

510(k) Summary – AMPLICOR CT/NG test for *Neisseria gonorrhoeae* with Roche Scripts for AMPLICOR CT/NG Test Accessory

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact Roche Diagnostics
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Indianapolis IN 46250
(317) 521-3723

Contact person: Theresa A Bush

Date prepared: Jan 17, 2007

Device Name Proprietary Name: AMPLICOR CT/NG test for *Neisseria gonorrhoeae*; Roche Scripts for use on the Tecan Genesis RSP 150 Workstation (Roche Scripts Accessory)

Common name: *Neisseria gonorrhoeae* test system ; software accessory

Classification name: DNA reagents, *Neisseria*

Device Description The AMPLICOR CT/NG test for *Neisseria gonorrhoeae* is a qualitative in vitro test for the detection of *N. gonorrhoeae* DNA in urine from symptomatic or asymptomatic males, in endocervical swab specimens from symptomatic or asymptomatic females, and in urethral swab specimens from symptomatic males as evidence infection with *N. gonorrhoeae*. *N. gonorrhoeae* DNA is detected by Polymerase Chain Reaction (PCR) amplification of target DNA and by hybridization capture of amplified target using the AMPLICOR analyzer.

The Roche Scripts for AMPLICOR CT/NG Test accessory consists of a compact disc (CDs) containing scripts to direct the automated Tecan Genesis RSP 150 workstation to process swab samples or control material for analysis.

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510(k) Summary, Continued

Intended use The AMPLICOR CT/NG test for *Neisseria gonorrhoeae* is a qualitative in vitro test for the detection of *N. gonorrhoeae* DNA in urine from symptomatic or asymptomatic males, in endocervical swab specimens from symptomatic or asymptomatic females, and in urethral swab specimens from symptomatic males as evidence infection with *N. gonorrhoeae*. *N. gonorrhoeae* DNA is detected by Polymerase Chain Reaction (PCR) amplification of target DNA and by hybridization capture of amplified target using the AMPLICOR analyzer.

The Roche Scripts for AMPLICOR CT/NG Test are intended to provide software scripts to direct the automated Tecan Genesis RSP 150 Workstation to process swab samples or control material for analysis using either of the following 510(k)-cleared assay test systems:

- AMPLICOR ® CT/NG test for Chlamydia trachomatis
- AMPLICOR ® CT/NG test for Neisseria gonorrhoeae

Predicate Device We claim equivalence to the currently marketed AMPLICOR CT/NG test for *Neisseria gonorrhoeae* cleared under K974503.

Comparison - similarities The table below shows the similarities between the AMPLICOR CT/NG test for *Neisseria gonorrhoeae* with optional Roche Scripts accessory and the predicate device:

Feature	Predicate Device: K974503 AMPLICOR CT/NG test for <i>Neisseria gonorrhoeae</i>	Current Device: AMPLICOR CT/NG test for <i>Neisseria gonorrhoeae</i> with optional Roche Scripts accessory
Product features		

Intended use	The AMPLICOR CT/NG test for <i>Neisseria gonorrhoeae</i> is a qualitative in vitro test for the detection of <i>N. gonorrhoeae</i> DNA in urine from symptomatic or asymptomatic males, in endocervical swab specimens from symptomatic or asymptomatic females, and in urethral swab specimens from symptomatic males as evidence of infection with <i>N. gonorrhoeae</i> . <i>N. gonorrhoeae</i> DNA is detected by Polymerase Chain Reaction (PCR) amplification of target DNA and by hybridization capture of amplified target.	Same intended use for AMPLICOR CT/NG test. Roche Scripts for AMPLICOR CT/NG Test: The Roche Scripts for AMPLICOR CT/NG Test are intended to provide software scripts to direct the automated Tecan Genesis RSP 150 Workstation to process swab samples or control material for analysis using either of the following 510(k)-cleared assay test systems: <ul style="list-style-type: none"> • AMPLICOR ® CT/NG test for Chlamydia trachomatis • AMPLICOR ® CT/NG test for Neisseria gonorrhoeae
Test principle	DNA detection via PCR amplification of target DNA followed by hybridization capture of amplified target using the AMPLICOR Analyzer	Same
Controls provided	<u>Positive control:</u> plasmid DNA from <i>N. gonorrhoeae</i> <u>Negative control:</u> plasmid DNA from <i>C. trachomatis</i> <u>Optional internal control:</u> plasmid DNA with CT primer binding regions and a unique probe binding region	Same
Labeled test performance		
Analytical specificity	Negative results from 130 bacteria, 6 fungal, 1 protozoan and 11 viral strains. Some isolates from <i>N. cinerea</i> and <i>N. subflava</i> may give false positive results.	Same

