

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

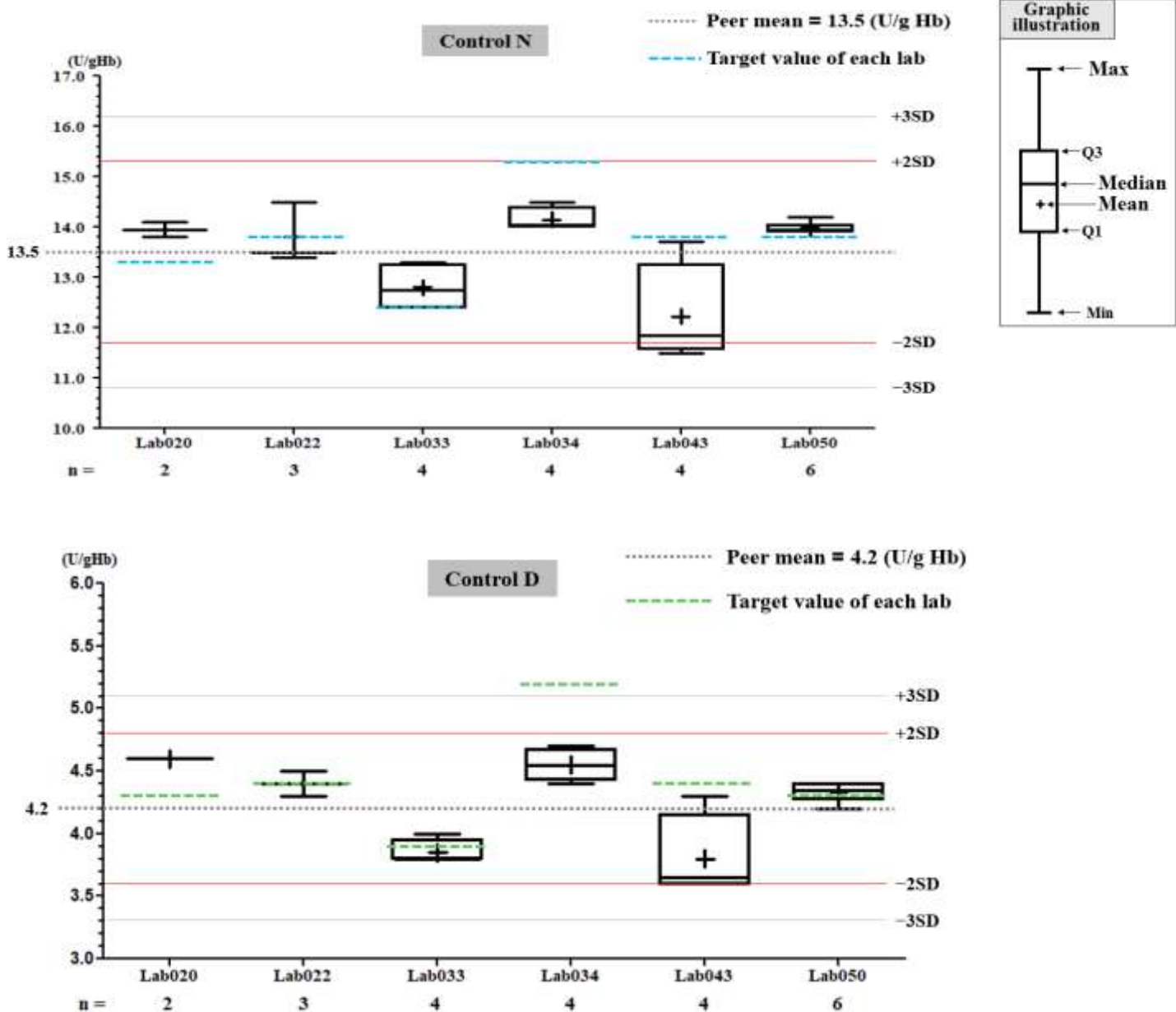
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	6	6
Received results number (n)	23	23
Median	13.9 (U/g Hb)	4.3 (U/g Hb)
Mean	13.5 (U/g Hb)	4.2 (U/g Hb)
SD	0.9	0.3
CV	6.7%	7.1%
Range of G6PD	11.5 ~ 14.5 (U/g Hb)	3.6 ~ 4.7 (U/g Hb)
Range of Hb	2.0 ~ 2.5 (g/dL)	1.9 ~ 2.4 (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)

