

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - November 2020 -

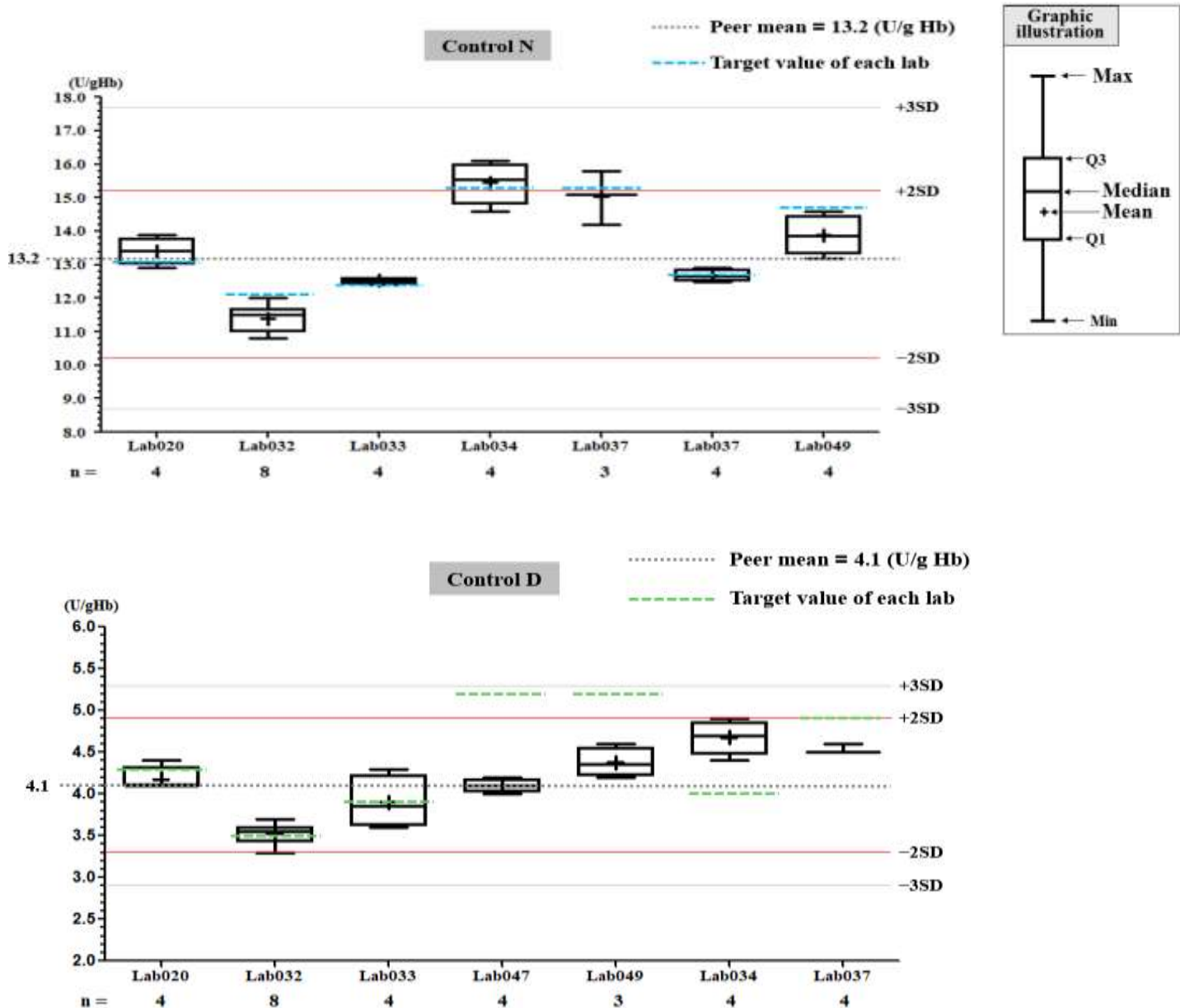
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	7	7
Received results number (n)	31	31
Median	12.9 (U/gHb)	4.1 (U/gHb)
Mean	13.2 (U/gHb)	4.1 (U/gHb)
SD	1.5	0.4
CV	11.4%	9.8%
Range of G6PD	10.8 ~ 16.1 (U/gHb)	3.3 ~ 4.9 (U/gHb)
Range of Hb	1.8 ~ 2.3 (g/dL)	2.0 ~ 2.5 (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)

