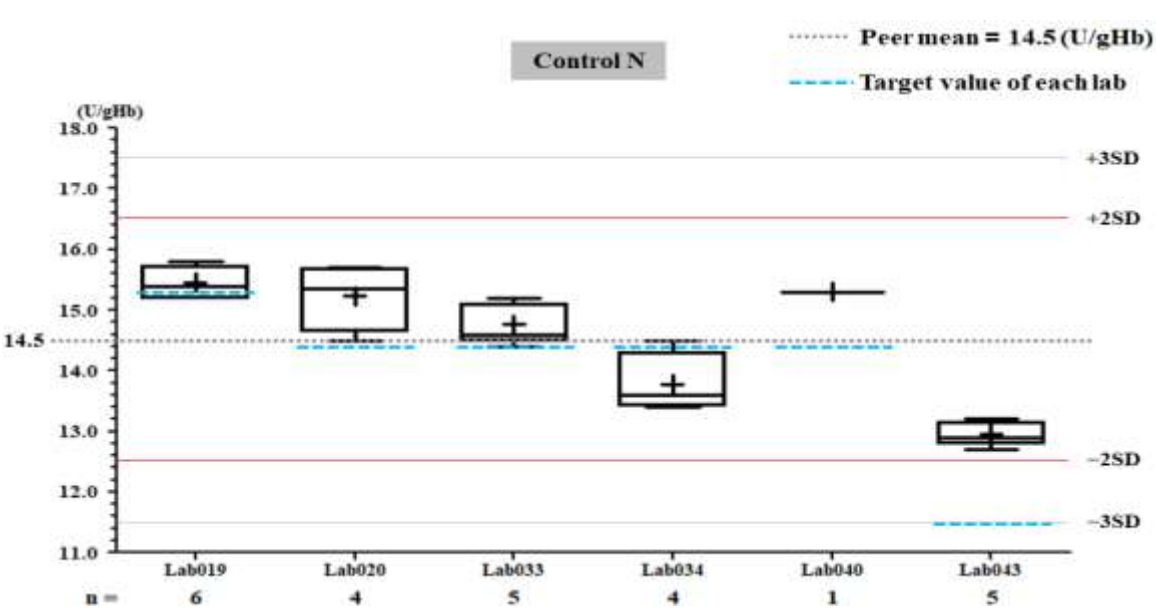
Summary Report of IQC program for G6PD Quantitative Test - Medicon Group
- January 2019 -

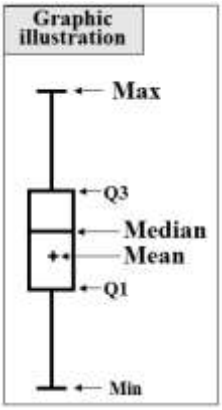
I. The statistic results of all laboratories in this month

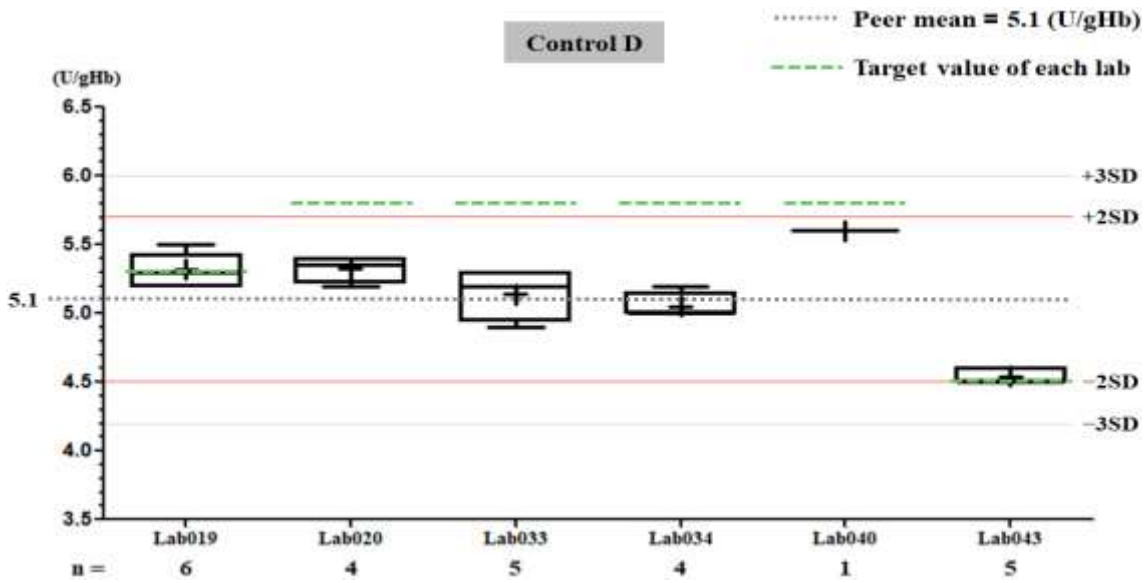
G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	6	6
Received results number (n)	25	25
Median	14.6 (U/gHb)	5.2 (U/gHb)
Mean	14.5 (U/gHb)	5.1 (U/gHb)
SD	1.0	0.3
CV	6.9%	5.9%
Range of G6PD	12.7 ~ 15.8 (U/gHb)	4.5 ~ 5.6 (U/gHb)
Range of Hb	1.7 ~ 2.0 (g/dL)	2.0 ~ 2.6 (g/dL)

