

List of *in vitro* Companion Diagnostics or Medical Devices (CDx Products) Approved in Japan

	Therapeutic products used with CDx products			CDx products	
No.	Proprietary name	Active substance name	Indications	<i>In vitro</i> companion diagnostics or medical devices*	Biomarkers
1	ERBITUX Injection 100mg, 500mg	Cetuximab (genetical recombination)	Colorectal cancer	MEBGEN RASKET-B kit	KRAS/NRAS mutation
				OncoBEAM RAS CRC Kit	
				FoundationOne CDx	
				Idylla RAS-BRAF Mutation Test (NichireiBio)	
				Guardant360 CDx	
2	ALUNBRIG Tablets 30mg, 90mg	Brigatinib	Non-small cell lung cancer	Vysis ALK Break Apart FISH probe kit	ALK fusion
				AmoyDx Pan Lung Cancer PCR Panel	
				Oncomine Dx Target Test	
				FoundationOne CDx	
				Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System	
				Genetic Analysis Program MINTS Analyzer MINTS Lung Cancer Multi-CDx Library Prep Kit	
				Ventana OptiView ALK (D5F3)	ALK protein
				Histofine ALK iAEP kit	
3	ALECENSA Capsules 150mg	Alectinib Hydrochloride	Non-small cell lung cancer	Histofine ALK iAEP kit**	CCR4 protein
				Ventana OptiView ALK (D5F3)	
				Vysis ALK Break Apart FISH probe kit**	ALK fusion
				Oncomine Dx Target Test	
				FoundationOne CDx	
				FoundationOne Liquid CDx	
				AmoyDx Pan Lung Cancer PCR Panel	
				Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System	
				Genetic Analysis Program MINTS Analyzer MINTS Lung Cancer Multi-CDx Library Prep Kit	
4	IRESSA Tablets 250	Gefitinib	Non-small cell lung cancer	Cobas EGFR mutation test v2.0	EGFR mutation
				Oncomine Dx Target Test	
				therascreen EGFR RGQ PCR kit	
				FoundationOne CDx	
				EGFR LIQUID	
				FoundationOne Liquid CDx	
				AmoyDx Pan Lung Cancer PCR Panel	
				Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System	
				Genetic Analysis Program MINTS Analyzer MINTS Lung Cancer Multi-CDx Library Prep Kit	
5	VITRAKVI capsules 25mg, 100mg VITRAKVI oral solution 20mg/mL	Larotrectinib Sulfate	Solid cancer	FoundationOne CDx	NTRK1/2/3 fusion
6	VANFLYTA TABLETS 17.7mg, 26.5mg	Quizartinib Hydrochloride	Acute myeloid leukemia	LeukoStrat CDx FLT3 Mutation Assay	FLT3 mutation
7	ENHERTU FOR INTRAVENOUS DRIP INFUSION 100mg	Trastuzumab Deruxtecan (genetical recombination)	Breast cancer	Ventana ultraView Pathway HER2 (4B5)	HER2 protein
			Non-small cell lung cancer	Oncomine Dx Target Test	HER2 mutation
				Guardant360 CDx	
8	Augtyro capsules 40mg	Repotrectinib	Non-small cell lung cancer	AmoyDx Pan Lung Cancer PCR Panel	ROS1 fusion
9	OPDIVO I.V.Infusion 20mg, 100mg, 120mg, 240mg	Nivolumab (genetical recombination)	Colorectal cancer	MSI kit (FALCO)	MSI-High
				FoundationOne CDx	
				Guardant360 CDx	
				Idylla MSI Test (NichireiBio)	

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10	KEYTRUDA Injection 100mg	Pembrolizumab (genetical recombination)	Non-small cell lung cancer	PD-L1 IHC 22C3 pharmDx [Dako]	PD-L1 protein
			Esophageal cancer		
			Breast cancer		
			Solid cancer	MSI kit (FALCO)	MSI-High
				FoundationOne CDx	
				Guardant360 CDx	
				VENTANA OptiView PMS2 (A16-4)	mismatch repair deficiency
				VENTANA OptiView MSH2 (G219-1129)	
				VENTANA OptiView MSH6 (SP93)	
				VENTANA OptiView MLH1 (M1)	
				FoundationOne CDx	Tumor mutation burden
			Colorectal cancer	MSI kit (FALCO)	MSI-High
				FoundationOne CDx	
				Guardant360 CDx	
				Idylla MSI Test (NichireiBio)	
				VENTANA OptiView PMS2 (A16-4)	mismatch repair deficiency
				VENTANA OptiView MSH2 (G219-1129)	
				VENTANA OptiView MSH6 (SP93)	
				VENTANA OptiView MLH1 (M1)	
