

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 (2020/01)	CUM (2019/08/15~2020/01/31)	Month (2020/01)	CUM (2019/08/15~2020/01/31)
Runs (N)	6	26	6	26
Mean (U/gHb)	14.2	14.4	4.3	4.4
SD	0.2	0.4	0.1	0.3
CV (%)	1.4	2.8	2.3	6.8
Target Value (U/gHb)	15.3	15.3	5.2	5.2
Total Error (%)	10.0	11.4	22.0	29.0
TEa (%)	20	20	20	20
σ	>6	5.0	1.2	0.7

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

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

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

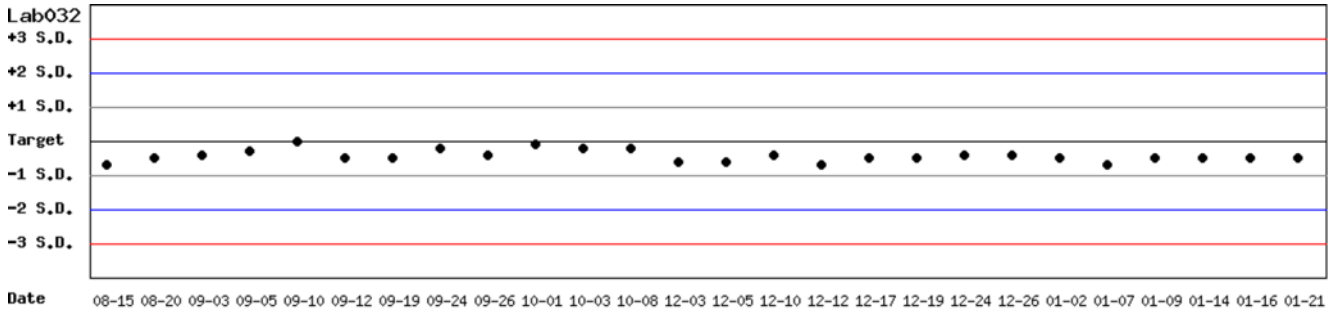
Month : 2020 01 [Change](#) ; Cumulative : from 2019 08 15 to 2020 01 31 [Change](#)

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-08-15 to 2020-01-31 ; Target : 15.3 ; SD : 2.20

Lab032



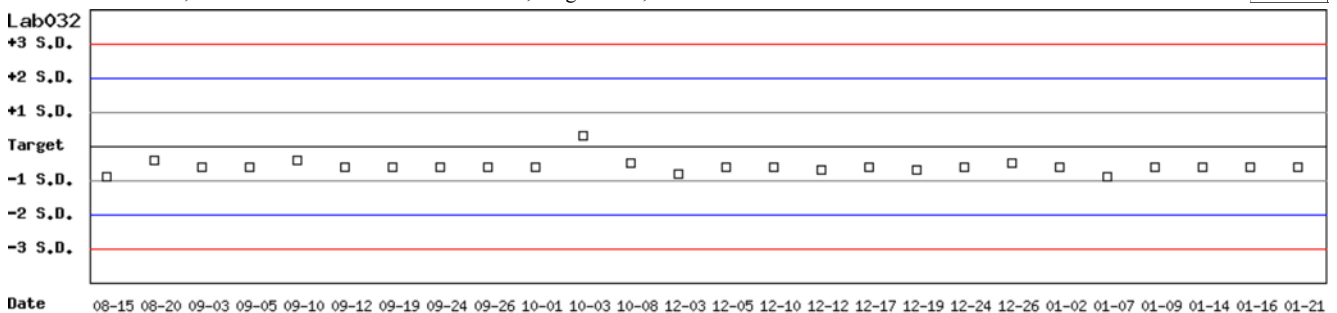
Month : 2020 01 [Change](#) ; Cumulative : from 2019 08 15 to 2020 01 31 [Change](#)

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2019-08-15 to 2020-01-31 ; Target : 5.2 ; SD : 1.40

Lab032



Month : 2020 01 [Change](#) ; Cumulative : from 2019 08 15 to 2020 01 31 [Change](#)

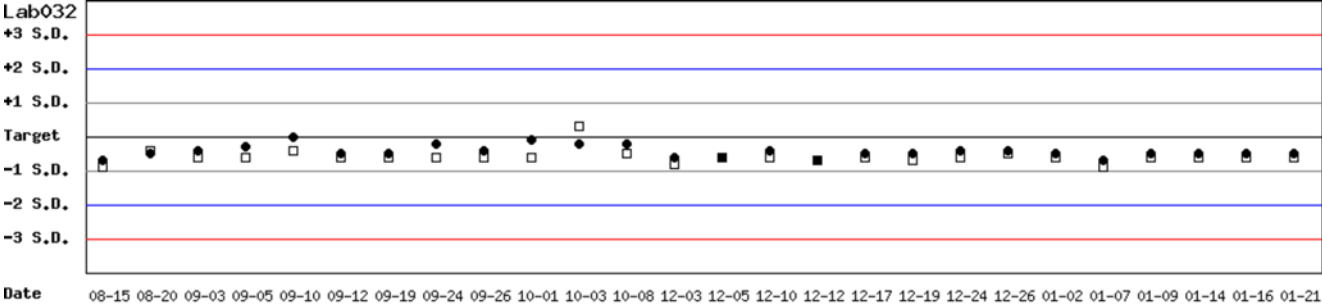
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-08-15 to 2020-01-31 ; Target : 15.3 ; SD : 2.20 (●)

