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US news

FDA approves first at-home test for cervical cancer screening

Teal Health offers alternative to pap smear tests that need to be undertaken at a doctor's office, slated for June rollout

Reuters

Fri 9 May 2025 20:15 BST

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 Teal Health's Teal Wand self-collection device for at-home cervical cancer screening. Photograph: Nicole Morrison

The US Food and Drug Administration (FDA) has approved the first at-home test for cervical cancer screening, its maker Teal **Health** said on Friday,

Pap smear tests have significantly reduced cancer incidence from when they were first introduced 80 years ago. But they can be uncomfortable and inconvenient owing to the requirement for an in-clinic exam.

Teal Health said the FDA's decision was based on a study in more than 600 women that showed self-collected samples using its test had the same performance as clinician-collected samples.

The approval is “not just about an innovative new product, it's about finally giving women an option that makes sense for their lives, something that can be done quickly and comfortably at home”, said Teal's co-founder and chief executive, Kara Egan.

Each year in the US, about 11,500 new cases of cervical cancer are diagnosed and about 4,000 women die of the disease, according to the Centers for Disease Control and Prevention (CDC).

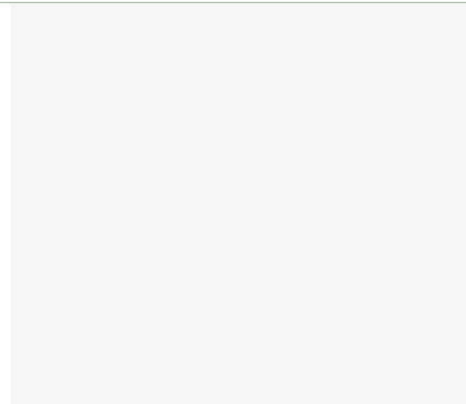
The startup company's test, Teal Wand, detects human papillomavirus (HPV), which is responsible for nearly all cervical cancers, similar to Roche's cobas HPV test. But Teal Wand allows women to collect samples from home and send it to a certified lab for testing, while Roche's test is approved for use in the clinic.

Teal Health did not disclose the test's price, but said it was working with major insurance providers for coverage and flexible payment options.

Egan pointed to another at-home test called Cologuard, made by Exact Sciences, to detect colon cancer.

“Cologuard [is] fully covered by most insurance, but also, if you have to pay out pocket, it's around \$600. We plan to be less than that,” she told Reuters.

Teal Health plans to begin rolling out the kits in June for patients aged 25 to 65.



