

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

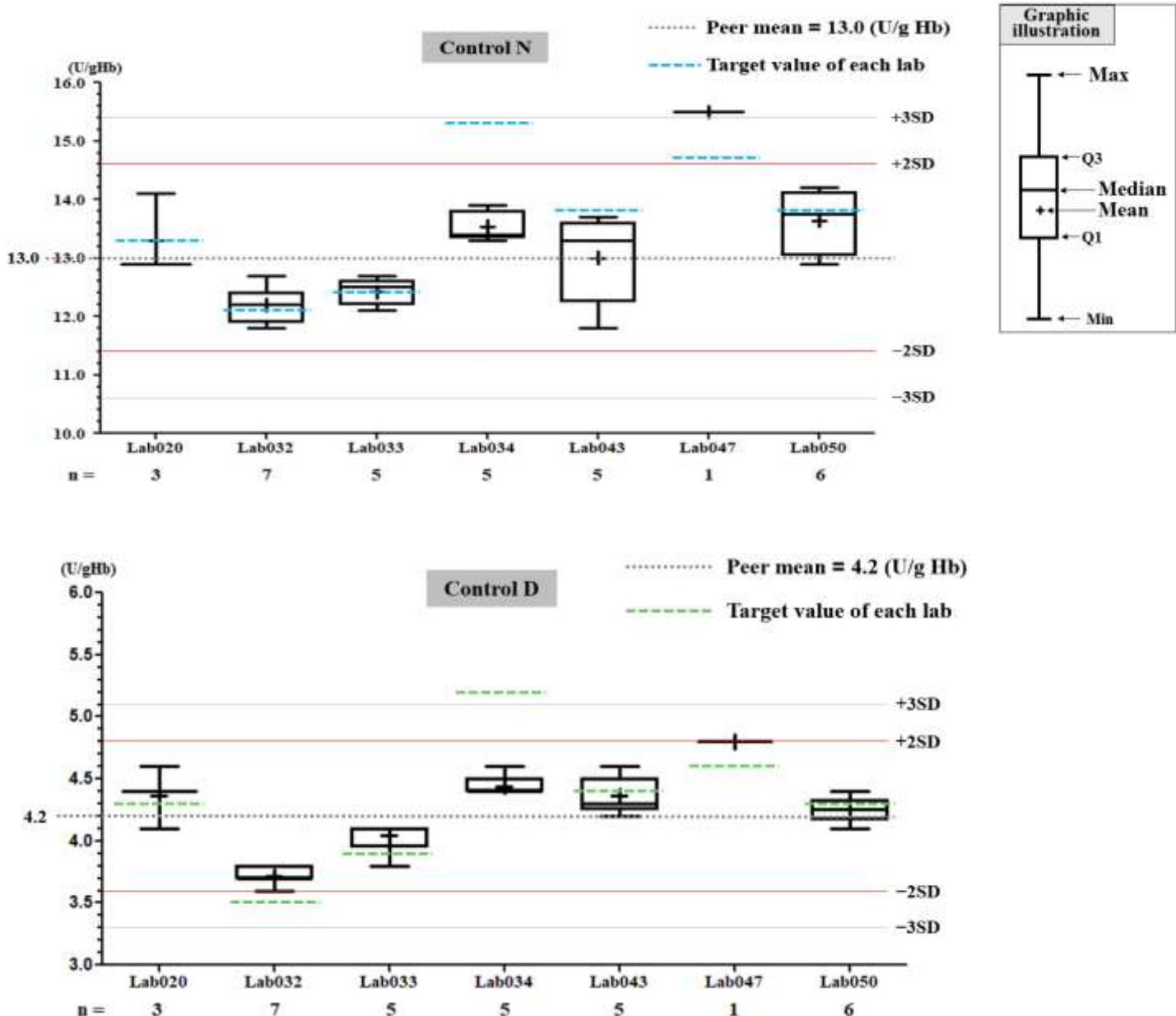
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	7	7
Received results number (n)	32	32
Median	12.9 (U/g Hb)	4.2 (U/g Hb)
Mean	13.0 (U/g Hb)	4.2 (U/g Hb)
SD	0.8	0.3
CV	6.2%	7.1%
Range of G6PD	11.8 ~ 15.5 (U/g Hb)	3.6 ~ 4.8 (U/g Hb)
Range of Hb	1.9 ~ 2.8 (g/dL)	2.0 ~ 2.7 (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

Lab032

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/07)	CUM (2021/01/26~2021/07/31)	Month (2021/07)	CUM (2021/01/26~2021/07/31)
Runs (N)	7	26	7	26
Mean (U/gHb)	12.2	12.0	3.7	3.7
SD	0.3	0.4	0.1	0.1
CV (%)	2.5	3.3	2.7	2.7
Target Value (U/gHb)	12.1	12.1	3.5	3.5
Total Error (%)	5.7	7.5	11.1	11.1
TEa (%)	20	20	20	20
σ	>6	5.8	5.3	5.3

