

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

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

Lab018

QC Control Lot No.	Control N		Control D	
	AE0909N		AE0909D	
Duration of the Analyzing	Month (2021/08)	CUM (2019/10/17~2021/08/31)	Month (2021/08)	CUM (2019/10/17~2021/08/31)
Runs (N)	7	26	7	26
Mean (U/gHb)	16.5	14.6	5.5	5.3
SD	0.4	1.2	0.1	0.2
CV (%)	2.4	8.2	1.8	3.8
Target Value (U/gHb)	14.2	14.2	5.5	5.5
Total Error (%)	21.0	19.3	3.6	11.2
TEa (%)	20	20	20	20
σ	1.6	2.1	>6	4.3

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

Month : ; Cumulative : from to

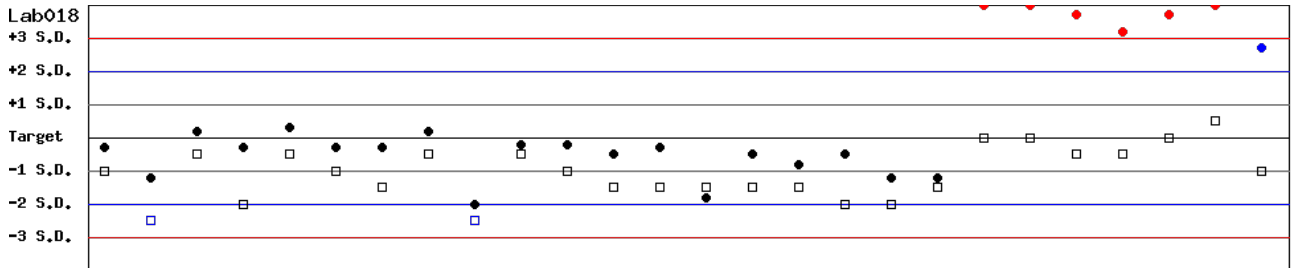
[\[TOP\]](#)

Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-10-17 to 2021-08-31 ; Target : 14.2 ; SD : 0.60 (●)

Lot No.: AE0909D ; Duration : 2019-10-17 to 2021-08-31 ; Target : 5.5 ; SD : 0.20 (□)

Lab018



Date 10-17 10-19 10-24 10-26 10-31 11-02 11-07 11-09 11-14 11-16 11-22 11-23 11-28 11-30 12-06 12-07 12-13 12-20 12-26 08-02 08-09 08-16 08-18 08-23 08-30 08-31

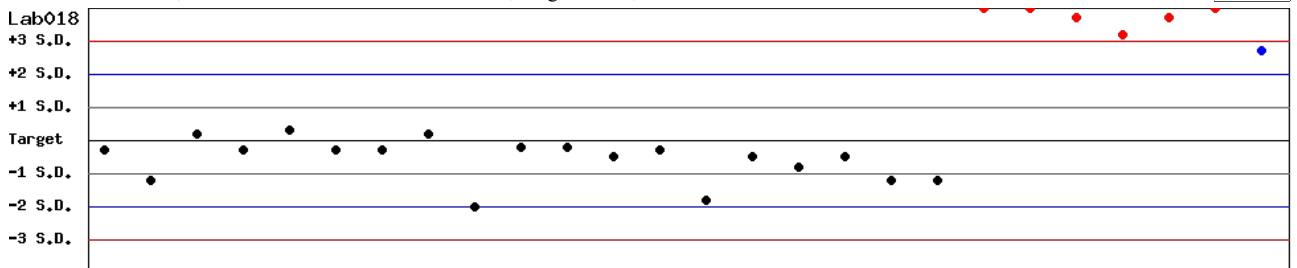
Month : ; Cumulative : from to

[\[TOP\]](#)

Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2019-10-17 to 2021-08-31 ; Target : 14.2 ; SD : 0.60