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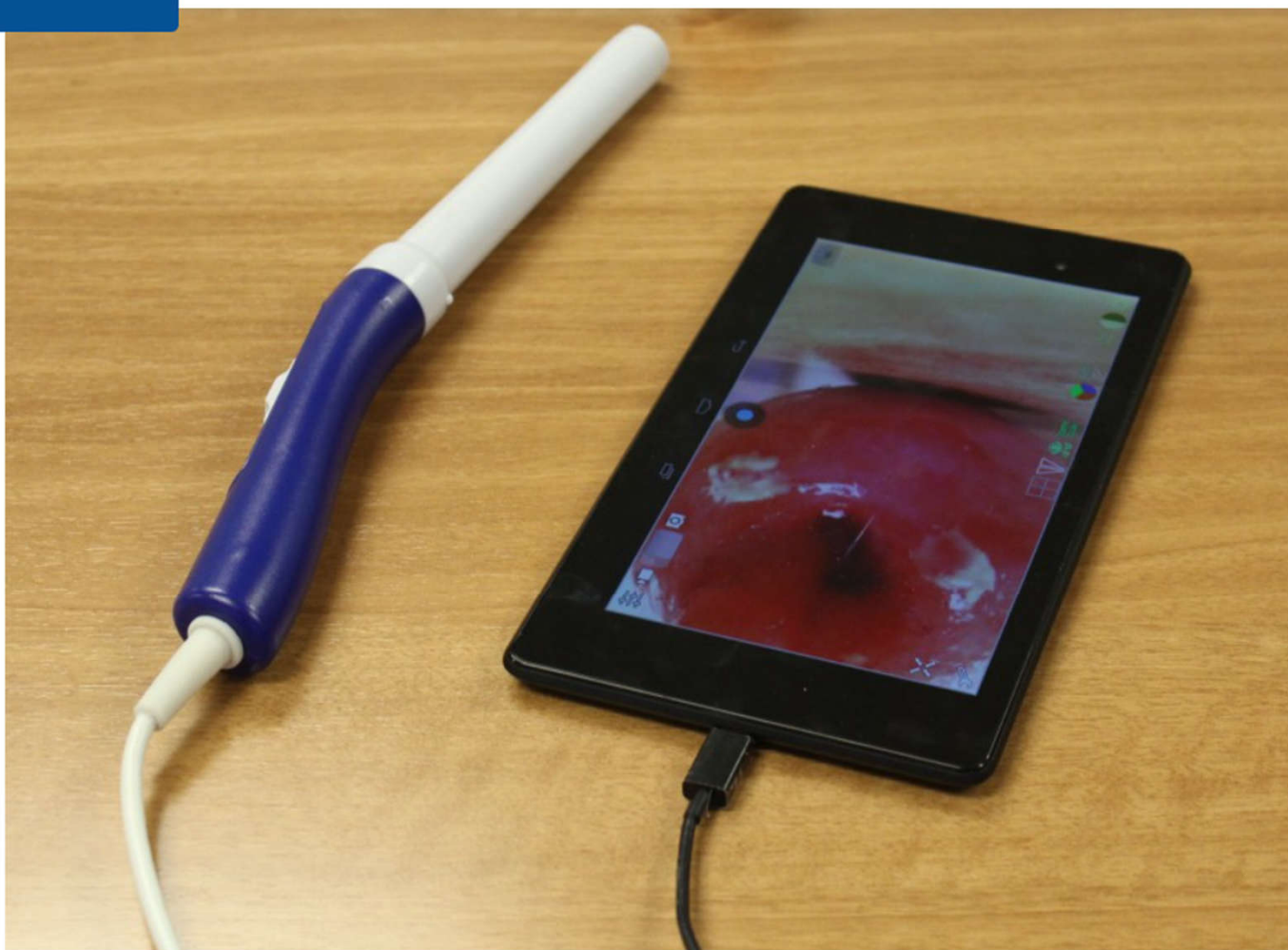
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A Randomized Clinical Trial Comparing Visual Inspection with Acetic Acid (VIA) to Pocket Colposcopy for the Triage of HPV+ women living with HIV in Kisumu, Kenya

 Mary E. Dotson,  Eliza Steinberg,  Maria Olivia Santos, Jeniffer Ambaka, Megan Huchko, Nimmi Ramanujam

doi: <https://doi.org/10.1101/2024.11.05.24316753>

This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.

Abstract

Full Text

Info/History

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Abstract

Objective The World Health Organization recommends a “screen, triage, treat” approach for cervical cancer screening for Women Living with HIV (WLWH) in resource-limited settings, with Human Papillomavirus (HPV) testing preferred for screening. We assessed the use of the Pocket colposcope as an adjunct tool to

Methods We carried out a randomized clinical trial across six clinics in Kisumu, Kenya between November 2022 and April 2023 (NCT04998318). WLWH who screened positive with self-collected HPV were randomized to either the VIA or Pocket arm. Exam positivity was determined by presence or absence of aceto-white epithelium (AWE). Directed biopsies were performed on AWE; if negative, two random biopsies were taken. Pathology was used to determine diagnostic accuracy. Providers and participants took brief surveys after each exam.

Findings The rate of a positive exams was 17.3% for VIA compared to 14.3% for the Pocket. The overall rate of CIN2/3 was 15.4%, with 12.2% in the VIA Arm and is 18.8% in the Pocket Arm. Pocket and VIA performed comparably on all sensitivity, specificity and negative predictive value (NPV). For Pocket compared to VIA, Sensitivity was 26.3% vs 25.0%; specificity was 88.9% vs 84.0%; and NPV was 82.9% vs 87.1%. However, the positive predictive value (PPV) of the Pocket colposcope arm was almost a factor of two higher than that of the VIA arm (Pocket arm PPV was 37.5% and that of the VIA arm was 20.6%). The Pocket Colposcope was acceptable to providers and patients for clinic-based triage of HPV positivity.

Conclusion Provider assessment with the Pocket colposcope detected significantly more treatable disease, thereby reducing the need for overtreatment. This study indicates that the Pocket colposcope is a feasible, lower cost colposcopic device, which could facilitate biopsy-confirmation of disease, increase provider training, patient education and facilitate remote diagnosis.

FDA clears Genius Digital Diagnostics System for cervical cancer screening

February 2, 2024

By Celeste Krewson, Assistant Editor

News

Article



Hologic's Genius Digital Diagnostics System, the first FDA-cleared digital cytology system using AI and advanced imaging, promises improved sensitivity in detecting pre-cancerous lesions and cervical cancer cells.

