



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

A *companion diagnostic device* can be 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 is stipulated in the instructions for use in the labeling of the diagnostic device, either including a specific therapeutic product(s) or, if approved for oncology products, a specific group of oncology therapeutic products (for information see the guidance for industry Developing and Labeling In vitro Companion Diagnostic Devices for a Specific Group of Oncology Therapeutic Products). In addition, the use of an IVD companion diagnostic device is stipulated in the labeling of the therapeutic product, as well as in the labeling of any generic equivalents and biosimilar equivalents of the therapeutic product.

For FDA cleared or approved nucleic acid based tests, see [Nucleic Acid Based Tests](#).

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	Indication(s) Trade Name (Generic) - NDA/BLA	Device Indication for a Specific Group of Oncology Therapeutic Products and Trade Name (Generic) – NDA/BLA
BRACAnalysis CDx	<a href="#">P140020/S016</a> <a href="#">P140020/S019</a> <a href="#">P140020/S020</a>	Myriad Genetic Laboratories, Inc.	Breast cancer <ul style="list-style-type: none"><li>• Lynparza (olaparib) - NDA <a href="#">208558</a></li><li>• Talzenna (talazoparib) – NDA <a href="#">211651</a></li></ul> Ovarian cancer <ul style="list-style-type: none"><li>• Lynparza (olaparib) - NDA <a href="#">208558</a></li><li>• Rubraca (rucaparib) – NDA <a href="#">209115</a></li></ul> Pancreatic cancer	

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			<ul style="list-style-type: none"> <li>• Lynparza (olaparib) - NDA <a href="#">208558</a></li> </ul> Metastatic castrate resistant prostate cancer (mCRPC) <ul style="list-style-type: none"> <li>• Lynparza (olaparib) - NDA <a href="#">208558</a></li> </ul>	
<b>therascreen EGFR RGQ PCR Kit</b>	<a href="#">P120022/S018</a>	Qiagen Manchester, Ltd.	Non-small cell lung cancer <ul style="list-style-type: none"> <li>• Iressa (gefitinib) - NDA <a href="#">206995</a></li> <li>• Gilotrif (afatinib)- NDA <a href="#">201292</a></li> <li>• Vizimpro (dacomitinib)- NDA <a href="#">211288</a></li> </ul>	
<b>cobas EGFR Mutation Test v2</b>	<a href="#">P120019</a> <a href="#">P120019/S007</a> <a href="#">P120019/S016</a> <a href="#">P120019/S018</a> <a href="#">P120019/S019</a> <a href="#">P120019/S031</a>	Roche Molecular Systems, Inc.	Non-small cell lung cancer EGFR exon 19 deletions EGFR exon 21(L858R) Tissue and Plasma: See next Column	Non-small cell lung cancer (tissue) “identifying patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor approved by FDA for that indication” List of tyrosine kinase inhibitors approved by FDA for this indication: <ul style="list-style-type: none"> <li>• Tarceva (erlotinib) - NDA <a href="#">021743</a></li> <li>• Tagrisso (osimertinib) - NDA <a href="#">208065</a></li> <li>• Iressa (gefitinib) - NDA <a href="#">206995</a></li> </ul>

