

Výrobky společnosti **TestLine Clinical Diagnostics s.r.o.** (výrobce),

Křížíkova 68, 612 00 Brno, Česká republika, SRN: CZ-MF-000001803

u nichž bylo v souladu se směrnicí EP a Rady 98/79/ES nebo nařízením (EU) 2017/746 (IVDR) týkající se diagnostických zdravotnických prostředků in vitro provedeno posouzení shody. EU prohlášení o shodě se vydává na výhradní odpovědnost výrobce pro potřeby příslušných orgánů, zákazníků a hospodářských subjektů.

Postup posuzování shody:

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|------------|---|
| IVD | Směrnice 98/79/ES, příloha III |
| IVD B | Směrnice 98/79/ES, příloha IV (systém komplexního zabezpečování jakosti) |
| IVDR tř. A | Nařízení (EU) 2017/746 (IVDR), TD dle příloh II a III, prohlášení o shodě dle přílohy IV, označení CE dle přílohy V |
| IVDR tř. B | Nařízení (EU) 2017/746 (IVDR), TD dle přílohy IX, prohlášení o shodě dle přílohy IV, označení CE dle přílohy V |
| IVDR tř. C | Nařízení (EU) 2017/746 (IVDR), TD dle přílohy IX, prohlášení o shodě dle přílohy IV, označení CE dle přílohy V |

HUMÁNNÍ CLIA SOUPRAVY

| Kat. číslo | Název výrobku | Klasifikace | Základní UDI-DI | Kód GMDN |
|------------|-------------------------------|-------------|-----------------|----------|
| CL-ADP050 | CLIA Adiponectin | IVD | 8595635311390C8 | 43540 |
| CL-BRG100 | CLIA Borrelia recombinant IgG | IVD | 8595635309915E5 | 65420 |
| CL-BRM100 | CLIA Borrelia recombinant IgM | IVD | 8595635309922E2 | 64702 |
| CL-CAGs100 | CLIA Campylobacter Ag Stool | IVD | 8595635311406BW | 63153 |
| CL-CEN050 | CLIA Centromere | IVD | 8595635309939EK | 59745 |
| CL-CMA100 | CLIA CMV IgA | IVD B | 8595635309946EG | 58428 |
| CL-CMG100 | CLIA CMV IgG | IVD B | 8595635309953ED | 49713 |
| CL-CMM100 | CLIA CMV IgM | IVD B | 8595635309960EA | 49724 |
| CL-CoNA100 | CLIA COVID-19 NP IgA | IVD | 8595635309762E4 | 65062 |
| CL-CoNG100 | CLIA COVID-19 NP IgG | IVD | 8595635309755E7 | 64760 |
| CL-CoNM100 | CLIA COVID-19 NP IgM | IVD | 8595635309779EM | 64761 |
| CL-CoRA100 | CLIA COVID-19 RBD IgA | IVD | 8595635309793EF | 65062 |
| CL-CoRG100 | CLIA COVID-19 RBD IgG | IVD | 8595635309786EJ | 64760 |
| CL-CoRM100 | CLIA COVID-19 RBD IgM | IVD | 8595635309809E5 | 64761 |
| CL-CRP100 | CLIA CRP wide-range | IVD | 8595635311413BT | 65695 |
| CL-CysC100 | CLIA Cystatin C | IVD | 8595635311420BQ | 62598 |
| CL-DNA050 | CLIA dsDNA | IVD | 8595635310508BY | 61266 |
| CL-EAG100 | CLIA EBV EA-D IgG | IVD | 8595635309991EM | 60683 |
| CL-EAM100 | CLIA EBV EA-D IgM | IVD | 8595635310003AV | 60684 |
| CL-EBG100 | CLIA EBV EBNA-1 IgG | IVD | 8595635310010AS | 60683 |
| CL-EBM100 | CLIA EBV EBNA-1 IgM | IVD | 8595635310027BB | 60684 |
| CL-VCA100 | CLIA EBV VCA IgA | IVD | 8595635310034B8 | 66047 |
| CL-VCG100 | CLIA EBV VCA IgG | IVD | 8595635310041B5 | 60683 |

