

List 1 : Information on CDx Products approved in Japan for the purpose of identifying the eligible patients

List 1 : Information on CDx Products approved in Japan for the purpose of identifying the eligible patients					
	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	ELEVIDYS for Intravenous Infusion	Delandistrogene moxeparvovec	Duchenne muscular dystrophy	Elecsys Anti-AAVrh74	Anti-adeno-associated virus serotype rhesus 74 (AAVrh74) antibody
8	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	
9	Augtyro capsules 40mg	Repotrectinib	Non-small cell lung cancer	AmoyDx Pan Lung Cancer PCR Panel	ROS1 fusion
10	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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11	KEYTRUDA Injection 100mg	Pembrolizumab (genetical recombination)	Non-small cell lung cancer	PD-L1 IHC 22C3 pharmDx [Dako]	PD-L1 protein
			Esophageal cancer		
			Breast cancer		
			Gastric 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)	
12	XALKORI Capsules 200mg, 250mg	Crizotinib	Non-small cell lung cancer	Histofine ALK iAEP kit**	ALK protein
				Ventana OptiView ALK (D5F3)	ALK fusion
				FoundationOne CDx	
				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	ROS1 fusion
				MINTS Lung Cancer Multi-CDx Library Prep Kit	
				OncoGuide AmoyDx ROS1 Gene Fusions Detection Kit	
				Oncomine Dx Target Test	
13	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	

No.	Proprietary name	Active substance name	Indications	<i>In vitro</i> companion diagnostics or medical devices*	Biomarkers
14	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	
15	Zejula capsules 100mg Zejula tablets 100mg	Niraparib Tosilate Hydrate	Ovarian cancer	myChoice CDx	Homologous recombination deficiency
16	ZELBORAF Tablets 240mg	Vemurafenib	Malignant melanoma	Cobas BRAF V600 mutation test**	BRAF mutation
				FoundationOne CDx	
17	XOSPATA Tablets 40mg	Gilteritinib Fumarate	Acute myeloid leukemia	LeukoStrat CDx FLT3 Mutation Assay	FLT3 mutation
18	ZOLGENSMA for i.v. infusions	Onasemnogene abeparvovec	Spinal muscular atrophy	MEBCDX AAV9 TEST	Anti-adeno-associated virus type 9 (AAV9) antibody
19	TALZENNA capsules 0.1mg,0.25mg,1mg	Talazoparib Tosilate	Prostate cancer	FoundationOne CDx	BRCA1/2 mutation
			Breast cancer	BRACAnalysis CDx	
20	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	
21	TASFYGO Tablets 35 mg	Tasurgratinib Succinate	Biliary tract cancer	AmoyDx FGFR2 Gene Break-apart FISH Probe Kit	FGFR2 fusion
22	Tazverik tablets 200mg	Tazemetostat Hydrobromide	Follicular lymphoma	cobas EZH2 Mutation Test	EZH2 mutation
23	1) Tafinlar Capsules 50mg, 75mg Tafinlar Dispersible tablets for Pediatric 10mg 2) Mekinist Tablets 0.5mg, 2mg Mekinist Dry syrup for Pediatric 4.7mg	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	
24	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	
25	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	
26	TIBSOVO Tablets 250mg	Ivosidenib	Acute myeloid leukemia	ipsogen IDH1 RGQ PCR Kit	IDH1 mutation

