

Declaration of Conformity

We

NovaTec Immundiagnostica GmbH
Waldstraße 23 A6, 63128 Dietzenbach, Germany

herewith declare under our own responsibility, that the products listed below are in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct. 27, 1998 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures in Annex III (2 – 5).

Dietzenbach, 2018-02-07

NOVATEC
IMMUNDIAGNOSTICA GmbH
Waldstraße 23 A6
63128 Dietzenbach, Germany

[Signature]
Britta-Maria Duchmann Berlie
General Manager

Prod. No.	Name and Description
1.	ADVA0010 Adenovirus IgA
2.	ADVG0010 Adenovirus IgG
3.	ADVM0010 Adenovirus IgM
4.	ASCG0020 Ascaris lumbricoides IgG
5.	ASPG0680 Aspergillus fumigatus IgG
6.	ASPM0680 Aspergillus fumigatus IgM
7.	BOPA0030 Bordetella pertussis IgA
8.	BOPG0030 Bordetella pertussis IgG
9.	BOPM0030 Bordetella pertussis IgM
10.	BPTA0610 Bordetella pertussis toxin (PT) IgA
11.	BPTG0610 Bordetella pertussis toxin (PT) IgG
12.	BORG0040 Borrelia burgdorferi IgG
13.	BORM0040 Borrelia burgdorferi IgM
14.	BRUG0050 Brucella IgG
15.	BRUM0050 Brucella IgM
16.	CANA0060 Candida albicans IgA
17.	CANG0060 Candida albicans IgG
18.	CANM0060 Candida albicans IgM
19.	TRYP0570 Chagas
20.	CHIG0590 Chikungunya IgG capture
21.	CHIM0590 Chikungunya IgM μ -capture
22.	CORG0090 Corynebacterium diphtheriae toxin IgG
23.	CORG5009 Corynebacterium diphtheriae toxin 5S IgG
24.	PCORG009 Corynebacterium diphtheriae toxin 5S IgG plus
25.	COX1G0600 Coxiella burnetii (Q-Fever) Phase 1 IgG
26.	COX2G0600 Coxiella burnetii (Q-Fever) Phase 2 IgG
27.	COX2M0600 Coxiella burnetii (Q-Fever) Phase 2 IgM
28.	DENG0120 Dengue Virus IgG
29.	DENM0120 Dengue Virus IgM
30.	DVM0460 Dengue Virus IgM μ -capture
31.	ECHG0130 Echinococcus IgG
32.	ENTG0140 Entamoeba histolytica IgG
33.	EBVA0150 Epstein-Barr Virus (VCA) IgA
34.	EBVG0150 Epstein-Barr Virus (VCA) IgG
35.	AEBV7150 Avidity Epstein-Barr Virus (VCA) IgG
36.	EBVM0150 Epstein-Barr Virus (VCA) IgM
37.	EBVG0580 Epstein-Barr Virus (EBNA) IgG
38.	FIL0760 Filariasis
39.	GIA0160S Giardia lamblia antigen
40.	HANG0670 Hantavirus IgG
41.	HANM0670 Hantavirus IgM
42.	HELA0220 Helicobacter pylori IgA
43.	PHELA022 Helicobacter pylori IgA plus
44.	HELG0220 Helicobacter pylori IgG
45.	PHELG022 Helicobacter pylori IgG plus
46.	HSVG0250 Herpes simplex Virus 1+2 (HSV) IgG
47.	HSVM0250 Herpes simplex Virus 1+2 (HSV) IgM

