A Clinician’s Perspective: Improving Quality of Care for Patients Living with HIV and AIDS Using the T-SPOT.® TB Test

Sharon Murphy, RN, ACRN  
*Executive Director*
*McGregor Clinic*
*Fort Myers, Florida*

Jenna Hess  
*Laboratory Supervisor*
*McGregor Clinic*
*Fort Myers, Florida*

**Introduction**

The primary treatment goal for patients infected with the human immunodeficiency virus (HIV) is maintenance of optimal health; however, co-infection with opportunistic pathogens remains a serious health threat for these patients. Individuals co-infected with HIV and *Mycobacterium tuberculosis* (MTB) are 20 to 30 times more likely to develop TB disease than those individuals without MTB infection through the reactivation of a latent tuberculosis infection (LTBI).1,2 Thus, accurately detecting and effectively treating LTBI in these patients is of paramount importance.

For more than 100 years, the tuberculin skin test (TST) has been used to detect LTBI; however, the sensitivity of the TST is reduced for patients with HIV, and some patients develop anergy,3,4 thus increasing the potential for false-negative results. Other issues with the use of the TST include the need for a second visit for the TST reading, and the potential for false-positive results from previous administration of the bacille Calmette-Guérin (BCG) vaccine or from a common nontuberculosis mycobacteria such as *Mycobacterium avium*.

**What is an IGRA?**

Interferon-gamma release assays (IGRAs) are *in vitro* blood tests for TB infection. These tests detect cell-mediated responses to MTB antigens. Unlike the subjectivity of reading the TST, IGRAs provide an objective measurement of the patient’s T-cell response in a laboratory setting.

While two commercially available IGRAs are currently FDA-approved, only the T-SPOT.® TB test addresses the different immune statuses of patients. The T-SPOT.TB test isolates peripheral blood mononuclear cells (PBMC) from the patient’s blood sample and uses a standard number of PBMCs in the assay to directly measure the secretion of interferon-gamma (IFN-γ), the immune response to infection with MTB. The T-SPOT.TB test uses two antigens that are specific to MTB: ESAT-6 and CFP10. Importantly, these antigens do not cross-react with BCG or most common environmental mycobacteria; therefore, BCG vaccination status of the patient and exposure to nontuberculosis mycobacteria do not affect the T-SPOT.TB test results. IGRAs eliminate the multiple visits required by the TST as they require only one patient visit for the blood draw. According to the Centers for Disease Control and Prevention (CDC), “As laboratory-based assays, IGRAs are not subject to the biases and errors associated with TST placement and reading.”5 In addition, unlike the TST boosting that can occur in two-step testing, IGRAs cannot boost subsequent IGRA tests. In 2010, the CDC issued updated guidelines for IGRAs that recommend the T-SPOT.TB test over the TST in all situations that require TB testing.
How does the test work?
A standard number of PBMCs in combination with ESAT-6 and CFP10 are added to the wells of microtiter plates that are coated with high-affinity antibodies to IFN-γ. Activated effector T cells secrete IFN-γ in response to the specific antigens. The IFN-γ is captured by the IFN-γ antibodies coated within the well. After removal of the T cells and antigens, conjugated second antibody followed by a substrate are added to produce spots where IFN-γ was secreted by the T cells. Thus, the number of spots provides a measure of the abundance of MTB-sensitive effector T cells.

How are T-SPOT.TB tests processed?
Collecting and processing specimens is a simple, straightforward process. Blood is collected in one standard green-top blood collection tube, kept at room temperature, and then packaged in validated shipping containers, which are shipped to Oxford Diagnostic Laboratories® via FedEx® for processing. The shipping containers, provided by Oxford Diagnostic Laboratories, are designed to keep the specimens at room temperature during transit. Shipping with FedEx allows specimens to be collected throughout the day, Monday through Friday, with the option for arranging weekend pickup if needed. Results are then reported within 36 hours after receipt of the specimens via encrypted email or secure online portal.

Oxford Diagnostic Laboratories is a national reference lab dedicated only to TB testing and operates 7 days a week. It currently serves 1000 customers nationwide, including customers from public health clinics, hospitals, and universities, as well as physicians in private practice.
Screening patients living with HIV and AIDS using the T-SPOT.TB test

The McGregor Clinic provides health services for medically needy and underserved persons living with HIV and AIDS within Lee County, Florida. Their catchment area is about 150 miles with limited public transportation. Because the McGregor Clinic provides primary care, the clinic staff also treats diabetes, hypertension, and other comorbidities and co-infections. Currently, about 750 patients ranging in age from 17 to 81 years old are being treated at the clinic. Of these, 51% are minorities and about 40% are women. Only 10% of the patients are privately insured; most have no insurance and receive their care through the Ryan White CARE Act, Medicaid, and/or Medicare.

