

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

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

[Print Table](#)

Lab033

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2020/04)	CUM (2019/10/17~2020/04/30)	Month (2020/04)	CUM (2019/10/17~2020/04/30)
Runs (N)	1	26	1	26
Mean (U/gHb)	12.9	12.4	4.1	3.9
SD	-	0.4	-	0.1
CV (%)	-	3.2	-	2.6
Target Value (U/gHb)	12.4	12.4	3.9	3.9
Total Error (%)	-	6.5	-	5.1
TEa (%)	20	20	20	20
σ	-	>6	-	>6

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

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

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

Month : 2020 04 [Change](#) ; Cumulative : from 2019 10 17 to 2020 04 30 [Change](#)

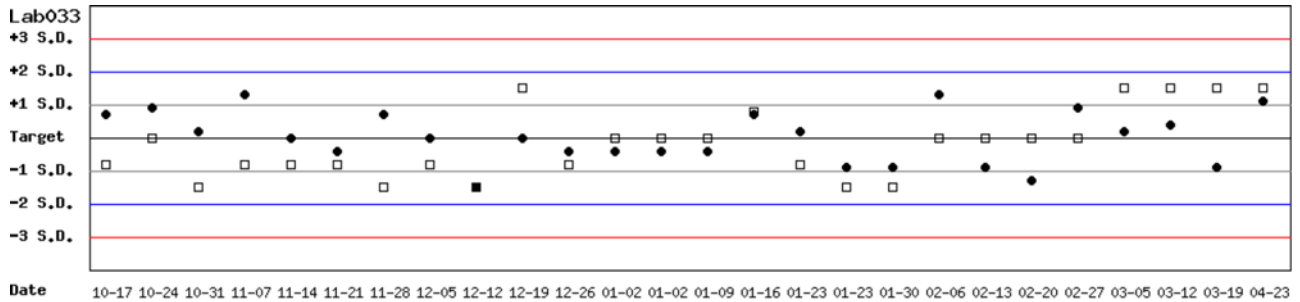
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-10-17 to 2020-04-30 ; Target : 12.4 ; SD : 0.46 (●)

Lot No.: AH1220D ; Duration : 2019-10-17 to 2020-04-30 ; Target : 3.9 ; SD : 0.13 (□)

Lab033



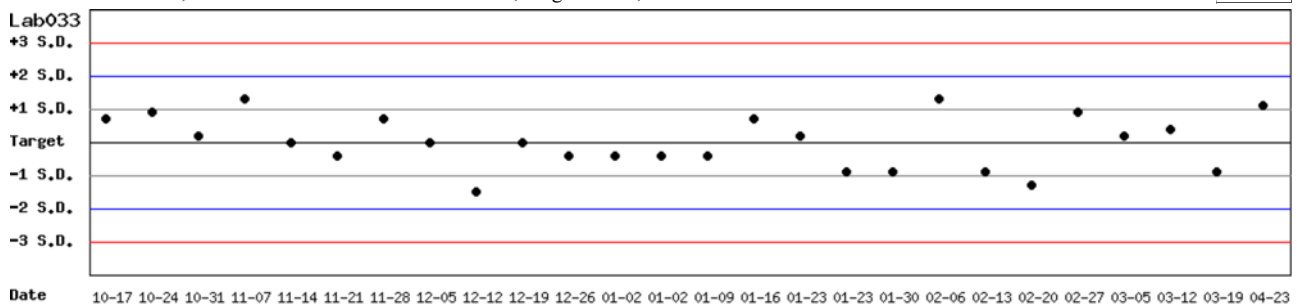
Month : 2020 04 [Change](#) ; Cumulative : from 2019 10 17 to 2020 04 30 [Change](#)

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-10-17 to 2020-04-30 ; Target : 12.4 ; SD : 0.46

