NZX/ASX Announcement

1 May 2025

Published Saudi Arabia study confirms TruScreen's high sensitivity and specificity compared to pap smear

TruScreen Group Limited (NZX/ASX:TRU) is pleased to share that the preliminary publication in July 2024 of a Saudi Arabia study investigating TruScreen's performance versus pap smears in cervical cancer detection, has now been peer reviewed and published by globally renowned BMC Women's Health.

The study, entitled "Beyond Tradition: Investigating TruScreen's Performance Versus Pap Smear in Cervical Cancer Detection" [1] tested 507 women and was first published on Research Square1 Link on 25 July 2024. Results showed that TruScreen demonstrated:

- High Sensitivity: Truscreen 83.3%, compared to Pap Smear 66.7%
- High Specificity: Truscreen 95%, compared to Pap Smear 98.2%

The authors concluded that TruScreen "represents a reliable, practical screening tool for cervical neoplasms" and that their results "provide an evidence-based approach for policymakers when selecting the optimal cervical cancer screening strategy in countries without an established national screening program."

BMC's peer review[2] outlines TruScreen's "potential as a screening tool for cervical neoplasms" and also highlights that "the tool did not require cervical samples, laboratory equipment, or highly trained personnel." Further research is encouraged.

BMC Women's Health is an open access, peer-reviewed journal that considers articles on all aspects of the health and wellbeing of adolescent girls and women, with a particular focus on the physical (including gynecological diseases), mental, and emotional health of women in developed and developing nations.

This announcement has been approved by the Board.

ENDS

1. Majed Alhudhud, Shazia Maqsood, Maab El Hussein et al. Beyond Tradition: Investigating TruScreen's Performance Versus Pap Smear in Cervical Cancer Detection, 25 July 2024, PREPRINT (Version 1) available at Research Square [https://doi.org/10.21203/rs.3.rs-4638793/v1]
2. Alhudhud, M., Maqsood, S., Hussein, M.E. *et al.* Cervical cancer screening: a comparative study of TruScreen vs. Pap Smear. *BMC Women's Health* **25**, 198 (2025). https://doi.org/10.1186/s12905-025-03733-z

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For more information, visit www.truscreen.com or contact:

Martin Dillion
Chief Executive Officer
martindillon@truscreen.com

Guy Robertson
Chief Financial Officer
guyrobertson@truscreen.com

About TruScreen:

TruScreen Group Limited (NZX/ASX: TRU) is a medical device company that has developed and manufactures an AI-enabled device for detecting abnormalities in the cervical tissue in real-time via measurements of the low level of optical and electrical stimuli.

TruScreen's cervical screening technology enables cervical screening, negating sampling and processing of biological tissues, failed samples, missed follow-up, discomfort, and the need for costly, specialised personnel and supporting laboratory infrastructure.

The TruScreen device, TruScreen Ultra®, is registered as a primary screening device for cervical cancer screening.

The device is CE Marked/EC certified, ISO 13485 compliant and is registered for clinical use with the TGA (Australia), MHRA (UK), NMPA (China), SFDA (Saudi Arabia), Roszdravnadzor (Russia), and COFEPRIS (Mexico). It has Ministry of Health approval for use in Vietnam, Israel, Ukraine, and the Philippines, among others and has distributors in 23 countries. In 2021, TruScreen established a manufacturing facility in China for devices marketed and sold in China, with the "Made in China" registration.

TruScreen technology has been recognised in CSCCP's (*Chinese Society for Colposcopy and Cervical Pathology*) China Cervical Cancer Screening Management Guideline.

TruScreen has been recognised in a China Blue Paper "Cervical Cancer Three Stage Standardized Prevent and Treatment" published on 28 April 2023, by COGA (*Chinese Obstetricians and Gynaecologists Association)*.

In financial year 2023 alone, over 140000[1] examinations have been performed with TruScreen device. To date, over 200 devices have been installed and used in China, Vietnam, Mexico, Zimbabwe, Russia, and Saudi Arabia. TruScreen's vision is "A world without the cervical cancer"©.

To learn more, please visit: www.truscreen.com/.

[1]*Based on Single Use Sensor sales.*

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Glossary:

Pap smear (the Papanicolaou smear) test involves gathering a sample of cells from the cervix, with a special brush. The sample is placed on a glass slide or in a bottle containing a solution to preserve the cells. Then it is sent to a laboratory for a pathologist to examine under a microscope. https://www.cancer.net/navigating-cancer-care/diagnosing-cancer/tests-and-procedures/pap-test

LBC (the liquid-based cytology) test, transfers a thin layer of cells, collected with a brush from the cervix, onto a slide after removing blood or mucus from the sample. The sample is preserved so other tests can be done at the same time, such as the human papillomavirus (HPV) test https://www.cancer.net/cancer-types/cervical-cancer/diagnosis

HPV (human papilloma virus) test is done on a sample of cells removed from the cervix, the same sample used for the Pap test or LBC. This sample is tested for the strains of HPV most commonly linked to cervical cancer. HPV testing may be done by itself or combined with a Pap test and/or LBC. This test may also be done on a sample of cells which a person can collect on their own. https://www.cancer.net/cancer-types/cervical-cancer/screening-and-prevention

Sensitivity* and *specificity mathematically describe the accuracy of a test which reports the presence or absence of a condition. If individuals who have the condition are considered "positive" and those who don't are considered "negative", then sensitivity is a measure of how well a test can identify true positives and specificity is a measure of how well a test can identify true negatives:

- **Sensitivity** (true positive rate) is the probability of a positive test result, conditioned on the individual truly being positive.
- **Specificity** (true negative rate) is the probability of a negative test result, conditioned on the individual truly being negative (Sensitivity and specificity – Wikipedia).

For more information about the cervical cancer and cervical cancer screening in New Zealand and Australia, please see useful links:

New Zealand: National Cervical Screening Programme | National Screening Unit (nsu.govt.nz)
Australia: Cervical cancer | Causes, Symptoms & Treatments | Cancer Council