

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 (2022/01)	CUM (2021/10/07~2022/01/28)	Month (2022/01)	CUM (2021/10/07~2022/01/28)
Runs (N)	7	26	7	26
Mean (U/gHb)	14.2	14.2	4.4	4.4
SD	0.3	0.3	0.1	0.1
CV (%)	2.1	2.1	2.3	2.3
Target Value (U/gHb)	13.8	13.8	4.3	4.3
Total Error (%)	7.1	7.1	6.9	6.9
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

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

Month : 2022 01 ; Cumulative : from 2021 10 07 to 2022 01 28

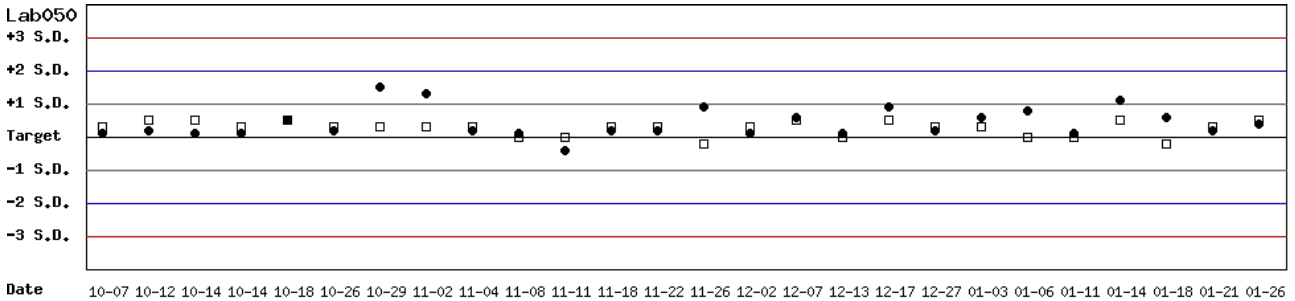
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-10-07 to 2022-01-28 ; Target : 13.8 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2021-10-07 to 2022-01-28 ; Target : 4.3 ; SD : 0.4 (□)

Lab050



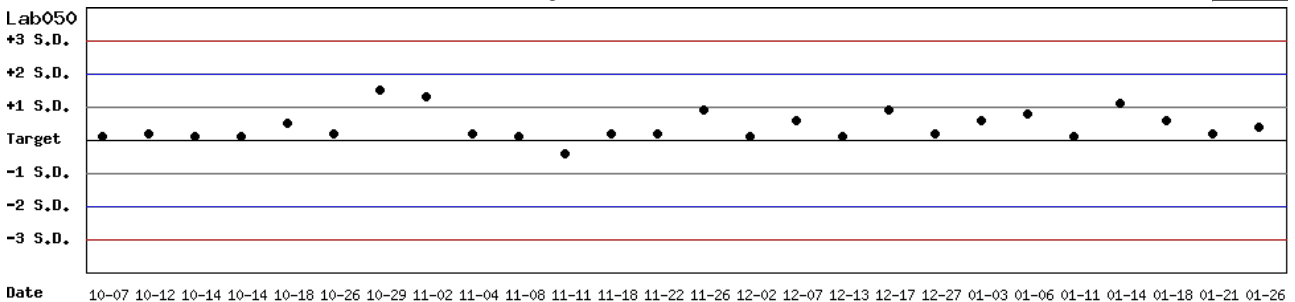
Month : 2022 01 ; Cumulative : from 2021 10 07 to 2022 01 28

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-10-07 to 2022-01-28 ; Target : 13.8 ; SD : 0.8

Lab050



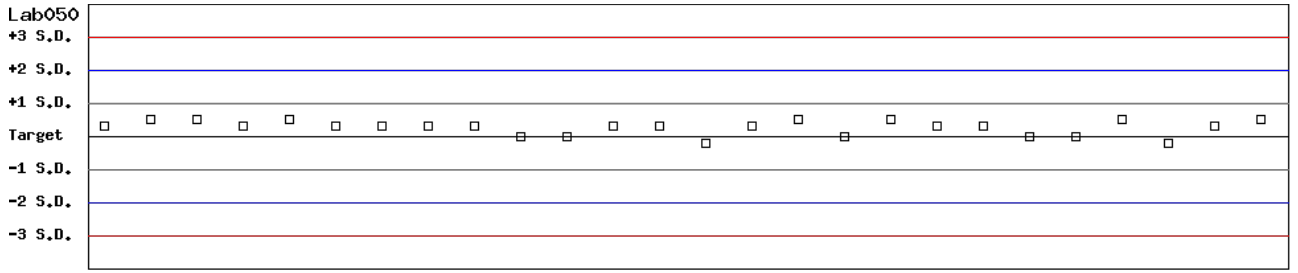
Month : 2022 01 ; Cumulative : from 2021 10 07 to 2022 01 28

