

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

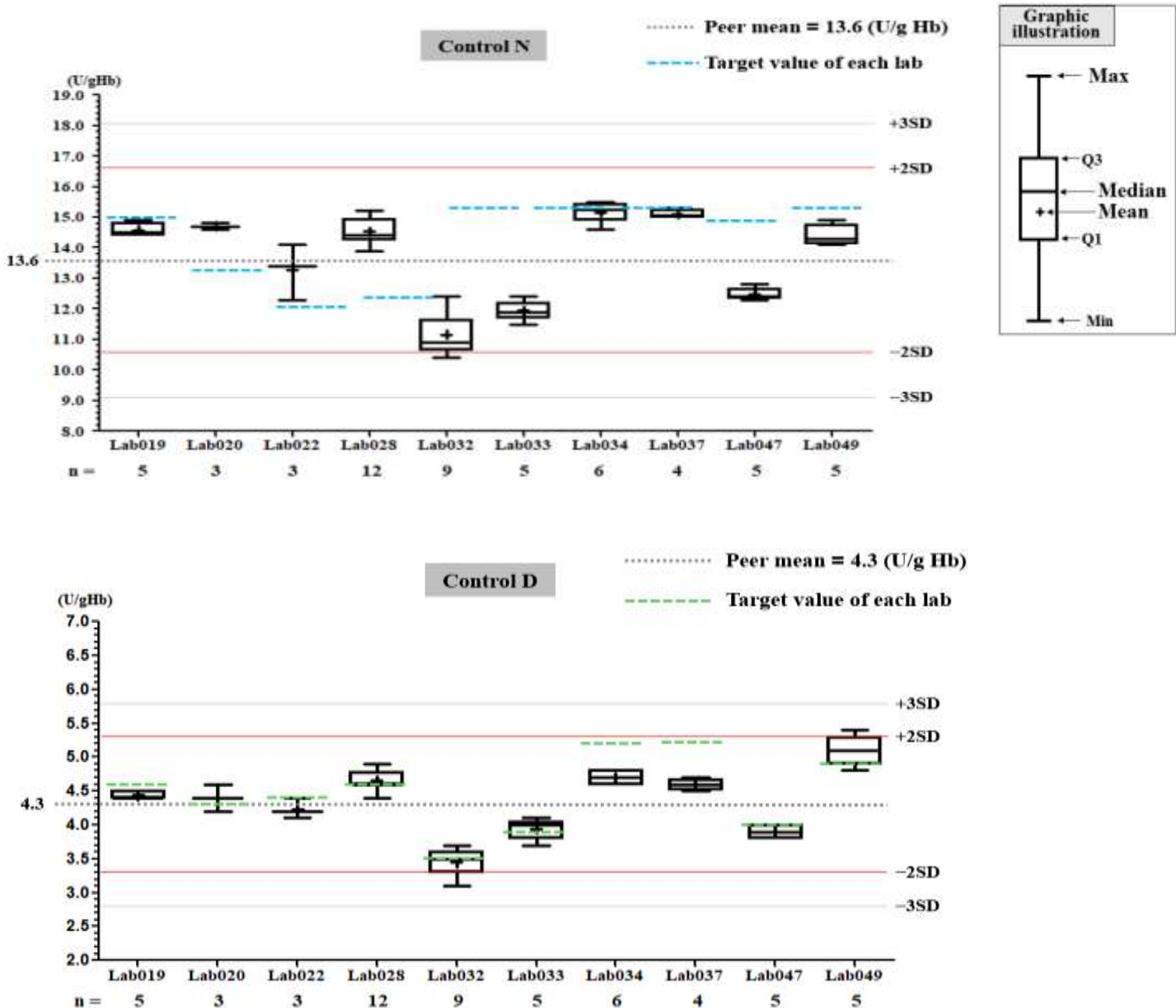
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	10	10
Received results number (n)	57	57
Median	14.4 (U/gHb)	4.5 (U/gHb)
Mean	13.6 (U/gHb)	4.3 (U/gHb)
SD	1.5	0.5
CV	11.0%	11.6%
Range of G6PD	10.4 ~ 15.5 (U/gHb)	3.1 ~ 5.4 (U/gHb)
Range of Hb	1.9 ~ 2.5 (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

