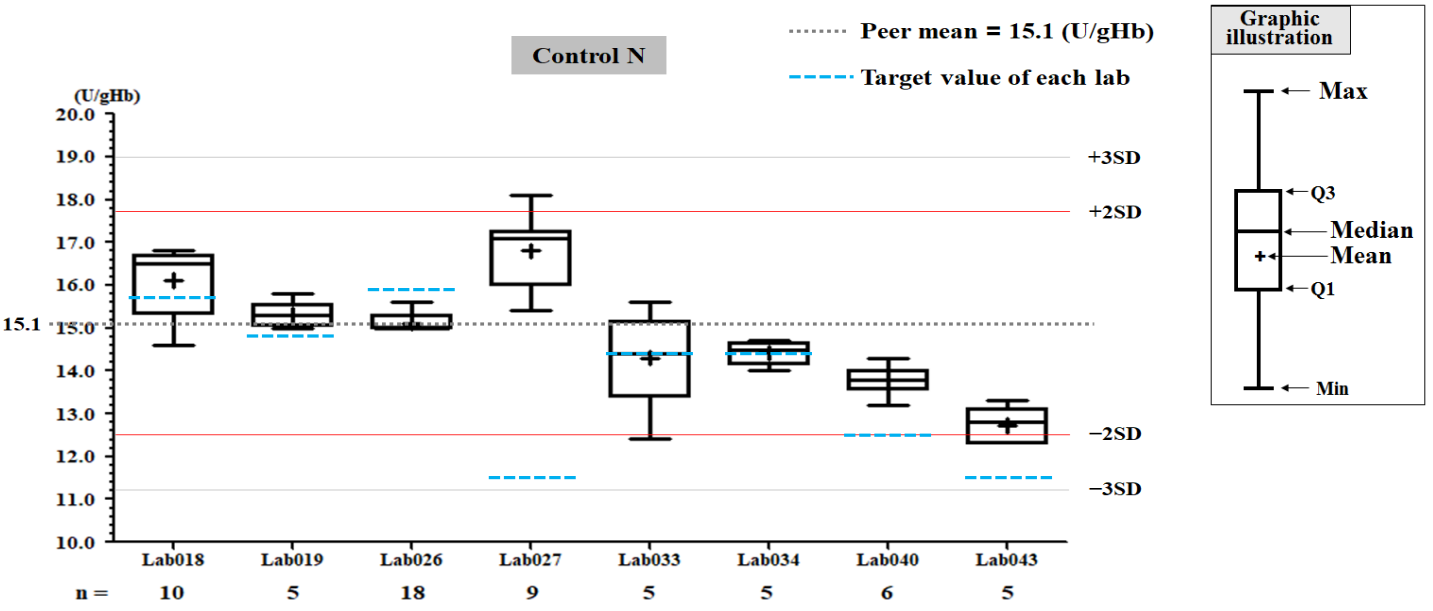
Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - August 2018 -

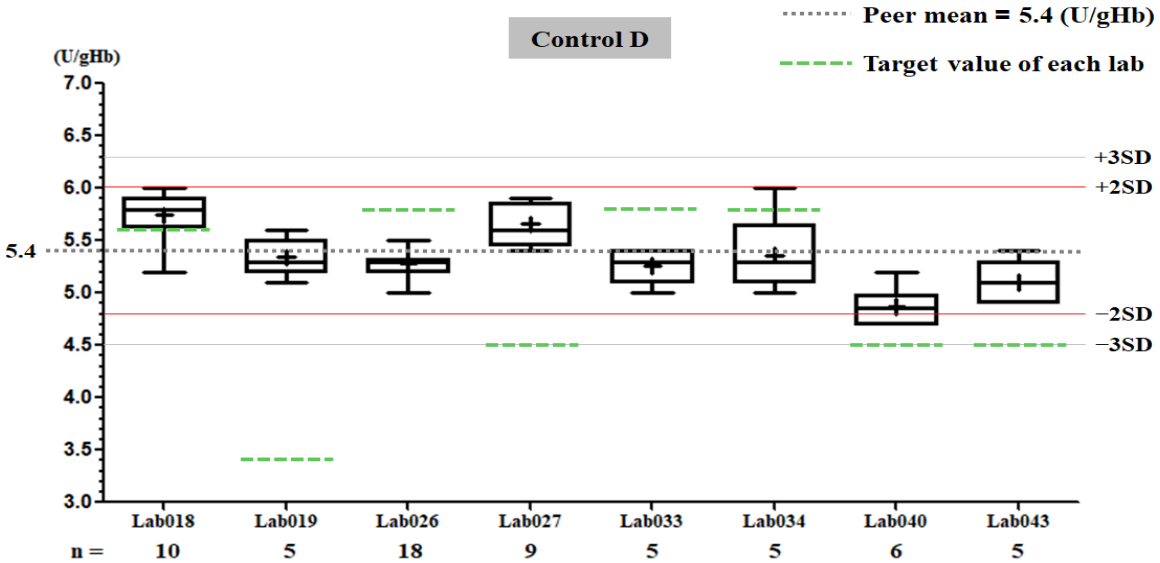
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	8	8
Received results number (n)	63	63
Median	15.0 (U/gHb)	5.3 (U/gHb)
Mean	15.1 (U/gHb)	5.4 (U/gHb)
SD	1.3	0.3
CV	8.6%	5.6%
Range of G6PD	12.3 ~ 18.1 (U/gHb)	4.7 ~ 6.0 (U/gHb)
Range of Hb	1.5 ~ 2.7 (g/dL)	1.6 ~ 2.7 (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