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|------------|--------------------------------|------------|-----------------|-------|
| CL-VCM100 | CLIA EBV VCA IgM | IVD | 8595635310058BN | 60684 |
| CL-ENA100 | CLIA ENA screen plus | IVD | 8595635309748EA | 59748 |
| CL-GDA100 | CLIA Gliadin DA IgA | IVD | 8595635310065BK | 54948 |
| CL-GDG100 | CLIA Gliadin DA IgG | IVD | 8595635310072BG | 54948 |
| CL-HAgS100 | CLIA Helicobacter Ag Stool | IVD | 8595635311437C9 | 61971 |
| CL-HMA100 | CLIA Helicobacter MONO IgA | IVD | 8595635310089BZ | 65628 |
| CL-HMG100 | CLIA Helicobacter MONO IgG | IVD | 8595635310096BW | 61971 |
| CL-HSVG100 | CLIA HSV 1+2 IgG | IVDR tř. C | 8595635310126BE | 49543 |
| CL-HSVM100 | CLIA HSV 1+2 IgM | IVDR tř. C | 8595635310133BB | 49547 |
| CL-CPA100 | CLIA Chlamydia pneumoniae IgA | IVD B | 8595635310164BN | 65361 |
| CL-CPG100 | CLIA Chlamydia pneumoniae IgG | IVD B | 8595635310171BK | 65362 |
| CL-CPM100 | CLIA Chlamydia pneumoniae IgM | IVD B | 8595635310188C4 | 65363 |
| CL-ChtA100 | CLIA Chlamydia trachomatis IgA | IVD B | 8595635310195BZ | 63332 |
| CL-ChtG100 | CLIA Chlamydia trachomatis IgG | IVD B | 8595635310201B3 | 63328 |
| CL-ChtM100 | CLIA Chlamydia trachomatis IgM | IVD B | 8595635310218BL | 65360 |
| CL-IL6100 | CLIA IL-6 | IVD | 8595635311444C6 | 53858 |
| CL-Jo1050 | CLIA Jo-1 | IVD | 8595635310225BH | 59067 |
| CL-MxA050 | CLIA MxA | IVD | 8595635311451C3 | 65778 |
| CL-MyA100 | CLIA Mycoplasma IgA | IVDR tř. B | 8595635310232BE | 66992 |
| CL-MyG100 | CLIA Mycoplasma IgG | IVDR tř. B | 8595635310249BX | 63427 |
| CL-MyM100 | CLIA Mycoplasma IgM | IVDR tř. B | 8595635310256BU | 63403 |
| CL-PVG050 | CLIA Parvovirus B19 IgG | IVDR tř. C | 8595635310492CA | 63423 |
| CL-PVM050 | CLIA Parvovirus B19 IgM | IVDR tř. C | 8595635310485CD | 63404 |
| CL-PCT100 | CLIA Procalcitonin | IVD | 8595635311475CH | 58731 |
| CL-RubG100 | CLIA Rubella IgG | IVD B | 8595635310263BR | 60990 |
| CL-RubM100 | CLIA Rubella IgM | IVD B | 8595635310270BN | 60991 |
| CL-Scl050 | CLIA Scl-70 | IVD | 8595635310287C7 | 59747 |
| CL-Sm0050 | CLIA Sm | IVD | 8595635310294C4 | 59888 |
| CL-SSA050 | CLIA SS-A | IVD | 8595635310300B6 | 59744 |
| CL-Ro5250 | CLIA SS-A/Ro52 | IVD | 8595635310317BP | 59744 |
| CL-Ro6050 | CLIA SS-A/Ro60 | IVD | 8595635310324BL | 59744 |
| CL-SSB050 | CLIA SS-B | IVD | 8595635310331BH | 61221 |
| CL-TBG100 | CLIA TBE Virus IgG | IVD | 8595635309717DX | 65639 |
| CL-TBM050 | CLIA TBE Virus IgM | IVD | 8595635309700DE | 65640 |
| CL-TetG100 | CLIA Tetanus Toxoid IgG | IVDR tř. B | 8595635311925CT | 65621 |
| CL-tTA100 | CLIA Transglutaminase IgA | IVD | 8595635309731DR | 58965 |
| CL-tTG100 | CLIA Transglutaminase IgG | IVD | 8595635309724DU | 58965 |
| CL-RNP050 | CLIA U1RNP | IVD | 8595635310379CD | 59857 |
| CL-UMOD050 | CLIA Uromodulin | IVD | 8595635311482CE | 61293 |
| CL-VZVA100 | CLIA VZV IgA | IVDR tř. C | 8595635310386CA | 49634 |
| CL-VZVG100 | CLIA VZV IgG | IVDR tř. C | 8595635310393C7 | 49622 |
| CL-VZVM100 | CLIA VZV IgM | IVDR tř. C | 8595635310409BV | 49628 |

HUMÁNNÍ ELISA SOUPRAVY

| Kat. číslo | Název výrobku | Klasifikace | Základní UDI-DI | Kód GMDN |
|------------|--|-------------|-----------------|----------|
| AdA096 | EIA Adenovirus IgA | IVD | 8595635308840DQ | 49867 |
| AdG096 | EIA Adenovirus IgG | IVD | 8595635308857E9 | 49869 |
| AdM096 | EIA Adenovirus IgM | IVD | 8595635308864E6 | 49872 |
| ScA096 | EIA ASCA IgA | IVD | 8595635303821CH | 52100 |
| ScG096 | EIA ASCA IgG | IVD | 8595635303838D2 | 52108 |
| BppA96 | EIA Bordetella parapertussis IgA | IVD | 8595635305054C6 | 50512 |
| BppG96 | EIA Bordetella parapertussis IgG | IVD | 8595635305061C3 | 50512 |
| BppM96 | EIA Bordetella parapertussis IgM | IVD | 8595635305078CL | 50512 |
| BpAT96 | EIA Bordetella pertussis Toxin IgA | IVD | 8595635301209BF | 50517 |
| BpGT96 | EIA Bordetella pertussis Toxin IgG | IVD | 8595635301179BX | 50521 |
| BpMT96 | EIA Bordetella pertussis Toxin IgM | IVD | 8595635304217C3 | 50525 |
| BaM192 | EIA Borrelia afzelii IgM (192) | IVD | 8595635302602BU | 50585 |
| BaGVD2 | EIA Borrelia afzelii VlsE IgG (192) | IVD | 8595635300561BR | 50581 |
| BsM096 | EIA Borrelia b. sensu stricto IgM | IVD | 8595635302619CD | 50564 |
| BsGV96 | EIA Borrelia b. sensu stricto VlsE IgG | IVD | 8595635303357CD | 50560 |
| BgM192 | EIA Borrelia garinii IgM (192) | IVD | 8595635302534C4 | 50597 |
| BgGVD2 | EIA Borrelia garinii VlsE IgG (192) | IVD | 8595635300745C5 | 50593 |
| BM0096 | EIA Borrelia IgM | IVD | 8595635302626CA | 50564 |
| BrG192 | EIA Borrelia recombinant IgG (192) | IVD | 8595635302633C7 | 50560 |
| BrM192 | EIA Borrelia recombinant IgM (192) | IVD | 8595635302640C4 | 50564 |
| BGV096 | EIA Borrelia VlsE IgG | IVD | 8595635302657CM | 50560 |
| CCPA96 | EIA CCP IgA | IVD | 8595635302664CJ | 54896 |
| CCPG96 | EIA CCP IgG | IVD | 8595635302671CF | 54896 |
| CMA096 | EIA CMV IgA | IVD B | 8595635303210BE | 49729 |
| CMG096 | EIA CMV IgG | IVD B | 8595635302688CY | 49729 |
| CMM096 | EIA CMV IgM | IVD B | 8595635302695CV | 49729 |
| CoNA96 | EIA COVID-19 NP IgA | IVD | 8595635309021CK | 64830 |
| CoNG96 | EIA COVID-19 NP IgG | IVD | 8595635309038D4 | 64824 |
| CoNM96 | EIA COVID-19 NP IgM | IVD | 8595635309045CZ | 64800 |
| CoRA96 | EIA COVID-19 RBD IgA | IVD | 8595635309335DD | 64830 |
| CoRG96 | EIA COVID-19 RBD IgG | IVD | 8595635309328DG | 64824 |
| CoRM96 | EIA COVID-19 RBD IgM | IVD | 8595635309311CX | 64800 |
| DNA096 | EIA dsDNA | IVD | 8595635307478DN | 54902 |
| EAG096 | EIA EBV EA-D IgG | IVD | 8595635302701BX | 49657 |
| EAM096 | EIA EBV EA-D IgM | IVD | 8595635302718CG | 49662 |
| EBG096 | EIA EBV EBNA-1 IgG | IVD | 8595635302725CD | 49657 |
| EBM096 | EIA EBV EBNA-1 IgM | IVD | 8595635302749CT | 49662 |
| VCA096 | EIA EBV VCA IgA | IVD | 8595635302756CQ | 60621 |
| VCG096 | EIA EBV VCA IgG | IVD | 8595635302763CM | 49657 |
| VCM096 | EIA EBV VCA IgM | IVD | 8595635302787D3 | 49662 |
| ENAp12 | EIA ENA profile plus | IVD | 8595635307607D9 | 54823 |
| ENA096 | EIA ENA screen plus | IVD | 8595635300769CK | 54823 |
| GDA096 | EIA Gliadin DA IgA | IVD | 8595635303159C7 | 54947 |

