

DAC-SpectroMed S.R.L. Chisinau	Declaration of EC-Conformity	File No.	F-PS-10-05
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Annex I

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Cat. No	Product	Method	Cornformity
2002A45	ACP-DAC	Kinetic	CE
2005A100	ALP-DAC	Kinetic	CE
2006A50	ALP-DEA-DAC	Kinetic	CE
2006A100	ALP-DEA-DAC	Kinetic	CE
2006A125	ALP-DEA-DAC	Kinetic	CE
2006A500	ALP-DEA-DAC	Kinetic	CE
2019A30	Amylo D-DAC.Lq	Kinetic	CE
2019A100	Amylo D-DAC.Lq	Kinetic	CE
2019A120	Amylo D-DAC.Lq	Kinetic	CE
2019A500	Amylo D-DAC.Lq	Kinetic	CE
2019A600	Amylo D-DAC.Lq	Kinetic	CE
2017A50	Amylo-DAC.Lq	Kinetic	CE
2017A125	Amylo-DAC.Lq	Kinetic	CE
2017A600	Amylo-DAC.Lq	Kinetic	CE
2015A200	Amylo-DAC	End point	CE
2021A75	Amylo Pancrea-DAC.Lq	Kinetic	CE
2010A60	ALT-UV-DAC.Lq	Kinetic UV	CE
2010A75	ALT-UV-DAC.Lq	Kinetic UV	CE
2010A150	ALT-UV-DAC.Lq	Kinetic UV	CE
2010A600	ALT-UV-DAC.Lq	Kinetic UV	CE
2010A1200	ALT-UV-DAC.Lq	Kinetic UV	CE
2008A200	ALT-DAC	End point	CE
2008A600	ALT-DAC	End point	CE
2008A1200	ALT-DAC	End point	CE
2025A60	AST-UV-DAC.Lq	Kinetic UV	CE
2025A75	AST-UV-DAC.Lq	Kinetic UV	CE
2025A150	AST-UV-DAC.Lq	Kinetic UV	CE
2025A600	AST-UV-DAC.Lq	Kinetic UV	CE
2025A1200	AST-UV-DAC.Lq	Kinetic UV	CE
2023A200	AST-DAC	End point	CE
2023A600	AST-DAC	End point	CE
2023A1200	AST-DAC	End point	CE
2030C60	Cholin - DAC	Kinetic	CE
2030C150	Cholin - DAC	Kinetic	CE
2035C60	CK - DAC	Kinetic	CE
2035C125	CK - DAC	Kinetic	CE
2035C150	CK - DAC	Kinetic	CE
2035C500	CK - DAC	Kinetic	CE
2037C30	CK-MB-DAC	Kinetic	CE
2037C120	CK-MB-DAC	Kinetic	CE
2060C2	CK-MB-Control serum	Kinetic	CE
2040G50	GGT - DAC.Lq	Kinetic UV	CE
2040G100	GGT - DAC.Lq	Kinetic UV	CE

