

Společnost **TestLine Clinical Diagnostics s.r.o.**,

Křižíkova 68, 612 00 Brno, Česká republika,

prohlašuje, že níže uvedené výrobky nejsou považovány za nebezpečné přípravky dle NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY (ES) č. 1272/2008 ze dne 16. prosince 2008 o klasifikaci, označování a balení látek a směsí, o změně a zrušení směrnic 67/548/EHS a 1999/45/ES a o změně nařízení (ES) č. 1907/2006.

V souladu s tímto není pro tyto produkty nutné vypracování bezpečnostního listu.

HUMÁNNÍ CLIA SOUPRAVY

Kat. číslo	Název výrobku	Klasifikace	Kód GMDN
CL-ADP050	CLIA Adiponectin	IVD	43540
CL-BRG100	CLIA Borrelia recombinant IgG	IVD	65420
CL-BRM100	CLIA Borrelia recombinant IgM	IVD	64702
CL-CAGS100	CLIA Campylobacter Ag Stool	IVD	63153
CL-CEN050	CLIA Centromere	IVD	59745
CL-CMA100	CLIA CMV IgA	IVD B	58428
CL-CMG100	CLIA CMV IgG	IVD B	49713
CL-CMM100	CLIA CMV IgM	IVD B	49724
CL-CoNA100	CLIA COVID-19 NP IgA	IVD	65062
CL-CoNG100	CLIA COVID-19 NP IgG	IVD	64760
CL-CoNM100	CLIA COVID-19 NP IgM	IVD	64761
CL-CoRA100	CLIA COVID-19 RBD IgA	IVD	65062
CL-CoRG100	CLIA COVID-19 RBD IgG	IVD	64760
CL-CoRM100	CLIA COVID-19 RBD IgM	IVD	64761
CL-CRP100	CLIA CRP wide-range	IVD	65695
CL-CysC100	CLIA Cystatin C	IVD	62598
CL-DNA050	CLIA dsDNA	IVD	61266
CL-EAG100	CLIA EBV EA-D IgG	IVD	60683
CL-EAM100	CLIA EBV EA-D IgM	IVD	60684
CL-EBG100	CLIA EBV EBNA-1 IgG	IVD	60683
CL-EBM100	CLIA EBV EBNA-1 IgM	IVD	60684
CL-VCA100	CLIA EBV VCA IgA	IVD	66047
CL-VCG100	CLIA EBV VCA IgG	IVD	60683
CL-VCM100	CLIA EBV VCA IgM	IVD	60684
CL-ENA100	CLIA ENA screen plus	IVD	59748
CL-GDA100	CLIA Gliadin DA IgA	IVD	54948
CL-GDG100	CLIA Gliadin DA IgG	IVD	54948
CL-HAgS100	CLIA Helicobacter Ag Stool	IVD	61971
CL-HMA100	CLIA Helicobacter MONO IgA	IVD	65628
CL-HMG100	CLIA Helicobacter MONO IgG	IVD	61971
CL-CPA100	CLIA Chlamydia pneumoniae IgA	IVD B	65361

CL-CPG100	CLIA Chlamydia pneumoniae IgG	IVD B	65362
CL-CPM100	CLIA Chlamydia pneumoniae IgM	IVD B	65363
CL-ChtA100	CLIA Chlamydia trachomatis IgA	IVD B	63332
CL-ChtG100	CLIA Chlamydia trachomatis IgG	IVD B	63328
CL-ChtM100	CLIA Chlamydia trachomatis IgM	IVD B	65360
CL-IL6100	CLIA IL-6	IVD	53858
CL-Jo1050	CLIA Jo-1	IVD	59067
CL-MxA050	CLIA MxA	IVD	65778
CL-PCT100	CLIA Procalcitonin	IVD	58731
CL-RubG100	CLIA Rubella IgG	IVD B	60990
CL-RubM100	CLIA Rubella IgM	IVD B	60991
CL-Scl050	CLIA Scl-70	IVD	59747
CL-Sm0050	CLIA Sm	IVD	59888
CL-SSA050	CLIA SS-A	IVD	59744
CL-Ro5250	CLIA SS-A/Ro52	IVD	59744
CL-Ro6050	CLIA SS-A/Ro60	IVD	59744
CL-SSB050	CLIA SS-B	IVD	61221
CL-TBG100	CLIA TBE Virus IgG	IVD	65639
CL-TBM050	CLIA TBE Virus IgM	IVD	65640
CL-tTA100	CLIA Transglutaminase IgA	IVD	58965
CL-tTG100	CLIA Transglutaminase IgG	IVD	58965
CL-RNP050	CLIA U1RNP	IVD	59857
CL-UMOD050	CLIA Uromodulin	IVD	61293

