

Konformitätserklärung / Declaration of Conformity

Virotech Diagnostics GmbH, Waldstrasse 23 A2, 63128 Dietzenbach, Germany, erklärt in alleiniger Verantwortung, gemäß der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostika, dass folgende Produkte die grundlegenden Anforderungen gemäß Anhang I der Richtlinie 98/79/EG erfüllen und dass das Konformitätsbewertungsverfahren gemäß Anhang III der Richtlinie 98/79/EG angewendet wurde.

Virotech Diagnostics GmbH, Waldstrasse 23 A2, 63128 Dietzenbach, Germany, declares under sole responsibility and referring to the Directive 98/79/EC of the European Parliament and the Council on In-Vitro-Diagnostics dated 27th October 1998 that the following products fulfil the basic requirements according to Annex I, Directive 98/79/EC and that the conformity assessment module acc. to Annex III of Directive 98/79/EC has been applied.

Produktname Product Name	Art. Nummer Order #
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Adenovirus

VIROTECH Adenovirus IgG / IgM ELISA	EC121.00
Adenovirus IgG/IgM/IgA MTP	EC121.01
Adenovirus IgA Set	EC121.08
Adenovirus IgG Ctrl-Set	EN121K60
Adenovirus IgM Ctrl-Set	EN121K80
Adenovirus IgG ELISA neg. Ctrl.	112101
Adenovirus IgG ELISA Cut off Ctrl.	112102
Adenovirus IgG ELISA pos. Ctrl.	112103
Adenovirus IgM ELISA neg. Ctrl.	112104
Adenovirus IgM ELISA Cut off Ctrl.	112105
Adenovirus IgM ELISA pos. Ctrl.	112106
Adenovirus IgA ELISA neg. Ctrl	112107
Adenovirus IgA ELISA Cut off Ctrl.	112108
Adenovirus IgA ELISA pos. Ctrl.	112109

Lyme/Borrelia IgG

Borrelia + VlsE IgG MTP	EC022G01
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VIROTECH Borrelia + VlsE IgG Europe ELISA	EC024G00
Borrelia + VlsE IgG EU Ctrl-Set	EN024K60
Borrelia + VlsE IgG EU ELISA neg. Ctrl.	102401
Borrelia + VlsE IgG EU ELISA Cut off Ctrl.	102402
Borrelia + VlsE IgG EU ELISA pos. Ctrl.	102403

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VIROTECH Borrelia + VlsE IgG ELISA	EC022G00
Borrelia + VlsE IgG Ctrl-Set	EN022K60
Borrelia + VlsE IgG Liquor/CSF Standards	EC022L60
Borrelia + VlsE IgG Liquor/CSF AI Ctrl-Set	EN022L65
Borrelia + VlsE IgG ELISA neg. Ctrl.	102201
Borrelia + VlsE IgG ELISA Cut off Ctrl.	102202
Borrelia + VlsE IgG ELISA pos. Ctrl.	102203
Borrelia + VlsE IgG Liquor/CSF STD1 (1,5wME)	102230
Borrelia + VlsE IgG Liquor/CSF STD2 (6,2wME)	102231
Borrelia + VlsE IgG Liquor/CSF STD3 (25wME)	102232
Borrelia + VlsE IgG Liquor/CSF STD4 (100wME)	102233
Borrelia + VlsE IgG Liquor/CSF AI Ctrl. 1	102242
Borrelia + VlsE IgG Liquor/CSF AI Ctrl. 2	102243
Borrelia + VlsE IgG Serum AI Ctrl. 1	102244
Borrelia + VlsE IgG Serum AI Ctrl. 2	102245

VIROTECH Borrelia Europe IgG LINE Immunoblot	WE224G32 WE224G96
Borrelia EU IgG LINE Cut off Ctrl	WE224C60
Borrelia EU IgG LINE pos. Ctrl	WE224P60
Borrelia EU IgG/IgM LINE neg. Ctrl	WE224N10

VIROTECH Borrelia Europe + TpN17 IgG LINE Immunoblot	WE225G32 WE225G96
Borrelia EU + TpN17 IgG LINE Cut off Ctrl	WE225C60
Borrelia EU + TpN17 IgG LINE pos. Ctrl	WE225P60
Borrelia EU + TpN17 IgG LINE neg. Ctrl	WE225N60

VIROTECH Borrelia in vivo + TpN17 IgG LINE Immunoblot	WE223G32 WE223G96
Borrelia in vivo + TpN17 IgG LINE Cut off Ctrl	WE223C60
Borrelia in vivo + TpN17 IgG LINE pos. Ctrl	WE223P60
Borrelia in vivo + TpN17 IgG LINE neg. Ctrl	WE223N60

VIROTECH Borrelia in vivo IgG LINE Immunoblot	WE222G32 WE222G96
Borrelia in vivo IgG LINE Cut off Ctrl	WE222C60
Borrelia in vivo IgG LINE pos. Ctrl	WE222P60
Borrelia in vivo IgG/IgM LINE neg. Ctrl	WE222N10

Lyme/Borrelia IgM

VIROTECH Borrelia IgM ELISA	EC022M00
Borrelia IgM MTP	EC022M01
Borrelia IgM Ctrl-Set	EN022K80
Borrelia IgM Liquor/CSF Standards	EC022L80

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Borrelia IgM ELISA neg. Ctrl.	102204
Borrelia IgM ELISA Cut off Ctrl.	102205
Borrelia IgM ELISA pos. Ctrl.	102206
Borrelia IgM Liquor/CSF STD1 (1,5wME)	102234
Borrelia IgM Liquor/CSF STD2 (6,2wME)	102235
Borrelia IgM Liquor/CSF STD3 (25wME)	102236
Borrelia IgM Liquor/CSF STD4 (100wME)	102237

