

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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Lab032

QC Control Lot No.	Control N		Control D	
	AE0909N		AE0909D	
Duration of the Analyzing	Month (2017/05)	CUM (2016/02/01~2017/05/31)	Month (2017/05)	CUM (2016/02/01~2017/05/31)
Runs (N)	6	6	6	6
Mean (U/gHb)	12.4	12.4	4.8	4.8
SD	0.6	0.6	0.3	0.3
CV (%)	4.8	4.8	6.3	6.3
Target Value (U/gHb)	11.5	11.5	4.5	4.5
Total Error (%)	17.5	17.5	19.2	19.2
TEa (%)	20	20	20	20
σ	2.5	2.5	2.1	2.1

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

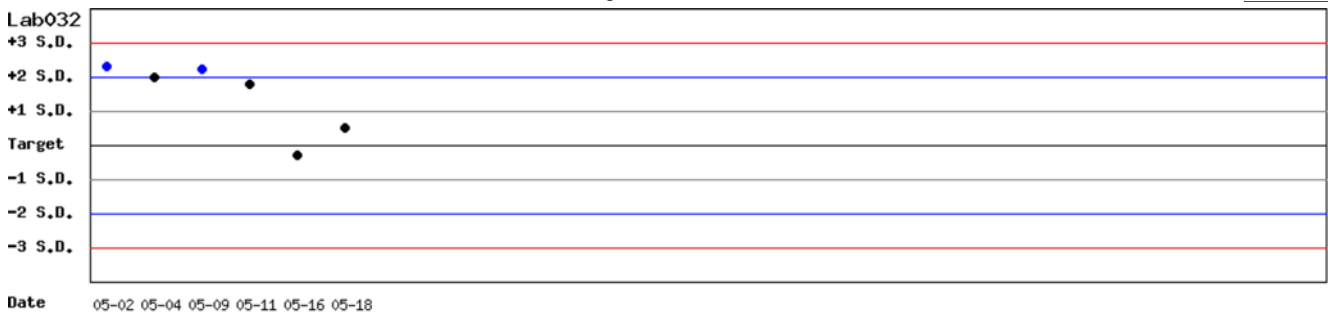
Month : 2017 05 [Change](#) ; Cumulative : from 2016 02 01 to 2017 05 31 [Change](#)

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Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2017-05-31 ; Target : 11.5 ; SD : 0.6

Lab032



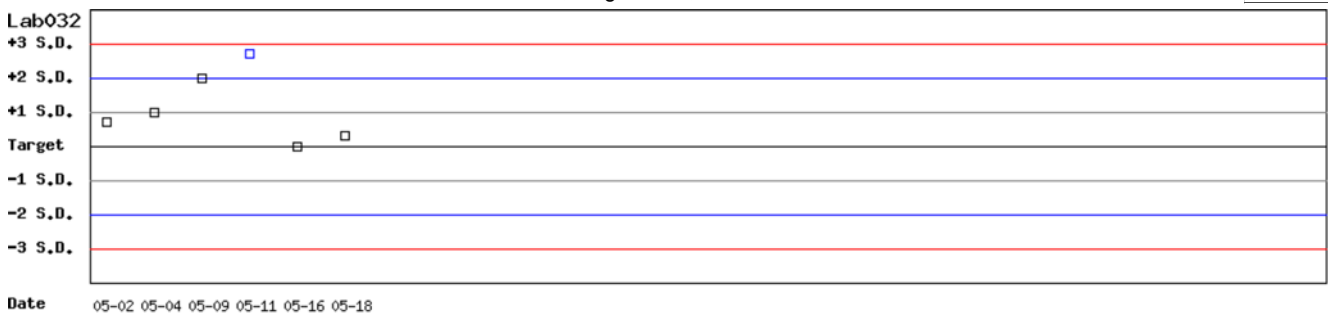
Month : 2017 05 [Change](#) ; Cumulative : from 2016 02 01 to 2017 05 31 [Change](#)

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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2016-02-01 to 2017-05-31 ; Target : 4.5 ; SD : 0.3