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|--------|----------------------------------|-------|-----------------|-------|
| GDG096 | EIA Gliadin DA IgG | IVD | 8595635303166C4 | 54947 |
| GIA096 | EIA Gliadin IgA | IVD | 8595635303142BN | 54947 |
| GIG096 | EIA Gliadin IgG | IVD | 8595635303173BZ | 54947 |
| HMA096 | EIA Helicobacter MONO IgA | IVD | 8595635302800C2 | 51004 |
| HMG096 | EIA Helicobacter MONO IgG | IVD | 8595635302817CK | 51008 |
| HMM096 | EIA Helicobacter MONO IgM | IVD | 8595635302824CG | 51012 |
| HS1G96 | EIA HSV 1 IgG | IVD | 8595635309694EC | 49534 |
| HS1M96 | EIA HSV 1 IgM | IVD | 8595635309625DR | 49534 |
| HS2G96 | EIA HSV 2 IgG | IVD | 8595635309632DN | 49534 |
| HS2M96 | EIA HSV 2 IgM | IVD | 8595635309649E7 | 49534 |
| HSVG96 | EIA HSV 1+2 IgG | IVD | 8595635302831CD | 49534 |
| HSVM96 | EIA HSV 1+2 IgM | IVD | 8595635302848CW | 49534 |
| ChA096 | EIA Chlamydia IgA | IVD B | 8595635302855CT | 50720 |
| ChG096 | EIA Chlamydia IgG | IVD B | 8595635302862CQ | 50722 |
| ChM096 | EIA Chlamydia IgM | IVD B | 8595635302879D9 | 50724 |
| ChpA96 | EIA Chlamydia pneumoniae IgA | IVD B | 8595635302886D6 | 50741 |
| ChpG96 | EIA Chlamydia pneumoniae IgG | IVD B | 8595635302893D3 | 50737 |
| ChpM96 | EIA Chlamydia pneumoniae IgM | IVD B | 8595635302909CR | 50733 |
| CpAR96 | EIA Chlamydia pneumoniae REC IgA | IVD B | 8595635304460CE | 50741 |
| CpGR96 | EIA Chlamydia pneumoniae REC IgG | IVD B | 8595635304477CX | 50737 |
| ChtA96 | EIA Chlamydia trachomatis IgA | IVD B | 8595635302916CN | 50773 |
| ChtG96 | EIA Chlamydia trachomatis IgG | IVD B | 8595635302923CK | 50768 |
| ChtM96 | EIA Chlamydia trachomatis IgM | IVD B | 8595635302930CG | 50763 |
| InAA96 | EIA Influenza A IgA | IVD | 8595635308406D4 | 49183 |
| InAG96 | EIA Influenza A IgG | IVD | 8595635308390DE | 49178 |
| InAM96 | EIA Influenza A IgM | IVD | 8595635308413CZ | 49173 |
| InBA96 | EIA Influenza B IgA | IVD | 8595635308468DS | 49219 |
| InBG96 | EIA Influenza B IgG | IVD | 8595635308451D9 | 49214 |
| InBM96 | EIA Influenza B IgM | IVD | 8595635308475DP | 49209 |
| Jo1096 | EIA Jo-1 | IVD | 8595635304064C2 | 55005 |
| MeG096 | EIA Measles IgG | IVD | 8595635307881DX | 49287 |
| MeM096 | EIA Measles IgM | IVD | 8595635307898EG | 49280 |
| MiA096 | EIA Milk IgA | IVD | 8595635303180BW | 41410 |
| MiG096 | EIA Milk IgG | IVD | 8595635303197CF | 41410 |
| MiM096 | EIA Milk IgM | IVD | 8595635303203BH | 41410 |
| MuA096 | EIA Mumps IgA | IVD | 8595635307997EK | 49338 |
| MuG096 | EIA Mumps IgG | IVD | 8595635308000C4 | 49338 |
| MuM096 | EIA Mumps IgM | IVD | 8595635308017CM | 49338 |
| MyA096 | EIA Mycoplasma IgA | IVD | 8595635302947CZ | 51212 |
| MyG096 | EIA Mycoplasma IgG | IVD | 8595635302954CW | 51207 |
| MyM096 | EIA Mycoplasma IgM | IVD | 8595635302961CT | 51202 |
| MyAR96 | EIA Mycoplasma REC IgA | IVD | 8595635307522CY | 51212 |
| MyGR96 | EIA Mycoplasma REC IgG | IVD | 8595635307539DH | 51207 |
| MyMR96 | EIA Mycoplasma REC IgM | IVD | 8595635307515D3 | 51202 |
| PaiA96 | EIA Parainfluenza mix IgA | IVD | 8595635308529DM | 49388 |