Lab043

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/08)	CUM (2021/03/04~2021/08/31)	Month (2021/08)	CUM (2021/03/04~2021/08/31)
Runs (N)	4	16	4	16
Mean (U/gHb)	12.2	12.8	3.8	4.1
SD	1.0	0.7	0.3	0.3
CV (%)	8.2	5.5	7.9	7.3
Target Value (U/gHb)	13.8	13.8	4.4	4.4
Total Error (%)	28.0	18.2	29.4	21.5
TEa (%)	20	20	20	20
σ	1.0	2.3	0.8	1.8

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

Month : ; Cumulative : from to

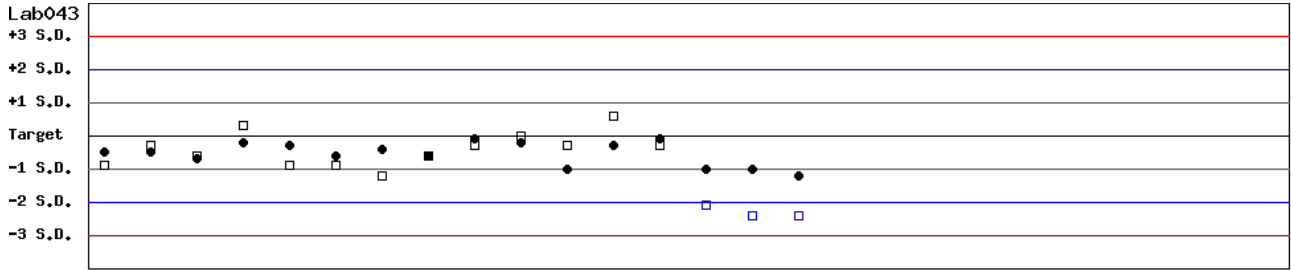
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-03-04 to 2021-08-31 ; Target : 13.8 ; SD : 1.95 (●)

Lot No.: AH1220D ; Duration : 2021-03-04 to 2021-08-31 ; Target : 4.4 ; SD : 0.34 (□)

Lab043



Date 03-04 03-11 03-18 03-25 04-01 04-08 06-17 07-02 07-09 07-15 07-22 07-29 08-05 08-12 08-19 08-26

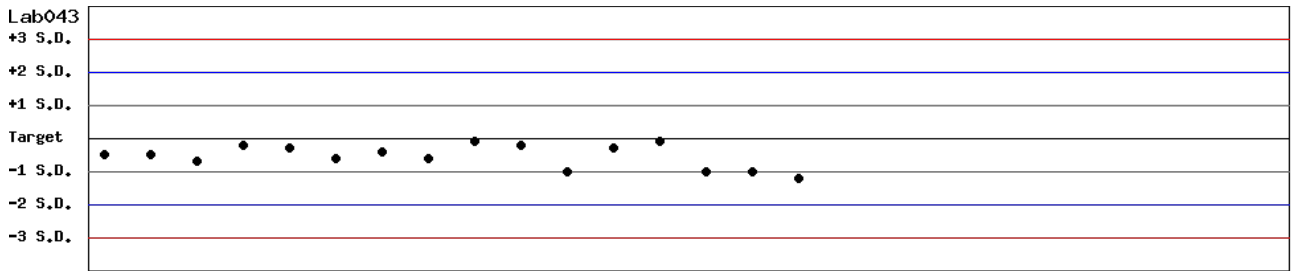
Month : ; Cumulative : from to

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-03-04 to 2021-08-31 ; Target : 13.8 ; SD : 1.95

