

Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - July 2018 -

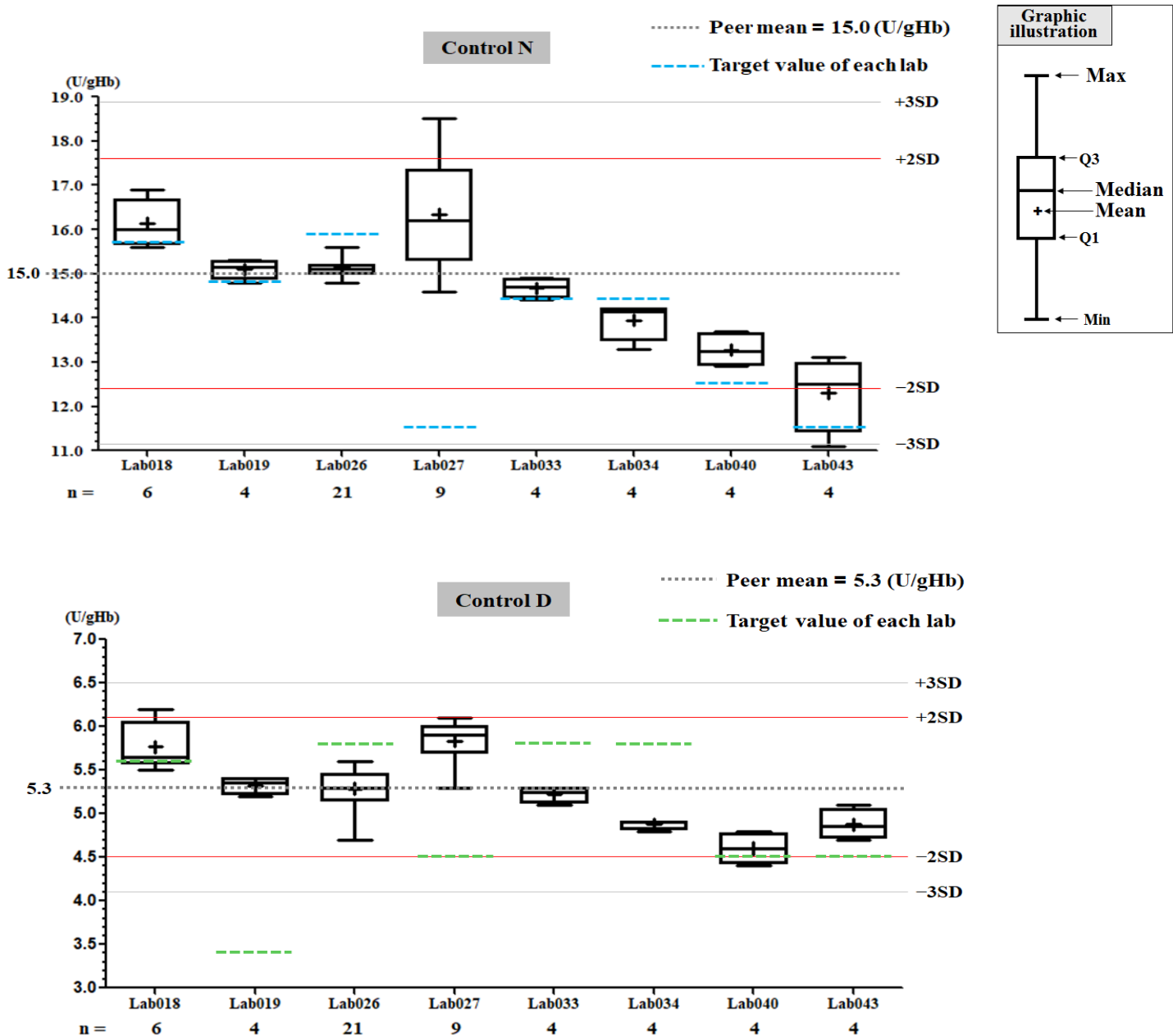
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	8	8
Received results number (n)	56	56
Median	15.1 (U/gHb)	5.3 (U/gHb)
Mean	15.0 (U/gHb)	5.3 (U/gHb)
SD	1.3	0.4
CV	8.7%	7.5%
Range of G6PD	11.1 ~ 18.5 (U/gHb)	4.4 ~ 6.2 (U/gHb)
Range of Hb	1.4 ~ 2.2 (g/dL)	1.6 ~ 3.0 (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](#)

