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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 McS  |          |
|-----------|---|----------|
| Order No. | Product Description   | Format   |
| ADVA0010  | Adenovirus IgA<br>Highly purified native antigen.   | 96 tests |
| ADVG0010  | Adenovirus IgG<br>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<br>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<br>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<br>Allows detection of antibodies against all 4 DENV types.  | 96 tests |
| DENM0120  | Dengue Virus IgM<br>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<br>Screening assay for the detection of heterotypic IgG antibodies with<br>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/<br>EC202.00 | Epstein-Barr Virus EA-D IgG  | 96 tests |
| EBVG0580/<br>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<br>Validated for cerebrospinal fluid testing.   | 96 tests |
| EBVA0150              | Epstein-Barr Virus VCA IgA   | 96 tests |
| EBVG0150/<br>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/<br>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<br>Recombinant antigen, contains four species/serotypes to detect it worldwide.   | 96 tests |
| HANM0670              | Hantavirus IgM<br>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<br>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<br>Highly-specific recombinant glycoprotein gG1 antigen.  | 96 tests |
| HSV1M0500             | Herpes Simplex Virus 1 IgM<br>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<br>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<br>Highly-specific recombinant glycoprotein gG2 antigen.  | 96 tests |
| HSV2M0540             | Herpes Simplex Virus 2 IgM<br>Highly-specific recombinant glycoprotein gG2 antigen.  | 96 tests |
| INFA0290/<br>EC118A00 | Influenza Virus A IgA<br>EC118A00 with seasonal updated antigens.  | 96 tests |
| INFG0290              | Influenza Virus A IgG  | 96 tests |
| EC118.00              | Influenza Virus A IgG/IgM<br>Seasonal updated antigens.  | 96 tests |
| INFM0290              | Influenza Virus A IgM  | 96 tests |
| INFA0300/<br>EC119A00 | Influenza Virus B IgA<br>EC119A00 with seasonal updated antigens.  | 96 tests |
| INFG0300              | Influenza Virus B IgG  | 96 tests |
| EC119.00              | Influenza Virus B IgG/IgM<br>Seasonal updated antigens.  | 96 tests |
| INFM0300              | Influenza Virus B IgM  | 96 tests |

