

EIAgen

MicroELISA & Blood Bank Assays Menu



Adaltis offers a wide and competitive range of CE-IVD marked microplate assays based on colourimetric detection. Our EIAgen microELISA kits provide you reliable assays for your daily laboratory routine, either for screening or a more advanced sample classification.

EIAgen microELISA assay features:

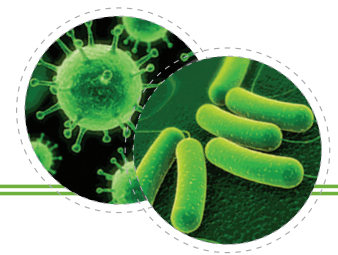
- Large menu of assays/kits
- Excellent performance for an affordable price
- Long stability

EIAgen assays in combination with our completely automated microplate analysers; Personal LAB 2-microplate analyser and NEXgen 7-plate analyser, are providing you a reliable and easy to operate system for your daily test routine. All validated application protocols are pre-loaded on the instruments for your immediate operation, and eliminate programming errors.

Adaltis' microELISA assays are CE-IVD marked and produced under ISO 9001 and ISO 13485 certification.

Excellent performance for accurate diagnosis





MicroElisa assays

The EIAgen line is a complete range of microplate assays able to satisfy the requirements of the most demanding laboratories.

- The excellent quality of Adaltis products, outstanding performance and ease of use, make the EIAgen assays the best solution for every laboratory.
- The kits use our TMB-substrate 'Blue Star', this world renowned component is ready to use and has long stability and shelf life.
- Almost all assays include reagents that are ready to use and have a shelf life of **at least 12-15 months**.

Our wide offer of assays includes the following lines:

- Respiratory SARS CoV-2
- Retrovirus
- ToRCH
- Hepatitis
- Syphilis
- Hormones

MicroELISA assays for Blood Banks

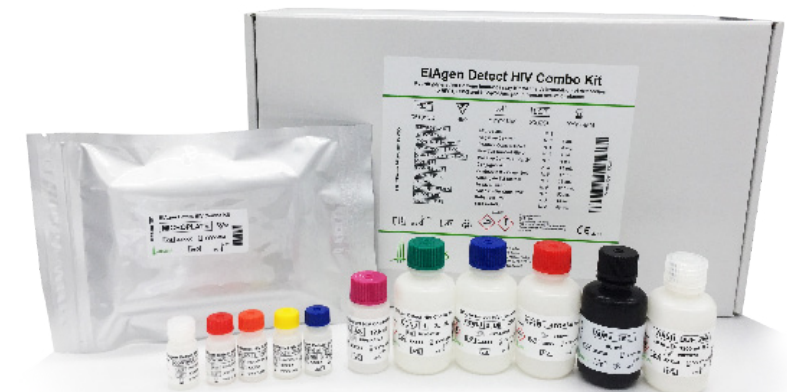
Adaltis offers to blood banks a range of high performance microELISA assays to increase the safety of blood products:

- HIV
- Syphilis
- HCV
- HTLV I/II
- HBsAg
- Cytomegalovirus

Adaltis is a pioneer in the blood screening solutions with its complete line of serological tests that are available to blood and plasma screening laboratories.

Our broad range of microELISA assays in combination with our new Personal Lab 2 microplates processor and NEXgen 5+2 microplates processor, is continuously providing you a state of the art system, fully automated and high-throughput for your returning work routine. With a maximum loading capacity of almost 620 primary sample tubes for routine analysis against a variety of tests, you will meet superior flexibility without compromising the quality of test results.

Adaltis' combined solution of both serology tests and analysers provide blood and plasma screening centres with high sensitivity and specificity on automated platforms designed for efficiency and reliability.

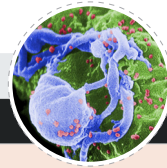


EIAgen Detect HIV Combo Kit
480 tests



RETROVIRUS

HIV and HTLV are both retroviruses and can be passed through blood and sexual contact, but they are only very remotely related, and HTLV does not cause AIDS and does not have the same devastating effects on a person's immune system that HIV does have.



Product Code	Description	Package
HIV		
081311C	EIAgen Detect HIV Combo	96 tests
081312C	EIAgen Detect HIV Combo	192 tests
081315C	EIAgen Detect HIV Combo	480 tests

The EIAgen Detect HIV Combo Kit is a new screening assay for the simultaneous detection of HIV-1 antibodies, HIV-2 antibodies and HIV-p24 antigen, in human serum or plasma. This 4th generation assay combines the HIV-antigen and the HIV-antibody detection, resulting in an earlier detection of an HIV-infection.

