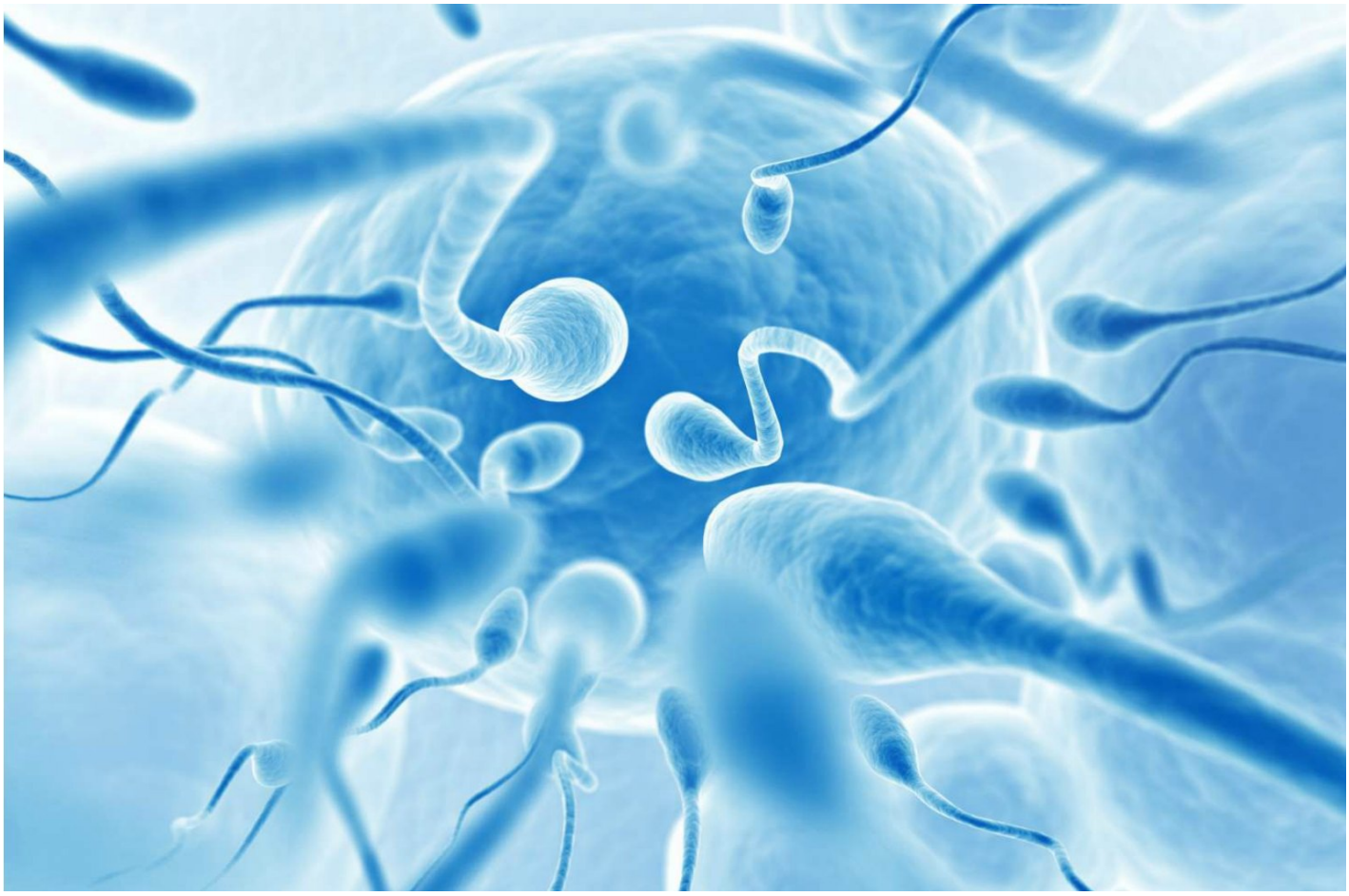
Home Test Confirms Post-Vasectomy Sterilization

University of Virginia Patent Foundation



Similar to the convenience women have with home pregnancy tests, SpermCheck® Vasectomy allows men to check their postvasectomy fertility status in the privacy of the home. The device tests sperm in the ejaculate without necessitating a trip to the physician's office or a laboratory with semen samples, as has traditionally been required to confirm sub-fertile sperm levels.

SpermCheck® Vasectomy is one of several products founded on technology developed by John C.Herr, Ph.D., professor, University of Virginia (U.Va.) Department of Cell Biology and director of the U.Va. Center for Research in Contraceptive and Reproductive Health. It is the first immunodiagnostic test to receive FDA clearance for monitoring sperm count after vasectomy.

With the at-home device, the paradigm for post-vasectomy sperm monitoring now shifts from the microscope to a simple, easy to use, highly sensitive, hand-held device that affords privacy and cost savings. "This is particularly important on a global basis where access to post-vasectomy testing is much more difficult," said Edward J.Leary,

president and CFO of ContraVac Inc. a U.Va startup company. A number of global organizations, including the World Health Organization, have expressed interest in SpermCheck® Vasectomy for this reason.

