

Steam D-value Determination Report

Date started _____ Date completed _____

Temperature 118 121 124 126 132 Other _____

Lot # _____ Batch # _____

Carrier _____ Population/unit (N₀) _____

of BI's per run (u) _____ TSB media lot # _____

At least 3 runs showing dichotomous results are required.

Fraction Negative (Spearman-Kärber)

Time	#BIs sterile
	0
	0 (f ₁)
	(f ₂)
	(f _{k-1})
	(f _k)
	(f _{k+1})

f₁ = all BI's survive and adjacent to a dichotomous result

T = time to achieve f_k

d = time interval between runs in minutes

u = # of BI's per run (i.e. 10)

N₀ = Population of BI unit (use most recently determined value)

U = mean time until sterility

D = D-value

f_k = all BIs sterile and adjacent to a dichotomous result

$$U = T - d/2 - (d/u \times \Sigma f_{k-1} \text{ to } f_1)$$

$$U = \text{_____} - \text{_____}/2 - (\text{_____}/\text{_____} \times \text{_____})$$

$$U = \text{_____}$$

$$D = U / (\log N_0 + 0.2507) \quad [\log N_0 + 0.2507 = (\text{_____} + 0.2507) = \text{_____}]$$

$$D = \text{_____} / \text{_____}$$

$$D = \text{_____} \text{ minutes}$$

Calculations By _____ Date _____

Calculations Reviewed By _____ Date _____

QA Review _____ Date _____