

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

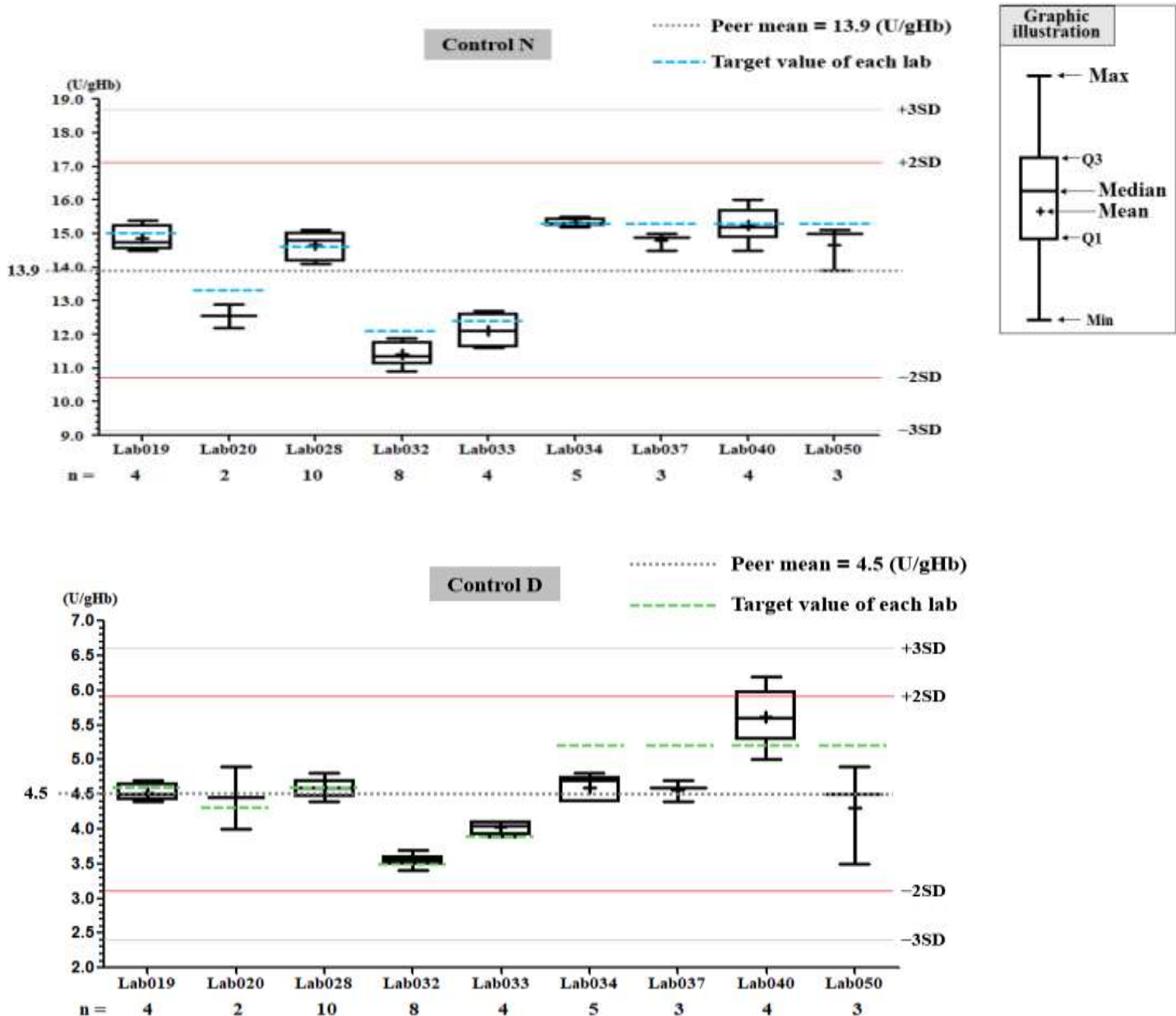
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	9	9
Received results number (n)	45	45
Median	14.7 (U/gHb)	4.5 (U/gHb)
Mean	13.9 (U/gHb)	4.5 (U/gHb)
SD	1.6	0.7
CV	11.5%	15.6%
Range of G6PD	10.9 ~ 16.0 (U/gHb)	3.4 ~ 6.2 (U/gHb)
Range of Hb	1.7 ~ 2.9 (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)

Lab028

	Control N		Control D	
QC Control Lot No.	AH1220N		AH1220D	
Duration of the Analyzing	Month (2020/08)	CUM (2020/08/04~2020/08/31)	Month (2020/08)	CUM (2020/08/04~2020/08/31)
Runs (N)	10	10	10	10
Mean (U/gHb)	14.7	14.7	4.6	4.6
SD	0.4	0.4	0.1	0.1
CV (%)	2.7	2.7	2.2	2.2
Target Value (U/gHb)	14.6	14.6	4.6	4.6
Total Error (%)	6.1	6.1	4.3	4.3
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