HUMÁNNÍ CLIA SOUPRAVY – KONTROLNÍ SADA

Kat. číslo	Název výrobku	Klasifikace	Kód GMDN
CL-XXXXCON	Control set CLIA	-	-

HUMÁNNÍ ELISA SOUPRAVY *Platí také pro EIA soupravy ve verzi Smartkit.*

Kat. číslo	Název výrobku	Klasifikace	Kód GMDN
AdA096	EIA Adenovirus IgA	IVD	49867
AdG096	EIA Adenovirus IgG	IVD	49869
AdM096	EIA Adenovirus IgM	IVD	49872
ScA096	EIA ASCA IgA	IVD	52100
ScG096	EIA ASCA IgG	IVD	52108
BppA96	EIA Bordetella parapertussis IgA	IVD	50512
BppG96	EIA Bordetella parapertussis IgG	IVD	50512
BppM96	EIA Bordetella parapertussis IgM	IVD	50512
BpAT96	EIA Bordetella pertussis Toxin IgA	IVD	50517
BpGT96	EIA Bordetella pertussis Toxin IgG	IVD	50521
BpMT96	EIA Bordetella pertussis Toxin IgM	IVD	50525
BaM192	EIA Borrelia afzelii IgM (192)	IVD	50585
BaGVD2	EIA Borrelia afzelii VlsE IgG (192)	IVD	50581
BsM096	EIA Borrelia b. sensu stricto IgM	IVD	50564
BsGV96	EIA Borrelia b. sensu stricto VlsE IgG	IVD	50560
BgM192	EIA Borrelia garinii IgM (192)	IVD	50597

BgGVD2	EIA Borrelia garinii VlsE IgG (192)	IVD	50593
BM0096	EIA Borrelia IgM	IVD	50564
BrG192	EIA Borrelia recombinant IgG (192)	IVD	50560
BrM192	EIA Borrelia recombinant IgM (192)	IVD	50564
BGV096	EIA Borrelia VlsE IgG	IVD	50560
CCPA96	EIA CCP IgA	IVD	54896
CCPG96	EIA CCP IgG	IVD	54896
CEN096	EIA Centromere	IVD	54886
CMA096	EIA CMV IgA	IVD B	49729
CMG096	EIA CMV IgG	IVD B	49729
CMM096	EIA CMV IgM	IVD B	49729
CoNA96	EIA COVID-19 NP IgA	IVD	64830
CoNG96	EIA COVID-19 NP IgG	IVD	64824
CoNM96	EIA COVID-19 NP IgM	IVD	64800
CoRA96	EIA COVID-19 RBD IgA	IVD	64830
CoRG96	EIA COVID-19 RBD IgG	IVD	64824
CoRM96	EIA COVID-19 RBD IgM	IVD	64800
DNA096	EIA dsDNA	IVD	54902
EAG096	EIA EBV EA-D IgG	IVD	49682
EAM096	EIA EBV EA-D IgM	IVD	49682
EBG096	EIA EBV EBNA-1 IgG	IVD	49677
EBM096	EIA EBV EBNA-1 IgM	IVD	49677
VCA096	EIA EBV VCA IgA	IVD	49657
VCG096	EIA EBV VCA IgG	IVD	49657
VCM096	EIA EBV VCA IgM	IVD	49657
ENA012	EIA ENA profile	IVD	54823
ENAp12	EIA ENA profile plus	IVD	54823
ENA096	EIA ENA screen plus	IVD	54823
GDA096	EIA Gliadin DA IgA	IVD	54947
GDG096	EIA Gliadin DA IgG	IVD	54947
GIA096	EIA Gliadin IgA	IVD	54947
GIG096	EIA Gliadin IgG	IVD	54947
HMA096	EIA Helicobacter MONO IgA	IVD	51004
HMG096	EIA Helicobacter MONO IgG	IVD	51008
HMM096	EIA Helicobacter MONO IgM	IVD	51012
HS1G96	EIA HSV 1 IgG	IVD	49534
HS1M96	EIA HSV 1 IgM	IVD	49534
HS2G96	EIA HSV 2 IgG	IVD	49534
HS2M96	EIA HSV 2 IgM	IVD	49534
HSVG96	EIA HSV 1+2 IgG	IVD	49534
HSVM96	EIA HSV 1+2 IgM	IVD	49534
ChA096	EIA Chlamydia IgA	IVD B	50720
ChG096	EIA Chlamydia IgG	IVD B	50722
ChM096	EIA Chlamydia IgM	IVD B	50724
ChpA96	EIA Chlamydia pneumoniae IgA	IVD B	50741

