

PLATELIA™ HSV 1 IgG

1 plate - Σ 96

REF 72820

**QUALITATIVE DETECTION OF IgG ANTIBODIES TO
HSV 1 IN HUMAN SERUM OR PLASMA BY ENZYME
IMMUNOASSAY**



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BIO-RAD

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1. INTENDED USE

Platelia™ HSV 1 IgG is an indirect ELISA immunoassay for qualitative detection of IgG antibodies to Herpes simplex virus type 1 in human serum or plasma.

2. CLINICAL VALUE

Herpes simplex virus (HSV) is a common human pathogen found worldwide. Two serological subtypes of HSV have been described: HSV-1 and HSV-2. HSV-1 is primarily associated with infection in the tongue, mouth, lips, pharynx and eyes; whereas HSV-2 is primarily associated with genital and neonatal infection. However, both types can cause genital infections, and HSV-1 is increasingly recognized as a cause of genital symptoms. Herpes simplex virus is transmitted through direct contact with secretions from an infected person, who may or may not have disease symptoms at the time. In fact, most genital infections are transmitted in the absence of symptoms. Primary infection with HSV can occur at any age, affecting neonates, children, and adults. Following primary infection, HSV establishes lifelong latency in sensory nerve ganglia, causing subsequent recurrence of symptoms when latent virus is reactivated.

Expectant mothers who acquire HSV type-1 or type-2 during pregnancy can transmit the virus to the infant before birth or during delivery. In utero infections are associated with spontaneous abortion and premature delivery. The greatest risk of neonatal herpes is to babies whose mother's contract genital infection in the final trimester of pregnancy. Congenital and neonatal HSV can occur with primary or recurrent, symptomatic or asymptomatic, maternal HSV infection and can cause skin, eye or mouth infections, damage to the central nervous system.

In primary HSV infections, IgM antibodies usually appear between the third and seventh day after onset of symptoms. IgM antibody titer peaks in four to six weeks and usually decline to undetectable levels after two months. IgM antibodies to HSV can sometimes be found in recurrent infections. However, production and detection of anti-HSV-IgM antibodies in patients with recurrent infections is less predictable and may be related to the severity of infection. IgG antibodies to HSV usually appear one to two weeks after the onset of infection and persist at various levels for life.

A number of serologic procedures has been developed to detect antibodies to HSV. These include complement fixation, indirect immunofluorescent antibody, plaque neutralization, and ELISA. When compared to other serologic tests, ELISA may be a very specific, sensitive and reliable method for detection of antibodies to HSV. However, most of these serologic methods for assessing HSV sero-status use viral lysate as antigens.

Due to significant cross-reactivity between HSV-1 and HSV-2 and the very high prevalence of HSV-1 infection, the viral lysate assays are unable to differentiate HSV-1 infections from HSV-2 infections with confidence (2). Recently, HSV type-specific serological assays have been developed using the significant difference between the gG-1 protein of HSV-1 and the gG-2 of HSV-2.(2)

The Platelia™ HSV 1 IgG kit uses purified recombinant type-specific gG-1 antigen immobilized on microwells to ensure best specificity and distinguish accurately HSV 1 infection from HSV 2 infection.

3. PRINCIPLE

Platelia™ HSV 1 IgG is a qualitative test for detection of IgG antibodies to HSV 1 in human serum or plasma using an indirect ELISA immuno-enzymatic method.

Recombinants gG-1 antigens are used for coating the microplate. A polyclonal antibody labeled with peroxydase which is specific for human gamma chains (anti-IgG) is used as the conjugate. The test uses the following steps:

- **Step 1**

Patients samples and controls are diluted 1/21 and then distributed in the wells of the microplate. During this incubation of one hour at 37°C, IgG antibodies to HSV 1 present in the sample bind to the HSV 1 antigen coated on microplate wells. After incubation, unbound non specific antibodies and other serum proteins are removed by washings.

- **Step 2**

The conjugate (peroxydase labeled polyclonal antibody specific for human gamma chains) is added to the microplate wells. During this incubation of one hour at 37°C, the labeled monoclonal antibody binds to the serum IgG captured by the HSV 1 antigen. The unbound conjugate is removed by washings at the end of the incubation.

- **Step 3**

The presence of immun-complexes (HSV 1 Antigen, IgG antibodies to HSV 1, anti-IgG conjugate) is demonstrated by the addition in each well of an enzymatic development solution.

- **Step 4**

After incubation at room temperature (+18-30°C), the enzymatic reaction is stopped by addition of 1N sulfuric acid solution. The optical density reading obtained with a spectrophotometer set at 450/620 nm is proportional to the amount of IgG antibodies to HSV 1 present in the sample.

4. PRODUCT INFORMATION

Supplied quantities of reagents have been calculated to allow 96 tests. All reagents are exclusively for *in vitro* diagnostic use.