48.	HSV1G0500	Herpes simplex Virus 1 (HSV 1) IgG
49.	HSV1M0500	Herpes simplex Virus 1 (HSV 1) IgM
50.	HSV2G0540	Herpes simplex Virus 2 (HSV 2) IgG
51.	HSV2M0540	Herpes simplex Virus 2 (HSV 2) IgM
52.	INFA0290	Influenza Virus A IgA
53.	INFG0290	Influenza Virus A IgG
54.	INFM0290	Influenza Virus A Ig M
55.	INFA0300	Influenza Virus B IgA
56.	INFG0300	Influenza Virus B IgG
57.	INFM0300	Influenza Virus B IgM
58.	LEGG0650	Legionella pneumophila IgG
59.	LEGM0650	Legionella pneumophila IgM
60.	LEPG0660	Leptospira IgG
61.	LEPM0660	Leptospira IgM
62.	LEIG0310	Leishmania infantum IgG
63.	MAL0620	Malaria
64.	MEAG0330	Measles Virus IgG
65.	AMEA7330	Avidity Measles Virus IgG
66.	MEAM0330	Measles Virus IgM
67.	MUMG0340	Mumps Virus IgG
68.	MUMM0340	Mumps Virus IgM
69.	MYCA0350	Mycoplasma pneumoniae IgA
70.	MYCG0350	Mycoplasma pneumoniae IgG
71.	MYCM0350	Mycoplasma pneumoniae IgM
72.	PAIA0360	Parainfluenza Virus 1,2,3 IgA
73.	PAIG0360	Parainfluenza Virus 1,2,3 IgG
74.	PARG0370	Parvovirus B19 IgG
75.	PARM0370	Parvovirus B19 IgM
76.	RSVA0380	Respiratory Syncytial Virus IgA
77.	RSVG0380	Respiratory syncytial Virus IgG
78.	RSVM0380	Respiratory syncytial Virus IgM
79.	SCHG0410	Schistosoma mansoni IgG
80.	SCHM0410	Schistosoma mansoni IgM
81.	STRO0690	Strongyloides
82.	TAEG0420	Taenia solium IgG
83.	TETG0430	Clostridium tetani toxin IgG
84.	TETG5043	Clostridium tetani toxin 5S IgG
85.	PTETG043	Clostridium tetani toxin 5S IgG plus
86.	TICG0440	TBE/ FSME IgG
87.	TICM0440	TBE/ FSME IgM
88.	PTICG044	TBE/ FSME IgG plus
89.	TOCG0450	Toxocara canis IgG
90.	TRIG0480	Trichinella spiralis IgG
91.	VZVA0490	Varicella-Zoster Virus (VZV) IgA
92.	VZVG0490	Varicella-Zoster Virus (VZV) IgG
93.	VZVM0490	Varicella-Zoster Virus (VZV) IgM
94.	ZVG0790	Zika Virus IgG capture
95.	ZVM0790	Zika Virus IgM μ -capture
96.	ATG1010	Anti-TG
97.	ATPO1020	Anti-TPO
98.	TSH1030	TSH

99.	RFM3010	Rheumatoid Factor IgM
100.	DNOV001	Cortisol
101.	DNOV002	Testosterone
102.	DNOV003	17 beta-Estradiol
103.	DNOV004	17-OH Progesterone
104.	DNOV005	DHEA-S
105.	DNOV006	Progesterone
106.	DNOV007	Free Estriol
107.	DNOV008	Androstenedione
108.	DNOV009	Free Testosterone
109.	DNOV010	Urinary Cortisol
110.	DNOV011	Total Estriol
111.	DNOV012	Aldosterone
112.	DSNOV20	Cortisol Saliva
113.	DSNOV21	Testosterone Saliva
114.	DSNOV22	17 beta-Estradiol Saliva
115.	DSNOV24	DHEA-S Saliva
116.	DSNOV25	Progesterone Saliva
117.	DSNOV26	Estriol Saliva
118.	DSNOV27	Androstenedione Saliva
119.	DNOV030	LH
120.	DNOV031	FSH
121.	DNOV032	Prolactin
122.	DNOV033	AFP
123.	DNOV034	beta-HCG
124.	DNOV051	Free T3
125.	DNOV052	Free T4
126.	DNOV053	Total T3
127.	DNOV054	Total T4
128.	DNOV057	Thyroglobulin
129.	DNOV060	CEA
130.	DNOV061	CA 125
131.	DNOV062	CA 15-3
132.	DNOV063	CA 19-9
133.	DNOV093	CIC-C1q
134.	DNOV094	CIC-C3d
135.	DNOV096	CH-50
136.	DNOV100	Ferritin
137.	DNOV101	HGH
138.	DNOV102	IgE
139.	DNOV111	Insulin
140.	DNOV112	C-Peptide