

Certificate

mdc medical device certification GmbH
certifies that



NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

for the scope

**development, manufacturing and distribution of
in-vitro diagnostics (ELISA, PCR)**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2019-11-08
Valid until	2021-12-03
Registration no.	D1055500016
Report no.	P19-01184-160369
Stuttgart	2019-11-08



Head of Certification Body





NovaLisa®

ELISA Diagnostics Assays

NovaLisa® is the IVD ELISA Kits product line for the human market. We offer a wide range of products with focus on Infectious Diseases: Virology, Bacteriology, Parasites, Worms and Fungi. All the reagents are ready to use and user friendly.

- CE approved
- Standardized methods
- Ready-to-use, color-coded reagents
- Special IgM-buffer to avoid interferences with rheumatoid factors
- EIAs with cut-off-controls
- Snap-off microtiter strips
- QC performed manually as well as on several automated systems
- Avidity tests available

Virology	Order No.
Adenovirus IgA	ADVA0010
Adenovirus IgG	ADVG0010
Adenovirus IgM	ADVM0010
Chikungunya Virus IgG capture	CHIG0590
Chikungunya Virus IgM μ -capture	CHIM0590
Cytomegalovirus (CMV) IgG	CMVG0110
Avidity Cytomegalovirus (CMV) IgG	ACMV7110
Cytomegalovirus (CMV) IgM	CMVM0110
Dengue Virus IgG	DENG0120
Dengue Virus IgM	DENM0120
Dengue Virus IgM μ -capture	DVM0640
Dengue Virus NS1 Antigen	NS1D4020
Epstein-Barr Virus (VCA) IgA	EBVA0150
Epstein-Barr Virus (VCA) IgG	EBVG0150
Avidity Epstein-Barr Virus (VCA) IgG	AEBV7150
Epstein-Barr Virus (VCA) IgM	EBVM0150
Epstein-Barr Virus (EBNA) IgG	EBVG0580
Hantavirus IgG *	HANG0670
Hantavirus IgM *	HANM0670
Hepatitis E Virus (HEV) IgG *	HEVG0780
Hepatitis E Virus (HEV) IgM *	HEVM0780
Herpes simplex Virus 1+2 (HSV) IgG	HSVG0250
Herpes simplex Virus 1+2 (HSV) IgM	HSVM0250
Herpes simplex Virus 1 (HSV-1) IgG *	HSV1G0500
Herpes simplex Virus 1 (HSV-1) IgM *	HSV1M0500
Herpes simplex Virus 2 (HSV-2) IgG *	HSV2G0540
Herpes simplex Virus 2 (HSV-2) IgM*	HSV2M0540
Influenza Virus A IgA	INFA0290
Influenza Virus A IgG	INFG0290
Influenza Virus A IgM	INFM0290
Influenza Virus B IgA	INFA0300
Influenza Virus B IgG	INFG0300
Influenza Virus A IgM	INFM0300
Measles Virus IgG	MEAG0330
Avidity Measles Virus IgG	AMEA7330
Measles Virus IgM	MEAM0330
Mumps Virus IgG	MUMG0340
Mumps Virus IgM	MUMM0340
Parainfluenza Virus 1,2,3 IgA	PAIA0360
Parainfluenza Virus 1,2,3 IgG	PAIG0360
Parvovirus B 19 IgG *	PARG0370
Parvovirus B 19 IgM *	PARM0370
Respiratory syncytial Virus IgA	RSVA0380
Respiratory syncytial Virus IgG	RSVG0380
Respiratory syncytial Virus IgM	RSVM0380
Rubella Virus IgG **	RUBG0400
Avidity Rubella Virus IgG ***	ARUB7400
Rubella Virus IgM μ -capture	RUBM0400

Virology	Order No.
SARS-CoV-2 (COVID-19) IgA	COVA0940
SARS-CoV-2 (COVID-19) IgG	COVG0940
SARS-CoV-2 (COVID-19) IgM	COVM0940
GSD NovaLisa SARS-CoV-2 quantitative IgG	CVGQ0970
TBE / FSME IgG ***	TICG0440
TBE / FSME IgM	TICM0440
TBE / FSME IgG plus ***	PTICG044
Varicella-Zoster Virus (VZV) IgA	VZVA0490
Varicella-Zoster Virus (VZV) IgG	VZVG0490
Varicella-Zoster Virus (VZV) IgM	VZVM0490
Zika Virus IgG capture *	ZVG0790
Zika Virus IgM μ -capture *	ZVM0790