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|--------|------------------------------|-------|-----------------|-------|
| PaiG96 | EIA Parainfluenza mix IgG | IVD | 8595635308512D4 | 49384 |
| PaiM96 | EIA Parainfluenza mix IgM | IVD | 8595635308536DJ | 49380 |
| PVG096 | EIA Parvovirus B19 IgG | IVD | 8595635310515BV | 50157 |
| PVM096 | EIA Parvovirus B19 IgM | IVD | 8595635310546C8 | 50164 |
| PCG096 | EIA PCP IgG | IVD | 8595635303869DD | 51783 |
| RFA096 | EIA RF IgA | IVD | 8595635302978DC | 55107 |
| RFG096 | EIA RF IgG | IVD | 8595635302985D9 | 55107 |
| RFM096 | EIA RF IgM | IVD | 8595635302992D6 | 55107 |
| RSA096 | EIA RSV IgA | IVD | 8595635308949EF | 49519 |
| RSG096 | EIA RSV IgG | IVD | 8595635308932DW | 49513 |
| RSM096 | EIA RSV IgM | IVD | 8595635308956EC | 49508 |
| RubG96 | EIA Rubella IgG | IVD B | 8595635305016BW | 50265 |
| RubM96 | EIA Rubella IgM | IVD B | 8595635305023BT | 50268 |
| Scl096 | EIA Scl-70 | IVD | 8595635304101BF | 55126 |
| Sm0096 | EIA Sm | IVD | 8595635304118BY | 55160 |
| SSA096 | EIA SS-A | IVD | 8595635304026BS | 55129 |
| SSB096 | EIA SS-B | IVD | 8595635304071BX | 55132 |
| TBG096 | EIA TBE Virus IgG | IVD | 8595635303005BB | 49027 |
| TBM096 | EIA TBE Virus IgM | IVD | 8595635303012B8 | 49023 |
| TeTG96 | EIA Tetanus Toxoid IgG | IVD | 8595635309410D2 | 50874 |
| TcA096 | EIA Toxocara IgA | IVD | 8595635303999DT | 52418 |
| TcG096 | EIA Toxocara IgG | IVD | 8595635303036BN | 52418 |
| TgA096 | EIA Toxoplasma IgA | IVD B | 8595635303043BK | 52444 |
| TgE096 | EIA Toxoplasma IgE | IVD B | 8595635303050BG | 52444 |
| TgG096 | EIA Toxoplasma IgG | IVD B | 8595635303067BZ | 52444 |
| TgM096 | EIA Toxoplasma IgM | IVD B | 8595635303074BW | 52444 |
| tTA096 | EIA Transglutaminase IgA | IVD | 8595635303715CH | 55223 |
| tTG096 | EIA Transglutaminase IgG | IVD | 8595635303722CE | 55223 |
| TpG096 | EIA Treponema pallidum IgG | IVD | 8595635303081BT | 51804 |
| TpM096 | EIA Treponema pallidum IgM | IVD | 8595635303098CC | 51809 |
| Tp0096 | EIA Treponema pallidum TOTAL | IVD | 8595635303104BE | 51798 |
| RNP096 | EIA U1RNP | IVD | 8595635304095CD | 55165 |
| VZVA96 | EIA VZV IgA | IVD | 8595635304224BY | 49639 |
| VZVG96 | EIA VZV IgG | IVD | 8595635304231BV | 49639 |
| VZVM96 | EIA VZV IgM | IVD | 8595635304248CE | 49639 |
| YeA096 | EIA Yersinia IgA | IVD | 8595635309441DD | 51900 |
| YeG096 | EIA Yersinia IgG | IVD | 8595635309458DW | 51904 |
| YeM096 | EIA Yersinia IgM | IVD | 8595635309465DT | 51912 |

HUMÁNNÍ SMART ELISA SOUPRAVY

| Kat. číslo | Název výrobku | Klasifikace | Základní UDI-DI | Kód GMDN |
|------------|-------------------------|-------------|-----------------|----------|
| SK-AdA096 | SmartEIA Adenovirus IgA | IVD | 8595635308871E3 | 49867 |
| SK-AdG096 | SmartEIA Adenovirus IgG | IVD | 8595635308888EL | 49869 |
| SK-AdM096 | SmartEIA Adenovirus IgM | IVD | 8595635308895EH | 49872 |
| SK-ScA096 | SmartEIA ASCA IgA | IVD | 8595635306570D4 | 52100 |

