

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

Select LotNo : AC1203N (2014-01-01 ~ 2100-12-31) Change

Print Table

Lab037

QC Control Lot No.	Control N		Control D	
	AC1203N		AC1203D	
Duration of the Analyzing	Month (2018/03)	CUM (2017/06/16~2018/03/31)	Month (2018/03)	CUM (2017/06/16~2018/03/31)
Runs (N)	1	26	1	26
Mean (U/gHb)	15.9	14.4	3.6	3.3
SD	-	1.6	-	0.3
CV (%)	-	11.1	-	9.1
Target Value (U/gHb)	12.6	12.6	3.0	3.0
Total Error (%)	-	36.5	-	28.2
TEa (%)	20	20	20	20
σ	-	0.5	-	1.1

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

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

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

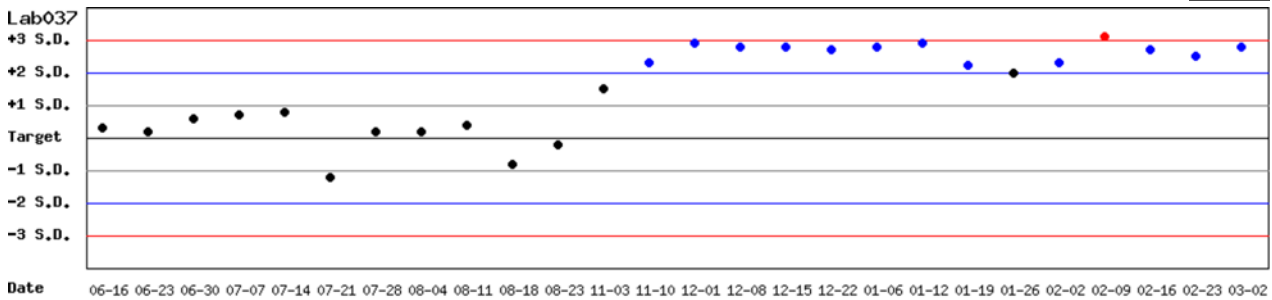
Month : 2018 03 Change ; Cumulative : from 2017 06 16 to 2018 03 31 Change

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Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2017-06-16 to 2018-03-31 ; Target : 12.6 ; SD : 1.20

Lab037



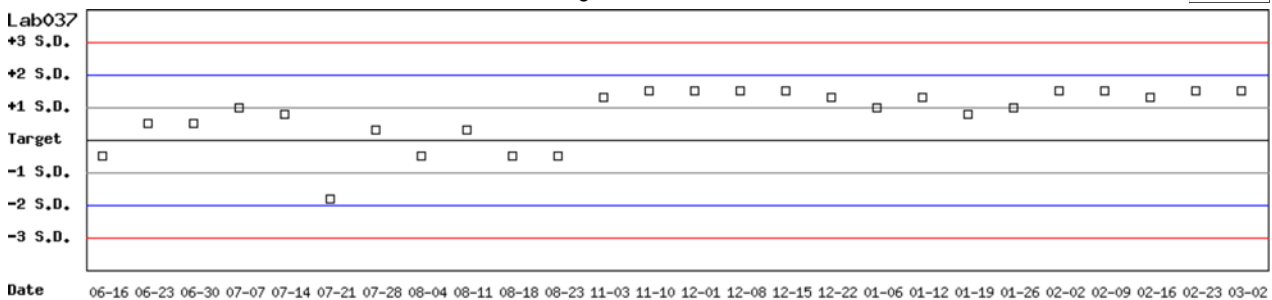
Month : 2018 03 Change ; Cumulative : from 2017 06 16 to 2018 03 31 Change

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Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2017-06-16 to 2018-03-31 ; Target : 3.0 ; SD : 0.40

Lab037



Month : 2018 03 Change ; Cumulative : from 2017 06 16 to 2018 03 31 Change

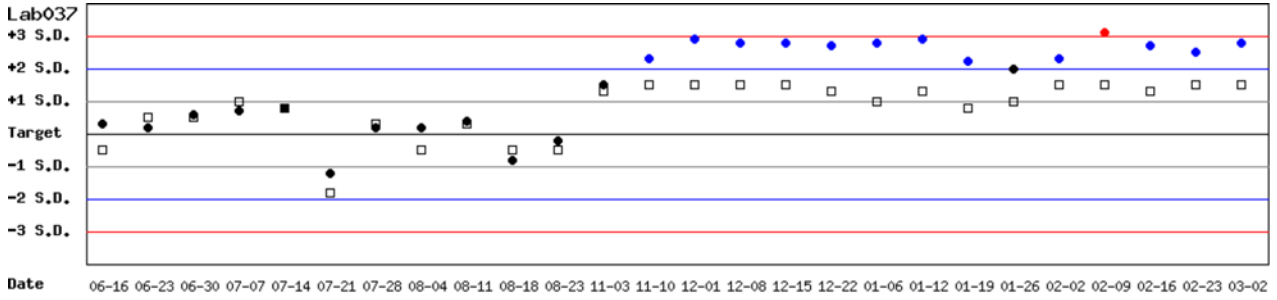
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Control N and Control D SDI QC Chart

Lot No.: AC1203N ; Duration : 2017-06-16 to 2018-03-31 ; Target : 12.6 ; SD : 1.20 (●)

Lot No.: AC1203D ; Duration : 2017-06-16 to 2018-03-31 ; Target : 3.0 ; SD : 0.40 (□)

Lab037



Month : 2018 03 Change ; Cumulative : from 2017 06 16 to 2018 03 31 Change

Peer Group Statistics (Table 1)

