



List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)

A *companion diagnostic device* can be an in vitro diagnostic device or an imaging tool that provides information that is essential for the safe and effective use of a corresponding therapeutic product.

The use of an IVD companion diagnostic device with a specific therapeutic product is stipulated in the instructions for use in the labeling of both the diagnostic device and the corresponding therapeutic product, as well as in the labeling of any generic equivalents and biosimilar equivalents of the therapeutic product.

This table lists devices in the order of approval, with most recently approved device at the top.

Diagnostic Name	PMA/ 510(k)/ HDE	Diagnostic Manufacturer	Trade Name (Generic) - NDA/BLA
BRACAnalysis CDx	P140020/S016	Myriad Genetic Laboratories, Inc.	Breast Cancer <ul style="list-style-type: none"> • Lynparza (olaparib) - NDA 208558 • Talzenna (talazoparib) – NDA 211651 Ovarian Cancer <ul style="list-style-type: none"> • Lynparza (olaparib) - NDA 208558 • Rubraca (rucaparib) – NDA 209115
therascreen EGFR RGQ PCR Kit	P120022/S018	Qiagen Manchester, Ltd.	Non-small cell lung cancer <ul style="list-style-type: none"> • Iressa (gefitinib) - NDA 206995 • Gilotrif (afatinib)- NDA 201292 • Vizimpro (dacomitinib)- NDA 211288
cobas EGFR Mutation Test v2	P120019/S019	Roche Molecular Systems, Inc.	Non-small cell lung cancer (tissue and plasma) <ul style="list-style-type: none"> • Tarceva (erlotinib) - NDA 021743 • Tagrisso (osimertinib) - NDA 208065 • Iressa (gefitinib) - NDA 206995
PD-L1 IHC 22C3 pharmDx	P150013/S011	Dako North America, Inc.	Non-small cell lung cancer, gastric or gastroesophageal junction adenocarcinoma, cervical cancer, and urothelial carcinoma <ul style="list-style-type: none"> • Keytruda (pembrolizumab) - BLA 125514

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VENTANA PD-L1(SP142) Assay	P160002/S006	Ventana Medical Systems, Inc.	Non-small cell lung cancer and urothelial carcinoma <ul style="list-style-type: none"> Tecentriq (atezolizumab) – sBLA 761034/S012
Abbott RealTime IDH1	P170041	Abbott Molecular, Inc.	Acute myeloid leukemia <ul style="list-style-type: none"> Tibsovo (ivosidenib) - NDA 211192
MRDx BCR-ABL Test	K173492	MolecularMD Corporation	Chronic myeloid leukemia <ul style="list-style-type: none"> Tasigna (nilotinib) - NDA 022068/S026
FoundationOne CDx	P170019	Foundation Medicine, Inc.	<p>Non-small cell lung cancer</p> <ul style="list-style-type: none"> Gilotrif (afatinib) - NDA 201292 Iressa (gefitinib) - NDA 206995 Tarceva (erlotinib) - NDA 021743 Tagrisso (osimertinib) NDA 208065 Alecensa (alectinib) - NDA 208434 Xalkori (crizotinib) - NDA 202570 Zykadia (ceritinib) - NDA 205755 Tafinlar (dabrafenib) - NDA 202806 in combination with Mekinist (trametinib) - NDA 204114 <p>Melanoma</p> <ul style="list-style-type: none"> Tafinlar (dabrafenib) - NDA 202806 Zelboraf (vemurafenib) - NDA 202429 Mekinist (trametinib) - NDA 204114 or Cotellic (cobimetinib) - NDA 206192 in combination with Zelboraf (vemurafenib) - NDA 202429 <p>Breast cancer</p> <ul style="list-style-type: none"> Herceptin (trastuzumab) - BLA 103792 Perjeta (pertuzumab) - BLA 125409 Kadcyla (ado-trastuzumab emtansine) - BLA 125427