“SpermCheck® Vasectomy is the result of many years of basic scientific research coupled with clinical chemistry know-how,” said Herr. A 20-year collaboration with Stuart S. Howards, M.D., professor, U.Va. Department of Urology, began with a shared interest in studying the effect of anti-sperm antibodies. In the course of research, Howards pointed out that a simple test for sperm monitoring would be helpful. The challenge, said Herr, was to find a suitable biomarker. The interdisciplinary clinical collaboration included work with Charles J. Flicklinger, M.D., professor emeritus, U.Va. Department of Cell Biology.

The FDA approved SpermCheck® Vasectomy is based on more than a decade of research in Herr’s lab on the sperm specific protein SP-10 and its encoding gene (ACRVI). Critical experiments validated that the SP-10 protein was useful in sperm detection and quantification. The work included efforts to develop immunoreagents (monoclonal antibodies) to bind with and detect SP-10 protein so it could be quantified. A correlation was found between the concentration of SP-10 and the concentration of sperm.

SP-10 is very soluble and highly expressed, making it an ideal target for diagnostic testing. SpermCheck® Vasectomy uses monoclonal antibodies that bind specifically to the SP-10 protein to detect as little as a few nanograms of SP-10 protein present in a sample.

Calibrated to detect extremely low levels of sperm, the portable device enables a man to determine the appropriate time at which to discontinue the use of other forms of contraception. SpermCheck® Vasectomy will return accurate results indicating fertile or infertile levels seven minutes after the semen sample is added to the device.

Translational research, as was executed in developing SpermCheck® Vasectomy, is essential to bringing new developments in basic-science biomedical research to patients, said Herr. “This was a team effort involving communities of basic and clinical scientists, a start-up biotech company, angel investors, a manufacturing partner, the cooperation of donor subjects in clinical and consumer trials, excellent patent counsel, and exceptional support from the FDA, who gave early advice on the design of clinical studies.”

ContraVac and Virginia’s Commonwealth Technology Fund funded the research on incorporating antibodies into a platform and recruited patients for clinical and consumer trials. In 2004 ContraVac entered into a strategic partnership granting Princeton BioMeditech Corporation the exclusive worldwide manufacturing rights of the SpermCheck® products. PBM held patents on the diagnosticplatform, which were combined with patents held by the University of Virginia Patent Foundation.

The 17 years from cloning of the ACRVI gene to FDA approval included various levels of support by the National Institutes of Health, CONRAD, United States Agency for International Development, Virginia Commonwealth Technology Research Fund and Schering AG, Berlin (now known as Bayer Schering Pharma). During that time span, Herr, Flickinger and Howards authored more than 60 papers on related topics.

“It’s important to appreciate that there needs to be balance between basic funding and translation of discoveries,” said Herr. “Careful basic science is the foundation of innovation, and I believe applied research is the responsibility of

anyone who receives public money to do basic research." As an added benefit, Herr said it is very exciting to see "something you labored on at the bench to finally have a practical use in society."

On the flip side, Leary is grateful for the partnership agreement with U.Va. "In addition to a research agreement, U.Va. has a sperm donor program to develop and test our products."

Worldwide, approximately two million men undergo vasectomies each year. In the United States one in six men over age 35 has had a vasectomy, making vasectomy among the most popular contraceptive options among married couples, according to the National Institutes of Child Health and Human Development, a division of the National Institutes of Health.

Many studies indicate that a surprising number of men never return to their physician for postvasectomy sperm testing to confirm the success of their vasectomy. In addition, most men never bother to confirm their sterility status in the years following a vasectomy in order to monitor the occurrence of recanalization (when a vasectomy naturally heals itself resulting in fertility). A study published in the Journal of Urology, July 2005, shows that of 43,642 vasectomies, 1 in 238 resulted in failure or recanalization.

> *"The inconvenience and indignity associated with returning to the physician's office or a laboratory to supply semen samples has created an environment where nearly as many as 35 percent of men do not return for their first post-vasectomy test and 72 percent of men may fail to return for their second test.*

SpermCheck® Vasectomy can have a role in improving compliance and improving communication between patients and their physicians following a vasectomy. ContraVac recommends that testing at two different time intervals within the first three months following a vasectomy. Two consecutive negative results provide a high degree of certainty that a man is sterile. In addition, to detect possible recanalization, ContraVac recommends testing six months following a vasectomy with additional testing once per year for the first three years.

Herr said that research know-how developed in the course of creating SpermCheck® Vasectomy will be critical to the development of male birth contraceptive pills. "Availability of a sperm check test which can detect low sperm levels we hope will spur the clinical testing of male contraceptives for which a companion diagnostic test is also needed to monitor when men reach safe sperm levels." He believes there needs to be a seamless continuum between basic discovery, patenting and applied development. "Louis Pasteur said it best—there is no fundamental distinction between pure and applied science, there is only science in the cause of man."

This story was originally published in 2009.

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