

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

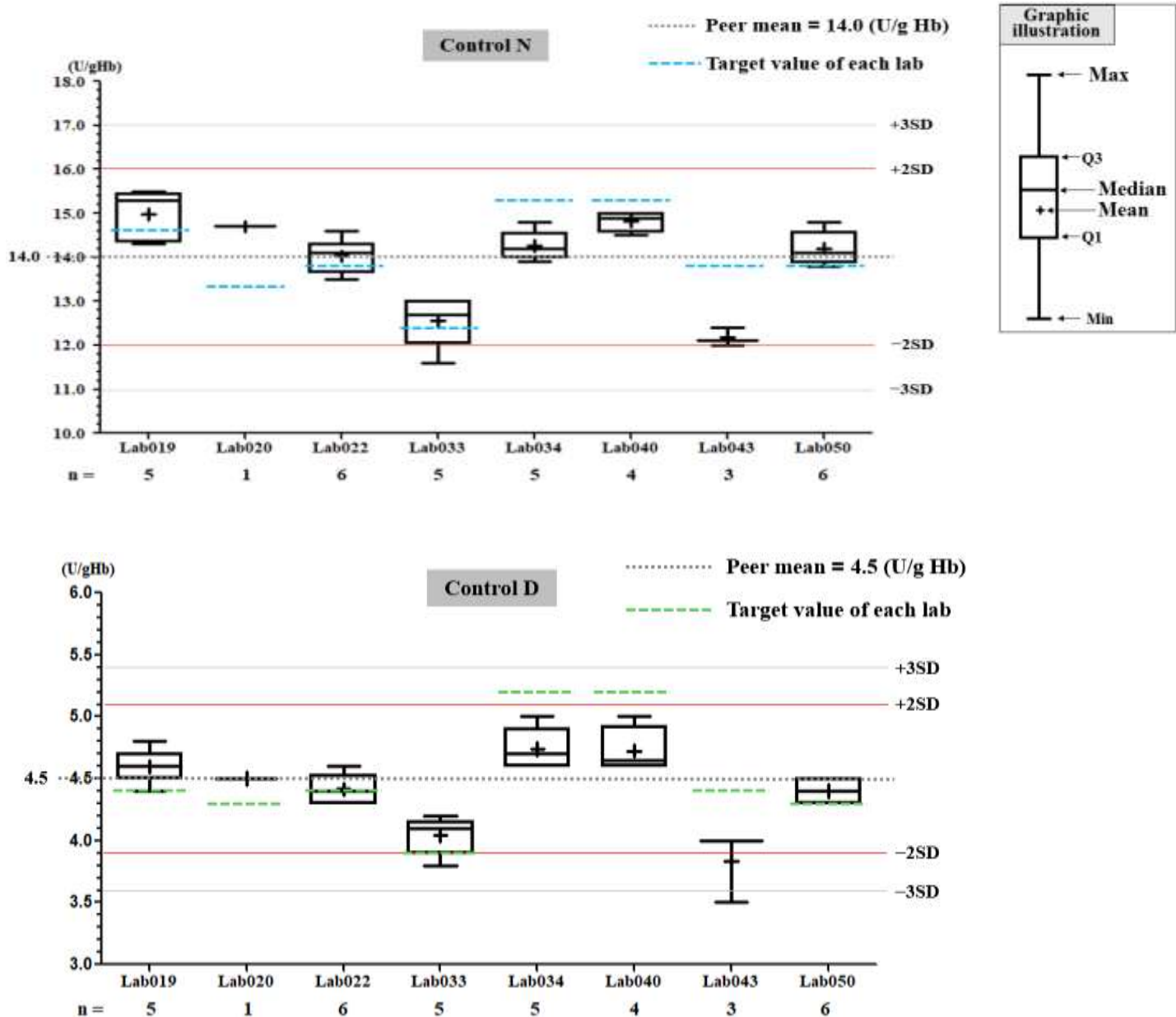
## I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	8	8
Received results number (n)	35	35
Median	14.2 (U/g Hb)	4.5 (U/g Hb)
Mean	14.0 (U/g Hb)	4.4 (U/g Hb)
SD	1.0	0.3
CV	7.1%	6.8%
Range of G6PD	11.6 ~ 15.5 (U/g Hb)	3.5 ~ 5.0 (U/g Hb)
Range of Hb	2.0 ~ 2.5 (g/dL)	2.0 ~ 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)

## Lab020

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/09)	CUM (2021/01/14~2021/09/30)	Month (2021/09)	CUM (2021/01/14~2021/09/30)
Runs (N)	1	26	1	26
Mean (U/gHb)	14.7	14.3	4.5	4.5
SD	-	0.7	-	0.1
CV (%)	-	4.9	-	2.2
Target Value (U/gHb)	13.3	13.3	4.3	4.3
Total Error (%)	-	17.3	-	9.1
TEa (%)	20	20	20	20
$\sigma$	-	2.5	-	>6

