

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

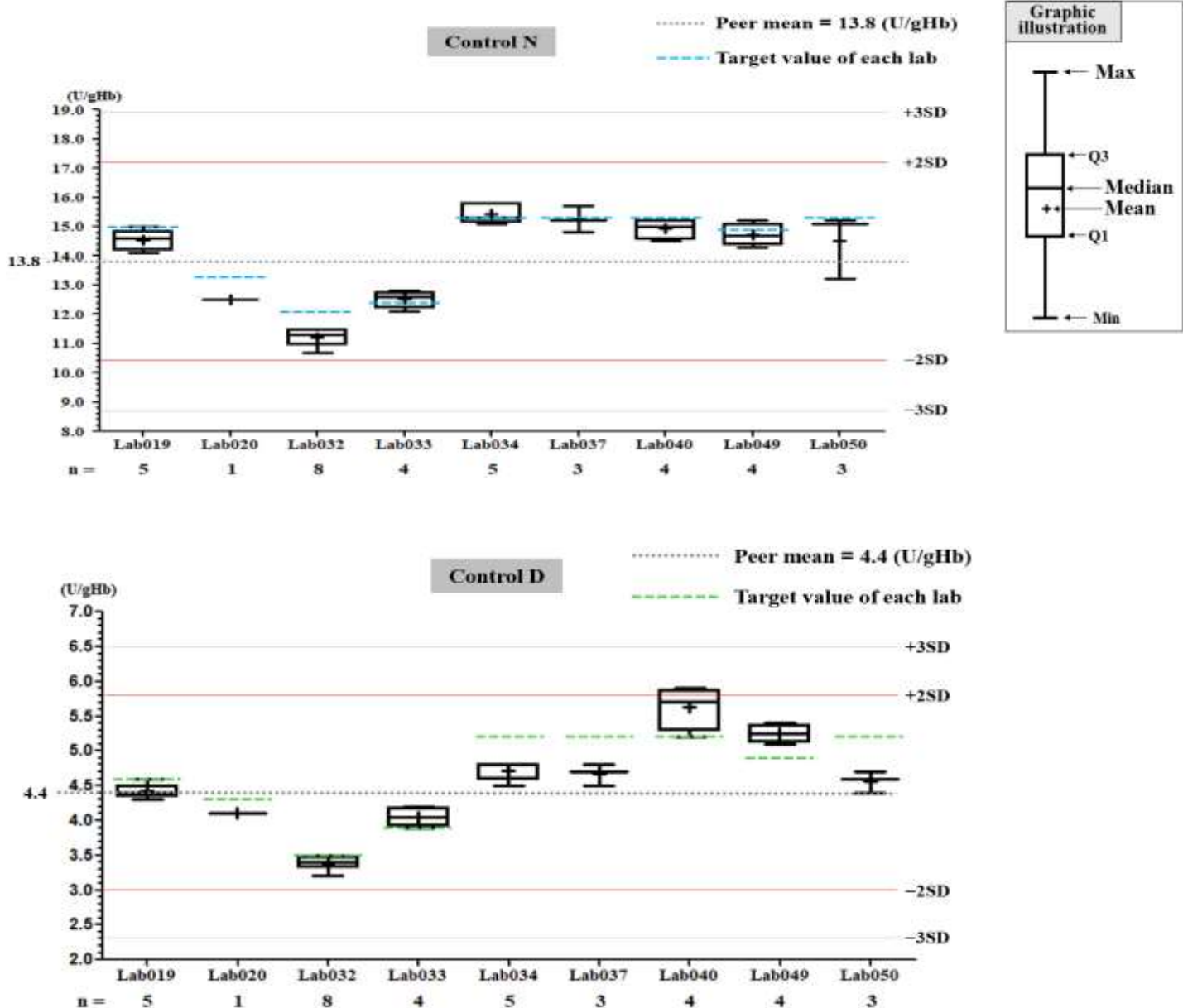
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	9	9
Received results number (n)	37	37
Median	14.6 (U/gHb)	4.5 (U/gHb)
Mean	13.8 (U/gHb)	4.4 (U/gHb)
SD	1.7	0.7
CV	10.7%	15.9%
Range of G6PD	10.7 ~ 15.8 (U/gHb)	3.2 ~ 5.9 (U/gHb)
Range of Hb	1.7 ~ 2.3 (g/dL)	2.0 ~ 2.6 (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

