



MicroELISA & Blood Bank Assays Menu CE-IVD



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:

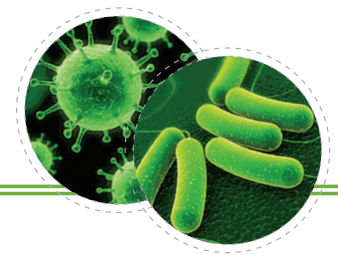
- Large menu of assays/kits
- Excellent performance for an affordable price
- Long stability

EIAgen assays in combination with our completely automated microplate analysers Personal LAB and the new NEXgen 7-plates 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 ISO13485 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:

- ToRCH
- Retrovirus
- Hepatitis
- Syphilis
- Gastric Function
- Vitamins
- Autoimmunity
- Hormones
- Tumour Markers

Bloodbank assays package

Adaltis offers to blood banks a range of high performance and fully CE-IVD compliant microELISA assays to increase the safety of blood products:

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



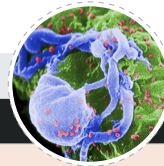


RETROVIRUS



The EIAgen microELISA Test Menu

Product Code	Description	Package
HIV		
081311	EIAgen Detect HIV 4 Total Screening	96 tests
081312	EIAgen Detect HIV 4 Total Screening	192 tests
081315	EIAgen Detect HIV 4 Total Screening	480 tests



The **EIAgen Detect HIV 4 Total Screening 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. The 4th generation assay combines the HIV antigen and the HIV antibody detection, resulting in an earlier detection of HIV infection

The EIAgen Detect HIV 4 Total Screening 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 4 Total Screening 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)

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
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)



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	ElAgen Toxoplasma IgG	96 tests
091001	ElAgen Toxoplasma IgM	96 tests
Rubella		
091002	ElAgen Rubella IgG	96 tests
091003	ElAgen Rubella IgM	96 tests
Cytomegalovirus		
091004	ElAgen Cytomegalovirus IgG	96 tests
091005	ElAgen Cytomegalovirus IgM	96 tests
Herpes		
0810071F1	ElAgen Herpes Simplex Virus 1 IgG	96 tests
0810072F1	ElAgen Herpes Simplex Virus 2 IgG	96 tests
0810081F1	ElAgen Herpes Simplex Virus 1 IgM	96 tests
0810082F1	ElAgen Herpes Simplex Virus 2 IgM	96 tests

* Alternative packaging formats can be supplied upon request.



ElAgen 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%.

One package size for each of the IgM and IgG, 15 months of shelf life.

- Diagnostic Sensitivity 98%
- Diagnostic Specificity 98%
- Samples: Serum or Plasma (EDTA, Heparin, Citrate)



The EIAgen microELISA Test Menu

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)



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
071131	EIAgen HBsAb	96 tests
071004	EIAgen HBeAb&Ag	96 tests
071009	EIAgen Anti-CORE 2-steps (a-HBc)	96 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

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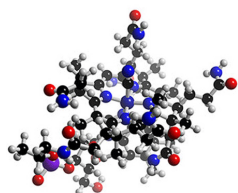
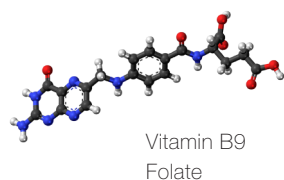
VITAMINS

NEW

The Adaltis EIAgen 25OH Vitamin D Total Kit is an immunoenzymetric assay for the in vitro quantitative measurement of 25-hydroxyvitamin D2 and D3 (25OH-D2 and 25OH-D3) in human serum.

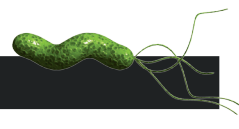
Vitamins B are a class of water-soluble vitamins that play important roles in cell metabolism. Vitamin B12, is a water-soluble vitamin with a key role in the normal functioning of the brain and nervous system, and for the formation of blood. Vitamin B9, is essential for numerous body functions.

Product Code	Description	Package
1425OHVDT	EIAgen 25OH Vitamin D Total	96 tests
LI5000	EIAgen Vitamin B-12	96 tests
LI5001	EIAgen Folate (Vitamin B9)	96 tests



Vitamin B12
Cobalamin

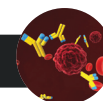
GASTRIC FUNCTION



Adaltis offer ELISA kits for the qualitative determination of IgG and IgA antibodies for Helicobacter Pylori, intended to be used on human serum and plasma.

Product Code	Description	Package
081022	EIAgen Helicobacter Pylori IgG	96 tests
081047	EIAgen Helicobacter Pylori IgA	96 tests

AUTOIMMUNITY



Adaltis offer a range of the most common tests for the diagnosis of the Autoimmune disorders.

The kits are qualitative/quantitative and intended to be used on human serum or plasma.

Product Code	Description	Package
Organ-specific Autoantibodies		
11TT-100F1	EIAgen Anti-Thyroglobulin	96 tests
11TPO-100F1	EIAgen Anti-TPO	96 tests
11TG-100F1	EIAgen Thyroglobulin	96 tests



Product Code	Description	Package
Fertility		
LI4041F1	EIAgen 17 β -Estradiol	96 tests
LI4043F1	EIAgen Progesterone (C21)	96 tests
LI4011KF1	EIAgen Testosterone	96 tests
LI10042F1	EIAgen Free Testosterone	96 tests
LI4012	EIAgen TOTAL hCG	96 tests
LI4013F1	EIAgen FSH	96 tests
LI4014F1	EIAgen LH	96 tests
LI4015F1	EIAgen Prolactin	96 tests
LI10040F1	EIAgen 17 α -OH Progesterone	96 tests



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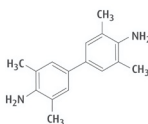
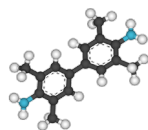
Adaltis provide special services for selected customers.
Among them:

- 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 (fluoroisotiocyanate).
- 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.