

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

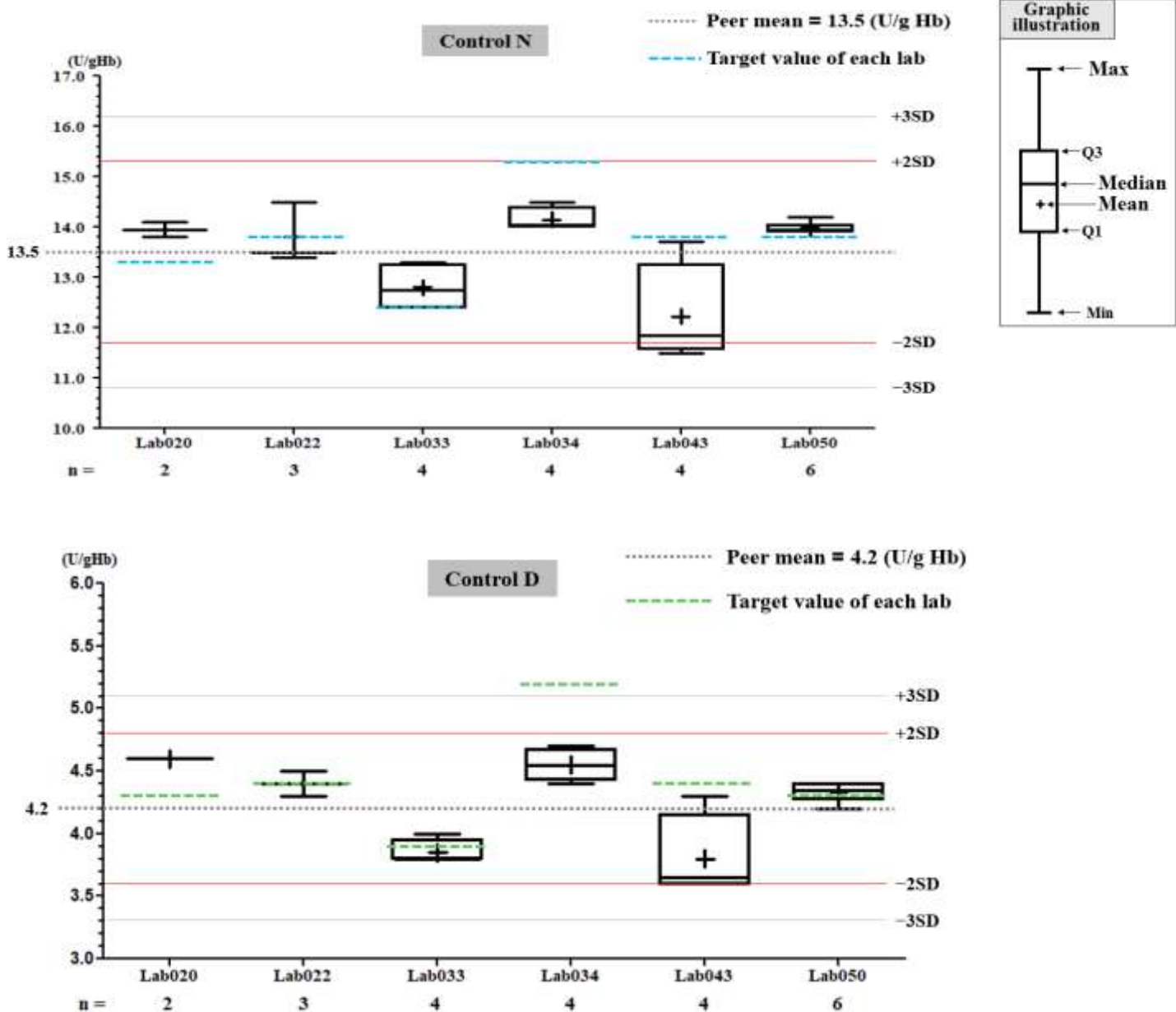
## I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	6	6
Received results number (n)	23	23
Median	13.9 (U/g Hb)	4.3 (U/g Hb)
Mean	13.5 (U/g Hb)	4.2 (U/g Hb)
SD	0.9	0.3
CV	6.7%	7.1%
Range of G6PD	11.5 ~ 14.5 (U/g Hb)	3.6 ~ 4.7 (U/g Hb)
Range of Hb	2.0 ~ 2.5 (g/dL)	1.9 ~ 2.4 (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 (IQC)for G6PD Quantitative Test

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

## Lab033

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/08)	CUM (2021/03/04~2021/08/31)	Month (2021/08)	CUM (2021/03/04~2021/08/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	12.8	12.5	3.9	4.0
SD	0.5	0.5	0.1	0.1
CV (%)	3.9	4.0	2.6	2.5
Target Value (U/gHb)	12.4	12.4	3.9	3.9
Total Error (%)	11.0	8.8	5.1	7.6
TEa (%)	20	20	20	20
$\sigma$	4.3	4.8	>6	>6

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

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

$\sigma$  (Sigma) = [TEa% - Bias (%) ] / CV (%)

