SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

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Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

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EC Certificate IVDD 22 012 0147

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices
Annex IV section 4

Certificate holder: **Adaltis S.r.l.**

Via Durini 27, 20122 Milano, Italy

Other Facility(ies): Via Luigi Einaudi 7, 00012 Guidonia Montecelio (RM), Italy

The certificate was issued with respect to the following scope:

ElAgen HBsAg Kit

This certificate is effective from 25 May 2022 until 26 May 2025 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 25 May 2022.

Certification has been authorized by

Digitally signed by Radovan Máčaj

Radovan Macaj
Head of Notified body

Digitally signed by Monastîrschii Viorica
Date: 2023.12.22 12:34:55 EET
Reason: MoldSign Signature
Location: Moldova

bqs.
Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed an examination of the design dossier in accordance with Annex IV section 4 of the directive and found that the design of the device conforms to the requirements laid down by Annex IV. For the placing on the market of List A devices an EC full quality assurance to Annex IV is required. Please see also notes overleaf if any.

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Additional information on certification

Related to certificate number:

IVDD 22 012 0147

Description of product(s) within the certification scope:

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

Types/Categories/Models:	071011 (96 tests) 071012 (192 tests) 071015 (480 tests)
Classification:	List A
Validity conditions:	-

This certificate is effective from 25 May 2022 until 26 May 2025 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 25 May 2022.

bqs.
Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed an examination of the design dossier in accordance with Annex IV section 4 of the directive and found that the design of the device conforms to the requirements laid down by Annex IV. For the placing on the market of List A devices an EC full quality assurance to Annex IV is required. Please see also notes overleaf if any.

DICHIARAZIONE DI CONFORMITÀ "CE" PER DISPOSITIVI MEDICI DIAGNOSTICI IN VITRO

EC Declaration of Conformity for IN VITRO DIAGNOSTIC MEDICAL DEVICES

La sottoscritta, fabbricante,
We, the undersigned manufacturer

Adaltis S.r.l.
Con Sede Legale in
Whit Registered Office in

Via Durini, 27
20122 Milano - Italy

Adaltis S.r.l.
Con Sede Produttiva in
With Manufacturing Site in

Via Luigi Einaudi, 7
00012 Guidonia Montecelio (RM) - Italy

Dichiara sotto la propria responsabilità che il prodotto descritto di seguito:
Herewith declare under our sole responsibility that the product described here below:

EIAgen HBsAg Kit

Codici/Codes 071011 / 071012 / 071015 - Nr. 96 / 192 / 480 tests

E' CLASSIFICATO COME DISPOSITIVO DIAGNOSTICO IN VITRO APPARTENENTE ALL'"ALLEGATO II Lista A"; VALUTAZIONE DELLA CONFORMITA' SECONDO:
ALLEGATO IV eccetto sezioni 4 & 6 certificato N. IVDD 22 012 0146 Scadenza 2025-05-26;
ALLEGATO IV paragrafo 4 certificato N. IVDD 22 012 0147 Scadenza 2025-05-26;
Ente Notificato: bqs. s.r.o. 2854

is classified as a IVD listed in Annex II List A; conformity assessment route:
ANNEX IV excluding sections 4 & 6 certificate N. IVDD 22 012 0146 Exp. Date 2025-05-26
ANNEX IV paragraph 4 certificate N. IVDD 22 012 0147 Exp. Date 2025-05-26;
Notified Body: bqs. s.r.o. 2854

Ed è in conformità con i requisiti della
And it is in compliance with the requirements of the

DIRETTIVA 98/79/CE IVDD del Parlamento europeo e del Consiglio, del 27 ottobre 1998, relativa ai dispositivi medico-diagnostici in vitro, pubblicata nella Gazzetta Ufficiale il 7 dicembre 1998.
EC COUNCIL DIRECTIVE IVDD 98/79/CE of the European Parliament and of the Council of 27th October 1998 of In Vitro Diagnostic Medical Device, published in the Official Journal on 7th December 1998.

Inoltre, sono applicate le seguenti Norme Armonizzate:
In addition, the following Harmonized Standards are applied:
EN ISO 13485:2016 (A11:2021), EN ISO 14971:2019, EN 13641:2002, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2021, EN 13612:2002, EN 62366-1:2015, EN ISO 23640:2015 and CTS.

The product is in compliance with Common Technical Specifications as they are defined within Commission Decision (2009/886/EC) of 27 November 2009 amending Decision 2002/364/EC on Common Technical Specifications for in vitro diagnostic medical devices

La documentazione tecnica a dimostrazione della conformità è conservata dal produttore e può essere resa disponibile da Adaltis S.r.l.
Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by Adaltis S.r.l.

Prima Emissione/*First Emission*: ___*26 May 2022*___ /___*26 Maggio 2022*__

_____
RESPONSABILE ASSICURAZIONE QUALITA' & AFFARI REGOLATORI / Quality Assurance & Regulatory Affairs Manager
(Roberto Steinhaus)

_____
DIRETTORE GENERALE / General Manager
(Marco Spadaccioli)

Place Guidonia Montecelio Rome - Italy

To: **Agenţia Medicamentului şi Dispozitivelor Medicale**
Chisinau str. Korolenko 2/1
MD-2028 Moldova

MANUFACTURER AUTHORISATION FORM

Italy, 27 November 2023

We, Adaltis S.r.l., certified ISO 9001 and ISO 13485, as the manufacturer of In Vitro Diagnostic Medical Devices (Instruments and Reagents), with legal site in Via Durini 27, 20122 Milano - Italy and production site in Via Luigi Einaudi 7, 00012 Guidonia Montecelio (RM) – Italy,

we hereby authorise company **SRL SANMEDICO** having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova,

to register with entitled institutions in Moldova, to commercialise as our distributor, to proceed and sign and submit offers and sign contracts on their behalf, deliver the goods for the following of our products for the tender/ project '*CENTER FOR CENTRALIZED PUBLIC PROCUREMENT IN HEALTH, no. ocds-b3wdp1-MD-1699619738481, The centralized purchase of Reagents for the Immunological Laboratory according to the needs of public medical and sanitary institutions (IMSP) for the year 2024',* in Moldova:

- **ElAgen HCV Ab (v.4)** *item 071067 (96T/kit)*
- **ElAgen HCV Ab (v.4)** *item 071064 (192T/kit)*
- **ElAgen HBsAg** *item 071011 (96T/kit)*
- **ElAgen HBsAg** *item 071012 (192T/kit)*

This authorisation is issued 27 November 2023 and shall expire 12 (twelve) months later, for all purposes. This authorisation may be renewable on request only.

ADALTIS S.r.l.

Adaltis S.r.l.
Via Luigi Einaudi, 7
00012 Guidonia Montecelio - Roma
Cod. Fis. 06797400964
P. IVA 06797400964

Marc Eijkhout
Sales Director

Adaltis S.r.l.
Headquarter
Via Luigi Einaudi, 7
00012 Guidonia Montecelio (RM) - Italy
Tel. +39 0774 579.1
Fax +39 0774 353085
service@adaltis.net - info@adaltis.net

Legal site
Via Durini, 27
20122 Milano - Italy
Cap. Soc. € 11.000,00 - REA: MI1915413
C.F. 06797400964 - P.I. IT06797400964
order@adaltis.net - www.adaltis.net

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Adaltis S.r.l.
Via Durini, 27
Milan
20122
Italy

Holds Certificate Number: **MD 718042**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture, distribution and service for in vitro diagnostic instruments for applications in the field of infectious diseases and clinical chemistry. Design, manufacture and distribution for in vitro diagnostic reagents for applications in the field of infectious diseases and clinical chemistry

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-12-10
Latest Revision Date: 2022-03-24

Effective Date: 2022-03-26
Expiry Date: 2025-03-25

...making excellence a habit.™

Certificate No: **MD 718042**

Location	Registered Activities
Adaltis S.r.l. Via Durini, 27 Milan 20122 Italy	Legal Manufacturer
Adaltis S.r.l. Via Luigi Einaudi, 7 Guidonia Montecelio (Roma) 00012 Italy	Design, Marketing/Sales, Reagents Production & Quality Control, Instruments Division - Software Development/Quality Control, Planning/Purchasing, Warehouse/Shipment, Quality Assurance, Human Resource, Order Entry and Order Processing, Customer Care Centre, Regulatory Affairs.

Original Registration Date: 2019-12-10
Latest Revision Date: 2022-03-24

Effective Date: 2022-03-26
Expiry Date: 2025-03-25

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Adaltis S.r.l
Via Durini 27
Milan
20122
Italy

Holds Certificate Number: FM 718043

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, manufacture, distribution and service for in vitro diagnostic instruments for applications in the field of infectious diseases and clinical chemistry. Design, manufacture and distribution for in vitro diagnostic reagents for applications in the field of infectious diseases and clinical chemistry.

