

K955136

JUL 29 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  
Card Test Kit 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  
RPR CARD TEST**

**PERFORMANCE CHARACTERISTICS**

University of Texas  
Dr. Beth Hartwell  
&  
Michigan Department of Public Health  
Mr. Harlan Stiefel

Two batches of RPR antigen were tested at the Univ. of Texas in comparison to the BD RPR antigen. Antigen #1 was made by REMEL and evaluated by the CDC before use in determining its performance characteristics. This material was considered "Satisfactory" by the CDC (copy of report enclosed). Antigen #2 was made for REMEL at LEE Laboratories in Grayson, GA and was also tested and deemed "Satisfactory" by the CDC. Both materials were evaluated since REMEL would like the option to make or purchase this antigen as needed.

The REMEL manufactured RPR antigen (Ag#1) was tested at U. of Texas without any significant discrepancies. It was tested vs the BD RPR antigen, and MHA-TP (for all reactives). Patient genders were documented for all specimens. Patient gender did not affect the outcome of the tests. Many of the reactive samples were titered for both RPR antigens and there was no statistically significant difference in performance between the two. Additionally, data is provided on several of the reactive samples which includes stage of infection with *Treponema pallidum* and history of treatment. Reactive results are consistent with the history of treatment and staging of illness.

The LEE Labs RPR antigen (Ag#2) was tested at both the Univ. of Texas vs the BD RPR antigen and Michigan Dept. of Health. vs the Difco USR antigen. Again, patient genders were recorded. Gender had no affect on the outcome of the tests. Also, stage of infection with *Treponemal pallidum* and historical treatment on many of the reactive samples were recorded. All reactive samples were also tested vs the MHA-TP test with results consistent with the history of treatment and staging of illness. There were a number of the reactive samples tested at the U. of Texas that were read as nonreactive with the Ag#2 and reactive (undiluted endpoint titer) with the BD Ag. Repeat testing of the same samples with the same material at the U. of Texas yielded the same results. Because the same antigen (#2) was used at the Michigan site without any significant # of discrepancies, the remainder of the U. of Texas discrepant samples along with 12 known reactive samples and 12 known nonreactive samples were sent blinded to Michigan. Michigan reported results which were consistent between the known results at Texas and between RPR and USR. Additionally, except with only a couple of samples, the RPR results were consistent with the USR test in the discrepant samples. The raw data is enclosed and a summary of the testing follows.

8/10