NZX/ASX Announcement

11 Feb 2026

TruScreen validated as Superior Primary Screening Tool by World's largest Opto-Electronic Cervical Cancer Screening Study

- **Landmark Chinese Obstetricians and Gynaecologists Association (COGA) clinical study results have been published by leading journal BMC Cancer and Springer Nature Link**
- **The 2018-2021 study, conducted in 64 hospitals, across 9 Provinces with 14,982 women, validates TruScreen as a superior primary cervical cancer screening tool over Liquid Based Cytology (LBC) and high-risk Human Papillomavirus (hrHPV) testing**
- **The trial is the largest ever study of opto-electronic screening conducted internationally, and is a significant milestone for TruScreen and the global cervical cancer screening community**

TruScreen Group Limited (NZX/ASX: TRU), ("TruScreen" or "the Company"), a global leader in AI-enabled cervical cancer screening, is pleased to announce the publication of the largest ever study of opto-electronic screening conducted, validating TruScreen as a superior primary cervical cancer screening tool.

The study - ***"A real-world multicenter study on opportunistic cervical cancer screening in hospital in China: comparison of TruScreen device, cytology, and HPV testing for detecting high-grade cervical lesions"*** – was conducted by the Chinese Obstetricians and Gynaecologists Association (COGA) from 2018-2021, in 64 teaching hospitals across 9 provinces in China, with 14,982 women.

The full study, published by BMC Cancer, can be viewed on Springer Nature here: https://link.springer.com/article/10.1186/s12885-026-15590-6.

A summary of the GOGA study was previously presented by Professor Chen Fei at the American CSCCP conference in San Diego in April 2022. The major study was published after independent peer reviews.

The study compared TruScreen against Liquid Based Cytology (LBC) and high-risk Human Papillomavirus (hrHPV) testing for the detection of cervical intraepithelial neoplasia grade 2 or higher (CIN2+).

The results for detection of severe pre-cancerous lesions - cervical intraepithelial neoplasia (CIN) grade 2 and 3 showing superior sensitivity (the detection of true positives) and negative predictive value (the absence of disease) to LBC and comparable to HPVDNA as shown below

	TruScreen	LBC	HPV DNA
CIN 2 Sensitivity	**87.0%**	**66.4%**	**91.9%**
CIN 2 Negative Predictive Value	**93.3%**	**83.5%**	**91.9%**
CIN 3 Sensitivity	**90.0%**	**62.7%**	**91.3%**
CIN 3 Negative Predictive Value	**97.9%**	**92.4%**	**96.4%**

The study's authors concluded that

"Truscreen has the highest AUC (area under curve) for both CIN2+(0.72) and CIN3+(0.70), indicating it was the most accurate test overall...*. The robust performance of the TS [TruScreen] test - validated against pathological findings in this study - provides solid data for future research in primary health centers and remote rural areas. This study demonstrates that the TruScreen (TS) test exhibits sensitivity, PPV, and RR comparable to hrHPV testing, supporting its* ***potential integration into cervical cancer (CC) screening programs in China...."***

China is TruScreen's largest market, with an estimated 476 million women of screening age.* TruScreen has been included in the Chinese Society for Colposcopy and Cervical Pathology (CSCCP) guidelines and the Chinese Obstetricians and Gynaecologists Association (COGA) Blue Book since 2024. The Blue Book sets out a clinical reference guideline that summarises expert consensus, best-practice recommendations, and treatment standards for a specific area of women's health care.

Following this landmark publication:

- The CSCCP will be issued with an 'Expert Consensus for TruScreen' and be requested to include this in the next update to its guidelines.
- The 2nd edition of the COGA Blue Book is due to be published in 2026 and these results will reinforce the current TruScreen reference
- The clear reference to TruScreen's **"potential integration into screening programs"** will be impressed upon public health officials responsible with the conduct of major public screening programs in our largest market.

The publishing of these results by an internationally respected journal, the Springer BMC Cancer journal and the higher re-rating of TruScreen's inclusions in the CSCCP and COGA guidelines will reiterate the medical efficacy and application of TruScreen's technology over conventional screening methods to our China and global distributors. TruScreen has also been collaborating with a number of emerging markets to assist them with their development of public screening programs.

A recent review of 202 countries and territories estimated that the 5-year screening coverage in women aged 30–49 years was only 32%, with substantial disparities between high-income countries (HICs) and low- and middle-income countries (LMICs) (77% vs 24%).** The World Health Organization's target is 70% screening coverage by 2030 – **meaning there is a major screening gap which TruScreen is well suited to help close.**

TruScreen CEO Marty Dillon comments:

> *"This publication represents a major highpoint and a milestone for TruScreen and our efforts to significantly lift screening rates globally to support WHO's strategy to eliminate cervical cancer. TruScreen's superiority as a primary screening method proven on such a large scale, together with the device's particular suitability for emerging markets with low pathology infrastructure settings (where cytology and HPV DNA based screening is impractical), makes TruScreen ideal to lead screening programs as an alternative to conventional laboratory and infrastructure dependent methods."*

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* CIA World Factbook

** Bruni L, Serrano B, Roura E, et al. Cervical cancer screening programmes and age-specific coverage estimates for 202 countries and territories worldwide: a review and synthetic analysis. Lancet Glob Health. 2022;10:e1115–27. doi: 10.1016/S2214-109X(22)00241-8. [DOI] [PMC free article] [PubMed] [Google Scholar]

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This announcement has been approved by the Board.

Ends

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

Martin Dillon
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 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 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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Glossary:

Pap test/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/TCT (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 is a virus and is short for human papillomavirus and are a group of more than 200 related viruses. Each **HPV type** has a number. For example, HPV 6, HPV 11, HPV 16, and HPV 18 are just 4 types of HPV that a person might have. https://www.cancer.org/cancer/risk-prevention/hpv/what-is-hpv.html

HPV DNA is the genetic material of the human papilloma virus.

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 An HPV test looks for cervical HPV infection. It detects high-risk types of HPV that are more likely to cause precancers and cancers of the cervix. But an HPV test cannot detect precancer or cancer itself. https://www.cancer.org/cancer/risk-prevention/hpv/hpv-and-hpv-testing.html

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