The FDA has provided clearance to the Genius Digital Diagnostics System for identifying pre-cancerous lesions and cervical cancer cells, according to Hologic Inc.

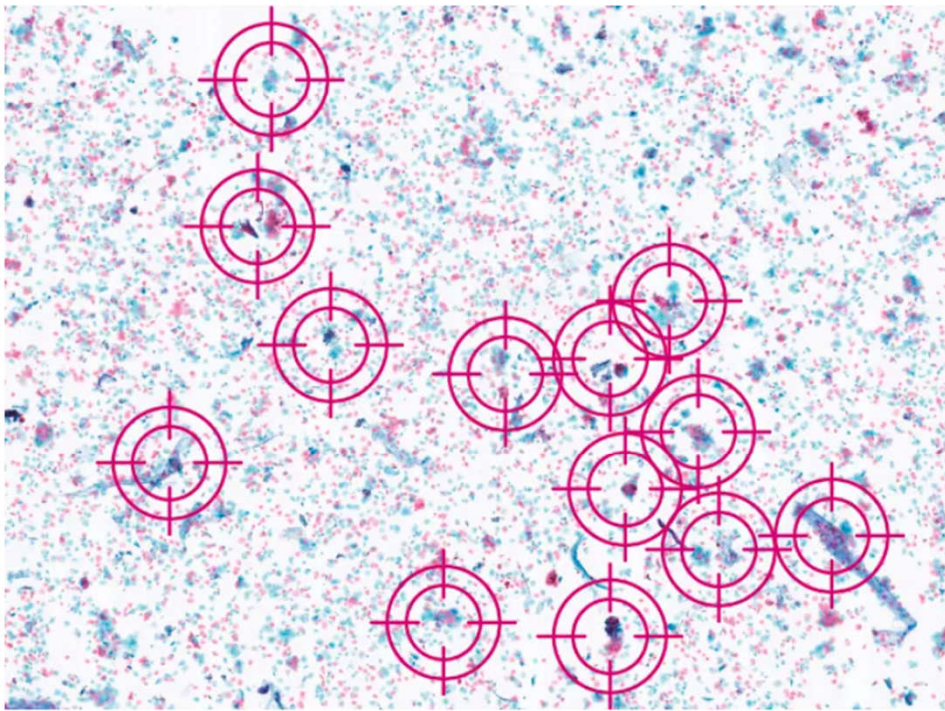
The American Cancer Society has stated that in 2024, an estimated 13,820 invasive cervical cancer diagnoses will be confirmed in the United States, with approximately 4360 associated mortalities. Early detection is vital to reduce incidence and mortality.

Cervical cancer is highly treatable when detected early. Traditionally, a Pap test is used to screen for cervical cancer, though the most significant sensitivity has been observed from a combination of a Pap test and HPV test

