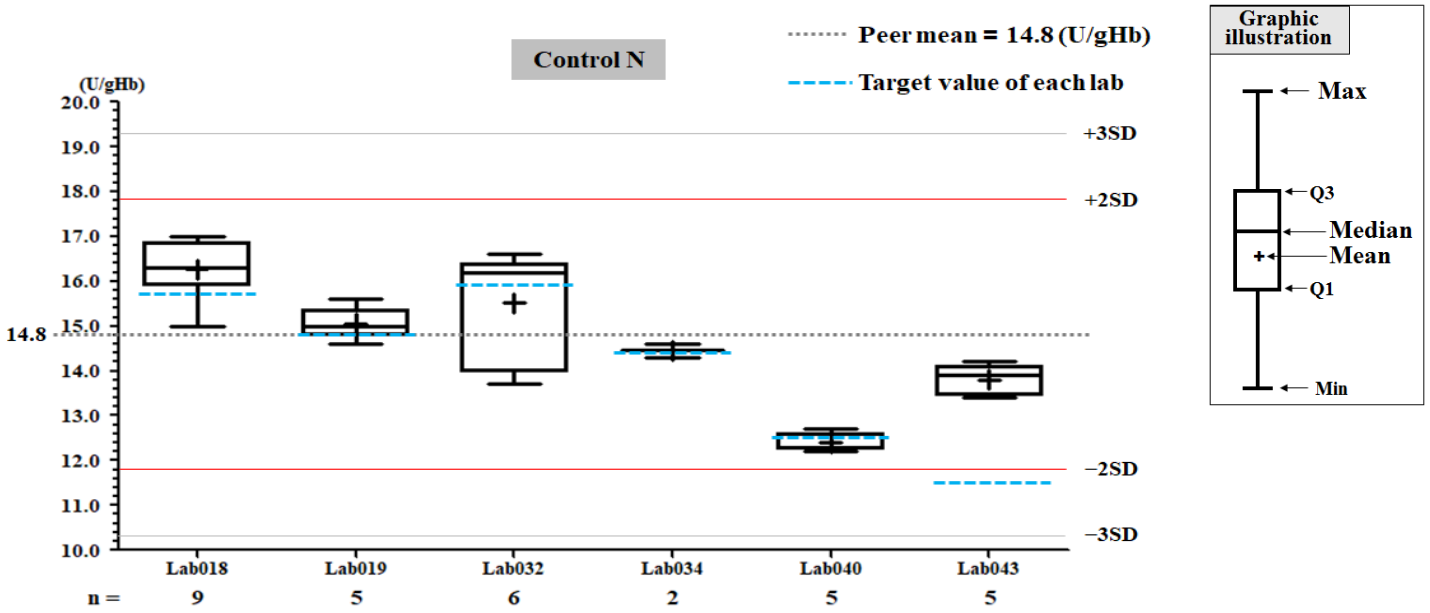
Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - March 2018 -

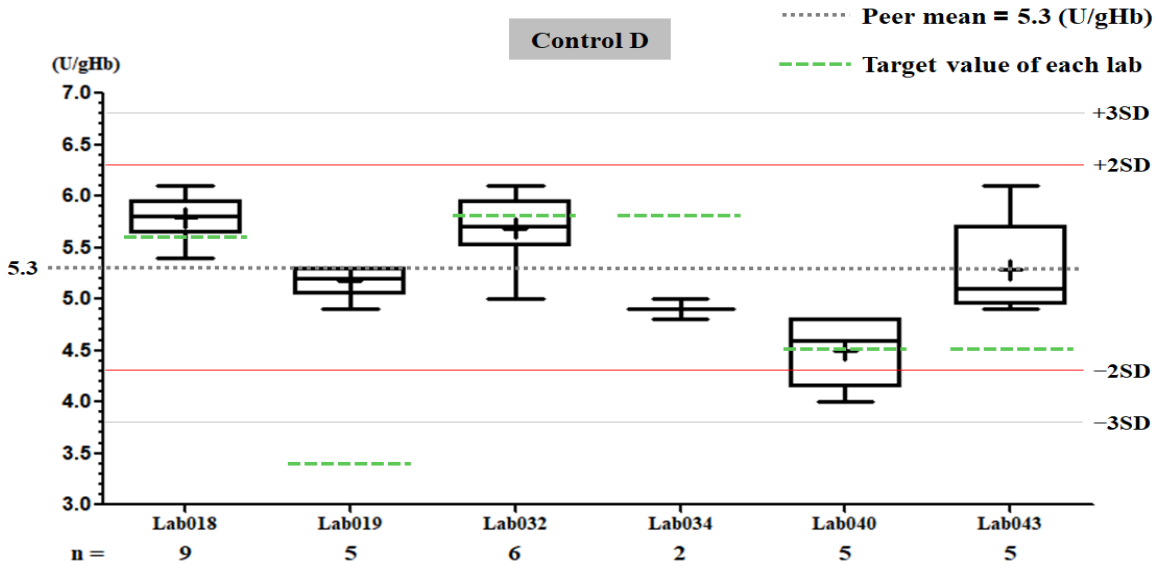
I. The statistic results of all laboratories in this month

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





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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

