

First at-home test for vasectomized men proves to be safe, accurate

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In a report now available online and scheduled to be the cover story of the December 2008 issue of the *Journal of Urology*, University of Virginia Health System researcher John C. Herr, PhD and his colleagues have confirmed the accuracy and reliability of SpermCheck Vasectomy, the first FDA approved at-home immunodiagnostic test for detecting low concentrations of sperm.

Herr, a professor of Cell Biology and director of UVA's Center for Research in Contraceptive and Reproductive Health, discovered and patented the biomarker on which SpermCheck is based. The newly reported research consisted of a clinical trial and consumer study.

In the clinical trial, researchers used SpermCheck to evaluate a cohort of 144 post-vasectomy semen samples. The test achieved an accuracy rate of 96 percent in identifying whether sperm counts were greater or less than a threshold of 250,000 sperm per ml – a level associated with little or no risk of causing pregnancy. SpermCheck proved to be 100 percent accurate in identifying whether sperm counts were greater or less than 384,000 sperm per ml.

According to the World Health Organization Manual on Semen Analysis, normal sperm counts range from 20,000,000/ml to as high as 200,000,000/ml. When the count is below 1,000,000/ml, there is only a remote chance of achieving pregnancy without assisted reproductive techniques such as intra-uterine insemination, in-vitro fertilization and intra-cytoplasmic sperm injection.

In the consumer study of SpermCheck, 109 lay volunteers demonstrated its ease of use. Volunteers obtained the correct or expected test result in every case and achieved a 97 percent correct response rate on a 20-question survey about the test.

Herr, who is now involved in commercializing SpermCheck through a start-up company, believes the product will make it easier for men to comply with post-vasectomy monitoring. Traditionally, the process has involved bringing semen samples to a physician's office or laboratory at two- and three-month intervals after the procedure. Monitoring is important because vasectomies are not 100 percent successful, and men who have had them can experience recanalization, or the spontaneous healing or restoration of the vas deferens, which restores their fertility.

Source: University of Virginia Health System

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