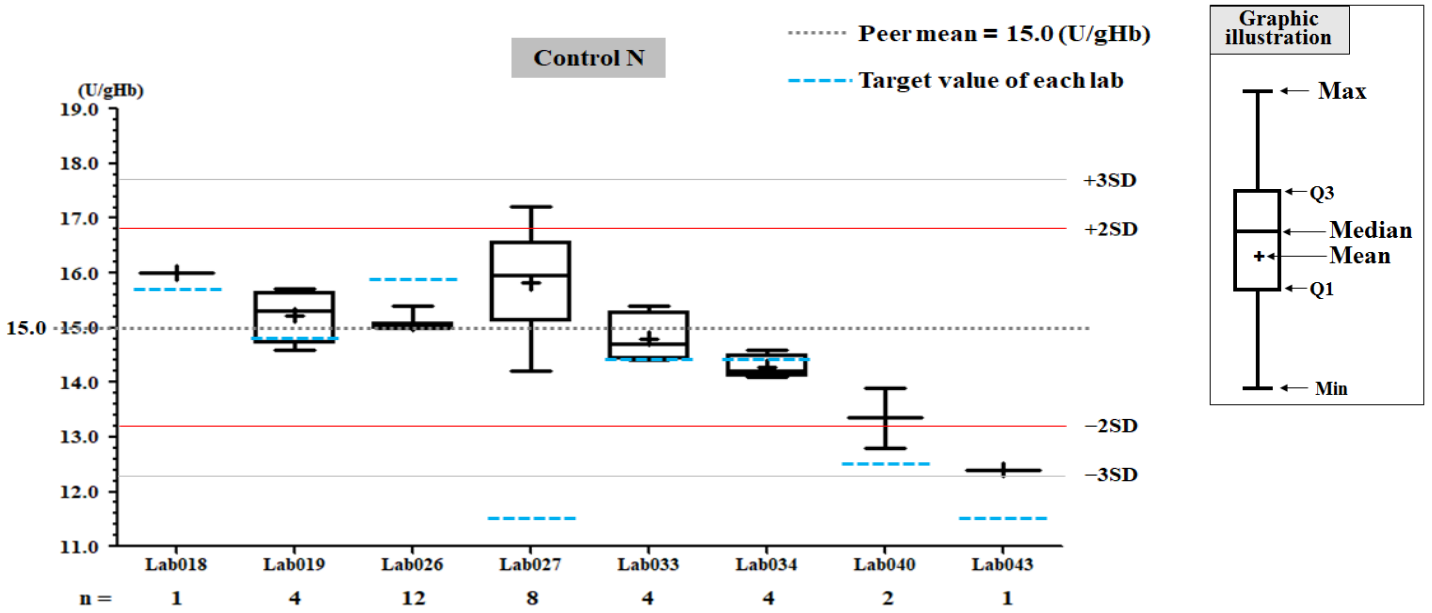
Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - June 2018 -

