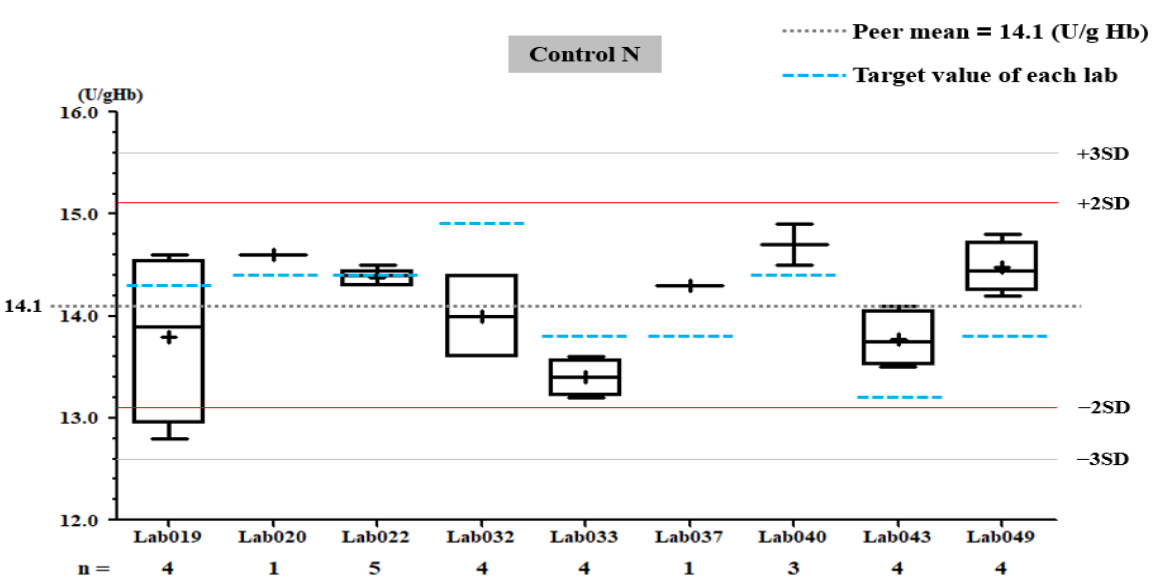
Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - April 2023 -

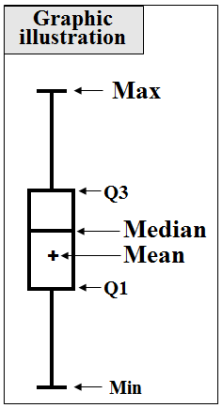
I. The statistic results of all laboratories in this month

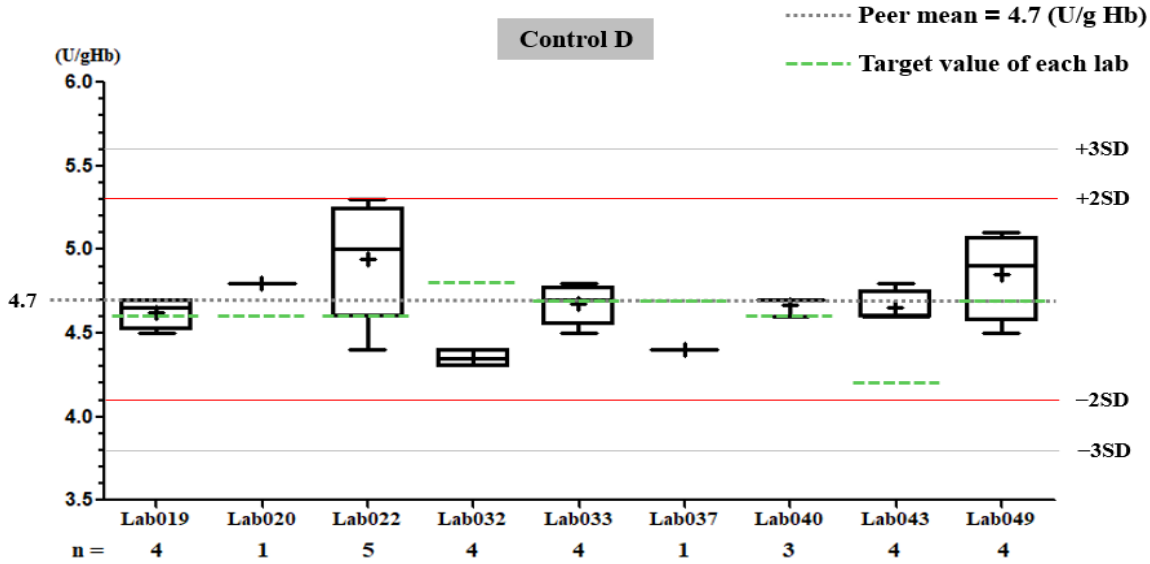
G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	9	9
Received results number (n)	30	30
Median	14.3 (U/g Hb)	4.7 (U/g Hb)
Mean	14.1 (U/g Hb)	4.7 (U/g Hb)
SD	0.5	0.3
CV	3.5%	4.3%
Range of G6PD	12.8 ~ 14.9 (U/g Hb)	4.3 ~ 5.3 (U/g Hb)
Range of Hb	2.1 ~ 2.8 (g/dL)	1.9 ~ 2.4 (g/dL)

