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

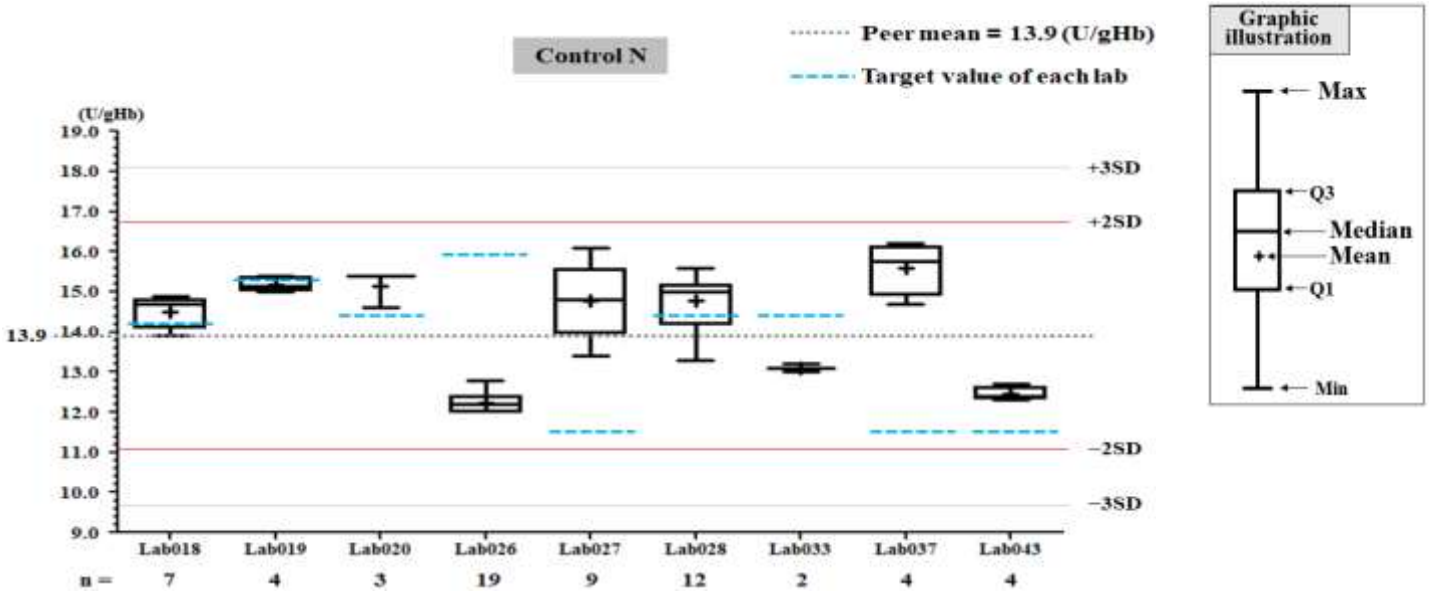
I. The statistic results of all laboratories in this month

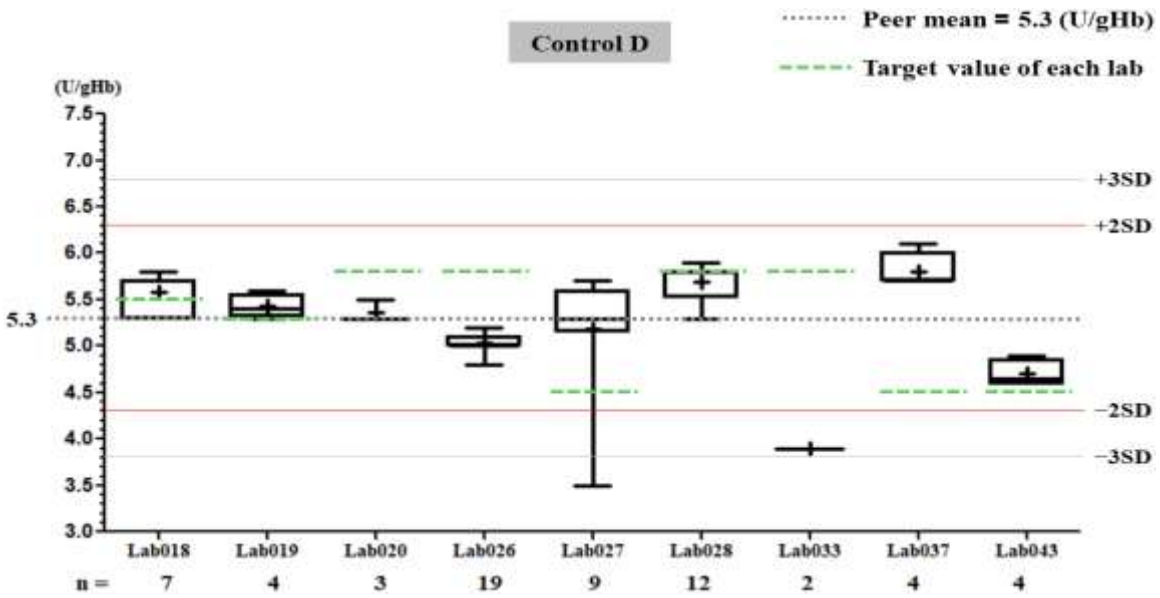
G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	9	9
Received results number (n)	64	64
Median	14.2 (U/gHb)	5.3 (U/gHb)
Mean	13.9 (U/gHb)	5.3 (U/gHb)
SD	1.4	0.5
CV	10.1%	6.1%
Range of G6PD	12.0 ~ 16.2 (U/gHb)	3.5 ~ 6.1 (U/gHb)
Range of Hb	1.6 ~ 3.3 (g/dL)	1.0 ~ 2.5 (g/dL)

