

Updated 06/13/2022

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

Below, you would find a sortable and searchable [table](#) that lists all active indications.

A *companion diagnostic device* can be *in vitro* diagnostic (IVD) 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.

Some devices have indication for a specific group of oncology therapeutic (group labeling). Their detailed information can be found in a second [table](#) below the main one.

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

Please submit any questions to DICE@fda.hhs.gov.

Updated 06/13/2022

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

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA/BLA	Biomarker(s)	Biomarker(s) (Details)	PMA/510(k)/513(f)(2)/HDE (Approval/Clearance /Grant Date)
Abbott RealTime IDH1 (Abbott Molecular, Inc.)	Acute Myeloid Leukemia - Peripheral Blood or Bone Marrow	Tibsovo (ivosidenib) NDA 211192	IDH1	R132 mutations (R132C, R132H, R132G, R132S, and R132L)	P170041 (07/20/2018)
Abbott RealTime IDH2 (Abbott Molecular, Inc.)	Acute Myeloid Leukemia - Peripheral Blood or Bone Marrow	Idhifa (enasidenib) NDA 209606	IDH2	R140Q, R140L, R140G, R140W, R172K, R172M, R172G, R172S, and R172W	P170005 (08/01/2017)
Bond Oracle HER2 IHC System (Leica Biosystems)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	ERBB2 (HER2)	HER-2 protein overexpression	P090015 (04/18/2012)
BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.)	Ovarian Cancer - Whole Blood	Lynparza (olaparib) NDA 208558	BRCA1 and BRCA2	Mutations	P140020 (12/19/2014)
BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.)	Breast Cancer - Whole Blood	Lynparza (olaparib) NDA 208558	BRCA1 and BRCA2	Mutations	P140020/S012 (01/12/2018)
BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.)	Breast Cancer - Whole Blood	Talzenna (talazoparib) NDA 211651	BRCA1 and BRCA2	Mutations	P140020/S015 (10/16/2018)
BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.)	Ovarian Cancer - Whole Blood	Rubraca (rucaparib) NDA 209115	BRCA1 and BRCA2	Mutations	P140020/S016 (10/16/2018)
BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.)	Pancreatic Cancer - Whole Blood	Lynparza (olaparib) NDA 208558	BRCA1 and BRCA2	Mutations	P140020/S019 (12/27/2019)
BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.)	Metastatic Castrate Resistant Prostate Cancer (mCRPC) - Whole Blood	Lynparza (olaparib) NDA 208558	BRCA1 and BRCA2	Mutations	P140020/S020 (05/19/2020)
cobas 4800 BRAF V600 Mutation Test (Roche Molecular Systems, Inc.)	Melanoma - Tissue	Zelboraf (vemurafenib) NDA 202429	BRAF	V600E	P110020 (08/17/2011)
cobas 4800 BRAF V600 Mutation Test (Roche Molecular Systems, Inc.)	Melanoma - Tissue	Cotellic (cobimetinib) NDA 206192 in combination with Zelboraf (vemurafenib) NDA 202429	BRAF	V600E or V600K	P110020/S016 (11/07/2016)
cobas EGFR Mutation Test v1 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tarceva (erlotinib) NDA 021743	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P120019 (07/15/2013)
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tagrisso (osimertinib) NDA 208065	EGFR (HER1)	T790M	P120019/S007 (11/13/2015)
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tagrisso (osimertinib) NDA 208065	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P120019/S016 (04/18/2018)
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Tagrisso (osimertinib) NDA 208065	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P120019/S018 (04/18/2018)
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue or Plasma	Iressa (gefitinib) NDA 206995	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P120019/S019 (08/22/2018)
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue or Plasma	Iressa (gefitinib) NDA 206995	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P120019/S031 (10/27/2020) Group Labeling, see table below
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue or Plasma	Tarceva (erlotinib) NDA 021743	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P120019/S031 (10/27/2020) Group Labeling, see table below

