

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

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

## Lab019

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/12)	CUM (2021/04/14~2021/12/30)	Month (2021/12)	CUM (2021/04/14~2021/12/30)
Runs (N)	5	26	5	26
Mean (U/gHb)	15.6	15.0	4.7	4.5
SD	0.6	0.5	0.2	0.2
CV (%)	3.8	3.3	4.3	4.4
Target Value (U/gHb)	14.6	14.6	4.4	4.4
Total Error (%)	14.5	9.4	15.3	11.2
TEa (%)	20	20	20	20
$\sigma$	3.5	5.2	3.1	4.0

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

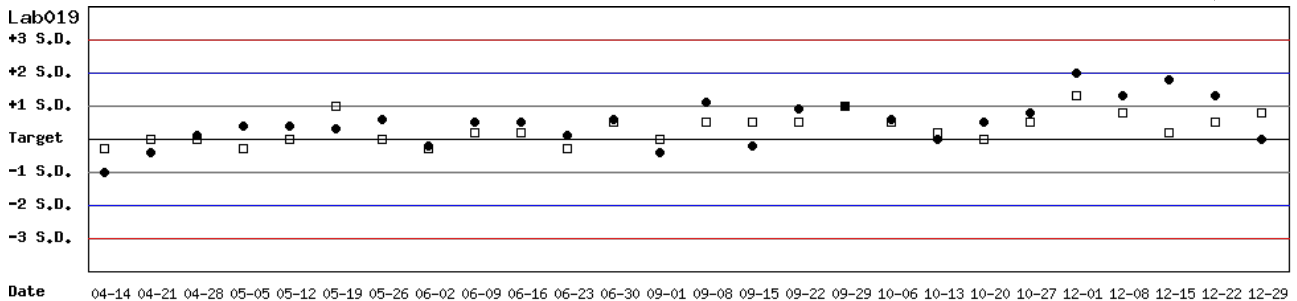
Month :    ; Cumulative : from    to

[TOP](#)

## Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-04-14 to 2021-12-30 ; Target : 14.6 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2021-04-14 to 2021-12-30 ; Target : 4.4 ; SD : 0.4 (□)

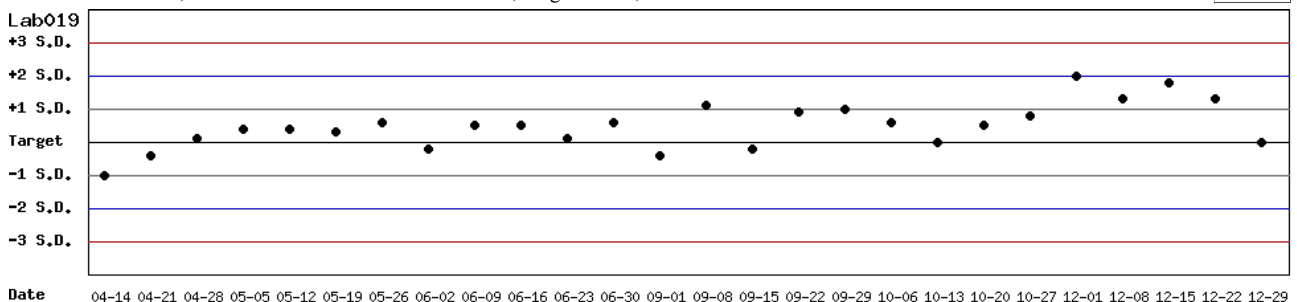


Month :    ; Cumulative : from    to

[TOP](#)

## Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-04-14 to 2021-12-30 ; Target : 14.6 ; SD : 0.8



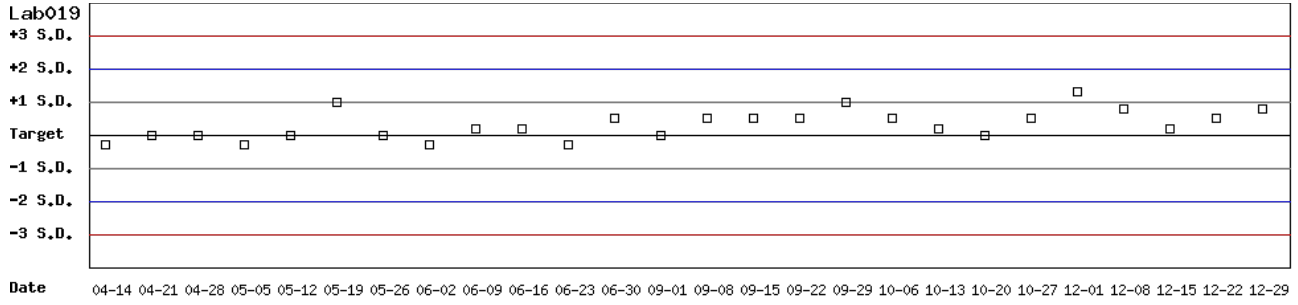
Month :    ; Cumulative : from    to

[TOP](#)

## Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2021-04-14 to 2021-12-30 ; Target : 4.4 ; SD : 0.4

Lab019



Month : 2021 12 Change ; Cumulative : from 2021 04 14 to 2021 12 30 Change

[\[TOP\]](#)

## 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 : 2021 12 Change

UnitID <sup>↑</sup>	Reagent Kit (Code) <sup>↑</sup>	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
<a href="#">Lab019</a>	5	14.6	15.6	5	0.6	3.8	14.5	20	3.5	4.4	4.7	5	0.2	4.3	15.3	20	3.1
<a href="#">Lab033</a>	5	12.4	12.6	5	0.4	3.2	8.0	20	5.7	3.9	4.0	5	0.2	5.0	12.6	20	3.5
<a href="#">Lab050</a>	5	13.8	14.1	5	0.3	2.1	6.4	20	>6	4.3	4.4	5	0.1	2.3	6.9	20	>6
Total	-	-	14.1	15	1.3	9.2	-	-	-	-	4.4	15	0.3	6.8	-	-	-

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 2021 12 31 Change

UnitID <sup>↑</sup>	Reagent Kit (Code) <sup>↑</sup>	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
<a href="#">Lab019</a>	5	14.6	14.8	67	0.5	3.4	8.1	20	5.5	4.4	4.5	67	0.2	4.4	11.2	20	4.0
<a href="#">Lab020</a>	5	13.3	14.3	65	1.0	7.0	21.5	20	1.8	4.3	4.5	65	0.2	4.4	13.5	20	3.5
<a href="#">Lab022</a>	5	13.8	13.0	88	0.9	6.9	19.6	20	2.1	4.4	4.2	88	0.2	4.8	14.1	20	3.2
<a href="#">Lab028</a>	5	14.6	14.6	53	0.4	2.7	5.5	20	>6	4.6	4.6	53	0.2	4.3	8.7	20	4.7
<a href="#">Lab032</a>	5	12.1	12.9	136	1.4	10.9	28.3	20	1.2	3.5	4.0	136	0.5	12.5	39.3	20	0.5
<a href="#">Lab033</a>	5	12.4	12.5	138	0.4	3.2	7.2	20	6.0	3.9	3.9	138	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	15.3	14.5	68	1.0	6.9	19.0	20	2.1	5.2	4.6	68	0.2	4.3	20.2	20	2.0
<a href="#">Lab037</a>	5	15.3	15.2	55	0.4	2.6	5.9	20	>6	5.2	4.7	55	0.2	4.3	18.1	20	2.4
<a href="#">Lab040</a>	5	15.3	15.0	19	0.4	2.7	7.3	20	>6	5.2	5.3	19	0.5	9.4	20.8	20	1.9
<a href="#">Lab043</a>	5	13.8	12.7	19	0.7	5.5	19.0	20	2.2	4.4	4.1	19	0.3	7.3	21.5	20	1.8
<a href="#">Lab047</a>	5	14.7	13.7	26	1.2	8.8	24.3	20	1.5	4.6	4.3	26	0.3	7.0	20.5	20	1.9
<a href="#">Lab049</a>	5	14.7	14.3	42	0.5	3.5	9.7	20	4.9	4.9	4.7	42	0.3	6.4	16.8	20	2.5
<a href="#">Lab050</a>	5	13.8	14.0	71	0.5	3.6	8.6	20	5.2	4.3	4.4	71	0.2	4.5	11.4	20	3.9
Total	-	-	13.7	847	1.2	8.8	-	-	-	-	4.3	847	0.4	9.3	-	-	-

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

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

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

[\[TOP\]](#)

