

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

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

Print Table

Lab022

	Control N		Control D	
QC Control Lot No.	AH1220N		AH1220D	
Duration of the Analyzing	Month (2019/09)	CUM (2019/02/01~2019/09/30)	Month (2019/09)	CUM (2019/02/01~2019/09/30)
Runs (N)	1	18	1	18
Mean (U/gHb)	12.7	12.4	3.9	4.0
SD	-	0.3	-	0.1
CV (%)	-	2.4	-	2.5
Target Value (U/gHb)	12.4	12.4	4.1	4.1
Total Error (%)	-	4.8	-	7.4
TEa (%)	20	20	20	20
σ	-	>6	-	>6

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

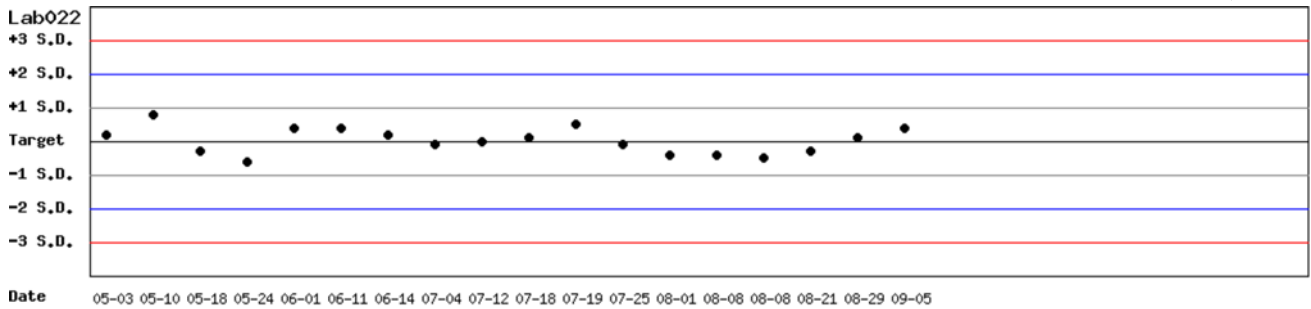
Month : 2019 09 Change ; Cumulative : from 2019 02 01 to 2019 09 30 Change

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-02-01 to 2019-09-30 ; Target : 12.4 ; SD : 0.8

Lab022



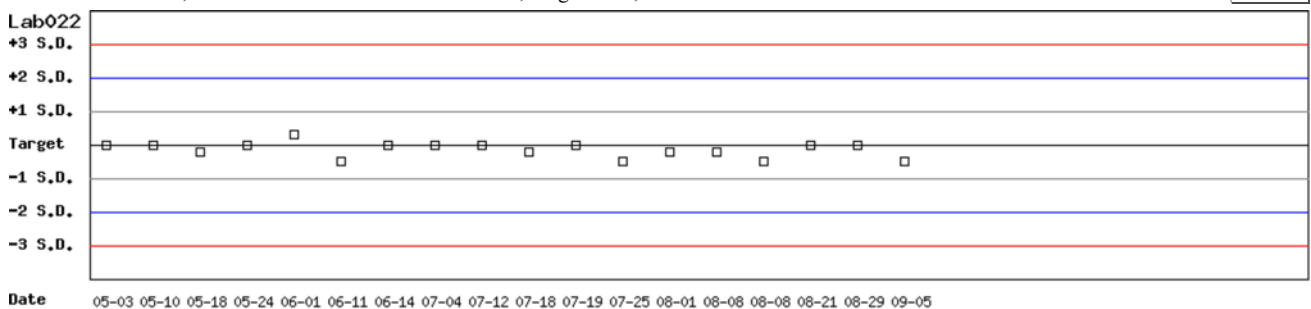
Month : 2019 09 Change ; Cumulative : from 2019 02 01 to 2019 09 30 Change

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2019-02-01 to 2019-09-30 ; Target : 4.1 ; SD : 0.4

