

# Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - December 2020 -

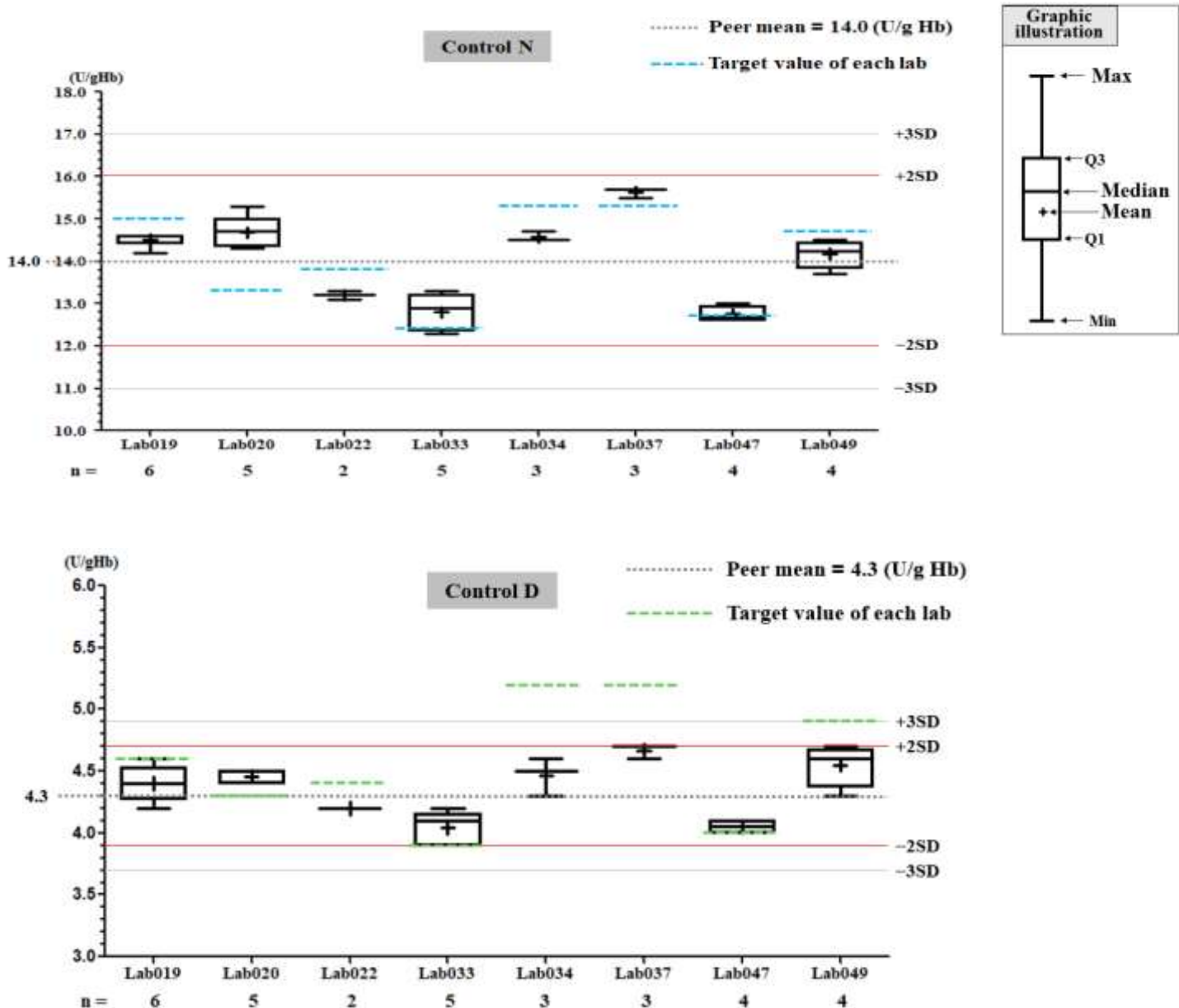
## I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	8	8
Received results number (n)	32	32
Median	14.4 (U/gHb)	4.4 (U/gHb)
Mean	14.0 (U/gHb)	4.3 (U/gHb)
SD	1.0	0.2
CV	7.1%	4.7%
Range of G6PD	12.3 ~ 15.7 (U/gHb)	3.9 ~ 4.7 (U/gHb)
Range of Hb	2.0 ~ 2.3 (g/dL)	2.0 ~ 2.7 (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)

