

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

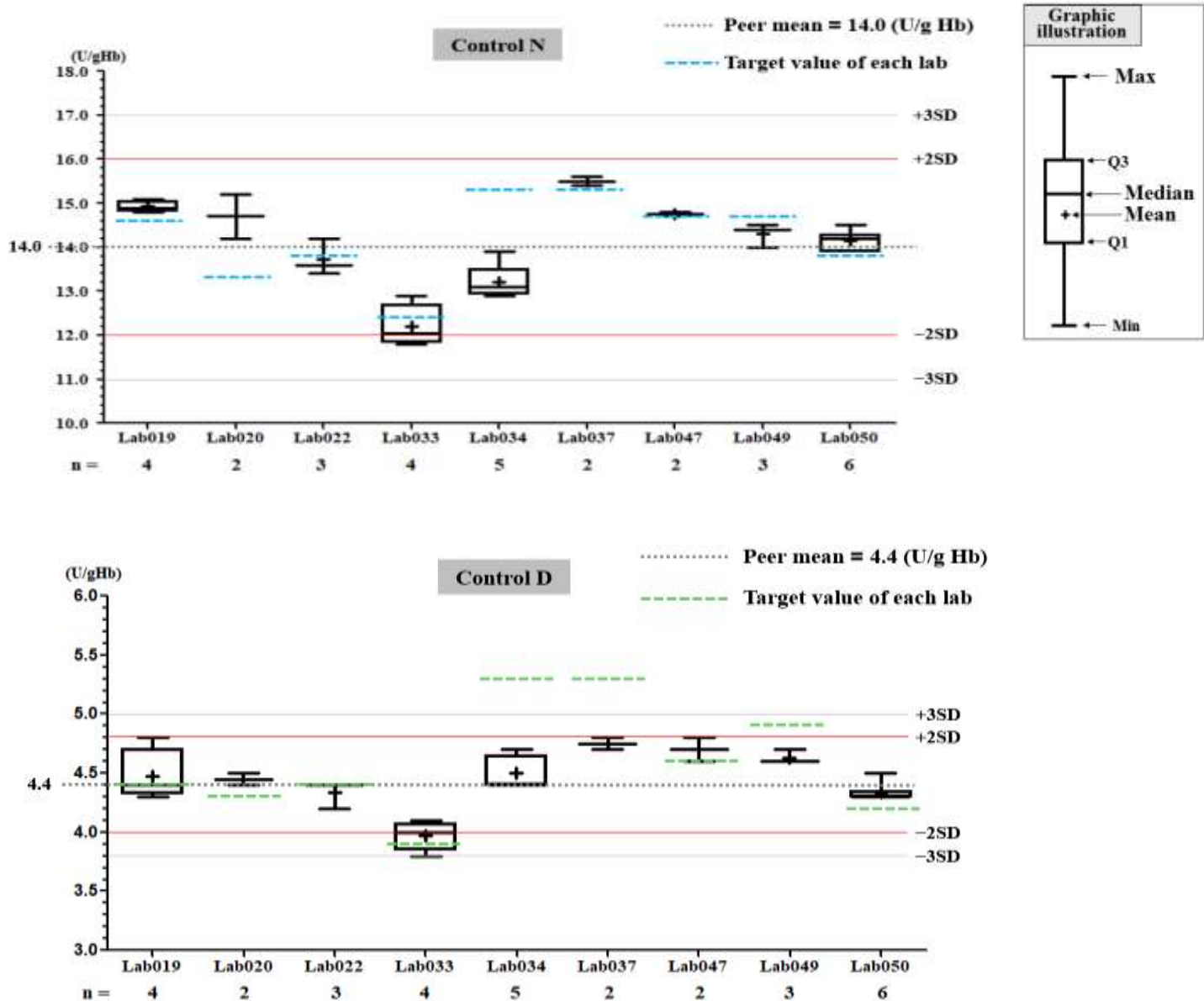
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	9	9
Received results number (n)	31	31
Median	14.2 (U/g Hb)	4.4 (U/g Hb)
Mean	14.0 (U/g Hb)	4.4 (U/g Hb)
SD	1.0	0.2
CV	7.1%	4.5%
Range of G6PD	11.8 ~ 15.6 (U/g Hb)	3.8 ~ 4.8 (U/g Hb)
Range of Hb	2.0 ~ 2.5 (g/dL)	2.0 ~ 3.0 (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)

