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|---|-------------------------------------|-----------|------------|
| DAC-SpectroMed S.R.L. Chisinau | Declaration of EC-Conformity | File No. | F-PS-10-05 |
| | | Rev. No. | 1 |
| | | Rev. Date | 07-16-2019 |
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DAC-SpectroMed SRL
Nicolae Testemitanu str. 37
MD-2025, Chisinau
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hereby declares under its own responsibility that the *in-vitro diagnostics* medical devices **listed in Annex I-II**

- are in accordance with the Annex I of the EC Council Directive 98/79/EC from 27th October 1998 on in-vitro diagnostic medical devices;
- are in accordance with the Annex II of the EC Council Directive 98/79/EC from 27th October 1998 on in-vitro diagnostic medical devices;
- conform to the relevant provisions of the EC Council Directive 98/79/EC from 27th October 1998 on in-vitro diagnostic medical devices.


Harmonized standards applied:

EN ISO 9001:2015
 EN ISO 14971:2012
 EN ISO 18113-1:2011
 EN ISO 18113-2:2011
 EN ISO 23640:2011
 EN ISO 13612:2002
 EN ISO 15223-1:2012
 EN ISO 13485:2016

DAC-SpectroMed SRL has a Quality System in place based on EN ISO 9001:2015 and EN ISO 13485:2016, issued by the IQNet&SRAC.

Our Authorized Representative in EU is Qarad B.V., with address at Flight Forum 40, 5657 DB Eindhoven, The Netherlands




 General Manager
 Virschi Roman
 16.07.2019

Head of Normative-Technical Documentation
 and Certification Department

 Emet Natalia
 16.07.2019

Annex I

Declaration of Conformity according to European Directive of in vitro diagnostic medical devices (98/79/EG) of the Medical Devices Act (MPG)

| 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 |
| 2019A30 | Amylo D-DAC.Lq | Kinetic | CE |
| 2019A120 | Amylo D-DAC.Lq | Kinetic | CE |
| 2019A600 | Amylo D-DAC.Lq | Kinetic | CE |
| 2017A30 | Amylo-DAC.Lq | Kinetic | CE |
| 2017A120 | 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 |
| 2010A150 | ALT-UV-DAC.Lq | Kinetic UV | CE |
| 2010A600 | ALT-UV-DAC.Lq | Kinetic UV | CE |
| 2008A1200 | ALT-DAC | End point | CE |
| 2025A60 | AST-UV-DAC.Lq | Kinetic UV | CE |
| 2025A150 | AST-UV-DAC.Lq | Kinetic UV | CE |
| 2025A600 | AST-UV-DAC.Lq | Kinetic UV | CE |
| 2023A1200 | AST-DAC | End point | CE |
| 2030C60 | Cholin - DAC | Kinetic | CE |
| 2030C150 | Cholin - DAC | Kinetic | CE |
| 2035C60 | CK - DAC | Kinetic | CE |
| 2035C150 | CK - DAC | Kinetic | CE |
| 2037C30 | CK-MB-DAC | Kinetic | CE |
| 2037C120 | CK-MB-DAC | Kinetic | CE |
| 2040G50 | GGT - DAC.Lq | Kinetic UV | CE |
| 2040G200 | GGT - DAC.Lq | Kinetic UV | CE |
| 2044L50 | LDH-DAC.Lq | Kinetic | CE |
| 2044L200 | LDH-DAC.Lq | Kinetic | CE |
| 2046L75 | Lipase-DAC.Lq | Kinetic | CE |
| 3002A55 | Albu-DAC.Lq | End point | CE |
| 3002A50 | Albu-DAC.Lq | End point | CE |
| 3002A250 | Albu-DAC.Lq | End point | CE |
| 3002A1000 | Albu-DAC.Lq | End point | CE |
| 3002A5 | Albu-DAC.Lq Albumin Standard | 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 |
| 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 |
| 3030C260 | Crea – DAC | End point | CE |
| 3035C5 | Crea Kinetic - DAC.Lq | Kinetic (increasing) | CE |
| 3035C50 | Crea Kinetic - DAC.Lq | Kinetic (increasing) | CE |
| 3035C100 | 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 |
| 3044G200 | Gluco - DAC.Lq | End point | CE |
| 3044G250 | Gluco - DAC.Lq | End point | CE |
| 3044G500 | Gluco - DAC.Lq | End point | CE |
| 3044G1000 | Gluco - DAC.Lq | End point | CE |
| 3042G60 | Gluco HK-DAC | End point | CE |
| 3042G200 | Gluco HK-DAC | End point | CE |
| 1105G20 | GlycoHb-DAC | End point | CE |
| 1105G50 | GlycoHb-DAC | End point | CE |
| 3050H130 | Helico-DAC | End point | CE |
| 3048H2000 | Hemo - DAC.Lq | End point | CE |
| 3048H3000 | Hemo - 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 |

