Currently Approved CBER Device Premarket Applications (PMAs) As of 31-AUG-2026

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 DetermineTM 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 Systerm 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 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 Immunodiagnostics Products Anti-HIV 1+2 Calibrator
VITROS Immunodiagnostics 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 Technologico de Bizkaia
Derio, Bizkaia,
Trade Name: ID CORE XT
Approved Date: 11-OCT-2018

BP160050-0 Roche Diagnostics Operations, Inc.
9115 Hague Road
PO Box 50457
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
PO Box 50457
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/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 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 HIV-1 Antibody Test Kit
Approved Date: 29-NOV-2010

BP251179-0 bioLytical Laboratories, Inc
406 - 13251 Delf Place,
Richmond, British Columbia, British Columbia, V6V 2A2 CANADA V6V 2A2
Approved Date: 09-OCT-2025