Lab037

	Control N		Control D	
QC Control Lot No.	AH1220N		AH1220D	
Duration of the Analyzing	Month (2020/11)	CUM (2020/03/05~2020/11/30)	Month (2020/11)	CUM (2020/03/05~2020/11/30)
Runs (N)	3	26	3	26
Mean (U/gHb)	15.0	15.1	4.5	4.7
SD	0.8	0.4	0.1	0.2
CV (%)	5.3	2.6	2.2	4.3
Target Value (U/gHb)	15.3	15.3	5.2	5.2
Total Error (%)	12.6	6.6	17.9	18.1
TEa (%)	20	20	20	20
σ	3.4	>6	3.0	2.4

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

Month : 2020 11 ; Cumulative : from 2020 03 05 to 2020 11 30

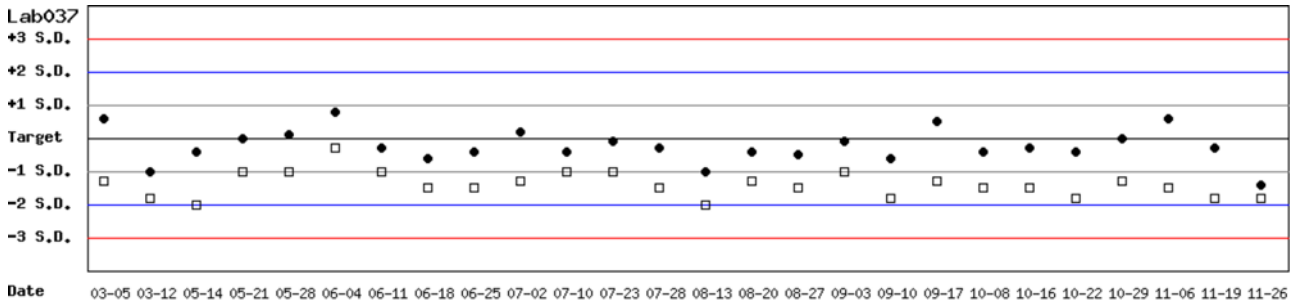
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-03-05 to 2020-11-30 ; Target : 15.3 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2020-03-05 to 2020-11-30 ; Target : 5.2 ; SD : 0.4 (□)

Lab037



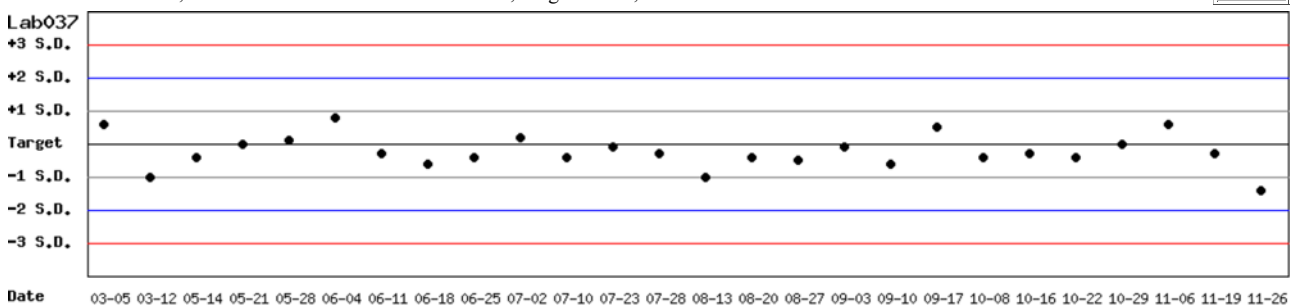
Month : 2020 11 ; Cumulative : from 2020 03 05 to 2020 11 30

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-03-05 to 2020-11-30 ; Target : 15.3 ; SD : 0.8