Reagent Kit	Reagent Code
Medicon	5

## Peer Group Statistics (Table 2)

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

Select Reagent Kit : 5 - Medicon

### Control N Month vs. Cumulative

Control N (Lot No.: AH1220N)																	
		Month (2021/12)									CUM (2019/02/01~2021/12/31)						
UnitID <sup>†</sup>	Reagent Kit (Code) <sup>†</sup>	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
<a href="#">Lab019</a>	5	14.6	15.6	5	0.6	3.8	14.5	20	3.5	14.6	14.8	67	0.5	3.4	8.1	20	5.5
<a href="#">Lab020</a>	5	13.3	-	0	-	-	-	20	-	13.3	14.3	65	1.0	7.0	21.5	20	1.8
<a href="#">Lab022</a>	5	13.8	-	0	-	-	-	20	-	13.8	13.0	88	0.9	6.9	19.6	20	2.1
<a href="#">Lab028</a>	5	14.6	-	0	-	-	-	20	-	14.6	14.6	53	0.4	2.7	5.5	20	>6
<a href="#">Lab032</a>	5	12.1	-	0	-	-	-	20	-	12.1	12.9	136	1.4	10.9	28.3	20	1.2
<a href="#">Lab033</a>	5	12.4	12.6	5	0.4	3.2	8.0	20	5.7	12.4	12.5	138	0.4	3.2	7.2	20	6.0
<a href="#">Lab034</a>	5	15.3	-	0	-	-	-	20	-	15.3	14.5	68	1.0	6.9	19.0	20	2.1
<a href="#">Lab037</a>	5	15.3	-	0	-	-	-	20	-	15.3	15.2	55	0.4	2.6	5.9	20	>6
<a href="#">Lab040</a>	5	15.3	-	0	-	-	-	20	-	15.3	15.0	19	0.4	2.7	7.3	20	>6
<a href="#">Lab043</a>	5	13.8	-	0	-	-	-	20	-	13.8	12.7	19	0.7	5.5	19.0	20	2.2
<a href="#">Lab047</a>	5	14.7	-	0	-	-	-	20	-	14.7	13.7	26	1.2	8.8	24.3	20	1.5
<a href="#">Lab049</a>	5	14.7	-	0	-	-	-	20	-	14.7	14.3	42	0.5	3.5	9.7	20	4.9
<a href="#">Lab050</a>	5	13.8	14.1	5	0.3	2.1	6.4	20	>6	13.8	14.0	71	0.5	3.6	8.6	20	5.2
Total	-	-	14.1	15	1.3	9.2	-	-	-	-	13.7	847	1.2	8.8	-	-	-

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

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

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

Month : 2021

Cumulative : from 2019   to 2021

[TOP](#)

### Control D Month vs. Cumulative

Control D (Lot No.: AH1220D)																	
		Month (2021/12)									CUM (2019/02/01~2021/12/31)						
UnitID <sup>†</sup>	Reagent Kit (Code) <sup>†</sup>	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
<a href="#">Lab019</a>	5	4.4	4.7	5	0.2	4.3	15.3	20	3.1	4.4	4.5	67	0.2	4.4	11.2	20	4.0
<a href="#">Lab020</a>	5	4.3	-	0	-	-	-	20	-	4.3	4.5	65	0.2	4.4	13.5	20	3.5
<a href="#">Lab022</a>	5	4.4	-	0	-	-	-	20	-	4.4	4.2	88	0.2	4.8	14.1	20	3.2
<a href="#">Lab028</a>	5	4.6	-	0	-	-	-	20	-	4.6	4.6	53	0.2	4.3	8.7	20	4.7
<a href="#">Lab032</a>	5	3.5	-	0	-	-	-	20	-	3.5	4.0	136	0.5	12.5	39.3	20	0.5
<a href="#">Lab033</a>	5	3.9	4.0	5	0.2	5.0	12.6	20	3.5	3.9	3.9	138	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	5.2	-	0	-	-	-	20	-	5.2	4.6	68	0.2	4.3	20.2	20	2.0
<a href="#">Lab037</a>	5	5.2	-	0	-	-	-	20	-	5.2	4.7	55	0.2	4.3	18.1	20	2.4
<a href="#">Lab040</a>	5	5.2	-	0	-	-	-	20	-	5.2	5.3	19	0.5	9.4	20.8	20	1.9
<a href="#">Lab043</a>	5	4.4	-	0	-	-	-	20	-	4.4	4.1	19	0.3	7.3	21.5	20	1.8
<a href="#">Lab047</a>	5	4.6	-	0	-	-	-	20	-	4.6	4.3	26	0.3	7.0	20.5	20	1.9
<a href="#">Lab049</a>	5	4.9	-	0	-	-	-	20	-	4.9	4.7	42	0.3	6.4	16.8	20	2.5
<a href="#">Lab050</a>	5	4.3	4.4	5	0.1	2.3	6.9	20	>6	4.3	4.4	71	0.2	4.5	11.4	20	3.9
Total	-	-	4.4	15	0.3	6.8	-	-	-	-	4.3	847	0.4	9.3	-	-	-

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

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

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

Month : 2021

Cumulative : from 2019   to 2021

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5

