

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

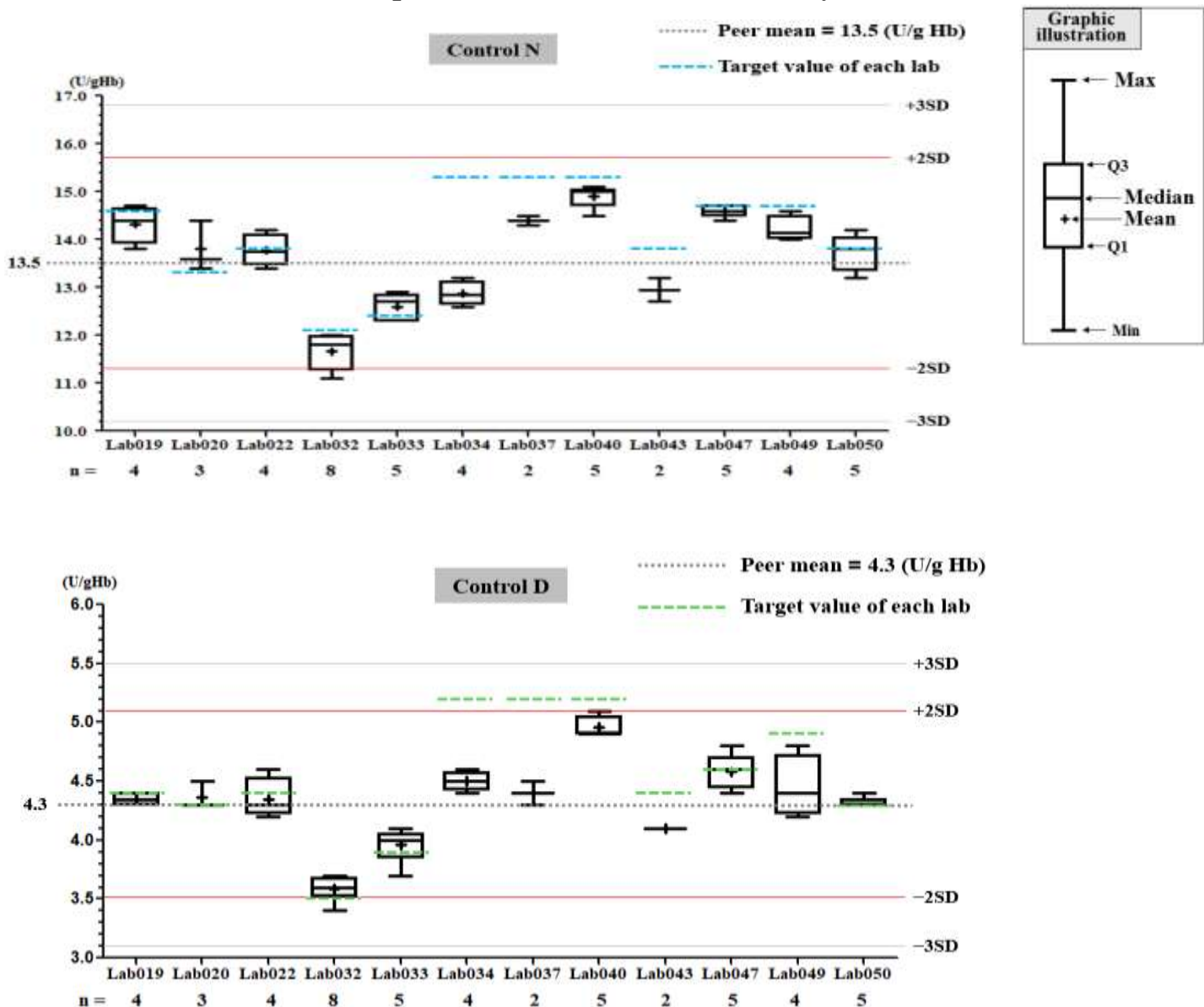
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	12	12
Received results number (n)	51	51
Median	13.8 (U/gHb)	4.3 (U/gHb)
Mean	13.5 (U/gHb)	4.3 (U/gHb)
SD	1.1	0.4
CV	8.1%	9.3%
Range of G6PD	11.1 ~ 15.1 (U/gHb)	3.4 ~ 5.1 (U/gHb)
Range of Hb	1.9 ~ 2.5 (g/dL)	2.0 ~ 2.9 (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 :