VIROTECH Borrelia Europe IgM LINE Immunoblot	WE224M32 WE224M96
Borrelia EU IgM LINE Cut off Ctrl	WE224C80
Borrelia EU IgM LINE pos. Ctrl	WE224P80

VIROTECH Borrelia in vivo IgM LINE Immunoblot	WE222M32 WE222M96
Borrelia in vivo IgM LINE Cut off Ctrl	WE222C80
Borrelia in vivo IgM LINE pos. Ctrl	WE222P80

Bordetella pertussis / parapertussis

VIROTECH Bordetella pertussis + CatACT IgA LINE Immunoblot	WE116A32 WE116A96
B. pertussis + CatACT IgA LINE Cut off Ctrl	WE116C40
B. pertussis + CatACT IgA LINE pos. Ctrl	WE116P40

VIROTECH Bordetella pertussis + CatACT IgG LINE Immunoblot	WE116G32 WE116G96
B. pertussis + CatACT IgG LINE Cut off Ctrl	WE116C60
B. pertussis + CatACT IgG LINE pos. Ctrl	WE116P60
B. pertussis + CatACT IgG/IgA LINE neg. Ctrl	WE116N20

VIROTECH Bordetella pertussis (FHA+PT) IgG/IgA ELISA	EC115.00
B. pertussis FHA+PT IgG/IgA MTP	EC115.01
B. pertussis FHA+PT IgA Ctrl-Set	EN115K40
B. pertussis FHA+PT IgG Ctrl-Set	EN115K60
B. pertussis FHA+PT IgG ELISA neg. Ctrl.	111501
B. pertussis FHA+PT IgG ELISA Cut off Ctrl.	111502
B. pertussis FHA+PT IgG ELISA pos. Ctrl.	111503
B. pertussis FHA+PT IgA ELISA neg. Ctrl.	111507
B. pertussis FHA+PT IgA ELISA Cut off Ctrl.	111508
B. pertussis FHA+PT IgA ELISA pos. Ctrl.	111509

VIROTECH Bordetella pertussis Toxin (PT) IgA ELISA	EC215A00
B. pertussis PT IgA MTP	EC215A01
B. pertussis PT IgA Ctrl-Set	EN215K40
B. pertussis PT IgA ELISA neg. Ctrl.	121507

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B. pertussis PT IgA ELISA Cut off Ctrl.	121508
B. pertussis PT IgA ELISA pos. Ctrl.	121509

VIROTECH Bordetella pertussis Toxin (PT) IgG ELISA	EC215G00
B. pertussis PT IgG MTP	EC215G01
B. pertussis PT IgG Ctrl-Set	EN215K60
B. pertussis PT IgG Quant.-Set	EN215Q60
B. pertussis PT IgG ELISA neg. Ctrl.	121501
B. pertussis PT IgG ELISA Cut off Ctrl.	121502
B. pertussis PT IgG ELISA pos. Ctrl.	121503
B. pertussis PT IgG ELISA CAL Ctrl.	121554
B. pertussis PT IgG ELISA hoch/high pos. Ctrl.	121555
B. pertussis PT IgG ELISA schwach/low pos. Ctrl.	121556

VIROTECH Bordetella pertussis Toxin (PT) IgM ELISA	EC215M00
B. pertussis PT IgM MTP	EC215M01
B. pertussis Toxin IgM Ctrl-Set	EN215K80
B. pertussis PT IgM ELISA neg. Ctrl.	121504
B. pertussis PT IgM ELISA Cut off Ctrl.	121505
B. pertussis PT IgM ELISA pos. Ctrl.	121506

Brucella

VIROTECH Brucella IgG/IgM ELISA	EC101.00
Brucella IgG/IgM/IgA MTP	EC101.01
Brucella IgA-Set	EC101.08
Brucella IgG Ctrl-Set	EN101K60
Brucella IgM Ctrl-Set	EN101K80
Brucella IgG ELISA neg. Ctrl.	110101
Brucella IgG ELISA Cut off Ctrl.	110102
Brucella IgG ELISA pos. Ctrl.	110103
Brucella IgM ELISA neg. Ctrl.	110104
Brucella IgM ELISA Cut off Ctrl.	110105
Brucella IgM ELISA pos. Ctrl.	110106
Brucella IgA ELISA neg. Ctrl.	110107
Brucella IgA ELISA Cut off Ctrl.	110108
Brucella IgA ELISA pos. Ctrl.	110109

Candida albicans

VIROTECH Candida albicans IgG/IgM ELISA	EC111.00
C. albicans IgG/IgM/IgA MTP	EC111.01
C. albicans IgA-Set	EC111.08
C. albicans IgG Ctrl-Set	EN111K60
C. albicans IgM Ctrl-Set	EN111K80
C. albicans IgG ELISA neg. Ctrl.	111101

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C. albicans IgG ELISA Cut off Ctrl.	111102
C. albicans IgG ELISA pos. Ctrl.	111103
C. albicans IgM ELISA neg. Ctrl.	111104
C. albicans IgM ELISA Cut off Ctrl.	111105
C. albicans IgM ELISA pos. Ctrl.	111106
C. albicans IgA ELISA neg. Ctrl.	111107
C. albicans IgA ELISA Cut off Ctrl.	111108
C. albicans IgA ELISA pos. Ctrl.	111109

Diphtheria (*Corynebacterium diphtheriae*)

