

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

	Control N		Control D	
QC Control Lot No.	AH1220N		AH1220D	
Duration of the Analyzing	Month (2019/08)	CUM (2019/02/01~2019/08/31)	Month (2019/08)	CUM (2019/02/01~2019/08/31)
Runs (N)	6	19	6	19
Mean (U/gHb)	14.5	14.3	4.4	4.6
SD	0.5	0.6	0.2	0.6
CV (%)	3.4	4.2	4.5	13.0
Target Value (U/gHb)	15.3	15.3	5.2	5.2
Total Error (%)	12.1	14.9	24.5	37.6
TEa (%)	20	20	20	20
σ	4.3	3.2	1.0	0.7

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

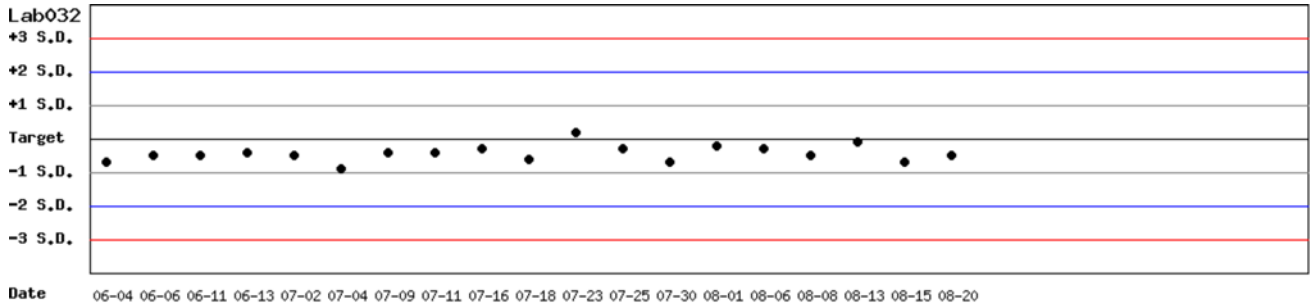
Month : 2019 08 [Change](#) ; Cumulative : from 2019 02 01 to 2019 08 31 [Change](#)

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-02-01 to 2019-08-31 ; Target : 15.3 ; SD : 2.20

Lab032



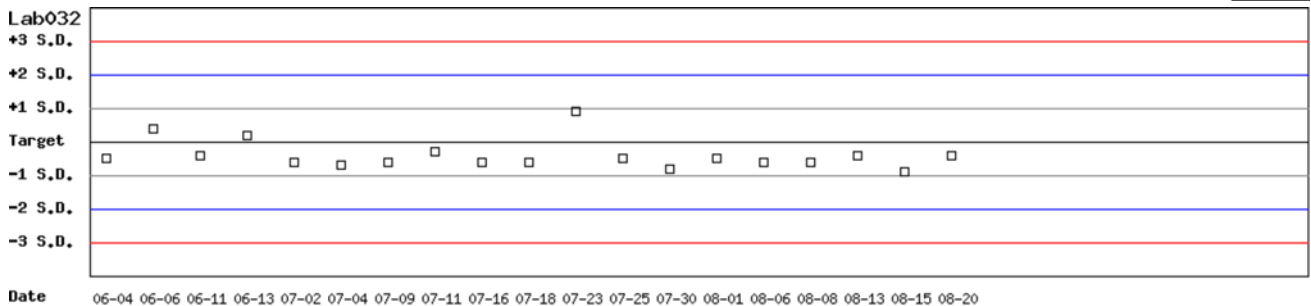
Month : 2019 08 [Change](#) ; Cumulative : from 2019 02 01 to 2019 08 31 [Change](#)

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2019-02-01 to 2019-08-31 ; Target : 5.2 ; SD : 1.40

Lab032



Month : 2019 08 [Change](#) ; Cumulative : from 2019 02 01 to 2019 08 31 [Change](#)

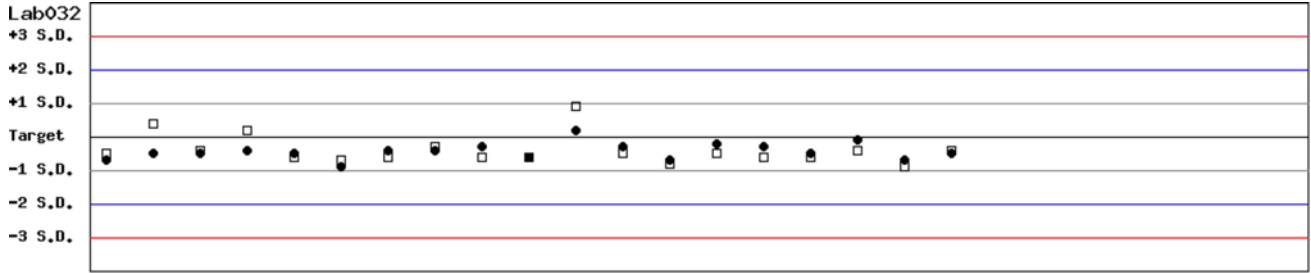
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-02-01 to 2019-08-31 ; Target : 15.3 ; SD : 2.20 (●)

