

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

Select LotNo :

## Lab040

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2022/01)	CUM (2020/08/04~2022/01/28)	Month (2022/01)	CUM (2020/08/04~2022/01/28)
Runs (N)	4	23	4	23
Mean (U/gHb)	14.5	14.9	4.9	5.2
SD	0.3	0.4	0.2	0.5
CV (%)	2.1	2.7	4.1	9.6
Target Value (U/gHb)	15.3	15.3	5.2	5.2
Total Error (%)	9.4	8.0	13.9	19.2
TEa (%)	20	20	20	20
$\sigma$	>6	>6	3.5	2.1

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

Month :    ; Cumulative : from    to

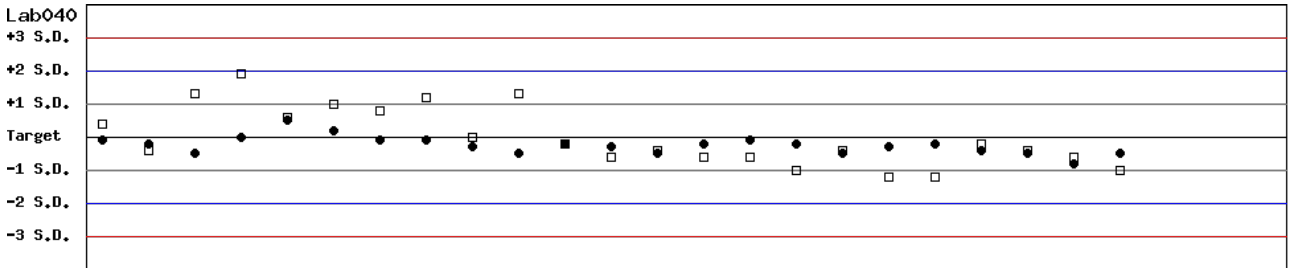
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## Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-08-04 to 2022-01-28 ; Target : 15.3 ; SD : 1.53 (●)

Lot No.: AH1220D ; Duration : 2020-08-04 to 2022-01-28 ; Target : 5.2 ; SD : 0.52 (□)

Lab040



Date 08-04 08-07 08-11 08-14 08-20 08-27 09-04 09-10 09-21 09-26 04-01 04-08 04-15 04-22 04-29 09-03 09-10 09-17 09-24 01-08 01-15 01-21 01-27

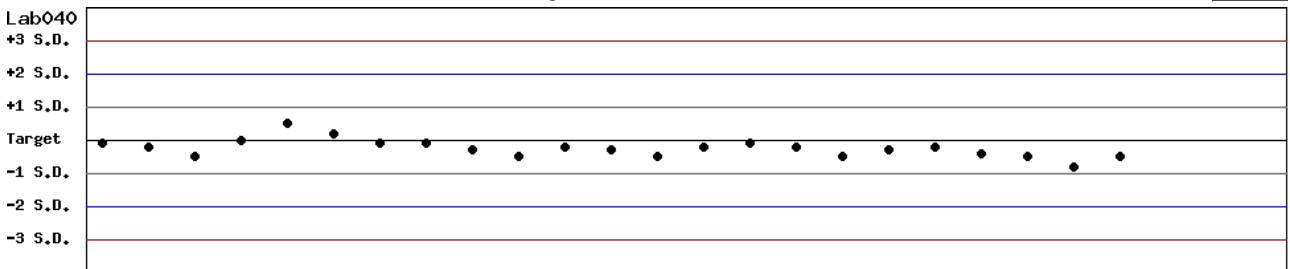
Month :    ; Cumulative : from    to

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## Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2020-08-04 to 2022-01-28 ; Target : 15.3 ; SD : 1.53

Lab040



Date 08-04 08-07 08-11 08-14 08-20 08-27 09-04 09-10 09-21 09-26 04-01 04-08 04-15 04-22 04-29 09-03 09-10 09-17 09-24 01-08 01-15 01-21 01-27

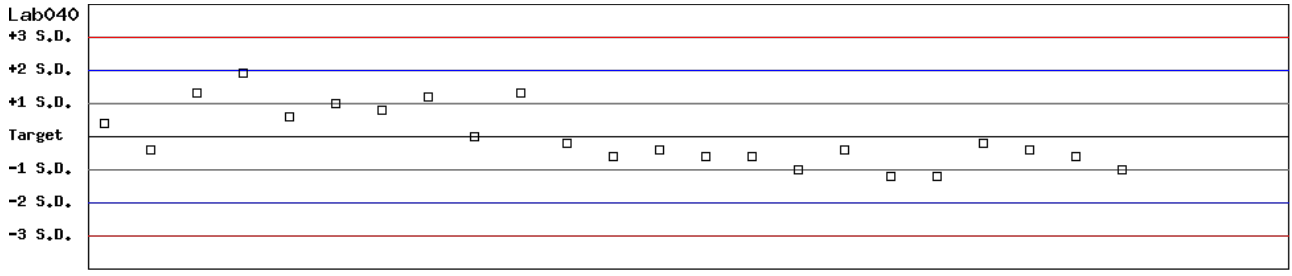
Month :    ; Cumulative : from    to

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## Control D SDI QC Chart

Lot No.: AH1220D ; Duration : 2020-08-04 to 2022-01-28 ; Target : 5.2 ; SD : 0.52