VIROTECH Diphtherie/Diphtheria IgG ELISA	EC129.00
Diphtherie/Diphtheria IgG MTP	EC129.01
Diphtherie/Diphtheria IgG Ctrl-Standard-Set	EN129K60
Diphtherie IgG ELISA STD1 (0,001 IU/ml)	112922
Diphtherie IgG ELISA STD2 (0,002 IU/ml)	112923
Diphtherie IgG ELISA STD3 (0,005 IU/ml)	112924
Diphtherie IgG ELISA STD4 (0,010 IU/ml)	112925
Diphtherie IgG ELISA STD5 (0,020 IU/ml)	112926
Diphtherie IgG ELISA STD6 (0,050 IU/ml)	112927
Diphtherie IgG ELISA schwach/low pos. Ctrl.	112928
Diphtherie IgG ELISA hoch/high pos. Ctrl.	112929

EBV (Epstein-Barr Virus)

VIROTECH EBV EA-D IgG ELISA	EC202.00
EBV EA-D IgG MTP	EC202.01
EBV EA-D IgG Ctrl-Set	EN202K60
EBV EA-D IgG ELISA neg. Ctrl.	120201
EBV EA-D IgG ELISA Cut off Ctrl.	120202
EBV EA-D IgG ELISA pos. Ctrl.	120203

VIROTECH EBV EBNA1 IgG ELISA	EC204.00
EBV EBNA1 IgG MTP	EC204.01
EBV EBNA1 IgG Ctrl-Set	EN204K60
EBV EBNA1 IgG ELISA neg. Ctrl.	120401
EBV EBNA1 IgG ELISA Cut off Ctrl.	120402
EBV EBNA1 IgG ELISA pos. Ctrl.	120403

VIROTECH EBV IgG/IgM ELISA	EC102.00
EBV IgG/IgM MTP	EC102.01
EBV IgG Ctrl-Set	EN102K60
EBV IgM Ctrl-Set	EN102K80
EBV IgG Liquor/CSF Standards	EC102L60
EBV IgG Liquor/CSF AI Ctrl-Set	EN102L65
EBV IgG ELISA neg. Ctrl.	110201

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EBV IgG ELISA Cut off Ctrl.	110202
EBV IgG ELISA pos. Ctrl.	110203
EBV IgM ELISA neg. Ctrl.	110204
EBV IgM ELISA Cut off Ctrl.	110205
EBV IgM ELISA pos. Ctrl.	110206
EBV IgG Liquor/CSF STD1 (1,5wME)	110230
EBV IgG Liquor/CSF STD2 (6,2wME)	110231
EBV IgG Liquor/CSF STD3 (25wME)	110232
EBV IgG Liquor/CSF STD4 (100wME)	110233
EBV IgG Liquor/CSF AI Ctrl. 1	110242
EBV IgG Liquor/CSF AI Ctrl. 2	110243
EBV IgG Serum AI Ctrl. 1	110244
EBV IgG Serum AI Ctrl. 2	110245

VIROTECH EBV IgG LINE Immunoblot	WE102G32 WE102G96
EBV IgG LINE Cut off Ctrl	WE102C60
EBV IgG LINE pos. Ctrl	WE102P60
EBV IgG/IgM LINE neg. Ctrl	WE102N10

VIROTECH EBV IgM LINE Immunoblot	WE102M32 WE102M96
EBV IgM LINE Cut off Ctrl	WE102C80
EBV IgM LINE pos. Ctrl	WE102P80

VIROTECH EBV VCA IgG ELISA	EC205G00
EBV VCA IgG MTP	EC205G01
EBV VCA IgG Ctrl-Set	EN205K60
EBV VCA IgG ELISA neg. Ctrl.	120501
EBV VCA IgG ELISA Cut off Ctrl.	120502
EBV VCA IgG ELISA pos. Ctrl.	120503

VIROTECH EBV VCA IgM ELISA	EC203M00
EBV VCA IgM MTP	EC203M01
EBV VCA IgM Ctrl-Set	EN203K80
EBV VCA IgM ELISA neg. Ctrl.	120304
EBV VCA IgM ELISA Cut off Ctrl.	120305
EBV VCA IgM ELISA pos. Ctrl.	120306

Enterovirus

VIROTECH Enterovirus IgA ELISA	EC116A00
Enterovirus IgA MTP	EC116A01
Enterovirus IgA Ctrl-Set	EN116K40
Enterovirus IgA ELISA neg. Ctrl.	111607
Enterovirus IgA ELISA Cut off Ctrl.	111608

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Enterovirus IgA ELISA pos. Ctrl.	111609
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VIROTECH Enterovirus IgG ELISA	EC116G00
Enterovirus IgG MTP	EC116G01
Enterovirus IgG Ctrl-Set	EN116K60
Enterovirus IgG ELISA neg. Ctrl.	111601
Enterovirus IgG ELISA Cut off Ctrl.	111602
Enterovirus IgG ELISA pos. Ctrl.	111603

VIROTECH Enterovirus IgM ELISA	EC116M00
Enterovirus IgM MTP	EC116M01
Enterovirus Kontroll-Antigen/Ctrl Ag MTP	EC116M02
Enterovirus IgM Ctrl-Set	EN116K80
Enterovirus IgM ELISA neg. Ctrl.	111604
Enterovirus IgM ELISA Cut off Ctrl.	111605
Enterovirus IgM ELISA pos. Ctrl.	111606

