

BD Biosciences
2350 Qume Drive
San Jose, CA 95131

To: Tom Polen, Chairman, CEO and President of BD (Becton, Dickinson and Company)

CC:

Henok Tilahun, Senior Global Marketing Manager, BD
Caitlin Asjes, Senior Director Global Public Health, BD
Adam Zerda, Senior Director International Affairs, BD
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
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Dr Philippe Duneton, Unitaid
Dr Bill Rodriguez, FIND
Nqobile Ndlovu, ASLM

29 June 2023

Open Letter: Urgent action to ensure future access to CD4 diagnostics for people living with HIV

Dear BD representatives,

The undersigned individuals and organizations from communities affected by HIV and working with people living with HIV are writing to express our deep sense of urgency and concern regarding the acute crisis unfolding in the realm of advanced HIV disease/AIDS, specifically concerning the rapidly changing landscape of point of care CD4 instruments.

We are startled and gravely concerned about the Becton Dickinson (BD) November 2022 announcement of its phase-out of its critical CD4 cartridges and FACSPresto and FACSCount instruments by 2024, and to end its service and support for existing CD4 instruments by 2026.¹

Despite significant progress in the fight against HIV, approximately one-third of all people living with HIV enter care with advanced HIV disease (AHD), and roughly every minute there is another death from AIDS-defining illnesses.² Research has demonstrated that relying solely on symptomatic screening for AHD without a CD4 count could miss up to half of the people living with AHD/AIDS.³ The World Health Organization (WHO), recognizing the importance of CD4

count in assessing an individual's immune status, guiding clinical management decisions, and evaluating the risk of opportunistic infections, made CD4 cell count the 'gateway'/surrogate marker to promptly initiate the life-saving AHD package of care.⁴

BD, a self-described leader in "[advancing the world of health](#),"⁵ has been instrumental in producing two WHO-prequalified quantitative CD4 diagnostics: FACSPresto⁶ and FACSCount.⁷ Particularly, in low and middle-income countries (LMICs) these instruments are among the "workhorses" used initially to support ART initiation and now diagnose AHD/AIDS which is essential for linking individuals to proper care in a timely manner.⁸ The discontinuation of the critical point of care CD4 instruments within the next three years would require countries to fully transition away from BD instruments within that time frame. The decision to phase out these optimal diagnostics from the market could substantially impact timely access to lifesaving AHD package of care and CD4 diagnostics, thereby undermining the global commitment to reduce HIV/AIDS-related deaths to below 250,000 by 2025.⁹

As civil society, community representatives, clinicians, and countries affected by BD's decision, we are concerned that timely access to AHD care and more specifically CD4 point-of-care instruments and tests hinges on BD correcting its current course of action. We are calling for BD to recommit to supporting the long-term production of point-of-care CD4 instruments and tests and maintaining a sustained supply for LMICs. We strongly urge BD to reconsider its decision to phase out FACSPresto and FACSCount, a decision that directly impacts the health outcomes and quality of life for millions of people globally.

Specifically, we ask BD to:

- **Work with the global community to make the case for better CD4 monitoring:** BD and people living with HIV and their allies have a common goal in increasing the use of CD4 monitoring to better detect AHD and link people to life-saving care. Rather than backing away, BD should advocate and bring regular reporting on CD4 procurement and utilization to the effort. One way to help support the global health actors is to conduct an assessment and mapping of the current platforms in an effort to identify those in need of servicing, replacement, or redistribution for AHD.
- **Information on supply and production challenges:** We understand that BD claims the discontinuation is linked 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 BD with the supplier to address this problem.
- **Provide the minimum threshold needed to sustain production:** Given that the need for CD4 tests is estimated to be approximately 8 million according to CHAI¹⁰, and the Global Fund to Fight AIDS, TB, and Malaria¹¹ as well as PEPFAR's renewed support for AHD¹², we request BD to reconsider its decision to discontinue the production of FACSPresto and FACSCount instruments and tests.
- **Commit to maintain its production capacity:** Should it not reverse course, commitment to continuing production is critical as part of a transition strategy. This is essential to provide countries and donors sufficient time for transition to alternative CD4 testing

strategies, thereby ensuring a sustainable continuum of care for individuals living with HIV/AIDS.

- **Commit to continuing services and support:** Relatedly, And to commit to providing services and support to existing and new FACSPresto and FACSCount instruments beyond 2026 given countries have invested in these instruments. Additionally, we ask that BD work with national governments, donors, and global health actors to maximize the utilization of existing devices by providing ongoing support, maintenance, and necessary sub-components to ensure uninterrupted access to CD4 diagnostics until replacement diagnostics are available on the market.

