NZX/ASX Announcement

11 November 2024

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Report published by leading research journal, Germany's Springer Nature concluded that TruScreen cervical cancer screening results were comparable and even better (for patients with type 3 TZ) than conventional LBC (Liquid based Cytology)

Highlights

- **Evaluation of a real-time optoelectronic method for the detection of cervical intraepithelial neoplasia and cervical cancer in patients with different transformation zone (TZ) types**
- **A cohort of 1,908 women aged 34.0±7.3 years who have received cytology (LBC), human papillomavirus (HPV) testing, TruScreen, and colposcopy were evaluated**
- **TruScreen detection accuracy was comparable to liquid-based cytology (LBC and performs even better in patients with type 3 TZ**

TruScreen Group Limited **(NZX/ASX: TRU)** is pleased to advise the publication of "Evaluation of a real-time optoelectronic method for the detection of cervical intraepithelial neoplasia and cervical cancer in patients with different transformation zone types" conducted by Dr Fengyi Xiao & Professor Long Sui from The Cervical Diseases Centre, Obstetrics and Gynaecology Hospital of Fudan University, Shanghai, China. The study evaluated the diagnostic value of TruScreen, a real-time diagnostic technology, for cervical lesions in patients with different transformation zone (TZ) types.

Full report can be downloaded from the below link.

https://www.nature.com/articles/s41598-024-78773-w

The Obstetrics and Gynaecology Hospital of Fudan University study concluded that TruScreen optoelectronic real time screening detection accuracy was comparable to liquid-based cytology (LBC) and outperformed in patients with type 3 TZ.

The publication of the Fudan University's study results reiterated the COGA (Chinese Obstetricians and Gynaecologists Association) large scale clinical trial of 15,661 patients conducted across 9 China Provinces over 3 years, that determined TruScreen to be a simple, effective and rapid real-time method to screen for cervical cancer. The COGA trial results highlighted the superiority of TruScreen against alternative screening methods as well as the potential benefits of a TruScreen-HPV co-testing ***(see NZX/ASX announcement 05 April 2022).***

The Fudan University patient cohort have received cytology, human papillomavirus (HPV) testing, TruScreen, and colposcopy. The clinical performances of these tests were evaluated for their detection of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma in situ (AIS), or more severe lesions in patients with different TZ types.

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The results of the study found:

- TruScreen's sensitivity[1] **(65.08%)** was higher to that for LBC **(57.14%),**
- TruScreen's specificity[2] **(64.76%)** was similar to that of LBC **(64.47%).**

For patients with type 3 TZ, TruScreen results outperformed LBC

- TruScreen's sensitivity[3] **(72.29%)** was higher to that for LBC **(65.06%),**
- TruScreen's specificity[4] **(67.39%)** was higher to that of LBC **(64.29%).**

Martin Dillon, CEO said: *"The Fudan University study by Dr Fengyi Xiao and Professor Long Sui affirms the TruScreen AI enabled optoelectronic cervical cancer screening technology. As member nations of the World Health Organisation embrace the WHO's objective of eliminating cervical cancer by the end of the century, TruScreen real time screening technology is a vital medical device to support the global task of achieving WHO's strategy.*

The TruScreen real time technology does not require expensive pathology infrastructure and is the screening technology of choice for countries with regional areas with limited access to pathology laboratory testing infrastructure and qualified clinicians to interpret the results." "TruScreen is approved and on the national cervical cancer screening guidelines of China and Russia, and on the national Technical List of Vietnam's MoH and Cofepris of Mexico for use in the public health sector. Several countries are currently evaluating TruScreen for inclusion into its national screening guidelines"

This announcement was approved for release by the Board.

-ENDS-

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[1] **Sensitivity** measures correctly a positive result for patients who have the condition that is being tested for (also known as the "true positive" rate). A test that is highly sensitive will indicate patients who have the disease.

[2] **Specificity** measures correctly a negative result for people who do not have the condition that is being tested for (also known as the " true negative" rate). A high-specificity test will correctly rule out patients who do not have the disease.

[3] **Sensitivity** measures correctly a positive result for patients who have the condition that is being tested for (also known as the "true positive" rate). A test that is highly sensitive will indicate patients who have the disease.

[4] **Specificity** measures correctly a negative result for people who do not have the condition that is being tested for (also known as the " true negative" rate). A high-specificity test will correctly rule out patients who do not have the disease.

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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 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