Lab019

QC Control Lot No.	Control N		Control D	
	AE0909N		AE0909D	
Duration of the Analyzing	Month (2018/07)	CUM (2016/02/01~2018/07/31)	Month (2018/07)	CUM (2016/02/01~2018/07/31)
Runs (N)	4	24	4	24
Mean (U/gHb)	15.1	15.1	5.3	5.3
SD	0.2	0.4	0.1	0.2
CV (%)	1.3	2.6	1.9	3.8
Target Value (U/gHb)	14.8	14.8	3.4	3.4
Total Error (%)	4.7	7.3	59.7	63.4
TEa (%)	20	20	20	20
σ	>6	>6	-18.9	-9.4

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

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

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

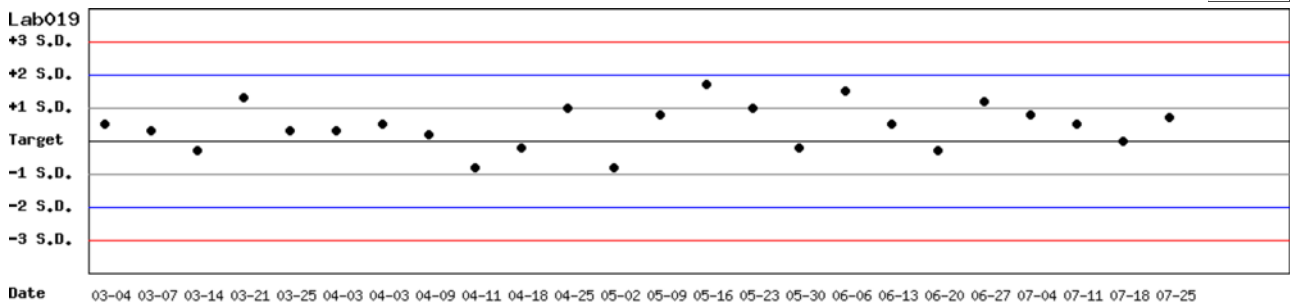
Month : 2018 07 [Change](#) ; Cumulative : from 2016 02 01 to 2018 07 31 [Change](#)

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Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2018-07-31 ; Target : 14.8 ; SD : 0.6

Lab019



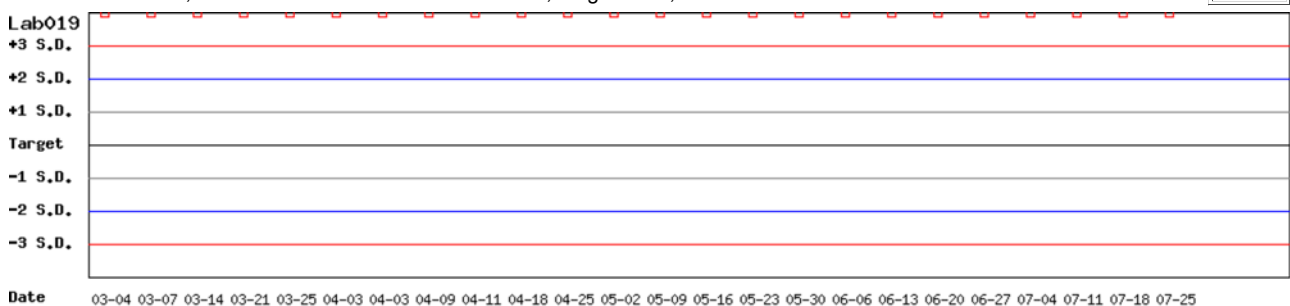
Month : 2018 07 [Change](#) ; Cumulative : from 2016 02 01 to 2018 07 31 [Change](#)

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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2016-02-01 to 2018-07-31 ; Target : 3.4 ; SD : 0.3

Lab019



Month : 2018 07 [Change](#) ; Cumulative : from 2016 02 01 to 2018 07 31 [Change](#)

