

# THERE'S ONLY

ONE SURE WAY

# TO CATCH

GONORRHEA AND

CHLAMYDIA.

SPECIFICITY SENSITIVITY HEALTH ECONOMICS

OVER AND OVER AND OVER AGAIN.

# The COBAS AMPLICOR CT/NG Test. The highly sensitive, specific, cost-effective assay for detecting sexually transmitted diseases.

The need for accurate, reliable chlamydia and gonorrhea screening has never been greater. Worldwide, every year, approximately 89 million people become infected with chlamydia and an estimated 62 million with gonorrhea. Many infected men and women are asymptomatic, and can infect their partners without knowing it.

To make matters worse, conventional screening methods

can fail to detect the presence of these two sexually transmitted diseases (STDs). Left untreated, they cause Pelvic Inflammatory Disease (PID) which may lead to infertility and ectopic pregnancy.

Now, with the COBAS AMPLICOR CT/NG Test, physicians and labs have the most sensitive assay that can detect chlamydia and gonorrhea at the same time—from the same sample. The Nobel Prize-winning technology, Polymerase Chain Reaction (PCR), forms the basis of the COBAS AMPLICOR CT/NG sensitivity and specificity. PCR enables the amplification of DNA from one bacterium into millions of copies, so the presence of infection can be detected even when patients are asymptomatic. By combining our AmpErase (uracil-N-glycosylase, UNG) contamination control system with the co-amplification of chlamydia, gonorrhea and the Internal Control, the COBAS AMPLICOR CT/NG Test produces reliable results and more true positives.

The COBAS AMPLICOR CT/NG Test fully automates the amplification, detection and results reporting steps to improve laboratory efficiency and assure results integrity. This assay is also available in a microwell plate (MWP) format. The MWP-based AMPLICOR CT/NG Test offers comparable performance to the automated COBAS AMPLICOR version.

The COBAS AMPLICOR CT/NG Test. It gives physicians and laboratories the benefit of fast test results—while maximizing resources. And because it provides the reliability physicians need to make confident decisions about patient treatment, it truly is the most beneficial way to catch elusive STDs. No doubt.



## SPECIFICITY

IS IT POSSIBLE FOR US TO INCREASE ASSAY SENSITIVITY WITHOUT COMPROMISING RESULTS?

POSITIVELY.



With some assays, the more sensitive they are, the more likely they are to give false positive results. That's because their sensitivity was achieved at the expense of specificity. And inaccurate results are the last thing physicians and laboratories

need when dealing with the serious public health consequences of chlamydia and gonorrhea.

Fortunately, the COBAS AMPLICOR CT/NG Test is among the exceptions. This assay provides the highest level of specificity—without a loss of sensitivity. So physicians know if their patients have one, or both, of these sexually transmitted diseases (STDs).



### SENSITIVITY

WHEN CHLAMYDIA AND GONORRHEA SYMPTOMS ARE ABSENT, WHAT SHOULD YOU LOOK FOR?

THE COBAS AMPLICOR CT/NG TEST.

Individuals who carry chlamydia and gonorrhea are often asymptomatic. Therefore, public screening has become increasingly important in preventing the spread of these



sexually transmitted diseases (STDs). That's why it's vitally important to have a sensitive assay that can detect low level infection of both these diseases—so physicians can be absolutely sure that the patient is reliably diagnosed and treated.

That's why you should always use the COBAS AMPLICOR CT/NG Test.



### HEALTH ECONOMICS

OUR CHLAMYDIA AND GONORRHEA ASSAY CAN HELP YOU MANAGE SOMETHING ALMOST AS IMPORTANT AS PATIENTS.

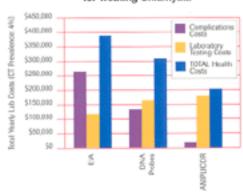
Costs.

Now, physicians and laboratories have a way to detect chlamydia and gonorrhea cases more accurately and save money in the process. With the COBAS AMPLICOR CT/NG Test.

Based on advanced, award-winning PCR technology, this

assay provides physicians and laboratories higher levels of sensitivity and specificity than other DNA probe methods. In fact, it's up to 40% more sensitive than culture tests. And because it's automated, it's far less labor-intensive to use—resulting in significant cost savings.

#### Projected Health Care Costs for Treating Chlamydia<sup>1</sup>



Wish the COBAS AMPLICOR CT/NG Test, overall health costs are significantly reduced.

#### One sample preparation. Two detections.

The COBAS AMPLICOR
CT/NG Test is the only assay
that can simultaneously detect
chlamydia and genorrhea from
a single amplification reaction.
With other assays, two or three
separate amplification reactions
are required to determine the

presence of sexually transmitted diseases (STDs). And for those who only need to detect one disease, the COBAS AMPLICOR CT/NG Test offers the option to reduce testing costs by detecting only one of the pathogens.

