

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

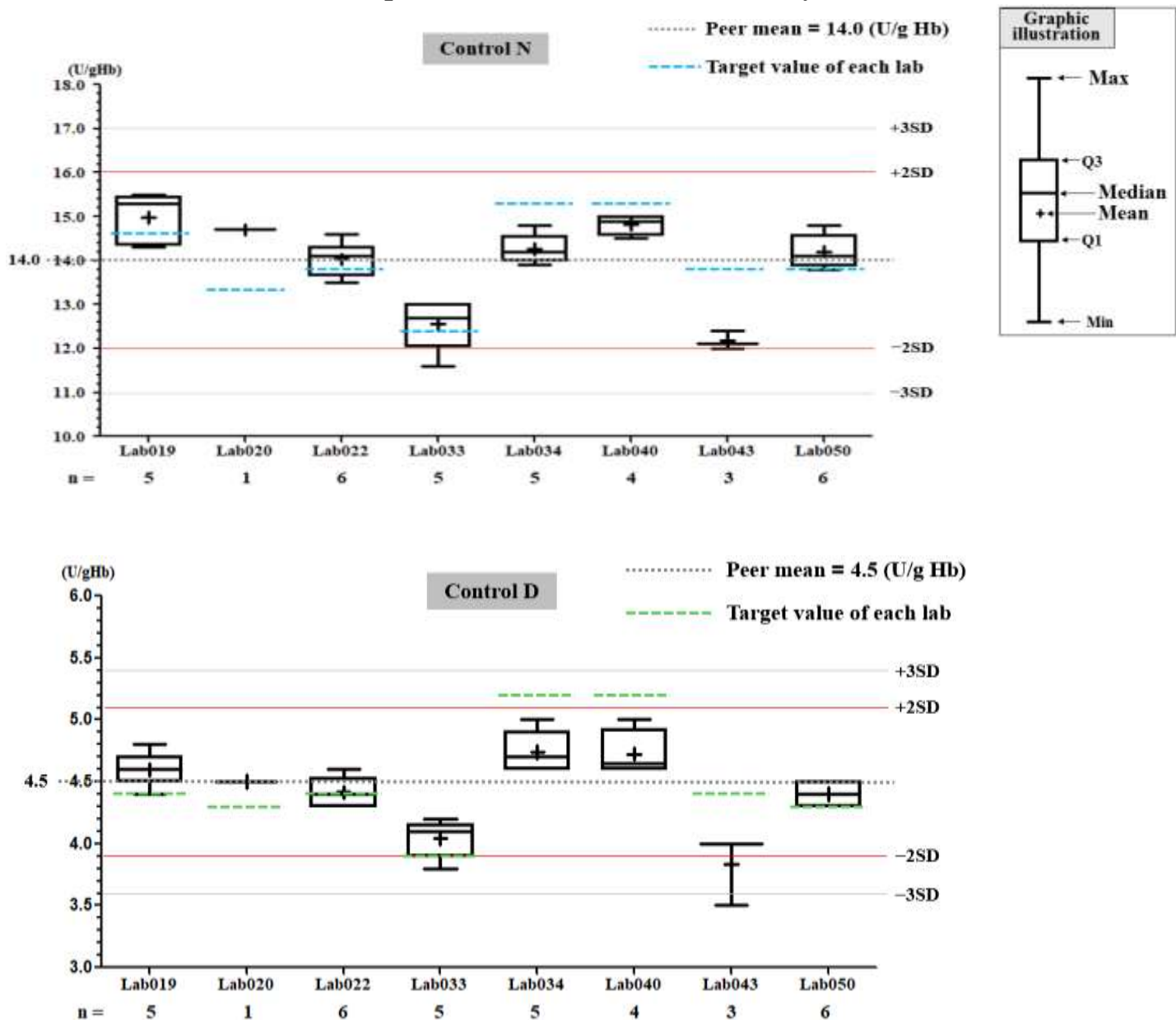
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	8	8
Received results number (n)	35	35
Median	14.2 (U/g Hb)	4.5 (U/g Hb)
Mean	14.0 (U/g Hb)	4.4 (U/g Hb)
SD	1.0	0.3
CV	7.1%	6.8%
Range of G6PD	11.6 ~ 15.5 (U/g Hb)	3.5 ~ 5.0 (U/g Hb)
Range of Hb	2.0 ~ 2.5 (g/dL)	2.0 ~ 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) Change

[Print Table](#)

Lab050

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/09)	CUM (2021/05/24~2021/09/30)	Month (2021/09)	CUM (2021/05/24~2021/09/30)
Runs (N)	6	26	6	26
Mean (U/gHb)	14.2	13.9	4.4	4.3
SD	0.4	0.5	0.1	0.1
CV (%)	2.8	3.6	2.3	2.3
Target Value (U/gHb)	13.8	13.8	4.3	4.3
Total Error (%)	8.5	7.9	6.9	4.7
TEa (%)	20	20	20	20
σ	>6	5.4	>6	>6

