

Instructions for Use

IBL

Herpes-simplex-Virus II IgM ELISA

The Herpes-simplex-Virus II IgM ELISA is intended for the qualitative determination of IgM class antibodies against Herpes-simplex-Virus II in human serum.

REF

RE57931



96



2-8°C



Novatec GmbH,
Germany



For the U.S.:
For Research Use Only.

IBL IMMUNO BIOLOGICAL LABORATORIES

www.IBL-Hamburg.com
www.IBL-America.com

www.IBL-Japan.co.jp
www.IBL-Turkey.com

CONTENTS

1. INTRODUCTION	2
2. INTENDED USE	2
3. PRINCIPLE OF THE ASSAY	2
4. MATERIALS	2
4.1. REAGENTS SUPPLIED	2
4.2. MATERIALS SUPPLIED	3
4.3. MATERIALS AND EQUIPMENT NEEDED	3
5. STABILITY AND STORAGE	3
6. REAGENT PREPARATION	3
6.1. COATED SNAP-OFF STRIPS	3
6.2. HSV TYPE 2 ANTI-IGM CONJUGATE	3
6.3. CONTROLS	3
6.4. IGM SAMPLE DILUENT	3
6.5. WASHING SOLUTION (20XCONC.)	3
6.6. TMB SUBSTRATE SOLUTION	3
6.7. STOP SOLUTION	4
7. SPECIMEN COLLECTION AND PREPARATION	4
7.1. SAMPLE DILUTION	4
8. ASSAY PROCEDURE	4
8.1. TEST PREPARATION	4
8.2. MEASUREMENT	4
9. RESULTS	5
9.1. RUN VALIDATION CRITERIA	5
9.2. CALCULATION OF RESULTS	5
9.3. INTERPRETATION OF RESULTS	5
9.3.1. RESULTS IN UNITS	5
10. SPECIFIC PERFORMANCE CHARACTERISTICS	5
10.1. PRECISION	5
10.2. DIAGNOSTIC SPECIFICITY	5
10.3. DIAGNOSTIC SENSITIVITY	5
10.4. INTERFERENCES	5
10.5. CROSS-REACTIVITY	6
11. LIMITATIONS OF THE PROCEDURE	6
12. PRECAUTIONS AND WARNINGS	6
12.1. DISPOSAL CONSIDERATIONS	6
13. LITERATURE	7

1. INTRODUCTION

Herpes simplex is an enveloped DNA virus (150-200 nm in diameter) belonging to the alpha-herpesviridae. Based on antigenic, biochemical and biologically differences it can be divided into two serotypes, HSV-1 and HSV-2. Man is the only known natural host and source of the virus. HSV type 1 typically causes oral herpes, while HSV type 2 typically affects the genital area. Most of the time, HSV-1 and HSV-2 are inactive, or "silent", and cause no symptoms, but some infected people have "outbreaks" of blisters and ulcers. Once infected with HSV, people remain infected for life. Herpes simplex viruses are amongst the most common infectious agents of man, and either HSV type appears to be capable of infecting similar body sites. A high percentage of the adult population is seropositive (appr. 90% HSV-1, in dependence on the socio-economic status 10-30% HSV-2). Primary HSV-1 infection usually occurs in early childhood (6 to 18 months of age). HSV-2 usually produces mild symptoms, and most people have no recognized symptoms. Persons at risk are children with inherited T-cell deficiencies and patients who are immunosuppressed because of infection (e.g. HIV), transplantation, or cancer therapy.

HSV-2 can cause potentially fatal infections in infants if the mother is shedding virus at the time of delivery. - HSV-2 may play a major role in the heterosexual spread of HIV: herpes can make people more susceptible to HIV infection, and HIV-infected individuals more infectious.

Species	Disease	Symptoms	Mechanism of Infection
HSV-2 (Herpes genitalis)	Genital herpes Neonatal herpes	Self-healing lesions, flu-like symptoms (fever, swollen glands),Ulcers	Sexually transmitted disease (STD)

The presence of virus resp. infection may be identified by

- Microscopy: CPE, IF
- PCR
- Serology: Detection of antibodies by ELISA

2. INTENDED USE

The HSV 2 IgM recombinant ELISA allows the detection of HSV 2 infection in presence of antibodies to HSV 1.