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2040G125	GGT - DAC.Lq	Kinetic UV	CE
2040G200	GGT - DAC.Lq	Kinetic UV	CE
2040G450	GGT - DAC.Lq	Kinetic UV	CE
2040G500	GGT - DAC.Lq	Kinetic UV	CE
2044L50	LDH-DAC.Lq	Kinetic	CE
2044L200	LDH-DAC.Lq	Kinetic	CE
2046L75	Lipase-DAC.Lq	Kinetic	CE
3002A50	Albu-DAC.Lq	End point	CE
3002A90	Albu-DAC.Lq	End point	CE
3002A125	Albu-DAC.Lq	End point	CE
3002A250	Albu-DAC.Lq	End point	CE
3002A600	Albu-DAC.Lq	End point	CE
3002A1000	Albu-DAC.Lq	End point	CE
3004B100	Bili D-DAC.Lq	End point	CE
3004B500	Bili D-DAC.Lq	End point	CE
3006B100	Bili T-DAC.Lq	End point	CE
3006B500	Bili T-DAC.Lq	End point	CE
3005B200	Bili DT-DAC.Lq	End point	CE
3005B1000	Bili DT-DAC.Lq	End point	CE
3115B100	Bili D-DAC-CF	End point	CE
3115B500	Bili D-DAC-CF	End point	CE
3116B100	Bili T-DAC-CF	End point	CE
3115B500	Bili T-DAC-CF	End point	CE
3117B200	Bili DT-DAC-CF	End point	CE
3117B1000	Bili DT-DAC-CF	End point	CE
3008B500	Bili-DAC-CF	End point	CE
3104B120	Bili D-DAC-VND	End point	CE
3104B600	Bili D-DAC-VND	End point	CE
3106B120	Bili T-DAC-VND	End point	CE
3106B600	Bili T-DAC-VND	End point	CE
3108B240	Bili DT-DAC-VND	End point	CE
3108B1200	Bili DT-DAC-VND	End point	CE
3007B5	Bili St-DAC	End point	CE
3030C260	Crea – DAC	End point	CE
3035C100	Crea Kinetic - DAC.Lq	Kinetic (increasing)	CE
3035C200	Crea Kinetic - DAC.Lq	Kinetic (increasing)	CE
3035C250	Crea Kinetic - DAC.Lq	Kinetic (increasing)	CE
3035C500	Crea Kinetic - DAC.Lq	Kinetic (increasing)	CE
3035C1000	Crea Kinetic - DAC.Lq	Kinetic (increasing)	CE
3036C100	Creatinine Enzym-DAC.Lq	End point	CE
3037F100	Fructosamine – DAC	Kinetic	CE
3044G100	Gluko - DAC.Lq	End point	CE
3044G125	Gluko - DAC.Lq	End point	CE
3044G200	Gluko - DAC.Lq	End point	CE
3044G450	Gluko - DAC.Lq	End point	CE
3044G500	Gluko - DAC.Lq	End point	CE
3044G600	Gluko - DAC.Lq	End point	CE

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3044G1000	Gluco - DAC.Lq	End point	CE
3042G200	Gluco HK-DAC	End point	CE
1105G20	GlycoHb-DAC	End point	CE
1105G20x3	GlycoHb-DAC	End point	CE
1105G50	GlycoHb-DAC	End point	CE
1105G50x3	GlycoHb-DAC	End point	CE
1108GS1	GlycoHbStandard	End point	CE
1111GC2	GlycoHb Controls	End point	CE
3050H130	Helico-DAC	End point	CE
3046H1000	Hb Chr - DAC.Lq	End point	CE
3046H3000	Hb Chr - DAC.Lq	End point	CE
3070H70	Homocysteine-DAC.Lq	Kinetic	CE
3072P50	Prote - DAC.Lq	End point	CE
3072P90	Prote – DAC.Lq	End point	CE
3072P125	Prote – DAC.Lq	End point	CE
3072P250	Prote – DAC.Lq	End point	CE
3072P600	Prote – DAC.Lq	End point	CE
3072P1000	Prote - DAC.Lq	End point	CE
3076U50	Prot Ure - DAC.Lq	End point	CE
3076U90	Prot Ure - DAC.Lq	End point	CE
3076U250	Prot Ure - DAC.Lq	End point	CE
3081S200	Sulfo – DAC	End point	CE
3087T500	Thymol - DAC	End point	CE
3087T1500	Thymol - DAC	End point	CE
3087T1500St	Thymol - DAC	End point	CE
3088T15	Thymol-DAC-Standard	End point	CE
3088T125	Thymol-DAC-Standard	End point	CE
3094U60	Ure UV - DAC.Lq	Kinetic UV	CE
3094U100	Ure UV - DAC.Lq	Kinetic UV	CE
3094U500	Ure UV - DAC.Lq	Kinetic UV	CE
3094U1000	Ure UV - DAC.Lq	Kinetic UV	CE
3092U100	Ure - DAC.Lq	End point	CE
3092U180	Ure - DAC.Lq	End point	CE
3092U200	Ure - DAC.Lq	End point	CE
3092U500	Ure - DAC.Lq	End point	CE
3092U1000	Ure - DAC.Lq	End point	CE
3096U50	Uric Acid - DAC.Lq	End point	CE
3096U100	Uric Acid – DAC.Lq	End point	CE
3096U200	Uric Acid – DAC.Lq	End point	CE
3096U500	Uric Acid – DAC.Lq	End point	CE
3096U1000	Uric Acid – DAC.Lq	End point	CE
3017C5	Chol-DAC.Lq	End point	CE
3017C50	Chol-DAC.Lq	End point	CE
3017C90	Chol-DAC.Lq	End point	CE
3017C100	Chol-DAC.Lq	End point	CE
3017125	Chol-DAC.Lq	End point	CE
3017C200	Chol-DAC.Lq	End point	CE