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

Month :    ; Cumulative : from    to

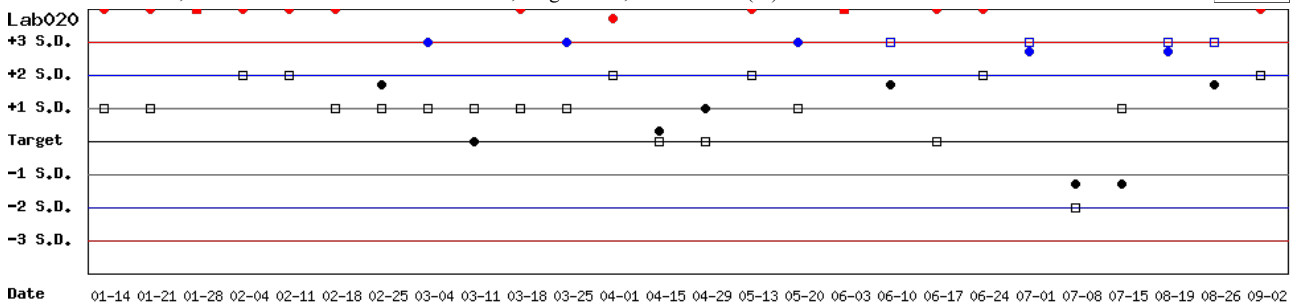
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## Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-01-14 to 2021-09-30 ; Target : 13.3 ; SD : 0.30 (●)

Lot No.: AH1220D ; Duration : 2021-01-14 to 2021-09-30 ; Target : 4.3 ; SD : 0.10 (□)

Lab020



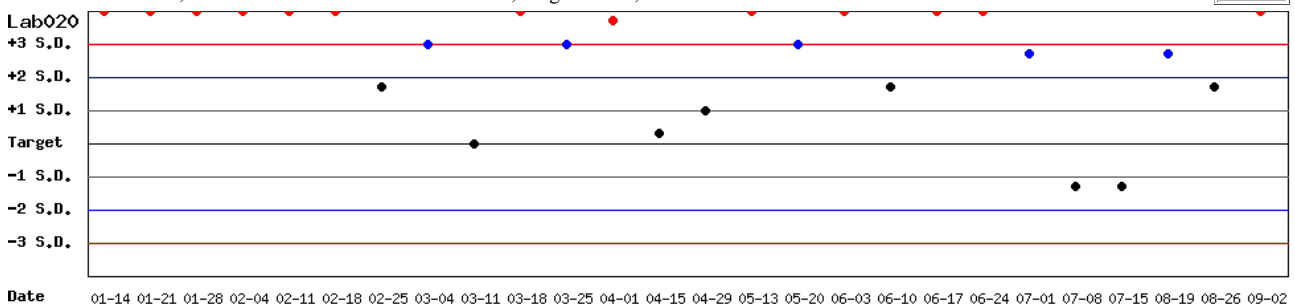
Month :    ; Cumulative : from    to

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## Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-01-14 to 2021-09-30 ; Target : 13.3 ; SD : 0.30

Lab020



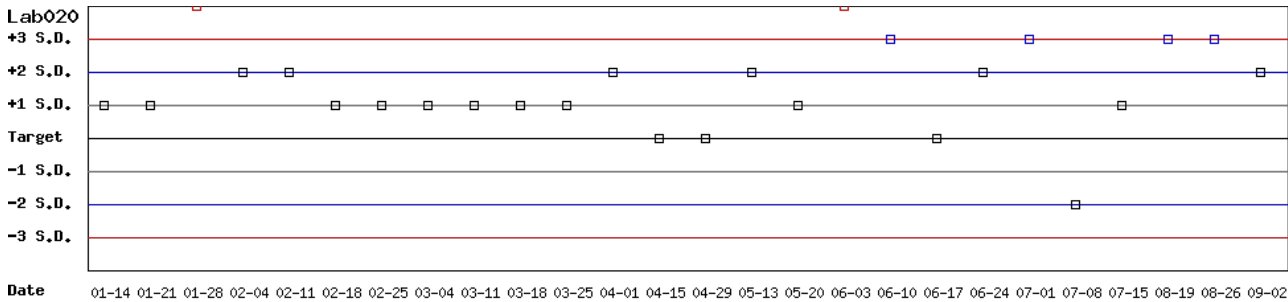
Month :    ; Cumulative : from    to

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# Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2021-01-14 to 2021-09-30 ; Target : 4.3 ; SD : 0.10

Lab020



Month :    ; Cumulative : from    to

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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 : 2021

