

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 (2020/03)	CUM (2019/12/17~2020/03/31)	Month (2020/03)	CUM (2019/12/17~2020/03/31)
Runs (N)	8	26	8	26
Mean (U/gHb)	14.2	14.1	4.4	4.3
SD	0.3	0.3	0.1	0.1
CV (%)	2.1	2.1	2.3	2.3
Target Value (U/gHb)	15.3	15.3	5.2	5.2
Total Error (%)	11.4	12.1	19.9	22.0
TEa (%)	20	20	20	20
σ	>6	5.8	2.0	1.2

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

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

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

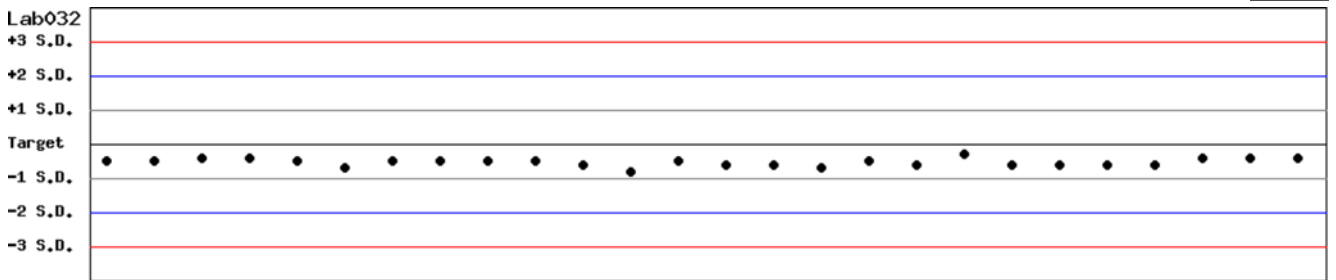
Month : 2020 03 [Change](#) ; Cumulative : from 2019 12 17 to 2020 03 31 [Change](#)

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-12-17 to 2020-03-31 ; Target : 15.3 ; SD : 2.20

Lab032



Date 12-17 12-19 12-24 12-26 01-02 01-07 01-09 01-14 01-16 01-21 02-04 02-06 02-11 02-13 02-18 02-20 02-25 02-27 03-03 03-05 03-10 03-12 03-17 03-19 03-24 03-31

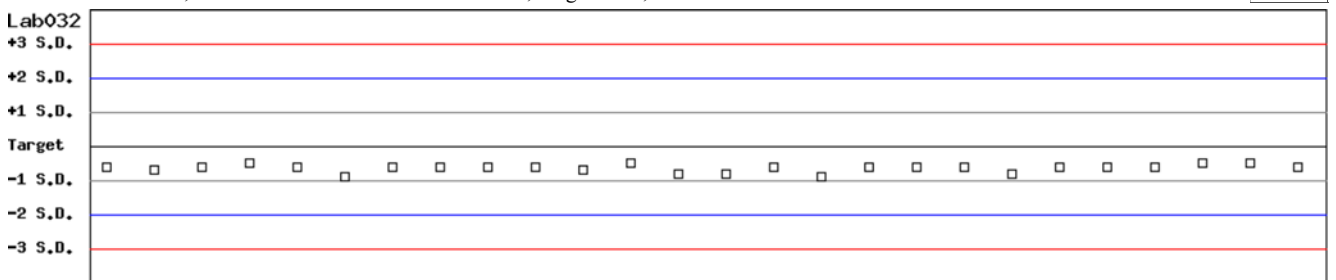
Month : 2020 03 [Change](#) ; Cumulative : from 2019 12 17 to 2020 03 31 [Change](#)

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2019-12-17 to 2020-03-31 ; Target : 5.2 ; SD : 1.40

Lab032



Date 12-17 12-19 12-24 12-26 01-02 01-07 01-09 01-14 01-16 01-21 02-04 02-06 02-11 02-13 02-18 02-20 02-25 02-27 03-03 03-05 03-10 03-12 03-17 03-19 03-24 03-31

Month : 2020 03 [Change](#) ; Cumulative : from 2019 12 17 to 2020 03 31 [Change](#)

