



Certificate No. 2505-12-2024-1

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(10 Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above device product(s) may be marketed in, and legally exported from, the United States of America at this time. While the manufacturing plant(s) in which the device product(s) is produced is subject to inspection, FDA does not routinely inspect manufacturing firms that only make Class 1 medical devices. However, the firm has certified that it is currently operating in substantial compliance with current good manufacturing practice requirements for the device product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from December 11, 2024 to December 10, 2026.



To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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

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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Corporate Headquarters

Diagnostic BioSystems
6616 Owens Drive
Pleasanton, CA
USA 94588

Name of Manufacturer

Manufacturer

DIAGNOSTIC BIOSYSTEMS
6616 Owens Drive
Pleasanton, CA
USA 94588

Name of Distributor

DIAGNOSTIC BIOSYSTEMS
6616 Owens Drive
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----END OF MANUFACTURER/DISTRIBUTOR LIST----





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Name of Product(s)

IMMUNOHISTOCHEMISTRY REAGENTS AND KITS

Actin, Muscle (HHF35) - Mob002, Mob002-01, Mob002-05, PDM002, PDM002-10MM, PDM002-HL
Actin, Sarcomeric (5C5) - Mob128, Mob128-01, Mob128-05, PDM099, PDM099-10MM, PDM099-HL
Actin, α -Smooth Muscle - Mob001, Mob001-01, Mob001-05, PDM003, PDM003-10MM, PDM003-25, PDM003-HL
Adenovirus - Mob355, Mob355-01, Mob355-05
Adrenocorticotrophic Hormone (ACTH) (AH26) - Mob244, Mob244-01, Mob244-05, PDM583, PDM583-HL
Albumin - RP046, RP046-01, RP046-05
Amyloid A Component - Mob003, Mob003-05, PDM118, PDM118-10MM, PDM118-HL
Amyloid Precursor Protein (APP) - RP123, RP123-01, RP123-05, PDR178, PDR178-HL
Anaplastic Lymphoma Kinase (ALK) p80 (SP8) - RMAB007, RMPD007
Androgen Receptor - Mob245, Mob245-01, Mob245-05, PDM167, PDM167-HL
Anti-Isocitrate Dehydrogenase 1 (IDH1)-R132H - Mob580, Mob580-01, Mob580-05, PDM580, PDM580-HL
Anti-Isocitrate Dehydrogenase 1 (IDH1)-R132S - Mob582, Mob582-01, Mob582-05, PDM582, PDM582-HL
Bcl-10 - Mob442, Mob442-01, Mob442-05, PDM442
Bcl-2 Oncoprotein - Mob005, Mob005-01, Mob005-05, PDM016, PDM016-10MM
Bcl-2 Oncoprotein - Mob130, Mob130-01, Mob130-05, PDM209, PDM209-HL
BRCA1 - Mob424, Mob424-01, Mob424-05
C4d - Mob471, Mob471-01, Mob471-05, PDM184, PDM184-10MM, PDM184-HL
CA 125 - Mob110, Mob110-01, Mob110-05, PDM323
CA 15-3 - Mob549, Mob549-01, Mob549-05, PDM549, PDM549-10MM, PDM549-HL
CA 19-9 - Mob109, Mob109-01, Mob109-05, PDM567, PDM567-25, PDM567-HL
Cadherin, Pan - Mob228, Mob228-01, Mob228-05
Cadherin 17 - Mob604, Mob604-01, Mob604-05, PDM604, PDM604-10, PDM604-HL
Calbindin-D-28K - Mob554, Mob554-01, Mob554-05
Calcitonin - RP050, RP050-01, RP050-05, PDR024, PDR024-10RP, PDR024-HL
Calcitonin (SP17) - RMAB009, RMAB009-01, RMAB009-05, RMPD009, RMPD009-HL
Caldesmon - Mob556, Mob556-01, Mob556-05, PDM223, PDM223-10MM, PDM223-25, PDM223-HL
Calponin-1 - Mob345, Mob345-01, Mob345-05, PDM219, PDM219-10MM, PDM219-25, PDM219-HL
CAM 5.2 - RMAB086, RMPD086, RMPD086-HL
Carcinoembryonic Antigen (CEA) - Mob008, Mob008-01, Mob008-05, PDM005, PDM005-HL
Caspase 3 (3CSP03) - Mob309, Mob309-01, Mob309-05
Caspase 3/CPP32 - RP096, RP096-01, RP096-05, PDR172
Catenin, β - RP080, RP080-01, RP080-05, PDR060, PDR060-10RP, PDR060-HL
Cathepsin D - RP004, RP004-01, RP004-05, PDR004, PDR004-HL
CD138 (EP201) - RMAB040, RMAB040-01, RMAB040-05, RMPD040, RMPD040-HL
CD10 (EP195) - RMAB037, RMAB037-01, RMAB037-05, RMPD037, RMPD037-HL
CD10/CALLA - Mob240, Mob240-01, Mob240-05, PDM107, PDM107-10MM, PDM107-HL