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

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

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

Month : 2021 07 Change ; Cumulative : from 2021 01 26 to 2021 07 31 Change

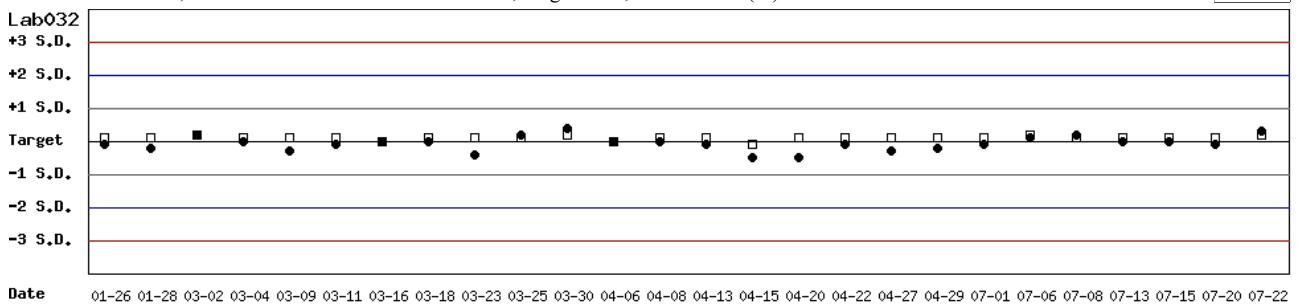
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-01-26 to 2021-07-31 ; Target : 12.1 ; SD : 2.00 (●)

Lot No.: AH1220D ; Duration : 2021-01-26 to 2021-07-31 ; Target : 3.5 ; SD : 1.50 (□)

Lab032



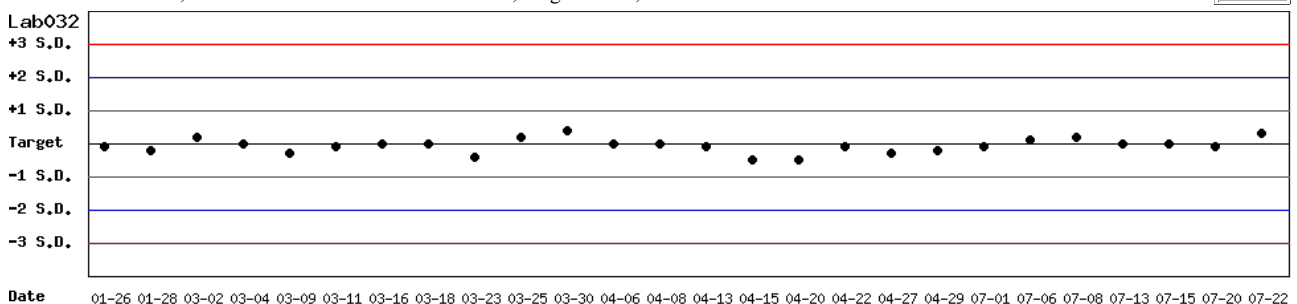
Month : 2021 07 Change ; Cumulative : from 2021 01 26 to 2021 07 31 Change

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-01-26 to 2021-07-31 ; Target : 12.1 ; SD : 2.00

Lab032



Month : 2021 07 Change ; Cumulative : from 2021 01 26 to 2021 07 31 Change

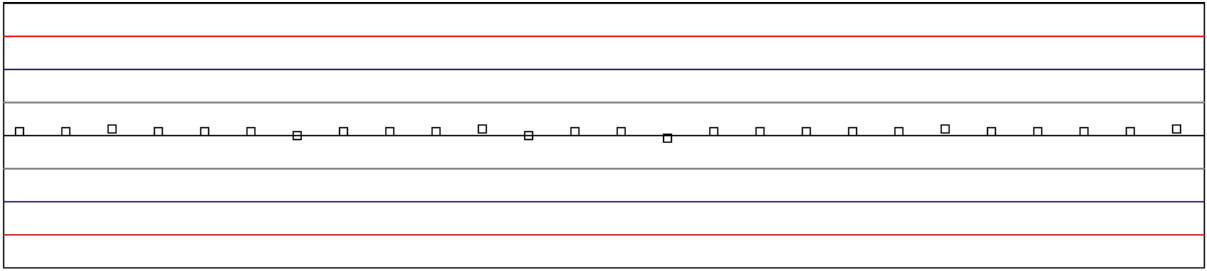
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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2021-01-26 to 2021-07-31 ; Target : 3.5 ; SD : 1.50

Lab032

Lab032
+3 S.D.
+2 S.D.
+1 S.D.
Target
-1 S.D.
-2 S.D.
-3 S.D.