For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2019-03-19
Effective Date: 2022-03-26
Latest Revision Date: 2022-03-02
Expiry Date: 2025-03-25

...making excellence a habit.™

Certificate No: FM 718043

Location	Registered Activities
Adaltis S.r.l. Via Durini, 27 Milan 20122 Italy	Legal Manufacturer.
Adaltis S.r.l. Via Luigi Einaudi, 7 Guidonia Montecelio (Roma) 00012 Italy	Design, Marketing / Sales, Reagents Production & Quality Control, Planning / Purchasing, Warehouse, Shipment, Quality Assurance, Human Resource, Order Entry and Order Processing, Customer Care Center, Regulatory Affairs.

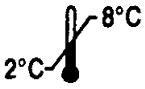
Original Registration Date: 2019-03-19
Effective Date: 2022-03-26
Latest Revision Date: 2022-03-02
Expiry Date: 2025-03-25

ADALTIS

ElAgen

HBsAg Kit

REF	071011	Σ	96
REF	071012	Σ	192
REF	071015	Σ	480



IVD

CE 2854

This package insert must be read carefully before product use.
Package insert instructions must be carefully followed.
Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package.

Manufacturer:
Adaltis S.r.l
Via Durini, 27
20122 Milano (Italy)
Tel. +39-0774-5791 - Fax +39-0774-353085
www.adaltis.net

en

SYMBOLS USED ON LABELS							
English EN	IVD	REF	LOT				Σ
	In Vitro Diagnostic Medical Device	Catalogue Number	Lot Number	Attention, See Instructions For Use	Temperature Limitation	Use By	Number of Test
					MICROPLATE	CONTROL +	CONTROL -
	Manufacturer	Keep away from Sunlight	Date of Manufacture	Biological Risk	Microplate	Positive Control	Negative Control
	CONJ	DIL AS	SUBS A UP	SUBS B TMB	SOLN STOP	WASH BUF 20X	
	Conjugate	Assay Diluent	Substrate A (Urea Peroxide)	Substrate B (TMB)	Stop Solution (0,5 M H_2SO_4)	Wash Buffer Conc. (20x)	Danger
	Warning						

Attention:
Negative Control, Positive Control, Conjugate, Assay Diluent and Substrate Solution A classified as: Skin Sens. 1 and Aquatic Chronic 3

- ***Signal word:***
  Warning
- ***Hazard-determining components of labelling:***
  Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)
- ***Hazard statements:***
  H317 May cause an allergic skin reaction.
  H412 Harmful to aquatic life with long lasting effects.
- ***Precautionary statements:***
  P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  P273 Avoid release to the environment.
  P280 Wear protective gloves/protective clothing/eye protection/face protection.
  P362+P364 Take off contaminated clothing and wash it before reuse.
  P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
  P321 Specific treatment (see medical advice on this label).
  P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Attention:
Substrate Solution B classified as: Carc. 1B and Repr. 1B

- ***Signal word:***
  Danger
- ***Hazard-determining components of labelling:***
  N,N-dimethylformamide
- ***Hazard statements:***
  H350 May cause cancer.
  H360D May damage the unborn child.
- ***Precautionary statements:***
  P201 Obtain special instructions before use.
  P202 Do not handle until all safety precautions have been read and understood.
  P280 Wear protective gloves/protective clothing/eye protection/face protection.
  P308+P313 IF exposed or concerned: Get medical advice/attention.
  P405 Store locked up.
  P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Refer to www.adaltis.net for the Safety Data Sheets.

EN *ENGLISH*

A. INTENDED USE

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.
For "in vitro" diagnostic use only.

B. INTRODUCTION

Hepatitis B virus (HBV) is an enveloped, double-stranded DNA virus belonging to the Hepadnaviridae family and is recognized as the major cause of blood transmitted hepatitis together with hepatitis C virus (HCV). Infection with HBV induces a spectrum of clinical manifestations ranging from mild, inapparent disease to fulminant hepatitis, severe chronic liver diseases, which in some cases can lead to cirrhosis and carcinoma of the liver. Classification of a hepatitis B infection requires the identification of several serological markers expressed during three phases (incubation, acute and convalescent) of the infection. Now several diagnostic test are used for screening, clinical diagnosis and management of the disease. Hepatitis B surface antigen or HBsAg, previously described as Australia antigen, is the most important protein of the envelope of Hepatitis B Virus. The surface antigen contains the determinant "a", common to all known viral subtypes and immunologically distinguished in two distinct subgroups (ay and ad). HBV has 10 major serotypes and four HBsAg subtypes have been recognized (adw, ady, ayw, and ayr). HBsAg can be detected 2 to 4 weeks before the ALT levels become abnormal and 3 to 5 weeks before symptoms develop. The serological detection of HBsAg is a powerful method for the diagnosis and prevention of HBV infection and ELISA has become an extensively used analytical system for screening of blood donors and clinical diagnosis of HBV in infected individuals.

C. PRINCIPLE OF THE TEST

For detection of HBsAg, EIAgen HBsAg Kit uses antibody "sandwich" ELISA method in which, polystyrene microwell strips are pre-coated with monoclonal antibodies specific to HBsAg. Patient's serum or plasma sample is added to the microwells. During incubation, the specific immunocomplex formed in case of presence of HBsAg in the sample, is captured on the solid phase. Then the second antibody conjugated the enzyme horseradish peroxidase (the HRP-Conjugate) directed against a different epitope of HBsAg is added into the wells. During the second incubation step, these HRP-conjugated antibodies will be bound to any anti-HBs-HBsAg complexes previously formed during the first incubation, and the unbound HRP-conjugate is then removed by washing. Chromogen solutions containing tetramethyl-benzidine (TMB) and urea peroxide are added to the wells. In presence of the antibody-antigen-antibody(HRP) "sandwich" immunocomplex, the colorless Chromogens are hydrolyzed by the bound HRP-conjugate to a blue-colored product. The blue color turns yellow after stopping the reaction with sulfuric acid. The amount of color intensity can be measured and it is proportional to the amount of antigen captured in the wells, and to its amount in the sample respectively. Wells containing samples negative for HBsAg remain colorless.

D. COMPONENTS

The kit contains reagents for 96 tests (code 071011), 192 tests (code 071012), or 480 tests (code 071015).

Microplate	1
Negative Control	1 x 1.5 mL/vial
Positive Control	1 x 1.5 mL/vial
Conjugate	1 x 6 mL/vial
Assay Diluent	1 x 5 mL/vial
Substrate Solution A (Urea Peroxide)	1 x 6 mL/vial
Substrate Solution B (TMB)	1 x 6 mL/vial
Stop Solution (H_2SO_4 - 0.5M)	1 x 6 mL/vial
Wash Buffer Concentrate 20X	1 x 30 mL/vial
Plate Sealing Foils	2
Plastic Sealable Bag	1
Number of tests	96
Code	071011

Microplate	2
Negative Control	1 x 1.5 mL/vial
Positive Control	1 x 1.5 mL/vial
Conjugate	2 x 6 mL/vial
Assay Diluent	2 x 5 mL/vial
Substrate Solution A (Urea Peroxide)	2 x 6 mL/vial
Substrate Solution B (TMB)	2 x 6 mL/vial
Stop Solution (H_2SO_4 - 0.5M)	2 x 6 mL/vial
Wash Buffer Concentrate 20X	2 x 30 mL/vial
Plate Sealing Foils	3
Plastic Sealable Bag	2
Number of tests	192
Code	071012

Microplate	5
Negative Control	4 x 1.5 mL/vial
Positive Control	4 x 1.5 mL/vial
Conjugate	5 x 6 mL/vial
Assay Diluent	4 x 5 mL/vial
Substrate Solution A (Urea Peroxide)	5 x 6 mL/vial
Substrate Solution B (TMB)	5 x 6 mL/vial
Stop Solution (H_2SO_4 - 0.5M)	1 x 30 mL/vial
Wash Buffer Concentrate 20X	3 x 50 mL/vial
Plate Sealing Foils	6
Plastic Sealable Bag	5
Number of tests	480
Code	071015

1. Microplate
Blank microwell strips fixed on white strip holder.
12 strips of 8 microwells coated with monoclonal antibodies reactive to HBsAg (anti-HBs).
Plates are sealed into a aluminium pouch with desiccant.
The microwell strips can be broken to be used separately. Place unused wells or strips in the provided plastic sealable storage bag together with the desiccant and return to 2…8°C. Once open, stable for one month at 2…8°C.

2. Negative Control
Yellowish liquid filled in a vial with natural screw cap.
Protein-stabilized buffer tested non-reactive for HBsAg.
Ready to use as supplied. It contains 0,1% Proclin™ 300 as preservative.

Once open, stable for one month at 2…8°C.

3. Positive Control
Red-colored liquid filled in a vial with red screw cap.
HBsAg diluted in protein-stabilized buffer.
Ready to use as supplied. It contains 0,1% Proclin™ 300 as preservative.
Once open, stable for one month at 2…8°C.
Important Note: *The absence of viable pathogens in the Positive Control can not be fully ensured, and therefore, the reagent should be handled as potentially biohazardous, in accordance with good laboratory practices*.

4. Conjugate
Red-colored liquid in a white vial with green screw cap.
Horseradish peroxidase-conjugated anti-HBs antibodies.
Ready to use as supplied. It contains 0,1% Proclin™ 300 as preservative.
Once open, stable for one month at 2…8°C.