3. PRINCIPLE OF THE ASSAY

Recombinant gG2 protein of HSV-2 show diffuse band in SDS electrophoresis corresponding to gG2 which is found at approximately 43 kD. This antigen will allow the detection of HSV 2 infection in the presence of antibodies to HSV 1. This is important as the % of the population with HSV 1 increases throughout life up to >90 % at old age. HSV 2 is generally sexually transmitted and in all societies is associated with the amount of sexual activity and number of partners. Genital herpes is important to diagnose in pregnancy as shedding virus can lead to congenital infection of the child which is invariably serious. The qualitative immunoenzymatic determination of IgM-class antibodies against HSV Type 2 is based on the ELISA (Enzyme-linked Immunosorbent Assay) technique. Microtiter strip wells are precoated with HSV Type 2 recombinant antigens to bind corresponding antibodies of the specimen. After washing the wells to remove all unbound sample material horseradish peroxidase (HRP) labelled anti-human IgM conjugate is added. This conjugate binds to the captured HSV Type 2 specific antibodies. The immune complex formed by the bound conjugate is visualized by adding Tetramethylbenzidine (TMB) substrate which gives a blue reaction product. The intensity of this product is proportional to the amount of HSV Type 2 specific IgM antibodies in the specimen. Sulphuric acid is added to stop the reaction. This produces a yellow endpoint colour. Absorbance at 450 nm is read using an ELISA microwell plate reader.

4. MATERIALS

4.1. Reagents supplied

- **HSV Type 2 Coated Wells (IgM):** 12 breakapart 8-well snap-off strips coated with HSV Type 2 recombinant antigen; vacuum sealed, in resealable aluminium foil.
- **IgM Sample Diluent ***:** 1 bottle containing 100 ml of buffer for sample dilution; containing antihuman-IgG; pH 7.2 ± 0.2; coloured green; ready to use; white cap.
- **Stop Solution:** 1 bottle containing 15 ml sulphuric acid, 0.2 mol/l; ready to use; red cap.
- **Washing Solution (20x conc.):*** 1 bottle containing 50 ml of a 20-fold concentrated buffer (pH 7.2 ± 0.2) for washing the wells; white cap.
- **HSV Type 2 anti-IgM Conjugate**:** 1 bottle containing 20 ml of peroxidase labelled rabbit antibody to human IgM; coloured red, ready to use; black cap.
- **TMB Substrate Solution:** 1 bottle containing 15 ml 3,3',5,5'-tetramethylbenzidine (TMB); ready to use; yellow cap.

- **HSV Type 2 IgM Positive Control***:** 1 bottle containing 2 ml; coloured yellow; ready to use; red cap.
- **HSV Type 2 IgM Cut-off Control***:** 1 bottle containing 2 ml; coloured yellow; ready to use; green cap.
- **HSV Type 2 IgM Negative Control***:** 1 bottle containing 2 ml; coloured yellow; ready to use; blue cap.

* contains 0.01 % Kathon after dilution

** contains 0.2 % Bronidox L

*** contains 0.1 % Kathon

4.2. Materials supplied

- 1 Strip holder
- 2 Cover foils
- 1 Test protocol
- 1 distribution and identification plan

4.3. Materials and Equipment needed

- ELISA microwell plate reader, equipped for the measurement of absorbance at 450/620nm
- Incubator 37°C
- Manual or automatic equipment for rinsing wells
- Pipettes to deliver volumes between 10 and 1000 µl
- Vortex tube mixer
- Deionised or (freshly) distilled water
- Disposable tubes
- Timer

5. STABILITY AND STORAGE

The reagents are stable up to the expiry date stated on the label when stored at 2...8 °C.

6. REAGENT PREPARATION

It is very important to bring all reagents, samples and controls to room temperature (20...25°C) before starting the test run!

