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# **ABOUT US**

The Gold Standard Diagnostics Group is a leading healthcare provider of diagnostic solutions composed of 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



# **IMMUNOLOGY**

# **ELISA · SEROLOGY**

- Complete kits, IgA sets to complement IgG/IgM kits, and standards and controls for CSF
- 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

Note: Multiple order numbers per product separated by a slash correspond to the Novatec and Virotech format respectively.

# **VIROLOGY** • Complete Kits

	Complete Mis	
Order No.	Product Description	Format
ADVA0010	Adenovirus IgA Highly purified native antigen.	96 tests
ADVG0010	Adenovirus IgG Highly purified native antigen.	96 tests
EC121.00	Adenovirus IgG/IgM Additional IgA set available with order number EC121.08.	96 tests
ADVM0010	Adenovirus IgM Highly purified native antigen.	96 tests
CHIG0590	Chikungunya Virus IgG Capture Capture-technology for IgG to increase specificity.	96 tests
CHIM0590	Chikungunya Virus IgM µ-Capture Capture-technology for IgM to increase specificity.	96 tests
CMVG0110	Cytomegalovirus IgG	96 tests
ACMV7110	Cytomegalovirus IgG Avidity As an aid in the differentiation between primary and past infection.	48 tests
EC113.00	Cytomegalovirus IgG/IgM  Mix of native and purified antigens. Validated for cerebrospinal fluid testing.	96 tests
CMVM0110	Cytomegalovirus IgM	96 tests
DENG0120	Dengue Virus IgG Allows detection of antibodies against all 4 DENV types.	96 tests
DENM0120	Dengue Virus IgM Allows detection of antibodies against all 4 DENV types.	96 tests
DVM0640	Dengue Virus IgM µ-Capture Allows detection of antibodies against all 4 DENV types. Capture-technology to increase specificity.	96 tests
NS1D4020	Dengue Virus NS1 Antigen Detects acute infections.	96 tests
EC116A00	Enterovirus IgA Screening assay for the detection of heterotypic IgA antibodies with coxsackievirus B5 and echovirus 24 antigens.	96 tests
EC116G00	Enterovirus IgG Screening assay for the detection of heterotypic IgG antibodies with coxsackievirus B5 and echovirus 24 antigens.	96 tests
EC116M00	Enterovirus IgM Screening assay for the detection of heterotypic IgM antibodies with coxsackievirus B5 and echovirus 24 antigens.	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 EC204.00 provides a special formula that allows a distinction between primary and past infection in unclear cases.	96 tests
EC102.00	Epstein-Barr Virus IgG/IgM Validated for cerebrospinal fluid testing.	96 tests
EBVA0150	Epstein-Barr Virus VCA IgA	96 tests
EBVG0150/ EC205G00	Epstein-Barr Virus VCA IgG EC205G00 includes gp125 and p18 as highly specific markers.	96 tests
AEBV7150	Epstein-Barr Virus VCA IgG Avidity As an aid in the differentiation between primary and past infection.	48 tests
EBVM0150/ EC203M00	Epstein-Barr Virus VCA IgM EC203M00 provides a special formula that allows a distinction between primary and past infection in unclear cases.	96 tests
HANG0670	Hantavirus IgG Recombinant antigen, contains four species/serotypes to detect it worldwide.	96 tests
HANM0670	Hantavirus IgM Recombinant antigen, contains four species/serotypes to detect it worldwide.	96 tests
HEVG0780	Hepatitis E Virus IgG Recombinant antigen for high sensitivity and specificity.	96 tests
HEVM0780	Hepatitis E Virus IgM Recombinant antigen for high sensitivity and specificity.	96 tests
EC130.00	Herpes Simplex Virus 1 (gG1) IgG/IgM  Highly-specific recombinant glycoprotein gG1 antigen, validated for cerebrospinal fluid testing.	96 tests
HSV1G0500	Herpes Simplex Virus 1 IgG Highly-specific recombinant glycoprotein gG1 antigen.	96 tests
HSV1M0500	Herpes Simplex Virus 1 IgM Highly-specific recombinant glycoprotein gG1 antigen.	96 tests
HSVG0250	Herpes Simplex Virus 1+2 IgG	96 tests
HSVM0250	Herpes Simplex Virus 1+2 IgM	96 tests
EC108.00	Herpes Simplex Virus Screen IgG/IgM Validated for cerebrospinal fluid testing.	96 tests
EC131.00	Herpes Simplex Virus 2 (gG2) IgG/IgM Highly-specific affinity-purified glycoprotein gG2 antigen, validated for cerebrospinal fluid testing.	96 tests
HSV2G0540	Herpes Simplex Virus 2 IgG Highly-specific recombinant glycoprotein gG2 antigen.	96 tests
HSV2M0540	Herpes Simplex Virus 2 IgM Highly-specific recombinant glycoprotein gG2 antigen.	96 tests
INFA0290/ EC118A00	Influenza Virus A IgA EC118A00 with seasonal updated antigens.	96 tests
INFG0290	Influenza Virus A IgG	96 tests
EC118.00	Influenza Virus A IgG/IgM Seasonal updated antigens.	96 tests
INFM0290	Influenza Virus A IgM	96 tests
INFA0300/ EC119A00	Influenza Virus B IgA EC119A00 with seasonal updated antigens.	96 tests
INFG0300	Influenza Virus B IgG	96 tests
EC119.00	Influenza Virus B IgG/IgM Seasonal updated antigens.	96 tests
INFM0300	Influenza Virus B IgM	96 tests

