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July 11, 2023

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

Dear Fight AIDS Coalition, Diagnostics Equity Consortium and Signatories of Open Letter to BD:

We appreciate your outreach to BD and the continued challenges facing the world with HIV disease/AIDS. As a company that pioneered CD4 testing for patients with HIV and has trained clinicians and labs around the world to advance the standard of care in this area, we remain highly committed to providing CD4/CD8 testing to support patients with HIV/AIDS globally. BD has a very strong track record of collaborating with the global community with an emphasis on supporting low- and middle-income countries (LMICs) to increase access to diagnostics, including a partnership with UNITAID and the Clinton Health Access Initiative (CHAI) to expand CD4 testing in sub-Saharan Africa. BD also partnered with the U.S. Centers for Disease Prevention and Control (CDC) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) for more than a decade to develop and strengthen medical laboratories in LMICs through the "Labs for Life" program. Through this work, we are aware of the diagnostic challenges facing LMICs.

The BD FACSPresto™ system has been an important part of the HIV/AIDS response for nearly 10 years, though recent updates in guidelines have favored newer diagnostic approaches. Unfortunately, because suppliers have discontinued several critical components and the reagent manufacturing facility is closing in July 2024, BD cannot continue production of BD FACSPresto™ instruments beyond

December 2023 or reagents beyond July 2024. However, we will support the system through June 2026, and we will also continue to offer CD4 testing on other BD platforms.

Out of respect for our customers and LMICs, the discontinuation of BD FACSPresto™ instrument and reagents was originally communicated in November 2022 to provide nearly four years of advanced notice so that LMICs could transition to one of our other centralized lab testing platforms that BD will continue to offer, or identify alternative testing methods. BD plans to produce reagent cartridges as normal until the planned closure of our manufacturing facility at the end of July 2024, and given the 23-month shelf life of the reagents, BD will continue to offer support and service for BD FACSPresto™ until June 2026. This means that BD can support customers who choose to place large orders as a means to create safety stock of reagents and extend the use of their BD FACSPresto™ instrument through June 2026. As we communicated previously, any final orders should be submitted by March 31, 2024 to ensure sufficient time to manufacture.

Our internal diligence suggests that significant reengineering would be required to maintain the product on the market. With the significant decrease in demand for CD4 testing due to multiple market factors — including the shift to viral load testing as the preferred method for HIV treatment monitoring — combined with the manufacturing challenges noted above, BD has determined that the BD FACSPresto™ product line is no longer viable. In the event a third party is available to support reengineering and manufacturing of the FACSPresto™ system, BD would be willing to explore ways that it could be of assistance, potentially including a technology transfer. However, the extremely complex manufacturing process and discontinuation of necessary components make this scenario highly unlikely. This opinion was recently reinforced by another global health partner of BD that has experience developing medical technology devices. This partner recently communicated to BD that they investigated their ability to support manufacture of the FACSPresto™ instrument and determined it was beyond their scope.

BD will provide the highest quality products and service to our customers, along with a migration path to a newer technology platform for centralized lab testing. We would welcome discussions with you about this matter, as well as any LMICs to help evaluate their laboratory needs and recommendations on suitable lab-based CD4 testing solutions.

Sincerely,



Steve Conly
President
BD Biosciences



Adam Zerda
Senior Director, International Affairs
BD (Becton, Dickinson and Company)