Lab032

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2018/03)	CUM (2017/05/09~2018/03/31)	Month (2018/03)	CUM (2017/05/09~2018/03/31)
Runs (N)	6	26	6	26
Mean (U/gHb)	15.5	15.3	5.7	5.6
SD	1.3	1.7	0.4	0.5
CV (%)	8.4	11.1	7.0	8.9
Target Value (U/gHb)	15.9	15.9	5.8	5.8
Total Error (%)	19.3	26.0	15.8	21.3
TEa (%)	20	20	20	20
σ	2.1	1.5	2.6	1.9

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

Month : 2018 03 Change ; Cumulative : from 2017 05 09 to 2018 03 31 Change

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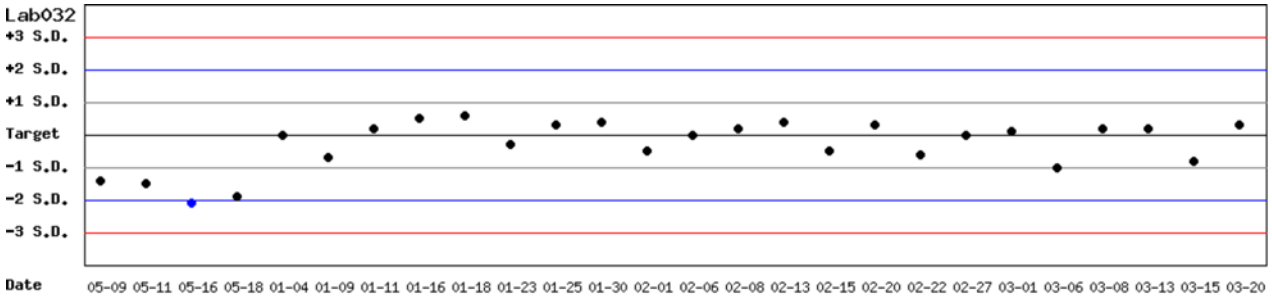
Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2017-05-09 to 2018-03-31 ; Target : 15.9 ; SD : 2.20

Lab032



Month : 2018 03 Change ; Cumulative : from 2017 05 09 to 2018 03 31 Change

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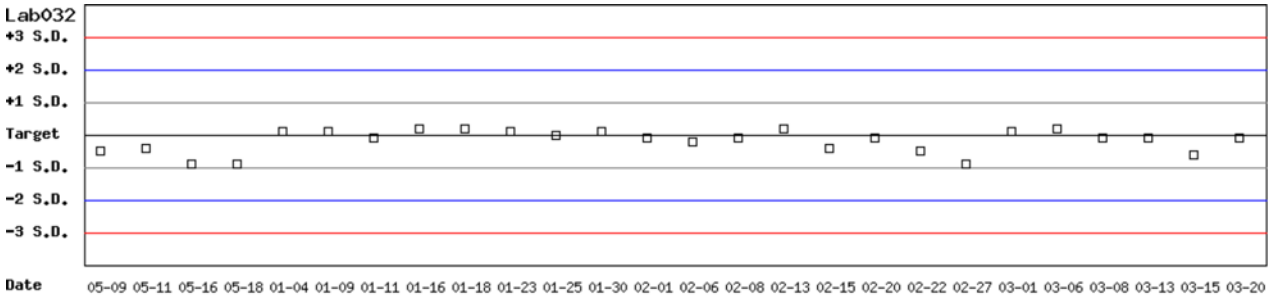
Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2017-05-09 to 2018-03-31 ; Target : 5.8 ; SD : 1.40

Lab032



Month : 2018 03 Change ; Cumulative : from 2017 05 09 to 2018 03 31 Change

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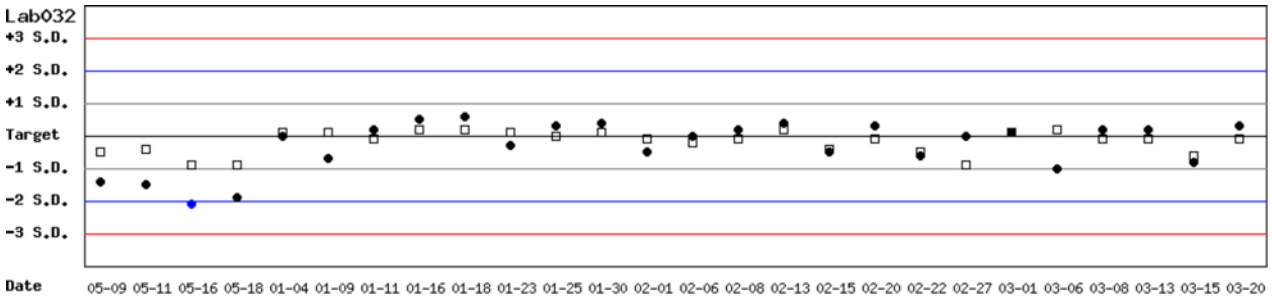
Control N and **Control D SDI**
QC Chart

Lot No.: AE0909N ; Duration : 2017-05-09 to 2018-03-31 ; Target : 15.9 ; SD : 2.20 (●)

Lot No.: AE0909D ; Duration : 2017-05-09 to 2018-03-31 ; Target : 5.8 ; SD : 1.40 (□)

Lab032



Month : 2018 03 Change ; Cumulative : from 2017 05 09 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

		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	16.3	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

		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	16.2	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

[TOP]

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