11	XALKORI Capsules 200mg, 250mg	Crizotinib	Non-small cell lung cancer	Histofine ALK iAEP kit**	ALK protein
				Ventana OptiView ALK (D5F3)	
				FoundationOne CDx	ALK fusion
				Oncomine Dx Target Test	
				Vysis ALK Break Apart FISH probe kit**	
				FoundationOne Liquid CDx	
				AmoyDx Pan Lung Cancer PCR Panel	
				Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System	
				Genetic Analysis Program MINTS Analyzer MINTS Lung Cancer Multi-CDx Library Prep Kit	
				OncoGuide AmoyDx ROS1 Gene Fusions Detection Kit	ROS1 fusion
				Oncomine Dx Target Test	
				AmoyDx Pan Lung Cancer PCR Panel	
				Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System	
12	Giotrif Tablets 20mg, 30mg, 40mg, 50mg	Afatinib Maleate	Non-small cell lung cancer	Cobas EGFR mutation test v2.0	EGFR mutation
				Oncomine Dx Target Test	
				therascreen EGFR RGQ PCR kit	
				FoundationOne CDx	
				EGFR LIQUID	
				FoundationOne Liquid CDx	
				AmoyDx Pan Lung Cancer PCR Panel	
				Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System	
				Genetic Analysis Program MINTS Analyzer MINTS Lung Cancer Multi-CDx Library Prep Kit	
13	ZYKADIA capsules 150mg, ZYKADIA tablets 150mg	Ceritinib	Non-small cell lung cancer	Ventana OptiView ALK (D5F3)	ALK protein
				Histofine ALK iAEP kit	
				FoundationOne CDx	ALK fusion
				FoundationOne Liquid CDx	
				Genetic Analysis Program MINTS Analyzer MINTS Lung Cancer Multi-CDx Library Prep Kit	

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14	Zejula capsules 100mg Zejula tablets 100mg	Niraparib Tosilate Hydrate	Ovarian cancer	myChoice CDx	Homologous recombination deficiency
15	ZELBORAF Tablets 240mg	Vemurafenib	Malignant melanoma	Cobas BRAF V600 mutation test**	BRAF mutation
				FoundationOne CDx	
16	XOSPATA Tablets 40mg	Gilteritinib Fumarate	Acute myeloid leukemia	LeukoStrat CDx FLT3 Mutation Assay	FLT3 mutation
17	ZOLGENSMA for i.v. infusions	Onasemnogene abeparvovec	Spinal muscular atrophy	MEBCDX AAV9 TEST	Anti-adeno-associated virus type 9 (AAV9) antibody
18	TALZENNA capsules 0.1mg,0.25mg,1mg	Talazoparib Tosilate	Prostate cancer	FoundationOne CDx	BRCA1/2 mutation
			Breast cancer	BRACAnalysis CDx	
19	TAGRISSO Tablets 40mg, 80mg	Osimertinib Mesilate	Non-small cell lung cancer	Cobas EGFR mutation test v2.0	EGFR mutation
				Oncomine Dx Target Test	
				FoundationOne CDx	
				FoundationOne Liquid CDx	
				AmoyDx Pan Lung Cancer PCR Panel	
				Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System	
				Genetic Analysis Program MINTS Analyzer MINTS Lung Cancer Multi-CDx Library Prep Kit	
20	TASFYGO Tablets 35 mg	Tasurgratinib Succinate	Biliary tract cancer	AmoyDx FGFR2 Gene Break-apart FISH Probe Kit	FGFR2 fusion
21	Tazverik tablets 200mg	Tazemetostat Hydrobromide	Follicular lymphoma	cobas EZH2 Mutation Test	EZH2 mutation
22	1) Tafinlar Capsules 50mg, 75mg 2) Mekinist Tablets 0.5mg, 2mg	1) Dabrafenib Mesilate 2) Trametinib Dimethyl Sulfoxide	Malignant melanoma	THxID BRAF kit	BRAF mutation
				FoundationOne CDx	
				MEBGEN BRAF Kit	
			Non-small cell lung cancer	Oncomine Dx Target Test	BRAF mutation
				AmoyDx Pan Lung Cancer PCR Panel	
				Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System	
				Genetic Analysis Program MINTS Analyzer MINTS Lung Cancer Multi-CDx Library Prep Kit	
Solid tumors (Excluding colorectal cancer and malignant melanoma)	MEBGEN BRAF 3 Kit				
Hairy cell leukemia	MEBGEN BRAF 3 Kit				
23	TABRECTA tablets 150mg, 200mg	Capmatinib Hydrochloride Hydrate	Non-small cell lung cancer	FoundationOne CDx	MET exon 14 skipping alteration
				FoundationOne Liquid CDx	
