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

Select LotNo： AE0909N (2016-01-01 ~ 2100-12-31) Change

Print Table

Lab018

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2019/07)	CUM (2019/05/01~2019/07/31)	Month (2019/07)	CUM (2019/05/01~2019/07/31)
Runs (N)	8	26	8	26
Mean (U/gHb)	13.9	14.1	5.3	5.4
SD	0.5	0.4	0.1	0.2
CV (%)	3.6	2.8	1.9	3.7
Target Value (U/gHb)	14.2	14.2	5.5	5.5
Total Error (%)	9.3	6.4	7.4	9.2
TEa (%)	20	20	20	20
σ	5.0	>6	>6	4.9

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

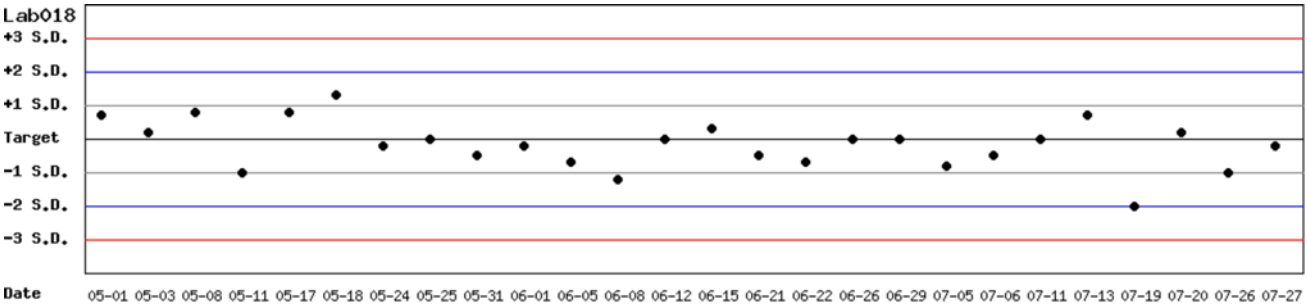
Month : 2019 07 Change ; Cumulative : from 2019 05 01 to 2019 07 31 Change

[TOP]

Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-05-01 to 2019-07-31 ; Target : 14.2 ; SD : 0.60

Lab018



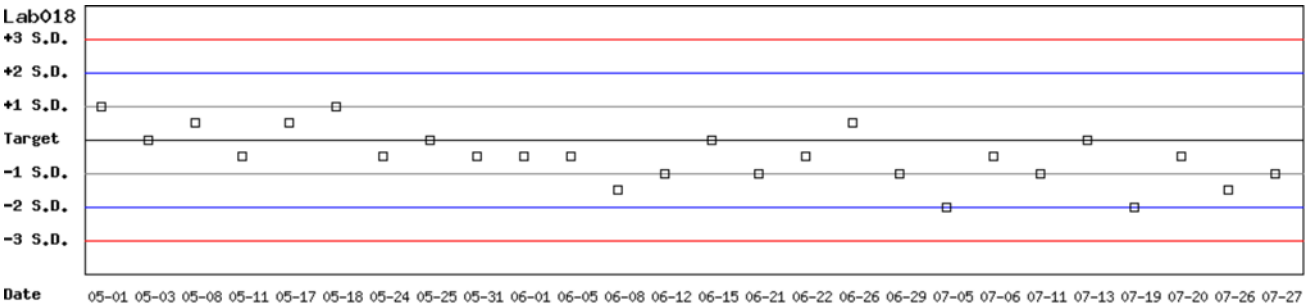
Month : 2019 07 Change ; Cumulative : from 2019 05 01 to 2019 07 31 Change

[TOP]

Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2019-05-01 to 2019-07-31 ; Target : 5.5 ; SD : 0.20

Lab018



Month : 2019 07 Change ; Cumulative : from 2019 05 01 to 2019 07 31 Change

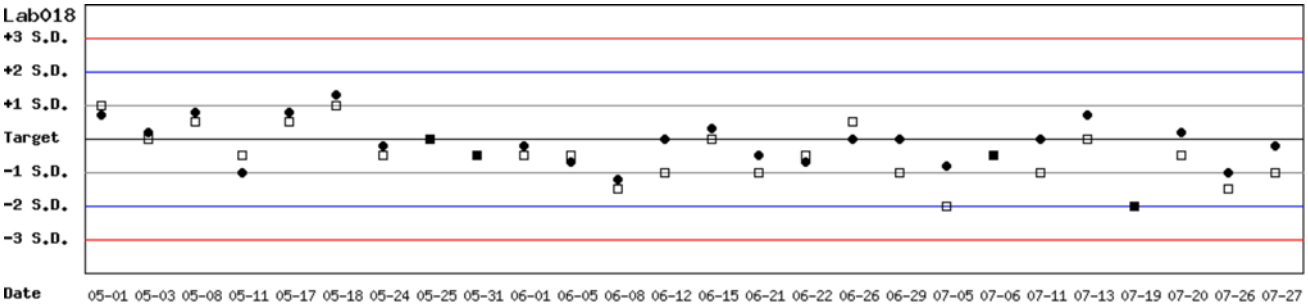
[TOP]