Updated 06/13/2022

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cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue or Plasma	Gilotrif (afatinib) NDA 201292	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P120019/S031 (10/27/2020) Group Labeling, see table below
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue or Plasma	Tagrisso (osimertinib) NDA 208065	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P120019/S031 (10/27/2020) Group Labeling, see table below
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Tagrisso (osimertinib) NDA 208065	EGFR (HER1)	T790M	P150044 (09/28/2016)
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Tarceva (erlotinib) NDA 021743	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P150047 (06/01/2016)
cobas EZH2 Mutation Test (Roche Molecular Systems, Inc.)	Follicular Lymphoma Tumor - Tissue	Tazverik (tazemetostat) NDA 213400	EZH2	Y646N, Y646F or Y646X (Y646H, Y646S, or Y646C), A682G, and A692V of the EZH2 gene	P200014 (06/18/2020)
cobas KRAS Mutation Test (Roche Molecular Systems, Inc.)	Colorectal Cancer - Tissue	Erbix (cetuximab) BLA 125084	KRAS	Mutations in codons 12 and 13 of KRAS gene	P140023 (05/07/2015)
cobas KRAS Mutation Test (Roche Molecular Systems, Inc.)	Colorectal Cancer - Tissue	Vectibix (panitumumab) BLA 125147	KRAS	Mutations in codons 12 and 13 of KRAS gene	P140023 (05/07/2015)
Dako c-KIT pharmDx (Dako North America, Inc.)	Gastrointestinal Stromal Tumors - Tissue	Gleevec (imatinib mesylate) NDA 021588	C-Kit	C-Kit protein expression in CD117 antigen-expressing cells	P040011 (06/27/2005)
Dako EGFR pharmDx Kit (Dako North America, Inc.)	Colorectal Cancer - Tissue	Erbix (cetuximab) BLA 125084	EGFR (HER1)	EGFR (HER1) protein expression	P030044 (02/12/2004)
Dako EGFR pharmDx Kit (Dako North America, Inc.)	Colorectal Cancer - Tissue	Vectibix (panitumumab) BLA 125147	EGFR (HER1)	EGFR (HER1) protein expression	P030044/S002 (09/27/2006)
FerriScan (Resonance Health Analysis Services Pty Ltd)	Non-Transfusion-Dependent Thalassemia - Tissue	Exjade (deferasirox) NDA 021882	Liver iron concentration imaging	Liver iron concentration based on the proton transverse relaxation rate of MRI images	DEN130012/K12406 (01/23/2013)
FoundationFocus CDxBRCA Assay (Foundation Medicine, Inc.)	Ovarian Cancer - Tissue	Rubraca (rucaparib) NDA 209115	BRCA1 and BRCA2	BRCA1 and BRCA2 alterations	P160018 (12/19/2016)
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Gilotrif (afatinib) NDA 201292	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P170019 (11/30/2017)
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Iressa (gefitinib) NDA 206995	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P170019 (11/30/2017)
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tarceva (erlotinib) NDA 021743	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P170019 (11/30/2017)
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tagrisso (osimertinib) NDA 208065	EGFR (HER1)	T790M	P170019 (11/30/2017)
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Alecensa (alectinib) NDA 208434	ALK	ALK rearrangements	P170019 (11/30/2017)
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Xalkori (crizotinib) NDA 202570	ALK	ALK rearrangements	P170019 (11/30/2017)
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Zykadia (ceritinib) NDA 211225	ALK	ALK rearrangements	P170019 (11/30/2017)
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tafinlar (dabrafenib) NDA 202806 in combination with Mekinist (trametinib) NDA 204114	BRAF	V600E	P170019 (11/30/2017)