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CD117/c-kit - RP063, RP063-05, PDR045, PDR045-HL, RMAB119, RMAB119-01, RMAB119-05, RMPD119
CD15/Reed-Sternberg Cell Marker - Mob365, Mob365-01, Mob365-05, PDM127, PDM127-HL
CD163 - Mob460, Mob460-01, Mob460-05, PDM579, PDM579-25, PDM579-HL
CD1a - Mob363, Mob363-01, Mob363-05, PDM173, PDM173-HL
CD1a (EP80) - RMAB062, RMPD062
CD20, B-cell (L26) - Mob004, Mob004-01, Mob004-05, PDM004, PDM004-10MM, PDM004-HL
CD21, B cell (1F8) - Mob028, Mob028-01, Mob028-05, PDM122, PDM122-HL
CD23 (1B12) - Mob294, Mob294-01, Mob294-05, PDM143, PDM143-10MM, PDM143-HL
CD23 (SP23) - RMAB013, RMAB013-01, RMAB013-05, RMPD013, RMPD013-HL
CD25/IL-2R α - Mob254, PDM144
CD3 (F7.2.38) - Mob422, Mob422-01, Mob422-05, PDM422, PDM422-25
CD3 (SP7) - RMAB005, RMAB005-01, RMAB005-05, RMPD005, RMPD005-HL
CD3, T Cell - RP005, RP005-01, RP005-05, PDR002, PDR002-HL
CD3, T Cell (PS1) - Mob112, Mob112-05, PDM126, PDM126-10MM
CD30/Ki-1 Antigen - Mob032, Mob032-01, Mob032-05, PDM018, PDM018-10MM, PDM018-HL
CD31, Endothelial Cell - Mob034, Mob034-01, Mob034-05, PDM020, PDM020-HL
CD34, Endothelial Cell - Mob098, Mob098-01, Mob098-05, PDM050, PDM050-10MM, PDM050-HL
CD4 - Mob119, Mob119-05, PDM093
CD43, T Cell - Mob039, Mob039-01, Mob039-05, PDM060, PDM060-10MM, PDM060-25, PDM060-HL
CD44/HCAM - Mob256, Mob256-01, Mob256-05, PDM172, PDM172-10MM, PDM172-25, PDM172-HL
CD45RO, T Cell - Mob043, Mob043-01, Mob043-05, PDM015, PDM015-10MM, PDM015-HL
CD5 (4C7) - Mob138, PDM095
CD5 (SP19) - RMAB011, RMAB011-01, RMAB011-05, RMPD011, RMPD011-HL
CD56/Neural Cell Adhesion Molecule-1 (NCAM-1) - Mob261, Mob261-01, Mob261-05, PDM110, PDM110-10MM, PDM110-HL
CD57 - Mob163, Mob163-01, Mob163-05, PDM130, PDM130-10MM, PDM130-HL
CD61/Platelet Glycoprotein IIIa - Mob164, Mob164-01, Mob164-05, PDM064
CD63 - Mob301, Mob301-01, Mob301-05, PDM212, PDM212-10MM, PDM212-HL
CD68, Macrophage (KP1) - Mob167, Mob167-01, Mob167-05, PDM066, PDM066-25, PDM066-HL
CD68, Macrophage (PG-M1) - Mob094, Mob094-01, Mob094-05, PDM065, PDM065-HL
CD74, Lymphoid Marker - Mob168, Mob168-01, Mob168-05, PDM033, PDM033-HL
CD79a Antigen (HM47/A9) - Mob242, Mob242-01, Mob242-05, PDM125, PDM125-25, PDM125-HL
CD79a, B Cell (HM57) - Mob118, Mob118-01, Mob118-05, PDM271
CD8 (SP16) - RMAB012, RMAB012-01, RMAB012-05, RMPD012, RMPD012-HL
CD8, T Cell - Mob117, Mob117-01, Mob117-05, PDM094, PDM094-10MM, PDM094-HL
CD99/MIC2, Ewing's Sarcoma Marker - Mob262, Mob262-01, Mob262-05, PDM106, PDM106-10MM, PDM106-HL
Cdc25A - Mob337, Mob337-01, Mob337-05
Cdc47/MCM7 - Mob340, PDM340, PDM340-10MM
CDX2 (EP25) - RMAB059, RMAB059-01, RMAB059-05, RMPD059, RMPD059-HL
CEACAM5 - RMAB118, RMAB118-01, RMAB118-05, RMPD118, RMPD118-HL
c-erbB-2 Oncoprotein - RP006, RP006-01, RP006-05, PDR003, PDR003-25, PDR003-HL
c-erbB-2 Oncoprotein (SP3) - RMAB008, RMAB008-01, RMAB008-05, RMPD008, RMPD008-25, RMPD008-HL
Chorionic Gonadotropin (hCG) - RP007, RP007-01, RP007-05, PDR030, PDR030-HL
Chromogranin A - RP008, RP008-01, RP008-05, PDR061, PDR061-HL
Chromogranin A (LK2H10) - Mob048, Mob048-01, Mob048-05, PDM067, PDM067-10MM, PDM067-25, PDM067-HL
Chromogranin A (SP12) - RMAB015, RMAB015-01, RMAB015-05, RMPD015, RMPD015-HL
Claudin 1 - RP153, RP153-05
Claudin 4 - Mob613, Mob613-01, Mob613-05, PDM613
Claudin18.2 - RMAB116, RMAB116-01, RMAB116-05, RMPD116, RMPD116-HL
CMV Cocktail (DDG9 + CCH2) - Mob049, Mob049-01, Mob049-05, PDM075, PDM075-HL
c-myc - Mob231, Mob231-01, Mob231-05, PDM211, PDM211-25, PDM211-HL
Collagen Type IV - Mob229, Mob229-01, Mob229-05, PDM276, PDM276-25
Cyclin D1 (SP4) - RMAB003, RMAB003-01, RMAB003-05, RMPD003, RMPD003-HL
Cyclin E Protein (HE12) - Mob266, Mob266-01, Mob266-05, PDM145, PDM145-HL
Cyclooxygenase-2 (COX-2) - RP111, RP111-01, RP111-05
Cytokeratin - Mob052, Mob052-01, Mob052-05, PDM116, PDM116-HL





