

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

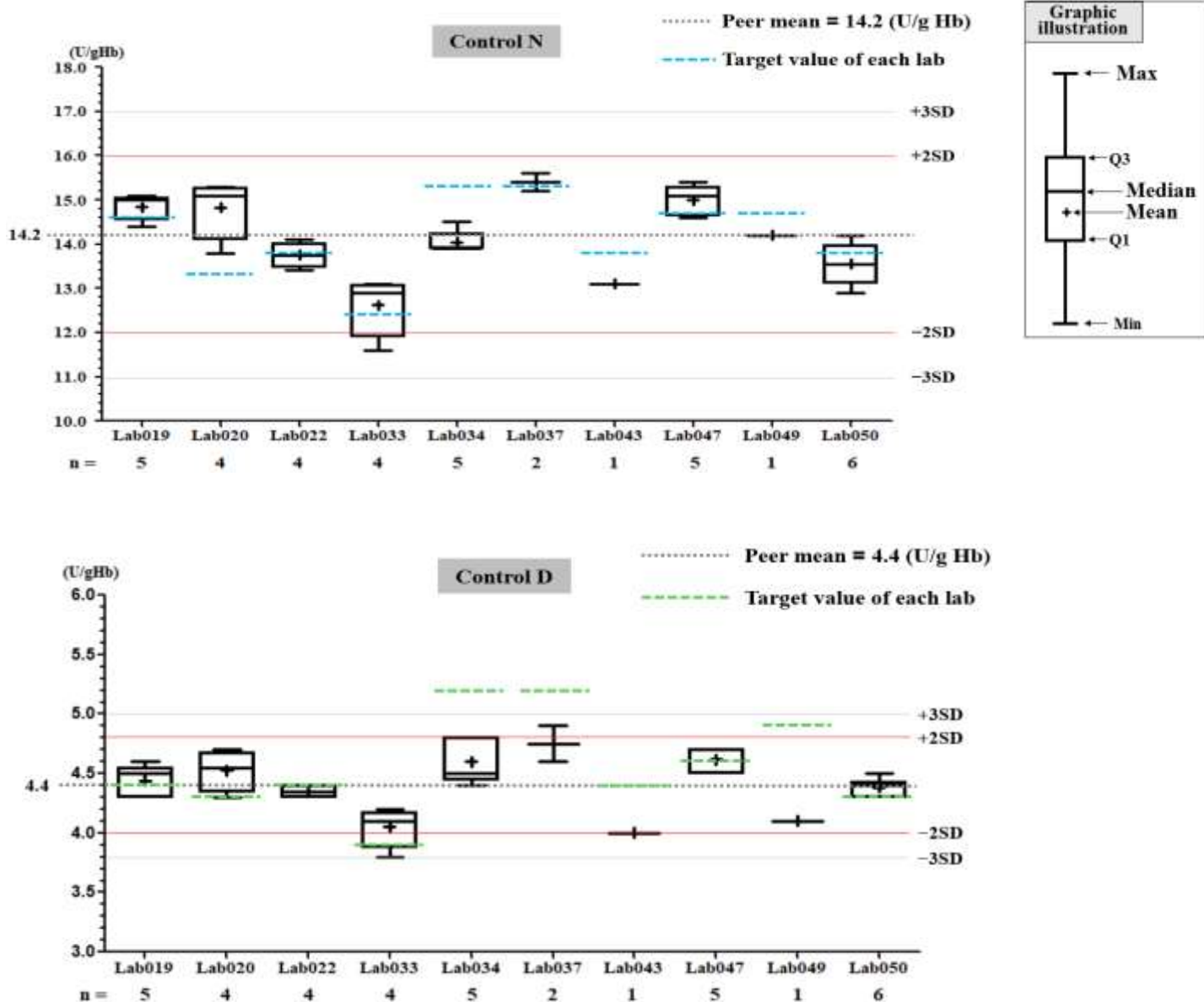
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AH1220N)	Control D (Lot No.:AH1220D)
Labs	10	10
Received results number (n)	37	37
Median	14.1 (U/g Hb)	4.4 (U/g Hb)
Mean	14.2 (U/g Hb)	4.4 (U/g Hb)
SD	0.9	0.2
CV	6.3%	4.5%
Range of G6PD	11.6 ~ 15.6 (U/g Hb)	3.8 ~ 4.9 (U/g Hb)
Range of Hb	1.9 ~ 2.9 (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](#)