Order No.	Product Description	Format
MEAG0330/ EC105G00	Measles Virus IgG  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.	96 tests
AMEA7330	Measles Virus IgG Avidity As an aid in the differentiation between primary and past infection.	48 tests
MEAM0330/ EC105M00	Measles Virus IgM MEAM0330 detects present and past contact with measles due to wild-virus or vaccination.	96 tests
MUMG0340	Mumps Virus IgG Detects present and past contact with mumps due to wild-virus or vaccination.	96 tests
EC106.00	Mumps Virus IgG/IgM  Detects acute infections in IgM, the serostatus in IgG, and is validated for cerebrospinal fluid testing.	96 tests
MUMM0340	Mumps Virus IgM Detects present and past contact with mumps due to wild-virus.	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 Additional IgA set available with order number EC148.08.	96 tests
PARG0370	Parvovirus B19 IgG Recombinant antigen.	96 tests
PARM0370	Parvovirus B19 IgM Recombinant antigen.	96 tests
RSVA0380	Respiratory Syncytial Virus IgA	96 tests
RSVG0380	Respiratory Syncytial Virus IgG	96 tests
EC107.00	Respiratory Syncytial Virus IgG/IgM Additional IgA set available with order number EC107.08.	96 tests
RSVM0380	Respiratory Syncytial Virus IgM	96 tests
EC109L00	Rubella Virus CSF IgG For cerebrospinal fluid testing only, additional available standards and control sets.	96 tests
RUBG0400	Rubella Virus IgG	96 tests
ARUB7400	Rubella Virus IgG Avidity As an aid in the differentiation between primary and past infection.	48 tests
RUBM0400	Rubella Virus IgM µ-Capture Capture technology to increase specificity.	96 tests
COVA0940	SARS-CoV-2 (COVID-19) Virus IgA	96 tests
COVG0940	SARS-CoV-2 (COVID-19) Virus IgG	96 tests
CVGQ0970	SARS-CoV-2 (COVID-19) quantitative IgG Quantitative determination of antibodies to the spike (S) protein. Calibrators correlate to the "First WHO International Standard for anti SARS-CoV-2 immunoglobulin (human)".	96 tests
TICG0440	Tick-Borne Encephalitis IgG Quantitative assay with antibody titer profile to verify immune status.	96 tests
PTICG044	Tick-Borne Encephalitis IgG plus Quantitative assay with antibody titer profile to verify immune status. Contains an additional control.	96 tests
EC117.00	Tick-Borne Encephalitis IgG/IgM  Detects acute/recent infection and vaccination antibodies. Validated for cerebrospinal fluid testing.	96 tests
TICM0440	Tick-Borne Encephalitis IgM Can be used to verify immune status.	96 tests

Order No.	Product Description	Format
VZVA0490	Varicella-Zoster Virus IgA	96 tests
VZVG0490	Varicella-Zoster Virus IgG Can be used for measuring antibody response after varicella vaccination.	96 tests
EC110.00	Varicella-Zoster Virus IgG/IgM 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.	96 tests
VZVM0490	Varicella-Zoster Virus IgM	96 tests
ZVG0790	Zika Virus IgG Capture Recombinant NS1 antigen. Capture-technology increases specificity and reduces cross reactivity.	96 tests
ZVM0790	Zika Virus IgM µ-Capture Recombinant NS1 antigen. Capture-technology increases specificity and reduces cross reactivity.	96 tests

