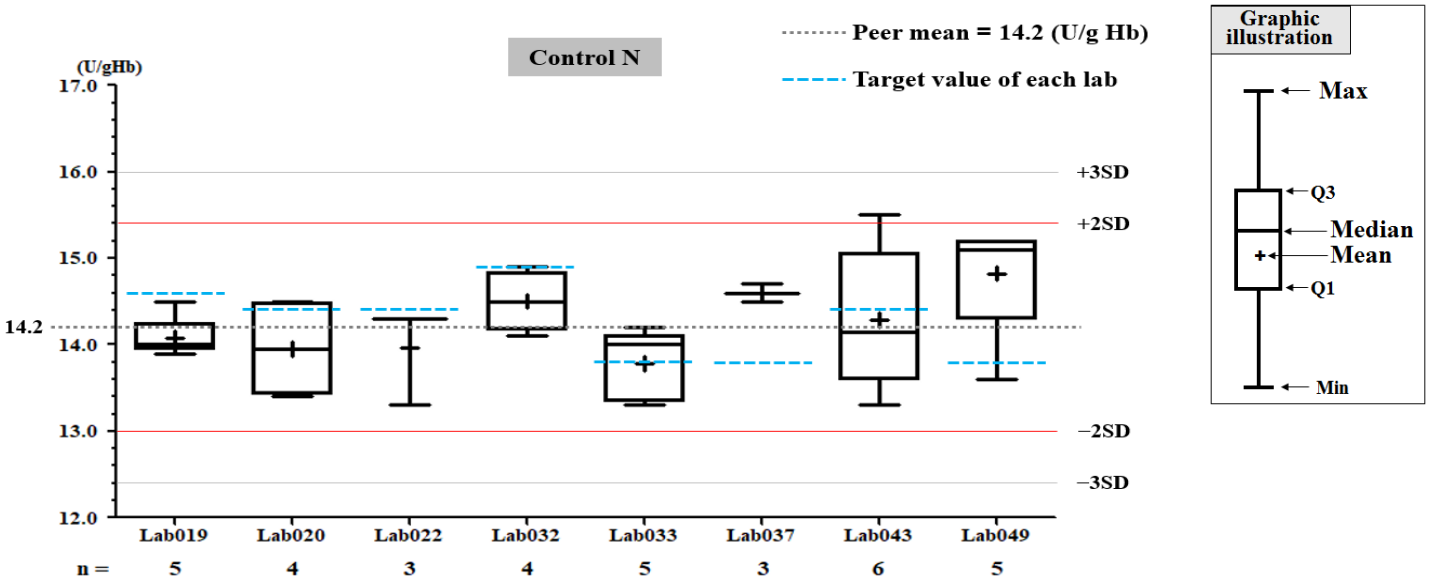
Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - June 2022 -

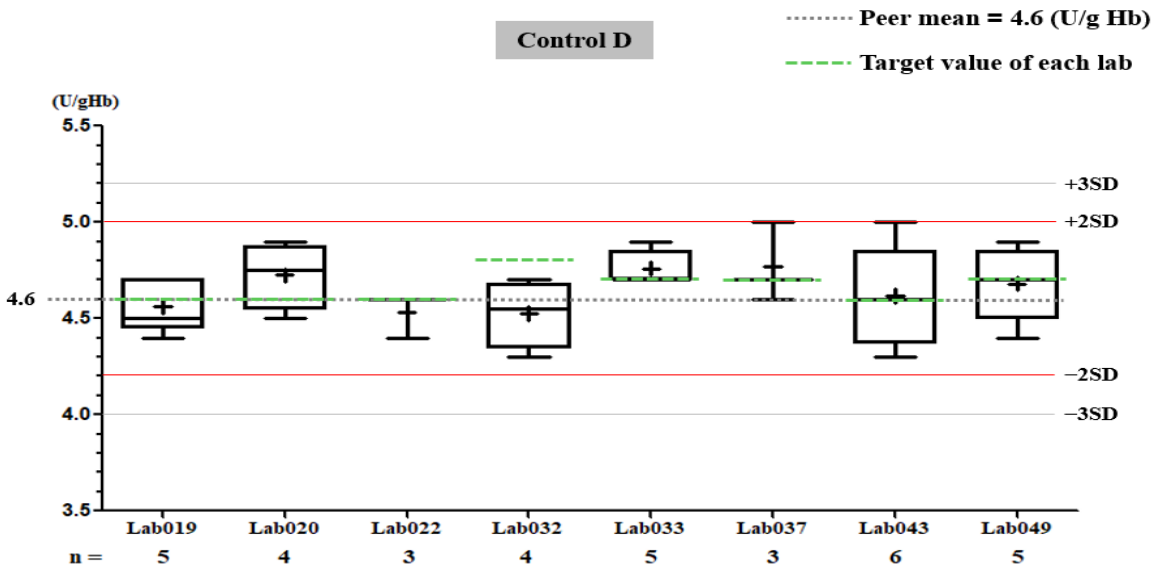
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	8	8
Received results number (n)	35	35
Median	14.3 (U/g Hb)	4.7 (U/g Hb)
Mean	14.2 (U/g Hb)	4.6 (U/g Hb)
SD	0.6	0.2
CV	4.2%	4.3%
Range of G6PD	13.3 ~ 15.5 (U/g Hb)	4.3 ~ 5.0 (U/g Hb)
Range of Hb	2.1 ~ 2.8 (g/dL)	1.9 ~ 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： BJ0922N (2021-01-01 ~ 2100-12-31) Change

