

# Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - January 2021 -

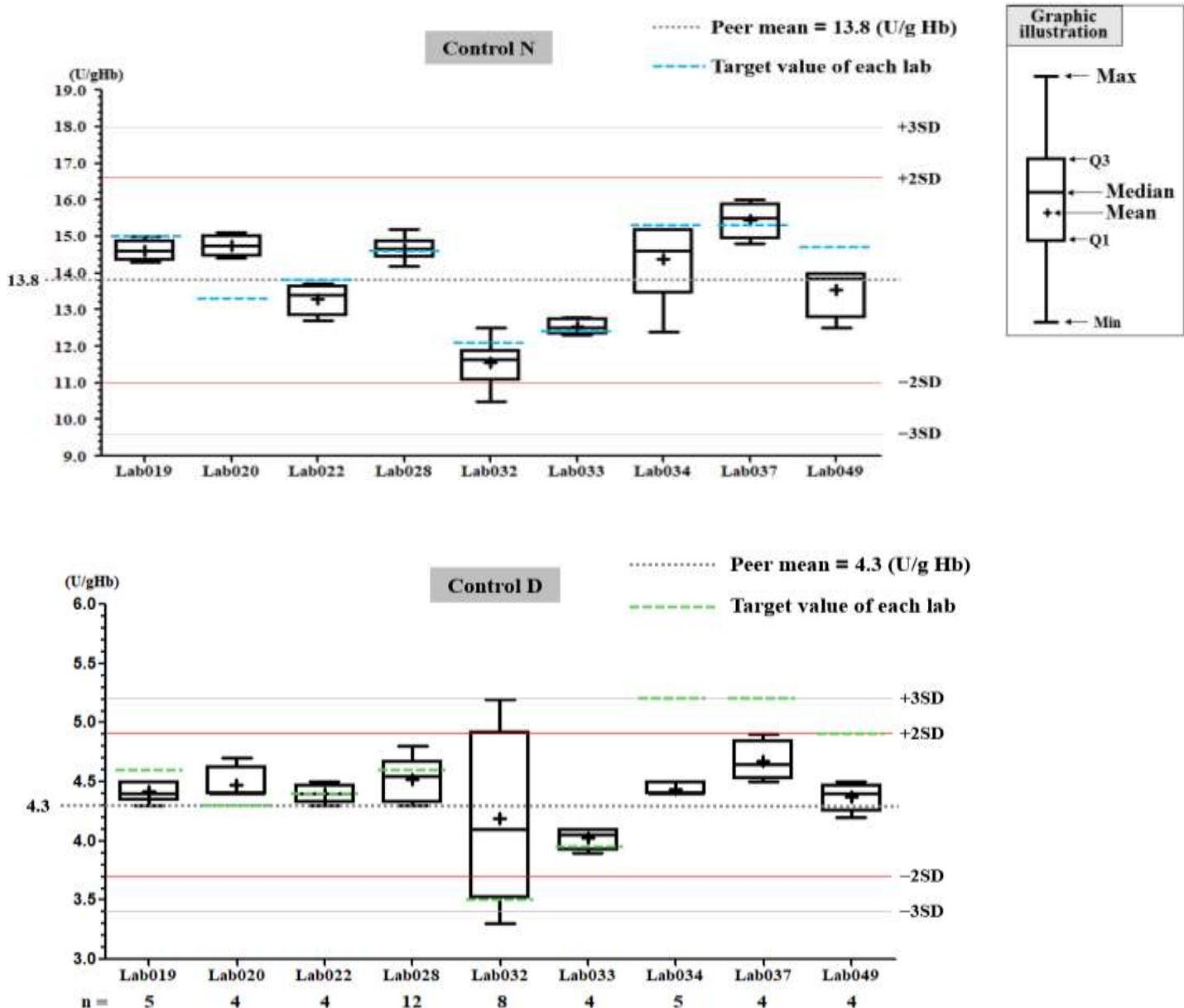
## I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	9	9
Received results number (n)	50	50
Median	14.4 (U/gHb)	4.4 (U/gHb)
Mean	13.8 (U/gHb)	4.4 (U/gHb)
SD	1.4	0.3
CV	10.1%	6.8%
Range of G6PD	10.5 ~ 16.0 (U/gHb)	3.3 ~ 5.2 (U/gHb)
Range of Hb	2.0 ~ 2.5 (g/dL)	2.0 ~ 2.8 (g/dL)