# **BACTERIOLOGY** • Complete Kits

Order No.	Product Description	Format
BAR0900	Bartonella Total antibody assay coated with highly purified native antigen.	96 tests
EC115.00	Bordetella pertussis (FHA+PT) IgG/IgA Sensitive screening assay coated with PT and FHA antigens.	96 tests
BOPA0030	Bordetella pertussis IgA Sensitive screening assay coated with PT and FHA antigens.	96 tests
BOPG0030	Bordetella pertussis IgG Sensitive screening assay coated with PT and FHA antigens.	96 tests
ВОРМ0030	Bordetella pertussis IgM	96 tests
BPTA0610/ EC215A00	Bordetella pertussis toxin IgA Pure PT antigens, adjusted to the WHO standards.	96 tests
BPTG0610/ EC215G00	Bordetella pertussis toxin IgG Pure PT antigens, adjusted to the WHO standards. EC215G00 available with additional IgG quantification set.	96 tests
EC215M00	Bordetella pertussis toxin IgM Pure PT antigens.	96 tests
EC022G00	Borrelia + VIsE IgG 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.	96 tests
EC024G00	Borrelia + VIsE IgG Europe Validated for cerebrospinal fluid testing.	96 tests
EC022M00	Borrelia IgM Borrelia strain Pko for high sensitivity. Validated for cerebrospinal fluid testing.	96 tests
BORG0040	Borrelia burgdorferi IgG Recombinant antigen, validated for serum, plasma, and cerebrospinal fluid testing.	96 tests
BORM0040	Borrelia burgdorferi IgM Recombinant antigen, validated for serum, plasma, and cerebrospinal fluid testing.	96 tests
BRUG0050	Brucella IgG	96 tests
EC101.00	Brucella IgG/IgM Additional IgA set available with order number EC101.08.	96 tests
BRUM0050	Brucella IgM	96 tests

Order No.	Product Description	Format
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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
COX1G0600	Coxiella burnetii phase 1 IgG	96 tests
COX2G0600	Coxiella burnetii phase 2 IgG	96 tests
COX2M0600	Coxiella burnetii phase 2 IgM	96 tests
CORG5009	Diphtheria toxin 5S IgG Quantitative assay with 5 standards for verification of immune status due to vaccination or contact with Corynebacterium diphtheriae.	96 tests
PCORG009	<b>Diphtheria toxin 5S IgG plus</b> Quantitative assay with 5 standards and one additional control for verification of immune status due to vaccination or contact with Corynebacterium diphtheriae.	96 tests
CORG0090/ EC129.00	Diphtheria toxin IgG Quantitative assay. CORG0090 allows verification of immune status due to vaccination or contact with Corynebacterium diphtheriae. EC129.00 is adjusted to the WHO standards.	96 tests
EC143A00	Helicobacter pylori IgA	96 tests
HELG0220/ EC143G00	Helicobacter pylori IgG HELG0220 is a quantitative assay with recombinant antigen.	96 tests
PHELG022	Helicobacter pylori IgG plus Quantitative assay with recombinant antigen plus one control.	96 tests
HELM0220	Helicobacter pylori IgM	96 tests
LEGG0650	Legionella pneumophila IgG Assay with antigens from a pool of different serovars to increase sensitivity.	96 tests
LEGM0650	Legionella pneumophila IgM Assay with antigens from a pool of different serovars to increase sensitivity.	96 tests
LEPG0660	Leptospira IgG	96 tests
LEPM0660	Leptospira IgM	96 tests
MYCA0350	Mycoplasma pneumoniae IgA Highly purified antigens.	96 tests
MYCG0350	Mycoplasma pneumoniae IgG Highly purified antigens.	96 tests
EC114.00	Mycoplasma pneumoniae IgG/IgM Detects acute infections in IgG and offers specific cut-off adjustment for infant samples. Additional IgA set available with order number EC114.08.	96 tests
MYCM0350	Mycoplasma pneumoniae IgM Highly purified antigens.	96 tests
TETG5043	<b>Tetanus toxin 5S IgG</b> Quantitative assay adjusted to the WHO standards with recombinant antigen and 5 standards.	96 tests
PTETG043	<b>Tetanus toxin 5S IgG plus</b> Quantitative assay adjusted to the WHO standards with recombinant antigen and 5 standards plus one control.	96 tests
TETG0430	<b>Tetanus toxin IgG</b> Quantitative assay adjusted to the WHO standards with recombinant antigen.	96 tests
EC124.00	Tetanus toxoid IgG Quantitative assay adjusted to the WHO standards.	96 tests