5. Assay Diluent
Green-colored in a vial with pink screw cap.
Buffer solution containing protein.
Ready to use as supplied. It contains 0,1% Proclin™ 300 as preservative.
Once open, stable for one month at 2…8°C.

6. Substrate Solution "A"
Colorless liquid filled in a white vial with grey screw cap.
Urea peroxide solution.
Ready to use as supplied.
Once open, stable for one month at 2…8°C.

7. Substrate Solution "B"
Colorless liquid filled in a black vial with black screw cap.
TMB (Tetramethyl benzidine solution) and N,N-dimethylformamide.
Ready to use as supplied.
Once open, stable for one month at 2…8°C.
Note: To be stored protected from light as sensitive to strong illumination.

8. Stop Solution
Colorless liquid in a white vial with red screw cap.
Diluted sulfuric acid solution (0.5M H_2SO_4).
Ready to use as supplied.
Once open, stable for one month at 2…8°C.

9. Wash Buffer Concentrate 20x
Colorless liquid filled in a clear bottle with natural screw cap. Buffer solution containing surfactant Tween-20.
The concentrate must be diluted **1 to 20** with distilled/ deionized water before use.
Once diluted, stable for one week at room temperature, or for two weeks when stored at 2…8°C.

E. MATERIALS REQUIRED BUT NOT PROVIDED

1. Calibrated Micropipettes (20, 50, 100 µL) and disposable plastic tips.
2. EIA grade water (bidistilled or deionised, charcoal treated to remove oxidizing chemicals used as disinfectants).
3. Timer with 60 minute range or higher.
4. Absorbent paper tissues.
5. Calibrated ELISA microplate thermostatic incubator capable to provide a temperature of 37 ± 0.5°C.
6. Calibrated ELISA microwell reader with 450nm (reading) and possibly with 620-630nm (blanking) filters.
7. Calibrated ELISA microplate washer.
8. Vortex or similar mixing tools.

F. WARNINGS AND PRECAUTIONS

1. The kit has to be used by skilled and properly trained technical personnel only, under the supervision of a medical doctor responsible of the laboratory.
   This package insert must be read carefully before product use.
2. Read carefully the Safety Data Sheet (SDS) before product use.
3. When the kit is used for the screening of blood units and blood components, it has to be used in a laboratory certified and qualified by the national authority in that field (Ministry of Health or similar entity) to carry out this type of analysis.
4. All the personnel involved in performing the assay have to wear protective laboratory clothes, talc-free gloves and glasses. The use of any sharp (needles) or cutting (blades) devices should be avoided. All the personnel involved should be trained in biosafety procedures, as recommended by the Center for Disease Control, Atlanta, U.S. and reported in the National Institute of Health's publication: "Biosafety in Microbiological and Biomedical Laboratories", ed. 1984.
5. All the personnel involved in sample handling should be vaccinated for HBV and HAV, for which vaccines are available, safe and effective.
6. The laboratory environment should be controlled so as to avoid contaminants such as dust or air-born microbial agents, when opening kit vials and microplates and when performing the test. Protect the Substrate Solution "B" (TMB) from strong light and avoid vibration of the bench surface where the test is undertaken.
7. Upon receipt, store the kit at 2...8°C into a temperature controlled refrigerator or cold room.
8. Do not interchange components between different lots of the kits. It is recommended that components between two kits of the same lot should not be interchanged.
9. Check that the reagents are clear and do not contain visible heavy particles or aggregates. If not, advise the laboratory supervisor to initiate the necessary procedures for kit replacement.
10. Avoid cross-contamination between serum/plasma samples by using disposable tips and changing them after each sample.
11. Avoid cross-contamination between kit reagents by using disposable tips and changing them between the use of each one.
12. Do not use the kit after the expiration date stated on the external container and internal (vials) labels.
13. Treat all specimens as potentially infective. All human serum specimens should be handled at Biosafety Level 2, as recommended by the Center for Disease Control, Atlanta, U.S. in compliance with what reported in the Institutes of Health's publication: "Biosafety in Microbiological and Biomedical

Laboratories", ed. 1984. Materials from human origin may have been used in the preparation of the Negative Control of the kit. These materials have been tested with tests kits with accepted performance and found negative for antibodies to HIV 1/2, HCV, TP and HBsAg. However, there is no analytical method that can assure that infectious agents in the specimens or reagents are completely absent. Therefore, handle reagents and specimens with extreme caution as if capable of transmitting infectious diseases. Bovine derived sera have been used for stabilizing of the positive and negative controls. Bovine serum albumin (BSA) and fetal calf sera (FCS) are derived from animals from BSE/TSE free-geographical areas.

14. The use of disposable plastic-ware is recommended in the preparation of the liquid components or in transferring components into automated workstations, in order to avoid cross contamination.
15. Waste produced during the use of the kit has to be discarded in compliance with national directives and laws concerning laboratory waste of chemical and biological substances. In particular, liquid waste generated from the washing procedure, from residuals of controls and from samples has to be treated as potentially infective material and inactivated before waste. Suggested procedures of inactivation are treatment with a 10% final concentration of household bleach for 16-18 hrs or heat inactivation by autoclave at 121°C for 20 min.
16. Accidental spills from samples and operations have to be adsorbed with paper tissues soaked with household bleach and then with water. Tissues should then be discarded in proper containers designated for laboratory/hospital waste.
17. The Stop Solution contains 0.5M sulphuric acid. Avoid contact with skin and eyes. In the event of contact, rinse immediately with plenty of water.
18. ProClin™ 300, 0.1% used as preservative, can cause sensation of the skin. Wipe up spills immediately or wash with water if come into contact with the skin or eyes.
19. Do not smoke, eat, drink or apply cosmetics in areas in which specimens or kit reagents are handled
20. Other waste materials generated from the use of the kit (example: tips used for samples and controls, used microplates) should be handled as potentially infective and disposed according to national directives and laws concerning laboratory wastes.
21. Do not pipette by mouth.

G. SPECIMEN: PREPARATION AND RECOMMANDATIONS

1. **Specimen Collection**:
   No special patient's preparation required. Collect the specimen in accordance with the normal laboratory practice. Either fresh serum or plasma specimens can be used with this assay. Blood collected by venipuncture should be allowed to clot naturally and completely - the serum/plasma must be separated from the clot as early as possible as to avoid haemolysis of the RBC. Care should be taken to ensure that the serum specimens are clear and not contaminated by microorganisms. Any visible particular matters in the specimen should be removed by centrifugation at 3000 RPM (round per minutes) for 20 minutes at room temperature or by filtration.
2. Plasma specimens collected into EDTA, sodium citrate or heparin may be tested, but ***highly lipaemic, icteric, or hemolytic specimens should not be used*** as they can give false results in the assay. ***Do not heat inactivate specimens***. This can cause deterioration of the target analyte. Samples with visible microbial contamination should never be used.
3. EIAgen HBsAg Kit is intended ONLY for testing of individual serum or plasma samples. Do not use the assay for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
4. **Transportation and Storage:** Store specimens at 2…8°C. Specimens not required for assaying within 7 days should be stored frozen (-20°C or lower). Multiple freeze-thaw cycles should be avoided. For shipment, samples should be packaged and labeled in accordance with the existing local and international regulations for transportation of clinical samples and ethological agents.

H. PREPARATION OF COMPONENTS AND WARNINGS

The components of the kit will remain stable through the expiration date indicated on the label and package when stored between 2…8°C, do not freeze. To assure maximum performance of EIAgen HBsAg Kit, during storage, protect the reagents from contamination with microorganism or chemicals.

1. Microplates:
Allow the microplate to reach room temperature (18…30°C), about 1 hr, before opening the pouch. Unused strips have to be placed inside the plastic sealable bag, with the desiccant supplied and stored at 2...8°C. After first opening, remaining strips are stable one month at 2…8°C.

2. Negative Control:
Ready to use. Mix well on vortex before use.

3. Positive Control:
Ready to use. Mix well on vortex before use. Handle this component as potentially infectious.

4. Conjugate:
Ready to use. Mix well on vortex before use.
Be careful not to contaminate the liquid with oxidizing chemicals, air-driven dust or microbes. If this component has to be transferred use only plastic, possibly sterile disposable containers.

5. Assay Diluent:
Ready to use. Mix well on vortex before use.

6. Substrate Solution "A" and "B":
Ready to use. Mix well on vortex before use.
Avoid contamination of the liquid with oxidizing chemicals, air-driven dust or microbes. Do not expose to strong illumination, oxidizing agents and metallic surfaces. If this component has to be transferred use only plastic, and if possible, sterile disposable container.

7. Stop Solution:
Ready to use. Mix well on vortex before use.

8. Wash Buffer Concentrate 20x (vial of 30 mL):
The whole content of the 20x concentrated solution has to be diluted with distilled/deionized water up to 600 mL (up to 1000 mL for the vial of 50 mL), the volume is reported on the label, and mixed gently end-over-end before use. As some salt crystals may be present into the vial, take care to dissolve all the content when preparing the solution. During preparation avoid foaming as the presence of bubbles could impact on the efficiency of the washing cycles.
Note: Once diluted, the wash solution is stable for 1 week at room temperature and two weeks at 2...8°C.