We ask that BD provides its responses to the requests above in writing. In addition, we would like to request a meeting with BD's team at your earliest convenience to discuss this matter.

Thank you for considering this urgent request. We look forward to hearing from you within two weeks of receipt of this letter.

Sincerely,

Fight AIDS Coalition (FAC)

Diagnostics Equity Consortium (DEC)

Government and research entities:

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

BC-Centre for Excellence in HIV/AIDS, Canada

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

Drugs for Neglected Diseases initiative (DNDi), Switzerland

Institute of HIV Research and Innovation (IHRI), Thailand

Mbarara University of Science and Technology, Uganda

Ministry of Health, AIDS Control Program, Uganda

International and regional organizations:

amfAR - The Foundation for AIDS Research, USA

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)
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
Action Group for Health Human Rights and HIV, Uganda
ADAP Advocacy Association, USA
Advocacy Core Team (ACT), Zimbabwe
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
Comité de protection des personnes VIH (CPPVIH), Maroc
Community Access National Network, USA
Community Network for Empowerment (CoNE), India
Community of Women Living with 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
Health HIV, USA
Heartland Alliance LTD/GTE (HALG), Nigeria
HIV i-Base, UK
Housing Works, Inc., USA
Initiative for Youth Development Change in Nigeria (IYDCN), Nigeria
Jamaica Community of Positive Women-ICW, Jamaica
Jaringan Indonesia Positif (JIP), Indonesia
Joint Initiatives For Vulnerables Support (Mzeituni), Tanzania
Jointed Hands Welfare Organisation, 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), Myanmar
NAM aidsmap, United Kingdom
National Coalition for LGBTQ Health, USA
National Councils of People Living with HIV (NACOPHA), Tanzania
National Coalition of People living with HIV in India (NCPI+), India
National Minority AIDS Council (NMAC), USA
The National Organisation for People Living with Hepatitis B (NOPLHB), Uganda
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

ONG LES Batisseurs, Democratic Republic of the Congo
OurEquity NPC, South Africa
People PLUS, Belarus
Positive Women Network Mizoram (PWNM), India
Positively Aware magazine, USA
Public Citizen, USA
Rainbow Sunrise Mapambazuko, Democratic Republic of Congo
Red Ribbon Istanbul Association, Turkey
South African Health and Technology Advocacy Coalition (SAHTAC), South Africa
STOPAIDS, UK
Support on AIDS and Life Through Telephone Helpline (SALT), Uganda
Suruwat, Nepal
Swaziland Network of Young Positives (SNYP+), Eswatini
Tabene Youth Advocacy Network, Zambia
Tanzania Community Health and Environment Organization (TACHEO), Tanzania
Tanzania Community Health Information and Support (TaCHIS), Tanzania
Tanzania Community Rights Organisation, Tanzania
Tanzania Health Summit, Tanzania
Tanzania Organisation of Serving Orphans and Vulnerable Children (TOSOVC), Tanzania
Tanzania Network of Women Living with HIV (TNW+), Tanzania
Thai Network of People Living with HIV/AIDS (TNP+), Thailand
Treatment Action Group (TAG), USA
Treatment Advocacy and Literacy Campaign (TALC), Zambia
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
We Rise And Prosper (WRAP), Uganda
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Youth And Women Emancipation (YAWE), Tanzania
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Signatures in individual capacities:

Clinicians, professors, researchers, lab and government personnel:

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William Worodria, Physician, Uganda

Civil society individual endorsements:

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Juliet Bosa, United Kingdom
Sanjib Chakraborty, India
Ashmita Chetri, India
Trandan Chutia, India
Mohamed Daddi, Member CCM/1st Representative of PLWHIV instance de coordination national, Morocco
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Rajesh Didiya, CEO, National TB Network, Nepal
Rajiv Dua, Executive Director, India HIV/AIDS Alliance, India
Rajesh Dutta, India
Maura Elaripe, CCM TB Community Representative, ACT AP, Papua New Guinea
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Mundrika Gahlot, India
Suparna Gawade, India
Manitosh Ghildiyal, India
Birinchi Gogoi, India
Maurice Greenham, United Kingdom
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Bandana Kumari, India
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Daisy Montero, USA
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Rahul Narah, Indian
Puneswar Nath, India
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Faith Onu, Young Persons Network for Sustainable Lifestyle and Health (YOUPEN4SLAH), Nigeria
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