

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

Select LotNo : AH1220N (2019-01-28 ~ 2100-12-31)

Lab050

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/12)	CUM (2021/09/03~2021/12/30)	Month (2021/12)	CUM (2021/09/03~2021/12/30)
Runs (N)	5	26	5	26
Mean (U/gHb)	14.1	14.1	4.4	4.4
SD	0.3	0.4	0.1	0.1
CV (%)	2.1	2.8	2.3	2.3
Target Value (U/gHb)	13.8	13.8	4.3	4.3
Total Error (%)	6.4	7.8	6.9	6.9
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

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

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

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

Month : ; Cumulative : from to

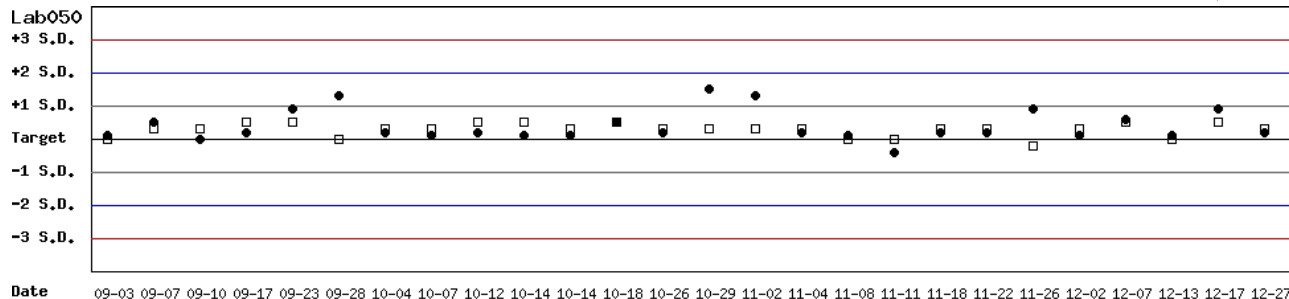
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-09-03 to 2021-12-30 ; Target : 13.8 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2021-09-03 to 2021-12-30 ; Target : 4.3 ; SD : 0.4 (□)

Lab050



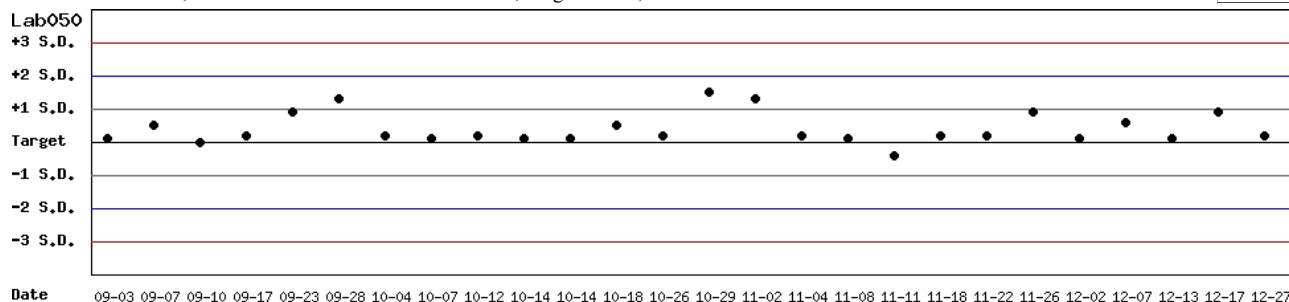
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-09-03 to 2021-12-30 ; Target : 13.8 ; SD : 0.8

Lab050



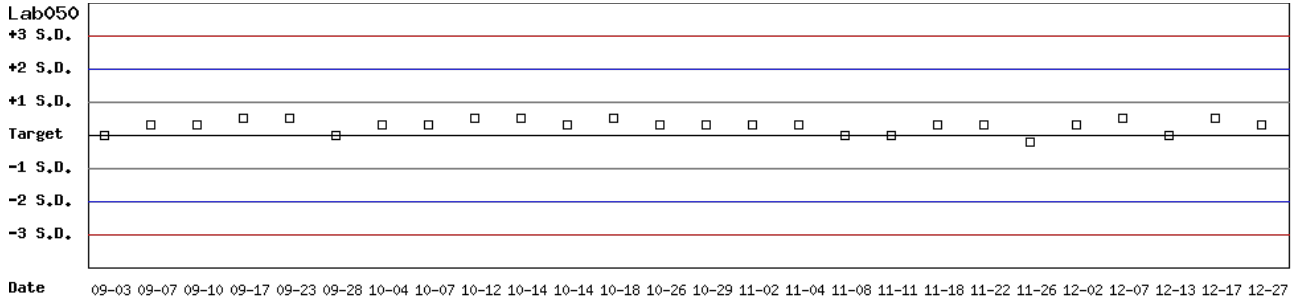
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2021-09-03 to 2021-12-30 ; Target : 4.3 ; SD : 0.4

