

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

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

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Lab032

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2020/06)	CUM (2020/02/11~2020/06/30)	Month (2020/06)	CUM (2020/02/11~2020/06/30)
Runs (N)	3	26	3	26
Mean (U/gHb)	13.1	13.8	4.0	4.2
SD	0.2	0.7	0.1	0.3
CV (%)	1.5	5.1	2.5	7.1
Target Value (U/gHb)	15.3	15.3	5.2	5.2
Total Error (%)	17.4	19.9	28.1	33.5
TEa (%)	20	20	20	20
σ	3.7	2.0	-1.2	0.1

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

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

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

Month : 2020 06 [Change](#) ; Cumulative : from 2020 02 11 to 2020 06 30 [Change](#)

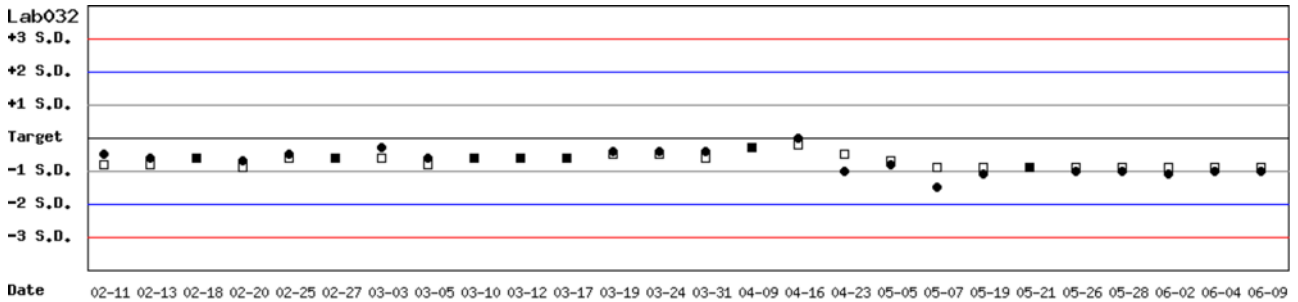
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-02-11 to 2020-06-30 ; Target : 15.3 ; SD : 2.20 (●)

Lot No.: AH1220D ; Duration : 2020-02-11 to 2020-06-30 ; Target : 5.2 ; SD : 1.40 (□)

Lab032



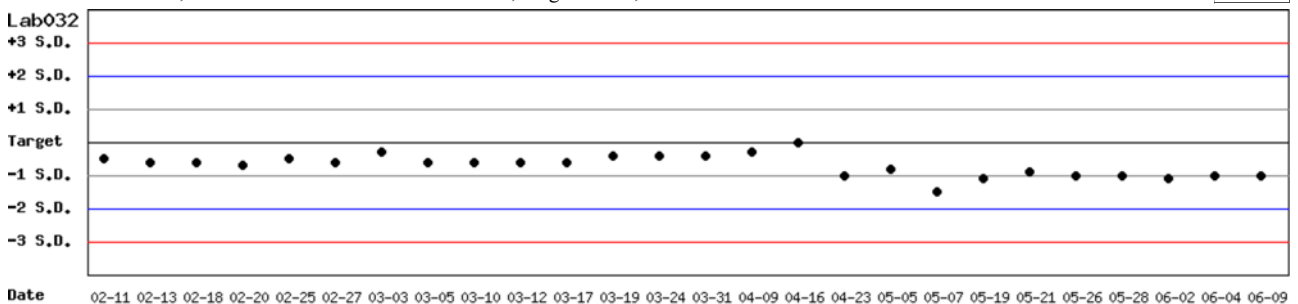
Month : 2020 06 [Change](#) ; Cumulative : from 2020 02 11 to 2020 06 30 [Change](#)

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-02-11 to 2020-06-30 ; Target : 15.3 ; SD : 2.20

Lab032



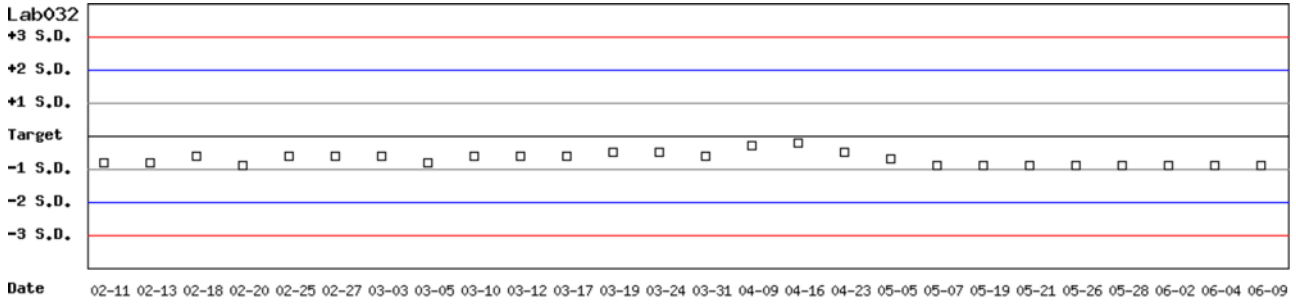
Month : 2020 06 [Change](#) ; Cumulative : from 2020 02 11 to 2020 06 30 [Change](#)

