

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - March 2019 -

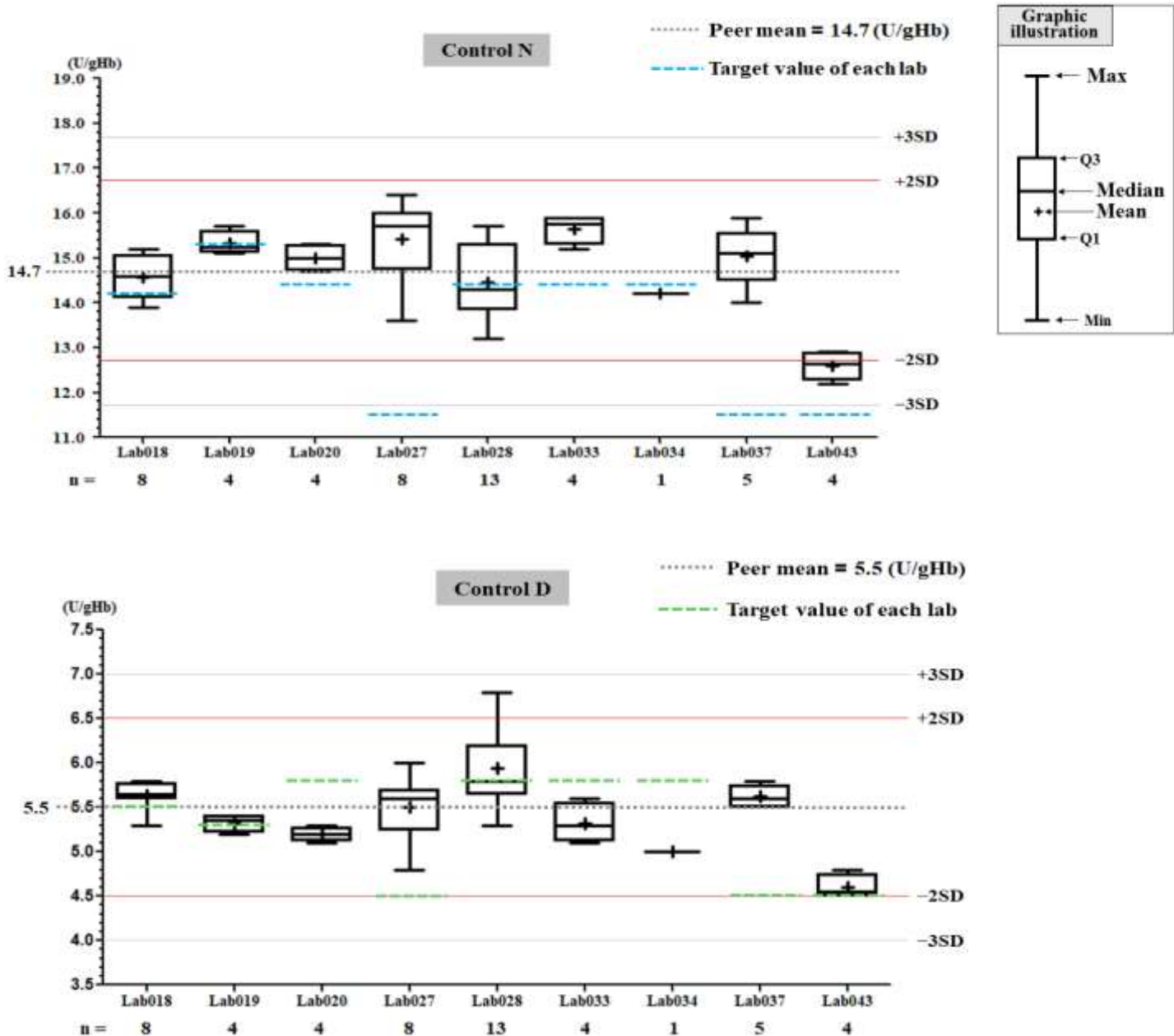
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	9	9
Received results number (n)	51	51
Median	15.0 (U/gHb)	5.6 (U/gHb)
Mean	14.7 (U/gHb)	5.5 (U/gHb)
SD	1.0	0.5
CV	6.8%	9.1%
Range of G6PD	12.2 ~ 16.4 (U/gHb)	4.5 ~ 6.8 (U/gHb)
Range of Hb	1.6 ~ 2.2 (g/dL)	1.7 ~ 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 : AE0909N (2016-01-01 ~ 2100-12-31) [Change](#)

[Print Table](#)

