TO: Mr. Peter Sands, The Global Fund to Fight AIDS, Tuberculosis and Malaria
Dr. Hanan Balkhy, World Health Organization
Dr. Sergio Carmona, FIND

CC: Dr. Tedros Adhanom Ghebreyesus, World Health Organization
Dr. Catharina Boehme, World Health Organization
Dr. Philippe Duneton, Unitaid
Mr. Ira Magaziner, CHAI
Ms. Etleva Kadilli, UNICEF
Dr. Olusoji Adeyi, World Bank
Ms. Adriana Costa, World Bank
Dr. Emilio Emini, Bill & Melinda Gates Foundation
Dr. John Nkengasong, Africa CDC
Dr. Benjamin Djoudalbaye, African Union
Mr. Nqobile Ndlovu, African Society for Laboratory Medicine
Honorable Zweli Mkhize, National Department of Health, South Africa
Honorable Rajesh Bhushan, Ministry of Health and Family Welfare, India
Honorable Eduardo Pazuello, Ministry of Health, Brazil
Honorable Mutahi Kagwe, Ministry of Health, Kenya
Mr. Balram Bhargava, Indian Council of Medical Research
Dr. Jarbas Barbosa, PAHO
Ms. Gloria D. Steele, USAID
Global Fund Members of the Board
Unitaid Members of the Board
ACT-A Facilitation Council Members
ACT-A Diagnostics Pillar and Diagnostics Consortium Members
Integrated Diagnostics Consortium Members

June 15, 2021

Dear Mr. Peter Sands, Dr. Hanan Balkhy, and Dr. Sergio Carmona,

The Time for $5 Coalition welcomes your response to our April 1st open letter calling on donors, country governments, and other health actors to take concrete actions to improve pricing and access to GeneXpert tests and other rapid molecular diagnostics. We acknowledge the ongoing efforts of the ACT-Accelerator Diagnostics Pillar and its recent commitments, including to continue negotiations with Cepheid for improved pricing and access to Xpert tests for COVID-19, to develop a standardized cost-of-goods-sold (COGS) methodology to feed into discussions on fair pricing, and to further promote access to testing for COVID-19 by scaling up innovations and further diversifying the portfolio of available diagnostic tools.

The ACT-Accelerator Diagnostics Pillar is focused on access to testing for COVID-19, but pricing and access barriers are shared across diseases, especially for molecular technologies such as GeneXpert tests for TB, HIV, HBV, HCV, HPV, STIs, and COVID-19. Any solutions or planned interventions should therefore ensure benefits are shared across diseases. Many of the organizations comprising the ACT-Accelerator Diagnostics Pillar are also represented among the members of the Integrated Diagnostics Consortium (IDC),

which is working to improve integration of testing across diseases and to advance all-inclusive pricing models for GeneXpert tests.

Across diseases, Cepheid's GeneXpert tests utilize the same instruments and benefit from the same manufacturing efficiencies achieved through high sales volumes. The Médecins Sans Frontières-commissioned independent COGS analysis showed that the negligible differences in cartridge design between the virology and TB cartridges do not warrant separate production lines. A $5 price for all tests, inclusive of service and maintenance, would reflect the estimated cost of production of Cepheid's GeneXpert tests,[1] especially at current sales volumes. Cepheid expects that global sales volumes of GeneXpert SARS-CoV-2 tests will amount to 45 million tests in 2021,[2] in addition to sales volumes of Xpert tests for other diseases. Price negotiations should thus take into account Cepheid's overall high sales volumes and corresponding lower manufacturing costs across disease assays, as well as the extensive public funding that underpinned the development of GeneXpert technology. The public return on the significant public investments in the development and rollout of GeneXpert technologies over the last decade should be realized through fair pricing of tests, based on COGS plus a reasonable profit markup and with volume-based price reductions. COGS transparency and COGS- and volume-based pricing should be required as pro-access conditions in all future public funding agreements with diagnostics companies.

We appeal to the organizations represented on the ACT-Accelerator Diagnostics Pillar and the IDC to de-silo ongoing discussions and planned interventions to improve access to rapid molecular tests for COVID-19 and other diseases, including by advancing collective negotiations with Cepheid to secure $5 all-inclusive prices across diseases and favorable terms of service and maintenance (i.e., AccessCare) of testing instruments (irrespective of instrument size or placement).

To increase competition in the automated rapid molecular diagnostics market and provide additional leverage to pressure Cepheid to reduce GeneXpert prices and improve service and maintenance, we also call on the members of the ACT-Accelerator and IDC to accelerate investments in scaling up other rapid molecular testing platforms suitable for the point of care and capable of supporting integrated testing, including Molbio's Truenat system, which currently has tests for TB, COVID-19, HBV, HCV, HPV, STIs, and other diseases.

The Time for $5 Coalition looks forward to working together with the members of the ACT-Accelerator Diagnostics Pillar and IDC to support the development of a coordinated strategy for advancing equitable access to rapid molecular tests, including through joint negotiations with Cepheid for price reductions across diseases and increased investments in Molbio's Truenat and other alternative rapid molecular test platforms, and to being included in the relevant working groups to operationalize this strategy.

Sincerely,

David Branigan on behalf of the Time for $5 Coalition

About the Time for $5 Coalition

The Time for $5 Coalition is comprised of more than 150 civil society organizations working across countries and diseases to improve access to rapid diagnostic testing. Since 2019, the civil society Time for $5 Coalition has demanded that Cepheid lower the price of Xpert tests to $5 per test across diseases, inclusive of service and maintenance, based on the available evidence of Cepheid's cost of production of Xpert tests.[3] In 2021, the Coalition called on Cepheid to improve access to COVID-19 tests in low- and middle-income countries (LMICs) by lowering the price of the tests and increasing the volumes available to LMICs.[4] Cepheid has continued to refuse to reduce the prices of Xpert tests to $5 per test for LMICs, to overcharge the global public for these essential tests, and to prioritize making profit over saving lives.

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[1] Cambridge Consultants/Médecins Sans Frontières. Cost of goods and manufacturing analysis of GeneXpert cartridges. 2019 March 27. https://msfaccess.org/sites/default/files/2019-12/2018%20COGS%20analysis%20of%20Xpert%20MTB_RIF%20Ultra%20cartridges.pdf.

[2] Ketchum K. Demand for Cepheid SARS-CoV-2 point-of-care tests expected to continue through 2022. 360DX. 2021 Apr 22. https://www.360dx.com/covid-19/demand-cepheid-sars-cov-2-point-care-tests-expected-continue-through-2022#.YJFNO31KjUJ.

[3] TB Online. Time to lower the price of Xpert cartridges to $5. 2020 April. http://tbonline.info/posts/2020/4/4/time-lowerprice-xpert-cartridges-us-5/.

[4] TB Online. Advocates request Cepheid increase access to GeneXpert SARS-CoV-2 tests in LMICs. 2021 April. https://www.tbonline.info/posts/2021/2/25/advocates-request-cepheid-increase-access-genexper/.