

# 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  $\mu$ -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	<b>Adenovirus IgA</b> <i>Highly purified native antigen.</i>	96 tests
ADVG0010	<b>Adenovirus IgG</b> <i>Highly purified native antigen.</i>	96 tests
EC121.00	<b>Adenovirus IgG/IgM</b> <i>Additional IgA set available with order number EC121.08.</i>	96 tests
ADVM0010	<b>Adenovirus IgM</b> <i>Highly purified native antigen.</i>	96 tests
CHIG0590	<b>Chikungunya Virus IgG Capture</b> <i>Capture-technology for IgG to increase specificity.</i>	96 tests
CHIM0590	<b>Chikungunya Virus IgM <math>\mu</math>-Capture</b> <i>Capture-technology for IgM to increase specificity.</i>	96 tests
CMVG0110	<b>Cytomegalovirus IgG</b>	96 tests
ACMV7110	<b>Cytomegalovirus IgG Avidity</b> <i>As an aid in the differentiation between primary and past infection.</i>	48 tests
EC113.00	<b>Cytomegalovirus IgG/IgM</b> <i>Mix of native and purified antigens. Validated for cerebrospinal fluid testing.</i>	96 tests
CMVM0110	<b>Cytomegalovirus IgM</b>	96 tests
DENG0120	<b>Dengue Virus IgG</b> <i>Allows detection of antibodies against all 4 DENV types.</i>	96 tests
DENM0120	<b>Dengue Virus IgM</b> <i>Allows detection of antibodies against all 4 DENV types.</i>	96 tests
DVM0640	<b>Dengue Virus IgM <math>\mu</math>-Capture</b> <i>Capture-technology to increase specificity.</i>	96 tests
NS1D4020	<b>Dengue Virus NS1 Antigen</b> <i>Detects acute infections.</i>	96 tests
EC116A00	<b>Enterovirus IgA</b> <i>Screening assay for the detection of heterotypic IgA antibodies with coxsackievirus B5 and echovirus 24 antigens.</i>	96 tests
EC116G00	<b>Enterovirus IgG</b> <i>Screening assay for the detection of heterotypic IgG antibodies with coxsackievirus B5 and echovirus 24 antigens.</i>	96 tests
EC116M00	<b>Enterovirus IgM</b> <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	<b>Epstein-Barr Virus EA-D IgG</b>	96 tests
EBVG0580/ EC204.00	<b>Epstein-Barr Virus EBNA IgG</b> <i>EC204.00 provides a special formula that allows a distinction between primary and past infection in unclear cases.</i>	96 tests
EC102.00	<b>Epstein-Barr Virus IgG/IgM</b> <i>Validated for cerebrospinal fluid testing.</i>	96 tests
EBVA0150	<b>Epstein-Barr Virus VCA IgA</b>	96 tests
EBVG0150/ EC205G00	<b>Epstein-Barr Virus VCA IgG</b> <i>EC205G00 includes gp125 and p18 as highly specific markers.</i>	96 tests
AEBV7150	<b>Epstein-Barr Virus VCA IgG Avidity</b> <i>As an aid in the differentiation between primary and past infection.</i>	48 tests
EBVM0150/ EC203M00	<b>Epstein-Barr Virus VCA IgM</b> <i>EC203M00 provides a special formula that allows a distinction between primary and past infection in unclear cases.</i>	96 tests
HANG0670	<b>Hantavirus IgG</b> <i>Recombinant antigen, contains four species/serotypes to detect it worldwide.</i>	96 tests
HANM0670	<b>Hantavirus IgM</b> <i>Recombinant antigen, contains four species/serotypes to detect it worldwide.</i>	96 tests
HEVG0780	<b>Hepatitis E Virus IgG</b> <i>Recombinant antigen for high sensitivity and specificity.</i>	96 tests
HEVM0780	<b>Hepatitis E Virus IgM</b> <i>Recombinant antigen for high sensitivity and specificity.</i>	96 tests
EC130.00	<b>Herpes Simplex Virus 1 (gG1) IgG/IgM</b> <i>Highly-specific recombinant glycoprotein gG1 antigen, validated for cerebrospinal fluid testing.</i>	96 tests
HSV1G0500	<b>Herpes Simplex Virus 1 IgG</b> <i>Highly-specific recombinant glycoprotein gG1 antigen.</i>	96 tests
HSV1M0500	<b>Herpes Simplex Virus 1 IgM</b> <i>Highly-specific recombinant glycoprotein gG1 antigen.</i>	96 tests
HSVG0250	<b>Herpes Simplex Virus 1+2 IgG</b>	96 tests
HSVM0250	<b>Herpes Simplex Virus 1+2 IgM</b>	96 tests
EC131.00	<b>Herpes Simplex Virus 2 (gG2) IgG/IgM</b> <i>Highly-specific affinity-purified glycoprotein gG2 antigen, validated for cerebrospinal fluid testing.</i>	96 tests
HSV2G0540	<b>Herpes Simplex Virus 2 IgG</b> <i>Highly-specific recombinant glycoprotein gG2 antigen.</i>	96 tests
HSV2M0540	<b>Herpes Simplex Virus 2 IgM</b> <i>Highly-specific recombinant glycoprotein gG2 antigen.</i>	96 tests
EC108.00	<b>Herpes Simplex Virus Screen IgG/IgM</b> <i>Validated for cerebrospinal fluid testing.</i>	96 tests
INFA0290/ EC118A00	<b>Influenza Virus A IgA</b> <i>EC118A00 with seasonal updated antigens.</i>	96 tests
INFG0290	<b>Influenza Virus A IgG</b>	96 tests
EC118.00	<b>Influenza Virus A IgG/IgM</b> <i>Seasonal updated antigens.</i>	96 tests
INFM0290	<b>Influenza Virus A IgM</b>	96 tests
INFA0300/ EC119A00	<b>Influenza Virus B IgA</b> <i>EC119A00 with seasonal updated antigens.</i>	96 tests
INFG0300	<b>Influenza Virus B IgG</b>	96 tests
EC119.00	<b>Influenza Virus B IgG/IgM</b> <i>Seasonal updated antigens.</i>	96 tests
INFM0300	<b>Influenza Virus B IgM</b>	96 tests

