Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - May 2019 -
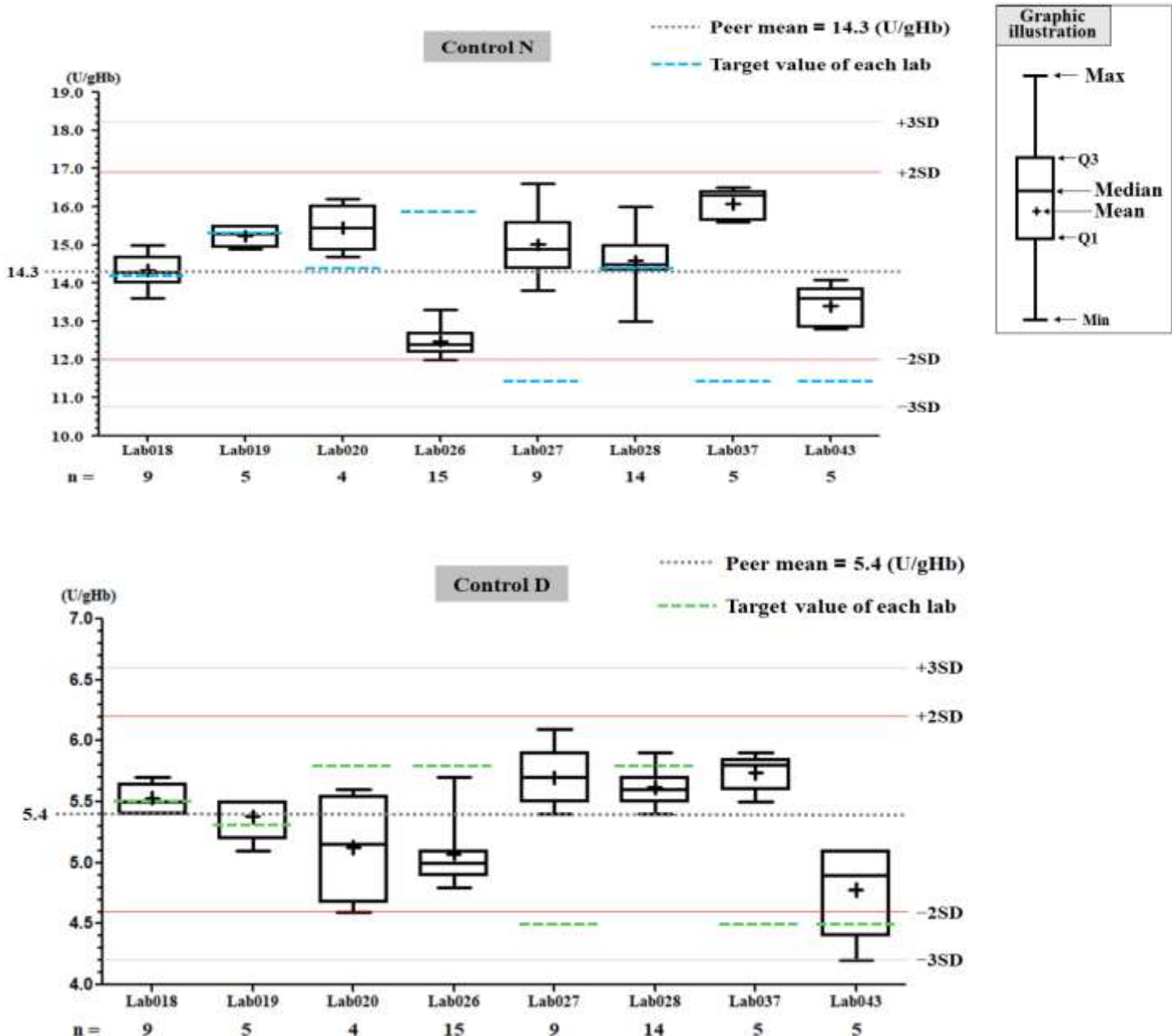
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	8	8
Received results number (n)	66	66
Median	14.5 (U/gHb)	5.5 (U/gHb)
Mean	14.3 (U/gHb)	5.4 (U/gHb)
SD	1.3	0.4
CV	9.1%	7.4%
Range of G6PD	12.0 ~ 16.6 (U/gHb)	4.2 ~ 6.1 (U/gHb)
Range of Hb	1.6 ~ 3.3 (g/dL)	1.9 ~ 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