Lab040



**Date**    08-04 08-07 08-11 08-14 08-20 08-27 09-04 09-10 09-21 09-26 04-01 04-08 04-15 04-22 04-29 09-03 09-10 09-17 09-24 01-08 01-15 01-21 01-27

Month :    ; Cumulative : from    to

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## Peer Group Statistics (Table 1)

Select LotNo : AH1220N (2019-01-28 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

[Print Table 1](#)

### Monthly

Month : 2022 01 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	Control N (Lot No.: AH1220N)								Control D (Lot No.: AH1220D)							
		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="#">Lab033</a>	5	12.4	12.6	4	0.2	1.6	4.8	20	>6	3.9	3.9	4	0.1	2.6	5.1	20	>6
<a href="#">Lab034</a>	5	15.3	14.1	3	0.4	2.8	13.5	20	4.3	5.2	5.4	3	1.6	29.6	63.1	20	0.5
<a href="#">Lab040</a>	5	15.3	14.5	4	0.3	2.1	9.4	20	>6	5.2	4.9	4	0.2	4.1	13.9	20	3.5
<a href="#">Lab050</a>	5	13.8	14.2	7	0.3	2.1	7.1	20	>6	4.3	4.4	7	0.1	2.3	6.9	20	>6
Total	-	-	13.9	18	0.8	5.8	-	-	-	-	4.6	18	0.8	17.4	-	-	-

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

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

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

[\[TOP\]](#)

### Cumulative

Cumulative : from 2019 02 01 to 2022 01 31 Change

UnitID <small>↑</small>	Reagent Kit (Code) <small>↑</small>	Control N (Lot No.: AH1220N)								Control D (Lot No.: AH1220D)							
		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="#">Lab019</a>	5	15.0	14.8	67	0.5	3.4	8.1	20	5.5	4.6	4.5	67	0.2	4.4	11.1	20	4.1
<a href="#">Lab020</a>	5	13.3	14.3	65	1.0	7.0	21.5	20	1.8	4.3	4.5	65	0.2	4.4	13.5	20	3.5
<a href="#">Lab022</a>	5	13.8	13.0	88	0.9	6.9	19.6	20	2.1	4.4	4.2	88	0.2	4.8	14.1	20	3.2
<a href="#">Lab028</a>	5	14.6	14.6	53	0.4	2.7	5.5	20	>6	4.6	4.6	53	0.2	4.3	8.7	20	4.7
<a href="#">Lab032</a>	5	12.1	12.9	136	1.4	10.9	28.3	20	1.2	3.5	4.0	136	0.5	12.5	39.3	20	0.5
<a href="#">Lab033</a>	5	12.4	12.5	142	0.4	3.2	7.2	20	6.0	3.9	3.9	142	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	15.3	14.5	71	1.0	6.9	19.0	20	2.1	5.2	4.6	71	0.4	8.7	28.9	20	1.0
<a href="#">Lab037</a>	5	15.3	15.2	55	0.4	2.6	5.9	20	>6	5.2	4.7	55	0.2	4.3	18.1	20	2.4
<a href="#">Lab040</a>	5	15.3	14.9	23	0.4	2.7	8.0	20	>6	5.2	5.2	23	0.5	9.6	19.2	20	2.1
<a href="#">Lab043</a>	5	13.8	12.7	19	0.7	5.5	19.0	20	2.2	4.4	4.1	19	0.3	7.3	21.5	20	1.8
<a href="#">Lab047</a>	5	14.7	13.7	26	1.2	8.8	24.3	20	1.5	4.6	4.3	26	0.3	7.0	20.5	20	1.9
<a href="#">Lab049</a>	5	14.7	14.3	42	0.5	3.5	9.7	20	4.9	4.9	4.7	42	0.3	6.4	16.8	20	2.5
<a href="#">Lab050</a>	5	13.8	14.0	78	0.5	3.6	8.6	20	5.2	4.3	4.4	78	0.2	4.5	11.4	20	3.9
Total	-	-	13.7	865	1.2	8.8	-	-	-	-	4.3	865	0.4	9.3	-	-	-

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 : AH1220N (2019-01-28 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

[Print Table 2](#)

