

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

Select LotNo :

Lab026

QC Control Lot No.	Control N		Control D	
	AE0909N		AE0909D	
Duration of the Analyzing	Month (2023/11)	CUM (2023/08/22~2023/11/23)	Month (2023/11)	CUM (2023/08/22~2023/11/23)
Runs (N)	6	26	6	26
Mean (U/gHb)	12.9	12.9	4.9	4.8
SD	0.1	0.1	0.1	0.1
CV (%)	0.8	0.8	2.0	2.1
Target Value (U/gHb)	15.9	15.9	5.8	5.8
Total Error (%)	20.4	20.4	19.6	21.4
TEa (%)	20	20	20	20
σ	1.4	1.4	2.2	1.3

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

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

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

Month : ; Cumulative : from to

[\[TOP\]](#)

Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2023-08-22 to 2023-11-23 ; Target : 15.9 ; SD : 2.20 (●)

Lot No.: AE0909D ; Duration : 2023-08-22 to 2023-11-23 ; Target : 5.8 ; SD : 1.40 (□)

Lab026



Date 08-22 08-24 08-29 08-31 09-05 09-07 09-12 09-14 09-19 09-21 09-26 09-28 10-03 10-05 10-10 10-12 10-17 10-19 10-24 10-31 11-07 11-09 11-14 11-16 11-21 11-23

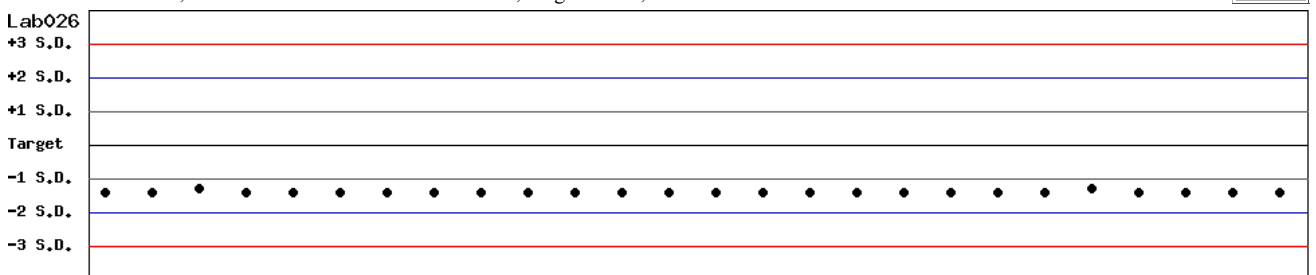
Month : ; Cumulative : from to

[\[TOP\]](#)

Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2023-08-22 to 2023-11-23 ; Target : 15.9 ; SD : 2.20

Lab026



Date 08-22 08-24 08-29 08-31 09-05 09-07 09-12 09-14 09-19 09-21 09-26 09-28 10-03 10-05 10-10 10-12 10-17 10-19 10-24 10-31 11-07 11-09 11-14 11-16 11-21 11-23

Month : ; Cumulative : from to

[\[TOP\]](#)

Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2023-08-22 to 2023-11-23 ; Target : 5.8 ; SD : 1.40

Lab026

Lab026

+3 S.D.

+2 S.D.

+1 S.D.

Target

-1 S.D.

-2 S.D.

-3 S.D.



Date

08-22 08-24 08-29 08-31 09-05 09-07 09-12 09-14 09-19 09-21 09-26 09-28 10-03 10-05 10-10 10-12 10-17 10-19 10-24 10-31 11-07 11-09 11-14 11-16 11-21 11-23

Month : 2023 11 Change ; Cumulative : from 2023 08 22 to 2023 11 23 Change

[TOP](#)

Peer Group Statistics (Table 1)

Select LotNo : AE0909N (2016-01-01 ~ 2100-12-31)

Select Reagent Kit : 5 - Medicon

Monthly

Month : 2023

UnitID	Reagent Kit (Code)	Control N (Lot No.: AE0909N)								Control D (Lot No.: AE0909D)							
		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
Lab026	5	15.9	12.9	6	0.1	0.8	20.4	20	1.4	5.8	4.9	6	0.1	2.0	19.6	20	2.2
Total	-	-	12.9	6	0.1	0.8	-	-	-	-	4.9	6	0.1	2.0	-	-	-

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

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

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

[TOP](#)