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|-----------|---|-------|-----------------|-------|
| SK-ScG096 | SmartEIA ASCA IgG | IVD | 8595635306587DM | 52108 |
| SK-BppA96 | SmartEIA Bordetella parapertussis IgA | IVD | 8595635306068CQ | 50512 |
| SK-BppG96 | SmartEIA Bordetella parapertussis IgG | IVD | 8595635306051C7 | 50512 |
| SK-BppM96 | SmartEIA Bordetella parapertussis IgM | IVD | 8595635306044CA | 50512 |
| SK-BpAT96 | SmartEIA Bordetella pertussis Toxin IgA | IVD | 8595635306020BU | 50517 |
| SK-BpGT96 | SmartEIA Bordetella pertussis Toxin IgG | IVD | 8595635306037CD | 50521 |
| SK-BpMT96 | SmartEIA Bordetella pertussis Toxin IgM | IVD | 8595635306075CM | 50525 |
| SK-BaM096 | SmartEIA Borrelia afzelii IgM | IVD | 8595635305672D6 | 50585 |
| SK-BaGV96 | SmartEIA Borrelia afzelii VlsE IgG | IVD | 8595635305740CW | 50581 |
| SK-BsM096 | SmartEIA Borrelia b. sensu stricto IgM | IVD | 8595635305689DP | 50564 |
| SK-BsGV96 | SmartEIA Borrelia b. sensu stricto VlsE IgG | IVD | 8595635305733CZ | 50560 |
| SK-BgM096 | SmartEIA Borrelia garinii IgM | IVD | 8595635305665D9 | 50597 |
| SK-BgGV96 | SmartEIA Borrelia garinii VlsE IgG | IVD | 8595635305757DF | 50593 |
| SK-BM0096 | SmartEIA Borrelia IgM | IVD | 8595635305696DL | 50564 |
| SK-BrG096 | SmartEIA Borrelia recombinant IgG | IVD | 8595635305702CN | 50560 |
| SK-BrM096 | SmartEIA Borrelia recombinant IgM | IVD | 8595635305719D7 | 50564 |
| SK-BGV096 | SmartEIA Borrelia VlsE IgG | IVD | 8595635305726D4 | 50560 |
| SK-CCPA96 | SmartEIA CCP IgA | IVD | 8595635306303CB | 54896 |
| SK-CCPG96 | SmartEIA CCP IgG | IVD | 8595635306297D9 | 54896 |
| SK-CMA096 | SmartEIA CMV IgA | IVD B | 8595635306266CW | 49729 |
| SK-CMG096 | SmartEIA CMV IgG | IVD B | 8595635306280CQ | 49729 |
| SK-CMM096 | SmartEIA CMV IgM | IVD B | 8595635306273CT | 49729 |
| SK-CoNA96 | SmartEIA COVID-19 NP IgA | IVD | 8595635309083D9 | 64830 |
| SK-CoNG96 | SmartEIA COVID-19 NP IgG | IVD | 8595635309090D6 | 64824 |
| SK-CoNM96 | SmartEIA COVID-19 NP IgM | IVD | 8595635309106CU | 64800 |
| SK-CoRA96 | SmartEIA COVID-19 RBD IgA | IVD | 8595635309274DJ | 64830 |
| SK-CoRG96 | SmartEIA COVID-19 RBD IgG | IVD | 8595635309267DM | 64824 |
| SK-CoRM96 | SmartEIA COVID-19 RBD IgM | IVD | 8595635309250D4 | 64800 |
| SK-DNA096 | SmartEIA dsDNA | IVD | 8595635307461D5 | 54902 |
| SK-EAG096 | SmartEIA EBV EA-D IgG | IVD | 8595635305917DD | 49657 |
| SK-EAM096 | SmartEIA EBV EA-D IgM | IVD | 8595635305924DA | 49662 |
| SK-EBG096 | SmartEIA EBV EBNA-1 IgG | IVD | 8595635305931D7 | 49657 |
| SK-EBM096 | SmartEIA EBV EBNA-1 IgM | IVD | 8595635305948DQ | 49662 |
| SK-VCA096 | SmartEIA EBV VCA IgA | IVD | 8595635305955DM | 60621 |
| SK-VCG096 | SmartEIA EBV VCA IgG | IVD | 8595635305962DJ | 49657 |
| SK-VCM096 | SmartEIA EBV VCA IgM | IVD | 8595635305979E3 | 49662 |
| SK-ENAp12 | SmartEIA ENA profile plus | IVD | 8595635307591DK | 54823 |
| SK-ENA096 | SmartEIA ENA screen plus | IVD | 8595635306082CJ | 54823 |
| SK-GDA096 | SmartEIA Gliadin DA IgA | IVD | 8595635306549DD | 54947 |
| SK-GDG096 | SmartEIA Gliadin DA IgG | IVD | 8595635306556DA | 54947 |
| SK-GIA096 | SmartEIA Gliadin IgA | IVD | 8595635306532CU | 54947 |
| SK-GIG096 | SmartEIA Gliadin IgG | IVD | 8595635306563D7 | 54947 |
| SK-HMA096 | SmartEIA Helicobacter MONO IgA | IVD | 8595635306372CW | 51004 |
| SK-HMG096 | SmartEIA Helicobacter MONO IgG | IVD | 8595635306365CZ | 51008 |
| SK-HMM096 | SmartEIA Helicobacter MONO IgM | IVD | 8595635306358D4 | 51012 |

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|-----------|---------------------------------------|-------|-----------------|-------|
| SK-HS1G96 | SmartEIA HSV 1 IgG | IVD | 8595635309656E4 | 49534 |
| SK-HS1M96 | SmartEIA HSV 1 IgM | IVD | 8595635309663DZ | 49534 |
| SK-HS2G96 | SmartEIA HSV 2 IgG | IVD | 8595635309670DW | 49534 |
| SK-HS2M96 | SmartEIA HSV 2 IgM | IVD | 8595635309687EF | 49534 |
| SK-HSVG96 | SmartEIA HSV 1+2 IgG | IVD | 8595635306341CK | 49534 |
| SK-HSVM96 | SmartEIA HSV 1+2 IgM | IVD | 8595635306334CN | 49534 |
| SK-ChA096 | SmartEIA Chlamydia IgA | IVD B | 8595635305764DC | 50720 |
| SK-ChG096 | SmartEIA Chlamydia IgG | IVD B | 8595635305771D9 | 50722 |
| SK-ChM096 | SmartEIA Chlamydia IgM | IVD B | 8595635305788DS | 50724 |
| SK-ChpA96 | SmartEIA Chlamydia pneumoniae IgA | IVD B | 8595635305795DP | 50741 |
| SK-ChpG96 | SmartEIA Chlamydia pneumoniae IgG | IVD B | 8595635305801CR | 50737 |
| SK-ChpM96 | SmartEIA Chlamydia pneumoniae IgM | IVD B | 8595635305818DA | 50733 |
| SK-CpAR96 | SmartEIA Chlamydia pneumoniae REC IgA | IVD B | 8595635305894DS | 50741 |
| SK-CpGR96 | SmartEIA Chlamydia pneumoniae REC IgG | IVD B | 8595635305900CU | 50737 |
| SK-ChtA96 | SmartEIA Chlamydia trachomatis IgA | IVD B | 8595635305863DF | 50773 |
| SK-ChtG96 | SmartEIA Chlamydia trachomatis IgG | IVD B | 8595635305870DC | 50768 |
| SK-ChtM96 | SmartEIA Chlamydia trachomatis IgM | IVD B | 8595635305887DV | 50763 |
| SK-InAA96 | SmartEIA Influenza A IgA | IVD | 8595635308376DL | 49183 |
| SK-InAG96 | SmartEIA Influenza A IgG | IVD | 8595635308369DP | 49178 |
| SK-InAM96 | SmartEIA Influenza A IgM | IVD | 8595635308383DH | 49173 |
| SK-InBA96 | SmartEIA Influenza B IgA | IVD | 8595635308437DF | 49219 |
| SK-InBG96 | SmartEIA Influenza B IgG | IVD | 8595635308420CW | 49214 |
| SK-InBM96 | SmartEIA Influenza B IgM | IVD | 8595635308444DC | 49209 |
| SK-Jo1096 | SmartEIA Jo-1 | IVD | 8595635306310C8 | 55005 |
| SK-MeG096 | SmartEIA Measles IgG | IVD | 8595635307867E5 | 49287 |
| SK-MeM096 | SmartEIA Measles IgM | IVD | 8595635307874E2 | 49280 |
| SK-MiA096 | SmartEIA Milk IgA | IVD | 8595635306426CU | 41410 |
| SK-MiG096 | SmartEIA Milk IgG | IVD | 8595635306433CR | 41410 |
| SK-MiM096 | SmartEIA Milk IgM | IVD | 8595635306440CN | 41410 |
| SK-MuA096 | SmartEIA Mumps IgA | IVD | 8595635307904DJ | 49338 |
| SK-MuG096 | SmartEIA Mumps IgG | IVD | 8595635307911DF | 49338 |
| SK-MuM096 | SmartEIA Mumps IgM | IVD | 8595635307928DY | 49338 |
| SK-MyA096 | SmartEIA Mycoplasma IgA | IVD | 8595635306396DC | 51212 |
| SK-MyG096 | SmartEIA Mycoplasma IgG | IVD | 8595635306402CE | 51207 |
| SK-MyM096 | SmartEIA Mycoplasma IgM | IVD | 8595635306419CX | 51202 |
| SK-MyAR96 | SmartEIA Mycoplasma REC IgA | IVD | 8595635307553DB | 51212 |
| SK-MyGR96 | SmartEIA Mycoplasma REC IgG | IVD | 8595635307560D8 | 51207 |
| SK-MyMR96 | SmartEIA Mycoplasma REC IgM | IVD | 8595635307546DE | 51202 |
| SK-PaiA96 | SmartEIA Parainfluenza mix IgA | IVD | 8595635308499E5 | 49388 |
| SK-PaiG96 | SmartEIA Parainfluenza mix IgG | IVD | 8595635308482DL | 49384 |
| SK-PaiM96 | SmartEIA Parainfluenza mix IgM | IVD | 8595635308505D7 | 49380 |
| SK-PVG096 | SmartEIA Parvovirus B19 IgG | IVD | 8595635310539CB | 50157 |
| SK-PVM096 | SmartEIA Parvovirus B19 IgM | IVD | 8595635310560C2 | 50164 |
| SK-PCG096 | SmartEIA PCP IgG | IVD | 8595635306389DF | 51783 |
| SK-RFA096 | SmartEIA RF IgA | IVD | 8595635306129CK | 55107 |

