

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

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

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Lab018

QC Control Lot No.	Control N		Control D	
	AE0909N		AE0909D	
Duration of the Analyzing	Month (2017/07)	CUM (2016/02/01~2017/07/31)	Month (2017/07)	CUM (2016/02/01~2017/07/31)
Runs (N)	4	16	4	16
Mean (U/gHb)	9.7	10.4	3.7	4.0
SD	0.3	0.6	0.2	0.3
CV (%)	3.1	5.8	5.4	7.5
Target Value (U/gHb)	10.5	10.5	4.1	4.1
Total Error (%)	13.8	12.5	20.6	17.4
TEa (%)	20	20	20	20
σ	4.0	3.3	1.9	2.3

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

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

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

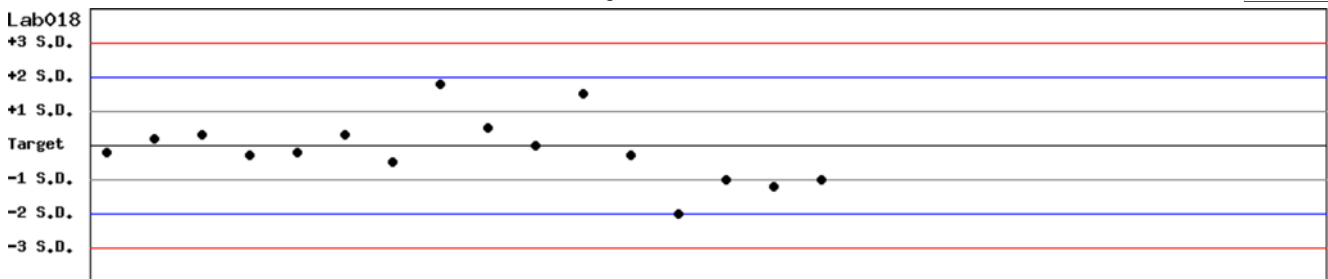
Month : 2017 07 Change ; Cumulative : from 2016 02 01 to 2017 07 31 Change

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Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2017-07-31 ; Target : 10.5 ; SD : 0.6

Lab018



Date 05-05 05-10 05-16 05-20 05-26 06-01 06-06 06-09 06-13 06-16 06-23 06-30 07-07 07-14 07-15 07-20

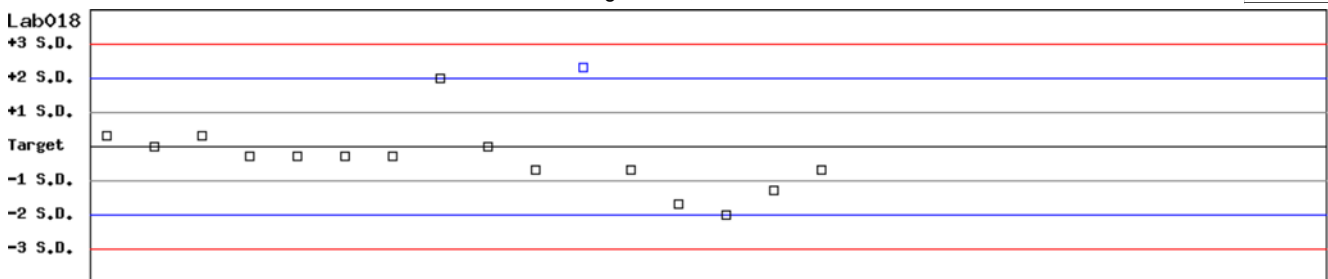
Month : 2017 07 Change ; Cumulative : from 2016 02 01 to 2017 07 31 Change

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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2016-02-01 to 2017-07-31 ; Target : 4.1 ; SD : 0.3

Lab018



Date 05-05 05-10 05-16 05-20 05-26 06-01 06-06 06-09 06-13 06-16 06-23 06-30 07-07 07-14 07-15 07-20

