

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

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

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## Lab026

QC Control Lot No.	Control N		Control D	
	AE0909N		AE0909D	
Duration of the Analyzing	Month (2021/09)	CUM (2021/07/06~2021/09/30)	Month (2021/09)	CUM (2021/07/06~2021/09/30)
Runs (N)	11	26	11	26
Mean (U/gHb)	12.9	12.9	4.9	4.9
SD	0.1	0.1	0.1	0.1
CV (%)	0.8	0.8	2.0	2.0
Target Value (U/gHb)	15.9	15.9	5.8	5.8
Total Error (%)	20.4	20.4	19.6	19.6
TEa (%)	20	20	20	20
$\sigma$	1.4	1.4	2.2	2.2

Bias (%) =  $[(| \text{Mean} - \text{Target} |) / \text{Target}] \times 100\%$

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

$\sigma$  (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2021 09 Change ; Cumulative : from 2021 07 06 to 2021 09 30 Change

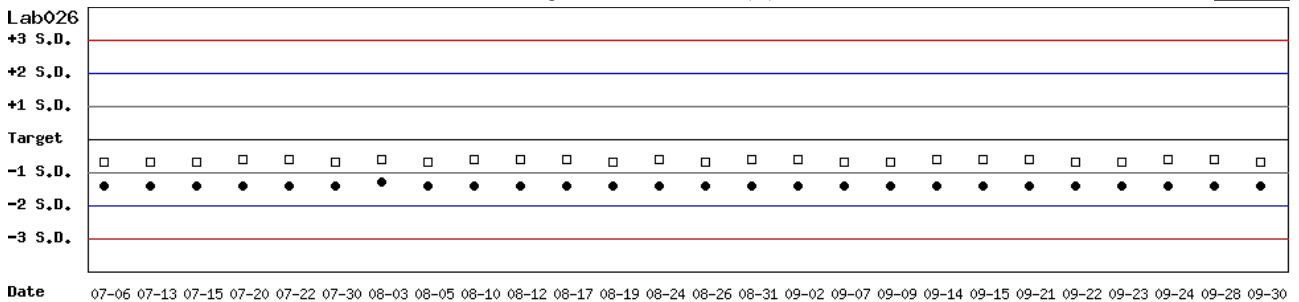
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## Control N and Control D SDI QC Chart

Lot No.: AE0909N ; Duration : 2021-07-06 to 2021-09-30 ; Target : 15.9 ; SD : 2.20 (●)

Lot No.: AE0909D ; Duration : 2021-07-06 to 2021-09-30 ; Target : 5.8 ; SD : 1.40 (□)

Lab026



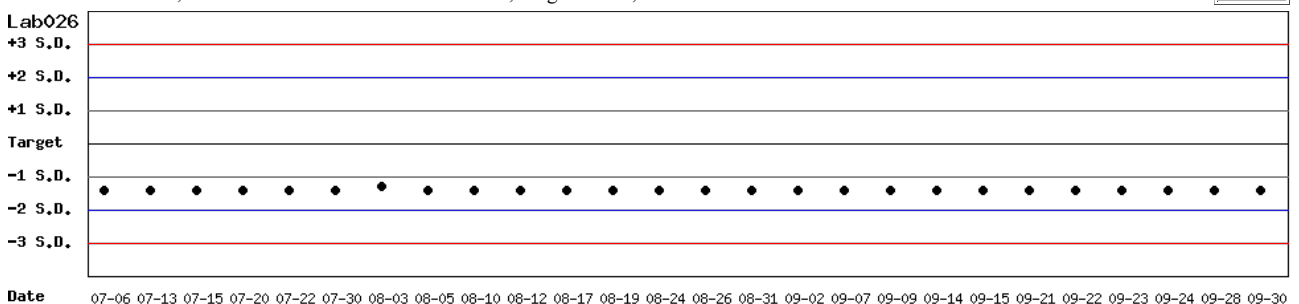
Month : 2021 09 Change ; Cumulative : from 2021 07 06 to 2021 09 30 Change

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## Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2021-07-06 to 2021-09-30 ; Target : 15.9 ; SD : 2.20

Lab026



Month : 2021 09 Change ; Cumulative : from 2021 07 06 to 2021 09 30 Change

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# Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2021-07-06 to 2021-09-30 ; 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

07-06 07-13 07-15 07-20 07-22 07-30 08-03 08-05 08-10 08-12 08-17 08-19 08-24 08-26 08-31 09-02 09-07 09-09 09-14 09-15 09-21 09-22 09-23 09-24 09-28 09-30

Month : 2021 09 Change ; Cumulative : from 2021 07 06 to 2021 09 30 Change

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# Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon

## Monthly

Month : 2021  09

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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
<a href="#">Lab026</a>	5	15.9	12.9	11	0.1	0.8	20.4	20	1.4	5.8	4.9	11	0.1	2.0	19.6	20	2.2
Total	-	-	12.9	11	0.1	0.8	-	-	-	-	4.9	11	0.1	2.0	-	-	-