Month :    ; Cumulative : from    to

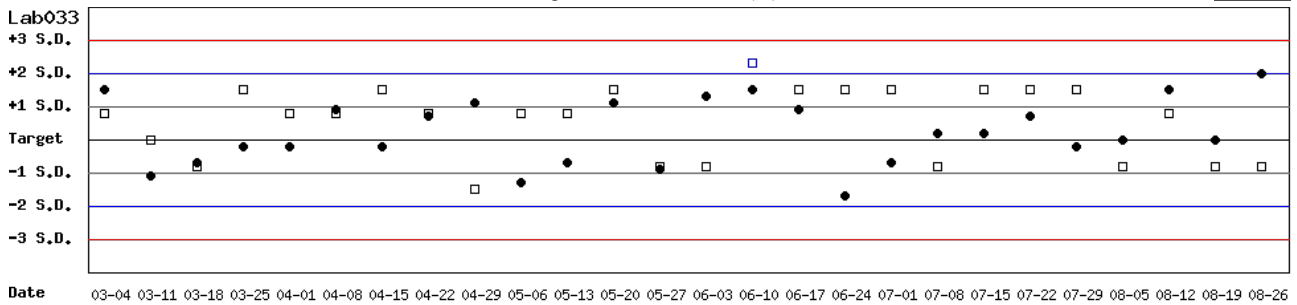
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## Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-03-04 to 2021-08-31 ; Target : 12.4 ; SD : 0.46 (●)

Lot No.: AH1220D ; Duration : 2021-03-04 to 2021-08-31 ; Target : 3.9 ; SD : 0.13 (□)

Lab033



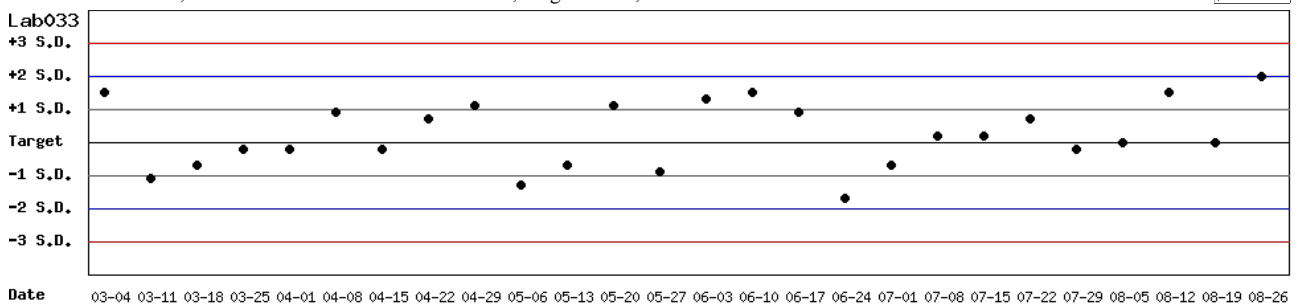
Month :    ; Cumulative : from    to

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## Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-03-04 to 2021-08-31 ; Target : 12.4 ; SD : 0.46

Lab033



Month :    ; Cumulative : from    to

[\[TOP\]](#)

## Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2021-03-04 to 2021-08-31 ; Target : 3.9 ; SD : 0.13

Lab033

Lab033

+3 S.D.

+2 S.D.

+1 S.D.

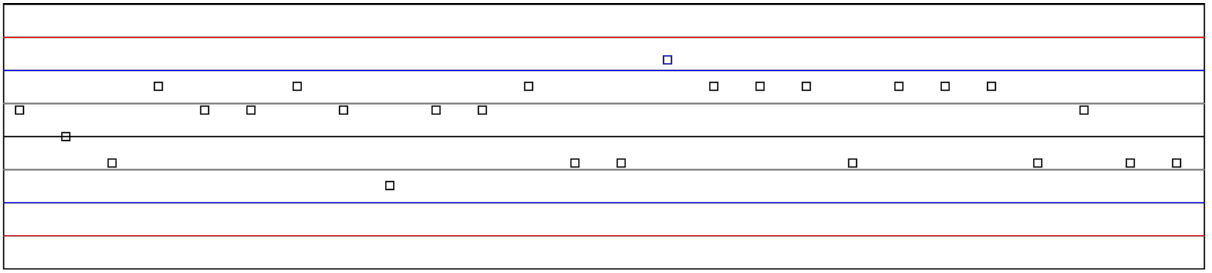
Target

-1 S.D.

-2 S.D.

-3 S.D.