Lab050



Month : 2021 12 Change ; Cumulative : from 2021 09 03 to 2021 12 30 Change

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Peer Group Statistics (Table 1)

Select LotNo : AH1220N (2019-01-28 ~ 2100-12-31) ▾ Change

Select Reagent Kit : 5 - Medicon ▾ Change

Print Table 1

Monthly

Month : 2021 ▾ 12 ▾ Change

UnitID [↑]	Reagent Kit (Code) [↑]	Control N (Lot No.: AH1220N)								Control D (Lot No.: AH1220D)							
		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
Lab019	5	14.6	15.6	5	0.6	3.8	14.5	20	3.5	4.4	4.7	5	0.2	4.3	15.3	20	3.1
Lab033	5	12.4	12.6	5	0.4	3.2	8.0	20	5.7	3.9	4.0	5	0.2	5.0	12.6	20	3.5
Lab050	5	13.8	14.1	5	0.3	2.1	6.4	20	>6	4.3	4.4	5	0.1	2.3	6.9	20	>6
Total	-	-	14.1	15	1.3	9.2	-	-	-	-	4.4	15	0.3	6.8	-	-	-

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

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

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

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Cumulative

Cumulative : from 2019 ▾ 02 ▾ 01 ▾ to 2021 ▾ 12 ▾ 31 ▾ Change

UnitID [↑]	Reagent Kit (Code) [↑]	Control N (Lot No.: AH1220N)								Control D (Lot No.: AH1220D)							
		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
Lab019	5	14.6	14.8	67	0.5	3.4	8.1	20	5.5	4.4	4.5	67	0.2	4.4	11.2	20	4.0
Lab020	5	13.3	14.3	65	1.0	7.0	21.5	20	1.8	4.3	4.5	65	0.2	4.4	13.5	20	3.5
Lab022	5	13.8	13.0	88	0.9	6.9	19.6	20	2.1	4.4	4.2	88	0.2	4.8	14.1	20	3.2
Lab028	5	14.6	14.6	53	0.4	2.7	5.5	20	>6	4.6	4.6	53	0.2	4.3	8.7	20	4.7
Lab032	5	12.1	12.9	136	1.4	10.9	28.3	20	1.2	3.5	4.0	136	0.5	12.5	39.3	20	0.5
Lab033	5	12.4	12.5	138	0.4	3.2	7.2	20	6.0	3.9	3.9	138	0.2	5.1	10.3	20	3.9
Lab034	5	15.3	14.5	68	1.0	6.9	19.0	20	2.1	5.2	4.6	68	0.2	4.3	20.2	20	2.0
Lab037	5	15.3	15.2	55	0.4	2.6	5.9	20	>6	5.2	4.7	55	0.2	4.3	18.1	20	2.4
Lab040	5	15.3	15.0	19	0.4	2.7	7.3	20	>6	5.2	5.3	19	0.5	9.4	20.8	20	1.9
Lab043	5	13.8	12.7	19	0.7	5.5	19.0	20	2.2	4.4	4.1	19	0.3	7.3	21.5	20	1.8
Lab047	5	14.7	13.7	26	1.2	8.8	24.3	20	1.5	4.6	4.3	26	0.3	7.0	20.5	20	1.9
Lab049	5	14.7	14.3	42	0.5	3.5	9.7	20	4.9	4.9	4.7	42	0.3	6.4	16.8	20	2.5
Lab050	5	13.8	14.0	71	0.5	3.6	8.6	20	5.2	4.3	4.4	71	0.2	4.5	11.4	20	3.9
Total	-	-	13.7	847	1.2	8.8	-	-	-	-	4.3	847	0.4	9.3	-	-	-

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 : AH1220N (2019-01-28 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 2

