

To: Mr. Warren C. Kocmond  
President, Chief Operating Officer  
Cepheid  
904 E Caribbean Drive  
Sunnyvale, CA 94089  
United States

Cc: Thomas P. Joyce, Jr., President and Chief Executive Officer, Danaher  
William K. Daniel, II, Executive Vice President, Danaher  
Peter Farrell, Executive Vice President, Global Commercial Operations, Cepheid  
David H. Persing, Executive Vice President, Chief Medical and Technology Officer, Cepheid  
Philippe Jacon, Senior Vice President, Global Access, Cepheid  
Martin Colla, Director, Global Access, Cepheid  
Cristina H. Kepner, Board Member, Cepheid  
Robert J. Easton, Board Member, Cepheid  
Thomas L. Gutshall, Board Member, Cepheid  
Hollings C. Renton, Board Member, Cepheid  
Glenn D. Steele Jr., Board Member, Cepheid

## **OPEN LETTER: Time to Lower the Price of Xpert Cartridges to US\$ 5**

21 October 2019

Dear Mr. Kocmond,

The GeneXpert system has revolutionized rapid, accurate testing for the diagnosis of tuberculosis (TB) since entering the market in 2010, and the World Health Organization (WHO) recommends Xpert MTB/RIF and Xpert MTB/RIF Ultra as the initial test for diagnosing TB.<sup>1,2</sup> Yet in large part due to the high price of Xpert cartridges, most high TB-burden countries have not sufficiently scaled up their procurement and use of Xpert as the initial TB diagnostic test.<sup>3,4</sup> Instead, they continue to rely on the significantly less accurate, but more affordable method of sputum smear microscopy, leading to gaps in TB diagnosis and rapid linkage to effective treatment.<sup>5</sup> In order to improve the scale-up of Xpert tests to help close these gaps, Cepheid must reduce the price of Xpert MTB/RIF and Xpert MTB/RIF Ultra cartridges to US\$ 5, inclusive of service and maintenance.

The undersigned organizations and individuals working to end the neglect of people with TB request that Cepheid reduce the price of Xpert cartridges to US\$ 5 per test for the public sector. This price reduction would fairly reflect both the volume-based cost of manufacturing, and the significant public and philanthropic investments behind Xpert's development and dissemination. Furthermore, it is essential that this price is inclusive of a comprehensive service and maintenance plan, as many high TB-burden countries cannot afford to purchase the extended warranties currently required for the service and maintenance of their GeneXpert systems.<sup>6</sup>

This US\$ 5 price point should also be available in the private sector, especially in high TB-burden countries, where a majority of TB patients seek care and shoulder costs personally.<sup>7</sup> According to a 2017-2018 survey, people in several high TB-burden countries were being charged US\$ 100 or more for an Xpert test.<sup>8</sup> Making the US\$ 5 price per test available to private sector purchasers will increase scale-

up, further expand the already high volumes of sales, and bring Cepheid closer to fulfilling its stated mission to “improve patient outcomes by enabling access to molecular diagnostic testing everywhere.”<sup>9</sup>

The current public-sector price of US\$ 9.98 per Xpert cartridge for high TB-burden countries was set in 2012, as a result of a buy-down agreement in which Unitaid, the United States government and the Bill & Melinda Gates Foundation paid Cepheid US\$ 11.1 million to reduce the price of Xpert cartridges from US\$ 16.86.<sup>10</sup> Since 2012, the volumes of sales of Xpert tests increased dramatically from 1.3 million to nearly 12 million cartridges sold in 2018 to the public sector alone,<sup>11</sup> which is expected to have resulted in significant manufacturing efficiencies and cost savings. According to an independent cost-of-goods analysis commissioned by Médecins Sans Frontières (MSF), at annual volumes of 10 million, Cepheid’s manufacturing cost per cartridge is estimated to be as low as US\$ 3.<sup>12</sup> Therefore, the US\$ 5 price point would enable Cepheid to include a comprehensive service and maintenance plan as well as a reasonable margin of profit within the price per cartridge, while also meeting the WHO target product profile price of under US\$ 6 for rapid molecular TB diagnostic tests.<sup>13</sup> In light of the volumes of sales and the resulting efficiencies that can be expected with regard to the cost of goods, it is time for Cepheid to reduce the price of Xpert MTB/RIF and Xpert MTB/RIF Ultra tests to US\$ 5.

Cepheid developed GeneXpert and its assays over the past two decades largely through public and philanthropic funding, which included an estimated US\$ 120 million from the US Department of Defense, US\$ 45 million from the US National Institutes of Health (NIH), and over US\$ 20 million via the Foundation for Innovative New Diagnostics (FIND), with funding largely from the Bill & Melinda Gates Foundation.<sup>14</sup> In 2010, Cepheid stated: “the Xpert MTB/RIF test truly represents what can be accomplished in a successful academic-public-private partnership.”<sup>15</sup> It is now time for the public to receive a larger return on this investment. Xpert tests must be affordable and accessible to high TB-burden countries, to enable them to implement WHO recommendations and fully scale up the use of Xpert as the initial TB diagnostic test.