Updated 06/13/2022

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FoundationOne CDx (Foundation Medicine, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	<i>ERBB2</i> (<i>HER2</i>)	<i>ERBB2</i> (<i>HER2</i>) amplification	P170019 (11/30/2017)
FoundationOne CDx (Foundation Medicine, Inc.)	Breast Cancer - Tissue	Perjeta (pertuzumab) BLA 125409	<i>ERBB2</i> (<i>HER2</i>)	<i>ERBB2</i> (<i>HER2</i>) amplification	P170019 (11/30/2017)
FoundationOne CDx (Foundation Medicine, Inc.)	Breast Cancer - Tissue	Kadcyla (ado-trastuzumab emtansine) BLA 125427	<i>ERBB2</i> (<i>HER2</i>)	<i>ERBB2</i> (<i>HER2</i>) amplification	P170019 (11/30/2017)
FoundationOne CDx (Foundation Medicine, Inc.)	Colorectal Cancer - Tissue	Erbix (cetuximab) BLA 125084	<i>KRAS</i>	<i>KRAS</i> wild-type (absence of mutations in codons 12 and 13)	P170019 (11/30/2017)
FoundationOne CDx (Foundation Medicine, Inc.)	Colorectal Cancer - Tissue	Vectibix (panitumumab) BLA 125147	<i>KRAS</i> and <i>NRAS</i>	<i>KRAS</i> wild-type (absence of mutations in exons 2, 3, and 4) and <i>NRAS</i> wild type (absence of mutations in exons 2, 3, and 4)	P170019 (11/30/2017)
FoundationOne CDx (Foundation Medicine, Inc.)	Ovarian Cancer - Tissue	Rubraca (rucaparib) NDA 209115	<i>BRCA1</i> and <i>BRCA2</i>	<i>BRCA1</i> and <i>BRCA2</i> alterations	P170019 (11/30/2017)
FoundationOne CDx (Foundation Medicine, Inc.)	Melanoma - Tissue	Mekinist (trametinib) NDA 204114	<i>BRAF</i>	V600E and V600K	P170019 (11/30/2017) Group Labeling, See table below
FoundationOne CDx (Foundation Medicine, Inc.)	Ovarian Cancer - Tissue	Lynparza (olaparib) NDA 208558	<i>BRCA1</i> and <i>BRCA2</i>	<i>BRCA1</i> and <i>BRCA2</i> alterations	P170019/S004 (07/01/2019)
FoundationOne CDx (Foundation Medicine, Inc.)	Breast Cancer - Tissue	Lynparza (olaparib) NDA 212526	<i>PIK3CA</i>	C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y	P170019/S006 (12/03/2019)
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tagrisso (osimertinib) NDA 208065	<i>EGFR</i> (<i>HER1</i>)	Exon 19 deletion or exon 21 L858R substitution mutation	P170019/S008 (07/01/2019) Group Labeling, See table below
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tabrecta (capmatinib) NDA 213591	<i>MET</i>	<i>MET</i> single nucleotide variants and indels that lead to <i>MET</i> exon 14 skipping	P170019/S011 (05/06/2020)
FoundationOne CDx (Foundation Medicine, Inc.)	Cholangiocarcinoma - Tissue	Pemazyre (pemigatinib) NDA 213736	<i>FGFR2</i>	<i>FGFR2</i> fusions and select rearrangements	P170019/S013 (04/17/2020)
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Rozlytrek (entrectinib) NDA 212725	<i>NTRK1</i> , <i>NTRK2</i> and <i>NTRK3</i>	<i>NTRK1</i> , <i>NTRK2</i> and <i>NTRK3</i> fusions	P170019/S014 (06/07/2022)
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Rozlytrek (entrectinib) NDA 212725	<i>ROS1</i>	<i>ROS1</i> fusions	P170019/S014 (06/07/2022)
FoundationOne CDx (Foundation Medicine, Inc.)	Metastatic Castrate Resistant Prostate Cancer (mCRPC) - Tissue	Lynparza (olaparib) NDA 208558	Homologous recombination repair (HRR) genes	<i>BRCA1</i> , <i>BRCA2</i> , <i>ATM</i> , <i>BARD1</i> , <i>BRIP1</i> , <i>CDK12</i> , <i>CHEK1</i> , <i>CHEK2</i> , <i>FANCL</i> , <i>PALB2</i> , <i>RAD51B</i> , <i>RAD51C</i> , <i>RAD51D</i> and <i>RAD54L</i> alterations	P170019/S015 (05/19/2020)
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	TMB	TMB ≥ 10 mutations per megabase	P170019/S016 (06/16/2020)
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Vitrakvi (larotrectinib) NDA 210861	<i>NTRK1</i> , <i>NTRK2</i> and <i>NTRK3</i>	<i>NTRK1</i> , <i>NTRK2</i> and <i>NTRK3</i> fusions	P170019/S017 (10/23/2020)
FoundationOne CDx (Foundation Medicine, Inc.)	Cholangiocarcinoma - Tissue	Truseltiq (infigratinib) NDA 214622	<i>FGFR2</i>	<i>FGFR2</i> fusions/rearrangements	P170019/S021 (05/28/2021)
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	MSI-High	Microsatellite instability-High (MSI-H)	P170019/S029 (02/18/2022)

