

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

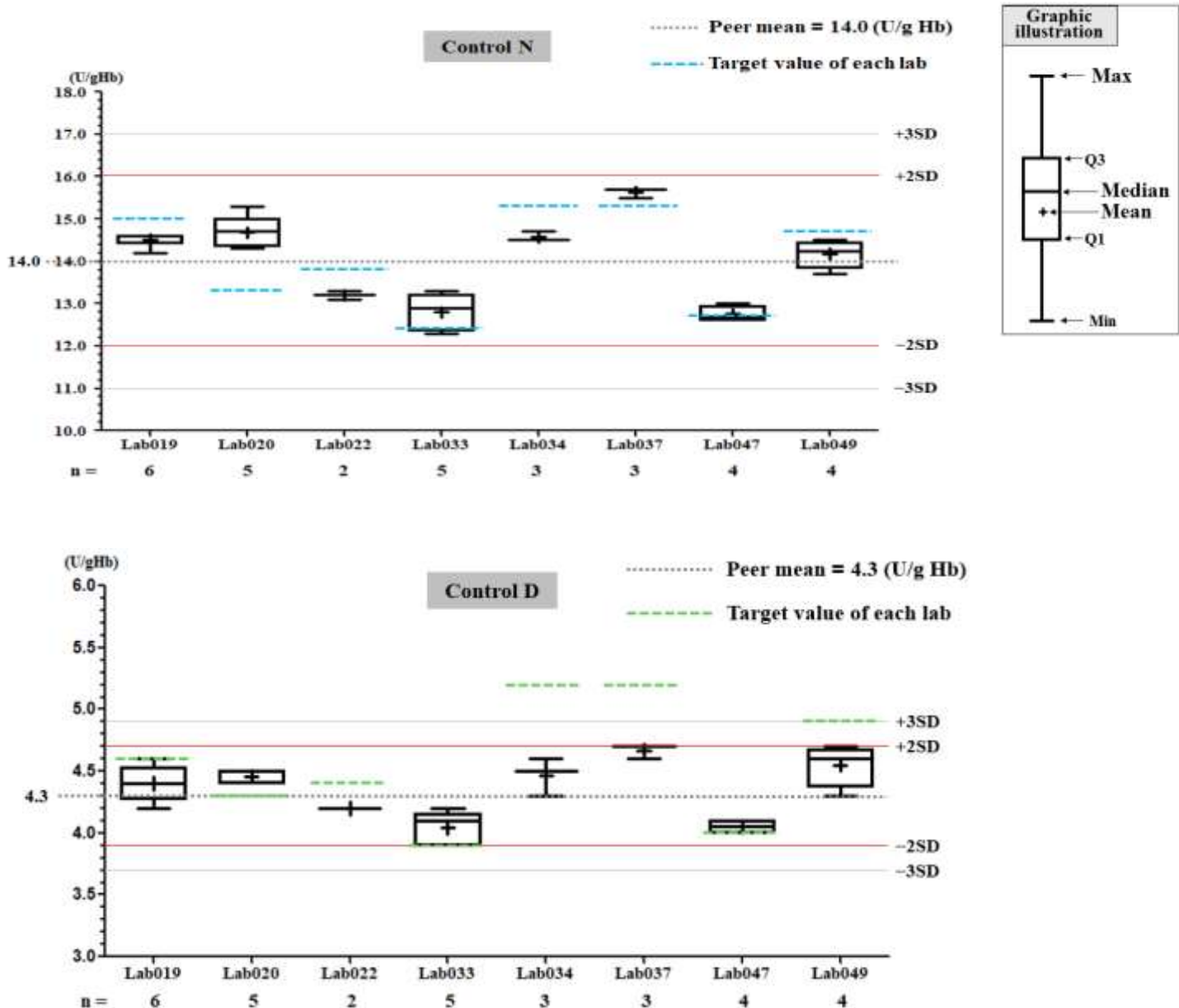
I. The statistic results of all laboratories in this month

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)

Lab020

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2020/12)	CUM (2019/09/19~2020/12/31)	Month (2020/12)	CUM (2019/09/19~2020/12/31)
Runs (N)	5	26	5	26
Mean (U/gHb)	14.7	14.0	4.5	4.4
SD	0.4	1.1	0.1	0.3
CV (%)	2.7	7.9	2.2	6.8
Target Value (U/gHb)	13.3	13.3	4.3	4.3
Total Error (%)	16.0	21.0	9.1	16.0
TEa (%)	20	20	20	20
σ	3.5	1.9	>6	2.6

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

Month : 2020 12 ; Cumulative : from 2019 09 19 to 2020 12 31

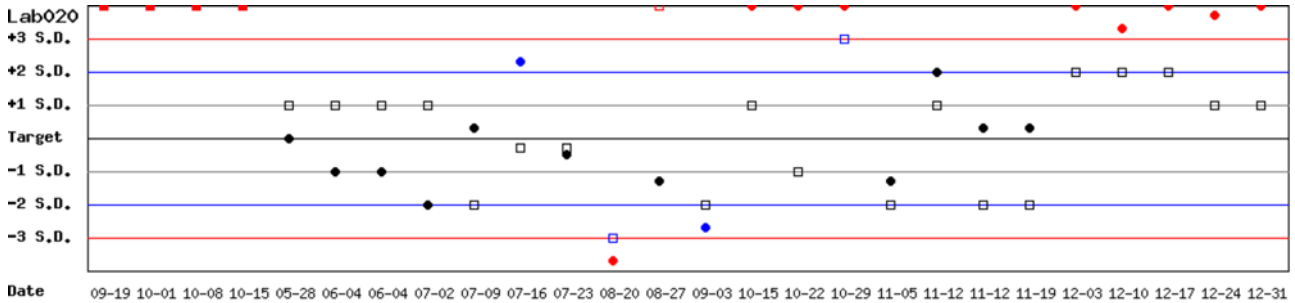
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-09-19 to 2020-12-31 ; Target : 13.3 ; SD : 0.30 (●)