Print Table

Lab019

	Control N		Control D	
QC Control Lot No.	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2022/06)	CUM (2022/01/05~2022/06/30)	Month (2022/06)	CUM (2022/01/05~2022/06/30)
Runs (N)	5	24	5	24
Mean (U/gHb)	14.1	14.6	4.6	4.6
SD	0.2	0.6	0.1	0.1
CV (%)	1.4	4.1	2.2	2.2
Target Value (U/gHb)	14.6	14.6	4.6	4.6
Total Error (%)	6.3	8.2	4.3	4.3
TEa (%)	20	20	20	20
σ	>6	4.9	>6	>6

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

Month : 2022 06 Change ; Cumulative : from 2022 01 05 to 2022 06 30 Change

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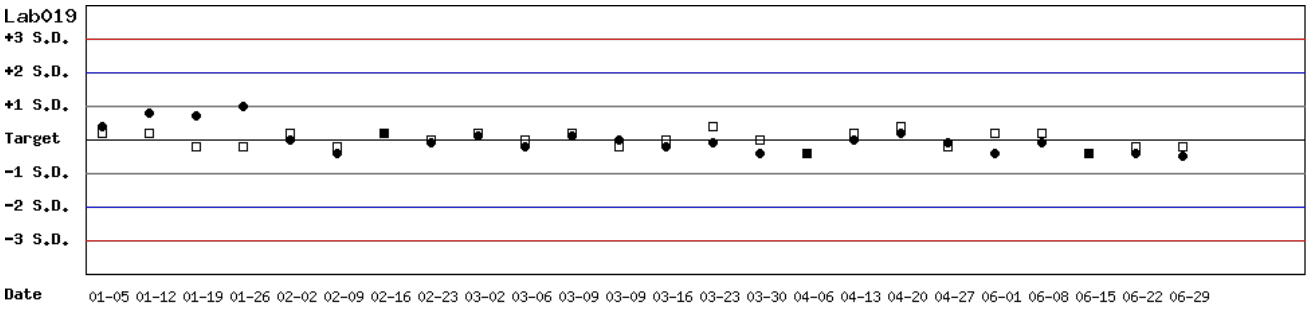
Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-01-05 to 2022-06-30 ; Target : 14.6 ; SD : 1.38 (●)

Lot No.: BJ0922D ; Duration : 2022-01-05 to 2022-06-30 ; Target : 4.6 ; SD : 0.47 (□)

Lab019



Month : 2022 06 Change ; Cumulative : from 2022 01 05 to 2022 06 30 Change

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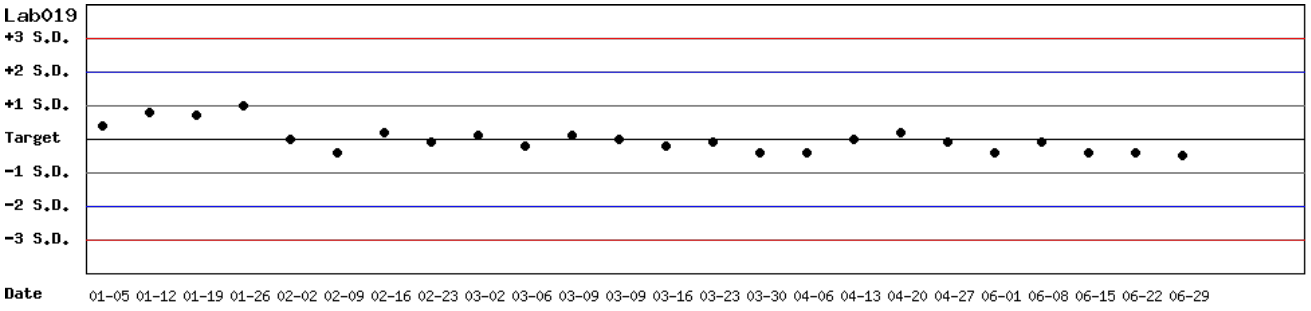
Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-01-05 to 2022-06-30 ; Target : 14.6 ; SD : 1.38