Updated 06/13/2022

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FoundationOne CDx (Foundation Medicine, Inc.)	Melanoma - Tissue	Tecentriq (atezolizumab) BLA 761034 in combination with Cotellic (cobimetinib) NDA 206192 and Zelboraf (vemurafenib) NDA 202429	<i>BRAF</i>	<i>BRAF</i> V600 mutations	P170019/S030 (01/19/2022)
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Iressa (gefitinib) NDA 206995	<i>EGFR (HER1)</i>	Exon 19 deletion or exon 21 L858R substitution mutation	P190032 (08/26/2020)
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Tagrisso (osimertinib) NDA 208065	<i>EGFR (HER1)</i>	Exon 19 deletion or exon 21 L858R substitution mutation	P190032 (08/26/2020)
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Tarceva (erlotinib) NDA 021743	<i>EGFR (HER1)</i>	Exon 19 deletion or exon 21 L858R substitution mutation	P190032 (08/26/2020)
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Metastatic Castrate Resistant Prostate Cancer (mCRPC) - Plasma	Rubraca (rucaparib) NDA 209115	<i>BRCA1</i> and <i>BRCA2</i>	<i>BRCA1</i> and <i>BRCA2</i> alterations	P190032 (08/26/2020)
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Tabrecta (capmatinib) NDA 213591	<i>MET</i>	<i>MET</i> single nucleotide variants and indels that lead to <i>MET</i> exon 14 skipping	P190032/S001 (07/15/2021)
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Alecensa (alectinib) NDA 208434	<i>ALK</i>	<i>ALK</i> rearrangements	P200006 (10/26/2020)
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Ovarian Cancer - Plasma	Rubraca (rucaparib) NDA 209115	<i>BRCA1</i> and <i>BRCA2</i>	<i>BRCA1</i> and <i>BRCA2</i> alterations	P200006 (10/26/2020)
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Breast Cancer - Plasma	Piqray (alpelisib) NDA 212526	<i>PIK3CA</i>	C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y	P200006 (10/26/2020)
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Metastatic Castrate Resistant Prostate Cancer (mCRPC) - Plasma	Lynparza (olaparib) NDA 208558	<i>BRCA1</i> , <i>BRCA2</i> and <i>ATM</i>	<i>BRCA1</i> , <i>BRCA2</i> , and <i>ATM</i> alterations	P200006 (10/26/2020)
Guardant360 CDx (Guardant Health, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Tagrisso (osimertinib) NDA 208065	<i>EGFR (HER1)</i>	<i>EGFR</i> exon 19 deletions, <i>EGFR</i> exon 21 L858R, and T790M	P200010 (08/07/2020)
Guardant360 CDx (Guardant Health, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Rybrevant (amivantamb) BLA 761210	<i>EGFR (HER1)</i>	<i>EGFR</i> exon 20 insertions	P200010/S001 (05/21/2021)
Guardant360 CDx (Guardant Health, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Lumakras (sotorasib) NDA 214665	<i>KRAS</i>	G12C	P200010/S002 (05/28/2021)
HER2 CISH pharmDx Kit (Dako Denmark A/S)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	<i>ERBB2 (HER2)</i>	HER-2/neu (<i>ERBB2</i>) gene amplification	P100024 (11/30/2011)
HER2 FISH pharmDx Kit (Dako Denmark A/S)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	<i>ERBB2 (HER2)</i>	HER-2/neu (<i>ERBB2</i>) gene amplification	P040005 (05/03/2005)
HER2 FISH pharmDx Kit (Dako Denmark A/S)	Gastric and Gastroesophageal Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	<i>ERBB2 (HER2)</i>	HER-2/neu (<i>ERBB2</i>) gene amplification	P040005/S005 (10/20/2010)
HER2 FISH pharmDx Kit (Dako Denmark A/S)	Breast Cancer - Tissue	Perjeta (pertuzumab) BLA 125409	<i>ERBB2 (HER2)</i>	HER-2/neu (<i>ERBB2</i>) gene amplification	P040005/S006 (06/08/2012)
HER2 FISH pharmDx Kit (Dako Denmark A/S)	Breast Cancer - Tissue	Kadcyla (ado-trastuzumab emtansine) BLA 125427	<i>ERBB2 (HER2)</i>	HER-2/neu (<i>ERBB2</i>) gene amplification	P040005/S009 (02/22/2013)
HercepTest (Dako Denmark A/S)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	<i>ERBB2 (HER2)</i>	HER-2 protein overexpression	P980018 (09/25/1998)
HercepTest (Dako Denmark A/S)	Gastric and Gastroesophageal Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	<i>ERBB2 (HER2)</i>	HER-2 protein overexpression	P980018/S010 (10/20/2010)
HercepTest (Dako Denmark A/S)	Breast Cancer - Tissue	Perjeta (pertuzumab) BLA 125409	<i>ERBB2 (HER2)</i>	HER-2 protein overexpression	P980018/S015 (06/08/2012)
HercepTest (Dako Denmark A/S)	Breast Cancer - Tissue	Kadcyla (ado-trastuzumab emtansine) BLA 125427	<i>ERBB2 (HER2)</i>	HER-2 protein overexpression	P980018/S016 (02/22/2013)