Label		Nature of reagents	Presentation
R1	Microplate	Microplate (Ready-to-use): 12 strips with 8 breakable wells, coated with gG-1 recombinant antigen	1
R2	Concentrated Washing Solution (20x)	Concentrated Washing Solution (20x): Tampon TRIS-NaCl (pH 7.4), 2% Tween® 20 Preservative : 0.04% ProClin™ 300	1 x 70 mL
R3	Negative Control	Negative Control: Human serum negative for IgG antibodies to HSV 1, and negative for HBs antigen, anti-HIV1, anti- HIV2 and anti-HCV Preservative : 0.10% ProClin™ 300	1 x 0.75 ml
R4	Calibrator	Calibrator: Human serum reactive for IgG antibodies to HSV 1, and negative for HBs antigen, anti-HIV1, anti-HIV2 and anti-HCV Preservative : 0.10% ProClin™ 300	1 x 0.75 ml
R5	Positive Control	Positive Control: Human serum reactive for IgG antibodies to HSV 1, and negative for HBs antigen, anti-HIV1, anti-HIV2 and anti-HCV Preservative : 0.10% ProClin™ 300	1 x 0.75 ml
R6	Conjugate (51x)	Conjugate (51x): Goat polyclonal antibody to human gamma-chains coupled to horseradish peroxidase Preservative : 0.15% ProClin™ 300	1 x 0.7 ml
R7	Diluent	Diluent for samples and conjugate (Ready-to-use): Tris-NaCl (pH 7.7), fetal calf serum, phenol red Preservative : 0.11% ProClin™ 300	1 x 80 ml

	Label	Nature of reagents	Presentation
R9	Chromogen TMB	Chromogen (Ready-to-use): 3,3',5,5' tetramethylbenzidine (< 0.1%), H ₂ O ₂ (<1%)	1 x 28 ml
R10	Stopping Solution	Stopping Solution (Ready-to-use): 1N sulfuric acid solution	1 x 28 ml

For storage conditions and expiration date, please refer to the indications mentioned on the box.

5. WARNINGS AND PRECAUTIONS

The reliability of the results depends on correct implementation of the following Good Laboratory Practices:

- Do not use expired reagents.
- Do not mix or associate within a given run reagents from different lots.

REMARK: For Washing Solution (R2, label identification: 20x colored green), Chromogen (R9, label identification: TMB colored turquoise) and Stopping Solution (R10, label identification: 1N colored red), it is possible to use other lots than those contained in the kit, provided these reagents are strictly equivalent and the same lot is used within a given test run.

REMARK: In addition, the Washing Solution (R2, label identification: 20x colored green) can be mixed with the 2 other washing solutions included in various Bio-Rad reagent kits (R2, label identifications: 10x colored blue or 10x colored orange) when properly reconstituted, provided only one mixture is used within a given test run.

- Before use, wait for 30 minutes to allow reagents to reach room temperature (+18-30°C).
- Carefully reconstitute or dilute the reagents avoiding any contamination.
- Do not carry out the test in the presence of reactive vapors (acid, alkaline, aldehyde vapors) or dust that could alter the enzyme activity of the conjugate.
- Use glassware thoroughly washed and rinsed with deionized water or, preferably disposable material.
- Washing the microplate is a critical step in the procedure: follow the recommended number of washings cycles and make sure that all wells are completely filled and then completely emptied. Incorrect washings may lead to inaccurate results.

- Do not allow the microplate to dry between the end of the washings operation and the reagent distribution.
- Never use the same container to distribute the conjugate and the development solution.
- The enzymatic reaction is very sensitive to metal or metal ions. Consequently, do not allow any metal element to come into contact with the various solutions containing the conjugate or the chromogen.
- Chromogen solution (R9) should be colorless. The appearance of a blue color indicates that the reagent cannot be used and must be replaced.
- Use a new pipette tip for each sample.
- Check the pipettes and other equipments for accuracy and correct operations.

HEALTH AND SAFETY INSTRUCTIONS

Human origin material used in the preparation of reagents has been tested and founded non-reactive for hepatitis B surface antigen (HBs Ag), antibodies for hepatitis C virus (anti-HCV), and to human immunodeficiency virus (anti-HIV1 et anti-HIV2). Because no method can absolutely guarantee the absence of infectious agents, handle reagents of human origin and patient samples as potentially capable of transmitting infectious diseases.

- Any material, including washings solutions, that comes directly in contact with samples and reagents containing materials of human origin should be considered capable of transmitting infectious diseases.
- Wear disposable gloves when handling samples and reagents.
- Do not pipette by mouth.
- Avoid spilling samples or solutions containing samples. Spills must be rinsed with bleach diluted to 10 %. In the event of a spill with an acid, it must be first neutralized with sodium bicarbonate, and then cleaned with bleach diluted to 10% and dried with adsorbent paper. The material used for cleaning must be discarded in a contaminated residue container.
- Patient samples, reagents containing human origin material, as well as contaminated material and products should be discarded after decontamination only:
 - either by immersion in bleach at the final concentration of 5 % of sodium hypochloride during 30 minutes,
 - or by autoclaving at 121°C for 2 hours at the minimum.

CAUTION: Do not introduce solutions containing sodium hypochloride into the autoclave

- Avoid any contact of Stopping Solution with skin and mucosa.
- Chemical and biological residues must be handled and disposed off in accordance with Good Laboratories Practices.
- All reagents in the kit are exclusively for *in vitro* diagnostic use.
- For hazard and precaution recommendations related to some chemical components in this test kit, please refer to the pictogram(s) mentioned on the labels and the information supplied at the end of instruction for use. The Safety Data Sheet is available on www.bio-rad.com.