Lab033

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/05)	CUM (2020/12/03~2021/05/31)	Month (2021/05)	CUM (2020/12/03~2021/05/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	12.2	12.5	4.0	4.0
SD	0.5	0.4	0.1	0.1
CV (%)	4.1	3.2	2.5	2.5
Target Value (U/gHb)	12.4	12.4	3.9	3.9
Total Error (%)	9.8	7.2	7.6	7.6
TEa (%)	20	20	20	20
σ	4.5	6.0	>6	>6

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

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

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

Month : ; Cumulative : from to

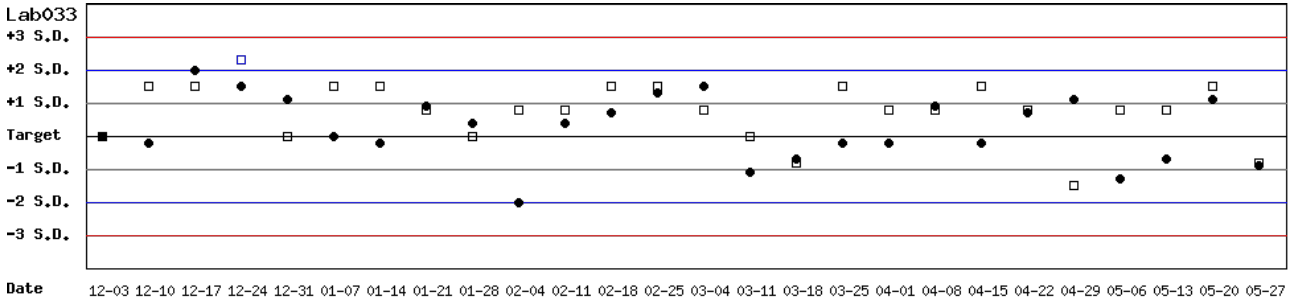
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-12-03 to 2021-05-31 ; Target : 12.4 ; SD : 0.46 (●)

Lot No.: AH1220D ; Duration : 2020-12-03 to 2021-05-31 ; Target : 3.9 ; SD : 0.13 (□)

Lab033



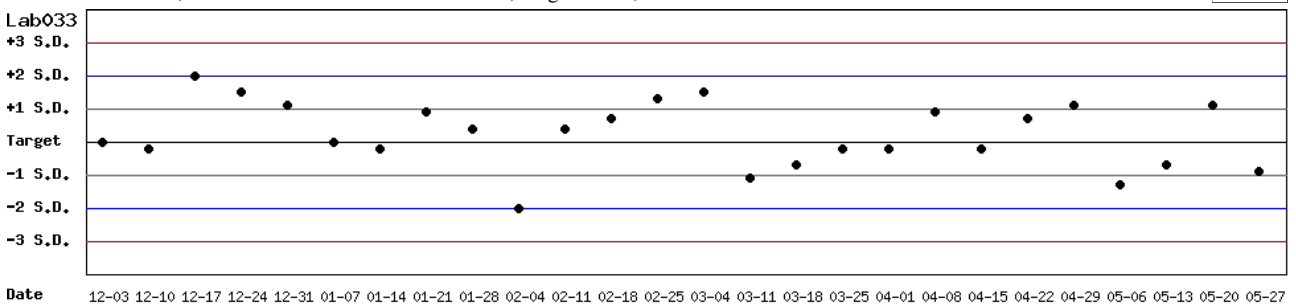
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-12-03 to 2021-05-31 ; Target : 12.4 ; SD : 0.46

