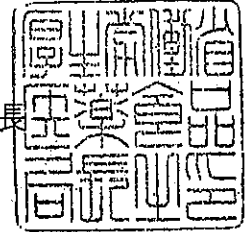


薬食発0329第10号

平成23年3月29日

各都道府県知事 殿

厚生労働省医薬食品局長



体外診断用医薬品の一般的名称の改正等について

体外診断用医薬品の取扱いについては、それぞれ一般的名称を定め、その一般的名称ごとにリスク分類を定めることとしており、体外診断用医薬品の一般的名称、定義、クラス分類、分類コード等は、平成17年4月1日付け薬食発第0401031号厚生労働省医薬食品局長通知「体外診断用医薬品の一般的名称について」（以下、「局長通知」という。）により示してきたところである。

今般、「薬事法第14条第1項の規定により厚生労働大臣が基準を定めて指定する体外診断用医薬品の一部を改正する件」（平成23年厚生労働省告示第82号。）及び「薬事法第23条の2第1項の規定により厚生労働大臣が基準を定めて指定する体外診断用医薬品の一部を改正する件」（平成23年厚生労働省告示第83号。）を平成23年3月29日に告示し、同日から適用されたこと、及び新たな体外診断用医薬品が承認されたことに伴い、局長通知の一部を下記のとおり改正したので、御了知の上、貴管下関係業者、団体等に対し周知徹底を図られたい。

なお、本通知の写しを各地方厚生局長、独立行政法人医薬品医療機器総合機構理事長、日本医療機器産業連合会会長、米国医療機器・IVD工業会会長、欧州ビジネス協会医療機器委員会委員長及び薬事法登録認証機関協議会代表幹事宛、送付することとしていることを申し添える。

記

1. 局長通知の別添一覧表について、

- (1) 体外診断用医薬品として、別添1に掲げるものを追加するとともに、

別添2に掲げるものを削除したこと。

(2) 一般的名称、定義等を別添3のとおり改めたこと。

また、参考までに改正後の別添一覧表の内容をCD-ROMに記録して添付する。

		Zn	30184002			
		Cl)	30188002			
			81005000			
		E IgE) E IgE)	81004000			
			81003000			
		AT	30583001			
		S S	30589001			S
		C C C	30588001			C
			83014000			
		ChE	38506001			
			83017000			
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		UA	30183021			
		UN	30158021			
		CRE	30161011			
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		UN	30158011			
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			83018000			

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		Mg	30190021			
		IP	30191021			
		Ca	30187011			
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		IP	30191011			
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			30394001			
		PSP)	83016000			
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			-	84051000	-	
				84045000		
				84041000		
		WT1) mRNA		84028000	()	WT1 mRNA) (MDS)
		SMRP)		84058000		SMRP SMRP

			30377010			
	p53		84039000			p53 p53
	19mRNA		84042000			19mRNA 19mRNA
			84034000			UBC)
			84033000			
			84054000			
			84030000			
	PCT)		84040000			
	DNA RNA		84055000			
	DNA RNA		84056000			
	E (HEV)		84057000			E E
	pdmRNA A RNA	A H1N1	84052000			
	RNA H5		84044000			H5 H5
			30802023			
			84029000			
			84032000			
			84031000			
	B DNA	HBV	84050000			B B
	B	HBV	84059000			
			84048000			

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		TPO	30317001			
		Ab Tg ATG	30490001			
		GM IgG	84037000			GM IgG
		GQ blgG	84038000			GQ blgG
		BP18QNC16a	84036000			BP18QNC16a
			84035000			
			84049000			
		TARC	84043000			TARC Th2
			84053000			KRAS KRAS
		CYP2D6, CYP2C19	84047000			P450 CYP450
		PRL PRL	30325001			
		ucOC	85003000			ucOC
		N NT-proBNP	85002000			N NT-proBNP
			80055002			
			80056003			