6. SPECIMEN COLLECTION, PREPARATION AND STORAGE

1. Serum and plasma (EDTA, sodium heparin or sodium citrate) are the recommended sample types.
2. Observe the following recommendations for handling, processing and storage of blood samples:
 - Collect all blood samples observing routine precaution for venipuncture.
 - For serum, allow samples to clot completely before centrifugation.
 - Keep tubes stoppered at all times.
 - After centrifugation, separate the serum or plasma from the clot or red cells in a tightly stoppered storage tube.
 - The specimens can be stored at +2-8°C if test is performed within 7 days.
 - If test will not be completed within 7 days, or for shipment, freeze the samples at -20°C or colder.
 - Do not use samples that have been thawed more than five times. Previously frozen specimens should be thoroughly mixed (Vortex) after thawing prior to testing.
3. Samples containing 90 g/l of albumin or 100 mg/l of unconjugated bilirubin, lipemic samples containing the equivalent of 36 g/l of triolein (triglyceride), and hemolysed samples containing up to 10 g/l of hemoglobin do not affect the results.
4. Do not heat the samples.

7. ASSAY PROCEDURE

7.1 MATERIALS REQUIRED BUT NOT PROVIDED

- Vortex mixer.
- Microplate reader equipped with 450 nm and 620 nm filters (*).
- Microplate incubator thermostatically set at 37±1°C (*).
- Automatic, semi-automatic or manual microplate washer (*).
- Sterile distilled or deionized water.
- Disposable gloves.

- Goggles or safety glasses.
- Adsorbent paper.
- Automatic or semi-automatic, adjustable or preset, pipettes or multi-pipettes, to measure and dispense 10 µl to 1000 µl, and 1 ml, 2 ml and 10 ml.
- Graduated cylinders of 25 ml, 50 ml, 100 ml and 1000 ml capacity.
- Sodium hypochloride (bleach) and sodium bicarbonate.
- Container for biohazard waste.
- Disposable tubes.

(* Consult our technical department for detailed information about the recommended equipment.

7.2 REAGENTS RECONSTITUTION

- **R1:** Bring reagent at room temperature (+18-30°C) 30 minutes before opening the bag. Take out the carrier tray and return unused strips to the bag immediately and check for the presence of desiccant. Carefully reseal the bag and store it at +2-8°C.
- **R2:** Dilute 1/20 the washing solution R2 in distilled water: for example 50 ml of R2 and 950 ml of distilled water to get the ready-to-use washing solution. Prepare 350 ml of diluted washing solution for one plate of 12 strips if washing manually.
- **R3, R4, R5:** Dilute 1/21 in Diluent (R7) (example: 15 µL of R3 + 300 µL of R7).
- **R6+R7:** Conjugate (R6) is concentrated 51x and must be homogenized before use. Dilute 1/51 in Diluent (R7). For one plate, dilute 0.5 ml of Conjugate (R6) in 25 ml of Diluent (R7). Divide these volumes by 5 to obtain the volume needed for two strips.

7.3 STORAGE AND VALIDITY OF OPENED AND / OR RECONSTITUTED REAGENTS

The kit must be stored at +2-8°C. When the kit is stored at +2-8°C before opening, each component can be used until the expiration date indicated on the outer label of the kit.

- **R1:** Once opened, the strips remain stable for up to 8 weeks if stored at +2-8°C in the same carefully closed bag (check the presence of desiccant).
- **R2:** Once diluted, the Washing Solution can be kept for 2 weeks at +2-30°C. Once opened, the concentrated Washing Solution stored at +2-30°C, in absence of contamination, is stable until the expiration date indicated on the label.

- **R3, R4, R5, R6, R7:** Once opened and without any contamination, the reagents stored at +2-8°C are stable for up to 8 weeks.
- **R6+R7:** Once diluted, the conjugate working solution is stable for 8 hours at room temperature (+18-30°C) or 24 hours at +2-8°C.
- **R9:** Once opened and without any contamination, the reagent stored at +2-8°C is stable for up to 8 weeks.
- **R10:** Once opened and without any contamination, the reagent stored at +2-8°C is stable until the expiration date indicated on the label.

7.4 PROCEDURE

Strictly follow the assay procedure and Good Laboratory Practices.

Before use, allow reagents to reach room temperature (+18-30°C).

The use of breakable wells requires a special attention during handling.

Use the negative, cut-off and positive controls with each run to validate the assay results.

1. Carefully establish the distribution and identification plan for controls and patients samples.
2. Prepare the diluted Washing Solution (R2) [*Refer to Section 7.2*].
3. Take the carrier tray and the strips (R1) out of the protective pouch [*Refer to Section 7.2*].
4. Dilute controls R3 and R5, calibrator R4 and patients samples (S1, S2...) in Diluent (R7) to give a 1/21 dilution: 15 µl of sample and 300 µL of Diluent (R7). Vortex diluted samples.
5. Strictly following the indicated sequence below, distribute in each well 200µl of diluted controls, calibrator and patient samples:

	1	2	3	4	5	6	7	8	9	10	11	12
A	R3	S5	S13									
B	R4	S6										
C	R4	S7										
D	R5	S8										
E	S1	S9										
F	S2	S10										
G	S3	S11										
H	S4	S12										

6. Cover the microplate with an adhesive plate sealer, then press firmly onto the plate to ensure a tight seal. Incubate the microplate immediately in a thermostat controlled water bath or in a dry incubator for 1 hour ± 5 minutes at 37°C ± 1°C.

