

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

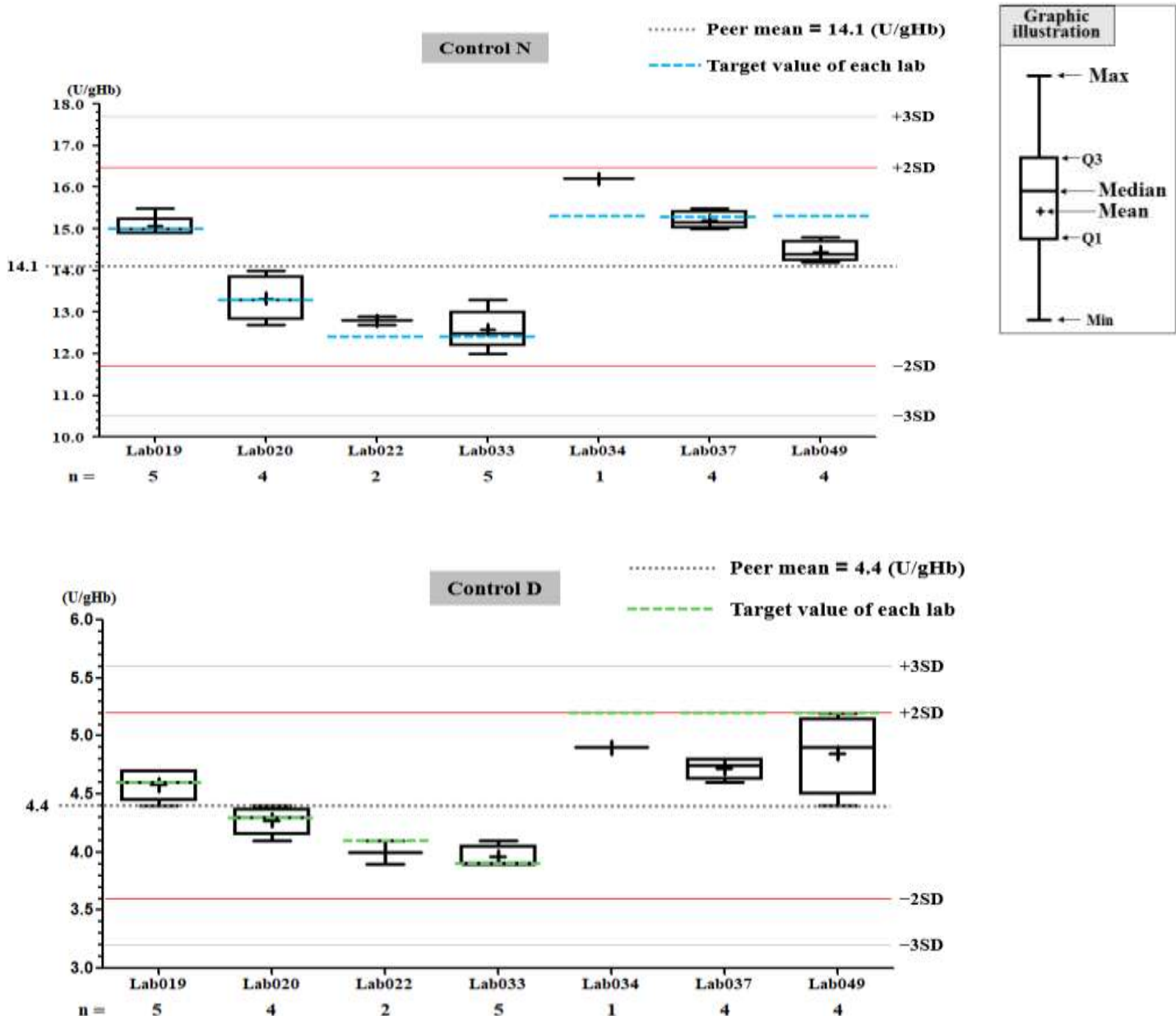
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	7	7
Received results number (n)	25	25
Median	14.4 (U/gHb)	4.4 (U/gHb)
Mean	14.1 (U/gHb)	4.4 (U/gHb)
SD	1.2	0.4
CV	8.5%	9.1%
Range of G6PD	12.0 ~ 16.2 (U/gHb)	3.9 ~ 5.2 (U/gHb)
Range of Hb	1.9 ~ 2.4 (g/dL)	2.0 ~ 2.5 (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) Change

Print Table

Lab020

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2020/07)	CUM (2019/06/18~2020/07/31)	Month (2020/07)	CUM (2019/06/18~2020/07/31)
Runs (N)	4	23	4	23
Mean (U/gHb)	13.3	14.7	4.3	4.6
SD	0.5	1.1	0.1	0.3
CV (%)	3.8	7.5	2.3	6.5
Target Value (U/gHb)	13.3	13.3	4.3	4.3
Total Error (%)	7.5	25.5	4.7	20.0
TEa (%)	20	20	20	20
σ	5.3	1.3	>6	2.0