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
<a href="#">Lab019</a>	5	14.6	15.0	5	0.6	4.0	10.7	20	4.3	4.4	4.6	5	0.1	2.2	8.9	20	>6
<a href="#">Lab020</a>	5	13.3	14.7	1	-	-	-	20	-	4.3	4.5	1	-	-	-	20	-
<a href="#">Lab022</a>	5	13.8	14.0	6	0.4	2.9	7.2	20	>6	4.4	4.4	6	0.1	2.3	4.5	20	>6
<a href="#">Lab033</a>	5	12.4	12.6	5	0.6	4.8	11.1	20	3.8	3.9	4.0	5	0.2	5.0	12.6	20	3.5
<a href="#">Lab034</a>	5	15.3	14.3	5	0.3	2.1	10.7	20	>6	5.2	4.7	5	0.2	4.3	18.1	20	2.4
<a href="#">Lab040</a>	5	15.3	14.8	4	0.2	1.4	6.0	20	>6	5.2	4.7	4	0.2	4.3	18.1	20	2.4
<a href="#">Lab043</a>	5	13.8	12.2	3	0.2	1.6	14.9	20	5.3	4.4	3.8	3	0.3	7.9	29.4	20	0.8
<a href="#">Lab050</a>	5	13.8	14.2	6	0.4	2.8	8.5	20	>6	4.3	4.4	6	0.1	2.3	6.9	20	>6
Total	-	-	14.0	35	1.0	7.1	-	-	-	-	4.4	35	0.3	6.8	-	-	-

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   to 2021

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
<a href="#">Lab019</a>	5	14.6	14.7	58	0.4	2.7	6.1	20	>6	4.4	4.5	58	0.1	2.2	6.7	20	>6
<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	12.8	76	0.9	7.0	21.3	20	1.8	4.4	4.1	76	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	126	0.4	3.2	7.2	20	6.0	3.9	3.9	126	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	15.3	14.5	65	1.0	6.9	19.0	20	2.1	5.2	4.6	65	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	51	0.5	3.6	8.6	20	5.2	4.3	4.4	51	0.2	4.5	11.4	20	3.9
Total	-	-	13.7	791	1.3	9.5	-	-	-	-	4.3	791	0.4	9.3	-	-	-

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 (2021/09)								CUM (2019/02/01~2021/09/30)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	15.0	5	0.6	4.0	10.7	20	4.3	14.6	14.7	58	0.4	2.7	6.1	20	>6
<a href="#">Lab020</a>	5	13.3	14.7	1	-	-	-	20	-	13.3	14.3	65	1.0	7.0	21.5	20	1.8
<a href="#">Lab022</a>	5	13.8	14.0	6	0.4	2.9	7.2	20	>6	13.8	12.8	76	0.9	7.0	21.3	20	1.8
<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	0.6	4.8	11.1	20	3.8	12.4	12.5	126	0.4	3.2	7.2	20	6.0
<a href="#">Lab034</a>	5	15.3	14.3	5	0.3	2.1	10.7	20	>6	15.3	14.5	65	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	14.8	4	0.2	1.4	6.0	20	>6	15.3	15.0	19	0.4	2.7	7.3	20	>6
<a href="#">Lab043</a>	5	13.8	12.2	3	0.2	1.6	14.9	20	5.3	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	14.2	6	0.4	2.8	8.5	20	>6	13.8	14.0	51	0.5	3.6	8.6	20	5.2
Total	-	-	14.0	35	1.0	7.1	-	-	-	-	13.7	791	1.3	9.5	-	-	-

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

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

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

Month : 2021 09 Change

Cumulative : from 2019 02 01 to 2021 09 30 Change

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### Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2021/09)								CUM (2019/02/01~2021/09/30)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	4.6	5	0.1	2.2	8.9	20	>6	4.4	4.5	58	0.1	2.2	6.7	20	>6
<a href="#">Lab020</a>	5	4.3	4.5	1	-	-	-	20	-	4.3	4.5	65	0.2	4.4	13.5	20	3.5
<a href="#">Lab022</a>	5	4.4	4.4	6	0.1	2.3	4.5	20	>6	4.4	4.1	76	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	4.0	5	0.2	5.0	12.6	20	3.5	3.9	3.9	126	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	5.2	4.7	5	0.2	4.3	18.1	20	2.4	5.2	4.6	65	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	4.7	4	0.2	4.3	18.1	20	2.4	5.2	5.3	19	0.5	9.4	20.8	20	1.9
<a href="#">Lab043</a>	5	4.4	3.8	3	0.3	7.9	29.4	20	0.8	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	6	0.1	2.3	6.9	20	>6	4.3	4.4	51	0.2	4.5	11.4	20	3.9
Total	-	-	4.4	35	0.3	6.8	-	-	-	-	4.3	791	0.4	9.3	-	-	-

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

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

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

Month : 2021 09 Change

Cumulative : from 2019 02 01 to 2021 09 30 Change

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Reagent Kit	Reagent Code
Medicon	5