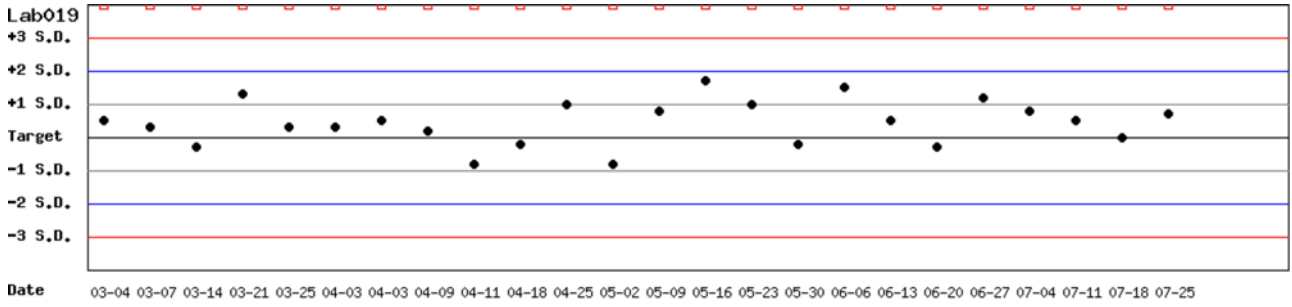
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Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2018-07-31 ; Target : 14.8 ; SD : 0.6 (●)

Lot No.: AE0909D ; Duration : 2016-02-01 to 2018-07-31 ; Target : 3.4 ; SD : 0.3 (□)

Lab019



Month : 2018 | 07 | ; Cumulative : from 2016 | 02 | 01 | to 2018 | 07 | 31 |

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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 : 2018 07 Change

		Control N (Lot No.: AE0909N)								Control D (Lot No.: AE0909D)							
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	15.7	16.1	6	0.5	3.1	8.8	20	5.6	5.6	5.8	6	0.3	5.2	13.9	20	3.2
Lab019	5	14.8	15.1	4	0.2	1.3	4.7	20	>6	3.4	5.3	4	0.1	1.9	59.7	20	-18.9
Lab026	5	15.9	15.2	21	0.2	1.3	7.0	20	>6	5.8	5.3	21	0.2	3.8	16.2	20	3.0
Lab027	5	11.5	16.3	9	1.2	7.4	56.5	20	-2.9	4.5	5.8	9	0.3	5.2	39.2	20	-1.7
Lab033	5	14.4	14.7	4	0.2	1.4	4.8	20	>6	5.8	5.2	4	0.1	1.9	14.2	20	5.1
Lab034	5	14.4	14.0	4	0.4	2.9	8.5	20	5.9	5.8	4.9	4	0.1	2.0	19.6	20	2.2
Lab040	5	12.5	13.3	4	0.4	3.0	12.4	20	4.5	4.5	4.6	4	0.2	4.3	10.9	20	4.1
Lab043	5	11.5	12.3	4	0.9	7.3	21.6	20	1.8	4.5	4.9	4	0.2	4.1	17.1	20	2.7
Total	-	-	15.0	56	1.3	8.7	-	-	-	-	5.3	56	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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Cumulative

Cumulative : from 2016 02 01 to 2018 07 31 Change

		Control N (Lot No.: AE0909N)								Control D (Lot No.: AE0909D)							
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	15.7	16.1	44	0.8	5.0	12.5	20	3.5	5.6	5.7	44	0.3	5.3	12.3	20	3.4
Lab019	5	14.8	15.1	24	0.4	2.6	7.3	20	>6	3.4	5.3	24	0.2	3.8	63.4	20	-9.4
Lab026	5	15.9	15.4	68	0.5	3.2	9.6	20	5.3	5.8	5.2	68	0.5	9.6	29.6	20	1.0
Lab027	5	11.5	15.7	35	1.4	8.9	54.4	20	-1.9	4.5	5.6	35	0.4	7.1	38.7	20	-0.6
Lab032	5	15.9	15.8	22	1.0	6.3	13.3	20	3.1	5.8	5.7	22	0.4	7.0	15.8	20	2.6
Lab033	5	14.4	14.9	14	0.4	2.7	8.8	20	>6	5.8	5.2	14	0.2	3.8	18.0	20	2.5
Lab034	5	14.4	13.9	19	0.5	3.6	10.7	20	4.6	5.8	4.9	19	0.1	2.0	19.6	20	2.2
Lab040	5	12.5	12.9	27	0.6	4.7	12.5	20	3.6	4.5	4.6	27	0.3	6.5	15.3	20	2.7
Lab043	5	11.5	13.7	24	1.3	9.5	38.1	20	0.1	4.5	5.1	24	0.3	5.9	25.1	20	1.1
Total	-	-	15.0	277	1.3	8.7	-	-	-	-	5.3	277	0.5	9.4	-	-	-

