K964507

510(k) Summary

JUN 13 1997

Roche COBAS AMPLICOR™ Chlamydia trachomatis Test
Roche Molecular Systems, Inc.
1080 U.S. Highway 202
Somerville, New Jersey 08876-1760
(908) 253-7200

Intended Use:

The COBAS AMPLICOR™ *Chlamydia trachomatis* (CT) Test is a qualitative *in vitro* diagnostic test for the detection of *Chlamydia trachomatis* in clinical specimens on the COBAS AMPLICOR analyzer. The test utilizes the Polymerase Chain Reaction (PCR) nucleic acid amplification technique and nucleic acid hybridization for the detection of *Chlamydia trachomatis* plasmid DNA in endocervical, urethral (male), and urine (male) samples.

Description of the Device:

The Roche COBAS AMPLICOR™ *Chlamydia trachomatis* test performed on the COBAS AMPLICOR analyzer is an automated modification of the Roche AMPLICOR *Chlamydia trachomatis* Microwell Plate Test performed using the Perkin Elmer 9600 thermal cycler and a conventional photometric microwell plate reader (K922906/C). The AMPLICOR™ *Chlamydia trachomatis* Test was previously shown to be substantially equivalent to tissue culture with immunofluorescent staining for the detection of *Chlamydia trachomatis* in urogenital swab and male urine samples. The AMPLICOR *Chlamydia trachomatis* Test has been modified to allow the automation of the amplification and detection test procedure using the COBAS AMPLICOR analyzer. Specimen collection, transport and processing and target amplification with the COBAS AMPLICOR *Chlamydia Trachomatis* Test are identical to the AMPLICOR *Chlamydia Trachomatis* Test. COBAS AMPLICOR and microwell AMPLICOR *Chlamydia Trachomatis* Test detection reagents incorporate identical probes using the appropriate solid support. The clinical and non-clinical performance of the COBAS AMPLICOR *Chlamydia Trachomatis* Test is substantially equivalent to the AMPLICOR *Chlamydia Trachomatis* Test.

Similarities and Differences to Predicate Device:

The COBAS AMPLICOR *Chlamydia trachomatis* Test is similar in design, reagent composition, function and intended use to the commercial microwell plate format AMPLICOR *Chlamydia trachomatis* Test (K922906/C). The COBAS AMPLICOR *Chlamydia trachomatis* Test uses without modification the AMPLICOR *Chlamydia trachomatis* Test STD Swab Specimen Collection and Transport Kit, the AMPLICOR STD Swab and the Urine Specimen Preparation Kits for specimen collection, specimen preparation and PCR amplification (see Table 1). The COBAS AMPLICOR Detection Kit reagents are similar in function and formulation to those in the AMPLICOR *Chlamydia trachomatis* Detection Test. The solid support for the DNA detection probe has been changed from a polystyrene microwell plate to magnetic microparticles to permit automation of the detection reaction on the COBAS AMPLICOR.

Similarities

- AMPLICOR STD Specimen Collection and Transport Kit (P/N 83075) for the collection and transport of male and female swab specimens.
- AMPLICOR STD Specimen Preparation Kits (P/N 83002 and 83006) for the processing of swab and urine specimens.
- AMPLICOR CT Amplification Kit (P/N 83008).
- Identical biotinylated primers (CP24 and CP27) for defining the CT DNA target sequence for amplification.

- Hybridization of biotinylated amplicon generated in the PCR reaction to the same CP35 CT-specific DNA probe
- Identical Detection Reagent formulations (Denaturation Solution, Substrate A, Substrate B and 10-X Wash Concentrate)
- Identical detection reactions based on the measurement chromophore absorbance following oxidation of 3,3',5,5'-tetramethybenzidine by horseradish peroxidase in the presence of hydrogen peroxide.

Differences

- Automated pipetting of amplified samples and reagent, washing, thermal cycling, hybridization and detection steps of the test procedure.
- The avidin-HRP Conjugate Buffer in the COBAS AMPLICOR *Chlamydia trachomatis* Test contains bovine serum albumin compared to bovine gamma globulin in the AMPLICOR *Chlamydia trachomatis* MWP Test.
- Change of solid support from polystyrene microwell plate to magnetic microparticles,
- Slightly modified thermal cycle profile for the COBAS AMPLICOR to give equivalent performance to the Perkin Elmer 9600 thermal cycler.
- No Stop Reagent is required with the COBAS AMPLICOR assay. Since the automated analyzer precisely times each step of the hybridization and detection procedures, it is not necessary to add Stop Reagent at the conclusion of the substrate incubation step. Accordingly, the optical density of the oxidation products from the detection reaction is measured at 660 nm in the COBAS AMPLICOR *Chlamydia trachomatis* Test as compared to 450 nm in the AMPLICOR *Chlamydia trachomatis* MWP Test system since the Stop Reagent modifies the oxidation state of the TMB reaction product, from the detection reaction, shifting the absorbance maximum of the chromophore from 660 nm to 450 nm.