Lab033



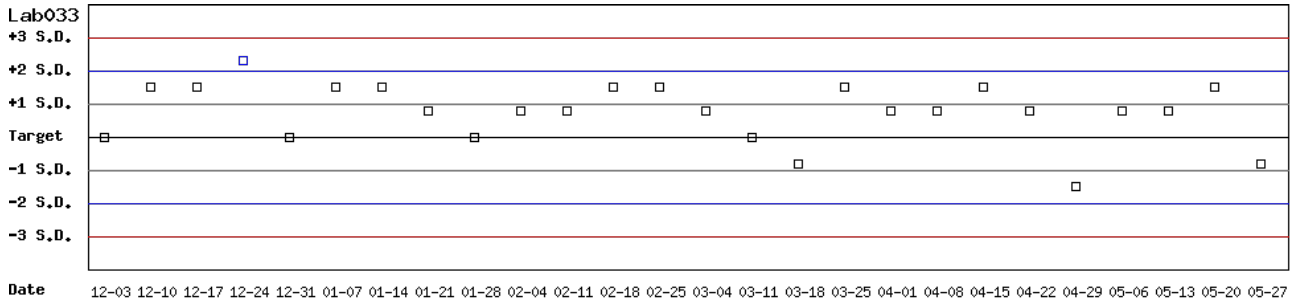
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-12-03 to 2021-05-31 ; Target : 3.9 ; SD : 0.13

Lab033



Month : 2021 05 Change ; Cumulative : from 2020 12 03 to 2021 05 31 Change

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Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon v Change

Print Table 1

Monthly

Month : 2021 v 05 v 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	14.6	14.9	4	0.1	0.7	3.4	20	>6	4.4	4.5	4	0.2	4.4	11.2	20	4.0
Lab020	5	13.3	14.7	2	-	-	-	20	-	4.3	4.5	2	-	-	-	20	-
Lab022	5	13.8	13.7	3	0.4	2.9	6.6	20	>6	4.4	4.3	3	0.1	2.3	6.9	20	>6
Lab033	5	12.4	12.2	4	0.5	4.1	9.8	20	4.5	3.9	4.0	4	0.1	2.5	7.6	20	>6
Lab034	5	15.3	13.2	5	0.4	3.0	19.8	20	2.1	5.2	4.5	5	0.1	2.2	17.9	20	3.0
Lab037	5	15.3	15.5	2	-	-	-	20	-	5.2	4.8	2	-	-	-	20	-
Lab047	5	14.7	14.8	2	-	-	-	20	-	4.6	4.7	2	-	-	-	20	-
Lab049	5	14.7	14.3	3	0.3	2.1	6.9	20	>6	4.9	4.6	3	0.1	2.2	10.5	20	>6
Lab050	5	13.8	14.2	6	0.2	1.4	5.7	20	>6	4.3	4.3	6	0.1	2.3	4.7	20	>6
Total	-	-	14.0	31	1.0	7.1	-	-	-	-	4.4	31	0.2	4.5	-	-	-

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

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

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

[TOP](#)