| Cat. No | Product | Method | Cornformity |
|-----------|--------------------------------------|------------|-------------|
| 3072P250 | Prote - DAC.Lq | End point | CE |
| 3072P1000 | Prote - DAC.Lq | End point | CE |
| 3073P5 | Prote - DAC.Lq Protein Standard | End point | CE |
| 3076U50 | Prot Ure - DAC.Lq | End point | CE |
| 3076U250 | Prot Ure - DAC.Lq | End point | CE |
| 3075U5 | Prot Ure - DAC.Lq Prote Ure Standard | End point | CE |
| 3081S200 | Sulfo – DAC | End point | CE |
| 3084S10 | Sulfo – DAC Standard | End point | CE |
| 3087T500 | Thymol - DAC | End point | CE |
| 3087T1500 | Thymol - DAC | End point | CE |
| 3094U40 | 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 |
| 3092U5 | 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 |
| 3096U5 | Uric Acid - DAC.Lq | End point | CE |
| 3096U50 | Uric Acid - DAC.Lq | End point | CE |
| 3096U200 | Uric Acid - DAC.Lq | End point | CE |
| 3096U500 | Uric Acid - DAC.Lq | End point | CE |
| 3017C5 | Chol-DAC.Lq | End point | CE |
| 3017C50 | Chol-DAC.Lq | End point | CE |
| 3017C200 | Chol-DAC.Lq | End point | CE |
| 3017C250 | Chol-DAC.Lq | End point | CE |
| 3017C500 | Chol-DAC.Lq | End point | CE |
| 3017C1000 | Chol-DAC.Lq | End point | CE |
| 3017C5 | Chol-DAC.Lq Cholesterol Standard | End point | CE |
| 3019C200 | Chol HDL-DAC.Lq | End point | CE |
| 3023C5 | Chol HDL-PR | 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 |
| 3085T250 | TG-DAC.Lq | End point | CE |
| 3085T1000 | TG-DAC.Lq | End point | CE |
| 3086T100 | Total Lipids-DAC.Lq | End point | CE |
| 3010C50 | Calcium Ars-DAC.Lq | End point | CE |
| 3010C200 | Calcium Ars-DAC.Lq | End point | CE |
| 3010C500 | Calcium Ars-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 |
| 3016C5 | Chlor-DAC.Lq | End point | CE |
| 3016C100 | 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 |
| 3052I5 | Iron Ch-DAC.Lq | End point | CE |
| 3052I100 | 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 |
| 3064P50 | Phosph-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 |
| 3026C100 | Citric Acid Sp-DAC | End point | CE |
| 3101Z50 | Zinc Sp-DAC.Lq | End point | CE |
| 3007B5 | Bili St-DAC | End point | CE |
| 2060C2 | CK-MB-Control serum | Kinetic | CE |
| 3038G05 | Gluco-cont | End point | CE |
| 1108GS1 | GlycoHbStandard | End point | CE |
| 1111GC2 | GlycoHb Controls | End point | CE |
| 3088T125 | Thymol-DAC-Standard | End point | CE |