*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

Lab033

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2019/01)	CUM (2018/08/09~2019/01/31)	Month (2019/01)	CUM (2018/08/09~2019/01/31)
Runs (N)	5	26	5	26
Mean (U/gHb)	14.8	14.9	5.1	5.3
SD	0.3	0.6	0.2	0.2
CV (%)	2.0	4.0	3.9	3.8
Target Value (U/gHb)	14.4	14.4	5.8	5.8
Total Error (%)	6.8	11.5	19.9	16.2
TEa (%)	20	20	20	20
σ	>6	4.1	2.0	3.0

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

Month : 2019 01 Change ; Cumulative : from 2018 08 09 to 2019 01 31 Change

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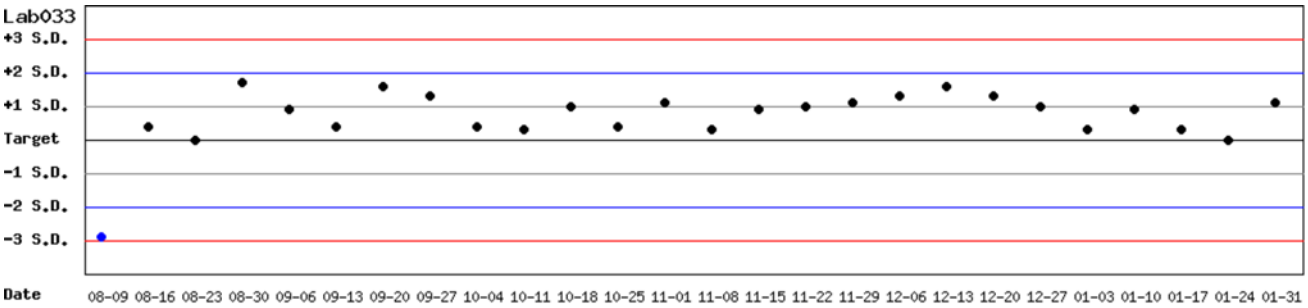
Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-08-09 to 2019-01-31 ; Target : 14.4 ; SD : 0.70

Lab033



Month : 2019 01 Change ; Cumulative : from 2018 08 09 to 2019 01 31 Change

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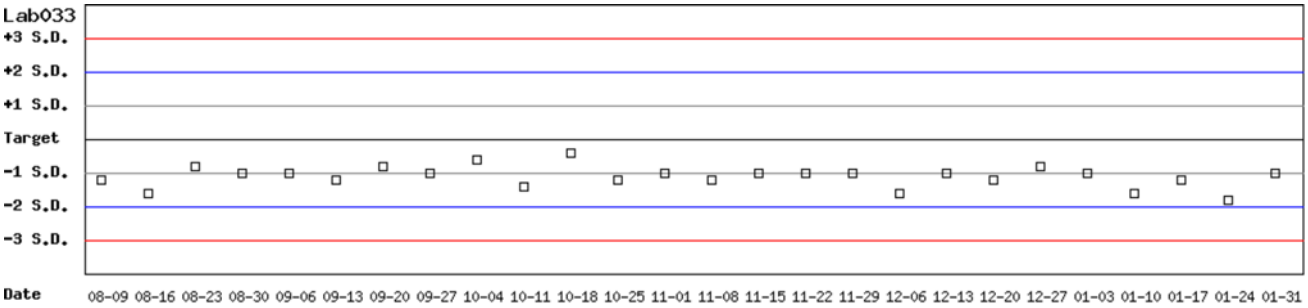
Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2018-08-09 to 2019-01-31 ; Target : 5.8 ; SD : 0.50

