

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

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

Lab040

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2022/04)	CUM (2020/09/04~2022/04/29)	Month (2022/04)	CUM (2020/09/04~2022/04/29)
Runs (N)	5	26	5	26
Mean (U/gHb)	13.9	14.4	4.6	4.9
SD	0.2	0.6	0.1	0.4
CV (%)	1.4	4.2	2.2	8.2
Target Value (U/gHb)	13.9	13.9	4.6	4.6
Total Error (%)	2.9	11.9	4.3	22.8
TEa (%)	20	20	20	20
σ	>6	3.9	>6	1.6

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

Month : 2022 04 ; Cumulative : from 2020 09 04 to 2022 04 29

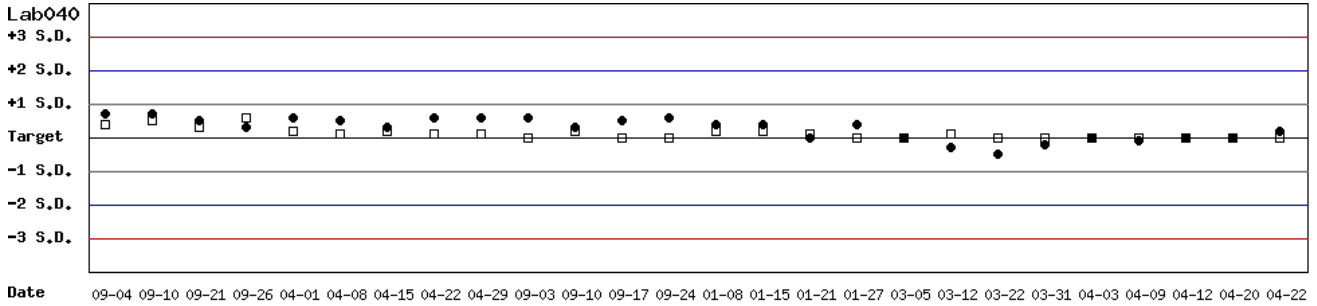
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-09-04 to 2022-04-29 ; Target : 13.9 ; SD : 2.00 (●)

Lot No.: AH1220D ; Duration : 2020-09-04 to 2022-04-29 ; Target : 4.6 ; SD : 2.30 (□)

Lab040



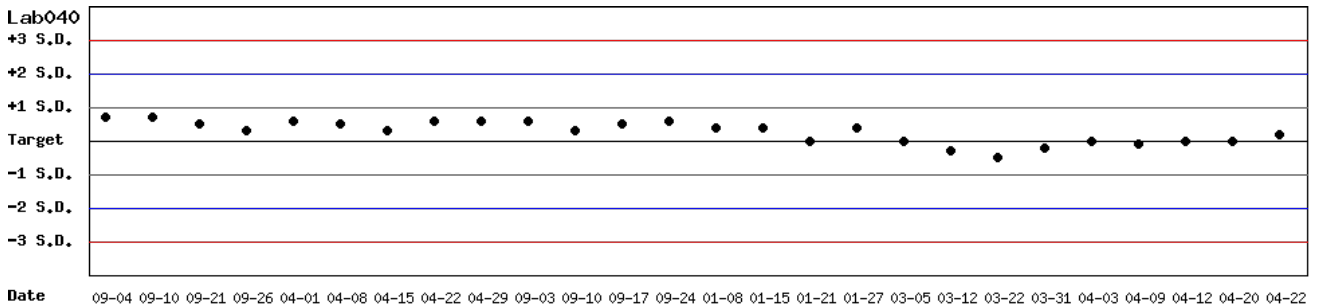
Month : 2022 04 ; Cumulative : from 2020 09 04 to 2022 04 29

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-09-04 to 2022-04-29 ; Target : 13.9 ; SD : 2.00

