

K972904

FEB 20 1998

510(k) Summary

FEDERAL FOOD, DRUG AND COSMETIC ACT
510(k) SUMMARY
DOCUMENT MOLECULAR PATHOLOGY *CHLAMYDIA TRACHOMATIS* CONTROL

1. Submitted by: CASCO Standards
P.O. Box 970
Yarmouth, ME 04096

Attention: Christine V. Beach
Manager, Regulatory Affairs

(207) 878-7550
(207) 878-7578 FAX

February 11, 1998 (revision to June 27, 1997 submission)

2. Product Name:

Proprietary Name: DOCUMENT MOLECULAR PATHOLOGY *CHLAMYDIA TRACHOMATIS*
CONTROL

Classification Name: Control, single analyte, unassayed.

3. Predicate Device:

Negative:

Abbott LCx Chlamydia Negative Control

Positive

Urine, Human, Positive for *Chlamydia trachomatis*, as recommended in the package insert for the Abbott Chlamydia Amplification Kit.

4. Product Description: The **DOCUMENT MOLECULAR PATHOLOGY CHLAMYDIA TRACHOMATIS Control** is composed of plastic screw cap bottles, 2 mL each, containing two (2) levels of control, positive and negative, for *Chlamydia trachomatis* in a stabilized biological matrix. The formulation design provides a liquid matrix that is compatible with the Abbott Chlamydia Amplification Kit for assay on the LCx Probe System for the direct, qualitative determination of *Chlamydia trachomatis*.

5. Intended Use: This product is intended for use with the Abbott Chlamydia Amplification Kit in the Abbott LCx Probe System for the direct, qualitative determination of *Chlamydia trachomatis*.

6. Comparison to the Predicate Device:

Characteristic	DOCUMENT MOLECULAR PATHOLOGY <i>CHLAMYDIA TRACHOMATIS</i> Negative Control	Abbott LCx Chlamydia Negative Control	DOCUMENT MOLECULAR PATHOLOGY <i>CHLAMYDIA TRACHOMATIS</i> Positive Control	Urine, Human <i>Chlamydia trachomatis</i> Positive
Intended Use	Unassayed control intended for use with the Abbott Chlamydia Amplification Kit in the Abbott LCx Probe System for the direct, qualitative determination of <i>Chlamydia trachomatis</i>	Automatically assessed by LCx, in conjunction with the calibrator, to determine the validity of the analytical run	Unassayed control intended for use with the Abbott Chlamydia Amplification Kit in the Abbott LCx Probe System for the direct, qualitative determination of <i>Chlamydia trachomatis</i>	N/A
Number of Levels	One (1)	One (1)	One (1)	N/A
Type	Negative	Negative	Positive	Positive
Analytes	1	1	1	N/A
Instrument Output	Rate	Rate	Rate	Rate
Measurement	S/CO Ratio	Instrument Pre-set	S/CO Ratio	S/CO Ratio
Volume	2 mL	0.48 mL	2 mL	N/A
Matrix	Stabilized biological matrix	Buffered solution	Stabilized biological matrix	N/A
Dilution	None required	Activation	None required	None required
Unopened Stability	Until Expiration Date 12 Months	Until Expiration Date	Until Expiration Date 12 Months	N/A
Open Stability	30 Days	48 hrs. post-activation	30 Days	N/A
Container	Plastic, Screw Cap	Glass	Plastic, Screw Cap	N/A



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Christine V. Beach
Manager, QA/RA
CASCO Standards
P.O. Box 970
Yarmouth, Maine 04096-1970

FEB 20 1998

Re: K972904
Trade Name: DOCUMENT Molecular Pathology *Chlamydia*
Trachomatis Control
Regulatory Class: I
Product Codes: JJY 75, LSK 83
Dated: December 2, 1997
Received: December 5, 1997

Dear Ms. Beach:

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 [(for the indications for use stated in the enclosure)] 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.

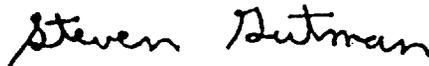
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 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 : K972904

Device Name: **DOCUMENT[®] MOLECULAR PATHOLOGY CHLAMYDIA
TRACHOMATIS[®] Control**

Indications for Use:

This product is intended for use as an unassayed control material on the Abbott LCx Probe System with the Abbott Chlamydia Amplification Kit in the qualitative determination of *Chlamydia trachomatis*.

This product is intended to serve as an unassayed control material to monitor the analytical precision of the LCR amplification system incorporated in the Abbott LCx Probe System used in conjunction with the Abbott Chlamydia Amplification Kit. Response ratios (S/CO) have been set at appropriate positive (+) and negative (-) levels.

This product is intended for *in vitro* use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the -Counter Use

(Optional Format 1-2-96)