

August 6, 2013

Mr. Avi Pelossof
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OPEN LETTER RE: Responsible marketing and access plans for Alere's Determine TB-LAM antigen test for active TB

Dear Mr. Pelossof,

We congratulate Alere on developing the Determine TB-LAM antigen test for detecting active tuberculosis (TB) in people living with HIV, a very important population to diagnose and treat in many parts of the world. We are writing to request that Alere develop responsible marketing and access plans that are mindful of different settings' unique disease burdens, and share these plans with us.

In particular, we request that you:

- 1) register your test, make it affordable and accessible, and responsibly market your test in areas in Eastern Europe and Central Asia with high rates of HIV and TB co-infection, and
- 2) ensure that the Determine TB-LAM antigen test is not used inappropriately in India and elsewhere.

Your Determine TB-lipoarabinomannan (LAM) antigen test detects TB best in people living with HIV with CD4 counts less than 100 cells/mm³, and who have TB symptoms. Without your test, it is extremely difficult to diagnose TB in people with HIV with low CD4 counts. The Determine TB-LAM test is also a simple, non-invasive and rapid tool. We appreciate the important role that this test can play in allowing people with TB and HIV to be diagnosed and linked to care.

We therefore encourage Alere to expand access to this product in settings that can utilize it appropriately, especially areas in Russia, as well as other countries in Eastern Europe and Central Asia. The Eastern European and Central Asian region has one of the highest burdens of TB (with 180,000 people in Russia alone with TB), and the rate of TB/HIV co-infection is increasing at an alarming pace. In 2011, some 30,000 people were registered as having HIV and TB, which is 18.4% more than in the previous year, and 12 times more than in 2002. TB remains the leading AIDS-

defining disease, and the leading cause of death among people with HIV. This region urgently needs access to appropriate diagnostic tools such as Determine TB-LAM. Alere should register the Determine TB-LAM with corresponding regulatory authorities in Eastern Europe and Central Asia. Mindful of the lack of stringency or capacity of many regulators in this region to enforce appropriate marketing post-approval, we also urge Alere to develop a responsible post-approval marketing and surveillance strategy to ensure the test is being used only to test for active TB in people with HIV with very low CD4 counts and TB symptoms.

We similarly request that in the Indian market, Alere carefully weigh any plans for registration of this test against the likely potential for its misuse. As you know, the Government of India banned the use of serodiagnostic antibody-based tests for TB in 2012. We are concerned that in their stead, other tests may be inappropriately used, including Quantiferon TB Gold¹ and TB Platinum.² We are similarly concerned that the Determine TB-LAM test will be misused, given the rampant misuse of other tests, and the relatively low proportion of Indians with TB who are co-infected with HIV. If you do plan to register your test in India, can you please share with us your strategy for preventing misuse of the test? This includes misuse of the test in the HIV-uninfected persons who make up the vast majority of Indians with suspected TB, and misuse of the test by reliance on blood (rather than urine) samples.

In all settings, we urge you to market your test only as indicated according to data from clinical trials, and take action to stop any unethical, off-label use of the test.

We look forward to hearing from you about your strategy to address our concerns.

Best regards,



On behalf of:

Eastern Europe and Central Asia Community Advisory Board (EECA CAB)
Global Tuberculosis Community Advisory Board (TB CAB)
India Community Advisory Board (India CAB)
International Treatment Preparedness Coalition, Russia (ITPCru)
Kaliningrad Regional Non-Profit Organization "Status-Plus"
National Coalition of PLHIV in India (NCPI+)
Non-Profit Partnership to Increase the Quality of Life for Women Living with and Affected by HIV-Infection and Other Socially Significant Diseases (EVT)
Treatment Action Group (TAG)

¹ http://tbonline.info/media/uploads/documents/qiagen_open_letter_final.pdf

² http://www.tbonline.info/media/uploads/documents/tb_platinum_immunoshop_letter_tag_tbcab-1.pdf

cc: Dr Mario Raviglione, Director, Stop TB Department, WHO, Geneva
Dr. V. M. Katoch, Director General, Indian Council of Medical Research
Dr GN Singh, Drug Controller General of India, New Delhi
Dr. RS Gupta, Deputy Director General – TB, Central TB Division, Ministry of Health and Family Welfare, New Delhi
Dr. KS Sachdeva, Chief Medical Officer, Central TB Division, Ministry of Health and Family Welfare, New Delhi
Dr. Reba Kanungo, President, Indian Association of Medical Microbiologists
Dr. Ram Gopalakrishnan, President, Clinical Infectious Diseases Society of India
Dr. K Vijayakumar, President, Indian Medical Association
Dr. Irina Anatolyevna Vasilieva, Chief External Specialist of the Ministry of Health
Dr. Elena Mikhailovna Bogorodskaya, Director, Moscow Research and Practice Institute of TB, Healthcare Department of Moscow
Larisa Alexandrovna Dementyeva, Deputy Head, Epidemiological Surveillance Department of the Federal Service on Customer's Rights Protection and Human Well-Being Surveillance
Dr. Luigi Migliorini, World Health Organization (WHO) Russia