I. INSTRUMENTS AND TOOLS USED IN COMBINATION WITH THE KIT

1. Micropipettes have to be calibrated to deliver the correct volume required by the assay and must be submitted to regular decontamination (household alcohol, 10% solution of bleach, hospital grade disinfectants) of those parts that could accidentally come in contact with the sample or the components of the kit. They should also be regularly maintained in order to show a precision of 1% and a trueness of ±2%. Decontamination of spills or residues of kit components should also be carried out regularly.
2. The ELISA incubator has to be set at +37°C (tolerance of ±0.5°C) and regularly checked to ensure the correct temperature is maintained. Both dry incubators and water baths are suitable for the incubations, provided that the instrument is validated for the incubation of ELISA tests.
3. INSTRUCTIONS FOR WASHING
   The ELISA washer is extremely important to the overall performances of the assay:
   - A good washing procedure is essential in order to obtain correct and precise analytical data.
   - It is therefore, recommended to use a good quality ELISA microplate washer, maintained at the best level of washing performances. In general, no less than **5** automatic washing cycles of 350-400 µL/well are sufficient to avoid false positive reactions and high background.
   - To avoid cross-contaminations of the plate with specimen or HRP-conjugate, after incubation, do not discard the content of the wells but allow the plate washer to aspirate it automatically.
   - Assure that the microplate washer liquid dispensing channels are not blocked or contaminated and sufficient volume of Wash buffer is dispensed each time into the wells.
   - In case of manual washing, we suggest to carry out **5 washing cycles,** dispensing 350-400 µL/well and aspirating the liquid for **5** times. If poor results (high background) are observed, increase the washing cycles or soaking time per well.
   - In any case, the liquid aspirated out the strips should be treated with a sodium hypochlorite solution at a final concentration of 2.5% for 24 hours, before they are wasted in an appropriate way**.**
   - The concentrated Wash buffer should be diluted **1:20** before use. If less than a whole plate is used, prepare the proportional volume of solution.
4. The ELISA microplate reader has to be equipped with a reading filter of 450nm and ideally with a second filter (630nm) for blanking purposes. Its standard performances should be (a) bandwidth ≤ 10 nm; (b) absorbance range from 0 to ≥ 2.0; (c) linearity to ≥2.0; repeatability ≥ 1%. Blanking is carried out on the well identified in section "Assay Procedure". The optical system of the reader has to be calibrated regularly to ensure that the correct optical density is measured. It should be regularly maintained according to the manufacturer's instructions.
5. When using an ELISA automated work station, all critical steps (dispensation, incubation, washing, reading, shaking, data handling) have to be carefully set, calibrated, controlled and regularly serviced in order to match the values reported in section O "Internal Quality Control". The assay protocol has to be installed in the operating system of the unit and validated as for the washer and the reader. In addition, the liquid handling part of the station (dispensation and washing) has to be validated and correctly set. Particular attention must be paid to avoid carry over by the needles used for dispensing samples and for washing. This must be studied and controlled to minimize the possibility of contamination of adjacent wells due to strongly reactive samples, leading to false positive results. The use of ELISA automated work stations is recommended for blood screening and when the number of samples to be tested exceed 20-30 units per run. If using fully automated equipment, during incubation, do not cover the plates with the plate cover. The tapping out of the remainders inside the plate after washing, can also be omitted.

L. PRE ASSAY CONTROLS AND OPERATIONS

1. Check the expiration date of the kit printed on the external label of the kit box. Do not use if expired.
2. Check that the liquid components are not contaminated by naked-eye visible particles or aggregates. Check that the Substrate Solutions "A" and "B" are colorless or pale blue by aspirating a small volume of it with a sterile transparent plastic pipette. Check that no breakage occurred in transportation and no spillage of liquid is present inside the box. Check that the aluminum pouch, containing the microplate, is not punctured or damaged.
3. Dilute all the content of the 20x concentrated Wash Buffer as described above.
4. Allow all the other components to reach room temperature (18…30°C), about 1 hr and then mix as described.
5. Set the ELISA incubator at +37°C and prepare the ELISA washer by priming with the diluted wash solution, according to the manufacturers instructions. Set the right number of washing cycles as found in section I.3.
6. Check that the ELISA reader has been turned on at least 20 minutes before reading.

7. If using an automated workstation, turn it on, check settings and be sure to use the right assay protocol.
8. Check that the micropipettes are set to the required volume.
9. Check that all the other equipment is available and ready to use.
10. In case of problems, do not proceed further with the test and advise the supervisor.

M. ASSAY PROCEDURE

The assay has to be carried out according to what reported below, taking care to maintain the same incubation time for all the samples in testing.

MANUAL ASSAY:

1. **Preparation:** Mark three wells as Negative control **(e.g. B1, C1, D1)**, two wells as Positive control **(e.g. E1, F1)** and one Blank (**e.g. A1**, neither samples nor Conjugate should be added into the Blank well). If the results will be determined by using dual wavelength plate reader, the requirement for use of Blank well could be omitted. Use only number of strips required for the test.
2. **Adding Diluent:** Add **20µL** of Assay Diluent into each well except the Blank.
3. **Adding Sample:** Add **100µL** of Positive control, Negative control, and Specimen into their respective wells except the Blank. **Note: Use a separate disposal pipette tip for each specimen, Negative Control, Positive Control to avoid cross-contamination. Mix by tapping the plate gently.**
4. **Incubating:** Cover the plate with the plate cover and incubate for **60 minutes at 37°C**.
5. **Adding Conjugate:** At the end of the incubation, remove and discard the plate cover. Add **50µL** Conjugate into each well except the Blank, and mix by tapping the plate gently.
6. **Incubating:** Cover the plate with the plate cover and incubate for **30 minutes at 37°C**.
7. **Washing:** At the end of the incubation, remove and discard the plate cover. Wash each well **5 times** with diluted Washing buffer. Each time allow the microwells to soak for **30-60 seconds**. After the final washing cycle, turn down the plate onto blotting paper or clean towel and tap it to remove any remainders (see section I.3).
8. **Coloring:** Add **50µL** of Substrate Solution "A" and **50µL** Substrate Solution "B" into each well including the Blank. Incubate the plate at **37°C for 30 minutes avoiding light**. The enzymatic reaction between the Substrate Solutions and the Conjugate produces blue color in Positive control and HBsAg positive sample wells.
9. **Stopping Reaction:** Using a multichannel pipette or manually, add **50µL** Stop solution into each well and mix gently. Intensive yellow color develops in Positive control and HBsAg positive sample wells.
10. **Measuring the Absorbance:** Calibrate the plate reader with the Blank well and read the absorbance at **450nm**. If a dual filter instrument is used, set the reference wavelength at **630nm**. Calculate the Cut-off value and evaluate the results. (**Note:** read the absorbance within **10 minutes** after stopping the reaction).

Important notes:

1. *If the second filter is not available, ensure that no finger prints are present on the bottom of the microwell before reading at 450nm. Finger prints could generate false positive results on reading.*
2. *Reading has should ideally be performed immediately after the addition of the Stop Solution but definitely no longer than 10 minutes afterwards. Some self oxidation of the substrate can occur leading to a higher background.*

N. ASSAY SCHEME

Steps	**Operations**
Assay Diluent	20 µL
Controls and Samples	100 µL
1st incubation	**60 min**
Temperature	+37°C
Conjugate	50 µL
2nd incubation	**30 min**
Temperature	+37°C
Wash Step	5 cycles (see section I.3)
Substrate "A"	50 µL
Substrate "B"	50 µL
3rd incubation	**30 min (avoiding light)**
Temperature	+37°C
Stop Solution	50 µL
Reading OD	450/630nm

An example of dispensation scheme is reported below (valid for both incubation time procedures):

Microplate

	1	2	3	4	5	6	7	8	9	10	11	12
A	BLK	S3										
B	NC	S4										
C	NC	S5										
D	NC	S6										
E	PC	S7										
F	PC	S8										
G	S1	S9										
H	S2	S10										

Legenda: BLK = Blank NC = Negative Control
PC = Positive Control S = Sample

O. INTERNAL QUALITY CONTROL

The test results are valid if the Quality Control criteria are fulfilled. It is recommended that each laboratory must establish appropriate quality control system with quality control material similar to or identical with the patient sample being analyzed.

- The A value of the Blank well, which contains only Chromogen and Stop Solution, is < 0.080 at 450 nm.
- The A values of the Positive Control must be ≥ 0.800 at 450/630nm or at 450nm after blanking.
- The A values of the Negative Control must be < 0.100 at 450/630nm or at 450nm after blanking.

If one of the Negative control A values does not meet the Quality Control criteria, it should be discarded and the mean value calculated again using the remaining two values. If more than one Negative control A values do

not meet the Quality Control Range specifications, the test is invalid and must be repeated.