Date 01-26 01-28 03-02 03-04 03-09 03-11 03-16 03-18 03-23 03-25 03-30 04-06 04-08 04-13 04-15 04-20 04-22 04-27 04-29 07-01 07-06 07-08 07-13 07-15 07-20 07-22

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 07 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	13.3	3	0.7	5.3	10.5	20	3.8	4.3	4.4	3	0.3	6.8	16.0	20	2.6
Lab032	5	12.1	12.2	7	0.3	2.5	5.7	20	>6	3.5	3.7	7	0.1	2.7	11.1	20	5.3
Lab033	5	12.4	12.4	5	0.2	1.6	3.2	20	>6	3.9	4.0	5	0.1	2.5	7.6	20	>6
Lab034	5	15.3	13.5	5	0.3	2.2	16.2	20	3.7	5.2	4.4	5	0.1	2.3	19.9	20	2.0
Lab043	5	13.8	13.0	5	0.8	6.2	18.1	20	2.3	4.4	4.4	5	0.2	4.5	9.1	20	4.4
Lab047	5	14.7	15.5	1	-	-	-	20	-	4.6	4.8	1	-	-	-	20	-
Lab050	5	13.8	13.6	6	0.5	3.7	8.8	20	5.0	4.3	4.3	6	0.1	2.3	4.7	20	>6
Total	-	-	13.0	32	0.8	6.2	-	-	-	-	4.2	32	0.3	7.1	-	-	-

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

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

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

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Cumulative

Cumulative : from 2019 02 01 to 2021 07 31 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	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	62	1.0	7.0	21.5	20	1.8	4.3	4.5	62	0.2	4.4	13.5	20	3.5
Lab022	5	13.8	12.6	67	0.8	6.3	21.4	20	1.8	4.4	4.1	67	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	117	0.4	3.2	7.2	20	6.0	3.9	3.9	117	0.2	5.1	10.3	20	3.9
Lab034	5	15.3	14.6	56	1.1	7.5	19.6	20	2.1	5.2	4.6	56	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	13.0	12	0.5	3.8	13.5	20	3.7	4.4	4.3	12	0.2	4.7	11.6	20	3.8
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	39	0.6	4.3	10.0	20	4.3	4.3	4.4	39	0.2	4.5	11.4	20	3.9
Total	-	-	13.7	733	1.3	9.5	-	-	-	-	4.3	733	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 (2021/07)								CUM (2019/02/01~2021/07/31)							
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	-	0	-	-	-	20	-	14.6	14.6	53	0.3	2.1	4.1	20	>6
Lab020	5	13.3	13.3	3	0.7	5.3	10.5	20	3.8	13.3	14.3	62	1.0	7.0	21.5	20	1.8
Lab022	5	13.8	-	0	-	-	-	20	-	13.8	12.6	67	0.8	6.3	21.4	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	12.2	7	0.3	2.5	5.7	20	>6	12.1	12.9	136	1.4	10.9	28.3	20	1.2
Lab033	5	12.4	12.4	5	0.2	1.6	3.2	20	>6	12.4	12.5	117	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	13.5	5	0.3	2.2	16.2	20	3.7	15.3	14.6	56	1.1	7.5	19.6	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	13.0	5	0.8	6.2	18.1	20	2.3	13.8	13.0	12	0.5	3.8	13.5	20	3.7
Lab047	5	14.7	15.5	1	-	-	-	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	13.6	6	0.5	3.7	8.8	20	5.0	13.8	14.0	39	0.6	4.3	10.0	20	4.3
Total	-	-	13.0	32	0.8	6.2	-	-	-	-	13.7	733	1.3	9.5	-	-	-

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

Month : 2021 07 Change

Cumulative : from 2019 02 01 to 2021 07 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2021/07)								CUM (2019/02/01~2021/07/31)							
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	-	0	-	-	-	20	-	4.4	4.4	53	0.1	2.3	4.5	20	>6
Lab020	5	4.3	4.4	3	0.3	6.8	16.0	20	2.6	4.3	4.5	62	0.2	4.4	13.5	20	3.5
Lab022	5	4.4	-	0	-	-	-	20	-	4.4	4.1	67	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	3.7	7	0.1	2.7	11.1	20	5.3	3.5	4.0	136	0.5	12.5	39.3	20	0.5
Lab033	5	3.9	4.0	5	0.1	2.5	7.6	20	>6	3.9	3.9	117	0.2	5.1	10.3	20	3.9
Lab034	5	5.2	4.4	5	0.1	2.3	19.9	20	2.0	5.2	4.6	56	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	4.4	5	0.2	4.5	9.1	20	4.4	4.4	4.3	12	0.2	4.7	11.6	20	3.8
Lab047	5	4.6	4.8	1	-	-	-	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	39	0.2	4.5	11.4	20	3.9
Total	-	-	4.2	32	0.3	7.1	-	-	-	-	4.3	733	0.4	9.3	-	-	-

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

Month : 2021 07 Change

Cumulative : from 2019 02 01 to 2021 07 31 Change

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Reagent Kit	Reagent Code
Medicon	5