#### Full automation for additional savings.

The COBAS AMPLICOR
CT/NG Test is performed on the
COBAS AMPLICOR Analyzer,
which fully automates amplification, detection, and results
reporting processes. Laboratory
personnel can load up to 48
prepared samples, then walk
away and perform other tasks,
greatly improving productivity.
Full automation also allows
laboratories to get results in
as little as 4 hours, compared

to 48 hours for culture results.

This eliminates costly, timeconsuming labor while reducing
the possibility of human error.

The COBAS AMPLICOR
CT/NG Test. It's the easy-to-use
CT/NG assay that delivers
reliable results—for less.

For more information, please contact your local Roche sales representative.

A cost effectiveness analysis of 3 strategies. Howell et al., Annuals of Internal Medicine, 1998; 128:277-284.



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#### A higher degree of sensitivity for a higher degree of confidence.

The COBAS AMPLICOR
CT/NG Test utilizes polymerase
chain reaction (PCR) technology
to detect extremely low levels of
bacteria in a sample. This high
level of sensitivity reduces the
likelihood of missing a positive

result—and gives physicians real confidence in the result. Unlike other assays, the COBAS AMPLICOR CT/NG Test provides sensitivity without a reduction in specificity. And COBAS AMPLICOR CT/NG Tests can also be performed on urine samples, a sample that is far easier to collect (especially with asymptomatic patients who may be reluctant to undergo any type of testing).

# CT Performances of ROCHE versus ABBOTT<sup>1</sup> 103.0% 93.0% 93.0% 88.0% 70.0% 56.0% 56.0% 56.0% 88.0% 88.0% 88.0% 88.0% 88.0% 88.0% 88.0% 88.0% 88.0% 88.0% 88.0% 88.0% 88.0% 88.0% 88.0%

The COBAS AMPLICOR CT/NG Test gives you high levels of sensitivity and specificity without sacrificing one for the other.

#### The numbers prove it.

Recently, the Department of Pathology at Vrije Universiteit in The Netherlands conducted a study to detect chlamydia in urine samples obtained from 2,906 asymptomatic men and women. The results: COBAS AMPLICOR CT/NG produced a sensitivity level of 98.8%, compared to 78.6% for a competing assay.<sup>1</sup> COBAS AMPLICOR CT/NG also demonstrates a high sensitivity when testing for gonorrhea. For gonorrhea, our tests achieve an overall sensitivity of 95.9% and 97.3% in female and male samples, respectively.<sup>12</sup>

#### Significantly reduces false negatives.

To further ensure results integrity, the COBAS AMPLICOR CT/NG Test is the only commercially available assay that includes an Internal Control. This identifies specimens that contain inhibitors of the amplification enzyme, which is one of the reasons why nucleic acid tests don't always deliver true positive test results. Internal Control

also assures the integrity of the amplification reaction.

The COBAS AMPLICOR CT/NG Test. It's an even more reliable indicator of chlamydia and gonorrhea than the symptoms themselves.

For more information, please contact your local Roche sales representative.

Cl performances of ROCHE versus ABBOTT in an asymptomatic population. Moore, et al., Journal of Clinical Microbiology, 1999; 37:3092-3096.
 CCBAS AMPLICOR CLING Test, Method Manual.



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# CT Performances of ROCHE versus ABBOTT<sup>1</sup> 100.0% 80.0% 70.0% 50.0% CDBAS MARPICON 00.0% ADDOTT LCA 70.0% 90.7% 00.0% 00

The COBAS AMPLICOR CT/NG Test gives you high levels of sensitivity and specificity without sacrificing one for the other.

#### As close to perfect as it gets.

In recent studies the COBAS

AMPLICOR CT/NG Test exhibited specificities between 98.4% and 99.9% for male urine and 99.0% and 99.9% for female urine specimens when detecting Chlamydia trachomatis.<sup>12</sup>

#### Reduces the chances for false positives.

With the COBAS AMPLICOR
CT/NG Test, you can be sure
of the reliability of the results.
It features AmpErase (uracilN-glycosylase, UNG), a
contamination control system
that destroys deoxyuridinecontaining amplicon. With other
nucleic acid tests, this active
material could erroneously
indicate the presence of
bacteria—and give a false
positive result.

The COBAS AMPLICOR CT/NG Test. When it comes to accurate STD test results, it's a truly positive development.

For more information, please contact your local Roche sales representative.

1. CT paternances of ROCHE versus ASBOTT in an asymptomatic pepulation Moore, et al., Journal of Clinical Microbiology, JCM 1999, 17:2093-6-2. Renters Vier Der Pol, in press. Journal of Clinical Microbiology, JCM #1183-99



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