



truscreen
a world without
cervical cancer

NZX/ASX Announcement

5 August 2024

TruScreen Cervical Cancer Screening Test Outperforms traditional Pap Smear in Saudi Arabia Study

Highlights

- 507 women tested from 2021-2022, results published in July 2024
- High Sensitivity and Specificity: TruScreen demonstrated a sensitivity of 83.3% and a specificity of 95% for detecting cervical lesions (neoplasms), compared to 66.7% and 98.2% for Pap smear, respectively¹.
- Real-Time Results: The TruScreen device provides immediate screening results, eliminating the need for laboratory equipment and pathology staff.
- Practical and Reliable: The study confirmed that TruScreen is a practical and reliable screening tool, suitable for use in various healthcare settings.

TruScreen Group Limited (NZX/ASX:TRU) is pleased to announce the preliminary publication, on 25 July 2024, of a study titled “Beyond Tradition: Investigating TruScreen’s Performance Versus Pap Smear in Cervical Cancer Detection” on Research Square¹ [Link](#). The preliminary publication is subject to peer review.

	TruScreen	Pap Smear	Combined Pap + TruScreen
Sensitivity	83.3%	66.7%	100%
Specificity	95%	98.2%	99.8%

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.”

This study reinforces TruScreen’s commitment to providing innovative and accessible healthcare solutions. The positive results validate TruScreen’s technology and opens new opportunities in the global healthcare market.

For more information, please visit our website at www.truscreen.com.

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>]

This announcement has been approved by the Board.



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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 29 countries. In 2021, TruScreen established a manufacturing facility in China for devices marketed and sold in China.

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.

In Dec 2023 TruScreen technology was added to the Vietnam Ministry of Health approved National Technical List, for use in Vietnam's public and private healthcare sectors

In financial year 2024 alone, over 200,000* 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/.

**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](#)

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