

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), resp. Annex IV.3.

Dietzenbach, 2017-10-23



Dr. Claudia Rezmer
Management Representative

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.	CHAG0560 Chagas (Trypanosoma cruzi) IgG
20.	TRYP0570 Chagas
21.	CHIG0590 Chikungunya IgG capture
22.	CHIM0590 Chikungunya IgM μ -capture
23.	CHLA0070 Chlamydia trachomatis IgA
24.	CHLG0070 Chlamydia trachomatis IgG
25.	CHLM0070 Chlamydia trachomatis IgM
26.	CHLA0510 Chlamydia pneumoniae IgA
27.	CHLG0510 Chlamydia pneumoniae IgG
28.	CHLM0510 Chlamydia pneumoniae IgM
29.	CMVG0110 Cytomegalovirus (CMV) IgG
30.	ACMV7110 Avidity Cytomegalovirus (CMV) IgG
31.	CMVM0110 Cytomegalovirus (CMV) IgM
32.	CORG0090 Corynebacterium diphtheriae toxin IgG
33.	CORG5009 Corynebacterium diphtheriae toxin 5S IgG
34.	PCORG009 Corynebacterium diphtheriae toxin 5S IgG plus
35.	COX1G0600 Coxiella burnetii (Q-Fever) Phase 1 IgG
36.	COX2G0600 Coxiella burnetii (Q-Fever) Phase 2 IgG
37.	COX2M0600 Coxiella burnetii (Q-Fever) Phase 2 IgM
38.	DENG0120 Dengue Virus IgG
39.	DENM0120 Dengue Virus IgM
40.	DVM0460 Dengue Virus IgM μ -capture
41.	ECHG0130 Echinococcus IgG
42.	ENTG0140 Entamoeba histolytica IgG
43.	EBVA0150 Epstein-Barr Virus (VCA) IgA
44.	EBVG0150 Epstein-Barr Virus (VCA) IgG
45.	AEBV7150 Avidity Epstein-Barr Virus (VCA) IgG
46.	EBVM0150 Epstein-Barr Virus (VCA) IgM
47.	EBVG0580 Epstein-Barr Virus (EBNA) IgG

The conformity of the above mentioned product is checked at least every 3 years.
This is documented by rechecking and signing the general requirements.

48.	FIL0760	Filariasis
49.	GIA0160S	Giardia lamblia antigen
50.	HANG0670	Hantavirus IgG
51.	HANM0670	Hantavirus IgM
52.	HELA0220	Helicobacter pylori IgA
53.	PHELA022	Helicobacter pylori IgA plus
54.	HELG0220	Helicobacter pylori IgG
55.	PHELG022	Helicobacter pylori IgG plus
56.	HSVG0250	Herpes simplex Virus 1+2 (HSV) IgG
57.	HSVM0250	Herpes simplex Virus 1+2 (HSV) IgM
58.	HSV1G0500	Herpes simplex Virus 1 (HSV 1) IgG
59.	HSV1M0500	Herpes simplex Virus 1 (HSV 1) IgM
60.	HSV2G0540	Herpes simplex Virus 2 (HSV 2) IgG
61.	HSV2M0540	Herpes simplex Virus 2 (HSV 2) IgM
62.	INFA0290	Influenza Virus A IgA
63.	INFG0290	Influenza Virus A IgG
64.	INFM0290	Influenza Virus A IgM
65.	INFA0300	Influenza Virus B IgA
66.	INFG0300	Influenza Virus B IgG
67.	INFM0300	Influenza Virus B IgM
68.	LEGG0650	Legionella pneumophila IgG
69.	LEGM0650	Legionella pneumophila IgM
70.	LEIG0310	Leishmania infantum IgG
71.	LEPG0660	Leptospira IgG
72.	LEPM0660	Leptospira IgM
73.	LEIG0310	Leishmania infantum IgG
74.	MAL0620	Malaria
75.	MEAG0330	Measles Virus IgG
76.	AEA7330	Avidity Measles Virus IgG
77.	MEAM0330	Measles Virus IgM
78.	MUMG0340	Mumps Virus IgG
79.	MUMM0340	Mumps Virus IgM
80.	MYCA0350	Mycoplasma pneumoniae IgA
81.	MYCG0350	Mycoplasma pneumoniae IgG
82.	MYCM0350	Mycoplasma pneumoniae IgM
83.	PAIA0360	Parainfluenza Virus 1,2,3 IgA
84.	PAIG0360	Parainfluenza Virus 1,2,3 IgG
85.	PARG0370	Parvovirus B19 IgG
86.	PARM0370	Parvovirus B19 IgM
87.	RSVA0380	Respiratory Syncytial Virus IgA
88.	RSVG0380	Respiratory syncytial Virus IgG
89.	RSVM0380	Respiratory syncytial Virus IgM
90.	RUBG0400	Rubella Virus IgG
91.	ARUB7400	Avidity Rubella Virus IgG
92.	RUBM0400	Rubella Virus IgM μ -capture
93.	SCHG0410	Schistosoma mansoni IgG
94.	SCHM0410	Schistosoma mansoni IgM
95.	STRO0690	Strongyloides
96.	TAEG0420	Taenia solium IgG
97.	TETG0430	Clostridium tetani toxin IgG
98.	TETG5043	Clostridium tetani toxin 5S IgG