Order No.	Product Description	Format
YERA0990	Yersinia enterocolitica IgA Mix of purified native antigens and recombinant antigens YopD, YopB and YopE.	96 tests
EC142.00	Yersinia enterocolitica IgG/ IgA	96 tests
YERG0990	Yersinia enterocolitica IgG	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  Designed to detect acute infections, offers an additional IgA set with order number EC111.08.	96 tests
CANM0060	Candida albicans IgM	96 tests

# **PARASITES** • Complete Kits

Order No.	Product Description	Format
ASCG0020	Ascaris lumbricoides IgG Native antigen for high sensitivity.	96 tests
CHAG0560	Chagas IgG Chimeric-recombinant antigens to reduce cross-reactivity to Leishmania and Malaria.	96 tests
ECHG0130	Echinococcus IgG	96 tests
ENTG0140	Entamoeba histolytica IgG	96 tests
FILO760	Filariasis Detects antibodies against main genus of filarial worms (Onchocerca, Loa loa, and Wuchereria).	96 tests
LEIG0310	Leishmania infantum IgG Specific antigens to reduce cross reactivity to Chagas.	96 tests
MAL0620	Malaria Recombinant antigens to reduce cross reactivity to other parasites.	96 tests
SCHG0410	Schistosoma mansoni IgG	96 tests
SCHM0410	Schistosoma mansoni IgM	96 tests
STRO0690	Strongyloides Chimeric-recombinant antigen to increase specificity. Detects the main human pathogen species.	96 tests
TAEG0420	Taenia solium IgG Native antigen for high sensitivity.	96 tests
TOCG0450	Toxocara canis IgG	96 tests
TOXA0460	Toxoplasma gondii IgA	96 tests
TOXG0460	Toxoplasma gondii IgG Quantitative assay. Calibrated against WHO standards.	96 tests
ATOX7460	Toxoplasma gondii IgG Avidity As an aid in the differentiation between primary and past infection.	48 tests
TOXM0460	Toxoplasma gondii IgM μ-Capture Capture assay to reduce cross-reactivity.	96 tests
TRIG0480	Trichinella spiralis IgG	96 tests

# **HORMONES-AUTOIMMUNITY •** Complete Kits

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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	96 tests
ATPO1020	Anti-TPO (Recombinant antigen)	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
DNOVIII	Insulin	96 tests
DNOV030	LH	96 tests
DNOV006	Progesterone	96 tests
DNOV032	Prolactin	96 tests
RFM3010	Rheumatoid Factor IgM (Fc fragments of human IgG for high specificity)	96 tests
DNOV002	Testosterone	96 tests
DSNOV21	Testosterone Saliva	96 tests
DNOV057	Thyroglobulin	96 tests
DNOV064	Total PSA (RUO)	96 tests
DNOV053	Total T3	96 tests
DNOV054	Total T4	96 tests
TSH1030	TSH (Quantitative assay adjusted to the WHO standard)	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 + VIsE IgG CSF AI Control Set	EC022G00/EC024G00	4 x 1 ml
EC022L60	Borrelia + VIsE 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

# **ELISA · STOOL ANTIGEN DETECTION**

Gold Standard Diagnostics Europe distributes the Serazym® ELISA kits from Seramun Diagnostica GmbH related to gastrointestinal infections. 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 HW/E-017-A2	Serazym® Adenovirus	96 tests 2 x 96 tests
HW/E-045 HW/E-045-A2	Serazym <sup>®</sup> Astrovirus	96 tests 2 x 96 tests
HW/E-093 HW/E-093-A2	Serazym® Campylobacter	96 tests 2 x 96 tests
HW/E-107 HW/E-107-A2	Serazym® Clostridium difficile GDH	96 tests 2 x 96 tests
HW/E-040 HW/E-040-A2	Serazym® Clostridium difficile Toxin A+B	96 tests 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 HW/E-061-A2	Serazym® Norovirus	96 tests 2 x 96 tests
HW/E-020 HW/E-020-A2	Serazym® Rotavirus	96 tests 2 x 96 tests
HW/E-030 HW/E-030-A2	Serazym® Verotoxin 1+2	96 tests 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**

Line immunoassays for the detection of pathogen-specific IgG, IgM, and IgA antibodies in human serum.

