

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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Lab043

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2017/09)	CUM (2016/02/01~2017/09/30)	Month (2017/09)	CUM (2016/02/01~2017/09/30)
Runs (N)	4	6	4	6
Mean (U/gHb)	10.8	10.8	4.1	4.1
SD	0.4	0.3	0.2	0.2
CV (%)	3.7	2.8	4.9	4.9
Target Value (U/gHb)	11.5	11.5	4.5	4.5
Total Error (%)	13.5	11.6	18.6	18.6
TEa (%)	20	20	20	20
σ	3.8	5.0	2.3	2.3

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

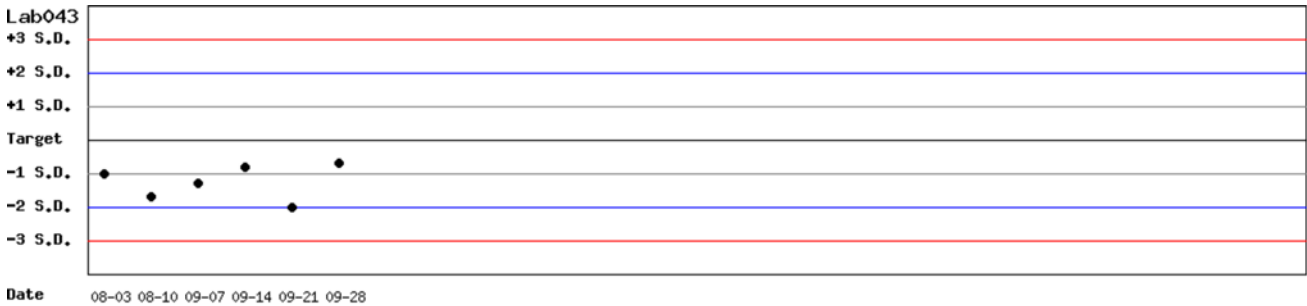
Month : 2017 09 [Change](#) ; Cumulative : from 2016 02 01 to 2017 09 30 [Change](#)

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Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2017-09-30 ; Target : 11.5 ; SD : 0.6

Lab043



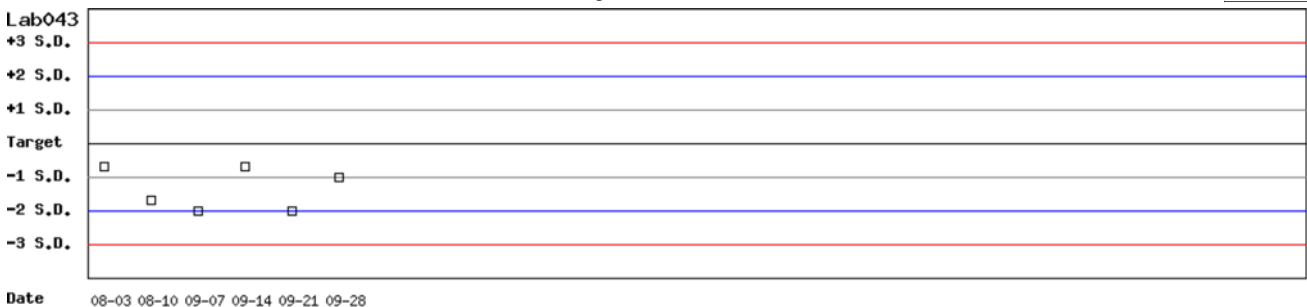
Month : 2017 09 [Change](#) ; Cumulative : from 2016 02 01 to 2017 09 30 [Change](#)

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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2016-02-01 to 2017-09-30 ; Target : 4.5 ; SD : 0.3

Lab043



Month : 2017 09 [Change](#) ; Cumulative : from 2016 02 01 to 2017 09 30 [Change](#)

