

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 (2020/05)	CUM (2020/01/21~2020/05/30)	Month (2020/05)	CUM (2020/01/21~2020/05/30)
Runs (N)	6	26	6	26
Mean (U/gHb)	13.0	13.9	4.0	4.3
SD	0.5	0.7	0.1	0.3
CV (%)	3.8	5.0	2.5	7.0
Target Value (U/gHb)	15.3	15.3	5.2	5.2
Total Error (%)	22.7	19.2	28.1	31.3
TEa (%)	20	20	20	20
σ	1.3	2.2	-1.2	0.4

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

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

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

Month : 2020 05 [Change](#) ; Cumulative : from 2020 01 21 to 2020 05 30 [Change](#)

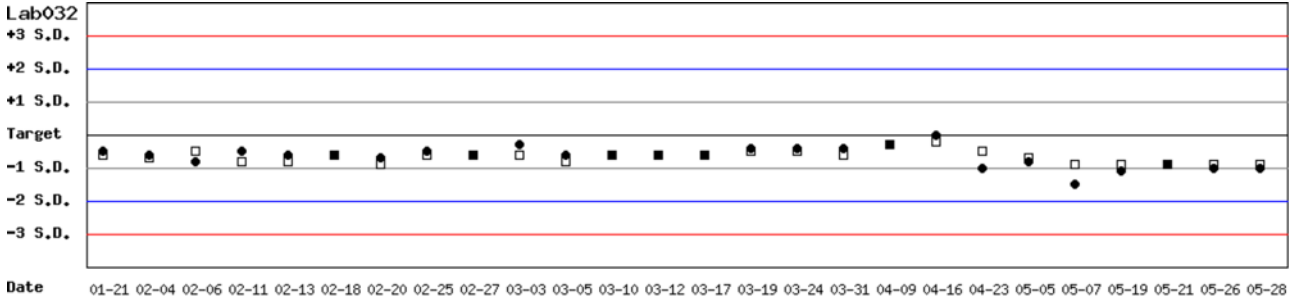
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-01-21 to 2020-05-30 ; Target : 15.3 ; SD : 2.20 (●)

Lot No.: AH1220D ; Duration : 2020-01-21 to 2020-05-30 ; Target : 5.2 ; SD : 1.40 (□)

Lab032



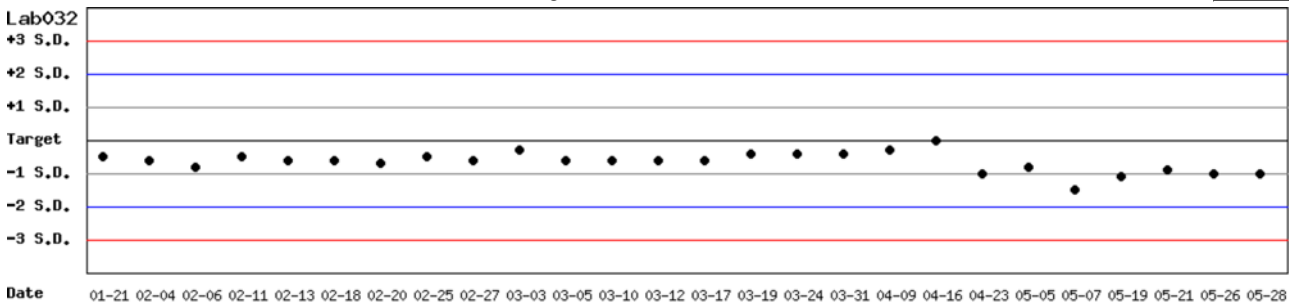
Month : 2020 05 [Change](#) ; Cumulative : from 2020 01 21 to 2020 05 30 [Change](#)

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-01-21 to 2020-05-30 ; Target : 15.3 ; SD : 2.20