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				<ul style="list-style-type: none"> <li>• Gilotrif (afatinib)- NDA <a href="#">201292</a></li> <li>• Vizimpro (dacomitinib)- NDA <a href="#">211288</a></li> </ul> <p>Non-small cell lung cancer (plasma) “identifying patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor approved by FDA for that indication”</p> <p>List of tyrosine kinase inhibitors approved by FDA for this indication:</p> <ul style="list-style-type: none"> <li>• Tarceva (erlotinib) - NDA <a href="#">021743</a></li> <li>• Tagrisso (osimertinib) - NDA <a href="#">208065</a></li> <li>• Iressa (gefitinib) - NDA <a href="#">206995</a></li> </ul>
			<p>EGFR T790M (Tissue and Plasma)</p> <ul style="list-style-type: none"> <li>• Tagrisso (osimertinib) - NDA <a href="#">208065</a></li> </ul>	
<p><b>PD-L1 IHC 22C3 pharmDx</b></p>	<p><a href="#">P150013</a> <a href="#">P150013/S006</a> <a href="#">P150013/S009</a> <a href="#">P150013/S011</a> <a href="#">P150013/S014</a> <a href="#">P150013/S016</a></p>	<p>Dako North America, Inc.</p>	<p>Non-small cell lung cancer (NSCLC), gastric or gastroesophageal junction adenocarcinoma, cervical cancer, urothelial carcinoma, head and neck squamous cell carcinoma (HNSCC), esophageal squamous cell carcinoma (ESCC) and triple-</p>	

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	<a href="#">P150013/S020</a> <a href="#">P150013/S021</a>		negative breast cancer (TNBC) <ul style="list-style-type: none"> <li>• KEYTRUDA (pembrolizumab) - BLA <a href="#">125514</a></li> <li>• Libtayo (cemiplimab-rwlc) – BLA <a href="#">761097</a></li> </ul>	
<b>Abbott RealTime IDH1</b>	<a href="#">P170041</a>	Abbott Molecular, Inc.	Acute myeloid leukemia <ul style="list-style-type: none"> <li>• Tibsovo (ivosidenib) - NDA <a href="#">211192</a></li> </ul>	
<b>MRDx BCR-ABL Test</b>	<a href="#">K173492</a>	MolecularMD Corporation	Chronic myeloid leukemia <ul style="list-style-type: none"> <li>• Tassigna (nilotinib) - NDA <a href="#">022068/S026</a></li> </ul>	
<b>FoundationOne CDx</b>	<a href="#">P170019</a> <a href="#">P170019/S004</a> <a href="#">P170019/S006</a> <a href="#">P170019/S008</a> <a href="#">P170019/S011</a> <a href="#">P170019/S013</a> <a href="#">P170019/S015</a> <a href="#">P170019/S016</a> <a href="#">P170019/S017</a>	Foundation Medicine, Inc.	Non-small cell lung cancer <ul style="list-style-type: none"> <li>• Gilotrif (afatinib) - NDA <a href="#">201292</a></li> <li>• Iressa (gefitinib) - NDA <a href="#">206995</a></li> <li>• Tarceva (erlotinib) - NDA <a href="#">021743</a></li> <li>• Tagrisso (osimertinib) NDA <a href="#">208065</a></li> <li>• Alecensa (alectinib) - NDA <a href="#">208434</a></li> <li>• Xalkori (crizotinib) - NDA <a href="#">202570</a></li> <li>• Zykadia (ceritinib) - NDA <a href="#">205755</a></li> <li>• Tafinlar (dabrafenib) - NDA <a href="#">202806</a> in combination with Mekinist (trametinib) - NDA <a href="#">204114</a></li> <li>• Tabrecta (capmatinib) - NDA <a href="#">213591</a></li> </ul> Melanoma <ul style="list-style-type: none"> <li>• Tafinlar (dabrafenib) - NDA <a href="#">202806</a></li> </ul>	