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|-----------|-----------------------------------|-------|-----------------|-------|
| SK-RFG096 | SmartEIA RF IgG | IVD | 8595635306112C2 | 55107 |
| SK-RFM096 | SmartEIA RF IgM | IVD | 8595635306105C5 | 55107 |
| SK-RSA096 | SmartEIA RSV IgA | IVD | 8595635308918E4 | 49519 |
| SK-RSG096 | SmartEIA RSV IgG | IVD | 8595635308901DK | 49513 |
| SK-RSM096 | SmartEIA RSV IgM | IVD | 8595635308925DZ | 49508 |
| SK-RubG96 | SmartEIA Rubella IgG | IVD B | 8595635306013BX | 50265 |
| SK-RubM96 | SmartEIA Rubella IgM | IVD B | 8595635306006C2 | 50268 |
| SK-Sci096 | SmartEIA Sci-70 | IVD | 8595635306198D6 | 55126 |
| SK-Sm0096 | SmartEIA Sm | IVD | 8595635306181CM | 55160 |
| SK-SSA096 | SmartEIA SS-A | IVD | 8595635306211C5 | 55129 |
| SK-SSB096 | SmartEIA SS-B | IVD | 8595635306204C8 | 55132 |
| SK-TBG096 | SmartEIA TBE Virus IgG | IVD | 8595635306457D7 | 49027 |
| SK-TBM096 | SmartEIA TBE Virus IgM | IVD | 8595635306464D4 | 49023 |
| SK-TeTG96 | SmartEIA Tetanus Toxoid IgG | IVD | 8595635309403D5 | 50874 |
| SK-TcA096 | SmartEIA Toxocara IgA | IVD | 8595635305986DY | 52418 |
| SK-TcG096 | SmartEIA Toxocara IgG | IVD | 8595635305993DV | 52418 |
| SK-TgA096 | SmartEIA Toxoplasma IgA | IVD B | 8595635305856DJ | 52444 |
| SK-TgE096 | SmartEIA Toxoplasma IgE | IVD B | 8595635305849DM | 52444 |
| SK-TgG096 | SmartEIA Toxoplasma IgG | IVD B | 8595635305832D4 | 52444 |
| SK-TgM096 | SmartEIA Toxoplasma IgM | IVD B | 8595635305825D7 | 52444 |
| SK-tTA096 | SmartEIA Transglutaminase IgA | IVD | 8595635306518D2 | 55223 |
| SK-tTG096 | SmartEIA Transglutaminase IgG | IVD | 8595635306525CX | 55223 |
| SK-TpG096 | SmartEIA Treponema pallidum IgG | IVD | 8595635306488DJ | 51804 |
| SK-TpM096 | SmartEIA Treponema pallidum IgM | IVD | 8595635306495DF | 51809 |
| SK-Tp0096 | SmartEIA Treponema pallidum TOTAL | IVD | 8595635306501CH | 51798 |
| SK-RNP096 | SmartEIA U1RNP | IVD | 8595635306242CG | 55165 |
| SK-VZVA96 | SmartEIA VZV IgA | IVD | 8595635306150CA | 49639 |
| SK-VZVG96 | SmartEIA VZV IgG | IVD | 8595635306143CD | 49639 |
| SK-VZVM96 | SmartEIA VZV IgM | IVD | 8595635306136CG | 49639 |
| SK-YeA096 | SmartEIA Yersinia IgA | IVD | 8595635309472DQ | 51900 |
| SK-YeG096 | SmartEIA Yersinia IgG | IVD | 8595635309489E9 | 51904 |
| SK-YeM096 | SmartEIA Yersinia IgM | IVD | 8595635309496E6 | 51912 |