Lab018

QC Control Lot No.	Control N		Control D	
	AE0909N		AE0909D	
Duration of the Analyzing	Month (2019/03)	CUM (2018/07/24~2019/03/31)	Month (2019/03)	CUM (2018/07/24~2019/03/31)
Runs (N)	8	26	8	26
Mean (U/gHb)	14.6	15.7	5.6	5.7
SD	0.5	1.0	0.2	0.2
CV (%)	3.4	6.4	3.6	3.5
Target Value (U/gHb)	14.2	14.2	5.5	5.5
Total Error (%)	9.7	23.3	9.0	10.7
TEa (%)	20	20	20	20
σ	5.1	1.5	5.1	4.7

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

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

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

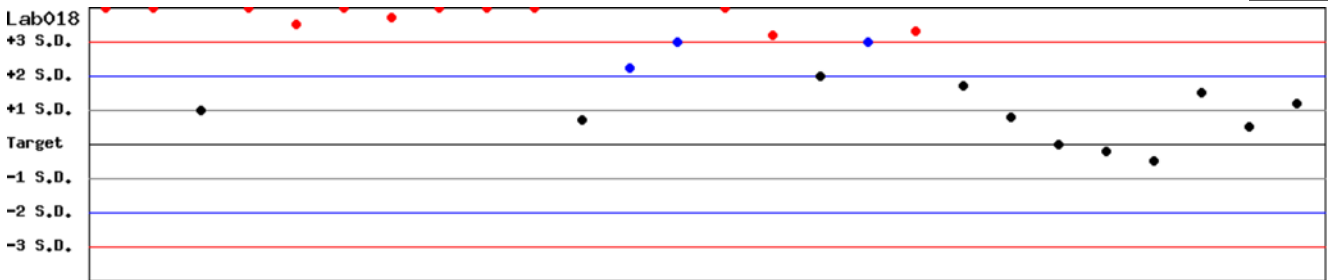
Month : 2019 03 [Change](#) ; Cumulative : from 2018 07 24 to 2019 03 31 [Change](#)

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Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-07-24 to 2019-03-31 ; Target : 14.2 ; SD : 0.60

Lab018



Date 07-24 07-27 08-01 08-03 08-08 08-10 08-16 08-17 08-23 08-24 08-30 08-31 09-05 09-07 09-14 09-21 09-27 09-28 03-02 03-06 03-13 03-16 03-16 03-22 03-23 03-27

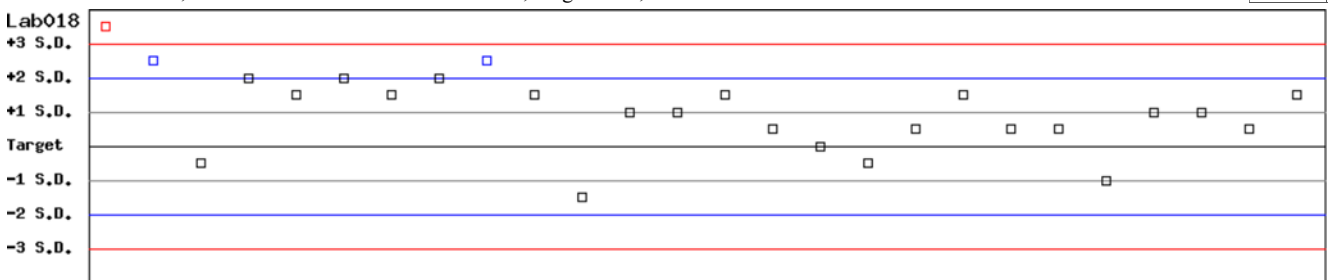
Month : 2019 03 [Change](#) ; Cumulative : from 2018 07 24 to 2019 03 31 [Change](#)

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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2018-07-24 to 2019-03-31 ; Target : 5.5 ; SD : 0.20

Lab018



Date 07-24 07-27 08-01 08-03 08-08 08-10 08-16 08-17 08-23 08-24 08-30 08-31 09-05 09-07 09-14 09-21 09-27 09-28 03-02 03-06 03-13 03-16 03-16 03-22 03-23 03-27

Month : 2019 03 [Change](#) ; Cumulative : from 2018 07 24 to 2019 03 31 [Change](#)

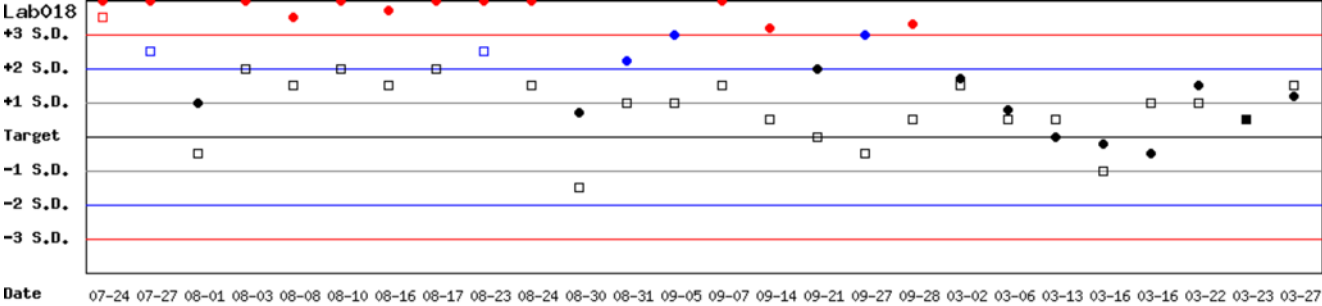
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Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-07-24 to 2019-03-31 ; Target : 14.2 ; SD : 0.60 (●)