Lab034

	Control N		Control D	
QC Control Lot No.	AH1220N		AH1220D	
Duration of the Analyzing	Month (2021/06)	CUM (2021/01/14~2021/06/30)	Month (2021/06)	CUM (2021/01/14~2021/06/30)
Runs (N)	5	26	5	26
Mean (U/gHb)	14.0	14.2	4.6	4.6
SD	0.3	1.1	0.2	0.2
CV (%)	2.1	7.7	4.3	4.3
Target Value (U/gHb)	15.3	15.3	5.2	5.2
Total Error (%)	12.8	22.7	20.2	20.2
TEa (%)	20	20	20	20
σ	5.5	1.7	2.0	2.0

Bias (%) = $\left(\frac{|\text{Mean} - \text{Target}|}{\text{Target}} \right) \times 100\%$

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

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

Month : 2021 06 Change ; Cumulative : from 2021 01 14 to 2021 06 30 Change

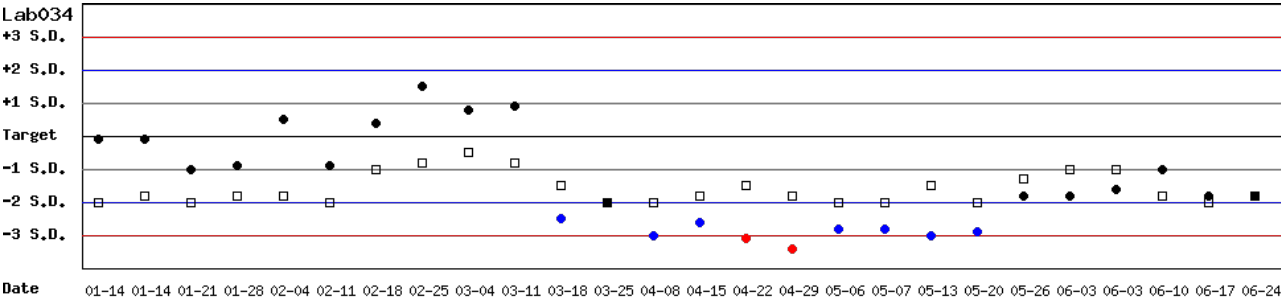
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Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-01-14 to 2021-06-30 ; Target : 15.3 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2021-01-14 to 2021-06-30 ; Target : 5.2 ; SD : 0.4 (□)

Lab034



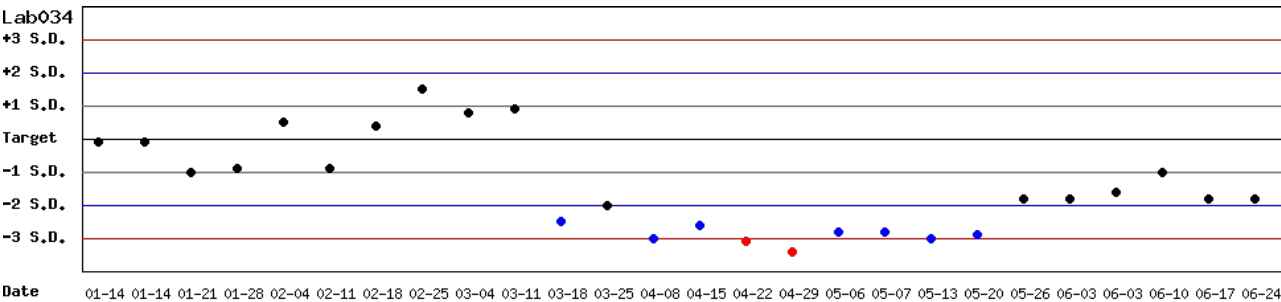
Month : 2021 06 Change ; Cumulative : from 2021 01 14 to 2021 06 30 Change

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Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2021-01-14 to 2021-06-30 ; Target : 15.3 ; SD : 0.8