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

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

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

Month : 2020 07 Change ; Cumulative : from 2019 06 18 to 2020 07 31 Change

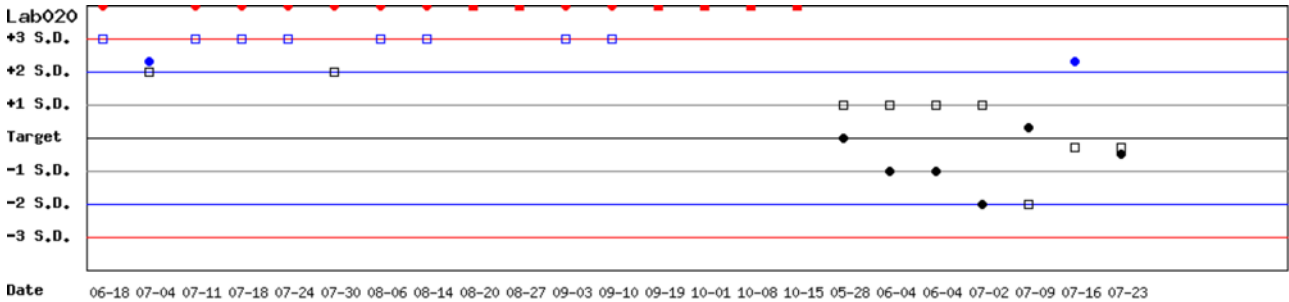
[TOP](#)

Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-06-18 to 2020-07-31 ; Target : 13.3 ; SD : 0.30 (●)

Lot No.: AH1220D ; Duration : 2019-06-18 to 2020-07-31 ; Target : 4.3 ; SD : 0.10 (□)

Lab020



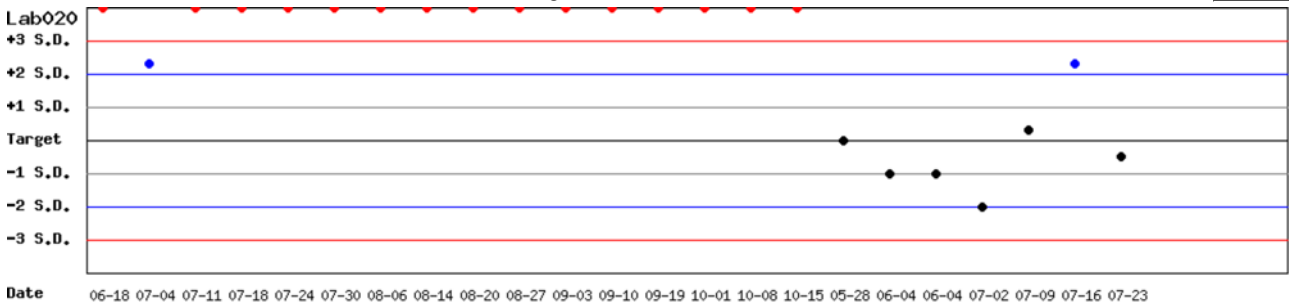
Month : 2020 07 Change ; Cumulative : from 2019 06 18 to 2020 07 31 Change

[TOP](#)

Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-06-18 to 2020-07-31 ; Target : 13.3 ; SD : 0.30

Lab020



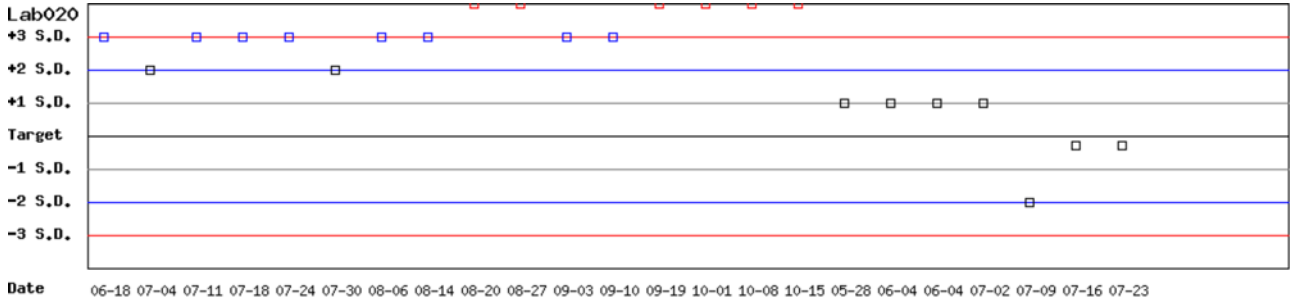
Month : 2020 07 Change ; Cumulative : from 2019 06 18 to 2020 07 31 Change

[TOP](#)

Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2019-06-18 to 2020-07-31 ; Target : 4.3 ; SD : 0.10

Lab020



Month : 2020 07 ; Cumulative : from 2019 06 18 to 2020 07 31

[\[TOP\]](#)

