

# *News Release*

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**LAKE CONSUMER PRODUCTS INTRODUCES FIRST,  
FDA-APPROVED OVER-THE-COUNTER AT-HOME MALE INFERTILITY  
TEST TO U.S. CONSUMERS**

***FertilMARQ™ Checks Sperm Concentration***

**Product Offers Fast, Private Analysis to Couples Trying to Conceive**

VERNON HILLS, IL, October 17, 2002—Lake Consumer Products (LCP), a provider of health and personal care products here, today announced the national launch of FertilMARQ, a revolutionary test for a problem faced annually by more than two million American men: infertility.

Soon to be available to consumers at national, regional and local drug stores, and major mass merchandise chain stores, FertilMARQ is the first, FDA-approved home diagnostic test to assess sperm concentration, one of the more important parameters for evaluating male infertility during a preliminary reproductive workup.

Developed by Dr. Juan Alvarez, now Director of the Institute of Male Infertility, Unidad de La Mujer, La Coruña, Spain, while a Professor at Harvard Medical School, the test is manufactured by Embryotech Laboratories in Wilmington, MA, and is being distributed by Lake Consumer Products. FertilMARQ allows couples trying to conceive a child to evaluate two separate semen samples in the privacy of their home. The kit includes an instruction book in English and Spanish and a “test results” form to present to a fertility specialist, if necessary, to

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facilitate a preliminary evaluation. It is the first product for men from the BabyStart™ family products, which offers a complete line of home fertility tests for women.

In September, 2001, FertilMARQ received FDA approval as a fertility diagnostic and has been available in Europe since the spring of this year. Introduced in Spain, home to its inventor, Dr. Alvarez, this April, sales already exceed 10,000 units. FertilMARQ's technology is protected by two US patents and has international patents pending worldwide.

### ***Infertility a Male Problem 40 Percent of the Time***

“FertilMARQ was created in response to a pressing need for an over-the-counter screening method for early diagnosis of male infertility that could be done privately, in the home,” said Dr. Alvarez. Though popular perception of infertility is that it is largely a woman's problem, he noted, in fact, 40 percent of infertility problems can be attributed to the male, 40 percent to the female, and 20 percent are either mutual, or cannot be explained.

“FertilMARQ's unique features—privacy and the ability to have results in less than 30 minutes—are what will attract men to this test,” noted Embryotech president Eric Dorman. “We know that FertilMARQ is going to be a valuable tool for men to get some answers about their fertility status.”

To use FertilMARQ, a man collects a semen sample and places it in a treated cup provided in the kit, where the semen will liquefy. After waiting 15 minutes, he takes the liquefied sample, combines it with a solution from the kit, and places it in a well in the test cassette. The semen solution will turn a shade of blue. By comparing the color of the semen solution in the test well to a standard reference color on the cassette, a couple can determine if the man's sperm concentration meets the minimum fertility requirement of 20 million sperm per milliliter of ejaculate established by the World Health Organization (WHO).

Dr. Alvarez explained that there are five criteria used to evaluate healthy sperm: concentration, count, morphology--the size and shape of the sperm, motility--its ability to move, and speed. “Although FertilMARQ measures sperm concentration alone, and not motility or morphology, it is known that 80 to 90 percent of semen samples with sperm concentrations below the WHO standard also have low motility and/or abnormal morphology. Therefore the test is indirectly measuring these parameters.”

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### ***Experts Agree FertilMARQ Will Help***

“A diagnosis of infertility can be a major life crisis. Couples are faced with something beyond their control that they didn’t cause and just can’t fix,” said Brookline, MA clinical social worker specializing in infertility Jeane Ungerleider, LICSW. “Generally speaking, when a couple decides to see a fertility specialist, some men are uncomfortable having to produce a sperm sample at the doctor’s office. To have the opportunity to test one’s own sperm, preliminarily, in private, and on one’s own time, can make a difference.”

According to Dr. Abraham Morgentaler, Associate Clinical Professor of Urology at Harvard Medical School and Director of Men’s Health Boston, who worked with Dr. Alvarez on the early stages of the test, “There are two critical elements in a traditional semen sample—how many sperm there are and what percent are alive. FertilMARQ addresses the first—which is, are there an adequate number of sperm to achieve a pregnancy?” A low number is a signal for a man to seek help; a number at or above the WHO standard means the couple may want to try a little longer to conceive before visiting a physician, he added.

At Village Pharmacy in Brookline, MA, which specializes in infertility, Clinical Pharmacist Patrick Carpenter noted that it is estimated that less than half the couples with fertility problems ever seek treatment. “A test for sperm concentration which provides a clear cut answer to whether a man’s sperm is greater than 20 million parts per milliliter will give a couple more information, and perhaps encourage them to seek the help of a fertility specialist.”

### **Tests Prove FertilMARQ Easy for Home User**

In tests conducted during its FDA application process, semen samples from 194 males were analyzed by both professional and home testers. The results between the two groups were the same 87 percent of the time. Home testers got the same results as professionals 141 out of 158 times when reporting positive results; home testers got the same result as professionals 27 out of 36 times when reporting negative results. Other clinical studies showed similar predictive success of approximately 88 percent.

Prior to this test, there was no effective FDA-approved, home diagnostic for the screening of male infertility. “We believe FertilMARQ’s accuracy, coupled with the ability to take the test quickly and in one’s home, provides a gentle introduction for couples to a sensitive condition

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that is largely misunderstood by the general public,” said Gary Burns, president, CEO and chairman of LCP.

With a suggested retail price of \$39.99, Walgreen’s and Eckerd are the first national chain stores to carry FertilMARQ. Regional chains such as Brooks and Longs are stocking the product, as well as a variety of local and specialty pharmacies. It is generally found in the family planning area near the pregnancy tests.

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*LCP is already a leader in the women’s health category, offering a broad range of personal care products including: BABYSTART, ovulation and pregnancy tests; VAGI•GARD, vaginal creams, douches, cleansers and deodorants; YEAST•GARD and FEMIZOL-M, yeast infection treatments; MOIST AGAIN, WONDERGEL and VAGI•GARD, vaginal moisturizers; ESTREX, for natural relief from menopausal symptoms; and Foot Fetiche Foot Pampering treatments. For further information, contact Lake Consumer Products at 1-800-537-8658 or visit their web site at [www.lakeconsumer.com](http://www.lakeconsumer.com).*

*Embryotech Laboratories specializes in male reproductive health diagnostics (MARQ™) and fresh or cryo-preserved mouse embryo and hamster ova for quality control of laboratory systems and devices. Its Embryology Laboratory offers various toxicity assays including MEA (mouse embryo assay), human sperm survival, and endotoxin testing services for ART (assisted reproductive technologies) facilities or medical-device manufacturers requiring routine quality control or regulatory accreditation.*

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