Lab033



Month : 2019 01 Change ; Cumulative : from 2018 08 09 to 2019 01 31 Change

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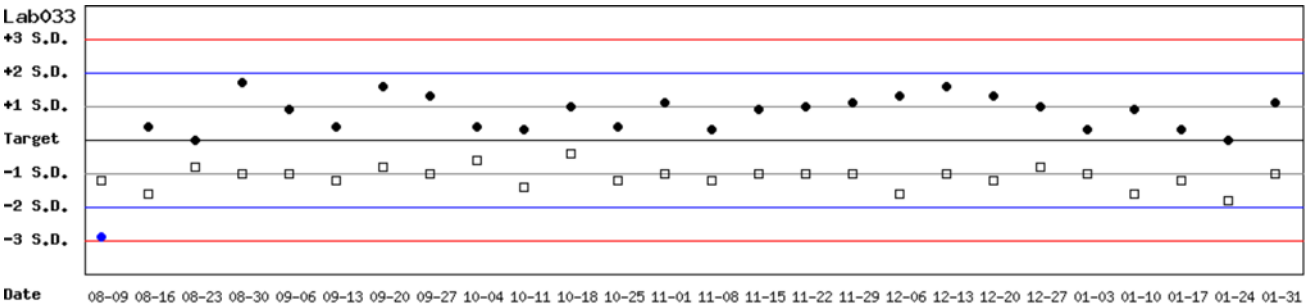
Control N and **Control D SDI**
QC Chart

Lot No.: AE0909N ; Duration : 2018-08-09 to 2019-01-31 ; Target : 14.4 ; SD : 0.70 (●)

Lot No.: AE0909D ; Duration : 2018-08-09 to 2019-01-31 ; Target : 5.8 ; SD : 0.50 (□)

Lab033



Month : 2019 01 Change ; Cumulative : from 2018 08 09 to 2019 01 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 : 2019 01 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	15.5	6	0.3	1.9	5.2	20	>6		5.3	5.3	6	0.1	1.9	3.8	20	>6
Lab020	5	14.4	15.2	4	0.6	3.9	13.5	20	3.7		5.8	5.3	4	0.1	1.9	12.4	20	6.0
Lab033	5	14.4	14.8	5	0.3	2.0	6.8	20	>6		5.8	5.1	5	0.2	3.9	19.9	20	2.0
Lab034	5	14.4	13.8	4	0.5	3.6	11.4	20	4.4		5.8	5.1	4	0.1	2.0	16.0	20	4.0
Lab040	5	14.4	15.3	1	-	-	-	20	-		5.8	5.6	1	-	-	-	20	-
Lab043	5	11.5	13.0	5	0.2	1.5	16.1	20	4.6		4.5	4.5	5	0.1	2.2	4.4	20	>6
Total	-	-	14.5	25	1.0	6.9	-	-	-		-	5.1	25	0.3	5.9	-	-	-