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3017C250	Chol-DAC.Lq	End point	CE
3017C500	Chol-DAC.Lq	End point	CE
3017C600	Chol-DAC.Lq	End point	CE
3017C1000	Chol-DAC.Lq	End point	CE
3019C200	Chol HDL-DAC.Lq	End point	CE
3020C80	Chol HDL-Direct.Lq	End point	CE
3021C80	Chol LDL-Direct.Lq	End point	CE
3062P50	PhosphoLipid-DAC	End point	CE
3085T50	TG-DAC.Lq	End point	CE
3085T90	TG-DAC.Lq	End point	CE
3085T125	TG-DAC.Lq	End point	CE
3085T250	TG-DAC.Lq	End point	CE
3085T600	TG-DAC.Lq	End point	CE
3085T1000	TG-DAC.Lq	End point	CE
3086T100	Total Lipids-DAC.Lq	End point	CE
3010C100	Calcium Ars-DAC.Lq	End point	CE
3010C125	Calcium Ars-DAC.Lq	End point	CE
3010C200	Calcium Ars-DAC.Lq	End point	CE
3010C450	Calcium Ars-DAC.Lq	End point	CE
3010C500	Calcium Ars-DAC.Lq	End point	CE
3012C100	Calcium Cr-DAC.Lq	End point	CE
3012C250	Calcium Cr-DAC.Lq	End point	CE
3012C200	Calcium Cr-DAC.Lq	End point	CE
3012C500	Calcium Cr-DAC.Lq	End point	CE
3014C30	Calcium Free-DAC.Lq	End point	CE
3016C100	Chlor-DAC.Lq	End point	CE
3016C125	Chlor-DAC.Lq	End point	CE
3028C50	Copper-DAC.Lq	End point	CE
3056I100	Iron Ferr-DAC.Lq	End point	CE
3055I100	Iron Ferene-DAC.Lq	End point	CE
3052I100	Iron Ch-DAC.Lq	End point	CE
3052I250	Iron Ch-DAC.Lq	End point	CE
3054I20	Iodine - DAC	End point	CE
3054I50	Iodine - DAC	End point	CE
3083T120	TIBC-DAC	End point	CE
3058L60	Lithium Enzym-DAC.Lq	Kinetic	CE
3060M100	Magne-DAC.Lq	End point	CE
3064P100	Phosph-DAC.Lq	End point	CE
3064P200	Phosph-DAC.Lq	End point	CE
3066P50	Potassium-DAC.Lq	End point	CE
3066P250	Potassium-DAC.Lq	End point	CE
3067P50	Potassium Enzym-DAC.Lq	Kinetic	CE
3078S50	Sodium-DAC.Lq	End point	CE
3078S250	Sodium-DAC.Lq	End point	CE
3079S80	Sodium Enzym-DAC	Kinetic	CE
3102Z50	Zinc-DAC.Lq	End point	CE
3033F100	Fructose Sp – DAC.Lq	End point	CE

