

Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois, USA 60064-3500

**OPEN LETTER TO ABBOTT: PEOPLE LIVING WITH HIV NEED YOUR HIV TESTS
TIME FOR A COURSE CORRECTION ON PIMA**

29 June 2023

To: Robert B. Ford, Chairman and CEO

CC:

Olaf Such, Site Director ARDx, Jena GmbH, Abbott
Jenifer Healy, Senior Director, International Government Affairs, Abbott
Duncan Blair, Vice President, Global Health Initiatives, Abbott
Dr Tedros Adhanom Ghebreyesus and Dr Meg Doherty, WHO
Peter Sands, Global Fund to Fight AIDS, TB, and Malaria
Dr John Nkengasong and Dr Mamadi Yilla, PEPFAR
Winnie Byanyima and Dr Angeli Achrekar, UNAIDS
Dr Jean Kaseyam and Dr Yenew Kebede Tebeje, African Union and Africa CDC
Mark Suzman and Dr Yogan Pillay, BMGF
Dr Philippe Duneton, Unitaid
Dr Bill Rodriguez, FIND
Nqobile Ndlovu, ASLM

Dear all,

We are writing on behalf of the Fight AIDS Coalition, concerned civil society, clinicians, Ministries of Health, and other signatories to this letter.

We are writing out of deep concern regarding Abbott's May 2022 announcement that it will no longer produce new PIMA instruments as of 25 May 2022, only the CD4 cartridges and services for existing instruments will remain available for the time being.¹

This decision will impact the ability of national HIV programs to prevent unnecessary loss of life.

CD4 testing at the point of care is crucial in diagnosing advanced HIV disease (AHD) in people living with HIV, due to the high and rapid rates of morbidity and mortality. In 2021, an estimated 650,000 people died of AIDS-related illnesses.² Advanced HIV is defined by WHO as a CD4 cell count below 200 cells/mm³ or a WHO clinical stage 3 or 4 of HIV in any adult, adolescent, or child aged 5 years and above.

Without the use of CD4 tests to identify AHD, up to 50% of asymptomatic AHD cases would be missed.² It is estimated that up to 30% of people initiating HIV treatment have AHD with severe

immunosuppression, putting them at a high risk of opportunistic infections and death.³ The PIMA instrument, manufactured by Abbott and prequalified by WHO, has been an essential tool in diagnosing AHD and providing accurate, rapid, quantitative CD4 cell counts,⁴ at the point of care, which is preferable to centralized alternatives, in terms of turnaround times and timely provision of the AHD care package, whereas getting CD4 results back from centralized facilities can take weeks and sometimes months.⁵

Specifically, we call on Abbott to reverse this dangerous reckless course and change the decision to discontinue manufacturing the PIMA instruments. In addition, we are seeking specific clarification on several important issues regarding the discontinuation of the production of equipment and Abbott's long-term strategies to mitigate harm. These questions are found on the pages in an annex accompanying this letter.

We ask that Abbott stays committed to the needs of people living with HIV including ensuring continued access to CD4 point-of-care testing. Therefore, we ask that Abbott provides in writing concrete steps for a long-term solution to sustainable access to point-of-care CD4 tests.

As civil society, communities, clinicians, and countries affected by Abbott's decision, we commit to continued engagement with national ministries of health and HIV programs to optimally use existing CD4 testing capacity. We will also be requesting Ministries to map and provide data on used versus non-used machines in-country. We ask Abbott to revert the decision to discontinue manufacturing of point-of-care CD4 instruments.

Thank you for your attention to these matters, and we look forward to your prompt written response within two weeks of receipt of this letter, and an opportunity to meet with you to discuss these issues at your earliest convenience.