Lab022



Month : 2019 09 Change ; Cumulative : from 2019 02 01 to 2019 09 30 Change

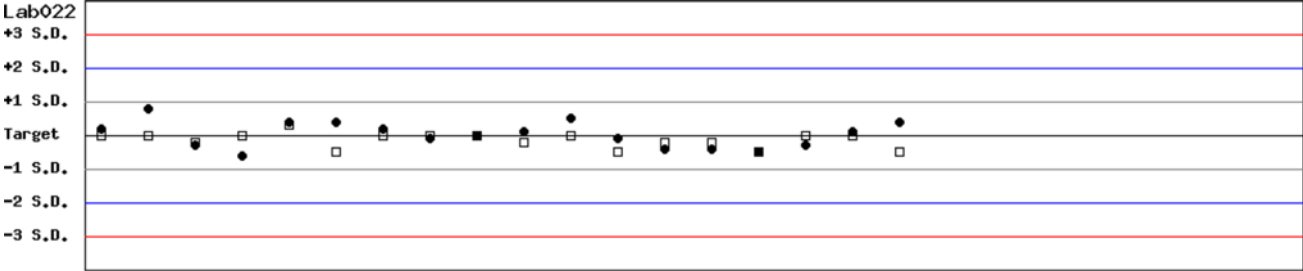
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-02-01 to 2019-09-30 ; Target : 12.4 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2019-02-01 to 2019-09-30 ; Target : 4.1 ; SD : 0.4 (□)

Lab022



Date 05-03 05-10 05-18 05-24 06-01 06-11 06-14 07-04 07-12 07-18 07-19 07-25 08-01 08-08 08-08 08-21 08-29 09-05

Month : 2019 09 ; Cumulative : from 2019 02 01 to 2019 09 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 : 2019 ▼ 09 ▼ 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	3	0.1	0.7	5.1	20	>6	5.2	4.6	3	0.1	2.2	15.9	20	3.8
Lab022	5	12.4	12.7	1	-	-	-	20	-	4.1	3.9	1	-	-	-	20	-
Lab032	5	15.3	14.6	7	0.4	2.7	10.1	20	5.7	5.2	4.4	7	0.1	2.3	19.9	20	2.0
Lab033	5	12.4	12.6	4	0.2	1.6	4.8	20	>6	3.9	3.8	4	0.1	2.6	7.8	20	>6
Total	-	-	14.1	15	1.1	7.8	-	-	-	-	4.2	15	0.3	7.1	-	-	-

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 2019 ▼ 09 ▼ 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	15.2	13	0.5	3.3	11.0	20	4.7	5.2	4.6	13	0.2	4.3	20.2	20	2.0
Lab022	5	12.4	12.4	18	0.3	2.4	4.8	20	>6	4.1	4.0	18	0.1	2.5	7.4	20	>6
Lab032	5	15.3	14.4	26	0.5	3.5	12.8	20	4.0	5.2	4.6	26	0.5	10.9	33.3	20	0.8
Lab033	5	12.4	12.5	25	0.4	3.2	7.2	20	6.0	3.9	3.9	25	0.1	2.6	5.1	20	>6
Total	-	-	13.5	82	1.2	8.9	-	-	-	-	4.2	82	0.5	11.9	-	-	-

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 (2019/09)								CUM (2019/02/01~2019/09/30)							
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	15.3	3	0.1	0.7	5.1	20	>6	15.9	15.2	13	0.5	3.3	11.0	20	4.7
Lab022	5	12.4	12.7	1	-	-	-	20	-	12.4	12.4	18	0.3	2.4	4.8	20	>6
Lab032	5	15.3	14.6	7	0.4	2.7	10.1	20	5.7	15.3	14.4	26	0.5	3.5	12.8	20	4.0
Lab033	5	12.4	12.6	4	0.2	1.6	4.8	20	>6	12.4	12.5	25	0.4	3.2	7.2	20	6.0
Total	-	-	14.1	15	1.1	7.8	-	-	-	-	13.5	82	1.2	8.9	-	-	-

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

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

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

Month : 2019 ▼ 09 ▼ Change Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2019 ▼ 09 ▼ 30 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2019/09)								CUM (2019/02/01~2019/09/30)							
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	4.6	3	0.1	2.2	15.9	20	3.8	5.2	4.6	13	0.2	4.3	20.2	20	2.0
Lab022	5	4.1	3.9	1	-	-	-	20	-	4.1	4.0	18	0.1	2.5	7.4	20	>6
Lab032	5	5.2	4.4	7	0.1	2.3	19.9	20	2.0	5.2	4.6	26	0.5	10.9	33.3	20	0.8
Lab033	5	3.9	3.8	4	0.1	2.6	7.8	20	>6	3.9	3.9	25	0.1	2.6	5.1	20	>6
Total	-	-	4.2	15	0.3	7.1	-	-	-	-	4.2	82	0.5	11.9	-	-	-

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

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

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

Month : 2019 ▼ 09 ▼ Change Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2019 ▼ 09 ▼ 30 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5