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3026C100	Citric Acid Sp-DAC	End point	CE
3101Z50	Zinc Sp-DAC.Lq	End point	CE
3121A75	Alcohol-DAC	End point	CE
3121A150	Alcohol-DAC	End point	CE
3013C20	Control Ca Free-DAC.Lq	End point	CE
2053M3	Multi H St-DAC	Kinetic + end point	CE
2053M18	Multi H St-DAC	Kinetic + end point	CE
2053M60	Multi H St-DAC	Kinetic + end point	CE
2062S5	Sera hN-DAC	Kinetic + end point	CE
2062S30	Sera hN-DAC	Kinetic + end point	CE
2062S100	Sera hN-DAC	Kinetic + end point	CE
2064S5	Sera hP-DAC	Kinetic + end point	CE
2064S30	Sera hP-DAC	Kinetic + end point	CE
2064S100	Sera hP-DAC	Kinetic + end point	CE
4005A25	APTT-DAC-EA	Coagulation time	CE
4005A50	APTT-DAC-EA	Coagulation time	CE
4005A100	APTT-DAC-EA	Coagulation time	CE
4005A160	APTT-DAC-EA	Coagulation time	CE
4005A200	APTT-DAC-EA	Coagulation time	CE
4008H350	Haemostaz-DAC-I	Coagulation time	CE
4010H50	Haemostaz-DAC-II	Coagulation time	CE
4010H100	Haemostaz-DAC-II	Coagulation time	CE
4013P25	Prothrombin-DAC.Lq ISI	Coagulation time	CE
4013P50	Prothrombin-DAC.Lq ISI	Coagulation time	CE
4013P100	Prothrombin-DAC.Lq ISI	Coagulation time	CE
4013P200	Prothrombin-DAC.Lq ISI	Coagulation time	CE
4012P100	Prothrombin-DAC-ISI	Coagulation time	CE
4012P240	Prothrombin-DAC-ISI	Coagulation time	CE
4012P300	Prothrombin-DAC-ISI	Coagulation time	CE
4011P80	Prothrombin-DAC-mono ISI	Coagulation time	CE
4011P200	Prothrombin-DAC-mono ISI	Coagulation time	CE
4011P4x10	Prothrombin-DAC-mono ISI	Coagulation time	CE
4011P500	Prothrombin-DAC-mono ISI	Coagulation time	CE
4015T120	Thrombin-DAC-mono	Coagulation time	CE
4015T300	Thrombin-DAC-mono	Coagulation time	CE
4020F60	Fibrinogen-DAC	Coagulation time	CE
4020F120	Fibrinogen-DAC	Coagulation time	CE
4020F160	Fibrinogen-DAC	Coagulation time	CE
4020F400	Fibrinogen-DAC	Coagulation time	CE
4022I60	Imidasol-DAC	Coagulation time	CE
4024C64	Calcium Choride-DAC	Coagulation time	CE
4006C2	Coagulo-cont N	Coagulation time	CE
4006C3	Coagulo-cont N	Coagulation time	CE

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4006C10	Coagulo-cont N	Coagulation time	CE
4007C2	Coagulo-cont P	Coagulation time	CE
4007C3	Coagulo-cont P	Coagulation time	CE
4007C10	Coagulo-cont P	Coagulation time	CE
4030C2	Coagulo-cont P+	Coagulation time	CE
4032C2	Control Plasma L1	Coagulation time	CE
4033C2	Control Plasma L2	Coagulation time	CE
4034C2	Control Plasma L2+	Coagulation time	CE
4032C4	Control Plasma L1+L2	Coagulation time	CE
4018C1	Coagulo-St-DAC	Coagulation time	CE
4018C10	Coagulo-St-DAC	Coagulation time	CE
1178A50	α_1 -Antitrypsin-DAC	Turbidimetry	CE
1203G50	α_1 -Glycoprotein Acid-DAC	Turbidimetry	CE
1162C50	Ceruloplasmin - DAC	Turbidimetry	CE
1166C50	Complement C3 - DAC	Turbidimetry	CE
1168C50	Complement C4 - DAC	Turbidimetry	CE
1191H50	Haptoglobin-DAC	Turbidimetry	CE
1156IA50	IgA Turbi – DAC	Turbidimetry	CE
1158IG50	IgG Turbi – DAC	Turbidimetry	CE
1160IM50	IgM Turbi – DAC	Turbidimetry	CE
1164T50	Transferrin - DAC	Turbidimetry	CE
1170P2	Protein St - DAC	Turbidimetry	CE
1172P1	Protein Sera - DAC	Turbidimetry	CE
1172P4	Protein Sera - DAC	Turbidimetry	CE
1174A50	Apolipoprotein A1-DAC	Turbidimetry	CE
1176A50	Apolipoprotein B-DAC	Turbidimetry	CE
1195C1	Calibrator Apo A1/B-DAC	Turbidimetry	CE
1197C1	Control Apo A1/B-DAC	Turbidimetry	CE
1135A50	ASLO-Turbilatex	Turbidimetry	CE
1129R50	RF-Turbilatex	Turbidimetry	CE
1150C50	CRP-Turbilatex	Turbidimetry	CE
1151C1	Control ASLO/CRP/RF-DAC Level L	Turbidimetry	CE
1152C1	Control ASLO/CRP/RF-DAC Level H	Turbidimetry	CE
1201CU50	CRP-ultra Turbilatex	Turbidimetry	CE
1141M50	β_2 -Microglobulin-DAC	Turbidimetry	CE
1140C2	Control β_2 -Microglobulin-DAC	Turbidimetry	CE
1144F50	Ferritin-DAC	Turbidimetry	CE
1148C2	Control Ferritin-DAC	Turbidimetry	CE
1161IE30	IgE Turbi - DAC	Turbidimetry	CE
1102H75	HbA _{1c} -Turbi-DAC	Turbidimetry	CE
1102H180	HbA _{1c} -Turbi-DAC	Turbidimetry	CE
1103H2	HbA1c Calibrator (4 levels)	Turbidimetry	CE
1104H4	HbA1c Control (2 levels)	Turbidimetry	CE
1033C50	CRP-Latex	Slide agglunation	CE