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99.	PTETG043	Clostridium tetani toxin 5S IgG plus
100.	TICG0440	TBE/ FSME IgG
101.	TICM0440	TBE/ FSME IgM
102.	PTICG044	TBE/ FSME IgG plus
103.	TOCG0450	Toxocara canis IgG
104.	TOXA0460	Toxoplasma gondii IgA
105.	TOXG0460	Toxoplasma gondii IgG
106.	ATOX7460	Avidity Toxoplasma gondii IgG
107.	TOXM0460	Toxoplasma gondii IgM μ -capture
108.	TRIG0480	Trichinella spiralis IgG
109.	VZVA0490	Varicella-Zoster Virus (VZV) IgA
110.	VZVG0490	Varicella-Zoster Virus (VZV) IgG
111.	VZVM0490	Varicella-Zoster Virus (VZV) IgM
112.	ZVG0790	Zika Virus IgG capture
113.	ZVM0790	Zika Virus IgM μ -capture
114.	ATG1010	Anti-TG
115.	ATPO1020	Anti-TPO
116.	TSH1030	TSH
117.	RFM3010	Rheumatoid Factor IgM
118.	DNOV001	Cortisol
119.	DNOV002	Testosterone
120.	DNOV003	17 beta-Estradiol
121.	DNOV004	17-OH Progesterone
122.	DNOV005	DHEA-S
123.	DNOV006	Progesterone
124.	DNOV007	Free Estriol
125.	DNOV008	Androstenedione
126.	DNOV009	Free Testosterone
127.	DNOV010	Urinary Cortisol
128.	DNOV011	Total Estriol
129.	DNOV012	Aldosterone
130.	DSNOV20	Cortisol Saliva
131.	DSNOV21	Testosterone Saliva
132.	DSNOV22	17 beta-Estradiol Saliva
133.	DSNOV24	DHEA-S Saliva
134.	DSNOV25	Progesterone Saliva
135.	DSNOV26	Estriol Saliva
136.	DSNOV27	Androstenedione Saliva
137.	DNOV030	LH
138.	DNOV031	FSH
139.	DNOV032	Prolactin
140.	DNOV033	AFP
141.	DNOV034	beta-HCG
142.	DNOV051	Free T3
143.	DNOV052	Free T4
144.	DNOV053	Total T3
145.	DNOV054	Total T4
146.	DNOV057	Thyroglobulin
147.	DNOV060	CEA
148.	DNOV061	CA 125
149.	DNOV062	CA 15-3

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150.	DNOV063	CA 19-9
151.	DNOV093	CIC-C1q
152.	DNOV094	CIC-C3d
153.	DNOV096	CH-50
154.	DNOV100	Ferritin
155.	DNOV101	HGH
156.	DNOV102	IgE
157.	DNOV111	Insulin
158.	DNOV112	C-Peptide

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