

Nanostics Expands ClarityDX Prostate Clinical Study into the United States

Summary

- *Nanostics is expanding its ClarityDX Prostate clinical validation study into the US by opening the Florida-based Century Clinical Research Inc. recruitment site.*
- *US expansion will significantly accelerate the clinical study timeline and increase patient cohort diversity.*
- *US and Canadian samples will be processed and analyzed in partnership with DynaLIFE Medical Labs in Edmonton, Alberta.*
- *Funding for including US patient samples comes from the Bird Dogs for Prostate Cancer Research, Alberta Cancer Foundation, Alberta Innovates-ASBIRI and the University of Alberta.*
- *Implementing ClarityDX Prostate could dramatically improve North American men's healthcare and quality of life by eliminating 600,000 unnecessary biopsies, 24,000 hospitalizations and 50% of unnecessary prostate cancer treatments; estimated at over \$1.4B per year in healthcare cost savings.*

Edmonton, Alberta – Nanostics Inc. today announces the expansion of its pivotal clinical validation study into the United States for ClarityDX Prostate test, a novel liquid biopsy test for the early diagnosis of clinically significant prostate cancer. We are excited to announce the opening of our first clinical recruitment site in the US; with Century Clinical Research Inc., based in Daytona Beach, Florida.

The clinical validation study, co-sponsored by the Alberta Prostate Cancer Research Initiative (APCaRI), is targeting the recruitment of 2,800 patients with elevated levels of prostate specific antigen (PSA). Expansion of recruitment into the US will significantly accelerate the clinical study timeline while also increasing patient cohort diversity.

Funding support for the inclusion of US patient samples into the clinical study comes from the Bird Dogs for Prostate Cancer Research, Alberta Cancer Foundation, Alberta Innovates-ASBIRI program and the University of Alberta. The US and Canadian study samples will continue to be processed and analyzed in partnership with DynaLIFE Medical Labs in Edmonton, Alberta.

“We’re very happy to partner with Century Clinical Research to recruit US men to our study,” John Lewis, CEO of Nanostics said, “the Florida recruitment site will help us increase the regional diversity of our cohort and strengthen the results of our ClarityDX Prostate study, ultimately, allowing us to make the test available to men across North America.”

The potential impact of the ClarityDX Prostate test is considerable; implementation could eliminate up to 600,000 unnecessary biopsies, 24,000 hospitalizations and up to 50% of unnecessary treatments for prostate cancer in North America. Beyond estimated cost savings to the healthcare system of more than \$1.4B per year, this will have a dramatic impact on the healthcare experience and quality of life for men.

“Our extensive clinical trial research experience and diverse patient population in Daytona Beach makes us a perfect partner for what Nanostics requires,” said Thomas Gaskin, Vice-President & CFO of Century Clinical Research, Inc., “we look forward to working with Nanostics to develop their ClarityDX Prostate test to help improve prostate cancer outcomes.”

About Nanostics Inc.

Nanostics is a privately held company focused on the development and commercialization of novel and non-invasive diagnostic tests. Our core technology can diagnose disease from a simple blood test by combining a highly sensitive extracellular vesicle (EV) detection platform with advanced machine learning algorithms. Our novel technology is applicable to a wide range of cancers and other diseases. Our lead product, ClarityDX Prostate, is set to become the first clinically validated test using this exciting new EV detection technology.

About Century Clinical Research, Inc.

Century Clinical Research, Inc. has over ten years of clinical research experience in multiple specialties, including hematology and oncology. Our staff has successfully completed numerous industry-sponsored clinical trials in phases II-IV and has an excellent track record in quality completion of critical trials. Century Clinical Research, Inc. offers a full research infrastructure and our research staff has been trained in electronic data capture with multiple sponsors. We use a computerized clinical research program for tracking study participation and regulatory documents.

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