

We, **TestLine Clinical Diagnostics s.r.o.** (manufacturer),

Křižíkova 68, 612 00 Brno, Czech Republic,

hereby declare on our own responsibility that the below in vitro diagnostic medical devices meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices which apply to them.

Conformity assessment procedure:

General IVDs Directive 98/79/EC, Annex III

Annex II List B IVDs Directive 98/79/EC, Annex IV (Full QA System)

HUMAN CLIA KITS

Cat. number	Product name	Classification	GMDN code
CL-BRG100	CLIA Borrelia recombinant IgG	General IVD	65420
CL-BRM100	CLIA Borrelia recombinant IgM	General IVD	64702
CL-CoNA100	CLIA COVID-19 NP IgA	General IVD	65062
CL-CoNG100	CLIA COVID-19 NP IgG	General IVD	64760
CL-CoNM100	CLIA COVID-19 NP IgM	General IVD	64761
CL-CoRA100	CLIA COVID-19 RBD IgA	General IVD	65062
CL-CoRG100	CLIA COVID-19 RBD IgG	General IVD	64760
CL-CoRM100	CLIA COVID-19 RBD IgM	General IVD	64761
CL-TBG100	CLIA TBE Virus IgG	General IVD	65639
CL-TBM050	CLIA TBE Virus IgM	General IVD	65640

HUMAN ELISA KITS

This is also valid for EIA kits version Smartkit.

Cat. number	Product name	Classification	GMDN code
AdA096	EIA Adenovirus IgA	General IVD	49867
AdG096	EIA Adenovirus IgG	General IVD	49869
AdM096	EIA Adenovirus IgM	General IVD	49872
ScA096	EIA ASCA IgA	General IVD	52100
ScG096	EIA ASCA IgG	General IVD	52108
BppA96	EIA Bordetella parapertussis IgA	General IVD	50512
BppG96	EIA Bordetella parapertussis IgG	General IVD	50512
BppM96	EIA Bordetella parapertussis IgM	General IVD	50512
BpAT96	EIA Bordetella pertussis Toxin IgA	General IVD	50517
BpGT96	EIA Bordetella pertussis Toxin IgG	General IVD	50521
BpMT96	EIA Bordetella pertussis Toxin IgM	General IVD	50525
BaM192	EIA Borrelia afzelii IgM (192)	General IVD	50585
BaGVD2	EIA Borrelia afzelii VlsE IgG (192)	General IVD	50581
BgM192	EIA Borrelia garinii IgM (192)	General IVD	50597
BgGVD2	EIA Borrelia garinii VlsE IgG (192)	General IVD	50593

BM0096	EIA Borrelia IgM	General IVD	50564
BrG192	EIA Borrelia recombinant IgG (192)	General IVD	50560
BrM192	EIA Borrelia recombinant IgM (192)	General IVD	50564
BGV096	EIA Borrelia VlsE IgG	General IVD	50560
CCPA96	EIA CCP IgA	General IVD	54896
CCPG96	EIA CCP IgG	General IVD	54896
CEN096	EIA Centromere	General IVD	54886
CMA096	EIA CMV IgA	Annex II, List B	49729
CMG096	EIA CMV IgG	Annex II, List B	49729
CMM096	EIA CMV IgM	Annex II, List B	49729
CoNA96	EIA COVID-19 NP IgA	General IVD	64830
CoNG96	EIA COVID-19 NP IgG	General IVD	64824
CoNM96	EIA COVID-19 NP IgM	General IVD	64800
CoRA96	EIA COVID-19 RBD IgA	General IVD	64830
CoRG96	EIA COVID-19 RBD IgG	General IVD	64824
CoRM96	EIA COVID-19 RBD IgM	General IVD	64800
DNA096	EIA dsDNA	General IVD	54902
EAG096	EIA EBV EA-D IgG	General IVD	49682
EAM096	EIA EBV EA-D IgM	General IVD	49682
EBG096	EIA EBV EBNA-1 IgG	General IVD	49677
EBM096	EIA EBV EBNA-1 IgM	General IVD	49677
VCA096	EIA EBV VCA IgA	General IVD	49657
VCG096	EIA EBV VCA IgG	General IVD	49657
VCM096	EIA EBV VCA IgM	General IVD	49657
ENA012	EIA ENA profile	General IVD	54823
ENAp12	EIA ENA profile plus	General IVD	54823
ENA096	EIA ENA screen plus	General IVD	54823
GDA096	EIA Gliadin DA IgA	General IVD	54947
GDG096	EIA Gliadin DA IgG	General IVD	54947
GIA096	EIA Gliadin IgA	General IVD	54947
GIG096	EIA Gliadin IgG	General IVD	54947
HMA096	EIA Helicobacter MONO IgA	General IVD	51004
HMG096	EIA Helicobacter MONO IgG	General IVD	51008
HMM096	EIA Helicobacter MONO IgM	General IVD	51012
HS1G96	EIA HSV 1 IgG	General IVD	49534
HS1M96	EIA HSV 1 IgM	General IVD	49534
HS2G96	EIA HSV 2 IgG	General IVD	49534
HS2M96	EIA HSV 2 IgM	General IVD	49534
HSVG96	EIA HSV 1+2 IgG	General IVD	49534
HSVM96	EIA HSV 1+2 IgM	General IVD	49534
ChA096	EIA Chlamydia IgA	Annex II, List B	50720
ChG096	EIA Chlamydia IgG	Annex II, List B	50722
ChM096	EIA Chlamydia IgM	Annex II, List B	50724
ChpA96	EIA Chlamydia pneumoniae IgA	Annex II, List B	50741
ChpG96	EIA Chlamydia pneumoniae IgG	Annex II, List B	50737