Lab043



Date 03-04 03-11 03-18 03-25 04-01 04-08 06-17 07-02 07-09 07-15 07-22 07-29 08-05 08-12 08-19 08-26

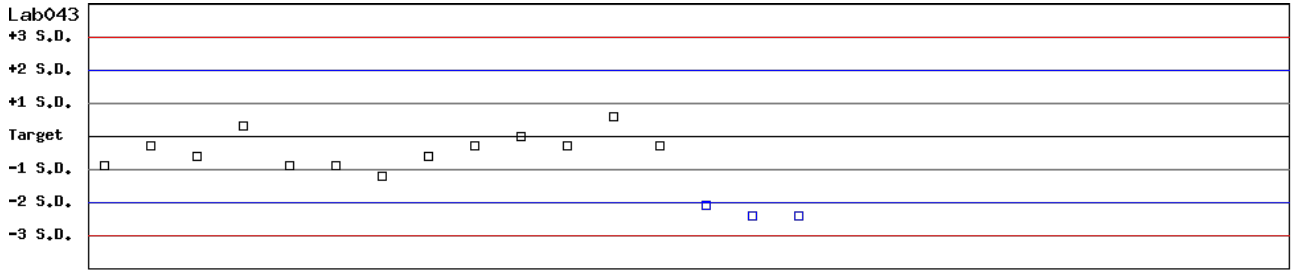
Month : ; Cumulative : from to

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2021-03-04 to 2021-08-31 ; Target : 4.4 ; SD : 0.34

Lab043



Date 03-04 03-11 03-18 03-25 04-01 04-08 06-17 07-02 07-09 07-15 07-22 07-29 08-05 08-12 08-19 08-26

Month : 2021 08 Change ; Cumulative : from 2021 03 04 to 2021 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 : 2021 ▼ 08 ▼ 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
Lab020	5	13.3	14.0	2	-	-	-	20	-	4.3	4.6	2	-	-	-	20	-
Lab022	5	13.8	13.8	3	0.6	4.3	8.7	20	4.7	4.4	4.4	3	0.1	2.3	4.5	20	>6
Lab033	5	12.4	12.8	4	0.5	3.9	11.0	20	4.3	3.9	3.9	4	0.1	2.6	5.1	20	>6
Lab034	5	15.3	14.2	4	0.2	1.4	10.0	20	>6	5.2	4.6	4	0.1	2.2	15.9	20	3.8
Lab043	5	13.8	12.2	4	1.0	8.2	28.0	20	1.0	4.4	3.8	4	0.3	7.9	29.4	20	0.8
Lab050	5	13.8	14.0	6	0.1	0.7	2.9	20	>6	4.3	4.3	6	0.1	2.3	4.7	20	>6
Total	-	-	13.5	23	0.9	6.7	-	-	-	-	4.2	23	0.3	7.1	-	-	-

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 ▼ 08 ▼ 31 ▼ 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	53	0.3	2.1	4.1	20	>6	4.4	4.4	53	0.1	2.3	4.5	20	>6
Lab020	5	13.3	14.3	64	1.0	7.0	21.5	20	1.8	4.3	4.5	64	0.2	4.4	13.5	20	3.5
Lab022	5	13.8	12.7	70	0.8	6.3	20.6	20	1.9	4.4	4.1	70	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	12.9	136	1.4	10.9	28.3	20	1.2	3.5	4.0	136	0.5	12.5	39.3	20	0.5
Lab033	5	12.4	12.5	121	0.4	3.2	7.2	20	6.0	3.9	3.9	121	0.2	5.1	10.3	20	3.9
Lab034	5	15.3	14.5	60	1.0	6.9	19.0	20	2.1	5.2	4.6	60	0.2	4.3	20.2	20	2.0
Lab037	5	15.3	15.2	55	0.4	2.6	5.9	20	>6	5.2	4.7	55	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	12.8	16	0.7	5.5	18.2	20	2.3	4.4	4.1	16	0.3	7.3	21.5	20	1.8
Lab047	5	14.7	13.7	26	1.2	8.8	24.3	20	1.5	4.6	4.3	26	0.3	7.0	20.5	20	1.9
Lab049	5	14.7	14.3	42	0.5	3.5	9.7	20	4.9	4.9	4.7	42	0.3	6.4	16.8	20	2.5
Lab050	5	13.8	14.0	45	0.5	3.6	8.6	20	5.2	4.3	4.4	45	0.2	4.5	11.4	20	3.9
Total	-	-	13.7	756	1.3	9.5	-	-	-	-	4.3	756	0.4	9.3	-	-	-

