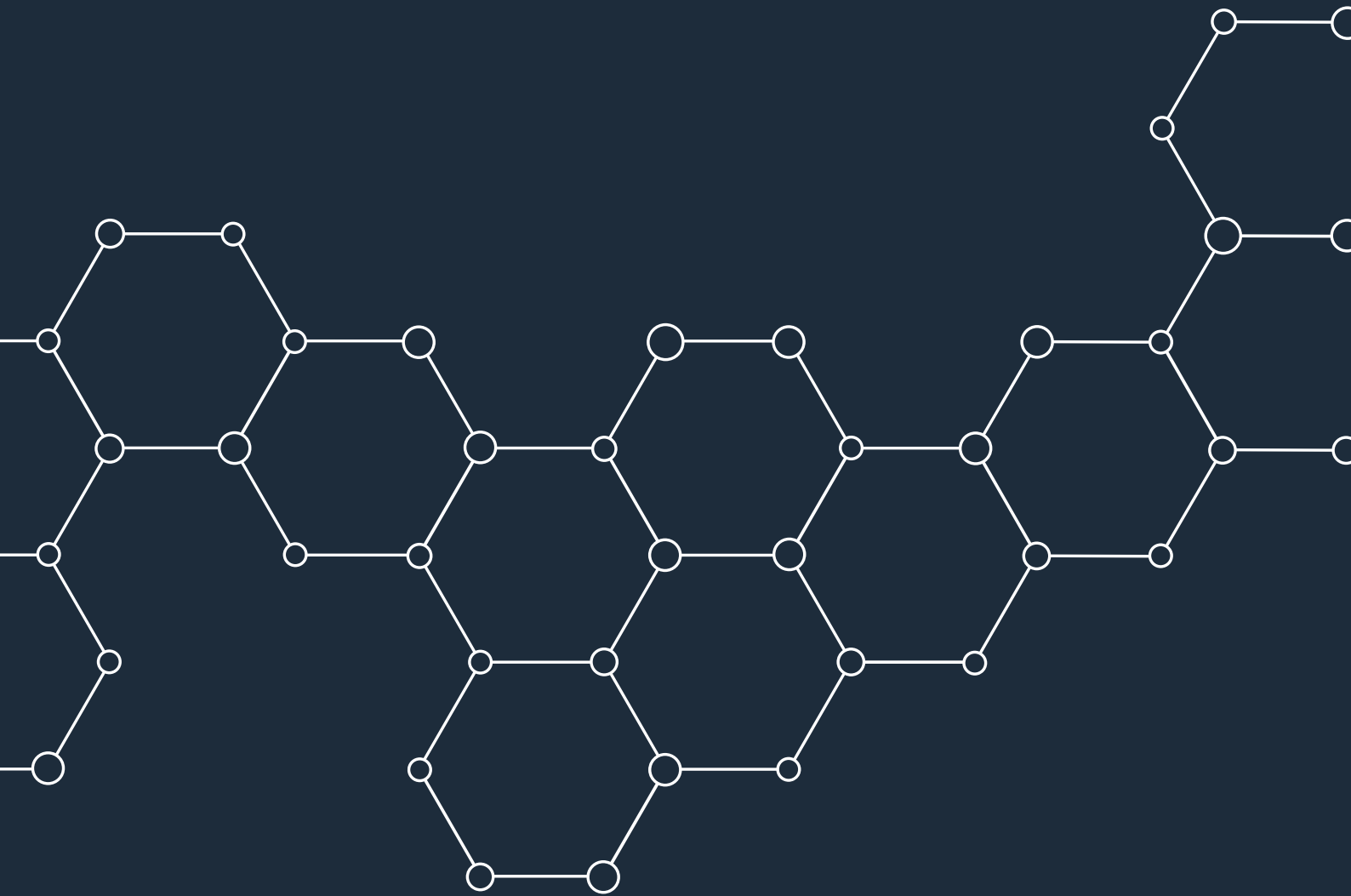


DIAGNOSTIC ASSAYS & INSTRUMENTS

GOLD STANDARD DIAGNOSTICS EUROPE
2022 INTERNATIONAL CATALOGUE





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About Us

The Gold Standard Diagnostics Group is a leading healthcare provider of diagnostic solutions composed by three companies with extensive experience in the clinical market: Gold Standard Diagnostics Inc., Novatec Immundiagnostica GmbH, and Virotech Diagnostics GmbH. The European branch, located in Dietzenbach (Germany), concentrates the business of the Group outside the United States of America.

Gold Standard Diagnostics Europe provides automated platforms and a broad menu of diagnostic tests in the fields of virology, bacteriology, parasitology, mycology, tumor markers, hormones, and autoimmune diseases.

The company is engaged in innovative development, quality manufacturing, and outstanding commercialization of diagnostic solutions. Our aim is to be at the forefront of what the laboratories need, and we are committed to delivering best-in-class assays and services to our vast network worldwide. We will continue to devote all our efforts to improving patient care.

Novatec Immundiagnostica and Virotech Diagnostics are ISO 13485:2016 certified, and most of the products in this catalogue are CE marked, fulfilling the European Directive 98/79/CE on *in vitro* diagnostic medical devices.

Additionally, we participate in several External Quality Assessment Control Programs such as:

- INSTAND
- UK NEQAS
- ESfEQA
- RfB
- Labquality
- College of American Pathologists



ELISA Kits

Serology

Wide range of Enzyme-linked Immunosorbent Assays for detecting antibodies against infectious diseases. The ELISA product offering includes complete kits, IgA sets to complement IgG/IgM diagnostics, and standards and controls for CSF Diagnostics. Multiple order numbers per product separated by a slash correspond to the different Novatec and Virotech format respectively.

