

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

Select LotNo : AH1220N (2019-01-28 ~ 2100-12-31) [Change](#)

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Lab032

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2019/10)	CUM (2019/06/13~2019/10/31)	Month (2019/10)	CUM (2019/06/13~2019/10/31)
Runs (N)	3	26	3	26
Mean (U/gHb)	14.9	14.5	4.8	4.6
SD	0.2	0.5	0.7	0.5
CV (%)	1.3	3.4	14.6	10.9
Target Value (U/gHb)	15.3	15.3	5.2	5.2
Total Error (%)	5.3	12.1	36.9	33.3
TEa (%)	20	20	20	20
σ	>6	4.3	0.8	0.8

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

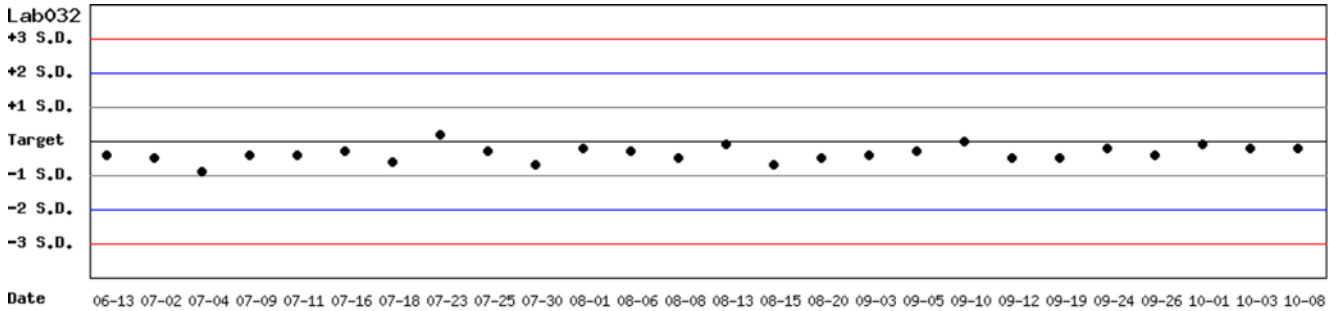
Month : 2019 10 [Change](#) ; Cumulative : from 2019 06 13 to 2019 10 31 [Change](#)

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-06-13 to 2019-10-31 ; Target : 15.3 ; SD : 2.20

Lab032



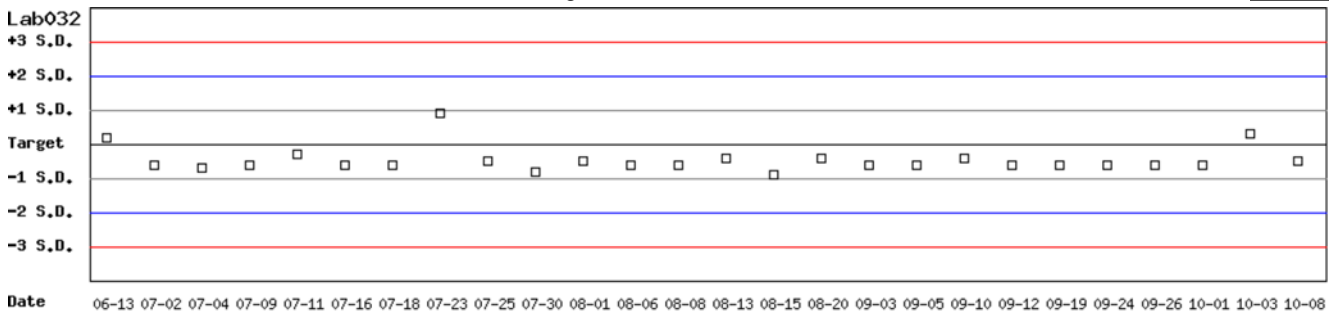
Month : 2019 10 [Change](#) ; Cumulative : from 2019 06 13 to 2019 10 31 [Change](#)

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2019-06-13 to 2019-10-31 ; Target : 5.2 ; SD : 1.40

Lab032



Month : 2019 10 [Change](#) ; Cumulative : from 2019 06 13 to 2019 10 31 [Change](#)

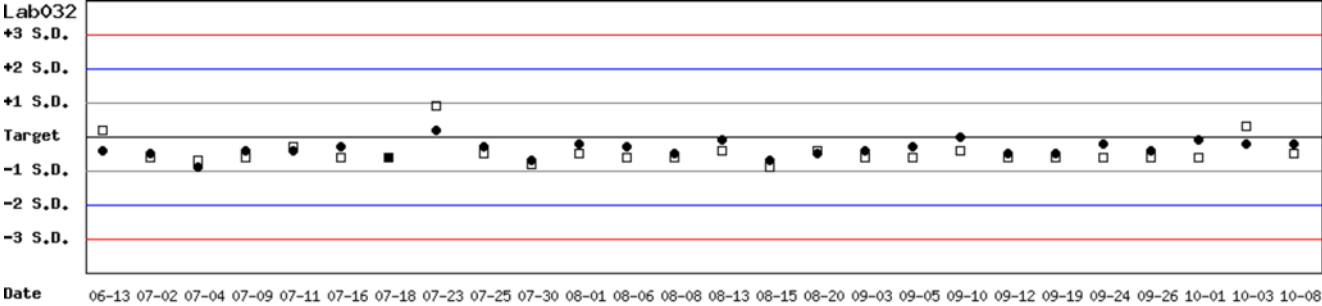
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-06-13 to 2019-10-31 ; Target : 15.3 ; SD : 2.20 (●)