Lab037



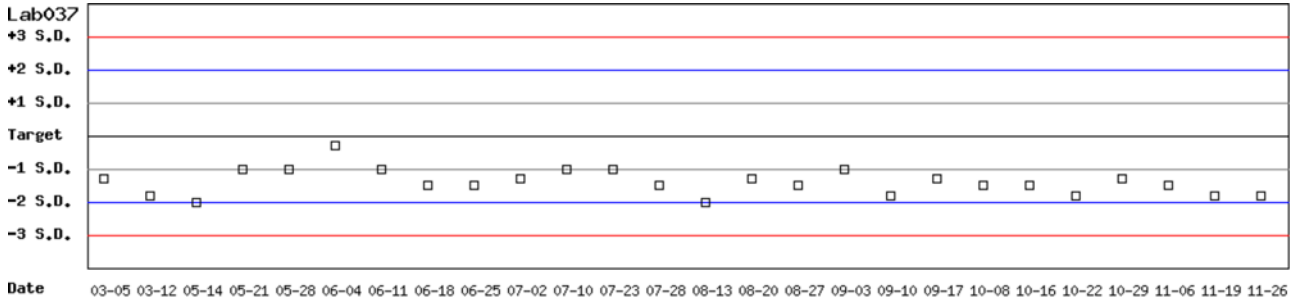
Month : 2020 11 ; Cumulative : from 2020 03 05 to 2020 11 30

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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-03-05 to 2020-11-30 ; Target : 5.2 ; SD : 0.4

Lab037



Month : 2020 ▾ 11 ▾ Change ; Cumulative : from 2020 ▾ 03 ▾ 05 ▾ to 2020 ▾ 11 ▾ 30 ▾ 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 : 2020 11 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
Lab020	5	13.3	13.4	4	0.4	3.0	6.7	20	>6	4.3	4.2	4	0.2	4.8	11.8	20	3.7
Lab032	5	12.1	11.4	8	0.4	3.5	12.8	20	4.1	3.5	3.5	8	0.1	2.9	5.7	20	>6
Lab033	5	12.4	12.5	4	0.1	0.8	2.4	20	>6	3.9	3.9	4	0.3	7.7	15.4	20	2.6
Lab034	5	15.3	15.5	4	0.6	3.9	9.0	20	4.8	5.2	4.7	4	0.2	4.3	18.1	20	2.4
Lab037	5	15.3	15.0	3	0.8	5.3	12.6	20	3.4	5.2	4.5	3	0.1	2.2	17.9	20	3.0
Lab047	5	12.7	12.7	4	0.2	1.6	3.1	20	>6	4.0	4.1	4	0.1	2.4	7.4	20	>6
Lab049	5	14.7	13.9	4	0.6	4.3	14.1	20	3.4	4.9	4.4	4	0.2	4.5	19.3	20	2.2
Total	-	-	13.2	31	1.5	11.4	-	-	-	-	4.1	31	0.4	9.8	-	-	-