## Lab037

	Control N		Control D	
QC Control Lot No.	AH1220N		AH1220D	
Duration of the Analyzing	Month (2020/12)	CUM (2020/05/21~2020/12/31)	Month (2020/12)	CUM (2020/05/21~2020/12/31)
Runs (N)	3	26	3	26
Mean (U/gHb)	15.6	15.2	4.7	4.7
SD	0.1	0.4	0.1	0.1
CV (%)	0.6	2.6	2.1	2.1
Target Value (U/gHb)	15.3	15.3	5.2	5.2
Total Error (%)	3.2	5.9	13.9	13.9
TEa (%)	20	20	20	20
$\sigma$	>6	>6	4.9	4.9

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

Month : 2020  12  ; Cumulative : from 2020  05  21  to 2020  12  31

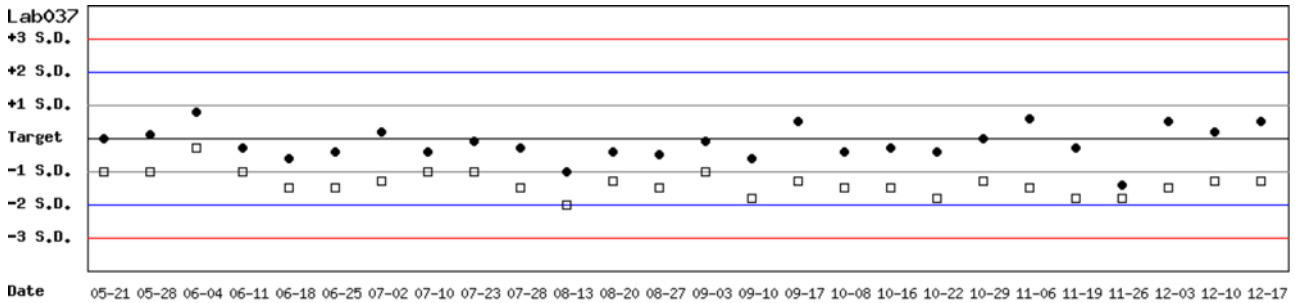
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## Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-05-21 to 2020-12-31 ; Target : 15.3 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2020-05-21 to 2020-12-31 ; Target : 5.2 ; SD : 0.4 (□)

Lab037



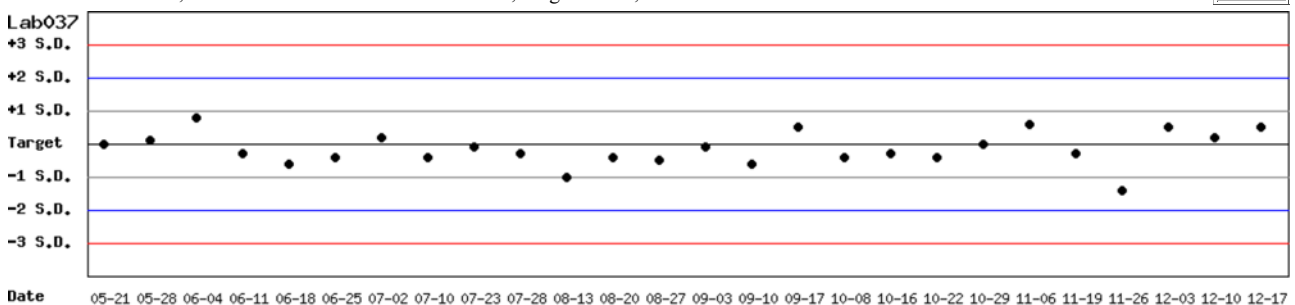
Month : 2020  12  ; Cumulative : from 2020  05  21  to 2020  12  31

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## Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-05-21 to 2020-12-31 ; Target : 15.3 ; SD : 0.8