Lot No.: AH1220D ; Duration : 2019-08-15 to 2020-01-31 ; Target : 5.2 ; SD : 1.40 (□)

Lab032



Month : 2020 | 01 | ; Cumulative : from 2019 | 08 | 15 to 2020 | 01 | 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 : 2020 01

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	Control N (Lot No.: AH1220N)								Control D (Lot No.: AH1220D)							
		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	12.0	5	0.5	4.2	11.6	20	4.0	4.1	3.9	5	0.1	2.6	10.0	20	5.8
Lab032	5	15.3	14.2	6	0.2	1.4	10.0	20	>6	5.2	4.3	6	0.1	2.3	22.0	20	1.2
Lab033	5	12.4	12.3	7	0.3	2.4	5.7	20	>6	3.9	3.8	7	0.1	2.6	7.8	20	>6
Lab037	5	15.3	15.6	3	0.3	1.9	5.8	20	>6	5.2	4.8	3	0.1	2.1	11.9	20	5.9
Total	-	-	13.2	21	1.4	10.6	-	-	-	-	4.1	21	0.4	9.8	-	-	-

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

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

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

[TOP](#)

Cumulative

Cumulative : from 2019 02 01 to 2020 01 31

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	Control N (Lot No.: AH1220N)								Control D (Lot No.: AH1220D)							
		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	12.3	38	0.3	2.4	5.7	20	>6	4.1	4.0	38	0.1	2.5	7.4	20	>6
Lab032	5	15.3	14.4	43	0.5	3.5	12.8	20	4.0	5.2	4.5	43	0.5	11.1	35.7	20	0.6
Lab033	5	12.4	12.5	45	0.4	3.2	7.2	20	6.0	3.9	3.8	45	0.1	2.6	7.8	20	>6
Lab037	5	15.3	15.4	7	0.3	1.9	4.5	20	>6	5.2	4.8	7	0.1	2.1	11.9	20	5.9
Total	-	-	13.4	149	1.3	9.7	-	-	-	-	4.2	149	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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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

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Control N Month vs. Cumulative

		Control N (Lot No.: AH1220N)															
		Month (2020/01)								CUM (2019/02/01~2020/01/31)							
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	-	0	-	-	-	20	-	15.9	15.3	16	0.6	3.9	11.6	20	4.2
Lab022	5	12.4	12.0	5	0.5	4.2	11.6	20	4.0	12.4	12.3	38	0.3	2.4	5.7	20	>6
Lab032	5	15.3	14.2	6	0.2	1.4	10.0	20	>6	15.3	14.4	43	0.5	3.5	12.8	20	4.0
Lab033	5	12.4	12.3	7	0.3	2.4	5.7	20	>6	12.4	12.5	45	0.4	3.2	7.2	20	6.0
Lab037	5	15.3	15.6	3	0.3	1.9	5.8	20	>6	15.3	15.4	7	0.3	1.9	4.5	20	>6
Total	-	-	13.2	21	1.4	10.6	-	-	-	-	13.4	149	1.3	9.7	-	-	-

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

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

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

Month : 2020 01 Change Cumulative : from 2019 02 01 to 2020 01 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2020/01)								CUM (2019/02/01~2020/01/31)							
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	-	0	-	-	-	20	-	5.2	4.7	16	0.2	4.3	18.1	20	2.4
Lab022	5	4.1	3.9	5	0.1	2.6	10.0	20	5.8	4.1	4.0	38	0.1	2.5	7.4	20	>6
Lab032	5	5.2	4.3	6	0.1	2.3	22.0	20	1.2	5.2	4.5	43	0.5	11.1	35.7	20	0.6
Lab033	5	3.9	3.8	7	0.1	2.6	7.8	20	>6	3.9	3.8	45	0.1	2.6	7.8	20	>6
Lab037	5	5.2	4.8	3	0.1	2.1	11.9	20	5.9	5.2	4.8	7	0.1	2.1	11.9	20	5.9
Total	-	-	4.1	21	0.4	9.8	-	-	-	-	4.2	149	0.4	9.5	-	-	-

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

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

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

Month : 2020 01 Change Cumulative : from 2019 02 01 to 2020 01 31 Change

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Reagent Kit	Reagent Code
Medicon	5