



PANEL TRACK PMA SUPPLEMENT APPROVAL ORDER
November 5, 2020

Hologic, Inc.
Attention: Katerina Capkova, PhD
10210 Genetic Center Drive
San Diego, CA 92121

Re: BP150318/20
Device: Aptima HIV-1 Quant Dx Assay
Product Code: MZF
Filed: May 20, 2020
Amended: August 24, 2020; October 7, 2020; October 20, 2020; October 29, 2020;
November 4, 2020

Dear Dr. Capkova:

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) supplement for the Aptima HIV-1 Quant Dx Assay. This device is an in vitro nucleic acid amplification test (NAAT) for the detection and quantitation of human immunodeficiency virus type 1 (HIV-1) on the fully automated Panther system. It is intended to be used as an additional test to aid in diagnosis for HIV-1 infection using appropriate HIV testing algorithms. The presence of HIV-1 nucleic acid in the plasma or serum of individuals without antibodies to HIV-1 is indicative of acute or primary infection.

The Aptima HIV-1 Quant Dx assay may also be used as a supplemental test, when it is reactive, to confirm HIV-1 infection in an individual whose plasma or serum specimen is reactive with an approved assay with an indication as an aid in the diagnosis of HIV-1 infection.

The Aptima HIV-1 Quant Dx assay is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in monitoring the effects of antiretroviral treatment, as measured by changes in plasma HIV-1 RNA levels. The Aptima HIV-1 Quant Dx assay quantitates HIV-1 RNA groups M, N, and O over the range of 30 to 10,000,000 copies/ mL. One international unit is equivalent to 0.35 copies of HIV-1 RNA for the 3rd HIV-1 WHO International Standard (subtype B, NIBSC code: 10/152).

This assay is not intended to be used as a donor screening test for HIV-1. Performance of this test has not been evaluated for use in pregnant women or in a pediatric population.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. 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 located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> identifies combination product submissions.

The sale and distribution of this device is restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

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, 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.

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. For more information, please refer to 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>.

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 postmarketing safety reporting (21 CFR 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 postmarketing safety reporting is available at (see <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 postmarketing safety reporting requirements (21 CFR 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 an amendment 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 (please see note below)**, 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

Please note:

CBER's Document Control Center (DCC) will not process any submission received by mail or courier including submissions provided on paper and electronic media (e.g., CDs, USB) until further notice. Device submissions, for CBER regulated devices, can still be submitted electronically using the Electronic Submissions Gateway (ESG) (under 10GB) or in some cases via email (under 150MB) in accordance with final industry guidance, eCOPY Program for Medical Devices Submissions found at <https://www.fda.gov/media/83522/download>. CBER strongly encourages sending submissions through the ESG, FDA's preferred secure method of transmission. Instructions for setting up an ESG

account can be found at <https://www.fda.gov/industry/electronic-submissions-gateway>.

Submissions regarding this file may also be submitted electronically via email at CBERDCC_eMailSub@fda.hhs.gov. We will accept submissions through this email option only during the COVID-19 public health emergency. For additional information regarding CBER operations during this public health emergency, please see the CBER COVID -19 CBER Regulated Biologics page found at <https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics>.

If you have any questions concerning the contents of the letter, please contact the Regulatory Project Manager, Dr. Vasantha Kumar, at (240) 402-8413 or Vasantha.Kumar@fda.hhs.gov.

Sincerely,

Hira L. Nakhasi, PhD
Director
Division of Emerging and
Transfusion Transmitted Diseases
Office of Blood Research and Review
Center for Biologics Evaluation and Research