Control N and **Control D SDI**
QC Chart

Lot No.: AE0909N ; Duration : 2019-05-01 to 2019-07-31 ; Target : 14.2 ; SD : 0.60 (●)

Lot No.: AE0909D ; Duration : 2019-05-01 to 2019-07-31 ; Target : 5.5 ; SD : 0.20 (□)

Lab018



Month : 2019 07 Change ; Cumulative : from 2019 05 01 to 2019 07 31 Change

[TOP]

Peer Group Statistics (Table 1)

Select LotNo：AE0909N (2016-01-01 ~ 2100-12-31) Change

Select Reagent Kit：5 - Medicon Change

Print Table 1

Monthly

Month : 2019 07 Change

		Control N (Lot No.: AE0909N)									Control D (Lot No.: AE0909D)							
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
Lab018	5	14.2	13.9	8	0.5	3.6	9.3	20	5.0		5.5	5.3	8	0.1	1.9	7.4	20	>6
Lab019	5	15.3	15.1	5	0.3	2.0	5.3	20	>6		5.3	5.4	5	0.1	1.9	5.6	20	>6
Lab026	5	15.9	12.8	17	0.4	3.1	25.7	20	0.2		5.8	5.0	17	0.1	2.0	17.8	20	3.1
Lab027	5	15.5	14.7	8	0.7	4.8	14.7	20	3.1		5.4	5.5	8	0.2	3.6	9.1	20	5.0
Lab028	5	14.4	14.2	12	0.3	2.1	5.6	20	>6		5.8	5.5	12	0.1	1.8	8.8	20	>6
Lab034	5	14.4	14.6	4	0.7	4.8	11.0	20	3.9		5.8	5.8	4	0.7	12.1	24.1	20	1.7
Total	-	-	13.9	54	0.9	6.5	-	-	-		-	5.3	54	0.3	5.7	-	-	-

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

[TOP]

Cumulative

Cumulative : from 2016 02 01 to 2019 07 31 Change

		Control N (Lot No.: AE0909N)									Control D (Lot No.: AE0909D)							
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
Lab018	5	14.2	15.3	101	1.1	7.2	22.1	20	1.7		5.5	5.6	101	0.3	5.4	12.5	20	3.4
Lab019	5	15.3	15.2	79	0.3	2.0	4.6	20	>6		5.3	5.3	79	0.1	1.9	3.8	20	>6
Lab020	5	14.4	15.2	28	0.5	3.3	12.1	20	4.4		5.8	5.3	28	0.3	5.7	19.9	20	2.0
Lab026	5	15.9	14.3	192	1.4	9.8	29.6	20	1.0		5.8	5.2	192	0.4	7.7	25.7	20	1.3
Lab027	5	15.5	15.6	103	1.3	8.3	17.3	20	2.3		5.4	5.6	103	0.4	7.1	18.0	20	2.3
Lab028	5	14.4	14.5	74	0.7	4.8	10.3	20	4.0		5.8	5.6	74	0.3	5.4	14.2	20	3.1
Lab032	5	15.3	15.9	38	0.9	5.7	15.2	20	2.8		5.2	5.7	38	0.3	5.3	20.1	20	2.0
Lab033	5	14.4	14.9	49	0.6	4.0	11.5	20	4.1		5.8	5.2	49	0.2	3.8	18.0	20	2.5
Lab034	5	14.4	14.3	54	0.6	4.2	9.1	20	4.6		5.8	5.1	54	0.3	5.9	23.8	20	1.3
Lab037	5	14.9	15.2	30	0.8	5.3	12.5	20	3.4		5.4	5.5	30	0.3	5.5	12.8	20	3.3
Lab040	5	14.4	13.3	39	0.7	5.3	18.2	20	2.3		5.8	4.7	39	0.3	6.4	31.7	20	0.2
Lab043	5	11.5	13.1	68	0.9	6.9	27.7	20	0.9		4.5	4.9	68	0.3	6.1	21.1	20	1.8
Total	-	-	14.7	855	1.3	8.8	-	-	-		-	5.3	855	0.4	7.5	-	-	-