- Firm strips sorted in a booklet
- Additional control sets available for every kit (positive, negative and cut off controls)
- Standardized methods suitable for automated procedures
- Interpretation software available
- CE marked

### **VIROLOGY**

Order No.	Product Description	Format
WE102G32 WE102G96	Epstein-Barr Virus IgG Differentiates between primary and past infection and offers a special cut-off strategy for the EBNA1 interpretation.	32 tests 96 tests
WE102M32 WE102M96	Epstein-Barr Virus IgM Differentiates between primary and past infection and offers a special cut-off strategy for the EBNA1 interpretation.	32 tests 96 tests
WE130G16 WE130G32	Herpes Simplex Virus IgG Use of gG1-recombinant and gG2-purified as well as a native total antigen to differentiate between HSV1 and 2.	16 tests 32 tests

### **BACTERIOLOGY**

Order No.	Product Description	Format
WE116A32 WE116A96	Bordetella pertussis + CatACT IgA  Differentiates between vaccination and infection, and gives notice of a parapertussis infection.	32 tests 96 tests
WE116G32 WE116G96	Bordetella pertussis + CatACT IgG  Differentiates between vaccination and infection, and gives notice of a parapertussis infection.	32 tests 96 tests
WE225G32 WE225G96	Borrelia Europe + TpN17 IgG Includes the Treponema-band TpN17 as exclusion marker, validated for cerebrospinal fluid testing.	32 tests 96 tests
WE224G32 WE224G96	Borrelia Europe IgG Combination of purified lysate antigens (OspC, DbpA-PKo) and recombinant antigens (VIsE, p83, p58, p39, DbpA-mix), validated for cerebrospinal fluid testing.	32 tests 96 tests
WE224M32 WE224M96	Borrelia Europe IgM Combination of purified lysate antigens (OspC) and recombinant antigens (VISE, p39, DbpA-mix), provides an additional EBV band as exclusion marker, validated for cerebrospinal fluid testing.	32 tests 96 tests
WE223G32 WE223G96	Borrelia in vivo + TpN17 IgG Includes the Treponema-band TpN17 as exclusion marker, validated for cerebrospinal fluid testing.	32 tests 96 tests
WE222G32 WE222G96	Borrelia in vivo IgG Combination of the most important common antigens (VIsE, p39, p83/100) with well-known "in-vivo" antigens. Validated for cerebrospinal fluid testing.	32 tests 96 tests
WE222M32 WE222M96	Borrelia in vivo IgM Combination of the most important common antigens (OspC, VIsE, p39) and EBV-band as exclusion marker. Validated for cerebrospinal fluid testing.	32 tests 96 tests

Order No.	Product Description	Format
WE243A32 WE243A96	Helicobacter pylori IgA Therapy-relevant differentiation of virulent and non-virulent strains with CagA and VacA.	32 tests 96 tests
WE243G32 WE243G96	Helicobacter pylori IgG  Therapy-relevant differentiation of virulent and non-virulent strains with CagA and VacA.	32 tests 96 tests
WE214A16	Mycoplasma pneumoniae IgA Detection of acute or recent infection.	16 tests
WE214G16	Mycoplasma pneumoniae IgG Detection of acute or recent infection.	16 tests
WE214M16	Mycoplasma pneumoniae IgM Detection of acute or recent infection.	16 tests
WE150G16 WE150G32	Syphilis IgG Uses recombinant proteins.	16 tests 32 tests
WE150M16 WE150M32	Syphilis IgM Uses recombinant proteins.	16 tests 32 tests
WE242A32 WE242A96	Yersinia enterocolitica IgA Detection of reactive bands contributes towards the diagnosis of Yersinia- associated sequelae, as reactive arthritis.	32 tests 96 tests
WE242G32 WE242G96	Yersinia enterocolitica IgG  Detection of reactive bands contributes towards the diagnosis of Yersinia- associated sequelae, as reactive arthritis.	32 tests 96 tests

