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

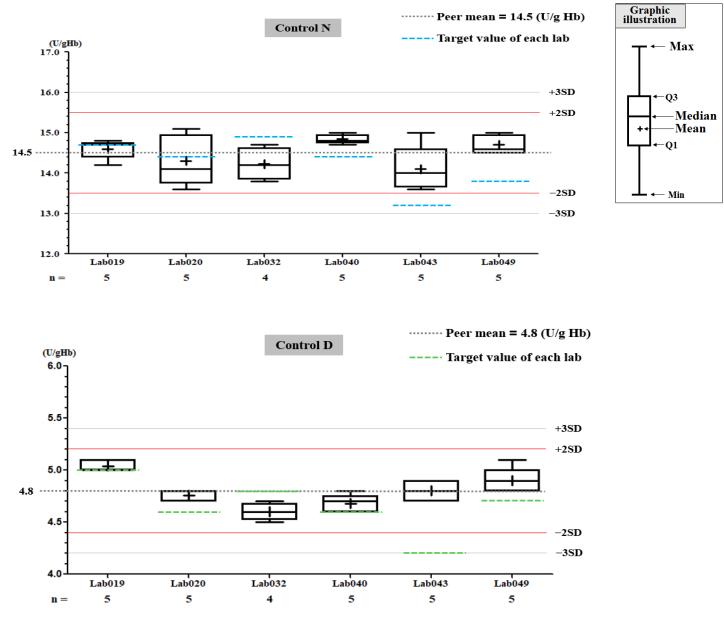
G6P	D	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Lab	S	6	6
Received result	s number (n)	29	29
Medi	an	14.6 (U/g Hb)	4.8 (U/g Hb)
Mea	n	14.5 (U/g Hb)	4.8 (U/g Hb)
SD		0.5	0.2
CV		3.4%	4.2%
Range of		13.6 ~ 15.1 (U/g Hb)	4.5 ~ 5.1 (U/g Hb)
Range o	f Hb	1.7 ~ 3.2 (g/dL)	1.6 ~ 2.7 (g/dL)

I. The statistic results of all laboratories in this month

*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



PAF

QC Chart of Internal Quality Control (IQC) for G6PD Quantitative Test

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

-1

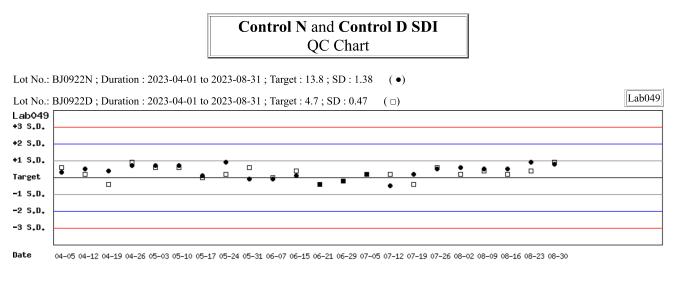
		Lab049						
			1					
		Control N	Control D					
QC Control Lot No.		BJ0922N		BJ0922D				
Duration of the Analyzing	Month (2023/08)	CUM (2023/04/01~2023/08/31)	Month (2023/08)	CUM (2023/04/01~2023/08/31)				
Runs (N)	5	22	5	22				
Mean (U/gHb)	14.7	14.3	4.9	4.8				
SD	0.2	0.6	0.1	0.2				
CV (%)	1.4	4.2	2.0	4.2				
Target Value (U/gHb)	13.8	13.8	4.7	4.7				
Total Error (%)	9.2	12.0	8.3	10.5				
TEa (%)	20	20	20	20				
σ	>6	3.9	>6	4.3				

Bias (%) = [(| Mean - Target |) / Target] x 100% TE : Total Error(%) = Bias (%) + $2 \times CV$ (%)

 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

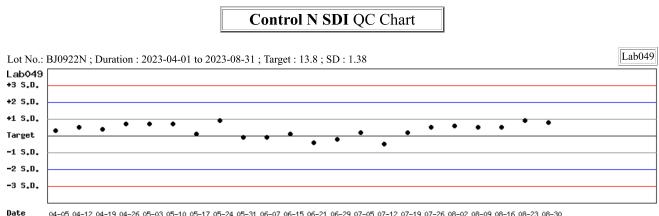
Month : 2023 v 08 v Change ; Cumulative : from 2023 v 04 v 01 v to 2023 v 08 v 31 v Change