- Ready-to-use, color-coded reagents, and breakable strip plates
- Standardized methods suitable for automated procedures
- Avidity and μ -capture tests available for some parameters
- Special IgM-buffer to avoid interferences with rheumatoid factor
- Validated for cerebrospinal fluid testing where diagnostically relevant
- CE marked

VIROLOGY • Complete kits

Order No.	Product description	Format
ADVA0010	Adenovirus IgA <i>Highly purified native antigen.</i>	96 tests
ADVG0010	Adenovirus IgG <i>Highly purified native antigen.</i>	96 tests
EC121.00	Adenovirus IgG/IgM <i>Additional IgA set available with order number EC121.08.</i>	96 tests
ADVM0010	Adenovirus IgM <i>Highly purified native antigen.</i>	96 tests
CHIG0590	Chikungunya Virus IgG Capture <i>Capture-technology for IgG to increase specificity.</i>	96 tests
CHIM0590	Chikungunya Virus IgM μ-Capture <i>Capture-technology for IgM to increase specificity.</i>	96 tests
CMVG0110	Cytomegalovirus IgG	96 tests
ACMV7110	Cytomegalovirus IgG Avidity <i>Can be used to determine the time of infection.</i>	48 tests
EC113.00	Cytomegalovirus IgG/IgM <i>Mix of native and purified antigens. Validated for cerebrospinal fluid testing.</i>	96 tests
CMVM0110	Cytomegalovirus IgM	96 tests
DENG0120	Dengue Virus IgG <i>It allows detection of antibodies against all 4 DENV types.</i>	96 tests
DENM0120	Dengue Virus IgM <i>It allows detection of antibodies against all 4 DENV types.</i>	96 tests
DVM0640	Dengue Virus IgM μ-Capture <i>Capture-technology to increase specificity.</i>	96 tests
NSID4020	Dengue Virus NS1 Antigen <i>Detects of acute infections.</i>	96 tests
EC116A00	Enterovirus IgA <i>Screening assay for the detection of heterotypic IgA antibodies with coxsackievirus B5 and echovirus 24 antigens.</i>	96 tests
EC116G00	Enterovirus IgG <i>Screening assay for the detection of heterotypic IgG antibodies with coxsackievirus B5 and echovirus 24 antigens.</i>	96 tests
EC116M00	Enterovirus IgM <i>Screening assay for the detection of heterotypic IgM antibodies with coxsackievirus B5 and echovirus 24 antigens.</i>	96 tests

Order No.	Product description	Format
EBVG0080/ EC202.00	Epstein-Barr Virus EA-D IgG	96 tests
EBVG0580/ EC204.00	Epstein-Barr Virus EBNA IgG <i>EC204.00 provides a special formula that allows a distinction between primary and past infection in unclear cases.</i>	96 tests
EC102.00	Epstein-Barr Virus IgG/IgM <i>Validated for cerebrospinal fluid testing.</i>	96 tests
EBVA0150	Epstein-Barr Virus VCA IgA	96 tests
EBVG0150/ EC205G00	Epstein-Barr Virus VCA IgG <i>EC205G00 includes gp125 and p18 as highly specific markers.</i>	96 tests
AEBV7150	Epstein-Barr Virus VCA IgG Avidity <i>Can be used to distinguish between acute and past infection.</i>	48 tests
EBVM0150/ EC203M00	Epstein-Barr Virus VCA IgM <i>EC203M00 provides a special formula that allows a distinction between primary and past infection in unclear cases.</i>	96 tests
HANG0670	Hantavirus IgG <i>Recombinant antigen, contains four species/serotypes to detect it worldwide.</i>	96 tests
HANM0670	Hantavirus IgM <i>Recombinant antigen, contains four species/serotypes to detect it worldwide.</i>	96 tests
HEVG0780	Hepatitis E Virus IgG <i>Recombinant antigen for high sensitivity and specificity.</i>	96 tests
HEVM0780	Hepatitis E Virus IgM <i>Recombinant antigen for high sensitivity and specificity.</i>	96 tests
EC130.00	Herpes Simplex Virus 1 (gG1) IgG/IgM <i>Highly-specific recombinant glycoprotein gG1 antigen, validated for cerebrospinal fluid testing.</i>	96 tests
HSV1G0500	Herpes Simplex Virus 1 IgG <i>Highly-specific recombinant glycoprotein gG1 antigen.</i>	96 tests
HSV1M0500	Herpes Simplex Virus 1 IgM <i>Highly-specific recombinant glycoprotein gG1 antigen.</i>	96 tests
HSVG0250	Herpes Simplex Virus 1+2 IgG	96 tests
HSVM0250	Herpes Simplex Virus 1+2 IgM	96 tests
EC131.00	Herpes Simplex Virus 2 (gG2) IgG/IgM <i>Highly-specific affinity-purified glycoprotein gG2 antigen, validated for cerebrospinal fluid testing.</i>	96 tests
HSV2G0540	Herpes Simplex Virus 2 IgG <i>Highly-specific recombinant glycoprotein gG2 antigen.</i>	96 tests
HSV2M0540	Herpes Simplex Virus 2 IgM <i>Highly-specific recombinant glycoprotein gG2 antigen.</i>	96 tests
EC108.00	Herpes Simplex Virus Screen IgG/IgM <i>Validated for cerebrospinal fluid testing.</i>	96 tests
INFA0290/ EC118A00	Influenza Virus A IgA <i>EC118A00 with seasonal updated antigens.</i>	96 tests
INFG0290	Influenza Virus A IgG	96 tests
EC118.00	Influenza Virus A IgG/IgM <i>Seasonal updated antigens.</i>	96 tests
INFM0290	Influenza Virus A IgM	96 tests
INFA0300/ EC119A00	Influenza Virus B IgA <i>EC119A00 with seasonal updated antigens.</i>	96 tests
INFG0300	Influenza Virus B IgG	96 tests
EC119.00	Influenza Virus B IgG/IgM <i>Seasonal updated antigens.</i>	96 tests
INFM0300	Influenza Virus B IgM	96 tests