Lab040



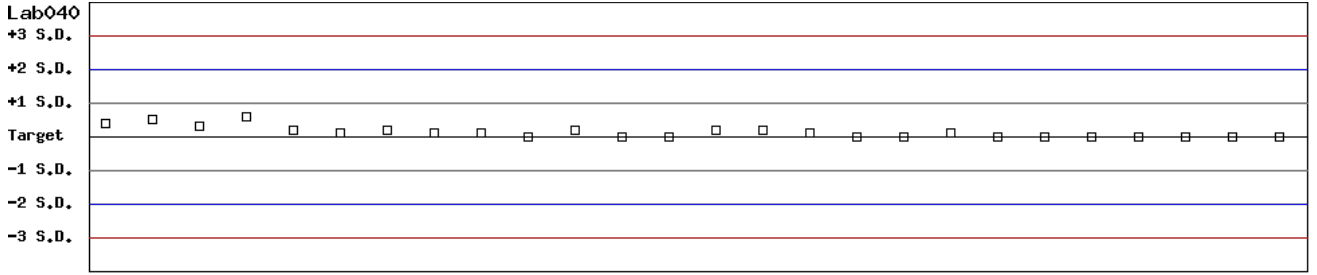
Month : 2022 04 ; Cumulative : from 2020 09 04 to 2022 04 29

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-09-04 to 2022-04-29 ; Target : 4.6 ; SD : 2.30

Lab040



Date 09-04 09-10 09-21 09-26 04-01 04-08 04-15 04-22 04-29 09-03 09-10 09-17 09-24 01-08 01-15 01-21 01-27 03-05 03-12 03-22 03-31 04-03 04-09 04-12 04-20 04-22

Month : 2022 ▾ 04 ▾ Change ; Cumulative : from 2020 ▾ 09 ▾ 04 ▾ to 2022 ▾ 04 ▾ 29 ▾ 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 : 2022 04 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
Lab034	5	15.3	15.6	1	-	-	-	20	-	5.2	5.2	1	-	-	-	20	-
Lab040	5	13.9	13.9	5	0.2	1.4	2.9	20	>6	4.6	4.6	5	0.1	2.2	4.3	20	>6
Lab050	5	13.8	13.8	4	0.5	3.6	7.2	20	5.6	4.3	4.3	4	0.1	2.3	4.7	20	>6
Total	-	-	14.1	10	0.6	4.3	-	-	-	-	4.6	10	0.3	6.5	-	-	-

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 2022 04 30 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	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	14.5	73	1.0	6.9	19.0	20	2.1	5.2	4.6	73	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	13.9	14.6	32	0.7	4.8	14.6	20	3.1	4.6	5.0	32	0.5	10.0	28.7	20	1.1
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	14.1	94	0.5	3.5	9.3	20	5.1	4.3	4.4	94	0.2	4.5	11.4	20	3.9
Total	-	-	13.7	894	1.2	8.8	-	-	-	-	4.3	894	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 (2022/04)									CUM (2019/02/01~2022/04/30)						
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	-	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	15.6	1	-	-	-	20	-	15.3	14.5	73	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	13.9	13.9	5	0.2	1.4	2.9	20	>6	13.9	14.6	32	0.7	4.8	14.6	20	3.1
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	13.8	4	0.5	3.6	7.2	20	5.6	13.8	14.1	94	0.5	3.5	9.3	20	5.1
Total	-	-	14.1	10	0.6	4.3	-	-	-	-	13.7	894	1.2	8.8	-	-	-

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

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

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

Month : 2022 ▼ 04 ▼ Change

Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2022 ▼ 04 ▼ 30 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2022/04)									CUM (2019/02/01~2022/04/30)						
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	4.6	-	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	5.2	1	-	-	-	20	-	5.2	4.6	73	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	4.6	4.6	5	0.1	2.2	4.3	20	>6	4.6	5.0	32	0.5	10.0	28.7	20	1.1
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	4.3	4	0.1	2.3	4.7	20	>6	4.3	4.4	94	0.2	4.5	11.4	20	3.9
Total	-	-	4.6	10	0.3	6.5	-	-	-	-	4.3	894	0.4	9.3	-	-	-

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

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

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

Month : 2022 ▼ 04 ▼ Change

Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2022 ▼ 04 ▼ 30 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5