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NZX/ASX Announcement

9 Mar 2026

Sichuan University clinical study confirms superiority of TruScreen + hr-HPV co-testing

- **A 297-patient study was published and peer-reviewed in Journal of Sichuan University**
- **TruScreen combined with hr-HPV testing confirmed superior performance in cervical cancer screening compared with Thinprep cytology test (TCT) combined with hr-HPV test**
- **Study provides further validation for the use of Dalton BioSciences HPV IVD test with TruScreen's opto-electronic technology for distribution through TruScreen's global distribution network**

TruScreen Group Limited (NZX/ASX: TRU) ("TruScreen" or "the Company"), a global leader in AI-enabled cervical cancer screening, advises that an independent clinical study comparing TruScreen with Thinprep cytology test (TCT) and in combination with high-risk human papillomavirus (hr-HPV) testing, has been published and peer-reviewed in *Journal of Sichuan University (Medical Science Edition)*.

The study can be accessed in *Journal of Sichuan University* here: TruScreen联合高危HPV检测与液基细胞学联合HPV检测在宫颈癌筛查中的对比研究, or on PubMed here:

https://pubmed.ncbi.nlm.nih.gov/40964107/

The study, titled *"TruScreen Combined With High-Risk Human Papillomavirus Testing vs Thinprep Cytology Test Combined With High-Risk Human Papillomavirus Testing for Cervical Cancer Screening: A Comparative Clinical Study",* screened 297 women (21 to 57 years old) at Panzhihua Central Hospital between June 2020 and December 2023.

The primary objective was to compare the diagnostic performance of **TruScreen + hr-HPV co-testing**, and **TCT + hr-HPV co-testing,** for the detection of low-grade squamous intraepithelial lesion positive (LSIL+) and high-grade squamous intraepithelial lesion positive (HSIL+) cervical lesions.

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Results

- Histopathology identified 128 LSIL+ cases (43.10%) and 67 HSIL+ cases (22.56%) in the study
- **TruScreen + hr-HPV achieved a significantly higher area under the ROC curve (AUC)** than TCT + hr-HPV for both LSIL+ and HSIL+ ($P < 0.05$).
- TruScreen + hr-HPV delivered **high sensitivity for HSIL+ lesions with improved specificity and negative predictive value** compared with TCT + hr-HPV.
- Overall, **TruScreen + hr-HPV showed superior diagnostic performance and accuracy** versus the cytology-based co-testing algorithm.

The authors concluded that:

> *"TruScreen combined with hr-HPV demonstrates superior performance in cervical cancer screening compared with TCT combined with hr-HPV test and may serve as an alternative to conventional cytology-based methods in China."*

Strategic and clinical significance

This publication adds to TruScreen's expanding clinical evidence base, which now comprises more than 30 trials and large studies involving over 40,000 women worldwide. The findings are consistent with the Company's larger clinical evaluations, including the landmark **COGA study of 14,982 women** – the world's largest opto-electronic cervical cancer screening study - published in February 2026 in Germany's *BMC Cancer* and **confirming TruScreen's superiority as a primary screening tool compared with liquid-based cytology and hr-HPV testing.**

This 297-patient study provides additional evidence in support of **TruScreen + hr-HPV co-testing strategies**, demonstrating performance advantages over TCT + hr-HPV while utilising TruScreen's real-time, point-of-care, AI-enabled technology that does not require cytology laboratories or specialist cytologists.

TruScreen Executive Chairman Tony Ho comments:

> *"These results continue to support TruScreen's suitability for integration into cervical cancer screening initiatives globally, particularly in markets where access to pathology infrastructure is limited. They also further validate the company's strategic partnership with Dalton BioSciences, a leading Chinese manufacturer of HPV test kits, to distribute HPV IVD products through TruScreen's global distribution network."*

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This announcement has been approved by the Board.

Ends

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

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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 is recognised in CSCCP's (Chinese Society for Colposcopy and Cervical Pathology) China Cervical Cancer Screening Management Guidelines and the COGA Blue Book.

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 and in 2024 was added to the Russian guidelines for the screening of cervical cancer.

In financial year 2024 alone, over 200,000* examinations were performed with the 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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About DaltonBio:

DALTON BioSciences ("DALTONbio") is a global, innovative medical technology company focusing on in vitro diagnosis (IVD) in women's health and oncology. DALTONbio is the leader in human papillomavirus (HPV) nucleic acid testing and comprehensive cervical cancer detection and screening. Its HPV DNA detection kits (DH HPV test series) are the world's only products based on its third-generation proprietary hybrid-capture technology, which provides HPV genotyping without requiring nucleic acid extractions and amplifications. This technology is well-suited for the detection of high-risk types of HPV and cervical cancer screening. DALTONbio's exceptional, clinically proven products have served tens of millions of lives in the world. They have aided health professionals in detecting, diagnosing, and treating illnesses earlier and more effectively, resulting in healthier people everywhere, every day.
To learn more, please visit: www.daltonbio.com/.

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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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