Summary Report of IQC program for G6PD Quantitative Test - Medicon Group
- March 2018 -
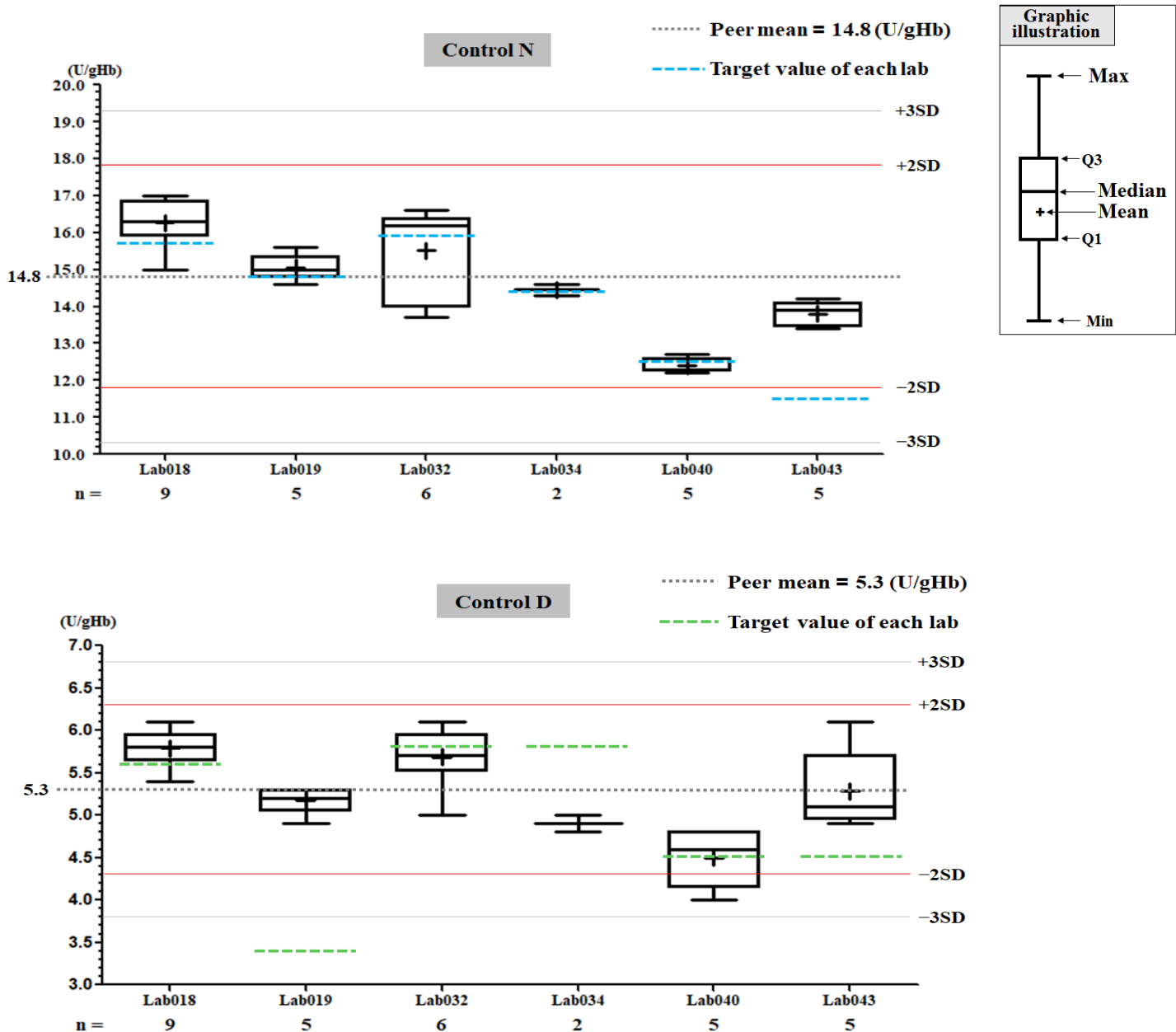
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	6	6
Received results number (n)	32	32
Median	15.0 (U/gHb)	5.3 (U/gHb)
Mean	14.8 (U/gHb)	5.3 (U/gHb)
SD	1.5	0.5
CV	10.1%	9.4%
Range of G6PD	12.2 ~ 17.0 (U/gHb)	4.0 ~ 6.1 (U/gHb)
Range of Hb	1.0 ~ 2.7 (g/dL)	1.9 ~ 2.6 (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

Lab018

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2018/03)	CUM (2017/12/08~2018/03/31)	Month (2018/03)	CUM (2017/12/08~2018/03/31)
Runs (N)	9	26	9	26
Mean (U/gHb)	16.3	16.3	5.8	5.8
SD	0.6	0.7	0.2	0.3
CV (%)	3.7	4.3	3.4	5.2
Target Value (U/gHb)	15.7	15.7	5.6	5.6
Total Error (%)	11.2	12.4	10.5	13.9
TEa (%)	20	20	20	20
σ	4.4	3.8	4.8	3.2