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1033C100	CRP-Latex	Slide agglunation	CE
1033C200	CRP-Latex	Slide agglunation	CE
1033C250	CRP-Latex	Slide agglunation	CE
1033C500	CRP-Latex	Slide agglunation	CE
1031A100	ASLO-DAC	Slide agglunation	CE
1031A200	ASLO-DAC	Slide agglunation	CE
1031A250	ASLO-DAC	Slide agglunation	CE
1031A500	ASLO-DAC	Slide agglunation	CE
1039R100	RefaTex-DAC	Slide agglunation	CE
1039R200	RefaTex-DAC	Slide agglunation	CE
1039R250	RefaTex-DAC	Slide agglunation	CE
1039R500	RefaTex-DAC	Slide agglunation	CE
1041R100	ReumoScreen-DAC	Slide agglunation	CE
1041R250	ReumoScreen-DAC	Slide agglunation	CE
1041R500	ReumoScreen-DAC	Slide agglunation	CE
1045W100	Waalder-Rose-DAC	Slide agglunation	CE
1045W250	Waalder-Rose-DAC	Slide agglunation	CE
1045W500	Waalder-Rose-DAC	Slide agglunation	CE
1035I100	IM-DAC	Slide agglunation	CE
1035I250	IM-DAC	Slide agglunation	CE
1035I500	IM-DAC	Slide agglunation	CE
1040R100	RPR-Carbon-DAC	Slide agglunation	CE
1040R250	RPR-Carbon-DAC	Slide agglunation	CE
1040R200D	RPR-Carbon-DAC	Slide agglunation	CE
1040R250D	RPR-Carbon-DAC	Slide agglunation	CE
1040R500	RPR-Carbon-DAC	Slide agglunation	CE
1040R500D	RPR-Carbon-DAC	Slide agglunation	CE
1040R1000	RPR-Carbon-DAC	Slide agglunation	CE
1043S100	SLE-DAC	Slide agglunation	CE
1043S250	SLE-DAC	Slide agglunation	CE
1043S500	SLE-DAC	Slide agglunation	CE
1044T100	TPHA-DAC	Microplate agglutination	CE
1044T200	TPHA-DAC	Microplate agglutination	CE
1047C100	Candida-Latex	Slide agglunation	CE
1049T100	Trihomono-Latex	Slide agglunation	CE
1051D50	D-dimer-DAC	Slide agglunation	CE
1054A50	AntiSperm-Latex	Slide agglunation	CE
1053A50	AntiOvary-Latex	Slide agglunation	CE
1052A50	Anti-Zona Pellucida-Latex	Slide agglunation	CE
1032C218	CIC-DAC	End point	CE
1032C435	CIC-DAC	End point	CE
1036N305	NBT-DAC	End point	CE
4051G100	DAC-1G	Paper-thin layer chromatography	CE
4055K50	DAC-1K	Paper-thin layer	CE

