



United States Department of State

Washington, D.C. 20520

February 27, 2017

Erica Lessom
Treatment Action Group

Dear Ms Lessom –

Thank you for your recent open letter asking PEPFAR to promote the use of the Determine urine lipoarabinomannin (LAM) antigen test. You stated the case for use of the assay beautifully – we appreciate the time and attention you have given this matter, and your passion for improving the lives and health of the patients we serve.

We agree that the LAM antigen assay is a useful test, with the potential to save lives. For this reason, we have explicitly mentioned it in our 2017 Country Operating Plan (COP) guidance as a diagnostic tool that can be purchased under the HVTB budget code. All country teams are aware that they are able to procure these test kits, specifically, under their COP. A potential obstacle, however, is that this assay is not mentioned in many national guidelines and, as you point out, is not registered in many countries. Additionally, it is important that users are made aware that the test is to be targeted to specific populations and that even in those populations, it is not sensitive, and a negative test is not sufficient to rule out a diagnosis of TB. To promote use and understanding of this test, we are working through the technical working groups (TWGs) to identify PEPFAR-supported countries that are best poised to take a lead on this. Through the TWGs, we will provide technical assistance to those countries to help develop the policy and programming that will allow use in PEPFAR-supported facilities. As you may know, the Global Laboratory Initiative (GLI) is planning to recommend algorithms for the evaluation of TB in persons living with HIV very soon, and once they are released, we plan to use these algorithms to promote use of the assay.

In many countries, Global Fund against AIDS, Tuberculosis and Malaria (GF) funding is used as the primary source for procuring commodities such as medicines and HIV and TB-related diagnostics. The 2017 COP process and the development of GF funding requests are both underway now, and PEPFAR country teams are currently working directly with their national HIV and TB programs to ensure that PEPFAR and GF funding are complementary. During this process, it is important to educate all relevant parties; including PEPFAR country teams, GF representatives and officers from the national programs; on the utility of this test and the forthcoming GLI recommendations. We will work to ensure that our country teams are considering this test, and working with national colleagues to develop the necessary guidelines. Participants from community service organizations (CSOs) will also inform the decision-making process at the country level, and will help implement programming in the current COP cycle. In the weeks leading up to the COP signing in April, we encourage the CSOs to actively engage the country teams on this issue, and encourage you to reach out to them to advocate for this.

Thanks again for your attention to and willingness to focus on this issue. Please keep us informed of your efforts and your progress on this front. We look forward to coordinating with you on this important effort and maintaining an ongoing dialogue.

Sincerely,

A handwritten signature in blue ink, consisting of a stylized 'D' followed by a horizontal line that curves upwards at the end.

Ambassador Deborah L. Birx, MD
U.S. Ambassador-at-Large and U.S. Special Representative for Global Health Diplomacy
Coordinator of U.S. Government Activities to Combat Global HIV/AIDS
U.S. President's Emergency Plan for AIDS Relief (PEPFAR)
U.S. Department of State