	Control N		Control D	
QC Control Lot No.	AH1220N		AH1220D	
Duration of the Analyzing	Month (2020/10)	CUM (2019/07/18~2020/10/31)	Month (2020/10)	CUM (2019/07/18~2020/10/31)
Runs (N)	3	26	3	26
Mean (U/gHb)	14.7	14.4	4.4	4.5
SD	0.1	1.2	0.2	0.3
CV (%)	0.7	8.3	4.5	6.7
Target Value (U/gHb)	13.3	13.3	4.3	4.3
Total Error (%)	11.9	24.9	11.4	18.0
TEa (%)	20	20	20	20
σ	>6	1.4	3.9	2.3

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

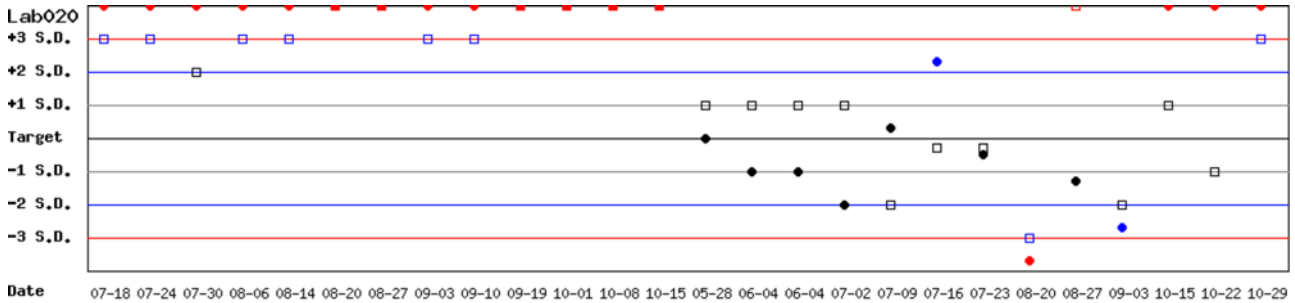
Month : 2020 10 ; Cumulative : from 2019 07 18 to 2020 10 31

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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-07-18 to 2020-10-31 ; Target : 13.3 ; SD : 0.30 (●)

Lot No.: AH1220D ; Duration : 2019-07-18 to 2020-10-31 ; Target : 4.3 ; SD : 0.10 (□)

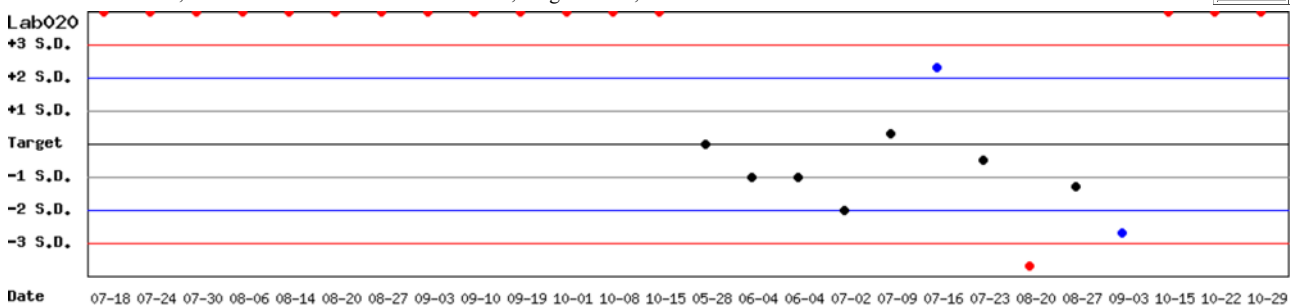


Month : 2020 10 ; Cumulative : from 2019 07 18 to 2020 10 31

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-07-18 to 2020-10-31 ; Target : 13.3 ; SD : 0.30