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4055K100	DAC-1K	Paper-thin layer chromatography	CE
4057B100	DAC-1B	Paper-thin layer chromatography	CE
4059P100	DAC-1P	Paper-thin layer chromatography	CE
4070CM50	DAC-2CM	Paper-thin layer chromatography	CE
4070CM100	DAC-2CM	Paper-thin layer chromatography	CE
4066GK100	DAC-2GK	Paper-thin layer chromatography	CE
4068GP100	DAC-2GP	Paper-thin layer chromatography	CE
4076D100	DAC-3	Paper-thin layer chromatography	CE
4083B100	DAC-4B	Paper-thin layer chromatography	CE
4087S100	DAC-4S	Paper-thin layer chromatography	CE
4091D100	DAC-5	Paper-thin layer chromatography	CE
4094D100	DAC-6	Paper-thin layer chromatography	CE
4101D100	DAC-7	Paper-thin layer chromatography	CE
4103N100	DAC-8	Paper-thin layer chromatography	CE
4113D100	DAC-9	Paper-thin layer chromatography	CE
4117D100	DAC-10	Paper-thin layer chromatography	CE
4121D100	DAC-11	Paper-thin layer chromatography	CE
4124D50	DAC-12	Paper-thin layer chromatography	CE
4124D100	DAC-12	Paper-thin layer chromatography	CE
4125D100	DAC-13	Paper-thin layer chromatography	CE
4062UC16	UreControl-DAC	Paper-thin layer chromatography	CE

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Cat. No	Product	Method	Cornformity
4282IAB1	Influenza A/B 2-Panel-DAC	chromatographic immunoassay	CE
4215HP1	HP-Cart-DAC	chromatographic immunoassay	CE
4250HP1	HP-F-Cart-DAC	chromatographic immunoassay	CE
4217M1	Malaria P.f/P.v Ab-Cart-DAC	chromatographic immunoassay	CE
4218M1	Malaria P.f Ag-Cart-DAC	chromatographic immunoassay	CE
4279AR1	Adeno/Rota-Cart-DAC	chromatographic immunoassay	CE
4281M1	Mononucleosis-Cart-DAC	chromatographic immunoassay	CE
4151HCG-2,5	HCG-U-Strip-DAC-2,5	chromatographic immunoassay	CE
4151HCG-3,5	HCG-U-Strip-DAC-3,5	chromatographic immunoassay	CE
4152HCG1	HCG-U-Cart-DAC	chromatographic immunoassay	CE
4204CEA1	CEA-S-Strip-DAC	chromatographic immunoassay	CE
4198AFP1	AFP-S-Strip-DAC	chromatographic immunoassay	CE
4199AFP1	AFP-S-Cart-DAC	chromatographic immunoassay	CE
4201FOB1	FOB-F-Strip-DAC	chromatographic immunoassay	CE
4202FOB1	FOB-F-Cart-DAC	chromatographic immunoassay	CE
4261OPI1	OPI-Strip-DAC	chromatographic immunoassay	CE
42620PI1	OPI-Cart-DAC	chromatographic immunoassay	CE
4241THC1	THC-Strip-DAC	chromatographic immunoassay	CE
4242THC1	THC-Cart-DAC	chromatographic immunoassay	CE
4251D6	6-Drugs-DAC	chromatographic immunoassay	CE
4257D10	10-Drugs-DAC	chromatographic immunoassay	CE
4270CRP1	CRP-Cart-DAC	chromatographic immunoassay	CE

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4283AU1	Albumin Urine-Cart-DAC	chromatographic immunoassay	CE
4285DD1	D-Dimer-Cart-DAC	chromatographic immunoassay	CE
4294P1	Procalcitonin-Cart-DAC	chromatographic immunoassay	CE
4295IG1	IGFBP-1-Cart-DAC	chromatographic immunoassay	CE
4214SA1	Streptococ A-Cart-DAC	chromatographic immunoassay	CE
4276SB1	Streptococ B-Cart-DAC	chromatographic immunoassay	CE