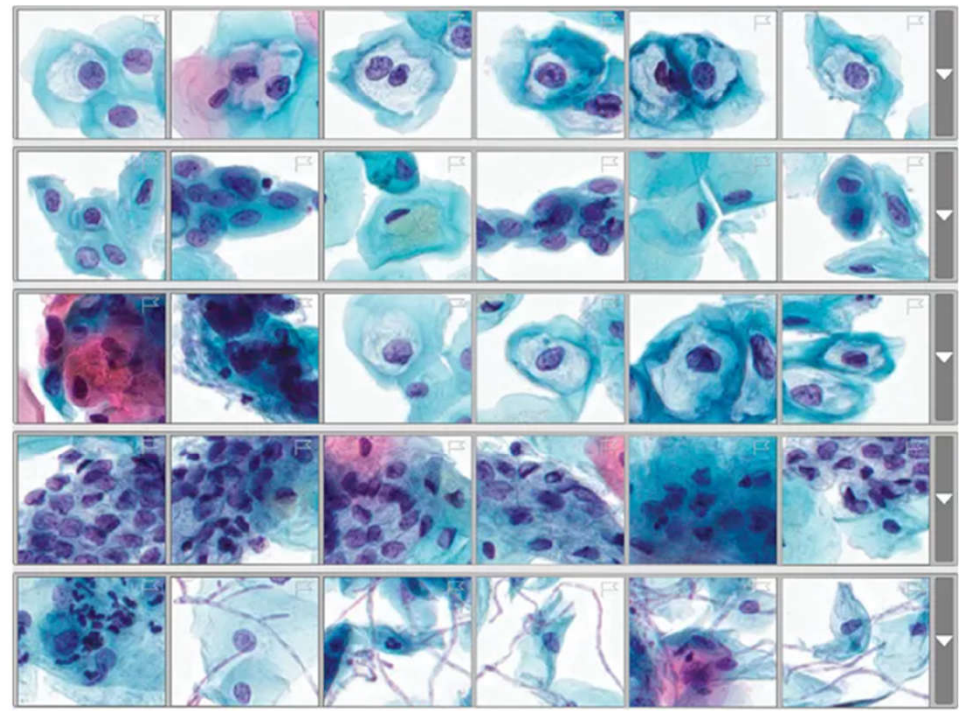


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Genius Cervical AI narrows your screening from tens of thousands of objects down to a curated gallery of images for targeted and efficient review.



Genius Cervical AI objectively analyzes every cell on a digital image and intelligently identifies those clinically relevant



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APRIL 21, 2025

New Screening/Surveillance Approaches For BE May Uncover More Cancers

Improved means for preventing [esophageal cancer](#), including nonendoscopic screening approaches and molecular surveillance for Barrett's esophagus, are being tested in ongoing prospective clinical trials. Sanford Markowitz, MD, PhD, who is leading a team investigating some of these new approaches, discussed their research at the 2025 [ASCO](#) Gastrointestinal Cancers Symposium.

A biomarker-based strategy to intercept progression of [BE](#) to esophageal cancer (EAC) often has eluded clinicians, noted Dr. Markowitz, the Ingalls Professor of Cancer Genetics at Case Western Reserve University School of Medicine and University Hospitals Seidman Cancer Center, in Cleveland. Despite the American College of Gastroenterology (ACG) screening guidelines ([Am J Gastroenterol 2022;117\[4\]:559-587](#)) essentially calling for screening of several high-risk groups, including all white male patients older than 50 years of age with long-standing reflux, endoscopic screening for BE, he said, has been "an abysmal failure due to a lack of acceptance by both patients and physicians." Almost all EAC diagnoses occur in patients who were never screened, he said.

Balloon Sampling Device For Screening

A biomarker-based strategy to intercept progression of [BE](#) to esophageal cancer (EAC) often has eluded clinicians, noted Dr. Markowitz, the Ingalls Professor of Cancer Genetics at Case Western Reserve University School of Medicine and University Hospitals Seidman Cancer Center, in Cleveland. Despite the American College of Gastroenterology (ACG) screening guidelines ([Am J Gastroenterol 2022;117\[4\]:559-587](#)) essentially calling for screening of several high-risk groups, including all white male patients older than 50 years of age with long-standing reflux, endoscopic screening for



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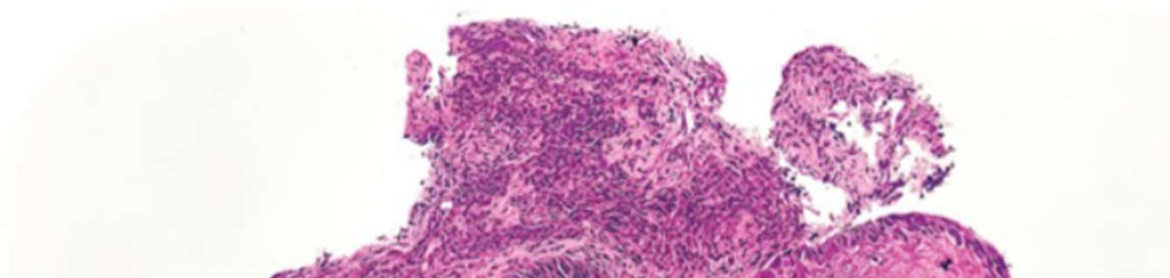
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Balloon Sampling Device For Screening

Dr. Markowitz and his team developed a swallowable balloon used for obtaining cells from the gastroesophageal junction and distal esophagus to screen for BE. This nonendoscopic sampling device has a balloon tip the size of a vitamin pill with an attached catheter that patients swallow. Air is then injected through the catheter to deploy the balloon, allowing procurement of a swab of cells. Air is suctioned back into the capsule to protect the sample and enable its safe withdrawal.

The sample is run through a methylated DNA panel, consisting of methylated *VIM* [vimentin] and *CCNA1* [cyclin A1]), which achieves high sensitivity and specificity in differentiating BE from normal esophageal tissue.