*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

Lab040

	Control N		Control D	
QC Control Lot No.	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2023/04)	CUM (2022/11/08~2023/04/30)	Month (2023/04)	CUM (2022/11/08~2023/04/30)
Runs (N)	3	26	3	26
Mean (U/gHb)	14.7	14.8	4.7	4.7
SD	0.2	0.2	0.1	0.1
CV (%)	1.4	1.4	2.1	2.1
Target Value (U/gHb)	14.4	14.4	4.6	4.6
Total Error (%)	4.8	5.5	6.4	6.4
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

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

Month : 2023 04 Change ; Cumulative : from 2022 11 08 to 2023 04 30 Change

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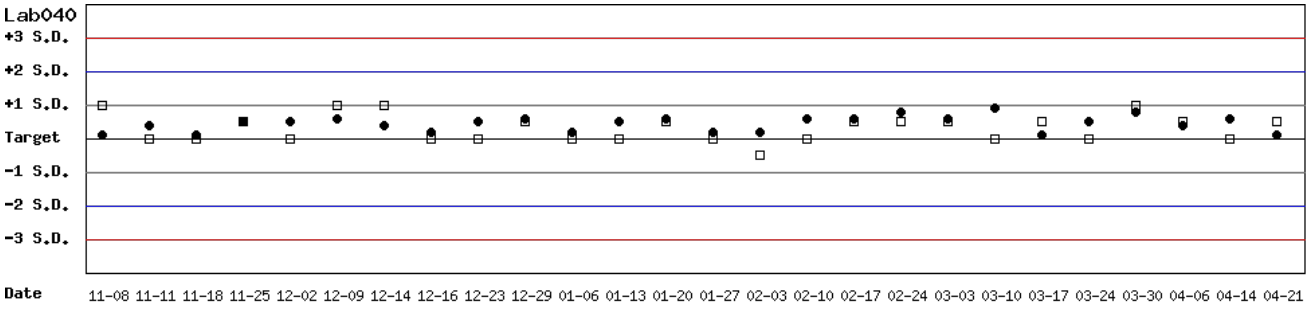
Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-11-08 to 2023-04-30 ; Target : 14.4 ; SD : 0.80 (●)

Lot No.: BJ0922D ; Duration : 2022-11-08 to 2023-04-30 ; Target : 4.6 ; SD : 0.20 (□)

Lab040



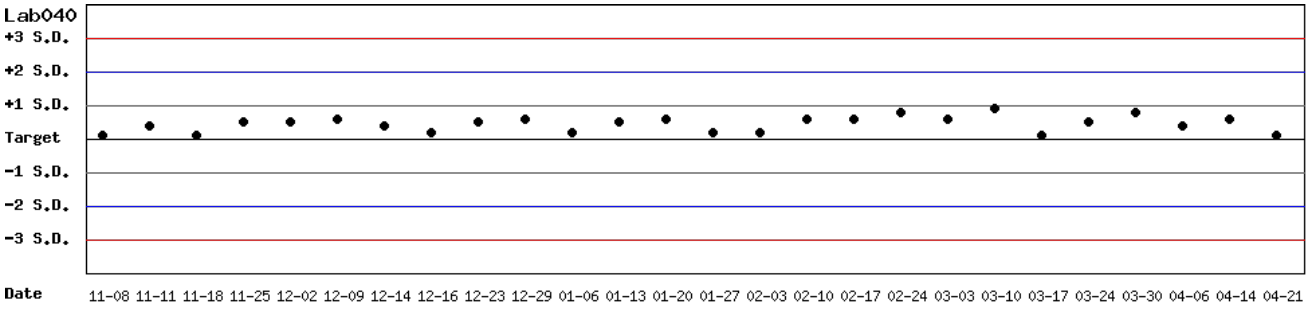
Month : 2023 04 Change ; Cumulative : from 2022 11 08 to 2023 04 30 Change