ChpM96	EIA Chlamydia pneumoniae IgM	Annex II, List B	50733
CpAR96	EIA Chlamydia pneumoniae REC IgA	Annex II, List B	50741
CpGR96	EIA Chlamydia pneumoniae REC IgG	Annex II, List B	50737
ChtA96	EIA Chlamydia trachomatis IgA	Annex II, List B	50773
ChtG96	EIA Chlamydia trachomatis IgG	Annex II, List B	50768
ChtM96	EIA Chlamydia trachomatis IgM	Annex II, List B	50763
InAA96	EIA Influenza A IgA	General IVD	49183
InAG96	EIA Influenza A IgG	General IVD	49178
InAM96	EIA Influenza A IgM	General IVD	49173
InBA96	EIA Influenza B IgA	General IVD	49219
InBG96	EIA Influenza B IgG	General IVD	49214
InBM96	EIA Influenza B IgM	General IVD	49209
Jo1096	EIA Jo-1	General IVD	55005
MeG096	EIA Measles IgG	General IVD	49287
MeM096	EIA Measles IgM	General IVD	49280
MiA096	EIA Milk IgA	General IVD	41410
MiG096	EIA Milk IgG	General IVD	41410
MiM096	EIA Milk IgM	General IVD	41410
MuA096	EIA Mumps IgA	General IVD	49338
MuG096	EIA Mumps IgG	General IVD	49338
MuM096	EIA Mumps IgM	General IVD	49338
MyA096	EIA Mycoplasma IgA	General IVD	51212
MyG096	EIA Mycoplasma IgG	General IVD	51207
MyM096	EIA Mycoplasma IgM	General IVD	51202
MyAR96	EIA Mycoplasma REC IgA	General IVD	51212
MyGR96	EIA Mycoplasma REC IgG	General IVD	51207
MyMR96	EIA Mycoplasma REC IgM	General IVD	51202
PaiA96	EIA Parainfluenza mix IgA	General IVD	49388
PaiG96	EIA Parainfluenza mix IgG	General IVD	49384
PaiM96	EIA Parainfluenza mix IgM	General IVD	49380
PCG096	EIA PCP IgG	General IVD	51783
RFA096	EIA RF IgA	General IVD	55107
RFG096	EIA RF IgG	General IVD	55107
RFM096	EIA RF IgM	General IVD	55107
RF0096	EIA RF screen	General IVD	54845
RSA096	EIA RSV IgA	General IVD	49519
RSG096	EIA RSV IgG	General IVD	49513
RSM096	EIA RSV IgM	General IVD	49508
RubG96	EIA Rubella IgG	Annex II, List B	50265
RubM96	EIA Rubella IgM	Annex II, List B	50268
Scl096	EIA Scl-70	General IVD	55126
Sm0096	EIA Sm	General IVD	55160
SSA096	EIA SS-A	General IVD	55129
Ro5296	EIA SS-A/Ro52	General IVD	55129
Ro6096	EIA SS-A/Ro60	General IVD	55129

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

HUMAN IMUNOBLOT KITS

Cat. number	Product name	Classification	GMDN code
TcGB16	BLOT Toxocara IgG	General IVD	52421
ANAL20	BLOT-LINE ANA	General IVD	54810
ApGL10	BLOT-LINE Anaplasma IgG	General IVD	51345
ApML10	BLOT-LINE Anaplasma IgM	General IVD	51341
ANC3L20	BLOT-LINE ANCA-3	General IVD	55063
BpAL20	BLOT-LINE Bordetella IgA	General IVD	50512
BpGL20	BLOT-LINE Bordetella IgG	General IVD	50512
BpML20	BLOT-LINE Bordetella IgM	General IVD	50512
BaGL20	BLOT-LINE Borrelia afzelii IgG	General IVD	50555
BaML20	BLOT-LINE Borrelia afzelii IgM	General IVD	50555
BsGL20	BLOT-LINE Borrelia b. sensu stricto IgG	General IVD	50555
BsML20	BLOT-LINE Borrelia b. sensu stricto IgM	General IVD	50555
BgGL20	BLOT-LINE Borrelia garinii IgG	General IVD	50555
BgML20	BLOT-LINE Borrelia garinii IgM	General IVD	50555
BGL020	BLOT-LINE Borrelia/HGA IgG	General IVD	50555
BML020	BLOT-LINE Borrelia/HGA IgM	General IVD	50555
CMGL20	BLOT-LINE CMV IgG	Annex II, List B	49735
CMML20	BLOT-LINE CMV IgM	Annex II, List B	49735