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

Month : 2018 03 Change   ;   Cumulative : from 2017 12 08 to 2018 03 31 Change

[TOP]

Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2017-12-08 to 2018-03-31 ; Target : 15.7 ; SD : 0.90
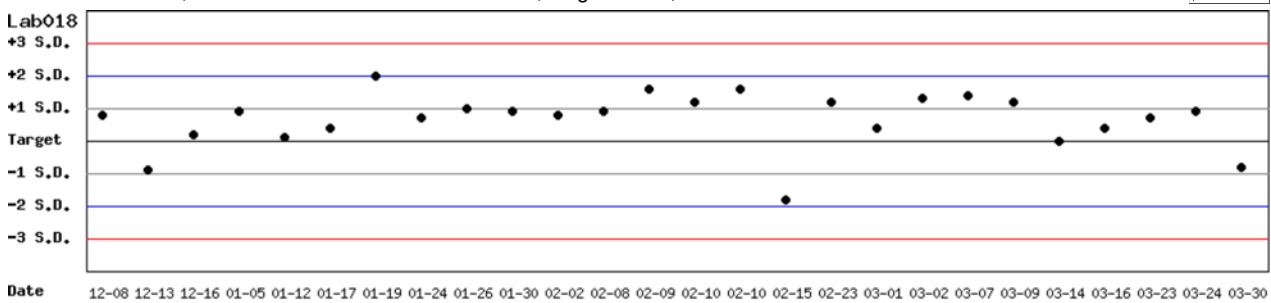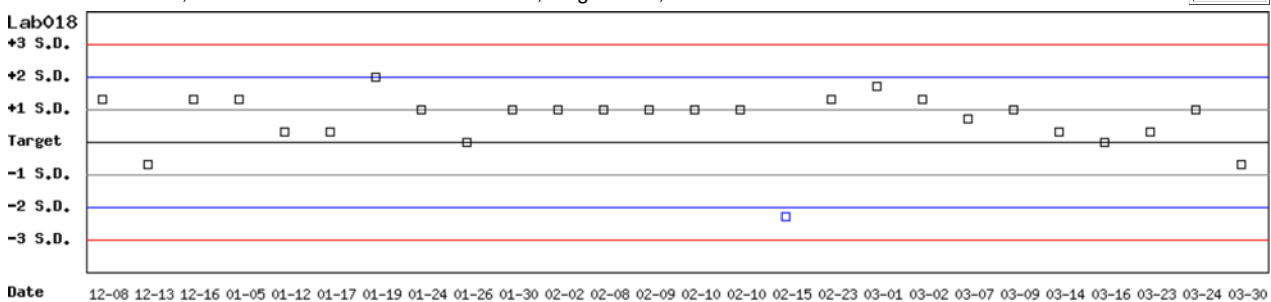

Month : 2018 03 Change   ;   Cumulative : from 2017 12 08 to 2018 03 31 Change

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Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2017-12-08 to 2018-03-31 ; Target : 5.6 ; SD : 0.30

Month : 2018 03 Change   ;   Cumulative : from 2017 12 08 to 2018 03 31 Change
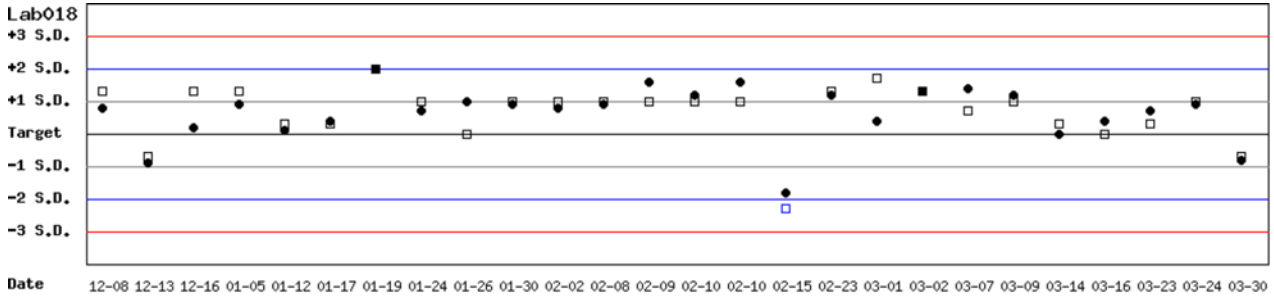
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Control N and Control D SDI
QC Chart

Lot No.: AE0909N ; Duration : 2017-12-08 to 2018-03-31 ; Target : 15.7 ; SD : 0.90   (●)

Lot No.: AE0909D ; Duration : 2017-12-08 to 2018-03-31 ; Target : 5.6 ; SD : 0.30   (□)