We request Cepheid immediately reduce the price of Xpert tests to US\$ 5, inclusive of service and maintenance. **Before October 28<sup>th</sup>, we look forward to your response, which should articulate a plan for how Cepheid intends to lower the price of all Xpert cartridges to reflect the cost-of-goods efficiencies generated from the increased volumes of sales, as well as the public and philanthropic investments that supplemented the development of GeneXpert and the Xpert MTB/RIF and MTB/RIF Ultra assays.** Please direct your response to David Branigan, [David.Branigan@treatmentactiongroup.org](mailto:David.Branigan@treatmentactiongroup.org).

Respectfully submitted,



David Branigan  
TB Project Officer  
Treatment Action Group

**On behalf of the undersigned organizations and individuals**

**Organizational Endorsements:**

ACTION, Global  
Afrihealth Optonet Association (CSO Network), Nigeria  
Alliance for Public Health (APH), Global  
Asia Pacific Network of People Living with HIV (APN+)  
Assam Network of Positive People (ANP+), India  
Carmelo Hospital of Chokwe, Mozambique  
Citizen News Service (CNS), India  
Community and Family Aid Foundation, Ghana  
Cultura LLC, United States  
Dr. Uzo Adirieje Foundation (DUZAFOUND), Nigeria  
Drug Resistant TB Scale Up Treatment Action Team (DR-TB STAT), Global  
Eastern Africa National Networks of AIDS and Health Service Organisations (EANNASO)  
Epidemiological Laboratory for Research and Development, Sudan  
Fondation Femme Plus, Democratic Republic of the Congo  
Friends for International TB Relief (FIT), Germany/Vietnam  
Global Alliance for Human Rights, India  
Global Coalition of TB Activists, Global  
Global Media Foundation, Ghana  
Grupo de Ativistas em Tratamentos (GAT), Portugal/Europe  
Health and Development Alliance (HEAD), Cambodia  
Indian Network for People Living with HIV/AIDS (INP+), India  
Institute for Research and Development, Ukraine  
Interagency Coalition on AIDS and Development (ICAD), Global  
International Council of AIDS Service Organizations (ICASO), Global  
Jan Kalyankari Trust, Sanghmitra Group, India  
Jointed Hands Welfare Organisation, Zimbabwe  
Kenya AIDS NGOs Consortium, Kenya  
Kwanhliziyonye Resource Care Center (KRCC), South Africa  
LHL International Tuberculosis Foundation, Global  
Love Life Society, Delhi, India  
Médecins Sans Frontières (MSF), Global  
Medical IMPACT, Mexico  
National Coalition of People Living with HIV in India, India  
National Empowerment Network of People living with HIV/AIDS in Kenya (NEPHAK), Kenya  
National Tuberculosis Reference Laboratory (NTRL), Research Institute for Tropical Medicine, Philippines  
Nelson Mandela TB HIV Community Information and Resource Center, Kenya  
Network of Maharashtra People Living With HIV/AIDS (NMP+), India  
Pamoja TB Group, Kenya  
Partners In Health (PIH), Global  
Peace and Life Enhancement Initiative International (PLEII), Nigeria  
Radanar Ayar Association, Myanmar  
REACH Ethiopia, Ethiopia  
Respiratory Society of Kenya, Kenya  
RESULTS Australia, Australia  
RESULTS UK, United Kingdom  
Romanian Angel Appeal Foundation, Romania  
Russ Foundation, Madurai, India

Society for Conservation & Sustainability of Energy & Environment in Nigeria (SOCSEEN), Nigeria  
TALAKU Community Based Organization, Kenya  
Tamilnad Network of Positive People (TNPP+), India  
TB Alert, United Kingdom  
TB Proof, South Africa  
The Reunion Project (TRP), United States  
Touched by TB, India  
Treatment Action Group (TAG), Global  
U.S. People Living With HIV Caucus, United States  
Vision Makers CBO, Kenya  
Volunteer Health Services, Ethiopia  
Volunteers for Development Nepal (VFDN), Nepal  
World Vision India, India