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

[TOP]

Reagent Kit	Reagent Code
Medicon	5

Peer Group Statistics (Table 2)

Select LotNo：AE0909N (2016-01-01 ~ 2100-12-31) Change

Select Reagent Kit：5 - Medicon Change

Print Table 2

Control N Month vs. Cumulative

		Control N (Lot No.: AE0909N)															
		Month (2019/07)								CUM (2016/02/01~2019/07/31)							
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
Lab018	5	14.2	13.9	8	0.5	3.6	9.3	20	5.0	14.2	15.3	101	1.1	7.2	22.1	20	1.7
Lab019	5	15.3	15.1	5	0.3	2.0	5.3	20	>6	15.3	15.2	79	0.3	2.0	4.6	20	>6
Lab020	5	14.4	-	0	-	-	-	20	-	14.4	15.2	28	0.5	3.3	12.1	20	4.4
Lab026	5	15.9	12.8	17	0.4	3.1	25.7	20	0.2	15.9	14.3	192	1.4	9.8	29.6	20	1.0
Lab027	5	15.5	14.7	8	0.7	4.8	14.7	20	3.1	15.5	15.6	103	1.3	8.3	17.3	20	2.3
Lab028	5	14.4	14.2	12	0.3	2.1	5.6	20	>6	14.4	14.5	74	0.7	4.8	10.3	20	4.0
Lab032	5	15.3	-	0	-	-	-	20	-	15.3	15.9	38	0.9	5.7	15.2	20	2.8
Lab033	5	14.4	-	0	-	-	-	20	-	14.4	14.9	49	0.6	4.0	11.5	20	4.1
Lab034	5	14.4	14.6	4	0.7	4.8	11.0	20	3.9	14.4	14.3	54	0.6	4.2	9.1	20	4.6
Lab037	5	14.9	-	0	-	-	-	20	-	14.9	15.2	30	0.8	5.3	12.5	20	3.4
Lab040	5	14.4	-	0	-	-	-	20	-	14.4	13.3	39	0.7	5.3	18.2	20	2.3
Lab043	5	11.5	-	0	-	-	-	20	-	11.5	13.1	68	0.9	6.9	27.7	20	0.9
Total	-	-	13.9	54	0.9	6.5	-	-	-	-	14.7	855	1.3	8.8	-	-	-

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

Month : 2019 07 Change Cumulative : from 2016 02 01 to 2019 07 31 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2019/07)								CUM (2016/02/01~2019/07/31)							
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
Lab018	5	5.5	5.3	8	0.1	1.9	7.4	20	>6	5.5	5.6	101	0.3	5.4	12.5	20	3.4
Lab019	5	5.3	5.4	5	0.1	1.9	5.6	20	>6	5.3	5.3	79	0.1	1.9	3.8	20	>6
Lab020	5	5.8	-	0	-	-	-	20	-	5.8	5.3	28	0.3	5.7	19.9	20	2.0
Lab026	5	5.8	5.0	17	0.1	2.0	17.8	20	3.1	5.8	5.2	192	0.4	7.7	25.7	20	1.3
Lab027	5	5.4	5.5	8	0.2	3.6	9.1	20	5.0	5.4	5.6	103	0.4	7.1	18.0	20	2.3
Lab028	5	5.8	5.5	12	0.1	1.8	8.8	20	>6	5.8	5.6	74	0.3	5.4	14.2	20	3.1
Lab032	5	5.2	-	0	-	-	-	20	-	5.2	5.7	38	0.3	5.3	20.1	20	2.0
Lab033	5	5.8	-	0	-	-	-	20	-	5.8	5.2	49	0.2	3.8	18.0	20	2.5
Lab034	5	5.8	5.8	4	0.7	12.1	24.1	20	1.7	5.8	5.1	54	0.3	5.9	23.8	20	1.3
Lab037	5	5.4	-	0	-	-	-	20	-	5.4	5.5	30	0.3	5.5	12.8	20	3.3
Lab040	5	5.8	-	0	-	-	-	20	-	5.8	4.7	39	0.3	6.4	31.7	20	0.2
Lab043	5	4.5	-	0	-	-	-	20	-	4.5	4.9	68	0.3	6.1	21.1	20	1.8
Total	-	-	5.3	54	0.3	5.7	-	-	-	-	5.3	855	0.4	7.5	-	-	-

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

Month : 2019 07 Change Cumulative : from 2016 02 01 to 2019 07 31 Change

[TOP]

Reagent Kit	Reagent Code
Medicon	5