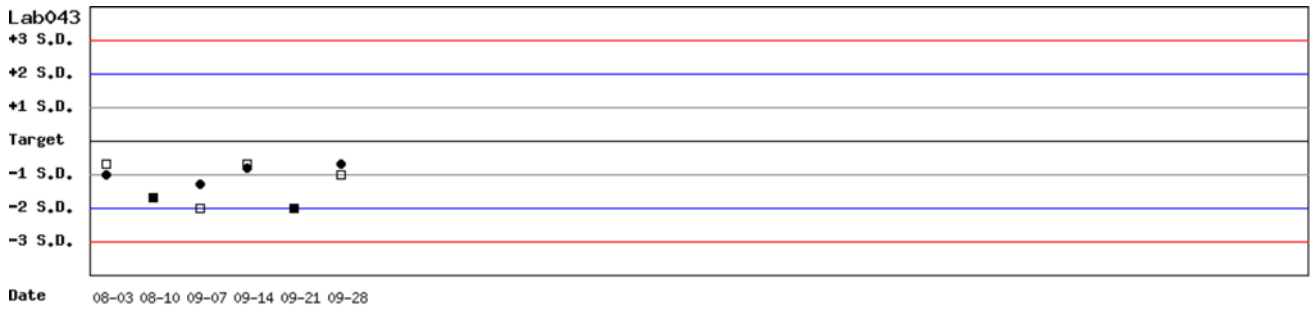
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Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2017-09-30 ; Target : 11.5 ; SD : 0.6 (●)

Lot No.: AE0909D ; Duration : 2016-02-01 to 2017-09-30 ; Target : 4.5 ; SD : 0.3 (□)

Lab043



Month : 2017 09 ; Cumulative : from 2016 02 01 to 2017 09 30

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Peer Group Statistics (Table 1)

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

Select Reagent Kit : 2 - AMP ▼ Change

Print Table 1

Monthly

Month : 2017 ▼ 09 ▼ 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
Lab043	2	11.5	10.8	4	0.4	3.7	13.5	20	3.8	4.5	4.1	4	0.2	4.9	18.6	20	2.3
Total	-	-	10.8	4	0.4	3.7	-	-	-	-	4.1	4	0.2	4.9	-	-	-

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

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

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

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Cumulative

Cumulative : from 2016 ▼ 02 ▼ 01 ▼ to 2017 ▼ 09 ▼ 30 ▼ 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	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	2.3
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	2.1
Lab043	2	11.5	10.8	6	0.3	2.8	11.6	20	5.0	4.5	4.1	6	0.2	4.9	18.6	20	2.3
Total	-	-	10.9	28	0.9	8.3	-	-	-	-	4.2	28	0.4	9.5	-	-	-

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
AMP	2

Peer Group Statistics (Table 2)

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

Select Reagent Kit : 2 - AMP Change

Print Table 2

Control N Month vs. Cumulative

Control N (Lot No.: AE0909N)																	
		Month (2017/09)								CUM (2016/02/01~2017/09/30)							
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
Lab018	2	10.5	-	0	-	-	-	20	-	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
Lab043	2	11.5	10.8	4	0.4	3.7	13.5	20	3.8	11.5	10.8	6	0.3	2.8	11.6	20	5.0
Total	-	-	10.8	4	0.4	3.7	-	-	-	-	10.9	28	0.9	8.3	-	-	-

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

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

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

Month : 2017 09 Change Cumulative : from 2016 02 01 to 2017 09 30 Change

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Control D Month vs. Cumulative

Control D (Lot No.: AE0909D)																	
		Month (2017/09)								CUM (2016/02/01~2017/09/30)							
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
Lab018	2	4.1	-	0	-	-	-	20	-	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
Lab043	2	4.5	4.1	4	0.2	4.9	18.6	20	2.3	4.5	4.1	6	0.2	4.9	18.6	20	2.3
Total	-	-	4.1	4	0.2	4.9	-	-	-	-	4.2	28	0.4	9.5	-	-	-

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

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

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

Month : 2017 09 Change Cumulative : from 2016 02 01 to 2017 09 30 Change

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Reagent Kit	Reagent Code
AMP	2