				Oncomine Dx Target Test	
				AmoyDx Pan Lung Cancer PCR Panel	
24	TARCEVA Tablets 25mg, 100mg, 150mg	Erlotinib Hydrochloride	Non-small cell lung cancer	Cobas EGFR mutation test v2.0	EGFR mutation
				Oncomine Dx Target Test	
				therascreen EGFR RGQ PCR kit	
				FoundationOne CDx	
				EGFR LIQUID	
				FoundationOne Liquid CDx	
				AmoyDx Pan Lung Cancer PCR Panel	
				Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System	
				Genetic Analysis Program MINTS Analyzer MINTS Lung Cancer Multi-CDx Library Prep Kit	
25	TIBSOVO Tablets 250mg	Ivosidenib	Acute myeloid leukemia	ipsogen IDH1 RGQ PCR Kit	IDH1 mutation
26	TECENTRIQ for Intravenous Infusion 840mg	Atezolizumab (genetical recombination)	Breast cancer	VENTANA OptiView PD-L1 (SP142)	PD-L1 protein
	TECENTRIQ for Intravenous Infusion 1200mg		Non-small cell lung cancer		
			Non-small cell lung cancer (adjuvant treatment)		
27	TEPMETKO Tablets 250mg	Tepotinib Hydrochloride Hydrate	Non-small cell lung cancer	AmoyDx Pan Lung Cancer PCR Panel	MET exon 14 skipping alteration
				Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System	
				Oncomine Dx Target Test	
28	TRUQAP Tablets 160mg,200mg	Capivasertib	Breast cancer	FoundationOne CDx	PIK3CA mutation、AKT1 mutation、PTEN mutation

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29	①PERJETA for Intravenous Infusion 420 mg/14 mL ②HERCEPTIN for Intravenous Infusion 60, 150	①Pertuzumab (genetical recombination) ②Trastuzumab (genetical recombination)	Colorectal cancer	PathVysion HER-2 DNA Probe Kit	HER2 gene amplification status
				Histra HER2 FISH Kit	
				VENTANA ultraView PATHWAY HER2 (4B5)	HER2 protein
				Guardant360 CDx	ERBB2 amplification
30	Haiyitan tablets 50mg	Gumarontinib Hydrate	Non-small cell lung cancer	AmoyDx Pan Lung Cancer PCR Panel	MET exon 14 skipping alteration
31	HERCEPTIN for Intravenous Infusion 60, 150	Trastuzumab (genetical recombination)	Breast cancer	FoundationOne CDx	ERBB2 amplification
			Salivary gland tumors	VENTANA DISH HER2 kit	HER2 gene amplification status
				VENTANA ultraView PATHWAY HER2 (4B5)	HER2 protein
32	BALVERSA Tablets 3mg, 4mg, 5mg	Erdafitinib	Urothelial Cancer	therascreen FGFR RGQ RT-PCR Kit	FGFR3 mutation, FGFR3 fusion
33	VIZIMPRO Tablets 15mg, 45mg	Dacomitinib Hydrate	Non-small cell lung cancer	Cobas EGFR mutation test v2.0	EGFR mutation
				therascreen EGFR RGQ PCR kit	
				FoundationOne CDx	
				Oncomine Dx Target Test	
				Genetic Analysis Program MINTS Analyzer MINTS Lung Cancer Multi-CDx Library Prep Kit	
34	BRAFTOVI Capsules 50mg, 75mg	Encorafenib	Colorectal cancer	MEBGEN RASKET-B Kit	BRAF mutation
				therascreen BRAF V600E RGQ PCR Kit	
				Idylla RAS-BRAF Mutation Test (NichireiBio)	
				Guardant360 CDx	
35	1) BRAFTOVI Capsules 50mg, 75mg 2) MEKTOVI Tablets 15mg	1) Encorafenib 2) Binimetinib	Malignant melanoma	THxID BRAF kit	BRAF mutation
				FoundationOne CDx	
				MEBGEN BRAF Kit	
			Colorectal cancer	MEBGEN RASKET-B Kit	
				therascreen BRAF V600E RGQ PCR Kit	
				Idylla RAS-BRAF Mutation Test (NichireiBio)	
				Guardant360 CDx	
			Thyroid cancer	Oncomine Dx Target Test	
				MEBGEN BRAF 2 Kit	
36	VYLOY for Intravenous Infuion 100mg	Zolbetuximab (genetical recombination)	Stomach cancer	VENTANA CLDN18 (43-14A) RxDx Assay W	CLDN18 protein
37	PHESGO Combination for Subcutaneous Injection MA PHESGO Combination for Subcutaneous Injection IN	Pertuzumab (genetical recombination)/Trastuzumab (genetical recombination)/Vorhyaluronidase Alfa (genetical recombination)	Colorectal cancer	VENTANA ultraView PATHWAY HER2 (4B5)	HER2 protein