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

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

Print Table

Lab043

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2019/05)	CUM (2018/12/01~2019/05/31)	Month (2019/05)	CUM (2018/12/01~2019/05/31)
Runs (N)	5	26	5	26
Mean (U/gHb)	13.4	12.8	4.8	4.6
SD	0.5	0.5	0.4	0.2
CV (%)	3.7	3.9	8.3	4.3
Target Value (U/gHb)	11.5	11.5	4.5	4.5
Total Error (%)	24.0	19.1	23.3	10.9
TEa (%)	20	20	20	20
σ	0.9	2.2	1.6	4.1

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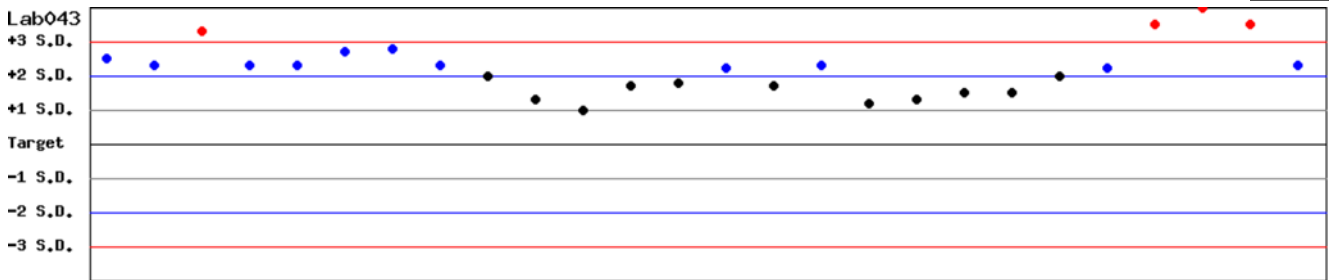σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2019 05 Change ； Cumulative : from 2018 12 01 to 2019 05 31 Change

[TOP]

Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-12-01 to 2019-05-31 ; Target : 11.5 ; SD : 0.6

Month : 2019 05 Change ； Cumulative : from 2018 12 01 to 2019 05 31 Change

[TOP]

Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2018-12-01 to 2019-05-31 ; Target : 4.5 ; SD : 0.3

Month : 2019 05 Change ； Cumulative : from 2018 12 01 to 2019 05 31 Change

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

Lot No.: AE0909N ; Duration : 2018-12-01 to 2019-05-31 ; Target : 11.5 ; SD : 0.6　(●)

Lot No.: AE0909D ; Duration : 2018-12-01 to 2019-05-31 ; Target : 4.5 ; SD : 0.3　(□)

Lab043

Lab043
+3 S.D.
+2 S.D.
+1 S.D.
Target
-1 S.D.
-2 S.D.
-3 S.D.