Cumulative

Cumulative : from 2016 to 2023

UnitID	Reagent Kit (Code)	Control N (Lot No.: AE0909N)								Control D (Lot No.: AE0909D)							
		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	15.2	173	1.2	7.9	22.0	20	1.8	5.5	5.5	173	0.3	5.5	10.9	20	3.6
Lab019	5	15.3	15.2	111	0.3	2.0	4.6	20	>6	5.3	5.3	111	0.2	3.8	7.5	20	5.3
Lab020	5	14.4	15.2	28	0.5	3.3	12.1	20	4.4	5.8	5.3	28	0.3	5.7	19.9	20	2.0
Lab026	5	15.9	13.2	723	1.0	7.6	32.1	20	0.4	5.8	5.0	723	0.3	6.0	25.8	20	1.0
Lab027	5	15.5	15.5	107	1.3	8.4	16.8	20	2.4	5.4	5.6	107	0.5	8.9	21.6	20	1.8
Lab028	5	14.8	14.5	134	0.7	4.8	11.7	20	3.7	4.8	5.6	134	0.3	5.4	27.4	20	0.6
Lab032	5	15.3	15.9	38	0.9	5.7	15.2	20	2.8	5.2	5.7	38	0.3	5.3	20.1	20	2.0
Lab033	5	14.4	14.9	49	0.6	4.0	11.5	20	4.1	5.8	5.2	49	0.2	3.8	18.0	20	2.5
Lab034	5	15.5	14.7	96	0.9	6.1	17.4	20	2.4	4.8	5.0	96	0.4	8.0	20.2	20	2.0
Lab037	5	14.9	15.2	30	0.8	5.3	12.5	20	3.4	5.4	5.5	30	0.3	5.5	12.8	20	3.3
Lab040	5	14.4	13.2	40	0.7	5.3	18.9	20	2.2	5.8	4.7	40	0.3	6.4	31.7	20	0.2
Lab043	5	11.5	13.0	88	0.9	6.9	26.9	20	1.0	4.5	4.8	88	0.4	8.3	23.3	20	1.6
Total	-	-	14.1	1617	1.4	9.9	-	-	-	-	5.2	1617	0.4	7.7	-	-	-

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 : 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 (2023/11)								CUM (2016/02/01~2023/11/30)							
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	15.2	173	1.2	7.9	22.0	20	1.8
Lab019	5	15.3	-	0	-	-	-	20	-	15.3	15.2	111	0.3	2.0	4.6	20	>6
Lab020	5	14.4	-	0	-	-	-	20	-	14.4	15.2	28	0.5	3.3	12.1	20	4.4
Lab026	5	15.9	12.9	6	0.1	0.8	20.4	20	1.4	15.9	13.2	723	1.0	7.6	32.1	20	0.4
Lab027	5	15.5	-	0	-	-	-	20	-	15.5	15.5	107	1.3	8.4	16.8	20	2.4
Lab028	5	14.8	-	0	-	-	-	20	-	14.8	14.5	134	0.7	4.8	11.7	20	3.7
Lab032	5	15.3	-	0	-	-	-	20	-	15.3	15.9	38	0.9	5.7	15.2	20	2.8
Lab033	5	14.4	-	0	-	-	-	20	-	14.4	14.9	49	0.6	4.0	11.5	20	4.1
Lab034	5	15.5	-	0	-	-	-	20	-	15.5	14.7	96	0.9	6.1	17.4	20	2.4
Lab037	5	14.9	-	0	-	-	-	20	-	14.9	15.2	30	0.8	5.3	12.5	20	3.4
Lab040	5	14.4	-	0	-	-	-	20	-	14.4	13.2	40	0.7	5.3	18.9	20	2.2
Lab043	5	11.5	-	0	-	-	-	20	-	11.5	13.0	88	0.9	6.9	26.9	20	1.0
Total	-	-	12.9	6	0.1	0.8	-	-	-	-	14.1	1617	1.4	9.9	-	-	-

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

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

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

Month : 2023 11 Change

Cumulative : from 2016 02 01 to 2023 11 30 Change

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2023/11)								CUM (2016/02/01~2023/11/30)							
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	173	0.3	5.5	10.9	20	3.6
Lab019	5	5.3	-	0	-	-	-	20	-	5.3	5.3	111	0.2	3.8	7.5	20	5.3
Lab020	5	5.8	-	0	-	-	-	20	-	5.8	5.3	28	0.3	5.7	19.9	20	2.0
Lab026	5	5.8	4.9	6	0.1	2.0	19.6	20	2.2	5.8	5.0	723	0.3	6.0	25.8	20	1.0
Lab027	5	5.4	-	0	-	-	-	20	-	5.4	5.6	107	0.5	8.9	21.6	20	1.8
Lab028	5	4.8	-	0	-	-	-	20	-	4.8	5.6	134	0.3	5.4	27.4	20	0.6
Lab032	5	5.2	-	0	-	-	-	20	-	5.2	5.7	38	0.3	5.3	20.1	20	2.0
Lab033	5	5.8	-	0	-	-	-	20	-	5.8	5.2	49	0.2	3.8	18.0	20	2.5
Lab034	5	4.8	-	0	-	-	-	20	-	4.8	5.0	96	0.4	8.0	20.2	20	2.0
Lab037	5	5.4	-	0	-	-	-	20	-	5.4	5.5	30	0.3	5.5	12.8	20	3.3
Lab040	5	5.8	-	0	-	-	-	20	-	5.8	4.7	40	0.3	6.4	31.7	20	0.2
Lab043	5	4.5	-	0	-	-	-	20	-	4.5	4.8	88	0.4	8.3	23.3	20	1.6
Total	-	-	4.9	6	0.1	2.0	-	-	-	-	5.2	1617	0.4	7.7	-	-	-

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

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

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

Month : 2023 11 Change

Cumulative : from 2016 02 01 to 2023 11 30 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5