Diagnostic Name	PMA/ 510(k)/ HDE	Diagnostic Manufacturer	Trade Name (Generic) - NDA/BLA
			Colorectal cancer <ul style="list-style-type: none"> • Erbitux (cetuximab) - BLA 125084 • Vectibix (panitumumab) - BLA 125147 Ovarian cancer <ul style="list-style-type: none"> • Rubraca (rucaparib) - NDA 209115
VENTANA ALK (D5F3) CDx Assay	P140025/S006	Ventana Medical Systems, Inc.	Non-small cell lung cancer <ul style="list-style-type: none"> • Zykadia (ceritinib) - NDA 205755 • Xalkori (crizotinib) - NDA 202570 • Alecensa (alectinib) - NDA 208434
Abbott RealTime IDH2	P170005	Abbott Molecular, Inc.	Acute myeloid leukemia <ul style="list-style-type: none"> • Idhifa (enasidenib) – NDA 209606
Praxis Extended RAS Panel	P160038	Illumina, Inc.	Colorectal cancer <ul style="list-style-type: none"> • Vectibix (panitumumab) – NDA 125147
Oncomine Dx Target Test	P160045	Life Technologies Corporation	Non-small cell lung cancer <ul style="list-style-type: none"> • Tafinlar (dabrafenib) - NDA 202806 • Mekinist (trametinib) - NDA 204114 • Xalkori (crizotinib) - NDA 202570 • Iressa (gefitinib) - NDA 206995
LeukoStrat CDx FLT3 Mutation Assay	P160040	Invivoscribe Technologies, Inc.	Acute myelogenous leukemia <ul style="list-style-type: none"> • Rydapt (midostaurin) – NDA 207997 • Xospata (gilterinib) – NDA 211349
FoundationFocus CDxBRCA Assay	P160018	Foundation Medicine, Inc.	Ovarian cancer <ul style="list-style-type: none"> • Rubraca (rucaparib) – NDA 209115
Vysis CLL FISH Probe Kit	P150041	Abbott Molecular, Inc.	B-cell chronic lymphocytic leukemia <ul style="list-style-type: none"> • Venclexta (venetoclax) – NDA 208573
<i>KIT</i> D816V Mutation Detection by PCR for Gleevec Eligibility in Aggressive Systemic Mastocytosis (ASM)	H140006	ARUP Laboratories, Inc.	Aggressive systemic mastocytosis <ul style="list-style-type: none"> • Gleevec (imatinib mesylate) – NDA 021335

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PDGFRB FISH for Gleevec Eligibility in Myelodysplastic Syndrome / Myeloproliferative Disease (MDS/MPD)	H140005	ARUP Laboratories, Inc.	Myelodysplastic syndrome/myeloproliferative disease <ul style="list-style-type: none"> Gleevec (imatinib mesylate) – NDA 021335
cobas KRAS Mutation Test	P140023	Roche Molecular Systems, Inc.	Colorectal cancer <ul style="list-style-type: none"> Erbitux (cetuximab) - BLA 125084 Vectibix (panitumumab) - BLA 125147
therascreen KRAS RGQ PCR Kit	P110030 P110027	Qiagen Manchester, Ltd.	Colorectal cancer <ul style="list-style-type: none"> Erbitux (cetuximab) - BLA 125084 Vectibix (panitumumab) - BLA 125147
Dako EGFR pharmDx Kit	P030044/S002	Dako North America, Inc.	Colorectal cancer <ul style="list-style-type: none"> Erbitux (cetuximab) - BLA 125084 Vectibix (panitumumab) - BLA 125147
FerriScan	DEN130012/K124065	Resonance Health Analysis Services Pty Ltd	Non-transfusion-dependent thalassemia <ul style="list-style-type: none"> Exjade (deferasirox) – NDA 021882
Dako c-KIT pharmDx	P040011	Dako North America, Inc.	Gastrointestinal stromal tumors <ul style="list-style-type: none"> Gleevec (imatinib mesylate) – NDA 021335 Glivec (imatinib mesylate) – NDA 021588
INFORM HER-2/neu	P940004	Ventana Medical Systems, Inc.	Breast cancer <ul style="list-style-type: none"> Herceptin (trastuzumab) - BLA 103792
PathVysion HER-2 DNA Probe Kit	P980024	Abbott Molecular Inc.	Breast cancer <ul style="list-style-type: none"> Herceptin (trastuzumab) - BLA 103792
PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody	P990081/S001-S028	Ventana Medical Systems, Inc.	Breast cancer <ul style="list-style-type: none"> Herceptin (trastuzumab) - BLA 103792