Select LotNo : AC1203N (2014-01-01 ~ 2100-12-31)

Select Reagent Kit : 5 - Medicon

Monthly

Month : 2018 03

UnitID ↑	Reagent Kit (Code) ↑	Control N (Lot No.: AC1203N)								Control D (Lot No.: AC1203D)							
		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	14.8	15.1	2	-	-	-	20	-	3.4	5.1	2	-	-	-	20	-
Lab020	5	14.2	15.3	4	0.4	2.6	13.0	20	4.7	3.3	3.4	4	0.1	2.9	8.9	20	5.9
Lab021	5	12.3	15.3	3	0.4	2.6	29.6	20	-1.7	2.8	3.4	3	0.1	2.9	27.3	20	-0.5
Lab028	5	14.2	15.2	15	0.8	5.3	17.6	20	2.4	3.3	3.6	15	0.2	5.6	20.2	20	1.9
Lab037	5	12.6	15.9	1	-	-	-	20	-	3.0	3.6	1	-	-	-	20	-
Total	-	-	15.3	25	0.7	4.6	-	-	-	-	3.7	25	0.5	13.5	-	-	-

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

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

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

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Cumulative

Cumulative : from 2014 02 01 to 2018 03 31

UnitID ↑	Reagent Kit (Code) ↑	Control N (Lot No.: AC1203N)								Control D (Lot No.: AC1203D)							
		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	14.8	14.9	30	0.7	4.7	10.1	20	4.1	3.4	3.6	30	0.6	16.7	39.2	20	0.8
Lab020	5	14.2	15.3	12	0.3	2.0	11.7	20	>6	3.3	3.5	12	0.1	2.9	11.8	20	4.8
Lab021	5	12.3	15.3	3	0.4	2.6	29.6	20	-1.7	2.8	3.4	3	0.1	2.9	27.3	20	-0.5
Lab026	5	14.6	14.7	16	0.5	3.4	7.5	36	>6	3.2	3.2	16	0.1	3.1	6.3	36	>6
Lab028	5	14.2	15.1	38	0.9	6.0	18.3	20	2.3	3.3	3.6	38	0.2	5.6	20.2	20	1.9
Lab037	5	12.6	15.7	15	0.5	3.2	31.0	20	-1.4	3.0	3.5	15	0.1	2.9	22.4	20	1.1
Lab041	5	12.8	12.9	1	-	-	-	20	-	2.9	3.2	1	-	-	-	20	-
Total	-	-	15.1	115	0.8	5.3	-	-	-	-	3.5	115	0.3	8.6	-	-	-

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 : AC1203N (2014-01-01 ~ 2100-12-31) ▼ Change

Select Reagent Kit : 5 - Medicon ▼ Change

Print Table 2

Control N Month vs. Cumulative

		Control N (Lot No.: AC1203N)															
		Month (2018/03)								CUM (2014/02/01~2018/03/31)							
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
Lab019	5	14.8	15.1	2	-	-	-	20	-	14.8	14.9	30	0.7	4.7	10.1	20	4.1
Lab020	5	14.2	15.3	4	0.4	2.6	13.0	20	4.7	14.2	15.3	12	0.3	2.0	11.7	20	>6
Lab021	5	12.3	15.3	3	0.4	2.6	29.6	20	-1.7	12.3	15.3	3	0.4	2.6	29.6	20	-1.7
Lab026	5	14.6	-	0	-	-	-	36	-	14.6	14.7	16	0.5	3.4	7.5	36	>6
Lab028	5	14.2	15.2	15	0.8	5.3	17.6	20	2.4	14.2	15.1	38	0.9	6.0	18.3	20	2.3
Lab037	5	12.6	15.9	1	-	-	-	20	-	12.6	15.7	15	0.5	3.2	31.0	20	-1.4
Lab041	5	12.8	-	0	-	-	-	20	-	12.8	12.9	1	-	-	-	20	-
Total	-	-	15.3	25	0.7	4.6	-	-	-	-	15.1	115	0.8	5.3	-	-	-

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

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

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

Month : 2018 ▼ 03 ▼ Change Cumulative : from 2014 ▼ 02 ▼ 01 ▼ to 2018 ▼ 03 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AC1203D)															
		Month (2018/03)								CUM (2014/02/01~2018/03/31)							
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
Lab019	5	3.4	5.1	2	-	-	-	20	-	3.4	3.6	30	0.6	16.7	39.2	20	0.8
Lab020	5	3.3	3.4	4	0.1	2.9	8.9	20	5.9	3.3	3.5	12	0.1	2.9	11.8	20	4.8
Lab021	5	2.8	3.4	3	0.1	2.9	27.3	20	-0.5	2.8	3.4	3	0.1	2.9	27.3	20	-0.5
Lab026	5	3.2	-	0	-	-	-	36	-	3.2	3.2	16	0.1	3.1	6.3	36	>6
Lab028	5	3.3	3.6	15	0.2	5.6	20.2	20	1.9	3.3	3.6	38	0.2	5.6	20.2	20	1.9
Lab037	5	3.0	3.6	1	-	-	-	20	-	3.0	3.5	15	0.1	2.9	22.4	20	1.1
Lab041	5	2.9	-	0	-	-	-	20	-	2.9	3.2	1	-	-	-	20	-
Total	-	-	3.7	25	0.5	13.5	-	-	-	-	3.5	115	0.3	8.6	-	-	-

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

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

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

Month : 2018 ▼ 03 ▼ Change Cumulative : from 2014 ▼ 02 ▼ 01 ▼ to 2018 ▼ 03 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5