Lab037



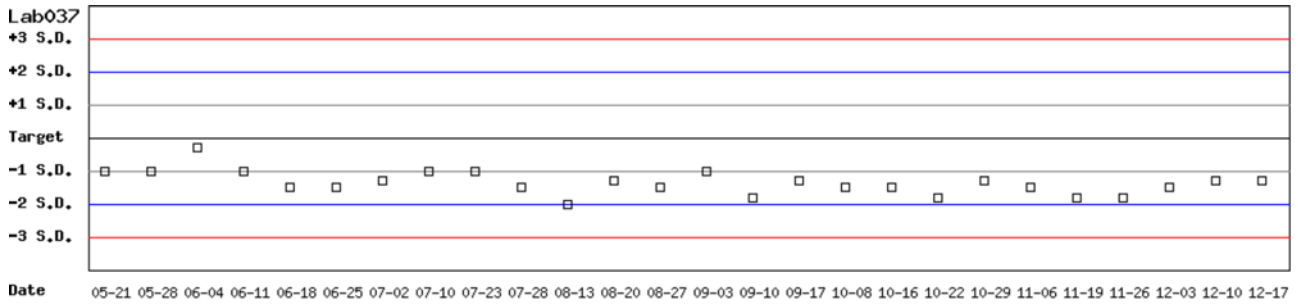
Month : 2020  12  ; Cumulative : from 2020  05  21  to 2020  12  31

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## Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-05-21 to 2020-12-31 ; Target : 5.2 ; SD : 0.4

Lab037



Month : 2020 ▾ 12 ▾  ; Cumulative : from 2020 ▾ 05 ▾ 21 ▾ to 2020 ▾ 12 ▾ 31 ▾

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## 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 : 2020 12 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	14.5	6	0.2	1.4	6.1	20	>6	4.6	4.4	6	0.2	4.5	13.4	20	3.5
<a href="#">Lab020</a>	5	13.3	14.7	5	0.4	2.7	16.0	20	3.5	4.3	4.5	5	0.1	2.2	9.1	20	>6
<a href="#">Lab022</a>	5	13.8	13.2	2	-	-	-	20	-	4.4	4.2	2	-	-	-	20	-
<a href="#">Lab033</a>	5	12.4	12.8	5	0.4	3.1	9.5	20	5.4	3.9	4.0	5	0.1	2.5	7.6	20	>6
<a href="#">Lab034</a>	5	15.3	14.6	3	0.1	0.7	5.9	20	>6	5.2	4.5	3	0.2	4.4	22.4	20	1.5
<a href="#">Lab037</a>	5	15.3	15.6	3	0.1	0.6	3.2	20	>6	5.2	4.7	3	0.1	2.1	13.9	20	4.9
<a href="#">Lab047</a>	5	12.7	12.8	4	0.2	1.6	3.9	20	>6	4.0	4.1	4	0.1	2.4	7.4	20	>6
<a href="#">Lab049</a>	5	14.7	14.2	4	0.3	2.1	7.6	20	>6	4.9	4.6	4	0.2	4.3	14.8	20	3.2
Total	-	-	14.0	32	1.0	7.1	-	-	-	-	4.3	32	0.2	4.7	-	-	-

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

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

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

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### Cumulative

Cumulative : from 2019 02 01 to 2020 12 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	25	0.3	2.0	6.1	20	>6	4.6	4.5	25	0.1	2.2	6.6	20	>6
<a href="#">Lab020</a>	5	13.3	14.4	38	1.1	7.6	23.5	20	1.5	4.3	4.5	38	0.3	6.7	18.0	20	2.3
<a href="#">Lab022</a>	5	13.8	12.3	52	0.6	4.9	20.6	20	1.9	4.4	4.0	52	0.2	5.0	19.1	20	2.2
<a href="#">Lab028</a>	5	14.6	14.6	22	0.4	2.7	5.5	20	>6	4.6	4.6	22	0.1	2.2	4.3	20	>6
<a href="#">Lab032</a>	5	12.1	13.2	104	1.5	11.4	31.8	20	1.0	3.5	4.1	104	0.6	14.6	46.4	20	0.2
<a href="#">Lab033</a>	5	12.4	12.5	87	0.4	3.2	7.2	20	6.0	3.9	3.9	87	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	15.3	15.3	24	0.5	3.3	6.5	20	>6	5.2	4.7	24	0.2	4.3	18.1	20	2.4
<a href="#">Lab037</a>	5	15.3	15.2	40	0.4	2.6	5.9	20	>6	5.2	4.7	40	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	14.3	21	0.5	3.5	9.7	20	4.9	4.9	4.8	21	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	442	1.4	10.3	-	-	-	-	4.3	442	0.5	11.6	-	-	-

