

Currently Approved CBER Device Premarket Applications (PMAs)  
As of Sep 06, 2017  
Sorted by Applicant Name

BP090080-0 Abbott Laboratories  
100 Abbott Park Road  
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.

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

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

BP090032-0 bioLytical Laboratories, Inc  
1108-13351 Commerce Parkway  
Richmond, BC, British Columbia Canada V6V 2X7  
Trade Name: INSTI; HIV-1 Antibody Test Kit  
Approved Date: 29-NOV-2010

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

BP850001-0 Fenwal Inc  
Three Corporate Drive  
2nd Floor

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 Epitope, 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 Immunodiagnosics Products Anti-HIV 1+2  
Calibrator  
VITROS Immunodiagnosics Products Anti-HIV 1+2  
Reagent Pack  
Approved Date: 27-MAR-2008

BP160050-0 Roche Diagnostics  
9115 Hague Road  
Indianapolis, IN 46250  
Trade Name: Elecsys HIV combi PT  
Approved Date: 21-JUN-2017

BP050069-0 Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
P.O. Box 9002  
Pleasanton,, CA 94588-0900

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  
P.O. Box 9002  
Pleasanton,, CA 94588-0900  
Trade Name: cobas HIV-1  
Approved Date: 18-DEC-2015

BP050030-0 Siemens Healthcare Diagnostics  
511 Benedict Ave  
Tarrytown, NY 10591  
Trade Name: ADVIA Centaur HIV 1/O/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  
2711 Citrus Road  
Rancho Cordova, CA 95742  
Trade Name: CryoSeal FS System  
Approved Date: 26-JUL-2007

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