Order No.	Product description	Format
MEAG0330/ EC105G00	Measles Virus IgG <i>Detects present and past contact with measles due to wild-virus or vaccination. EC105G00 is adjusted to the WHO standards and is validated for cerebrospinal fluid testing.</i>	96 tests
AMEA7330	Measles Virus IgG Avidity <i>Can be used to differentiate between acute and past infection.</i>	48 tests
MEAM0330/ EC105M00	Measles Virus IgM <i>MEAM0330 detects present and past contact with measles due to wild-virus or vaccination.</i>	96 tests
MUMG0340	Mumps Virus IgG <i>Detects present and past contact with mumps due to wild-virus or vaccination.</i>	96 tests
EC106.00	Mumps Virus IgG/IgM <i>Detects acute infections in IgM, the serostatus in IgG, and is validated for cerebrospinal fluid testing.</i>	96 tests
MUMM0340	Mumps Virus IgM <i>Detects present and past contact with mumps due to wild-virus.</i>	96 tests
PAIA0360	Parainfluenza Virus 1, 2, 3 IgA	96 tests
PAIG0360	Parainfluenza Virus 1, 2, 3 IgG	96 tests
EC148.00	ParaScreen Virus IgG/IgM <i>Additional IgA set available with order number EC148.08.</i>	96 tests
PARG0370	Parvovirus B19 IgG <i>Recombinant antigen.</i>	96 tests
PARM0370	Parvovirus B19 IgM <i>Recombinant antigen.</i>	96 tests
RSVA0380	Respiratory Syncytial Virus IgA	96 tests
RSVG0380	Respiratory Syncytial Virus IgG	96 tests
EC107.00	Respiratory Syncytial Virus IgG/IgM <i>Additional IgA set available with order number EC107.08.</i>	96 tests
RSVM0380	Respiratory Syncytial Virus IgM	96 tests
EC109L00	Rubella Virus CSF IgG <i>For cerebrospinal fluid testing only, additional available standards and control sets.</i>	96 tests
RUBG0400	Rubella Virus IgG	96 tests
ARUB7400	Rubella Virus IgG Avidity <i>Can be used to differentiate between acute and past infection.</i>	48 tests
RUBM0400	Rubella Virus IgM μ-Capture <i>Capture technology to increase specificity.</i>	96 tests
EC123A00	SARS-CoV-2 (COVID-19) Virus IgA	96 tests
EC123G00	SARS-CoV-2 (COVID-19) Virus IgG <i>Offered with high and low prevalence cut-off adjustment.</i>	96 tests
EC123M00	SARS-CoV-2 (COVID-19) Virus IgM	96 tests
CVGQ0970	SARS-CoV-2 (COVID-19) quantitative IgG <i>Quantitative determination of antibodies to the spike (S) protein. Calibrators correlate to the "First WHO International Standard for anti SARS-CoV-2 immunoglobulin (human)".</i>	96 tests
TICG0440	Tick-Borne Encephalitis IgG <i>Quantitative assay with antibody titer profile to verify immune status.</i>	96 tests
PTICG044	Tick-Borne Encephalitis IgG plus <i>Quantitative assay with antibody titer profile to verify immune status. It contains an additional control.</i>	96 tests
EC117.00	Tick-Borne Encephalitis IgG/IgM <i>Detects acute/recent infection and vaccination antibodies. Validated for cerebrospinal fluid testing.</i>	96 tests
TICM0440	Tick-Borne Encephalitis IgM <i>Can be used to verify immune status.</i>	96 tests

Order No.	Product description	Format
VZVA0490	Varicella-Zoster Virus IgA	96 tests
VZVG0490	Varicella-Zoster Virus IgG <i>Can be used for measuring antibody response after varicella vaccination.</i>	96 tests
EC110.00	Varicella-Zoster Virus IgG/IgM <i>IgG cut-off adjusted to follow Robert Koch Institute recommendations of seropositivity; IgG is aligned to the WHO standards. Additional IgA set available with order number EC110.08. Validated for cerebrospinal fluid testing.</i>	96 tests
VZVM0490	Varicella-Zoster Virus IgM	96 tests
ZVG0790	Zika Virus IgG Capture <i>Recombinant NS1 antigen. Capture-technology increases specificity and reduces cross reactivity.</i>	96 tests
ZVM0790	Zika Virus IgM μ-Capture <i>Recombinant NS1 antigen. Capture-technology increases specificity and reduces cross reactivity.</i>	96 tests

