

INSTITUTE OF TUBERCULOSIS AND LUNG DISEASES
National Reference Laboratory for Mycobacteria
Department of Microbiology
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Warsaw, 26.04.2024

To:

Mr. Rainer M. Blair
President and Chief Executive Officer of Danaher
2200 Pennsylvania Avenue, NW
Suite 800W
Washington, DC 20037

Copy:

Mr. Vitor Rocha
President of Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089

Dear Mr. Blair,

I am writing on behalf of the National Reference Laboratory for Tuberculosis in Poland.

In recent years, Poland has been facing a significant increase in the burden of drug-resistant tuberculosis (DR TB) due to a substantial influx of refugees from Ukraine as well as increased work-related migration in general. Our National Tuberculosis Registry, managed by the Department of Epidemiology at the National Institute of Tuberculosis and Lung Diseases, reports approximately 5,000 cases of tuberculosis annually, of which there are 90 cases of drug-resistant tuberculosis.

We welcome your decision to reduce the price of Xpert MTB/RIF Ultra cartridges to \$7.97 in low- and middle-income countries, but we also hope for a similar reduction in high-income countries. The current price for the Xpert MTB cartridges in Poland is much higher as it is around \$50.

In our country, we have purchased and installed 46 GeneXpert systems as part of the tuberculosis care system. All of these machines are 10-color systems capable of running Cepheid's MTB/XDR cartridges. We perform approximately 30,000 molecular tests annually using the GeneXpert system.

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Currently, the Polish Society of Lung Diseases is finalizing national guidelines for the diagnosis and treatment of tuberculosis, which will be published in the coming weeks. These guidelines require molecular testing for all suspected cases of tuberculosis, both new and retreatment cases, in which Xpert MTB/RIF Ultra and Xpert MTB/XDR cartridges play a crucial role. With the introduction of a microbiological diagnostic algorithm that mandates molecular testing for all suspected TB cases, we anticipate a significant increase in the consumption of both types of cartridges within our system.

Many of our drug-resistant cases are already resistant to fluoroquinolones, so the ability to detect an extended profile of drug-resistant tuberculosis near the hospital is crucial for our healthcare providers to promptly select the appropriate DR-TB treatment regimen.

Considering these significant issues, we kindly request a reduction in the price of both Xpert MTB tests to a similar level. Additionally, publicly available evidence from Médecins Sans Frontières (MSF) has shown that there is no significant difference in production costs between disease cartridges, and in fact, many production costs are fixed across cartridges.

We anticipate a reduction in the price of the Xpert MTB/XDR cartridge so that our NTP can scale up decentralized DR-TB testing, and our tuberculosis care providers can provide the appropriate treatment regimen to individuals with DR-TB in a timely manner.

Sincerely

Professor Ewa Augustynowicz Kopec PhD
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Head of the National Reference Laboratory for Mycobacteria
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