

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

Křížíkova 68, 612 00 Brno, Czech Republic, SRN: CZ-MF-000001803

hereby declare on our own responsibility that the below in vitro diagnostic medical devices meet the provisions of the Directive 98/79/EC or Regulation 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices which apply to them. The EU declaration of conformity is issued under the sole responsibility of the manufacturer for the use of competent authorities, customers and economic operators.

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)
IVDR class A	Regulation (EU) 2017/746 (IVDR), TD following Annexes II and III, Declaration of conformity following Annex IV, CE marking following Annex V
IVDR class C	Regulation (EU) 2017/746 (IVDR), TD following Annex IX, Declaration of conformity following Annex IV, CE marking following Annex V

HUMAN CLIA KITS

Cat. number	Product name	Classification	Basic UDI-DI	GMDN code
CL-ADP050	CLIA Adiponectin	General IVD	-	43540
CL-BRG100	CLIA Borrelia recombinant IgG	General IVD	-	65420
CL-BRM100	CLIA Borrelia recombinant IgM	General IVD	-	64702
CL-CAGS100	CLIA Campylobacter Ag Stool	General IVD	-	63153
CL-CEN050	CLIA Centromere	General IVD	-	59745
CL-CMA100	CLIA CMV IgA	Annex II, List B	-	58428
CL-CMG100	CLIA CMV IgG	Annex II, List B	-	49713
CL-CMM100	CLIA CMV IgM	Annex II, List B	-	49724
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-CRP100	CLIA CRP wide-range	General IVD	-	65695
CL-CysC100	CLIA Cystatin C	General IVD	-	62598
CL-DNA050	CLIA dsDNA	General IVD	-	61266
CL-EAG100	CLIA EBV EA-D IgG	General IVD	-	60683
CL-EAM100	CLIA EBV EA-D IgM	General IVD	-	60684
CL-EBG100	CLIA EBV EBNA-1 IgG	General IVD	-	60683
CL-EBM100	CLIA EBV EBNA-1 IgM	General IVD	-	60684
CL-VCA100	CLIA EBV VCA IgA	General IVD	-	66047
CL-VCG100	CLIA EBV VCA IgG	General IVD	-	60683
CL-VCM100	CLIA EBV VCA IgM	General IVD	-	60684
CL-ENA100	CLIA ENA screen plus	General IVD	-	59748

CL-GDA100	CLIA Gliadin DA IgA	General IVD	-	54948
CL-GDG100	CLIA Gliadin DA IgG	General IVD	-	54948
CL-HAgS100	CLIA Helicobacter Ag Stool	General IVD	-	61971
CL-HMA100	CLIA Helicobacter MONO IgA	General IVD	-	65628
CL-HMG100	CLIA Helicobacter MONO IgG	General IVD	-	61971
CL-CPA100	CLIA Chlamydia pneumoniae IgA	Annex II, List B	-	65361
CL-CPG100	CLIA Chlamydia pneumoniae IgG	Annex II, List B	-	65362
CL-CPM100	CLIA Chlamydia pneumoniae IgM	Annex II, List B	-	65363
CL-ChtA100	CLIA Chlamydia trachomatis IgA	Annex II, List B	-	63332
CL-ChtG100	CLIA Chlamydia trachomatis IgG	Annex II, List B	-	63328
CL-ChtM100	CLIA Chlamydia trachomatis IgM	Annex II, List B	-	65360
CL-IL6100	CLIA IL-6	General IVD	-	53858
CL-Jo1050	CLIA Jo-1	General IVD	-	59067
CL-MxA050	CLIA MxA	General IVD	-	65778
CL-PVG050	CLIA Parvovirus B19 IgG	IVDR class C	8595635310492CA	63423
CL-PVM050	CLIA Parvovirus B19 IgM	IVDR class C	8595635310485CD	63404
CL-PCT100	CLIA Procalcitonin	General IVD	-	58731
CL-RubG100	CLIA Rubella IgG	Annex II, List B	-	60990
CL-RubM100	CLIA Rubella IgM	Annex II, List B	-	60991
CL-ScI050	CLIA ScI-70	General IVD	-	59747
CL-Sm0050	CLIA Sm	General IVD	-	59888
CL-SSA050	CLIA SS-A	General IVD	-	59744
CL-Ro5250	CLIA SS-A/Ro52	General IVD	-	59744
CL-Ro6050	CLIA SS-A/Ro60	General IVD	-	59744
CL-SSB050	CLIA SS-B	General IVD	-	61221
CL-TBG100	CLIA TBE Virus IgG	General IVD	-	65639
CL-TBM050	CLIA TBE Virus IgM	General IVD	-	65640
CL-tTA100	CLIA Transglutaminase IgA	General IVD	-	58965
CL-tTG100	CLIA Transglutaminase IgG	General IVD	-	58965
CL-RNP050	CLIA U1RNP	General IVD	-	59857
CL-UMOD050	CLIA Uromodulin	General IVD	-	61293