	Control N		Control D	
QC Control Lot No.	AH1220N		AH1220D	
Duration of the Analyzing	Month (2020/09)	CUM (2019/06/18~2020/09/30)	Month (2020/09)	CUM (2019/06/18~2020/09/30)
Runs (N)	1	26	1	26
Mean (U/gHb)	12.5	14.4	4.1	4.6
SD	-	1.3	-	0.3
CV (%)	-	9.0	-	6.5
Target Value (U/gHb)	13.3	13.3	4.3	4.3
Total Error (%)	-	26.3	-	20.0
TEa (%)	20	20	20	20
σ	-	1.3	-	2.0

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

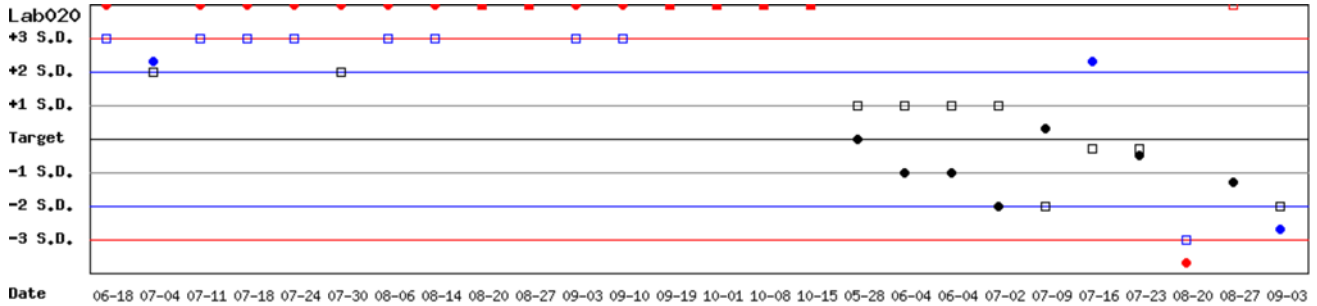
Month : 2020 ▼ 09 Change ; Cumulative : from 2019 ▼ 06 ▼ 18 ▼ to 2020 ▼ 09 ▼ 30 Change

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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-06-18 to 2020-09-30 ; Target : 13.3 ; SD : 0.30 (●)

Lot No.: AH1220D ; Duration : 2019-06-18 to 2020-09-30 ; Target : 4.3 ; SD : 0.10 (□)

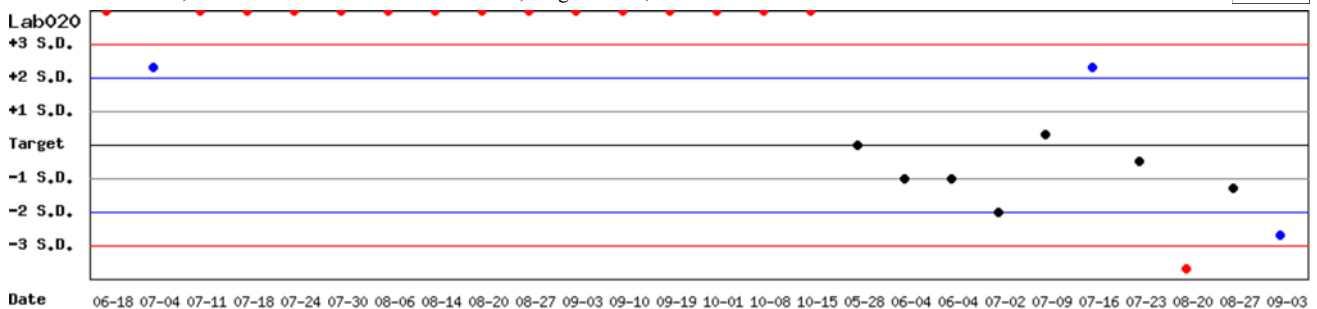


Month : 2020 ▼ 09 Change ; Cumulative : from 2019 ▼ 06 ▼ 18 ▼ to 2020 ▼ 09 ▼ 30 Change

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2019-06-18 to 2020-09-30 ; Target : 13.3 ; SD : 0.30