[TOP]

Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2022-11-08 to 2023-04-30 ; Target : 14.4 ; SD : 0.80

Lab040



Month : 2023 04 Change ; Cumulative : from 2022 11 08 to 2023 04 30 Change

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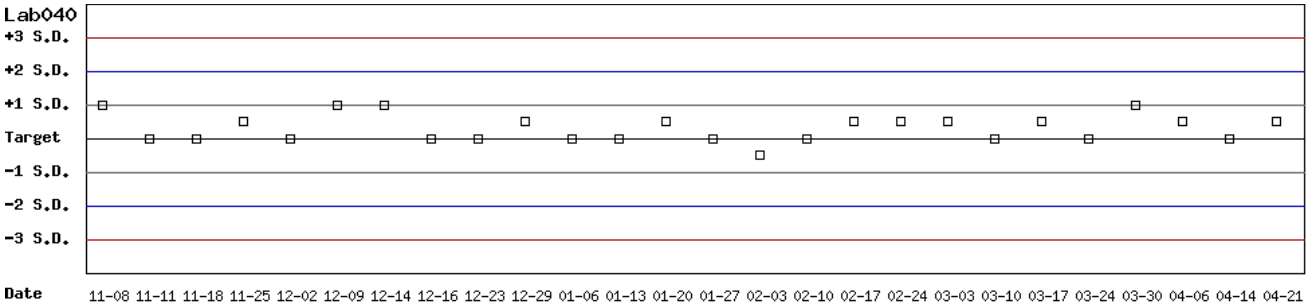
Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2022-11-08 to 2023-04-30 ; Target : 4.6 ; SD : 0.20

Lab040



Month : 2023 04 Change ; Cumulative : from 2022 11 08 to 2023 04 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 : 2023 04 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	14.3	13.8	4	0.8	5.8	15.1	20	2.8	4.6	4.6	4	0.1	2.2	4.3	20	>6
Lab020	5	14.4	14.6	1	-	-	-	20	-	4.6	4.8	1	-	-	-	20	-
Lab022	5	14.4	14.4	5	0.1	0.7	1.4	20	>6	4.6	4.9	5	0.4	8.2	22.8	20	1.6
Lab032	5	14.9	14.0	4	0.5	3.6	13.2	20	3.9	4.8	4.4	4	0.1	2.3	12.9	20	5.1
Lab033	5	13.8	13.4	4	0.2	1.5	5.9	20	>6	4.7	4.7	4	0.1	2.1	4.3	20	>6
Lab037	5	13.8	14.3	1	-	-	-	20	-	4.7	4.4	1	-	-	-	20	-
Lab040	5	14.4	14.7	3	0.2	1.4	4.8	20	>6	4.6	4.7	3	0.1	2.1	6.4	20	>6
Lab043	5	13.2	13.8	4	0.3	2.2	8.9	20	>6	4.2	4.7	4	0.1	2.1	16.2	20	3.9
Lab049	5	13.8	14.5	4	0.3	2.1	9.2	20	>6	4.7	4.9	4	0.3	6.1	16.5	20	2.6
Total	-	-	14.1	30	0.5	3.5	-	-	-	-	4.7	30	0.3	6.4	-	-	-

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 2023 04 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	16.4	8	0.4	2.4	6.1	20	>6	5.5	5.5	8	0.2	3.6	7.3	20	5.6
Lab019	5	14.3	14.3	54	0.6	4.2	8.4	20	4.8	4.6	4.6	54	0.2	4.3	8.7	20	4.7
Lab020	5	14.4	14.4	60	0.5	3.5	6.9	20	5.7	4.6	4.7	60	0.1	2.1	6.4	20	>6
Lab022	5	14.4	14.4	27	0.5	3.5	6.9	20	5.7	4.6	4.7	27	0.3	6.4	14.9	20	2.8
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	14.3	123	0.4	2.8	9.6	20	5.7	4.8	4.5	123	0.2	4.4	15.1	20	3.1
Lab033	5	13.8	13.7	68	0.6	4.4	9.5	20	4.4	4.7	4.6	68	0.3	6.5	15.2	20	2.7
Lab037	5	13.8	14.5	53	0.5	3.4	12.0	20	4.4	4.7	4.7	53	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.7	47	0.2	1.4	4.8	20	>6	4.6	4.6	47	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.7	85	1.3	9.5	22.8	20	1.7	4.2	4.5	85	0.5	11.1	29.4	20	1.2
Lab049	5	13.8	14.5	91	0.7	4.8	14.7	20	3.1	4.7	4.7	91	0.2	4.3	8.5	20	4.7
Total	-	-	14.3	650	0.8	5.6	-	-	-	-	4.6	650	0.3	6.5	-	-	-