| Cat. No | Product | Method | Cornformity |
|-----------|--------------------------------------|---------------------|-------------|
| 2053M3 | Multi H St-DAC | Kinetic + end point | CE |
| 2053M18 | Multi H St-DAC | Kinetic + end point | CE |
| 2051M5 | Multi B St-DAC | Kinetic + end point | CE |
| 2051M30 | Multi B St-DAC | Kinetic + end point | CE |
| 2055S5 | Sera N-DAC | Kinetic + end point | CE |
| 2055S30 | Sera N-DAC | Kinetic + end point | CE |
| 2057S5 | Sera P-DAC | Kinetic + end point | CE |
| 2057S30 | Sera P-DAC | Kinetic + end point | CE |
| 2062S5 | Sera hN-DAC | Kinetic + end point | CE |
| 2062S30 | Sera hN-DAC | Kinetic + end point | CE |
| 2064S5 | Sera hP-DAC | Kinetic + end point | CE |
| 2064S30 | Sera hP-DAC | Kinetic + end point | CE |
| 4004A120 | APTT-DAC | Coagulation time | CE |
| 4005A160 | APTT-DAC-EA | Coagulation time | CE |
| 4005A400 | APTT-DAC-EA | Coagulation time | CE |
| 4008H350 | Haemostaz-DAC-I | Coagulation time | CE |
| 4010H100 | Haemostaz-DAC-II | 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 |
| 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 |
| 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 |
| 4007C2 | 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 |
| 4018C1 | Coagulo-St-DAC | Coagulation time | CE |
| 1178A50 | α_1 -ANTITRYPSIN-DAC | Turbidimetry | CE |
| 1203G50 | α_1 -GLYCOPROTEIN ACID-DAC | Turbidimetry | CE |
| 1127A50 | ANTITHROMBIN III-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 |
| 1122PA50 | Pre-Albumin-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 |
| 1202C2 | Control CRP-ultra TURBILATEX | Turbidimetry | CE |
| 1187L24 | LP (A)-DAC | Turbidimetry | CE |
| 1189C1 | Calibrator LP (A)-DAC | Turbidimetry | CE |
| 1188C1 | Control LP (A)-DAC | 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 |
| 1163C1 | Calibrator IgE-DAC | Turbidimetry | CE |
| 1165C2 | Control IgE-DAC | Turbidimetry | CE |
| 1181M32 | Myoglobin-DAC | Turbidimetry | CE |
| 1183C1 | Calibrator Myoglobin-DAC | Turbidimetry | CE |
| 1185C2 | Control Myoglobin-DAC | Turbidimetry | CE |

| Cat. No | Product | Method | Cornformity |
|-----------|---|---------------------------------|-------------|
| 1136M50 | Microalbumin-DAC | Turbidimetry | CE |
| 1140C2 | Control Microalbumin-DAC | Turbidimetry | CE |
| 1199A30 | AFP-DAC | Turbidimetry | CE |
| 1200C2 | Control AFP-DAC | Turbidimetry | CE |
| 1193C24 | Cystatin C-DAC | Turbidimetry | CE |
| 1192C10 | Calibrator Cystatin C-DAC (5 Levels) | Turbidimetry | CE |
| 1194C4 | Control Cystatin C-DAC | Turbidimetry | CE |
| 1102H75 | HbA _{1c} -Turbi-DAC | Turbidimetry | CE |
| 1102H180 | HbA _{1c} -Turbi-DAC | Turbidimetry | CE |
| 1103H2 | HbA _{1c} Calibrator (4 levels) | Turbidimetry | CE |
| 1104H4 | HbA _{1c} Control (2 levels) | Turbidimetry | CE |
| 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 |
| 1038R200 | RefaTex-conf | Slide agglunation | CE |
| 1041R100 | ReumoScreen-DAC | Slide agglunation | CE |
| 1045W100 | Waalser-Rose-DAC | Slide agglunation | CE |
| 1035I100 | IM-DAC | Slide agglunation | CE |
| 1040R100 | RPR-Carbon-DAC | Slide agglunation | CE |
| 1040R250 | RPR-Carbon-DAC | Slide agglunation | CE |
| 1040R500 | RPR-Carbon-DAC | Slide agglunation | CE |
| 1040R1000 | RPR-Carbon-DAC | Slide agglunation | CE |
| 1043S100 | 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 |
| 1032C435 | CIC-DAC | End point | CE |
| 1036N305 | NBT-DAC | End point | CE |
| 4051G100 | DAC-1G | Paper-thin layer chromatography | CE |
| 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 |
| 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 |
| 4062UC24 | UreControl-DAC | Paper-thin layer chromatography | CE |