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Cytokeratin 10 (DE-K10) - Mob055, Mob055-05
Cytokeratin 13 - Mob443, Mob443-01, Mob443-05
Cytokeratin 14 - Mob186, Mob186-01, Mob186-05, PDM138, PDM138-10MM, PDM138-HL
Cytokeratin 15 - Mob305, Mob305-01, Mob305-05, PDM596
Cytokeratin 16 - Mob273, Mob273-01, Mob273-05, PDM273
Cytokeratin 17 - Mob127, Mob127-01, Mob127-05, PDM206, PDM206-10MM, PDM206-HL
Cytokeratin 18 (DC10) - Mob187, Mob187-01, Mob187-05, PDM164, PDM164-10MM, PDM164-HL
Cytokeratin 19 (A53-B/A2.26) - Mob274, Mob274-01, Mob274-05, PDM192, PDM192-10MM, PDM192-25, PDM192-HL
Cytokeratin 20 (EP23) - RMAB060, RMPD060
Cytokeratin 20 (KS 20.8) - Mob123, Mob123-01, Mob123-05, PDM049, PDM049-HL
Cytokeratin 20 (KS 20.8) - Mob123, PDM049, PDM049-HL
Cytokeratin 5 (XM26) - Mob361, Mob361-01, Mob361-05, PDM139, PDM139-10MM, PDM139-HL
Cytokeratin 5/14 - Mob433, Mob433-01, Mob433-05, PDM140, PDM140-HL
Cytokeratin 5/6 - Mob362, Mob362-01, Mob362-05, PDM123, PDM123-HL
Cytokeratin 7 - Mob057, Mob057-01, Mob057-05, PDM097, PDM097-25, PDM097-HL
Cytokeratin 8, Low Molecular Weight - Mob054, Mob054-01, Mob054-05, PDM117, PDM117-10MM, PDM117-HL
Cytokeratin 8/18 - Mob189, Mob189-01, Mob189-05, PDM070, PDM070-10MM, PDM070-HL
Cytokeratin AE1, Acidic - Mob092, Mob092-01, Mob092-05, PDM043, PDM043-25, PDM043-HL
Cytokeratin AE1/AE3 - Mob190, Mob190-01, Mob190-05, PDM072, PDM072-10MM, PDM072-25, PDM072-HL
Cytokeratin AE3, Basic - Mob093, Mob093-01, Mob093-05, PDM044, PDM044-25, PDM044-HL
Cytokeratin (CAM5.2) - Mob469, Mob469-01, Mob469-05, PDM181, PDM181-HL
Cytokeratin, High Molecular Weight (34βE12) - Mob059, Mob059-01, Mob059-05, PDM074, PDM074-10MM, PDM074-HL
Cytokeratin, Wide Spectrum - RP010, RP010-01, RP010-05, PDR035, PDR035-HL
Desmin (D33) - Mob060, Mob060-01, Mob060-05, PDM006, PDM006-HL
Desmin (DE-R-11) - Mob610, Mob610-01, Mob610-05, PDM610
DOG 1 - Mob466, Mob466-01, Mob466-05, PDM170, PDM170-10MM PDM170-HL
E2F-1 Transcription Factor - Mob381, Mob381-01, Mob381-05
E-Cadherin (SPM471) - Mob550, Mob550-01, Mob550-05, PDM182, PDM182-10MM, PDM182-HL
EGFR - Mob615, Mob615-01, Mob615-05, PDM615
Elastin - Mob230, Mob230-01, Mob230-05, PDM300, PDM300-25, PDM300-HL
Epidermal Growth Factor Receptor (EGFR) - 31G7 - Mob461, PDM226, PDM226-10MM
Epithelial Antigen (Ber-EP4) - Mob406, Mob406-01, Mob406-05, PDM131, PDM131-HL
Epithelial Antigen (VU-1D9) - Mob062, Mob062-01, Mob062-05, PDM077, PDM077-10MM, PDM077-HL
Epithelial Membrane Antigen (EMA) E29 - Mob401, Mob401-01, Mob401-05, PDM204, PDM204-25, PDM204-HL
Epstein-Barr Virus (EBV) - Mob194, Mob194-01, Mob194-05, PDM128, PDM128-HL
ERCC1 - Mob336, Mob336-01, Mob336-05, PDM151, PDM151-10MM, PDM151-HL
ERG - RMPD034, RMPD034-10RM, RMPD034-HL
Estrogen Receptor (6F11) - Mob121, Mob121-01, Mob121-05, PDM048, PDM048-10MM
Estrogen Receptor (SP1) - RMAB001, RMAB001-01, RMAB001-05, RMPD001, RMPD001-25, RMPD001-HL
Ezrin/p81/Cytovillin - Mob380, Mob380-01, Mob380-05
Factor VIII Related Antigen/Von Willebrand Factor - RP012, RP012-01, Rp012-05, PDR014, PDR014-10RP, PDR014-HL
Factor VIII Related Antigen/Von Willebrand Factor (F8/86) - Mob196, Mob196-01, Mob196-05, PDM019, PDM019-HL
Factor XIII-A - RP103, RP103-01, RP103-05, PDR054, PDR054-HL
Factor XIII-A (AC-1A1) - Mob321, Mob321-01, Mob321-05, PDM141, PDM141-HL
Fibronectin - RP013, RP013-01, RP013-05, PDR170, PDR170-HL
Flk-1/KDR/VEGFR2 - RP076, RP076-01, RP076-05, PDR171
Flt-1/VEGFR1 - RP077, RP077-01, RP077-05
Gastrin - RP044, RP044-01, RP044-05, PDR027, PDR027-HL
Glial Fibrillary Acidic Protein (GFAP) (GA5) - Mob064, Mob064-01, Mob064-05, PDM008, PDM008-10MM, PDM008-25, PDM008-HL
Glial Fibrillary Acidic Protein, GFAP - RP014, RP014-01, RP014-05, PDR028
GLUT-1 - RP128, RP128-01, RP128-05