ChpG96	EIA Chlamydia pneumoniae IgG	IVD B	50737
ChpM96	EIA Chlamydia pneumoniae IgM	IVD B	50733
CpAR96	EIA Chlamydia pneumoniae REC IgA	IVD B	50741
CpGR96	EIA Chlamydia pneumoniae REC IgG	IVD B	50737
ChtA96	EIA Chlamydia trachomatis IgA	IVD B	50773
ChtG96	EIA Chlamydia trachomatis IgG	IVD B	50768
ChtM96	EIA Chlamydia trachomatis IgM	IVD B	50763
InAA96	EIA Influenza A IgA	IVD	49183
InAG96	EIA Influenza A IgG	IVD	49178
InAM96	EIA Influenza A IgM	IVD	49173
InBA96	EIA Influenza B IgA	IVD	49219
InBG96	EIA Influenza B IgG	IVD	49214
InBM96	EIA Influenza B IgM	IVD	49209
Jo1096	EIA Jo-1	IVD	55005
MeG096	EIA Measles IgG	IVD	49287
MeM096	EIA Measles IgM	IVD	49280
MiA096	EIA Milk IgA	IVD	41410
MiG096	EIA Milk IgG	IVD	41410
MiM096	EIA Milk IgM	IVD	41410
MuA096	EIA Mumps IgA	IVD	49338
MuG096	EIA Mumps IgG	IVD	49338
MuM096	EIA Mumps IgM	IVD	49338
MyA096	EIA Mycoplasma IgA	IVD	51212
MyG096	EIA Mycoplasma IgG	IVD	51207
MyM096	EIA Mycoplasma IgM	IVD	51202
MyAR96	EIA Mycoplasma REC IgA	IVD	51212
MyGR96	EIA Mycoplasma REC IgG	IVD	51207
MyMR96	EIA Mycoplasma REC IgM	IVD	51202
PaiA96	EIA Parainfluenza mix IgA	IVD	49388
PaiG96	EIA Parainfluenza mix IgG	IVD	49384
PaiM96	EIA Parainfluenza mix IgM	IVD	49380
PVG096	EIA Parvovirus B19 IgG	IVD	50157
PVM096	EIA Parvovirus B19 IgM	IVD	50164
PCG096	EIA PCP IgG	IVD	51783
RFA096	EIA RF IgA	IVD	55107
RFG096	EIA RF IgG	IVD	55107
RFM096	EIA RF IgM	IVD	55107
RF0096	EIA RF screen	IVD	54845
RSA096	EIA RSV IgA	IVD	49519
RSG096	EIA RSV IgG	IVD	49513
RSM096	EIA RSV IgM	IVD	49508
RubG96	EIA Rubella IgG	IVD B	50265
RubM96	EIA Rubella IgM	IVD B	50268
Scl096	EIA Scl-70	IVD	55126
Sm0096	EIA Sm	IVD	55160

