

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

Select LotNo : AC1203N (2014-01-01 ~ 2100-12-31) [Change](#)

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Lab020

QC Control Lot No.	Control N		Control D	
	AC1203N		AC1203D	
Duration of the Analyzing	Month (2018/06)	CUM (2017/07/27~2018/06/30)	Month (2018/06)	CUM (2017/07/27~2018/06/30)
Runs (N)	4	26	4	26
Mean (U/gHb)	16.2	15.4	3.6	3.5
SD	0.7	1.2	0.2	0.2
CV (%)	4.3	7.8	5.6	5.7
Target Value (U/gHb)	14.2	14.2	3.3	3.3
Total Error (%)	22.7	24.0	20.2	17.5
TEa (%)	20	20	20	20
σ	1.4	1.5	1.9	2.4

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

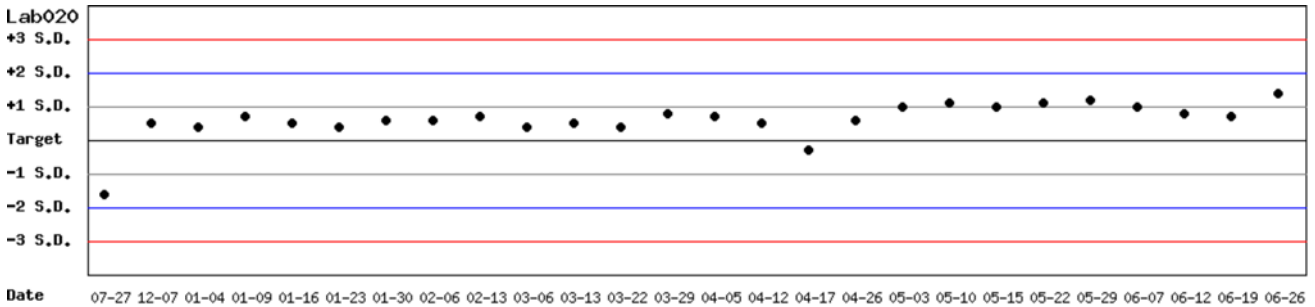
Month : 2018 06 [Change](#) ; Cumulative : from 2017 07 27 to 2018 06 30 [Change](#)

[TOP](#)

Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2017-07-27 to 2018-06-30 ; Target : 14.2 ; SD : 2.10

Lab020



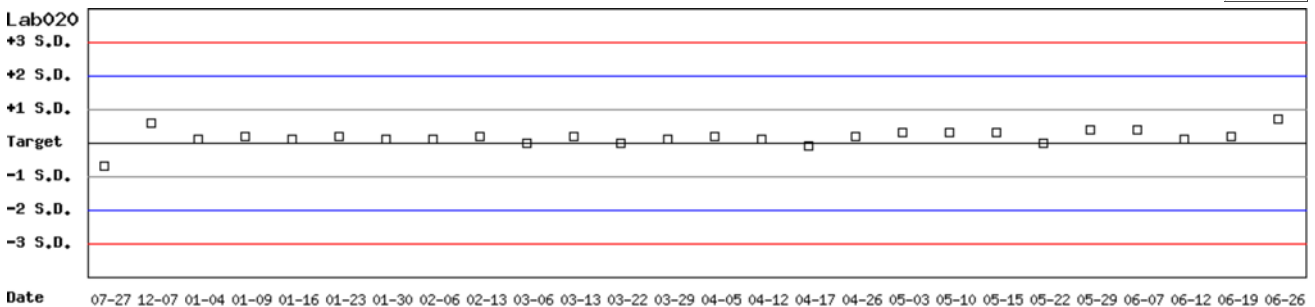
Month : 2018 06 [Change](#) ; Cumulative : from 2017 07 27 to 2018 06 30 [Change](#)

[TOP](#)

Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2017-07-27 to 2018-06-30 ; Target : 3.3 ; SD : 0.90

Lab020



Month : 2018 06 [Change](#) ; Cumulative : from 2017 07 27 to 2018 06 30 [Change](#)

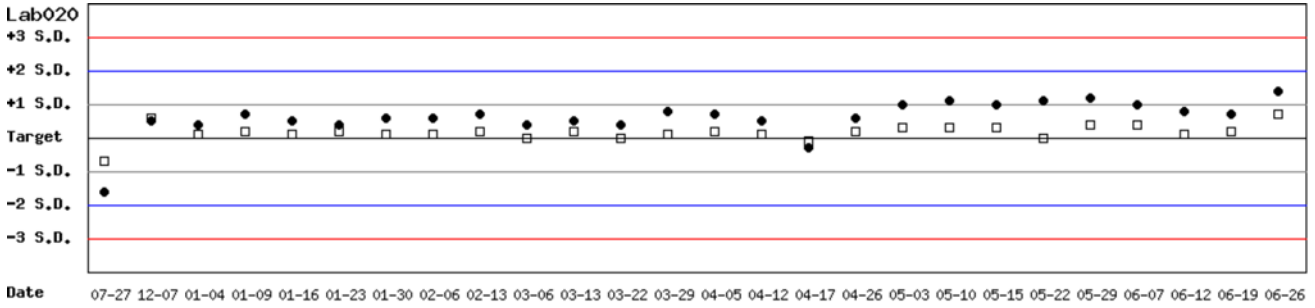
[TOP](#)

Control N and Control D SDI QC Chart

Lot No.: AC1203N ; Duration : 2017-07-27 to 2018-06-30 ; Target : 14.2 ; SD : 2.10 (●)