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Glycophorin A - Mob066, Mob066-01, Mob066-05, PDM124, PDM124-HL
Glycophorin C - Mob067, Mob067-01, Mob067-05, PDM578, PDM578-25, PDM578-HL
Granzyme B - RP105, RP105-01, RP105-05, PDR050, PDR050-HL
Hairy Cell Leukemia - Mob200, Mob200-01, Mob200-05, PDM024, PDM024-10MM, PDM024-HL
Heat Shock Protein 70 (HSP 70) (W27) - Mob269, Mob269-01, Mob269-05, PDM597, PDM597-HL
Helicobacter Pylori - RP016, RP016-01, RP016-05, PDR053, PDR053-25, PDR053-HL
Helicobacter Pylori (DBM15.75) - Mob559, Mob559-01, Mob559-05
Hepatitis B Surface Antigen, HBsAg (5C3) - Mob570, Mob570-01, Mob570-05, PDM570, PDM570-25
Hepatocyte Specific Antigen (OCH1E5) - Mob426, Mob426-01, Mob426-05, PDM162, PDM162-HL
Herpes Simplex Virus Type I (HSV1) - RP018, RP018-01, RP018-05, PDR032, PDR032-HL
Herpesvirus 8 (HHV8) - Mob395, Mob395-01, Mob395-05, PDM395
HLA-DR (β chain of DP, DQ & DR) (CR3/43) - Mob069, Mob069-01, Mob069-05, PDM082, PDM082-HL
Human Papilloma Virus Type 16, HPV 16 - Mob394, Mob394-01, Mob394-05, PDM166, PDM166-HL
IgA - RP020, RP020-01, RP020-05, PDR017, PDR017-10RP, PDR017-HL
IgD - RP021, RP021-05
IgE - RP022, RP022-05
IgG - RP023, RP023-01, RP023-05, PDR018, PDR018-HL
IgM - RP024, RP024-01, RP024-05, PDR019, PDR019-HL
IgM (R1/69) - Mob074, Mob074-01, Mob074-05, PDM053
Inhibin α - Mob435, Mob435-01, Mob435-05, PDM178, PDM178-10MM, PDM178-HL
Insulin (K36aC10) - Mob234, Mob234-01, Mob234-05, PDM270
Kappa Light Chain - RP025, RP025-01, RP025-05, PDR015, PDR015-10RP, PDR015-HL
Kappa Light Chain (KP-53) - Mob544, Mob544-01, Mob544-05, PDM055, PDM055-10MM, PDM055-HL
Ki-67 - RP026, RP026-01, RP026-05, PDR048, PDR048-HL
Ki-67 (SP6) - RMAB004, RMAB004-01, RMAB004-05, RMPD004, RMPD004-25, RMPD004-HL
KU (P70) (H-6) - Mob557, Mob557-01, Mob557-05
Lambda Light Chain - RP027, RP027-05, PDR016
Lambda Light Chain (N10/2) - Mob077, Mob077-01, Mob077-05, PDM056, PDM056-HL
Laminin - Mob202, Mob202-01, Mob202-05, PDM568, PDM568-HL
Leukocyte Common Antigen (LCA)/CD45 - Mob040, Mob040-01, Mob040-05, PDM009, PDM009-10MM, PDM009-HL
Lysozyme/Muramidase - RP028, RP028-01, RP028-05, PDR005, PDR005-HL
Mammaglobin A - RMAB036, RMAB036-01, RMAB036-05, RMPD036
MART-1/Melan-A, Melanoma Marker - Mob277, Mob277-01, Mob277-05, PDM153, PDM153-10MM, PDM153-HL
Mast Cell Chymase - Mob346, Mob346-01, Mob346-05, PDM159
Mast Cell Tryptase - Mob347, Mob347-01, Mob347-05, PDM160, PDM160-HL
Melanoma (HMB45) - Mob079, Mob079-01, Mob079-05, PDM011, PDM011-HL
Melanoma (PNL2) - Mob421, Mob421-01, Mob421-05, PDM213
Melanoma Cocktail Antibody - Mob428, Mob428-01, Mob428-05, PDM146, PDM146-HL
Mesothelioma - Mob349, Mob349-01, Mob349-05, PDM134, PDM134-HL
Microphthalmia Transcription Factor, MITF - Mob462, Mob462-01, Mob462-05, PDM168, PDM168-HL
MLH-1 - Mob430, Mob430-01, Mob430-05, PDM148, PDM148-HL
MMP-9 - RP066, RP066-01, RP066-05
MSH6 - Mob429, Mob429-01, Mob429-05, PDM147, PDM147-10MM, PDM147-HL
Mucin 5AC/Gastric Mucin - Mob357, Mob357-01, Mob357-05, PDM163, PDM163-HL
MUM1 Protein - Mob420, Mob420-01, Mob420-05, PDM420, PDM420-10MM, PDM420-HL
Myeloperoxidase - RP053, RP053-01, RP053-05, PDR049, PDR049-HL
Myeloperoxidase (59A5) - Mob551, Mob551-01, Mob551-05, PDM551, PDM551-10MM, PDM551-HL
MyoD1 (5.8A) - Mob553, PDM239-10MM
MyoD1 (5.2F) - Mob278, Mob278-01, Mob278-05, PDM120, PDM120-HL
Myogenin - Mob322, Mob322-01, Mob322-05, PDM158, PDM158-HL
Myosin, Skeletal (Fast) - Mob207, Mob207-01, Mob207-05, PDM085, PDM085-10MM, PDM085-HL
Napsin A - Mob463, Mob463-01, Mob463-05, PDM154, PDM154-HL
Neurofilaments - Mob080, Mob080-01, Mob080-05, PDM012, PDM012-HL
Neuron Specific Enolase (NSE) - Mob212, PDM321, PDM321-HL
Neuron Specific Enolase, NSE - RP054, RP054-01, RP054-05, PDR006, PDR006-HL
Neuron Specific Enolase, NSE - Mob616, Mob616-01, Mob616-05, PDM616, PDM616-25