Lab020

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/04)	CUM (2020/10/22~2021/04/30)	Month (2021/04)	CUM (2020/10/22~2021/04/30)
Runs (N)	3	26	3	26
Mean (U/gHb)	13.8	14.2	4.4	4.4
SD	0.5	0.6	0.1	0.1
CV (%)	3.6	4.2	2.3	2.3
Target Value (U/gHb)	13.3	13.3	4.3	4.3
Total Error (%)	11.0	15.2	6.9	6.9
TEa (%)	20	20	20	20
σ	4.5	3.2	>6	>6

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

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

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

Month : ; Cumulative : from to

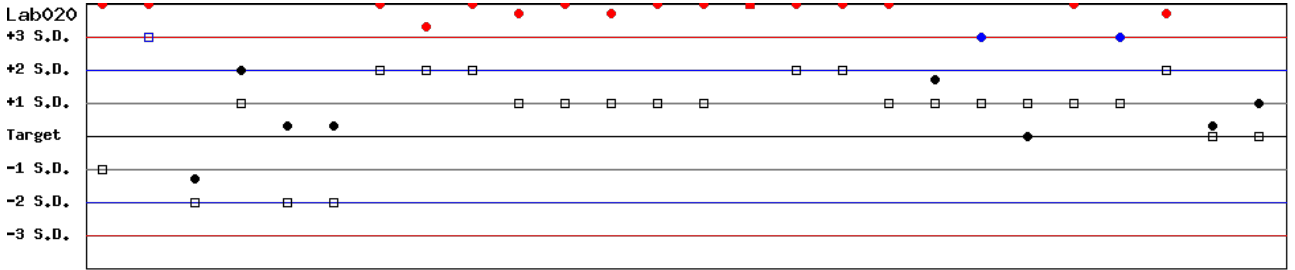
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-10-22 to 2021-04-30 ; Target : 13.3 ; SD : 0.30 (●)

Lot No.: AH1220D ; Duration : 2020-10-22 to 2021-04-30 ; Target : 4.3 ; SD : 0.10 (□)

Lab020



Date 10-22 10-29 11-05 11-12 11-12 11-19 12-03 12-10 12-17 12-24 12-31 01-07 01-14 01-21 01-28 02-04 02-11 02-18 02-25 03-04 03-11 03-18 03-25 04-01 04-15 04-29

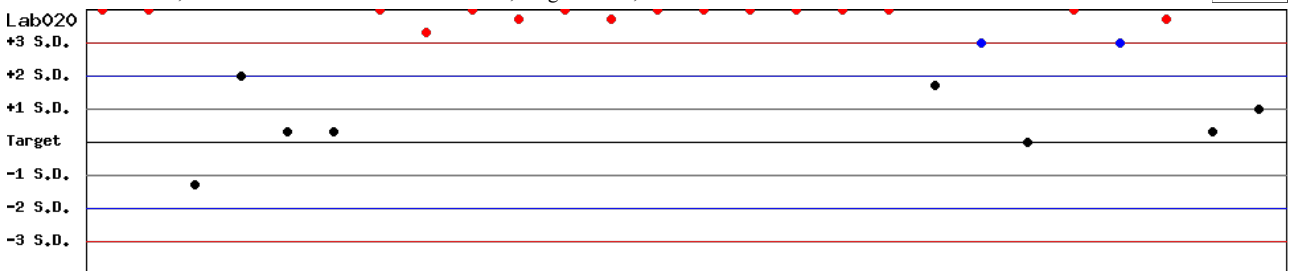
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-10-22 to 2021-04-30 ; Target : 13.3 ; SD : 0.30

Lab020



Date 10-22 10-29 11-05 11-12 11-12 11-19 12-03 12-10 12-17 12-24 12-31 01-07 01-14 01-21 01-28 02-04 02-11 02-18 02-25 03-04 03-11 03-18 03-25 04-01 04-15 04-29

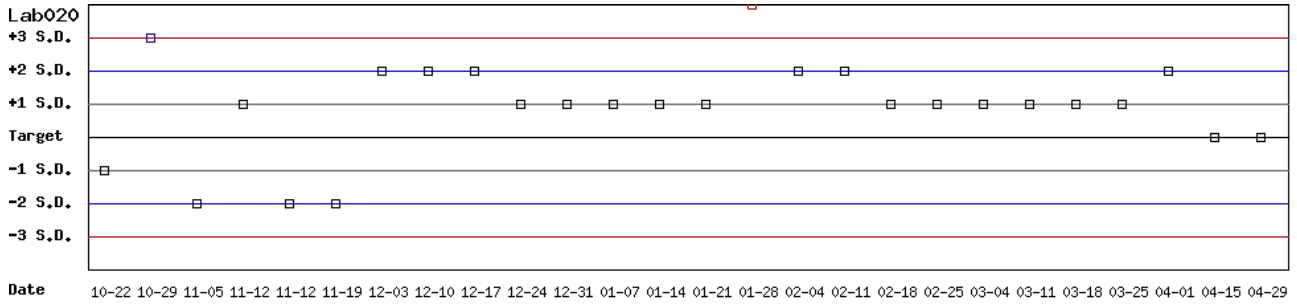
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-10-22 to 2021-04-30 ; Target : 4.3 ; SD : 0.10