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			<ul style="list-style-type: none"> <li>• Zelboraf (vemurafenib) - NDA <a href="#">202429</a></li> <li>• Mekinist (trametinib) - NDA <a href="#">204114</a> or Cotellic (cobimetinib) - NDA <a href="#">206192</a> in combination with Zelboraf (vemurafenib) - NDA <a href="#">202429</a></li> </ul> <p>Breast cancer</p> <ul style="list-style-type: none"> <li>• Herceptin trastuzumab) - BLA <a href="#">103792</a></li> <li>• Perjeta (pertuzumab) - BLA <a href="#">125409</a></li> <li>• Kadcyla (ado-trastuzumab emtansine) - BLA <a href="#">125427</a></li> <li>• Piqray (alpelisib) - NDA <a href="#">212526</a></li> </ul> <p>Colorectal cancer</p> <ul style="list-style-type: none"> <li>• Erbitux (cetuximab) - BLA <a href="#">125084</a></li> <li>• Vectibix (panitumumab) - BLA <a href="#">125147</a></li> </ul> <p>Ovarian cancer</p> <ul style="list-style-type: none"> <li>• Rubraca (rucaparib) - NDA <a href="#">209115</a></li> <li>• Lynparza (olaparib) - NDA <a href="#">208558</a></li> </ul> <p>Cholangiocarcinoma</p> <ul style="list-style-type: none"> <li>• Pemazyre (pemigatinib) - NDA <a href="#">213736</a></li> </ul> <p>Metastatic castrate resistant prostate cancer (mCRPC)</p> <ul style="list-style-type: none"> <li>• Lynparza (olaparib) - NDA <a href="#">208558</a></li> </ul>	

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			Solid tumors (TMB ≥ 10 mutations per megabase) • Keytruda (pembrolizumab) - BLA <a href="#">125514</a>  Solid tumors ( <i>NTRK1/2/3</i> fusions) • Vitrakvi (larotrectinib) - NDA <a href="#">210861</a> , <a href="#">211710</a>	
<b>VENTANA ALK (D5F3) CDx Assay</b>	<a href="#">P140025/S006</a> <a href="#">P140025/S014</a>	Ventana Medical Systems, Inc.	Non-small cell lung cancer • Zykadia (ceritinib) - NDA <a href="#">205755</a> • Xalkori (crizotinib) - NDA <a href="#">202570</a> • Alecensa (alectinib) - NDA <a href="#">208434</a> • Lorbrena (lorlatinib) - NDA <a href="#">210868</a>	
<b>Abbott RealTime IDH2</b>	<a href="#">P170005</a>	Abbott Molecular, Inc.	Acute myeloid leukemia • Idhifa (enasidenib) – NDA <a href="#">209606</a>	
<b>Praxis Extended RAS Panel</b>	<a href="#">P160038</a>	Illumina, Inc.	Colorectal cancer • Vectibix (panitumumab) – NDA <a href="#">125147</a>	
<b>Oncomine Dx Target Test</b>	<a href="#">P160045</a> <a href="#">P160045/S019</a>	Life Technologies Corporation	Non-small cell lung cancer • Tafinlar (dabrafenib) in combination with Mekinist (trametinib) – NDA <a href="#">202806</a> and NDA <a href="#">204114</a> • Iressa (gefitinib) - NDA <a href="#">206995</a> • Xalkori (crizotinib) - NDA <a href="#">202570</a> • Gavreto (pralsetinib) - NDA <a href="#">213721</a>	

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<b>LeukoStrat CDx FLT3 Mutation Assay</b>	<a href="#">P160040</a>	Invivoscribe Technologies, Inc.	Acute myelogenous leukemia <ul style="list-style-type: none"> <li>• Rydapt (midostaurin) – NDA <a href="#">207997</a></li> <li>• Xospata (gilterinib) – NDA <a href="#">211349</a></li> </ul>	
<b>FoundationFocus CDxBRCA Assay</b>	<a href="#">P160018</a>	Foundation Medicine, Inc.	Ovarian cancer <ul style="list-style-type: none"> <li>• Rubraca (rucaparib) – NDA <a href="#">209115</a></li> </ul>	
<b>Vysis CLL FISH Probe Kit</b>	<a href="#">P150041</a>	Abbott Molecular, Inc.	B-cell chronic lymphocytic leukemia <ul style="list-style-type: none"> <li>• Venclexta (venetoclax) – NDA <a href="#">208573</a></li> </ul>	
<b>KIT D816V Mutation Detection by PCR for Gleevec Eligibility in Aggressive Systemic Mastocytosis (ASM)</b>	<a href="#">H140006</a>	ARUP Laboratories, Inc.	Aggressive systemic mastocytosis <ul style="list-style-type: none"> <li>• Gleevec (imatinib mesylate) – NDA <a href="#">021335</a></li> </ul>	
<b>PDGFRB FISH for Gleevec Eligibility in Myelodysplastic Syndrome / Myeloproliferative Disease (MDS/MPD)</b>	<a href="#">H140005</a>	ARUP Laboratories, Inc.	Myelodysplastic syndrome/myeloproliferative disease <ul style="list-style-type: none"> <li>• Gleevec (imatinib mesylate) – NDA <a href="#">021335</a></li> </ul>	