Date　12-06 12-13 12-20 12-27 01-03 01-10 01-17 01-24 01-31 02-07 02-14 02-21 02-28 03-07 03-14 03-21 03-28 04-04 04-11 04-18 04-25 05-02 05-09 05-16 05-23 05-30
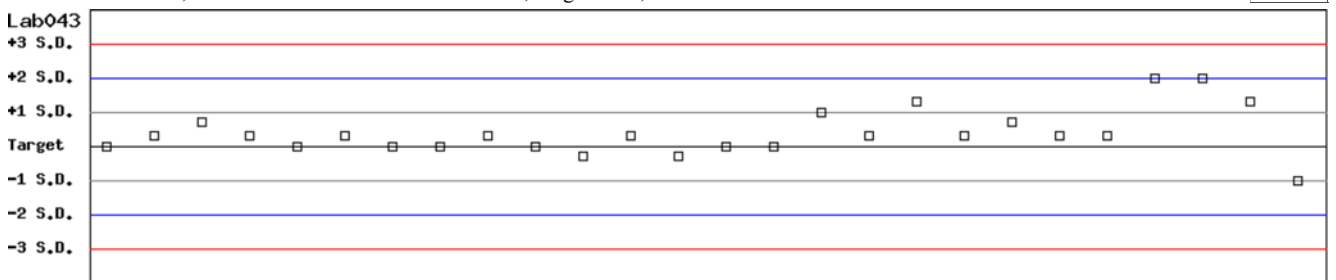
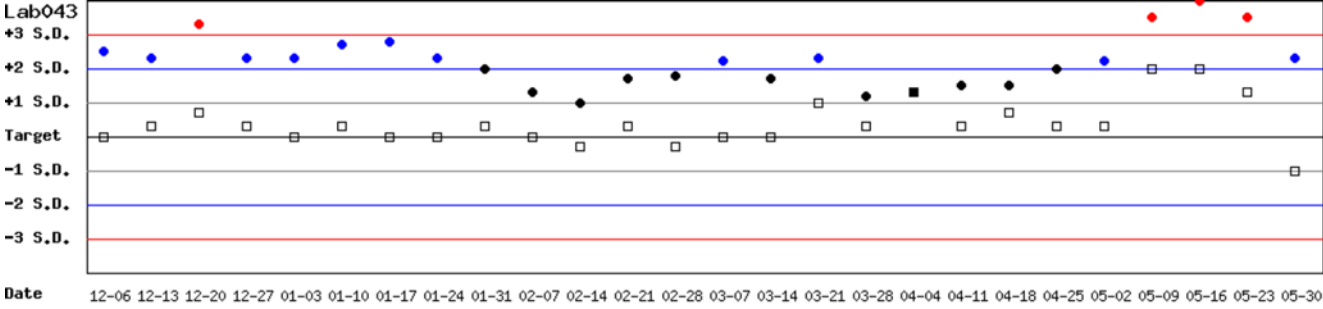Month :　2019　05　Change　;　Cumulative : from　2018　12　01　to　2019　05　31　Change

[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 ▾] [05 ▾] [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	14.3	9	0.4	2.8	6.3	20	>6	5.5	5.5	9	0.1	1.8	3.6	20	>6
Lab019	5	15.3	15.2	5	0.3	2.0	4.6	20	>6	5.3	5.4	5	0.2	3.7	9.3	20	4.9
Lab020	5	14.4	15.5	4	0.6	3.9	15.4	20	3.2	5.8	5.1	4	0.5	9.8	31.7	20	0.8
Lab026	5	15.9	12.5	15	0.4	3.2	27.8	20	-0.4	5.8	5.1	15	0.2	3.9	19.9	20	2.0
Lab027	5	11.5	15.0	9	0.9	6.0	42.4	20	-1.7	4.5	5.7	9	0.2	3.5	33.7	20	-1.9
Lab028	5	14.4	14.6	14	0.7	4.8	11.0	20	3.9	5.8	5.6	14	0.1	1.8	7.0	20	>6
Lab037	5	11.5	16.1	5	0.4	2.5	45.0	20	-8.0	4.5	5.7	5	0.2	3.5	33.7	20	-1.9
Lab043	5	11.5	13.4	5	0.5	3.7	24.0	20	0.9	4.5	4.8	5	0.4	8.3	23.3	20	1.6
Total	-	-	14.3	66	1.3	9.1	-	-	-	-	5.4	66	0.4	7.4	-	-	-

