



## FOR IMMEDIATE RELEASE

### **Sandstone Diagnostics Announces FDA 510(k) Clearance for the Trak® Male Fertility Testing System**

-- Integrated diagnostic and digital health tool addresses growing problem of male fertility contributing to 50% of all infertility cases<sup>1</sup> --

LIVERMORE, Calif., June 9, 2016 – Sandstone Diagnostics, a diagnostic and digital health company developing sophisticated connected wellness products that allow consumers to measure, monitor, and improve key health markers at home, announced that the U.S. Food and Drug Administration (FDA) has issued 510(k) clearance for the company's Trak Male Fertility Testing System.

"This FDA clearance represents a monumental milestone for Sandstone Diagnostics as we prepare to launch Trak as a radically new approach to personal fertility management," said Greg Sommer, Sandstone CEO. "Male infertility is a dramatically under-appreciated condition affecting millions of couples every year. Trak is a complete system that not only gives couples the ability to conveniently measure semen quality at home, but also provides digital health tools and population-based data to help men take charge of their reproductive health in a whole new way."

Data suggest that men contribute to up to half of all infertility cases, but couples currently have very few options for tackling the male half of the conception equation <sup>1</sup>. Today's standard practice of medical evaluation by clinical semen analysis done in an office setting is generally viewed as an awkward and embarrassing experience for men, which further contributes to low rates of male evaluation and treatment.

Trak, which will be available for purchase beginning October 2016, is an in-home test that allows couples to measure and track sperm count conveniently and privately as they try to conceive. The innovative design uses centrifugal force to isolate and quantify sperm cells using specially designed disposable cartridges. The system includes the Trak Engine and several disposable test kits for repeat testing.

Trak is the first device cleared by the FDA that provides semi-quantitative results, classifying sperm counts as "Low", "Moderate" or "Optimal" based on World Health Organization guidelines and clinical studies that correlate higher sperm counts with faster time to pregnancy. A fully-integrated digital health system, the Trak System pairs with the Trak mobile app (available free on Google Play, the Apple App Store and Amazon), to allow men to enter, track and compare their results to population statistics via the cloud-based community of users and clinical databases, and receive personalized feedback on lifestyle and wellness steps that may boost their sperm count.



“This is a game changer for men’s health,” said Michael Eisenberg MD, director of Male Reproductive Medicine & Surgery at Stanford University Medical Center. “Sperm count provides a window into a man’s overall health and it’s very exciting to see a technology that lowers the barrier for men to get tested, see changes and address fertility concerns. I believe with the convenience and availability of in-home testing, we are poised to improve our understanding of male fertility and empower men to better manage their health.”

## **About Sandstone Diagnostics**

Sandstone Diagnostics is a Bay Area diagnostic and digital health company developing sophisticated connected wellness products that allow consumers to measure, monitor, and improve key health markers at home. The company’s first product, the Trak® Male Fertility System, received FDA clearance in June 2016. For more information, please visit [www.sandstonediagnosics.com](http://www.sandstonediagnosics.com)

1. American Society of Reproductive Medicine (ASRM) Practice Committee. Diagnostic evaluation of the infertile male: a committee opinion. *Fertility & Sterility* 2015 Mar; 103(3):318-25.

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