

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

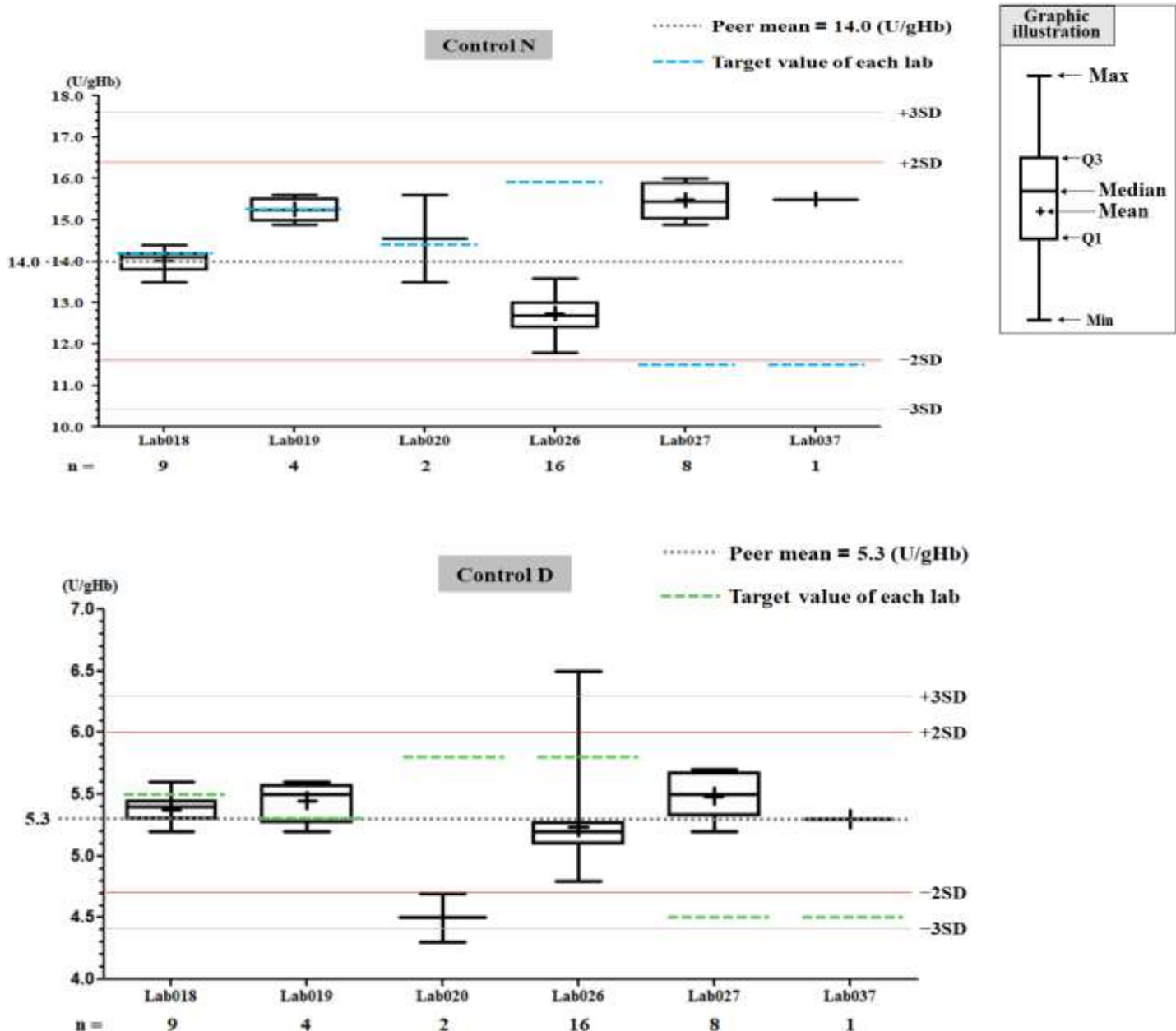
## I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	6	6
Received results number (n)	40	40
Median	13.9 (U/gHb)	5.3 (U/gHb)
Mean	14.0 (U/gHb)	5.3 (U/gHb)
SD	1.2	0.3
CV	8.6%	7.4%
Range of G6PD	11.8 ~ 16.0 (U/gHb)	4.3 ~ 6.5 (U/gHb)
Range of Hb	1.7 ~ 2.4 (g/dL)	1.9 ~ 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](#)