*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





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QC Chart of Internal Quality Control (IQC)for G6PD Quantitative Test

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

Print Table

Lab020

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2019/04)	CUM (2016/02/01~2019/04/30)	Month (2019/04)	CUM (2016/02/01~2019/04/30)
Runs (N)	3	22	3	22
Mean (U/gHb)	15.1	15.2	5.4	5.4
SD	0.5	0.4	0.1	0.1
CV (%)	3.3	2.6	1.9	1.9
Target Value (U/gHb)	14.4	14.4	5.8	5.8
Total Error (%)	11.5	10.8	10.6	10.6
TEa (%)	20	20	20	20
σ	4.6	5.6	>6	>6

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

Month : 2019 04 Change ; Cumulative : from 2016 02 01 to 2019 04 30 Change

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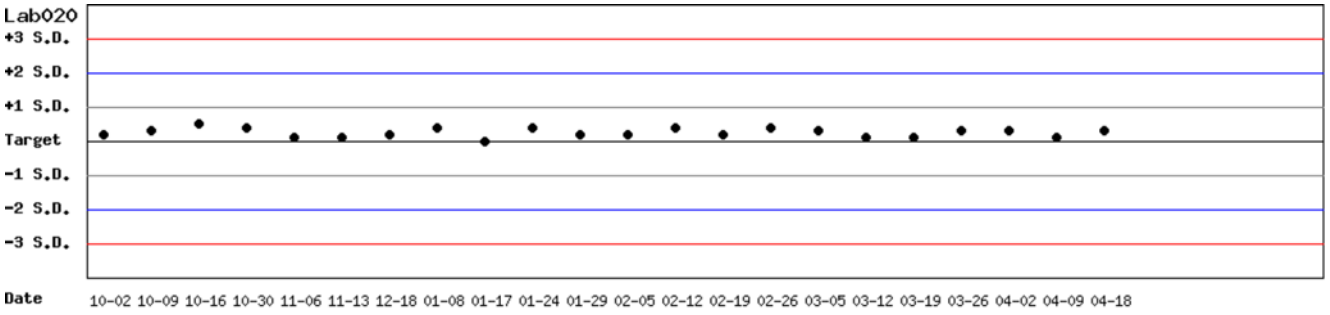
Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2019-04-30 ; Target : 14.4 ; SD : 2.90

Lab020



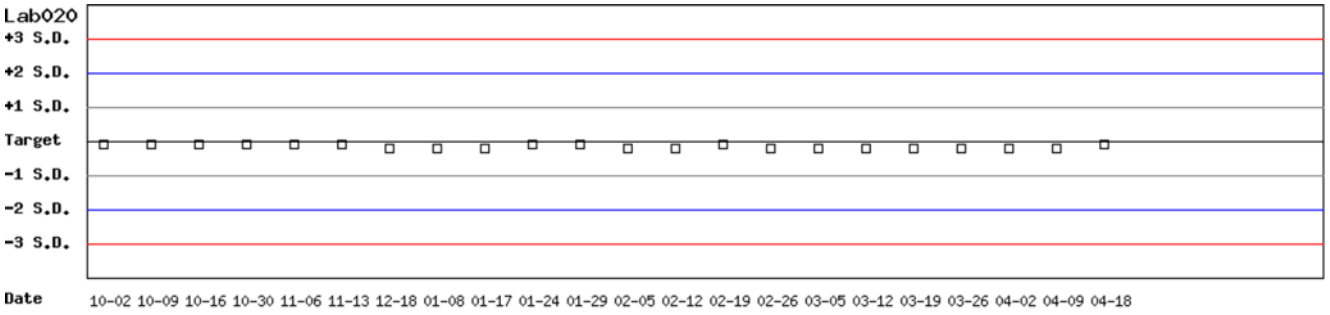
Month : 2019 04 Change ; Cumulative : from 2016 02 01 to 2019 04 30 Change

