

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 (2020/08)	CUM (2019/04/25~2020/08/31)	Month (2020/08)	CUM (2019/04/25~2020/08/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	12.3	13.0	4.1	4.7
SD	0.4	0.6	0.1	0.3
CV (%)	3.3	4.6	2.4	6.4
Target Value (U/gHb)	11.5	11.5	4.5	4.5
Total Error (%)	13.5	22.3	13.8	17.2
TEa (%)	20	20	20	20
σ	4.0	1.5	4.6	2.4

Bias (%) = $[(| \text{Mean} - \text{Target} |) / \text{Target}] \times 100\%$

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

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

Month : 2020 ▾ 08 ▾ Change ; Cumulative : from 2019 ▾ 04 ▾ 25 ▾ to 2020 ▾ 08 ▾ 31 ▾ Change

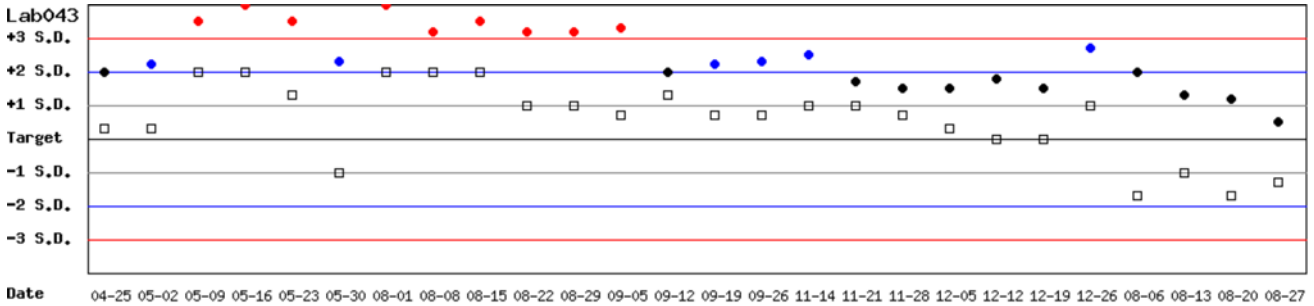
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Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-04-25 to 2020-08-31 ; Target : 11.5 ; SD : 0.6 (●)

Lot No.: AE0909D ; Duration : 2019-04-25 to 2020-08-31 ; Target : 4.5 ; SD : 0.3 (□)

Lab043



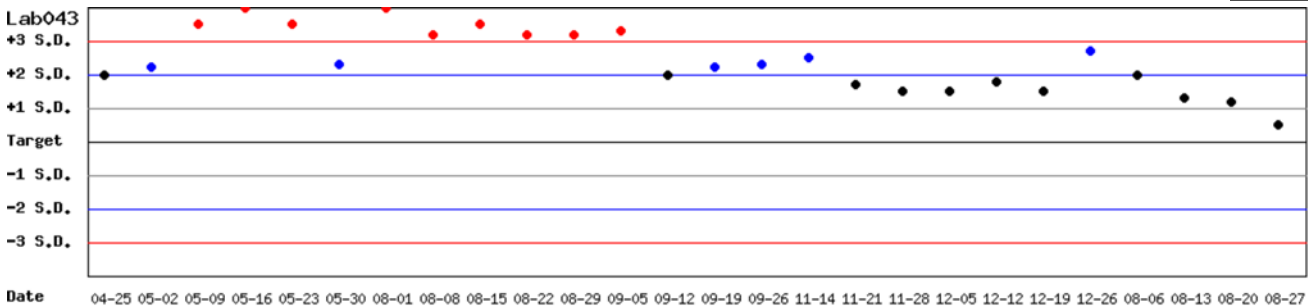
Month : 2020 ▾ 08 ▾ Change ; Cumulative : from 2019 ▾ 04 ▾ 25 ▾ to 2020 ▾ 08 ▾ 31 ▾ Change

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Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-04-25 to 2020-08-31 ; Target : 11.5 ; SD : 0.6

Lab043



Month : 2020 ▾ 08 ▾ Change ; Cumulative : from 2019 ▾ 04 ▾ 25 ▾ to 2020 ▾ 08 ▾ 31 ▾ Change

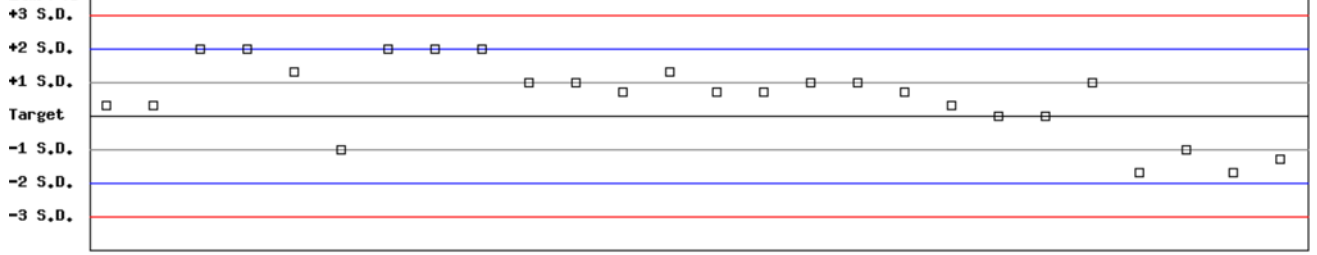
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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2019-04-25 to 2020-08-31 ; Target : 4.5 ; SD : 0.3

