

# Free Home Chlamydia Tests Net High Return

BY BETSY BATES

LOS ANGELES — Free home swab test kits requested via the Internet have detected hundreds of cases of chlamydia, gonorrhea, and *Trichomonas* using a simple online recruitment strategy that was so effective that it is now being extended to several states.

The novel “I Want the Kit” program was devised by Johns Hopkins University

(Baltimore) researchers in 2004, alerting young women to facts about chlamydia and other sexually transmitted diseases, and offering kits with prepaid postage to allow for confidential testing. Word went out via radio, magazine, and newspaper advertisements in Baltimore initially, but soon Internet traffic began to dominate responses.

“Our original objective was to reach out to teens who might have issues with fear

and privacy going to a clinic,” Dr. Charlotte A. Gaydos said at the annual meeting of the Society for Adolescent Medicine, where she presented interim study results.

Nearly 5,000 kits have been requested to date, 97% through the study’s site, www.iwantthekit.org. About one-third of the kits were returned with vaginal swab samples collected at home, with positive chlamydia results in 10% and positive gonorrhea tests in 1%. Dr. Gaydos, professor of infectious diseases at the university, said in an interview. *Trichomonas* testing was added in 2006 and has resulted in a detection rate of 12% in 1,032 returned samples.

Dr. Gaydos reported that more than 98% of women said the instructions for collection were easy, 97% said the collection itself was easy, and 92% said they would use an Internet-based program again for STD testing.

After someone requests a kit, it arrives at her home in a plain envelope, listing as the return address only the street address of the project in Baltimore. The packet contains detailed instructions, the test swab, and return packaging—including postage. “I’m reaching out to the 14-year-old who has no money for postage and is not going to tell her mother she’s sexually active,” said Dr. Gaydos.

Completed samples can be dropped off in any mailbox and are tested by nucleic acid amplification tests for all three STDs. The test method has been found in previous research to be highly accurate—and even more so with self-collected vaginal swabs than with urine specimens. Positive test results are followed up by referrals to free treatment clinics close to the adolescents’ or women’s homes.

The researchers also were able to obtain demographic and sexual information from women who responded. A few 14-year-olds participated but none were positive for chlamydia. However, more than one-quarter of all respondents were aged 15-19 years, and they had the highest prevalence for chlamydia of any age group, at 15%.

About one-third of the respondents were aged 20-24 years. In this group, the prevalence rate was 11%. Somewhat surprising to researchers was the high rate of participation among women 25-29 years (18% of

respondents, with a prevalence rate of 7%) and those over 30 years (22% of the respondents, with a prevalence rate of 1%).

The researchers found a high rate of sexual risk among women participating in the study, with 55% reporting a history of an STD, 59% reporting more than one sex partner in the previous 90 days, 39% reporting a new partner in the previous 90 days, more than half reporting drinking before sex, 31% reporting anal sex, and 23% reporting a history of forced sex.

In a multivariate logistic regression analysis, only three factors were independently associated with a positive chlamydia test: black race versus white (odds ratio, 3.4); age less than 25 years (OR, 3.4); and having a new partner during the past 90 days (OR, 1.7).

Among all respondents (most of whom did not test positive for an STD), 62% reported at least one symptom, including vaginal discharge (48%), lower abdominal pain (17%), pain during intercourse (15%), abnormal vaginal bleeding (7%), and/or pain during urination (6%). Several audience members expressed concern about undiagnosed conditions in the population, but Dr. Gaydos assured them that the Web site makes it clear that respondents should seek medical attention in the face of symptoms and have a regular care provider.

A parallel study is ongoing for males, she said.

The “I Want the Kit” testing is currently available via the Internet to girls and young women in Maryland; West Virginia; Washington, D.C.; Denver; and some counties in Illinois. “Theoretically, this program could go anywhere in the U.S.,” she said. Every state receives Centers for Disease Control and Prevention funding for free STD testing through the CDC Infertility Prevention Program, and this strategy may reach a very high-risk group with intensive education and a means of confidentially, conveniently accessing a reliable test. Involving public health systems is critical, said Dr. Gaydos, because many commercial Internet sites offering STD tests use unreliable testing protocols. In fact, some are completely fraudulent.