Lab032



Month : 2017 05 [Change](#) ; Cumulative : from 2016 02 01 to 2017 05 31 [Change](#)

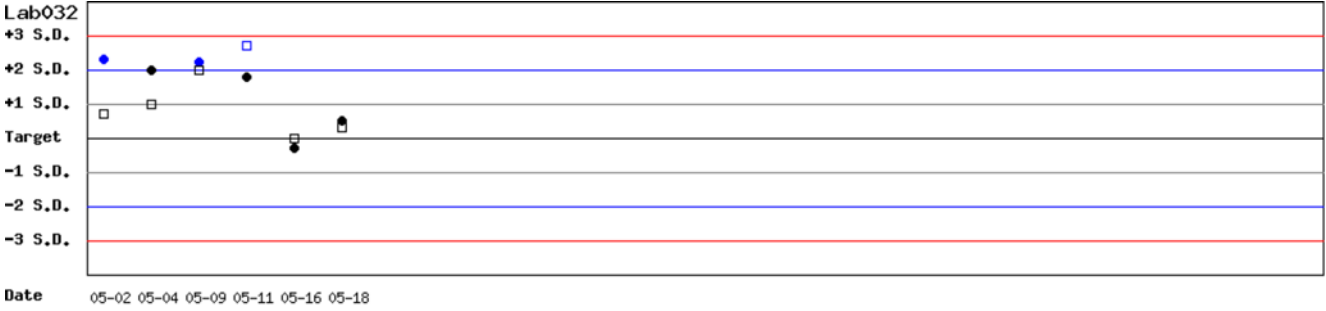
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Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2017-05-31 ; Target : 11.5 ; SD : 0.6 (●)

Lot No.: AE0909D ; Duration : 2016-02-01 to 2017-05-31 ; Target : 4.5 ; SD : 0.3 (□)

Lab032



Month : 2017 05 ; Cumulative : from 2016 02 01 to 2017 05 31

Peer Group Statistics (Table 1)

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

Select Reagent Kit : 2 - AMP Change

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Monthly

Month : 2017 05 Change

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 (%)	σ
Lab018	2	11.5	10.5	5	0.2	1.9	12.5	20	5.9	4.5	4.1	5	0.1	2.4	13.8	20	4.6
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
Total	-	-	11.5	11	1.1	9.6	-	-	-	-	4.5	11	0.4	8.9	-	-	-

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 2016 02 01 to 2017 05 31 Change

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 (%)	σ
Lab018	2	11.5	10.5	5	0.2	1.9	12.5	20	5.9	4.5	4.1	5	0.1	2.4	13.8	20	4.6
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
Total	-	-	11.5	11	1.1	9.6	-	-	-	-	4.5	11	0.4	8.9	-	-	-

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 : 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 (2017/05)								CUM (2016/02/01~2017/05/31)							
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	11.5	10.5	5	0.2	1.9	12.5	20	5.9	11.5	10.5	5	0.2	1.9	12.5	20	5.9
Lab032	2	11.5	12.4	6	0.6	4.8	17.5	20	2.5	11.5	12.4	6	0.6	4.8	17.5	20	2.5
Total	-	-	11.5	11	1.1	9.6	-	-	-	-	11.5	11	1.1	9.6	-	-	-

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

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

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

Month : 2017 ▼ 05 ▼ Change Cumulative : from 2016 ▼ 02 ▼ 01 ▼ to 2017 ▼ 05 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2017/05)								CUM (2016/02/01~2017/05/31)							
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	4.5	4.1	5	0.1	2.4	13.8	20	4.6	4.5	4.1	5	0.1	2.4	13.8	20	4.6
Lab032	2	4.5	4.8	6	0.3	6.3	19.2	20	2.1	4.5	4.8	6	0.3	6.3	19.2	20	2.1
Total	-	-	4.5	11	0.4	8.9	-	-	-	-	4.5	11	0.4	8.9	-	-	-

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

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

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

Month : 2017 ▼ 05 ▼ Change Cumulative : from 2016 ▼ 02 ▼ 01 ▼ to 2017 ▼ 05 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
AMP	2