

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

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

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## Lab034

QC Control Lot No.	Control N		Control D	
	AH1220N		AH1220D	
Duration of the Analyzing	Month (2024/02)	CUM (2023/04/20~2024/02/15)	Month (2024/02)	CUM (2023/04/20~2024/02/15)
Runs (N)	2	26	2	26
Mean (U/gHb)	14.5	14.3	5.2	5.1
SD	-	0.7	-	0.3
CV (%)	-	4.9	-	5.9
Target Value (U/gHb)	15.3	15.3	5.2	5.2
Total Error (%)	-	16.3	-	13.7
TEa (%)	20	20	20	20
$\sigma$	-	2.7	-	3.1

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

Month : 2024 02 Change ; Cumulative : from 2023 04 20 to 2024 02 15 Change

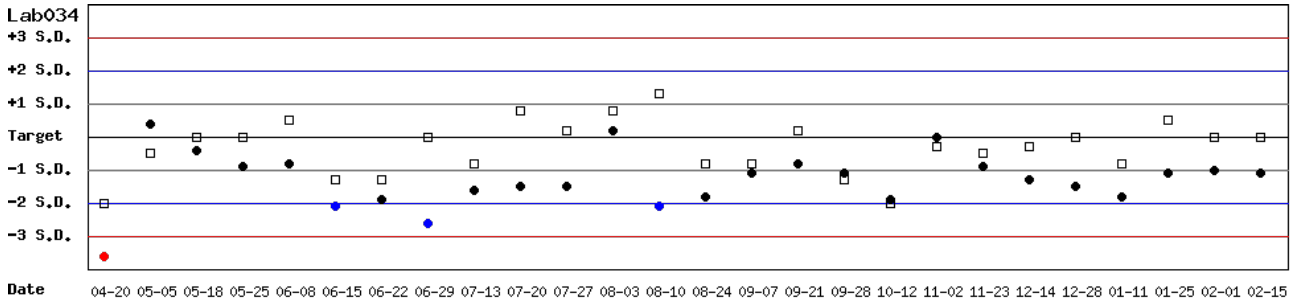
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## Control N and Control D SDI QC Chart

Lot No.: AH1220N ; Duration : 2023-04-20 to 2024-02-15 ; Target : 15.3 ; SD : 0.8 (●)

Lot No.: AH1220D ; Duration : 2023-04-20 to 2024-02-15 ; Target : 5.2 ; SD : 0.4 (□)

Lab034



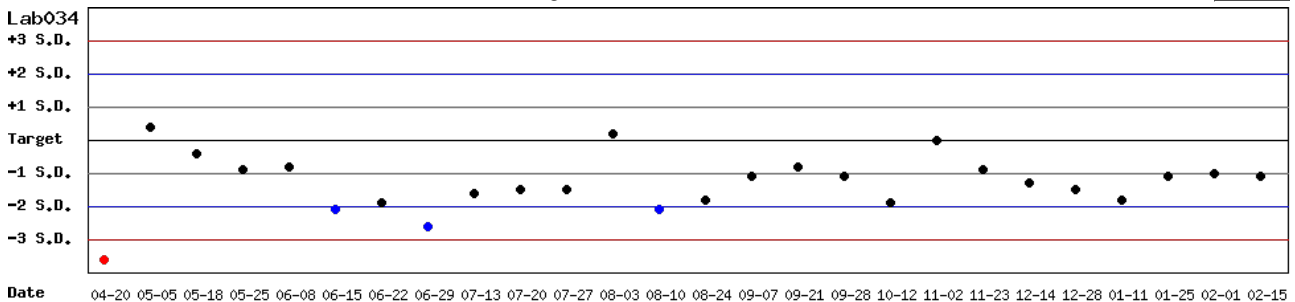
Month : 2024 02 Change ; Cumulative : from 2023 04 20 to 2024 02 15 Change

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## Control N SDI QC Chart

Lot No.: AH1220N ; Duration : 2023-04-20 to 2024-02-15 ; Target : 15.3 ; SD : 0.8