[TOP]



Month : 2023 v 08 v Change ; Cumulative : from 2023 v 04 v 01 v to 2023 v 08 v 31 v Change

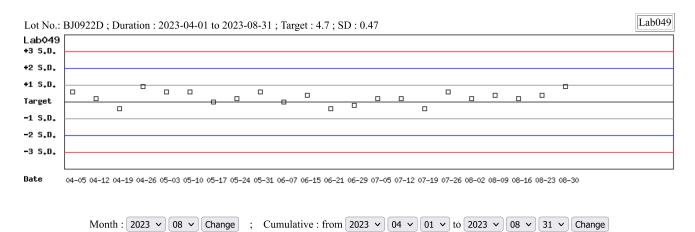
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^{04-05 04-12 04-19 04-26 05-03 05-10 05-17 05-24 05-31 06-07 06-15 06-21 06-29 07-05 07-12 07-19 07-26 08-02 08-09 08-16 08-23 08-30}

Print Table

Control D SDI QC Chart



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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 : $\begin{bmatrix} 2023 \\ \checkmark \end{bmatrix} \begin{bmatrix} 08 \\ \checkmark \end{bmatrix} \begin{bmatrix} Change \end{bmatrix}$

		Control N (Lot No.: BJ0922N)									Control D) (Lot I	No.:	BJ09	22D)		
UnitID 👤	Reagent Kit (Code) 1	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	14.7	14.6	5	0.2	1.4	3.4	20	>6	5.0	5.0	5	0.1	2.0	4.0	20	>6
Lab020	5	14.4	14.3	5	0.6	4.2	9.1	20	4.6	4.6	4.8	5	0.1	2.1	8.5	20	>6
Lab032	5	14.9	14.2	4	0.4	2.8	10.3	20	5.5	4.8	4.6	4	0.1	2.2	8.5	20	>6
Lab040	5	14.4	14.8	5	0.1	0.7	4.1	20	>6	4.6	4.7	5	0.1	2.1	6.4	20	>6
Lab043	5	13.2	14.1	5	0.6	4.3	15.3	20	3.1	4.2	4.8	5	0.1	2.1	18.5	20	2.7
Lab049	5	13.8	14.7	5	0.2	1.4	9.2	20	>6	4.7	4.9	5	0.1	2.0	8.3	20	>6
Total	-	-	14.5	29	0.5	3.4	-	-	-	-	4.8	29	0.2	4.2	-	-	-

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

[TOP]

Cumulative

Cumulative : from $2021 \vee 01 \vee 01 \vee to 2023 \vee 08 \vee 31 \vee Change$

			Control N	l (Lot N	No.: 2	BJ09	22N)				Control I) (Lot]	No.:	BJ09	22D)		
UnitID 1	Reagent Kit (Code) 1	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	14.7	14.4	75	0.6	4.2	10.4	20	4.3	5.0	4.7	75	0.3	6.4	18.8	20	2.2
Lab020	5	14.4	14.4	76	0.5	3.5	6.9	20	5.7	4.6	4.7	76	0.2	4.3	10.7	20	4.1
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	131	0.4	2.8	9.6	20	5.7	4.8	4.5	131	0.2	4.4	15.1	20	3.1
Lab033	5	13.8	13.6	81	0.7	5.1	11.7	20	3.6	4.7	4.6	81	0.3	6.5	15.2	20	2.7
Lab037	5	13.8	14.5	59	0.5	3.4	12.0	20	4.4	4.7	4.7	59	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.7	60	0.2	1.4	4.8	20	>6	4.6	4.6	60	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.8	101	1.2	8.7	21.9	20	1.8	4.2	4.5	101	0.5	11.1	29.4	20	1.2
Lab049	5	13.8	14.4	149	0.6	4.2	12.7	20	3.7	4.7	4.7	149	0.2	4.3	8.5	20	4.7
Total	-	-	14.3	801	0.8	5.6	-	-	-	-	4.7	801	0.3	6.4	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%

TE : Total Error(%) = Bias (%) + 2 × CV (%)