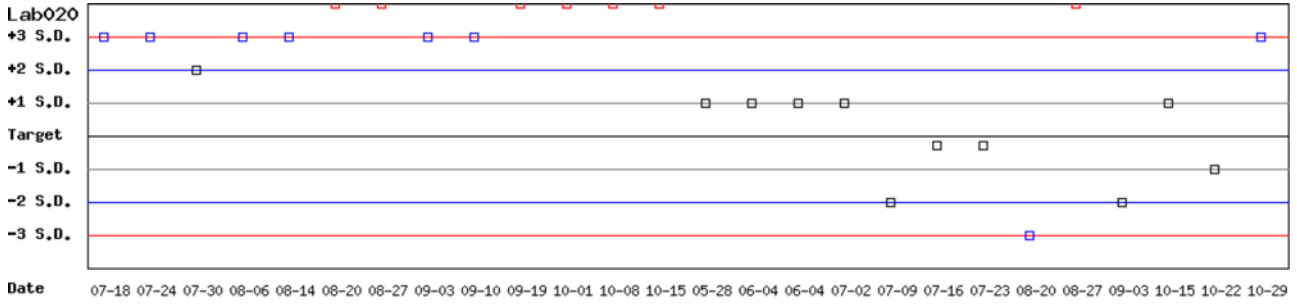
Month : 2020 10 ; Cumulative : from 2019 07 18 to 2020 10 31

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2019-07-18 to 2020-10-31 ; Target : 4.3 ; SD : 0.10

Lab020



Month : 2020 ▾ 10 ▾ ; Cumulative : from 2019 ▾ 07 ▾ 18 ▾ to 2020 ▾ 10 ▾ 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 10 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	14.6	5	0.2	1.4	5.4	20	>6	4.6	4.4	5	0.1	2.3	8.9	20	>6
Lab020	5	13.3	14.7	3	0.1	0.7	11.9	20	>6	4.3	4.4	3	0.2	4.5	11.4	20	3.9
Lab022	5	13.8	13.3	3	0.9	6.8	17.2	20	2.4	4.4	4.2	3	0.2	4.8	14.1	20	3.2
Lab028	5	14.6	14.5	12	0.4	2.8	6.2	20	>6	4.6	4.7	12	0.1	2.1	6.4	20	>6
Lab032	5	12.1	11.2	9	0.7	6.3	19.9	20	2.0	3.5	3.4	9	0.2	5.9	14.6	20	2.9
Lab033	5	12.4	11.9	5	0.3	2.5	9.1	20	>6	3.9	3.9	5	0.2	5.1	10.3	20	3.9
Lab034	5	15.3	15.2	6	0.3	2.0	4.6	20	>6	5.2	4.7	6	0.1	2.1	13.9	20	4.9
Lab037	5	15.3	15.1	4	0.1	0.7	2.6	20	>6	5.2	4.6	4	0.1	2.2	15.9	20	3.8
Lab047	5	12.7	12.5	5	0.2	1.6	4.8	20	>6	4.0	3.9	5	0.1	2.6	7.6	20	>6
Lab049	5	14.7	14.4	5	0.3	2.1	6.2	20	>6	4.9	5.1	5	0.2	3.9	11.9	20	4.1
Total	-	-	13.6	57	1.5	11.0	-	-	-	-	4.3	57	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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Cumulative