Lab018



Date 10-17 10-19 10-24 10-26 10-31 11-02 11-07 11-09 11-14 11-16 11-22 11-23 11-28 11-30 12-06 12-07 12-13 12-20 12-26 08-02 08-09 08-16 08-18 08-23 08-30 08-31

Month : ; Cumulative : from to

[\[TOP\]](#)

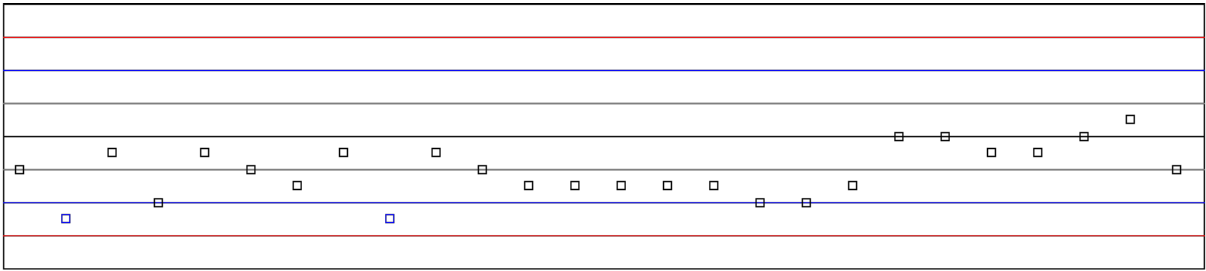
Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2019-10-17 to 2021-08-31 ; Target : 5.5 ; SD : 0.20

Lab018

Lab018

+3 S.D.
+2 S.D.
+1 S.D.
Target
-1 S.D.
-2 S.D.
-3 S.D.



Date 10-17 10-19 10-24 10-26 10-31 11-02 11-07 11-09 11-14 11-16 11-22 11-23 11-28 11-30 12-06 12-07 12-13 12-20 12-26 08-02 08-09 08-16 08-18 08-23 08-30 08-31

Month : 2021 08 Change ; Cumulative : from 2019 10 17 to 2021 08 31 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 : 2021 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
Lab018	5	14.2	16.5	7	0.4	2.4	21.0	20	1.6	5.5	5.5	7	0.1	1.8	3.6	20	>6
Lab026	5	15.9	12.9	9	0.1	0.8	20.4	20	1.4	5.8	4.9	9	0.1	2.0	19.6	20	2.2
Total	-	-	14.5	16	1.9	13.1	-	-	-	-	5.1	16	0.3	5.9	-	-	-

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 2021 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	14.2	15.0	149	1.2	8.0	21.6	20	1.8	5.5	5.5	149	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	13.4	506	1.1	8.2	32.1	20	0.5	5.8	5.0	506	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	1376	1.3	9.2	-	-	-	-	5.2	1376	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 (2021/08)									CUM (2016/02/01~2021/08/31)						
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	14.2	16.5	7	0.4	2.4	21.0	20	1.6	14.2	15.0	149	1.2	8.0	21.6	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	9	0.1	0.8	20.4	20	1.4	15.9	13.4	506	1.1	8.2	32.1	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	-	-	14.5	16	1.9	13.1	-	-	-	-	14.2	1376	1.3	9.2	-	-	-

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

Month : 2021 08 Change

Cumulative : from 2016 02 01 to 2021 08 31 Change

[TOP](#)

Control D Month vs. Cumulative

Control D (Lot No.: AE0909D)																	
		Month (2021/08)									CUM (2016/02/01~2021/08/31)						
UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	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	5.5	7	0.1	1.8	3.6	20	>6	5.5	5.5	149	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	9	0.1	2.0	19.6	20	2.2	5.8	5.0	506	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	-	-	5.1	16	0.3	5.9	-	-	-	-	5.2	1376	0.4	7.7	-	-	-

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

Month : 2021 08 Change

Cumulative : from 2016 02 01 to 2021 08 31 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5