7. At the end of the first incubation period, remove the adhesive plate sealer. Aspirate the content of all wells into a container for biohazard waste (containing sodium hypochloride). Wash microplate **5 times** with 350 µl of the Washing Solution (R2). Invert the microplate and gently tap on adsorbent paper to remove remaining liquid.
8. Prepare the conjugate working solution (R6+R7) [Refer to Section 7.2]. Distribute 200 µl of the conjugate working solution (R6+R7) immediately in all wells. The solution must be shaken gently before use.
9. Cover the microplate with an adhesive plate sealer, then press firmly onto the plate to ensure a tight seal. Incubate the microplate immediately in a thermostat controlled water bath or in a dry incubator for 1 hour ± 5 minutes at 37°C ± 1°C.
10. At the end of the second incubation period, remove the adhesive plate sealer. Aspirate the contents of all wells into a container for biohazard waste (containing sodium hypochloride). Wash microplate **5 times** with 350 µl of the Washing Solution (R2). Invert the microplate and gently tap on adsorbent paper to remove remaining liquid.
11. Quickly distribute into each well and away from light 200 µl of Chromogen solution (R9). **Allow the reaction to develop in the dark for 30 ± 5 minutes at room temperature (+18-30°C)**. Do not use adhesive plate sealer during this incubation.
12. Stop the enzymatic reaction by adding 100 µl of Stopping Solution (R10) in each well. Use the same sequence and rate of distribution as for the development solution.
13. Carefully wipe the plate bottom. Read the optical density at 450/620 nm using a plate reader within 30 minutes after stopping the reaction. The strips must always be kept away from light before reading.
14. Before reporting results, check for agreement between the reading and the distribution plan of plate and samples.

8. CALCULATION AND INTERPRETATION OF RESULTS

8.1 CALCULATION OF THE CUT-OFF VALUE (CO)

The Cut-Off value (CO) corresponds to the mean value of the optical densities (OD) of the calibrator duplicates (R4):

- CO = mean of OD R4

8.2 CALCULATION OF THE SAMPLE RATIO

Sample result is expressed by Ratio using the following formula:

- Sample Ratio = Sample OD/CO

8.3 QUALITY CONTROL

Include all the controls for each microplate and for each run, and analyse the obtained results. For validation of the assay, the following criteria must be met:

- Optical density values :
 - $CO \geq 0.300$
 - $0.80 \times CO < OD \text{ R4 Replicate 1} < 1.20 \times CO$
 - $0.80 \times CO < OD \text{ R4 Replicate 2} < 1.20 \times CO$

(Individual OD of each duplicate of the calibrator (R4) must not differ more than 20% of the CO value).

- Optical density ratios :
 - Ratio R3 ($OD \text{ R3} / CO$) ≤ 0.50
 - Ratio R5 ($OD \text{ R5} / CO$) ≥ 1.80

If those quality control criteria are not met, the test run should be repeated.

8.4 INTERPRETATION OF RESULTS

Sample Ratio	Result	Interpretation
Ratio < 0.90	Negative	The sample is considered non reactive for the presence of IgG antibodies to HSV 1.
$0.90 \leq \text{Ratio} < 1.10$	Equivocal	The sample is considered equivocal for the presence of IgG antibodies to HSV 1. The result must be confirmed by another test done on a second sample drawn 4 to 12 weeks later after the initial one.
Ratio ≥ 1.10	Positive	The sample is considered reactive for the presence of IgG antibodies to HSV 1.

If an infection is suspected, complementary serological tests like the detection of IgM anti-HSV antibodies can be useful to confirm the diagnosis.

A detailed attention must be paid to the other elements of diagnosis for the results close to the gray zone.

8.5 TROUBLE SHOOTING GUIDE

Non validated or non repeatable reactions are often caused by:

- Inadequate microplate washings.
- Contamination of negative samples by serum or plasma with a high antibody titer.
- Contamination of the development solution by chemical oxidizing agents.
- Contamination of the Stopping Solution.

9. PERFORMANCES

Platelia™ HSV 1 IgG was evaluated on 2 different sites on a total of 726 fresh or frozen samples. Results with Platelia™ HSV 1 IgG were compared to results obtained with other commercialized EIA assays.

9.1 PREVALENCE

Prevalence determination of IgG antibodies to Herpes Simplex Virus Type 1 in human serum was estimated using a panel of 180 samples obtained from pregnant women. The following results were obtained: 37 negative, one doubtful and 142 positive sera. Prevalence using the Platelia™ HSV 1 IgG assay is established at 78.8% (142/180).

9.2 SPECIFICITY

Specificity was estimated on a total of 303 samples:

- on site 1, a panel of 156 samples from blood donor, pregnant women & commercial panels (CDC^(A) /BBI^(B)).
- on site 2, a panel of 147 samples from hospitalized patients.

On both sites, samples were selected on negative results obtained with a commercialized EIA assay and considered as a reference.

	Panel of samples	Negative	Doubtful ⁽¹⁾	Positive	Specificity
Site 1	N = 156	154	1	1	99.4% (154/155) [96.5%-100%]
Site 2	N = 147	146	0	1	99.3% (146/147) [96.3%-100%]
Total	N = 303	300	1	2	99.3% (300/302) [97.6%-99.9%]

⁽¹⁾ doubtful results were excluded for calculation of specificity
IC 95%: 95% confidence interval.