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： 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 (2023/04)								CUM (2021/01/01~2023/04/30)							
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	16.4	8	0.4	2.4	6.1	20	>6
Lab019	5	14.3	13.8	4	0.8	5.8	15.1	20	2.8	14.3	14.3	54	0.6	4.2	8.4	20	4.8
Lab020	5	14.4	14.6	1	-	-	-	20	-	14.4	14.4	60	0.5	3.5	6.9	20	5.7
Lab022	5	14.4	14.4	5	0.1	0.7	1.4	20	>6	14.4	14.4	27	0.5	3.5	6.9	20	5.7
Lab028	5	15.2	-	0	-	-	-	20	-	15.2	15.1	34	1.1	7.3	15.2	20	2.6
Lab032	5	14.9	14.0	4	0.5	3.6	13.2	20	3.9	14.9	14.3	123	0.4	2.8	9.6	20	5.7
Lab033	5	13.8	13.4	4	0.2	1.5	5.9	20	>6	13.8	13.7	68	0.6	4.4	9.5	20	4.4
Lab037	5	13.8	14.3	1	-	-	-	20	-	13.8	14.5	53	0.5	3.4	12.0	20	4.4
Lab040	5	14.4	14.7	3	0.2	1.4	4.8	20	>6	14.4	14.7	47	0.2	1.4	4.8	20	>6
Lab043	5	13.2	13.8	4	0.3	2.2	8.9	20	>6	13.2	13.7	85	1.3	9.5	22.8	20	1.7
Lab049	5	13.8	14.5	4	0.3	2.1	9.2	20	>6	13.8	14.5	91	0.7	4.8	14.7	20	3.1
Total	-	-	14.1	30	0.5	3.5	-	-	-	-	14.3	650	0.8	5.6	-	-	-

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

Month : 2023 04 Change Cumulative : from 2021 01 01 to 2023 04 30 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2023/04)								CUM (2021/01/01~2023/04/30)							
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	5.5	8	0.2	3.6	7.3	20	5.6
Lab019	5	4.6	4.6	4	0.1	2.2	4.3	20	>6	4.6	4.6	54	0.2	4.3	8.7	20	4.7
Lab020	5	4.6	4.8	1	-	-	-	20	-	4.6	4.7	60	0.1	2.1	6.4	20	>6
Lab022	5	4.6	4.9	5	0.4	8.2	22.8	20	1.6	4.6	4.7	27	0.3	6.4	14.9	20	2.8
Lab028	5	4.9	-	0	-	-	-	20	-	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	4.8	4.4	4	0.1	2.3	12.9	20	5.1	4.8	4.5	123	0.2	4.4	15.1	20	3.1
Lab033	5	4.7	4.7	4	0.1	2.1	4.3	20	>6	4.7	4.6	68	0.3	6.5	15.2	20	2.7
Lab037	5	4.7	4.4	1	-	-	-	20	-	4.7	4.7	53	0.2	4.3	8.5	20	4.7
Lab040	5	4.6	4.7	3	0.1	2.1	6.4	20	>6	4.6	4.6	47	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.7	4	0.1	2.1	16.2	20	3.9	4.2	4.5	85	0.5	11.1	29.4	20	1.2
Lab049	5	4.7	4.9	4	0.3	6.1	16.5	20	2.6	4.7	4.7	91	0.2	4.3	8.5	20	4.7
Total	-	-	4.7	30	0.3	6.4	-	-	-	-	4.6	650	0.3	6.5	-	-	-

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

Month : 2023 04 Change Cumulative : from 2021 01 01 to 2023 04 30 Change

[TOP]

Reagent Kit	Reagent Code
Medicon	5