TBE (tick-borne encephalitis) Virus/ FSME (Frühsommer-Meningoenzephalitis) Virus

VIROTECH FSME/TBE IgG/IgM ELISA	EC117.00
FSME/TBE IgG/IgM MTP	EC117.01
FSME/TBE IgG Ctrl-Set	EN117K60
FSME/TBE IgG Liquor/CSF Standards	EC117L60
FSME/TBE IgG Liquor/CSF AI Ctrl-Set	EN117L65
FSME/TBE IgM Ctrl-Set	EN117K80
FSME/TBE IgM Liquor/CSF Standards	EC117L80
FSME/TBE IgG ELISA neg. Ctrl.	111701
FSME/TBE IgG ELISA Cut off Ctrl.	111702
FSME/TBE IgG ELISA pos. Ctrl.	111703
FSME/TBE IgM ELISA neg. Ctrl.	111704
FSME/TBE IgM ELISA Cut off Ctrl.	111705
FSME/TBE IgM ELISA pos. Ctrl.	111706
FSME/TBE IgG Liquor/CSF STD1 (1,5wME)	111730
FSME/TBE IgG Liquor/CSF STD2 (6,2wME)	111731
FSME/TBE IgG Liquor/CSF STD3 (25wME)	111732
FSME/TBE IgG Liquor/CSF STD4 (100wME)	111733
FSME/TBE IgM Liquor/CSF STD1 (1,5wME)	111734
FSME/TBE IgM Liquor/CSF STD2 (6,2wME)	111735
FSME/TBE IgM Liquor/CSF STD3 (25wME)	111736
FSME/TBE IgM Liquor/CSF STD4 (100wME)	111737
FSME/TBE IgG Liquor/CSF AI Ctrl. 1	111742
FSME/TBE IgG Liquor/CSF AI Ctrl. 2	111743
FSME/TBE IgG Serum AI Ctrl. 1	111744
FSME/TBE IgG Serum AI Ctrl. 2	111745

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Helicobacter pylori

VIROTECH Helicobacter pylori IgA ELISA	EC143A00
H. pylori IgA MTP	EC143A01
H. pylori IgA Ctrl-Set	EN143K40
H. pylori IgA ELISA neg. Ctrl.	114307
H. pylori IgA ELISA Cut off Ctrl.	114308
H. pylori IgA ELISA pos. Ctrl.	114309

VIROTECH Helicobacter pylori IgG ELISA	EC143G00
H. pylori IgG MTP	EC143G01
H. pylori IgG Ctrl-Set	EN143K60
H. pylori IgG ELISA neg. Ctrl.	114301
H. pylori IgG ELISA Cut off Ctrl.	114302
H. pylori IgG ELISA pos. Ctrl.	114303

VIROTECH Helicobacter pylori IgA LINE Immunoblot	WE243A32 WE243A96
H. pylori IgA LINE Cut off Ctrl	WE243C40
H. pylori IgA LINE pos. Ctrl	WE243P40

VIROTECH Helicobacter pylori IgG LINE Immunoblot	WE243G32 WE243G96
H. pylori IgG LINE Cut off Ctrl	WE243C60
H. pylori IgG LINE pos. Ctrl	WE243P60
H. pylori IgG/IgA LINE neg. Ctrl	WE243N20

HSV 1 (Herpes simplex Virus 1)

VIROTECH HSV 1 (gG1) IgG/IgM ELISA	EC130.00
HSV 1 (gG1) IgG/IgM MTP	EC130.01
HSV 1 (gG1) IgG Ctrl-Set	EN130K60
HSV 1 (gG1) IgG Liquor/CSF Standards	EC130L60
HSV 1 (gG1) IgG ELISA neg. Ctrl.	113001
HSV 1 (gG1) IgG ELISA Cut off Ctrl.	113002
HSV 1 (gG1) IgG ELISA pos. Ctrl.	113003
HSV 1 (gG1) IgG Liquor/CSF STD1 (1,5wME)	113030
HSV 1 (gG1) IgG Liquor/CSF STD2 (6,2wME)	113031
HSV 1 (gG1) IgG Liquor/CSF STD3 (25wME)	113032
HSV 1 (gG1) IgG Liquor/CSF STD4 (100wME)	113033
HSV 1 (gG1) IgM Ctrl-Set	EN130K80
HSV 1 (gG1) IgM ELISA neg. Ctrl.	113004
HSV 1 (gG1) IgM ELISA Cut off Ctrl.	113005
HSV 1 (gG1) IgM ELISA pos. Ctrl.	113006

HSV 2 (Herpes simplex Virus 2)

VIROTECH HSV 2 (gG2) IgG/IgM ELISA	EC131.00
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Produktname Product Name	Art. Nummer Order #
HSV 2 (gG2) IgG/IgM MTP	EC131.01
HSV 2 (gG2) IgG Ctrl-Set	EN131K60
HSV 2 (gG2) IgG Liquor/CSF Standards	EC131L60
HSV 2 (gG2) IgG ELISA neg. Ctrl.	113101
HSV 2 (gG2) IgG ELISA Cut off Ctrl.	113102
HSV 2 (gG2) IgG ELISA pos. Ctrl.	113103
HSV 2 (gG2) IgG Liquor/CSF STD1 (1,5wME)	113130
HSV 2 (gG2) IgG Liquor/CSF STD2 (6,2wME)	113131
HSV 2 (gG2) IgG Liquor/CSF STD3 (25wME)	113132
HSV 2 (gG2) IgG Liquor/CSF STD4 (100wME)	113133
HSV 2 (gG2) IgM Ctrl-Set	EN131K80
HSV 2 (gG2) IgM ELISA neg. Ctrl.	113104
HSV 2 (gG2) IgM ELISA Cut off Ctrl.	113105
HSV 2 (gG2) IgM ELISA pos. Ctrl.	113106