Updated 06/13/2022

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INFORM HER2 Dual ISH DNA Probe Cocktail (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	<i>ERBB2</i> (<i>HER2</i>)	<i>HER-2/neu</i> (<i>ERBB2</i>) gene amplification	P100027 (06/14/2011)
INFORM HER2 Dual ISH DNA Probe Cocktail (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Kadcyla (ado-trastuzumab emtansine) BLA 125427	<i>ERBB2</i> (<i>HER2</i>)	<i>HER-2/neu</i> (<i>ERBB2</i>) gene amplification	P100027/S030 (05/03/2019)
INFORM HER-2/neu (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	<i>ERBB2</i> (<i>HER2</i>)	<i>HER-2/neu</i> (<i>ERBB2</i>) gene amplification	P940004 (12/30/1997)
InSite Her-2/neu (CB11) Monoclonal Antibody (Biogenex Laboratories, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	<i>ERBB2</i> (<i>HER2</i>)	HER-2 protein overexpression	P040030 (12/22/2004)
Ki-67 IHC MIB-1 pharmDx (Dako Omnis) (Agilent Technologies)	Breast Cancer - Tissue	Verzenio (abemaciclib) NDA 208716	Ki-67	Ki-67 protein expression	P210026 (10/12/2021)
KIT D816V Assay (ARUP Laboratories, Inc.)	Aggressive Systemic Mastocytosis - Bone Marrow	Gleevec (imatinib mesylate) NDA 021588	<i>KIT</i>	D816V	H140006 (12/18/2015)
LeukoStrat CDx FLT3 Mutation Assay (Invivoscribe Technologies, Inc.)	Acute Myelogenous Leukemia - Peripheral Blood or Bone Marrow	Rydapt (midostaurin) NDA 207997	<i>FLT3</i> (ITD/TDK)	ITD mutations and TKD mutations D835 and I836	P160040 (04/28/2017)
LeukoStrat CDx FLT3 Mutation Assay (Invivoscribe Technologies, Inc.)	Acute Myelogenous Leukemia - Peripheral Blood or Bone Marrow	Xospata (gilterinib) NDA 211349	<i>FLT3</i> (ITD/TDK)	ITD mutations and TKD mutations D835 and I836	P160040/S002 (11/28/2018)
MRDx BCR-ABL Test (MolecularMD Corporation)	Chronic Myeloid Leukemia - Peripheral Blood	Tasigna (nilotinib) NDA 022068	t(9;21) Philadelphia chromosome	<i>BCR-ABL</i> fusion	K173492 (12/22/2017)
Myriad myChoice CDx (Myriad Genetic Laboratories, Inc.)	Ovarian Cancer - Tissue	ZeJula (niraparib) NDA 208447	Myriad HRD	Deleterious or suspected deleterious mutations in <i>BRCA1</i> and <i>BRCA2</i> genes and/or positive Genomic Instability Score)	P190014 (10/23/2019)
Myriad myChoice CDx (Myriad Genetic Laboratories, Inc.)	Ovarian Cancer - Tissue	Lynparza (olaparib) NDA 208558	Myriad HRD	Deleterious or suspected deleterious mutations in <i>BRCA1</i> and <i>BRCA2</i> genes and/or positive Genomic Instability Score)	P190014/S003 (05/08/2020)
ONCO/Reveal Dx Lung & Colon Cancer Assay (O/RDx-LCCA) (Pillar Biosciences, Inc.)	Colorectal Cancer - Tissue	Erbix (cetuximab) BLA 125084	<i>KRAS</i>	<i>KRAS</i> wild-type (absence of mutations in codons 12 and 13)	P200011 (07/30/2021)
ONCO/Reveal Dx Lung & Colon Cancer Assay (O/RDx-LCCA) (Pillar Biosciences, Inc.)	Colorectal Cancer - Tissue	Vectibix (panitumumab) BLA 125147	<i>KRAS</i>	<i>KRAS</i> wild-type (absence of mutations in codons 12 and 13)	P200011 (07/30/2021)
ONCO/Reveal Dx Lung & Colon Cancer Assay (O/RDx-LCCA) (Pillar Biosciences, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Iressa (gefitinib) NDA 206995	<i>EGFR</i> (<i>HER1</i>)	Exon 19 deletion or exon 21 L858R substitution mutation	P200011 (07/30/2021)
ONCO/Reveal Dx Lung & Colon Cancer Assay (O/RDx-LCCA) (Pillar Biosciences, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Gilotrif (afatinib) NDA 201292	<i>EGFR</i> (<i>HER1</i>)	Exon 19 deletion or exon 21 L858R substitution mutation	P200011 (07/30/2021)
ONCO/Reveal Dx Lung & Colon Cancer Assay (O/RDx-LCCA) (Pillar Biosciences, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tarceva (erlotinib) NDA 021743	<i>EGFR</i> (<i>HER1</i>)	Exon 19 deletion or exon 21 L858R substitution mutation	P200011 (07/30/2021)
ONCO/Reveal Dx Lung & Colon Cancer Assay (O/RDx-LCCA) (Pillar Biosciences, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Vizimpro (dacomitinib) NDA 211288	<i>EGFR</i> (<i>HER1</i>)	Exon 19 deletion or exon 21 L858R substitution mutation	P200011 (07/30/2021)
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tafinlar (dabrafenib) NDA 202806 in combination with Mekinist (trametinib) NDA 204114	<i>BRAF</i>	V600E	P160045 (06/22/2017)
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Xalkori (crizotinib) NDA 202570	<i>ROS1</i>	<i>ROS1</i> fusions	P160045 (06/22/2017)
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Iressa (gefitinib) NDA 206995	<i>EGFR</i> (<i>HER1</i>)	Exon 19 deletion or exon 21 L858R substitution mutation	P160045 (06/22/2017)
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Gavreto (pralsetinib) NDA 213721	<i>RET</i>	<i>RET</i> fusions	P160045/S019 (09/04/2020)
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Rybrevant (amivantamb) BLA 761210	<i>EGFR</i> (<i>HER1</i>)	Exon 20 insertion mutations	P160045/S027 (12/01/2021)