			43274000			
			80001001			

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		CK (CK-MM	38512012			(CK-MM
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			84001000			
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		IgE	30278000			
		CEA	30288000			CEA
		- AFP	30295000			- AFP
		-	43480000			-
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		CA125 CA125 CA125 CA125	30283000			CA-125 CA-
		602	43034000			602 602
		CA130	43150000			CA130 CA130
		CA15-3 CA15-3 CA15-3	30279000			CA15-3
		BCA225	43825000			BCA225 BCA225
		CA19-9 CA19-9 CA19-9 19-9	30280000			CA19-9
		CA50	30281000			50 CA50) 50 CA50)
		CA72-4 CA72-4	30282000			72-4 CA72-4 72-4
		Tn STN	43306000			Tn STN Tn
		KMD1	43309000			KMD1

		DUPAN-2	43308000			DUPAN-2 DUPAN-2
			43824000	Le i		SLX Le i SLX Le i
		NCC-ST-439	43307000			NCC-ST-439 NCC-ST-439
		SPan-1	43823000			SPan-1 SPan-1
		SCC	30291000			SCC SCC
		-Sm	43428000			-
		TPA TPA	30292000			TPA TPA
		(IAP	36010010			(IAP
		PAP	34226000			PAP PAP
		PA PSA	37286000			
			37287000			PA PSA
		1- PSA-ACT	43145000			PSA-ACT PSA-ACT 1- 1-
		NSE	30301000			NSE NSE
		GAT	43195000			GAT GAT
		SP1	44325000			SP1 SP1
		PIVKA-	44379003			PIVKA- PIVKA-
		19	30287000			19 19
		ProGRP(31-98)	44438000			ProGRP(31-98) ProGRP(31-98)
		CA54/61	43196000			54 61 CA54/61 54 61 CA54/61
			43237000			
		ErbB- c-erbB c-erb	43270000			ErbB- c-erbB c-erbB ErbB-
		Le CSLEX	42825000			Le CSLEX CSLEX Le

		NMP22	43197000			NMP22 NMP22
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		- -	42941000			- -
		NT N-	43299000			NT N- NT NT
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			44432000			
		DPD	30348000			
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		Lung cancer associated protein	44430000			
		K TK	44254013			
			84004000			c- erb
			84027000			c- erb
			30714000			D- 1
		D- 1				
		TBGL Glicopeptidolipid(GPL) core	30700000			TBGL GPL core
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		2 2	<u>30802013</u>			2
			<u>41759013</u>			
			<u>41759003</u>			
			<u>84026010</u>			
			<u>38877003</u>			

		19	<u>38877013</u>			19
		19	<u>38877023</u>			19
		TSH	30489000			
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		MRSA	<u>30656003</u>			MRSA MRSA
			<u>30656013</u>			
		(<u>44408013</u>			
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		A B	30710000			T A A
		CA125 CA19-9 1- - (AACT) (AFP) (ER) (CEA) (PSAP) (PSAP) (PAP) (NSE) HER2/ neu EGFR	30628023			
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			<u>80003002</u>			
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			80011001			
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			80013003			
			80014001			
			80015002			
			80016003			
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(2)	63	10	0	73
(3)	69	12	1	80
(1)	103	8	0	111
(2)	56	6	0	62
(3)	85	10	0	95
(4)	64	10	0	74
	63	3	0	66
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(OTC)	3	0	0	3
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			30228002			
		M IgM	30234002			
			30253002			
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C-			30336002			C-
			43378002			
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		FSH	30322002			
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			81003000		-	

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		PLT	41755000		
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	(32411000		(
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	(43095000		(
	(43321000		(
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			30541000		
			43421000		

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		FDP E	43361000			
		D FDP D FDP D-D	30576000			D
		FPA)	30563000			FPA)
		F1	30567000			F
		(AT	30583000			
		TAT	30568000			
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		- 2PI	30574000			
		- PIC,PPI,PAP	30566000			
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		(t-PA PAI-1	43073000			(t-PA PAI-1
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			30544000			
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			30549000			
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			30552000			
		a	30555000			a