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

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

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

Month : 2020 ; Cumulative : from 2020 08 04 to 2020 08 31

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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-08-04 to 2020-08-31 ; Target : 14.6 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2020-08-04 to 2020-08-31 ; Target : 4.6 ; SD : 0.4 (□)

Lab028



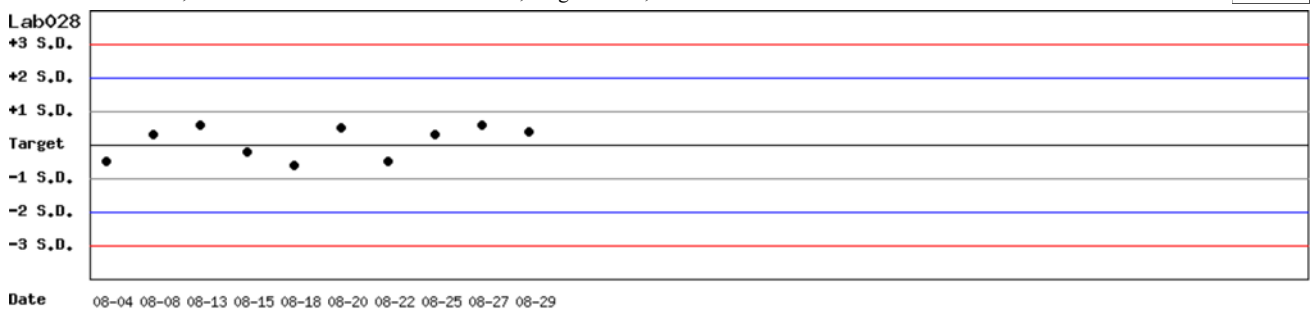
Month : 2020 ; Cumulative : from 2020 08 04 to 2020 08 31

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-08-04 to 2020-08-31 ; Target : 14.6 ; SD : 0.8

Lab028



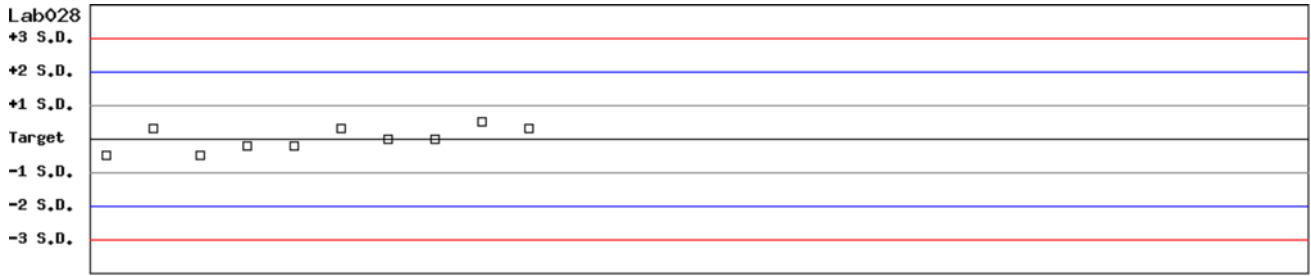
Month : 2020 ; Cumulative : from 2020 08 04 to 2020 08 31

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-08-04 to 2020-08-31 ; Target : 4.6 ; SD : 0.4

Lab028



Date 08-04 08-08 08-13 08-15 08-18 08-20 08-22 08-25 08-27 08-29

Month : 2020 08 Change ; Cumulative : from 2020 08 04 to 2020 08 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 08 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	14.9	4	0.4	2.7	6.0	20	>6	4.6	4.5	4	0.1	2.2	6.6	20	>6
Lab020	5	13.3	12.6	2	-	-	-	20	-	4.3	4.5	2	-	-	-	20	-
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	11.4	8	0.4	3.5	12.8	20	4.1	3.5	3.6	8	0.1	2.8	8.4	20	>6
Lab033	5	12.4	12.1	4	0.5	4.1	10.7	20	4.3	3.9	4.0	4	0.1	2.5	7.6	20	>6
Lab034	5	15.3	15.3	5	0.1	0.7	1.3	20	>6	5.2	4.6	5	0.2	4.3	20.2	20	2.0
Lab037	5	15.3	14.8	3	0.3	2.0	7.3	20	>6	5.2	4.6	3	0.2	4.3	20.2	20	2.0
Lab040	5	15.3	15.3	6	0.5	3.3	6.5	20	>6	5.2	5.6	6	0.4	7.1	22.0	20	1.7
Lab050	5	15.3	14.7	3	0.7	4.8	13.4	20	3.3	5.2	4.3	3	0.7	16.3	49.9	20	0.2
Total	-	-	13.9	45	1.6	11.5	-	-	-	-	4.5	45	0.7	15.6	-	-	-