HUMÁNNÍ IMUNOBLLOT SOUPRAVY

| Kat. číslo | Název výrobku | Klasifikace | Základní UDI-DI | Kód GMDN |
|------------|--------------------------------|-------------|-----------------|----------|
| TcGB16 | BLOT Toxocara IgG | IVD | 8595635300684CA | 52421 |
| ANAL20 | BLOT-LINE ANA | IVD | 8595635300790CA | 54810 |
| ApGL10 | BLOT-LINE Anaplasma IgG | IVD | 8595635305153C9 | 51345 |
| ApML10 | BLOT-LINE Anaplasma IgM | IVD | 8595635305146CC | 51341 |
| ANC3L20 | BLOT-LINE ANCA-3 | IVD | 8595635307034CE | 55063 |
| BpAL20 | BLOT-LINE Bordetella IgA | IVD | 8595635304446CL | 50512 |
| BpGL20 | BLOT-LINE Bordetella IgG | IVD | 8595635304453CH | 50512 |
| BpML20 | BLOT-LINE Bordetella IgM | IVD | 8595635305610CG | 50512 |
| BaGL20 | BLOT-LINE Borrelia afzelii IgG | IVD | 8595635301032AY | 50576 |

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|-----------|---|-------|-----------------|-------|
| BaML20 | BLOT-LINE Borrelia afzelii IgM | IVD | 8595635301049BH | 50576 |
| BsGL20 | BLOT-LINE Borrelia b. sensu stricto IgG | IVD | 8595635304187CK | 50555 |
| BsML20 | BLOT-LINE Borrelia b. sensu stricto IgM | IVD | 8595635304194CG | 50555 |
| BgGL20 | BLOT-LINE Borrelia garinii IgG | IVD | 8595635301056BE | 50596 |
| BgML20 | BLOT-LINE Borrelia garinii IgM | IVD | 8595635301063BB | 50600 |
| BGL020 | BLOT-LINE Borrelia/HGA IgG | IVD | 8595635300721BP | 50555 |
| BML020 | BLOT-LINE Borrelia/HGA IgM | IVD | 8595635300738C8 | 50555 |
| CMGL20 | BLOT-LINE CMV IgG | IVD B | 8595635309533DK | 49735 |
| CMML20 | BLOT-LINE CMV IgM | IVD B | 8595635309526DN | 49735 |
| EBAL20 | BLOT-LINE EBV IgA | IVD | 8595635309212CU | 62754 |
| EBGL20 | BLOT-LINE EBV IgG | IVD | 8595635307652DE | 49669 |
| EBML20 | BLOT-LINE EBV IgM | IVD | 8595635307645DH | 49667 |
| HpAL20 | BLOT-LINE Helicobacter IgA | IVD | 8595635306792DQ | 51020 |
| HpGL20 | BLOT-LINE Helicobacter IgG | IVD | 8595635306785DT | 51020 |
| CAL020 | BLOT-LINE Chlamydia IgA | IVD B | 8595635304422C6 | 50720 |
| CGL020 | BLOT-LINE Chlamydia IgG | IVD B | 8595635304439CP | 50722 |
| CpAL20 | BLOT-LINE Chlamydia pneumoniae IgA | IVD B | 8595635304408CC | 50720 |
| CpGL20 | BLOT-LINE Chlamydia pneumoniae IgG | IVD B | 8595635304415C9 | 50722 |
| CpML20 | BLOT-LINE Chlamydia pneumoniae IgM | IVD B | 8595635305184CL | 50748 |
| CtAL20 | BLOT-LINE Chlamydia trachomatis IgA | IVD B | 8595635304033BP | 50792 |
| CtGL20 | BLOT-LINE Chlamydia trachomatis IgG | IVD B | 8595635304040BL | 50792 |
| MyAL20 | BLOT-LINE Mycoplasma IgA | IVD | 8595635308307CZ | 51197 |
| MyGL20 | BLOT-LINE Mycoplasma IgG | IVD | 8595635308314CW | 51197 |
| MyML20 | BLOT-LINE Mycoplasma IgM | IVD | 8595635308321CT | 51197 |
| TgAL20 | BLOT-LINE Toxoplasma IgA | IVD B | 8595635309595E9 | 52458 |
| TgGL20 | BLOT-LINE Toxoplasma IgG | IVD B | 8595635309588EC | 52458 |
| TgML20 | BLOT-LINE Toxoplasma IgM | IVD B | 8595635309571DT | 52458 |
| TpGL20 | BLOT-LINE Treponema IgG | IVD | 8595635301124B6 | 51818 |
| TpML20 | BLOT-LINE Treponema IgM | IVD | 8595635301131B3 | 51818 |
| YAL020 | BLOT-LINE Yersinia IgA | IVD | 8595635307232CL | 51890 |
| YGL020 | BLOT-LINE Yersinia IgG | IVD | 8595635307249D5 | 51890 |
| YML020 | BLOT-LINE Yersinia IgM | IVD | 8595635307256D2 | 51890 |
| BD-BpAL24 | BlueBLOT-LINE Bordetella IgA | IVD | 8595635306860DG | 50512 |
| BD-BpGL24 | BlueBLOT-LINE Bordetella IgG | IVD | 8595635306914DE | 50512 |
| BD-BGL024 | BlueBLOT-LINE Borrelia IgG | IVD | 8595635305214C4 | 50555 |
| BD-BML024 | BlueBLOT-LINE Borrelia IgM | IVD | 8595635305207C7 | 50555 |
| BD-EBGL24 | BlueBLOT-LINE EBV IgG | IVD | 8595635308239D9 | 49669 |
| BD-EBML24 | BlueBLOT-LINE EBV IgM | IVD | 8595635308222CQ | 49667 |
| BD-HpAL24 | BlueBLOT-LINE Helicobacter IgA | IVD | 8595635307812DC | 51020 |
| BD-HpGL24 | BlueBLOT-LINE Helicobacter IgG | IVD | 8595635307805DF | 51020 |
| BD-CAL024 | BlueBLOT-LINE Chlamydia IgA | IVD B | 8595635306815DB | 50720 |
| BD-CGL024 | BlueBLOT-LINE Chlamydia IgG | IVD B | 8595635306846DN | 50722 |
| BD-MyAL24 | BlueBLOT-LINE Mycoplasma IgA | IVD | 8595635309816E2 | 51197 |
| BD-MyGL24 | BlueBLOT-LINE Mycoplasma IgG | IVD | 8595635309823DX | 51197 |
| BD-MyML24 | BlueBLOT-LINE Mycoplasma IgM | IVD | 8595635309830DU | 51197 |