HSV (Herpes simplex Virus) IgG LINE

VIROTECH HSV IgG LINE Immunoblot	WE130G16 WE130G32
HSV IgG LINE Cut off Ctrl	WE130C60
HSV IgG LINE pos. Ctrl	WE130P60
HSV IgG LINE neg. Ctrl	WE130N60

HSV (Herpes simplex Virus) Screen

VIROTECH HSV Screen IgG/IgM ELISA	EC108.00
HSV Screen IgG/IgM MTP	EC108.01
HSV Screen IgG Ctrl-Set	EN108K60
HSV Screen IgG Liquor/CSF Standards	EC108L60
HSV Screen IgG Liquor/CSF AI Ctrl-Set	EN108L65
HSV Screen IgG ELISA neg. Ctrl.	110801
HSV Screen IgG ELISA Cut off Ctrl.	110802
HSV Screen IgG ELISA pos. Ctrl.	110803
HSV Screen IgG Liquor/CSF STD1 (1,5wME)	110830
HSV Screen IgG Liquor/CSF STD2 (6,2wME)	110831
HSV Screen IgG Liquor/CSF STD3 (25wME)	110832
HSV Screen IgG Liquor/CSF STD4 (100wME)	110833
HSV Screen IgG Liquor/CSF AI Ctrl. 1	110842
HSV Screen IgG Liquor/CSF AI Ctrl. 2	110843
HSV Screen IgG Serum AI Ctrl. 1	110844
HSV Screen IgG Serum AI Ctrl. 2	110845
HSV Screen IgM Ctrl-Set	EN108K80
HSV Screen IgM ELISA neg. Ctrl.	110804
HSV Screen IgM ELISA Cut off Ctrl.	110805
HSV Screen IgM ELISA pos. Ctrl.	110806

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Influenza & Para Influenza Virus

VIROTECH Influenza A IgG/IgM ELISA	EC118.00
Influenza A IgG/IgM MTP	EC118.01
Influenza A IgG Ctrl-Set	EN118K60
Influenza A IgM Ctrl-Set	EN118K80
Influenza A IgG ELISA neg. Ctrl.	111801
Influenza A IgG ELISA Cut off Ctrl.	111802
Influenza A IgG ELISA pos. Ctrl.	111803
Influenza A IgM ELISA neg. Ctrl.	111804
Influenza A IgM ELISA Cut off Ctrl.	111805
Influenza A IgM ELISA pos. Ctrl.	111806

VIROTECH Influenza A IgA ELISA	EC118A00
Influenza A IgA MTP	EC118A01
Influenza A IgA Ctrl-Set	EN118K40
Influenza A IgA ELISA neg. Ctrl.	111807
Influenza A IgA ELISA Cut off Ctrl.	111808
Influenza A IgA ELISA pos. Ctrl.	111809

VIROTECH Influenza B IgG/IgM ELISA	EC119.00
Influenza B IgG/IgM MTP	EC119.01
Influenza B IgG Ctrl-Set	EN119K60
Influenza B IgM Ctrl-Set	EN119K80
Influenza B IgG ELISA neg. Ctrl.	111901
Influenza B IgG ELISA Cut off Ctrl.	111902
Influenza B IgG ELISA pos. Ctrl.	111903
Influenza B IgM ELISA neg. Ctrl.	111904
Influenza B IgM ELISA Cut off Ctrl.	111905
Influenza B IgM ELISA pos. Ctrl.	111906

VIROTECH Influenza B IgA ELISA	EC119A00
Influenza B IgA MTP	EC119A01
Influenza B IgA Ctrl-Set	EN119K40
Influenza B IgA ELISA neg. Ctrl.	111907
Influenza B IgA ELISA Cut off Ctrl.	111908
Influenza B IgA ELISA pos. Ctrl.	111909

VIROTECH ParaScreen IgG/IgM ELISA	EC148.00
ParaScreen IgG/IgM/IgA MTP	EC148.01
ParaScreen IgA-Set	EC148.08
ParaScreen IgG Ctrl-Set	EN148K60
ParaScreen IgM Ctrl-Set	EN148K80
ParaScreen IgG ELISA neg. Ctrl.	114801
ParaScreen IgG ELISA Cut off Ctrl.	114802
ParaScreen IgG ELISA pos. Ctrl.	114803

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ParaScreen IgM ELISA neg. Ctrl.	114804
ParaScreen IgM ELISA Cut off Ctrl.	114805
ParaScreen IgM ELISA pos. Ctrl.	114806
ParaScreen IgA ELISA neg. Ctrl.	114807
ParaScreen IgA ELISA Cut off Ctrl.	114808
ParaScreen IgA ELISA pos. Ctrl.	114809

Measles/Masern Virus

VIROTECH Masern/Measles IgG ELISA	EC105G00
Masern/Measles IgG MTP	EC105G01
Masern/Measles IgG Ctrl-Set	EN105K60
Masern/Measles IgG Liquor/CSF Standards	EC105L60
Masern/Measles IgG Liquor/CSF AI Ctrl-Set	EN105L65
Masern/Measles IgG ELISA neg. Ctrl.	110501
Masern/Measles IgG ELISA Cut off Ctrl.	110502
Masern/Measles IgG ELISA pos. Ctrl.	110503
Masern/Measles IgG Liquor/CSF STD1 (1,5wME)	110530
Masern/Measles IgG Liquor/CSF STD2 (6,2wME)	110531
Masern/Measles IgG Liquor/CSF STD3 (25wME)	110532
Masern/Measles IgG Liquor/CSF STD4 (100wME)	110533
Masern/Measles IgG Liquor/CSF AI Ctrl. 1	110542
Masern/Measles IgG Liquor/CSF AI Ctrl. 2	110543
Masern/Measles IgG Serum AI Ctrl. 1	110544
Masern/Measles IgG Serum AI Ctrl. 2	110545