Lab018

Month : 2018 03 Change ; Cumulative : from 2017 12 08 to 2018 03 31 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 : [2018 ▼] [03 ▼] [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	15.7	16.3	9	0.6	3.7	11.2	20	4.4	5.6	5.8	9	0.2	3.4	10.5	20	4.8
Lab019	5	14.8	15.1	5	0.4	2.6	7.3	20	>6	3.4	5.2	5	0.2	3.8	60.6	20	-8.7
Lab032	5	15.9	15.5	6	1.3	8.4	19.3	20	2.1	5.8	5.7	6	0.4	7.0	15.8	20	2.6
Lab034	5	14.4	14.5	2	-	-	-	20	-	5.8	4.9	2	-	-	-	20	-
Lab040	5	12.5	12.4	5	0.2	1.6	4.0	20	>6	4.5	4.5	5	0.3	6.7	13.3	20	3.0
Lab043	5	11.5	13.8	5	0.3	2.2	24.3	20	0.0	4.5	5.3	5	0.5	9.4	36.6	20	0.2
Total	-	-	14.8	32	1.5	10.1	-	-	-	-	5.3	32	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 [2018 ▼] [03 ▼] [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	15.7	16.2	29	0.8	4.9	13.1	20	3.4	5.6	5.8	29	0.3	5.2	13.9	20	3.2
Lab019	5	14.8	15.1	5	0.4	2.6	7.3	20	>6	3.4	5.2	5	0.2	3.8	60.6	20	-8.7
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
Lab034	5	14.4	14.5	2	-	-	-	20	-	5.8	4.9	2	-	-	-	20	-
Lab040	5	12.5	12.4	10	0.2	1.6	4.0	20	>6	4.5	4.5	10	0.3	6.7	13.3	20	3.0
Lab043	5	11.5	14.6	12	0.9	6.2	39.3	20	-1.1	4.5	5.3	12	0.3	5.7	29.1	20	0.4
Total	-	-	15.2	80	1.5	9.9	-	-	-	-	5.5	80	0.5	9.1	-	-	-

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 (2018/03) | | | | | | | | CUM (2016/02/01~2018/03/31) | | | | | | | |
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	16.3	9	0.6	3.7	11.2	20	4.4	15.7	16.2	29	0.8	4.9	13.1	20	3.4
Lab019	5	14.8	15.1	5	0.4	2.6	7.3	20	>6	14.8	15.1	5	0.4	2.6	7.3	20	>6
Lab032	5	15.9	15.5	6	1.3	8.4	19.3	20	2.1	15.9	15.8	22	1.0	6.3	13.3	20	3.1
Lab034	5	14.4	14.5	2	-	-	-	20	-	14.4	14.5	2	-	-	-	20	-
Lab040	5	12.5	12.4	5	0.2	1.6	4.0	20	>6	12.5	12.4	10	0.2	1.6	4.0	20	>6
Lab043	5	11.5	13.8	5	0.3	2.2	24.3	20	0.0	11.5	14.6	12	0.9	6.2	39.3	20	-1.1
Total	-	-	14.8	32	1.5	10.1	-	-	-	-	15.2	80	1.5	9.9	-	-	-

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

Month : [2018 ▼] [03 ▼] [Change]   Cumulative : from [2016 ▼] [02 ▼] [01 ▼] to [2018 ▼] [03 ▼] [31 ▼] [Change]

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Control D Month vs. Cumulative

| | | Control D (Lot No.: AE0909D) | | | | | | | | | | | | | | | |
| | | Month (2018/03) | | | | | | | | CUM (2016/02/01~2018/03/31) | | | | | | | |
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	9	0.2	3.4	10.5	20	4.8	5.6	5.8	29	0.3	5.2	13.9	20	3.2
Lab019	5	3.4	5.2	5	0.2	3.8	60.6	20	-8.7	3.4	5.2	5	0.2	3.8	60.6	20	-8.7
Lab032	5	5.8	5.7	6	0.4	7.0	15.8	20	2.6	5.8	5.7	22	0.4	7.0	15.8	20	2.6
Lab034	5	5.8	4.9	2	-	-	-	20	-	5.8	4.9	2	-	-	-	20	-
Lab040	5	4.5	4.5	5	0.3	6.7	13.3	20	3.0	4.5	4.5	10	0.3	6.7	13.3	20	3.0
Lab043	5	4.5	5.3	5	0.5	9.4	36.6	20	0.2	4.5	5.3	12	0.3	5.7	29.1	20	0.4
Total		-	5.3	32	0.5	9.4	-	-	-	-	5.5	80	0.5	9.1	-	-	-

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

Month : [2018 ▼] [03 ▼] [Change]   Cumulative : from [2016 ▼] [02 ▼] [01 ▼] to [2018 ▼] [03 ▼] [31 ▼] [Change]

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Reagent Kit	Reagent Code
Medicon	5