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

HUMAN MICROBLLOT KITS

Cat. number	Product name	Classification	GMDN code
ANAMA96	Microblot-Array ANA	General IVD	54810
ANApMA96	Microblot-Array ANA plus	General IVD	54810

BaGMA96	Microblot-Array Borrelia afzelii IgG	General IVD	50555
BaMMA96	Microblot-Array Borrelia afzelii IgM	General IVD	50555
BsGMA96	Microblot-Array Borrelia b. sensu stricto IgG	General IVD	50555
BsMMA96	Microblot-Array Borrelia b. sensu stricto IgM	General IVD	50555
BgGMA96	Microblot-Array Borrelia garinii IgG	General IVD	50555
BgMMA96	Microblot-Array Borrelia garinii IgM	General IVD	50555
BGMA096	Microblot-Array Borrelia IgG	General IVD	50555
BMMA096	Microblot-Array Borrelia IgM	General IVD	50555
CoVAMA96	Microblot-Array COVID-19 IgA	General IVD	64867
CoVGMA96	Microblot-Array COVID-19 IgG	General IVD	64867
CoVMMA96	Microblot-Array COVID-19 IgM	General IVD	64867
EBAMA96	Microblot-Array EBV IgA	General IVD	62754
EBGMA96	Microblot-Array EBV IgG	General IVD	62754
EBMMA96	Microblot-Array EBV IgM	General IVD	62754
CAMA096	Microblot-Array Chlamydia IgA	Annex II, List B	50720
CGMA096	Microblot-Array Chlamydia IgG	Annex II, List B	50722

ANTIGENS AND COMPONENTS FOR CFR, AGGLUTINATION AND MICROAGGLUTINATION

Cat. number	Product name	Classification	GMDN code
Bp0500	Barbital buffer for CF – 5× conc.	General IVD	58208
BppAg5	Bordetella parapertussis-AR-Ag	General IVD	50511
BppP01	Bordetella parapertussis-AR-Positive Control lyophil.	General IVD	50511
BpeAg5	Bordetella pertussis-AR-Ag	General IVD	50511
BpeP01	Bordetella pertussis-AR-Positive Control lyophil.	General IVD	50511
KFAs00	CF - AMBOCEPTORset (0,5 ml)	General IVD	52448
KFAs01	CF - AMBOCEPTORset (1ml)	General IVD	52448
KFC001	CF - COMPLEMENT (1ml)	General IVD	58366
CMvKF1	CMV - CF - Ag lyofil.	Annex II, List B	49710
TgKF02	Toxo - CF - Ag lyophil. (0.2 ml)	Annex II, List B	52448
TgKF05	Toxo - CF - Ag lyophil. (0.5 ml)	Annex II, List B	52448
Tg-KF1	Toxo - CF - Ag lyophil. (1 ml)	Annex II, List B	52448
TgKFN2	Toxo - CF - Negative Control lyophil.	Annex II, List B	52448
TgKFP2	Toxo - CF - Positive Control lyophil.	Annex II, List B	52448

TESTS FOR BACTERIOLOGY

Cat. number	Product name	Classification	GMDN code
Hs0050	HIPPUstrip	General IVD	51747
Is0100	INDOXYLstrip	General IVD	56773
LM0020	LEPTOSPIRA-MEDIUM	General IVD	51112
LMb100	LEPTOSPIRA-MEDIUM BULK	General IVD	51112
LMm020	LEPTOSPIRA-MEDIUM MEDIKOVANÉ	General IVD	51112
Os0100	OXLstrip	General IVD	50423
Ps0050	PYRstrip	General IVD	58597
Ts0300	TRIBUstrip	General IVD	50423
Ut0050	UREASAtest 50	General IVD	52787

BLs100	β-LACTAstrip	General IVD	58599
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COMPONENTS AND CONSUMABLE

Cat. number	Product name	Classification	GMDN code
rp0090	Dilution buffer for GIEMSA	General IVD	41750
Gi00L1	GIEMSA - 10x. conc. solution	General IVD	41750
Gir0L1	GIEMSA-ready	General IVD	41750
Gs0000	GRAM – kompletní sada roztoků	General IVD	41750
RFs010	RF - sorb (10 ml)	General IVD	54848
RFs002	RF - sorb (2 ml)	General IVD	54848

KITS FOR IMMUNOLOGY

Cat. number	Product name	Classification	GMDN code
RIDCIP	RID CIC Profiling kit (5x32)	General IVD	54894
CIK240	TA Immunocomplex	General IVD	54894

SOFTWARE

Cat. number	Product name	Classification	GMDN code
SwAI01	Antibody index - software	General IVD	42838
SwIm03	Immunoblot Software	General IVD	42838

INSTRUMENTS

Cat. number	Product name	Classification	GMDN code
ARCXIX096	Array Reader C-series	General IVD	57862

Brno, 09/08/2021



Lenka Hanáková

Quality Manager