				Histra HER2 FISH Kit	HER2 gene amplification status
				PathVysion HER-2 DNA Probe Kit	
				Guardant360 CDx	ERBB2 amplification
38	Vectibix 100mg, 400mg	Panitumumab (genetical recombination)	Colorectal cancer	MEBGEN RASKET-B kit	KRAS/NRAS mutation
				FoundationOne CDx	
				OncoBEAM RAS CRC Kit	
				Idylla RAS-BRAF Mutation Test (NichireiBio)	
				Guardant360 CDx	
39	Pemazyre Tablets 4.5mg	Pemigatinib	Biliary tract cancer	FoundationOne CDx	FGFR2 fusion
40	POTELIGEO Injection 20mg	Mogamulizumab (genetical recombination)	Adult T-cell leukemia/lymphoma Peripheral T-cell lymphoma	POTELIGEO TEST FCM**	CCR4 protein
				POTELIGEO TEST IHC**	
41	RYBREVANT Intravenous Infusion 350 mg	Amivantamab (genetical recombination)	Non-small cell lung cancer	Oncomine Dx Target Test	EGFR exon 20 Insertion
				Guardant360 CDx	
42	①RYBREVANT Intravenous Infusion 350 mg ②LAZCLUZE Tablets 80 mg, 240 mg	①Amivantamab (genetical recombination) ②Lazertinib Mesilate Hydrate	Non-small cell lung cancer	Cobas EGFR mutation test v2.0	EGFR mutation
43	LYTGOBI tablets 4mg	Futibatinib	Biliary tract cancer	OncoGuide NCC Oncopanel System	FGFR2 fusion

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44	Lynparza Tablets 100mg, 150mg	Olaparib	Breast cancer	BRACAnalysis CDx	BRCA1 /2 mutation	
				myChoice CDx		
			Ovarian cancer	BRACAnalysis CDx		Homologous recombination deficiency
				FoundationOne CDx		
				myChoice CDx		
			Prostate cancer	FoundationOne CDx	BRCA1 /2 mutation	
				BRACAnalysis CDx		
				FoundationOne Liquid CDx		
			Pancreatic cancer	BRACAnalysis CDx		mismatch repair proficiency
			endometrial cancer	VENTANA OptiView PMS2 (A16-4)		
VENTANA OptiView MSH2 (G219-1129)						
VENTANA OptiView MSH6 (SP93)						
VENTANA OptiView MLH1 (M1)						
45	LUMAKRAS Tablets 120mg	Sotorasib	Non-small cell lung cancer	therascreen KRAS RGQ PCR Kit	KRAS G12C mutation	
				Guardant360 CDx		
				AmoyDx Pan Lung Cancer PCR Panel		
				Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System		
46	Retevmo Capsules 40mg, 80mg	Selpercatinib	Non-small cell lung cancer	Oncomine Dx Target Test	RET fusion	
				AmoyDx Pan Lung Cancer PCR Panel		
				Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System		
			Thyroid cancer	Oncomine Dx Target Test	RET mutation	
			Medullary thyroid cancer			
			Solid cancer		FoundationOne CDx	RET fusion
47	ROZLYTREK Capsules 100mg, 200mg	Entrectinib	Solid cancer	FoundationOne CDx	NTRK1 /2 /3 fusion	
				FoundationOne Liquid CDx		
			Non-small cell lung cancer	FoundationOne CDx	ROS1 fusion	
				Oncomine Dx Target Test		
				FoundationOne Liquid CDx		
				AmoyDx Pan Lung Cancer PCR Panel		
				OncoGuide AmoyDx ROS1 Gene Fusions Detection Kit		
48	LORBRENA Tablets 25mg, 100mg	Lorlatinib	Non-small cell lung cancer	Ventana OptiView ALK (D5F3)	ALK protein	
				Histofine ALK iAEP kit		
				Oncomine Dx Target Test	ALK fusion	
				Genetic Analysis Program MINTS Analyzer MINTS Lung Cancer Multi-CDx Library Prep Kit		
* For biosimilars, companion diagnostics approved for the original biopharmaceutical can be used to assist in identifying eligible patients. (Notification of the Pharmaceuticals and Drugs Agency, No. 0501-1, May 1, 2024; Pharmaceuticals and Medical Devices Agency, No. 0501-1).						
** CDx products that are submitted for approval application on or after July 1, 2014 based on the PFSB/ELD Notification No. 0701-10 issued on July 1, 2013.						
*** In vitro diagnostics or medical devices reviewed as companion diagnostics, which are submitted for approval application before July 1, 2014.						