Lot No.: AH1220D ; Duration : 2019-06-13 to 2019-10-31 ; Target : 5.2 ; SD : 1.40 (□)

Lab032



Month : 2019 | 10 | ; Cumulative : from 2019 | 06 | 13 to 2019 | 10 | 31 |

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Peer Group Statistics (Table 1)

Select LotNo : AH1220N (2019-01-28 ~ 2100-12-31) ▼ Change

Select Reagent Kit : 5 - Medicon ▼ Change

Print Table 1

Monthly

Month : 2019 ▼ 10 ▼ Change

		Control N (Lot No.: AH1220N)								Control D (Lot No.: AH1220D)							
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
Lab020	5	15.9	15.9	3	0.8	5.0	10.1	20	4.0	5.2	5.1	3	0.1	2.0	5.8	20	>6
Lab022	5	12.4	12.3	7	0.3	2.4	5.7	20	>6	4.1	4.1	7	0.1	2.4	4.9	20	>6
Lab032	5	15.3	14.9	3	0.2	1.3	5.3	20	>6	5.2	4.8	3	0.7	14.6	36.9	20	0.8
Lab033	5	12.4	12.8	5	0.3	2.3	7.9	20	>6	3.9	3.8	5	0.1	2.6	7.8	20	>6
Total	-	-	13.5	18	1.5	11.1	-	-	-	-	4.3	18	0.5	11.6	-	-	-

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

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

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

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Cumulative

Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2019 ▼ 10 ▼ 31 ▼ Change

		Control N (Lot No.: AH1220N)								Control D (Lot No.: AH1220D)							
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
Lab020	5	15.9	15.3	16	0.6	3.9	11.6	20	4.2	5.2	4.7	16	0.2	4.3	18.1	20	2.4
Lab022	5	12.4	12.4	25	0.3	2.4	4.8	20	>6	4.1	4.1	25	0.1	2.4	4.9	20	>6
Lab032	5	15.3	14.5	29	0.5	3.4	12.1	20	4.3	5.2	4.6	29	0.5	10.9	33.3	20	0.8
Lab033	5	12.4	12.6	30	0.4	3.2	8.0	20	5.7	3.9	3.9	30	0.1	2.6	5.1	20	>6
Total	-	-	13.5	100	1.3	9.6	-	-	-	-	4.3	100	0.5	11.6	-	-	-

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 : AH1220N (2019-01-28 ~ 2100-12-31) ▼ Change

Select Reagent Kit : 5 - Medicon ▼ Change

Print Table 2

Control N Month vs. Cumulative

		Control N (Lot No.: AH1220N)															
		Month (2019/10)								CUM (2019/02/01~2019/10/31)							
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
Lab020	5	15.9	15.9	3	0.8	5.0	10.1	20	4.0	15.9	15.3	16	0.6	3.9	11.6	20	4.2
Lab022	5	12.4	12.3	7	0.3	2.4	5.7	20	>6	12.4	12.4	25	0.3	2.4	4.8	20	>6
Lab032	5	15.3	14.9	3	0.2	1.3	5.3	20	>6	15.3	14.5	29	0.5	3.4	12.1	20	4.3
Lab033	5	12.4	12.8	5	0.3	2.3	7.9	20	>6	12.4	12.6	30	0.4	3.2	8.0	20	5.7
Total	-	-	13.5	18	1.5	11.1	-	-	-	-	13.5	100	1.3	9.6	-	-	-

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

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

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

Month : 2019 ▼ 10 ▼ Change Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2019 ▼ 10 ▼ 31 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2019/10)								CUM (2019/02/01~2019/10/31)							
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
Lab020	5	5.2	5.1	3	0.1	2.0	5.8	20	>6	5.2	4.7	16	0.2	4.3	18.1	20	2.4
Lab022	5	4.1	4.1	7	0.1	2.4	4.9	20	>6	4.1	4.1	25	0.1	2.4	4.9	20	>6
Lab032	5	5.2	4.8	3	0.7	14.6	36.9	20	0.8	5.2	4.6	29	0.5	10.9	33.3	20	0.8
Lab033	5	3.9	3.8	5	0.1	2.6	7.8	20	>6	3.9	3.9	30	0.1	2.6	5.1	20	>6
Total	-	-	4.3	18	0.5	11.6	-	-	-	-	4.3	100	0.5	11.6	-	-	-

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

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

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

Month : 2019 ▼ 10 ▼ Change Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2019 ▼ 10 ▼ 31 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5