(A): Center for Disease Control, (B) BBI mixed titer HSV panel

9.3 SENSITIVITY

Sensitivity was estimated on a total of 423 samples:

- on site 1, a panel of 270 samples from blood donor, pregnant women & commercial panels (CDC^(A) /BBI^(B)).
- on site 2, a panel of 153 samples from hospitalized patients.

On both sites, samples were selected on positive results obtained with a commercialized EIA assay and considered as a reference.

	Panel of samples	Negative	Doubtful ⁽¹⁾	Positive	Specificity
Site 1	N = 270	2	3	265	99.3% (265/267) [97.3%-99.9%]
Site 2	N = 153	3	0	150	98.0% (150/153) [94.4%-99.6%]
Total	N = 423	5	3	415	98.8% (415/420) [97.2%-99.6%]

⁽¹⁾ doubtful results were excluded for calculation of sensitivity

9.4 PRECISION

- Within-run precision (repeatability) :

In order to evaluate intra-assay repeatability, one negative, one equivocal and one positive samples were tested 30 times during the same run. The ratio (Sample OD / CO) was determined for each sample. Mean Ratio, Standard Deviation (SD) and Coefficient of Variation (%CV) for each of the three specimens are listed in the table below:

N=30	Negative Sample	Doubtful sample	Low Positive sample
	Ratio (Sample OD / Cut-Off value)		
Mean	0.72	1.05	1.36
SD	0.08	0.06	0.08
% CV	10.58%	5.33%	5.91%

- Between-run precision (reproducibility):

In order to evaluate inter-assay reproducibility, one negative and three positive samples (low, medium, high positive) were tested in duplicate in two runs per day over a 20 days period. The ratio (Sample OD / CO) was determined for each sample. Mean Ratio, Standard Deviation (SD) and Coefficient of Variation (%CV) for each of the four specimens are listed in table below:

N=80	Negative Sample	Low positive sample	Medium positive sample	High positive sample
	Ratio (Sample OD / Cut-Off value)			
Mean	0.24	1.69	2.67	3.64
SD	0.03	0.17	0.30	0.29
% CV	12.1%	10.3%	11.1%	7.9%

9.5 CROSS REACTIVITY

110 samples with characteristics which could potentially result in non specific reactions were tested with the Platelia™ HSV 1 IgG assay. Results are presented in the following table:

Panel	Number of samples	Equivocal ⁽¹⁾	Positive	Positive results confirmation by reference serology
VZV	10	0	7	7/7
CMV	10	0	6	6/6
EBV	10	0	7	7/7
Rheumatoid Factor	13	0	8	8/8
Heterophile antibodies (HAMA)	20	0	13	13/13
Anti-nuclear antibodies (ANA)	7	0	4	4/4
HHV 6	10	0	9	9/9
HIV	10	0	8	8/8
Mumps	10	0	6	6/6
Measles	10	1	6	6/6
TOTAL	110	1	74	74/74

⁽¹⁾ Equivocal results were excluded for evaluation of cross-reactivity.

All the positive results with the Platelia™ HSV 1 IgG assay were confirmed positive with the commercialized EIA assay.

10. LIMITATIONS OF THE PROCEDURE

Diagnosis of Herpes simplex virus infection can only be established on the basis of a combination of clinical and biological data. The result of a single test of detection of IgG anti-HSV antibodies does not constitute sufficient proof for the diagnosis of infection by Herpes simplex virus.

11. QUALITY CONTROL OF THE MANUFACTURER

All manufactured reagents are prepared according to our Quality System, starting from reception of raw material to commercialization of the final product. Each lot is submitted to quality control assessments and is released to the market only after conforming to pre-defined acceptance criteria. The records related to production and controls of each single lot are kept within Bio-Rad.

12- REFERENCES

1. Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines 2002. MMWR 2002:51 (No. RR-6).
2. Arvin, A, C Prober. Herpes Simplex Viruses. 876-883. In Murray, P, E Baron, M Pfaller, F Tenover, and R Tenover (eds.). Manual of Clinical Microbiology. 6th Ed. ASM, Washington, D.C.

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- (SE)** • Denna produkt innehåller beståndsdelar från människa eller djur. Hantera produkten varsamt.
- (SI)** • Izdelek vsebuje človeške ali živalske sestavine. Rokujte previdno.
- (SK)** • Tento výrobok obsahuje ľudské alebo zvieracie zložky. Narábajte s ním opatrne.



H314-H317
P280-P305+P351+P338-
P301+P330+P331-P303+P361+P353-
P333+P313-P501

(BG)

опасно

Причинява тежки изгаряния на кожата и сериозно увреждане на очите. Може да причини алергична кожна реакция.

Използвайте предпазни ръкавици/предпазно облекло/предпазни очила/предпазна маска за лице. **ПРИ КОНТАКТ С ОЧИТЕ:** Промивайте внимателно с вода в продължение на няколко минути. Свалете контактните лещи, ако има такива и доколкото това е възможно. Продължавайте да промивате. **ПРИ ПОГЛЪЩАНЕ:** изплакнете устата. **НЕ** предизвиквайте повръщане. **ПРИ КОНТАКТ С КОЖАТА** (или косата): Незабавно свалете цялото облекло/предпазно облекло. Облейте кожата с вода/ вземете душ При поява на кожно дразнене или обрив на кожата: Потърсете медицински съвет/ помощ. Изхвърлете съдържанието/контейнера в съответствие с местните/регионалните/ националните/международните разпоредби.