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 (2021/08)								CUM (2019/02/01~2021/08/31)							
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	14.6	-	0	-	-	-	20	-	14.6	14.6	53	0.3	2.1	4.1	20	>6
Lab020	5	13.3	14.0	2	-	-	-	20	-	13.3	14.3	64	1.0	7.0	21.5	20	1.8
Lab022	5	13.8	13.8	3	0.6	4.3	8.7	20	4.7	13.8	12.7	70	0.8	6.3	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	-	0	-	-	-	20	-	12.1	12.9	136	1.4	10.9	28.3	20	1.2
Lab033	5	12.4	12.8	4	0.5	3.9	11.0	20	4.3	12.4	12.5	121	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	14.2	4	0.2	1.4	10.0	20	>6	15.3	14.5	60	1.0	6.9	19.0	20	2.1
Lab037	5	15.3	-	0	-	-	-	20	-	15.3	15.2	55	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	12.2	4	1.0	8.2	28.0	20	1.0	13.8	12.8	16	0.7	5.5	18.2	20	2.3
Lab047	5	14.7	-	0	-	-	-	20	-	14.7	13.7	26	1.2	8.8	24.3	20	1.5
Lab049	5	14.7	-	0	-	-	-	20	-	14.7	14.3	42	0.5	3.5	9.7	20	4.9
Lab050	5	13.8	14.0	6	0.1	0.7	2.9	20	>6	13.8	14.0	45	0.5	3.6	8.6	20	5.2
Total	-	-	13.5	23	0.9	6.7	-	-	-	-	13.7	756	1.3	9.5	-	-	-

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

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

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

Month : 2021 08 Change

Cumulative : from 2019 02 01 to 2021 08 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2021/08)								CUM (2019/02/01~2021/08/31)							
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	4.4	-	0	-	-	-	20	-	4.4	4.4	53	0.1	2.3	4.5	20	>6
Lab020	5	4.3	4.6	2	-	-	-	20	-	4.3	4.5	64	0.2	4.4	13.5	20	3.5
Lab022	5	4.4	4.4	3	0.1	2.3	4.5	20	>6	4.4	4.1	70	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	136	0.5	12.5	39.3	20	0.5
Lab033	5	3.9	3.9	4	0.1	2.6	5.1	20	>6	3.9	3.9	121	0.2	5.1	10.3	20	3.9
Lab034	5	5.2	4.6	4	0.1	2.2	15.9	20	3.8	5.2	4.6	60	0.2	4.3	20.2	20	2.0
Lab037	5	5.2	-	0	-	-	-	20	-	5.2	4.7	55	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	3.8	4	0.3	7.9	29.4	20	0.8	4.4	4.1	16	0.3	7.3	21.5	20	1.8
Lab047	5	4.6	-	0	-	-	-	20	-	4.6	4.3	26	0.3	7.0	20.5	20	1.9
Lab049	5	4.9	-	0	-	-	-	20	-	4.9	4.7	42	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	45	0.2	4.5	11.4	20	3.9
Total	-	-	4.2	23	0.3	7.1	-	-	-	-	4.3	756	0.4	9.3	-	-	-

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

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

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

Month : 2021 08 Change

Cumulative : from 2019 02 01 to 2021 08 31 Change

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Reagent Kit	Reagent Code
Medicon	5