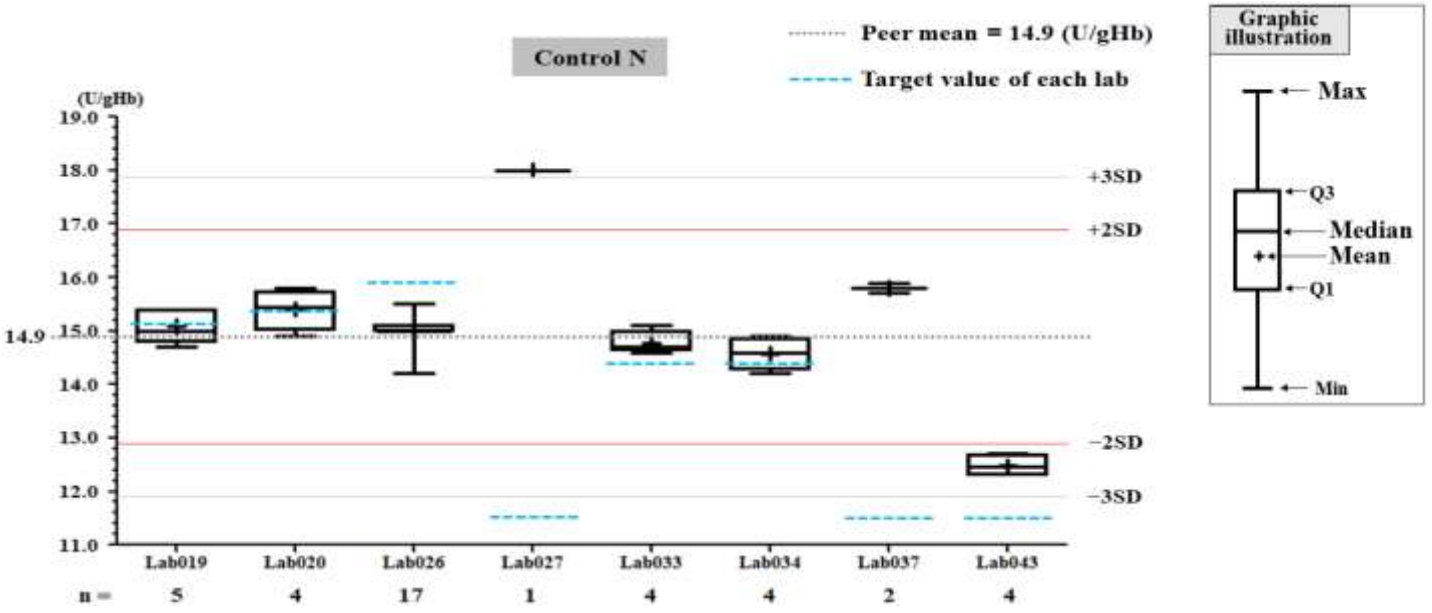
Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - October 2018 -

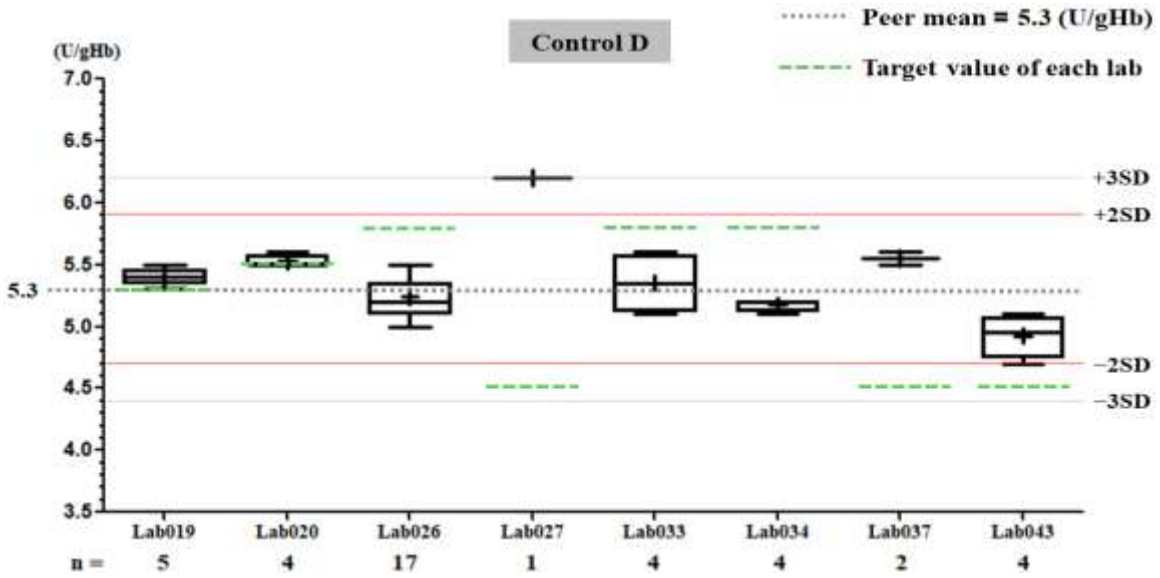
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	8	8
Received results number (n)	41	41
Median	15.0 (U/gHb)	5.3 (U/gHb)
Mean	14.9 (U/gHb)	5.3 (U/gHb)
SD	1.0	0.3
CV	6.7%	5.7%
Range of G6PD	12.3 ~ 18.0 (U/gHb)	4.7 ~ 6.2 (U/gHb)
Range of Hb	1.7 ~ 2.1 (g/dL)	2.0 ~ 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





