



## Validation for Bacterial Endotoxin Using Kinetic Chromogenic Analysis (KCA)

(Ref: [MICLAB 085](#))

Product:	
Concentration:	mg/mL
Maximum Valid Dilution:	
Dilution used:	1 :
Diluent used:	
pH adjustment necessary:	
Validation Requirements met:	
Reagent Supplier:	

Position:	Name:	Signature:	Date:
Senior Microbiology Staff			
Microbiology Manager			



# Maximum Valid Dilution for Products Tested By LAL KCA Method

(Ref. MICLAB 085)

Product:		
M = Maximum human dose/kg/hr		mg/Kg/hr
C = Concentration of Product		mg/ml
λ (Sensitivity of Lysate)		EU/mL
K = 5.0 EU/kg/hr for parenteral preparations (Intravenous)		
K = 0.2 EU/kg/hr for parenteral preparations (Intrathecal)		
K = Threshold pyrogenic dose of endotoxin per kilogram of body mass in a single hour period.		

Formula:

$$MVD = \frac{K \times C}{M} \times \frac{1}{\lambda}$$

= Result

Calculations:

$$\frac{\quad \times \quad}{\quad} \times \frac{\quad}{\quad}$$

=

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