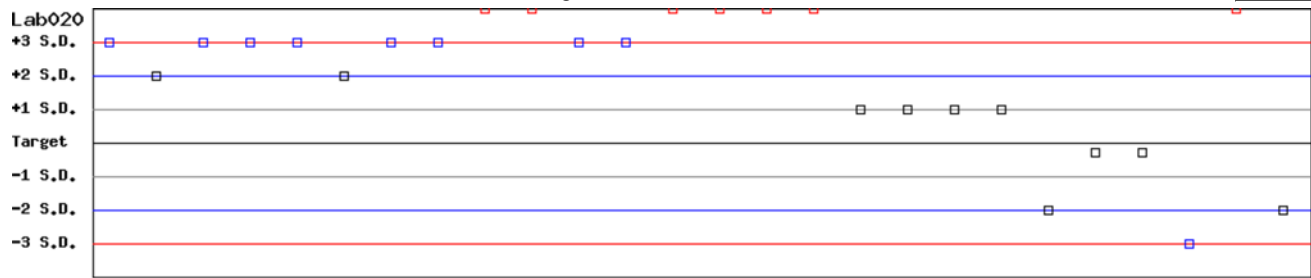
Month : 2020 ▼ 09 Change ; Cumulative : from 2019 ▼ 06 ▼ 18 ▼ to 2020 ▼ 09 ▼ 30 Change

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2019-06-18 to 2020-09-30 ; Target : 4.3 ; SD : 0.10

Lab020



Date 06-18 07-04 07-11 07-18 07-24 07-30 08-06 08-14 08-20 08-27 09-03 09-10 09-19 10-01 10-08 10-15 05-28 06-04 06-04 07-02 07-09 07-16 07-23 08-20 08-27 09-03

Month : 2020 ▾ 09 ▾ Change ; Cumulative : from 2019 ▾ 06 ▾ 18 ▾ to 2020 ▾ 09 ▾ 30 ▾ 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 09 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	5	0.4	2.8	8.9	20	6.0	4.6	4.4	5	0.1	2.3	8.9	20	>6
Lab020	5	13.3	12.5	1	-	-	-	20	-	4.3	4.1	1	-	-	-	20	-
Lab032	5	12.1	11.2	8	0.3	2.7	12.8	20	4.7	3.5	3.4	8	0.1	2.9	8.7	20	5.9
Lab033	5	12.4	12.5	4	0.3	2.4	5.6	20	>6	3.9	4.1	4	0.1	2.4	10.0	20	>6
Lab034	5	15.3	15.4	5	0.3	1.9	4.5	20	>6	5.2	4.7	5	0.1	2.1	13.9	20	4.9
Lab037	5	15.3	15.2	3	0.5	3.3	7.2	20	5.9	5.2	4.7	3	0.2	4.3	18.1	20	2.4
Lab040	5	15.3	14.9	4	0.3	2.0	6.6	20	>6	5.2	5.6	4	0.3	5.4	18.4	20	2.3
Lab049	5	14.9	14.7	4	0.4	2.7	6.8	20	>6	4.9	5.3	4	0.1	1.9	11.9	20	>6
Lab050	5	15.3	14.5	3	1.1	7.6	20.4	20	1.9	5.2	4.6	3	0.2	4.3	20.2	20	2.0
Total	-	-	13.8	37	1.7	12.3	-	-	-	-	4.4	37	0.7	15.9	-	-	-

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

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

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

[TOP](#)