Lab034



Month : 2021 06 Change ; Cumulative : from 2021 01 14 to 2021 06 30 Change

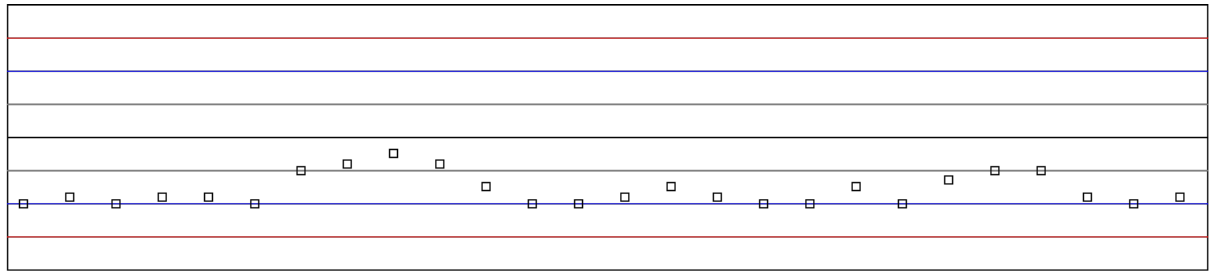
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Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2021-01-14 to 2021-06-30 ; Target : 5.2 ; SD : 0.4

Lab034

Lab034
+3 S.D.
+2 S.D.
+1 S.D.
Target
-1 S.D.
-2 S.D.
-3 S.D.



Date 01-14 01-14 01-21 01-28 02-04 02-11 02-18 02-25 03-04 03-11 03-18 03-25 04-08 04-15 04-22 04-29 05-06 05-07 05-13 05-20 05-26 06-03 06-03 06-10 06-17 06-24

Month : 2021 06 Change ; Cumulative : from 2021 01 14 to 2021 06 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 : 2021 06 Change

		Control N (Lot No.: AH1220N)									Control D (Lot No.: AH1220D)							
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	14.8	5	0.3	2.0	5.4	20	>6		4.4	4.4	5	0.1	2.3	4.5	20	>6
Lab020	5	13.3	14.8	4	0.7	4.7	20.7	20	1.9		4.3	4.5	4	0.2	4.4	13.5	20	3.5
Lab022	5	13.8	13.8	4	0.3	2.2	4.3	20	>6		4.4	4.4	4	0.1	2.3	4.5	20	>6
Lab033	5	12.4	12.6	4	0.7	5.6	12.7	20	3.3		3.9	4.1	4	0.2	4.9	14.9	20	3.0
Lab034	5	15.3	14.0	5	0.3	2.1	12.8	20	5.5		5.2	4.6	5	0.2	4.3	20.2	20	2.0
Lab037	5	15.3	15.4	2	-	-	-	20	-		5.2	4.8	2	-	-	-	20	-
Lab043	5	13.8	13.1	1	-	-	-	20	-		4.4	4.0	1	-	-	-	20	-
Lab047	5	14.7	15.0	5	0.3	2.0	6.0	20	>6		4.6	4.6	5	0.1	2.2	4.3	20	>6
Lab049	5	14.7	14.2	1	-	-	-	20	-		4.9	4.1	1	-	-	-	20	-
Lab050	5	13.8	13.6	6	0.5	3.7	8.8	20	5.0		4.3	4.4	6	0.1	2.3	6.9	20	>6
Total	-	-	14.2	37	0.9	6.3	-	-	-		-	4.4	37	0.2	4.5	-	-	-