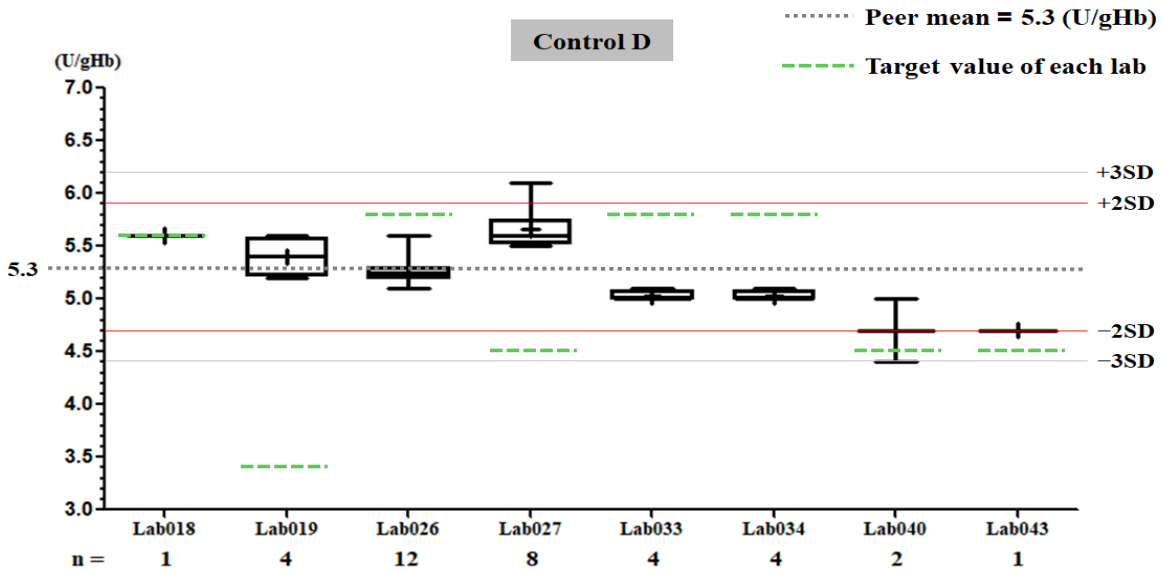
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	8	8
Received results number (n)	36	36
Median	15.0 (U/gHb)	5.3 (U/gHb)
Mean	15.0 (U/gHb)	5.3 (U/gHb)
SD	0.9	0.3
CV	6.0%	5.7%
Range of G6PD	12.4 ~ 17.2 (U/gHb)	4.4 ~ 6.1 (U/gHb)
Range of Hb	1.4 ~ 2.4 (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





Preventive Medicine Foundation TEL:+886-2-2703-6080 ; FAX:+886-2-2703-6070 ; <g6pd@g6pd.tw> ; <http://iqc.g6pd.tw/>

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

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

Print Table

Lab026

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2018/06)	CUM (2018/05/10~2018/06/30)	Month (2018/06)	CUM (2018/05/10~2018/06/30)
Runs (N)	12	26	12	26
Mean (U/gHb)	15.1	15.2	5.3	5.3
SD	0.1	0.4	0.2	0.3
CV (%)	0.7	2.6	3.8	5.7
Target Value (U/gHb)	15.9	15.9	5.8	5.8
Total Error (%)	6.4	9.7	16.2	19.9
TEa (%)	20	20	20	20
σ	>6	6.0	3.0	2.0

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

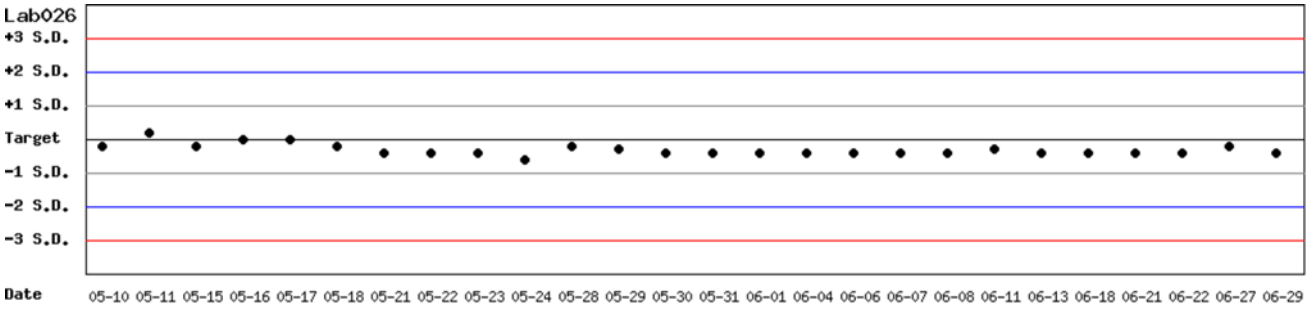
Month : 2018 06 Change ; Cumulative : from 2018 05 10 to 2018 06 30 Change

[TOP]

Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-05-10 to 2018-06-30 ; Target : 15.9 ; SD : 2.20

Lab026



Month : 2018 06 Change ; Cumulative : from 2018 05 10 to 2018 06 30 Change

[TOP]

Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2018-05-10 to 2018-06-30 ; Target : 5.8 ; SD : 1.40

Lab026

Month : 2018 06 Change ; Cumulative : from 2018 05 10 to 2018 06 30 Change

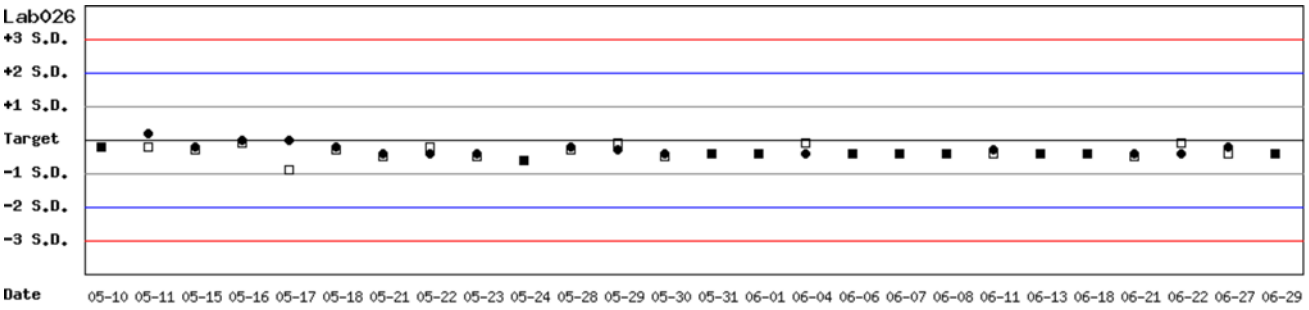
[TOP]

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

Lot No.: AE0909N ; Duration : 2018-05-10 to 2018-06-30 ; Target : 15.9 ; SD : 2.20 (●)

Lot No.: AE0909D ; Duration : 2018-05-10 to 2018-06-30 ; Target : 5.8 ; SD : 1.40 (□)

Lab026



Month : 2018 06 Change ; Cumulative : from 2018 05 10 to 2018 06 30 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 : 2018 06 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	16.0	1	-	-	-	20	-	5.6	5.6	1	-	-	-	20	-
Lab019	5	14.8	15.2	4	0.5	3.3	9.3	20	5.2	3.4	5.4	4	0.2	3.7	66.2	20	-10.5
Lab026	5	15.9	15.1	12	0.1	0.7	6.4	20	>6	5.8	5.3	12	0.2	3.8	16.2	20	3.0
Lab027	5	11.5	15.8	8	0.9	5.7	48.8	20	-3.1	4.5	5.7	8	0.2	3.5	33.7	20	-1.9
Lab033	5	14.4	14.8	4	0.5	3.4	9.5	20	5.1	5.8	5.0	4	0.1	2.0	17.8	20	3.1
Lab034	5	14.4	14.3	4	0.2	1.4	3.5	20	>6	5.8	5.0	4	0.1	2.0	17.8	20	3.1
Lab040	5	12.5	13.4	2	-	-	-	20	-	4.5	4.7	2	-	-	-	20	-
Lab043	5	11.5	12.4	1	-	-	-	20	-	4.5	4.7	1	-	-	-	20	-
Total	-	-	15.0	36	0.9	6.0	-	-	-	-	5.3	36	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 2016 02 01 to 2018 06 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	15.7	16.1	38	0.8	5.0	12.5	20	3.5	5.6	5.7	38	0.3	5.3	12.3	20	3.4
Lab019	5	14.8	15.1	20	0.4	2.6	7.3	20	>6	3.4	5.3	20	0.2	3.8	63.4	20	-9.4
Lab026	5	15.9	15.5	47	0.5	3.2	9.0	20	5.5	5.8	5.2	47	0.6	11.5	33.4	20	0.8
Lab027	5	11.5	15.5	26	1.5	9.7	54.1	20	-1.5	4.5	5.5	26	0.4	7.3	36.8	20	-0.3
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	10	0.4	2.7	8.8	20	>6	5.8	5.2	10	0.2	3.8	18.0	20	2.5
Lab034	5	14.4	13.9	15	0.6	4.3	12.1	20	3.8	5.8	4.9	15	0.2	4.1	23.7	20	1.1
Lab040	5	12.5	12.9	23	0.6	4.7	12.5	20	3.6	4.5	4.6	23	0.3	6.5	15.3	20	2.7
Lab043	5	11.5	13.9	20	1.2	8.6	38.1	20	-0.1	4.5	5.2	20	0.3	5.8	27.1	20	0.8
Total	-	-	15.0	221	1.3	8.7	-	-	-	-	5.3	221	0.5	9.4	-	-	-