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InSite Her-2/neu KIT	P040030	Biogenex Laboratories, Inc.	Breast cancer <ul style="list-style-type: none"> Herceptin (trastuzumab) - BLA 103792
SPOT-LIGHT HER2 CISH Kit	P050040/S001-S003	Life Technologies Corporation	Breast cancer <ul style="list-style-type: none"> Herceptin (trastuzumab) - BLA 103792
Bond Oracle HER2 IHC System	P090015	Leica Biosystems	Breast cancer <ul style="list-style-type: none"> Herceptin (trastuzumab) - BLA 103792
HER2 CISH pharmDx Kit	P100024	Dako Denmark A/S	Breast cancer <ul style="list-style-type: none"> Herceptin (trastuzumab) - BLA 103792
INFORM HER2 Dual ISH DNA Probe Cocktail	P100027	Ventana Medical Systems, Inc.	Breast cancer <ul style="list-style-type: none"> Herceptin (trastuzumab) - BLA 103792
HercepTest	P980018/S018	Dako Denmark A/S	Breast cancer <ul style="list-style-type: none"> Herceptin (trastuzumab) - BLA 103792 Perjeta (pertuzumab) - BLA 125409 Kadcyla (ado-trastuzumab emtansine) - BLA 125427 Gastic and gastroesophageal cancer <ul style="list-style-type: none"> Herceptin (trastuzumab) - BLA 103792
HER2 FISH pharmDx Kit	P040005/S009	Dako Denmark A/S	Breast cancer <ul style="list-style-type: none"> Herceptin (trastuzumab) - BLA 103792 Perjeta (pertuzumab) - BLA 125409 Kadcyla (ado-trastuzumab emtansine) - BLA 125427 Gastic and gastroesophageal cancer <ul style="list-style-type: none"> Herceptin (trastuzumab) - BLA 103792

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THXID BRAF Kit	P120014	bioMérieux Inc.	Melanoma <ul style="list-style-type: none"> • Braftovi (encorafenib) in combination with Mektovi (binimetinib) – NDA_ 210496 and NDA 210498 • Mekinist (tramatenib) - NDA 204114 • Tafinlar (dabrafenib) – NDA 202806
Vysis ALK Break Apart FISH Probe Kit	P110012	Abbott Molecular Inc.	Non-small cell lung cancer <ul style="list-style-type: none"> • Xalkori (crizotinib) – NDA 202570
cobas 4800 BRAF V600 Mutation Test	P110020/S016	Roche Molecular Systems, Inc.	Melanoma <ul style="list-style-type: none"> • Zelboraf (vemurafenib) - NDA 202429 • Cotellic (cobimetinib) - NDA 206192 in combination with Zelboraf (vemurafenib) - NDA 202429
VENTANA PD-L1(SP142) Assay	P160002/S009	Ventana Medical Systems, Inc.	Triple-Negative Breast Carcinoma (TNBC), Non-small cell lung cancer and urothelial carcinoma <ul style="list-style-type: none"> • Tecentriq (atezolizumab) – sBLA 761034/S012
therascreen FGFR RGQ RT-PCR Kit	P180043	QIAGEN Manchester Ltd.	Urothelial cancer <ul style="list-style-type: none"> • BALVERSA (erdafitinib) - NDA 212018
therascreen PIK3CA RGQ PCR Kit	P190001 P190004	QIAGEN GmbH	Breast cancer (tissue and plasma) <ul style="list-style-type: none"> • PIQRAY (alpelisib) - NDA 212526