The EIAgen Detect HIV Combo Kit is a 4th generation assay, developed and evaluated in compliance with the new Common Technical Specifications 2009/886/EC (CTS) as required by the article 5 of the IVD Directive 98/79/EC:

- ✓ Monoclonal antibodies against HIV p24-antigen
- ✓ Antigens HIV-1 gp41 and HIV-2 gp36
- ✓ Recombinant antigens and synthetic peptides

Three different package sizes, 18-months of shelf life and 2-months of stability after first opening, guarantee the maximum flexibility to the laboratory in terms of stock management.

The EIAgen Detect HIV Combo Kit is the state of the art assay providing superior performances:

- ✓ Diagnostic Sensitivity 100%
- ✓ Diagnostic Specificity $\geq 99,7\%$
- ✓ Detection limit for p24-antigen: 1 IU/ml, based on the WHO 1st International Ref. (Code 90/636)
- ✓ Samples: Serum or Plasma (EDTA, Heparin, Citrate)



EIAgen Detect HIV Combo Kit
192 tests



Product Code	Description	Package
HTLV		
081321	EIAgen HTLV I-II Ab	96 tests
081322	EIAgen HTLV I-II Ab	192 tests
081325	EIAgen HTLV I-II Ab	480 tests

The EIAgen HTLV I-II Ab Kit assay is a solid phase enzyme immunoassay utilising a mixture of antigens for the in vitro diagnostic screening in human serum or plasma of antibodies to Human T-cell Lymphotropic Virus type I&II or HTLV I&II antibodies. The kit may be used for the screening of blood units of HTLV I&II-infected patients.

Three different package sizes, 18 months of shelf life and 6 months stability after first opening.

- Diagnostic Sensitivity 100%
- Diagnostic Specificity $\geq 99,8\%$
- Samples: Serum or Plasma (EDTA, Heparin, Citrate)



EIAgen HTLV I-II Ab
Kit



HORMONES

Adaltis offer a complete range of ELISA kits for the quantitative detection of Hormones: Thyroid for use on human serum and plasma.

Product Code	Description	Package
Thyroid		
LI4019B	EIAgen Total T3	96 tests
LI4020	EIAgen Total T4	96 tests
LI4025K	EIAgen U-TSH	96 tests
LI4025KF1	EIAgen TSH	96 tests



EIAgen Total T4 Kit
96 tests

ToRCH

ADALTIS' ToRCH line (Toxoplasmosis, Rubella, Cytomegalovirus, Herpes simplex) is a complete ToRCH panel available worldwide in classic microELISA sandwich method for the detection of IgG antibodies and in ELISA "capture" method for the IgM-class antibodies, intended to be used on human serum and plasma.

Product Code	Description	Package
Toxoplasma		
091000	EIAgen Toxoplasma IgG	96 tests
091001	EIAgen Toxoplasma IgM	96 tests
Rubella		
091002	EIAgen Rubella IgG	96 tests
091003	EIAgen Rubella IgM	96 tests
Cytomegalovirus		
091004	EIAgen Cytomegalovirus IgG	96 tests
091005	EIAgen Cytomegalovirus IgM	96 tests
Herpes		
091007	EIAgen Herpes Simplex Virus IgG	96 tests
091008	EIAgen Herpes Simplex Virus IgM	96 tests

* Alternative packaging formats can be supplied upon request.

EIAgen Cytomegalovirus IgG or IgM Ab kit assay although donor blood is not routinely tested for CMV for certain recipients such as neonates or immunocompromised patients this test may be advisable. The prevalence of CMV antibody can be as high as 80%.

* Alternative packaging formats can be supplied upon request.



SYPHILIS

ADALTIS Syphilis line of Elisa kit for screening of blood donors and pregnant women.

Product Code	Description	Package
081141	EIAGEN Syphilis Ab	96 tests
081142	EIAGEN Syphilis Ab	192 tests
081145	EIAGEN Syphilis Ab	480 tests

The EIAGEN Syphilis Ab Kit assay is a third generation solid phase enzyme immunoassay for the qualitative detection of antibodies against *Treponema pallidum* (TP), the causative agent of Syphilis, in human sera or plasma.