Date



03-04 03-11 03-18 03-25 04-01 04-08 04-15 04-22 04-29 05-06 05-13 05-20 05-27 06-03 06-10 06-17 06-24 07-01 07-08 07-15 07-22 07-29 08-05 08-12 08-19 08-26

Month : 2021 08 Change ; Cumulative : from 2021 03 04 to 2021 08 31 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 08 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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="#">Lab020</a>	5	13.3	14.0	2	-	-	-	20	-	4.3	4.6	2	-	-	-	20	-
<a href="#">Lab022</a>	5	13.8	13.8	3	0.6	4.3	8.7	20	4.7	4.4	4.4	3	0.1	2.3	4.5	20	>6
<a href="#">Lab033</a>	5	12.4	12.8	4	0.5	3.9	11.0	20	4.3	3.9	3.9	4	0.1	2.6	5.1	20	>6
<a href="#">Lab034</a>	5	15.3	14.2	4	0.2	1.4	10.0	20	>6	5.2	4.6	4	0.1	2.2	15.9	20	3.8
<a href="#">Lab043</a>	5	13.8	12.2	4	1.0	8.2	28.0	20	1.0	4.4	3.8	4	0.3	7.9	29.4	20	0.8
<a href="#">Lab050</a>	5	13.8	14.0	6	0.1	0.7	2.9	20	>6	4.3	4.3	6	0.1	2.3	4.7	20	>6
Total	-	-	13.5	23	0.9	6.7	-	-	-	-	4.2	23	0.3	7.1	-	-	-

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 08 31 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	14.6	53	0.3	2.1	4.1	20	>6	4.4	4.4	53	0.1	2.3	4.5	20	>6
<a href="#">Lab020</a>	5	13.3	14.3	64	1.0	7.0	21.5	20	1.8	4.3	4.5	64	0.2	4.4	13.5	20	3.5
<a href="#">Lab022</a>	5	13.8	12.7	70	0.8	6.3	20.6	20	1.9	4.4	4.1	70	0.2	4.9	16.6	20	2.7
<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	121	0.4	3.2	7.2	20	6.0	3.9	3.9	121	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	15.3	14.5	60	1.0	6.9	19.0	20	2.1	5.2	4.6	60	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	15	0.4	2.7	7.3	20	>6	5.2	5.4	15	0.4	7.4	18.7	20	2.2
<a href="#">Lab043</a>	5	13.8	12.8	16	0.7	5.5	18.2	20	2.3	4.4	4.1	16	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	45	0.5	3.6	8.6	20	5.2	4.3	4.4	45	0.2	4.5	11.4	20	3.9
Total	-	-	13.7	756	1.3	9.5	-	-	-	-	4.3	756	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) Change

Select Reagent Kit : 5 - Medicon Change

[Print Table 2](#)

### Control N Month vs. Cumulative

		Control N (Lot No.: AH1220N)															
		Month (2021/08)								CUM (2019/02/01~2021/08/31)							
UnitID <span style="font-size: small;">↑</span>	Reagent Kit (Code) <span style="font-size: small;">↑</span>	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	-	0	-	-	-	20	-	14.6	14.6	53	0.3	2.1	4.1	20	>6
<a href="#">Lab020</a>	5	13.3	14.0	2	-	-	-	20	-	13.3	14.3	64	1.0	7.0	21.5	20	1.8
<a href="#">Lab022</a>	5	13.8	13.8	3	0.6	4.3	8.7	20	4.7	13.8	12.7	70	0.8	6.3	20.6	20	1.9
<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	12.8	4	0.5	3.9	11.0	20	4.3	12.4	12.5	121	0.4	3.2	7.2	20	6.0
<a href="#">Lab034</a>	5	15.3	14.2	4	0.2	1.4	10.0	20	>6	15.3	14.5	60	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	15	0.4	2.7	7.3	20	>6
<a href="#">Lab043</a>	5	13.8	12.2	4	1.0	8.2	28.0	20	1.0	13.8	12.8	16	0.7	5.5	18.2	20	2.3
<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	14.0	6	0.1	0.7	2.9	20	>6	13.8	14.0	45	0.5	3.6	8.6	20	5.2
Total	-	-	13.5	23	0.9	6.7	-	-	-	-	13.7	756	1.3	9.5	-	-	-

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

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

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

Month : 2021 08 Change

Cumulative : from 2019 02 01 to 2021 08 31 Change

[TOP](#)

### Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2021/08)								CUM (2019/02/01~2021/08/31)							
UnitID <span style="font-size: small;">↑</span>	Reagent Kit (Code) <span style="font-size: small;">↑</span>	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	-	0	-	-	-	20	-	4.4	4.4	53	0.1	2.3	4.5	20	>6
<a href="#">Lab020</a>	5	4.3	4.6	2	-	-	-	20	-	4.3	4.5	64	0.2	4.4	13.5	20	3.5
<a href="#">Lab022</a>	5	4.4	4.4	3	0.1	2.3	4.5	20	>6	4.4	4.1	70	0.2	4.9	16.6	20	2.7
<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	3.9	4	0.1	2.6	5.1	20	>6	3.9	3.9	121	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	5.2	4.6	4	0.1	2.2	15.9	20	3.8	5.2	4.6	60	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	5.4	15	0.4	7.4	18.7	20	2.2
<a href="#">Lab043</a>	5	4.4	3.8	4	0.3	7.9	29.4	20	0.8	4.4	4.1	16	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	4.3	6	0.1	2.3	4.7	20	>6	4.3	4.4	45	0.2	4.5	11.4	20	3.9
Total	-	-	4.2	23	0.3	7.1	-	-	-	-	4.3	756	0.4	9.3	-	-	-

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

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

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

Month : 2021 08 Change

Cumulative : from 2019 02 01 to 2021 08 31 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5