### Control N Month vs. Cumulative

		Control N (Lot No.: AH1220N)															
		Month (2022/01)								CUM (2019/02/01~2022/01/31)							
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
<a href="#">Lab019</a>	5	15.0	-	0	-	-	-	20	-	15.0	14.8	67	0.5	3.4	8.1	20	5.5
<a href="#">Lab020</a>	5	13.3	-	0	-	-	-	20	-	13.3	14.3	65	1.0	7.0	21.5	20	1.8
<a href="#">Lab022</a>	5	13.8	-	0	-	-	-	20	-	13.8	13.0	88	0.9	6.9	19.6	20	2.1
<a href="#">Lab028</a>	5	14.6	-	0	-	-	-	20	-	14.6	14.6	53	0.4	2.7	5.5	20	>6
<a href="#">Lab032</a>	5	12.1	-	0	-	-	-	20	-	12.1	12.9	136	1.4	10.9	28.3	20	1.2
<a href="#">Lab033</a>	5	12.4	12.6	4	0.2	1.6	4.8	20	>6	12.4	12.5	142	0.4	3.2	7.2	20	6.0
<a href="#">Lab034</a>	5	15.3	14.1	3	0.4	2.8	13.5	20	4.3	15.3	14.5	71	1.0	6.9	19.0	20	2.1
<a href="#">Lab037</a>	5	15.3	-	0	-	-	-	20	-	15.3	15.2	55	0.4	2.6	5.9	20	>6
<a href="#">Lab040</a>	5	15.3	14.5	4	0.3	2.1	9.4	20	>6	15.3	14.9	23	0.4	2.7	8.0	20	>6
<a href="#">Lab043</a>	5	13.8	-	0	-	-	-	20	-	13.8	12.7	19	0.7	5.5	19.0	20	2.2
<a href="#">Lab047</a>	5	14.7	-	0	-	-	-	20	-	14.7	13.7	26	1.2	8.8	24.3	20	1.5
<a href="#">Lab049</a>	5	14.7	-	0	-	-	-	20	-	14.7	14.3	42	0.5	3.5	9.7	20	4.9
<a href="#">Lab050</a>	5	13.8	14.2	7	0.3	2.1	7.1	20	>6	13.8	14.0	78	0.5	3.6	8.6	20	5.2
Total	-	-	13.9	18	0.8	5.8	-	-	-	-	13.7	865	1.2	8.8	-	-	-

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

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

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

Month : 2022 01 Change

Cumulative : from 2019 02 01 to 2022 01 31 Change

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### Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2022/01)								CUM (2019/02/01~2022/01/31)							
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
<a href="#">Lab019</a>	5	4.6	-	0	-	-	-	20	-	4.6	4.5	67	0.2	4.4	11.1	20	4.1
<a href="#">Lab020</a>	5	4.3	-	0	-	-	-	20	-	4.3	4.5	65	0.2	4.4	13.5	20	3.5
<a href="#">Lab022</a>	5	4.4	-	0	-	-	-	20	-	4.4	4.2	88	0.2	4.8	14.1	20	3.2
<a href="#">Lab028</a>	5	4.6	-	0	-	-	-	20	-	4.6	4.6	53	0.2	4.3	8.7	20	4.7
<a href="#">Lab032</a>	5	3.5	-	0	-	-	-	20	-	3.5	4.0	136	0.5	12.5	39.3	20	0.5
<a href="#">Lab033</a>	5	3.9	3.9	4	0.1	2.6	5.1	20	>6	3.9	3.9	142	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	5.2	5.4	3	1.6	29.6	63.1	20	0.5	5.2	4.6	71	0.4	8.7	28.9	20	1.0
<a href="#">Lab037</a>	5	5.2	-	0	-	-	-	20	-	5.2	4.7	55	0.2	4.3	18.1	20	2.4
<a href="#">Lab040</a>	5	5.2	4.9	4	0.2	4.1	13.9	20	3.5	5.2	5.2	23	0.5	9.6	19.2	20	2.1
<a href="#">Lab043</a>	5	4.4	-	0	-	-	-	20	-	4.4	4.1	19	0.3	7.3	21.5	20	1.8
<a href="#">Lab047</a>	5	4.6	-	0	-	-	-	20	-	4.6	4.3	26	0.3	7.0	20.5	20	1.9
<a href="#">Lab049</a>	5	4.9	-	0	-	-	-	20	-	4.9	4.7	42	0.3	6.4	16.8	20	2.5
<a href="#">Lab050</a>	5	4.3	4.4	7	0.1	2.3	6.9	20	>6	4.3	4.4	78	0.2	4.5	11.4	20	3.9
Total	-	-	4.6	18	0.8	17.4	-	-	-	-	4.3	865	0.4	9.3	-	-	-

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

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

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

Month : 2022 01 Change

Cumulative : from 2019 02 01 to 2022 01 31 Change

[TOP](#)

Reagent Kit	Reagent Code
Medicon	5