

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - January 2021 -

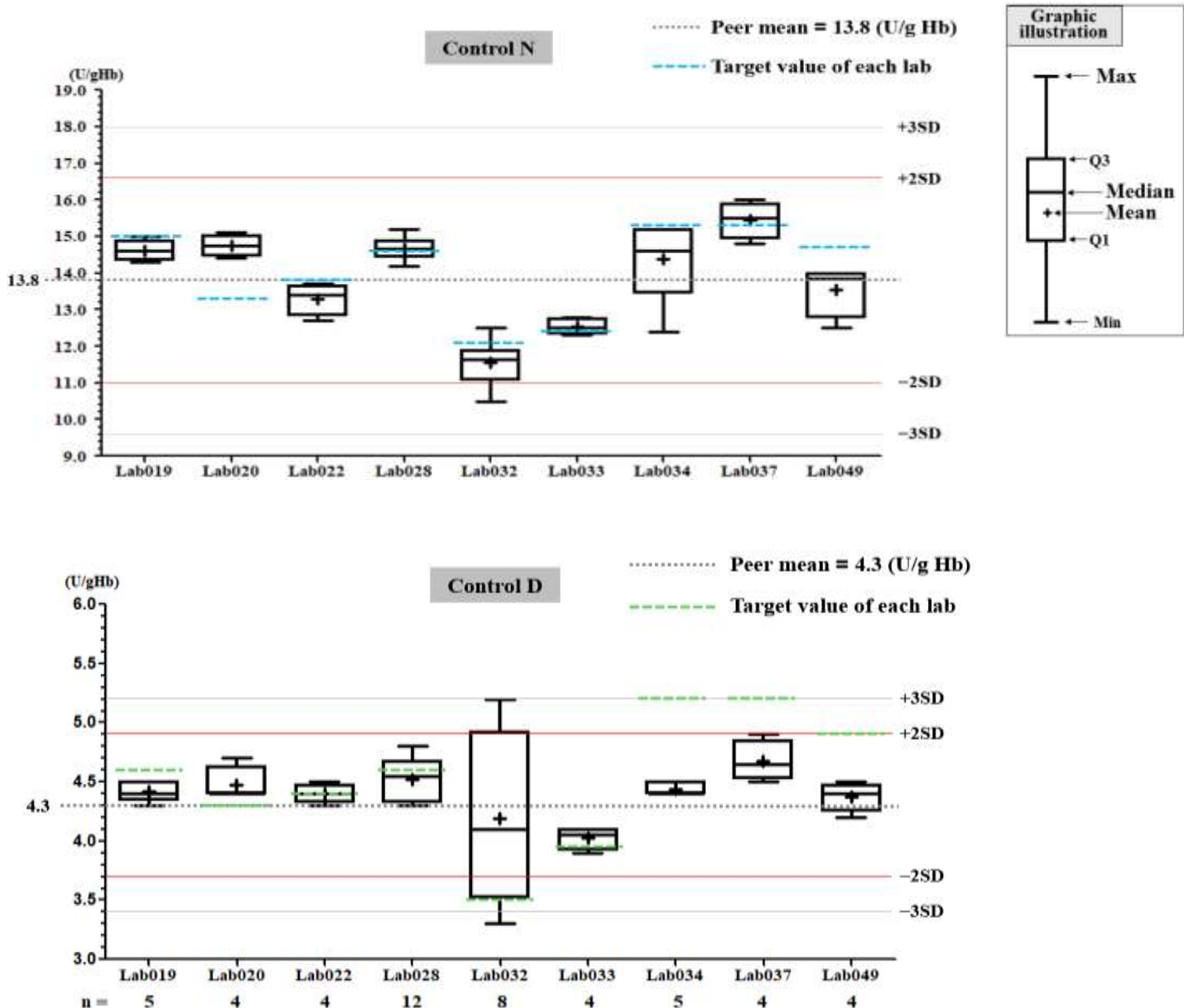
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	9	9
Received results number (n)	50	50
Median	14.4 (U/gHb)	4.4 (U/gHb)
Mean	13.8 (U/gHb)	4.4 (U/gHb)
SD	1.4	0.3
CV	10.1%	6.8%
Range of G6PD	10.5 ~ 16.0 (U/gHb)	3.3 ~ 5.2 (U/gHb)
Range of Hb	2.0 ~ 2.5 (g/dL)	2.0 ~ 2.8 (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 (IQ)for G6PD Quantitative Test

