

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

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

Print Table

Lab034

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2023/03)	CUM (2022/09/29~2023/03/31)	Month (2023/03)	CUM (2022/09/29~2023/03/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.1	14.1	4.8	4.7
SD	0.8	0.9	0.1	0.3
CV (%)	5.7	6.4	2.1	6.4
Target Value (U/gHb)	15.3	15.3	5.2	5.2
Total Error (%)	19.2	20.6	11.9	22.4
TEa (%)	20	20	20	20
σ	2.1	1.9	5.9	1.6

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

Month : 2023 03 Change ; Cumulative : from 2022 09 29 to 2023 03 31 Change

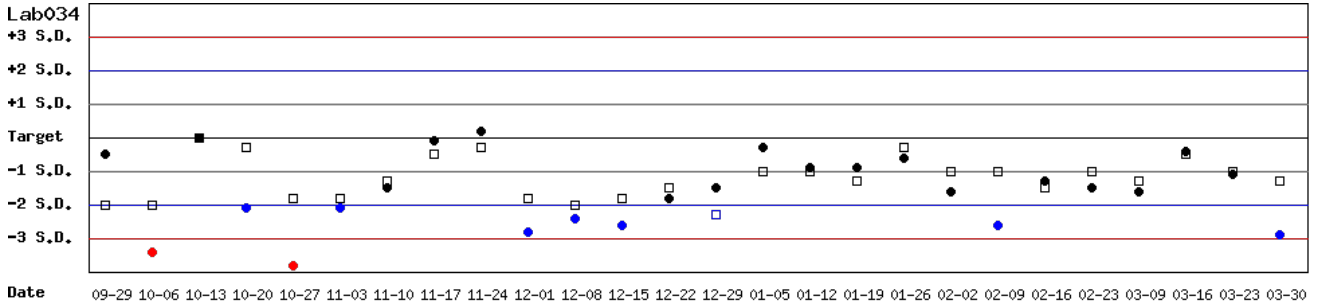
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2022-09-29 to 2023-03-31 ; Target : 15.3 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2022-09-29 to 2023-03-31 ; Target : 5.2 ; SD : 0.4 (□)

Lab034



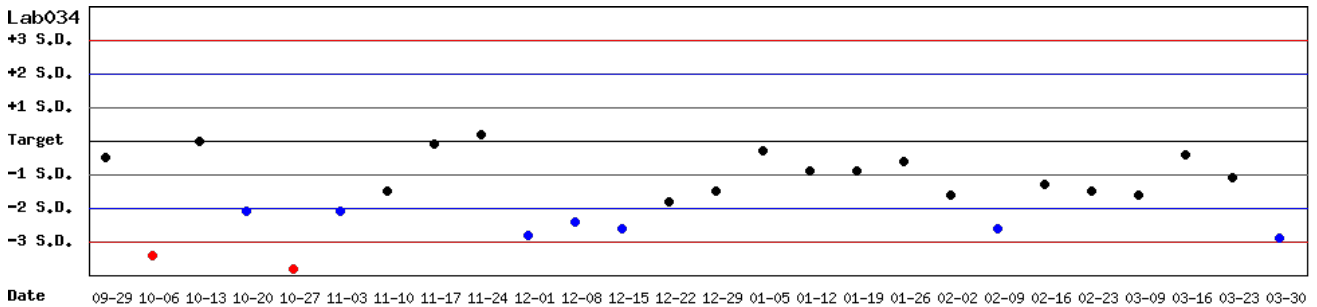
Month : 2023 03 Change ; Cumulative : from 2022 09 29 to 2023 03 31 Change

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2022-09-29 to 2023-03-31 ; Target : 15.3 ; SD : 0.8

Lab034



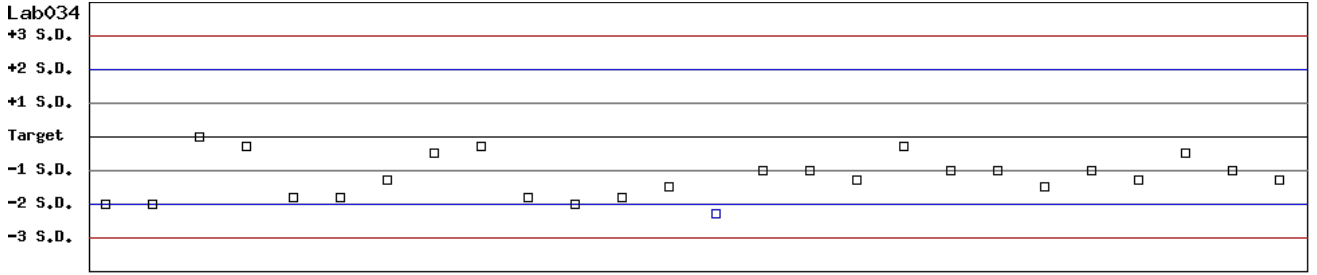
Month : 2023 03 Change ; Cumulative : from 2022 09 29 to 2023 03 31 Change