Lot No.: AH1220D ; Duration : 2019-09-19 to 2020-12-31 ; Target : 4.3 ; SD : 0.10 (□)

Lab020



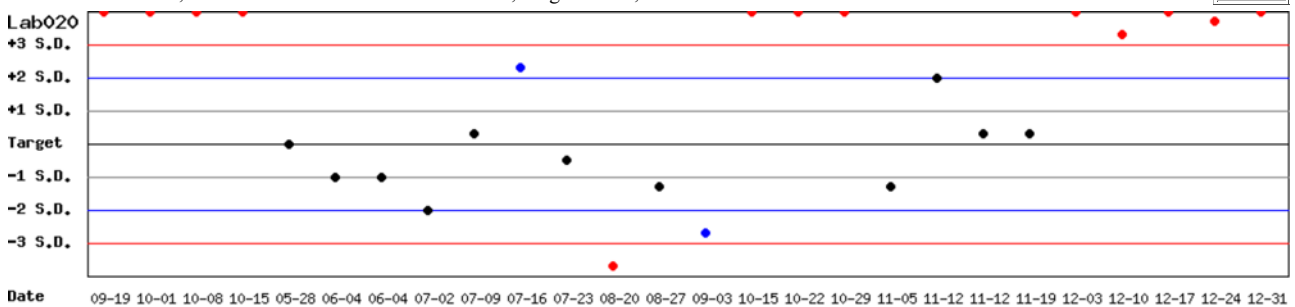
Month : 2020 12 ; Cumulative : from 2019 09 19 to 2020 12 31

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-09-19 to 2020-12-31 ; Target : 13.3 ; SD : 0.30

Lab020



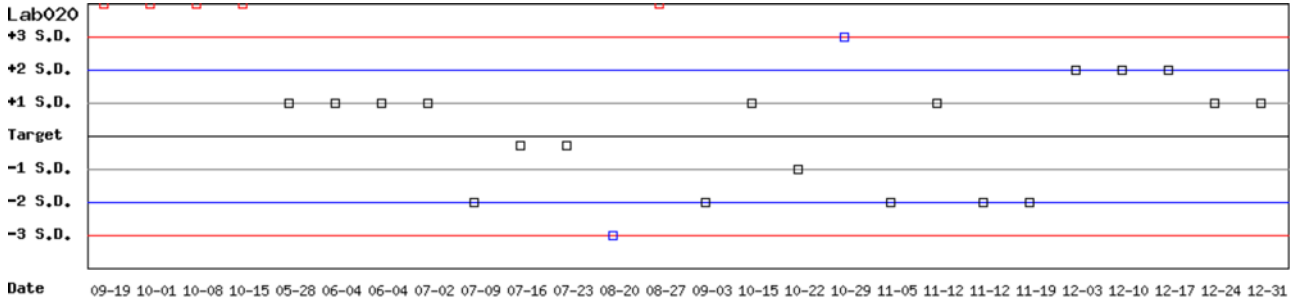
Month : 2020 12 ; Cumulative : from 2019 09 19 to 2020 12 31

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2019-09-19 to 2020-12-31 ; Target : 4.3 ; SD : 0.10

Lab020



Month : 2020 ▾ 12 ▾ Change ; Cumulative : from 2019 ▾ 09 ▾ 19 ▾ to 2020 ▾ 12 ▾ 31 ▾ Change

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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
Lab019	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
Lab020	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
Lab022	5	13.8	13.2	2	-	-	-	20	-	4.4	4.2	2	-	-	-	20	-
Lab033	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
Lab034	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
Lab037	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
Lab047	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
Lab049	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
Lab019	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
Lab020	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
Lab022	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
Lab028	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
Lab032	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
Lab033	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
Lab034	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
Lab037	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
Lab040	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
Lab047	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
Lab049	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
Lab050	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
Lab019	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
Lab020	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
Lab022	5	13.8	13.2	2	-	-	-	20	-	13.8	12.3	52	0.6	4.9	20.6	20	1.9
Lab028	5	14.6	-	0	-	-	-	20	-	14.6	14.6	22	0.4	2.7	5.5	20	>6
Lab032	5	12.1	-	0	-	-	-	20	-	12.1	13.2	104	1.5	11.4	31.8	20	1.0
Lab033	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
Lab034	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
Lab037	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
Lab040	5	15.3	-	0	-	-	-	20	-	15.3	15.1	10	0.5	3.3	7.9	20	5.7
Lab047	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
Lab049	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
Lab050	5	15.3	-	0	-	-	-	20	-	15.3	14.6	6	0.8	5.5	15.5	20	2.8
Total	-	-	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
Lab019	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
Lab020	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
Lab022	5	4.4	4.2	2	-	-	-	20	-	4.4	4.0	52	0.2	5.0	19.1	20	2.2
Lab028	5	4.6	-	0	-	-	-	20	-	4.6	4.6	22	0.1	2.2	4.3	20	>6
Lab032	5	3.5	-	0	-	-	-	20	-	3.5	4.1	104	0.6	14.6	46.4	20	0.2
Lab033	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
Lab034	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
Lab037	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
Lab040	5	5.2	-	0	-	-	-	20	-	5.2	5.6	10	0.4	7.1	22.0	20	1.7
Lab047	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
Lab049	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
Lab050	5	5.2	-	0	-	-	-	20	-	5.2	4.4	6	0.5	11.4	38.1	20	0.4
Total	-	-	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