

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

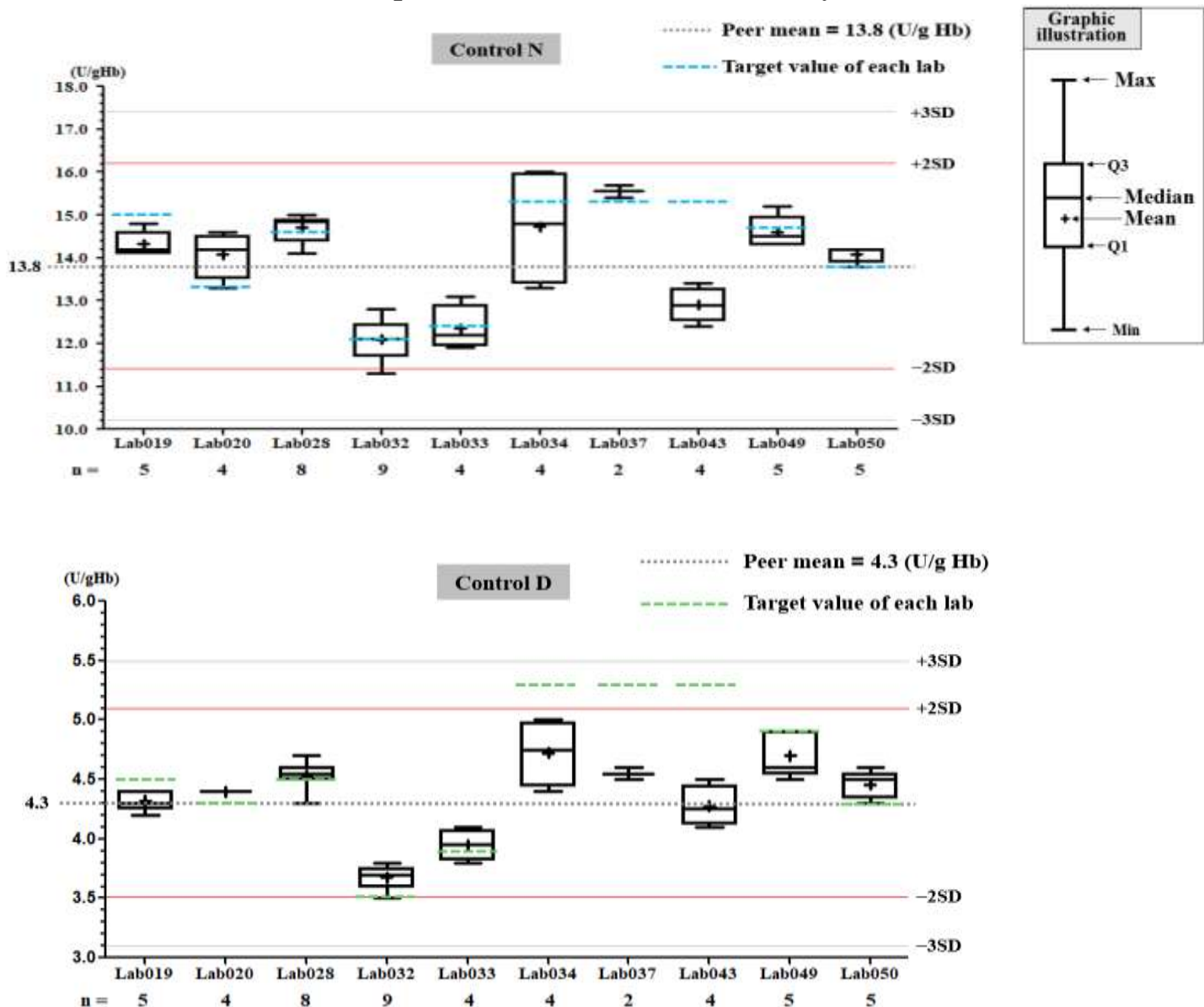
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	10	10
Received results number (n)	50	50
Median	14.2 (U/gHb)	4.4 (U/gHb)
Mean	13.8 (U/gHb)	4.3 (U/gHb)
SD	1.2	0.1
CV	8.7%	9.3%
Range of G6PD	11.3 ~ 16.0 (U/gHb)	3.5 ~ 5.0 (U/gHb)
Range of Hb	1.9 ~ 2.5 (g/dL)	2.0 ~ 3.3 (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