Lab019



Month : 2022 06 Change ; Cumulative : from 2022 01 05 to 2022 06 30 Change

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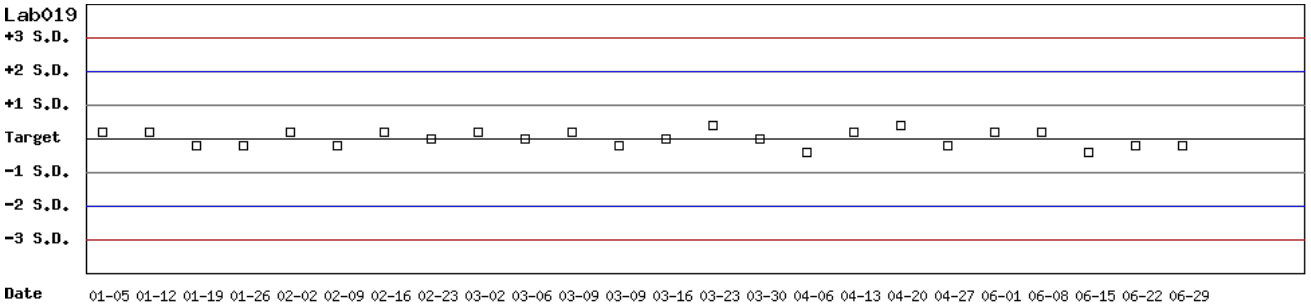
Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2022-01-05 to 2022-06-30 ; Target : 4.6 ; SD : 0.47

Lab019



Month : 2022 06 Change ; Cumulative : from 2022 01 05 to 2022 06 30 Change

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Peer Group Statistics (Table 1)

Select LotNo : BJ0922N (2021-01-01 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 1

Monthly

Month : 2022 06 Change

		Control N (Lot No.: BJ0922N)								Control D (Lot No.: BJ0922D)							
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	14.6	14.1	5	0.2	1.4	6.3	20	>6	4.6	4.6	5	0.1	2.2	4.3	20	>6
Lab020	5	14.4	14.0	4	0.6	4.3	11.3	20	4.0	4.6	4.7	4	0.2	4.3	10.7	20	4.1
Lab022	5	14.4	14.0	3	0.6	4.3	11.3	20	4.0	4.6	4.5	3	0.1	2.2	6.6	20	>6
Lab032	5	14.9	14.5	4	0.3	2.1	6.8	20	>6	4.8	4.5	4	0.2	4.4	15.1	20	3.1
Lab033	5	13.8	13.8	5	0.4	2.9	5.8	20	>6	4.7	4.8	5	0.1	2.1	6.3	20	>6
Lab037	5	13.8	14.6	3	0.1	0.7	7.2	20	>6	4.7	4.8	3	0.2	4.2	10.5	20	4.3
Lab043	5	14.4	14.3	6	0.8	5.6	11.9	20	3.4	4.6	4.6	6	0.3	6.5	13.0	20	3.1
Lab049	5	13.8	14.8	5	0.7	4.7	16.7	20	2.7	4.7	4.7	5	0.2	4.3	8.5	20	4.7
Total	-	-	14.2	35	0.6	4.2	-	-	-	-	4.6	35	0.2	4.3	-	-	-

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

[TOP]

Cumulative

Cumulative : from 2021 01 01 to 2022 06 30 Change

		Control N (Lot No.: BJ0922N)								Control D (Lot No.: BJ0922D)							
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	16.2	16.5	5	0.4	2.4	6.7	20	>6	5.5	5.6	5	0.2	3.6	9.0	20	5.1
Lab019	5	14.6	14.6	24	0.6	4.1	8.2	20	4.9	4.6	4.6	24	0.1	2.2	4.3	20	>6
Lab020	5	14.4	14.4	34	0.6	4.2	8.3	20	4.8	4.6	4.7	34	0.2	4.3	10.7	20	4.1
Lab022	5	14.4	14.4	7	0.6	4.2	8.3	20	4.8	4.6	4.4	7	0.2	4.5	13.4	20	3.5
Lab028	5	15.2	15.1	34	1.1	7.3	15.2	20	2.6	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	14.9	14.4	79	0.4	2.8	8.9	20	5.9	4.8	4.5	79	0.1	2.2	10.7	20	>6
Lab033	5	13.8	13.4	26	0.6	4.5	11.9	20	3.8	4.7	4.4	26	0.4	9.1	24.6	20	1.5
Lab037	5	13.8	14.7	28	0.5	3.4	13.3	20	4.0	4.7	4.7	28	0.2	4.3	8.5	20	4.7
Lab043	5	14.4	13.2	47	1.5	11.4	31.1	20	1.0	4.6	4.2	47	0.5	11.9	32.5	20	0.9
Lab049	5	13.8	14.9	56	0.6	4.0	16.0	20	3.0	4.7	4.7	56	0.2	4.3	8.5	20	4.7
Total	-	-	14.4	340	1.0	6.9	-	-	-	-	4.6	340	0.4	8.7	-	-	-