Bias (%) = $[(\text{Mean} - \text{Target}) / \text{Target}] \times 100\%$

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

σ (Sigma) = $[\text{TEa}\% - \text{Bias}(\%)] / \text{CV}(\%)$

Month : 2021 09 Change ; Cumulative : from 2021 05 24 to 2021 09 30 Change

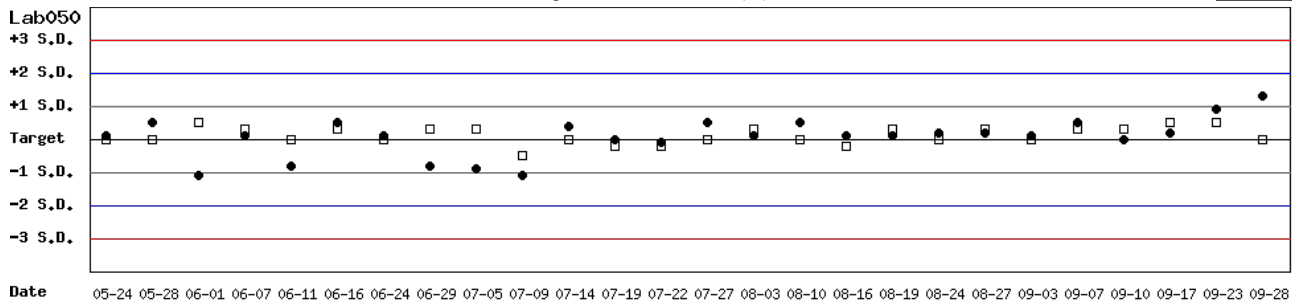
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-05-24 to 2021-09-30 ; Target : 13.8 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2021-05-24 to 2021-09-30 ; Target : 4.3 ; SD : 0.4 (□)

Lab050



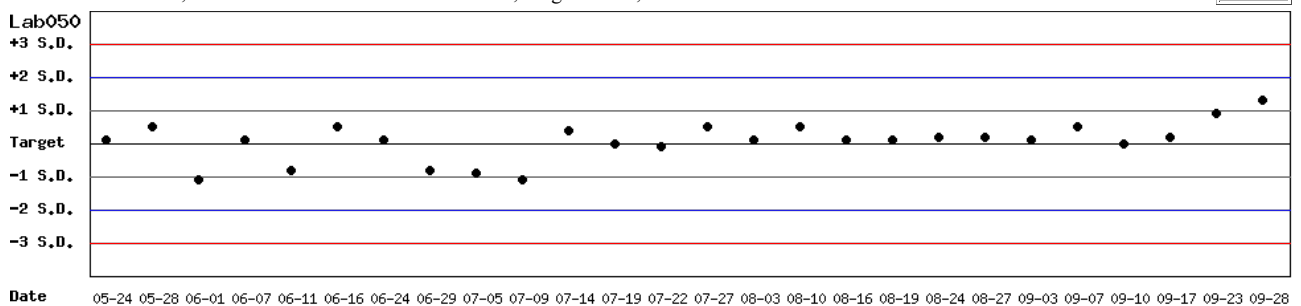
Month : 2021 09 Change ; Cumulative : from 2021 05 24 to 2021 09 30 Change

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-05-24 to 2021-09-30 ; Target : 13.8 ; SD : 0.8

Lab050



Month : 2021 09 Change ; Cumulative : from 2021 05 24 to 2021 09 30 Change

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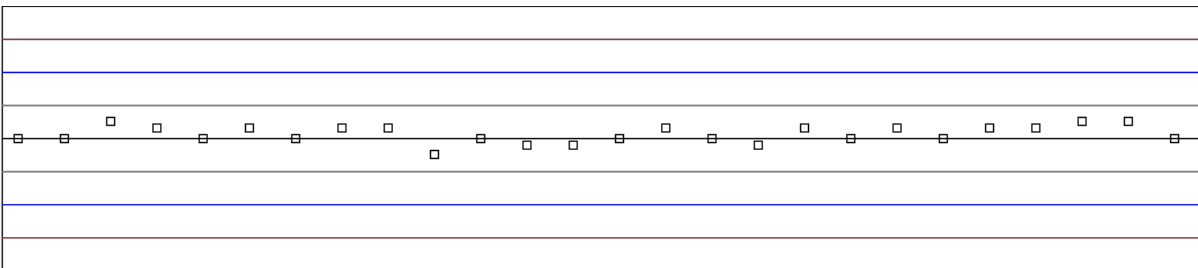
Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2021-05-24 to 2021-09-30 ; Target : 4.3 ; SD : 0.4

Lab050

Lab050

+3 S.D.
+2 S.D.
+1 S.D.
Target
-1 S.D.
-2 S.D.
-3 S.D.



