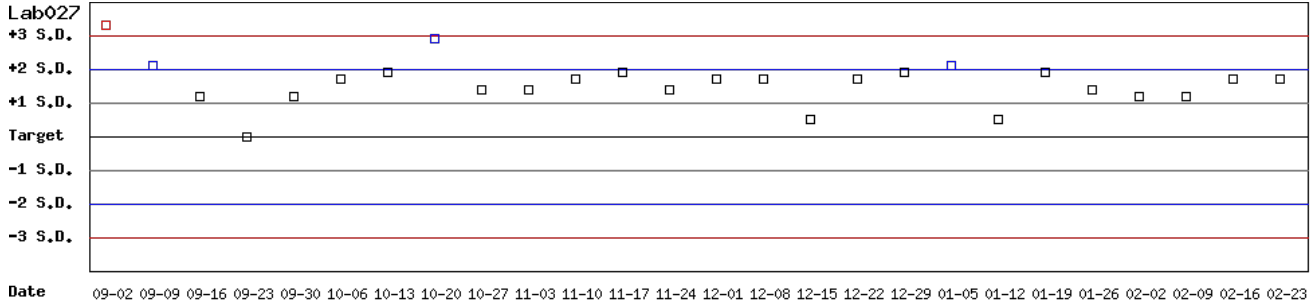
Month : 2023 02 Change ; Cumulative : from 2022 09 02 to 2023 02 28 Change

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Control D SDI QC Chart

Lot No.: BA1116D ; Duration : 2022-09-02 to 2023-02-28 ; Target : 4.2 ; SD : 0.42

Lab027



Month : 2023 02 Change ; Cumulative : from 2022 09 02 to 2023 02 28 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 : 2023 02 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
Lab027	5	12.8	14.9	4	0.2	1.3	19.1	20	2.8	4.2	4.8	4	0.1	2.1	18.5	20	2.7
Total	-	-	14.9	4	0.2	1.3	-	-	-	-	4.8	4	0.1	2.1	-	-	-

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 2023 02 28 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	13.6	56	0.3	2.2	4.4	20	>6	4.3	4.3	56	0.1	2.3	4.7	20	>6
Lab027	5	12.8	15.0	39	0.7	4.7	26.5	20	0.6	4.2	4.8	39	0.3	6.3	26.8	20	0.9
Total	-	-	14.2	95	0.9	6.3	-	-	-	-	4.5	95	0.3	6.7	-	-	-

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 (2023/02)								CUM (2022/06/01~2023/02/28)							
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	13.6	56	0.3	2.2	4.4	20	>6
Lab027	5	12.8	14.9	4	0.2	1.3	19.1	20	2.8	12.8	15.0	39	0.7	4.7	26.5	20	0.6
Total	-	-	14.9	4	0.2	1.3	-	-	-	-	14.2	95	0.9	6.3	-	-	-

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

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

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

Month : 2023 ▼ 02 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 02 ▼ 28 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BA1116D)															
		Month (2023/02)								CUM (2022/06/01~2023/02/28)							
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	4.3	56	0.1	2.3	4.7	20	>6
Lab027	5	4.2	4.8	4	0.1	2.1	18.5	20	2.7	4.2	4.8	39	0.3	6.3	26.8	20	0.9
Total	-	-	4.8	4	0.1	2.1	-	-	-	-	4.5	95	0.3	6.7	-	-	-

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

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

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

Month : 2023 ▼ 02 ▼ Change Cumulative : from 2022 ▼ 06 ▼ 01 ▼ to 2023 ▼ 02 ▼ 28 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5