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2022-09-29 to 2023-03-31 ; Target : 5.2 ; SD : 0.4

Lab034



Date 09-29 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 03-09 03-16 03-23 03-30

Month : ; Cumulative : from to

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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 : 2023 03 Change

		Control N (Lot No.: AH1220N)								Control D (Lot No.: AH1220D)							
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
Lab034	5	15.3	14.1	4	0.8	5.7	19.2	20	2.1	5.2	4.8	4	0.1	2.1	11.9	20	5.9
Lab050	5	13.8	14.1	6	0.3	2.1	6.4	20	>6	4.3	4.3	6	0.1	2.3	4.7	20	>6
Total	-	-	14.1	10	0.5	3.5	-	-	-	-	4.5	10	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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Cumulative

Cumulative : from 2019 02 01 to 2023 03 31 Change

		Control N (Lot No.: AH1220N)								Control D (Lot No.: AH1220D)							
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	15.0	14.8	67	0.5	3.4	8.1	20	5.5	4.6	4.5	67	0.2	4.4	11.1	20	4.1
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	144	0.4	3.2	7.2	20	6.0	3.9	3.9	144	0.2	5.1	10.3	20	3.9
Lab034	5	15.3	14.3	113	1.0	7.0	20.5	20	1.9	5.2	4.6	113	0.3	6.5	24.6	20	1.3
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	13.9	14.6	40	0.6	4.1	13.3	20	3.6	4.6	5.0	40	0.4	8.0	24.7	20	1.4
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	14.1	154	0.5	3.5	9.3	20	5.1	4.3	4.4	154	0.1	2.3	6.9	20	>6
Total	-	-	13.8	1002	1.2	8.7	-	-	-	-	4.3	1002	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 (2023/03)									CUM (2019/02/01~2023/03/31)						
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	15.0	-	0	-	-	-	20	-	15.0	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	-	0	-	-	-	20	-	12.4	12.5	144	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	14.1	4	0.8	5.7	19.2	20	2.1	15.3	14.3	113	1.0	7.0	20.5	20	1.9
Lab037	5	15.3	-	0	-	-	-	20	-	15.3	15.2	55	0.4	2.6	5.9	20	>6
Lab040	5	13.9	-	0	-	-	-	20	-	13.9	14.6	40	0.6	4.1	13.3	20	3.6
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	6	0.3	2.1	6.4	20	>6	13.8	14.1	154	0.5	3.5	9.3	20	5.1
Total	-	-	14.1	10	0.5	3.5	-	-	-	-	13.8	1002	1.2	8.7	-	-	-

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

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

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

Month : 2023 03 Change

Cumulative : from 2019 02 01 to 2023 03 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2023/03)									CUM (2019/02/01~2023/03/31)						
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	4.6	-	0	-	-	-	20	-	4.6	4.5	67	0.2	4.4	11.1	20	4.1
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	-	0	-	-	-	20	-	3.9	3.9	144	0.2	5.1	10.3	20	3.9
Lab034	5	5.2	4.8	4	0.1	2.1	11.9	20	5.9	5.2	4.6	113	0.3	6.5	24.6	20	1.3
Lab037	5	5.2	-	0	-	-	-	20	-	5.2	4.7	55	0.2	4.3	18.1	20	2.4
Lab040	5	4.6	-	0	-	-	-	20	-	4.6	5.0	40	0.4	8.0	24.7	20	1.4
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	4.3	6	0.1	2.3	4.7	20	>6	4.3	4.4	154	0.1	2.3	6.9	20	>6
Total	-	-	4.5	10	0.3	6.7	-	-	-	-	4.3	1002	0.4	9.3	-	-	-

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

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

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

Month : 2023 03 Change

Cumulative : from 2019 02 01 to 2023 03 31 Change

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Reagent Kit	Reagent Code
Medicon	5