[\[TOP\]](#)

Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2021-10-07 to 2022-01-28 ; Target : 4.3 ; SD : 0.4

Lab050



Date 10-07 10-12 10-14 10-14 10-18 10-26 10-29 11-02 11-04 11-08 11-11 11-18 11-22 11-26 12-02 12-07 12-13 12-17 12-27 01-03 01-06 01-11 01-14 01-18 01-21 01-26

Month : ; Cumulative : from to

[\[TOP\]](#)

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 : 2022 01 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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
Lab033	5	12.4	12.6	4	0.2	1.6	4.8	20	>6	3.9	3.9	4	0.1	2.6	5.1	20	>6
Lab034	5	15.3	14.1	3	0.4	2.8	13.5	20	4.3	5.2	5.4	3	1.6	29.6	63.1	20	0.5
Lab040	5	15.3	14.5	4	0.3	2.1	9.4	20	>6	5.2	4.9	4	0.2	4.1	13.9	20	3.5
Lab050	5	13.8	14.2	7	0.3	2.1	7.1	20	>6	4.3	4.4	7	0.1	2.3	6.9	20	>6
Total	-	-	13.9	18	0.8	5.8	-	-	-	-	4.6	18	0.8	17.4	-	-	-

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from 2019 02 01 to 2022 01 31 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	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	142	0.4	3.2	7.2	20	6.0	3.9	3.9	142	0.2	5.1	10.3	20	3.9
Lab034	5	15.3	14.5	71	1.0	6.9	19.0	20	2.1	5.2	4.6	71	0.4	8.7	28.9	20	1.0
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	14.9	23	0.4	2.7	8.0	20	>6	5.2	5.2	23	0.5	9.6	19.2	20	2.1
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	78	0.5	3.6	8.6	20	5.2	4.3	4.4	78	0.2	4.5	11.4	20	3.9
Total	-	-	13.7	865	1.2	8.8	-	-	-	-	4.3	865	0.4	9.3	-	-	-

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

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

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

[\[TOP\]](#)

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 (2022/01)								CUM (2019/02/01~2022/01/31)							
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	12.6	4	0.2	1.6	4.8	20	>6	12.4	12.5	142	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	14.1	3	0.4	2.8	13.5	20	4.3	15.3	14.5	71	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	14.5	4	0.3	2.1	9.4	20	>6	15.3	14.9	23	0.4	2.7	8.0	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	14.2	7	0.3	2.1	7.1	20	>6	13.8	14.0	78	0.5	3.6	8.6	20	5.2
Total	-	-	13.9	18	0.8	5.8	-	-	-	-	13.7	865	1.2	8.8	-	-	-

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

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

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

Month : 2022 01 Change

Cumulative : from 2019 02 01 to 2022 01 31 Change

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2022/01)								CUM (2019/02/01~2022/01/31)							
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	3.9	4	0.1	2.6	5.1	20	>6	3.9	3.9	142	0.2	5.1	10.3	20	3.9
Lab034	5	5.2	5.4	3	1.6	29.6	63.1	20	0.5	5.2	4.6	71	0.4	8.7	28.9	20	1.0
Lab037	5	5.2	-	0	-	-	-	20	-	5.2	4.7	55	0.2	4.3	18.1	20	2.4
Lab040	5	5.2	4.9	4	0.2	4.1	13.9	20	3.5	5.2	5.2	23	0.5	9.6	19.2	20	2.1
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	7	0.1	2.3	6.9	20	>6	4.3	4.4	78	0.2	4.5	11.4	20	3.9
Total	-	-	4.6	18	0.8	17.4	-	-	-	-	4.3	865	0.4	9.3	-	-	-

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

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

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

Month : 2022 01 Change

Cumulative : from 2019 02 01 to 2022 01 31 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5