Lab043

Lab043



Date 04-25 05-02 05-09 05-16 05-23 05-30 06-01 06-08 06-15 06-22 06-29 07-05 07-12 07-19 07-26 08-02 08-09 08-16 08-23 08-30 09-06 09-13 09-20 09-27 10-04 10-11 10-18 10-25 10-31 11-07 11-14 11-21 11-28 12-05 12-12 12-19 12-26 01-02 01-09 01-16 01-23 01-30 02-06 02-13 02-20 02-27

Month : 2020 ▾ 08 ▾ Change ; Cumulative : from 2019 ▾ 04 ▾ 25 ▾ to 2020 ▾ 08 ▾ 31 ▾ Change

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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 : 2020 ▼ 08 ▼ 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
Lab026	5	15.9	12.9	18	0.1	0.8	20.4	20	1.4	5.8	5.0	18	0.1	2.0	17.8	20	3.1
Lab043	5	11.5	12.3	4	0.4	3.3	13.5	20	4.0	4.5	4.1	4	0.1	2.4	13.8	20	4.6
Total	-	-	12.8	22	0.3	2.3	-	-	-	-	4.8	22	0.4	8.3	-	-	-

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 2020 ▼ 08 ▼ 31 ▼ 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	5	14.2	14.9	142	1.2	8.1	21.0	20	1.9	5.5	5.5	142	0.3	5.5	10.9	20	3.6
Lab019	5	15.3	15.2	111	0.3	2.0	4.6	20	>6	5.3	5.3	111	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	13.5	386	1.2	8.9	32.9	20	0.6	5.8	5.1	386	0.3	5.9	23.8	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	14.8	14.5	134	0.7	4.8	11.7	20	3.7	4.8	5.6	134	0.3	5.4	27.4	20	0.6
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	15.5	14.7	96	0.9	6.1	17.4	20	2.4	4.8	5.0	96	0.4	8.0	20.2	20	2.0
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	13.2	40	0.7	5.3	18.9	20	2.2	5.8	4.7	40	0.3	6.4	31.7	20	0.2
Lab043	5	11.5	13.0	88	0.9	6.9	26.9	20	1.0	4.5	4.8	88	0.4	8.3	23.3	20	1.6
Total	-	-	14.4	1249	1.3	9.0	-	-	-	-	5.2	1249	0.4	7.7	-	-	-

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 (2020/08)								CUM (2016/02/01~2020/08/31)							
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	-	0	-	-	-	20	-	14.2	14.9	142	1.2	8.1	21.0	20	1.9
Lab019	5	15.3	-	0	-	-	-	20	-	15.3	15.2	111	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	12.9	18	0.1	0.8	20.4	20	1.4	15.9	13.5	386	1.2	8.9	32.9	20	0.6
Lab027	5	15.5	-	0	-	-	-	20	-	15.5	15.5	107	1.3	8.4	16.8	20	2.4
Lab028	5	14.8	-	0	-	-	-	20	-	14.8	14.5	134	0.7	4.8	11.7	20	3.7
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	15.5	-	0	-	-	-	20	-	15.5	14.7	96	0.9	6.1	17.4	20	2.4
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	13.2	40	0.7	5.3	18.9	20	2.2
Lab043	5	11.5	12.3	4	0.4	3.3	13.5	20	4.0	11.5	13.0	88	0.9	6.9	26.9	20	1.0
Total	-	-	12.8	22	0.3	2.3	-	-	-	-	14.4	1249	1.3	9.0	-	-	-

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

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

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

Month : 2020 08 Change

Cumulative : from 2016 02 01 to 2020 08 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2020/08)								CUM (2016/02/01~2020/08/31)							
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	-	0	-	-	-	20	-	5.5	5.5	142	0.3	5.5	10.9	20	3.6
Lab019	5	5.3	-	0	-	-	-	20	-	5.3	5.3	111	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	5.0	18	0.1	2.0	17.8	20	3.1	5.8	5.1	386	0.3	5.9	23.8	20	1.3
Lab027	5	5.4	-	0	-	-	-	20	-	5.4	5.6	107	0.5	8.9	21.6	20	1.8
Lab028	5	4.8	-	0	-	-	-	20	-	4.8	5.6	134	0.3	5.4	27.4	20	0.6
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	4.8	-	0	-	-	-	20	-	4.8	5.0	96	0.4	8.0	20.2	20	2.0
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	40	0.3	6.4	31.7	20	0.2
Lab043	5	4.5	4.1	4	0.1	2.4	13.8	20	4.6	4.5	4.8	88	0.4	8.3	23.3	20	1.6
Total	-	-	4.8	22	0.4	8.3	-	-	-	-	5.2	1249	0.4	7.7	-	-	-

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

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

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

Month : 2020 08 Change

Cumulative : from 2016 02 01 to 2020 08 31 Change

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Reagent Kit	Reagent Code
Medicon	5