HUMAN ELISA KITS *This is also valid for EIA kits version Smartkit.*

Cat. number	Product name	Classification	Basic UDI-DI	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
BsM096	EIA Borrelia b. sensu stricto IgM	General IVD	-	50564
BsGV96	EIA Borrelia b. sensu stricto VlsE IgG	General IVD	-	50560
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
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
PVG096	EIA Parvovirus B19 IgG	General IVD	-	50157
PVM096	EIA Parvovirus B19 IgM	General IVD	-	50164
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
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

ScI096	EIA ScI-70	General IVD	-	55126
Sm0096	EIA Sm	General IVD	-	55160
SSA096	EIA SS-A	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
TeTG96	EIA Tetanus Toxoid IgG	General IVD	-	50874
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	Basic UDI-DI	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
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 MICROBLOT KITS

Cat. number	Product name	Classification	Basic UDI-DI	GMDN code
ANAMA96	Microblot-Array ANA	General IVD	-	54810
ANApMA96	Microblot-Array ANA plus	General IVD	-	54810
BpAMA48	Microblot-Array Bordetella IgA	General IVD	-	50512
BpGMA48	Microblot-Array Bordetella IgG	General IVD	-	50512
BpMMA48	Microblot-Array Bordetella IgM	General IVD	-	50512
BGMA096	Microblot-Array Borrelia IgG	General IVD	-	50555
BMMA096	Microblot-Array Borrelia IgM	General IVD	-	50555
CMGMA48	Microblot-Array CMV IgG	IVDR class C	8595635311703C7	49718
CMMMA48	Microblot-Array CMV IgM	IVDR class C	8595635311710C4	49728
CoVAMA96	Microblot-Array COVID-19 IgA	General IVD	-	64867
CoVGMA96	Microblot-Array COVID-19 IgG	General IVD	-	64867
CoVMA96	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
HpAMA48	Microblot-Array Helicobacter IgA	General IVD	-	51020
HpGMA48	Microblot-Array Helicobacter IgG	General IVD	-	51020
HSGMA48	Microblot-Array HSV 1+2 IgG	IVDR class C	8595635311741CF	49542
HSMMA48	Microblot-Array HSV 1+2 IgM	IVDR class C	8595635311758CY	49551
CAMA096	Microblot-Array Chlamydia IgA	Annex II, List B	-	50720
CGMA096	Microblot-Array Chlamydia IgG	Annex II, List B	-	50722
MyAMA48	Microblot-Array Mycoplasma IgA	General IVD	-	51197
MyGMA48	Microblot-Array Mycoplasma IgG	General IVD	-	51197
MyMMA48	Microblot-Array Mycoplasma IgM	General IVD	-	51197
YAMA048	Microblot-Array Yersinia IgA	General IVD	-	51890
YGMA048	Microblot-Array Yersinia IgG	General IVD	-	51890

ANTIGENS AND COMPONENTS FOR CFR, AGGLUTINATION AND MICROAGGLUTINATION

Cat. number	Product name	Classification	Basic UDI-DI	GMDN code
CMvKF1	CMV - CF - Ag lyophil.	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	Basic UDI-DI	GMDN code
Ut0050	UREASAtest 50	IVDR class A	859563530ureasaZ9	52787
Utb100	UREASAtest bulk	IVDR class A	859563530ureasaZ9	52787

SOFTWARE

Cat. number	Product name	Classification	Basic UDI-DI	GMDN code
SwIm03	Immunoblot Software	IVDR class A	8595635311338C6	42838

INSTRUMENTS

Cat. number	Product name	Classification	Basic UDI-DI	GMDN code
ARCXIX096	Array Reader C-series	IVDR class A	8595635311345C3	57862

Brno, 10. 07. 2023


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