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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

Lab033

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2018/10)	CUM (2018/05/01~2018/10/31)	Month (2018/10)	CUM (2018/05/01~2018/10/31)
Runs (N)	4	26	4	26
Mean (U/gHb)	14.8	14.7	5.4	5.2
SD	0.2	0.6	0.2	0.2
CV (%)	1.4	4.1	3.7	3.8
Target Value (U/gHb)	14.4	14.4	5.8	5.8
Total Error (%)	5.5	10.2	14.3	18.0
TEa (%)	20	20	20	20
σ	>6	4.4	3.5	2.5

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

Month : 2018 10 Change ; Cumulative : from 2018 05 01 to 2018 10 31 Change

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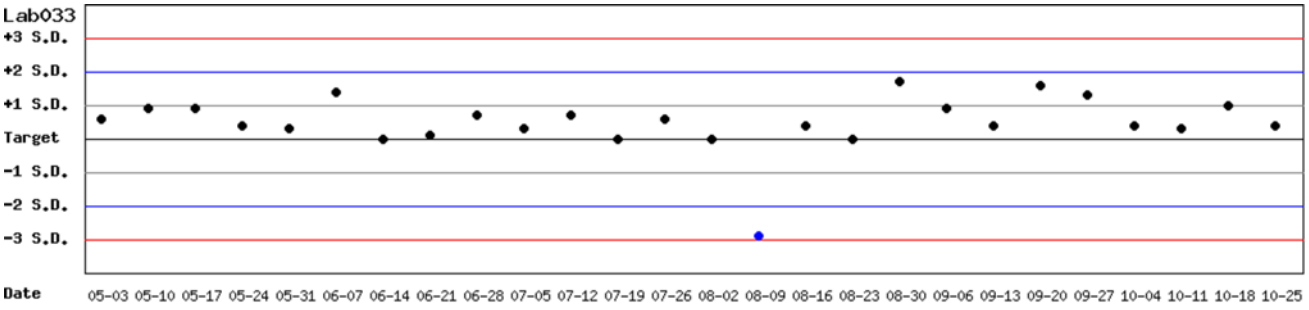
Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-05-01 to 2018-10-31 ; Target : 14.4 ; SD : 0.70

Lab033



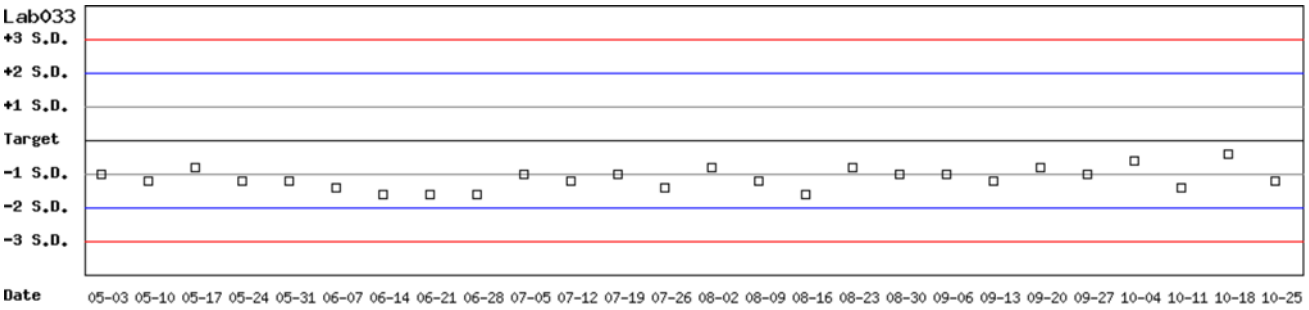
Month : 2018 10 Change ; Cumulative : from 2018 05 01 to 2018 10 31 Change

