SANOFI DIAGNOSTICS PASTEUR, INC.
1000 LAKE HAZELTINE DRIVE
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K960850

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
February 29, 1996

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990.

1. General Information

Applicant's Name and Address: Sanofi Diagnostics Pasteur, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318
(612)448-4848
Katia Breslawec

Device Classification Name: Chlamydia Serological Reagents

Device Trade Name: ACCESS® Chlamydia Reagents

2. Predicate Device

Syva MicroTrak® II Chlamydia EIA
Syva Company
3403 Yerba Buena Road P.O. Box 49013
San Jose, CA 95161

3. Device Description

The Sanofi Diagnostics Pasteur Inc. ACCESS® Chlamydia antigen and blocking assays are qualitative, paramagnetic-particle, chemiluminescent enzyme immunoassays for the direct detection and verification of chlamydia antigen in adult male urethral, female endocervical, and male urine specimens, using the ACCESS® Immunoassay System.

4. Summary of Studies

In clinical studies, the ACCESS® Chlamydia was compared to culture or DFA on 2092 urogenital and 572 male urine specimens. The respective sensitivity, specificity, PPV, and NPV by population category were:

high risk females	86%	99.7%	96%	99%
low risk females	100%	100%	100%	100%
symptomatic males	93%	99.7%	98%	99%
symptomatic males urine	88%	99%	94%	98%
asymptomatic males	88%	100%	100%	99.5%
asymptomatic males urine	56%	100%	100%	98%

A comparison to the Syva MicroTrak® II Chlamydia EIA was done on 1518 urogenital and 303 male urine specimens. The concordance was 98.1% and 95.4%, respectively.

Representative data for within run and total precision are 4.2% and 11.9% for negative, 5.6% and 17.5% for low positive, and 3.6% and 21.1% for high positive specimens.

5. Conclusion

The Sanofi Diagnostics Pasteur ACCESS® Chlamydia is substantially equivalent to a standard laboratory reference method (cell culture) and to another kit currently in commercial distribution for the direct detection of chlamydia in adult female endocervical, male urethral, and male urine specimens.