SSA096	EIA SS-A	IVD	55129
Ro5296	EIA SS-A/Ro52	IVD	55129
Ro6096	EIA SS-A/Ro60	IVD	55129
SSB096	EIA SS-B	IVD	55132
TBG096	EIA TBE Virus IgG	IVD	49027
TBM096	EIA TBE Virus IgM	IVD	49023
TBE096	EIA TBEV Ig	IVD	49031
TeTG96	EIA Tetanus Toxoid IgG	IVD	50874
Tg0096	EIA Thyroglobulin IgG	IVD	54372
TPOx96	EIA Thyroid Peroxidase IgG	IVD	55203
TcA096	EIA Toxocara IgA	IVD	52418
TcG096	EIA Toxocara IgG	IVD	52418
TgA096	EIA Toxoplasma IgA	IVD B	52444
TgE096	EIA Toxoplasma IgE	IVD B	52444
TgG096	EIA Toxoplasma IgG	IVD B	52444
TgM096	EIA Toxoplasma IgM	IVD B	52444
tTA096	EIA Transglutaminase IgA	IVD	55223
tTG096	EIA Transglutaminase IgG	IVD	55223
TpG096	EIA Treponema pallidum IgG	IVD	51804
TpM096	EIA Treponema pallidum IgM	IVD	51809
Tp0096	EIA Treponema pallidum TOTAL	IVD	51798
RNP096	EIA U1RNP	IVD	55165
VZVA96	EIA VZV IgA	IVD	49639
VZVG96	EIA VZV IgG	IVD	49639
VZVM96	EIA VZV IgM	IVD	49639
YeA096	EIA Yersinia IgA	IVD	51900
YeG096	EIA Yersinia IgG	IVD	51904
YeM096	EIA Yersinia IgM	IVD	51912

HUMÁNNÍ IMUNOBLOT SOUPRAVY

Kat. číslo	Název výrobku	Klasifikace	Kód GMDN
TcGB16	BLOT Toxocara IgG	IVD	52421
ANAL20	BLOT-LINE ANA	IVD	54810
ApGL10	BLOT-LINE Anaplasma IgG	IVD	51345
ApML10	BLOT-LINE Anaplasma IgM	IVD	51341
ANC3L20	BLOT-LINE ANCA-3	IVD	55063
BpAL20	BLOT-LINE Bordetella IgA	IVD	50512
BpGL20	BLOT-LINE Bordetella IgG	IVD	50512
BpML20	BLOT-LINE Bordetella IgM	IVD	50512
BaGL20	BLOT-LINE Borrelia afzelii IgG	IVD	50555
BaML20	BLOT-LINE Borrelia afzelii IgM	IVD	50555
BsGL20	BLOT-LINE Borrelia b. sensu stricto IgG	IVD	50555
BsML20	BLOT-LINE Borrelia b. sensu stricto IgM	IVD	50555
BgGL20	BLOT-LINE Borrelia garinii IgG	IVD	50555
BgML20	BLOT-LINE Borrelia garinii IgM	IVD	50555
BGL020	BLOT-LINE Borrelia/HGA IgG	IVD	50555