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cobas KRAS Mutation Test	<a href="#">P140023</a>	Roche Molecular Systems, Inc.	Colorectal cancer <ul style="list-style-type: none"> <li>• Erbitux (cetuximab) - BLA <a href="#">125084</a></li> <li>• Vectibix (panitumumab) - BLA <a href="#">125147</a></li> </ul>	
therascreen KRAS RGQ PCR Kit	<a href="#">P110030</a> <a href="#">P110027</a>	Qiagen Manchester, Ltd.	Colorectal cancer <ul style="list-style-type: none"> <li>• Erbitux (cetuximab) - BLA <a href="#">125084</a></li> <li>• Vectibix (panitumumab) - BLA <a href="#">125147</a></li> </ul>	
Dako EGFR pharmDx Kit	<a href="#">P030044/S002</a>	Dako North America, Inc.	Colorectal cancer <ul style="list-style-type: none"> <li>• Erbitux (cetuximab) - BLA <a href="#">125084</a></li> <li>• Vectibix (panitumumab) - BLA <a href="#">125147</a></li> </ul>	
FerriScan	<a href="#">DEN130012/K</a> <a href="#">124065</a>	Resonance Health Analysis Services Pty Ltd	Non-transfusion-dependent thalassemia <ul style="list-style-type: none"> <li>• Exjade (deferasirox) – NDA <a href="#">021882</a></li> </ul>	
Dako c-KIT pharmDx	<a href="#">P040011</a>	Dako North America, Inc.	Gastrointestinal stromal tumors <ul style="list-style-type: none"> <li>• Gleevec (imatinib mesylate) – NDA <a href="#">021335</a></li> <li>• Glivec (imatinib mesylate) – NDA <a href="#">021588</a></li> </ul>	
INFORM HER-2/neu	<a href="#">P940004</a>	Ventana Medical Systems, Inc.	Breast cancer <ul style="list-style-type: none"> <li>• Herceptin (trastuzumab) - BLA <a href="#">103792</a></li> </ul>	



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PathVysion HER-2 DNA Probe Kit	<a href="#">P980024</a>	Abbott Molecular Inc.	Breast cancer • Herceptin (trastuzumab) - BLA <a href="#">103792</a>	
PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody	<a href="#">P990081/S001-S028</a> <a href="#">P990081/S039</a>	Ventana Medical Systems, Inc.	Breast cancer • Herceptin (trastuzumab) - BLA <a href="#">103792</a> • Kadcyla (ado-trastuzumab emtansine) - BLA <a href="#">125427</a>	
InSite Her-2/neu KIT	<a href="#">P040030</a>	Biogenex Laboratories, Inc.	Breast cancer • Herceptin (trastuzumab) - BLA <a href="#">103792</a>	
SPOT-LIGHT HER2 CISH Kit	<a href="#">P050040/S001-S003</a>	Life Technologies Corporation	Breast cancer • Herceptin (trastuzumab) - BLA <a href="#">103792</a>	
Bond Oracle HER2 IHC System	<a href="#">P090015</a>	Leica Biosystems	Breast cancer • Herceptin (trastuzumab) - BLA <a href="#">103792</a>	
HER2 CISH pharmDx Kit	<a href="#">P100024</a>	Dako Denmark A/S	Breast cancer • Herceptin (trastuzumab) - BLA <a href="#">103792</a>	
INFORM HER2 Dual ISH DNA Probe Cocktail	<a href="#">P100027</a> <a href="#">P100027/S030</a>	Ventana Medical Systems, Inc.	Breast cancer • Herceptin (trastuzumab) - BLA <a href="#">103792</a>	