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 01 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	53	0.4	2.6	6.6	20	>6		5.3	5.3	53	0.1	1.9	3.8	20	>6
Lab020	5	14.4	15.2	11	0.4	2.6	10.8	20	5.6		5.8	5.4	11	0.1	1.9	10.6	20	>6
Lab026	5	15.9	15.3	125	0.5	3.3	10.3	20	4.9		5.8	5.2	125	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
Lab028	5	14.4	14.2	12	0.7	4.9	11.2	20	3.8		5.8	5.4	12	0.5	9.3	25.4	20	1.4
Lab032	5	15.9	15.9	30	0.9	5.7	11.3	20	3.5		5.8	5.7	30	0.4	7.0	15.8	20	2.6
Lab033	5	14.4	14.9	41	0.5	3.4	10.2	20	4.9		5.8	5.2	41	0.2	3.8	18.0	20	2.5
Lab034	5	14.4	14.1	45	0.5	3.5	9.2	20	5.1		5.8	5.1	45	0.2	3.9	19.9	20	2.0
Lab037	5	11.5	15.0	11	0.7	4.7	39.8	20	-2.2		4.5	5.4	11	0.2	3.7	27.4	20	0.0
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	13.2	51	1.0	7.6	29.9	20	0.7		4.5	5.0	51	0.3	6.0	23.1	20	1.5
Total	-	-	15.0	531	1.2	8.0	-	-	-		-	5.3	531	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 (2019/01)									CUM (2016/02/01~2019/01/31)						
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	15.5	6	0.3	1.9	5.2	20	>6		15.3	15.1	53	0.4	2.6	6.6	20	>6
Lab020	5	14.4	15.2	4	0.6	3.9	13.5	20	3.7		14.4	15.2	11	0.4	2.6	10.8	20	5.6
Lab026	5	15.9	-	0	-	-	-	20	-		15.9	15.3	125	0.5	3.3	10.3	20	4.9
Lab027	5	11.5	-	0	-	-	-	20	-		11.5	16.2	53	1.4	8.6	58.2	20	-2.4
Lab028	5	14.4	-	0	-	-	-	20	-		14.4	14.2	12	0.7	4.9	11.2	20	3.8
Lab032	5	15.9	-	0	-	-	-	20	-		15.9	15.9	30	0.9	5.7	11.3	20	3.5
Lab033	5	14.4	14.8	5	0.3	2.0	6.8	20	>6		14.4	14.9	41	0.5	3.4	10.2	20	4.9
Lab034	5	14.4	13.8	4	0.5	3.6	11.4	20	4.4		14.4	14.1	45	0.5	3.5	9.2	20	5.1
Lab037	5	11.5	-	0	-	-	-	20	-		11.5	15.0	11	0.7	4.7	39.8	20	-2.2
Lab040	5	14.4	15.3	1	-	-	-	20	-		14.4	13.3	39	0.7	5.3	18.2	20	2.3
Lab043	5	11.5	13.0	5	0.2	1.5	16.1	20	4.6		11.5	13.2	51	1.0	7.6	29.9	20	0.7
Total	-	-	14.5	25	1.0	6.9	-	-	-		-	15.0	531	1.2	8.0	-	-	-

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

Month : 2019 01 Change Cumulative : from 2016 02 01 to 2019 01 31 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2019/01)									CUM (2016/02/01~2019/01/31)						
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	5.3	6	0.1	1.9	3.8	20	>6		5.3	5.3	53	0.1	1.9	3.8	20	>6
Lab020	5	5.8	5.3	4	0.1	1.9	12.4	20	6.0		5.8	5.4	11	0.1	1.9	10.6	20	>6
Lab026	5	5.8	-	0	-	-	-	20	-		5.8	5.2	125	0.4	7.7	25.7	20	1.3
Lab027	5	4.5	-	0	-	-	-	20	-		4.5	5.6	53	0.4	7.1	38.7	20	-0.6
Lab028	5	5.8	-	0	-	-	-	20	-		5.8	5.4	12	0.5	9.3	25.4	20	1.4
Lab032	5	5.8	-	0	-	-	-	20	-		5.8	5.7	30	0.4	7.0	15.8	20	2.6
Lab033	5	5.8	5.1	5	0.2	3.9	19.9	20	2.0		5.8	5.2	41	0.2	3.8	18.0	20	2.5
Lab034	5	5.8	5.1	4	0.1	2.0	16.0	20	4.0		5.8	5.1	45	0.2	3.9	19.9	20	2.0
Lab037	5	4.5	-	0	-	-	-	20	-		4.5	5.4	11	0.2	3.7	27.4	20	0.0
Lab040	5	5.8	5.6	1	-	-	-	20	-		5.8	4.7	39	0.3	6.4	31.7	20	0.2
Lab043	5	4.5	4.5	5	0.1	2.2	4.4	20	>6		4.5	5.0	51	0.3	6.0	23.1	20	1.5
Total	-	-	5.1	25	0.3	5.9	-	-	-		-	5.3	531	0.4	7.5	-	-	-

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

Month : 2019 01 Change Cumulative : from 2016 02 01 to 2019 01 31 Change

[TOP]

Reagent Kit	Reagent Code
Medicon	5