

Currently Approved CBER Device Premarket Applications (PMAs)
As of October 01, 2012
Sorted by Applicant Name

BP060002 ABBOTT Molecular, Inc.
 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

BP090080 Abbott Laboratories
 100 Abbott Park Road
 Abbott Park, IL 60064-3500
Trade Name: ARCHITECT HIV Ag/Ab Combo Assay
Approved Date: 18-JUN-2010

BP090022 Avioq, Inc.
 9700 Great Seneca Hwy.
 Rockville, MD 20850
Trade Name: Avioq HIV-1 Microelisa System
Approved Date: 21-SEP-2009

BP090032 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

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

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

BP050009 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 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

- BP850001 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
- BP950002 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 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 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 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 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 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 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 OraSure Technologies, Inc
220 East First Street
Bethlehem, PA 18015-1360
Trade Name: OraQuick® In-Home HIV Test
Approved Date: 03-JUL-2012
- BP050051 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
- BP950005 Roche Molecular Systems, Inc.
1080 US Highway 202
Branchburg, Somerville, NJ 08876-3771
Trade Name: Roche Amplior HIV-1 Monitor (tm)
Test
Approved Date: 03-JUN-1996
- BP050069 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
- BP050030 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
- BP000028 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name: Quntiplex HIV-1 RNA 3.0 Assay
(bDNA)
Approved Date: 11-SEP-2002
Approved Under Bayer Corporation

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

BP030025 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