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27	TECENTRIQ for Intravenous Infusion 840mg	Atezolizumab (genetical recombination)	Breast cancer	VENTANA OptiView PD-L1 (SP142)	PD-L1 protein	
	Non-small cell lung cancer					
	TECENTRIQ for Intravenous Infusion 1200mg		Non-small cell lung cancer (adjuvant treatment)	VENTANA OptiView PD-L1 (SP263)		
28	TEPMETKO Tablets 250mg	Tepotinib Hydrochloride Hydrate	Non-small cell lung cancer	AmoyDx Pan Lung Cancer PCR Panel	<i>MET</i> exon 14 skipping alteration	
				Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System		
				Oncomine Dx Target Test		
29	TRUQAP Tablets 160mg,200mg	Capivasertib	Breast cancer	FoundationOne CDx	<i>PIK3CA</i> mutation、 <i>AKT1</i> mutation、 <i>PTEN</i> mutation	
30	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	<i>HER2</i> gene amplification status	
				Histra HER2 FISH Kit		
				VENTANA ultraView PATHWAY HER2 (4B5)	HER2 protein	
				Guardant360 CDx	<i>ERBB2</i> amplification	
31	Haiyitan tablets 50mg	Gumarontinib Hydrate	Non-small cell lung cancer	AmoyDx Pan Lung Cancer PCR Panel	<i>MET</i> exon 14 skipping alteration	
32	HERCEPTIN for Intravenous Infusion 60, 150	Trastuzumab (genetical recombination)	Breast cancer	FoundationOne CDx	<i>ERBB2</i> amplification	
			Salivary gland tumors	VENTANA DISH HER2 kit	<i>HER2</i> gene amplification status	
				VENTANA ultraView PATHWAY HER2 (4B5)	HER2 protein	
33	BALVERSA Tablets 3mg, 4mg, 5mg	Erdafitinib	Urothelial Cancer	therascreen FGFR RGQ RT-PCR Kit	<i>FGFR3</i> mutation, <i>FGFR3</i> fusion	
34	VIZIMPRO Tablets 15mg, 45mg	Dacomitinib Hydrate	Non-small cell lung cancer	Cobas EGFR mutation test v2.0	<i>EGFR</i> 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		
35	BRAFTOVI Capsules 50mg, 75mg	Encorafenib	Colorectal cancer	MEBGEN RASKET-B Kit	<i>BRAF</i> mutation	
				therascreen BRAF V600E RGQ PCR Kit		
				Idylla RAS-BRAF Mutation Test (NichireiBio)		
				Guardant360 CDx		
36	1) BRAFTOVI Capsules 50mg, 75mg 2) MEKTOVI Tablets 15mg	1) Encorafenib 2) Binimetinib	Malignant melanoma	THxID BRAF kit	<i>BRAF</i> mutation	
				FoundationOne CDx		
				MEBGEN BRAF Kit		
			Colorectal cancer	MEBGEN RASKET-B Kit		<i>BRAF</i> mutation
				therascreen BRAF V600E RGQ PCR Kit		
				Idylla RAS-BRAF Mutation Test (NichireiBio)		
				Guardant360 CDx		
			Thyroid cancer	Oncomine Dx Target Test		<i>BRAF</i> mutation
				MEBGEN BRAF 2 Kit		
37	VYLOY for Intravenous Infuion 100mg	Zolbetuximab (genetical recombination)	Gastric cancer	VENTANA CLDN18 (43-14A) RxDx Assay W	CLDN18 protein	
38	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	<i>HER2</i> gene amplification status	
				PathVysion HER-2 DNA Probe Kit		
				Guardant360 CDx	<i>ERBB2</i> amplification	
39	Vectibix 100mg, 400mg	Panitumumab (genetical recombination)	Colorectal cancer	MEBGEN RASKET-B kit	<i>KRAS/NRAS</i> mutation	
				FoundationOne CDx		
				OncoBEAM RAS CRC Kit		
				Idylla RAS-BRAF Mutation Test (NichireiBio)		
				Guardant360 CDx		
40	Pemazyre Tablets 4.5mg	Pemigatinib	Biliary tract cancer	FoundationOne CDx	<i>FGFR2</i> fusion	

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41	POTELIGEO Injection 20mg	Mogamulizumab (genetical recombination)	Adult T-cell leukemia/lymphoma Peripheral T-cell lymphoma	POTELIGEO TEST FCM**	CCR4 protein	
				POTELIGEO TEST IHC**		
42	RYBREVANT Intravenous Infusion 350 mg	Amivantamab (genetical recombination)	Non-small cell lung cancer	Oncomine Dx Target Test	EGFR exon 20 Insertion	
				Guardant360 CDx		
43	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	
44	LYTGOBI tablets 4mg	Futibatinib	Biliary tract cancer	OncoGuide NCC Oncopanel System	FGFR2 fusion	
45	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)		
			46	LUMAKRAS Tablets 120mg	Sotorasib	Non-small cell lung cancer
Guardant360 CDx						
AmoyDx Pan Lung Cancer PCR Panel						
Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System						
47	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			
48	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		
49	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.						