\*The statistic results are calculated from all labs reported in this month

\*\* G6PD Method = Medicon reagent kit, 37°C

## II. The distribution of G6PD reported for each lab in this survey



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

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

## Lab049

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/01)	CUM (2020/07/01~2021/01/30)	Month (2021/01)	CUM (2020/07/01~2021/01/30)
Runs (N)	4	25	4	25
Mean (U/gHb)	13.6	14.2	4.4	4.8
SD	0.7	0.6	0.1	0.4
CV (%)	5.1	4.2	2.3	8.3
Target Value (U/gHb)	14.7	14.7	4.9	4.9
Total Error (%)	17.8	11.9	14.7	18.7
TEa (%)	20	20	20	20
$\sigma$	2.5	4.0	4.3	2.2

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

Month : 2021  01  ; Cumulative : from 2020  07  01  to 2021  01  30

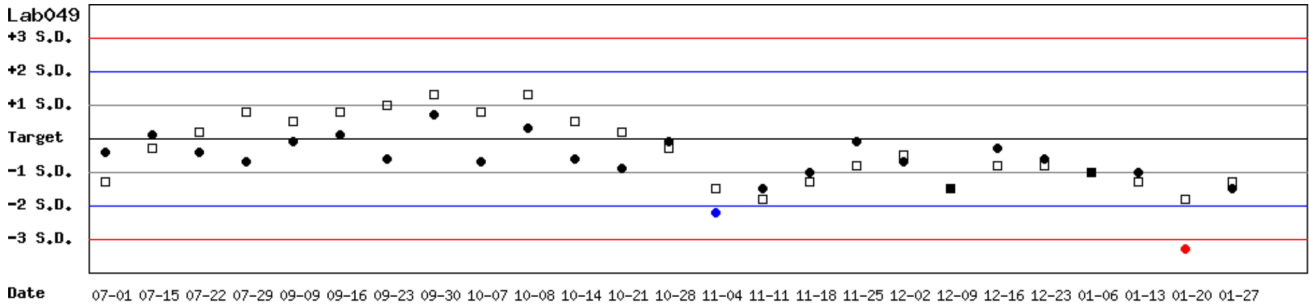
[\[TOP\]](#)

## Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-07-01 to 2021-01-30 ; Target : 14.7 ; SD : 0.67 (●)

Lot No.: AH1220D ; Duration : 2020-07-01 to 2021-01-30 ; Target : 4.9 ; SD : 0.40 (□)

Lab049



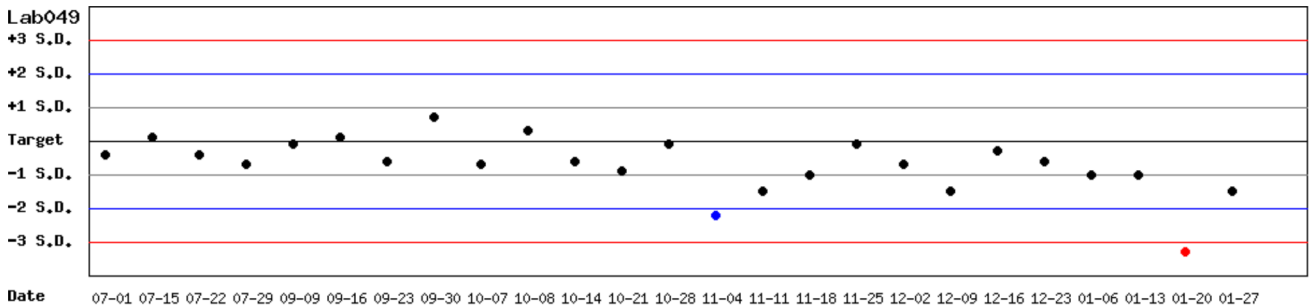
Month : 2021  01  ; Cumulative : from 2020  07  01  to 2021  01  30

[\[TOP\]](#)

## Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-07-01 to 2021-01-30 ; Target : 14.7 ; SD : 0.67

Lab049



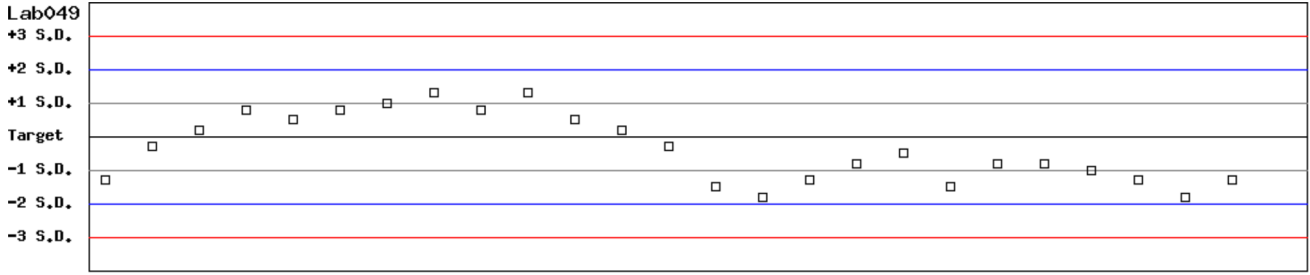
Month : 2021  01  ; Cumulative : from 2020  07  01  to 2021  01  30