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 08 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	15.0	9	0.3	2.0	4.0	20	>6	4.6	4.6	9	0.1	2.2	4.3	20	>6
Lab020	5	13.3	14.5	25	1.2	8.3	25.6	20	1.3	4.3	4.6	25	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	13.9	79	1.0	7.2	29.3	20	0.7	3.5	4.3	79	0.5	11.6	46.1	20	-0.2
Lab033	5	12.4	12.5	69	0.4	3.2	7.2	20	6.0	3.9	3.9	69	0.1	2.6	5.1	20	>6
Lab034	5	15.3	15.5	6	0.4	2.6	6.5	20	>6	5.2	4.7	6	0.2	4.3	18.1	20	2.4
Lab037	5	15.3	15.2	27	0.4	2.6	5.9	20	>6	5.2	4.7	27	0.2	4.3	18.1	20	2.4
Lab040	5	15.3	15.3	6	0.5	3.3	6.5	20	>6	5.2	5.6	6	0.4	7.1	22.0	20	1.7
Lab049	5	14.9	14.5	4	0.3	2.1	6.8	20	>6	4.9	4.9	4	0.3	6.1	12.2	20	3.3
Lab050	5	15.3	14.7	3	0.7	4.8	13.4	20	3.3	5.2	4.3	3	0.7	16.3	49.9	20	0.2
Total	-	-	13.6	285	1.3	9.6	-	-	-	-	4.3	285	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 (2020/08)								CUM (2019/02/01~2020/08/31)							
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	14.9	4	0.4	2.7	6.0	20	>6	15.0	15.0	9	0.3	2.0	4.0	20	>6
Lab020	5	13.3	12.6	2	-	-	-	20	-	13.3	14.5	25	1.2	8.3	25.6	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	14.7	10	0.4	2.7	6.1	20	>6	14.6	14.7	10	0.4	2.7	6.1	20	>6
Lab032	5	12.1	11.4	8	0.4	3.5	12.8	20	4.1	12.1	13.9	79	1.0	7.2	29.3	20	0.7
Lab033	5	12.4	12.1	4	0.5	4.1	10.7	20	4.3	12.4	12.5	69	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	15.3	5	0.1	0.7	1.3	20	>6	15.3	15.5	6	0.4	2.6	6.5	20	>6
Lab037	5	15.3	14.8	3	0.3	2.0	7.3	20	>6	15.3	15.2	27	0.4	2.6	5.9	20	>6
Lab040	5	15.3	15.3	6	0.5	3.3	6.5	20	>6	15.3	15.3	6	0.5	3.3	6.5	20	>6
Lab049	5	14.9	-	0	-	-	-	20	-	14.9	14.5	4	0.3	2.1	6.8	20	>6
Lab050	5	15.3	14.7	3	0.7	4.8	13.4	20	3.3	15.3	14.7	3	0.7	4.8	13.4	20	3.3
Total	-	-	13.9	45	1.6	11.5	-	-	-	-	13.6	285	1.3	9.6	-	-	-

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

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

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

Month : 2020 08 Change

Cumulative : from 2019 02 01 to 2020 08 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2020/08)								CUM (2019/02/01~2020/08/31)							
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	4.5	4	0.1	2.2	6.6	20	>6	4.6	4.6	9	0.1	2.2	4.3	20	>6
Lab020	5	4.3	4.5	2	-	-	-	20	-	4.3	4.6	25	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	4.6	10	0.1	2.2	4.3	20	>6	4.6	4.6	10	0.1	2.2	4.3	20	>6
Lab032	5	3.5	3.6	8	0.1	2.8	8.4	20	>6	3.5	4.3	79	0.5	11.6	46.1	20	-0.2
Lab033	5	3.9	4.0	4	0.1	2.5	7.6	20	>6	3.9	3.9	69	0.1	2.6	5.1	20	>6
Lab034	5	5.2	4.6	5	0.2	4.3	20.2	20	2.0	5.2	4.7	6	0.2	4.3	18.1	20	2.4
Lab037	5	5.2	4.6	3	0.2	4.3	20.2	20	2.0	5.2	4.7	27	0.2	4.3	18.1	20	2.4
Lab040	5	5.2	5.6	6	0.4	7.1	22.0	20	1.7	5.2	5.6	6	0.4	7.1	22.0	20	1.7
Lab049	5	4.9	-	0	-	-	-	20	-	4.9	4.9	4	0.3	6.1	12.2	20	3.3
Lab050	5	5.2	4.3	3	0.7	16.3	49.9	20	0.2	5.2	4.3	3	0.7	16.3	49.9	20	0.2
Total	-	-	4.5	45	0.7	15.6	-	-	-	-	4.3	285	0.5	11.6	-	-	-

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

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

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

Month : 2020 08 Change

Cumulative : from 2019 02 01 to 2020 08 31 Change

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Reagent Kit	Reagent Code
Medicon	5