Lot No.: AE0909D ; Duration : 2018-07-24 to 2019-03-31 ; Target : 5.5 ; SD : 0.20 (□)

Lab018



Month : 2019 | 03 | ; Cumulative : from 2018 | 07 | 24 to 2019 | 03 | 31 |

[\[TOP\]](#)

Peer Group Statistics (Table 1)

Select LotNo : AE0909N (2016-01-01 ~ 2100-12-31) ▼ Change

Select Reagent Kit : 5 - Medicon ▼ Change

Print Table 1

Monthly

Month : 2019 ▼ 03 ▼ Change

UnitID [↑]	Reagent Kit (Code) [↑]	Control N (Lot No.: AE0909N)								Control D (Lot No.: AE0909D)							
		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
Lab018	5	14.2	14.6	8	0.5	3.4	9.7	20	5.1	5.5	5.6	8	0.2	3.6	9.0	20	5.1
Lab019	5	15.3	15.3	4	0.3	2.0	3.9	20	>6	5.3	5.3	4	0.1	1.9	3.8	20	>6
Lab020	5	14.4	15.0	4	0.3	2.0	8.2	20	>6	5.8	5.2	4	0.1	1.9	14.2	20	5.1
Lab027	5	11.5	15.4	8	0.9	5.8	45.6	20	-2.4	4.5	5.5	8	0.4	7.3	36.8	20	-0.3
Lab028	5	14.4	14.5	13	0.8	5.5	11.7	20	3.5	5.8	5.9	13	0.5	8.5	18.7	20	2.2
Lab033	5	14.4	15.7	4	0.3	1.9	12.8	20	5.8	5.8	5.3	4	0.2	3.8	16.2	20	3.0
Lab034	5	14.4	14.2	1	-	-	-	20	-	5.8	5.0	1	-	-	-	20	-
Lab037	5	11.5	15.0	5	0.7	4.7	39.8	20	-2.2	4.5	5.6	5	0.1	1.8	28.0	20	-2.5
Lab043	5	11.5	12.6	4	0.3	2.4	14.3	20	4.3	4.5	4.6	4	0.1	2.2	6.6	20	>6
Total	-	-	14.7	51	1.0	6.8	-	-	-	-	5.5	51	0.5	9.1	-	-	-

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

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

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

[TOP](#)

Cumulative

Cumulative : from 2016 ▼ 02 ▼ 01 ▼ to 2019 ▼ 03 ▼ 31 ▼ Change

UnitID [↑]	Reagent Kit (Code) [↑]	Control N (Lot No.: AE0909N)								Control D (Lot No.: AE0909D)							
		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
Lab018	5	14.2	15.9	68	0.9	5.7	23.3	20	1.4	5.5	5.7	68	0.2	3.5	10.7	20	4.7
Lab019	5	15.3	15.2	61	0.4	2.6	5.9	20	>6	5.3	5.3	61	0.1	1.9	3.8	20	>6
Lab020	5	14.4	15.2	19	0.4	2.6	10.8	20	5.6	5.8	5.4	19	0.2	3.7	14.3	20	3.5
Lab026	5	15.9	15.3	125	0.5	3.3	10.3	20	4.9	5.8	5.2	125	0.4	7.7	25.7	20	1.3
Lab027	5	11.5	15.8	69	1.4	8.9	55.1	20	-2.0	4.5	5.6	69	0.4	7.1	38.7	20	-0.6
Lab028	5	14.4	14.5	36	0.8	5.5	11.7	20	3.5	5.8	5.7	36	0.5	8.8	19.3	20	2.1
Lab032	5	15.9	15.9	38	0.9	5.7	11.3	20	3.5	5.8	5.7	38	0.3	5.3	12.3	20	3.4
Lab033	5	14.4	14.9	49	0.6	4.0	11.5	20	4.1	5.8	5.2	49	0.2	3.8	18.0	20	2.5
Lab034	5	14.4	14.2	50	0.6	4.2	9.8	20	4.4	5.8	5.1	50	0.2	3.9	19.9	20	2.0
Lab037	5	11.5	14.9	20	0.7	4.7	39.0	20	-2.0	4.5	5.4	20	0.3	5.6	31.1	20	0.0
Lab040	5	14.4	13.3	39	0.7	5.3	18.2	20	2.3	5.8	4.7	39	0.3	6.4	31.7	20	0.2
Lab043	5	11.5	13.1	59	1.0	7.6	29.2	20	0.8	4.5	4.9	59	0.3	6.1	21.1	20	1.8
Total	-	-	14.9	633	1.2	8.1	-	-	-	-	5.3	633	0.4	7.5	-	-	-