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

Order No.	Product description	Format
VZVA0490	<b>Varicella-Zoster Virus IgA</b>	96 tests
VZVG0490	<b>Varicella-Zoster Virus IgG</b> <i>Can be used for measuring antibody response after varicella vaccination.</i>	96 tests
EC110.00	<b>Varicella-Zoster Virus IgG/IgM</b> <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	<b>Varicella-Zoster Virus IgM</b>	96 tests
ZVG0790	<b>Zika Virus IgG Capture</b> <i>Recombinant NS1 antigen. Capture-technology increases specificity and reduces cross reactivity.</i>	96 tests
ZVM0790	<b>Zika Virus IgM <math>\mu</math>-Capture</b> <i>Recombinant NS1 antigen. Capture-technology increases specificity and reduces cross reactivity.</i>	96 tests

## BACTERIOLOGY • Complete kits

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

Order No.	Product description	Format
CHLA0510	<b>Chlamydia pneumoniae IgA</b>	96 tests
CHLG0510	<b>Chlamydia pneumoniae IgG</b>	96 tests
CHLM0510	<b>Chlamydia pneumoniae IgM</b>	96 tests
CHLA0070	<b>Chlamydia trachomatis IgA</b>	96 tests
CHLG0070	<b>Chlamydia trachomatis IgG</b>	96 tests
CHLM0070	<b>Chlamydia trachomatis IgM</b>	96 tests
COX1G0600	<b>Coxiella burnetii phase 1 IgG</b>	96 tests
COX2G0600	<b>Coxiella burnetii phase 2 IgG</b>	96 tests
COX2M0600	<b>Coxiella burnetii phase 2 IgM</b>	96 tests
CORG5009	<b>Diphtheria toxin 5S IgG</b> <i>Quantitative assay with 5 standards for verification of immune status due to vaccination or contact with Corynebacterium diphtheriae.</i>	96 tests
PCORG009	<b>Diphtheria toxin 5S IgG plus</b> <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	<b>Diphtheria toxin IgG</b> <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	<b>Helicobacter pylori IgA</b>	96 tests
HELG0220/ EC143G00	<b>Helicobacter pylori IgG</b> <i>HELG0220 is a quantitative assay with recombinant antigen.</i>	96 tests
PHELG022	<b>Helicobacter pylori IgG plus</b> <i>Quantitative assay with recombinant antigen plus one control.</i>	96 tests
HELM0220	<b>Helicobacter pylori IgM</b>	96 tests
LEGG0650	<b>Legionella pneumophila IgG</b> <i>Assay with antigens from a pool of different serovars to increase sensitivity.</i>	96 tests
LEGM0650	<b>Legionella pneumophila IgM</b> <i>Assay with antigens from a pool of different serovars to increase sensitivity.</i>	96 tests
LEPM0660	<b>Leptospira IgM</b>	96 tests
LEPG0660	<b>Leptospira IgG</b>	96 tests
MYCA0350	<b>Mycoplasma pneumoniae IgA</b> <i>Highly purified antigens.</i>	96 tests
MYCG0350	<b>Mycoplasma pneumoniae IgG</b> <i>Highly purified antigens.</i>	96 tests
EC114.00	<b>Mycoplasma pneumoniae IgG/IgM</b> <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	<b>Mycoplasma pneumoniae IgM</b> <i>Highly purified antigens.</i>	96 tests
TETG5043	<b>Tetanus toxin 5S IgG</b> <i>Quantitative assay adjusted to the WHO standards with recombinant antigen and 5 standards.</i>	96 tests
PTETG043	<b>Tetanus toxin 5S IgG plus</b> <i>Quantitative assay adjusted to the WHO standards with recombinant antigen and 5 standards plus one control.</i>	96 tests
TETG0430	<b>Tetanus toxin IgG</b> <i>Quantitative assay adjusted to the WHO standards with recombinant antigen.</i>	96 tests
EC124.00	<b>Tetanus toxoid IgG</b> <i>Quantitative assay adjusted to the WHO standards.</i>	96 tests