| Order No.             | Product Description   | Format   |
|-----------------------|---|----------|
| MEAG0330/<br>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/<br>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<br>Additional IgA set available with order number EC148.08.  | 96 tests |
| PARG0370              | Parvovirus B19 IgG<br>Recombinant antigen.  | 96 tests |
| PARM0370              | Parvovirus B19 IgM<br>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<br>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<br>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<br>Quantitative assay with antibody titer profile to verify immune status.  | 96 tests |
| PTICG044              | Tick-Borne Encephalitis IgG plus<br>Quantitative assay with antibody titer profile to verify immune status.<br>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<br>Total antibody assay coated with highly purified native antigen.   | 96 tests |
| EC115.00              | Bordetella pertussis (FHA+PT) IgG/IgA<br>Sensitive screening assay coated with PT and FHA antigens.  | 96 tests |
| BOPA0030              | Bordetella pertussis IgA<br>Sensitive screening assay coated with PT and FHA antigens.   | 96 tests |
| BOPG0030              | Bordetella pertussis IgG<br>Sensitive screening assay coated with PT and FHA antigens.   | 96 tests |
| ВОРМ0030              | Bordetella pertussis IgM   | 96 tests |
| BPTA0610/<br>EC215A00 | Bordetella pertussis toxin IgA<br>Pure PT antigens, adjusted to the WHO standards.   | 96 tests |
| BPTG0610/<br>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<br>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<br>Validated for cerebrospinal fluid testing.   | 96 tests |
| EC022M00              | Borrelia IgM<br>Borrelia strain Pko for high sensitivity. Validated for cerebrospinal fluid testing.   | 96 tests |
| BORG0040              | Borrelia burgdorferi IgG<br>Recombinant antigen, validated for serum, plasma, and cerebrospinal fluid<br>testing.  | 96 tests |
| BORM0040              | Borrelia burgdorferi IgM<br>Recombinant antigen, validated for serum, plasma, and cerebrospinal fluid<br>testing.  | 96 tests |
| BRUG0050              | Brucella IgG   | 96 tests |
| EC101.00              | Brucella IgG/IgM<br>Additional IgA set available with order number EC101.08.   | 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 |
| COX1G0600             | Coxiella burnetii phase 1 lgG  | 96 tests |
| COX2G0600             | Coxiella burnetii phase 2 IgG  | 96 tests |
| COX2M0600             | Coxiella burnetii phase 2 IgM  | 96 tests |
| CORG5009              | Diphtheria toxin 5S IgG<br>Quantitative assay with 5 standards for verification of immune status due to<br>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/<br>EC129.00 | Diphtheria toxin IgG<br>Quantitative assay. CORG0090 allows verification of immune status due to<br>vaccination or contact with Corynebacterium diphtheriae. EC129.00 is adjusted<br>to the WHO standards. | 96 tests |
| EC143A00              | Helicobacter pylori IgA  | 96 tests |
| HELG0220/<br>EC143G00 | Helicobacter pylori IgG<br>HELG0220 is a quantitative assay with recombinant antigen.  | 96 tests |
| PHELG022              | Helicobacter pylori IgG plus<br>Quantitative assay with recombinant antigen plus one control.  | 96 tests |
| HELM0220              | Helicobacter pylori IgM  | 96 tests |
| LEGG0650              | Legionella pneumophila IgG<br>Assay with antigens from a pool of different serovars to increase sensitivity.   | 96 tests |
| LEGM0650              | Legionella pneumophila IgM<br>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<br>Highly purified antigens.   | 96 tests |
| MYCG0350              | Mycoplasma pneumoniae IgG<br>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<br>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              | Tetanus toxin 5S IgG plus 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<br>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<br>Native antigen for high sensitivity.   | 96 tests |
| CHAG0560  | Chagas IgG<br>Chimeric-recombinant antigens to reduce cross-reactivity to Leishmania and<br>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<br>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<br>Native antigen for high sensitivity.  | 96 tests |
| TOCG0450  | Toxocara canis IgG   | 96 tests |
| TOXA0460  | Toxoplasma gondii IgA  | 96 tests |
| TOXG0460  | Toxoplasma gondii IgG<br>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<br>Capture assay to reduce cross-reactivity.                                 | 96 tests |
| TRIG0480  | Trichinella spiralis IgG   | 96 tests |

# **HORMONES-AUTOIMMUNITY •** Complete Kits

| Oveley Ne | Draduat Description  | Fawarat. |
|-----------|--|----------|
| 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<br>161101<br>B/300.00 | RF-SorboTech Pre-adsorbance for all IgM ELISA assays starting with "EC" as well as EC215A00. | 10 ml<br>2 ml<br>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<br>HW/E-017-A2 | Serazym® Adenovirus                                     | 96 tests<br>2 x 96 tests |
| HW/E-045<br>HW/E-045-A2 | Serazym® Astrovirus                                     | 96 tests<br>2 x 96 tests |
| HW/E-093<br>HW/E-093-A2 | Serazym® Campylobacter                                  | 96 tests<br>2 x 96 tests |
| HW/E-107<br>HW/E-107-A2 | Serazym® Clostridium difficile GDH                      | 96 tests<br>2 x 96 tests |
| HW/E-040<br>HW/E-040-A2 | Serazym® Clostridium difficile Toxin A+B                | 96 tests<br>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<br>HW/E-061-A2 | Serazym® Norovirus                                      | 96 tests<br>2 x 96 tests |
| HW/E-020<br>HW/E-020-A2 | Serazym® Rotavirus                                      | 96 tests<br>2 x 96 tests |
| HW/E-030<br>HW/E-030-A2 | Serazym® Verotoxin 1+2                                  | 96 tests<br>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<br>WE102G96 | Epstein-Barr Virus IgG Differentiates between primary and past infection and offers a special cut-off strategy for the EBNA1 interpretation. | 32 tests<br>96 tests |
| WE102M32<br>WE102M96 | Epstein-Barr Virus IgM Differentiates between primary and past infection and offers a special cut-off strategy for the EBNA1 interpretation. | 32 tests<br>96 tests |
| WE130G16<br>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<br>32 tests |