Select LotNo : AH1220N (2019-01-28 ~ 2100-12-31)

Lab028

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/01)	CUM (2020/08/27~2021/01/30)	Month (2021/01)	CUM (2020/08/27~2021/01/30)
Runs (N)	12	26	12	26
Mean (U/gHb)	14.7	14.6	4.5	4.6
SD	0.3	0.4	0.2	0.2
CV (%)	2.0	2.7	4.4	4.3
Target Value (U/gHb)	14.6	14.6	4.6	4.6
Total Error (%)	4.8	5.5	11.1	8.7
TEa (%)	20	20	20	20
σ	>6	>6	4.1	4.7

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

Month : 2021 01 ; Cumulative : from 2020 08 27 to 2021 01 30

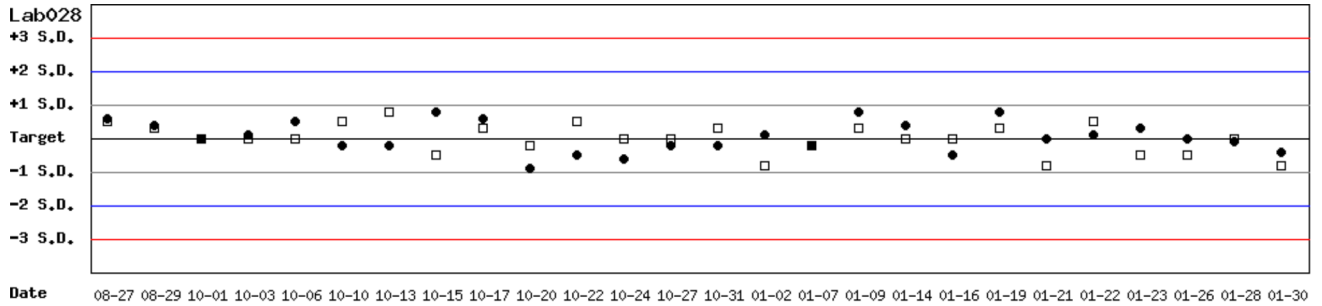
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-08-27 to 2021-01-30 ; Target : 14.6 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2020-08-27 to 2021-01-30 ; Target : 4.6 ; SD : 0.4 (□)

Lab028



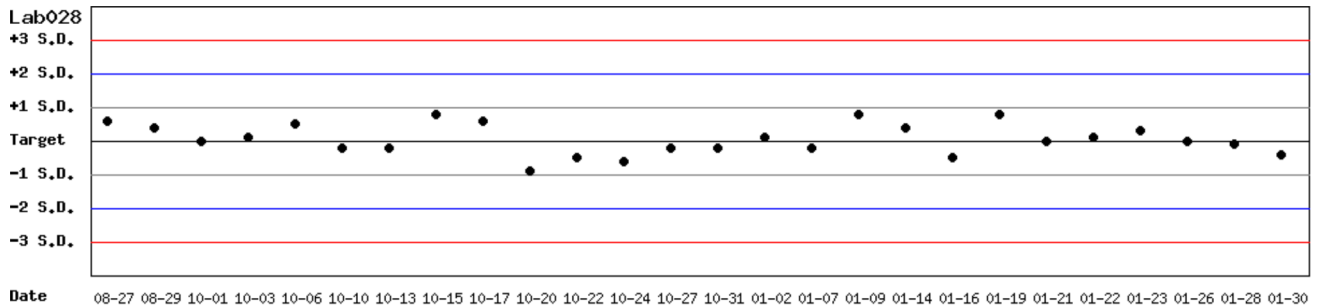
Month : 2021 01 ; Cumulative : from 2020 08 27 to 2021 01 30