Lot No.: AC1203D ; Duration : 2017-07-27 to 2018-06-30 ; Target : 3.3 ; SD : 0.90 (□)

Lab020



Month : 2018 06 ; Cumulative : from 2017 07 27 to 2018 06 30

[TOP](#)

Peer Group Statistics (Table 1)

Select LotNo :

Select Reagent Kit :

Monthly

Month :

UnitID ↑	Reagent Kit (Code) ↑	Control N (Lot No.: AC1203N)									Control D (Lot No.: AC1203D)						
		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
Lab020	5	14.2	16.2	4	0.7	4.3	22.7	20	1.4	3.3	3.6	4	0.2	5.6	20.2	20	1.9
Lab022	5	14.4	14.5	4	0.5	3.4	7.6	20	5.7	3.3	3.4	4	0.1	2.9	8.9	20	5.9
Lab028	5	14.2	14.9	13	0.7	4.7	14.3	20	3.2	3.3	3.7	13	0.2	5.4	22.9	20	1.5
Total	-	-	15.1	21	0.9	6.0	-	-	-	-	3.6	21	0.2	5.6	-	-	-

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

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

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

[\[TOP\]](#)

Cumulative

Cumulative : from to

UnitID ↑	Reagent Kit (Code) ↑	Control N (Lot No.: AC1203N)									Control D (Lot No.: AC1203D)						
		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	14.8	14.9	30	0.7	4.7	10.1	20	4.1	3.4	3.6	30	0.6	16.7	39.2	20	0.8
Lab020	5	14.2	15.6	25	0.7	4.5	18.8	20	2.3	3.3	3.5	25	0.2	5.7	17.5	20	2.4
Lab021	5	12.3	15.5	12	0.5	3.2	32.5	20	-1.9	2.8	4.5	12	1.1	24.4	109.6	20	-1.7
Lab022	5	14.4	14.8	9	0.4	2.7	8.2	20	>6	3.3	3.4	9	0.1	2.9	8.9	20	5.9
Lab026	5	14.6	14.7	16	0.5	3.4	7.5	36	>6	3.2	3.2	16	0.1	3.1	6.3	36	>6
Lab028	5	14.2	15.1	76	0.8	5.3	16.9	20	2.6	3.3	3.6	76	0.2	5.6	20.2	20	1.9
Lab037	5	12.6	15.7	15	0.5	3.2	31.0	20	-1.4	3.0	3.5	15	0.1	2.9	22.4	20	1.1
Lab041	5	12.8	12.9	1	-	-	-	20	-	2.9	3.2	1	-	-	-	20	-
Total	-	-	15.1	184	0.8	5.3	-	-	-	-	3.6	184	0.5	13.9	-	-	-

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 :

Select Reagent Kit :

Control N Month vs. Cumulative

		Control N (Lot No.: AC1203N)															
		Month (2018/06)								CUM (2014/02/01~2018/06/30)							
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
Lab019	5	14.8	-	0	-	-	-	20	-	14.8	14.9	30	0.7	4.7	10.1	20	4.1
Lab020	5	14.2	16.2	4	0.7	4.3	22.7	20	1.4	14.2	15.6	25	0.7	4.5	18.8	20	2.3
Lab021	5	12.3	-	0	-	-	-	20	-	12.3	15.5	12	0.5	3.2	32.5	20	-1.9
Lab022	5	14.4	14.5	4	0.5	3.4	7.6	20	5.7	14.4	14.8	9	0.4	2.7	8.2	20	>6
Lab026	5	14.6	-	0	-	-	-	36	-	14.6	14.7	16	0.5	3.4	7.5	36	>6
Lab028	5	14.2	14.9	13	0.7	4.7	14.3	20	3.2	14.2	15.1	76	0.8	5.3	16.9	20	2.6
Lab037	5	12.6	-	0	-	-	-	20	-	12.6	15.7	15	0.5	3.2	31.0	20	-1.4
Lab041	5	12.8	-	0	-	-	-	20	-	12.8	12.9	1	-	-	-	20	-
Total	-	-	15.1	21	0.9	6.0	-	-	-	-	15.1	184	0.8	5.3	-	-	-

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

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

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

Month :

Cumulative : from to

[TOP](#)

Control D Month vs. Cumulative

		Control D (Lot No.: AC1203D)															
		Month (2018/06)								CUM (2014/02/01~2018/06/30)							
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
Lab019	5	3.4	-	0	-	-	-	20	-	3.4	3.6	30	0.6	16.7	39.2	20	0.8
Lab020	5	3.3	3.6	4	0.2	5.6	20.2	20	1.9	3.3	3.5	25	0.2	5.7	17.5	20	2.4
Lab021	5	2.8	-	0	-	-	-	20	-	2.8	4.5	12	1.1	24.4	109.6	20	-1.7
Lab022	5	3.3	3.4	4	0.1	2.9	8.9	20	5.9	3.3	3.4	9	0.1	2.9	8.9	20	5.9
Lab026	5	3.2	-	0	-	-	-	36	-	3.2	3.2	16	0.1	3.1	6.3	36	>6
Lab028	5	3.3	3.7	13	0.2	5.4	22.9	20	1.5	3.3	3.6	76	0.2	5.6	20.2	20	1.9
Lab037	5	3.0	-	0	-	-	-	20	-	3.0	3.5	15	0.1	2.9	22.4	20	1.1
Lab041	5	2.9	-	0	-	-	-	20	-	2.9	3.2	1	-	-	-	20	-
Total	-	-	3.6	21	0.2	5.6	-	-	-	-	3.6	184	0.5	13.9	-	-	-

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

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

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

Month :

Cumulative : from to

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5