Updated 06/13/2022

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA/BLA	Biomarker(s)	Biomarker(s) (Details)	PMA/510(k)/513(f)(2)/HDE (Approval/Clearance /Grant Date)
Oncomine Dx Target Test (Life Technologies Corporation)	Cholangiocarcinoma - Tissue	Tibsovo (ivosidenib) NDA 211192	IDH1	Single nucleotide variants	P160045/S028 (08/25/2021)
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Exkivity (mobocertinib) NDA 215310	EGFR (HER1)	Exon 20 insertion mutations	P160045/S029 (09/15/2021)
PathVysion HER-2 DNA Probe Kit (Abbott Molecular Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	ERBB2 (HER2)	HER-2/neu (ERBB2) gene amplification	P980024 (12/11/1998)
PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	ERBB2 (HER2)	HER-2 protein overexpression	P990081 (11/28/2000)
PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Kadcyla (ado-trastuzumab emtansine) BLA 125427	ERBB2 (HER2)	HER-2 protein overexpression	P990081/S039 513(f) (05/03/2019)
PDGFRB FISH Assay (ARUP Laboratories, Inc.)	Myelodysplastic Syndrome/Myeloproliferative Disease - Bone Marrow	Gleevec (imatinib mesylate) NDA 021588	PDGFRB	PDGFRB gene rearrangement at 5q31~33	H140005 (12/18/2015)
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013 (10/02/2015)
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Cervical Cancer - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S009 (06/12/2018)
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Head and Neck Squamous Cell Carcinoma (HNSCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S014 (06/10/2019)
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Esophageal Squamous Cell Carcinoma (ESCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S016 (07/30/2019)
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Triple-Negative Breast Cancer (TNBC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S020 (11/13/2020)
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Libtayo (cemiplimab-rwlc) BLA 761097	PD-L1	PD-L1 protein expression [Tumor Proportion Score (TPS) ≥ 50%]	P150013/S021 (02/22/2021)
PD-L1 IHC 28-8 pharmDx (Dako North America, Inc.)	Non-small cell lung cancer (NSCLC) - Tissue	Opdivo (nivolumab) BLA 125554 in combination with Yervoy (ipilimumab) BLA 125377	PD-L1	PD-L1 protein expression (tumor cell staining ≥1%)	P150025/S013 (05/15/2020)
POMC/PCSK1/LEPR CDx Panel (PreventionGenetics, LLC)	Obesity - Blood or Saliva	Imcivree (setmelanotide acetate) NDA 213793	POMC, PCSK1 and LEPR	Variants (Pathogenic/Likely Pathogenic) and Variants of Uncertain Significance	DEN200059 (01/21/2022)
Praxis Extended RAS Panel (Illumina, Inc.)	Colorectal cancer - Tissue	Vectibix (panitumumab) BLA 125147	KRAS and NRAS	KRAS wild-type (absence of mutations in exons 2, 3, and 4) and NRAS wild type (absence of mutations in exons 2, 3, and 4)	P160038 (06/29/2017)
SPOT-LIGHT HER2 CISH Kit (Life Technologies Corporation)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	ERBB2 (HER2)	HER-2/neu (ERBB2) gene amplification	P050040 (07/01/2008)
therascreen EGFR RGQ PCR Kit (Qiagen Manchester, Ltd.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Gilotrif (afatinib) NDA 201292	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P120022 (07/12/2013)
therascreen EGFR RGQ PCR Kit (Qiagen Manchester, Ltd.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Iressa (gefitinib) NDA 206995	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P120022/S001 (07/10/2015)
therascreen EGFR RGQ PCR Kit (Qiagen Manchester, Ltd.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Gilotrif (afatinib) NDA 201292	EGFR (HER1)	L861Q, G719X and S768I	P120022/S016 (01/12/2016)
therascreen EGFR RGQ PCR Kit (Qiagen Manchester, Ltd.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Vizimpro (dacomitinib) NDA 211288	EGFR (HER1)	Exon 19 deletion or exon 21 L858R substitution mutation	P120022/S018 (09/27/2018)
therascreen KRAS RGQ PCR Kit (Qiagen Manchester, Ltd.)	Colorectal Cancer - Tissue	Vectibix (panitumumab) BLA 125147	KRAS	G12A, G12D, G12R, G12C, G12S, G12V, G13D	P110027 (05/23/2014)
therascreen KRAS RGQ PCR Kit (Qiagen Manchester, Ltd.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Lumakras (sotorasib) NDA 214665	KRAS	G12C	P110027/S012 (05/28/2021)