BML020	BLOT-LINE Borrelia/HGA IgM	IVD	50555
CMGL20	BLOT-LINE CMV IgG	IVD B	49735
CMML20	BLOT-LINE CMV IgM	IVD B	49735
EBAL20	BLOT-LINE EBV IgA	IVD	62754
EBGL20	BLOT-LINE EBV IgG	IVD	49669
EBML20	BLOT-LINE EBV IgM	IVD	49667
ENAL20	BLOT-LINE ENA plus	IVD	54824
HpAL20	BLOT-LINE Helicobacter IgA	IVD	51020
HpGL20	BLOT-LINE Helicobacter IgG	IVD	51020
CAL020	BLOT-LINE Chlamydia IgA	IVD B	50720
CGL020	BLOT-LINE Chlamydia IgG	IVD B	50722
CpAL20	BLOT-LINE Chlamydia pneumoniae IgA	IVD B	50720
CpGL20	BLOT-LINE Chlamydia pneumoniae IgG	IVD B	50722
CpML20	BLOT-LINE Chlamydia pneumoniae IgM	IVD B	50748
CtAL20	BLOT-LINE Chlamydia trachomatis IgA	IVD B	50792
CtGL20	BLOT-LINE Chlamydia trachomatis IgG	IVD B	50792
MyAL20	BLOT-LINE Mycoplasma IgA	IVD	51197
MyGL20	BLOT-LINE Mycoplasma IgG	IVD	51197
MyML20	BLOT-LINE Mycoplasma IgM	IVD	51197
TgAL20	BLOT-LINE Toxoplasma IgA	IVD B	52458
TgGL20	BLOT-LINE Toxoplasma IgG	IVD B	52458
TgML20	BLOT-LINE Toxoplasma IgM	IVD B	52458
TpGL20	BLOT-LINE Treponema IgG	IVD	51818
TpML20	BLOT-LINE Treponema IgM	IVD	51818
YAL020	BLOT-LINE Yersinia IgA	IVD	51890
YGL020	BLOT-LINE Yersinia IgG	IVD	51890
YML020	BLOT-LINE Yersinia IgM	IVD	51890
BD-BpAL24	BlueBLOT-LINE Bordetella IgA	IVD	50512
BD-BpGL24	BlueBLOT-LINE Bordetella IgG	IVD	50512
BD-BGL024	BlueBLOT-LINE Borrelia IgG	IVD	50555
BD-BML024	BlueBLOT-LINE Borrelia IgM	IVD	50555
BD-EBGL24	BlueBLOT-LINE EBV IgG	IVD	49669
BD-EBML24	BlueBLOT-LINE EBV IgM	IVD	49667
BD-HpAL24	BlueBLOT-LINE Helicobacter IgA	IVD	51020
BD-HpGL24	BlueBLOT-LINE Helicobacter IgG	IVD	51020
BD-CAL024	BlueBLOT-LINE Chlamydia IgA	IVD B	50720
BD-CGL024	BlueBLOT-LINE Chlamydia IgG	IVD B	50722
BD-MyAL24	BlueBLOT-LINE Mycoplasma IgA	IVD	51197
BD-MyGL24	BlueBLOT-LINE Mycoplasma IgG	IVD	51197
BD-MyML24	BlueBLOT-LINE Mycoplasma IgM	IVD	51197
BD-TpGL24	BlueBLOT-LINE Treponema IgG	IVD	51818
BD-TpML24	BlueBLOT-LINE Treponema IgM	IVD	51818
BD-YAL024	BlueBLOT-LINE Yersinia IgA	IVD	51890
BD-YGL024	BlueBLOT-LINE Yersinia IgG	IVD	51890

HUMÁNNÍ MICROBLLOT SOUPRAVY

Kat. číslo	Název výrobku	Klasifikace	Kód GMDN
ANAMA96	Microblot-Array ANA	IVD	54810
ANApMA96	Microblot-Array ANA plus	IVD	54810
BpAMA48	Microblot-Array Bordetella IgA	IVD	50512
BpGMA48	Microblot-Array Bordetella IgG	IVD	50512
BpMMA48	Microblot-Array Bordetella IgM	IVD	50512
BGMA096	Microblot-Array Borrelia IgG	IVD	50555
BMMA096	Microblot-Array Borrelia IgM	IVD	50555
CoVAMA96	Microblot-Array COVID-19 IgA	IVD	64867
CoVGMA96	Microblot-Array COVID-19 IgG	IVD	64867
CoVMMA96	Microblot-Array COVID-19 IgM	IVD	64867
EBAMA96	Microblot-Array EBV IgA	IVD	62754
EBGMA96	Microblot-Array EBV IgG	IVD	62754
EBMMA96	Microblot-Array EBV IgM	IVD	62754
HpAMA48	Microblot-Array Helicobacter IgA	IVD	51020
HpGMA48	Microblot-Array Helicobacter IgG	IVD	51020
CAMA096	Microblot-Array Chlamydia IgA	IVD B	50720
CGMA096	Microblot-Array Chlamydia IgG	IVD B	50722
MyAMA48	Microblot-Array Mycoplasma IgA	IVD	51197
MyGMA48	Microblot-Array Mycoplasma IgG	IVD	51197
MyMMA48	Microblot-Array Mycoplasma IgM	IVD	51197
YAMA048	Microblot-Array Yersinia IgA	IVD	51890
YGMA048	Microblot-Array Yersinia IgG	IVD	51890