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 ▾] [05 ▾] [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	15.6	84	1.0	6.4	22.7	20	1.6	5.5	5.7	84	0.2	3.5	10.7	20	4.7
Lab019	5	15.3	15.2	70	0.3	2.0	4.6	20	>6	5.3	5.3	70	0.1	1.9	3.8	20	>6
Lab020	5	14.4	15.2	26	0.4	2.6	10.8	20	5.6	5.8	5.3	26	0.2	3.8	16.2	20	3.0
Lab026	5	15.9	14.6	159	1.3	8.9	26.0	20	1.3	5.8	5.2	159	0.4	7.7	25.7	20	1.3
Lab027	5	11.5	15.6	87	1.4	9.0	53.6	20	-1.7	4.5	5.6	87	0.4	7.1	38.7	20	-0.6
Lab028	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
Lab032	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
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	15.2	29	0.8	5.3	42.7	20	-2.3	4.5	5.5	29	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	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	-	-	14.8	763	1.3	8.8	-	-	-	-	5.3	763	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 (2019/05)								CUM (2016/02/01~2019/05/31)							
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	14.3	9	0.4	2.8	6.3	20	>6	14.2	15.6	84	1.0	6.4	22.7	20	1.6
Lab019	5	15.3	15.2	5	0.3	2.0	4.6	20	>6	15.3	15.2	70	0.3	2.0	4.6	20	>6
Lab020	5	14.4	15.5	4	0.6	3.9	15.4	20	3.2	14.4	15.2	26	0.4	2.6	10.8	20	5.6
Lab026	5	15.9	12.5	15	0.4	3.2	27.8	20	-0.4	15.9	14.6	159	1.3	8.9	26.0	20	1.3
Lab027	5	11.5	15.0	9	0.9	6.0	42.4	20	-1.7	11.5	15.6	87	1.4	9.0	53.6	20	-1.7
Lab028	5	14.4	14.6	14	0.7	4.8	11.0	20	3.9	14.4	14.6	62	0.8	5.5	12.3	20	3.4
Lab032	5	15.3	-	0	-	-	-	20	-	15.3	15.9	38	0.9	5.7	15.2	20	2.8
Lab033	5	14.4	-	0	-	-	-	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	16.1	5	0.4	2.5	45.0	20	-8.0	11.5	15.2	29	0.8	5.3	42.7	20	-2.3
Lab040	5	14.4	-	0	-	-	-	20	-	14.4	13.3	39	0.7	5.3	18.2	20	2.3
Lab043	5	11.5	13.4	5	0.5	3.7	24.0	20	0.9	11.5	13.1	68	0.9	6.9	27.7	20	0.9
Total	-	-	14.3	66	1.3	9.1	-	-	-	-	14.8	763	1.3	8.8	-	-	-

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

Month : [2019 ▾] [05 ▾] [Change]   Cumulative : from [2016 ▾] [02 ▾] [01 ▾] to [2019 ▾] [05 ▾] [31 ▾] [Change]

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Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2019/05)								CUM (2016/02/01~2019/05/31)							
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	5.5	9	0.1	1.8	3.6	20	>6	5.5	5.7	84	0.2	3.5	10.7	20	4.7
Lab019	5	5.3	5.4	5	0.2	3.7	9.3	20	4.9	5.3	5.3	70	0.1	1.9	3.8	20	>6
Lab020	5	5.8	5.1	4	0.5	9.8	31.7	20	0.8	5.8	5.3	26	0.2	3.8	16.2	20	3.0
Lab026	5	5.8	5.1	15	0.2	3.9	19.9	20	2.0	5.8	5.2	159	0.4	7.7	25.7	20	1.3
Lab027	5	4.5	5.7	9	0.2	3.5	33.7	20	-1.9	4.5	5.6	87	0.4	7.1	38.7	20	-0.6
Lab028	5	5.8	5.6	14	0.1	1.8	7.0	20	>6	5.8	5.7	62	0.4	7.0	15.8	20	2.6
Lab032	5	5.2	-	0	-	-	-	20	-	5.2	5.7	38	0.3	5.3	20.1	20	2.0
Lab033	5	5.8	-	0	-	-	-	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	5.7	5	0.2	3.5	33.7	20	-1.9	4.5	5.5	29	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	4.8	5	0.4	8.3	23.3	20	1.6	4.5	4.9	68	0.3	6.1	21.1	20	1.8
Total	-	-	5.4	66	0.4	7.4	-	-	-	-	5.3	763	0.4	7.5	-	-	-

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

Month : [2019 ▾] [05 ▾] [Change]   Cumulative : from [2016 ▾] [02 ▾] [01 ▾] to [2019 ▾] [05 ▾] [31 ▾] [Change]

[TOP]

Reagent Kit	Reagent Code
Medicon	5