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NUT1 - RMAB115, RMAB115-01, RMAB115-05, RMPD115
O(6)-Methylguanine-DNA-Methyltransferase, MGMT - Mob423, Mob423-01, Mob423-05, PDM423, PDM423-HL
p27KIP1, Mitotic Inhibitor / Suppressor Protein - Mob281, Mob281-01, Mob281-05, PDM245, PDM245-10MM
p40 - RP163, RP163-01, RP163-05, PDR055, PDR055-HL
p504S/α-Methylacyl-CoA Racemase (AMACR) - RP134, RP134-01, RP134-05, PDR046, PDR046-HL
p53 (DO-7) - Mob082, Mob082-01, Mob082-05, PDM013, PDM013-HL
p53 (EP9) - RMAB067, RMPD067
p57Kip2 (57P06) - Mob291, Mob291-01, Mob291-05, PDM205, PDM205-10MM, PDM205-25, PDM205-HL
p80/Anaplastic Lymphoma Kinase - Mob416, Mob416-01, Mob416-05
Pancreatic Polypeptide - RP030, RP030-01, RP030-05
Pax-8 - PDM180, PDM180-10MM, PDM180-HL
Perforin - Mob555, Mob555-01, Mob555-05, PDM555
PIN5 Cocktail - PDR057, PDR057-HL
Placental Alkaline Phosphatase (PLAP) (SP15) - RMAB017, RMAB017-01, RMAB017-05, RMPD017, RMPD017-HL
PMS2 - PDM171, PDM171-10MM, PDM171-HL
Pneumocystis Carinii - Mob091, Mob091-01, Mob091-05, PDM584, PDM584-HL
Progesterone Receptor (SP2) - RMAB002, RMAB002-01, RMAB002-05, RMPD002, RMPD002-25, RMPD002-HL
Proliferating Cell Nuclear Antigen (PCNA) (PC10) - Mob083, Mob083-01, Mob083-05, PDM014, PDM014-10MM, PDM014-25 PDM014-HL
Prostate Specific Membrane Antigen (PSMA) (3E6) - Mob440, PDM581
Prostate Specific Antigen (PSA) (35H9) - Mob548, Mob548-01, Mob548-05, PDM548, PDM548-HL
Prostate Specific Antigen (PSA) - PDR007, PDR007-HL
Prostatic Acid Phosphatase, PSAP - Mob085, Mob085-01, Mob085-05, PDM037, PDM037-10MM, PDM037-HL
Protein Gene Product 9.5, PGP9.5 - RP087, RP087-05
Rad51 - Mob324, Mob324-01, Mob324-05
Renal Cell Carcinoma (gp200) - Mob465, Mob465-01, Mob465-05, PDM169, PDM169-HL
Ret Oncoprotein - Mob326, Mob326-05
Retinoblastoma Gene Protein, Rb - Mob220, Mob220-01, Mob220-05, PDM111, PDM111-10MM
RPA/p34 - Mob329, Mob329-01, Mob329-05
S-100 (4C4.9) - Mob377, Mob377-01, Mob377-05, PDM194, PDM194-10MM, PDM194-25 PDM194-HL
S-100 (SH-B1) - Mob111, Mob111-01, Mob111-05, PDM088, PDM088-10MM
S-100 Protein - RP035, RP035-01, RP035-05, PDR008, PDR008-10RP, PDR008-HL
Smooth Muscle Myosin (SMMS-1) - Mob467, Mob467-01, Mob467-05, PDM175, PDM175-HL
Somatostatin receptor - RP081, RP081-05
Stat6 - Mob605, Mob605-01, Mob605-05, PDM605
Survivin - RP068, RP068-05
Synaptophysin (SP11) - RMAB018, RMAB018-01, RMAB018-05, RMPD018, RMPD018-HL
Synaptophysin (SYP02) - Mob399, Mob399-01, Mob399-05, PDM592, PDM592-HL
TAG-72/CA 72-4 (B72.3) - Mob288, Mob288-01, Mob288-05, PDM100, PDM100-HL
Terminal Deoxynucleotidyl Transferase (Tdt) - Mob545, Mob545-01, Mob545-05, PDM096, PDM096-HL
Thrombospondin, TSP - Mob315, Mob315-01, Mob315-05
Thymidine Phosphorylase/Platelet-Derived Endothelial Cell Growth Factor - Mob292, Mob292-01, Mob292-05, PDM292
Thyroglobulin (1D4) - Mob223, Mob223-01, Mob223-05, PDM576, PDM576-25, PDM576-HL
Thyroid Peroxidase - Mob418, Mob418-01, Mob418-05, PDM418
Thyroid Transcription Factor-1, TTF-1, Thyroid and Lung Epithelial Marker - Mob285, Mob285-01, Mob285-05, PDM104, PDM104-HL
TIMP-2 - Mob318, Mob318-01, Mob318-05, PDM318, PDM318-25
Transglutaminase II - Mob353, Mob353-01, Mob353-05
TRPS1 - RMAB114, RMAB114-01, RMAB114-05, RMPD114, RMPD114-HL, RP181, RP181-01, RP181-05, PDR181
Tyrosinase, Melanoma Marker - Mob290, Mob290-01, Mob290-05, PDM150, PDM150-HL
Vascular Endothelial Growth Factor (VEGF) (VG1) - Mob308, Mob308-01, Mob308-05, PDM165, PDM165-10MM, PDM165-HL
Vimentin, Porcine - Mob090, Mob090-01, Mob090-05, PDM029, PDM029-HL
Wilms Tumor 1 Protein , (EP122) - RMAB070, RMPD070