Month : 2017 07 Change ; Cumulative : from 2016 02 01 to 2017 07 31 Change

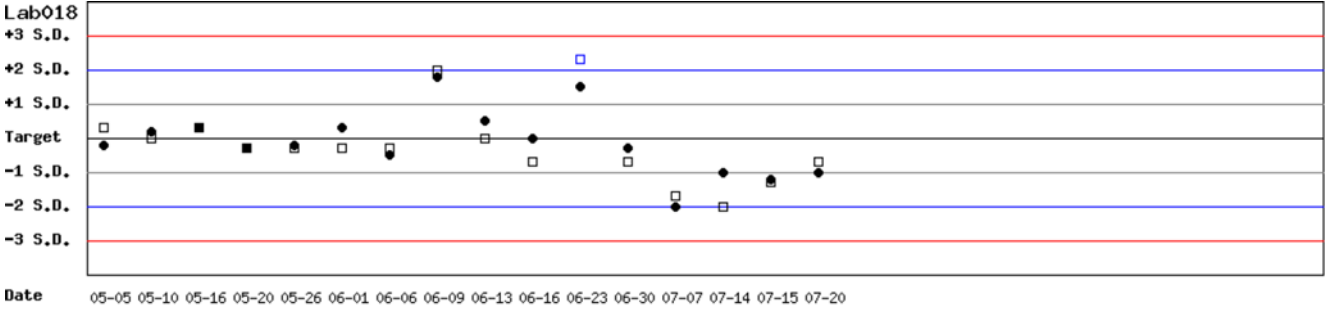
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Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2017-07-31 ; Target : 10.5 ; SD : 0.6 (●)

Lot No.: AE0909D ; Duration : 2016-02-01 to 2017-07-31 ; Target : 4.1 ; SD : 0.3 (□)

Lab018



Month : 2017 07 ; Cumulative : from 2016 02 01 to 2017 07 31

Peer Group Statistics (Table 1)

Select LotNo :

Select Reagent Kit :

Monthly

Month :

UnitID	Reagent Kit (Code)	Control N (Lot No.: AE0909N)								Control D (Lot No.: AE0909D)							
		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 (%)	
Lab018	2	10.5	9.7	4	0.3	3.1	13.8	20	4.0	4.1	3.7	4	0.2	5.4	20.6	20	
Total	-	-	9.7	4	0.3	3.1	-	-	-	-	3.7	4	0.2	5.4	-	-	

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 to

UnitID	Reagent Kit (Code)	Control N (Lot No.: AE0909N)								Control D (Lot No.: AE0909D)							
		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 (%)	
Lab018	2	10.5	10.4	16	0.6	5.8	12.5	20	3.3	4.1	4.0	16	0.3	7.5	17.4	20	
Lab032	2	11.5	12.4	6	0.6	4.8	17.5	20	2.5	4.5	4.8	6	0.3	6.3	19.2	20	
Total	-	-	11.0	22	1.1	10.0	-	-	-	-	4.3	22	0.5	11.6	-	-	

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
AMP	2

Peer Group Statistics (Table 2)

Select LotNo :

Select Reagent Kit :

Control N Month vs. Cumulative

Control N (Lot No.: AE0909N)																	
		Month (2017/07)								CUM (2016/02/01~2017/07/31)							
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	2	10.5	9.7	4	0.3	3.1	13.8	20	4.0	10.5	10.4	16	0.6	5.8	12.5	20	3.3
Lab032	2	11.5	-	0	-	-	-	20	-	11.5	12.4	6	0.6	4.8	17.5	20	2.5
Total	-	-	9.7	4	0.3	3.1	-	-	-	-	11.0	22	1.1	10.0	-	-	-

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

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

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

Month : Cumulative : from to

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Control D Month vs. Cumulative

Control D (Lot No.: AE0909D)																	
		Month (2017/07)								CUM (2016/02/01~2017/07/31)							
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	2	4.1	3.7	4	0.2	5.4	20.6	20	1.9	4.1	4.0	16	0.3	7.5	17.4	20	2.3
Lab032	2	4.5	-	0	-	-	-	20	-	4.5	4.8	6	0.3	6.3	19.2	20	2.1
Total	-	-	3.7	4	0.2	5.4	-	-	-	-	4.3	22	0.5	11.6	-	-	-

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

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

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

Month : Cumulative : from to

[TOP](#)

Reagent Kit	Reagent Code
AMP	2