Lab033



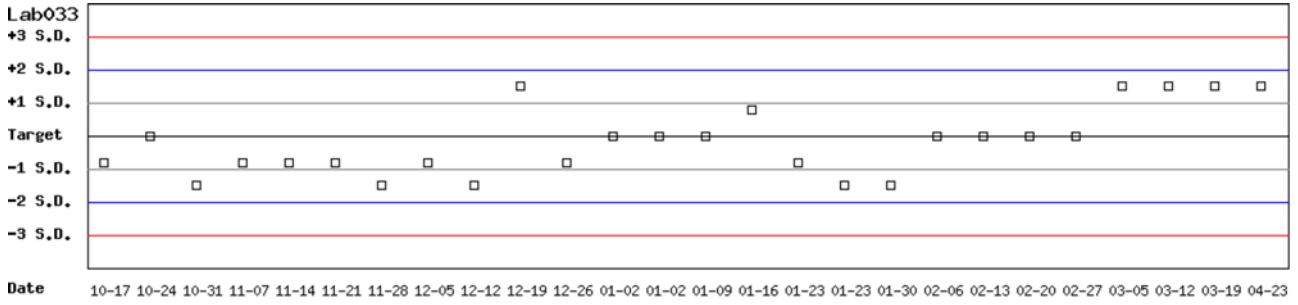
Month : 2020 04 [Change](#) ; Cumulative : from 2019 10 17 to 2020 04 30 [Change](#)

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2019-10-17 to 2020-04-30 ; Target : 3.9 ; SD : 0.13

Lab033



Month : 2020 04 ; Cumulative : from 2019 10 17 to 2020 04 30

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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 : 2020 04 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
Lab032	5	15.3	14.3	3	1.1	7.7	21.9	20	1.7	5.2	4.7	3	0.2	4.3	18.1	20	2.4
Lab033	5	12.4	12.9	1	-	-	-	20	-	3.9	4.1	1	-	-	-	20	-
Total	-	-	14.0	4	1.1	7.9	-	-	-	-	4.6	4	0.4	8.7	-	-	-

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 2020 04 30 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
Lab020	5	15.9	15.3	16	0.6	3.9	11.6	20	4.2	5.2	4.7	16	0.2	4.3	18.1	20	2.4
Lab022	5	12.4	12.3	41	0.4	3.3	7.3	20	5.8	4.1	4.0	41	0.1	2.5	7.4	20	>6
Lab032	5	15.3	14.3	62	0.5	3.5	13.5	20	3.8	5.2	4.5	62	0.4	8.9	31.2	20	0.7
Lab033	5	12.4	12.5	53	0.4	3.2	7.2	20	6.0	3.9	3.9	53	0.1	2.6	5.1	20	>6
Lab037	5	15.3	15.3	13	0.4	2.6	5.2	20	>6	5.2	4.7	13	0.1	2.1	13.9	20	4.9
Total	-	-	13.5	185	1.2	8.9	-	-	-	-	4.2	185	0.4	9.5	-	-	-

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 (2020/04)								CUM (2019/02/01~2020/04/30)							
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
Lab020	5	15.9	-	0	-	-	-	20	-	15.9	15.3	16	0.6	3.9	11.6	20	4.2
Lab022	5	12.4	-	0	-	-	-	20	-	12.4	12.3	41	0.4	3.3	7.3	20	5.8
Lab032	5	15.3	14.3	3	1.1	7.7	21.9	20	1.7	15.3	14.3	62	0.5	3.5	13.5	20	3.8
Lab033	5	12.4	12.9	1	-	-	-	20	-	12.4	12.5	53	0.4	3.2	7.2	20	6.0
Lab037	5	15.3	-	0	-	-	-	20	-	15.3	15.3	13	0.4	2.6	5.2	20	>6
Total	-	-	14.0	4	1.1	7.9	-	-	-	-	13.5	185	1.2	8.9	-	-	-

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

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

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

Month : 2020 04 Change Cumulative : from 2019 02 01 to 2020 04 30 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2020/04)								CUM (2019/02/01~2020/04/30)							
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
Lab020	5	5.2	-	0	-	-	-	20	-	5.2	4.7	16	0.2	4.3	18.1	20	2.4
Lab022	5	4.1	-	0	-	-	-	20	-	4.1	4.0	41	0.1	2.5	7.4	20	>6
Lab032	5	5.2	4.7	3	0.2	4.3	18.1	20	2.4	5.2	4.5	62	0.4	8.9	31.2	20	0.7
Lab033	5	3.9	4.1	1	-	-	-	20	-	3.9	3.9	53	0.1	2.6	5.1	20	>6
Lab037	5	5.2	-	0	-	-	-	20	-	5.2	4.7	13	0.1	2.1	13.9	20	4.9
Total	-	-	4.6	4	0.4	8.7	-	-	-	-	4.2	185	0.4	9.5	-	-	-

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

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

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

Month : 2020 04 Change Cumulative : from 2019 02 01 to 2020 04 30 Change

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Reagent Kit	Reagent Code
Medicon	5