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/03)	CUM (2020/08/27~2021/03/31)	Month (2021/03)	CUM (2020/08/27~2021/03/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.1	14.2	4.4	4.4
SD	0.6	0.7	0.0	0.2
CV (%)	4.3	4.9	0.0	4.5
Target Value (U/gHb)	13.3	13.3	4.3	4.3
Total Error (%)	14.5	16.6	2.3	11.4
TEa (%)	20	20	20	20
σ	3.3	2.7	>6	3.9

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

Month : 2021 03 Change ; Cumulative : from 2020 08 27 to 2021 03 31 Change

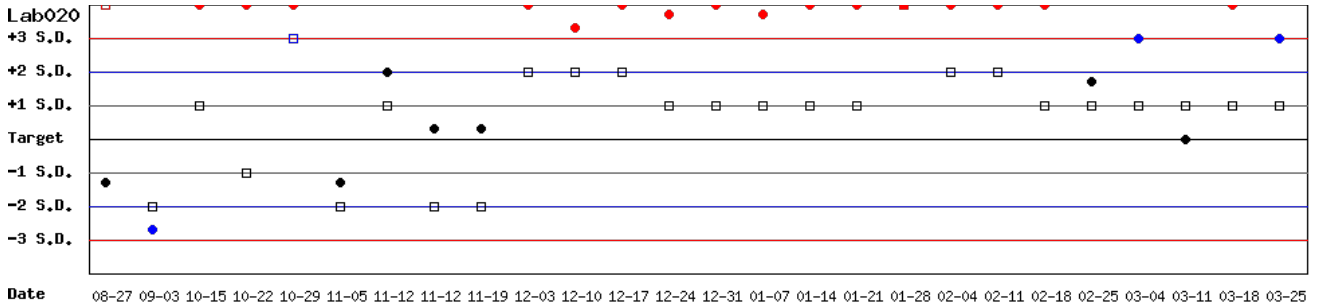
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-08-27 to 2021-03-31 ; Target : 13.3 ; SD : 0.30 (●)

Lot No.: AH1220D ; Duration : 2020-08-27 to 2021-03-31 ; Target : 4.3 ; SD : 0.10 (□)

Lab020



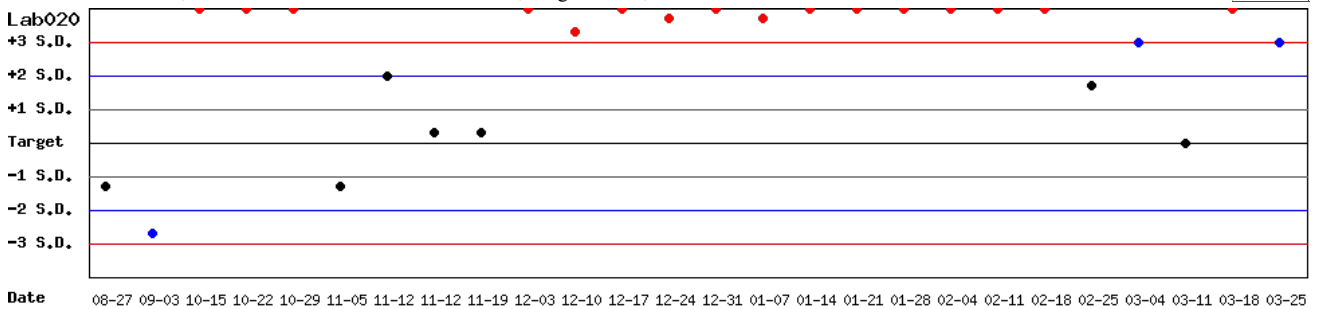
Month : 2021 03 Change ; Cumulative : from 2020 08 27 to 2021 03 31 Change

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-08-27 to 2021-03-31 ; Target : 13.3 ; SD : 0.30