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Wilm's Tumor 1 Protein, WT1 - Mob437, Mob437-01, Mob437-05, PDM177, PDM177-25, PDM177-HL
XRCC1 - Mob325, Mob325-01, Mob325-05
 α Fetoprotein (AFP) - Mob129, Mob129-01, Mob129-05, PDM057, PDM057-10MM, PDM057-HL
 α -1-Antichymotrypsin - RP047, PDR023, PDR023-HL
 α -1-Antitrypsin - RP048, Rp048-01, RP048-05, PDR021, PDR021-HL
 α -Actinin, Sarcomeric - Mob227, Mob227-01, Mob227-05
 β -Amyloid Protein - Mob410, Mob410-01, Mob410-05
Tau (Neurofibrillary Tangles Marker) - Mob472, Mob472-01, Mob472-05
SOX-10 - RMAB077, RMAB077-01, RMAB077-05, RMPD077, RMPD077-HL
CD3 (LN10) - Mob474, Mob474-01, Mob474-05, PDM186, PDM186-HL
CD4 (EP204) - RMAB083, RMAB083-01, RMAB083-05, RMPD083, RMPD083-HL
Chromogranin A - Mob476, PDM191, PDM191-10MM
Arginase 1 - Mob484, Mob484-01, Mob484-05, PDM197, PDM197-10MM, PDM197-25, PDM197-HL
NKX2.2 - Mob486, Mob486-01, Mob486-05, PDM199, PDM199-10MM, PDM199-HL
TRAcP (Tartrate-Resistant Acid Phosphatase) (Hairy Cell Leukemia Marker) - Mob490, Mob490-01, Mob490-05, PDM203, PDM203-10MM
TNF-alpha (Tumor Necrosis Factor alpha) - Mob502, Mob502-01, Mob502-05, PDM230, PDM230-10MM, PDM230-25, PDM230-HL
P504S - RMAB078, RMAB078-01, RMAB078-05, RMPD078, RMPD078-25, RMPD078-HL
GCDPF-15 - Mob526, Mob526-01, Mob526-05, PDM261, PDM261-25, PDM261-HL
Cytokeratin, Pan - RP167, RP167-01, RP167-05, PDR167, PDR167-25, PDR167-HL
Herpes Simplex Virus Type II (HSV2) - Mob542, Mob542-01, Mob542-05, PDM542, PDM542-10MM, PDM542-25, PDM542-HL
p120 Catenin - Mob529, Mob529-01, Mob529-05, PDM529, PDM529-10MM
Galectin-3(H-5) - Mob541, Mob541-01, Mob541-05, PDM541, PDM541-25, PDM541-HL
Podoplanin (D2-40) - Mob558, Mob558-01, Mob558-05, PDM558, PDM558-10MM, PDM558-25, PDM558-HL
Mammaglobin - PDM544, PDM544-10MM, PDM544-25, PDM544-HL
MOC-31 - Mob546, Mob546-01, Mob546-05, PDM546, PDM546-HL
Helicobacter pylori - Mob 559, PDM559, PDM559-HL
Cytokeratin 7 (LP1K) - Mob563, Mob563-01, Mob563-05, PDM563, PDM563-25, PDM563-HL
GATA3 (L50-823) - Mob564, Mob564-01, Mob564-05, PDM564, PDM564-25, PDM564-HL
Glypican-3 (GPC3) - Mob561, Mob561-01, Mob561-05, PDM561, PDM561-25, PDM561-HL
Adipophilin - Mob534, Mob534-01, Mob534-05, PDM534, PDM534-HL
Phosphohistone H3 - RP168, RP168-01, RP168-05, PDR168, PDR168-25, PDR168-HL
ALK - Mob566, Mob566-01, Mob566-05, PDM566, PDM566-HL
Fascin - Mob560, Mob560-01, Mob560-05, PDM560, PDM560-25, PDM560-HL
Cyclin D1 - RMAB106, RMAB106-01, RMAB106-05, RMPD106, RMPD106-25
Mesothelin (YP158) - RMAB107, RMAB107-01, RMAB107-05, RMPD107, RMPD107-25, RMPD107-HL
Phosphohistone H3 - RP168, PDR168
SOX10 (Melonoma Marker) - Mob565, Mob565-01, Mob565-05, PDM565
NKX3.1 - Mob569, PDM569, PDM569-HL
P16 - Mob575, Mob575-01, Mob575-05, PDM575, PDM575-25, PDM575-HL
p16/Ki-67 Cocktail - RMM001, RMM001-01, RMM001-05
PD-L1 - Mob572, Mob572-01, Mob572-05, PDM572, PDM572-25, PDM572-HL
CD79a, B Cell (HM57) - Mob573, Mob573-01, Mob573-05, PDM573, PDM573-25, PDM573-HL
PTEN - Mob574, Mob574-01, Mob574-05, PDM574, PDM574-25, PDM574-HL
Helicobacter pylori - RP169, RP169-01, RP169-05, PDR169, PDR169-25
Smad4 - RP173, RP173-01, RP173-05, PDR173, PDR173-HL
Pan TRK - RP176, RP176-01, RP176-05, PDR176, PDR176-HL
Caspase 1/Interleukin-1-b Converting Enzyme - PDR175, RP175-01, RP175-05
Mismatch repair Protein 2, MSH2 - Mob585, Mob585-01, Mob585-05, PDM585, PDM585-HL
INSM1 (A-8) - Mob586, Mob586-01, Mob586-05, PDM586
P63 - RMAB086, RMAB086-01, RMAB086-05, RMPD086, RMPD086-25, RMPD086-HL
ROS1 - RMPD108
Bcl-6 (PG-B6) - Mob587, Mob587-01, Mob587-05, PDM587, PDM587-HL
PRAME - RMAB109, RMAB109-01, RMAB109-05, RMPD109, RMPD109-HL
CD138 - Mob588, Mob588-01, Mob588-05, PDM588, PDM588-HL
Treponema Pallidum - Mob577, Mob577-01, Mob577-05, PDM577, PDM577-HL