Annex II

Declaration of Conformity according to European Directive of in vitro diagnostic medical devices (98/79/EG) of the Medical Devices Act (MPG)

| Cat. No | Product | Method | Conformity |
|-------------|-----------------------------|-----------------------------|------------|
| 4164HBs1 | HBsAg-S-Strip-DAC | chromatographic immunoassay | CE |
| 4166HBs1 | HBsAg-S-Cart-DAC | chromatographic immunoassay | CE |
| 4165HBs1 | HBsAg-WB-Strip-DAC | chromatographic immunoassay | CE |
| 4167HBs1 | HBsAg-WB-Cart-DAC | chromatographic immunoassay | CE |
| 4169AHBs1 | Anti-HBsAg-S-Strip-DAC | chromatographic immunoassay | CE |
| 4170AHBs1 | Anti-HBsAg-S-Cart-DAC | chromatographic immunoassay | CE |
| 4172HBe1 | HBeAg-S-Strip-DAC | chromatographic immunoassay | CE |
| 4173HBe1 | HBeAg-S-Cart-DAC | chromatographic immunoassay | CE |
| 4174AHBe1 | Anti-HBeAg-S-Strip-DAC | chromatographic immunoassay | CE |
| 4175AHBe1 | Anti-HBeAg-S-Cart-DAC | chromatographic immunoassay | CE |
| 4176AHBc1 | Anti-HBcAg-S-Strip-DAC | chromatographic immunoassay | CE |
| 4177AHBc1 | Anti-HBcAg-S-Cart-DAC | chromatographic immunoassay | CE |
| 4179HBV1 | HBV Multi 5-S-Panel-DAC | chromatographic immunoassay | CE |
| 4181AHCV1 | Anti-HCV-S-Strip-DAC | chromatographic immunoassay | CE |
| 4182AHCV1 | Anti-HCV-S-Cart-DAC | chromatographic immunoassay | CE |
| 4184AHCV1 | Anti-HCV-WB-Cart-DAC | chromatographic immunoassay | CE |
| 4185HAV1 | HAV IgG/IgM-S-Cart-DAC | chromatographic immunoassay | CE |
| 4178M1 | Multi 4-Panel-DAC | chromatographic immunoassay | CE |
| 4180M1 | Multi 3-S-Panel-DAC | chromatographic immunoassay | CE |
| 4192AH1 | Anti-HIV-S-Cart-DAC | chromatographic immunoassay | CE |
| 4193AH1 | Anti-HIV-WB-Cart-DAC | chromatographic immunoassay | CE |
| 4194AH1 | Anti-HIV-Cart-DAC | chromatographic immunoassay | CE |
| 4190AS1 | Anti-Syphilis-S-Strip-DAC | chromatographic immunoassay | CE |
| 4191AS1 | Anti-Syphilis-S-Cart-DAC | chromatographic immunoassay | CE |
| 4188C1 | Chlamydia-Cart-DAC | chromatographic immunoassay | CE |
| 4195G1 | Gonorrhea-Strip-DAC | chromatographic immunoassay | CE |
| 4196G1 | Gonorrhea-Cart-DAC | chromatographic immunoassay | CE |
| 4293C1 | Candida-Cart-DAC | chromatographic immunoassay | CE |
| 4280T1 | Trichomonas-Cart-DAC | chromatographic immunoassay | CE |
| 4299H1 | HPV 6/11-Cart-DAC | chromatographic immunoassay | CE |