Cumulative

Cumulative : from 2019 v 02 v 01 v to 2021 v 05 v 31 v 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	14.6	14.6	48	0.3	2.1	4.1	20	>6	4.4	4.4	48	0.1	2.3	4.5	20	>6
Lab020	5	13.3	14.4	55	1.0	6.9	22.2	20	1.7	4.3	4.5	55	0.2	4.4	13.5	20	3.5
Lab022	5	13.8	12.5	63	0.8	6.4	22.2	20	1.7	4.4	4.1	63	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	108	0.4	3.2	7.2	20	6.0	3.9	3.9	108	0.1	2.6	5.1	20	>6
Lab034	5	15.3	14.7	46	1.1	7.5	18.9	20	2.1	5.2	4.6	46	0.2	4.3	20.2	20	2.0
Lab037	5	15.3	15.2	53	0.4	2.6	5.9	20	>6	5.2	4.7	53	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	13.3	20	1.0	7.5	24.6	20	1.4	4.6	4.2	20	0.3	7.1	23.0	20	1.6
Lab049	5	14.7	14.3	41	0.5	3.5	9.7	20	4.9	4.9	4.7	41	0.3	6.4	16.8	20	2.5
Lab050	5	13.8	14.1	27	0.5	3.5	9.3	20	5.1	4.3	4.4	27	0.2	4.5	11.4	20	3.9
Total	-	-	13.7	664	1.3	9.5	-	-	-	-	4.3	664	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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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 (2021/05)									CUM (2019/02/01~2021/05/31)						
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	14.6	14.9	4	0.1	0.7	3.4	20	>6	14.6	14.6	48	0.3	2.1	4.1	20	>6
Lab020	5	13.3	14.7	2	-	-	-	20	-	13.3	14.4	55	1.0	6.9	22.2	20	1.7
Lab022	5	13.8	13.7	3	0.4	2.9	6.6	20	>6	13.8	12.5	63	0.8	6.4	22.2	20	1.7
Lab028	5	14.6	-	0	-	-	-	20	-	14.6	14.6	53	0.4	2.7	5.5	20	>6
Lab032	5	12.1	-	0	-	-	-	20	-	12.1	13.0	129	1.4	10.8	29.0	20	1.2
Lab033	5	12.4	12.2	4	0.5	4.1	9.8	20	4.5	12.4	12.5	108	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	13.2	5	0.4	3.0	19.8	20	2.1	15.3	14.7	46	1.1	7.5	18.9	20	2.1
Lab037	5	15.3	15.5	2	-	-	-	20	-	15.3	15.2	53	0.4	2.6	5.9	20	>6
Lab040	5	15.3	-	0	-	-	-	20	-	15.3	15.0	15	0.4	2.7	7.3	20	>6
Lab043	5	13.8	-	0	-	-	-	20	-	13.8	12.9	6	0.4	3.1	12.7	20	4.3
Lab047	5	14.7	14.8	2	-	-	-	20	-	14.7	13.3	20	1.0	7.5	24.6	20	1.4
Lab049	5	14.7	14.3	3	0.3	2.1	6.9	20	>6	14.7	14.3	41	0.5	3.5	9.7	20	4.9
Lab050	5	13.8	14.2	6	0.2	1.4	5.7	20	>6	13.8	14.1	27	0.5	3.5	9.3	20	5.1
Total	-	-	14.0	31	1.0	7.1	-	-	-	-	13.7	664	1.3	9.5	-	-	-

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

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

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

Month : 2021 05 Change

Cumulative : from 2019 02 01 to 2021 05 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2021/05)									CUM (2019/02/01~2021/05/31)						
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	4.4	4.5	4	0.2	4.4	11.2	20	4.0	4.4	4.4	48	0.1	2.3	4.5	20	>6
Lab020	5	4.3	4.5	2	-	-	-	20	-	4.3	4.5	55	0.2	4.4	13.5	20	3.5
Lab022	5	4.4	4.3	3	0.1	2.3	6.9	20	>6	4.4	4.1	63	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	-	0	-	-	-	20	-	3.5	4.0	129	0.6	15.0	44.3	20	0.4
Lab033	5	3.9	4.0	4	0.1	2.5	7.6	20	>6	3.9	3.9	108	0.1	2.6	5.1	20	>6
Lab034	5	5.2	4.5	5	0.1	2.2	17.9	20	3.0	5.2	4.6	46	0.2	4.3	20.2	20	2.0
Lab037	5	5.2	4.8	2	-	-	-	20	-	5.2	4.7	53	0.2	4.3	18.1	20	2.4
Lab040	5	5.2	-	0	-	-	-	20	-	5.2	5.4	15	0.4	7.4	18.7	20	2.2
Lab043	5	4.4	-	0	-	-	-	20	-	4.4	4.2	6	0.2	4.8	14.1	20	3.2
Lab047	5	4.6	4.7	2	-	-	-	20	-	4.6	4.2	20	0.3	7.1	23.0	20	1.6
Lab049	5	4.9	4.6	3	0.1	2.2	10.5	20	>6	4.9	4.7	41	0.3	6.4	16.8	20	2.5
Lab050	5	4.3	4.3	6	0.1	2.3	4.7	20	>6	4.3	4.4	27	0.2	4.5	11.4	20	3.9
Total	-	-	4.4	31	0.2	4.5	-	-	-	-	4.3	664	0.4	9.3	-	-	-

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

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

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

Month : 2021 05 Change

Cumulative : from 2019 02 01 to 2021 05 31 Change

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Reagent Kit	Reagent Code
Medicon	5