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Dear Ms. Lynch,

Abbott is committed to providing HIV testing to help support communities as we have been doing since we developed the first test in 1985. We appreciate your letter highlighting the importance of CD4 testing in the fight against HIV and we agree. However, there is context that it's important we share so everyone has a more complete picture.

After the guidance issued by the WHO in 2016 which revised the standard of care and prioritized viral load testing over CD4 testing, we saw a significant drop in CD4 testing. Specifically, of the 5,000 Abbott instruments in Africa, only 50% are currently being used. That means 2,500 instruments are sitting idle. And of the 50% that are active, their utilization is at 30%. As a result of that drop in CD4 testing, along with critical components for the analyzer becoming obsolete, we made the decision that we would no longer manufacture new testing instruments, which was communicated previously. However, even with this significant drop in testing, we have continued to and still will continue to manufacture the CD4 testing cartridges for our PIMA analyzers.

As you are aware, just recently another manufacturer has decided to exit the CD4 testing market completely, which we know has created new concerns. With this downward global trend in CD4 testing, along with the emergence of a lateral flow semi-quantitative CD4 test, even inclusive of the other manufacturer's exit, we believe we can still meet the need by continuing to manufacture and supply testing cartridges and service existing instruments.

To support HIV care and develop a sustainable future for CD4 testing, we need a global coordinated effort of the HIV community to reset the standard of care for CD4 testing – one that helps drive clear guidance, ensures accurate forecasting of the global testing needs and funding required to support it, and looks at new, long-term technology solutions. We believe there are steps Abbott can take together with the HIV community to support these efforts and ensure access to CD4 testing both in the short- and long-term. These include:

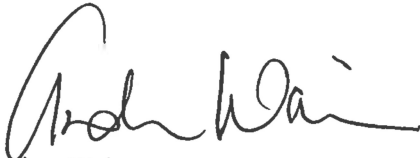
1. Continuing discussions with WHO and global HIV funders in their existing efforts to coordinate accurate forecasting needs for CD4 testing, and subsequently, the global funding community to allocate sufficient funds to support this need.
2. Partnering with WHO, global HIV funders, countries, and civil society on a plan to redeploy unused analyzers to places with the greatest need. This would require leadership from the HIV community to bring together the different stakeholders, and we are prepared to partner with them on a plan to redeploy or increase utilization of existing instruments. We estimate that this would support current instrument needs over the next 10 years – giving the HIV community time to determine a path forward on a next-generation solution.
3. Transferring the PIMA technology, including current design, bill of materials, documentation, and molds to another trusted manufacturer at no cost, recognizing that significant redesign and development efforts will be needed.

We know the important role testing plays in ending the HIV epidemic. Our history, heritage and innovation in this fight allows us to provide rapid, laboratory and molecular testing around the world. For nearly 30 years, we've had a team of scientists monitoring HIV for mutations to ensure our diagnostic testing can detect the virus. We hope to see the day where our collective efforts end the burden of HIV.

Improving access to CD4 testing for those who need it is an effort that no one country, organization or manufacturer can do alone. We need the HIV community to provide leadership by convening all the stakeholders to build a global coordinated effort on the areas above for clear guidelines, solutions, and redeployment of technologies. Abbott will engage and work with the HIV community to do what we can to support continued access to CD4 testing for those who need it.

We look forward to engaging with WHO and the broader HIV community in the next few weeks to discuss needed testing and possible solutions – and to future collaboration as we look to testing needs in the years ahead.

Sincerely,



Andrea Wainer

Executive Vice President, Rapid and Molecular Diagnostics
Abbott

CC:

Dr. Tedros Adhanom Ghebreyesus, Director-General, World Health Organization (WHO)

Dr. Meg Doherty, Director of Global HIV, Hepatitis and STI programs, World Health Organization (WHO)

Peter Sands, Executive Director, The Global Fund to Fight AIDS, Tuberculosis and Malaria

Ambassador Dr. John Nkengasong, U.S. Global AIDS Coordinator and Special Representative for Global Health Diplomacy, U.S. Department of State

Mamadi Yilla, PhD., Acting Principal Deputy U.S. Global AIDS Coordinator, U.S. Department of State

Winnie Byanyima, Executive Director of UNAIDS and Under-Secretary General of the United Nations

Angeli Achrekar, PhD., Deputy Executive Director for the Programme Branch of UNAIDS and Assistant Secretary-General of the United Nations

Dr. Jean Kaseya, Director General, Africa Centres for Disease Control and Prevention (AfCDC)

Dr. Yenew Kebede Tebeje, Head of Laboratory Systems and Networks, Africa Centres for Disease Control and Prevention (AfCDC)

Mark Suzman, PhD., Chief Executive Officer, the Bill and Melinda Gates Foundation

Yogan Pillay, Director of HIV and Tuberculosis Delivery, the Bill and Melinda Gates Foundation

Philippe Duneton, Executive Director, Unitaid

Dr. Bill Rodriguez, Chief Executive Officer, Foundation for Innovative New Diagnostics (FIND)

Nqobile Ndlovu, Chief Executive Officer, the African Society for Laboratory Medicine (ASLM)