# **RAPID TEST**

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**

### **NUCLEIC ACID EXTRACTION**

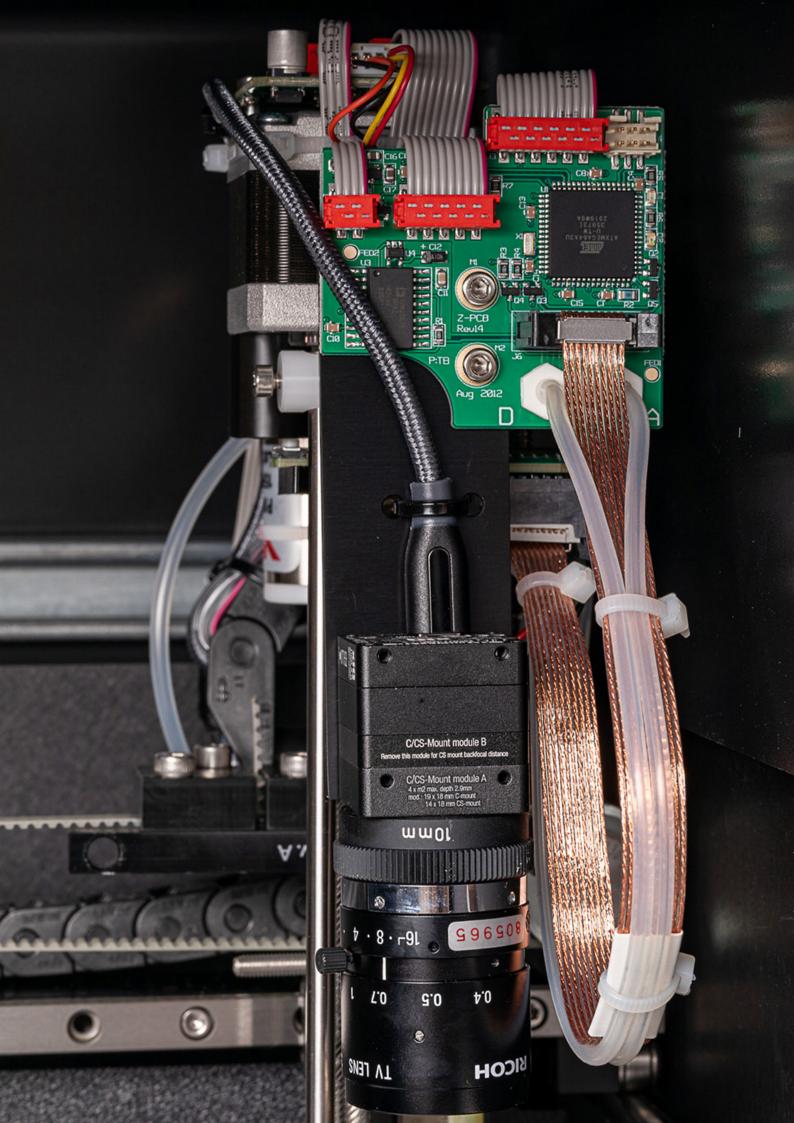
- Automated, magnetic bead extraction kits
- Efficient and reliable process which ensures the removal of potential inhibitors from sample matrices
- Perfect complement for virus detection assays

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

### **REAL-TIME PCR**

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

Order No.	Product Description	Format
PCOV6111 PCOV6113	GSD NovaPrime® TSP SARS-CoV-2 Contains specific primers and probes for the detection of SARS-CoV-2 genetic material and a heterologous amplification target to identify possible RT-PCR inhibition.	1 x 96 reactions 3 x 96 reactions
PCOV6181 PCOV6184	GSD NovaType Detect + Select K417N SARS-CoV-2 (RUO) Identifies N gene (N1/N2) and K417N mutation in one reaction.	1 x 96 reactions 4 x 96 reactions
PCOV6191T PCOV6194T	GSD NovaType IV SARS-CoV-2 Identifies S gene mutations K417N, E484K, and L452R.	1 x 96 reactions 4 x 96 reactions
PRES6131 PRES6134	Mplex SARS-CoV-2+, Flu A, Flu B (C1) Differentiates in a single reaction between Influenza A and B, and detects two SARS-CoV-2 targets (N-gene & RdRP-gene) in different channels.	1 x 96 reactions 4 x 96 reactions
PPOX6201	Mplex Monkeypox, Orthopox (RUO)  Detects the monkeypox virus and differentiates it from other orthopox viruses.	1 x 96 reactions
PRSV6161 PRSV6164	RSV A, RSV B Differentiates in a single reaction between RSV A and RSV B.	1 x 96 reactions 4 x 96 reactions



# INSTRUMENTATION

# 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. This walkaway instrument offers a modular design so that it can be configured according to your laboratory's needs in a cost-effective manner.