Updated 06/13/2022

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA/BLA	Biomarker(s)	Biomarker(s) (Details)	PMA/510(k)/513(f)(2)/HDE (Approval/Clearance /Grant Date)
<i>therascreen</i> KRAS RGQ PCR Kit (Qiagen Manchester, Ltd.)	Colorectal Cancer - Tissue	Erbix (cetuximab) BLA 125084	KRAS	G12A, G12D, G12R, G12C, G12S, G12V, G13D	P110030 (07/06/2012)
<i>therascreen</i> BRAF V600E RGQ PCR Kit (QIAGEN GmbH)	Colorectal Cancer - Tissue	Braftovi (encorafenib) NDA 210496 in combination with Erbix (cetuximab) BLA 125084	BRAF	V600E	P190026 (04/15/2020)
<i>therascreen</i> FGFR RGQ RT-PCR Kit (QIAGEN Manchester Ltd.)	Urothelial Cancer - Tissue	Balversa (erdafitinib) NDA 212018	FGFR3	Exon 7: R248C (c.742C>T), S249C (c.746C>G); exon 10: G370C (c.1108G>T) and Y373C (c.1118A>G); and fusions (<i>FGFR3-TACC3v1</i> and <i>FGFR3-TACC3v3</i>)	P180043 (04/12/2019)
<i>therascreen</i> PIK3CA RGQ PCR Kit (QIAGEN GmbH)	Breast Cancer - Tissue or Plasma	Piqray (alpelisib) NDA 212526	PIK3CA	C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y	P190001 (05/24/2019) P190004 (05/24/2019)
THXID BRAF Kit (bioMérieux Inc.)	Melanoma - Tissue	Mekinist (trametinib) NDA 204114	BRAF	V600E or V600K	P120014 (05/29/2013)
THXID BRAF Kit (bioMérieux Inc.)	Melanoma - Tissue	Tafinlar (dabrafenib) NDA 202806	BRAF	V600E	P120014 (05/29/2013)
THXID BRAF Kit (bioMérieux Inc.)	Melanoma - Tissue	Braftovi (encorafenib) NDA 210496 in combination with Mektovi (binimetinib) NDA 210498	BRAF	V600E or V600K	P120014/S008 (06/27/2018)
Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Xalkori (crizotinib) NDA 202570	ALK	ALK protein expression	P140025 (06/12/2015)
Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Zykadia (ceritinib) NDA 211225	ALK	ALK protein expression	P140025/S005 (05/26/2017)
Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Alecensa (alectinib) NDA 208434	ALK	ALK protein expression	P140025/S006 (11/06/2017)
Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Lorbrena (lorlatinib) NDA 210868	ALK	ALK protein expression	P140025/S014 (03/03/2021)
Ventana HER2 Dual ISH DNA Probe Cocktail (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792	ERBB2 (HER2)	<i>HER-2/neu (ERBB2)</i> gene amplification	P190031 (07/28/2020)
Ventana MMR Rx Dx Panel (Ventana Medical Systems, Inc.)	Endometrial Carcinoma (EC) - Tissue	Jemperli (dostarlimab-gxly) NDA 761174	deficient mismatch repair (dMMR) proteins	MLH1, PMS2, MSH2 and MSH6	P200019 (04/22/2021)
Ventana PD-L1 (SP142) Assay (Ventana Medical Systems, Inc.)	Urothelial Carcinoma - Tissue	Tecentriq (atezolizumab) BLA 761034	PD-L1	PD-L1 protein expression (PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 5% of the tumor area)	P160002 (05/18/2016)
Ventana PD-L1 (SP142) Assay (Ventana Medical Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tecentriq (atezolizumab) BLA 761034	PD-L1	PD-L1 protein expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%])	P160002/S006 (07/02/2018)
Ventana PD-L1 (SP263) Assay (Ventana Medical Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tecentriq (atezolizumab) BLA 761034	PD-L1	PD-L1 protein expression	P160046/S010 (10/15/2021)
Vysis ALK Break Apart FISH Probe Kit (Abbott Molecular Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Xalkori (crizotinib) NDA 202570	ALK	ALK gene rearrangements	P110012 (08/26/2011)
Vysis ALK Break Apart FISH Probe Kit (Abbott Molecular Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Alunbrig (brigatinib) NDA 208772	ALK	ALK gene rearrangements	P110012/S020 (05/22/2020)