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 (2020/12)									CUM (2019/02/01-2020/12/31)						
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	14.5	6	0.2	1.4	6.1	20	>6	15.0	14.7	25	0.3	2.0	6.1	20	>6
<a href="#">Lab020</a>	5	13.3	14.7	5	0.4	2.7	16.0	20	3.5	13.3	14.4	38	1.1	7.6	23.5	20	1.5
<a href="#">Lab022</a>	5	13.8	13.2	2	-	-	-	20	-	13.8	12.3	52	0.6	4.9	20.6	20	1.9
<a href="#">Lab028</a>	5	14.6	-	0	-	-	-	20	-	14.6	14.6	22	0.4	2.7	5.5	20	>6
<a href="#">Lab032</a>	5	12.1	-	0	-	-	-	20	-	12.1	13.2	104	1.5	11.4	31.8	20	1.0
<a href="#">Lab033</a>	5	12.4	12.8	5	0.4	3.1	9.5	20	5.4	12.4	12.5	87	0.4	3.2	7.2	20	6.0
<a href="#">Lab034</a>	5	15.3	14.6	3	0.1	0.7	5.9	20	>6	15.3	15.3	24	0.5	3.3	6.5	20	>6
<a href="#">Lab037</a>	5	15.3	15.6	3	0.1	0.6	3.2	20	>6	15.3	15.2	40	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	12.8	4	0.2	1.6	3.9	20	>6	12.7	12.6	13	0.2	1.6	4.0	20	>6
<a href="#">Lab049</a>	5	14.7	14.2	4	0.3	2.1	7.6	20	>6	14.7	14.3	21	0.5	3.5	9.7	20	4.9
<a href="#">Lab050</a>	5	15.3	-	0	-	-	-	20	-	15.3	14.6	6	0.8	5.5	15.5	20	2.8
<b>Total</b>	-	-	14.0	32	1.0	7.1	-	-	-	-	13.6	442	1.4	10.3	-	-	-

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

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

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

Month : 2020 12 Change

Cumulative : from 2019 02 01 to 2020 12 31 Change

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### Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2020/12)									CUM (2019/02/01-2020/12/31)						
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	6	0.2	4.5	13.4	20	3.5	4.6	4.5	25	0.1	2.2	6.6	20	>6
<a href="#">Lab020</a>	5	4.3	4.5	5	0.1	2.2	9.1	20	>6	4.3	4.5	38	0.3	6.7	18.0	20	2.3
<a href="#">Lab022</a>	5	4.4	4.2	2	-	-	-	20	-	4.4	4.0	52	0.2	5.0	19.1	20	2.2
<a href="#">Lab028</a>	5	4.6	-	0	-	-	-	20	-	4.6	4.6	22	0.1	2.2	4.3	20	>6
<a href="#">Lab032</a>	5	3.5	-	0	-	-	-	20	-	3.5	4.1	104	0.6	14.6	46.4	20	0.2
<a href="#">Lab033</a>	5	3.9	4.0	5	0.1	2.5	7.6	20	>6	3.9	3.9	87	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	5.2	4.5	3	0.2	4.4	22.4	20	1.5	5.2	4.7	24	0.2	4.3	18.1	20	2.4
<a href="#">Lab037</a>	5	5.2	4.7	3	0.1	2.1	13.9	20	4.9	5.2	4.7	40	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	4.1	4	0.1	2.4	7.4	20	>6	4.0	4.0	13	0.1	2.5	5.0	20	>6
<a href="#">Lab049</a>	5	4.9	4.6	4	0.2	4.3	14.8	20	3.2	4.9	4.8	21	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
<b>Total</b>	-	-	4.3	32	0.2	4.7	-	-	-	-	4.3	442	0.5	11.6	-	-	-

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

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

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

Month : 2020 12 Change

Cumulative : from 2019 02 01 to 2020 12 31 Change

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Reagent Kit	Reagent Code
Medicon	5