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Blue Light Cystoscopy

The UNC Department of Urology is one of only a few bladder cancer centers of excellence to offer blue light cystoscopy.

Blue Light Cystoscopy is a unique technology to detect and diagnose tumors in the bladder. Also known as Cysview[®], this enhanced imaging procedure helps oncologists find bladder tumors more easily than [standard cystoscopy](#) (examination of the bladder through a small scope), which can miss some tumors that are too small to find with standard cystoscopy.

Cysview[®] (hexaminolevulinate HCl) is a contrast solution that is taken up by rapidly growing cells (such as bladder cancer cells) and turns bright pink or red under a special blue light.

Cysview[®] is being used for patient diagnosis all around the world.

In the images below, the bladder cancer is invisible under regular white light (left). With Cysview[®], the tumor can be seen under blue light (right)

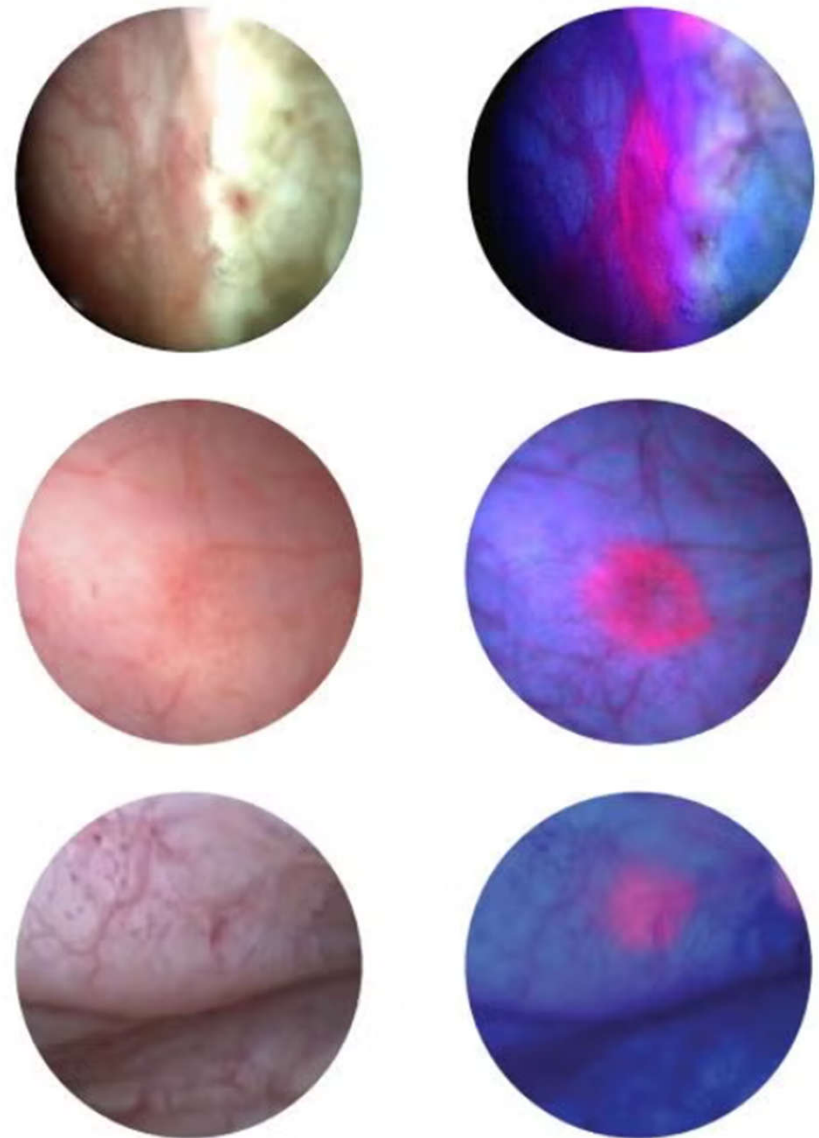
cancer, the benefits of blue light cystoscopy:

- Better inspection of the bladder for cancer, especially small or flat tumors
- Better removal of bladder tumors when they are first discovered
- Leads to fewer recurrences of bladder cancer
- Improved information to use to plan future care for bladder cancer

How is Cysview® used?

In the waiting area prior to cystoscopic surgery for bladder cancer, a catheter tube is placed into the bladder through the urethra and is used to place the Cysview® solution in the bladder. The solution is left in the bladder for about an hour prior to the surgery.

When surgery starts, a scope is used to inspect the



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