- Shaker, incubator, and reader are configurable options
- High sample loading capacity: 96 primary sample tubes
- Capable of running different protocols in a single batch
- LIS Connectivity
- Minimal consumables
- Dimensions: W: 48.3 cm, D: 53.3 cm, H: 55.8 cm
- Weight: 27 kg

# **AIX1000**®



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)
- Dimensions: W: 64 cm, D: 57 cm, H: 45 cm
- Weight: 30 kg

# **ThunderBolt®**



Order No.	Product Description
00300-CL	ThunderBolt <sup>®</sup> EIA/CLIA
00300	ThunderBolt® EIA

#### **Main Features**

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

- Program any EIA or CLIA protocol
- High sample loading capacity: 192 primary sample tubes
- Slide-in racks with positive sample identification
- Capable of running many different protocols in a single batch
- LIS Connectivity
- On-board camera allows remote troubleshooting
- Minimal consumables
- Dimensions: W: 64 cm, D: 57 cm, H: 45 cm
- Weight: 30 kg

# **Dynablot**



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
- Dimensions: W: 80 cm, D: 50 cm, H: 54 cm
- Weight: 35 kg

# AriaDx & AriaMx





AriaMx AriaDx

Order No.	Product Description
K893064001	AriaDx
G8830A	AriaMx (RUO)

#### **Main Features**

Modular and precise real time PCR instruments.

- 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
- Dimensions: W: 50 cm, D: 46 cm, H: 42 cm
- Weight: 35 kg

# **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.

- Automatic, fast, and simple
- Magnetic bead separation technology
- It can process 96 x 1 ml samples simultaneously and rapidly
- 8-plate position automatic identification design
- Intelligent operation with self-inspection
- Dimensions: W: 56 cm x D: 62 cm x H: 50 cm
- Weight: 54 kg

### **Ordering Information**

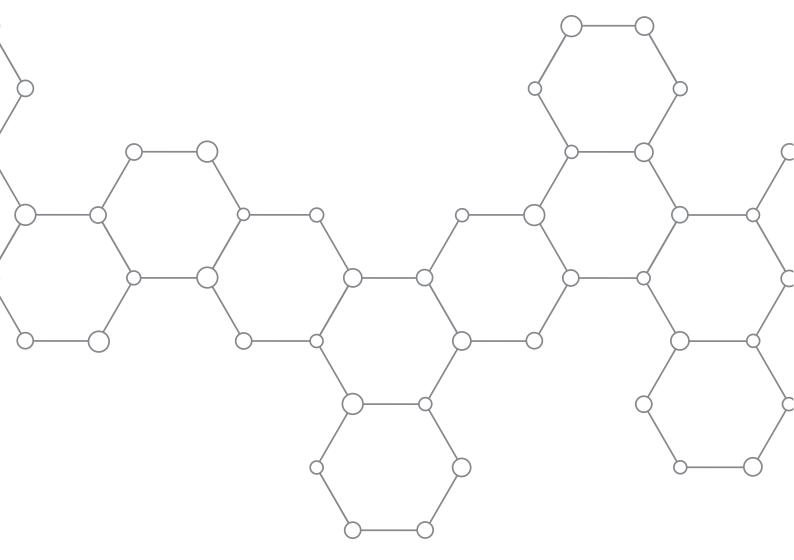
Please place your orders at order@golstandarddiagnostics.eu including the following:

- Company's name
- VAT No. (only for EU-countries)
- Ship to and bill to address
- Purchase order number
- Article number, description, quantity, and price
- Special shipping conditions, courier account number, and expected delivery date if necessary

Orders are regulated by our General Terms and Conditions for Supply that can be consulted on www.goldstandarddiagnostics.com

#### **Product Support**

For assistance and information regarding our products and instruments, please contact productsupport@goldstandarddiagnostics.eu









#### **Gold Standard Diagnostics Europe**