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 :

Select Reagent Kit :

Control N Month vs. Cumulative

		Control N (Lot No.: AE0909N)															
		Month (2018/07)								CUM (2016/02/01~2018/07/31)							
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	15.7	16.1	6	0.5	3.1	8.8	20	5.6	15.7	16.1	44	0.8	5.0	12.5	20	3.5
Lab019	5	14.8	15.1	4	0.2	1.3	4.7	20	>6	14.8	15.1	24	0.4	2.6	7.3	20	>6
Lab026	5	15.9	15.2	21	0.2	1.3	7.0	20	>6	15.9	15.4	68	0.5	3.2	9.6	20	5.3
Lab027	5	11.5	16.3	9	1.2	7.4	56.5	20	-2.9	11.5	15.7	35	1.4	8.9	54.4	20	-1.9
Lab032	5	15.9	-	0	-	-	-	20	-	15.9	15.8	22	1.0	6.3	13.3	20	3.1
Lab033	5	14.4	14.7	4	0.2	1.4	4.8	20	>6	14.4	14.9	14	0.4	2.7	8.8	20	>6
Lab034	5	14.4	14.0	4	0.4	2.9	8.5	20	5.9	14.4	13.9	19	0.5	3.6	10.7	20	4.6
Lab040	5	12.5	13.3	4	0.4	3.0	12.4	20	4.5	12.5	12.9	27	0.6	4.7	12.5	20	3.6
Lab043	5	11.5	12.3	4	0.9	7.3	21.6	20	1.8	11.5	13.7	24	1.3	9.5	38.1	20	0.1
Total	-	-	15.0	56	1.3	8.7	-	-	-	-	15.0	277	1.3	8.7	-	-	-

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

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

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

Month :

Cumulative : from to

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Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2018/07)								CUM (2016/02/01~2018/07/31)							
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	5.6	5.8	6	0.3	5.2	13.9	20	3.2	5.6	5.7	44	0.3	5.3	12.3	20	3.4
Lab019	5	3.4	5.3	4	0.1	1.9	59.7	20	-18.9	3.4	5.3	24	0.2	3.8	63.4	20	-9.4
Lab026	5	5.8	5.3	21	0.2	3.8	16.2	20	3.0	5.8	5.2	68	0.5	9.6	29.6	20	1.0
Lab027	5	4.5	5.8	9	0.3	5.2	39.2	20	-1.7	4.5	5.6	35	0.4	7.1	38.7	20	-0.6
Lab032	5	5.8	-	0	-	-	-	20	-	5.8	5.7	22	0.4	7.0	15.8	20	2.6
Lab033	5	5.8	5.2	4	0.1	1.9	14.2	20	5.1	5.8	5.2	14	0.2	3.8	18.0	20	2.5
Lab034	5	5.8	4.9	4	0.1	2.0	19.6	20	2.2	5.8	4.9	19	0.1	2.0	19.6	20	2.2
Lab040	5	4.5	4.6	4	0.2	4.3	10.9	20	4.1	4.5	4.6	27	0.3	6.5	15.3	20	2.7
Lab043	5	4.5	4.9	4	0.2	4.1	17.1	20	2.7	4.5	5.1	24	0.3	5.9	25.1	20	1.1
Total	-	-	5.3	56	0.4	7.5	-	-	-	-	5.3	277	0.5	9.4	-	-	-

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

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

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

Month :

Cumulative : from to

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Reagent Kit	Reagent Code
Medicon	5