## Lab037

QC Control Lot No.	Control N		Control D	
	AE0909N		AE0909D	
Duration of the Analyzing	Month (2019/06)	CUM (2018/11/16~2019/06/30)	Month (2019/06)	CUM (2018/11/16~2019/06/30)
Runs (N)	1	26	1	26
Mean (U/gHb)	15.5	15.1	5.3	5.5
SD	-	0.8	-	0.3
CV (%)	-	5.3	-	5.5
Target Value (U/gHb)	11.5	11.5	4.5	4.5
Total Error (%)	-	41.9	-	33.1
TEa (%)	20	20	20	20
$\sigma$	-	-2.1	-	-0.4

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

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

$\sigma$  (Sigma) = [TEa% - Bias (%) ] / CV (%)

Month : 2019 06 [Change](#) ; Cumulative : from 2018 11 16 to 2019 06 30 [Change](#)

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## Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-11-16 to 2019-06-30 ; Target : 11.5 ; SD : 0.6

Lab037



Date 11-16 11-23 11-30 12-08 12-14 12-21 12-28 02-01 02-08 02-15 02-22 03-01 03-08 03-15 03-22 03-29 04-05 04-12 04-19 04-26 05-03 05-10 05-17 05-24 05-31 06-07

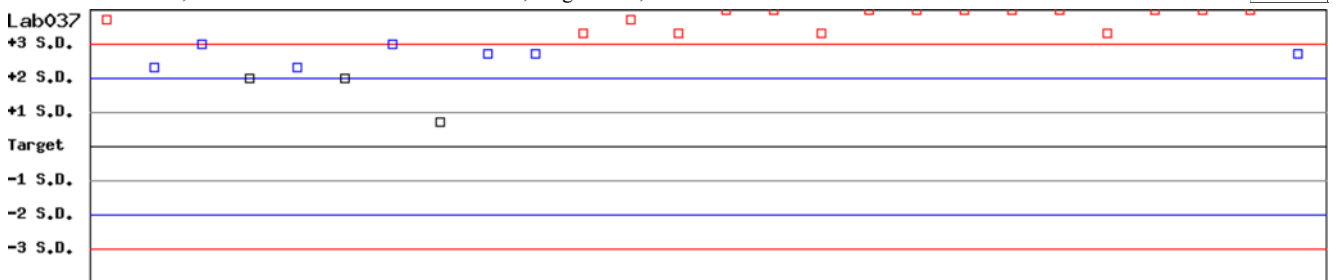
Month : 2019 06 [Change](#) ; Cumulative : from 2018 11 16 to 2019 06 30 [Change](#)

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## Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2018-11-16 to 2019-06-30 ; Target : 4.5 ; SD : 0.3

Lab037



Date 11-16 11-23 11-30 12-08 12-14 12-21 12-28 02-01 02-08 02-15 02-22 03-01 03-08 03-15 03-22 03-29 04-05 04-12 04-19 04-26 05-03 05-10 05-17 05-24 05-31 06-07

Month : 2019 06 [Change](#) ; Cumulative : from 2018 11 16 to 2019 06 30 [Change](#)

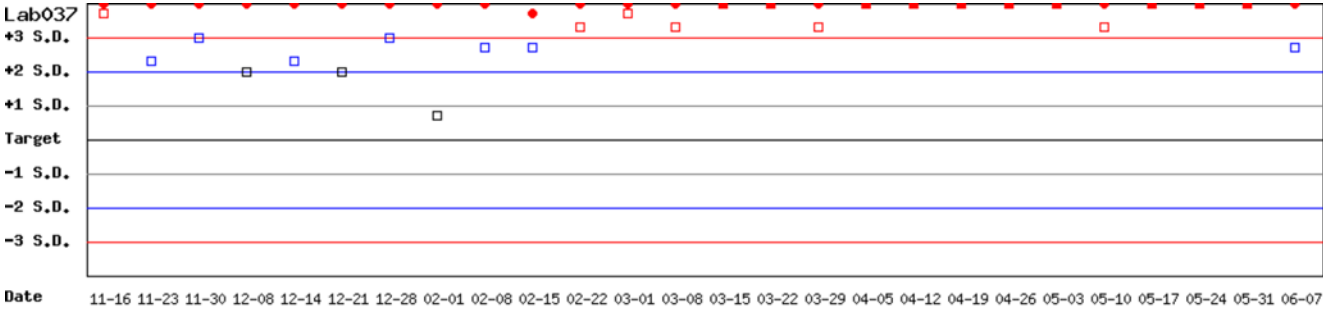
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## Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-11-16 to 2019-06-30 ; Target : 11.5 ; SD : 0.6 (●)

