

PRESS RELEASE

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A3P Biomedical and BioAgilytix enter partnership for Stockholm3 in the USA

A3P Biomedical AB, a Swedish company specialized in advanced prostate cancer diagnostics, and BioAgilytix, a global bioanalytical services provider, have entered a partnership with the aim of introducing Stockholm3, as a Lab Developed Test (LDT) designed to redefine the standard of care for early detection of prostate cancer in the USA.

Prostate cancer is the most common form of cancer in American men. In 2023, it is estimated that 288,300 men will be diagnosed with, and 34,700 will die from, prostate cancer in the United States. Early detection and reduced overdiagnosis are crucial for improved treatment outcomes, decreased mortality, and better use of healthcare resources.

Recognizing the critical need for improved prostate cancer diagnostics, A3P Biomedical and BioAgilytix have joined forces to introduce Stockholm3 as a novel LDT in the US market. Stockholm3 has the potential of significantly advancing diagnostics and early detection, offering new possibilities for individuals facing a potential risk of prostate cancer.

"The partnership with BioAgilytix on Stockholm3 underscores our shared commitment to innovation. Our goal is to introduce Stockholm3 as an LDT that identifies men with increased risk of prostate cancer early and, at the same time, reduces unnecessary interventions. The US market is one of the largest in the world and would clearly benefit from implementing prostate cancer diagnostics that improves men's health and quality of life," says David Rosén CEO of A3P Biomedical.

"A3P Biomedical's dedication to precision medicine and patient-centered diagnostics fully aligns with BioAgilytix's commitment to advancing new biologic products that can change and save lives. Together, we seek to redefine healthcare by introducing breakthrough innovations that address unmet medical needs," says Linda Robbie, PhD, COO of BioAgilytix.

Stockholm3 was recently mentioned as a biomarker test in the revised 2023 American Urological Association (AUA) guidelines for early detection of prostate cancer. The AUA guidelines cite a publication (Grönberg et al. 2015, Lancet Oncology) which has shown that Stockholm3 has a higher predictive accuracy compared to PSA alone, with the advantage of reducing unnecessary biopsies. The AUA guidelines further state that clinicians may use adjunctive biomarkers, such as Stockholm3, for men with elevated PSA levels as well as after a negative biopsy when the decision to perform a re-biopsy would be affected.

A3P Biomedical AB (publ)

About BioAgilytix

As a leading global bioanalytical services organization, BioAgilytix partners to deliver complex bioanalytical projects to pharmaceutical and biotechnology organizations across all drug development phases. The company maintains compliance to: GLP, GCP, GMP, and CLIA accreditations and provides diagnostic, pharmacokinetic (PK), immunogenicity, biomarkers, and cell-based assay services, from laboratories in Durham, North Carolina; Boston, Massachusetts; San Diego, California; Melbourne and Brisbane, Australia; and Hamburg, Germany. For more information, please visit www.bioagilytix.com.

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About A3P Biomedical

A3P Biomedical's mission is to improve quality of life of men by radically increasing the precision in prostate cancer diagnostics. The company's lead product is Stockholm3, a blood test for early detection of aggressive prostate cancer. Stockholm3 has been developed by scientists at Karolinska Institutet and validated in clinical studies including more than 75,000 men. A3P Biomedical is headquartered in Stockholm, Sweden. For more information, please visit www.a3p.com

About Stockholm3

Stockholm3 is a blood test that combines protein biomarkers, genetic biomarkers, clinical data, and a proprietary algorithm, to predict the risk of aggressive prostate cancer at an early stage. In clinical practice, Stockholm3 finds 100 percent more aggressive prostate cancers and reduces unnecessary biopsies by 50 percent compared to current practice with PSA (1).

Stockholm3 has been evaluated in clinical studies with more than 75,000 men. Data from the latest pivotal study, a randomized study including 12,750 men, was published in The Lancet Oncology in 2021. The study was also awarded the European Association of Urology (EAU) "Prostate Cancer Research Award 2022". Multiple additional studies have been published in high-impact journals, including a previous study with 58,000 men, published in The Lancet Oncology in 2015 (1).

Based on robust peer-reviewed clinical data, leading Nordic healthcare providers have replaced PSA with Stockholm3. Region Värmland in Sweden has introduced general screening for prostate cancer with the help of Stockholm3 for men in the age category 50-75, who benefit from a more precise test with increased sensitivity and specificity. At the same time, healthcare providers can reduce direct costs by 17 to 28 percent (1).

[\(1\) Publications, results and clinical validation.](#)

About prostate cancer

Prostate cancer is the second most common male cancer, and the fifth leading cause of cancer related death in men worldwide. According to WHO, 1.4 million men were diagnosed with prostate cancer and 375,000 deaths were reported in 2020. Incidence of prostate cancer is expected to increase by 70 percent until 2040, driven by an aging population.

Attachments

[A3P Biomedical and BioAgilytix enter partnership for Stockholm3 in the USA](#)