6.1. Coated snap-off Strips

The ready to use breakpoint snap-off strips are coated with HSV Type 2 antigen. Store at 2...8°C. The strips are vacuum sealed. *Immediately after removal of strips, the remaining strips should be resealed in the aluminium foil along with the desiccant supplied and stored at 2...8 °C; stability until expiry date.*

6.2. HSV Type 2 anti-IgM Conjugate

The bottle contains 20 ml of a solution with anti-human-IgG horseradish peroxidase, buffer, stabilizers, preservatives and an inert red dye. The solution is ready to use. Store at 2...8°C. *After first opening stability until expiry date when stored at 2...8°C.*

6.3. Controls

The bottles labelled with Positive, Cut-off and Negative Control contain a ready to use control solution. It contains 0.1% Kathon and has to be stored at 2...8°C. *After first opening stability until expiry date when stored at 2...8°C.*

6.4. IgM Sample Diluent

The bottle contains 100 ml phosphate buffer, anti human-IgG, stabilizers, preservatives and an inert green dye. It is used for the dilution of the patient specimen. The solution contains antihuman IgG class antibodies to eliminate competitive inhibition from specific IgG class antibody to remove rheumatoid factor. This ready to use solution has to be stored at 2...8°C. *After first opening stability until expiry date when stored at 2...8°C.*

6.5. Washing Solution (20xconc.)

The bottle contains 50 ml of a concentrated buffer, detergents and preservatives. Dilute washing solution 1+19; e.g. 10 ml washing solution + 190 ml fresh and germ free redistilled water. The diluted buffer is stable for 5 days at room temperature. *Crystals in the solution disappear by warming up to 37 °C in a water bath. After first opening the concentrate is stable until the expiry date.*

6.6. TMB Substrate Solution

The bottle contains 15 ml of a tetramethylbenzidine/hydrogen peroxide system. The reagent is ready to use and has to be stored at 2...8°C, away from the light. *The solution should be colourless or could have a slight blue tinge. If the substrate turns into blue, it may have become contaminated and should be thrown away. After first opening stability until expiry date when stored at 2...8°C.*

6.7. Stop Solution

The bottle contains 15 ml 0.2 M sulphuric acid solution (R 36/38, S 26). This ready to use solution has to be stored at 2...8°C.

After first opening stability until expiry date.

7. SPECIMEN COLLECTION AND PREPARATION

Use human serum samples with this assay. If the assay is performed within 24 hours after sample collection, the specimen should be kept at 2...8°C; otherwise they should be aliquoted and stored deep-frozen (-20 to -70°C). If samples are stored frozen, mix thawed samples well before testing. *Avoid repeated freezing and thawing.*

7.1. Sample Dilution

Before assaying all samples should be diluted 1+100 with IgM Sample Diluent. Dispense 10µl sample and 1 ml IgM Sample Diluent into tubes to obtain a 1+100 dilution and thoroughly mix with a Vortex. *Positive and negative controls are ready to use and must not be diluted.*

8. ASSAY PROCEDURE

8.1. Test Preparation

Please read the test protocol carefully **before** performing the assay. Result reliability depends on strict adherence to the test protocol as described. The following test procedure is only validated for manual procedure. If performing the test on ELISA automatic systems we recommend to increase the washing steps from three to five and the volume of washing solution from 300µl to 350µl to avoid washing effects. Prior to commencing the assay, the distribution and identification plan for all specimens and controls should be carefully established on the result sheet supplied in the kit. Select the required number of microtiter strips or wells and insert them into the holder.

Please allocate at least:

1 well	(e.g. A1)	for the substrate blank,
1 well	(e.g. B1)	for the negative control,
2 wells	(e.g. C1+D1)	for the cut-off control and
1 well	(e.g. E1)	for the positive control.

It is recommended to determine controls and patient samples in duplicate, if necessary.

Perform all assay steps in the order given and without any appreciable delays between the steps.

A clean, disposable tip should be used for dispensing each control and sample.

Adjust the incubator to 37° ± 1°C.

1. Dispense 100µl controls and diluted samples into their respective wells. Leave well A1 for substrate blank.
2. Cover wells with the foil supplied in the kit.
3. **Incubate for 1 hour ± 5 min at 37±1°C.**
4. When incubation has been completed, remove the foil, aspirate the content of the wells and wash each well three times with 300µl of Washing Solution. Avoid overflows from the reaction wells. The soak time between each wash cycle should be >5 sec. At the end carefully remove remaining fluid by tapping strips on tissue paper prior to the next step!

Note: Washing is critical! Insufficient washing results in poor precision and falsely elevated absorbance values.