Lab020



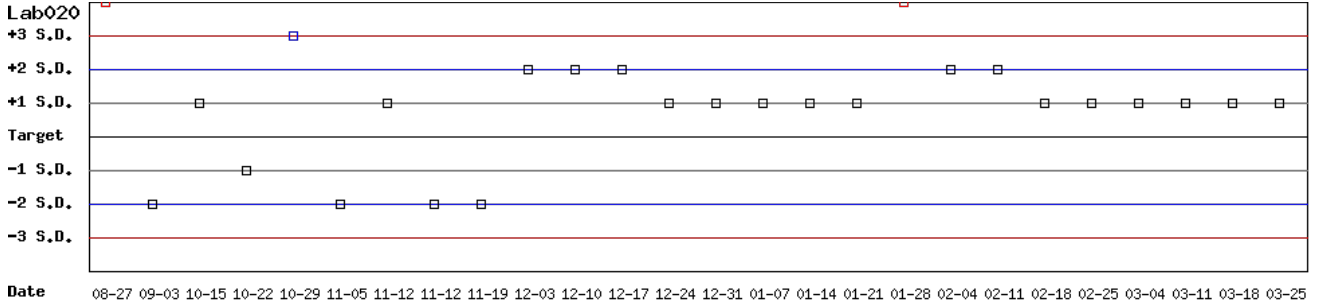
Month : 2021 03 Change ; Cumulative : from 2020 08 27 to 2021 03 31 Change

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-08-27 to 2021-03-31 ; Target : 4.3 ; SD : 0.10

Lab020



Month : ; Cumulative : from to

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Peer Group Statistics (Table 1)

Select LotNo :

Select Reagent Kit :

Monthly

Month :

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	14.3	5	0.3	2.1	8.9	20	>6	4.6	4.3	5	0.1	2.3	11.2	20	5.9
Lab020	5	13.3	14.1	4	0.6	4.3	14.5	20	3.3	4.3	4.4	4	0.0	0.0	2.3	20	>6
Lab028	5	14.6	14.7	8	0.3	2.0	4.8	20	>6	4.6	4.5	8	0.1	2.2	6.6	20	>6
Lab032	5	12.1	12.1	9	0.5	4.1	8.3	20	4.9	3.5	3.7	9	0.1	2.7	11.1	20	5.3
Lab033	5	12.4	12.4	4	0.5	4.0	8.1	20	5.0	3.9	4.0	4	0.1	2.5	7.6	20	>6
Lab034	5	15.3	14.7	4	1.4	9.5	23.0	20	1.7	5.2	4.7	4	0.3	6.4	22.4	20	1.6
Lab037	5	15.3	15.6	2	-	-	-	20	-	5.2	4.6	2	-	-	-	20	-
Lab043	5	15.3	12.9	4	0.4	3.1	21.9	20	1.4	5.2	4.3	4	0.2	4.7	26.6	20	0.6
Lab049	5	14.7	14.6	5	0.4	2.7	6.2	20	>6	4.9	4.7	5	0.2	4.3	12.6	20	3.7
Lab050	5	13.8	14.1	5	0.2	1.4	5.0	20	>6	4.3	4.5	5	0.1	2.2	9.1	20	>6
Total	-	-	13.8	50	1.2	8.7	-	-	-	-	4.3	50	0.4	9.3	-	-	-

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

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

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

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Cumulative

Cumulative : from to

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	40	0.3	2.1	6.8	20	>6	4.6	4.4	40	0.1	2.3	8.9	20	>6
Lab020	5	13.3	14.4	50	1.0	6.9	22.2	20	1.7	4.3	4.5	50	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	53	0.4	2.7	5.5	20	>6	4.6	4.6	53	0.2	4.3	8.7	20	4.7
Lab032	5	12.1	13.0	121	1.4	10.8	29.0	20	1.2	3.5	4.1	121	0.6	14.6	46.4	20	0.2
Lab033	5	12.4	12.5	99	0.4	3.2	7.2	20	6.0	3.9	3.9	99	0.2	5.1	10.3	20	3.9
Lab034	5	15.3	15.1	37	0.8	5.3	11.9	20	3.5	5.2	4.6	37	0.2	4.3	20.2	20	2.0
Lab037	5	15.3	15.2	49	0.4	2.6	5.9	20	>6	5.2	4.7	49	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
Lab043	5	15.3	12.9	4	0.4	3.1	21.9	20	1.4	5.2	4.3	4	0.2	4.7	26.6	20	0.6
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	34	0.6	4.2	11.1	20	4.1	4.9	4.7	34	0.4	8.5	21.1	20	1.9
Lab050	5	13.8	14.2	16	0.6	4.2	11.3	20	4.1	4.3	4.4	16	0.3	6.8	16.0	20	2.6
Total	-	-	13.7	582	1.3	9.5	-	-	-	-	4.3	582	0.5	11.6	-	-	-