Lot No.: AH1220D ; Duration : 2019-02-01 to 2019-08-31 ; Target : 5.2 ; SD : 1.40 (□)

Lab032



Date 06-04 06-06 06-11 06-13 07-02 07-04 07-09 07-11 07-16 07-18 07-23 07-25 07-30 08-01 08-06 08-08 08-13 08-15 08-20

Month : 2019 08 ; Cumulative : from 2019 02 01 to 2019 08 31

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Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon

Monthly

Month : 2019 08

		Control N (Lot No.: AH1220N)								Control D (Lot No.: AH1220D)							
UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	15.1	4	0.5	3.3	11.7	20	4.5	5.2	4.8	4	0.2	4.2	16.0	20	2.9
Lab022	5	12.4	12.2	5	0.2	1.6	4.9	20	>6	4.1	4.0	5	0.1	2.5	7.4	20	>6
Lab032	5	15.3	14.5	6	0.5	3.4	12.1	20	4.3	5.2	4.4	6	0.2	4.5	24.5	20	1.0
Lab033	5	12.4	12.8	5	0.3	2.3	7.9	20	>6	3.9	3.8	5	0.2	5.3	13.1	20	3.3
Total	-	-	13.6	20	1.2	8.8	-	-	-	-	4.2	20	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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Cumulative

Cumulative : from 2019 02 01 to 2019 08 31

		Control N (Lot No.: AH1220N)								Control D (Lot No.: AH1220D)							
UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	15.2	10	0.6	3.9	12.3	20	4.0	5.2	4.6	10	0.2	4.3	20.2	20	2.0
Lab022	5	12.4	12.4	17	0.3	2.4	4.8	20	>6	4.1	4.0	17	0.1	2.5	7.4	20	>6
Lab032	5	15.3	14.3	19	0.6	4.2	14.9	20	3.2	5.2	4.6	19	0.6	13.0	37.6	20	0.7
Lab033	5	12.4	12.5	21	0.4	3.2	7.2	20	6.0	3.9	3.9	21	0.1	2.6	5.1	20	>6
Total	-	-	13.4	67	1.2	9.0	-	-	-	-	4.2	67	0.5	11.9	-	-	-

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 (2019/08)								CUM (2019/02/01~2019/08/31)							
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
Lab020	5	15.9	15.1	4	0.5	3.3	11.7	20	4.5	15.9	15.2	10	0.6	3.9	12.3	20	4.0
Lab022	5	12.4	12.2	5	0.2	1.6	4.9	20	>6	12.4	12.4	17	0.3	2.4	4.8	20	>6
Lab032	5	15.3	14.5	6	0.5	3.4	12.1	20	4.3	15.3	14.3	19	0.6	4.2	14.9	20	3.2
Lab033	5	12.4	12.8	5	0.3	2.3	7.9	20	>6	12.4	12.5	21	0.4	3.2	7.2	20	6.0
Total	-	-	13.6	20	1.2	8.8	-	-	-	-	13.4	67	1.2	9.0	-	-	-

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

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

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

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

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2019/08)								CUM (2019/02/01~2019/08/31)							
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
Lab020	5	5.2	4.8	4	0.2	4.2	16.0	20	2.9	5.2	4.6	10	0.2	4.3	20.2	20	2.0
Lab022	5	4.1	4.0	5	0.1	2.5	7.4	20	>6	4.1	4.0	17	0.1	2.5	7.4	20	>6
Lab032	5	5.2	4.4	6	0.2	4.5	24.5	20	1.0	5.2	4.6	19	0.6	13.0	37.6	20	0.7
Lab033	5	3.9	3.8	5	0.2	5.3	13.1	20	3.3	3.9	3.9	21	0.1	2.6	5.1	20	>6
Total	-	-	4.2	20	0.4	9.5	-	-	-	-	4.2	67	0.5	11.9	-	-	-

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

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

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

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

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Reagent Kit	Reagent Code
Medicon	5