

Currently Approved CBER Device Premarket Applications (PMAs) As of 30-NOV-2024

- BP090080-0 Abbott Laboratories  
100 Abbott Park Road  
Dept T3M2 Bldg AP20  
Abbott Park, IL 60064-3500  
Trade Name: ARCHITECT HIV Ag/Ab Combo Assay  
Approved Date: 18-JUN-2010
- BP060002-0 Abbott Molecular  
1300 E. Touhy Avenue  
Des Plaines, IL 60018  
Trade Name: Abbott RealTime HIV-1 Amplification Reagent Kit  
Abbott RealTime HIV-1 Calibrator Kit  
Abbott RealTime HIV-1 Control Kit  
Approved Date: 11-MAY-2007  
Approved Under ABBOTT Molecular, Inc.
- BP200455-0 Abbott Molecular, Inc.  
1300 East Touhy Ave  
Des Plaines, IL 60018  
Trade Name: Alinity m HIV-1  
Approved Date: 02-JUL-2020
- BP120037-0 Alere Scarborough Inc  
10 Southgate Road  
Scarborough, ME 04074  
Trade Name: Alere Determine™ HIV-1/2 Ag/Ab Combo  
Approved Date: 08-AUG-2013  
Approved Under Alere Scarborough
- BP090022-0 Avioq, Inc.  
9700 Great Seneca Hwy.  
Rockville, MD 20850  
Trade Name: Avioq HIV-1 Microelisa System  
Approved Date: 21-SEP-2009
- BP180279-0 Avioq, Inc.  
104 TW Alexander Dr  
Building 6  
PO Box 12808  
Research Triangle Park, NC 27709  
Trade Name: VioOne HIV Profile Supplemental Assay  
Approved Date: 19-OCT-2020
- BP170122-0 Avita Medical  
28159 Avenue Stanford  
Suite 220  
Valencia, CA 91355-2271  
Trade Name: ReCell Autologous Cell Harvesting Device

Approved Date: 20-SEP-2018

BP220799-0 Avita Medical  
28159 Avenue Stanford  
Suite 220  
Valencia, CA 91355-2271  
Trade Name: RECELL Autologous Cell Harvesting Device  
Approved Date: 16-JUN-2023

BP140111-0 Bio-Rad Laboratories  
6565 185th Ave NE  
Clinical Diagnostics Group  
Redmond, WA 98052-5039  
Trade Name: BioPlex? 2200 HIV Ag-Ab  
Approved Date: 23-JUL-2015

BP040046-0 Bio-Rad Laboratories, Inc.  
6565 185th Avenue NE  
Redmond, WA 98052  
Trade Name: Multispot HIV-1/HIV-2 Rapid Test  
Approved Date: 12-NOV-2004  
Approved Under Bio-Rad Laboratories

BP100064-0 Bio-Rad Laboratories, Inc.  
6565 185th Avenue NE  
Redmond, WA 98052  
Trade Name: GS HIV Combo Ag/Ab EIA  
Approved Date: 22-JUL-2011  
Approved Under Bio-Rad Laboratories

BP140120-0 Bio-Rad Laboratories, Inc.  
6565 185th Avenue NE  
Redmond, WA 98052  
Trade Name: Bio-Rad Geenius HIV 1/2 Supplemental Assay  
Approved Date: 24-OCT-2014

BP130026-0 BioArray Solutions, Ltd.  
35 Technology Drive  
Suite 100  
Warren, NJ 07059  
Trade Name: Immucor PreciseType™ Human Erythrocyte Antigen Molecular  
BeadChip Test  
Approved Date: 21-MAY-2014

BP130076-0 Cerus Corporation  
2550 Stanwell Drive  
Concord, CA 94520  
Trade Name: INTERCEPT(R) Blood System for Plasma  
Approved Date: 16-DEC-2014

BP140143-0 Cerus Corporation  
2550 Stanwell Drive  
Concord, CA 94520  
Trade Name: INTERCEPT(R) Blood System for Platelets  
Approved Date: 18-DEC-2014