VIROTECH Masern/Measles IgM ELISA	EC105M00
Masern/Measles IgM MTP	EC105M01
Masern/Measles IgM Ctrl-Set	EN105K80
Masern/Measles IgM Liquor/CSF Standards	EC105L80
Masern/Measles IgM ELISA neg. Ctrl.	110504
Masern/Measles IgM ELISA Cut off Ctrl.	110505
Masern/Measles IgM ELISA pos. Ctrl.	110506
Masern/Measles IgM Liquor/CSF STD1 (1,5wME)	110534
Masern/Measles IgM Liquor/CSF STD2 (6,2wME)	110535
Masern/Measles IgM Liquor/CSF STD3 (25wME)	110536
Masern/Measles IgM Liquor/CSF STD4 (100wME)	110537

Mumps Virus

VIROTECH Mumps IgG/IgM ELISA	EC106.00
Mumps IgG/IgM MTP	EC106.01
Mumps IgG Ctrl-Set	EN106K60
Mumps IgM Ctrl-Set	EN106K80
Mumps IgG Liquor/CSF Standards	EC106L60
Mumps IgG ELISA neg. Ctrl.	110601

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Mumps IgG ELISA Cut off Ctrl.	110602
Mumps IgG ELISA pos. Ctrl.	110603
Mumps IgM ELISA neg. Ctrl.	110604
Mumps IgM ELISA Cut off Ctrl.	110605
Mumps IgM ELISA pos. Ctrl.	110606
Mumps IgG Liquor/CSF STD1 (1,5wME)	110630
Mumps IgG Liquor/CSF STD2 (6,2wME)	110631
Mumps IgG Liquor/CSF STD3 (25wME)	110632
Mumps IgG Liquor/CSF STD4 (100wME)	110633

Mycoplasma pneumoniae

VIROTECH Mycoplasma pneumoniae polyvalent IgG/IgA+IgM ELISA	EC214.00
M. pneumoniae polyv. IgG/IgA+IgM MTP	EC214.01
M. pneumoniae polyv. IgG Ctrl-Set	EN214K60
M. pneumoniae polyv. IgA+IgM Ctrl-Set	EN214K30
M. pneumoniae polyv. IgG ELISA neg. Ctrl.	121401
M. pneumoniae polyv. IgG ELISA Cut off Ctrl.	121402
M. pneumoniae polyv. IgG ELISA pos. Ctrl.	121403
M. pneumoniae polyv. IgA+IgM ELISA neg. Ctrl.	121416
M. pneumoniae polyv. IgA+IgM ELISA Cut off Ctrl.	121417
M. pneumoniae polyv. IgA+IgM ELISA pos. Ctrl.	121418

VIROTECH Mycoplasma pneumoniae IgG/IgM ELISA	EC114.00
M. pneumoniae IgG/IgM/IgA MTP	EC114.01
M. pneumoniae IgA-Set	EC114.08
M. pneumoniae IgG Ctrl-Set	EN114K60
M. pneumoniae IgM Ctrl-Set	EN114K80
M. pneumoniae IgG ELISA neg. Ctrl.	111401
M. pneumoniae IgG ELISA Cut off Ctrl.	111402
M. pneumoniae IgG ELISA pos. Ctrl.	111403
M. pneumoniae IgM ELISA neg. Ctrl.	111404
M. pneumoniae IgM ELISA Cut off Ctrl.	111405
M. pneumoniae IgM ELISA pos. Ctrl.	111406
M. pneumoniae IgA ELISA neg. Ctrl.	111407
M. pneumoniae IgA ELISA Cut off Ctrl.	111408
M. pneumoniae IgA ELISA pos. Ctrl.	111409

VIROTECH Mycoplasma pneumoniae IgA LINE Immunoblot	WE214A16
M. pneumoniae IgA LINE Cut off Ctrl	WE214C40
M. pneumoniae IgA LINE pos. Ctrl	WE214P40

VIROTECH Mycoplasma pneumoniae IgG LINE Immunoblot	WE214G16
M. pneumoniae IgG LINE Cut off Ctrl	WE214C60
M. pneumoniae IgG LINE pos. Ctrl	WE214P60

Produktname Product Name	Art. Nummer Order #
VIROTECH Mycoplasma pneumoniae IgM LINE Immunoblot	WE214M16
M. pneumoniae IgM LINE Cut off Ctrl	WE214C80
M. pneumoniae IgM LINE pos. Ctrl	WE214P80
M. pneumoniae IgG/IgM/IgA LINE neg. Ctrl	WE214N50

RSV (Respiratory Syncytial Virus)

VIROTECH RSV IgG/IgM ELISA	EC107.00
RSV IgG/IgM/IgA MTP	EC107.01
RSV IgA-Set	EC107.08
RSV IgG Ctrl-Set	EN107K60
RSV IgM Ctrl-Set	EN107K80
RSV IgG ELISA neg. Ctrl.	110701
RSV IgG ELISA Cut off Ctrl.	110702
RSV IgG ELISA pos. Ctrl.	110703
RSV IgM ELISA neg. Ctrl.	110704
RSV IgM ELISA Cut off Ctrl.	110705
RSV IgM ELISA pos. Ctrl.	110706
RSV IgA ELISA neg. Ctrl.	110707
RSV IgA ELISA Cut off Ctrl.	110708
RSV IgA ELISA pos. Ctrl.	110709