If the results of the test match the requirements stated above, proceed to the next section.
If they do not, do not proceed any further and perform the following checks:

Problems	Check
Blank well ≥ 0.080 OD at 450nm	1. that the Substrate Solutions have not become contaminated during the assay
Negative Control (NC) ≥ 0.100 OD at 450/630nm or at 450nm after blanking	1. that the washing procedure and the washer settings are as validated in the pre qualification study; 2. that the proper washing solution has been used and the washer has been primed with it before use; 3. that no mistake has been done in the assay procedure (dispensation of positive control instead of the negative one); 4. that no contamination of the negative control or of the wells where the control was dispensed has occurred due to spills of positive samples or of the conjugate; 5. that micropipettes have not become contaminated with positive samples or with the conjugate 6. that the washer needles are not blocked or partially obstructed.
Positive Control < 0.800 OD at 450/630nm or at 450nm after blanking	1. that the procedure has been correctly performed; 2. that no mistake has occurred during the distribution of the control (dispensation of negative control instead of positive control); 3. that the washing procedure and the washer settings are as validated in the pre qualification study; 4. that no external contamination of the positive control has occurred.

If any of the above problems have occurred, report the problem to the supervisor for further actions.

P. RESULTS

Each microplate should be considered separately when calculating and interpreting the results of the assay, regardless of the number of plates concurrently processed. The results are calculated by relating each specimen absorbance (A) value to the Cut-off value (C.O.) of the plate. If the Cut-off reading is based on single filter plate reader, the results should be calculated by subtracting the Blank well A value from the print report values of specimens and controls. In case the reading is based on dual filter plate reader, do not subtract the Blank well A value from the print report values of specimens and controls.

Cut-Off (C.O.) = NC mean + 0.06

The value found for the test is used for the interpretation of results as described in the next paragraph.

An example of calculation is reported below:

Example:

1. Quality Control

Blank well A value: A1= 0.025 at 450nm (Note: blanking is required only when reading with single filter at 450nm)

Well No.:	**B1**	**C1**	**D1**
Negative control A values after blanking:	0.020	0.012	0.016

Well No.:	**E1**	**F1**
Positive control A values after blanking:	2.421	2.369

All control values are within the stated quality control range

2. Calculation of Nc: = $\frac{(0.020+0.012+0.016)}{3}$ = 0.016

3. Calculation of the Cut-off: (C.O.) = 0.016 +0.06 = 0.076

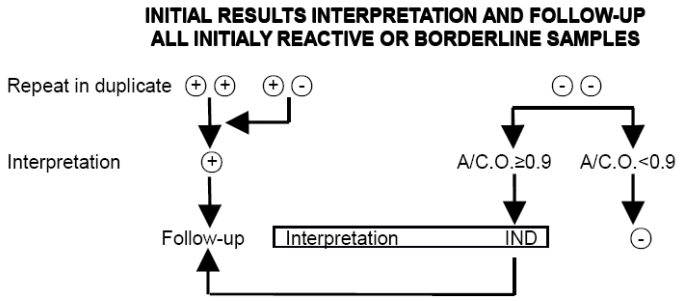
Q. INTERPRETATION OF RESULTS

Negative Results (A / C.O. < 0.9):
Specimens giving absorbance less than the Cut-off value are negative for this assay, which indicates that no hepatitis B virus surface antigen has been detected with EIAgen HBsAg Kit, therefore the patient is probably not infected with HBV and the blood unit do not contain hepatitis B virus surface antigen and could be transfused in case that other infectious diseases markers are also absent.

Positive Results (A / C.O. > 1.1):
Specimens giving an absorbance equal to or greater than the Cut-off value are considered initially reactive, which indicates that hepatitis B virus surface antigen has probably been detected using EIAgen HBsAg Kit. All initially reactive specimens should be retested in duplicates using EIAgen HBsAg Kit before the final assay results interpretation. Repeatedly reactive specimens can be considered positive for hepatitis B virus surface antigen with EIAgen HBsAg Kit.

Borderline (A / C.O. = 0.9-1.1):
Specimens with absorbance to Cut-off ratio between 0.9 and 1.1 are considered borderline and retesting of these specimens in duplicates is required to confirm the initial results.

Follow-up, confirmation and supplementary testing of any positive specimen with other analytical system (e.g. PCR) is required. Clinical diagnosis should not be established based on a single test result. It should integrate clinical and other laboratory data and findings.



IND = non interpretable

If, after retesting of the initially reactive samples, both wells are negative results (A/C.O.<0.9), these samples should be considered as non-repeatable positive (or false positive) and recorded as negative. As with many very sensitive ELISA assays, false positive results can occur due to the several reasons, most of which are connected with, but not limited to, inadequate washing step. For more information regarding “Troubleshooting Guide” (section S).
If after retesting in duplicates, one or both wells are positive results, the final result from this ELISA test should be recorded as repeatedly reactive. Repeatedly reactive specimens could be considered positive for hepatitis B virus surface antigen and therefore the patient is probably infected with HBV and the blood unit must be discarded.
After retesting in duplicates, samples with values close to the Cut-off value should be interpreted with caution and considered as "borderline" zone sample, or uninterpretable for the time of testing.

Important notes:

1. *Interpretation of results should be done under the supervision of the laboratory supervisor to reduce the risk of judgment errors and misinterpretations.*
2. *When test results are transmitted from the laboratory to another department, attention must be paid to avoid erroneous data transfer.*
3. *Diagnosis of viral hepatitis infection has to be taken and released to the patient by a suitably qualified medical doctor.*

R. PERFORMANCES

Evaluation of Performances has been conducted in accordance to what reported in the Common Technical Specifications or CTS (art. 5, Chapter 3 of IVD Directive 98/79/EC).
Evaluation studies carried out in Paul-Ehrlich-Institut (PEI), German Red Cross Institute Baden-Württemberg – Hessen, and three blood banks, demonstrated the following performance characteristics of EIAgen HBsAg Kit.

1. SPECIFICITY

When evaluated on European blood donors (n=5038), the overall diagnostic specificity of the kit was 99.78%.

During multi-center evaluation (Site A, B and C), EIAgen HBsAg Kit demonstrated specificity of 99.92%.

Laboratory	Number	EIAgen HBsAg Kit		
		-	+	Specificity
“A” blood bank	1958	1955	3	99.85%
“B” blood bank	2518	2516	2	99.92%
“C” blood bank	6344	6340	4	99.94%
Total	10820	10811	9	99.92%

2. SENSITIVITY

EIAgen HBsAg Kit was evaluated for sensitivity on 22 HBV commercial available HBV seroconversion panels, and on total 403 HBsAg positive including 146 HBsAg HBV genotyped and HBsAg subtyped plasma samples available at the Paul-Ehrlich-Institut. With respect to seroconversion sensitivity, the results for EIAgen HBsAg Kit on the 22 HBV seroconversion panels showed a sensitivity level at least equivalent with the range of current CE marked HBsAg screening assays for which PEI holds data. 10 additional seroconversion panels were tested in-house. The seroconversion sensitivity was comparable to other CE-marked HBsAg screening test. With respect to diagnostic sensitivity EIAgen HBsAg Kit detected all positive samples as positive, including the HBV genotypes A-F or HBsAg subtypes examined.

In conclusion, the overall score of EIAgen HBsAg Kit for the seroconversion sensitivity was comparable with other CE marked HBsAg test kits for which PEI holds data and all 403 HBsAg positive samples were reactive giving an overall sensitivity of 100%.

3. ANALYTICAL SENSITIVITY

0.067 IU/mL (NIBSC 00/588)

4. ANALYTICAL SPECIFICITY

No interference was observed with samples from patients with high-level of rheumatoid factor, and pregnant woman. Same day and frozen specimens have been tested to check for interferences due to collection and storage. Total of 100 samples reactive for anti-HBc, anti-HCV and anti-HIV-1 were screened for HBsAg with EIAgen HBsAg Kit. 98 out of 100 samples were negative for HBsAg. 200 blood samples from patients were also tested with EIAgen HBsAg Kit. 191 out of 200 samples had negative screening results for HBsAg. 8 out of 9 samples with initial reactive screening results had repeat reactive test results with EIAgen HBsAg Kit but hepatitis B virus was not confirmed in all cases.

5. DETECTION OF MUTATIONS

Panel of 108 samples sequenced by PCR were tested to demonstrate the performance of EIAgen HBsAg Kit in detection of HBsAg mutations. The results are given in the table below.