BP050009-0 Chembio Diagnostic Systems, Inc.  
3661 Horseblock Road  
Medford, NY 11763  
Trade Name: Chembio HIV Reactive/Nonreactive Controls  
SURE CHECK HIV 1/2 ASSAY  
Approved Date: 25-MAY-2006

BP050010-0 Chembio Diagnostic Systems, Inc.  
3661 Horseblock Road  
Medford, NY 11763  
Trade Name: Chembio HIV Reactive/Nonreactive Controls  
HIV 1/2 STAT-PAK ASSAY  
Approved Date: 25-MAY-2006

BP120032-0 Chembio Diagnostic Systems, Inc.  
3661 Horseblock Road  
Medford, NY 11763  
Trade Name: DPP HIV 1/2 Assay  
Approved Date: 19-DEC-2012

BP180191-0 Chembio Diagnostic Systems, Inc.  
3661 Horseblock Road  
Medford, NY 11763  
Trade Name: DPP? HIV-Syphilis System  
Approved Date: 01-OCT-2020

BP190437-0 DiaSorin, Inc.  
1951 Northwestern Ave  
Stillwater, MN 55082-0285  
Trade Name: LIAISON? XL MUREX Control HIV Ab/Ag HT  
LIAISON? XL MUREX HIV Ab/Ag HT  
Approved Date: 25-NOV-2020

BP850001-0 Fenwal, Inc.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Autopheresis-C Plasmapheresis System  
Approved Date: 24-MAR-1986  
Approved Under Baxter Healthcare Corporation

BP150318-0 Hologic, Inc.  
10210 Genetic Center Drive  
San Diego, CA 92121  
Trade Name: Aptima HIV-1 Quant Dx assay

Approved Date: 22-DEC-2016

BP950002-0 Home Access Health Corporation  
2401 West Hassell Road  
Suite 1510  
Hoffman Estates, IL 60169-5200  
Trade Name: Home Access HIV-1 Test System  
Approved Date: 22-JUL-1996

BP000009-0 Maxim Biomedical Inc  
1440 Fourth Street  
Berkeley, CA 94710  
Trade Name: Calypte HIV-1 Urine EIA  
Approved Date: 12-JAN-2001  
Approved Under Calypte Biomedical Corporation

BP010009-0 Maxim Biomedical Inc  
1265 Harbor Bay Parkway  
Alameda, CA 94502  
Trade Name: Cambridge Biotech HIV-1 Urine Western Blot  
Approved Date: 21-JUN-2001  
Approved Under Calypte Biomedical Corporation

BP000023-0 MedMira Labs  
155 Chain Lake Drive, Bayers Lake  
Halifax, Nova Scotia CANADA B3S 1B3  
Trade Name: MedMira Rapid HIV Test  
Approved Date: 16-APR-2003

BP910001-0 OraSure Technologies, Inc  
8505 SW Creekside Place  
Beaverton, OR 97005  
Trade Name: Orasure HIV-1 Oral Specimen Collection Device  
Approved Date: 23-DEC-1994  
Approved Under OraSure Technologies

BP950004-0 OraSure Technologies, Inc  
220 East First Street  
Bethlehem, PA 18015-1360  
Trade Name: OraSure HIV-1 Western Blot Kit  
Approved Date: 03-JUN-1996  
Approved Under Epitepe, Inc.

BP010047-0 OraSure Technologies, Inc  
150 Webster Street  
Bethlehem, PA 18015-1389  
Trade Name: OraQuick ADVANCE Rapid HIV-1/2 Antibody Test  
Approved Date: 07-NOV-2002  
Approved Under OraSure Technologies

BP120001-0 OraSure Technologies, Inc  
220 East First Street  
Bethlehem, PA 18015-1360  
Trade Name: OraQuick® In-Home HIV Test  
Approved Date: 03-JUL-2012

BP953200-0 Organogenesis, Inc.  
150 Dan Road  
Canton, MA 02021  
Trade Name: Apligraf