Cumulative : from 2019 02 01 to 2020 10 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	14.8	19	0.4	2.7	6.7	20	>6	4.6	4.5	19	0.1	2.2	6.6	20	>6
Lab020	5	13.3	14.5	29	1.2	8.3	25.6	20	1.3	4.3	4.5	29	0.3	6.7	18.0	20	2.3
Lab022	5	13.8	12.3	50	0.6	4.9	20.6	20	1.9	4.4	4.0	50	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	13.4	96	1.4	10.4	31.6	20	0.9	3.5	4.2	96	0.6	14.3	48.6	20	0.0
Lab033	5	12.4	12.5	78	0.4	3.2	7.2	20	6.0	3.9	3.9	78	0.1	2.6	5.1	20	>6
Lab034	5	15.3	15.4	17	0.4	2.6	5.8	20	>6	5.2	4.7	17	0.1	2.1	13.9	20	4.9
Lab037	5	15.3	15.2	34	0.3	2.0	4.6	20	>6	5.2	4.7	34	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	12.5	5	0.2	1.6	4.8	20	>6	4.0	3.9	5	0.1	2.6	7.6	20	>6
Lab049	5	14.7	14.5	13	0.3	2.1	5.5	20	>6	4.9	5.1	13	0.3	5.9	15.8	20	2.7
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	379	1.4	10.3	-	-	-	-	4.3	379	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 (2020/10)								CUM (2019/02/01~2020/10/31)							
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	14.6	5	0.2	1.4	5.4	20	>6	15.0	14.8	19	0.4	2.7	6.7	20	>6
Lab020	5	13.3	14.7	3	0.1	0.7	11.9	20	>6	13.3	14.5	29	1.2	8.3	25.6	20	1.3
Lab022	5	13.8	13.3	3	0.9	6.8	17.2	20	2.4	13.8	12.3	50	0.6	4.9	20.6	20	1.9
Lab028	5	14.6	14.5	12	0.4	2.8	6.2	20	>6	14.6	14.6	22	0.4	2.7	5.5	20	>6
Lab032	5	12.1	11.2	9	0.7	6.3	19.9	20	2.0	12.1	13.4	96	1.4	10.4	31.6	20	0.9
Lab033	5	12.4	11.9	5	0.3	2.5	9.1	20	>6	12.4	12.5	78	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	15.2	6	0.3	2.0	4.6	20	>6	15.3	15.4	17	0.4	2.6	5.8	20	>6
Lab037	5	15.3	15.1	4	0.1	0.7	2.6	20	>6	15.3	15.2	34	0.3	2.0	4.6	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	12.5	5	0.2	1.6	4.8	20	>6	12.7	12.5	5	0.2	1.6	4.8	20	>6
Lab049	5	14.7	14.4	5	0.3	2.1	6.2	20	>6	14.7	14.5	13	0.3	2.1	5.5	20	>6
Lab050	5	15.3	-	0	-	-	-	20	-	15.3	14.6	6	0.8	5.5	15.5	20	2.8
Total	-	-	13.6	57	1.5	11.0	-	-	-	-	13.6	379	1.4	10.3	-	-	-

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

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

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

Month : 2020 10 Change

Cumulative : from 2019 02 01 to 2020 10 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2020/10)								CUM (2019/02/01~2020/10/31)							
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	5	0.1	2.3	8.9	20	>6	4.6	4.5	19	0.1	2.2	6.6	20	>6
Lab020	5	4.3	4.4	3	0.2	4.5	11.4	20	3.9	4.3	4.5	29	0.3	6.7	18.0	20	2.3
Lab022	5	4.4	4.2	3	0.2	4.8	14.1	20	3.2	4.4	4.0	50	0.2	5.0	19.1	20	2.2
Lab028	5	4.6	4.7	12	0.1	2.1	6.4	20	>6	4.6	4.6	22	0.1	2.2	4.3	20	>6
Lab032	5	3.5	3.4	9	0.2	5.9	14.6	20	2.9	3.5	4.2	96	0.6	14.3	48.6	20	0.0
Lab033	5	3.9	3.9	5	0.2	5.1	10.3	20	3.9	3.9	3.9	78	0.1	2.6	5.1	20	>6
Lab034	5	5.2	4.7	6	0.1	2.1	13.9	20	4.9	5.2	4.7	17	0.1	2.1	13.9	20	4.9
Lab037	5	5.2	4.6	4	0.1	2.2	15.9	20	3.8	5.2	4.7	34	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	3.9	5	0.1	2.6	7.6	20	>6	4.0	3.9	5	0.1	2.6	7.6	20	>6
Lab049	5	4.9	5.1	5	0.2	3.9	11.9	20	4.1	4.9	5.1	13	0.3	5.9	15.8	20	2.7
Lab050	5	5.2	-	0	-	-	-	20	-	5.2	4.4	6	0.5	11.4	38.1	20	0.4
Total	-	-	4.3	57	0.5	11.6	-	-	-	-	4.3	379	0.5	11.6	-	-	-

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

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

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

Month : 2020 10 Change

Cumulative : from 2019 02 01 to 2020 10 31 Change

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Reagent Kit	Reagent Code
Medicon	5