Updated 06/13/2022

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA/BLA	Biomarker(s)	Biomarker(s) (Details)	PMA/510(k)/ 513(f)(2)/HDE (Approval/Clearance /Grant Date)
Vysis CLL FISH Probe Kit (Abbott Molecular, Inc.)	B-cell Chronic Lymphocytic Leukemia - Peripheral Blood	Venclexta (venetoclax) NDA 208573	TP53	Deletion chromosome 17p (17p-)	P150041 (04/11/2016)

Device Indication for a Specific Group of Oncology Therapeutic Products

Diagnostic Name (Manufacturer)	Indication(s) - Sample Type	PMA (Approval Date)	Device Indication for a Specific Group of Oncology Therapeutic Products and Trade Name (Generic) – <u>NDA/BLA</u>
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue or Plasma	P120019/S031 (10/27/2020)	Non-small cell lung cancer (tissue): "Identifying patients with NSCLC whose tumors have <i>EGFR</i> 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: Tarceva (erlotinib) - NDA 021743 Tagrisso (osimertinib) - NDA 208065 Iressa (gefitinib) - NDA 206995 Gilotrif (afatinib) - NDA 201292 Vizimpro (dacomitinib) - NDA 211288
			Non-small cell lung cancer (plasma) "Identifying patients with NSCLC whose tumors have <i>EGFR</i> 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: Tarceva (erlotinib) - NDA 021743 Tagrisso (osimertinib) - NDA 208065 Iressa (gefitinib) - NDA 206995
FoundationOne CDx (Foundation Medicine, Inc.)	Melanoma - Tissue	P170019/S025 (11/10/2021)	"Identifying patients with melanoma whose tumors have BRAF V600E and are suitable for treatment with BRAF Inhibitors approved by FDA for that indication" List of BRAF Inhibitors approved by FDA for this indication: Tafinlar (dabrafenib) - NDA 202806 Zelboraf (vemurafenib) - NDA 202429
	Non-Small Cell Lung Cancer (NSCLC) - Tissue	P170019/S033 (03/16/2022)	"Identifying patients with melanoma whose tumors have BRAF V600E and V600K and are suitable for treatment with BRAF/MEK Inhibitor Combinations approved by FDA for that indication" List of BRAF/MEK Inhibitor Combinations approved by FDA for this indication: Cotellic (cobimetinib) - NDA 206192 in combination with Zelboraf (vemurafenib) - NDA 202429 Braftovi (encorafenib) - NDA 210496 in combination with Mektovi (Binimetinib) - NDA 210498 Tafinlar (dabrafenib) - NDA 202806 in combination with Mekinist (trametinib) - NDA 204114
			"Identifying patients with NSCLC whose tumors have <i>EGFR</i> exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor (TKI) approved by FDA for that indication" List of tyrosine kinase inhibitors approved by FDA for this indication: Tarceva (erlotinib) - NDA 021743 Tagrisso (osimertinib) - NDA 208065 Iressa (gefitinib) - NDA 206995 Gilotrif (afatinib) - NDA 201292 Vizimpro (dacomitinib) - NDA 211288