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

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

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

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## Cumulative

Cumulative : from 2016  02  01  to 2021  09  30

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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
<a href="#">Lab018</a>	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
<a href="#">Lab019</a>	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
<a href="#">Lab020</a>	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
<a href="#">Lab026</a>	5	15.9	13.4	517	1.1	8.2	32.1	20	0.5	5.8	5.0	517	0.3	6.0	25.8	20	1.0
<a href="#">Lab027</a>	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
<a href="#">Lab028</a>	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
<a href="#">Lab032</a>	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
<a href="#">Lab033</a>	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
<a href="#">Lab034</a>	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
<a href="#">Lab037</a>	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
<a href="#">Lab040</a>	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
<a href="#">Lab043</a>	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	1387	1.3	9.2	-	-	-	-	5.2	1387	0.4	7.7	-	-	-

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

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

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

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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

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### Control N Month vs. Cumulative

Control N (Lot No.: AE0909N)																	
		Month (2021/09)								CUM (2016/02/01~2021/09/30)							
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
<a href="#">Lab018</a>	5	14.2	-	0	-	-	-	20	-	14.2	15.0	149	1.2	8.0	21.6	20	1.8
<a href="#">Lab019</a>	5	15.3	-	0	-	-	-	20	-	15.3	15.2	111	0.3	2.0	4.6	20	>6
<a href="#">Lab020</a>	5	14.4	-	0	-	-	-	20	-	14.4	15.2	28	0.5	3.3	12.1	20	4.4
<a href="#">Lab026</a>	5	15.9	12.9	11	0.1	0.8	20.4	20	1.4	15.9	13.4	517	1.1	8.2	32.1	20	0.5
<a href="#">Lab027</a>	5	15.5	-	0	-	-	-	20	-	15.5	15.5	107	1.3	8.4	16.8	20	2.4
<a href="#">Lab028</a>	5	14.8	-	0	-	-	-	20	-	14.8	14.5	134	0.7	4.8	11.7	20	3.7
<a href="#">Lab032</a>	5	15.3	-	0	-	-	-	20	-	15.3	15.9	38	0.9	5.7	15.2	20	2.8
<a href="#">Lab033</a>	5	14.4	-	0	-	-	-	20	-	14.4	14.9	49	0.6	4.0	11.5	20	4.1
<a href="#">Lab034</a>	5	15.5	-	0	-	-	-	20	-	15.5	14.7	96	0.9	6.1	17.4	20	2.4
<a href="#">Lab037</a>	5	14.9	-	0	-	-	-	20	-	14.9	15.2	30	0.8	5.3	12.5	20	3.4
<a href="#">Lab040</a>	5	14.4	-	0	-	-	-	20	-	14.4	13.2	40	0.7	5.3	18.9	20	2.2
<a href="#">Lab043</a>	5	11.5	-	0	-	-	-	20	-	11.5	13.0	88	0.9	6.9	26.9	20	1.0
Total	-	-	12.9	11	0.1	0.8	-	-	-	-	14.2	1387	1.3	9.2	-	-	-

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

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

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

Month : 2021 09 Change

Cumulative : from 2016 02 01 to 2021 09 30 Change

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### Control D Month vs. Cumulative

Control D (Lot No.: AE0909D)																	
		Month (2021/09)								CUM (2016/02/01~2021/09/30)							
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
<a href="#">Lab018</a>	5	5.5	-	0	-	-	-	20	-	5.5	5.5	149	0.3	5.5	10.9	20	3.6
<a href="#">Lab019</a>	5	5.3	-	0	-	-	-	20	-	5.3	5.3	111	0.2	3.8	7.5	20	5.3
<a href="#">Lab020</a>	5	5.8	-	0	-	-	-	20	-	5.8	5.3	28	0.3	5.7	19.9	20	2.0
<a href="#">Lab026</a>	5	5.8	4.9	11	0.1	2.0	19.6	20	2.2	5.8	5.0	517	0.3	6.0	25.8	20	1.0
<a href="#">Lab027</a>	5	5.4	-	0	-	-	-	20	-	5.4	5.6	107	0.5	8.9	21.6	20	1.8
<a href="#">Lab028</a>	5	4.8	-	0	-	-	-	20	-	4.8	5.6	134	0.3	5.4	27.4	20	0.6
<a href="#">Lab032</a>	5	5.2	-	0	-	-	-	20	-	5.2	5.7	38	0.3	5.3	20.1	20	2.0
<a href="#">Lab033</a>	5	5.8	-	0	-	-	-	20	-	5.8	5.2	49	0.2	3.8	18.0	20	2.5
<a href="#">Lab034</a>	5	4.8	-	0	-	-	-	20	-	4.8	5.0	96	0.4	8.0	20.2	20	2.0
<a href="#">Lab037</a>	5	5.4	-	0	-	-	-	20	-	5.4	5.5	30	0.3	5.5	12.8	20	3.3
<a href="#">Lab040</a>	5	5.8	-	0	-	-	-	20	-	5.8	4.7	40	0.3	6.4	31.7	20	0.2
<a href="#">Lab043</a>	5	4.5	-	0	-	-	-	20	-	4.5	4.8	88	0.4	8.3	23.3	20	1.6
Total	-	-	4.9	11	0.1	2.0	-	-	-	-	5.2	1387	0.4	7.7	-	-	-

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

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

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

Month : 2021 09 Change

Cumulative : from 2016 02 01 to 2021 09 30 Change

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Reagent Kit	Reagent Code
Medicon	5