### **BACTERIOLOGY**

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

| Order No.            | Product Description   | Format               |
|----------------------|---|----------------------|
| WE243A32<br>WE243A96 | Helicobacter pylori IgA Therapy-relevant differentiation of virulent and non-virulent strains with CagA and VacA.                                   | 32 tests<br>96 tests |
| WE243G32<br>WE243G96 | Helicobacter pylori IgG  Therapy-relevant differentiation of virulent and non-virulent strains with CagA and VacA.                                  | 32 tests<br>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<br>WE150G32 | Syphilis IgG<br>Uses recombinant proteins.  | 16 tests<br>32 tests |
| WE150M16<br>WE150M32 | Syphilis IgM Uses recombinant proteins.   | 16 tests<br>32 tests |
| WE242A32<br>WE242A96 | Yersinia enterocolitica IgA Detection of reactive bands contributes towards the diagnosis of Yersinia- associated sequelae, as reactive arthritis.  | 32 tests<br>96 tests |
| WE242G32<br>WE242G96 | Yersinia enterocolitica IgG  Detection of reactive bands contributes towards the diagnosis of Yersinia- associated sequelae, as reactive arthritis. | 32 tests<br>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**

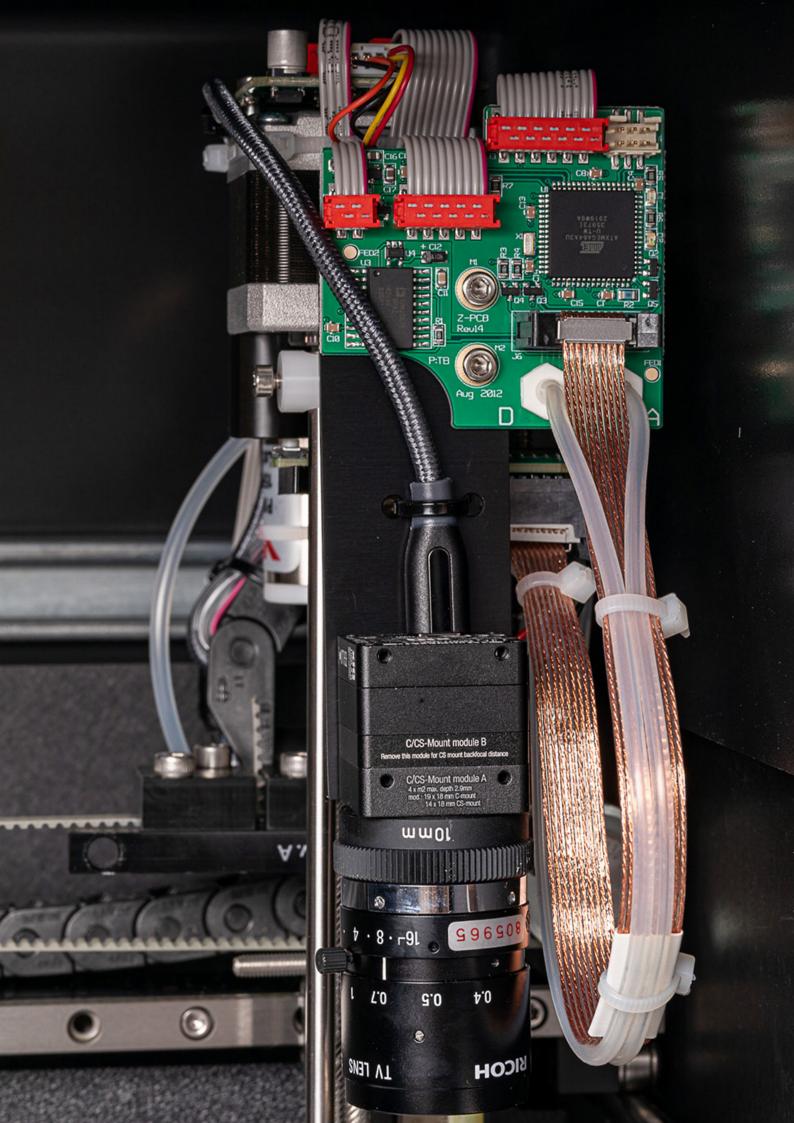
- Automated, magnetic bead extraction kits
- Efficient and reliable process which ensures the removal of potential inhibitors from sample matrices
- Perfect complement for virus detection assays