BACTERIOLOGY • Complete kits

Order No.	Product description	Format
BAR0900	Bartonella <i>Total antibody assay coated with highly purified native antigen.</i>	96 tests
EC115.00	Bordetella pertussis (FHA+PT) IgG/IgA <i>Sensitive screening assay coated with PT and FHA antigens.</i>	96 tests
BOPA0030	Bordetella pertussis IgA <i>Sensitive screening assay coated with PT and FHA antigens.</i>	96 tests
BOPG0030	Bordetella pertussis IgG <i>Sensitive screening assay coated with PT and FHA antigens.</i>	96 tests
BOPM0030	Bordetella pertussis IgM	96 tests
BPTA0610/ EC215A00	Bordetella pertussis toxin IgA <i>Pure PT antigens, adjusted to the WHO standards.</i>	96 tests
BPTG0610/ EC215G00	Bordetella pertussis toxin IgG <i>Pure PT antigens, adjusted to the WHO standards. EC215G00 available with additional IgG quantification set.</i>	96 tests
EC215M00	Bordetella pertussis toxin IgM <i>Pure PT antigens.</i>	96 tests
EC022G00	Borrelia + VlsE IgG <i>Antigen mix of B. afzelii Pko, B. garinii strain PBr, and B. burgdorferi strain ZS7 for high sensitivity and specificity. Validated for cerebrospinal fluid testing.</i>	96 tests
EC024G00	Borrelia + VlsE IgG Europe <i>Validated for cerebrospinal fluid testing.</i>	96 tests
EC022M00	Borrelia IgM <i>Borrelia strain Pko for high sensitivity. Validated for cerebrospinal fluid testing.</i>	96 tests
BORG0040	Borrelia burgdorferi IgG <i>Recombinant antigen, validated for serum, plasma, and cerebrospinal fluid testing.</i>	96 tests
BORM0040	Borrelia burgdorferi IgM <i>Recombinant antigen, validated for serum, plasma, and cerebrospinal fluid testing.</i>	96 tests
BRUG0050	Brucella IgG	96 tests
EC101.00	Brucella IgG/IgM <i>Additional IgA set available with order number EC101.08.</i>	96 tests
BRUM0050	Brucella IgM	96 tests

Order No.	Product description	Format
CHLA0510	Chlamydia pneumoniae IgA	96 tests
CHLG0510	Chlamydia pneumoniae IgG	96 tests
CHLM0510	Chlamydia pneumoniae IgM	96 tests
CHLA0070	Chlamydia trachomatis IgA	96 tests
CHLG0070	Chlamydia trachomatis IgG	96 tests
CHLM0070	Chlamydia trachomatis IgM	96 tests
CORG5009	Diphtheria toxin 5S IgG <i>Quantitative assay with 5 standards for verification of immune status due to vaccination or contact with Corynebacterium diphtheriae.</i>	96 tests
PCORG009	Diphtheria toxin 5S IgG plus <i>Quantitative assay with 5 standards and one additional control for verification of immune status due to vaccination or contact with Corynebacterium diphtheriae.</i>	96 tests
CORG0090/ EC129.00	Diphtheria toxin IgG <i>Quantitative assay. CORG0090 allows verification of immune status due to vaccination or contact with Corynebacterium diphtheriae. EC129.00 is adjusted to the WHO standards.</i>	96 tests
EC143A00	Helicobacter pylori IgA	96 tests
HELG0220/ EC143G00	Helicobacter pylori IgG <i>HELG0220 is a quantitative assay with recombinant antigen.</i>	96 tests
PHELG022	Helicobacter pylori IgG plus <i>Quantitative assay with recombinant antigen plus one control.</i>	96 tests
HELM0220	Helicobacter pylori IgM	96 tests
LEGG0650	Legionella pneumophila IgG <i>Assay with antigens from a pool of different serovars to increase sensitivity.</i>	96 tests
LEGM0650	Legionella pneumophila IgM <i>Assay with antigens from a pool of different serovars to increase sensitivity.</i>	96 tests
LEPM0660	Leptospira IgM	96 tests
LEPG0660	Leptospira IgG	96 tests
MYCA0350	Mycoplasma pneumoniae IgA <i>Highly purified antigens.</i>	96 tests
MYCG0350	Mycoplasma pneumoniae IgG <i>Highly purified antigens.</i>	96 tests
EC114.00	Mycoplasma pneumoniae IgG/IgM <i>Detects acute infections in IgG and offers specific cut-off adjustment for infant samples. Additional IgA set available with order number EC114.08.</i>	96 tests
MYCM0350	Mycoplasma pneumoniae IgM <i>Highly purified antigens.</i>	96 tests
TETG5043	Tetanus toxin 5S IgG <i>Quantitative assay adjusted to the WHO standards with recombinant antigen and 5 standards.</i>	96 tests
PTETG043	Tetanus toxin 5S IgG plus <i>Quantitative assay adjusted to the WHO standards with recombinant antigen and 5 standards plus one control.</i>	96 tests
TETG0430	Tetanus toxin IgG <i>Quantitative assay adjusted to the WHO standards with recombinant antigen.</i>	96 tests
EC124.00	Tetanus toxoid IgG <i>Quantitative assay adjusted to the WHO standards.</i>	96 tests
EC142.00	Yersinia enterocolitica IgG/IgA <i>Mix of purified native antigens and recombinant antigens YopD, YopB and YopE.</i>	96 tests
YERG0990	Yersinia enterocolitica IgG	96 tests
YERA0990	Yersinia enterocolitica IgA	96 tests

FUNGI • Complete kits

Order No.	Product description	Format
ASPG0680	Aspergillus fumigatus IgG	96 tests
ASPM0680	Aspergillus fumigatus IgM	96 tests
CANA0060	Candida albicans IgA	96 tests
CANG0060	Candida albicans IgG	96 tests
EC111.00	Candida albicans IgG/IgM <i>Designed to detect acute infections, offers an additional IgA set with order number EC111.08.</i>	96 tests
CANM0060	Candida albicans IgM	96 tests