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Villin (1D2C3) - Mob590, Mob590-01, Mob590-05, PDM590, PDM590-HL
SALL4 (6E3) - Mob591, Mob591-01, Mob591-05, PDM591, PDM591-HL
BOB.1 (SP92) - RMAB110, RMAB110-01, RMAB110-05, RMPD110
CD5 (CD5/54/F6) - Mob589, Mob589-01, Mob589-05, PDM589, PDM589-HL
Uroplakin III - Mob594, Mob594-01, Mob594-05, PDM594
Calretinin (H-5) - Mob593, Mob593-01, Mob593-05, PDM593
Uroplakin II - RP177, RP177-01, RP177-05, PDR177, PDR177-HL
Uroplakin II & III Cocktail - RPM001, RPM001-01, RPM001-05, PDRM002, PDRM002-HL
Uroplakin 3B - RMAB117, RMAB117-01, RMAB117-05, RMPD117, RMPD117-HL
BAP1 - PDM595
A20 (A-12) - Mob598, Mob598-01, Mob598-05, PDM598
SATB2 (EP 281) - RMAB112, RMAB112-01, RMAB112-05, RMPD112, RMPD112-HL
IBA1 (AIF1) - Mob602, Mob602-01, Mob602-05, PDM602, PDM602-25, PDM602-HL
ATRX (D-5) - Mob600, Mob600-01, Mob600-05, PDM600, PDM600-25
CD7 (CBC.37.80) - Mob599, Mob599-01, Mob599-05, PDM599, PDM599-25
Cytokeratin, AE1 + AE3 + CK 8/18 Cocktail - Mob601, Mob601-01, Mob601-05, PDM601, PDM601-25, PDM601-HL
DLL3 - RMAB120, RMAB120-01, RMAB120-05, RMPD120
BAP1 (BAP1/2667) - Mob603, Mob603-01, Mob603-05, PDM603, PDM603-10, PDM603-25, PDM603-HL
OCT3/4 (OCT4/6847R) - RMAB113, RMAB113-01, RMAB113-05, RMPD113, RMPD113-10, RMPD113-25, RMPD113-HL
p63/p504s Cocktail - PDRMP001, PDRMP001-HL
Rabbit Anti-Human Kappa Light Chain FITC-Conjugated - F001, F001-01
Rabbit Anti-Human Lambda Light Chain FITC-Conjugated - F002, F002-01
Rabbit Anti-Human C3c Complement FITC-Conjugated - F003, F003-01
Rabbit Anti-Human C4c Complement FITC-Conjugated - F005, F005-01
Rabbit Anti-Human Fibrinogen FITC-Conjugated - F006, F006-01
Rabbit Anti-Human IgA (alpha chain) FITC-Conjugated - F007, F007-01
Rabbit Anti-Human IgG (Gamma chain) FITC-Conjugated - F008, F008-01
Rabbit Anti-Human IgM (Mu chain) FITC-Conjugated - F009, F009-01
Rabbit Anti-Human C1q Complement FITC-Conjugated - F010, F010-01
HSV Cocktail (Rabbit anti-HSV I + Mouse anti HSV II - PDRM001, PDRM001-HL
CF TM 488 Complement 4d - FLC211
CF TM 488 Conjugated Cocktail (IgA+IgG+IgM) - FLC212
CF TM 488 Ig M (Mu chain) - FLC209
CF TM 488 IgA (alpha chain) - FLC207
CF TM 488 IgG (Gamma chain) - FLC208
CF TM 488 Conjugated Lambda Light Chain Antibody - FLC213
CF TM 488 Conjugated Kappa Light Chain Antibody - FLC214
CF TM 488 Conjugated Albumin Antibody - FLC 215
CF TM 488 Conjugated Rabbit Polyclonal Fibrinogen Antibody -FLC 216
MCM7 (MCM7/1466) - Mob612, Mob612-01, Mob612-05, PDM612
pH buffer
10X Antigen Retrieval Buffer High, pH 10.0 - K044
10X Citrate Buffer For Heat Induced Epitope Recovery, pH 6.0 - K035
10X Citrate Buffer For Heat Induced Epitope Recovery, pH 7.0 - K036
10X Citrate Buffer For Heat Induced Epitope Recovery, pH 8.0 - K037
10X Tris-EDTA Buffer For Heat Induced Epitope Recovery, pH 9.0 - K043
10X EDTA Buffer For Heat Induced Epitope Recovery, pH 8.0 - K038
10X Immuno Wash Buffer - K005, K005-500-HL
Montage™ IHC Wash Buffer - K005, K005-500AN
10X Immuno Wash Buffer Bx - K071
40X Immuno Wash Buffer - K080
QuatroSol I 10X Citrate Buffer for Heat Induced Epitope Recovery, pH 6.0 Kit - K085
QuatroSol II 10X Tris EDTA Buffer for Heat Induced Epitope Recovery, Ph 9.0 Kit - K086
Ready to use Citrate Buffer for Heat Induced Epitope Recovery, pH 6.0 (CA2) - K089-HL, K089-1000-HL
Ready to use Tris EDTA Buffer for Heat Induced Epitope Recovery, pH 9.0 (EA1) - K102-HL, K102-1000-HL
Ready to use EDTA Buffer For Heat Induced Epitope Recovery, pH 8.0 (EA2) - K090-HL, K090-1000-HL





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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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

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General purpose reagent

Montage™ Citrate Antigen Retrieval Solution - K035-500AN

Montage™ EDTA Antigen Retrieval Solution - K038-500AN

Unmasking Reagent 1 (UR1) - K069

Unmasking Reagent 2 (UR2) - K070

25X Proteinase K - K030

Alkaline Phosphatase Enhancer - K011

Background Blocker - K023

Broad Spectrum Negative Control - K053-xx

CC/Mount™ Aqueous Permanent Mounting Medium - K002-xx

Tissue Primer - K054

Elite Mini PAP Pen - K042

Fluoromount - K046-XX

Elite PAP Pen - K039

Fluoromount/Plus™ - K048-xx

Fluoromount™ - K024-xx

Peroxidase Block - K033

Primary Antibody Diluent - K004

Solution Pepsin - K009

TissueBond™ Reagent - K013, K013-200

Montage™ HistoZyme - K046-10AN

Montage™ DAB Gone Kit - K072-500AN

Montage™ Hematoxylin - K056-100AN

Montage™ Tween 20 - K067-125AN

Mouse on Mouse (MOM) Blocking Reagent - K065

Nuclear Fast Red Solution - K077, K077-100

ImmunoHisto-Sealer™ - K076, K076-1000, K076-200

FITC Diluent - FD001, FD001-100

DP3 for One-Step Deparaffinization - K082

DP1 and DP2 for Deparaffinization - DP1- K087-HL, K087-500-HL; DP2 - K088-HL, K088-500-HL