		FSF	30554000		
		Xa	43046000		Xa
		Von Willebrand	30558000		Von Willebrand
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			44416000		
		PIVKA-	44379002		
		TG	30573000		
		PF4	30570000		
		C C	30588000		
			30589000		
		TM	44439000		
			44418000		
			44419000		
		AT	30583001	-	
		S S	30589001	-	S
		C C	30588001	-	C
		TDT	43412000		
		EPO	30376000		
			44254002		
			82001000		
			44250000		

			30559000			

			30181001			
			30155001			
	A/G		43394000			A/G
			43264000			
	(TTT)		43203000			
	(ZTT)		43204000			
	(CCLF)		43202000			
			43347000			
			83014000			
	CK		38503000			
	CK (CK-MB		<u>38512002</u>			CK (CK-MB
	CK (CK-MM		<u>38512012</u>			(CK-MM
	GOT AST		38499000			
	AST m-GOT		42901000			m-GOT
	GPT ALT		38556000			
	LDH)		38504000			
	LD		42907002			
	LD1		42907011	LD1		LD1
	ALP		33165001			
	ALP ALP		38511000			ALP
	- -GTP		38507001			-

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		MAO	42870000		
			38506000		
		ChE	38506001		
			44171000		
			43201000		
		LAP	38546000		
		CAP)	43475000		
			38502001		
		P-AMY	38541001		P-AMY
			83001000		
			38505000		
			30272000		
			43349000		
			38543000		
		PSTI	43350000		
) A PLA	43200000		A
		'-	38540000		'-
		(ACP	38498000		
		(ACP ACP	42864000		ACP
		GLDH)	38544000		

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		OCT)	44317000		
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		TG	30182000			
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		(Cr)	44558000			
		(Mb)	43263000			
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		(Se)	42876000			
		(Co)	42930000			
		(Mh)	43275000			

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			30392000			
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			44442000			

			43373000			
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		-3 MVP-3	44647000			
			44211000			
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		SP-	43194000			
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			44155000			
			84026000			
		1-AGP	36010001	-	-	1-
		-N- Intact PINP	84046000	-	-	-N- PINP
		-N- PINP	84051000	-	-	
			84045000			
		CEA	30288000			CEA
		AFP	30295000			AFP
			43480000			
		BFP	44440000			BFP
		CA125	30283000			CA-125 CA-

		602	43034000			602 602
		CA130	43150000			CA130 CA130
		CA15-3 CA15-3 CA15-3	30279000			CA15-3 CA15-3
		BCA225	43825000			BCA225 BCA225
		CA19-9 CA19-9 19-9 CA19-9	30280000			CA19-9 CA19-9
		CA50	30281000			50 CA50) 50 CA50)
		CA72-4 CA72-4	30282000			CA72-4 72-4 CA72-4 72-4
		Tn STN	43306000			STN Tn STN Tn
		KMD1	43309000			KMD1 KMD1
		DUPAN-2	43308000			DUPAN-2 DUPAN-2
			43824000	Le i		SLX SLX Le i Le i
		NCC-ST-439	43307000			NCC-ST-439 NCC-ST-439
		SPan-1	43823000			SPan-1 SPan-1
		SCC	30291000			SCC SCC
		- Sm	43428000			- -

		TPA	TPA	30292000		TPA	TPA
			(IAP	36010010		(IAP	(IAP
		PAP		34226000		PAP	PAP
		PA	PSA	37286000			
				37287000		PA	PSA
		PSA-ACT	1-	43145000		PSA-ACT	1- PSA-ACT 1-
			NSE	30301000		NSE	NSE
		GAT		43195000		GAT	GAT
			SP1	44325000		SP1	SP1
		PIVKA-		44379003		PIVKA-	PIVKA-
			19	30287000		19	19
		ProGRP(31-98)		44438000		ProGRP(31-98)	ProGRP(31-98)
		CA54/61		43196000		54 61 CA54/61	54 61 CA54/61
				43237000			
		ErbB- c-erbB	c-erb	43270000		c-erbB	ErbB- c-erbB ErbB-