Lot No.: AE0909D ; Duration : 2018-11-16 to 2019-06-30 ; Target : 4.5 ; SD : 0.3 (□)

Lab037



Month : 2019 | 06 |  ; Cumulative : from 2018 | 11 | 16 to 2019 | 06 | 30 |

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# Peer Group Statistics (Table 1)

Select LotNo :

Select Reagent Kit :

## Monthly

Month :

UnitID <sup>↑</sup>	Reagent Kit (Code) <sup>↑</sup>	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
<a href="#">Lab018</a>	5	14.2	14.0	9	0.3	2.1	5.7	20	>6	5.5	5.4	9	0.1	1.9	5.5	20	>6
<a href="#">Lab019</a>	5	15.3	15.3	4	0.3	2.0	3.9	20	>6	5.3	5.5	4	0.2	3.6	11.0	20	4.5
<a href="#">Lab020</a>	5	14.4	14.6	2	-	-	-	20	-	5.8	4.5	2	-	-	-	20	-
<a href="#">Lab026</a>	5	15.9	12.7	16	0.5	3.9	28.0	20	0.0	5.8	5.2	16	0.4	7.7	25.7	20	1.3
<a href="#">Lab027</a>	5	11.5	15.5	8	0.4	2.6	39.9	20	-5.7	4.5	5.5	8	0.2	3.6	29.5	20	-0.6
<a href="#">Lab037</a>	5	11.5	15.5	1	-	-	-	20	-	4.5	5.3	1	-	-	-	20	-
Total	-	-	14.0	40	1.2	8.6	-	-	-	-	5.3	40	0.3	5.7	-	-	-

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

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

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

[\[TOP\]](#)

## Cumulative

Cumulative : from    to

UnitID <sup>↑</sup>	Reagent Kit (Code) <sup>↑</sup>	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
<a href="#">Lab018</a>	5	14.2	15.5	93	1.1	7.1	23.3	20	1.5	5.5	5.7	93	0.3	5.3	14.2	20	3.1
<a href="#">Lab019</a>	5	15.3	15.2	74	0.3	2.0	4.6	20	>6	5.3	5.3	74	0.2	3.8	7.5	20	5.3
<a href="#">Lab020</a>	5	14.4	15.2	28	0.5	3.3	12.1	20	4.4	5.8	5.3	28	0.3	5.7	19.9	20	2.0
<a href="#">Lab026</a>	5	15.9	14.5	175	1.3	9.0	26.7	20	1.2	5.8	5.2	175	0.4	7.7	25.7	20	1.3
<a href="#">Lab027</a>	5	11.5	15.6	95	1.3	8.3	52.3	20	-1.9	4.5	5.6	95	0.4	7.1	38.7	20	-0.6
<a href="#">Lab028</a>	5	14.4	14.6	62	0.8	5.5	12.3	20	3.4	5.8	5.7	62	0.4	7.0	15.8	20	2.6
<a href="#">Lab032</a>	5	15.3	15.9	38	0.9	5.7	15.2	20	2.8	5.2	5.7	38	0.3	5.3	20.1	20	2.0
<a href="#">Lab033</a>	5	14.4	14.9	51	0.7	4.7	12.9	20	3.5	5.8	5.2	51	0.3	5.8	21.9	20	1.7
<a href="#">Lab034</a>	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
<a href="#">Lab037</a>	5	11.5	15.2	30	0.8	5.3	42.7	20	-2.3	4.5	5.5	30	0.3	5.5	33.1	20	-0.4
<a href="#">Lab040</a>	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
<a href="#">Lab043</a>	5	11.5	13.1	68	0.9	6.9	27.7	20	0.9	4.5	4.9	68	0.3	6.1	21.1	20	1.8
Total	-	-	14.7	803	1.3	8.8	-	-	-	-	5.3	803	0.4	7.5	-	-	-