Sincerely,

Fight AIDS Coalition (FAC)

Diagnostics Equity Consortium (DEC)

Government and research entities:

amfAR - The Foundation for AIDS Research, USA

BC-Centre for Excellence in HIV/AIDS, Canada

Le Centre Régional de Recherche et de Formation à la Prise en Charge Clinique de Fann (CRCF CHU), Sénégal

City University of New York, Institute for Implementation Science in Population Health, United States

Drugs for Neglected Diseases initiative (DNDi), Switzerland

Mbarara University of Science and Technology, Uganda

Ministry of Health, AIDS Control Program, Uganda

Programme National de Lutte contre le VIH/SIDA et les Hépatites (PNLSH), Guinée

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AIDS Healthcare Foundation (AHF), USA
African Society for Laboratory Medicine (ASLM), South Africa
Asia Pacific Network of People Living with HIV (APN+), Thailand
Aurum Institute, South Africa
Children's AIDS Fund International, USA
Diagnostics Equity Consortium (DEC), Zimbabwe
Frontline AIDS, South Africa
Global Action For Fungal Infections (GAFFI), Switzerland
The Global Network of People Living with HIV (GNP+), The Netherlands
Health Global Access Project (GAP), USA
International AIDS Society (IAS), Switzerland
International Association of Providers of AIDS Care (IAPAC), USA
International Community of Women Living with HIV Eastern Africa (ICW-EA), Uganda
International Treatment Preparedness Coalition Global (ITPC), South Africa
International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPC-EECA)
International Treatment Preparedness Coalition in Guatemala/Latin America & Caribbean (ITPC-LATCA)
The International Community of Women Living with HIV (ICW), Argentina
Journalists Against AIDS (JAAIDS), Nigeria
Médecins Sans Frontières (MSF) Access Campaign, Switzerland
Partners in Health (PIH), USA
Prevention Access Campaign (global)

National organizations and entities:

Access Care Treatment and Support (ACTS), Ghana
Acción Ciudadana Contra el SIDA (ACCSI), Venezuela
Advocacy Core Team (ACT), Zimbabwe
AIDS Drug Assistance Program (ADAP) Advocacy Association, USA
Among Karsa, Indonesia
Anantha Network of Positives, India
Andrah Pradesh Drug Users Forum (APDUF), India
Assam Network of Positive People (ANP+), India
Association El Hayet des personnes vivant avec le VIH, Algérie
Association of People Living with HIV (APLHIV) Pakistan, Pakistan
Association of Positive People for Living Excellence, India
Association Tunisienne de Prévention Positive, Tunisie
Bangladesh NGOs Network for Radio and Communication, Bangladesh

Cancer Alliance, South Africa
Chasing Zero, UK
Child Way Uganda, Uganda
Coalition for Health Promotion and Social Development (HEPS), Uganda
Coalition of Women Living with HIV and AIDS (COWLHA), Malawi
Collaboration of Women In Development (CWID), Kenya
Comité de protection des personnes VIH (CPPVIH), Maroc
Community Access National Network, USA
Community Network for Empowerment (CoNE), India
Community of Women Living HIV Lesotho (ICW Lesotho), Lesotho
Dandora Community AIDS Support Association (DACASA), Kenya
Delhi Network of Positive People (DNP+), India
Dignity and Wellbeing for Women Living with HIV in Tanzania (DWWT), Tanzania
Educating Girls and Young Women for Development (EGYD), Zambia
Ex-Wenela Miners Association of Zimbabwe (EWMAZ), Zimbabwe
Facilitators of Community Transformation (FACT), Malawi
FHI 360, India
Five Horizons Health Services, United States
Gift of Hope Foundation, Tanzania
Global Alliance for Human Rights (GAHR), India
Haryana Drug Users Forum (HDUF), India
Heartland Alliance LTD/GTE (HALG), Nigeria
HIV i-Base, UK
Housing Works, Inc., USA
Initiative for Youth Development Change in Nigeria (IYDCN), Nigeria
Institute of HIV Research and Innovation (IHRI), Thailand
Jamaica Community of Positive Women-ICW, Jamaica
Jaringan Indonesia Positif (JIP), Indonesia
Joint Initiatives For Vulnerables Support (Mzeituni), Tanzania
Jointed Hands Welfare Organisation (JHWO), Zimbabwe
Just Treatment, UK
Kampala District Forum of PLHIV Networks, Uganda
Kamukunji Paralegal Trust (KAPLET), Republic of Kenya
Life Concern, Malawi
Life Health Education Development Foundation Trust, Zimbabwe
Live Alive Network (LIAN), Uganda
Médecins Sans Frontières (MSF) South Africa, South Africa
Meghalaya State Network of Positive People (MSNP+), India
Misbah Society, India
Mozambique Treatment Access Movement (MATRAM), Mozambique