5. Dispense 100µl HSV Type 2 anti-IgM Conjugate into all wells except for the blank well (e.g. A1). Cover with foil.
6. **Incubate for 30 min at 37°C. Do not expose to direct sunlight.**
7. Repeat step 4.
8. Dispense 100µl TMB Substrate Solution into all wells
9. **Incubate for exactly 30 min at room temperature in the dark.**
10. Dispense 100µl Stop Solution into all wells in the same order and at the same rate as for the TMB Substrate Solution.
Any blue colour developed during the incubation turns into yellow.

Note: Highly positive patient samples can cause dark precipitates of the chromogen! These precipitates have an influence when reading the optical density. Predilution of the sample with physiological sodium chloride solution, for example 1+1, is recommended. Then dilute the sample 1+100 with dilution buffer and multiply the results in Units by 2.

11. Measure the absorbance of the specimen at 450/620 nm within 30 min after addition of the Stop Solution.

8.2. Measurement

Adjust the ELISA Microwell Plate Reader **to zero** using the **substrate blank in well A1**.

If - due to technical reasons - the ELISA reader cannot be adjusted to zero using the substrate blank in well A1, subtract the absorbance value of well A1 from all other absorbance values measured in order to obtain reliable results!

Measure the absorbance of all wells at **450 nm** and record the absorbance values for each control and patient sample in the distribution and identification plan.

Dual wavelength reading using 620 nm as reference wavelength is recommended.

Where applicable calculate the **mean absorbance values** of all duplicates.

9. RESULTS

9.1. Run Validation Criteria

In order for an assay to be considered valid, the following criteria must be met:

- **Substrate blank** in A1: Absorbance value **lower than 0.100**.
- **Negative control** in B1: Absorbance value **lower than 0.200**.
- **Cut-off control** in C1 and D1: Absorbance value **between 0.250 and 0.900**.
- **Positive control** in E1: Absorbance value equal to or greater than the cut-off value.

9.2. Calculation of Results

The cut-off is the mean absorbance value of the Cut-off control determinations.

Example: Absorbance value Cut-off control 0.39 + absorbance value Cut-off control 0.37 = 0.76 / 2 = 0.38

$$\text{Cut-off} = 0.38$$

9.3. Interpretation of Results

Samples are considered **POSITIVE** if the absorbance value is higher than 10% over the cut-off.

Samples with an absorbance value of 10% above or below the cut-off should not be considered as clearly positive or negative

→ **grey zone**

It is recommended to repeat the test again 2 - 4 weeks later with a fresh sample. If results in the second test are again in the grey zone the sample has to be considered **NEGATIVE**.

Samples are considered **NEGATIVE** if the absorbance value is lower than 10% below the cut-off.

9.3.1. Results in Units

$$\frac{\text{Patient (mean) absorbance value} \times 10}{\text{Cut-off}} = [\text{Units} = \text{U}]$$

Example: $\frac{1.786 \times 10}{0.38} = 47 \text{ U (Units)}$

Cut-off:	10	U
Grey zone:	9-11	U
Negative:	<9	U
Positive:	>11	U

10. SPECIFIC PERFORMANCE CHARACTERISTICS

10.1. Precision

Interassay	n	Mean	Cv (%)
Pos. Serum	4	0.848	5.1
Intraassay	n	Mean	Cv (%)
Pos. Serum	12	0.816	5.4

10.2. Diagnostic Specificity

The diagnostic specificity is defined as the probability of the assay of scoring negative in the absence of the specific analyte. It is >95 %.

10.3. Diagnostic Sensitivity

The diagnostic sensitivity is defined as the probability of the assay of scoring positive in the presence of the specific analyte. It is >95 %.

10.4. Interferences

Interferences with hemolytic, lipemic or icteric sera are not observed up to a concentration of 10 mg/ml hemoglobin, 5 mg/ml triglycerides and 0.2 mg/ml bilirubin.

Note: The results refer to the groups of samples investigated; these are not guaranteed specifications.

10.5. Cross-Reactivity

Serum	Acute Infection	Elisa HSV-2 IgM
1	Adenovirus	neg.
3	CMV	neg.
8	EBV	neg.
9	Echinococcus	neg.
12	HBV	neg.
17	Influenza A	neg.
18	Influenza B	neg.
22	Leptospira	neg.
23	M. pneumoniae	neg.
26	Picornia	neg.
27	Q-Fever	neg.
29	Rubella	neg.
32	Toxoplasma	neg.
34	VZV	neg.