| Order No.                               | Product Description                       | Format  |
|---|---|---|
| 5524401101<br>5524401201<br>55244011100 | GSD NovaPrime® IVD RNA Extraction AE1     | 1 x 96 reactions<br>20 x 96 reactions<br>100 x 96 reactions |
| 5524411020<br>5524411100                | GSD NovaPrime® IVD RNA Extraction AE1 RTU | 20 x 96 reactions<br>100 x 96 reactions                     |
| 5524401301<br>5524401401                | GSD NovaPrime® IVD RNA Extraction AE2     | 1 x 96 reactions<br>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<br>PCOV6113   | GSD NovaPrime® TSP SARS-CoV-2<br>Contains specific primers and probes for the detection of SARS-CoV-2<br>genetic material and a heterologous amplification target to identify<br>possible RT-PCR inhibition. | 1 x 96 reactions<br>3 x 96 reactions |
| PCOV6181<br>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<br>4 x 96 reactions |
| PCOV6191T<br>PCOV6194T | GSD NovaType IV SARS-CoV-2 Identifies S gene mutations K417N, E484K, and L452R.  | 1 x 96 reactions<br>4 x 96 reactions |
| PRES6131<br>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<br>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<br>PRSV6164   | RSV A, RSV B Differentiates in a single reaction between RSV A and RSV B.  | 1 x 96 reactions<br>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**

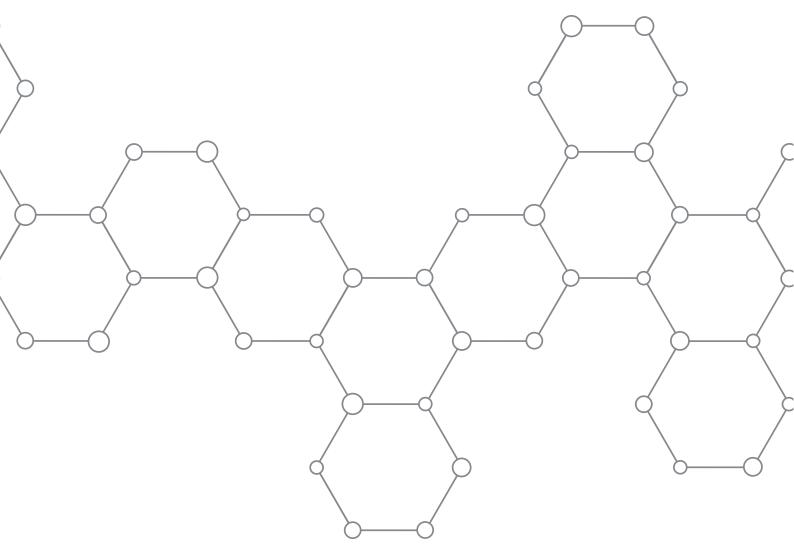
Please place your orders at order@goldstandarddiagnostics.eu including the following:

- 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**