Lab018

	Control N		Control D	
QC Control Lot No.	AE0909N		AE0909D	
Duration of the Analyzing	Month (2018/08)	CUM (2018/03/30~2018/08/31)	Month (2018/08)	CUM (2018/03/30~2018/08/31)
Runs (N)	10	26	10	26
Mean (U/gHb)	16.1	16.0	5.7	5.7
SD	0.8	0.7	0.3	0.2
CV (%)	5.0	4.4	5.3	3.5
Target Value (U/gHb)	15.7	15.7	5.6	5.6
Total Error (%)	12.5	10.7	12.3	8.8
TEa (%)	20	20	20	20
σ	3.5	4.1	3.4	5.2

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

Month : 2018 08 Change ; Cumulative : from 2018 03 30 to 2018 08 31 Change

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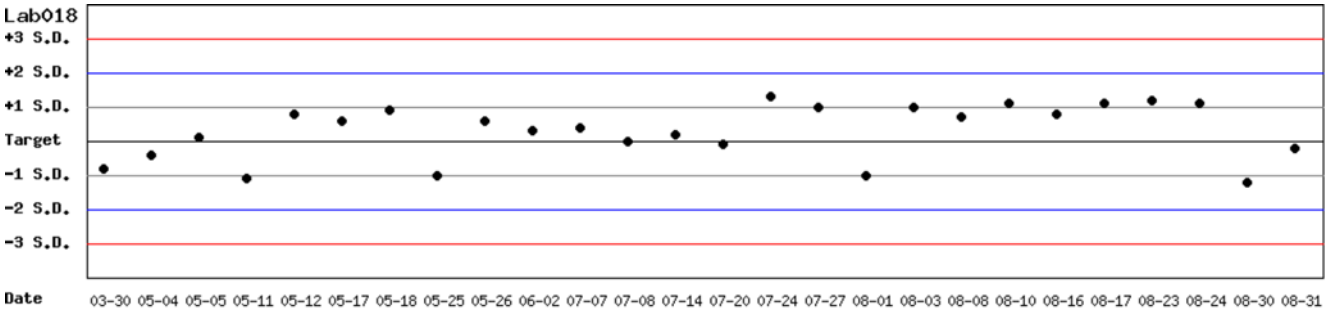
Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2018-03-30 to 2018-08-31 ; Target : 15.7 ; SD : 0.90