Rubella Virus IgG

VIROTECH Rubella Liquor/CSF IgG ELISA	EC109L00
Rubella Liquor/CSF IgG MTP	EC109G01
Rubella IgG Liquor/CSF Standards	EC109L60
Rubella IgG Liquor/CSF AI Ctrl-Set	EN109L65
Rubella IgG Liquor/CSF Standard 1 (1,5wME)	110930
Rubella IgG Liquor/CSF Standard 2 (6,2wME)	110931
Rubella IgG Liquor/CSF Standard 3 (25wME)	110932
Rubella IgG Liquor/CSF Standard 4 (100wME)	110933
Rubella IgG Liquor/CSF AI Ctrl. 1	110942
Rubella IgG Liquor/CSF AI Ctrl. 2	110943
Rubella IgG Serum AI Ctrl. 1	110944
Rubella IgG Serum AI Ctrl. 2	110945

SARS-CoV-2

SARS-CoV-2 IgG/IgM/IgA MTP	EC123.01
VIROTECH SARS-CoV-2 IgG ELISA	EC123G00
SARS-CoV-2 IgG ELISA neg. Ctrl.	112301
SARS-CoV-2 IgG ELISA Calibrator Ctrl.	112302
SARS-CoV-2 IgG ELISA pos. Ctrl.	112303
VIROTECH SARS-CoV-2 IgM ELISA	EC123M00



Produktname Product Name	Art. Nummer Order #
SARS-CoV-2 IgM ELISA neg. Ctrl.	112304
SARS-CoV-2 IgM ELISA Calibrator Ctrl.	112305
SARS-CoV-2 IgM ELISA pos. Ctrl.	112306
VIROTECH SARS-CoV-2 IgA ELISA	EC123A00
SARS-CoV-2 IgA ELISA neg. Ctrl.	112307
SARS-CoV-2 IgA ELISA Calibrator Ctrl.	112308
SARS-CoV-2 IgA ELISA pos. Ctrl.	112309

Tetanus (Clostridium tetani)

VIROTECH Tetanus IgG ELISA	EC124.00
Tetanus IgG MTP	EC124.01
Tetanus IgG Ctrl-Standard-Set	EN124K60
Tetanus IgG ELISA STD1 (0,001 IU/ml)	112422
Tetanus IgG ELISA STD2 (0,002 IU/ml)	112423
Tetanus IgG ELISA STD3 (0,005 IU/ml)	112424
Tetanus IgG ELISA STD4 (0,010 IU/ml)	112425
Tetanus IgG ELISA STD5 (0,020 IU/ml)	112426
Tetanus IgG ELISA STD6 (0,050 IU/ml)	112427
Tetanus IgG ELISA schwach/low pos. Ctrl.	112428
Tetanus IgG ELISA hoch/high pos. Ctrl.	112429

Syphilis (Treponema pallidum) IgG

VIROTECH Treponema pallidum IgG LINE Immunoblot	WE150G16 WE150G32
T. pallidum IgG LINE Cut off Ctrl	WE150C60
T. pallidum IgG LINE pos. Ctrl	WE150P60

Syphilis (Treponema pallidum) IgM

VIROTECH Treponema pallidum IgM LINE Immunoblot	WE150M16 WE150M32
T. pallidum IgM LINE Cut off Ctrl	WE150C80
T. pallidum IgM LINE pos. Ctrl	WE150P80
T. pallidum IgG/IgM LINE neg. Ctrl	WE150N10

VZV (Varicella Zoster Virus)

VIROTECH VZV IgG/IgM ELISA	EC110.00
VZV IgG/IgM/IgA MTP	EC110.01
VZV IgG Ctrl-Set	EN110K60
VZV IgG Liquor/CSF Standards	EC110L60
VZV IgG Liquor/CSF AI Ctrl-Set	EN110L65
VZV IgM Ctrl-Set	EN110K80
VZV IgM Liquor/CSF Standards	EC110L80
VZV IgA-Set	EC110.08
VZV IgA Liquor/CSF Standards	EC110L40

Produktname Product Name	Art. Nummer Order #
VZV IgG ELISA neg. Ctrl.	111001
VZV IgG ELISA Cut off Ctrl.	111002
VZV IgG ELISA pos. Ctrl.	111003
VZV IgM ELISA neg. Ctrl.	111004
VZV IgM ELISA Cut off Ctrl.	111005
VZV IgM ELISA pos. Ctrl.	111006
VZV IgA ELISA neg. Ctrl.	111007
VZV IgA ELISA Cut off Ctrl.	111008
VZV IgA ELISA pos. Ctrl.	111009
VZV IgG Liquor/CSF STD1 (1,5wME)	111030
VZV IgG Liquor/CSF STD2 (6,2wME)	111031
VZV IgG Liquor/CSF STD3 (25wME)	111032
VZV IgG Liquor/CSF STD4 (100wME)	111033
VZV IgM Liquor/CSF STD1 (1,5wME)	111034
VZV IgM Liquor/CSF STD2 (6,2wME)	111035
VZV IgM Liquor/CSF STD3 (25wME)	111036
VZV IgM Liquor/CSF STD4 (100wME)	111037
VZV IgA Liquor/CSF STD1 (1,5wME)	111038
VZV IgA Liquor/CSF STD2 (6,2wME)	111039
VZV IgA Liquor/CSF STD3 (25wME)	111040
VZV IgA Liquor/CSF STD4 (100wME)	111041
VZV IgG Liquor/CSF AI Ctrl. 1	111042
VZV IgG Liquor/CSF AI Ctrl. 2	111043
VZV IgG Serum AI Ctrl. 1	111044
VZV IgG Serum AI Ctrl. 2	111045