Lab020



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 04 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	14.6	14.3	4	0.4	2.8	7.6	20	>6	4.4	4.4	4	0.1	2.3	4.5	20	>6
Lab020	5	13.3	13.8	3	0.5	3.6	11.0	20	4.5	4.3	4.4	3	0.1	2.3	6.9	20	>6
Lab022	5	13.8	13.8	4	0.3	2.2	4.3	20	>6	4.4	4.4	4	0.2	4.5	9.1	20	4.4
Lab032	5	12.1	11.7	8	0.4	3.4	10.1	20	4.9	3.5	3.6	8	0.1	2.8	8.4	20	>6
Lab033	5	12.4	12.6	5	0.3	2.4	6.4	20	>6	3.9	4.0	5	0.2	5.0	12.6	20	3.5
Lab034	5	15.3	12.9	4	0.3	2.3	20.3	20	1.9	5.2	4.5	4	0.1	2.2	17.9	20	3.0
Lab037	5	15.3	14.4	2	-	-	-	20	-	5.2	4.4	2	-	-	-	20	-
Lab040	5	15.3	14.9	5	0.2	1.3	5.3	20	>6	5.2	5.0	5	0.1	2.0	7.8	20	>6
Lab043	5	13.8	13.0	2	-	-	-	20	-	4.4	4.1	2	-	-	-	20	-
Lab047	5	14.7	14.6	5	0.1	0.7	2.1	20	>6	4.6	4.6	5	0.2	4.3	8.7	20	4.7
Lab049	5	14.7	14.2	4	0.3	2.1	7.6	20	>6	4.9	4.5	4	0.3	6.7	21.5	20	1.8
Lab050	5	13.8	13.7	5	0.4	2.9	6.6	20	>6	4.3	4.3	5	0.1	2.3	4.7	20	>6
Total	-	-	13.5	51	1.1	8.1	-	-	-	-	4.3	51	0.4	9.3	-	-	-

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 2021 04 30 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	14.6	14.6	44	0.3	2.1	4.1	20	>6	4.4	4.4	44	0.1	2.3	4.5	20	>6
Lab020	5	13.3	14.4	53	1.0	6.9	22.2	20	1.7	4.3	4.5	53	0.2	4.4	13.5	20	3.5
Lab022	5	13.8	12.5	60	0.7	5.6	20.6	20	1.9	4.4	4.1	60	0.2	4.9	16.6	20	2.7
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	129	1.4	10.8	29.0	20	1.2	3.5	4.0	129	0.6	15.0	44.3	20	0.4
Lab033	5	12.4	12.5	104	0.4	3.2	7.2	20	6.0	3.9	3.9	104	0.2	5.1	10.3	20	3.9
Lab034	5	15.3	14.9	41	1.0	6.7	16.0	20	2.6	5.2	4.6	41	0.2	4.3	20.2	20	2.0
Lab037	5	15.3	15.2	51	0.4	2.6	5.9	20	>6	5.2	4.7	51	0.2	4.3	18.1	20	2.4
Lab040	5	15.3	15.0	15	0.4	2.7	7.3	20	>6	5.2	5.4	15	0.4	7.4	18.7	20	2.2
Lab043	5	13.8	12.9	6	0.4	3.1	12.7	20	4.3	4.4	4.2	6	0.2	4.8	14.1	20	3.2
Lab047	5	14.7	13.2	18	0.9	6.8	23.8	20	1.4	4.6	4.2	18	0.3	7.1	23.0	20	1.6
Lab049	5	14.7	14.3	38	0.5	3.5	9.7	20	4.9	4.9	4.7	38	0.4	8.5	21.1	20	1.9
Lab050	5	13.8	14.1	21	0.6	4.3	10.7	20	4.1	4.3	4.4	21	0.3	6.8	16.0	20	2.6
Total	-	-	13.7	633	1.3	9.5	-	-	-	-	4.3	633	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 (2021/04)								CUM (2019/02/01~2021/04/30)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	14.6	14.3	4	0.4	2.8	7.6	20	>6	14.6	14.6	44	0.3	2.1	4.1	20	>6
Lab020	5	13.3	13.8	3	0.5	3.6	11.0	20	4.5	13.3	14.4	53	1.0	6.9	22.2	20	1.7
Lab022	5	13.8	13.8	4	0.3	2.2	4.3	20	>6	13.8	12.5	60	0.7	5.6	20.6	20	1.9
Lab028	5	14.6	-	0	-	-	-	20	-	14.6	14.6	53	0.4	2.7	5.5	20	>6
Lab032	5	12.1	11.7	8	0.4	3.4	10.1	20	4.9	12.1	13.0	129	1.4	10.8	29.0	20	1.2
Lab033	5	12.4	12.6	5	0.3	2.4	6.4	20	>6	12.4	12.5	104	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	12.9	4	0.3	2.3	20.3	20	1.9	15.3	14.9	41	1.0	6.7	16.0	20	2.6
Lab037	5	15.3	14.4	2	-	-	-	20	-	15.3	15.2	51	0.4	2.6	5.9	20	>6
Lab040	5	15.3	14.9	5	0.2	1.3	5.3	20	>6	15.3	15.0	15	0.4	2.7	7.3	20	>6
Lab043	5	13.8	13.0	2	-	-	-	20	-	13.8	12.9	6	0.4	3.1	12.7	20	4.3
Lab047	5	14.7	14.6	5	0.1	0.7	2.1	20	>6	14.7	13.2	18	0.9	6.8	23.8	20	1.4
Lab049	5	14.7	14.2	4	0.3	2.1	7.6	20	>6	14.7	14.3	38	0.5	3.5	9.7	20	4.9
Lab050	5	13.8	13.7	5	0.4	2.9	6.6	20	>6	13.8	14.1	21	0.6	4.3	10.7	20	4.1
Total	-	-	13.5	51	1.1	8.1	-	-	-	-	13.7	633	1.3	9.5	-	-	-