Background		Number	EIAgen HBsAg Kit
adr (+)	wild type	35	33
	4 mutations	5	4
adw (+)	wild type	37	34
	16 mutations	25	24
ayw (+)	wild type	2	2
	2 mutations	2	2
ayr (+)	2 mutations	2	2
Total		108	101

S. SUGGESTIONS FOR TROUBLESHOOTING

Adherence to assay procedure and specifications, as well as a correct use of reagents and proper pipetting, may help to avoid the following kinds of errors:

ERROR	POSSIBLE CAUSES / SUGGESTIONS
OD very different (± 50%) from OD reported on QC	- incorrect dispensing volume of reagents (suggestion: check the correspondence between the volume dispensed by the pipette and the one required by the assay; re-calibrate again pipettes) -incorrect temperature or incorrect incubation time (suggestion: more care in the incubator maintenance; note down the beginning of the incubation) -error in washing or in photometer reading (suggestion: check operating or settings of respective instruments) -contamination of Substrate Solutions or Conjugate (suggestion: use only disposable and clean plastic containers)
Low reproducible results	-not constant dispensing volume of samples or reagents (suggestion: check the pipettes precision and the correspondence between the volume dispensed by the pipette and the one required by the assay; re-calibrate again pipettes) -error in washing or in reading (suggestion: check operating or settings of respective instruments) -contamination of Substrate Solutions (suggestion: use only disposable and clean plastic containers) -pollution or degradation of reagents (suggestion: use appropriate tips, disposable and clean plastic containers for reagents and high quality distilled or equivalent water)
no colorimetric reaction after addition of substrate solutions	-some reagent not pipetted - strong contamination of Conjugate or Substrate Solutions -errors in performing the assay procedure (e.g. accidental pipetting of reagents in a wrong sequence or from the wrong vial, etc.)
too low reaction (too low ODs)	-incubation time too short, incubation temperature too low -incorrect conjugate dilution
too high reaction (too high ODs)	-incorrect conjugate dilution -incubation time too long, incubation temperature too high -water quality for wash buffer insufficient (low grade of deionization) -insufficient washing (conjugates not properly removed)
unexplainable outliers	-contamination of pipettes, tips or containers -inconstant and insufficient washing (conjugates not properly removed)
too high within-run CV%	-reagents and/or strips not pre-warmed to Room Temperature prior to use - plate washer is not washing correctly (suggestion: clean washer head)
too high between-run CV%	-incubation conditions not constant (time, temperature) -controls and samples not dispensed at the same time (with the same intervals) (check pipetting order) -person-related variation

T. AUTOMATION

The procedures identified in this Instruction for Use are for manual testing only. When using automated instruments, follow the procedures that are contained in the operator's manual provided by the device manufacturer. Laboratories must follow their approved validation procedures to demonstrate compatibility of this product on automated systems.

U. LIMITATIONS

1. Positive results must be confirmed with another available method and interpreted in conjunction with the patient clinical information.
2. Antigens may be undetectable during the early stage of the disease. Therefore, negative results obtained with EIAgen HBsAg Kit are only indication that the sample does not contain detectable level of hepatitis B virus surface antigen and any negative result should not be considered as conclusive evidence that the individual is not infected with HBV or the blood unit is not infected with HBV.
3. If, after retesting of the initially reactive samples, the assay results are negative, these samples should be considered as non-repeatable (false positive) and interpreted as negative. As with many very sensitive ELISA assays, false positive results can occur due to the several reasons, most of which are related but not limited to inadequate washing step. For more information please refer to "Troubleshooting Guide", or contact Adaltis technical support for further assistance.
4. The most common assay mistakes are: using kits beyond the expiry date, bad washing procedures, contaminated reagents, incorrect assay procedure steps, insufficient aspiration during washing, failure to add specimens or reagents, improper operation with the laboratory equipment, timing errors, the use of highly hemolyzed specimens or specimens containing fibrin, incompletely clotted serum specimens.
5. The prevalence of the marker will affect the assay's predictive values.
6. This assay cannot be utilized to test pooled (mixed) plasma. EIAgen HBsAg Kit has been evaluated only with individual serum or plasma specimens.
7. EIAgen HBsAg Kit is a qualitative assay and the results cannot be used to measure antigen concentration.
8. INDICATIONS OF INSTABILITY DETERIORATION OF THE REAGENT:
   Values of the Positive or Negative controls, which are out of the indicated quality control range, are indicators of possible deterioration of the reagents and/or operator or equipment errors. In such case, the results should be considered as invalid and the samples must be retested. In case of constant erroneous results and proven deterioration or instability of the reagents, immediately substitute the reagents with new one or contact Adaltis technical support for further assistance.

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Claims regarding the quality of the kit should be addressed to:

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e-mail: info@adaltis.net

For further information and help, ask us at info@adaltis.net

Declaration Ref No: DC21-0035

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

Atlas Medical

Head office: Ludwig-Erhard-Ring 3
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Tel: +49 - 33708 – 3550 30
Email: info@atlas-medical.com

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (AnnexI) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED:
  Certificate N^0.: 36655 rev 1
  Expiry Date: October 8 th.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And
Intended for In-Vitro Professional use only.

Manufacturer
Atlas Medical
Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow , Germany.

Atlas Medical
Quality Diagnostic Products

Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	March.2021	09.03.2021		

Atlas Medical

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

Product Description
8.00.02.0.0100 : ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
8.00.00.0.0100: CRP Latex Kit, 100 Tests (4 ml Latex, 2x1.0 ml Controls)
8.00.04.0.0100: RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls)
8.00.17.0.0100: D-Dimer Latex Kit, 100 Tests
8.00.13.0.0300 : Streptococcus Latex Kit, 6 Groups, 6x50 Tests (5x1.5ml Latex (A,B,C,G,F), 1x3ml Latex(D), 1x1.0ml Positive Control, 1x2ml Extraction Reagent E, 1x1.5ml Extraction Reagent 1, 1x1.5ml Extraction Reagent 2, 2x2.5ml Extraction Reagent 3, Stirring Sticks, Glass Slide).
8.00.18.3.0500 : RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control) Without card,stirring sticks.
8.00.18.3.1000 RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests (Reagent only).

Atlas Medical
Quality Diagnostic Products

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.2

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

pour les activités
for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485: 2016

Début de validité */ Effective date* **October 9th, 2023 (included)**
Valable jusqu'au */ Expiry date :* **October 8th, 2026 (included)**
Etabli le */ Issued on :* **October 9th, 2023**

DocuSigned by:
Béatrice LYS
EF33BDA9BA...
GMED SAS GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

cofrac
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Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

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This certificate covers the following activities and sites:

French version :
Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.

English version:
Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for self-testing, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
GERMANY

French version:
Siège social, responsable de la mise sur le marché
English version:
Headquarter, legal manufacturer

****

Sahab Industrial Zone Area
King Abdullah II Industrial City
Amman 11512
JORDAN

French version:
Conception, fabrication et contrôle final
English version:
Design, manufacture and final control

****

2 sites / *2 sites*

DocuSigned by:
Beatrice Lys
FF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Atlas Medical

Date: 05/Jan/2023

STATEMENT

We, Atlas Medical having a registered office at Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Berlin, Germany assign SRL Sanmedico having a registered office at A. Corobceanu Street 7A, apt.9, Chisinau MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

On Behalf of Manufacturer:

General Manager

Haya Amawi

Signature: _____

Date: 05.01.2023

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Middle East Site: P.O Box 204, King Abdullah II Industrial Estate, Amman, 11512, Jordan
Tel: +962 6 4026468

Atlas Medical

ASO LATEX KIT

IVD For in -*vitro* diagnostic and professional use only

2°C 8°C Store at 2-8°C. CE

INTENDED USE

ATLAS ASO latex Test is used for the qualitative and semi-quantitative measurement of antibodies to Antistreptolysin-O in human serum.

INTRODUCTION

The group A ß-hemolytic streptococci produce various toxins that can act as antigens. One of these exotoxins streptolysin-O, was discovered by Todd in 1932.

A person infected with group A hemolytic streptococci produces specific antibodies against these exotoxins, one of which is antistreptolysin-O. The quantity of this antibody in a patient's serum will establish the degree of infection due to the hemolytic streptococcal.

The usual procedure for the determination of the antistreptolysin titer is based on the inhibitory effect that the patient's serum produces on the hemolytic power of a pre-titrated and reduced streptolysin-O. However, the antigen-antibody reaction occurs independently of the hemolytic activity of streptolysin-O. This property enables the establishment of a qualitative and quantitative test for the determination of the antistreptolysin-O by agglutination of latex particles on slide.

PRINCIPLE

ASO test method is based on an immunologic reaction between streptococcal exotoxins bound to biologically inert latex particles and streptococcal antibodies in the test sample. Visible agglutination occurs when increased antibody level is present in the test specimen.

MATERIALS

MATERIALS PROVIDED

- ASO Latex Reagent: Latex particles coated with streptolysin O, pH, 8,2. Preservative.
- ASO Positive Control (Red cap): Human serum with an ASO concentration > 200 IU/mL.Preservative.
- ASO Negative Control (Blue cap) Animal serum. Preservative
- Glass Slide.
- Stirring Sticks.

Note: This package insert is also used for individually packed reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pippetes 50 µL.
- Glycine Buffer-20x (1000 mmol/l): add one part to nineteen parts of distilled water before use.

Packaging contents

REF **8.00.02.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)**

PRECAUTIONS

- All reagents contain 0.1 %(w/v) sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- Reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For In Vitro diagnostic use.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (40µl). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.

REAGENT PREPARATION:

The ASO Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.

STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2-8°C).
- **DO NOT FREEZE.**
- The ASO Latex Reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- Reagents deterioration: Presence of particles and turbidity.