Order No.	Product description	Format
YERA0990	<b>Yersinia enterocolitica IgA</b> <i>Mix of purified native antigens and recombinant antigens YopD, YopB and YopE.</i>	96 tests
EC142.00	<b>Yersinia enterocolitica IgG/ IgA</b>	96 tests
YERG0990	<b>Yersinia enterocolitica IgG</b>	96 tests

### FUNGI • Complete kits

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

### PARASITES • Complete kits

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

### HORMONES-AUTOIMMUNITY • Complete kits

Order No.	Product description	Format
DNOV003	<b>17 beta-Estradiol</b>	96 tests
DNOV004	<b>17-OH Progesterone</b>	96 tests
DNOV033	<b>AFP</b>	96 tests
DNOV012	<b>Aldosterone</b>	96 tests
DNOV008	<b>Androstenedione</b>	96 tests
DSNOV27	<b>Androstenedione Saliva</b>	96 tests
ATG1010	<b>Anti-TG (Recombinant antigen)</b>	96 tests
ATPO1020	<b>Anti-TPO</b>	96 tests
DNOV034	<b>beta-HCG</b>	96 tests
DNOV061	<b>CA 125</b>	96 tests
DNOV062	<b>CA 15-3</b>	96 tests
DNOV063	<b>CA 19-9</b>	96 tests
DNOV060	<b>CEA</b>	96 tests
DNOV096	<b>CH-50</b>	96 tests
DNOV093	<b>CIC C1q</b>	96 tests
DNOV094	<b>CIC C3d</b>	96 tests
DNOV001	<b>Cortisol</b>	96 tests
DSNOV20	<b>Cortisol Saliva</b>	96 tests
DNOV112	<b>C-Peptide</b>	96 tests
DNOV005	<b>DHEA-S</b>	96 tests
DSNOV24	<b>DHEA-S Saliva</b>	96 tests
DNOV100	<b>Ferritin</b>	96 tests
DNOV051	<b>Free T3</b>	96 tests
FT41050	<b>Free T4</b>	96 tests
DNOV009	<b>Free Testosterone</b>	96 tests
DNOV031	<b>FSH</b>	96 tests
DNOV101	<b>HGH</b>	96 tests
DNOV102	<b>IgE</b>	96 tests
DNOV111	<b>Insulin</b>	96 tests
DNOV030	<b>LH</b>	96 tests
DNOV006	<b>Progesterone</b>	96 tests
DNOV032	<b>Prolactin</b>	96 tests
RFM3010	<b>Rheumatoid Factor IgM (Fc fragments of human IgG for high specificity)</b>	96 tests
DNOV002	<b>Testosterone</b>	96 tests
DSNOV21	<b>Testosterone Saliva</b>	96 tests
DNOV057	<b>Thyroglobulin</b>	96 tests
DNOV064	<b>Total PSA</b>	96 tests
DNOV053	<b>Total T3</b>	96 tests
DNOV054	<b>Total T4</b>	96 tests
TSH1030	<b>TSH (Quantitative assay adjusted to the WHO standard)</b>	96 tests
DNOV010	<b>Urinary Cortisol</b>	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 (For use with EC250.00.)	2.8 ml & 2 x 50 ml PBS buffer
161102 161101 B/300.00	RF-SorboTech Pre-adsorbance for all IgM ELISA assays starting with "EC" as well as EC215A00.	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 <sup>nd</sup> 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 <sup>nd</sup> 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	<b>Epstein-Barr Virus IgG</b> <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	<b>Epstein-Barr Virus IgM</b> <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	<b>Herpes Simplex Virus IgG</b> <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	<b>Bordetella pertussis + CatACT IgA</b> <i>Differentiates between vaccination and infection, and gives notice of a parapertussis infection.</i>	32 tests
WE116A96		96 tests
WE116G32	<b>Bordetella pertussis + CatACT IgG</b> <i>Differentiates between vaccination and infection, and gives notice of a parapertussis infection.</i>	32 tests
WE116G96		96 tests
WE225G32	<b>Borrelia Europe + TpN17 IgG</b> <i>Includes the Treponema-band TpN17 as exclusion marker, validated for cerebrospinal fluid testing.</i>	32 tests
WE225G96		96 tests
WE224G32	<b>Borrelia Europe IgG</b> <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	<b>Borrelia Europe IgM</b> <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 WE223G96	<b>Borrelia in vivo + TpN17 IgG</b> <i>Includes the Treponema-band TpN17 as exclusion marker, validated for cerebrospinal fluid testing.</i>	32 tests 96 tests
WE222G32 WE222G96	<b>Borrelia in vivo IgG</b> <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 96 tests
WE222M32 WE222M96	<b>Borrelia in vivo IgM</b> <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 96 tests
WE243A32 WE243A96	<b>Helicobacter pylori IgA</b> <i>Therapy-relevant differentiation of virulent and non-virulent strains with CagA and VacA.</i>	32 tests 96 tests
WE243G32 WE243G96	<b>Helicobacter pylori IgG</b> <i>Therapy-relevant differentiation of virulent and non-virulent strains with CagA and VacA.</i>	32 tests 96 tests
WE214A16	<b>Mycoplasma pneumoniae IgA</b> <i>Detection of acute or recent infection.</i>	16 tests
WE214G16	<b>Mycoplasma pneumoniae IgG</b> <i>Detection of acute or recent infection.</i>	16 tests
WE214M16	<b>Mycoplasma pneumoniae IgM</b> <i>Detection of acute or recent infection.</i>	16 tests
WE150G16 WE150G32	<b>Syphilis IgG</b> <i>Uses recombinant proteins.</i>	16 tests 32 tests
WE150M16 WE150M32	<b>Syphilis IgM</b> <i>Uses recombinant proteins.</i>	16 tests 32 tests
WE242A32 WE242A96	<b>Yersinia enterocolitica IgA</b> <i>Detection of reactive bands contributes towards the diagnosis of Yersinia-associated sequelae, as reactive arthritis.</i>	32 tests 96 tests
WE242G32 WE242G96	<b>Yersinia enterocolitica IgG</b> <i>Detection of reactive bands contributes towards the diagnosis of Yersinia-associated sequelae, as reactive arthritis.</i>	32 tests 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
CVAG4080B	<b>GSD NovaGen SARS-CoV-2 Ag Rapid Test (Nasal swab)</b>	20 tests
CVAG502H05	<b>GSD NovaGen SARS-CoV-2 Ag Rapid Test (Nasal swab) for self testing</b>	5 tests
CVAG4080A	<b>GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP swab)</b>	20 tests