Cumulative

Cumulative : from 2019 02 01 to 2020 09 30 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	14	0.4	2.7	6.7	20	>6	4.6	4.5	14	0.1	2.2	6.6	20	>6
Lab020	5	13.3	14.4	26	1.3	9.0	26.3	20	1.3	4.3	4.6	26	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
Lab028	5	14.6	14.7	10	0.4	2.7	6.1	20	>6	4.6	4.6	10	0.1	2.2	4.3	20	>6
Lab032	5	12.1	13.6	87	1.2	8.8	30.0	20	0.9	3.5	4.2	87	0.5	11.9	43.8	20	0.0
Lab033	5	12.4	12.5	73	0.4	3.2	7.2	20	6.0	3.9	3.9	73	0.1	2.6	5.1	20	>6
Lab034	5	15.3	15.5	11	0.3	1.9	5.2	20	>6	5.2	4.7	11	0.2	4.3	18.1	20	2.4
Lab037	5	15.3	15.2	30	0.4	2.6	5.9	20	>6	5.2	4.7	30	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
Lab049	5	14.9	14.6	8	0.3	2.1	6.1	20	>6	4.9	5.1	8	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	322	1.4	10.3	-	-	-	-	4.3	322	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 (2020/09)								CUM (2019/02/01~2020/09/30)							
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	5	0.4	2.8	8.9	20	6.0	15.0	14.8	14	0.4	2.7	6.7	20	>6
Lab020	5	13.3	12.5	1	-	-	-	20	-	13.3	14.4	26	1.3	9.0	26.3	20	1.3
Lab022	5	12.4	-	0	-	-	-	20	-	12.4	12.2	47	0.5	4.1	9.8	20	4.5
Lab028	5	14.6	-	0	-	-	-	20	-	14.6	14.7	10	0.4	2.7	6.1	20	>6
Lab032	5	12.1	11.2	8	0.3	2.7	12.8	20	4.7	12.1	13.6	87	1.2	8.8	30.0	20	0.9
Lab033	5	12.4	12.5	4	0.3	2.4	5.6	20	>6	12.4	12.5	73	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	15.4	5	0.3	1.9	4.5	20	>6	15.3	15.5	11	0.3	1.9	5.2	20	>6
Lab037	5	15.3	15.2	3	0.5	3.3	7.2	20	5.9	15.3	15.2	30	0.4	2.6	5.9	20	>6
Lab040	5	15.3	14.9	4	0.3	2.0	6.6	20	>6	15.3	15.1	10	0.5	3.3	7.9	20	5.7
Lab049	5	14.9	14.7	4	0.4	2.7	6.8	20	>6	14.9	14.6	8	0.3	2.1	6.1	20	>6
Lab050	5	15.3	14.5	3	1.1	7.6	20.4	20	1.9	15.3	14.6	6	0.8	5.5	15.5	20	2.8
Total	-	-	13.8	37	1.7	12.3	-	-	-	-	13.6	322	1.4	10.3	-	-	-

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

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

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

Month : 2020 09 Change

Cumulative : from 2019 02 01 to 2020 09 30 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2020/09)								CUM (2019/02/01~2020/09/30)							
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	14	0.1	2.2	6.6	20	>6
Lab020	5	4.3	4.1	1	-	-	-	20	-	4.3	4.6	26	0.3	6.5	20.0	20	2.0
Lab022	5	4.1	-	0	-	-	-	20	-	4.1	4.0	47	0.2	5.0	12.4	20	3.5
Lab028	5	4.6	-	0	-	-	-	20	-	4.6	4.6	10	0.1	2.2	4.3	20	>6
Lab032	5	3.5	3.4	8	0.1	2.9	8.7	20	5.9	3.5	4.2	87	0.5	11.9	43.8	20	0.0
Lab033	5	3.9	4.1	4	0.1	2.4	10.0	20	>6	3.9	3.9	73	0.1	2.6	5.1	20	>6
Lab034	5	5.2	4.7	5	0.1	2.1	13.9	20	4.9	5.2	4.7	11	0.2	4.3	18.1	20	2.4
Lab037	5	5.2	4.7	3	0.2	4.3	18.1	20	2.4	5.2	4.7	30	0.2	4.3	18.1	20	2.4
Lab040	5	5.2	5.6	4	0.3	5.4	18.4	20	2.3	5.2	5.6	10	0.4	7.1	22.0	20	1.7
Lab049	5	4.9	5.3	4	0.1	1.9	11.9	20	>6	4.9	5.1	8	0.3	5.9	15.8	20	2.7
Lab050	5	5.2	4.6	3	0.2	4.3	20.2	20	2.0	5.2	4.4	6	0.5	11.4	38.1	20	0.4
Total	-	-	4.4	37	0.7	15.9	-	-	-	-	4.3	322	0.5	11.6	-	-	-

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

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

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

Month : 2020 09 Change

Cumulative : from 2019 02 01 to 2020 09 30 Change

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Reagent Kit	Reagent Code
Medicon	5