Three different package sizes, 18 months of shelf life and 2 months stability after first opening.

- Diagnostic Sensitivity 100%
- Diagnostic Specificity $\geq 99.5\%$
- Samples: Serum or Plasma (EDTA, Heparin, Citrate)



EIAGEN Syphilis Ab Kit
192 tests

HEPATITIS

Adaltis offers a complete panel for hepatitis diagnostic tests.

They are used to prevent infection through screening of donor serum and plasma, to establish the clinical diagnosis and make better decisions regarding medical management of the patient.

Product Code	Description	Package
Hepatitis A		
070998	EIAGEN Anti-HAV	96 tests
070999	EIAGEN Anti-HAV IgM	96 tests
Hepatitis B		
071011	EIAGEN HBsAg	96 tests
071012	EIAGEN HBsAg	192 tests
071115	EIAGEN HBsAg	480 tests

EIAGEN HBsAg Kit is an enzyme-linked immunosorbent assay (ELISA) for qualitative detection of HBsAg in human serum or plasma (EDTA, sodium citrate or heparin). It is intended for screening of blood donors and for diagnosing of patients related to infection with hepatitis B virus.

Three different package sizes, 15 months of shelf life and one month stability after first opening.

- Diagnostic Sensitivity 100%
- Diagnostic Specificity $\geq 99.78\%$
- Samples: Serum or Plasma (EDTA, Heparin, Citrate)

The 4th generation Enzyme ImmunoAssay (ELISA) for the determination of antibodies to Hepatitis C Virus in human plasma and sera. The kit may be used for the screening of blood units of HCV-infected patients.

Three different package sizes, 15 months of shelf life and is stable after first opening until the humidity indicator turns from yellow to green.

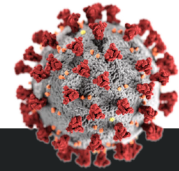
- Diagnostic Sensitivity 100%
- Diagnostic Specificity $\geq 99.5\%$
- Samples: Serum or Plasma (EDTA, Heparin, Citrate)

Product Code	Description	Package
Hepatitis C		
071067	EIAGEN HCV Ab (v.4)	96 tests
071064	EIAGEN HCV Ab (v.4)	192 tests
071068	EIAGEN HCV Ab (v.4)	480 tests
Hepatitis E		
071054	EIAGEN HEV IgG	96 tests
071050	EIAGEN HEV IgM	96 tests

* Alternative packaging formats can be supplied upon request.



EIAGEN HCV Ab (v.4) Kit
192 tests



SARS-CoV-2 ANTIBODY ASSAY KITS

RESPIRATORY

MicroELISA Testing Solutions

The EIAgen line is completed with SARS-CoV-2 fast and reliable microplate assays, as a response to COVID-19 Emergency.

Qualitative detection of IgM, IgG, IgA, antibodies to SARS-CoV-2 in human serum or plasma with the “Capture” system. It is intended for evaluating the immune response of patients suspected to be infected by SARS-CoV-2, for seroepidemiologic studies and as an aid in the diagnosis of Coronavirus disease 2019 (COVID-19).

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Product Code	Description	Package
COVID-19		
EIASARSCoV2-IgA	EIAgen SARS-CoV-2 IgA Kit	96 tests
081139	EIAgen U-SARS-CoV-2 IgM Kit	96 tests
081138	EIAgen U-SARS-CoV-2 IgG Kit	96 tests

EIAgen U-SARS-CoV-2 IgM Kit
96 tests

EIAgen U-SARS-CoV-2 IgG Kit
96 tests



SARS-CoV-2 IgM Kit

Enzyme Linked Immunosorbent Assay (ELISA) for the detection of IgM antibodies to SARS-CoV-2 in human serum or plasma with the “capture” system.

This new developed product of the EIAGEN line is used for evaluating the immune response of patients suspected to be infected by SARS-CoV-2, for seroepidemiologic studies and as an aid in the diagnosis of Coronavirus disease 2019 (COVID-19).

The serological test will be used for the monitoring of the immunological response upon vaccination and to validate the “New Digital Immune Passport” to let immune protected population travel and circulate without any risk to contract or transmit the SARS COV-2 disease.

This assay is based on the principle of “IgM capture” where IgM class antibodies in the sample are first captured by the solid phase coated with anti-IgM antibody.

