

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

Select LotNo :

Lab026

QC Control Lot No.	Control N		Control D	
	AE0909N		AE0909D	
Duration of the Analyzing	Month (2022/08)	CUM (2022/06/16~2022/08/30)	Month (2022/08)	CUM (2022/06/16~2022/08/30)
Runs (N)	10	26	10	26
Mean (U/gHb)	12.9	12.9	4.9	4.9
SD	0.1	0.1	0.0	0.0
CV (%)	0.8	0.8	0.0	0.0
Target Value (U/gHb)	15.9	15.9	5.8	5.8
Total Error (%)	20.4	20.4	15.5	15.5
TEa (%)	20	20	20	20
σ	1.4	1.4	>6	>6

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

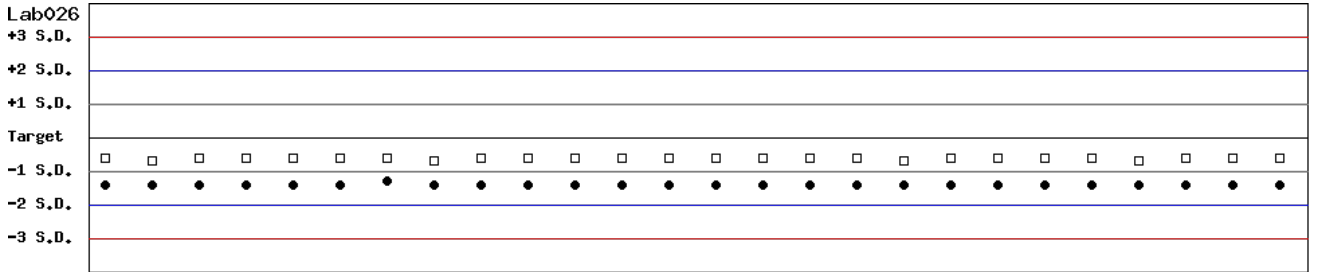
Month : ; Cumulative : from to

[\[TOP\]](#)

Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2022-06-16 to 2022-08-30 ; Target : 15.9 ; SD : 2.20 (●)

Lot No.: AE0909D ; Duration : 2022-06-16 to 2022-08-30 ; Target : 5.8 ; SD : 1.40 (□)



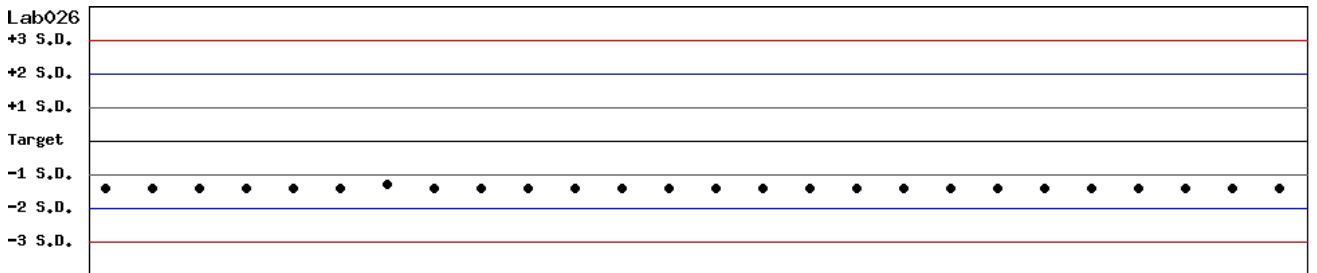
Date 06-16 06-21 06-22 06-23 06-28 06-30 07-05 07-05 07-07 07-12 07-13 07-14 07-19 07-21 07-26 07-28 08-02 08-04 08-09 08-11 08-16 08-18 08-19 08-23 08-25 08-30

Month : ; Cumulative : from to

[\[TOP\]](#)

Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2022-06-16 to 2022-08-30 ; Target : 15.9 ; SD : 2.20



Date 06-16 06-21 06-22 06-23 06-28 06-30 07-05 07-05 07-07 07-12 07-13 07-14 07-19 07-21 07-26 07-28 08-02 08-04 08-09 08-11 08-16 08-18 08-19 08-23 08-25 08-30

Month : ; Cumulative : from to

[\[TOP\]](#)

Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2022-06-16 to 2022-08-30 ; Target : 5.8 ; SD : 1.40

Lab026



Date 06-16 06-21 06-22 06-23 06-28 06-30 07-05 07-05 07-07 07-12 07-13 07-14 07-19 07-21 07-26 07-28 08-02 08-04 08-09 08-11 08-16 08-18 08-19 08-23 08-25 08-30

Month : 2022 v 08 v Change ; Cumulative : from 2022 v 06 v 16 v to 2022 v 08 v 30 v Change

[TOP](#)

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 : 2022 08 Change

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	10	0.1	0.8	20.4	20	1.4	5.8	4.9	10	0.0	0.0	15.5	20	>6
Total	-	-	12.9	10	0.1	0.8	-	-	-	-	4.9	10	0.0	0.0	-	-	-

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 2022 08 31 Change

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	13.3	600	1.0	7.5	31.4	20	0.5	5.8	5.0	600	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	-	-	14.2	1494	1.4	9.9	-	-	-	-	5.2	1494	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 (2022/08)									CUM (2016/02/01~2022/08/31)						
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	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	10	0.1	0.8	20.4	20	1.4	15.9	13.3	600	1.0	7.5	31.4	20	0.5
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	10	0.1	0.8	-	-	-	-	14.2	1494	1.4	9.9	-	-	-

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

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

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

Month : 2022 08 Change

Cumulative : from 2016 02 01 to 2022 08 31 Change

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2022/08)									CUM (2016/02/01~2022/08/31)						
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	5.5	-	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	10	0.0	0.0	15.5	20	>6	5.8	5.0	600	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	10	0.0	0.0	-	-	-	-	5.2	1494	0.4	7.7	-	-	-

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

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

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

Month : 2022 08 Change

Cumulative : from 2016 02 01 to 2022 08 31 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5