Date

05-24 05-28 06-01 06-07 06-11 06-16 06-24 06-29 07-05 07-09 07-14 07-19 07-22 07-27 08-03 08-10 08-16 08-19 08-24 08-27 09-03 09-07 09-10 09-17 09-23 09-28

Month : ; Cumulative : from to

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Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon

Monthly

Month : 2021

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	15.0	5	0.6	4.0	10.7	20	4.3	4.4	4.6	5	0.1	2.2	8.9	20	>6
Lab020	5	13.3	14.7	1	-	-	-	20	-	4.3	4.5	1	-	-	-	20	-
Lab022	5	13.8	14.0	6	0.4	2.9	7.2	20	>6	4.4	4.4	6	0.1	2.3	4.5	20	>6
Lab033	5	12.4	12.6	5	0.6	4.8	11.1	20	3.8	3.9	4.0	5	0.2	5.0	12.6	20	3.5
Lab034	5	15.3	14.3	5	0.3	2.1	10.7	20	>6	5.2	4.7	5	0.2	4.3	18.1	20	2.4
Lab040	5	15.3	14.8	4	0.2	1.4	6.0	20	>6	5.2	4.7	4	0.2	4.3	18.1	20	2.4
Lab043	5	13.8	12.2	3	0.2	1.6	14.9	20	5.3	4.4	3.8	3	0.3	7.9	29.4	20	0.8
Lab050	5	13.8	14.2	6	0.4	2.8	8.5	20	>6	4.3	4.4	6	0.1	2.3	6.9	20	>6
Total	-	-	14.0	35	1.0	7.1	-	-	-	-	4.4	35	0.3	6.8	-	-	-

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from 2019 to 2021

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	14.7	58	0.4	2.7	6.1	20	>6	4.4	4.5	58	0.1	2.2	6.7	20	>6
Lab020	5	13.3	14.3	65	1.0	7.0	21.5	20	1.8	4.3	4.5	65	0.2	4.4	13.5	20	3.5
Lab022	5	13.8	12.8	76	0.9	7.0	21.3	20	1.8	4.4	4.1	76	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	126	0.4	3.2	7.2	20	6.0	3.9	3.9	126	0.2	5.1	10.3	20	3.9
Lab034	5	15.3	14.5	65	1.0	6.9	19.0	20	2.1	5.2	4.6	65	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	19	0.4	2.7	7.3	20	>6	5.2	5.3	19	0.5	9.4	20.8	20	1.9
Lab043	5	13.8	12.7	19	0.7	5.5	19.0	20	2.2	4.4	4.1	19	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	51	0.5	3.6	8.6	20	5.2	4.3	4.4	51	0.2	4.5	11.4	20	3.9
Total	-	-	13.7	791	1.3	9.5	-	-	-	-	4.3	791	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 (2021/09)								CUM (2019/02/01~2021/09/30)							
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	15.0	5	0.6	4.0	10.7	20	4.3	14.6	14.7	58	0.4	2.7	6.1	20	>6
Lab020	5	13.3	14.7	1	-	-	-	20	-	13.3	14.3	65	1.0	7.0	21.5	20	1.8
Lab022	5	13.8	14.0	6	0.4	2.9	7.2	20	>6	13.8	12.8	76	0.9	7.0	21.3	20	1.8
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	12.6	5	0.6	4.8	11.1	20	3.8	12.4	12.5	126	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	14.3	5	0.3	2.1	10.7	20	>6	15.3	14.5	65	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	14.8	4	0.2	1.4	6.0	20	>6	15.3	15.0	19	0.4	2.7	7.3	20	>6
Lab043	5	13.8	12.2	3	0.2	1.6	14.9	20	5.3	13.8	12.7	19	0.7	5.5	19.0	20	2.2
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	14.2	6	0.4	2.8	8.5	20	>6	13.8	14.0	51	0.5	3.6	8.6	20	5.2
Total	-	-	14.0	35	1.0	7.1	-	-	-	-	13.7	791	1.3	9.5	-	-	-

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

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

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

Month : 2021 09 Change

Cumulative : from 2019 02 01 to 2021 09 30 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2021/09)								CUM (2019/02/01~2021/09/30)							
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	4.6	5	0.1	2.2	8.9	20	>6	4.4	4.5	58	0.1	2.2	6.7	20	>6
Lab020	5	4.3	4.5	1	-	-	-	20	-	4.3	4.5	65	0.2	4.4	13.5	20	3.5
Lab022	5	4.4	4.4	6	0.1	2.3	4.5	20	>6	4.4	4.1	76	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	4.0	5	0.2	5.0	12.6	20	3.5	3.9	3.9	126	0.2	5.1	10.3	20	3.9
Lab034	5	5.2	4.7	5	0.2	4.3	18.1	20	2.4	5.2	4.6	65	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	4.7	4	0.2	4.3	18.1	20	2.4	5.2	5.3	19	0.5	9.4	20.8	20	1.9
Lab043	5	4.4	3.8	3	0.3	7.9	29.4	20	0.8	4.4	4.1	19	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	4.4	6	0.1	2.3	6.9	20	>6	4.3	4.4	51	0.2	4.5	11.4	20	3.9
Total	-	-	4.4	35	0.3	6.8	-	-	-	-	4.3	791	0.4	9.3	-	-	-

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

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

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

Month : 2021 09 Change

Cumulative : from 2019 02 01 to 2021 09 30 Change

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Reagent Kit	Reagent Code
Medicon	5