Yersinia enterocolitica

VIROTECH Yersinia enterocolitica IgG/IgA ELISA	EC142.00
Y. enterocolitica IgG/IgA MTP	EC142.01
Y. enterocolitica IgG Ctrl-Set	EN142K60
Y. enterocolitica IgA Ctrl-Set	EN142K40
Y. enterocolitica IgG ELISA neg. Ctrl.	114201
Y. enterocolitica IgG ELISA Cut off Ctrl.	114202
Y. enterocolitica IgG ELISA pos. Ctrl.	114203
Y. enterocolitica IgA ELISA neg. Ctrl.	114207
Y. enterocolitica IgA ELISA Cut off Ctrl.	114208
Y. enterocolitica IgA ELISA pos. Ctrl.	114209

VIROTECH Yersinia enterocolitica IgA LINE Immunoblot	WE242A32 WE242A96
Y. enterocolitica IgA LINE Cut off Ctrl	WE242C40
Y. enterocolitica IgA LINE pos. Ctrl	WE242P40

VIROTECH Yersinia enterocolitica IgG LINE Immunoblot	WE242G32 WE242G96
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Produktname Product Name	Art. Nummer Order #
Y. enterocolitica IgG LINE Cut off Ctrl	WE242C60
Y. enterocolitica IgG LINE pos. Ctrl	WE242P60
Y. enterocolitica IgG/IgA LINE neg. Ctrl	WE242N20

Other Controls - Inf. Immunology

VIROTECH Validierung/Validation ELISA	EC250.00
Validierung/Validation MTP	EC250.01
Pipettierkontrollen/Pipetting Control-Set	EN250K60

Buffers, Supplem. Reagents, etc.

PBS-Verdünnungspuffer/Dilution Buffer ELISA	141301
VZV-IgM-Verdünnungspuffer/Dilution Buffer ELISA	141401
Verd./Waschpuffer Dilution-/Washbuffer LINE	WE200.08

Other Infectious Immunology Reagents

PBS-Waschlösung/Washing Solution ELISA	141201
TMB-Substrat/Substrate ELISA	151101
Citrat Stopplösung/Stopping Solution ELISA	141101
IgG Konjugat/Conjugate (anti-human) ELISA	131101
IgM Konjugat/Conjugate (anti-human) ELISA	131201
IgA Konjugat/Conjugate (anti-human) ELISA	131301
IgA 2 Konjugat/Conjugate (anti-human) ELISA	131601
IgA/IgM Konjugat/Conjugate (anti-human) ELISA	131401
SARS-CoV-2 IgG Konjugat/Conjugate(anti-human) ELISA	132201
SARS-CoV-2 IgM Konjugat/Conjugate(anti-human) ELISA	132301
SARS-CoV-2 IgA Konjugat/Conjugate(anti-human) ELISA	132401
IgG Konjugat/Conjugate (anti-human) LINE	WE400.62
IgM Konjugat/Conjugate (anti-human) LINE	WE400.82
IgA Konjugat/Conjugate (anti-human) LINE	WE400.42
Substrat/Substrate LINE	WE200.02

VIROTECH RF-SorboTech

RF-SorboTech - 2ml	161101
RF-SorboTech - 10ml	161102
RF-SorboTech - 80x	B/300.00

Produktname Product Name	Art. Nummer Order #
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Data Management Software/Consumables

LabCheck Liquor Auswertung (ELISA)	EX-Liquor-DE
LabCheck CSF Analysis (ELISA)	EX-CSF-GB
LabCheck 1-Punkt-Quantifizierung	EX-1-Punkt-Quanti
LabCheck Liquor LINE Verdünnungsrechner	EX-WE22X
VIROTECH LabImage LA SetCards	F/LabImSetCards
VIROTECH LabImage LA SetCards_GB	F/LabImSetCards-GB
LabSnap ELISA Auswertesoftware + Set	F/LabSnap_EA

Dietzenbach, 2022-03-17



 Rodrigo Berlie
 Geschäftsführer / Managing Director

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Die nächste Überprüfung der Konformitätserklärung erfolgt spätestens zum 2023-03-17.
The next verification of the declaration of conformity is scheduled for 2023-03-17.

Supplement to Declarations of Conformity

We, Virotech Diagnostics GmbH, declare in addition to the declarations of conformity, Rev 49:

Declarations of Conformity issued under the sole responsibility of Virotech Diagnostics GmbH and referring to Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices of 27 October 1998 are valid until 2025-03-31.

According to Regulation (EU) 2022/112 of the European Parliament and of the Council of Jan. 25, 2022, devices with a declaration of conformity issued before May 26, 2022, that did not require the intervention of a notified body under the IVD Directive, may be placed on the market or put into service until the following dates:

- (a) May 26, 2025, for class D devices;
- (b) May 26, 2026, for class C devices;
- (c) May 26, 2027, for Class B devices and Class A devices placed on the market in a sterile condition.

The individual controls of the VIROTECH ELISA and LINE Kits are only available in the Ctrl-Set. Single controls and microtiter plates can no longer be ordered.

Dietzenbach, 2023-03-16



Brigitte Ott-Schnetter
(Quality Management)