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

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

Print Table

Lab019

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2020/07)	CUM (2019/10/02~2020/07/30)	Month (2020/07)	CUM (2019/10/02~2020/07/30)
Runs (N)	1	26	1	26
Mean (U/gHb)	14.9	15.4	4.8	5.3
SD	-	0.2	-	0.3
CV (%)	-	1.3	-	5.7
Target Value (U/gHb)	15.3	15.3	5.3	5.3
Total Error (%)	-	3.3	-	11.3
TEa (%)	20	20	20	20
σ	-	>6	-	3.5

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

Month : 2020 07 Change ; Cumulative : from 2019 10 02 to 2020 07 30 Change

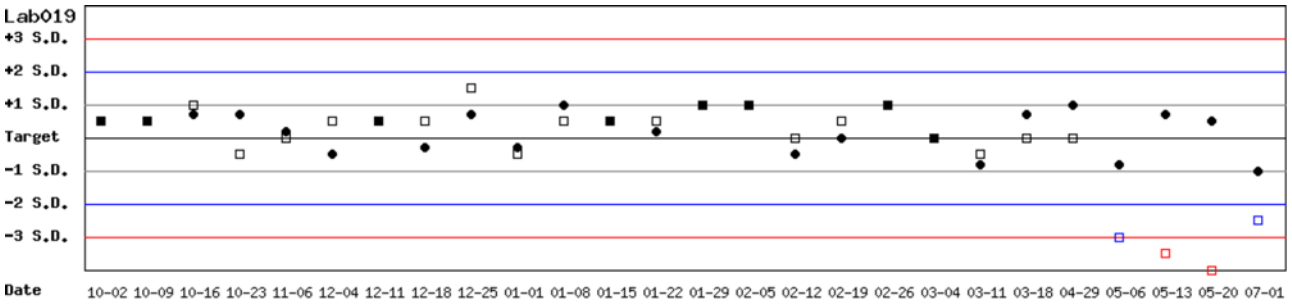
[TOP]

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

Lot No.: AE0909N ; Duration : 2019-10-02 to 2020-07-30 ; Target : 15.3 ; SD : 0.40 (●)

Lot No.: AE0909D ; Duration : 2019-10-02 to 2020-07-30 ; Target : 5.3 ; SD : 0.20 (□)

Lab019



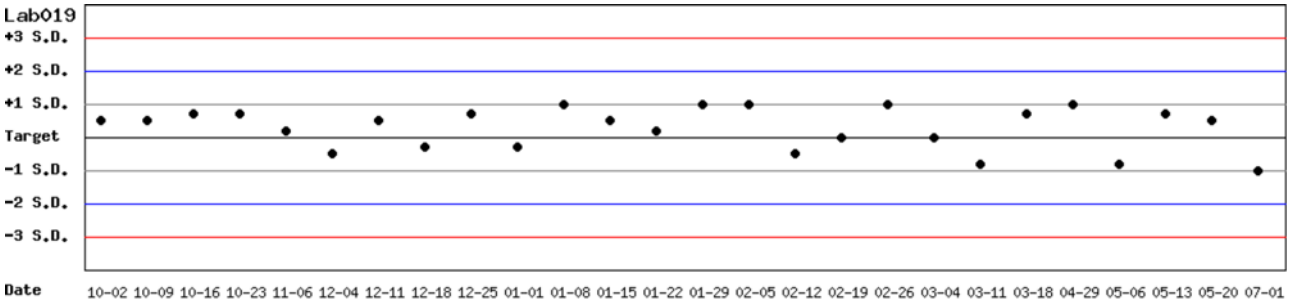
Month : 2020 07 Change ; Cumulative : from 2019 10 02 to 2020 07 30 Change

[TOP]

Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-10-02 to 2020-07-30 ; Target : 15.3 ; SD : 0.40

Lab019



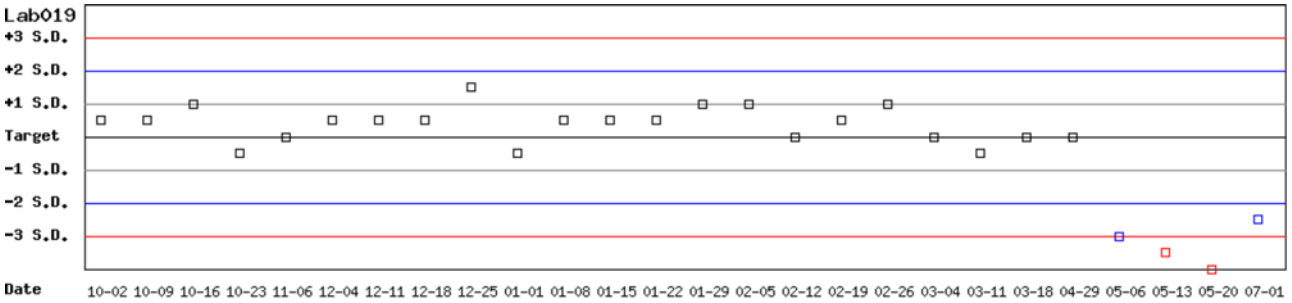
Month : 2020 07 Change ; Cumulative : from 2019 10 02 to 2020 07 30 Change

[TOP]

Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2019-10-02 to 2020-07-30 ; Target : 5.3 ; SD : 0.20