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

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

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

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5

Peer Group Statistics (Table 2)

Select LotNo :

Select Reagent Kit :

Control N Month vs. Cumulative

		Control N (Lot No.: AE0909N)															
		Month (2019/03)								CUM (2016/02/01~2019/03/31)							
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
Lab018	5	14.2	14.6	8	0.5	3.4	9.7	20	5.1	14.2	15.9	68	0.9	5.7	23.3	20	1.4
Lab019	5	15.3	15.3	4	0.3	2.0	3.9	20	>6	15.3	15.2	61	0.4	2.6	5.9	20	>6
Lab020	5	14.4	15.0	4	0.3	2.0	8.2	20	>6	14.4	15.2	19	0.4	2.6	10.8	20	5.6
Lab026	5	15.9	-	0	-	-	-	20	-	15.9	15.3	125	0.5	3.3	10.3	20	4.9
Lab027	5	11.5	15.4	8	0.9	5.8	45.6	20	-2.4	11.5	15.8	69	1.4	8.9	55.1	20	-2.0
Lab028	5	14.4	14.5	13	0.8	5.5	11.7	20	3.5	14.4	14.5	36	0.8	5.5	11.7	20	3.5
Lab032	5	15.9	-	0	-	-	-	20	-	15.9	15.9	38	0.9	5.7	11.3	20	3.5
Lab033	5	14.4	15.7	4	0.3	1.9	12.8	20	5.8	14.4	14.9	49	0.6	4.0	11.5	20	4.1
Lab034	5	14.4	14.2	1	-	-	-	20	-	14.4	14.2	50	0.6	4.2	9.8	20	4.4
Lab037	5	11.5	15.0	5	0.7	4.7	39.8	20	-2.2	11.5	14.9	20	0.7	4.7	39.0	20	-2.0
Lab040	5	14.4	-	0	-	-	-	20	-	14.4	13.3	39	0.7	5.3	18.2	20	2.3
Lab043	5	11.5	12.6	4	0.3	2.4	14.3	20	4.3	11.5	13.1	59	1.0	7.6	29.2	20	0.8
Total	-	-	14.7	51	1.0	6.8	-	-	-	-	14.9	633	1.2	8.1	-	-	-

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

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

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

Month :

Cumulative : from to

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2019/03)								CUM (2016/02/01~2019/03/31)							
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
Lab018	5	5.5	5.6	8	0.2	3.6	9.0	20	5.1	5.5	5.7	68	0.2	3.5	10.7	20	4.7
Lab019	5	5.3	5.3	4	0.1	1.9	3.8	20	>6	5.3	5.3	61	0.1	1.9	3.8	20	>6
Lab020	5	5.8	5.2	4	0.1	1.9	14.2	20	5.1	5.8	5.4	19	0.2	3.7	14.3	20	3.5
Lab026	5	5.8	-	0	-	-	-	20	-	5.8	5.2	125	0.4	7.7	25.7	20	1.3
Lab027	5	4.5	5.5	8	0.4	7.3	36.8	20	-0.3	4.5	5.6	69	0.4	7.1	38.7	20	-0.6
Lab028	5	5.8	5.9	13	0.5	8.5	18.7	20	2.2	5.8	5.7	36	0.5	8.8	19.3	20	2.1
Lab032	5	5.8	-	0	-	-	-	20	-	5.8	5.7	38	0.3	5.3	12.3	20	3.4
Lab033	5	5.8	5.3	4	0.2	3.8	16.2	20	3.0	5.8	5.2	49	0.2	3.8	18.0	20	2.5
Lab034	5	5.8	5.0	1	-	-	-	20	-	5.8	5.1	50	0.2	3.9	19.9	20	2.0
Lab037	5	4.5	5.6	5	0.1	1.8	28.0	20	-2.5	4.5	5.4	20	0.3	5.6	31.1	20	0.0
Lab040	5	5.8	-	0	-	-	-	20	-	5.8	4.7	39	0.3	6.4	31.7	20	0.2
Lab043	5	4.5	4.6	4	0.1	2.2	6.6	20	>6	4.5	4.9	59	0.3	6.1	21.1	20	1.8
Total	-	-	5.5	51	0.5	9.1	-	-	-	-	5.3	633	0.4	7.5	-	-	-

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

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

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

Month :

Cumulative : from to

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5