Purple Hematoxylin - K095

Rapid Histo-Sealer (10X)™ - K093

Mohs HRP-Green Kit - K092

Nuclear Fast Red - K098

Bluing Reagent - K099

Tissue Glue - K096

Blue Hematoxylin - K097

Blue Hematoxylin Kit - K100

Blue Hematoxylin -K097-HL

DAPI - K108, K108-10

HighLighter™ Tube Bright Cleaning Kit - K094-HL, K094-100-HL

A.F.B - KT001

Alcian Blue, pH 1.0 - KT002

Alcian Blue, pH 2.5 - KT003

Amyloid - KT008

Colloidal Iron stain - KT007

Combined Eosinophil-Mast Cell - KT004

Copper - KT033

Elastic stain - KT012

Fite's Stain Kit - KT013

Fontana-Masson - KT014

Giemsa Kit - KT016

G.M.S. Kit - KT015

Gram stain - KT018

H. Pylori Rapid Stain - KT019

Iron stain- KT021

Luxol Fast Blue - KT022

Mucicarmine - KT024





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Oil Red O - KT025
P.T.A.H. - KT029
Papanicolaou Stain - KT038
P.A.S - KT027
Picro Sirius Red Stain - KT037
Pneumocystis - KT030
Reticulum - KT031
Steiner - KT035
Trichrome Stain - KT034
Von Kossa - KT028
Warthin-Starry - KT036
PermaBlack/HRP - K062, K062-110
PermaBlue Plus/AP - K058, K058-110
PermaBlue/HRP - K063, K063-110
PermaGreenPlus/AP - K059, K059-110
PermaRed/AP - K049, K049-110, K049-AUTO
PermaRed/AP-Auto - K049-AUTO, K049-AUTO-110
PermaYellow/HRP - K060, K060-110
20X DAB Enhancer - K012
Intensi/Fire - K045
High Contrast DAB - K055
PermaBlue/AP-Auto - K051-Auto, K051-Auto-110
PermaRed/AP- AutoPlus - K057-AutoPlus, K057-AutoPlus-110
Mono AEC/Plus - K050, K050-110
Stable DAB/Plus - K047
PermaRed/HRP - K075, K075-110
PermaGreen/HRP - K074, K074-110
DAB Auto - K081, K081-AUTO, K081-AUTO-110, K081-AUTO-1L
Lung MultiPlex (Lung Adenocarcinoma vs. Mesothelioma) - MPK-001
Lung MultiPlex (Lung Adenocarcinoma vs. Mesothelioma) - MPK-001-25MP
Lung MultiPlex (Lung Adenocarcinoma vs. Mesothelioma) - MPK-002
Lung MultiPlex (Lung Adenocarcinoma vs. Mesothelioma) - MPK-002-25MP
Lung MultiPlex (Lung Adenocarcinoma vs. Tumor of Unknown Origin-Colon Carcinoma) - MPK-003
Lung MultiPlex (Lung Adenocarcinoma vs. Tumor of Unknown Origin-Colon Carcinoma) - MPK-003-25MP
Lung MultiPlex (Lung Adenocarcinoma vs. Squamous Cell Carcinoma) - MPK-004
Lung MultiPlex (Lung Adenocarcinoma vs. Squamous Cell Carcinoma) - MPK-004-25MP
Lung MultiPlex (Small Cell Lung Carcinoma vs. Lung Squamous Cell Carcinoma) - MPK-005
Lung MultiPlex (Small Cell Lung Carcinoma vs. Lung Squamous Cell Carcinoma) - MPK-005-25MP
Lung MultiPlex (Lymphoma vs. Small Cell Lung Carcinoma) - MPK-006
Lung MultiPlex (Lymphoma vs. Small Cell Lung Carcinoma) - MPK-006-25MP
Mouse on Mouse (MOM) UnoVue™ HRP/DAB Detection Kit - MMU100PDR, MMU25PDR
Mouse/Mouse Sequential Multiplex Detection System - MP002
Mouse/Rabbit Multiplex Detection System - MP001
Mouse & Rabbit Link - M006
Conjugated Enzyme Labels - M007, M008, M009, M010
Universal Alkaline Phosphatase Immunostaining Kit - KA-50F
Peroxidase Mouse & Rabbit Kit (DAB Liquid) - KP50L, KP500L
Peroxidase Mouse & Rabbit Kit - KP50, KP500
Instructions for Large Volume Universal Alkaline Phosphatase Immunostaining Kit (For Mouse and Rabbit Primary Antibodies) - KA-500
Mouse/Rabbit PolyVue Plus™ HRP/DAB Detection System - PVP25D, PVP100D, PVP250D, PVP1000D
Mouse/Rabbit PolyVue™ HRP/DAB Detection System - PV100D, PV1000D, PV1000L
Montage™ PolyVue Plus Auto Detection System - PVP100-AUTO
Mouse/Rabbit UnoVue Plus™ AP/PermaRed Detection System - UVP-25AR, UVP-100AR, UVP-1000AR
Montage™ UnoVue Plus Detection System - UVP100-AUTO
Mouse UnoVue™ HRP/DAB Detection System - UM100PD, UM25PD
Mouse/Rabbit UnoVue™ HRP/DAB Detection System - UMR25PD, UMR100PD, UMR250PD, UMR1000PD, UMR1000PD-L





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UnoVue™ Mouse AP Detection Reagent - MU-AP100, MU-AP1000
UnoVue™ Mouse/Rabbit AP Detection Reagent - MRU-AP100, MRU-AP1000
UnoVue™ Mouse HRP Detection Reagent - MU-HRP100, MU-HRP1000
UnoVue™ Rabbit AP Detection Reagent - RU-AP100, RU-AP1000
UnoVue™ Rabbit HRP Detection Reagent - RU-HRP100, RU-HRP1000
UnoVue™ Mouse/Rabbit HRP Detection Reagent - MRU-HRP100, MRU-HRP1000
BiotinStrep HRP Immunostaining Kit (For Mouse and Rabbit Primary Antibodies) - BSP-60, BSP-125, BSP-1L
Instructions for Universal HRP Immunostaining Kit (For Mouse and Rabbit Primary Antibodies) - KP-50L-S
MOHs DAB Kit - K083
HighLighter Core Kit - HL72K, HL720K
SITVue /DAB Detection System - SIT-25D, SIT-100D, SIT-1000D
Slide stainer, automated
Montage Opus 365 Combo - Combo365
Montage Opus 365 - AR365
Highlighter Auto Stainer - HL-AS360
-----END OF PRODUCT LIST-----