Lab018



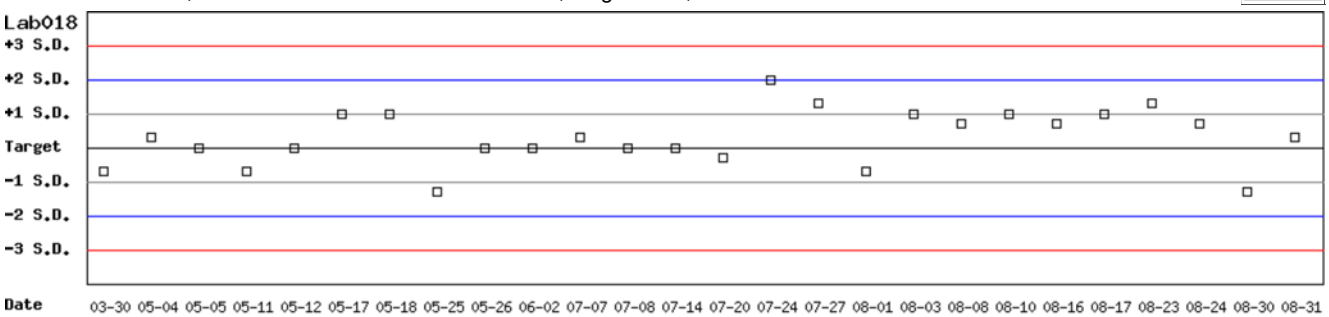
Month : 2018 08 Change ; Cumulative : from 2018 03 30 to 2018 08 31 Change

[TOP]

Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2018-03-30 to 2018-08-31 ; Target : 5.6 ; SD : 0.30

Lab018



Month : 2018 08 Change ; Cumulative : from 2018 03 30 to 2018 08 31 Change

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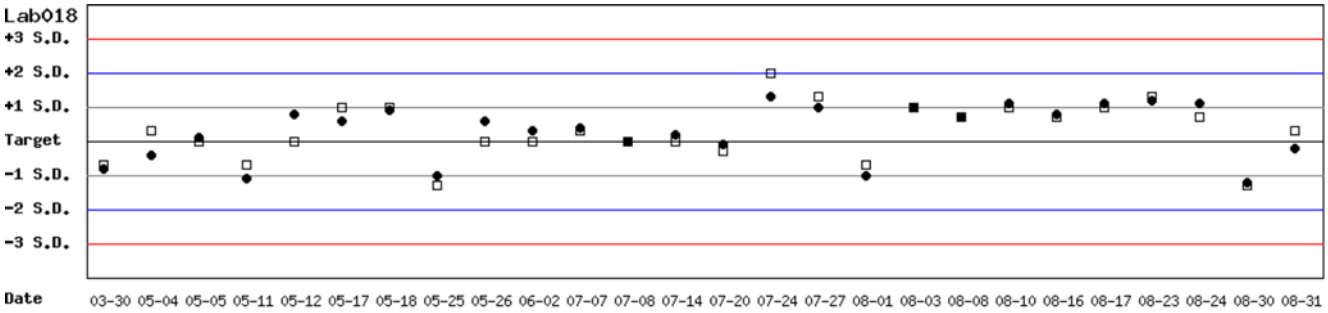
Control N and **Control D SDI**
QC Chart

Lot No.: AE0909N ; Duration : 2018-03-30 to 2018-08-31 ; Target : 15.7 ; SD : 0.90 (●)

Lot No.: AE0909D ; Duration : 2018-03-30 to 2018-08-31 ; Target : 5.6 ; SD : 0.30 (□)

Lab018



Month : 2018 08 Change ; Cumulative : from 2018 03 30 to 2018 08 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 08 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	10	0.8	5.0	12.5	20	3.5	5.6	5.7	10	0.3	5.3	12.3	20	3.4
Lab019	5	14.8	15.3	5	0.3	2.0	7.3	20	>6	3.4	5.3	5	0.2	3.8	63.4	20	-9.4
Lab026	5	15.9	15.1	18	0.2	1.3	7.7	20	>6	5.8	5.3	18	0.1	1.9	12.4	20	6.0
Lab027	5	11.5	16.8	9	0.9	5.4	56.8	20	-4.8	4.5	5.7	9	0.2	3.5	33.7	20	-1.9
Lab033	5	14.4	14.3	5	1.2	8.4	17.5	20	2.3	5.8	5.3	5	0.2	3.8	16.2	20	3.0
Lab034	5	14.4	14.4	5	0.3	2.1	4.2	20	>6	5.8	5.4	5	0.4	7.4	21.7	20	1.8
Lab040	5	12.5	13.8	6	0.4	2.9	16.2	20	3.3	4.5	4.9	6	0.2	4.1	17.1	20	2.7
Lab043	5	11.5	12.7	5	0.4	3.1	16.7	20	3.1	4.5	5.1	5	0.2	3.9	21.2	20	1.7
Total	-	-	15.1	63	1.3	8.6	-	-	-	-	5.4	63	0.3	5.6	-	-	-

