

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

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

[Print Table](#)

Lab043

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2019/08)	CUM (2019/01/10~2019/08/31)	Month (2019/08)	CUM (2019/01/10~2019/08/31)
Runs (N)	5	26	5	26
Mean (U/gHb)	13.5	12.9	5.0	4.7
SD	0.2	0.6	0.2	0.3
CV (%)	1.5	4.7	4.0	6.4
Target Value (U/gHb)	11.5	11.5	4.5	4.5
Total Error (%)	20.4	21.5	19.1	17.2
TEa (%)	20	20	20	20
σ	1.7	1.7	2.2	2.4

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

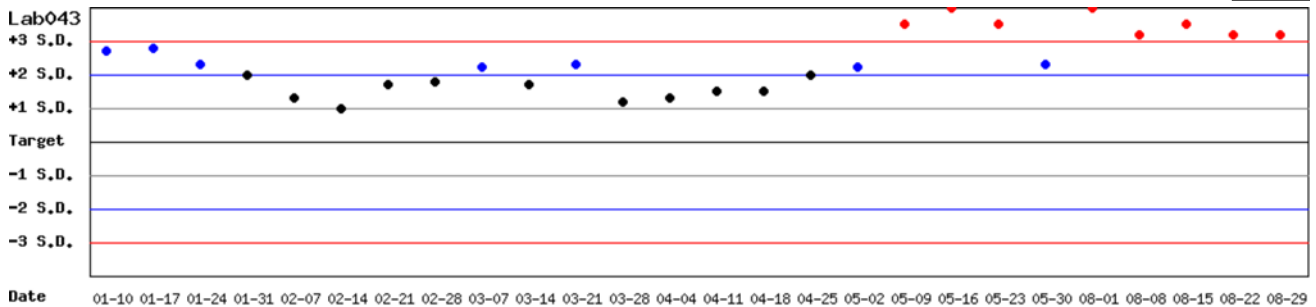
Month : 2019 08 [Change](#) ; Cumulative : from 2019 01 10 to 2019 08 31 [Change](#)

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Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-01-10 to 2019-08-31 ; Target : 11.5 ; SD : 0.6

Lab043



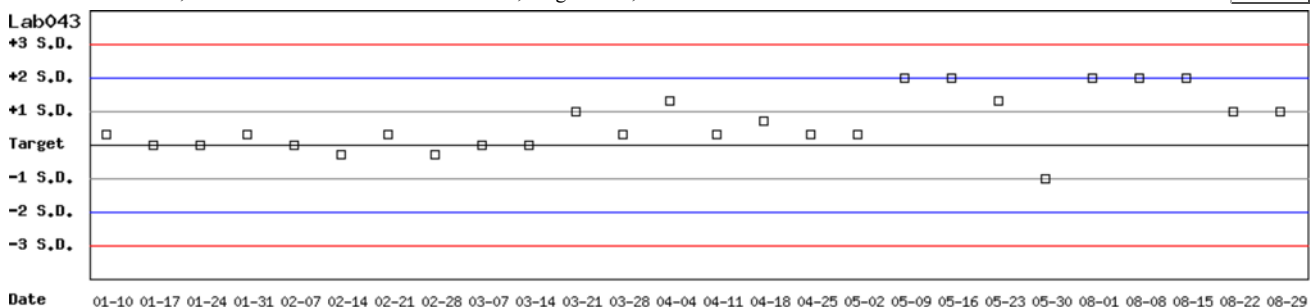
Month : 2019 08 [Change](#) ; Cumulative : from 2019 01 10 to 2019 08 31 [Change](#)

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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2019-01-10 to 2019-08-31 ; Target : 4.5 ; SD : 0.3

Lab043



Month : 2019 08 [Change](#) ; Cumulative : from 2019 01 10 to 2019 08 31 [Change](#)

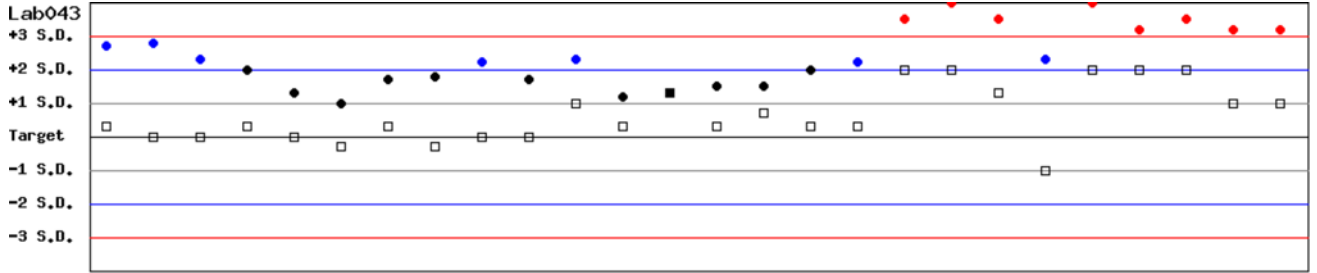
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Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-01-10 to 2019-08-31 ; Target : 11.5 ; SD : 0.6 (●)

Lot No.: AE0909D ; Duration : 2019-01-10 to 2019-08-31 ; Target : 4.5 ; SD : 0.3 (□)

Lab043



Date 01-10 01-17 01-24 01-31 02-07 02-14 02-21 02-28 03-07 03-14 03-21 03-28 04-04 04-11 04-18 04-25 05-02 05-09 05-16 05-23 05-30 08-01 08-08 08-15 08-22 08-29