| 4300M1 | Mycoplasma-Cart-DAC | chromatographic immunoassay | CE |
| 4275U1 | Ureaplasma-Cart-DAC | chromatographic immunoassay | CE |
| 4282IAB1 | Influenza A/B 2-Panel-DAC | chromatographic immunoassay | CE |
| 4186TB1 | TB-S-Cart-DAC | chromatographic immunoassay | CE |
| 4187MP1 | MP Ab-S-Cart-DAC | chromatographic immunoassay | CE |
| 4298V1 | Vaginosis-Cart-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 |
| 4220D1 | Dengue IgG/IgM-Cart-DAC | chromatographic immunoassay | CE |
| 4274BU1 | BU-Cart-DAC | chromatographic immunoassay | CE |
| 4277A1 | Adeno-Cart-DAC | chromatographic immunoassay | CE |
| 4278R1 | Rota-Cart-DAC | chromatographic immunoassay | CE |
| 4279AR1 | Adeno/Rota-Cart-DAC | chromatographic immunoassay | CE |
| 4281M1 | Mononucleosis-Cart-DAC | chromatographic immunoassay | CE |
| 4290ECo1 | E.Coli-Cart-DAC | chromatographic immunoassay | CE |
| 4291L1 | Listeria-Cart-DAC | chromatographic immunoassay | CE |
| 4292S1 | Salmonella-Cart-DAC | chromatographic immunoassay | CE |
| 4212T1 | Toxo-S-Cart-DAC-IgG/IgM | chromatographic immunoassay | CE |
| 4213CMV1 | CMV-S-Cart-DAC-IgG/IgM | chromatographic immunoassay | CE |
| 4222R1 | Rubella-S-Cart-DAC-IgG/IgM | chromatographic immunoassay | CE |
| 4223HSV11 | HSV-I-Cart-DAC-IgG/IgM | chromatographic immunoassay | CE |
| 4224HSV11 | HSV-II-Cart-DAC-IgG/IgM | chromatographic immunoassay | CE |
| 4225T1 | TORCH-Panel-DAC-IgG/IgM | chromatographic immunoassay | CE |
| 4150HCG-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 |
| 4155HCG1 | HCG-SU-Strip-DAC | chromatographic immunoassay | CE |
| 4153HCG1 | HCG-SU-Cart-DAC | chromatographic immunoassay | CE |
| 4154HCG1 | HCG-M-Cart-DAC | chromatographic immunoassay | CE |
| 4160LH1 | LH-U-Strip-DAC | chromatographic immunoassay | CE |
| 4161LH1 | LH-U-Cart-DAC | chromatographic immunoassay | CE |
| 4162LH1 | LH-M-Cart-DAC | chromatographic immunoassay | CE |
| 4156FSH1 | FSH-U-Strip-DAC | chromatographic immunoassay | CE |
| 4157FSH1 | FSH-U-Cart-DAC | chromatographic immunoassay | CE |
| 4158FSH1 | FSH-M-Cart-DAC | chromatographic immunoassay | CE |
| 4207PSA1 | PSA-S-Strip-DAC | chromatographic immunoassay | CE |
| 4208PSA1 | PSA-S-Cart-DAC | chromatographic immunoassay | CE |
| 4204CEA1 | CEA-S-Strip-DAC | chromatographic immunoassay | CE |
| 4205CEA1 | CEA-S-Cart-DAC | chromatographic immunoassay | CE |
| 4198AFP1 | AFP-S-Strip-DAC | chromatographic immunoassay | CE |