Non-Clinical Performance:

The analytical sensitivity (limit of detection) of the COBAS AMPLICOR *Chlamydia trachomatis* Test is 1 Inclusion Forming Unit for all 15 Chlamydia serovars (A, B, Ba, C, D, E, F, G, H, I, J, K, L1, L2, L3). The analytical specificity for the AMPLICOR *Chlamydia trachomatis* Test was evaluated using 105 bacteria, yeasts and viruses. No organism gave a result greater than 0.016 A_{660}. These results are consistent with those observed for the AMPLICOR *Chlamydia Trachomatis* Test.

The reproducibility of the Roche COBAS AMPLICOR *Chlamydia trachomatis* Test on the COBAS AMPLICOR analyzer was determined in a multi-operator analysis of swab samples spiked with *Chlamydia trachomatis* organism at four levels, AMPLICOR *C. trachomatis* positive and negative kit controls, and six patient samples spanning the reportable range for the assay (24 samples per test run; two complete A-tube rings). Samples were analyzed by independent operators for three days using three different analyzers. The test results for all samples (STM specimens spiked at 50, 10, 1 and 0 IFU/PCR, positive and negative kit controls, and the patient specimens) were 100% correct. The reproducibility of the assay was calculated from the absorbance values obtained from the replicates of the spiked STM specimens and the Kit Controls. The complete results of the Analysis of Variance calculations for these data are provided in Table 2.

Clinical Performance:

The comparative clinical performance between the COBAS AMPLICOR *Chlamydia trachomatis* Test and the AMPLICOR *Chlamydia Trachomatis* Test was determined using 639 clinical specimens (266 endocervical swabs, 93 male urethral swabs, and 280 male urine specimens). Equivalent results were obtained for specimens tested by the two test procedures.

March 31, 1997

TABLE 1
COBAS AMPLICOR Chlamydia trachomatis Test Reproducibility
Analysis of Variance - Statistical Summary

PRECISION MEASUREMENT	*TEST SAMPLE*					
	C. trachomatis Spiked STM (IFU/PCR Test)				*Kit Controls*	
	0	*1*	*10*	*50*	*Negative*	*Positive*
Total Replicates	27	27	27	27	27	27
Mean Absorbance	0.004	3.856	3.685	3.639	0.004	3.831
Minimum	0.000	3.646	3.220	3.220	0.000	3.279
Maximum	0.017	4.000	4.000	4.000	0.011	4.000
Between Day Variance	0.0000	0.0000	0.0040	0.0037	0.0000	0.0022
Standard Deviation	0.0013	0.0000	0.0632	0.0610	0.0000	0.0468
CV (%)	32.0	0.0	1.7	1.7	0.0	1.2
Between Operator Variance	0.0000	0.0145	0.0271	0.0230	0.0000	0.0587
Standard Deviation	0.0029	0.1206	0.1647	0.1517	0.0027	0.2422
CV (%)	72.4	3.1	4.5	4.2	69.7	6.3
Within Operator Variance	0.0000	0.0059	0.0162	0.0125	0.0000	0.0109
Standard Deviation	0.0035	0.0767	0.1274	0.1118	0.0026	0.1045
CV (%)	87.0	2.0	3.5	3.1	67.4	2.7
Total Variance	0.0000	0.0204	0.0474	0.0392	0.0000	0.0718
Standard Deviation	0.0047	0.1429	0.2176	0.1980	0.0037	0.2679
CV (%)	117.6	3.7	5.9	5.4	97.0	7.0

TABLE 2
Comparative Clinical Performance
COBAS AMPLICOR vs AMPLICOR Chlamydia Trachomatis Test

	Culture Positive		*Culture Negative*		
			AMPLICOR Positive		
	AMPLICOR Positive	*AMPLICOR Negative*	*MOMP Positive*	*MOMP Negative*	*AMPLICOR Negative*
FEMALE SWABS					
COBAS Positive	19	1	13	2*	0
COBAS Negative	0	1	0	1	229
MALE SWABS					
COBAS Positive	13	0	3	0	1**
COBAS Negative	0	0	0	0	76
MALE URINE					
COBAS Positive	32	2	30	1	2
COBAS Negative	2	3	3	0	202

* inconclusive results by MOMP alternative primer pair testing
** COBAS negative on repeat testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 13 1997

Alex Wesolowski
Director, Regulatory and Clinical Affairs
Roche Molecular Systems, Inc.
1080 U.S. Highway 202
Branchburg, NJ 08876-1760

Re: K964507
Trade Name: Roche Cobas Amplicor™ Chlamydia Trachomatis Test
Regulatory Class: I
Product Code: MKZ
Dated: November 7, 1996
Received: November 8, 1996

Dear Mr. Wesolowski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) _____

Device Name: COBAS AMPLICOR™ *Chlamydia Trachomatis* Test

Indications for Use:

The COBAS AMPLICOR™ *Chlamydia trachomatis* Test is a qualitative *in vitro* diagnostic test for the detection of *Chlamydia trachomatis* in clinical specimens on the COBAS AMPLICOR analyzer. The test utilizes the Polymerase Chain Reaction (PCR) nucleic acid amplification technique and nucleic acid hybridization for the detection of *Chlamydia trachomatis* plasmid DNA in endocervical, male urethral, and male urine samples.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K964507