11. LIMITATIONS OF THE PROCEDURE

Bacterial contamination or repeated freeze-thaw cycles of the specimen may affect the absorbance values. Diagnosis of an infectious disease should not be established on the basis of a single test result. A precise diagnosis should take into consideration clinical history, symptomatology as well as serological data. In immunocompromised patients and newborns serological data only have restricted value.

12. PRECAUTIONS AND WARNINGS

- In compliance with article 1 paragraph 2b European directive 98/79/EC the use of the in vitro diagnostic medical devices is intended by the manufacturer to secure suitability, performances and safety of the product. Therefore the test procedure, the information, the precautions and warnings in the instructions for use have to be strictly followed. The use of the testkits with analyzers and similar equipment has to be validated. Any change in design, composition and test procedure as well as for any use in combination with other products not approved by the manufacturer is not authorized; the user himself is responsible for such changes. The manufacturer is not liable for false results and incidents for these reasons. The manufacturer is not liable for any results by visual analysis of the patient samples.
- Only for in-vitro diagnostic use.
- All components of human origin used for the production of these reagents have been tested for anti-HIV antibodies, anti-HCV antibodies and HBsAg and have been found to be non-reactive. Nevertheless, all materials should still be regarded and handled as potentially infectious.
- Do not interchange reagents or strips of different production lots.
- No reagents of other manufacturers should be used along with reagents of this test kit.
- Do not use reagents after expiry date stated on the label.
- Use only clean pipette tips, dispensers, and lab ware.
- Do not interchange screw caps of reagent vials to avoid cross-contamination.
- Close reagent vials tightly immediately after use to avoid evaporation and microbial contamination.
- After first opening and subsequent storage check conjugate and control vials for microbial contamination prior to further use.
- To avoid cross-contamination and falsely elevated results pipette patient samples and dispense conjugate without splashing accurately to the bottom of wells.

WARNING: In the used concentration Bronidox L has hardly any toxicological risk upon contact with skin and mucous membranes!

WARNING: Sulphuric acid irritates eyes and skin. Keep out of the reach of children. Upon contact with the eyes, rinse thoroughly with water and consult a doctor!

12.1. Disposal Considerations

Residues of chemicals and preparations are generally considered as hazardous waste. The disposal of this kind of waste is regulated through national and regional laws and regulations. Contact your local authorities or waste management companies which will give advice on how to dispose hazardous waste.

13. LITERATURE

Corey, L.; P.G. Spear: Infections with herpes simplex viruses. *N. Engl. J. Med.* 314 (1986) 686-691

Dörries, R., R. Kaiser, H. Imrich et al.: Neuere Aspekte zur Diagnose zentralnervöser Virusinfektionen. *Lab. Med.* 15 (1991) 99-102

Felgenhauer, K.: Diagnostische Bedeutung der lokal synthetisierten spezifischen Antikörper des Liquor cerebrospinalis. *Lab. Med.* 15 (1991) 208

Kaufmann, H.E.; F. Martola and C. Dohlman: The use of 5-iodo-2'-deoxy-uridine (IDU) in the treatment of herpes simplex keratitis. *Arch. Ophthalm.* N. Y. 68 (1962) 235-239

Spaar, F.-W.: Die menschliche Herpes simplex Enzephalitis und -Meningitis. Eine klinisch-neurologische Untersuchung. G. Fischer Verlag, Stuttgart, New York (1976)

SCHEME OF THE ASSAY

HSV Type 2 recombinant gG2 IgM-ELISA

Test Preparation














Prepare reagents and samples as described.
Establish the distribution and identification plan for all specimens and controls on the result sheet supplied in the kit.
Select the required number of microtiter strips or wells and insert them into the holder.

