

## Portable cancer testing expands in sub-Saharan Africa

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Kaposis Sarcoma Lesions. Credit: OpenStax College/Wikimedia Commons, CC BY 3.0

A portable diagnostic device designed by researchers at Cornell Engineering and Weill Cornell Medicine has been deployed in clinical tests in Uganda to identify cases of Kaposi sarcoma, a common yet difficult-to-detect cancer that often signals the presence of HIV infection.

Now, the rollout is expanding to 11 sites throughout sub-Saharan Africa, including locations in Kenya, Tanzania, Rwanda, Botswana and Malawi—where a shortage of diagnostic testing and pathology experts has led to long waits and sometimes erroneous results.

The diagnostic, which has been deployed in Africa since 2017, is shown to be highly accurate.

By generating results within the hour at the point of care, the portable system, KS-COMPLETE, is accelerating the speed of accurate diagnosis, and eventually treatment, for patients.

"We are looking to deploy a technology that can change the paradigm of the way Kaposi sarcoma is In clinical tests based on 506 biopsies collected

diagnosed in sub-Saharan Africa," said project lead David Erickson, the Sibley College Professor of Mechanical Engineering in Cornell Engineering, who developed the technology with Dr. Ethel Cesarman, professor of pathology and laboratory medicine at Weill Cornell Medicine.

"We can hopefully reduce the amount of time-toresult by returning the diagnosis right there where the patient is, without having to send it out to an external expert," Erickson said. "If we're able to do that, hopefully that quicker return of a result can get the patient access to care quicker, and improve clinical outcomes."

Kaposi sarcoma (KS) is a cancer of the cells that line blood or lymphatic vessels, and it usually appears as lesions on the skin, inside the mouth, lymph nodes, or in the lungs or digestive tract. One of the most common and deadly cancers in sub-Saharan Africa, KS is frequently driven by immune suppression from HIV.

"While pathologic diagnosis is critical for KS diagnosis, unfortunately KS is most common in a part of the world there is a critical lack of pathologists and highly variable standards," Cesarman said. "The molecular approach provided by our new technologies should address the need of accurate and fast diagnosis of KS."

The KS-COMPLETE platform will consist of two components: SLICER and TINY.

The SLICER system automatically processes a biopsy sample into "micro-cores" that can be entered into the pint-sized TINY-short for Tiny Isothermal Nucleic acid quantification sYstem. The TINY diagnostic then identifies the presence of the Kaposi sarcoma-associated herpesvirus by isolating and magnifying its DNA through a process called loop-mediated isothermal amplification.



from patients at three HIV clinics in Uganda, TINY has achieved 97% sensitivity, 92% specificity and 96% accuracy, according to a forthcoming study from the project team, which includes researchers from the University of California, San Francisco, and the Infectious Diseases Institute in Kampala in Uganda.

In addition to expanding the KS-COMPLETE deployment, the five-year grant—awarded June 1—will focus on refining the SLICER system.

"The really challenging part is that upstream sample processing," Erickson said. "Once that biopsy comes out of a person, how do you mash it all up and get it into a condition that it can be suitable to go into the TINY? That turns out to be a really hard problem. A COVID test, for example, is just a little swab coming out of your nose and a few cells. Here, we have a big chunk of skin that we've got to somehow process quickly and efficiently."

The researchers are hopeful the KS-COMPLETE platform could eventually be used to diagnose other skin diseases beyond Kaposi sarcoma, as well as to provide large-scale screening, in areas such as wastewater treatment, for the coronavirus.

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