[TOP]

Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2018-05-01 to 2018-10-31 ; Target : 5.8 ; SD : 0.50

Lab033



Month : 2018 10 Change ; Cumulative : from 2018 05 01 to 2018 10 31 Change

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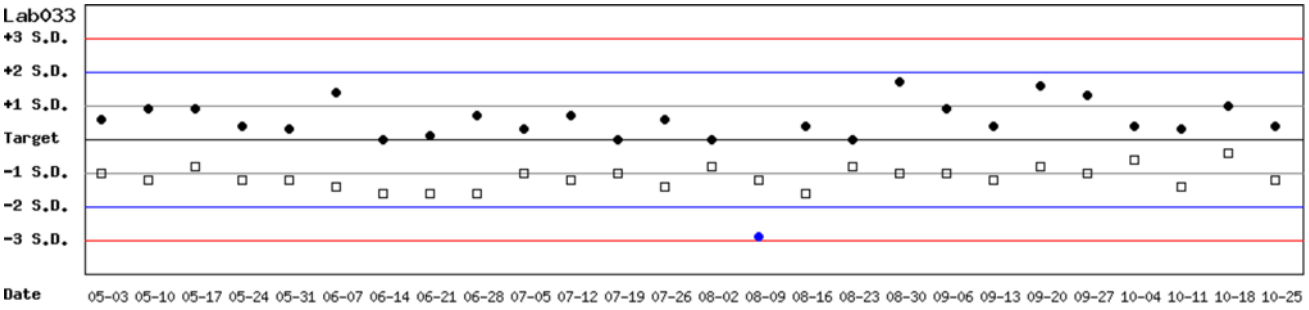
Control N and **Control D SDI**
QC Chart

Lot No.: AE0909N ; Duration : 2018-05-01 to 2018-10-31 ; Target : 14.4 ; SD : 0.70 (●)

Lot No.: AE0909D ; Duration : 2018-05-01 to 2018-10-31 ; Target : 5.8 ; SD : 0.50 (□)