Assay Procedure

	Substrate blank (e.g. A1)	Negative control	Positive control	Cut-off control	Sample (diluted 1+100)
Negative control	-	100µl	-	-	-
Positive control	-	-	100µl	-	-
Cut-off control	-	-	-	100µl	-
Sample (diluted 1+100)	-	-	-	-	100µl
Cover wells with foil supplied in the kit Incubate for 1 h at 37°C Wash each well three times with 300µl of washing solution					
Conjugate	-	100µl	100µl	100µl	100µl
Cover wells with foil supplied in the kit Incubate for 30 min at 37°C Wash each well three times with 300µl of washing solution					
TMB Substrate	100µl	100µl	100µl	100µl	100µl
Incubate for exactly 30 min at room temperature in the dark					
Stop Solution	100µl	100µl	100µl	100µl	100µl
Photometric measurement at 450 nm (reference wavelength: 620 nm)					

13062005

Symbols / Symbole / Symboles / Símbolos / Símbolos / Σύμβολα / Обозначения

	Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.º Cat.: / N.–Cat.: / Αριθμός-Κατ.: / № - по кат.:
	Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: / Αριθμός -Παραγωγή: / Партия №:
	Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Usar até: / Da utilizzare entro: / Χρησιμοποιείται από: / Годен до:
	No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / N.º de Testes: / Quantità dei tests: / Αριθμός εξετάσεων: / Число тестов:
	Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato / Συμπύκνωμα / Концентрат
	Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizado / Liofilizzato / Λυοφιλιασμένο / Лιοфилизат
	In Vitro Diagnostic Medical Device. / In-vitro-Diagnostikum. / Appareil Médical pour Diagnostics In Vitro. / Dispositivo Médico para Diagnóstico In Vitro. / Equipamento Médico de Diagnóstico In Vitro. / Dispositivo Medico Diagnostico In vitro. / Ιατρική συσκευή για In-Vitro Διάγνωση. / Набор для in-vitro диагностики.
	Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluació. / Kit de avaliação. / Kit di evaluazione. / Κιτ Αξιολόγησης. / Пробный набор.
	Read instructions before use. / Arbeitsanleitung lesen. / Lire la fiche technique avant emploi. / Lea las instrucciones antes de usar. / Ler as instruções antes de usar. / Leggere le istruzioni prima dell'uso. / Διαβάστε τις οδηγίες πριν την χρήση. / Прочитать инструкцию перед использованием.
	Keep away from heat or direct sun light. / Vor Hitze und direkter Sonneneinstrahlung schützen. / Garder à l'abri de la chaleur et de toute exposition lumineuse. / Manténgase alejado del calor o la luz solar directa. / Manter longe do calor ou luz solar directa. / Non esporre ai raggi solari. / Να φυλάσσεται μακριά από θερμότητα και άμεση επαφή με το φως του ηλίου. / Избегать нагревания или воздействия прямых солнечных лучей.
	Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazemar a: / Conservare a: / Αποθήκευση στους: / Хранить при:
	Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbicante: / Παραγωγός: / Изготовитель:
	Caution! / Vorsicht! / Attention! / ¡Precaución! / Cuidado! / Attenzione! / Προσοχή! / Внимание!
<p>Symbols of the kit components see MATERIALS SUPPLIED.</p> <p>Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben.</p> <p>Voir MATERIEL FOURNI pour les symboles des composants du kit.</p> <p>Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS.</p> <p>Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS.</p> <p>Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT.</p> <p>Για τα σύμβολα των συστατικών του κιτ συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.</p> <p>Обозначение компонентов набора смотреть в разделе КОМПЛЕКТАЦИЯ</p>	

 <p>Novatec Immundiagnostica GmbH Technologie und Waldpark Waldstr. 23 A6 D-63128 Dietzenbach, Germany Tel.: +49 (0) 6074-48 76 -0 Fax: -29</p>	<p>Distributed by IBL-Hamburg GmbH Flughafenstr. 52A, D-22335 Hamburg, Germany Tel.: + 49 (0) 40 - 53 28 91 -0 Fax: -11 E-MAIL: ibl@ibl-hamburg.com WEB:www.ibl-hamburg.com</p>
---	---

LIABILITY: Complaints will only be accepted in written and if all details of the test performance and results are included (complaint form available from IBL or supplier). Any modification of the test procedure or exchange or mixing of components of different lots could negatively affect the results. These cases invalidate any claim for replacement. Regardless, in the event of any claim, the manufacturer's liability is not to exceed the value of the test kit. Any damage caused to the kit during transportation is not subject to the liability of the manufacturer.