PARASITES • Complete kits

Order No.	Product description	Format
ASCG0020	Ascaris lumbricoides IgG <i>Native antigen for high sensitivity.</i>	96 tests
CHAG0560	Chagas IgG <i>Chimeric-recombinant antigens to reduce cross-reactivity to Leishmania and Malaria.</i>	96 tests
ECHG0130	Echinococcus IgG	96 tests
ENTG0140	Entamoeba histolytica IgG	96 tests
FIL0760	Filariasis <i>Detects antibodies against main genus of filarial worms (Onchocerca, Loa loa, and Wuchereria).</i>	96 tests
LEIG0310	Leishmania infantum IgG <i>Specific antigens to reduce cross reactivity to Chagas.</i>	96 tests
MAL0620	Malaria <i>Recombinant antigens to reduce cross reactivity to other parasites.</i>	96 tests
SCHG0410	Schistosoma mansoni IgG	96 tests
SCHM0410	Schistosoma mansoni IgM	96 tests
STRO0690	Strongyloides <i>Chimeric-recombinant antigen to increase specificity. Detects the main human pathogen species.</i>	96 tests
TAEG0420	Taenia solium IgG <i>Native antigen for high sensitivity.</i>	96 tests
TOCG0450	Toxocara canis IgG	96 tests
TOXA0460	Toxoplasma gondii IgA	96 tests
TOXG0460	Toxoplasma gondii IgG <i>Quantitative assay. Calibrated against WHO standard.</i>	96 tests
ATOX7460	Toxoplasma gondii IgG Avidity	48 tests
TOXM0460	Toxoplasma gondii IgM μ-Capture <i>Capture assay to reduce cross-reactivity.</i>	96 tests
TRIG0480	Trichinella spiralis IgG	96 tests

HORMONES-AUTOIMMUNITY • Complete kits

Order No.	Product description	Format
DNOV003	17 beta-Estradiol	96 tests
DNOV004	17-OH Progesterone	96 tests
DNOV033	AFP	96 tests
DNOV012	Aldosterone	96 tests
DNOV008	Androstenedione	96 tests
DSNOV27	Androstenedione Saliva	96 tests
ATG1010	Anti-TG (<i>Recombinant antigen</i>)	96 tests
ATPO1020	Anti-TPO	96 tests
DNOV034	beta-HCG	96 tests
DNOV061	CA 125	96 tests
DNOV062	CA 15-3	96 tests
DNOV063	CA 19-9	96 tests
DNOV060	CEA	96 tests
DNOV096	CH-50	96 tests
DNOV093	CIC C1q	96 tests
DNOV094	CIC C3d	96 tests
DNOV001	Cortisol	96 tests
DSNOV20	Cortisol Saliva	96 tests
DNOV112	C-Peptide	96 tests
DNOV005	DHEA-S	96 tests
DSNOV24	DHEA-S Saliva	96 tests
DNOV100	Ferritin	96 tests
DNOV051	Free T3	96 tests
FT41050	Free T4	96 tests
DNOV009	Free Testosterone	96 tests
DNOV031	FSH	96 tests
DNOV101	HGH	96 tests
DNOV102	IgE	96 tests
DNOV111	Insulin	96 tests
DNOV030	LH	96 tests
DNOV006	Progesterone	96 tests
DNOV032	Prolactin	96 tests
RFM3010	Rheumatoid Factor IgM (<i>Fc fragments of human IgG for high specificity</i>)	96 tests
DNOV002	Testosterone	96 tests
DSNOV21	Testosterone Saliva	96 tests
DNOV057	Thyroglobulin	96 tests
DNOV064	Total PSA	96 tests
DNOV053	Total T3	96 tests
DNOV054	Total T4	96 tests
TSH1030	TSH (<i>Quantitative assay adjusted to the WHO standard</i>)	96 tests
DNOV010	Urinary Cortisol	96 tests

ELISA • Additional products

IgA Sets for Serology Diagnostics

Order No.	Product description	Related Kit Order No.	Format
EC121.08	Adenovirus IgA Set	EC121.00	3 x 1.3 ml & 1 x 11 ml
EN215Q60	Bordetella pertussis IgG quantification	EC215G00	3 x 2 ml
EC101.08	Brucella IgA Set	EC101.00	3 x 1.3 ml & 1 x 11 ml
EC111.08	Candida albicans IgA Set	EC111.00	3 x 1.3 ml & 1 x 11 ml
EC114.08	Mycoplasma pneumoniae IgA Set	EC114.00	3 x 1.3 ml & 1 x 11 ml
EC148.08	ParaScreen Virus IgA Set	EC148.00	3 x 1.3 ml & 1 x 11 ml
EC107.08	Respiratory Syncytial Virus IgA Set	EC107.00	3 x 1.3 ml & 1 x 11 ml
EC110.08	Varicella-Zoster Virus IgA Set	EC110.00	3 x 1.3 ml & 1 x 11 ml