[TOP]

Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2016-02-01 to 2019-04-30 ; Target : 5.8 ; SD : 2.90

Lab020



Month : 2019 04 Change ; Cumulative : from 2016 02 01 to 2019 04 30 Change

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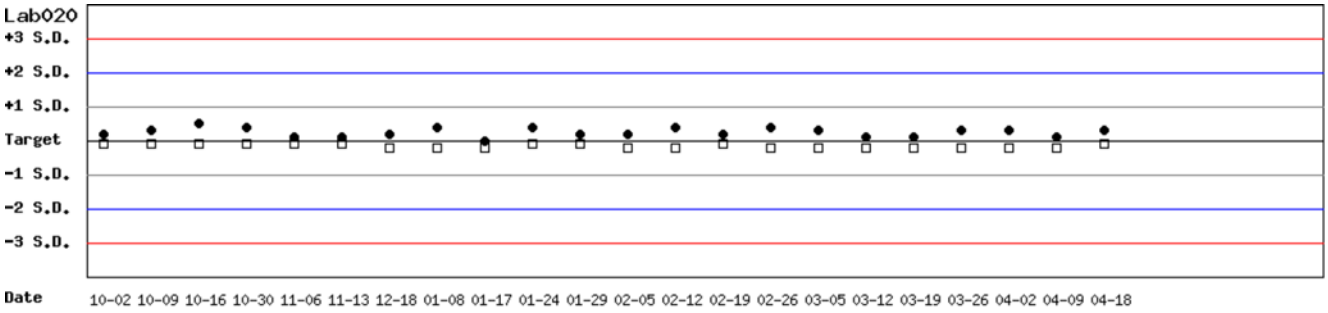
Control N and **Control D SDI**
QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2019-04-30 ; Target : 14.4 ; SD : 2.90 (●)

Lot No.: AE0909D ; Duration : 2016-02-01 to 2019-04-30 ; Target : 5.8 ; SD : 2.90 (□)

Lab020



Month : 2019 | 04 Change ; Cumulative : from 2016 02 01 to 2019 04 30 Change

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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 : 2019 04 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	14.2	14.5	7	0.4	2.8	7.6	20	>6	5.5	5.6	7	0.2	3.6	9.0	20	5.1
Lab019	5	15.3	15.2	4	0.2	1.3	3.3	20	>6	5.3	5.4	4	0.1	1.9	5.6	20	>6
Lab020	5	14.4	15.1	3	0.5	3.3	11.5	20	4.6	5.8	5.4	3	0.1	1.9	10.6	20	>6
Lab026	5	15.9	12.2	19	0.3	2.5	28.2	20	-1.3	5.8	5.0	19	0.1	2.0	17.8	20	3.1
Lab027	5	11.5	14.8	9	0.9	6.1	40.9	20	-1.4	4.5	5.2	9	0.7	13.5	42.5	20	0.3
Lab028	5	14.4	14.8	12	0.7	4.7	12.2	20	3.7	5.8	5.7	12	0.2	3.5	8.7	20	5.2
Lab033	5	14.4	13.1	2	-	-	-	20	-	5.8	3.9	2	-	-	-	20	-
Lab037	5	11.5	15.6	4	0.6	3.8	43.3	20	-4.1	4.5	5.8	4	0.2	3.4	35.8	20	-2.6
Lab043	5	11.5	12.5	4	0.2	1.6	11.9	20	>6	4.5	4.7	4	0.1	2.1	8.7	20	>6
Total	-	-	13.9	64	1.4	10.1	-	-	-	-	5.3	64	0.5	9.4	-	-	-