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|-----------|-----------------------------|-----|-----------------|-------|
| BD-TpGL24 | BlueBLOT-LINE Treponema IgG | IVD | 8595635306921DB | 51818 |
| BD-TpML24 | BlueBLOT-LINE Treponema IgM | IVD | 8595635306938DU | 51818 |
| BD-YAL024 | BlueBLOT-LINE Yersinia IgA | IVD | 8595635308291DB | 51890 |
| BD-YGL024 | BlueBLOT-LINE Yersinia IgG | IVD | 8595635308277DH | 51890 |

HUMÁNNÍ MICROBLOT SOUPRAVY

| Kat. číslo | Název výrobku | Klasifikace | Základní UDI-DI | Kód GMDN |
|------------|----------------------------------|-------------|-----------------|----------|
| ANAMA96 | Microblot-Array ANA | IVD | 8595635308079DB | 54810 |
| ANApMA96 | Microblot-Array ANA plus | IVD | 8595635308086D8 | 54810 |
| BpAMA48 | Microblot-Array Bordetella IgA | IVD | 8595635310614BY | 50512 |
| BpGMA48 | Microblot-Array Bordetella IgG | IVD | 8595635310621BV | 50512 |
| BpMMA48 | Microblot-Array Bordetella IgM | IVD | 8595635310638CE | 50512 |
| BGMA096 | Microblot-Array Borrelia IgG | IVD | 8595635306600CL | 50555 |
| BMMA096 | Microblot-Array Borrelia IgM | IVD | 8595635306617D5 | 50555 |
| CMGMA48 | Microblot-Array CMV IgG | IVDR tř. C | 8595635311703C7 | 49718 |
| CMMMA48 | Microblot-Array CMV IgM | IVDR tř. C | 8595635311710C4 | 49728 |
| CoVAMA96 | Microblot-Array COVID-19 IgA | IVD | 8595635309342DA | 64867 |
| CoVGMA96 | Microblot-Array COVID-19 IgG | IVD | 8595635309359DT | 64867 |
| CoVMAA96 | Microblot-Array COVID-19 IgM | IVD | 8595635309366DQ | 64867 |
| EBAMA96 | Microblot-Array EBV IgA | IVD | 8595635308734DQ | 62754 |
| EBGMA96 | Microblot-Array EBV IgG | IVD | 8595635308772DY | 62754 |
| EBMMA96 | Microblot-Array EBV IgM | IVD | 8595635308765E3 | 62754 |
| HpAMA48 | Microblot-Array Helicobacter IgA | IVD | 8595635310577CK | 51020 |
| HpGMA48 | Microblot-Array Helicobacter IgG | IVD | 8595635310584CG | 51020 |
| HSGMA48 | Microblot-Array HSV 1+2 IgG | IVDR tř. C | 8595635311741CF | 49542 |
| HSMMA48 | Microblot-Array HSV 1+2 IgM | IVDR tř. C | 8595635311758CY | 49551 |
| CAMA096 | Microblot-Array Chlamydia IgA | IVD B | 8595635306945DR | 50720 |
| CGMA096 | Microblot-Array Chlamydia IgG | IVD B | 8595635306952DN | 50722 |
| MyAMA48 | Microblot-Array Mycoplasma IgA | IVD | 8595635311284C8 | 51197 |
| MyGMA48 | Microblot-Array Mycoplasma IgG | IVD | 8595635311277CB | 51197 |
| MyMMA48 | Microblot-Array Mycoplasma IgM | IVD | 8595635311321BM | 51197 |
| YAMA048 | Microblot-Array Yersinia IgA | IVD | 8595635310676CN | 51890 |
| YGMA048 | Microblot-Array Yersinia IgG | IVD | 8595635310683CK | 51890 |

ANTIGENY A KOMPONENTY PRO KFR, AGLUTINACI A MIKROAGLUTINACI

| Kat. číslo | Název výrobku | Klasifikace | Základní UDI-DI | Kód GMDN |
|------------|---------------------------------------|-------------|-----------------|----------|
| CMvKF1 | CMV - CF - Ag lyofil. | IVD B | - | 49710 |
| TgKF02 | Toxo - CF - Ag lyophil. (0,2 ml) | IVD B | - | 52448 |
| TgKF05 | Toxo - CF - Ag lyophil. (0,5 ml) | IVD B | - | 52448 |
| Tg-KF1 | Toxo - CF - Ag lyophil. (1 ml) | IVD B | - | 52448 |
| TgKFN2 | Toxo - CF - Negative Control lyophil. | IVD B | - | 52448 |
| TgKFP2 | Toxo - CF - Positive Control lyophil. | IVD B | - | 52448 |

MIKROBIOLOGICKÁ DIAGNOSTIKA

| Kat. číslo | Název výrobku | Klasifikace | Základní UDI-DI | Kód GMDN |
|------------|-----------------|-------------|-------------------|----------|
| Ut0050 | UREASAtest 50 | IVDR tř. A | 859563530ureasaZ9 | 52787 |
| Utb100 | UREASAtest bulk | IVDR tř. A | 859563530ureasaZ9 | 52787 |

SOFTWARE

| Kat. číslo | Název výrobku | Klasifikace | Základní UDI-DI | Kód GMDN |
|------------|---------------------|-------------|-----------------|----------|
| Swlm03 | Immunoblot Software | IVDR tř. A | 8595635311338C6 | 42838 |

PŘÍSTROJE

| Kat. číslo | Název výrobku | Klasifikace | Základní UDI-DI | Kód GMDN |
|------------|-----------------------|-------------|-----------------|----------|
| ARCXIX096 | Array Reader C-series | IVDR tř. A | 8595635311345C3 | 57862 |

V Brně dne 01. 10. 2024



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|---|

Lenka Hanáková

*Vedoucí oddělení kontroly kvality**Jménem společnosti TestLine Clinical Diagnostics s.r.o.*