Bacteriology	Order No.
Bartonella	BAR0900
Bordetella pertussis IgA	BOPA0030
Bordetella pertussis IgG	BOPG0030
Bordetella pertussis IgM	BOPM0030
Bordetella pertussis toxin (PT) IgA **	BPTA0610
Bordetella pertussis toxin (PT) IgG **	BPTG0610
Borrelia burgdorferi IgG *	BORG0040
Borrelia burgdorferi IgM *	BORM0040
Brucella IgG	BRUG0050
Brucella IgM	BRUM0050
Chlamydia trachomatis IgA	CHLA0070
Chlamydia trachomatis IgG	CHLG0070
Chlamydia trachomatis IgM	CHLM0070
Chlamydia pneumoniae IgA	CHLA0510
Chlamydia pneumoniae IgG	CHLG0510
Chlamydia pneumoniae IgM	CHLM0510
Corynebacterium diphtheriae toxin IgG **	CORG0090
Corynebacterium diphtheriae toxin 5S IgG **	CORG5009
Corynebacterium diphtheriae toxin 5S IgG plus **	PCORG5009
Helicobacter pylori IgA *, ***	HELA0220
Helicobacter pylori IgG ***	HELG0220
Helicobacter pylori IgA plus *, ***	PHELA022
Helicobacter pylori IgG plus ***	PHELG022
Legionella pneumophila IgG	LEGG0650
Legionella pneumophila IgM	LEGM0650
Leptospira IgG	LEPG0660
Leptospira IgM	LEPM0660
Mycoplasma pneumoniae IgA	MYCA0350
Mycoplasma pneumoniae IgG	MYCG0350
Mycoplasma pneumoniae IgM	MYCM0350
Clostridium tetani toxin IgG **	TETG0430
Clostridium tetani toxin 5S IgG **	TETG5043
Clostridium tetani toxin 5S IgG plus **	PTETG043

Parasites	Order No.
Chagas (Trypanosoma cruzi) IgG *	CHAG0560
Chagas *	TRYP0570
Entamoeba histolytica IgG	ENTG0140
Leishmania infantum IgG	LEIG0310
Malaria *	MAL0620
Toxoplasma gondii IgA	TOXA0460
Toxoplasma gondii IgG **	TOXG0460
Avidity Toxoplasma gondii IgG **	ATOX7460
Toxoplasma gondii IgM μ -capture	TOXM0460

Worms	Order No.
Ascaris lumbricoides IgG	ASCG0020
Echinococcus IgG	ECHG0130
Filariasis	FIL0760
Schistosoma mansoni IgG	SCHG0410
Schistosoma mansoni IgM	SCHM0410
Strongyloides *	STRO0690
Taenia solium IgG	TAEG0420
Toxocara canis IgG	TOCG0450
Trichinella spiralis IgG	TRIG0480

Fungi	Order No.
Aspergillus fumigatus IgG	ASPG0680
Aspergillus fumigatus IgM	ASPM0680
Candida albicans IgA	CANA0060
Candida albicans IgG	CANG0060
Candida albicans IgM	CANM0060

Autoimmune	Order No.
Anti-TG *	ATG1010
Anti-TPO *	ATPO1020
Rheumatoid Factor IgM **	RFM3010

* Recombinant antigen

** Quantitative assays (WHO standardized)

*** Quantitative assays

Hormones	Order No.
Urinary Cortisol	DNOV010
Cortisol Saliva	DSNOV20
Testosterone Saliva	DSNOV21
DHEA-S Saliva	DSNOV24
Androstenedione Saliva	DSNOV27
LH (Lutenizing Hormone)	DNOV030
FSH (Follicle Stimulating Hormone)	DNOV031
Prolactin	DNOV032
AFP (alpha-Fetoprotein Precursor)	DNOV033
beta HCG	DNOV034
Anti-TG *	ATG1010
Anti-TPO *	ATPO1020
Rheumatoid Factor IgM **	RFM3010
Insulin	DNOV111
C-Peptide	DNOV112
CIC-C1q	DNOV093
CIC-C3d	DNOV094
CH-50	DNOV096
CEA	DNOV060
CA 125	DNOV062
CA 15-3	DNOV063
CA 19-9	DNOV064
Ferritin	DNOV100
HGH	DNOV101
IgE	DNOV102
Anti-TG ***	ATG1010
Anti-TPO ***	ATPO1020
Free T4 ***	FT41050
TSH **	TSH1030
Free T3	DNOV051
Total T3	DNOV053
Total T4	DNOV054
Thyroglobulin	DNOV057
Cortisol	DNOV001
Testosterone	DNOV002
17 beta-Estradiol	DNOV003
17-OH Progesterone	DNOV004
DHEA-S	DNOV005
Progesterone	DNOV006
Androstenedione	DNOV008
Free Testosterone	DNOV009
Total Estriol	DNOV011
Alosterone	DNOV012



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