Sharon Murphy, RN, ACRN, is the clinic’s executive director, and Jenna Hess is the clinic’s lab supervisor. Here they provide their perspectives on how using the T-SPOT.TB test has affected their ability to provide quality care at the McGregor Clinic.

Before adopting the use of the T-SPOT.TB test for TB screening, Sharon Murphy described their TB screening program as “hopeful.” She explains:

“We would place a TST and hope to see the patient again, but there were just so many barriers. We service a large immigrant population, many of whom don’t speak English, so communicating effectively about the test and the need for a return visit can be difficult, even though we do have translators on staff. In addition, many of our patients are unable to read, so they don’t know if they have been on TB medications in the past. Many of our patients rely on public transportation to get to our clinic and travel a long distance; having to come back 2 or 3 days later was not a high priority for them, and in some cases, just not possible. Our return rate was about 25%. Of those that came back to get a reading, about 50% were positive. Those people were then referred to the Health Department for treatment. We had patients who self-reported previous positive TSTs, but we weren’t confident that they remembered their medical history correctly, so we watched them closely for other issues. We also have patients who didn’t want a TST placed. For those we did cough assessments; however, those were unreliable too.

“My biggest issue with the TST was that we were missing people who needed to be in treatment. We’re in an epidemic here in Florida, because of our immigrant population and because people just aren’t entering into care. So, we’re seeing more and more infections come back that we thought were under control. Our patients are immunocompromised so it is important that we identify and treat TB infection and disease before it spreads. If we can identify even one patient with LTBI and prevent reactivation, we can reduce the exposure risk to others. Also, if we have their TB disease under control and their HIV in control we can return them to an optimal state of health. We don’t want to treat one infection and ignore the other and, without having clients return to have their TSTs read, that was what we were doing. We were treating the HIV but missing the elephant in the room and that elephant is TB infection. So using the TST just wasn’t working for us.

“Even though our primary concern for our TB screening program was patient compliance, we also needed to make sure that our staff were safe. Some of our staff have been working in the field for so long they would end up with positive TST reactions. They would have to undergo a chest x-ray and a symptom screen to make sure they did not have TB disease. Switching to the T-SPOT.TB test provides our staff with a reliable, accurate test for annual screening, and reduces our concern about exposure. TB is not something we want to bring home.

“We have found that using the T-SPOT.TB test has reduced our administrative time because we no longer have to track down patients to get the TST results. We get the results online within 36 hours and now our patient compliance is 100%. We screen all of our patients using the T-SPOT.TB test. We don’t have any gaps or misinformation from patient self-reporting.
“If the results are negative, we are confident that they don’t have LTBI. If the results are positive, we are able to refer them to the Health Department more quickly for follow-up. Patients are able to get appointments at the Health Department faster with a positive T-SPOT.TB test result than a positive TST result. The Health Department would retest the patients before beginning any therapy. Now they are using our T-SPOT.TB results as confirmatory and starting the patients on therapy sooner when needed.”

Using the T-SPOT.TB test has been a smooth transition for Jenna Hess, the lab supervisor at McGregor Clinic. She describes her experience with Oxford Diagnostic Laboratories:

“We typically draw blood from four to five patients a day for T-SPOT.TB testing. For our new patients, we draw blood for their T-SPOT.TB test on their second visit unless there is an identified risk. We can draw blood 5 days a week, which is a great change from only being able to place the TST 2 days a week, and we send the samples overnight to Oxford Diagnostic Laboratories.

“It has been wonderful working with Oxford Diagnostic Laboratories. Getting a quick response from a lab can sometimes be a challenge, but the customer service we receive from Oxford Diagnostic Laboratories is great. There is always a person to answer the phone and give us the information we need in a timely manner. They provide reliable, accurate service.

“Overall, Oxford Diagnostic Laboratories has helped us improve our service to our patients. The customer service we have received from them is translated to our patient care. It is great for us to be able to offer a great test, like the T-SPOT.TB test, to our patients and staff, but to compound that with great customer service for us is excellent, and it helps us provide better care for our patients.”

References