Lab019



Month : 2020 07 Change ; Cumulative : from 2019 10 02 to 2020 07 30 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 : 2020 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
Lab019	5	15.3	14.9	1	-	-	-	20	-	5.3	4.8	1	-	-	-	20	-
Lab026	5	15.9	12.9	17	0.1	0.8	20.4	20	1.4	5.8	4.9	17	0.2	4.1	23.7	20	1.1
Lab034	5	15.5	15.5	5	0.8	5.2	10.3	20	3.8	4.8	4.9	5	0.1	2.0	6.2	20	>6
Lab040	5	14.4	12.8	1	-	-	-	20	-	5.8	4.5	1	-	-	-	20	-
Total	-	-	13.5	24	1.2	8.9	-	-	-	-	4.9	24	0.2	4.1	-	-	-

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 2020 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	14.9	142	1.2	8.1	21.0	20	1.9	5.5	5.5	142	0.3	5.5	10.9	20	3.6
Lab019	5	15.3	15.2	111	0.3	2.0	4.6	20	>6	5.3	5.3	111	0.2	3.8	7.5	20	5.3
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	13.6	368	1.3	9.6	33.6	20	0.6	5.8	5.1	368	0.3	5.9	23.8	20	1.3
Lab027	5	15.5	15.5	107	1.3	8.4	16.8	20	2.4	5.4	5.6	107	0.5	8.9	21.6	20	1.8
Lab028	5	14.8	14.5	134	0.7	4.8	11.7	20	3.7	4.8	5.6	134	0.3	5.4	27.4	20	0.6
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	15.5	14.7	96	0.9	6.1	17.4	20	2.4	4.8	5.0	96	0.4	8.0	20.2	20	2.0
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	13.2	40	0.7	5.3	18.9	20	2.2	5.8	4.7	40	0.3	6.4	31.7	20	0.2
Lab043	5	11.5	13.1	84	0.9	6.9	27.7	20	0.9	4.5	4.9	84	0.3	6.1	21.1	20	1.8
Total	-	-	14.4	1227	1.3	9.0	-	-	-	-	5.3	1227	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 (2020/07)								CUM (2016/02/01~2020/07/31)							
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	-	0	-	-	-	20	-	14.2	14.9	142	1.2	8.1	21.0	20	1.9
Lab019	5	15.3	14.9	1	-	-	-	20	-	15.3	15.2	111	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	12.9	17	0.1	0.8	20.4	20	1.4	15.9	13.6	368	1.3	9.6	33.6	20	0.6
Lab027	5	15.5	-	0	-	-	-	20	-	15.5	15.5	107	1.3	8.4	16.8	20	2.4
Lab028	5	14.8	-	0	-	-	-	20	-	14.8	14.5	134	0.7	4.8	11.7	20	3.7
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	15.5	15.5	5	0.8	5.2	10.3	20	3.8	15.5	14.7	96	0.9	6.1	17.4	20	2.4
Lab037	5	14.9	-	0	-	-	-	20	-	14.9	15.2	30	0.8	5.3	12.5	20	3.4
Lab040	5	14.4	12.8	1	-	-	-	20	-	14.4	13.2	40	0.7	5.3	18.9	20	2.2
Lab043	5	11.5	-	0	-	-	-	20	-	11.5	13.1	84	0.9	6.9	27.7	20	0.9
Total	-	-	13.5	24	1.2	8.9	-	-	-	-	14.4	1227	1.3	9.0	-	-	-

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

Month : 2020 07 Change Cumulative : from 2016 02 01 to 2020 07 31 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2020/07)								CUM (2016/02/01~2020/07/31)							
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	-	0	-	-	-	20	-	5.5	5.5	142	0.3	5.5	10.9	20	3.6
Lab019	5	5.3	4.8	1	-	-	-	20	-	5.3	5.3	111	0.2	3.8	7.5	20	5.3
Lab020	5	5.8	-	0	-	-	-	20	-	5.8	5.3	28	0.3	5.7	19.9	20	2.0
Lab026	5	5.8	4.9	17	0.2	4.1	23.7	20	1.1	5.8	5.1	368	0.3	5.9	23.8	20	1.3
Lab027	5	5.4	-	0	-	-	-	20	-	5.4	5.6	107	0.5	8.9	21.6	20	1.8
Lab028	5	4.8	-	0	-	-	-	20	-	4.8	5.6	134	0.3	5.4	27.4	20	0.6
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	4.8	4.9	5	0.1	2.0	6.2	20	>6	4.8	5.0	96	0.4	8.0	20.2	20	2.0
Lab037	5	5.4	-	0	-	-	-	20	-	5.4	5.5	30	0.3	5.5	12.8	20	3.3
Lab040	5	5.8	4.5	1	-	-	-	20	-	5.8	4.7	40	0.3	6.4	31.7	20	0.2
Lab043	5	4.5	-	0	-	-	-	20	-	4.5	4.9	84	0.3	6.1	21.1	20	1.8
Total	-	-	4.9	24	0.2	4.1	-	-	-	-	5.3	1227	0.4	7.5	-	-	-

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

Month : 2020 07 Change Cumulative : from 2016 02 01 to 2020 07 31 Change

[TOP]

Reagent Kit	Reagent Code
Medicon	5