**Individual Endorsements:**

Amruta Soni, Bihar, India  
Andrea von Delft, TB Proof, South Africa  
Andrew Codlin, Friends for International TB Relief (FIT), Germany/Vietnam  
Aparna Iyer, Mumbai, India  
Arne von Delft, University of Cape Town & TB Proof, South Africa  
Arumugam Sankar, India  
Aschalew Ashagre, Ethiopian Thoracic Society (ETS), Addis Ababa, Ethiopia  
Berlin Jose, Madurai, India  
Bobby Khumanthem, New Delhi, India  
Brijesh Dubey, Chairman of Global Alliance for Human Rights, India  
Cecilia Coitinho Azevedo, MD, National Reference Laboratory, Uruguay  
Challa Ruda, KNCV Tuberculosis Foundation, Addis Ababa, Ethiopia  
Colleen Daniels, CD Global Consulting, Australia  
Daisy David, HIV and TB survivor, Tamilnad Network of Positive People (TNPP+), India  
Dr. Bobby John, New Delhi, India  
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Earl Mantes, Research Institute for Tropical Medicine, Manila, Philippines  
Eddie Sistoso Jr., Research Institute for Tropical Medicine, Philippines  
Edy Nacarapa, Carmelo Hospital of Chokwe, Mozambique  
Elzsa Jade Tayactac, Technical Assistance Group, National Tuberculosis Reference Laboratory, Philippines  
Endale Mengesha Goshu, Senior Laboratory Advisor, KNCV Tuberculosis Foundation, Addis Ababa, Ethiopia  
Endy Fekadu, Volunteer Health Services, Ethiopia  
Erick Okioma, Victory Post Test Group, Kenya  
Ganesh Acharya, TB Activist, Mumbai, India  
Grace Kahenya, Laboratory & Diagnostic Advisor, Philippines  
Hari Shanker Singh, India  
Jahnabi Goswami, Assam, India  
Jennifer Furin, Harvard Medical School, United States  
Jerry Amoah-Larbi, Ghana National TB Voice Network, Ghana  
Josphat Ambehi, Tuko Kazi Kapsabet, Kenya  
Joyce Munala, Kenya  
Kartik Chauhan, IQVIA (formerly QuintilesIMS), New Delhi, India

Kamlesh, Kasbale, India  
Kathleen England, Global Diagnostic Consultants, United States  
Luan Vo, Friends for International TB Relief, Hanoi, Vietnam  
Marco Tovar, Socios en Salud, Sucursal, Peru  
Meera Hada, National Tuberculosis Center, Nepal  
Mekdes Bekele, Health Worker, Addis Ababa, Ethiopia  
Mildred Fernando-Pancho, Global Coalition of TB Activists (GCTA), Manila, Philippines  
Mohammad Khakerah Rashidi, Global Health Systems Innovation (GHSI), Afghanistan  
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Monette Faner, University of the Philippines, Manila, Philippines  
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Olanrewaju Oladimeji, University of Namibia, Walter Sisulu University, South Africa & University of Jos,  
Nigeria  
Pardeep Kumar, Punjab, India  
Peter Francis Raguindin, Philippines  
Phindile Khumalo, Kwanhliziyonye Resource Care Center (KRCC), South Africa  
Prabha Mahesh, Touched by TB, Maharashtra, India  
Prashant Yende, India  
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Rahab Mwaniki, Nairobi, Kenya  
Rahul Dwivedi, Citizen News Service (CNS) Correspondent, India  
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Robyn Waite, Results Canada, Ottawa, Canada  
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Tara Rivera, Medical Center Manila, Philippines  
Tarit Chakraborty, Bengal Network for People Living with HIV/AIDS (BNP+), India  
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Thura Aung, Radanar Ayar Association, Myanmar  
Vida Joyce Nodque-Binarao, Philippines  
Waheedah Shabazz-El, The Reunion Project (TRP), United States  
Zahedul Islam, Alliance for Public Health (APH), Kyiv, Ukraine