Lab034



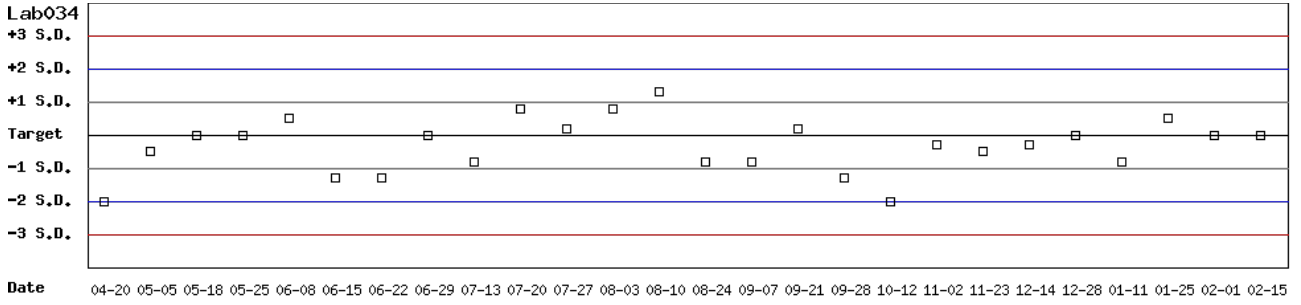
Month : 2024 02 Change ; Cumulative : from 2023 04 20 to 2024 02 15 Change

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### Control D SDI QC Chart

Lab034

Lot No.: AH1220D ; Duration : 2023-04-20 to 2024-02-15 ; Target : 5.2 ; SD : 0.4



Month :    ; Cumulative : from    to

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# Peer Group Statistics (Table 1)

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

Select Reagent Kit : 5 - Medicon

## Monthly

Month : 2024  02

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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="#">Lab034</a>	5	15.3	14.5	2	-	-	-	20	-	5.2	5.2	2	-	-	-	20	-
Total	-	-	14.5	2	-	-	-	-	-	-	5.2	2	-	-	-	-	-

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

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

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

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## Cumulative

Cumulative : from 2019  02  01  to 2024  02  29

UnitID <input type="button" value="↑"/>	Reagent Kit (Code) <input type="button" value="↑"/>	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	144	0.4	3.2	7.2	20	6.0	3.9	3.9	144	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	15.3	14.3	140	0.9	6.3	19.1	20	2.1	5.2	4.7	140	0.4	8.5	26.6	20	1.2
<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	13.9	14.6	40	0.6	4.1	13.3	20	3.6	4.6	5.0	40	0.4	8.0	24.7	20	1.4
<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	14.1	207	0.5	3.5	9.3	20	5.1	4.3	4.4	207	0.1	2.3	6.9	20	>6
Total	-	-	13.8	1082	1.2	8.7	-	-	-	-	4.4	1082	0.4	9.1	-	-	-

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

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### Control N Month vs. Cumulative

		Control N (Lot No.: AH1220N)															
		Month (2024/02)									CUM (2019/02/01~2024/02/29)						
UnitID <span style="font-size: small;">↑</span>	Reagent Kit (Code) <span style="font-size: small;">↑</span>	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	-	0	-	-	-	20	-	12.4	12.5	144	0.4	3.2	7.2	20	6.0
<a href="#">Lab034</a>	5	15.3	14.5	2	-	-	-	20	-	15.3	14.3	140	0.9	6.3	19.1	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	13.9	-	0	-	-	-	20	-	13.9	14.6	40	0.6	4.1	13.3	20	3.6
<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	-	0	-	-	-	20	-	13.8	14.1	207	0.5	3.5	9.3	20	5.1
<b>Total</b>	-	-	14.5	2	-	-	-	-	-	-	13.8	1082	1.2	8.7	-	-	-

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

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

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

Month : 2024 02 Change

Cumulative : from 2019 02 01 to 2024 02 29 Change

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### Control D Month vs. Cumulative

		Control D (Lot No.: AH1220D)															
		Month (2024/02)									CUM (2019/02/01~2024/02/29)						
UnitID <span style="font-size: small;">↑</span>	Reagent Kit (Code) <span style="font-size: small;">↑</span>	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	-	0	-	-	-	20	-	3.9	3.9	144	0.2	5.1	10.3	20	3.9
<a href="#">Lab034</a>	5	5.2	5.2	2	-	-	-	20	-	5.2	4.7	140	0.4	8.5	26.6	20	1.2
<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	4.6	-	0	-	-	-	20	-	4.6	5.0	40	0.4	8.0	24.7	20	1.4
<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	-	0	-	-	-	20	-	4.3	4.4	207	0.1	2.3	6.9	20	>6
<b>Total</b>	-	-	5.2	2	-	-	-	-	-	-	4.4	1082	0.4	9.1	-	-	-

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

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

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

Month : 2024 02 Change

Cumulative : from 2019 02 01 to 2024 02 29 Change

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Reagent Kit	Reagent Code
Medicon	5