SAMPLES

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- **DO NOT USE PLASMA.**

PROCEDURE

Qualitative method

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place (40 µL) of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the ASO-latex reagent vigorously or on a vortex mixer before using and add one drop (40 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

Semi-quantitative method

1. Make serial two-fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

QUALITY CONTROL

- Positive and Negative Controls should be included in each test batch.
- Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the ASO Negative Control and agglutination with large aggregates is observed with the ASO Positive Control.

CALCULATIONS

The approximate ASO concentration in the patient sample is calculated as follows:

200 x ASO Titer = IU/mL

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates an ASO concentration equal or greater than 200 IU/mL

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

REFERENCE VALUES

Up to 200 IU/mL(adults) and 100 IU/mL (children < 5 years old). Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity:

200 (±50) IU/ml.

PROZONE EFFECT

No prozone effect was detected up to 1500 IU/ml.

SENSITIVITY

98%.

SPECIFICITY

97%.

INTERFERENCES

NON-INTERFERING SUBSTANCES:

- Hemoglobin (10 g/L)
- Bilirubin(20 mg/dL)
- Lipids (10 g/L)
- Rheumatoid factors (300 IU/mL)
- Other substances may interfere.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds 2 minutes, drying of the reaction mixture may cause false positive result.
- Freezing the ASO Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative ASO concentration; therefore, screening reactions should not be graded.
- False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsilitis, several streptococcal infections and healthy carriers.
- Early infections and children from 6 months to 2 years may cause false negative results. A single ASO determination does not produce much information about the actual state of the disease.
- Titrations at biweekly intervals during 4 or 6 weeks are advisable to follow the disease evolution.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

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PPI2325A01
Rev A (05.01.2023)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL+	Positive control	CONTROL-	Negative control

Atlas Medical

CRP LATEX KIT

IVD For *in -vitro* diagnostic and professional use only

2°C 8°C Store at 2-8°C. CE

INTENDED USE

CRP Latex kit is used to measure the CRP in human serum qualitatively and semi- quantitatively.

INTRODUCTION

C-reactive protein (CRP), the classic acute-phase of human serum, is synthesized by hepatocytes. Normally, it is present only in trace amounts in serum, but it can increase as much as 1,000-fold in response to injury or infection. The clinical measurement of CRP in serum therefore appears to be a valuable screening test for organic disease and a sensitive index of disease activity in inflammatory, infective and ischemic conditions. MacLeod and Avery found that antibody produced against purified CRP provided a more sensitive test than the C-polysaccharide assay. Since that time a number of immunological assays have been devised to measure CRP such as capillary precipitation, double immunodiffusion and radical immunodiffusion.

The CRP reagent kit is based on the principle of the latex agglutination assay described by Singer and Plotz. The major advantage of this method is the rapid two (2) minute reaction time.

PRINCIPLE

The CRP reagent kit is based on an immunological reaction between CRP Antisera bound to biologically inert latex particles and CRP in the test specimen. When serum CRP equal or greater than the Reagent sensitivity (Indicated on the label of the latex vial) the visible agglutination occurs.

MATERIALS

MATERIALS PROVIDED

- CRP Latex Reagent: Latex particles coated with goat IgG anti-human CRP (approximately 1 %), pH 8.2 MIX **WELL BEFORE USE.**
- CRP Positive Control Serum (Red Cap): A stabilized pre-diluted human serum containing >20mg/L CRP.
- CRP Negative Control Serum (Blue Cap): A stabilized pre-diluted animal serum.
- Glass Slides.
- Stirring Sticks.
- Package insert.

NOTE: This package insert is also used for individually packed reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pippetes 50 µL.
- Glycine Buffer 20X (1000 mmol/L): add one part to nineteen parts of distilled water before use.

PACKAGING CONTENTS

REF **8.00.00.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)**

PRECAUTIONS

- All reagents contain 0.1 %(w/v) sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- Reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For In *Vitro* diagnostic use.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (40µl). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.

REAGENT PREPARATION:

The CRP Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.

STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2 - 8°C).
- **DO NOT FREEZE.**
- The CRP latex reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- Reagents deterioration: Presence of particles and turbidity.

SPECIMEN COLLECTION AND STORAGE

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- Do not use plasma.

PROCEDURE

A. QUALITATIVE TEST:

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place (40 µL) of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the CRP-latex reagent vigorously or on a vortex mixer before using and add one drop (40 µL) next to the samples to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

B. SEMI-QUANTITATIVE TEST:

1. Make serial two-fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- All result different from the negative control result, will be considered as a positive.

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.

The presence of agglutination indicates a CRP concentration equal or greater than the reagent sensitivity (mg/L CRP) (indicated on the label of the latex vial).

The titer, in semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS

The approximate CRP concentration in the patient sample is calculated as follows:

Sensitivity (Indicated on the label of the latex vial) x CRP Titer = mg/L

INTERFERENCES

NONE INTERFERING SUBSTANCES:

- Hemoglobin (10 g/dl)
- Bilirubin (20 mg/dl)
- Lipids (10 g/L)
- Other substances interfere, such as RF (100IU/ml).

NOTE

- High CRP concentration samples may give negative results. Retest the sample again using a drop of 20µl.
- The strength of agglutination is not indicative of the CRP concentration in the samples tested.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

LIMITATIONS

1. Reaction time is critical. If reaction time exceeds two (2) minutes, drying of the reaction mixture may cause false positive results.
2. Freezing the CRP Latex Reagent will result in spontaneous agglutination.
3. Intensity of agglutination is not necessarily indicative of relative CRP concentration; therefore, screening reactions should not be graded.
4. A false negative can be attributed to a prozone phenomenon (antigen excess). It is recommended, therefore, to check all negative sera by retesting at a 1:10 dilution with glycine buffer.

.REFERENCE VALUES

Up to the reagent sensitivity (Indicated on the label of the latex vial). Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

- **Sensitivity:** Refer to vial label.
- **Prozone effect:** No prozone effect was detected up to 1600 mg/L
- **Diagnostic sensitivity:** 95.6 %.
- **Diagnostic specificity:** 96.2 %.

REFERENCES

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Website: www.atlas-medical.com

PPI2327A01
Rev A (05.01.2023)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL+	Positive control	CONTROL-	Negative control

Atlas Medical

RF LATEX KIT

IVD For In-*Vitro* diagnostic and professional use only

2°C 8°C Store at 2-8°C CE

INTENDED USE

Atlas RF latex test for the qualitative and semi-quantitative measurement of RF in human serum.

INTRODUCTION

Rheumatoid factors (RF) are antibodies directed against antigenic sites in the Fc fragment of human and animal IgG. Their frequent occurrence in rheumatoid arthritis makes them useful for diagnosis and monitoring of the disease.

One method used for rheumatoid factor detection is based on the ability of rheumatoid arthritis sera to agglutinate sensitized sheep red cells, as observed by Waaler and Rose. A more sensitive reagent consisting of biologically inert latex beads coated with human gamma globulin was later described by Singer and Plotz. The RF kit is based on the principle of the latex agglutination assay of Singer and Plotz. The major advantage of this method is rapid performance (2-minutes reaction time) and lack of heterophile antibody interference.

PRINCIPLE

The RF reagent is based on an immunological reaction between human IgG bound to biologically inert latex particles and rheumatoid factors in the test specimen. When serum containing rheumatoid factors is mixed with the latex reagent, visible agglutination occurs.

MATERIALS

MATERIALS PROVIDED

- RF Latex Reagent: Latex particles coated with human gamma-globulin, pH, 8,2. Preservative.
- RF Positive Control Serum (Red Cap): Human serum with a RF concentration > 30 IU/Ml. Preservative.
- RF Negative Control Serum (Blue Cap): Animal serum. Preservative.
- Glass Slide
- Stirring sticks

NOTE: This package insert is also used for individually packed reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pippetes 50 µL
- Glycine Buffer 20x (1000mmol/L): add one part to nineteen parts of distilled water before use.

Packaging contents

REF **8.00.04.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)**

PRECAUTIONS

- All reagents contain 0.1 %(w/v) sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- Reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For In Vitro diagnostic use.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (40µl). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.

REAGENT PREPARATION:

- The RF Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.

STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2-8°C).
- Do not freeze.
- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- The RF latex reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Reagents deterioration: Presence of particles and turbidity.

SPECIMEN COLLECTION AND STORAGE

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- Do not use PLASMA.

PROCEDURE

Qualitative method

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place (40 µL) of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the RF-latex reagent rigorously or on a vortex mixer before using and add one drop (40 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

Semi-quantitative method

1. Make serial two-fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates a RF concentration equal or greater than 8 IU/mL (Note 1).

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS

The approximate RF concentration in the patient sample is calculated as follows:

8 x RF Titer = IU/mL

INTERFERENCES

NON-INTERFERING SUBSTANCES:

- Hemoglobin (10g/L)
- Bilirubin (20mg/dl)
- Lipids (10g/L)

Other substances may interfere.

QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- All result different from the negative control result, will be considered as a positive.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity

8 (6-16) IU/ml, under the described assay conditions.