Month : 2019 08 ; Cumulative : from 2019 01 10 to 2019 08 31

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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 : 2019 ▼ 08 ▼ 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	5	14.2	13.8	10	0.4	2.9	8.6	20	5.9	5.5	5.2	10	0.1	1.9	9.3	20	>6
Lab019	5	15.3	14.9	2	-	-	-	20	-	5.3	5.2	2	-	-	-	20	-
Lab026	5	15.9	12.5	17	0.3	2.4	26.2	20	-0.6	5.8	4.8	17	0.7	14.6	46.4	20	0.2
Lab027	5	15.5	14.6	4	0.3	2.1	9.9	20	>6	5.4	6.5	4	1.5	23.1	66.5	20	0.0
Lab034	5	14.4	14.2	5	1.1	7.7	16.9	20	2.4	5.8	5.1	5	0.5	9.8	31.7	20	0.8
Lab043	5	11.5	13.5	5	0.2	1.5	20.4	20	1.7	4.5	5.0	5	0.2	4.0	19.1	20	2.2
Total	-	-	13.4	43	0.9	6.7	-	-	-	-	5.1	43	0.8	15.7	-	-	-

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 2019 ▼ 08 ▼ 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	5	14.2	15.2	111	1.2	7.9	22.8	20	1.6	5.5	5.6	111	0.3	5.4	12.5	20	3.4
Lab019	5	15.3	15.2	81	0.3	2.0	4.6	20	>6	5.3	5.3	81	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	14.2	209	1.4	9.9	30.4	20	0.9	5.8	5.2	209	0.4	7.7	25.7	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	14.4	14.5	74	0.7	4.8	10.3	20	4.0	5.8	5.6	74	0.3	5.4	14.2	20	3.1
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	14.4	14.2	59	0.6	4.2	9.8	20	4.4	5.8	5.1	59	0.4	7.8	27.8	20	1.0
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	13.3	39	0.7	5.3	18.2	20	2.3	5.8	4.7	39	0.3	6.4	31.7	20	0.2
Lab043	5	11.5	13.1	73	0.9	6.9	27.7	20	0.9	4.5	4.9	73	0.3	6.1	21.1	20	1.8
Total	-	-	14.6	898	1.3	8.9	-	-	-	-	5.3	898	0.4	7.5	-	-	-

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
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 (2019/08)								CUM (2016/02/01~2019/08/31)							
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	13.8	10	0.4	2.9	8.6	20	5.9	14.2	15.2	111	1.2	7.9	22.8	20	1.6
Lab019	5	15.3	14.9	2	-	-	-	20	-	15.3	15.2	81	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	12.5	17	0.3	2.4	26.2	20	-0.6	15.9	14.2	209	1.4	9.9	30.4	20	0.9
Lab027	5	15.5	14.6	4	0.3	2.1	9.9	20	>6	15.5	15.5	107	1.3	8.4	16.8	20	2.4
Lab028	5	14.4	-	0	-	-	-	20	-	14.4	14.5	74	0.7	4.8	10.3	20	4.0
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	14.4	14.2	5	1.1	7.7	16.9	20	2.4	14.4	14.2	59	0.6	4.2	9.8	20	4.4
Lab037	5	14.9	-	0	-	-	-	20	-	14.9	15.2	30	0.8	5.3	12.5	20	3.4
Lab040	5	14.4	-	0	-	-	-	20	-	14.4	13.3	39	0.7	5.3	18.2	20	2.3
Lab043	5	11.5	13.5	5	0.2	1.5	20.4	20	1.7	11.5	13.1	73	0.9	6.9	27.7	20	0.9
Total	-	-	13.4	43	0.9	6.7	-	-	-	-	14.6	898	1.3	8.9	-	-	-

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

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

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

Month : 2019 ▼ 08 ▼ Change

Cumulative : from 2016 ▼ 02 ▼ 01 ▼ to 2019 ▼ 08 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2019/08)								CUM (2016/02/01~2019/08/31)							
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	5.2	10	0.1	1.9	9.3	20	>6	5.5	5.6	111	0.3	5.4	12.5	20	3.4
Lab019	5	5.3	5.2	2	-	-	-	20	-	5.3	5.3	81	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	4.8	17	0.7	14.6	46.4	20	0.2	5.8	5.2	209	0.4	7.7	25.7	20	1.3
Lab027	5	5.4	6.5	4	1.5	23.1	66.5	20	0.0	5.4	5.6	107	0.5	8.9	21.6	20	1.8
Lab028	5	5.8	-	0	-	-	-	20	-	5.8	5.6	74	0.3	5.4	14.2	20	3.1
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	5.8	5.1	5	0.5	9.8	31.7	20	0.8	5.8	5.1	59	0.4	7.8	27.8	20	1.0
Lab037	5	5.4	-	0	-	-	-	20	-	5.4	5.5	30	0.3	5.5	12.8	20	3.3
Lab040	5	5.8	-	0	-	-	-	20	-	5.8	4.7	39	0.3	6.4	31.7	20	0.2
Lab043	5	4.5	5.0	5	0.2	4.0	19.1	20	2.2	4.5	4.9	73	0.3	6.1	21.1	20	1.8
Total	-	-	5.1	43	0.8	15.7	-	-	-	-	5.3	898	0.4	7.5	-	-	-

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

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

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

Month : 2019 ▼ 08 ▼ Change

Cumulative : from 2016 ▼ 02 ▼ 01 ▼ to 2019 ▼ 08 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5