Lab033



Month : 2018 10 Change ; Cumulative : from 2018 05 01 to 2018 10 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 10 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
Lab019	5	15.3	15.1	5	0.3	2.0	5.3	20	>6	5.3	5.4	5	0.1	1.9	5.6	20	>6
Lab020	5	15.4	15.4	4	0.4	2.6	5.2	20	>6	5.5	5.5	4	0.1	1.8	3.6	20	>6
Lab026	5	15.9	15.0	17	0.3	2.0	9.7	20	>6	5.8	5.2	17	0.2	3.8	18.0	20	2.5
Lab027	5	11.5	18.0	1	-	-	-	20	-	4.5	6.2	1	-	-	-	20	-
Lab033	5	14.4	14.8	4	0.2	1.4	5.5	20	>6	5.8	5.4	4	0.2	3.7	14.3	20	3.5
Lab034	5	14.4	14.6	4	0.3	2.1	5.5	20	>6	5.8	5.2	4	0.1	1.9	14.2	20	5.1
Lab037	5	11.5	15.8	2	-	-	-	20	-	4.5	5.6	2	-	-	-	20	-
Lab043	5	11.5	12.5	4	0.2	1.6	11.9	20	>6	4.5	4.9	4	0.2	4.1	17.1	20	2.7
Total	-	-	14.9	41	1.0	6.7	-	-	-	-	5.3	41	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 10 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	16.1	60	0.7	4.3	11.2	20	4.1	5.6	5.7	60	0.3	5.3	12.3	20	3.4
Lab019	5	15.3	15.1	39	0.4	2.6	6.6	20	>6	5.3	5.3	39	0.2	3.8	7.5	20	5.3
Lab020	5	15.4	15.4	4	0.4	2.6	5.2	20	>6	5.5	5.5	4	0.1	1.8	3.6	20	>6
Lab026	5	15.9	15.3	117	0.4	2.6	9.0	20	>6	5.8	5.2	117	0.4	7.7	25.7	20	1.3
Lab027	5	11.5	16.2	53	1.4	8.6	58.2	20	-2.4	4.5	5.6	53	0.4	7.1	38.7	20	-0.6
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	14.8	27	0.6	4.1	10.9	20	4.2	5.8	5.3	27	0.2	3.8	16.2	20	3.0
Lab034	5	14.4	14.1	32	0.5	3.5	9.2	20	5.1	5.8	5.0	32	0.3	6.0	25.8	20	1.0
Lab037	5	11.5	15.8	2	-	-	-	20	-	4.5	5.6	2	-	-	-	20	-
Lab040	5	12.5	13.2	38	0.6	4.5	14.7	20	3.2	4.5	4.7	38	0.3	6.4	17.2	20	2.4
Lab043	5	11.5	13.3	37	1.1	8.3	32.2	20	0.5	4.5	5.1	37	0.3	5.9	25.1	20	1.1
Total	-	-	15.0	431	1.3	8.7	-	-	-	-	5.3	431	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 (2018/10)								CUM (2016/02/01~2018/10/31)							
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	-	0	-	-	-	20	-	15.7	16.1	60	0.7	4.3	11.2	20	4.1
Lab019	5	15.3	15.1	5	0.3	2.0	5.3	20	>6	15.3	15.1	39	0.4	2.6	6.6	20	>6
Lab020	5	15.4	15.4	4	0.4	2.6	5.2	20	>6	15.4	15.4	4	0.4	2.6	5.2	20	>6
Lab026	5	15.9	15.0	17	0.3	2.0	9.7	20	>6	15.9	15.3	117	0.4	2.6	9.0	20	>6
Lab027	5	11.5	18.0	1	-	-	-	20	-	11.5	16.2	53	1.4	8.6	58.2	20	-2.4
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	0.2	1.4	5.5	20	>6	14.4	14.8	27	0.6	4.1	10.9	20	4.2
Lab034	5	14.4	14.6	4	0.3	2.1	5.5	20	>6	14.4	14.1	32	0.5	3.5	9.2	20	5.1
Lab037	5	11.5	15.8	2	-	-	-	20	-	11.5	15.8	2	-	-	-	20	-
Lab040	5	12.5	-	0	-	-	-	20	-	12.5	13.2	38	0.6	4.5	14.7	20	3.2
Lab043	5	11.5	12.5	4	0.2	1.6	11.9	20	>6	11.5	13.3	37	1.1	8.3	32.2	20	0.5
Total	-	-	14.9	41	1.0	6.7	-	-	-	-	15.0	431	1.3	8.7	-	-	-

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

Month : 2018 10 Change Cumulative : from 2016 02 01 to 2018 10 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2018/10)								CUM (2016/02/01~2018/10/31)							
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	-	0	-	-	-	20	-	5.6	5.7	60	0.3	5.3	12.3	20	3.4
Lab019	5	5.3	5.4	5	0.1	1.9	5.6	20	>6	5.3	5.3	39	0.2	3.8	7.5	20	5.3
Lab020	5	5.5	5.5	4	0.1	1.8	3.6	20	>6	5.5	5.5	4	0.1	1.8	3.6	20	>6
Lab026	5	5.8	5.2	17	0.2	3.8	18.0	20	2.5	5.8	5.2	117	0.4	7.7	25.7	20	1.3
Lab027	5	4.5	6.2	1	-	-	-	20	-	4.5	5.6	53	0.4	7.1	38.7	20	-0.6
Lab032	5	5.8	-	0	-	-	-	20	-	5.8	5.7	22	0.4	7.0	15.8	20	2.6
Lab033	5	5.8	5.4	4	0.2	3.7	14.3	20	3.5	5.8	5.3	27	0.2	3.8	16.2	20	3.0
Lab034	5	5.8	5.2	4	0.1	1.9	14.2	20	5.1	5.8	5.0	32	0.3	6.0	25.8	20	1.0
Lab037	5	4.5	5.6	2	-	-	-	20	-	4.5	5.6	2	-	-	-	20	-
Lab040	5	4.5	-	0	-	-	-	20	-	4.5	4.7	38	0.3	6.4	17.2	20	2.4
Lab043	5	4.5	4.9	4	0.2	4.1	17.1	20	2.7	4.5	5.1	37	0.3	5.9	25.1	20	1.1
Total	-	-	5.3	41	0.3	5.7	-	-	-	-	5.3	431	0.4	7.5	-	-	-

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

Month : 2018 10 Change Cumulative : from 2016 02 01 to 2018 10 31 Change

[TOP]

Reagent Kit	Reagent Code
Medicon	5