Standards and Controls for CSF Diagnostics

Order No.	Product description	Related Kit Order No.	Format
EN022L65	Borrelia + VlsE IgG CSF AI Control Set	EC022G00/EC024G00	4 x 1 ml
EC022L60	Borrelia + VlsE IgG CSF Standards	EC022G00/EC024G00	4 x 1 ml
EC022L80	Borrelia afzelii IgM CSF Standards	EC022M00	4 x 1 ml
EC113L60	Cytomegalovirus IgG CSF Standards	EC113.00	4 x 1 ml
EN102L65	Epstein-Barr Virus IgG CSF AI Control Set	EC102.00	4 x 1 ml
EC102L60	Epstein-Barr Virus IgG CSF Standards	EC102.00	4 x 1 ml
EC130L60	Herpes Simplex Virus 1 (gG1) IgG CSF Standards	EC130.00	4 x 1 ml
EC131L60	Herpes Simplex Virus 2 (gG2) IgG CSF Standards	EC131.00	4 x 1 ml
EN108L65	Herpes Simplex Virus Screen IgG CSF AI Control Set	EC108.00	4 x 1 ml
EC108L60	Herpes Simplex Virus Screen IgG CSF Standards	EC108.00	4 x 1 ml
EN105L65	Measles Virus IgG CSF AI Control Set	EC105.00	4 x 1 ml
EC105L60	Measles Virus IgG CSF Standards	EC105.00	4 x 1 ml
EC106L60	Mumps Virus IgG CSF Standards	EC106.00	4 x 1 ml
EN109L65	Rubella Virus IgG CSF AI Control Set	EC109L00	4 x 1 ml
EC109L60	Rubella Virus IgG CSF Standards	EC109L00	4 x 1 ml
EN117L65	Tick-Borne Encephalitis IgG CSF AI Control Set	EC117.00	4 x 1 ml
EC117L60	Tick-Borne Encephalitis IgG CSF Standards	EC117.00	4 x 1 ml
EC117L80	Tick-Borne Encephalitis IgM CSF Standards	EC117.00	4 x 1 ml
EC110L40	Varicella-Zoster Virus IgA CSF Standards	EC117.00	4 x 1 ml
EN110L65	Varicella-Zoster Virus IgG CSF AI Control Set	EC110.00	4 x 1 ml
EC110L60	Varicella-Zoster Virus IgG CSF Standards	EC110.00	4 x 1 ml

Additional Components

Order No.	Product description	Format
EN250K60	Pipetting Control Set <i>(For use with EC250.00.)</i>	2.8 ml & 2 x 50 ml PBS buffer
161102 161101 B/300.00	RF-SorboTech <i>Pre-adsorbance for all IgM ELISA assays starting with "EC" as well as EC215A00.</i>	10 ml 2 ml 2 vials RF - 2 ml & buffer
EC250.00	Validation Kit	96 tests

Stool Antigen Detection

Gold Standard Diagnostics Europe distributes the stool testing products from Seramun Diagnostica GmbH. The Serazym® product range comprises ELISA tests and controls for the detection of different viral, bacterial, and parasitological antigens in faecal specimens. The external quality controls are offered twice a year; please contact us for further information.

COMPLETE KITS

Order No.	Product description	Format
HW/E-017	Serazym® Adenovirus	96 tests
HW/E-017-A2		2 x 96 tests
HW/E-045	Serazym® Astrovirus	96 tests
HW/E-045-A2		2 x 96 tests
HW/E-093	Serazym® Campylobacter	96 tests
HW/E-093-A2		2 x 96 tests
HW/E-107	Serazym® Clostridium difficile GDH	96 tests
HW/E-107-A2		2 x 96 tests
HW/E-040	Serazym® Clostridium difficile Toxin A+B	96 tests
HW/E-040-A2		2 x 96 tests
HW/E-039-A	Serazym® Cryptosporidium parvum	96 tests
HW/E-018-A	Serazym® Entamoeba histolytica	96 tests
HW/E-106-A	Serazym® Giardia	96 tests
HW/E-114-A	Serazym® Helicobacter pylori 2 nd Generation	96 tests
HW/E-061	Serazym® Norovirus	96 tests
HW/E-061-A2		2 x 96 tests
HW/E-020	Serazym® Rotavirus	96 tests
HW/E-020-A2		2 x 96 tests
HW/E-030	Serazym® Verotoxin 1+2	96 tests
HW/E-030-A2		2 x 96 tests

EXTERNAL CONTROLS

Order No.	Product description	Format
HW/EK-017	Adenovirus	2 x 0.4 ml
HW/EK-045	Astrovirus	2 x 0.4 ml
HW/EK-093	Campylobacter	2 x 0.4 ml
HW/EK-107	Clostridium difficile GDH	2 x 0.4 ml
HW/EK-040	Clostridium difficile Toxin A&B	2 x 0.4 ml
HW/EK-039	Cryptosporidium parvum	2 x 0.4 ml
HW/EK-018	Entamoeba histolytica	2 x 0.4 ml
HW/EK-106	Giardia	2 x 0.4 ml
HW/EK-114	Helicobacter pylori 2 nd Generation	2 x 0.4 ml
HW/EK-061	Norovirus	2 x 0.4 ml
HW/EK-020	Rotavirus	2 x 0.4 ml
HW/EK-030	Verotoxin 1+2	2 x 0.4 ml



Line Immunoblot

Wide range of Line Immunoassays for the qualitative detection of pathogen-specific IgG, IgM, and IgA antibodies in human serum.

