ORIGINAL PMA APPROVAL ORDER
October 9, 2025

bioLytical Laboratories, Inc.
Attention: Ana Subramanian
Suite 406
13251 Delf Place
Richmond, British Columbia
Canada V6V 2A2

Re:	**BP251179/0**
Device:	INSTI® HIV Self Test
Filed:	March 19, 2025
Amended:	March 20, 2025; March 25, 2025; April 1, 2025; April 2, 2025; April 11, 2025; April 17, 2025; April 22, 2025; April 29, 2025; May 5, 2025; May 6, 2025; May 7, 2025; May 15, 2025; May 27, 2025; May 28, 2025; June 11, 2025; July 15, 2025; August 11, 2025; August 13, 2025; August 14, 2025; August 18, 2025; August 22, 2025; August 28, 2025; September 4, 2025; September 17, 2025; September 18, 2025; September 19, 2025; September 29, 2025; October 1, 2025; October 3, 2025; October 6, 2025

Dear Ana Subramanian:

The Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the INSTI® HIV Self Test.

The INSTI HIV Self Test is a single use, rapid, in vitro diagnostic qualitative immunoassay for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and/or Type 2 (HIV-2) in human fingerstick whole blood. This test is intended for over-the-counter (OTC) consumer use as an aid in the diagnosis of infection with HIV-1 and HIV-2. The test is intended for use as a self test by users 18 years or older. It is not intended to be used with specimens other than fingerstick whole blood

Based upon the information submitted, the PMA is approved. You may start commercial distribution of the device upon receipt of this letter. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

Expiration dating for this device has been established and approved at 2°C to 30°C when stored in the original packaging in a cool, dry location. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "**Annual Report**" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, under 21 CFR 814.82(a)(9), the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

You have agreed via email dated September 4, 2025 to provide the following non-clinical information in a report, which may be followed by a PMA supplement where applicable.

1. You will conduct surveillance of the Customer Service/Technical Support center usage to collect and document the information on the problems with the test/questions asked, number of individuals reporting positive results, negative results and unknown results, action taken by call center (if any), as well as demographic information that does not breach caller confidentiality.

   Please submit this information annually in **PMA Post-Approval Study Report** described in our email of September 4, 2025 as a condition of approval of this device. These reports should be submitted annually for five years post-approval separately from the Annual Report, after which time we will consider if continued reporting is necessary.

2. You will provide a certificate of translation for all final labeling printed in Spanish.

Be advised that failure to comply with any post-approval requirement constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 21 CFR 814.46(a)(2).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include

the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. Additional information about changes that may require a PMA supplement are provided in the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" https://www.fda.gov/media/81431/download.

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production and process controls (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR Part 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product post-marketing safety reporting is available at https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products.

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR Part 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

CBER does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CBER will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CBER Internet HomePage located at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit a Product Correspondence to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified to the address below and should reference the above PMA number to facilitate processing.

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact, Dr. Vasantha Kumar at (240) 402-8413 or Vasantha.Kumar@fda.hhs.gov.

Sincerely,

Anne Eder, MD, PhD
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research