Myanmar Positive Group National PLHIV Network (MPG), Myanmar
NAM aidsmap, United Kingdom
National Coalition of People living with HIV in India (NCPI+), India
National Councils of People Living with HIV (NACOPHA), Tanzania
National Minority AIDS Council (NMAC), USA
National Coalition of People Living with HIV in India (NCPI+), India
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Network in Thane by People living with HIV(NTP+), India
Network of African People Living with HIV West Africa (NAP+WA), Côte d'Ivoire
Om Prakash Network of People Living with HIV/AIDS (OPNP), India
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OurEquity NPC, South Africa
People PLUS, Belarus
Positive Women Network Mizoram (PWNM), India
Positively Aware magazine, USA
Public Citizen, USA
Red Ribbon Istanbul Association, Turkey
Sexual Minorities Uganda (SMUG), Uganda
South African Health and Technology Advocacy Coalition (SAHTAC), South Africa
STOPAIDS, UK
Support on AIDS and Life Through Telephone Helpline (SALT), Uganda
Suruwat, Nepal
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Tanzania Community Health and Environment Organization (TACHEO), Tanzania
Tanzania Community Health Information and Support (TaCHIS), Tanzania
Tanzania Health Summit, Tanzania
Tanzania Organisation of Serving Orphans and Vulnerable Children (TOSOVC), Tanzania
Tanzania Network of Women Living with HIV (TNW+), Tanzania
Tanzania Youths Behavioral Change Organization (TAYOBECO), Tanzania
Thai Network of People Living with HIV/AIDS (TNP+), Thailand
Treatment Action Group (TAG), USA
Treatment Advocacy and Literacy Campaign (TALC), Zambia
Trust for Community Development (Trust4Code), Malawi
UK Community Advisory Board (UK-CAB), United Kingdom
Vietnam Network of People living with HIV (VNP+), Vietnam
Vihaan Care and Support Center (CSC), India
Vijana Na Children Foundation (VINACEF Uganda), Uganda
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Annex: Questions and considerations for Abbott to mitigate harm due to PIMA device discontinuation

1. ***Production challenges:*** We understand that Abbott claims the discontinuation is due to supply issues of a specific component(s) that facilitates production. We would like to know the component(s) causing the production challenge and the related supplier information, as well as the steps undertaken by Abbott with the supplier to mitigate this gap. We ask for Abbott's strategies in the short term and especially in the long term and solutions for the supply of the components to make the instruments. We cannot allow that manufacturers of critical components of live-saving technologies stop production and put the millions of lives at risk.
2. ***The supply of stock of PIMA instruments in Germany:*** It has come to our attention that there is a stock of PIMA instruments in the Jena facility in Germany. We would like to understand the size of this supply and your intentions and how it may impact existing instruments in terms of service, maintenance, and availability.
3. ***Existing instruments in countries:*** Many countries already possess PIMA instruments, some of which may no longer be under warranty or in functioning condition. We request clarification on how Abbott plans to address these instruments and ensure their continued use and provision of support to countries. Are there any plans to work with countries and global health actors to conduct mapping exercises to assess dormant machines in various countries? If so, it would be highly beneficial for the data resulting from these exercises

to be available to stakeholders, as it could inform actions needed to achieve optimal use of existing machines in countries.

4. **Honoring warranties:** It has been noted in Abbott’s communications that current active warranties will be honored, and new warranties will be supported for new instruments purchased from the stockpile in Germany. However, we seek further clarity on how Abbott plans to handle instruments that are no longer under warranty but are still functional or require repair.
5. **Long-term solutions and support:** What long-term plans has Abbott put in place regarding the availability of cartridges and the provision of service and maintenance? What are the long-term plans from Abbott to guarantee access to point-of-care CD4 testing, beyond the lifetimes of the existing PIMA instruments in countries? Can Abbott commit to transfer the PIMA technology, IP, data and any relevant information royalty-free to local manufacturers (s) in low- and middle-income countries?

References:

1. Abbott. Letter dated 11th May 2022. Pima™ Analyser Discontinuation REF: 260300003
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3. WHO. Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy, July 2017. *Behavior and Information Technology*. 2017;2(2):127-161.
4. MSF. Technical Brief. Make It Count: Access to Point of Care CD4 Testing Under Threat. 2022;
<https://msfaccess.org/make-it-count-access-point-care-cd4-testing-under-threat>
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