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-08-27 to 2021-01-30 ; Target : 14.6 ; SD : 0.8

Lab028



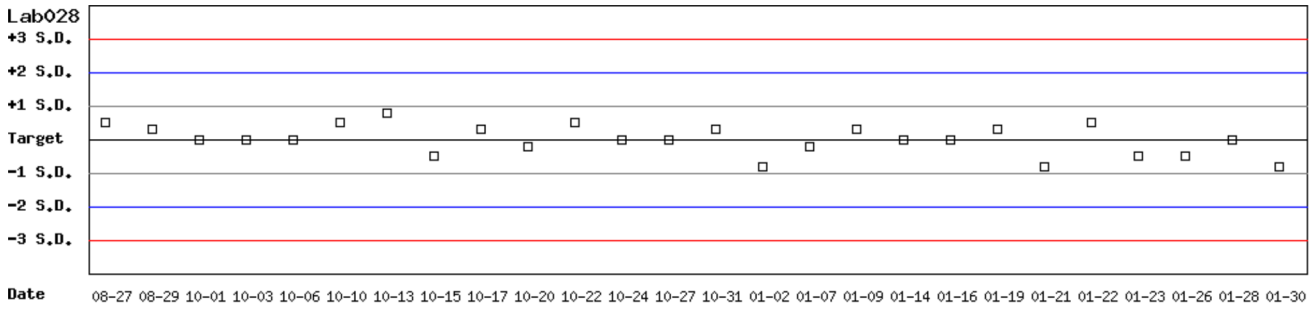
Month : 2021 01 ; Cumulative : from 2020 08 27 to 2021 01 30

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-08-27 to 2021-01-30 ; Target : 4.6 ; SD : 0.4

Lab028



Month : ; Cumulative : from to

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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 : 2021 01 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	0.3	2.1	6.8	20	>6	4.6	4.4	5	0.1	2.3	8.9	20	>6
Lab020	5	13.3	14.8	4	0.3	2.0	15.3	20	4.4	4.3	4.5	4	0.2	4.4	13.5	20	3.5
Lab022	5	13.8	13.3	4	0.4	3.0	9.6	20	5.5	4.4	4.4	4	0.1	2.3	4.5	20	>6
Lab028	5	14.6	14.7	12	0.3	2.0	4.8	20	>6	4.6	4.5	12	0.2	4.4	11.1	20	4.1
Lab032	5	12.1	11.6	8	0.6	5.2	14.5	20	3.1	3.5	4.2	8	0.7	16.7	53.3	20	0.0
Lab033	5	12.4	12.5	4	0.2	1.6	4.0	20	>6	3.9	4.0	4	0.1	2.5	7.6	20	>6
Lab034	5	15.3	14.4	5	1.2	8.3	22.5	20	1.7	5.2	4.4	5	0.1	2.3	19.9	20	2.0
Lab037	5	15.3	15.5	4	0.5	3.2	7.8	20	5.8	5.2	4.7	4	0.2	4.3	18.1	20	2.4
Lab049	5	14.7	13.6	4	0.7	5.1	17.8	20	2.5	4.9	4.4	4	0.1	2.3	14.7	20	4.3
Total	-	-	13.8	50	1.4	10.1	-	-	-	-	4.4	50	0.3	6.8	-	-	-