- Firm strips sorted in a booklet
- Positive and negative controls separately available
- Standardized methods suitable for automated procedures
- Interpretation software available
- CE marked

VIROLOGY

Order No.	Product description	Format
WE102G32	Epstein-Barr Virus IgG <i>Differentiates between primary and past infection and offers a special cut-off strategy for the EBNA1 interpretation.</i>	32 tests
WE102G96		96 tests
WE102M32	Epstein-Barr Virus IgM <i>Differentiates between primary and past infection and offers a special cut-off strategy for the EBNA1 interpretation.</i>	32 tests
WE102M96		96 tests
WE130G16	Herpes Simplex Virus IgG <i>Use of gG1-recombinant and gG2-purified as well as a native total antigen to differentiate between HSV 1 and 2.</i>	16 tests
WE130G32		32 tests

BACTERIOLOGY

Order No.	Product description	Format
WE116A32	Bordetella pertussis + CatACT IgA <i>Differentiates between vaccination and infection, and gives notice of a parapertussis infection.</i>	32 tests
WE116A96		96 tests
WE116G32	Bordetella pertussis + CatACT IgG <i>Differentiates between vaccination and infection, and gives notice of a parapertussis infection.</i>	32 tests
WE116G96		96 tests
WE225G32	Borrelia Europe + TpN17 IgG <i>Includes the Treponema-band TpN17 as exclusion marker, validated for cerebrospinal fluid testing.</i>	32 tests
WE225G96		96 tests
WE224G32	Borrelia Europe IgG <i>Combination of purified lysate antigens (OspC, DbpA-PKo) and recombinant antigens (VlsE, p83, p58, p39, DbpA-mix), validated for cerebrospinal fluid testing.</i>	32 tests
WE224G96		96 tests
WE224M32	Borrelia Europe IgM <i>Combination of purified lysate antigens (OspC) and recombinant antigens (VlsE, p39, DbpA-mix), provides an additional EBV band as exclusion marker, validated for cerebrospinal fluid testing.</i>	32 tests
WE224M96		96 tests

Order No.	Product description	Format
WE223G32	Borrelia in vivo + TpN17 IgG <i>Includes the Treponema-band TpN17 as exclusion marker, validated for cerebrospinal fluid testing.</i>	32 tests
WE223G96		96 tests
WE222G32	Borrelia in vivo IgG <i>Combination of the most important common antigens (VlsE, p39, p83/100) with well-known "in-vivo" antigens. Validated for cerebrospinal fluid testing.</i>	32 tests
WE222G96		96 tests
WE222M32	Borrelia in vivo IgM <i>Combination of the most important common antigens (OspC, VlsE, p39) and EBV-band as exclusion marker. Validated for cerebrospinal fluid testing.</i>	32 tests
WE222M96		96 tests
WE243A32	Helicobacter pylori IgA <i>Therapy-relevant differentiation of virulent and non-virulent strains with CagA and VacA.</i>	32 tests
WE243A96		96 tests
WE243G32	Helicobacter pylori IgG <i>Therapy-relevant differentiation of virulent and non-virulent strains with CagA and VacA.</i>	32 tests
WE243G96		96 tests
WE214A16	Mycoplasma pneumoniae IgA <i>Detection of acute or recent infection.</i>	16 tests
WE214G16	Mycoplasma pneumoniae IgG <i>Detection of acute or recent infection.</i>	16 tests
WE214M16	Mycoplasma pneumoniae IgM <i>Detection of acute or recent infection.</i>	16 tests
WE150G16	Syphilis IgG <i>Uses recombinant proteins.</i>	16 tests
WE150G32		32 tests
WE150M16	Syphilis IgM <i>Uses recombinant proteins.</i>	16 tests
WE150M32		32 tests
WE242A32	Yersinia enterocolitica IgA <i>Detection of reactive bands contributes towards the diagnosis of Yersinia-associated sequelae, as reactive arthritis.</i>	32 tests
WE242A96		96 tests
WE242G32	Yersinia enterocolitica IgG <i>Detection of reactive bands contributes towards the diagnosis of Yersinia-associated sequelae, as reactive arthritis.</i>	32 tests
WE242G96		96 tests

Rapid Tests

Rapid chromatographic immunoassays for the qualitative detection of SARS-CoV-2 Nucleocapsid (N) Protein antigens present in respiratory samples.

- Easy specimen collection
- High sensitivity and specificity
- Fast results in 15 minutes
- Intuitive visual interpretation
- CE marked

VIROLOGY

Order No.	Product description	Format
CVAG4080A	GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP swab)	20 tests
CVAG4080B	GSD NovaGen SARS-CoV-2 Ag Rapid Test (Nasal swab)	20 tests
CVAG502H05	GSD NovaGen SARS-CoV-2 Ag Rapid Test (Nasal swab) for self testing	5 tests



Molecular Diagnostics

NUCLEID ACID EXTRACTION

Assays for the isolation of high-quality RNA from human respiratory specimen types.

- Automated, magnetic bead extraction method
- Efficient and reliable process which ensures the removal of potential inhibitors from sample matrices
- Perfect complement for virus detection assays

Order No.	Product description	Format
5524401101	GSD NovaPrime® IVD RNA Extraction AE1	1 x 96 reactions
5524401201		20 x 96 reactions
55244011100		100 x 96 reactions
5524411020	GSD NovaPrime® IVD RNA Extraction AE1 RTU	20 x 96 reactions
5524411100		100 x 96 reactions
5524401301	GSD NovaPrime® IVD RNA Extraction AE2	1 x 96 reactions
5524401401		20 x 96 reactions

REAL TIME RT-PCR

High quality RT-PCR kits for detection of various infectious diseases.

