

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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Lab022

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2019/11)	CUM (2019/05/24~2019/11/30)	Month (2019/11)	CUM (2019/05/24~2019/11/30)
Runs (N)	4	26	4	26
Mean (U/gHb)	12.3	12.4	3.9	4.0
SD	0.3	0.3	0.2	0.1
CV (%)	2.4	2.4	5.1	2.5
Target Value (U/gHb)	12.4	12.4	4.1	4.1
Total Error (%)	5.7	4.8	15.1	7.4
TEa (%)	20	20	20	20
σ	>6	>6	3.0	>6

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

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

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

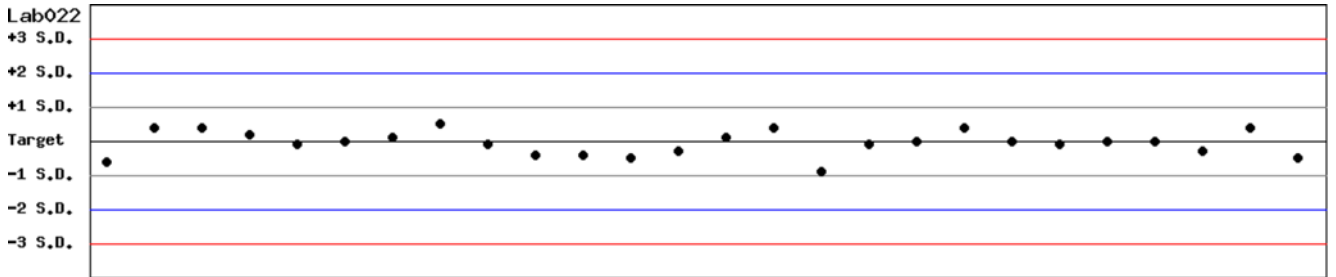
Month : 2019 11 [Change](#) ; Cumulative : from 2019 05 24 to 2019 11 30 [Change](#)

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-05-24 to 2019-11-30 ; Target : 12.4 ; SD : 0.8

Lab022



Date 05-24 06-01 06-11 06-14 07-04 07-12 07-18 07-19 07-25 08-01 08-08 08-08 08-21 08-29 09-05 10-02 10-03 10-10 10-15 10-21 10-23 10-31 11-07 11-12 11-20 11-29

Month : 2019 11 [Change](#) ; Cumulative : from 2019 05 24 to 2019 11 30 [Change](#)

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2019-05-24 to 2019-11-30 ; Target : 4.1 ; SD : 0.4

Lab022



Date 05-24 06-01 06-11 06-14 07-04 07-12 07-18 07-19 07-25 08-01 08-08 08-08 08-21 08-29 09-05 10-02 10-03 10-10 10-15 10-21 10-23 10-31 11-07 11-12 11-20 11-29

Month : 2019 11 [Change](#) ; Cumulative : from 2019 05 24 to 2019 11 30 [Change](#)

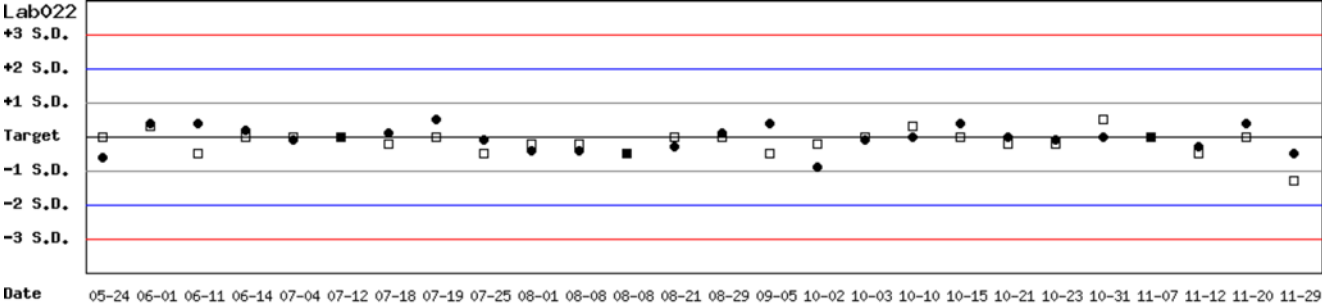
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**Control N and Control D SDI
QC Chart**

Lot No.: AH1220N ; Duration : 2019-05-24 to 2019-11-30 ; Target : 12.4 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2019-05-24 to 2019-11-30 ; Target : 4.1 ; SD : 0.4 (□)

Lab022



Month : 2019 | 11 | ; Cumulative : from 2019 | 05 | 24 to 2019 | 11 | 30 |

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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 11

		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
Lab022	5	12.4	12.3	4	0.3	2.4	5.7	20	>6	4.1	3.9	4	0.2	5.1	15.1	20	3.0
Lab033	5	12.4	12.6	4	0.4	3.2	8.0	20	5.7	3.9	3.8	4	0.1	2.6	7.8	20	>6
Total	-	-	12.5	8	0.3	2.4	-	-	-	-	3.9	8	0.2	5.1	-	-	-

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 11 30

		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	15.3	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	29	0.3	2.4	4.8	20	>6	4.1	4.0	29	0.1	2.5	7.4	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	34	0.4	3.2	8.0	20	5.7	3.9	3.8	34	0.1	2.6	7.8	20	>6
Total	-	-	13.4	108	1.2	9.0	-	-	-	-	4.2	108	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 (2019/11)										CUM (2019/02/01~2019/11/30)							
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	-	0	-	-	-	20	-	15.9	15.3	16	0.6	3.9	11.6	20	4.2
Lab022	5	12.4	12.3	4	0.3	2.4	5.7	20	>6	12.4	12.4	29	0.3	2.4	4.8	20	>6
Lab032	5	15.3	-	0	-	-	-	20	-	15.3	14.5	29	0.5	3.4	12.1	20	4.3
Lab033	5	12.4	12.6	4	0.4	3.2	8.0	20	5.7	12.4	12.6	34	0.4	3.2	8.0	20	5.7
Total	-	-	12.5	8	0.3	2.4	-	-	-	-	13.4	108	1.2	9.0	-	-	-

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

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

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

Month : 2019 11 Change Cumulative : from 2019 02 01 to 2019 11 30 Change

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Control D Month vs. Cumulative

Control D (Lot No.: AH1220D)																	
Month (2019/11)										CUM (2019/02/01~2019/11/30)							
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	-	0	-	-	-	20	-	5.2	4.7	16	0.2	4.3	18.1	20	2.4
Lab022	5	4.1	3.9	4	0.2	5.1	15.1	20	3.0	4.1	4.0	29	0.1	2.5	7.4	20	>6
Lab032	5	5.2	-	0	-	-	-	20	-	5.2	4.6	29	0.5	10.9	33.3	20	0.8
Lab033	5	3.9	3.8	4	0.1	2.6	7.8	20	>6	3.9	3.8	34	0.1	2.6	7.8	20	>6
Total	-	-	3.9	8	0.2	5.1	-	-	-	-	4.2	108	0.5	11.9	-	-	-

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

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

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

Month : 2019 11 Change Cumulative : from 2019 02 01 to 2019 11 30 Change

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Reagent Kit	Reagent Code
Medicon	5