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

Select Reagent Kit : 5 - Medicon Change

Print Table 2

### Control N Month vs. Cumulative

		Control N (Lot No.: AE0909N)															
		Month (2019/06)								CUM (2016/02/01~2019/06/30)							
UnitID <sup>†</sup>	Reagent Kit (Code) <sup>†</sup>	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
<a href="#">Lab018</a>	5	14.2	14.0	9	0.3	2.1	5.7	20	>6	14.2	15.5	93	1.1	7.1	23.3	20	1.5
<a href="#">Lab019</a>	5	15.3	15.3	4	0.3	2.0	3.9	20	>6	15.3	15.2	74	0.3	2.0	4.6	20	>6
<a href="#">Lab020</a>	5	14.4	14.6	2	-	-	-	20	-	14.4	15.2	28	0.5	3.3	12.1	20	4.4
<a href="#">Lab026</a>	5	15.9	12.7	16	0.5	3.9	28.0	20	0.0	15.9	14.5	175	1.3	9.0	26.7	20	1.2
<a href="#">Lab027</a>	5	11.5	15.5	8	0.4	2.6	39.9	20	-5.7	11.5	15.6	95	1.3	8.3	52.3	20	-1.9
<a href="#">Lab028</a>	5	14.4	-	0	-	-	-	20	-	14.4	14.6	62	0.8	5.5	12.3	20	3.4
<a href="#">Lab032</a>	5	15.3	-	0	-	-	-	20	-	15.3	15.9	38	0.9	5.7	15.2	20	2.8
<a href="#">Lab033</a>	5	14.4	-	0	-	-	-	20	-	14.4	14.9	51	0.7	4.7	12.9	20	3.5
<a href="#">Lab034</a>	5	14.4	-	0	-	-	-	20	-	14.4	14.2	50	0.6	4.2	9.8	20	4.4
<a href="#">Lab037</a>	5	11.5	15.5	1	-	-	-	20	-	11.5	15.2	30	0.8	5.3	42.7	20	-2.3
<a href="#">Lab040</a>	5	14.4	-	0	-	-	-	20	-	14.4	13.3	39	0.7	5.3	18.2	20	2.3
<a href="#">Lab043</a>	5	11.5	-	0	-	-	-	20	-	11.5	13.1	68	0.9	6.9	27.7	20	0.9
<b>Total</b>	-	-	14.0	40	1.2	8.6	-	-	-	-	14.7	803	1.3	8.8	-	-	-

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

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

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

Month : 2019 06 Change

Cumulative : from 2016 02 01 to 2019 06 30 Change

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### Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2019/06)								CUM (2016/02/01~2019/06/30)							
UnitID <sup>†</sup>	Reagent Kit (Code) <sup>†</sup>	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
<a href="#">Lab018</a>	5	5.5	5.4	9	0.1	1.9	5.5	20	>6	5.5	5.7	93	0.3	5.3	14.2	20	3.1
<a href="#">Lab019</a>	5	5.3	5.5	4	0.2	3.6	11.0	20	4.5	5.3	5.3	74	0.2	3.8	7.5	20	5.3
<a href="#">Lab020</a>	5	5.8	4.5	2	-	-	-	20	-	5.8	5.3	28	0.3	5.7	19.9	20	2.0
<a href="#">Lab026</a>	5	5.8	5.2	16	0.4	7.7	25.7	20	1.3	5.8	5.2	175	0.4	7.7	25.7	20	1.3
<a href="#">Lab027</a>	5	4.5	5.5	8	0.2	3.6	29.5	20	-0.6	4.5	5.6	95	0.4	7.1	38.7	20	-0.6
<a href="#">Lab028</a>	5	5.8	-	0	-	-	-	20	-	5.8	5.7	62	0.4	7.0	15.8	20	2.6
<a href="#">Lab032</a>	5	5.2	-	0	-	-	-	20	-	5.2	5.7	38	0.3	5.3	20.1	20	2.0
<a href="#">Lab033</a>	5	5.8	-	0	-	-	-	20	-	5.8	5.2	51	0.3	5.8	21.9	20	1.7
<a href="#">Lab034</a>	5	5.8	-	0	-	-	-	20	-	5.8	5.1	50	0.2	3.9	19.9	20	2.0
<a href="#">Lab037</a>	5	4.5	5.3	1	-	-	-	20	-	4.5	5.5	30	0.3	5.5	33.1	20	-0.4
<a href="#">Lab040</a>	5	5.8	-	0	-	-	-	20	-	5.8	4.7	39	0.3	6.4	31.7	20	0.2
<a href="#">Lab043</a>	5	4.5	-	0	-	-	-	20	-	4.5	4.9	68	0.3	6.1	21.1	20	1.8
<b>Total</b>	-	-	5.3	40	0.3	5.7	-	-	-	-	5.3	803	0.4	7.5	-	-	-

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

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

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

Month : 2019 06 Change

Cumulative : from 2016 02 01 to 2019 06 30 Change

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Reagent Kit	Reagent Code
Medicon	5