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-02-11 to 2020-06-30 ; Target : 5.2 ; SD : 1.40

Lab032



Month : 2020 06 Change ; Cumulative : from 2020 02 11 to 2020 06 30 Change

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Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon

Monthly

Month : 2020 06

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
Lab020	5	15.9	13.0	2	-	-	-	20	-	5.2	4.4	2	-	-	-	20	-
Lab022	5	12.4	11.3	4	0.9	8.0	24.8	20	1.4	4.1	3.7	4	0.3	8.1	26.0	20	1.3
Lab032	5	15.3	13.1	3	0.2	1.5	17.4	20	3.7	5.2	4.0	3	0.1	2.5	28.1	20	-1.2
Lab033	5	12.4	13.1	4	0.1	0.8	7.2	20	>6	3.9	4.1	4	0.1	2.4	10.0	20	>6
Lab037	5	15.3	15.2	4	0.5	3.3	7.2	20	5.9	5.2	4.8	4	0.2	4.2	16.0	20	2.9
Total	-	-	13.1	17	1.5	11.5	-	-	-	-	4.2	17	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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Cumulative

Cumulative : from 2019 02 01 to 2020 06 30

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
Lab020	5	15.9	15.0	19	1.0	6.7	19.0	20	2.1	5.2	4.7	19	0.2	4.3	18.1	20	2.4
Lab022	5	12.4	12.2	45	0.5	4.1	9.8	20	4.5	4.1	4.0	45	0.2	5.0	12.4	20	3.5
Lab032	5	15.3	14.1	71	0.6	4.3	16.4	20	2.8	5.2	4.4	71	0.4	9.1	33.6	20	0.5
Lab033	5	12.4	12.5	60	0.4	3.2	7.2	20	6.0	3.9	3.9	60	0.1	2.6	5.1	20	>6
Lab037	5	15.3	15.3	20	0.4	2.6	5.2	20	>6	5.2	4.7	20	0.2	4.3	18.1	20	2.4
Total	-	-	13.5	215	1.3	9.6	-	-	-	-	4.2	215	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 (2020/06)								CUM (2019/02/01~2020/06/30)							
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	13.0	2	-	-	-	20	-	15.9	15.0	19	1.0	6.7	19.0	20	2.1
Lab022	5	12.4	11.3	4	0.9	8.0	24.8	20	1.4	12.4	12.2	45	0.5	4.1	9.8	20	4.5
Lab032	5	15.3	13.1	3	0.2	1.5	17.4	20	3.7	15.3	14.1	71	0.6	4.3	16.4	20	2.8
Lab033	5	12.4	13.1	4	0.1	0.8	7.2	20	>6	12.4	12.5	60	0.4	3.2	7.2	20	6.0
Lab037	5	15.3	15.2	4	0.5	3.3	7.2	20	5.9	15.3	15.3	20	0.4	2.6	5.2	20	>6
Total	-	-	13.1	17	1.5	11.5	-	-	-	-	13.5	215	1.3	9.6	-	-	-

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

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

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

Month : 2020 06 Change Cumulative : from 2019 02 01 to 2020 06 30 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2020/06)								CUM (2019/02/01~2020/06/30)							
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	4.4	2	-	-	-	20	-	5.2	4.7	19	0.2	4.3	18.1	20	2.4
Lab022	5	4.1	3.7	4	0.3	8.1	26.0	20	1.3	4.1	4.0	45	0.2	5.0	12.4	20	3.5
Lab032	5	5.2	4.0	3	0.1	2.5	28.1	20	-1.2	5.2	4.4	71	0.4	9.1	33.6	20	0.5
Lab033	5	3.9	4.1	4	0.1	2.4	10.0	20	>6	3.9	3.9	60	0.1	2.6	5.1	20	>6
Lab037	5	5.2	4.8	4	0.2	4.2	16.0	20	2.9	5.2	4.7	20	0.2	4.3	18.1	20	2.4
Total	-	-	4.2	17	0.4	9.5	-	-	-	-	4.2	215	0.4	9.5	-	-	-

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

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

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

Month : 2020 06 Change Cumulative : from 2019 02 01 to 2020 06 30 Change

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Reagent Kit	Reagent Code
Medicon	5