Dr. Gaydos disclosed that Gen-Probe Inc. of San Diego provided free diagnostic kits for the study. ■

## Vigamox®

(moxifloxacin hydrochloride ophthalmic solution) 0.5% as base

**DESCRIPTION:** VIGAMOX® (moxifloxacin HCl ophthalmic solution) 0.5% is a sterile ophthalmic solution. It is an 8-methoxy fluoroquinolone anti-infective for topical ophthalmic use.

### CLINICAL PHARMACOLOGY:

#### Microbiology:

The following *in vitro* data are also available, but their clinical significance in ophthalmic infections is unknown. The safety and effectiveness of VIGAMOX® solution in treating ophthalmological infections due to these microorganisms have not been established in adequate and well-controlled trials.

The following organisms are considered susceptible when evaluated using systemic breakpoints. However, a correlation between the *in vitro* systemic breakpoint and ophthalmological efficacy has not been established. The list of organisms is provided as guidance only in assessing the potential treatment of conjunctival infections. Moxifloxacin exhibits *in vitro* minimal inhibitory concentrations (MICs) of 2 µg/ml or less (systemic susceptible breakpoint) against most (≥ 90%) strains of the following ocular pathogens.

#### Aerobic Gram-positive microorganisms:

<i>Listeria monocytogenes</i>	<i>Streptococcus mitis</i>
<i>Staphylococcus saprophyticus</i>	<i>Streptococcus pyogenes</i>
<i>Streptococcus agalactiae</i>	<i>Streptococcus Group C, G and F</i>

#### Aerobic Gram-negative microorganisms:

<i>Acinetobacter baumannii</i>	<i>Klebsiella pneumoniae</i>
<i>Acinetobacter calcoaceticus</i>	<i>Moraxella catarrhalis</i>
<i>Citrobacter freundii</i>	<i>Morganella morganii</i>
<i>Citrobacter koseri</i>	<i>Neisseria gonorrhoeae</i>
<i>Enterobacter aerogenes</i>	<i>Proteus mirabilis</i>
<i>Enterobacter cloacae</i>	<i>Proteus vulgaris</i>
<i>Escherichia coli</i>	<i>Pseudomonas stutzeri</i>
<i>Klebsiella oxytoca</i>	

#### Anaerobic microorganisms:

<i>Clostridium perfringens</i>	<i>Prevotella species</i>
<i>Fusobacterium species</i>	<i>Propionibacterium acnes</i>

#### Other microorganisms:

<i>Chlamydia pneumoniae</i>	<i>Mycobacterium marinum</i>
<i>Legionella pneumophila</i>	<i>Mycoplasma pneumoniae</i>
<i>Mycobacterium avium</i>	

#### Clinical Studies:

In two randomized, double-masked, multicenter, controlled clinical trials in which patients were dosed 3 times a day for 4 days, VIGAMOX® solution produced clinical cures on day 5-6 in 66% to 69% of patients treated for bacterial conjunctivitis. Microbiological success rates for the eradication of the baseline pathogens ranged from 84% to 94%. Please note that microbiologic eradication does not always correlate with clinical outcome in anti-infective trials.

**INDICATIONS AND USAGE:** VIGAMOX® solution is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms:

#### Aerobic Gram-positive microorganisms:

<i>Corynebacterium species*</i>	<i>Staphylococcus hominis</i>
<i>Micrococcus luteus*</i>	<i>Staphylococcus warneri*</i>
<i>Staphylococcus aureus</i>	<i>Streptococcus pneumoniae</i>
<i>Staphylococcus epidermidis</i>	<i>Streptococcus viridans group</i>
<i>Staphylococcus haemolyticus</i>	

#### Aerobic Gram-negative microorganisms:

<i>Acinetobacter lwoffii*</i>	<i>Haemophilus parainfluenzae*</i>
<i>Haemophilus influenzae</i>	

#### Other microorganisms:

<i>Chlamydia trachomatis</i>
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\*Efficacy for this organism was studied in fewer than 10 infections.

**CONTRAINDICATIONS:** VIGAMOX® solution is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication.

#### WARNINGS:

NOT FOR INJECTION.