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 2019 02 01 to 2020 11 30 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	15.0	14.8	19	0.4	2.7	6.7	20	>6	4.6	4.5	19	0.1	2.2	6.6	20	>6
Lab020	5	13.3	14.3	33	1.2	8.4	24.3	20	1.5	4.3	4.5	33	0.3	6.7	18.0	20	2.3
Lab022	5	13.8	12.3	50	0.6	4.9	20.6	20	1.9	4.4	4.0	50	0.2	5.0	19.1	20	2.2
Lab028	5	14.6	14.6	22	0.4	2.7	5.5	20	>6	4.6	4.6	22	0.1	2.2	4.3	20	>6
Lab032	5	12.1	13.2	104	1.5	11.4	31.8	20	1.0	3.5	4.1	104	0.6	14.6	46.4	20	0.2
Lab033	5	12.4	12.5	82	0.4	3.2	7.2	20	6.0	3.9	3.9	82	0.1	2.6	5.1	20	>6
Lab034	5	15.3	15.4	21	0.4	2.6	5.8	20	>6	5.2	4.7	21	0.2	4.3	18.1	20	2.4
Lab037	5	15.3	15.2	37	0.4	2.6	5.9	20	>6	5.2	4.7	37	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
Lab047	5	12.7	12.6	9	0.2	1.6	4.0	20	>6	4.0	4.0	9	0.1	2.5	5.0	20	>6
Lab049	5	14.7	14.4	17	0.5	3.5	9.0	20	5.1	4.9	4.9	17	0.4	8.2	16.3	20	2.4
Lab050	5	15.3	14.6	6	0.8	5.5	15.5	20	2.8	5.2	4.4	6	0.5	11.4	38.1	20	0.4
Total	-	-	13.6	410	1.4	10.3	-	-	-	-	4.3	410	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 (2020/11)								CUM (2019/02/01~2020/11/30)							
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	-	0	-	-	-	20	-	15.0	14.8	19	0.4	2.7	6.7	20	>6
Lab020	5	13.3	13.4	4	0.4	3.0	6.7	20	>6	13.3	14.3	33	1.2	8.4	24.3	20	1.5
Lab022	5	13.8	-	0	-	-	-	20	-	13.8	12.3	50	0.6	4.9	20.6	20	1.9
Lab028	5	14.6	-	0	-	-	-	20	-	14.6	14.6	22	0.4	2.7	5.5	20	>6
Lab032	5	12.1	11.4	8	0.4	3.5	12.8	20	4.1	12.1	13.2	104	1.5	11.4	31.8	20	1.0
Lab033	5	12.4	12.5	4	0.1	0.8	2.4	20	>6	12.4	12.5	82	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	15.5	4	0.6	3.9	9.0	20	4.8	15.3	15.4	21	0.4	2.6	5.8	20	>6
Lab037	5	15.3	15.0	3	0.8	5.3	12.6	20	3.4	15.3	15.2	37	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
Lab047	5	12.7	12.7	4	0.2	1.6	3.1	20	>6	12.7	12.6	9	0.2	1.6	4.0	20	>6
Lab049	5	14.7	13.9	4	0.6	4.3	14.1	20	3.4	14.7	14.4	17	0.5	3.5	9.0	20	5.1
Lab050	5	15.3	-	0	-	-	-	20	-	15.3	14.6	6	0.8	5.5	15.5	20	2.8
Total	-	-	13.2	31	1.5	11.4	-	-	-	-	13.6	410	1.4	10.3	-	-	-

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

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

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

Month : 2020 11 Change

Cumulative : from 2019 02 01 to 2020 11 30 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2020/11)								CUM (2019/02/01~2020/11/30)							
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	-	0	-	-	-	20	-	4.6	4.5	19	0.1	2.2	6.6	20	>6
Lab020	5	4.3	4.2	4	0.2	4.8	11.8	20	3.7	4.3	4.5	33	0.3	6.7	18.0	20	2.3
Lab022	5	4.4	-	0	-	-	-	20	-	4.4	4.0	50	0.2	5.0	19.1	20	2.2
Lab028	5	4.6	-	0	-	-	-	20	-	4.6	4.6	22	0.1	2.2	4.3	20	>6
Lab032	5	3.5	3.5	8	0.1	2.9	5.7	20	>6	3.5	4.1	104	0.6	14.6	46.4	20	0.2
Lab033	5	3.9	3.9	4	0.3	7.7	15.4	20	2.6	3.9	3.9	82	0.1	2.6	5.1	20	>6
Lab034	5	5.2	4.7	4	0.2	4.3	18.1	20	2.4	5.2	4.7	21	0.2	4.3	18.1	20	2.4
Lab037	5	5.2	4.5	3	0.1	2.2	17.9	20	3.0	5.2	4.7	37	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
Lab047	5	4.0	4.1	4	0.1	2.4	7.4	20	>6	4.0	4.0	9	0.1	2.5	5.0	20	>6
Lab049	5	4.9	4.4	4	0.2	4.5	19.3	20	2.2	4.9	4.9	17	0.4	8.2	16.3	20	2.4
Lab050	5	5.2	-	0	-	-	-	20	-	5.2	4.4	6	0.5	11.4	38.1	20	0.4
Total	-	-	4.1	31	0.4	9.8	-	-	-	-	4.3	410	0.5	11.6	-	-	-

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

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

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

Month : 2020 11 Change

Cumulative : from 2019 02 01 to 2020 11 30 Change

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Reagent Kit	Reagent Code
Medicon	5