		Le CSLEX	42825000			CSLEX Le CSLEX Le
		NMP22	43197000			NMP22 NMP22
		- -	42822000			- -
		- -	42941000			- -
		NT N-	43299000			NT N- NT N- NT
			44433000			
		BTA)	30510000	BTA		BTA) BTA)
		(ER	30293000			
			30294000			
			38217000			
			44432000			
		DPD	30348000			
		Major bcr- abl mRNA	44431000			Major bcr- abl mRNA Major bcr- abl mRNA Major bcr- abl CML
		Lung cancer associated protein	44430000			
		K TK	44254013			
			84004000			c-erb c-erb

			84027000			
			84041000		—	
		WT1) mRNA	84028000	()	—	WT1 mRNA) AML (MDS)
		SMRP)	84058000		—	SMRP SMRP
			30377010		—	
		p53	84039000		—	p53 p53
		19mRNA	84042000		—	19mRNA 19mRNA
			84034000		—	UBC)

			30676000		
			30677000		
			30678000		
			30680000		
			30679000		
			30681000		
		- ASO	37756000		-
		AS	30493000		
			44024000		
			30491000		
			30492000		
		-	44031000		
			30682000		
			30683000		
			42947000		
		Wdal	44028000		
			37723000		
			44021000		
			30689000		
			44204000		
			30691000		

			30716000		
			30687000		
			44429000		
			32450000		
			30697000		
		((30704000		
			30714000		D-1
		D-1			
		Weil Felix	30717000		Weil Felix
			43250000		
			44428000		
			37746000		
			37748000		
			37741000		
			30816000		
			30818000		
			30817000		
			30819000		
			30699000		
		Tuberculosis Bovis Africanum	Bovis Microti		

		TBGL Glycopeptidolipid(GPL) core	30700000					TBGL	GPL core
			84022000						
		0157	44023000			157		0157	O-
		H7	44030000					H7	O-157
			42846000						O-157
		0157	44025000			O-157		0157	
		- -D-	43226000					- -D-	
		B E k B C B C W135 A B	44198000						
			44029000						
		()	44203000						
			30713000						
		g	44202000						
)	30702000)
			44020000						
			44201000						
			84005000						
			30692000						

			84033000		-	
			84054000		-	
			84030000		-	
		PCT)	84040000		-	
		DNA RNA	84055000		-	
		DNA RNA	84056000		-	

			30720000			A
			30722000			
		HbC	30731000			B
			30733000			B
		HBe	30734000			B
		HBe	30737000			B
		HBe	36017000			B
		HBs	30723000			B
		HBs	30725000			B
		-	44200000	-		- B
		HBs	44199000	HBs		B HBs
			30730000			
			30742000			
			30740000			
			44292000			
			30743000			
			30744000			
			44324000			
			44426000			HCV

			44425000		
			30746000		
		HDV	30750000		D
		DNA	44017000		
		40/41	41274000		40/41
			30805000		
			30806000		
		CF	30804000		
			30802003		
		2 2	30802013		2
			41759013		
			41759003		
		G	44016000		G
			44027000		
			30797000		
			30799000		
			30800000		
			30801000		
EB EB		EBNA	30809000		
EB EB EB EB		EBNA	84006000	G	G

		EB EB	84007000			
		EB EB	EBNA			
		EB EB	33902000			
			37731000			
			37729000			
			37728000			
			44321000			
			30794000			
			30796000			
			30795000			
			30813000			
			43228000			
			32487000			
		RS RS RS	30814000		RS	RS
			84008000			
			44019000			
			84009000			
			84026010			
			37740000			

		HTLV-	30783000			
		HTLV-	30787000			
		HTLV-	30784000			
		HTLV-	30788000			
		HTLV-	84010000			
		HIV-1 HIV-1	30768000			
		HIV-1 24	30775000			
		HIV-1 24 HIV	84011000	HIV		24
		HIV-1	30765000			
		HIV-2	30773000			
		HIV-1	40436000			
		HIV-	84012000			
		HIV	84013000			
			43477000			
			43454000			
			37732000			
			44022000			
			30815000			
			44026000			
		SV5 SV5	43009000			SV5 SV5