VETERINÁRNÍ ELISA SOUPRAVY

Kat. číslo	Název výrobku	Klasifikace	Kód GMDN
AD0480	AD Ab ELISA	-	-
BHd480	BHV-1 Ab ELISA	-	-
BVD480	BVD-MD IgG ELISA	-	-
DBGM96	Dog EIA Borrelia IgG/IgM	-	-
EBL480	EBLV Ab ELISA	-	-
IBR192	IBR-gB ELISA (192)	-	-
IPN096	IPNV Ag ELISA	-	-
PTB480	PTB Ab ELISA 480	-	-
SVC096	SVCV Ag ELISA	-	-
VHS096	VHSV Ag ELISA	-	-

ANTIGENY A KOMPONENTY PRO KFR, AGLUTINACI A MIKROAGLUTINACI

Kat. číslo	Název výrobku	Klasifikace	Kód GMDN
Bp0500	Barbital buffer for CF – 5× conc.	RUO*	-
BppAg5	Bordetella parapertussis-AR-Ag	IVD	50511
BppP01	Bordetella parapertussis-AR-Positive Control lyophil.	IVD	50511
BpeAg5	Bordetella pertussis-AR-Ag	IVD	50511
BpeP01	Bordetella pertussis-AR-Positive Control lyophil.	IVD	50511
KFAs00	CF - AMBOCEPTORset (0,5 ml)	RUO*	-

KFAs01	CF - AMBOCEPTORset (1ml)	RUO*	-
KFC001	CF - COMPLEMENT (1ml)	RUO*	-
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	Kód GMDN
Hs0050	HIPPUstrip	RUO*	-
Is0100	INDOXYLstrip	RUO*	-
LM0020	LEPTOSPIRA-MEDIUM	RUO*	-
Lmb100	LEPTOSPIRA-MEDIUM BULK	IVD	51112
LMm020	LEPTOSPIRA-MEDIUM MEDIKOVANÉ	IVD	51112
Os0100	OXIstrip	RUO*	-
Ps0050	PYRstrip	RUO*	-
Ts0300	TRIBUstrip	RUO*	-
Ut0050	UREASAtest 50	IVDR tř. A	52787
Utb100	UREASAtest bulk	IVDR tř. A	52787
BLs100	β-LACTAstrip	IVD	58599

KOMPONENTY A SPOTŘEBNÍ MATERIÁL

Kat. číslo	Název výrobku	Klasifikace	Kód GMDN
rp0090	Dilution buffer for GIEMSA	IVD	41750
RFs010	RF - sorb (10 ml)	RUO*	-
RFs002	RF - sorb (2 ml)	IVD	54848

CERTIFIKOVANÁ KONTROLNÍ SÉRA

Kat. číslo	Název výrobku	Klasifikace	Kód GMDN
CKSTLX	CERTIFIED CONTROL SERUMTLX	IVD	53754
CKSTLX	CERTIFIED CONTROL SERUMTLX	IVD B	53754

SOUPRAVY PRO IMUNOLOGII

Kat. číslo	Název výrobku	Klasifikace	Kód GMDN
RIDCIP	RID CIC Profiling kit (5x32)	RUO*	-
CIK240	TA Immunocomplex	RUO*	-

* pro produkty zakoupené do 26. 5. 2022 platí klasifikace IVD

V Brně dne 11. 8. 2022



Ing. Petr Dobrovolný

Osoba odborně způsobilá k nakládání s nebezpečnými chemickými látkami