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

TE : Total Error(%) = Bias (%) + 2 x 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 (2021/03)								CUM (2019/02/01~2021/03/31)							
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	14.3	5	0.3	2.1	8.9	20	>6	15.0	14.6	40	0.3	2.1	6.8	20	>6
Lab020	5	13.3	14.1	4	0.6	4.3	14.5	20	3.3	13.3	14.4	50	1.0	6.9	22.2	20	1.7
Lab022	5	13.8	-	0	-	-	-	20	-	13.8	12.4	56	0.7	5.6	21.4	20	1.8
Lab028	5	14.6	14.7	8	0.3	2.0	4.8	20	>6	14.6	14.6	53	0.4	2.7	5.5	20	>6
Lab032	5	12.1	12.1	9	0.5	4.1	8.3	20	4.9	12.1	13.0	121	1.4	10.8	29.0	20	1.2
Lab033	5	12.4	12.4	4	0.5	4.0	8.1	20	5.0	12.4	12.5	99	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	14.7	4	1.4	9.5	23.0	20	1.7	15.3	15.1	37	0.8	5.3	11.9	20	3.5
Lab037	5	15.3	15.6	2	-	-	-	20	-	15.3	15.2	49	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
Lab043	5	15.3	12.9	4	0.4	3.1	21.9	20	1.4	15.3	12.9	4	0.4	3.1	21.9	20	1.4
Lab047	5	12.7	-	0	-	-	-	20	-	12.7	12.6	13	0.2	1.6	4.0	20	>6
Lab049	5	14.7	14.6	5	0.4	2.7	6.2	20	>6	14.7	14.3	34	0.6	4.2	11.1	20	4.1
Lab050	5	13.8	14.1	5	0.2	1.4	5.0	20	>6	13.8	14.2	16	0.6	4.2	11.3	20	4.1
Total	-	-	13.8	50	1.2	8.7	-	-	-	-	13.7	582	1.3	9.5	-	-	-

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

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

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

Month : 2021 03 Change

Cumulative : from 2019 02 01 to 2021 03 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2021/03)								CUM (2019/02/01~2021/03/31)							
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	4.3	5	0.1	2.3	11.2	20	5.9	4.6	4.4	40	0.1	2.3	8.9	20	>6
Lab020	5	4.3	4.4	4	0.0	0.0	2.3	20	>6	4.3	4.5	50	0.3	6.7	18.0	20	2.3
Lab022	5	4.4	-	0	-	-	-	20	-	4.4	4.0	56	0.2	5.0	19.1	20	2.2
Lab028	5	4.6	4.5	8	0.1	2.2	6.6	20	>6	4.6	4.6	53	0.2	4.3	8.7	20	4.7
Lab032	5	3.5	3.7	9	0.1	2.7	11.1	20	5.3	3.5	4.1	121	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	99	0.2	5.1	10.3	20	3.9
Lab034	5	5.2	4.7	4	0.3	6.4	22.4	20	1.6	5.2	4.6	37	0.2	4.3	20.2	20	2.0
Lab037	5	5.2	4.6	2	-	-	-	20	-	5.2	4.7	49	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
Lab043	5	5.2	4.3	4	0.2	4.7	26.6	20	0.6	5.2	4.3	4	0.2	4.7	26.6	20	0.6
Lab047	5	4.0	-	0	-	-	-	20	-	4.0	4.0	13	0.1	2.5	5.0	20	>6
Lab049	5	4.9	4.7	5	0.2	4.3	12.6	20	3.7	4.9	4.7	34	0.4	8.5	21.1	20	1.9
Lab050	5	4.3	4.5	5	0.1	2.2	9.1	20	>6	4.3	4.4	16	0.3	6.8	16.0	20	2.6
Total	-	-	4.3	50	0.4	9.3	-	-	-	-	4.3	582	0.5	11.6	-	-	-

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

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

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

Month : 2021 03 Change

Cumulative : from 2019 02 01 to 2021 03 31 Change

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Reagent Kit	Reagent Code
Medicon	5