PROZONE EFFECT

No prozone effect was detected up to 1500 IU/ml.

DIAGNOSTIC SENSITIVITY

100%.

DIAGNOSTIC SPECIFICITY

100%.

The diagnostic sensitivity and specificity have been obtained using 139 samples compared with the same method of a competitor.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds 2 minutes, drying of the reaction mixture may cause false positive result.
- Freezing the RF Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative RF concentration; therefore, screening reactions should not be graded.
- Increased levels of RF may be found in some diseases other than rheumatoid arthritis such as infectious mononucleosis, sarcoidosis, lupus erythematosus, Sjogren's syndrome.
- Certain patients with rheumatoid arthritis will not have the RF present in their serum.
- The incidence of false positive results is about 3-5 %. Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results.
- Diagnosis should not be solely based on the results of latex method but also should be complemented with a Waaler Rose test along with the clinical examination.

REFERENCE VALUES

Up to 8 IU/mL. Each laboratory should establish its own reference range.

NOTES

1. Results obtained with a latex method do not compare with those obtained with Waaler Rose test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

REFERENCES

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PPI2326A01
Rev A (05.01.2023)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL+	Positive control	CONTROL-	Negative control

浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD

CE-DOC-OG060
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

Fecal Occult Blood Rapid Test Strip (Feces)	GEFOB-601b
Fecal Occult Blood Rapid Test Cassette (Feces)	GEFOB-602b

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: November 28, 2017

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 092305 0001 Rev. 01

Holder of Certificate: **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01

Report No.: SH2198802

Valid from: 2022-04-11
Valid until: 2024-03-16

Date, 2022-04-11

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD Product Service

Certificate

No. Q5 092305 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

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STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as non-exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement letter will be valid from Feb.21th,2023 to Feb.20th, 2024.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2023/2/21

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
Add: **3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China**
电话 Tel:+86-572-5226111　　传真 Fax: +86-572-5226222　邮编 P.C.:313300

Fecal Occult Blood Rapid Test Cassette (Feces) CE

INTENDED USE

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces by professional laboratories or physician's offices. It is useful to detect bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.
Fecal Occult Blood Rapid Test Cassette (Feces) is recommended for use in1) routine physical examinations, 2) hospital monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

INTRODUCTION

Most of diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based method lacks sensitivity and specificity, and has diet-restriction prior to the testing.
Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid test to qualitatively detect low levels of fecal occult blood in feces. The test uses double antibod- sandwich assay to selectively detect as low as 50 ng/mL of hemoglobin or 6 µg hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

Fecal Occult Blood Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The membrane is pre-coated with anti-hemoglobin antibodies on the test line region of the device. During testing, the specimen reacts with the colloidal gold coated withl anti-hemoglobin antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

20 Test cassettes
20 Specimen collection tubes with buffer
1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers 2. Clock or timer

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out of the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Do not use specimen with visible blood for the testing.
6. Handel all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens.
7. Specimen extraction buffer contains Sodium Azide (0.1%). Avoid contact with skin or eyes. Do not ingest.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, ie. electric fan or strong airconditioning.

PATIENT PREPARATION

1. A specimen should not be collected from a patient with following conditions that may interfere with the test results:

- Menstrual bleeding
- Bleeding hemorrhoids
- Constipating bleeding
- Urinary bleeding.

2. Dietary restrictions are not necessary.
3. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, cortocosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, thus gives positive reactions. On the advice of the physician, such substances should be discontinued at least 48 hours prior to testing.

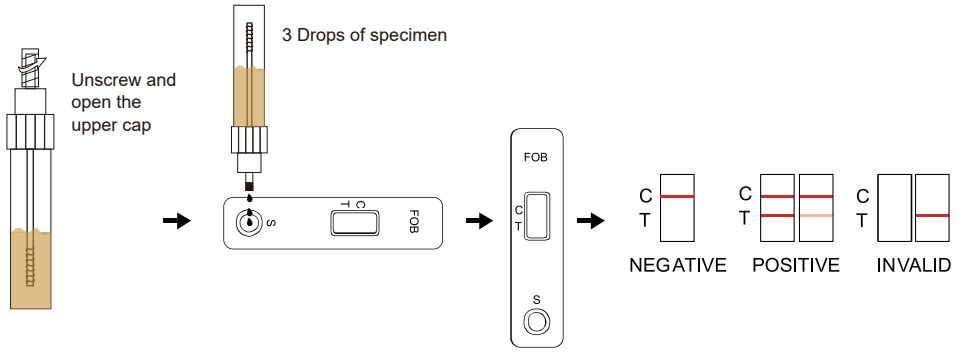
SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.
1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Randomly pierce the fecal specimen in at least five (5) different sites.
4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside grooves.
5. Replace the stick in the tube and tighten securely.
6. Shake the specimen collection bottle so that there is proper homogenisation of feces in buffer solution.

Note: Specimens prepared in the specimen collection tube may be stored at room temperature (15-30°C) for 3 days maximum, at 2-8°C for 7 days maximum or at -20°C for 3 months maximum if not tested within 1 hour after preparation.

TEST PROCEDURE

Allow the test cassette, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.
1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean, flat surface.
3. Shake the specimen collection tube several times.
4. Hold the specimen collection tube upright and then unscrew and open the upper cap.
5. Squeeze 3 drops (~90 µL) of the sample solution in the sample well of the cassette and start the timer.
6. Wait for the colored line(s) to appear. Read results in 5 minutes. Do not interpret the result after 5 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).
Invalid: Control line fails to appear. The test should be repeated using a new cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
NOTE:
1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and

Fecal Occult Blood Rapid Test Cassette (Feces)

cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correctl procedural technique. Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. This test kit is to be used for the qualitative detection of human hemoglobin in fecal samples. A positive result suggests the presence of human hemoglobin in fecal samples. In addition to intestinal bleeding the presence of blood in stools may have other causes such as hemorrhoids, blood in urine etc.
2. Not all colorectal bleedings are due to precancerous or cancerous polyps. The information obtained by this test should be used in conjunction with other clinical findings and testing methods, such as colonoscopy gathered by the physician.
3. Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
4. Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results. The use of a receptacle is recommended.
5. Feces specimens should not collect during the menstrual period and not three day before or afterwards, at bleeding due to constipation, bleeding haemorrhoids,or at taking rectally administered medication. It could cause false positive results.
6. This test may be less sensitive for detecting upper g.i. Bleeding because blood degrades as it passes through the g.i. Track.
7. The Fecal Occult Blood Rapid Test Cassette (Feces) is to aid indiagnosis and is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy, or X-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.

PERFORMANCE CHARACTERISTICS

1. Sensitivity: 99.6%
Fecal Occult Blood Rapid Test Cassette (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or 6 µg hemoglobin/g feces.
2. Prozone Effect:
It is observed that this FOB test can detect 2 mg/mL hemoglobin.
3. Specificity: 99.9%
Fecal Occult Blood Rapid Test Cassette (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration was tested on both positive and negative controls and showed no effects on test results at standards concentration.

Substances	Concentrations (Diluted with the extraction buffer)
Beef hemoglobin	2 mg/mL
Chicken hemoglobin	0.5 mg/mL
Pig hemoglobin	0.5 mg/mL
Goat hemoglobin	0.5 mg/mL
Horse hemoglobin	20 mg/mL
Rabbit hemoglobin	0.06 mg/mL

REFERENCES

1. Simon J.B. Occult Blood Screening for Colorectal Carcinoma: A Critical Review, Gastroenterology, Vol. 1985;88:820.
2. Blebea J. and Ncpherson RA. False-Positive Guaiac Testing With Iodine, Arch Pathol Lab Med, 1985;109:437-40.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

REF GEFOB-602b

Revision Date: 2023-04-18
B21056-04

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E-mail: agat@agat.ru, http://www.agat.ru

ПАСПОРТ

Масло иммерсионное, тип А (классическое), 100 мл

Серия **454/15** Дата выпуска **08.2020** Годен до **08.2023**
Количество флаконов в серии **20000**

Наименование показателя	Требования по ГОСТ 13739-78	Результаты анализа
1. Внешний вид	Жидкость от бесцветного до светло-желтого цвета	соответствует
2. Технические характеристики		
2.1. Вязкость кинематическая (ν), при 20 °С, м2/с*10-4, не менее	6	13
2.2. Коэффициент пропускания (Т), при толщине слоя 1 мм, %		
при длине волны 635 нм, не менее	95	96
при длине волны 440 нм, не менее	92	98
2.3. Коэффициент преломления (n), при 20 °С	1,515 ± 0,001	1,515
2.4. Средняя дисперсия (nf-nc) , при 20 °С	0,0106 +/- 0,0003	0,0107

Заключение ОКК ООО «Агат-Мед»:
Набор серии **454/15** требованиям ГОСТ 13739-78 соответствует.

Начальник ОКК ООО «АГАТ-МЕД» Гладун В.В.

« 1 » августа 2020 г.

"Агат-Мед"

МП

Копия для Электрогорск Соловьева Т.В. к документу РасходнаяБН № 604625 от 12.02.21 к товару поз. 4