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 2021 01 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	30	0.3	2.0	6.1	20	>6	4.6	4.5	30	0.1	2.2	6.6	20	>6
Lab020	5	13.3	14.4	42	1.1	7.6	23.5	20	1.5	4.3	4.5	42	0.3	6.7	18.0	20	2.3
Lab022	5	13.8	12.4	56	0.7	5.6	21.4	20	1.8	4.4	4.0	56	0.2	5.0	19.1	20	2.2
Lab028	5	14.6	14.6	34	0.4	2.7	5.5	20	>6	4.6	4.6	34	0.2	4.3	8.7	20	4.7
Lab032	5	12.1	13.1	112	1.5	11.5	31.2	20	1.0	3.5	4.1	112	0.6	14.6	46.4	20	0.2
Lab033	5	12.4	12.5	91	0.4	3.2	7.2	20	6.0	3.9	3.9	91	0.2	5.1	10.3	20	3.9
Lab034	5	15.3	15.1	29	0.7	4.6	10.6	20	4.1	5.2	4.6	29	0.2	4.3	20.2	20	2.0
Lab037	5	15.3	15.2	44	0.4	2.6	5.9	20	>6	5.2	4.7	44	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	14.2	25	0.6	4.2	11.9	20	4.0	4.9	4.8	25	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	492	1.4	10.3	-	-	-	-	4.3	492	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 (2021/01)								CUM (2019/02/01~2021/01/31)							
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	0.3	2.1	6.8	20	>6	15.0	14.7	30	0.3	2.0	6.1	20	>6
Lab020	5	13.3	14.8	4	0.3	2.0	15.3	20	4.4	13.3	14.4	42	1.1	7.6	23.5	20	1.5
Lab022	5	13.8	13.3	4	0.4	3.0	9.6	20	5.5	13.8	12.4	56	0.7	5.6	21.4	20	1.8
Lab028	5	14.6	14.7	12	0.3	2.0	4.8	20	>6	14.6	14.6	34	0.4	2.7	5.5	20	>6
Lab032	5	12.1	11.6	8	0.6	5.2	14.5	20	3.1	12.1	13.1	112	1.5	11.5	31.2	20	1.0
Lab033	5	12.4	12.5	4	0.2	1.6	4.0	20	>6	12.4	12.5	91	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	14.4	5	1.2	8.3	22.5	20	1.7	15.3	15.1	29	0.7	4.6	10.6	20	4.1
Lab037	5	15.3	15.5	4	0.5	3.2	7.8	20	5.8	15.3	15.2	44	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	-	0	-	-	-	20	-	12.7	12.6	13	0.2	1.6	4.0	20	>6
Lab049	5	14.7	13.6	4	0.7	5.1	17.8	20	2.5	14.7	14.2	25	0.6	4.2	11.9	20	4.0
Lab050	5	15.3	-	0	-	-	-	20	-	15.3	14.6	6	0.8	5.5	15.5	20	2.8
Total	-	-	13.8	50	1.4	10.1	-	-	-	-	13.6	492	1.4	10.3	-	-	-

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

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

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

Month : 2021 01 Change

Cumulative : from 2019 02 01 to 2021 01 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2021/01)								CUM (2019/02/01~2021/01/31)							
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	30	0.1	2.2	6.6	20	>6
Lab020	5	4.3	4.5	4	0.2	4.4	13.5	20	3.5	4.3	4.5	42	0.3	6.7	18.0	20	2.3
Lab022	5	4.4	4.4	4	0.1	2.3	4.5	20	>6	4.4	4.0	56	0.2	5.0	19.1	20	2.2
Lab028	5	4.6	4.5	12	0.2	4.4	11.1	20	4.1	4.6	4.6	34	0.2	4.3	8.7	20	4.7
Lab032	5	3.5	4.2	8	0.7	16.7	53.3	20	0.0	3.5	4.1	112	0.6	14.6	46.4	20	0.2
Lab033	5	3.9	4.0	4	0.1	2.5	7.6	20	>6	3.9	3.9	91	0.2	5.1	10.3	20	3.9
Lab034	5	5.2	4.4	5	0.1	2.3	19.9	20	2.0	5.2	4.6	29	0.2	4.3	20.2	20	2.0
Lab037	5	5.2	4.7	4	0.2	4.3	18.1	20	2.4	5.2	4.7	44	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	-	0	-	-	-	20	-	4.0	4.0	13	0.1	2.5	5.0	20	>6
Lab049	5	4.9	4.4	4	0.1	2.3	14.7	20	4.3	4.9	4.8	25	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	-	-	4.4	50	0.3	6.8	-	-	-	-	4.3	492	0.5	11.6	-	-	-

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

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

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

Month : 2021 01 Change

Cumulative : from 2019 02 01 to 2021 01 31 Change

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Reagent Kit	Reagent Code
Medicon	5