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： BJ0922N (2021-01-01 ~ 2100-12-31) Change

Select Reagent Kit： 5 - Medicon Change

Print Table 2

Control N Month vs. Cumulative

		Control N (Lot No.: BJ0922N)															
		Month (2022/06)								CUM (2021/01/01~2022/06/30)							
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	16.2	-	0	-	-	-	20	-	16.2	16.5	5	0.4	2.4	6.7	20	>6
Lab019	5	14.6	14.1	5	0.2	1.4	6.3	20	>6	14.6	14.6	24	0.6	4.1	8.2	20	4.9
Lab020	5	14.4	14.0	4	0.6	4.3	11.3	20	4.0	14.4	14.4	34	0.6	4.2	8.3	20	4.8
Lab022	5	14.4	14.0	3	0.6	4.3	11.3	20	4.0	14.4	14.4	7	0.6	4.2	8.3	20	4.8
Lab028	5	15.2	-	0	-	-	-	20	-	15.2	15.1	34	1.1	7.3	15.2	20	2.6
Lab032	5	14.9	14.5	4	0.3	2.1	6.8	20	>6	14.9	14.4	79	0.4	2.8	8.9	20	5.9
Lab033	5	13.8	13.8	5	0.4	2.9	5.8	20	>6	13.8	13.4	26	0.6	4.5	11.9	20	3.8
Lab037	5	13.8	14.6	3	0.1	0.7	7.2	20	>6	13.8	14.7	28	0.5	3.4	13.3	20	4.0
Lab043	5	14.4	14.3	6	0.8	5.6	11.9	20	3.4	14.4	13.2	47	1.5	11.4	31.1	20	1.0
Lab049	5	13.8	14.8	5	0.7	4.7	16.7	20	2.7	13.8	14.9	56	0.6	4.0	16.0	20	3.0
Total	-	-	14.2	35	0.6	4.2	-	-	-	-	14.4	340	1.0	6.9	-	-	-

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

Month : 2022 06 Change Cumulative : from 2021 01 01 to 2022 06 30 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2022/06)								CUM (2021/01/01~2022/06/30)							
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	5.5	-	0	-	-	-	20	-	5.5	5.6	5	0.2	3.6	9.0	20	5.1
Lab019	5	4.6	4.6	5	0.1	2.2	4.3	20	>6	4.6	4.6	24	0.1	2.2	4.3	20	>6
Lab020	5	4.6	4.7	4	0.2	4.3	10.7	20	4.1	4.6	4.7	34	0.2	4.3	10.7	20	4.1
Lab022	5	4.6	4.5	3	0.1	2.2	6.6	20	>6	4.6	4.4	7	0.2	4.5	13.4	20	3.5
Lab028	5	4.9	-	0	-	-	-	20	-	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	4.8	4.5	4	0.2	4.4	15.1	20	3.1	4.8	4.5	79	0.1	2.2	10.7	20	>6
Lab033	5	4.7	4.8	5	0.1	2.1	6.3	20	>6	4.7	4.4	26	0.4	9.1	24.6	20	1.5
Lab037	5	4.7	4.8	3	0.2	4.2	10.5	20	4.3	4.7	4.7	28	0.2	4.3	8.5	20	4.7
Lab043	5	4.6	4.6	6	0.3	6.5	13.0	20	3.1	4.6	4.2	47	0.5	11.9	32.5	20	0.9
Lab049	5	4.7	4.7	5	0.2	4.3	8.5	20	4.7	4.7	4.7	56	0.2	4.3	8.5	20	4.7
Total	-	-	4.6	35	0.2	4.3	-	-	-	-	4.6	340	0.4	8.7	-	-	-

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

Month : 2022 06 Change Cumulative : from 2021 01 01 to 2022 06 30 Change

[TOP]

Reagent Kit	Reagent Code
Medicon	5