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First here, then there—FISH testing in Kenya

For the first time, the doctors who treat Burkitt lymphoma patients in Eldoret, Kenya, and the pathologists they rely on, will have on-site access to FISH testing, thanks to Gail H. Vance, MD, and colleagues at Indiana University School of Medicine.

Last month, Teresa Lotodo, MD, a hematopathologist at Moi Teaching and Referral Hospital and lecturer at the Moi University School of Medicine in Eldoret, Kenya, traveled 8,000 miles to Dr. Vance's fluorescence in situ hybridization lab at IU School of Medicine. Accompanied by Nicholas Kigen, a lab scientist, Dr. Lotodo spent eight days learning how to perform and interpret FISH. After Dr. Vance visits Eldoret this month to validate the testing, Dr. Lotodo will travel a far shorter distance to use FISH to diagnose Kenyan patients suspected of having Burkitt lymphoma.



Dr. Lotodo (from left) in April at Indiana University School of Medicine with Dr. Vance, Ryan Stohler, and Nicholas Kigen

Dr. Vance, the Sutphin professor of cancer genetics, professor of medical and molecular genetics and of pathology and laboratory medicine, and director of the Division of Diagnostic Genomics, wrote a National Cancer Institute grant with Terry Vik, MD, professor of pediatrics and director of the IU fellowship program in pediatric hematology-oncology, to bring FISH testing to Kenya. Their proposal, "Improving diagnosis, staging and support for Kenyan children with Burkitt lymphoma," was written to benefit the Moi/Ampath clinical lab in Eldoret by bringing Dr. Lotodo and Kigen to IU for training and sending Dr. Vance to Eldoret for the validation.

Ampath is an IU-led partnership, which consists of a consortium of 10 other North American academic health centers and Moi University, Moi Teaching and Referral Hospital, and the Kenyan Ministry of Health. "A number of our faculty have gone there, and their faculty come here," Dr. Vance says of the MU Medical School and IU School of Medicine exchange program through Ampath. The April trip was Dr. Lotodo's second visit to IU, though it was the first time she worked with Dr. Vance.

"We get referrals from a very big region in the country," Dr. Lotodo says, "and we have a very recognized cancer center because of this collaboration with Indiana University. We are seeing ourselves in the next years to be a center of excellence for diagnosis and management of cancer patients in that region of Kenya."

Although Moi Teaching and Referral Hospital is the second largest referral hospital in Kenya, it faces challenges in reaching a conclusive diagnosis for patients with Burkitt lymphoma, in addition to other cancers, Dr. Lotodo says.

"We have mostly just been relying on morphological diagnosis, just looking at the slides," she says, "but FISH will be able to take us a step higher to be able to be sure we are dealing with that specific type of cancer, and that the treatment of the patient is targeted toward Burkitt lymphoma."

The NCI grant included funds for purchasing a fluorescent microscope; Dr. Vance supplemented the purchase with funds made available to her as a professor. She used the new microscope to train Dr. Lotodo and Kigen in her FISH lab in April, and planned to ship it to Eldoret in time for the validation this month.

"My goal, and I hope it's Teresa's as well, is to start with Burkitt lymphoma but then to go to other disorders, like chronic myeloid leukemia or acute lymphoblastic leukemia," Dr. Vance says.

The training and fluorescent microscope are just some of what Dr. Vance has had to consider in equipping Dr. Lotodo's lab for FISH testing. She is also working on a way to keep the lab supplied with FISH probes and other materials.

Ongoing diagnostic support from Indianapolis will be essential to Dr. Lotodo's long-term success with FISH, Dr. Vance adds. She and technician Ryan Stohler and the rest of her IU team will be available to Dr. Lotodo's team to troubleshoot, address supply issues, and answer diagnostic or protocol questions. IU faculty members travel to Eldoret often and could provide on-site assistance, if necessary.

"The whole point is to develop an ongoing relationship, but for them to be independent," Dr. Vance says. "This would be their practice." Dr. Lotodo envisions the collaboration between the two universities leading to new research and training opportunities via telepathology.

Since making her first trip to IU in 2013, when she worked in the flow lab with Magdalena Czader, MD, PhD, Dr. Lotodo says her diagnostic technique has improved significantly. "And this time again, we have come to learn FISH," she says. "It has been value added to my profession and to how I teach the students." —Amy Carpenter Aquino

FDA OKs PD-L1 biomarker test for urothelial carcinoma

Roche has obtained FDA approval of its Ventana PD-L1 (SP263) assay as a complementary diagnostic to provide PD-L1 status for patients with locally advanced or metastatic urothelial carcinoma who are being considered for treatment with the FDA-approved anti-PD-L1 immunotherapy Imfinzi (durvalumab, AstraZeneca). The test evaluates patient PD-L1 status using tumor and immune cell staining and scoring within the tumor

microenvironment.

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FDA clears Roche Cobas e 801 immunoassay module

Roche's dedicated high-volume testing immunoassay solution for the Cobas 8000 modular analyzer series, the Cobas e 801 module, has received 510(k) clearance from the Food and Drug Administration.

Roche says its new module is designed for maximum consolidation at a high throughput and reduces generated waste. It almost doubles the currently available immunoassay testing capacity on the same footprint, Roche says, delivering up to 300 tests per hour and providing 48 reagent channels. It is designed to use at least 25 percent less patient sample than its predecessor.

Up to four Cobas e 801 modules can be configured in a series, delivering up to 1,200 tests per hour across up to 192 reagent positions. The module allows for continuous, on-the-fly loading of reagents and consumables.

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DiaSorin granted EUA for fully automated Zika IgM test

DiaSorin received FDA emergency use authorization for the Liaison XL Zika Capture IgM assay, a fully automated serology assay for the detection of Zika virus infection.

"Using the proven Liaison XL platform along with an innovative assay format, utilizing the Zika NS1 antigen, DiaSorin was able to produce an assay that yields results in as little as 37 minutes after the specimen is placed on the platform," John Walter, DiaSorin president, said in a statement.

Specimens used with the Liaison XL Zika Capture IgM assay should be collected between eight days and 10 weeks after onset of symptoms or risk of exposure.

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Advia Centaur XPT has comprehensive ID menu

Siemens Healthineers' newest addition to the Advia Centaur portfolio, the XPT Immunoassay System, now offers a comprehensive infectious disease testing menu. The system can process up to 240 tests per hour and offers laboratories a portfolio of more than 70 assays.

It has assay features such as "Hot Zone" integration (for the HBsAg I assay) to reduce the need for additional testing and system software features such as the Smart algorithm to automate reflex testing.

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Roche CINTec Histology test receives FDA clearance

Roche received 510(k) clearance from the FDA for the CINTec Histology test. It is a clinically validated p16 biomarker test that, when used in conjunction with H&E staining, helps pathologists determine which women should receive treatment for cervical pre-cancer. This test is a part of the Roche cervical cancer portfolio, which includes the Cobas HPV test and the CINTec Plus Cytology test. FDA clearance was based on the results generated in the CERTAIN (Cervical Tissue Adjunctive Analysis) study.

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