# Molecular Diagnostics

## NUCLEIC 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>Identifies N gene (N1/N2) and K417N mutation in one reaction.</i>	1 x 96 reactions
PCOV6184		4 x 96 reactions
PCOV6191T	GSD NovaType IV SARS-CoV-2 <i>Identifies S gene mutations K417N, E484K, and L452R. Screening for S gene mutations K417N and L452R allows for active surveillance of variants Omicron and Delta, respectively.</i>	1 x 96 reactions
PCOV6194T		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
PPOX6201	Mplex Monkeypox, Orthopox (RUO) <i>Detects the monkeypox virus and differentiates it from other orthopox viruses.</i>	1 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
00300	ThunderBolt® EIA

### 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
00500-CL	The Bolt™ EIA/CLIA
00500	The Bolt™ EIA

### 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)



Order No.	Product description
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



AriaMx™



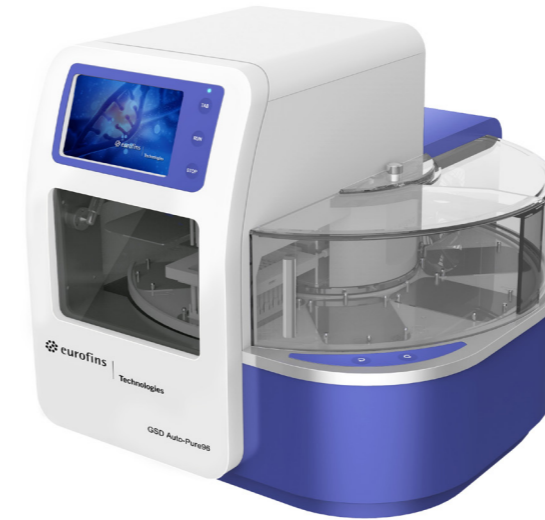
AriaDx™

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



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: 10 ml





**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.

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