Analytical sensitivity	5 IFU/test; equivalent to 100 IFU/mL for urine specimens and 400 IFU/mL for Culture Transport Medium (CTM) with swab specimen)	Manual preparation: Same Automated preparation: 100 cfu/mL for CTM with swab specimen
Precision	100% correct results for panel of CTM specimens. Three (out of 30) negative test results for one urine panel member.	Manual preparation: Same Automated preparation: 99.4% correct results for panels of CTM specimens
Clinical performance	<u>Sensitivity vs. culture:</u> <ul style="list-style-type: none"> • 95.9 % for females • 96.5 % for males <u>Specificity vs. culture:</u> <ul style="list-style-type: none"> • 98.7 % for females • 97.3 % for males (with internal control)	Manual preparation: Same Automated preparation: 99.0% concordance with manual method

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Comparison-differences

The table below shows the differences between the AMPLICOR CT/NG test for *Neisseria gonorrhoeae* with optional Roche Scripts accessory and the predicate device:

Feature	Predicate Device: K974503 AMPLICOR CT/NG test for <i>Neisseria gonorrhoeae</i>	Current Device: AMPLICOR CT/NG test for <i>Neisseria gonorrhoeae</i> with optional Roche Scripts accessory
Specimen and control preparation options	Manual	<ul style="list-style-type: none"> • Manual • Automated preparation using the Roche Scripts to direct the Tecan Genesis RSP 150 Workstation
Specimen types	Male urine specimens; endocervical and urethral swabs	Manual: same Automated preparation: endocervical and urethral swabs only (no urine samples)

Performance evaluation

The Roche Scripts were developed and evaluated according to FDA Guidance documents.

The AMPLICOR CT/NG test for *Neisseria gonorrhoeae* with Roche Scripts accessory was evaluated for analytical performance characteristics including analytical sensitivity, cross-contamination, precision, and non-clinical specificity. Results were equivalent to those obtained with manual specimen preparation.

A clinical evaluation was performed where the results obtained using the AMPLICOR CT/NG test for *Neisseria gonorrhoeae* with automated specimen preparation using the Roche Scripts to direct the Tecan Genesis RSP 150 workstation were compared to results obtained with the manual specimen preparation method. Results were equivalent to those obtained with manual specimen preparation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Tracy M. Ambrose Bush, PhD, RAC
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Regulatory Affairs
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, Indiana 46250

APR 17 2007

Re: k070172

Trade/Device Name: AMPLICOR™ CT/NG Test for *Neisseria gonorrhoeae*; Roche
Scripts for AMPLICOR CT/NG Test (Roche Scripts Accessory)

Regulation Number: 21 CFR 866.3390

Regulation Name: *Neisseria* species, Direct Serological Test Reagents

Regulatory Class: Class II

Product Code: LSL

Dated: January 17, 2007

Received: January 18, 2007

Dear Dr. Bush:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Sally A. Hojvat". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070172

Device Name: AMPLICOR CT/NG test for *Neisseria gonorrhoeae*

Indications For Use:

The AMPLICOR CT/NG test for *Neisseria gonorrhoeae* is a qualitative in vitro test for the detection of *N. gonorrhoeae* DNA in urine from symptomatic or asymptomatic males, in endocervical swab specimens from symptomatic or asymptomatic females, and in urethral swab specimens from symptomatic males as evidence of infection with *N. gonorrhoeae*. *N. gonorrhoeae* DNA is detected by Polymerase Chain Reaction (PCR) amplification of target DNA and by hybridization capture of amplified target.

Sample and control preparation can either be accomplished manually or automated using the optional Roche Scripts for AMPLICOR CT/NG Test Accessory to direct the Tecan Genesis RSP 150 Workstation. Urine specimens are not indicated for use with the automated sample preparation option.

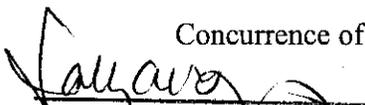
Prescription Use XXXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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Indications for Use

510(k) Number (if known): k070172

Device Name: Roche Scripts for AMPLICOR CT/NG Test Accessory

Indications For Use:

Roche Scripts for AMPLICOR CT/NG Test: The Roche Scripts for AMPLICOR CT/NG Test are intended to provide software scripts to direct the automated Tecan Genesis RSP 150 Workstation to process swab samples or control material for analysis using either of the following 510(k)-cleared assay test systems:

- AMPLICOR ® CT/NG test for Chlamydia trachomatis
- AMPLICOR ® CT/NG test for Neisseria gonorrhoeae

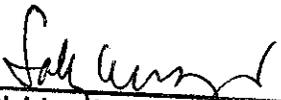
Prescription Use XXXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic
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