| Cat. No | Product | Method | Cornformity |
|------------|--------------------------|-----------------------------|-------------|
| 4199AFP1 | AFP-S-Cart-DAC | chromatographic immunoassay | CE |
| 4201FOB1 | FOB-F-Strip-DAC | chromatographic immunoassay | CE |
| 4202FOB1 | FOB-F-Cart-DAC | chromatographic immunoassay | CE |
| 4200C1 | CTCC-Cart-DAC | chromatographic immunoassay | CE |
| 4232AMP1 | AMP-Strip-DAC | chromatographic immunoassay | CE |
| 4233AMP1 | AMP-Cart-DAC | chromatographic immunoassay | CE |
| 4244BAR1 | BAR-Strip-DAC | chromatographic immunoassay | CE |
| 4245BAR1 | BAR-Cart-DAC | chromatographic immunoassay | CE |
| 4247BZ01 | BZO-Strip-DAC | chromatographic immunoassay | CE |
| 4248BZ01 | BZO-Cart-DAC | chromatographic immunoassay | CE |
| 4226COC1 | COC-Strip-DAC | chromatographic immunoassay | CE |
| 4227COC1 | COC-Cart-DAC | chromatographic immunoassay | CE |
| 4258MDMA1 | MDMA-Strip-DAC | chromatographic immunoassay | CE |
| 4259MDMA1 | MDMA-Cart-DAC | chromatographic immunoassay | CE |
| 4235mAMP1 | mAMP-Strip-DAC | chromatographic immunoassay | CE |
| 4236mAMP1 | mAMP-Cart-DAC | chromatographic immunoassay | CE |
| 4229MOP1 | MOP-Strip-DAC | chromatographic immunoassay | CE |
| 4230MOP1 | MOP-Cart-DAC | chromatographic immunoassay | CE |
| 4238MTD1 | MTD-Strip-DAC | chromatographic immunoassay | CE |
| 4239MTD1 | MTD-Cart-DAC | chromatographic immunoassay | CE |
| 4261OPI1 | OPI-Strip-DAC | chromatographic immunoassay | CE |
| 4262OPI1 | OPI-Cart-DAC | chromatographic immunoassay | CE |
| 4241THC1 | THC-Strip-DAC | chromatographic immunoassay | CE |
| 4242THC1 | THC-Cart-DAC | chromatographic immunoassay | CE |
| 4264TCA1 | TCA-Strip-DAC | chromatographic immunoassay | CE |
| 4265TCA1 | TCA-Cart-DAC | chromatographic immunoassay | CE |
| 4267PCP1 | PCP-Strip-DAC | chromatographic immunoassay | CE |
| 4268PCP1 | PCP-Cart-DAC | chromatographic immunoassay | CE |
| 4253D2 | 2-Drugs-DAC | chromatographic immunoassay | CE |
| 4254D3 | 3-Drugs-DAC | chromatographic immunoassay | CE |
| 4255D4 | 4-Drugs-DAC | chromatographic immunoassay | CE |
| 4256D5 | 5-Drugs-DAC | chromatographic immunoassay | CE |
| 4251D6 | 6-Drugs-DAC | chromatographic immunoassay | CE |
| 4257D10 | 10-Drugs-DAC | chromatographic immunoassay | CE |
| 4252D12 | 12-Drugs-DAC | chromatographic immunoassay | CE |
| 4216A1 | Alcohol-Strip-DAC | chromatographic immunoassay | CE |
| 4203A1 | Alcohol-U-Strip-DAC | chromatographic immunoassay | CE |
| 4270CRP1 | CRP-Cart-DAC | chromatographic immunoassay | CE |
| 4272IgE1 | IgE-S-Cart-DAC | chromatographic immunoassay | CE |
| 4283AU1 | Albumin Urine-Cart-DAC | chromatographic immunoassay | CE |
| 4284hsCRP1 | hsCRP-Cart-DAC | chromatographic immunoassay | CE |
| 4285DD1 | D-Dimer-Cart-DAC | chromatographic immunoassay | CE |
| 4286RF1 | RF-Cart-DAC | chromatographic immunoassay | CE |
| 4287NTSH1 | Neonatal TSH-WB-Cart-DAC | chromatographic immunoassay | CE |
| 4288TSH1 | TSH-Cart-DAC | chromatographic immunoassay | CE |
| 4289F1 | Ferritin-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 |