The capture assay is a highly specific procedure to avoid false positive results, which are present with indirect assays, caused by Rheumatoid Factor and other interfering factors and the presence of IgG in the sample.

After washing out all the other components of the sample and in particular IgG antibodies, the specific IgM captured on the solid phase are detected by the addition of a recombinant SARS-CoV-2 antigen labeled with peroxidase (HRP).

After incubation, micro-wells are washed to remove unbound conjugate and then the substrate is added.

In the presence of bound conjugate the colorless substrate is hydrolyzed to a colored end-product, whose optical density may be detected and is proportional to the amount of IgM antibodies to SARS-CoV-2 present in the sample.

SARS-CoV-2 IgG Kit

Enzyme Linked Immunosorbent Assay (ELISA) for the quantitative detection of IgG antibodies to SARS-CoV-2 in human serum or plasma.

This new developed product of the EIAGEN line is used for evaluating the immune response of patients suspected to be infected by SARS-CoV-2, for seroepidemiologic studies and as an aid in the diagnosis of Coronavirus disease 2019 (COVID-19).

Positive results can help to qualify people to donate blood that can be used to manufacture convalescent plasma for those who are seriously ill from COVID-19.

The serological test will be used for the monitoring of the immunological response upon vaccination and to validate the “New Digital Immune Passport” to let immune protected population travel and circulate without any risk to contract or transmit the SARS COV-2 disease.

Microplates are coated with a mixture of highly specific recombinant SARS-CoV-2 antigens selected to obtain the best performances in term of sensitivity and specificity. The solid phase is first incubated with the diluted sample and IgG to SARS-CoV-2 are captured, if present, by the SARS-CoV-2 antigens.

After washing out all the other components of the sample, in the 2nd incubation bound anti SARS-CoV-2 IgG are detected by the addition of polyclonal specific anti I IgG antibodies, labelled with peroxidase (HRP).

The enzyme captured on the solid phase, acting on the substrate/chromogen mixture, generates an optical signal that is proportional to the amount of anti SARS-CoV-2 IgG antibodies present in the sample.

A Standard Curve, calibrated against the NIBSC (National Institute for Biological Standards and Control) serum code 20/136 “First WHO International Standard Anti-SARS-CoV-2 Immunoglobulin (Human)” (Version 2.0, Dated 17/12/2020), makes possible a quantitative determination of the IgG antibody in the patient.

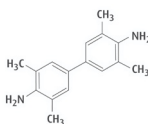
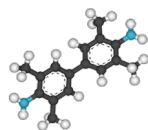
Adaltis provide special services for selected customers. Among them:

- Monoclonal antibodies purification methods: IgG purification by HPLC /FPLC and by affinity chromatography.
- Polyclonal antibodies purification methods:
 - Ammonium sulphate precipitation.
 - Protein A / G affinity purification.
- Antibody/Protein / Peptide Conjugation (including optimisation) with:
 - FITC (fluoroisotiocianate).
 - Biotin.
 - HRP and Alkaline Phosphatase
 - Keyhole - Limpet - Hemocyanin (KLH).
 - BSA and HSA.

BLUE STAR - The TMB Solution

TMB (3,3',5,5'-Tetramethylbenzidine) is a chromogen that yields a blue colour when oxidized, typically as a result of oxygen radicals produced by the hydrolysis of hydrogen peroxide by HRP.

For kinetic or non-stopped ELISA assays, the TMB chromogen has maximal absorbance at 370 nm and 650 nm. The colour then changes to yellow with the addition of sulphuric or phosphoric acid with maximum absorbance at 450 nm.



Product Specification

Ready for use

Stability : 25 months.

Storage: +2-8°C protected from light. Do not freeze.

pH 3.5 – 3.7

Blank < 0.050 OD

Product code

LSBLUEB

Product Size

10 litres	Sufficient for about 1000 microplates
20 litres	Sufficient for about 2000 microplates
50 litres	Sufficient for about 5000 microplates

For more details, please contact our Customer Care Centre via info@adaltis.net

- IVD development and prototyping: From the R&D phase into pilot and full-scale production.
- Solid phases coating:
 - Coating of microplates for ELISA applications.
 - Magnetic particle preparation.
- Reagents production: from preparation of solutions, to filling, capping and labelling.
- Packaging expertise: From (small) batch to finally labelled product/kits.



For more information

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ADALTIS is certified in compliance with ISO9001 and ISO 13485.
Our products are CE-IVD.