VIGAMOX® solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

In patients receiving systemically administered quinolones, including moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to moxifloxacin occurs, discontinue use of the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated.

#### PRECAUTIONS:

**General:** As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and, where appropriate, fluorescein staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

**Information for Patients:** Avoid contaminating the applicator tip with material from the eye, fingers or other source.

Systemically administered quinolones including moxifloxacin have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction.

**Drug Interactions:** Drug-drug interaction studies have not been conducted with VIGAMOX® solution. *In vitro* studies indicate that moxifloxacin does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP2C19, or CYP1A2 indicating that moxifloxacin is unlikely to alter the pharmacokinetics of drugs metabolized by these cytochrome P450 isozymes.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long term studies in animals to determine the carcinogenic potential of moxifloxacin have not been performed. However, in an accelerated study with initiators and promoters, moxifloxacin was not carcinogenic in rats following up to 38 weeks of oral dosing at 500 mg/kg/day (approximately 21,700 times the highest recommended total daily human ophthalmic dose for a 50 kg person, on a mg/kg basis).

Moxifloxacin was not mutagenic in four bacterial strains used in the Ames *Salmonella* reversion assay. As with other quinolones, the positive response observed with moxifloxacin in strain TA 102 using the same assay may be due to the inhibition of DNA gyrase. Moxifloxacin was not mutagenic in the CHO/HGPRT mammalian cell gene mutation assay. An equivocal result was obtained in the same assay when v79 cells were used. Moxifloxacin was clastogenic in the v79 chromosome aberration assay, but it did not induce unscheduled DNA synthesis in cultured rat hepatocytes. There was no evidence of genotoxicity *in vivo* in a micronucleus test or a dominant lethal test in mice.

Moxifloxacin had no effect on fertility in male and female rats at oral doses as high as 500 mg/kg/day, approximately 21,700 times the highest recommended total daily human ophthalmic dose. At 500 mg/kg orally there were slight effects on sperm morphology (head-tail separation) in male rats and on the estrous cycle in female rats.

#### Pregnancy: Teratogenic Effects.

**Pregnancy Category C:** Moxifloxacin was not teratogenic when administered to pregnant rats during organogenesis at oral doses as high as 500 mg/kg/day (approximately 21,700 times the highest recommended total daily human ophthalmic dose); however, decreased fetal body weights and slightly delayed fetal skeletal development were observed. There was no evidence of teratogenicity when pregnant Cynomolgus monkeys were given oral doses as high as 100 mg/kg/day (approximately 4,300 times the highest recommended total daily human ophthalmic dose). An increased incidence of smaller fetuses was observed at 100 mg/kg/day.

Since there are no adequate and well-controlled studies in pregnant women, VIGAMOX® solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nursing Mothers:** Moxifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercised when VIGAMOX® solution is administered to a nursing mother.

**Pediatric Use:** The safety and effectiveness of VIGAMOX® solution in infants below 1 year of age have not been established.

There is no evidence that the ophthalmic administration of VIGAMOX® solution has any effect on weight bearing joints, even though oral administration of some quinolones has been shown to cause arthropathy in immature animals.

**Geriatric Use:** No overall differences in safety and effectiveness have been observed between elderly and younger patients.

#### ADVERSE REACTIONS:

The most frequently reported ocular adverse events were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing. These events occurred in approximately 1-6% of patients.

Nonocular adverse events reported at a rate of 1-4% were fever, increased cough, infection, otitis media, pharyngitis, rash, and rhinitis.

#### Rx Only

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#### References:

1. Lichtenstein SJ, Dorfman M, Kennedy R, Stroman D. Controlling contagious bacterial conjunctivitis. *J Pediatr Ophthalmol Strabismus*. 2006;43:19-26.

2. Data on file. Alcon Laboratories, Inc.

## VERBATIM

*“In bringing discussions of the economy into the examining room, you also may be providing a safe space to assess and discuss serious repercussions of family stress and hardship: depression, alcoholism, substance abuse, or domestic violence. These should always be on your radar, but perhaps even more so now.”*

Dr. Michael S. Jellinek, page 20