Lab032



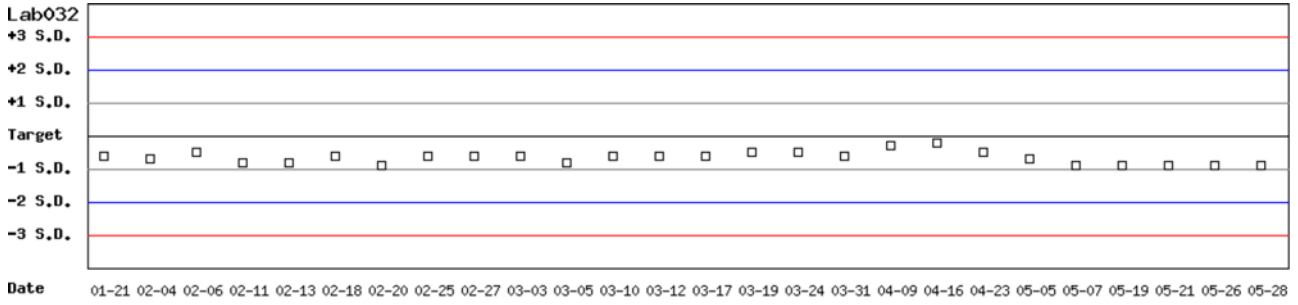
Month : 2020 05 [Change](#) ; Cumulative : from 2020 01 21 to 2020 05 30 [Change](#)

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-01-21 to 2020-05-30 ; Target : 5.2 ; SD : 1.40

Lab032



Month : 2020 05 ; Cumulative : from 2020 01 21 to 2020 05 30

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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 05

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	13.3	1	-	-	-	20	-	5.2	4.4	1	-	-	-	20	-
Lab032	5	15.3	13.0	6	0.5	3.8	22.7	20	1.3	5.2	4.0	6	0.1	2.5	28.1	20	-1.2
Lab033	5	12.4	12.3	3	0.2	1.6	4.1	20	>6	3.9	3.9	3	0.1	2.6	5.1	20	>6
Lab037	5	15.3	15.2	3	0.2	1.3	3.3	20	>6	5.2	4.7	3	0.2	4.3	18.1	20	2.4
Total	-	-	13.4	13	1.1	8.2	-	-	-	-	4.2	13	0.3	7.1	-	-	-

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

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

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

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Cumulative

Cumulative : from 2019 02 01 to 2020 05 31

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	15.2	17	0.8	5.3	14.9	20	2.9	5.2	4.7	17	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	14.2	68	0.6	4.2	15.6	20	3.1	5.2	4.4	68	0.4	9.1	33.6	20	0.5
Lab033	5	12.4	12.5	56	0.4	3.2	7.2	20	6.0	3.9	3.9	56	0.1	2.6	5.1	20	>6
Lab037	5	15.3	15.3	16	0.4	2.6	5.2	20	>6	5.2	4.7	16	0.2	4.3	18.1	20	2.4
Total	-	-	13.5	198	1.2	8.9	-	-	-	-	4.2	198	0.4	9.5	-	-	-

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

TE : Total Error(%) = Bias (%) + 2 x 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 (2020/05)								CUM (2019/02/01~2020/05/31)							
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	13.3	1	-	-	-	20	-	15.9	15.2	17	0.8	5.3	14.9	20	2.9
Lab022	5	12.4	-	0	-	-	-	20	-	12.4	12.3	41	0.4	3.3	7.3	20	5.8
Lab032	5	15.3	13.0	6	0.5	3.8	22.7	20	1.3	15.3	14.2	68	0.6	4.2	15.6	20	3.1
Lab033	5	12.4	12.3	3	0.2	1.6	4.1	20	>6	12.4	12.5	56	0.4	3.2	7.2	20	6.0
Lab037	5	15.3	15.2	3	0.2	1.3	3.3	20	>6	15.3	15.3	16	0.4	2.6	5.2	20	>6
Total	-	-	13.4	13	1.1	8.2	-	-	-	-	13.5	198	1.2	8.9	-	-	-

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

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

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

Month : 2020 ▼ 05 ▼ Change Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2020 ▼ 05 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2020/05)								CUM (2019/02/01~2020/05/31)							
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	1	-	-	-	20	-	5.2	4.7	17	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	4.0	6	0.1	2.5	28.1	20	-1.2	5.2	4.4	68	0.4	9.1	33.6	20	0.5
Lab033	5	3.9	3.9	3	0.1	2.6	5.1	20	>6	3.9	3.9	56	0.1	2.6	5.1	20	>6
Lab037	5	5.2	4.7	3	0.2	4.3	18.1	20	2.4	5.2	4.7	16	0.2	4.3	18.1	20	2.4
Total	-	-	4.2	13	0.3	7.1	-	-	-	-	4.2	198	0.4	9.5	-	-	-

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

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

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

Month : 2020 ▼ 05 ▼ Change Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2020 ▼ 05 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5