(CZ)

Nebezpečí

Způsobuje těžké poleptání kůže a poškození očí. Může vyvolat alergickou kožní reakci. Používejte ochranné rukavice/ochranný oděv/ ochranné brýle/obličejový štít. **PŘI ZASAŽENÍ OČÍ:** Několik minut opatrně vyplachujte vodou. Vyměňte kontaktní čočky, jsou-li nasazeny a pokud je lze vymýt snadno. Pokračujte ve vyplachování. **PŘI ZOŽITÍ:** Vypláchněte ústa. **NEVYVOLÁVEJTE** zvracení. **PŘI STYKU S KÚŽÍ** (nebo s vlasy): Veškeré kontaminované části oděvu okamžitě svlékněte. Opláchněte kůži vodou/ospřchujte. Při podráždění kůže nebo vyrážce: Vyhledejte lékařskou pomoc/ošetření. Obsah/nádobu likvidujte v souladu s místními/regionálními/národními/mezinárodními předpisy.

(DE)

Gefahr

Verursacht schwere Verätzungen der Haut und schwere Augenschäden. Kann allergische Hautreaktionen verursachen.

Schutzhandschuhe/Schutzkleidung/Augenschutz/ Gesichtsschutz tragen. **BEI KONTAKT MIT DEN AUGEN:** Einige Minuten lang behutsam mit Wasser spülen. Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen. **BEI VERSCHLUCKEN:** Mund ausspülen. **KEIN** Erbrechen herbeiführen. **BEI KONTAKT MIT DER HAUT** (oder dem Haar): Alle

beschmutzten, getränkten Kleidungsstücke sofort ausziehen. Haut mit Wasser abwaschen/duschen. Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen. Entsorgung des Inhalts / des Behälters gemäß den örtlichen / regionalen / nationalen/ internationalen Vorschriften.

(DK)

Fare

Forårsager svære forbrændinger af huden og øjenskader. Kan forårsage allergisk hudreaktion. Bær beskyttelseshandsker/beskyttelsestøj/ øjenbeskyttelse/ansigtsbeskyttelse **VED KONTAKT MED ØJNENE:** Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning. **I TILFÆLDE AF INDTAGELSE:** Skyl munden. Fremkald IKKE opkastning. **VED KONTAKT MED HUDEN** (eller håret): Tilmudset tøj tages straks af/fjernes. Skyl/ brus huden med vand. Ved hudirritation eller udslæt: Søg lægehjælp. Bortskaffelse af indholdet/ beholderen i henhold til de lokale/regionale/ nationale/internationale forskrifter.

(EE)

Ettevaatust

Põhjustab rasket nahasõõvitust ja silmakahjustusi. Võib põhjustada allergilist nahareaktsiooni. Kanda kaitsekindaid/kaitserõivastust/kaitseprille/ kaitsemaski. **SILMA SATTUMISE KORRAL:** loputada mitme minuti jooksul ettevaatlikult veega. Eemaldada kontaktläätsed, kui neid kasutatakse ja kui neid on kerge eemaldada. Loputada veel kord. **ALLANEELAMISE KORRAL:** loputada suud. **MITTE** kutsuda esile oksendamist. **NAHALE** (või juustele) **SATTUMISE KORRAL:** võtta viivitamata kõik saastunud rõivad seljast. Loputada nahka veega/loputada duši all. Nahaärrituse või _obe korral: pööruda arsti poole. Sisu/konteineri käitlus vastavuses kohalike/regionaalsete/rahvuslike/ rahvusvaheliste nõuetega.

(EN)

Danger

Causes severe skin burns and eye damage. May cause an allergic skin reaction.

Wear protective gloves/protective clothing/eye protection/face protection. **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **IF SWALLOWED:** rinse mouth. Do NOT induce vomiting. **IF ON SKIN** (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention. Dispose of contents/ container in accordance with local/regional/national/ international regulations.

(ES)

Peligro

Provoca quemaduras graves en la piel y lesiones oculares graves. Puede provocar una reacción alérgica en la piel.

Liever guantes que aislen del frío/gafas/máscara. EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando. EN CASO DE INGESTIÓN: Enjuagarse la boca. NO provocar el vómito. EN CASO DE CONTACTO CON LA PIEL (o el pelo): Quitarse inmediatamente las prendas contaminadas. Aclararse la piel con agua o ducharse. En caso de irritación o erupción cutánea: Consultar a un médico. Eliminar el contenido o el recipiente conforme a la reglamentación local/regional/nacional/internacional.

(FI)

Vaara

Voimakkaasti ihoa syövyttävää ja silmiä vaurioittavaa. Voi aiheuttaa allergisen ihoreaktion. Käytä suojakäsineitä/suojavaatetusta/silmiensuojainta/kasvosuojainta. JOS KEMIKAALIA JOUTUU SILMIIN: Huuho huolellisesti vedellä usean minuutin ajan. Poista piilolinssit, edical voi tehdä helposti. Jatka huuhtomista. JOS KEMIKAALIA ON NIELTY: Huuho suu. Ei saa oksennuttaa. JOS KEMIKAALIA JOUTUU IHOLLE (tai hiuksiin): Riisu saastunut vaatetus välittömästi. Huuho/suihkuta iho vedellä. Jos ilmenee ihöirästyistä tai ihottumaa: Hakeudu lääkäriin. Säilytä säiliö(t) noudattaen paikallisia/alueellisia/kansallisia/kansainvälisiä määräyksiä.

