

Q&A with Ms. Vera Leonard,  
Chief Executive Officer of CLX Investment Company

*The following Q&A with Ms. Vera Leonard, CEO of CLX Investment Company pertains to the planned launch of Zonda's HandiLab-C test for Chlamydia. Zonda, a developer and manufacturer of unique diagnostic tests for the medical and non-medical markets, is a CLX subsidiary company. CLX and Zonda are currently preparing to initiate clinical trials for the HandiLab-C product as part of the process to achieve FDA clearance for the product.*



**Q. Zonda has several products you could bring to market, why are you focusing on chlamydia?**

A. Well, that question requires a two-part answer. I'll shorten it as best I can.

First, chlamydia is now the most frequently reported sexually transmitted disease in the United States, and the incidence is growing quickly. In 2006, more than one million cases of chlamydia were reported to the CDC. This represents a 5.6% increase over the number of cases reported in 2005. As a result, CDC has updated its guidelines to recommend that all sexually active females aged 26 or younger be tested annually for chlamydia. This is a huge market. U.S. Census estimates count more than 30 million females between the ages of 15 and 29. So, under CDC guidelines, the vast majority of this 30 million-person market should be tested for chlamydia annually.

Now here's where it gets interesting. The screening isn't happening. Why not? Because there isn't a technology or testing device currently available that would allow doctors to screen patients in a rapid, cost effective and reliable manner. Our research estimates that as much as 70% of this target population is being missed. This is a hugely underserved market!

The second part is the technology. The rapid diagnostic devices currently on the market are immunological; that is, they are based on having an antigen (in this case the chlamydia organism) in the patient specimen react with a specific antibody in the testing device. The challenge with this technology is that the ability to detect the chlamydia antigen depends on how well it is extracted from the collection swab into a testing reagent. Once the antigen is extracted from the collection swab it can be applied to the test device. It is extremely difficult, however, to extract the antigen from the swab. The current procedures require various techniques from heating the specimen for 10 minutes to repeated steps of squeezing and twisting the swab against the side of the test tube. Some products have as many as 11 steps in the testing process. One thing I learned in my years as a Medical Technologist is that the opportunity for procedural error is directly proportional to the number of steps there are in a testing process.

By comparison, the HandiLab-C test for Chlamydia is an enzyme-based technology. There are no antigens to extract. Instead the process is simple, 2-step, self-contained and complete in 15 minutes or less.

**Q. That is interesting, but isn't most chlamydia testing done in laboratories, not doctors' offices?**

A. Yes. Most chlamydia tests are conducted in a laboratory using a procedure called Nucleic Acid Amplification Test (NAAT). NAAT procedures, such as Polymerase Chain Reaction (PCR) are able to amplify a very few copies of chlamydial DNA in a specimen to an amount that can be assayed. As a result, these test procedures are the standard for chlamydia testing worldwide.

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**Q. Why is it important to test for chlamydia?**

A. In order for me to answer that question there are a few important things you need to know about how the chlamydia disease works.

1) Chlamydia is a “silent” disease. It is often asymptomatic, and the CDC estimates that 75% of infected women do not know they have it.

2) Left untreated, the infection can spread into the uterus or fallopian tubes and cause pelvic inflammatory disease (PID). This happens in up to 40 % of women with untreated chlamydia. PID can cause permanent damage to the fallopian tubes, uterus, and surrounding tissues. The damage can lead to chronic pelvic pain, infertility, and potentially fatal ectopic pregnancy (pregnancy outside the uterus). Women infected with chlamydia are up to five times more likely to become infected with HIV, if exposed. Also Women who have persistent chlamydial infection are at an increased risk of developing cervical cancer, according to a study published in November issue of the American Journal of Obstetrics and Gynecology.

3) Once diagnosed, chlamydia can be treated and cured rather easily with a single dose of azithromycin or a week of doxycycline.

So a quick summary of the situation is:

- A lot of people have chlamydia.
- Most of them don't know they have it.
- It can lead to serious complications if not treated.
- It is easy to cure if identified.
- Detection requires widespread screening.
- There is no device currently available that addresses the need for widespread screening.

We believe the HandiLab-C test for Chlamydia will meet all the criteria the medical community requires in order to implement widespread screening.

**Q. Why would a doctor use a HandiLab test instead of a nucleic acid detection method?**

There are three major reasons a doctor would use the HandiLab chlamydia test instead of a laboratory-based test:

1. The HandiLab-C test can be conducted in the doctor office, while the patient is there. This allows the doctor to provide counseling and begin treatment immediately. A lab test can take several days for the test result to be reported. In a study at the University of Alabama, only 74% of the women who tested positive returned for treatment. The median interval between diagnosis and treatment was 14 days and 3% of them had developed PID in the interval between testing and treatment.

2. Doctors generally send tests for chlamydia to laboratories because the current rapid tests are not sufficiently sensitive. We expect clinical trials to establish sensitivity for HandiLab-C that is significantly higher than current rapid tests and comparable to nucleic acid methods.

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3. In addition to a lengthy turn-around time, nucleic acid methods are expensive - costing about \$25 per test. HandiLab-C is expected to cost less than half that amount. It is important to realize that when a doctor sends a sample to a laboratory for chlamydia testing, the doctor does not receive the reimbursement from the insurance company - the lab does. With HandiLab, any reimbursement or payment will be made to the doctor, allowing the doctor to bring greater revenue into his or her practice while utilizing a test that allows the patient to be tested and treated in the same visit.

**Q. What do you anticipate the U.S. market for HandiLab Chlamydia test to be?**

A. Based on an expected price to patients of \$17 - \$18 per test, if all 30 million females in the target population were tested, the market would be \$532,200,000. We believe a realistic five-year market forecast is about \$54 million dollars.