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 : 2020 07 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
Lab019	5	15.0	15.1	5	0.3	2.0	4.6	20	>6	4.6	4.6	5	0.1	2.2	4.3	20	>6
Lab020	5	13.3	13.3	4	0.5	3.8	7.5	20	5.3	4.3	4.3	4	0.1	2.3	4.7	20	>6
Lab022	5	12.4	12.8	2	-	-	-	20	-	4.1	4.0	2	-	-	-	20	-
Lab033	5	12.4	12.6	5	0.5	4.0	9.5	20	4.6	3.9	4.0	5	0.1	2.5	7.6	20	>6
Lab034	5	15.3	16.2	1	-	-	-	20	-	5.2	4.9	1	-	-	-	20	-
Lab037	5	15.3	15.2	4	0.2	1.3	3.3	20	>6	5.2	4.7	4	0.1	2.1	13.9	20	4.9
Lab049	5	15.3	14.5	4	0.3	2.1	9.4	20	>6	5.2	4.9	4	0.3	6.1	18.0	20	2.3
Total	-	-	14.1	25	1.2	8.5	-	-	-	-	4.4	25	0.4	9.1	-	-	-

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

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

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

[TOP](#)

Cumulative

Cumulative : from 2019 02 01 to 2020 07 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
Lab019	5	15.0	15.1	5	0.3	2.0	4.6	20	>6	4.6	4.6	5	0.1	2.2	4.3	20	>6
Lab020	5	13.3	14.7	23	1.1	7.5	25.5	20	1.3	4.3	4.6	23	0.3	6.5	20.0	20	2.0
Lab022	5	12.4	12.2	47	0.5	4.1	9.8	20	4.5	4.1	4.0	47	0.2	5.0	12.4	20	3.5
Lab032	5	15.3	14.1	71	0.6	4.3	16.4	20	2.8	5.2	4.4	71	0.4	9.1	33.6	20	0.5
Lab033	5	12.4	12.5	65	0.4	3.2	7.2	20	6.0	3.9	3.9	65	0.1	2.6	5.1	20	>6
Lab034	5	15.3	16.2	1	-	-	-	20	-	5.2	4.9	1	-	-	-	20	-
Lab037	5	15.3	15.3	24	0.4	2.6	5.2	20	>6	5.2	4.7	24	0.2	4.3	18.1	20	2.4
Lab049	5	15.3	14.5	4	0.3	2.1	9.4	20	>6	5.2	4.9	4	0.3	6.1	18.0	20	2.3
Total	-	-	13.5	240	1.3	9.6	-	-	-	-	4.2	240	0.4	9.5	-	-	-

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

TE : Total Error(%) = Bias (%) + 2 x 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 (2020/07)								CUM (2019/02/01~2020/07/31)							
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
Lab019	5	15.0	15.1	5	0.3	2.0	4.6	20	>6	15.0	15.1	5	0.3	2.0	4.6	20	>6
Lab020	5	13.3	13.3	4	0.5	3.8	7.5	20	5.3	13.3	14.7	23	1.1	7.5	25.5	20	1.3
Lab022	5	12.4	12.8	2	-	-	-	20	-	12.4	12.2	47	0.5	4.1	9.8	20	4.5
Lab032	5	15.3	-	0	-	-	-	20	-	15.3	14.1	71	0.6	4.3	16.4	20	2.8
Lab033	5	12.4	12.6	5	0.5	4.0	9.5	20	4.6	12.4	12.5	65	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	16.2	1	-	-	-	20	-	15.3	16.2	1	-	-	-	20	-
Lab037	5	15.3	15.2	4	0.2	1.3	3.3	20	>6	15.3	15.3	24	0.4	2.6	5.2	20	>6
Lab049	5	15.3	14.5	4	0.3	2.1	9.4	20	>6	15.3	14.5	4	0.3	2.1	9.4	20	>6
Total	-	-	14.1	25	1.2	8.5	-	-	-	-	13.5	240	1.3	9.6	-	-	-

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

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

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

Month : 2020 07 Change

Cumulative : from 2019 02 01 to 2020 07 31 Change

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2020/07)								CUM (2019/02/01~2020/07/31)							
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
Lab019	5	4.6	4.6	5	0.1	2.2	4.3	20	>6	4.6	4.6	5	0.1	2.2	4.3	20	>6
Lab020	5	4.3	4.3	4	0.1	2.3	4.7	20	>6	4.3	4.6	23	0.3	6.5	20.0	20	2.0
Lab022	5	4.1	4.0	2	-	-	-	20	-	4.1	4.0	47	0.2	5.0	12.4	20	3.5
Lab032	5	5.2	-	0	-	-	-	20	-	5.2	4.4	71	0.4	9.1	33.6	20	0.5
Lab033	5	3.9	4.0	5	0.1	2.5	7.6	20	>6	3.9	3.9	65	0.1	2.6	5.1	20	>6
Lab034	5	5.2	4.9	1	-	-	-	20	-	5.2	4.9	1	-	-	-	20	-
Lab037	5	5.2	4.7	4	0.1	2.1	13.9	20	4.9	5.2	4.7	24	0.2	4.3	18.1	20	2.4
Lab049	5	5.2	4.9	4	0.3	6.1	18.0	20	2.3	5.2	4.9	4	0.3	6.1	18.0	20	2.3
Total	-	-	4.4	25	0.4	9.1	-	-	-	-	4.2	240	0.4	9.5	-	-	-

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

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

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

Month : 2020 07 Change

Cumulative : from 2019 02 01 to 2020 07 31 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5