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			<ul style="list-style-type: none"> <li>• Kadcyła (ado-trastuzumab emtansine) - BLA <a href="#">125427</a></li> </ul>	
HercepTest	<a href="#">P980018/S018</a>	Dako Denmark A/S	Breast cancer <ul style="list-style-type: none"> <li>• Herceptin (trastuzumab) - BLA <a href="#">103792</a></li> <li>• Perjeta (pertuzumab) - BLA <a href="#">125409</a></li> <li>• Kadcyła (ado-trastuzumab emtansine) - BLA <a href="#">125427</a></li> </ul> Gastric and gastroesophageal cancer <ul style="list-style-type: none"> <li>• Herceptin (trastuzumab) - BLA <a href="#">103792</a></li> </ul>	
HER2 FISH pharmDx Kit	<a href="#">P040005</a> <a href="#">P040005/S005</a> <a href="#">P040005/S006</a> <a href="#">P040005/S009</a>	Dako Denmark A/S	Breast cancer <ul style="list-style-type: none"> <li>• Herceptin (trastuzumab) - BLA <a href="#">103792</a></li> <li>• Perjeta (pertuzumab) - BLA <a href="#">125409</a></li> <li>• Kadcyła (ado-trastuzumab emtansine) - BLA <a href="#">125427</a></li> </ul> Gastric and gastroesophageal cancer <ul style="list-style-type: none"> <li>• Herceptin (trastuzumab) - BLA <a href="#">103792</a></li> </ul>	
THXID BRAF Kit	<a href="#">P120014</a>	bioMérieux Inc.	Melanoma <ul style="list-style-type: none"> <li>• Braftovi (encorafenib) in combination with Mektovi</li> </ul>	

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			(binimetinib) – NDA <a href="#">210496</a> and NDA <a href="#">210498</a> <ul style="list-style-type: none"> <li>• Mekinist (tramatenib) - NDA <a href="#">204114</a></li> <li>• Tafinlar (dabrafenib) – NDA <a href="#">202806</a></li> </ul>	
<b>Vysis ALK Break Apart FISH Probe Kit</b>	<a href="#">P110012</a> <a href="#">P110012/S020</a>	Abbott Molecular Inc.	Non-small cell lung cancer (NSCLC) <ul style="list-style-type: none"> <li>• Xalkori (crizotinib) – NDA <a href="#">202570</a></li> <li>• Alunbrig (brigatinib) - NDA <a href="#">208772</a></li> </ul>	
<b>cobas 4800 BRAF V600 Mutation Test</b>	<a href="#">P110020/S016</a>	Roche Molecular Systems, Inc.	Melanoma <ul style="list-style-type: none"> <li>• Zelboraf (vemurafenib) - NDA <a href="#">202429</a></li> <li>• Cotellic (cobimetinib) - NDA <a href="#">206192</a> in combination with Zelboraf (vemurafenib) - NDA <a href="#">202429</a></li> </ul>	
<b>VENTANA PD-L1 (SP142) Assay</b>	<a href="#">P160002/S006</a> <a href="#">P160002/S009</a> <a href="#">P160002/S012</a>	Ventana Medical Systems, Inc.	Urothelial carcinoma, Triple-Negative Breast Carcinoma (TNBC) and Non-small cell lung cancer (NSCLC) <ul style="list-style-type: none"> <li>• TECENTRIQ (atezolizumab) – BLA <a href="#">761034</a></li> </ul>	
<b>therascreen FGFR RGQ RT-PCR Kit</b>	<a href="#">P180043</a>	QIAGEN Manchester Ltd.	Urothelial cancer <ul style="list-style-type: none"> <li>• BALVERSA (erdafitinib) - NDA <a href="#">212018</a></li> </ul>	
<b>therascreen PIK3CA RGQ PCR Kit</b>	<a href="#">P190001</a> <a href="#">P190004</a>	QIAGEN GmbH	Breast cancer (tissue and plasma) <ul style="list-style-type: none"> <li>• PIQRAY (alpelisib) - NDA <a href="#">212526</a></li> </ul>	

