

K955143

JUL 30 1996

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

RE: 510(k) Submission for RPR
Liquid Controls Summary
of Safety and
Effectiveness

November 8, 1995

Dear Sir:

In accordance with 21 CFR Chapter 1, Subpart E, Sec. 807.93, and as part of the 510(k) submission for the RPR Liquid Controls, the following information is provided.

Reasonable assurance that this device is safe and effective was determined through the use of valid scientific nonclinical investigations including in vitro studies. The results of these studies are summarized in the attached Technical Insert.

This device is effective when tested under the conditions for its intended use. Each test kit contains a technical insert which provides adequate directions and precautions for use. Lastly, each insert contains information on the limitations and the performance characteristics of the test (including relative sensitivity and specificity data) when used according to the directions.

SUMMARY OF SAFETY AND EFFECTIVENESS DATA:

Raw performance data
Intended use of the product
Limitations of the product
Relative sensitivity and specificity data
Directions for procedure
510(k) Submission

Should there be any questions concerning this matter, please contact me at (706)736-6011.

Sincerely,



David A. Wall
Manager, Immunodiagnostics

REMEL RCB CARD TEST CONTROLS Comparative Data										Sitic: Mch. Dept. PH
Date	REMEL Pos Cnt	Reference Pos Cnt	REMEL Neg Cnt	Reference Neg Cnt	Y SK	MOPT 6346	PH: H. Slatford			
7-10-95	R	R	N	N	—	—				
7-11-95	R	R	N	N	—	—				
7-14-95	R	R	N	N	—	—				
7-21-95	R	R	N	N	—	—				
7-22-95	R	R	N	N	—	—				
7-27-95	R	R	N	N	—	—				
7-28-95	R	R	N	N	—	—				
8-3-95	R	R	N	N	—	—				
8-8-95	R	R	N	N	—	—				
8-12-95	R	R	N	N	—	—				
8-17-95	R	R	N	N	—	—				
8-18-95	R	R	N	N	—	—				
8-21-95	R	R	N	N	—	—				
8-22-95	R	R	N	N	—	—				
8-23-95	R	R	N	N	—	—				
8-25-95	R	R	N	N	—	—				
8-28-95	R	R	N	N	—	—				
8-29-95	R	R	N	N	—	—				
8-30-95	R	R	N	N	—	—				
9-1-95	R	R	N	N	—	—				
9-5-95	R	R	N	N	—	—				
9-6-95	R	R	N	N	—	—				
9-9-95	R	R	N	N	—	—				
10-3-95	R	R	N	N	—	—				
10-31-95	R	R	N	N	—	—				

Site - UTex.
PI: Hartwell

REMEL RPR CARD TEST CONTROLS Comparative Data						
Date	REMEL Pos Ctrl	Reference Pos Ctrl	REMEL Neg Ctrl	Reference Neg Ctrl		
	R ⁽⁴⁺⁾ / mR ⁽³⁺⁾	R ⁽⁴⁺⁾ / mR ⁽³⁺⁾	NR	NR		
7/3/95	R / mR ⁽³⁺⁾	R / mR ⁽³⁺⁾	NR	NR		
7/5/95	R / mR	R / mR	NR	NR		
7/6/95	R / mR	R / mR	NR	NR		
7/12/95	R / mR	R / mR	NR	NR		
7/21/95	R / mR	R / mR	NR	NR		
7/24/95	R / mR	R / mR	NR	NR		
7/25/95	R / mR	R / mR	NR	NR		
7/26/95	R / mR	R / mR	NR	NR		
7/31/95	R / mR	R / mR	NR	NR		
8/1/95	R / mR	R / mR	NR	NR		
8/3/95	R / mR	R / mR	NR	NR		
8/4/95	R / mR	R / mR	NR	NR		

PI: Hartwell

[illegible]