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 04 30 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	14.2	15.8	75	0.9	5.7	22.7	20	1.5	5.5	5.7	75	0.2	3.5	10.7	20	4.7
Lab019	5	15.3	15.2	65	0.3	2.0	4.6	20	>6	5.3	5.3	65	0.1	1.9	3.8	20	>6
Lab020	5	14.4	15.2	22	0.4	2.6	10.8	20	5.6	5.8	5.4	22	0.1	1.9	10.6	20	>6
Lab026	5	15.9	14.9	144	1.1	7.4	21.1	20	1.9	5.8	5.2	144	0.4	7.7	25.7	20	1.3
Lab027	5	11.5	15.7	78	1.4	8.9	54.4	20	-1.9	4.5	5.5	78	0.4	7.3	36.8	20	-0.3
Lab028	5	14.4	14.6	48	0.8	5.5	12.3	20	3.4	5.8	5.7	48	0.4	7.0	15.8	20	2.6
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	51	0.7	4.7	12.9	20	3.5	5.8	5.2	51	0.3	5.8	21.9	20	1.7
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	15.0	24	0.7	4.7	39.8	20	-2.2	4.5	5.5	24	0.3	5.5	33.1	20	-0.4
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	63	0.9	6.9	27.7	20	0.9	4.5	4.9	63	0.3	6.1	21.1	20	1.8
Total	-	-	14.8	697	1.2	8.1	-	-	-	-	5.3	697	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：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 (2019/04)								CUM (2016/02/01~2019/04/30)							
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	14.5	7	0.4	2.8	7.6	20	>6	14.2	15.8	75	0.9	5.7	22.7	20	1.5
Lab019	5	15.3	15.2	4	0.2	1.3	3.3	20	>6	15.3	15.2	65	0.3	2.0	4.6	20	>6
Lab020	5	14.4	15.1	3	0.5	3.3	11.5	20	4.6	14.4	15.2	22	0.4	2.6	10.8	20	5.6
Lab026	5	15.9	12.2	19	0.3	2.5	28.2	20	-1.3	15.9	14.9	144	1.1	7.4	21.1	20	1.9
Lab027	5	11.5	14.8	9	0.9	6.1	40.9	20	-1.4	11.5	15.7	78	1.4	8.9	54.4	20	-1.9
Lab028	5	14.4	14.8	12	0.7	4.7	12.2	20	3.7	14.4	14.6	48	0.8	5.5	12.3	20	3.4
Lab032	5	15.9	-	0	-	-	-	20	-	15.9	15.9	38	0.9	5.7	11.3	20	3.5
Lab033	5	14.4	13.1	2	-	-	-	20	-	14.4	14.9	51	0.7	4.7	12.9	20	3.5
Lab034	5	14.4	-	0	-	-	-	20	-	14.4	14.2	50	0.6	4.2	9.8	20	4.4
Lab037	5	11.5	15.6	4	0.6	3.8	43.3	20	-4.1	11.5	15.0	24	0.7	4.7	39.8	20	-2.2
Lab040	5	14.4	-	0	-	-	-	20	-	14.4	13.3	39	0.7	5.3	18.2	20	2.3
Lab043	5	11.5	12.5	4	0.2	1.6	11.9	20	>6	11.5	13.1	63	0.9	6.9	27.7	20	0.9
Total	-	-	13.9	64	1.4	10.1	-	-	-	-	14.8	697	1.2	8.1	-	-	-

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

Month : 2019 04 Change Cumulative : from 2016 02 01 to 2019 04 30 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2019/04)								CUM (2016/02/01~2019/04/30)							
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	7	0.2	3.6	9.0	20	5.1	5.5	5.7	75	0.2	3.5	10.7	20	4.7
Lab019	5	5.3	5.4	4	0.1	1.9	5.6	20	>6	5.3	5.3	65	0.1	1.9	3.8	20	>6
Lab020	5	5.8	5.4	3	0.1	1.9	10.6	20	>6	5.8	5.4	22	0.1	1.9	10.6	20	>6
Lab026	5	5.8	5.0	19	0.1	2.0	17.8	20	3.1	5.8	5.2	144	0.4	7.7	25.7	20	1.3
Lab027	5	4.5	5.2	9	0.7	13.5	42.5	20	0.3	4.5	5.5	78	0.4	7.3	36.8	20	-0.3
Lab028	5	5.8	5.7	12	0.2	3.5	8.7	20	5.2	5.8	5.7	48	0.4	7.0	15.8	20	2.6
Lab032	5	5.8	-	0	-	-	-	20	-	5.8	5.7	38	0.3	5.3	12.3	20	3.4
Lab033	5	5.8	3.9	2	-	-	-	20	-	5.8	5.2	51	0.3	5.8	21.9	20	1.7
Lab034	5	5.8	-	0	-	-	-	20	-	5.8	5.1	50	0.2	3.9	19.9	20	2.0
Lab037	5	4.5	5.8	4	0.2	3.4	35.8	20	-2.6	4.5	5.5	24	0.3	5.5	33.1	20	-0.4
Lab040	5	5.8	-	0	-	-	-	20	-	5.8	4.7	39	0.3	6.4	31.7	20	0.2
Lab043	5	4.5	4.7	4	0.1	2.1	8.7	20	>6	4.5	4.9	63	0.3	6.1	21.1	20	1.8
Total	-	-	5.3	64	0.5	9.4	-	-	-	-	5.3	697	0.4	7.5	-	-	-

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

Month : 2019 04 Change Cumulative : from 2016 02 01 to 2019 04 30 Change

[TOP]

Reagent Kit	Reagent Code
Medicon	5