- Fast and reliable results in approximately 1 hour
- Validated for a variety of specimen types
- Excellent performance with high sensitivity and specificity
- Extraction/inhibition and positive control included
- Suitable for most PCR platforms

Order No.	Product description	Format
PCOV6111	GSD NovaPrime® TSP SARS-CoV-2 <i>Contains specific primers and probes for amplification and simultaneous detection of RNA sequences, and a heterologous amplification target to identify possible RT-PCR inhibition.</i>	1 x 96 reactions
PCOV6113		3 x 96 reactions
PCOV6181	GSD NovaType Detect + Select K417N SARS-CoV-2 (RUO) <i>Identification of N gene (N1/N2) and K417N mutation in one reaction.</i>	1 x 96 reactions
PCOV6184		4 x 96 reactions
PRES6131	Mplex SARS-CoV-2+, Flu A, Flu B (C1) <i>Differentiates in a single reaction between Influenza A and B, and simultaneously detects two independent gene targets in SARS-CoV-2 (N-gene + RdRP-gene).</i>	1 x 96 reactions
PRES6134		4 x 96 reactions
PRSV6161	RSV A, RSV B <i>Differentiates in a single reaction between RSV A and RSV B.</i>	1 x 96 reactions
PRSV6164		4 x 96 reactions

Instruments

ThunderBolt®



Order No.	Product description
00300-CL	ThunderBolt® EIA/CLIA Analyzer
00300	ThunderBolt® EIA Analyzer

Main features

2-plate, fully automated, open platform, that can run ELISA and Chemiluminescence (CLIA) assays.

- Slide-in racks with positive sample identification
- Simple workflow software that guides you through the process
- Designed to suit different laboratory demands
- High sample loading capacity: 192 primary sample tubes
- Capable of running many different protocols in a single batch
- On-board camera allows remote troubleshooting
- No disposable tips, minimal consumables, direct in-well dilution (up to 1:100)
- Occupies minimal bench space

The Bolt™



Order No.	Product description
EIA/CLIA-00500-CL	The Bolt™ EIA/CLIA Analyzer
EIA- 00500	The Bolt™ EIA Analyzer

Main features

1-plate, fully automated, open platform, that can run ELISA and Chemiluminescence (CLIA) assays.

- Slide-in racks with positive sample identification
- Simple workflow software that guides you through the process
- Designed to suit different laboratory demands
- High sample loading capacity: 96 primary sample tubes
- Capable of running many different protocols in a single batch
- No disposable tips, minimal consumables, direct in-well dilution (up to 1:100)
- Occupies 60 cm lab bench



Order No.	Product description
00400	AIX1000®

Main features

The AIX1000® is an FDA cleared, CE marked, fully automated system for nontreponemal, rapid plasma reagin (RPR) testing designed to simplify the processing, analysis, and results interpretation for RPR screens and titers. With the new universal slide-in rack system accommodating a variety of tube sizes, sample loading has become even easier and faster.

- Runs screens and titers – up to 192 samples in 90 minutes
- Full sample traceability: integrated barcode reading compatible with 1D and 2D barcodes
- Proprietary image recognition algorithm gives objective results
- Reduced labor overhead: reduced TAT and hands on
- Easy access to test results: save data and review on demand
- Improved Database Management cutting in half the time to perform backups/restore
- Remote data archiving capabilities and an expandable status log
- For use with AIX1000® RPR Reagent kit (order no. # GSD01-1600) and AIX1000® RPR Reagent bulk kit (order no. # GSD34-1600-R)

Dynablot



Order No.	Product description
T/D2144-CZ-DRY	Dynablot Automatic
T/D2144-CZC-DRY	Dynablot Automatic with camera

Main features

Fully automated instrument for Line Immunoblot testing.

- Automatic sample pipetting from primary tubes
- 44 samples per run
- Strip image capture by camera
- Drying of strips
- Walk-away operation
- User friendly software for easy and comprehensible operation
- Primary tubes bar code reader

Aria



AriaMx™



AriaDx™

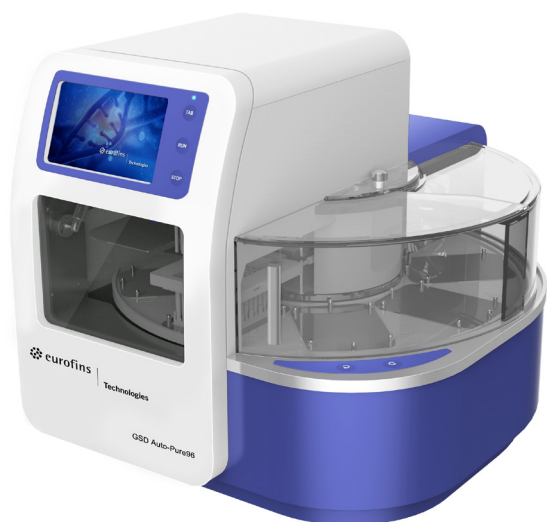
Order No.	Product description
K893064001	AriaDx™
G8830A	AriaMx™ (RUO)

Main features

Modular and precise real time PCR instrument.

- Standardized methods suitable for automated procedures
- 96 samples
- Scan all channels in less than three seconds
- Factory calibrated
- Intuitive touch screen interface
- Modular optical cartridges: 1-6 filter capability
- On board self-diagnostics

GSD Auto-Pure 96



Order No.	Product description
AS-17060-00	GSD Auto-Pure 96 - Nucleic Acid Purification System

Main features

Automatic extraction and purification system for DNA/RNA, proteins and cells.

- Built-in lighting LED lights
- 96 samples
- Front cover can be opened for quick stop, convenient for reagent optimization
- Intelligent operation with self-inspection, power protection function
- 8-plate position automatic identification design.
- No manual adjustment required
- Disposable consumables can eliminate the cross contamination between holes and batches.
- Built-in disinfection function
- High quality and rapid extraction: It can process 96×1ml samples simultaneously
- Maximum sample size: 10ml



Gold Standard Diagnostics Europe

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Not available in the U.S. with the exception of the AIX1000[®], ThunderBolt, and Bolt[®].

Contact your local representative for more details.

GSDB007.0522-EN