 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

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

Control N Month vs. Cumulative

			Control N (Lot No.: BJ0922N)														
			Μ	CUM (2021/01/01~2023/08/31)													
UnitID 👤	Reagent Kit (Code) 1	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	14.7	14.6	5	0.2	1.4	3.4	20	>6	14.7	14.4	75	0.6	4.2	10.4	20	4.3
Lab020	5	14.4	14.3	5	0.6	4.2	9.1	20	4.6	14.4	14.4	76	0.5	3.5	6.9	20	5.7
Lab022	5	14.4	-	0	-	-	-	20	-	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	14.2	4	0.4	2.8	10.3	20	5.5	14.9	14.3	131	0.4	2.8	9.6	20	5.7
Lab033	5	13.8	-	0	-	-	-	20	-	13.8	13.6	81	0.7	5.1	11.7	20	3.6
Lab037	5	13.8	-	0	-	-	-	20	-	13.8	14.5	59	0.5	3.4	12.0	20	4.4
Lab040	5	14.4	14.8	5	0.1	0.7	4.1	20	>6	14.4	14.7	60	0.2	1.4	4.8	20	>6
Lab043	5	13.2	14.1	5	0.6	4.3	15.3	20	3.1	13.2	13.8	101	1.2	8.7	21.9	20	1.8
Lab049	5	13.8	14.7	5	0.2	1.4	9.2	20	>6	13.8	14.4	149	0.6	4.2	12.7	20	3.7
Total	-	-	14.5	29	0.5	3.4	-	-	-	-	14.3	801	0.8	5.6	-	-	-

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

Month : 2023 v 08 v Change

Cumulative : from $\begin{bmatrix} 2021 \\ \mathbf{v} \end{bmatrix} \begin{bmatrix} 01 \\ \mathbf{v} \end{bmatrix} \begin{bmatrix} 01 \\ \mathbf{v} \end{bmatrix}$ to $\begin{bmatrix} 2023 \\ \mathbf{v} \end{bmatrix} \begin{bmatrix} 08 \\ \mathbf{v} \end{bmatrix} \begin{bmatrix} 31 \\ \mathbf{v} \end{bmatrix}$ Change

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Control D Month vs. Cumulative

			Control D (Lot No.: BJ0922D)															
			М	onth (2	023/0	8)				CUM (2021/01/01~2023/08/31)								
UnitID 👤	Reagent Kit (Code) 1	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
<u>Lab018</u>	5	5.5	-	0	-	-	-	20	-		5.5	5.5	8	0.2	3.6	7.3	20	5.6
<u>Lab019</u>	5	5.0	5.0	5	0.1	2.0	4.0	20	>6		5.0	4.7	75	0.3	6.4	18.8	20	2.2
<u>Lab020</u>	5	4.6	4.8	5	0.1	2.1	8.5	20	>6		4.6	4.7	76	0.2	4.3	10.7	20	4.1
Lab022	5	4.6	-	0	-	-	-	20	-		4.6	4.7	27	0.3	6.4	14.9	20	2.8
<u>Lab028</u>	5	4.9	-	0	-	-	-	20	-		4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	4.8	4.6	4	0.1	2.2	8.5	20	>6		4.8	4.5	131	0.2	4.4	15.1	20	3.1
Lab033	5	4.7	-	0	-	-	-	20	-		4.7	4.6	81	0.3	6.5	15.2	20	2.7
<u>Lab037</u>	5	4.7	-	0	-	-	-	20	-		4.7	4.7	59	0.2	4.3	8.5	20	4.7
<u>Lab040</u>	5	4.6	4.7	5	0.1	2.1	6.4	20	>6		4.6	4.6	60	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.8	5	0.1	2.1	18.5	20	2.7		4.2	4.5	101	0.5	11.1	29.4	20	1.2
<u>Lab049</u>	5	4.7	4.9	5	0.1	2.0	8.3	20	>6		4.7	4.7	149	0.2	4.3	8.5	20	4.7
Total	-	-	4.8	29	0.2	4.2	-	-	-		-	4.7	801	0.3	6.4	-	-	-

Bias (%) = $[(|Mean - Target|) / Target] \times 100\%$ TE : Total Error(%) = Bias (%) + $2 \times CV$ (%)

 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : $\begin{bmatrix} 2023 \\ \checkmark \end{bmatrix} \begin{bmatrix} 08 \\ \checkmark \end{bmatrix} \begin{bmatrix} Change \end{bmatrix}$

Cumulative : from 2021 v 01 v 01 v to 2023 v 08 v 31 v Change

	Reagent Kit	Reagent Code
Medicon		5

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Print Table 2