(FR)

Danger

Provoque des brûlures de la peau et des lésions oculaires graves. Peut provoquer une allergie cutanée. Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage. EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. EN CAS D'INGESTION: rincer la bouche. NE PAS faire vomir. EN CAS DE CONTACT AVEC LA PEAU (ou les cheveux): enlever immédiatement les vêtements contaminés. Rincer la peau à l'eau/se doucher. En cas d'irritation ou d'éruption cutanée: consulter un médecin. Éliminer le contenu/réceptacle conformément à la réglementation locale/régionale/nationale/internationale.

(GR)

Κίνδυνος

Προκαλεί σοβαρά δερματικά εγκαύματα και οφθαλμικές βλάβες. Μπορεί να προκαλέσει αλλεργική δερματική αντίδραση. Να φοράτε προστατευτικά γάντια/προστατευτικά ενδύματα/μέσα ατομικής προστασίας για ταμάτια/πρόσωπο. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΑ ΜΑΤΙΑ: Ξεπλύνετε προσεκτικά με νερό για αρκετά λεπτά. Εάν υπάρχουν φακοί επαφής, αφαιρέστε τους, εφόσον είναι εύκολο. Συνεχίστε να ξεπλένετε. ΣΕ ΠΕΡΙΠΤΩΣΗ ΚΑΤΑΠΟΣΗΣ: Ξεπλύνετε το στόμα. ΜΗΝ προκαλέσετε εμετό. ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ

ΜΕ ΤΟ ΔΕΡΜΑ (ή με τα μαλλιά): Αφαιρέστε αμέσως όλα τα μολυσμένα ενδύματα. Ξεπλύνετε το δέρμα με νερό/στόμους. Εάν παρατηρηθεί ερεθισμός του δέρματος ή εμφανιστεί εξάνθημα: Συμβουλευθείτε/Επισκεφθείτε/επιστρέψτε. Απορρίψτε τα περιεχόμενα/δοχεία σύμφωνα με τους τοπικούς/εθνικούς/διεθνείς κανονισμούς.

(HR)

Opasnost

Uzrokuje teške opekline kože i ozljede oka. Može izazvati alergijsku reakciju na koži. Nositi zaštitne rukavice/zaštitnu odjevu/zaštitu za oči/zaštitu za lice. U SLUČAJU DODIRA S OČIMA: oprezno ispirati vodom nekoliko minuta. Ukloniti kontaktno leće ukoliko ih nosite i ako se one lako uklanjaju. Nastaviti ispiranje. AKO SE PROGUTA: isprati usta. NE izazivati povraćanje. U SLUČAJU DODIRA S KOŽOM (ili kosom): odmah ukloniti/ skinuti svu zaganenu odjeću. Isprati kožu vodom/ tuširanjem. U slučaju nadražaja ili osipa na koži: zatražiti savjet/pomoć liječnika. Odložite sadržaje /spremnik u skladu s lokalnim/regionalnim/ nacionalnim/međunarodnim odredbama.

(HU)

Veszély

Smarkiai nudegina odą ir pažeidžia akis. Allergias bõrreakciõt válthat ki. Védõkesztyű/védõruha/szemvédõ/arcvédõ használatá kötelezõ. SZEMBE KERÜLÉS esetén: Több percig tartó óvatos öblítés vízzel. Adott esetben a kontaktlencsék eltávolítása, ha könnyen megoldható. Az öblítés folytatása. LENYELES ESETÉN: a szájat ki kell öblíteni. TILOS hánytatni. HA BÖRRE (vagy hajra) KERÜL: Az õsszes szennyezett ruhadarabot azonnal el kell távolítani/ le kell vetni. A bõrt le kell öblíteni vízzel/zuhanyozás. Bõrirritáció vagy kiütések megjelenése esetén: orvosi ellátást kell kérni. Az edény tartalmát / a tartályt a helyi/regionális/nemzeti/nemzetközi szabályozásoknak megfelelően kell hulladékként elhelyezni.

(IT)

Pericolo

Provoca gravi ustioni cutanee e gravi lesioni oculari. Può provocare una reazione allergica cutanea. Indossare guanti/indumenti protettivi/Proteggere gli occhi/il viso. IN CASO DI CONTATTO CON GLI OCCHI: sciacquare accuratamente per parecchi minuti. Togliere le eventuali lenti a contatto se è agevole farlo. Continuare a sciacquare. IN CASO DI INGESTIONE: sciacquare la bocca. NON provocare il vomito. IN CASO DI CONTATTO CON LA PELLE (o con i capelli): togliersi di dosso immediatamente tutti gli indumenti contaminati. Sciacquare la pelle/ fare una doccia. In caso di irritazione o eruzione della pelle: consultare un medico. Smettere il prodotto/recipiente in conformità con le disposizioni locali / regionali / nazionali / internazionali.

(LT)

Pavojinga

Smarkiai nudegina odą ir pažeidžia akis. Gali sukelti alerginę odos reakciją.