[\[TOP\]](#)

## Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-07-01 to 2021-01-30 ; Target : 4.9 ; SD : 0.40

Lab049



**Date**    07-01 07-15 07-22 07-29 09-09 09-16 09-23 09-30 10-07 10-08 10-14 10-21 10-28 11-04 11-11 11-18 11-25 12-02 12-09 12-16 12-23 01-06 01-13 01-20 01-27

Month :    ; Cumulative : from    to

[\[TOP\]](#)

## 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 01 Change

UnitID ↑	Reagent Kit (Code) ↑	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	15.0	14.6	5	0.3	2.1	6.8	20	>6	4.6	4.4	5	0.1	2.3	8.9	20	>6
<a href="#">Lab020</a>	5	13.3	14.8	4	0.3	2.0	15.3	20	4.4	4.3	4.5	4	0.2	4.4	13.5	20	3.5
<a href="#">Lab022</a>	5	13.8	13.3	4	0.4	3.0	9.6	20	5.5	4.4	4.4	4	0.1	2.3	4.5	20	>6
<a href="#">Lab028</a>	5	14.6	14.7	12	0.3	2.0	4.8	20	>6	4.6	4.5	12	0.2	4.4	11.1	20	4.1
<a href="#">Lab032</a>	5	12.1	11.6	8	0.6	5.2	14.5	20	3.1	3.5	4.2	8	0.7	16.7	53.3	20	0.0
<a href="#">Lab033</a>	5	12.4	12.5	4	0.2	1.6	4.0	20	>6	3.9	4.0	4	0.1	2.5	7.6	20	>6
<a href="#">Lab034</a>	5	15.3	14.4	5	1.2	8.3	22.5	20	1.7	5.2	4.4	5	0.1	2.3	19.9	20	2.0
<a href="#">Lab037</a>	5	15.3	15.5	4	0.5	3.2	7.8	20	5.8	5.2	4.7	4	0.2	4.3	18.1	20	2.4
<a href="#">Lab049</a>	5	14.7	13.6	4	0.7	5.1	17.8	20	2.5	4.9	4.4	4	0.1	2.3	14.7	20	4.3
Total	-	-	13.8	50	1.4	10.1	-	-	-	-	4.4	50	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 01 31 Change

UnitID ↑	Reagent Kit (Code) ↑	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	15.0	14.7	30	0.3	2.0	6.1	20	>6	4.6	4.5	30	0.1	2.2	6.6	20	>6
<a href="#">Lab020</a>	5	13.3	14.4	42	1.1	7.6	23.5	20	1.5	4.3	4.5	42	0.3	6.7	18.0	20	2.3
<a href="#">Lab022</a>	5	13.8	12.4	56	0.7	5.6	21.4	20	1.8	4.4	4.0	56	0.2	5.0	19.1	20	2.2
<a href="#">Lab028</a>	5	14.6	14.6	34	0.4	2.7	5.5	20	>6	4.6	4.6	34	0.2	4.3	8.7	20	4.7
<a href="#">Lab032</a>	5	12.1	13.1	112	1.5	11.5	31.2	20	1.0	3.5	4.1	112	0.6	14.6	46.4	20	0.2
<a href="#">Lab033</a>	5	12.4	12.5	91	0.4	3.2	7.2	20	6.0	3.9	3.9	91	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	15.3	15.1	29	0.7	4.6	10.6	20	4.1	5.2	4.6	29	0.2	4.3	20.2	20	2.0
<a href="#">Lab037</a>	5	15.3	15.2	44	0.4	2.6	5.9	20	>6	5.2	4.7	44	0.2	4.3	18.1	20	2.4
<a href="#">Lab040</a>	5	15.3	15.1	10	0.5	3.3	7.9	20	5.7	5.2	5.6	10	0.4	7.1	22.0	20	1.7
<a href="#">Lab047</a>	5	12.7	12.6	13	0.2	1.6	4.0	20	>6	4.0	4.0	13	0.1	2.5	5.0	20	>6
<a href="#">Lab049</a>	5	14.7	14.2	25	0.6	4.2	11.9	20	4.0	4.9	4.8	25	0.4	8.3	18.7	20	2.2
<a href="#">Lab050</a>	5	15.3	14.6	6	0.8	5.5	15.5	20	2.8	5.2	4.4	6	0.5	11.4	38.1	20	0.4
Total	-	-	13.6	492	1.4	10.3	-	-	-	-	4.3	492	0.5	11.6	-	-	-

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) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 2