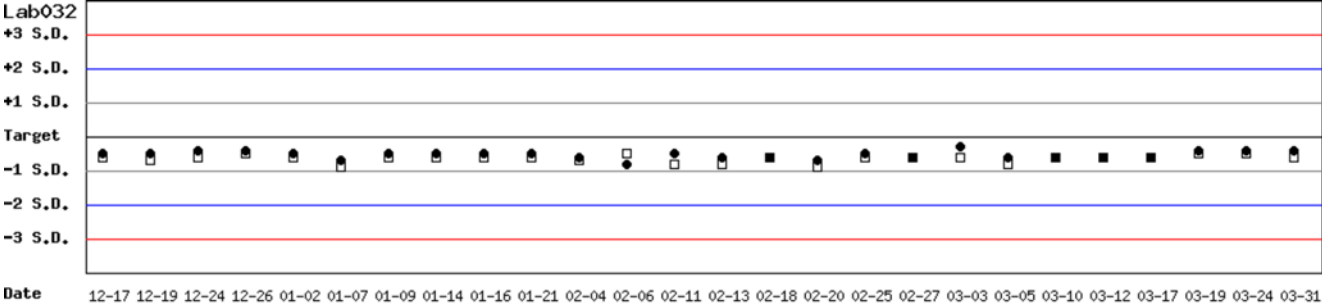
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**Control N and Control D SDI
QC Chart**

Lot No.: AH1220N ; Duration : 2019-12-17 to 2020-03-31 ; Target : 15.3 ; SD : 2.20 (●)

Lot No.: AH1220D ; Duration : 2019-12-17 to 2020-03-31 ; Target : 5.2 ; SD : 1.40 (◻)

Lab032



Month : 2020 | 03 | ; Cumulative : from 2019 | 12 | 17 to 2020 | 03 | 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 03

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
Lab032	5	15.3	14.2	8	0.3	2.1	11.4	20	>6	5.2	4.4	8	0.1	2.3	19.9	20	2.0
Lab033	5	12.4	12.4	3	0.3	2.4	4.8	20	>6	3.9	4.1	3	0.0	0.0	5.1	20	>6
Lab037	5	15.3	15.2	2	-	-	-	20	-	5.2	4.6	2	-	-	-	20	-
Total	-	-	13.9	13	1.0	7.2	-	-	-	-	4.3	13	0.2	4.7	-	-	-

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 03 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	41	0.4	3.3	7.3	20	5.8	4.1	4.0	41	0.1	2.5	7.4	20	>6
Lab032	5	15.3	14.3	59	0.5	3.5	13.5	20	3.8	5.2	4.4	59	0.4	9.1	33.6	20	0.5
Lab033	5	12.4	12.5	52	0.4	3.2	7.2	20	6.0	3.9	3.9	52	0.1	2.6	5.1	20	>6
Lab037	5	15.3	15.3	13	0.4	2.6	5.2	20	>6	5.2	4.7	13	0.1	2.1	13.9	20	4.9
Total	-	-	13.5	181	1.2	8.9	-	-	-	-	4.2	181	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

Print Table 2

Control N Month vs. Cumulative

		Control N (Lot No.: AH1220N)															
		Month (2020/03)								CUM (2019/02/01~2020/03/31)							
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	-	0	-	-	-	20	-	12.4	12.3	41	0.4	3.3	7.3	20	5.8
Lab032	5	15.3	14.2	8	0.3	2.1	11.4	20	>6	15.3	14.3	59	0.5	3.5	13.5	20	3.8
Lab033	5	12.4	12.4	3	0.3	2.4	4.8	20	>6	12.4	12.5	52	0.4	3.2	7.2	20	6.0
Lab037	5	15.3	15.2	2	-	-	-	20	-	15.3	15.3	13	0.4	2.6	5.2	20	>6
Total	-	-	13.9	13	1.0	7.2	-	-	-	-	13.5	181	1.2	8.9	-	-	-

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

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

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

Month : 2020 03 Change Cumulative : from 2019 02 01 to 2020 03 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2020/03)								CUM (2019/02/01~2020/03/31)							
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	-	0	-	-	-	20	-	4.1	4.0	41	0.1	2.5	7.4	20	>6
Lab032	5	5.2	4.4	8	0.1	2.3	19.9	20	2.0	5.2	4.4	59	0.4	9.1	33.6	20	0.5
Lab033	5	3.9	4.1	3	0.0	0.0	5.1	20	>6	3.9	3.9	52	0.1	2.6	5.1	20	>6
Lab037	5	5.2	4.6	2	-	-	-	20	-	5.2	4.7	13	0.1	2.1	13.9	20	4.9
Total	-	-	4.3	13	0.2	4.7	-	-	-	-	4.2	181	0.4	9.5	-	-	-

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

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

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

Month : 2020 03 Change Cumulative : from 2019 02 01 to 2020 03 31 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5