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 (2018/06)								CUM (2016/02/01~2018/06/30)							
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	15.7	16.0	1	-	-	-	20	-	15.7	16.1	38	0.8	5.0	12.5	20	3.5
Lab019	5	14.8	15.2	4	0.5	3.3	9.3	20	5.2	14.8	15.1	20	0.4	2.6	7.3	20	>6
Lab026	5	15.9	15.1	12	0.1	0.7	6.4	20	>6	15.9	15.5	47	0.5	3.2	9.0	20	5.5
Lab027	5	11.5	15.8	8	0.9	5.7	48.8	20	-3.1	11.5	15.5	26	1.5	9.7	54.1	20	-1.5
Lab032	5	15.9	-	0	-	-	-	20	-	15.9	15.8	22	1.0	6.3	13.3	20	3.1
Lab033	5	14.4	14.8	4	0.5	3.4	9.5	20	5.1	14.4	14.9	10	0.4	2.7	8.8	20	>6
Lab034	5	14.4	14.3	4	0.2	1.4	3.5	20	>6	14.4	13.9	15	0.6	4.3	12.1	20	3.8
Lab040	5	12.5	13.4	2	-	-	-	20	-	12.5	12.9	23	0.6	4.7	12.5	20	3.6
Lab043	5	11.5	12.4	1	-	-	-	20	-	11.5	13.9	20	1.2	8.6	38.1	20	-0.1
Total	-	-	15.0	36	0.9	6.0	-	-	-	-	15.0	221	1.3	8.7	-	-	-

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

Month : 2018 06 Change Cumulative : from 2016 02 01 to 2018 06 30 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2018/06)								CUM (2016/02/01~2018/06/30)							
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	5.6	5.6	1	-	-	-	20	-	5.6	5.7	38	0.3	5.3	12.3	20	3.4
Lab019	5	3.4	5.4	4	0.2	3.7	66.2	20	-10.5	3.4	5.3	20	0.2	3.8	63.4	20	-9.4
Lab026	5	5.8	5.3	12	0.2	3.8	16.2	20	3.0	5.8	5.2	47	0.6	11.5	33.4	20	0.8
Lab027	5	4.5	5.7	8	0.2	3.5	33.7	20	-1.9	4.5	5.5	26	0.4	7.3	36.8	20	-0.3
Lab032	5	5.8	-	0	-	-	-	20	-	5.8	5.7	22	0.4	7.0	15.8	20	2.6
Lab033	5	5.8	5.0	4	0.1	2.0	17.8	20	3.1	5.8	5.2	10	0.2	3.8	18.0	20	2.5
Lab034	5	5.8	5.0	4	0.1	2.0	17.8	20	3.1	5.8	4.9	15	0.2	4.1	23.7	20	1.1
Lab040	5	4.5	4.7	2	-	-	-	20	-	4.5	4.6	23	0.3	6.5	15.3	20	2.7
Lab043	5	4.5	4.7	1	-	-	-	20	-	4.5	5.2	20	0.3	5.8	27.1	20	0.8
Total	-	-	5.3	36	0.3	5.7	-	-	-	-	5.3	221	0.5	9.4	-	-	-

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

Month : 2018 06 Change Cumulative : from 2016 02 01 to 2018 06 30 Change

[TOP]

Reagent Kit	Reagent Code
Medicon	5