Control N Month vs. Cumulative

Control N (Lot No.: AH1220N)																	
		Month (2021/12)									CUM (2019/02/01~2021/12/31)						
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
Lab019	5	14.6	15.6	5	0.6	3.8	14.5	20	3.5	14.6	14.8	67	0.5	3.4	8.1	20	5.5
Lab020	5	13.3	-	0	-	-	-	20	-	13.3	14.3	65	1.0	7.0	21.5	20	1.8
Lab022	5	13.8	-	0	-	-	-	20	-	13.8	13.0	88	0.9	6.9	19.6	20	2.1
Lab028	5	14.6	-	0	-	-	-	20	-	14.6	14.6	53	0.4	2.7	5.5	20	>6
Lab032	5	12.1	-	0	-	-	-	20	-	12.1	12.9	136	1.4	10.9	28.3	20	1.2
Lab033	5	12.4	12.6	5	0.4	3.2	8.0	20	5.7	12.4	12.5	138	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	-	0	-	-	-	20	-	15.3	14.5	68	1.0	6.9	19.0	20	2.1
Lab037	5	15.3	-	0	-	-	-	20	-	15.3	15.2	55	0.4	2.6	5.9	20	>6
Lab040	5	15.3	-	0	-	-	-	20	-	15.3	15.0	19	0.4	2.7	7.3	20	>6
Lab043	5	13.8	-	0	-	-	-	20	-	13.8	12.7	19	0.7	5.5	19.0	20	2.2
Lab047	5	14.7	-	0	-	-	-	20	-	14.7	13.7	26	1.2	8.8	24.3	20	1.5
Lab049	5	14.7	-	0	-	-	-	20	-	14.7	14.3	42	0.5	3.5	9.7	20	4.9
Lab050	5	13.8	14.1	5	0.3	2.1	6.4	20	>6	13.8	14.0	71	0.5	3.6	8.6	20	5.2
Total	-	-	14.1	15	1.3	9.2	-	-	-	-	13.7	847	1.2	8.8	-	-	-

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

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

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

Month : 2021 ▾ 12 ▾ Change

Cumulative : from 2019 ▾ 02 ▾ 01 ▾ to 2021 ▾ 12 ▾ 31 ▾ Change

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Control D Month vs. Cumulative

Control D (Lot No.: AH1220D)																	
		Month (2021/12)									CUM (2019/02/01~2021/12/31)						
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
Lab019	5	4.4	4.7	5	0.2	4.3	15.3	20	3.1	4.4	4.5	67	0.2	4.4	11.2	20	4.0
Lab020	5	4.3	-	0	-	-	-	20	-	4.3	4.5	65	0.2	4.4	13.5	20	3.5
Lab022	5	4.4	-	0	-	-	-	20	-	4.4	4.2	88	0.2	4.8	14.1	20	3.2
Lab028	5	4.6	-	0	-	-	-	20	-	4.6	4.6	53	0.2	4.3	8.7	20	4.7
Lab032	5	3.5	-	0	-	-	-	20	-	3.5	4.0	136	0.5	12.5	39.3	20	0.5
Lab033	5	3.9	4.0	5	0.2	5.0	12.6	20	3.5	3.9	3.9	138	0.2	5.1	10.3	20	3.9
Lab034	5	5.2	-	0	-	-	-	20	-	5.2	4.6	68	0.2	4.3	20.2	20	2.0
Lab037	5	5.2	-	0	-	-	-	20	-	5.2	4.7	55	0.2	4.3	18.1	20	2.4
Lab040	5	5.2	-	0	-	-	-	20	-	5.2	5.3	19	0.5	9.4	20.8	20	1.9
Lab043	5	4.4	-	0	-	-	-	20	-	4.4	4.1	19	0.3	7.3	21.5	20	1.8
Lab047	5	4.6	-	0	-	-	-	20	-	4.6	4.3	26	0.3	7.0	20.5	20	1.9
Lab049	5	4.9	-	0	-	-	-	20	-	4.9	4.7	42	0.3	6.4	16.8	20	2.5
Lab050	5	4.3	4.4	5	0.1	2.3	6.9	20	>6	4.3	4.4	71	0.2	4.5	11.4	20	3.9
Total	-	-	4.4	15	0.3	6.8	-	-	-	-	4.3	847	0.4	9.3	-	-	-

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

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

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

Month : 2021 ▾ 12 ▾ Change

Cumulative : from 2019 ▾ 02 ▾ 01 ▾ to 2021 ▾ 12 ▾ 31 ▾ Change

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Reagent Kit	Reagent Code
Medicon	5