### Control N Month vs. Cumulative

		Control N (Lot No.: AH1220N)															
		Month (2021/01)								CUM (2019/02/01~2021/01/31)							
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
<a href="#">Lab019</a>	5	15.0	14.6	5	0.3	2.1	6.8	20	>6	15.0	14.7	30	0.3	2.0	6.1	20	>6
<a href="#">Lab020</a>	5	13.3	14.8	4	0.3	2.0	15.3	20	4.4	13.3	14.4	42	1.1	7.6	23.5	20	1.5
<a href="#">Lab022</a>	5	13.8	13.3	4	0.4	3.0	9.6	20	5.5	13.8	12.4	56	0.7	5.6	21.4	20	1.8
<a href="#">Lab028</a>	5	14.6	14.7	12	0.3	2.0	4.8	20	>6	14.6	14.6	34	0.4	2.7	5.5	20	>6
<a href="#">Lab032</a>	5	12.1	11.6	8	0.6	5.2	14.5	20	3.1	12.1	13.1	112	1.5	11.5	31.2	20	1.0
<a href="#">Lab033</a>	5	12.4	12.5	4	0.2	1.6	4.0	20	>6	12.4	12.5	91	0.4	3.2	7.2	20	6.0
<a href="#">Lab034</a>	5	15.3	14.4	5	1.2	8.3	22.5	20	1.7	15.3	15.1	29	0.7	4.6	10.6	20	4.1
<a href="#">Lab037</a>	5	15.3	15.5	4	0.5	3.2	7.8	20	5.8	15.3	15.2	44	0.4	2.6	5.9	20	>6
<a href="#">Lab040</a>	5	15.3	-	0	-	-	-	20	-	15.3	15.1	10	0.5	3.3	7.9	20	5.7
<a href="#">Lab047</a>	5	12.7	-	0	-	-	-	20	-	12.7	12.6	13	0.2	1.6	4.0	20	>6
<a href="#">Lab049</a>	5	14.7	13.6	4	0.7	5.1	17.8	20	2.5	14.7	14.2	25	0.6	4.2	11.9	20	4.0
<a href="#">Lab050</a>	5	15.3	-	0	-	-	-	20	-	15.3	14.6	6	0.8	5.5	15.5	20	2.8
Total	-	-	13.8	50	1.4	10.1	-	-	-	-	13.6	492	1.4	10.3	-	-	-

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

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

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

Month : 2021 ▾ 01 ▾ Change

Cumulative : from 2019 ▾ 02 ▾ 01 ▾ to 2021 ▾ 01 ▾ 31 ▾ Change

[TOP](#)

### Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2021/01)								CUM (2019/02/01~2021/01/31)							
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
<a href="#">Lab019</a>	5	4.6	4.4	5	0.1	2.3	8.9	20	>6	4.6	4.5	30	0.1	2.2	6.6	20	>6
<a href="#">Lab020</a>	5	4.3	4.5	4	0.2	4.4	13.5	20	3.5	4.3	4.5	42	0.3	6.7	18.0	20	2.3
<a href="#">Lab022</a>	5	4.4	4.4	4	0.1	2.3	4.5	20	>6	4.4	4.0	56	0.2	5.0	19.1	20	2.2
<a href="#">Lab028</a>	5	4.6	4.5	12	0.2	4.4	11.1	20	4.1	4.6	4.6	34	0.2	4.3	8.7	20	4.7
<a href="#">Lab032</a>	5	3.5	4.2	8	0.7	16.7	53.3	20	0.0	3.5	4.1	112	0.6	14.6	46.4	20	0.2
<a href="#">Lab033</a>	5	3.9	4.0	4	0.1	2.5	7.6	20	>6	3.9	3.9	91	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	5.2	4.4	5	0.1	2.3	19.9	20	2.0	5.2	4.6	29	0.2	4.3	20.2	20	2.0
<a href="#">Lab037</a>	5	5.2	4.7	4	0.2	4.3	18.1	20	2.4	5.2	4.7	44	0.2	4.3	18.1	20	2.4
<a href="#">Lab040</a>	5	5.2	-	0	-	-	-	20	-	5.2	5.6	10	0.4	7.1	22.0	20	1.7
<a href="#">Lab047</a>	5	4.0	-	0	-	-	-	20	-	4.0	4.0	13	0.1	2.5	5.0	20	>6
<a href="#">Lab049</a>	5	4.9	4.4	4	0.1	2.3	14.7	20	4.3	4.9	4.8	25	0.4	8.3	18.7	20	2.2
<a href="#">Lab050</a>	5	5.2	-	0	-	-	-	20	-	5.2	4.4	6	0.5	11.4	38.1	20	0.4
Total	-	-	4.4	50	0.3	6.8	-	-	-	-	4.3	492	0.5	11.6	-	-	-

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

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

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

Month : 2021 ▾ 01 ▾ Change

Cumulative : from 2019 ▾ 02 ▾ 01 ▾ to 2021 ▾ 01 ▾ 31 ▾ Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5