## References

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- <sup>1</sup> World Health Organization. Policy Statement: Automated Real-time Nucleic Acid Amplification Technology for Rapid and Simultaneous Detection of Tuberculosis and Rifampicin Resistance: Xpert MTB/RIF System. Geneva: World Health Organization; 2011.  
[https://apps.who.int/iris/bitstream/handle/10665/44586/9789241501545\\_eng.pdf?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/44586/9789241501545_eng.pdf?sequence=1).
- <sup>2</sup> World Health Organization. WHO Meeting Report of a Technical Expert Consultation: Non-inferiority analysis of Xpert MTB/RIF Ultra compared to Xpert MTB/RIF. Geneva: World Health Organization; 2017.  
<https://apps.who.int/iris/bitstream/handle/10665/254792/WHO-HTM-TB-2017.04-eng.pdf?sequence=1>.
- <sup>3</sup> Pantoja A, Fitzpatrick C, Vassall A, Weyer K, Floyd K. Xpert MTB/RIF for diagnosis of tuberculosis and drug-resistant tuberculosis: a cost and affordability analysis. *European Respiratory Journal* [Internet]. 2013 Sept [Cited 2019 Oct 13]; 42 (3) 708-720. Available from:  
[https://erj.ersjournals.com/content/42/3/708.long?utm\\_source=TrendMD&utm\\_medium=cpc&utm\\_campaign=\\_European\\_Respiratory\\_Journal\\_TrendMD\\_0](https://erj.ersjournals.com/content/42/3/708.long?utm_source=TrendMD&utm_medium=cpc&utm_campaign=_European_Respiratory_Journal_TrendMD_0).
- <sup>4</sup> Kik SV, Denkinger CM, Chedore P, Pai M. Replacing smear microscopy for the diagnosis of tuberculosis: what is the market potential? *European Respiratory Journal* [Internet]. 2014 [Cited 2019 Oct 13]; 43: 1793-1796. Available from:  
[https://erj.ersjournals.com/content/43/6/1793.long?utm\\_source=TrendMD&utm\\_medium=cpc&utm\\_campaign=\\_European\\_Respiratory\\_Journal\\_TrendMD\\_0](https://erj.ersjournals.com/content/43/6/1793.long?utm_source=TrendMD&utm_medium=cpc&utm_campaign=_European_Respiratory_Journal_TrendMD_0).
- <sup>5</sup> Qin ZZ, Pai M, Van Gemert W, Sahu S, Ghiasi M, Creswell J. How is Xpert MTB/RIF being implemented in 22 high tuberculosis burden countries? *European Respiratory Journal* [Internet]. 2015 Feb [Cited 2019 Oct 13]; 45 (2) 549-554. Available from: <https://erj.ersjournals.com/content/45/2/549>.
- <sup>6</sup> Albert H, Nathavitharana RR, Isaacs C, Pai M, Denkinger CM, Boehme CC. Development, roll-out and impact of Xpert MTB/RIF for tuberculosis: what lessons have we learnt and how can we do better? *European Respiratory Journal* [Internet]. 2016 Jul [Cited 2019 Oct 13]; ERJ-00543-2016. Available from:  
<https://erj.ersjournals.com/content/early/2016/07/13/13993003.00543-2016#sec-5>.
- <sup>7</sup> Puri L, Oghor C, Denkinger CM, Pai M. Xpert MTB/RIF for tuberculosis testing: access and price in highly privatised health markets. *Lancet* [Internet]. 2016 Feb [Cited 2019 Oct 13]; 4(2): PE94-E95. Available from:  
[https://doi.org/10.1016/S2214-109X\(15\)00269-7](https://doi.org/10.1016/S2214-109X(15)00269-7).
- <sup>8</sup> Cazabon D, Pande T, Kik S et al. Market penetration of Xpert MTB/RIF in high tuberculosis burden countries: A trend analysis from 2014 - 2016 [version 2; peer review: 4 approved]. *Gates Open Res* [Internet]. 2018 [Cited 2019 Oct 13]; 2:35. Available from: <https://doi.org/10.12688/gatesopenres.12842.2>.
- <sup>9</sup> Cepheid [Internet]. Our Mission. (Date unknown) [Cited 2019 October 13]. <https://www.cephheid.com/us/about-us/inside-cepheid/our-mission>.
- <sup>10</sup> Albert H, Nathavitharana RR, Isaacs C, Pai M, Denkinger CM, Boehme CC. Development, roll-out and impact of Xpert MTB/RIF for tuberculosis: what lessons have we learnt and how can we do better?
- <sup>11</sup> Technical Officer (Stop TB Partnership Global Drug Facility, Geneva, Switzerland). Personal communication with: David Branigan (Treatment Action Group, New York, NY). 2019 Oct 8.
- <sup>12</sup> TB Diagnostics and Laboratory Specialist (Médecins Sans Frontières Access Campaign, Geneva, Switzerland). Personal communication with: David Branigan (Treatment Action Group, New York, NY). 2019 Oct 8.
- <sup>13</sup> World Health Organization. WHO High-priority target product profiles for new tuberculosis diagnostics: report of a consensus meeting 28–29 April 2014 Geneva, Switzerland. Geneva: World Health Organization; 2014.  
[https://apps.who.int/iris/bitstream/handle/10665/135617/WHO-HTM\\_TB\\_2014.18\\_eng.pdf?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/135617/WHO-HTM_TB_2014.18_eng.pdf?sequence=1).
- <sup>14</sup> World Health Organization. Global Investments in Tuberculosis Research and Development: past, present and future. A policy paper prepared for the first WHO global ministerial conference on ending tuberculosis in the sustainable development era: a multisectoral response. Geneva: World Health Organization; 2017. Available from:  
<https://apps.who.int/iris/bitstream/handle/10665/259412/9789241513326-eng.pdf;jsessionid=1CFF87486B75690AB1FC3BFE2978CBFF?sequence=1>
- <sup>15</sup> Ibid.