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 2021 06 30 Change

		Control N (Lot No.: AH1220N)									Control D (Lot No.: AH1220D)							
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	14.6	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	14.4	59	1.0	6.9	22.2	20	1.7		4.3	4.5	59	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	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	112	0.4	3.2	7.2	20	6.0		3.9	3.9	112	0.2	5.1	10.3	20	3.9
Lab034	5	15.3	14.7	51	1.1	7.5	18.9	20	2.1		5.2	4.6	51	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	12.9	7	0.3	2.3	11.2	20	5.9		4.4	4.2	7	0.2	4.8	14.1	20	3.2
Lab047	5	14.7	13.7	25	1.1	8.0	22.9	20	1.6		4.6	4.3	25	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	33	0.6	4.3	10.0	20	4.3		4.3	4.4	33	0.2	4.5	11.4	20	3.9
Total	-	-	13.7	701	1.3	9.5	-	-	-		-	4.3	701	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)																	
UnitID 	Reagent Kit (Code) 	Month (2021/06)								CUM (2019/02/01~2021/06/30)							
		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	14.8	5	0.3	2.0	5.4	20	>6	14.6	14.6	53	0.3	2.1	4.1	20	>6
Lab020	5	13.3	14.8	4	0.7	4.7	20.7	20	1.9	13.3	14.4	59	1.0	6.9	22.2	20	1.7
Lab022	5	13.8	13.8	4	0.3	2.2	4.3	20	>6	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	-	0	-	-	-	20	-	12.1	13.0	129	1.4	10.8	29.0	20	1.2
Lab033	5	12.4	12.6	4	0.7	5.6	12.7	20	3.3	12.4	12.5	112	0.4	3.2	7.2	20	6.0
Lab034	5	15.3	14.0	5	0.3	2.1	12.8	20	5.5	15.3	14.7	51	1.1	7.5	18.9	20	2.1
Lab037	5	15.3	15.4	2	-	-	-	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	13.1	1	-	-	-	20	-	13.8	12.9	7	0.3	2.3	11.2	20	5.9
Lab047	5	14.7	15.0	5	0.3	2.0	6.0	20	>6	14.7	13.7	25	1.1	8.0	22.9	20	1.6
Lab049	5	14.7	14.2	1	-	-	-	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	33	0.6	4.3	10.0	20	4.3
Total	-	-	14.2	37	0.9	6.3	-	-	-	-	13.7	701	1.3	9.5	-	-	-

Bias (%) = $\left(\frac{|\text{Mean} - \text{Target}|}{\text{Target}} \right) \times 100\%$

TE : Total Error(%) = Bias (%) + $2 \times \text{CV}(\%)$

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

Month : 2021  06  Change

Cumulative : from 2019  02  01  to 2021  06  30  Change

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Control D Month vs. Cumulative

Control D (Lot No.: AH1220D)																	
UnitID 	Reagent Kit (Code) 	Month (2021/06)								CUM (2019/02/01~2021/06/30)							
		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	4.4	5	0.1	2.3	4.5	20	>6	4.4	4.4	53	0.1	2.3	4.5	20	>6
Lab020	5	4.3	4.5	4	0.2	4.4	13.5	20	3.5	4.3	4.5	59	0.2	4.4	13.5	20	3.5
Lab022	5	4.4	4.4	4	0.1	2.3	4.5	20	>6	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	-	0	-	-	-	20	-	3.5	4.0	129	0.6	15.0	44.3	20	0.4
Lab033	5	3.9	4.1	4	0.2	4.9	14.9	20	3.0	3.9	3.9	112	0.2	5.1	10.3	20	3.9
Lab034	5	5.2	4.6	5	0.2	4.3	20.2	20	2.0	5.2	4.6	51	0.2	4.3	20.2	20	2.0
Lab037	5	5.2	4.8	2	-	-	-	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	4.0	1	-	-	-	20	-	4.4	4.2	7	0.2	4.8	14.1	20	3.2
Lab047	5	4.6	4.6	5	0.1	2.2	4.3	20	>6	4.6	4.3	25	0.3	7.0	20.5	20	1.9
Lab049	5	4.9	4.1	1	-	-	-	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	33	0.2	4.5	11.4	20	3.9
Total	-	-	4.4	37	0.2	4.5	-	-	-	-	4.3	701	0.4	9.3	-	-	-

Bias (%) = $\left(\frac{|\text{Mean} - \text{Target}|}{\text{Target}} \right) \times 100\%$

TE : Total Error(%) = Bias (%) + $2 \times \text{CV}(\%)$

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

Month : 2021  06  Change

Cumulative : from 2019  02  01  to 2021  06  30  Change

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Reagent Kit	Reagent Code
Medicon	5