		SV5	42994000			SV5	SV5
		SV41 SV41	43955000			SV41	SV41
			30811000				
			38877003				
		19	38877013				19
		19	38877023			19	
			43251000			B	
		RNA	84014000				
		E (HEV)	84057000			E	E
		A H1N1 pdmRNA A RNA	84052000				
		H5 RNA	84044000			H5	H5
			30802023				
			84029000				
			84032000				
			84031000				
		B HBV DNA	84050000			B	B
		B HBV	84059000				
			84048000				

		ANA	30454000		ANA
			37725000		
			37765000		
			84015000		
		ACA	44308000		
		DNA	37724000		
		DNA			
		DNA			
		ENA (RNP Sm ss-A ss-B scl- 70 Jo-1)	44300000		ENA
		Sm	84016000		Sm
		RNP	33916000		RNP
		SS-A	43427000		SS-A
		SS-B	42899000		SS-B
		Scl- 70	30463000	Scl- 70	Scl- 70
			30500000		
			44310000		
			44385000		
			30476000		
			43106000		
			30490000		

			30488000		
			30317000		
	TSH		30489000		
			84017000		
			43074000		
			30475000		
			43075000		
	(PLTab)		43105000		
	ANCA		30484000		
	(C-				
	-3 (C-				
	MPO-ANCA		30483000		
			30498000		
	-1		30461000	-1	-1
			30340000		
			30587000		
	GBM		43128000		GBM
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			84019000		

			84023000			
			84024000			
		TSH	30489001		-	
		TPO	30317001		-	
		Tg Ab ATG	30490001		-	
		GM IgG	84037000		-	GM IgG
		GO blgG	84038000		-	GO blgG
		BP180NC16a	84036000		-	BP180NC16a
			84035000		-	
			84049000		-	
		ABO	30597000			ABO
		(D) RHo D Rh-Hr	30598000			(D)
		A- B-	43108000			
			43111000			
			43113000			
		HLA-A B C HLA	30608000			HLA-A B C HLA
		HLA DNA HLA-DR	30612000		DR	HLA DNA HLA-

			84020000			
		B B (CD19, CD20, HLA-DR)	43047000			B
		B (Kappa, Lambda)	43129000			B
		T T (CD3, CD5, CD7)	43079000			T
		T (HLA-DR) E- T (CD2) (CD3 CD4 CD8) (CD4) T (CD11b, CD62L)	43098000			
		NK (CD56, CD57, CD16)	43062000			NK
		(CD14, CD15)	43055000			
		(CD45)	43052000			
		CD61	84025000			
		(BrdU)	43086000			
		Common Acute Lymphoblastic Leukaemia (CALLA) (CD10)	43092000		Lymphoblastic Leukaemia	Common Acute
		(CD1a)	43059000			
		LeY (LeY)	43096000			LeY
		(CD15)	43068000			
			43083000			
		-	30619000			-

			43072000			
			30371000			
		TARC	84043000		-	TARC Th2
			43419000			
			30373000			
			84053000		-	KRAS KRAS
		CYP2D6, CYP2C19	84047000		-	P450 CYP450

		HGH (GH	30358001			
		- C	30359000			
		IGFBP IGFBP	30361000			
		IGFBP- 3	30362000			
		PRL (PRL	30325000			
		ACTH (ACTH	30357000			
		LH LH	38246001			
		LH LH	30515003			
			43148003			
		FSH	30322001			
			44329000			
		PRL PRL	30325001		-	
		TSH	30318000			
		T	30312000			
		-T (FT	30308000			
		T3-uptake T3-uptake	30313000			