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

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

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

Month : 2021 ▼ 04 ▼ Change

Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2021 ▼ 04 ▼ 30 ▼ Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2021/04)								CUM (2019/02/01~2021/04/30)							
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	4.4	4.4	4	0.1	2.3	4.5	20	>6	4.4	4.4	44	0.1	2.3	4.5	20	>6
Lab020	5	4.3	4.4	3	0.1	2.3	6.9	20	>6	4.3	4.5	53	0.2	4.4	13.5	20	3.5
Lab022	5	4.4	4.4	4	0.2	4.5	9.1	20	4.4	4.4	4.1	60	0.2	4.9	16.6	20	2.7
Lab028	5	4.6	-	0	-	-	-	20	-	4.6	4.6	53	0.2	4.3	8.7	20	4.7
Lab032	5	3.5	3.6	8	0.1	2.8	8.4	20	>6	3.5	4.0	129	0.6	15.0	44.3	20	0.4
Lab033	5	3.9	4.0	5	0.2	5.0	12.6	20	3.5	3.9	3.9	104	0.2	5.1	10.3	20	3.9
Lab034	5	5.2	4.5	4	0.1	2.2	17.9	20	3.0	5.2	4.6	41	0.2	4.3	20.2	20	2.0
Lab037	5	5.2	4.4	2	-	-	-	20	-	5.2	4.7	51	0.2	4.3	18.1	20	2.4
Lab040	5	5.2	5.0	5	0.1	2.0	7.8	20	>6	5.2	5.4	15	0.4	7.4	18.7	20	2.2
Lab043	5	4.4	4.1	2	-	-	-	20	-	4.4	4.2	6	0.2	4.8	14.1	20	3.2
Lab047	5	4.6	4.6	5	0.2	4.3	8.7	20	4.7	4.6	4.2	18	0.3	7.1	23.0	20	1.6
Lab049	5	4.9	4.5	4	0.3	6.7	21.5	20	1.8	4.9	4.7	38	0.4	8.5	21.1	20	1.9
Lab050	5	4.3	4.3	5	0.1	2.3	4.7	20	>6	4.3	4.4	21	0.3	6.8	16.0	20	2.6
Total	-	-	4.3	51	0.4	9.3	-	-	-	-	4.3	633	0.5	11.6	-	-	-

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

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

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

Month : 2021 ▼ 04 ▼ Change

Cumulative : from 2019 ▼ 02 ▼ 01 ▼ to 2021 ▼ 04 ▼ 30 ▼ Change

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Reagent Kit	Reagent Code
Medicon	5