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Myriad myChoice® CDx	<a href="#">P190014</a> <a href="#">P190014/S003</a>	Myriad Genetic Laboratories, Inc.	Ovarian cancer • Zejula® (niraparib) - NDA <a href="#">208447</a> • Lynparza (olaparib) - NDA <a href="#">208558</a>	
therascreen BRAF V600E RGQ PCR Kit	<a href="#">P1900026</a>	QIAGEN GmbH	Colorectal cancer • BRAFTOVI (encorafenib) – NDA <a href="#">210496</a> in combination with Erbitux (cetuximab) – BLA <a href="#">125084</a>	
PD-L1 IHC 28-8 pharmDx	<a href="#">P150025/S013</a>	Dako North America, Inc.	Non-small cell lung cancer (NSCLC) • OPDIVO (nivolumab) (BLA <a href="#">125554</a> ) in combination with YERVOY (ipilimumab) (BLA <a href="#">125377</a> )	
cobas EZH2 Mutation Test	<a href="#">P200014</a>	Roche Molecular Systems, Inc.	Follicular lymphoma tumor • Tazverik (tazemetostat) - NDA <a href="#">213400</a>	
VENTANA HER2 Dual ISH DNA Probe Cocktail	<a href="#">P190031</a>	Ventana Medical Systems, Inc.	Breast cancer • Herceptin (trastuzumab) - BLA <a href="#">103792</a>	
Guardant360® CDx	<a href="#">P200010</a> <a href="#">P200010/S001</a>	Guardant Health, Inc.	Non-small cell lung cancer (plasma) • Tagrisso (osimertinib) - NDA <a href="#">208065</a> • Rybrevant (amivantamab-vmjw) - BLA <a href="#">761210</a>	

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<b>FoundationOne® Liquid CDx</b>	<a href="#">P190032</a> <a href="#">P200006</a> <a href="#">P200016</a>	Foundation Medicine, Inc.	Non-small cell lung cancer (plasma) <ul style="list-style-type: none"> <li>• Iressa (gefitinib) - NDA <a href="#">206995</a></li> <li>• Tagrisso (osimertinib) - NDA <a href="#">208065</a></li> <li>• Tarceva (erlotinib) - NDA <a href="#">021743</a></li> <li>• Alecensa (alectinib) - NDA <a href="#">208434</a></li> </ul> Metastatic castrate resistant prostate cancer (mCRPC) (plasma) <ul style="list-style-type: none"> <li>• Rubraca (rucaparib) – NDA <a href="#">209115</a></li> <li>• Lynparza (olaparib) – NDA <a href="#">206162</a>, <a href="#">208558</a></li> </ul> Ovarian cancer (plasma) <ul style="list-style-type: none"> <li>• Rubraca (rucaparib) – NDA <a href="#">209115</a></li> </ul> Breast cancer (plasma) <ul style="list-style-type: none"> <li>• Piqray (alpelisib) - NDA <a href="#">212526</a></li> </ul>	
<b>VENTANA MMR RxDx Panel</b>	<a href="#">P200019</a>	Ventana Medical Systems, Inc.	Endometrial Carcinoma (EC) <ul style="list-style-type: none"> <li>• Jemperli (dostarlimab-gxly) – BLA <a href="#">761174</a></li> </ul>	