		T (T ₄)	30314000		
		FT FT	30309000		
		T	30315000		
		TBG TBG	30316000		
		TBC	43297000		
		PTH (PTH PTH-C (PTH-C (PTH-M PTH-M	30354000		
		(PTH-I PTH-I	30353000		
		PTH PTH	30355000		
			30342000		
			30338000		
		C-	3033600		C-
			30337000		
			42862000		
			44239000		
			42852000		

		17- 17-KS	30369000			17-
		17- 17-OHCS 17-OHCS	33238000			17-
			43259000			
		DHEA	30320000			
		DHEA-S	43159000			
		ALD	31428000			
			30319000			
			30440000			
			43149000			
		VMA	30453001			
			33293000			
		E (E	30329001			
		-16 - E -16	43443000			
		E	30321000			
		EI	30331000			
			30323000			

		17 17 -OHP	30324000			17
			30327001			
			30327002			
		H H	30332001			
		-HCG -HCG	30333001			
		HCG	43456000			
		HPL (HPL	30334000			
		Pd G	85001000			
		PRA	43444000			
		TRC I	31410000			I
		PRC	43439000			
			43457000			
		- AMP C-AMP	30347000			
		HANP (HANP	30260000			
		BNP	44443000			
			30352000			

		(CG	42868000			
		ucOC	85003000		—	ucOC
		N NT - proBNP	85002000		—	N NT - proBNP

		MRSA	44456000		
			33361000		
		MRSA	<u>30656003</u>		MRSA MRSA
			86001000		
			<u>30656013</u>		
			44172000		
			86002000		
			86003000		
		MRSA	44376000		MRSA MRSA
			43162000		
		(<u>44408013</u>		
			<u>44408003</u>		
			30654000		
		T A B	30710000		T A A

			86004000		
			30707000		
			37726000		
			37727000		
		O	30718000		O
			37752000		
		O	32508000		O
			43354000		
		O	30705000		O
			32506000		
			42957000		
			32504000		
			43353000		
		A	43175000		A A
			37758000		
			43193000		
			44450000		

		MRSA TSST-1 TSST-1	44449000			
			38852000			
			30631000			
			30658000			
			43242000			

		B (HBc) B (HBs) B (HBs) (HPV) HSV- HSV-1 HSV-II HSV-2	30628003		
			30628013		
		CA125 CA19-9 1- (AACT) - (AFP) (ER) (CEA) (PSAP) (PSAP) (PAP) (NSE) HER2/ HER2/neu EGFR	30628023		
		O(H)	30628033		
		B CDw75 B (LN1) CD74 B (LN2) E- T T T (T-cell UCHL-1) / T / T (LCA) DR(LN3)	30628042		
		(GH) (HGH) (FSH) Pro -MSH	30628052		
) (TSH)	30628062		
		VIP	30628072		
		- (-HCG) (HCG-) HCG (LH) (HPL)	30628082		

		P	30628092		
		-			
		1- (1- AT) (GFA) (GFAP) (GFAP) (GFAP)	30628102		
		S-100 S100 PP (EMA) (EMA)			
		A(IgA) G(IgG) M(IgM) Kappa L Lambda L	30628112		
		Ag) (R	30628122		
		()	30628132		

			30167012			
			30181012			
			33819002			

			80001001		
			80001002		
			80003003		
			80002001		
			80003002		
			80004003		
			80005001		
			80006002		
			80007003		
			80008001		
			80009002		
			80010003		
			80011001		
			80012002		
			80013003		
			80014001		

			<u>80015002</u>			
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			<u>80018002</u>			
			<u>80019003</u>			
			<u>80020002</u>			
			<u>80021003</u>			
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			<u>80026001</u>			
			<u>80027002</u>			
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			80031003			
			80032001			
			80033002			
			80034003			
			80035001			
			80036002			
			80037003			
			80038001			
			80039002			
			80040003			
			80041001			
			80042002			
			80043003			
			80044002			
			80045003			
			80046002			

			80047003			
			80048002			
			80049003			
			80050001			
			80051002			
			80052003			
			80053002			
			80054003			
			80055002		-	
			80056003		-	