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# Landmark Stockholm3 multi-ethnical trial published in top-ranked Journal of Clinical Oncology

The landmark SEPTA trial, with over 2,000 racially and ethnically diverse biopsied men recruited in the US and Canada has been published in the top ranked oncology journal, Journal of Clinical Oncology. Findings from the SEPTA trial demonstrate the utility and generalizability of Stockholm3 in reducing unneeded biopsies and detecting prostate cancer (PCa) in Asian, Black, Hispanic, and White men, representing an important improvement in the harm-benefit tradeoffs in PCa detection.

"A long-standing concern in PCa clinical trials is the limited racial and ethnic diversity, particularly relevant given the stark racial and ethnic disparities in the burden of PCa. Findings from the SEPTA trial demonstrate the utility and generalizability of Stockholm3 in reducing unneeded biopsies and detecting PCa in Asian, Black, Hispanic, and White men, representing an important improvement in the harm-benefit tradeoffs in PCa detection," Iona Cheng, PhD, MPH, Associate Editor Journal of Clinical Oncology writes in the journal.

Stockholm3 is well proven to improve prostate cancer detection for men with PSA 1.5-20 ng/ml, both in reducing unnecessary MRIs and biopsies as well as by identifying significant cancers in men with low or normal PSA values. Much of the evidence from Stockholm3 comes from Scandinavia, bringing into question the generalizability across different populations. SEPTA recruited patients from 17 different centers representing both community and academic practices with representation from Asian, Black, Hispanic and White men meeting local standards of care for biopsy in the US and Canada. In total 2,129 men underwent Stockholm3 prior to biopsy and 1,160 men were represented by non-White ethnicities (1).

The results show that the performance of Stockholm3 was nearly identical in Asian (AUC: 0.82), Black (0.82), and Hispanic (0.83) men compared to White (0.82) men. The results also show that Stockholm3 could reduce unnecessary biopsies by 45% and were consistent across different ethnicities. These results provide validation that the strong evidence built around Stockholm3 is generalizable to several populations, an important step to provide better care, while also reducing racial and ethnic disparities that exist within prostate cancer around the world.

The SEPTA trial results were presented earlier this year by Professor Scott Eggener at the ASCO-GU Cancer Symposium in San Francisco, California and are now published in the Journal of Clinical Oncology (DOI: https://doi.org/10.1200/JCO.24.00152)

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Prostate cancer is the most common form of cancer in American men. In 2024, it is estimated that 300,000 men will be diagnosed with, and 35,000 will die from prostate cancer in the United States (2). Early detection and reduced overdiagnosis are crucial for improved treatment outcomes, decreased mortality, and better use of healthcare resources.

The Stockholm3 test is available in the US at the CLIA-certified BioAgilytix Laboratory, headquartered in Durham, North Carolina. For US providers, tests can be ordered by emailing clientservices@stockholm3.com.

- Vigneswaran, H., Eklund, M., Discacciati, A., et al. Stockholm3 validation in a multi-ethnic cohort for prostate cancer (SEPTA) detection: A multicentered, prospective trial. Journal of Clinical Oncology (J Clin Oncol) Epub July 22, 2024
- Siegel RL, Giaquinto AN, Jemal A. Cancer statistics, 2024. CA Cancer J Clin. 2024 Jan-Feb;74 (1):12-49. doi: 10.3322/caac.21820. Epub Jan 17, 2024

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## About A3P Biomedical

A3P Biomedical is a company that specializes in advanced prostate cancer diagnostics. A3P's main product, Stockholm3, is a clinically and commercially validated blood test for early detection and risk stratification of aggressive prostate cancer. A3P Biomedical is headquartered in Stockholm, Sweden. For more information, please visit www.a3p.com

## About Stockholm3

Stockholm3 is a blood-based test, that runs a combination of protein biomarkers, genetic biomarkers and clinical information through an algorithm to find the probability of clinically significant cancer at biopsy. Using Stockholm3 leads to a more accurate risk assessment than the current PSA standard. Stockholm3 detects 40-90% more men with aggressive prostate cancer and, at the same time, reduces over-detection by 40-50% compared to PSA.

Stockholm3 has been evaluated in clinical studies including more than 90,000 men. The studies address both the specificity and sensitivity of Stockholm3 in multi-ethnic populations as well as health-economic benefits of implementing it in clinical care. Multiple studies have been published in high-impact journals such as The Lancet Oncology, Journal of Clinical Oncology, and European Urology. For more information about our clinical studies please visit www.a3p.com.

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#### About prostate cancer

Prostate cancer is the most common cancer in men. In 2020, the global incidence of new prostate cancer cases was 1.4 million, and prostate cancer specific mortality 370,000. Global prostate cancer incidence and mortality is expected to rise by 100% and 85% respectively by 2040, driven by an ageing population.

## Attachments

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