Approved Date: 22-MAY-1998

BP960700-0 Organogenesis, Inc.  
150 Dan Road  
Canton, MA 02021  
Trade Name: Dermagraft-TC (temporary covering)

Approved Date: 18-MAR-1997

BP003600-0 Organogenesis, Inc.  
150 Dan Road  
Canton, MA 02021  
Trade Name: Dermagraft

Approved Date: 28-SEP-2001

BP011600-0 Ortec International, Inc.  
3960 Broadway, 2nd Floor  
New Yoir, NY 10032  
Trade Name: Orcel

Approved Date: 31-AUG-2001

BP050051-0 Ortho-Clinical Diagnostics, Inc.  
100 Indigo Creek Drive  
Rochester, NY 14626-5101  
Trade Name: VITROS Immunodiagnositics Products Anti-HIV 1+2 Calibrator  
VITROS Immunodiagnositics Products Anti-HIV 1+2 Reagent Pack  
Approved Date: 27-MAR-2008

BP160122-0 Ortho-Clinical Diagnostics, Inc.  
100 Indigo Creek Drive  
Rochester, NY 14626-5101  
Trade Name: VITROS Immunodiagnostic Products HIV Combo Calibrator  
VITROS Immunodiagnostic Products HIV Combo Reagent Pack

Approved Date: 13-DEC-2017

- BP170154-0 Progenika Biopharma, S.A.  
Ibaizabal bidea, Edificio 504  
Parque Tecnologico de Bizkaia  
Derio, Bizkaia,  
Trade Name: ID CORE XT  
Approved Date: 11-OCT-2018
- BP160050-0 Roche Diagnostics Operations, Inc.  
9115 Hague Road  
Indianapolis, IN 46250-0416  
Trade Name: Elecsys HIV combi PT  
Approved Date: 21-JUN-2017  
Approved Under Roche Diagnostics
- BP190403-0 Roche Diagnostics Operations, Inc.  
9115 Hague Road  
Indianapolis, IN 46250-0416  
Trade Name: Elecsys HIV Duo  
Approved Date: 10-APR-2020  
Approved Under Roche Diagnostics
- BP050069-0 Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
Pleasanton,, CA 94588-2722  
Trade Name: COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, 48 Tests  
COBAS AmpliPrep/COBAS TaqMan Wash Reagent, 5.1 L  
Approved Date: 11-MAY-2007
- BP150262-0 Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
Pleasanton,, CA 94588-2722  
Trade Name: cobas HIV-1  
Approved Date: 18-DEC-2015
- BP190360-0 Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
Pleasanton,, CA 94588-2722  
Trade Name: cobas? HIV-1/HIV-2 Qualitative  
Approved Date: 12-AUG-2020
- BP050030-0 Siemens Healthcare Diagnostics  
511 Benedict Ave  
Tarrytown, NY 10591  
Trade Name: ADVIA Centaur HIV 1/0/2 Enhanced ReadyPack Reagents  
Approved Date: 18-MAY-2006  
Approved Under Bayer HealthCare
- BP140103-0 Siemens Healthcare Diagnostics, Inc.

511 Benedict Ave  
Tarrytown, NY 10591  
Trade Name: ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay  
Approved Date: 08-JUN-2015

BP060001-0 ThermoGenesis Corp  
2711 Citrus Road  
Rancho Cordova, CA 95742  
Trade Name: CryoSeal FS System  
Approved Date: 26-JUL-2007  
Approved Under Thermogenesis

BP030025-0 Trinity Biotech  
IDA Business Park  
Southern Cross Road  
, Bray, Co. Wicklow IRELAND  
Trade Name: Uni-Gold Recombigen HIV-1  
Approved Date: 23-DEC-2003  
Approved Under Trinity Biotech plc

BP090032-0 bioLytical Laboratories, Inc  
1108-13351 Commerce Parkway  
Richmond, British Columbia CANADA V6V 2X7  
Trade Name: INSTI<sub>2</sub> HIV-1 Antibody Test Kit  
Approved Date: 29-NOV-2010