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 08 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	54	0.8	5.0	12.5	20	3.5	5.6	5.7	54	0.3	5.3	12.3	20	3.4
Lab019	5	14.8	15.1	29	0.4	2.6	7.3	20	>6	3.4	5.3	29	0.2	3.8	63.4	20	-9.4
Lab026	5	15.9	15.3	86	0.4	2.6	9.0	20	>6	5.8	5.2	86	0.5	9.6	29.6	20	1.0
Lab027	5	11.5	16.0	44	1.4	8.8	56.6	20	-2.2	4.5	5.6	44	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	14.7	19	0.7	4.8	11.6	20	3.7	5.8	5.2	19	0.2	3.8	18.0	20	2.5
Lab034	5	14.4	14.0	24	0.5	3.6	9.9	20	4.8	5.8	5.0	24	0.3	6.0	25.8	20	1.0
Lab040	5	12.5	13.1	33	0.6	4.6	14.0	20	3.3	4.5	4.7	33	0.3	6.4	17.2	20	2.4
Lab043	5	11.5	13.5	29	1.2	8.9	35.2	20	0.3	4.5	5.1	29	0.3	5.9	25.1	20	1.1
Total	-	-	15.0	340	1.3	8.7	-	-	-	-	5.3	340	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 (2018/08)								CUM (2016/02/01~2018/08/31)							
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	16.1	10	0.8	5.0	12.5	20	3.5	15.7	16.1	54	0.8	5.0	12.5	20	3.5
Lab019	5	14.8	15.3	5	0.3	2.0	7.3	20	>6	14.8	15.1	29	0.4	2.6	7.3	20	>6
Lab026	5	15.9	15.1	18	0.2	1.3	7.7	20	>6	15.9	15.3	86	0.4	2.6	9.0	20	>6
Lab027	5	11.5	16.8	9	0.9	5.4	56.8	20	-4.8	11.5	16.0	44	1.4	8.8	56.6	20	-2.2
Lab032	5	15.9	-	0	-	-	-	20	-	15.9	15.8	22	1.0	6.3	13.3	20	3.1
Lab033	5	14.4	14.3	5	1.2	8.4	17.5	20	2.3	14.4	14.7	19	0.7	4.8	11.6	20	3.7
Lab034	5	14.4	14.4	5	0.3	2.1	4.2	20	>6	14.4	14.0	24	0.5	3.6	9.9	20	4.8
Lab040	5	12.5	13.8	6	0.4	2.9	16.2	20	3.3	12.5	13.1	33	0.6	4.6	14.0	20	3.3
Lab043	5	11.5	12.7	5	0.4	3.1	16.7	20	3.1	11.5	13.5	29	1.2	8.9	35.2	20	0.3
Total	-	-	15.1	63	1.3	8.6	-	-	-	-	15.0	340	1.3	8.7	-	-	-

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

Month : 2018 08 Change Cumulative : from 2016 02 01 to 2018 08 31 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2018/08)								CUM (2016/02/01~2018/08/31)							
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	5.7	10	0.3	5.3	12.3	20	3.4	5.6	5.7	54	0.3	5.3	12.3	20	3.4
Lab019	5	3.4	5.3	5	0.2	3.8	63.4	20	-9.4	3.4	5.3	29	0.2	3.8	63.4	20	-9.4
Lab026	5	5.8	5.3	18	0.1	1.9	12.4	20	6.0	5.8	5.2	86	0.5	9.6	29.6	20	1.0
Lab027	5	4.5	5.7	9	0.2	3.5	33.7	20	-1.9	4.5	5.6	44	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	5.3	5	0.2	3.8	16.2	20	3.0	5.8	5.2	19	0.2	3.8	18.0	20	2.5
Lab034	5	5.8	5.4	5	0.4	7.4	21.7	20	1.8	5.8	5.0	24	0.3	6.0	25.8	20	1.0
Lab040	5	4.5	4.9	6	0.2	4.1	17.1	20	2.7	4.5	4.7	33	0.3	6.4	17.2	20	2.4
Lab043	5	4.5	5.1	5	0.2	3.9	21.2	20	1.7	4.5	5.1	29	0.3	5.9	25.1	20	1.1
Total	-	-	5.4	63	0.3	5.6	-	-	-	-	5.3	340	0.5	9.4	-	-	-

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

Month : 2018 08 Change Cumulative : from 2016 02 01 to 2018 08 31 Change

[TOP]

Reagent Kit	Reagent Code
Medicon	5