Mūvėti apsaugines pirštines/dėvėti apsauginius drabužius/naudoti akių (veido) apsaugos priemones. PATEKUS Į AKIS: Kelias minutes atsargiai plauti vandeniu. Išimti kontaktinius lęšius, jeigu jie yra ir jeigu lengvai galima tai padaryti. Toliau plauti akis. PRARIJUS: išskalauti burną. NESKATINTI vėmimo. PATEKUS ANT ODOS (arba plaukų): Nedelsiant nuvilkti/pašalinti visus užterštus drabužius. Odą nuplauti vandeniu/čiurkšle. Jeigu sudirginama oda arba ją išberia: kreiptis į gydytoją. Turinį/talpa įšpilti (išmesti) - šalinti pagal vietines / regionines / nacionalines / tarptautines taisykles.

(NL)

Gevaar

Veroorzaakt ernstige brandwonden en oogletsel. Kan een allergische huidreactie veroorzaken. Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk; blijven spoelen. NA INSLIKKEN: de mond spoelen — GEEN braken opwekken. BIJ CONTACT MET DE HUID (of het haar): verontreinigde kleding onmiddellijk uittrekken — huid met water afspoelen/afdouchen. Bij huidirritatie of uitslag: een arts raadplegen. De inhoud en de verpakking verwerken volgens de plaatselijke/regionale/nationale/ internationale voorschriften.

(NO)

Fare

Forårsaker alvorlige hudforbrenninger og øyeskader. Kan forårsake allergiske hudreaksjoner. Bruk vernehansker/vermeklær/vernebriller/ansiktsskjerm. VED KONTAKT MED ØYNE: Skyll forsiktig med vann i opptil flere minutter. Fjern evt. kontaktlinser såfremt dette er lett mulig. Fortsett skyllingen. VED SVELGING: Skyll munnen. IKKE fremkall brekninger. VED HUDKONTAKT (eller kontakt med hår): Alle tilsølte klær må fjernes straks. Vask/dusj huden med vann. Ved hudirritasjon eller -utslett: Kontakt / tilkall lege. Innholdet / emballasjen skal avhendes i henhold til de lokale / regionale / nasjonale / internasjonale forskrifter.

(PL)

Niebezpieczeństwo

Powoduje poważne oparzenia skóry oraz uszkodzenia oczu. Może powodować reakcję alergiczną skóry. Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy. W PRZYPADKU DOSTANIA SIĘ DO OCZU: Nieodroźnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. W PRZYPADKU POŁKNIECIA: wypłukać usta. NIE wywoływać wymiotów. W PRZYPADKU KONTAKTU

ZE SKÓRĄ (lub z włosami): Natychmiast usunąć/zdjąć całą zanieczyszczoną odzież. Spłukać skórę pod strumieniem wody/prysznicem. W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza. Zawartość / pojemnik usunąć zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi.

(PT)

Perigo

Provoca queimaduras na pele e lesões oculares graves. Pode provocar uma reacção alérgica cutânea.

Usar luvas de protecção/vestuário de protecção/protecção ocular/protecção facial. SE ENTRAR EM CONTACTO COM OS OLHOS: enxaguar cuidadosamente com água durante vários minutos. Se usar lentes de contacto, retire-as, se tal lhe for possível. Continuar a enxaguar. EM CASO DE INGESTÃO: enxaguar a boca. NÃO provocar o vômito. SE ENTRAR EM CONTACTO COM A PELE (ou o cabelo): despir/retirar imediatamente toda a roupa contaminada. Enxaguar a pele com água/tomar um duche. Em caso de irritação ou erupção cutânea: consulte um médico. Eliminar o conteúdo/recipiente de acordo com a legislação local/regional/nacional/internacional.

(RO)

Pericol

Provoacă arsuri grave ale pielii și lezarea ochilor. Poate provoca o reacție alergică a pielii. Purtați mănuși de protecție/îmbrăcăminte de protecție/echipament de protecție a ochilor/chipament de protecție a feței. ÎN CAZ DE CONTACT CU OCHII: clătiți cu atenție cu apă timp de mai multe minute. Scoateți lentilele de contact, dacă este cazul și dacă acest lucru se poate face cu ușurință. Continuați să clătiți. ÎN CAZ DE ÎNGHIȚIRE: clătiți gura. NU provocați vomă. ÎN CAZ DE CONTACT CU PIELEA (sau părul): scoateți imediat toată îmbrăcăminte contaminată. Clătiți pielea cu apă/faceți duș. În caz de iritare a pielii sau de erupție cutanată: consultați medicul. Aruncați conținutul/containerul în acord cu regulamentele locale/regionale/naționale/internaționale.

(SE)

Fara

Orsakar allvariga frätskador på hud och ögon. Kan orsaka allergisk hudreaktion. Använd skyddshandskar/skyddskläder/ögonskydd/ansiktsskydd. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Ta ur eventuella kontaktlinser om det går lätt. Fortsätt att skölja. VID FÖRTÄRING: Skölj munnen. Framkalla INTE kräkning. VID HUDKONTAKT (även håret): Ta omedelbart av alla nedstänkta kläder. Skölj huden med vatten/duscha. Vid hudirritation eller utslag: Sök läkarhjälp. Innehållet / behållaren avfallshanteras enligt lokala / regionala / nationella / internationella föreskrifter.

(SI)**Nevarno**

Povzroča hude opekline kože in poškodbe oči.

Lahko povzroči alergijski odziv kože.

Nositi zaščitne rokavice/zaščitno obleko/zaščito za

oči/zaščito za obraz. PRI STIKU Z OČMI: previdno

izpirajte z vodo nekaj minut. Odstranite kontaktne

leče, če jih imate in če to lahko storite brez težav.

Nadaljujte z izpiranjem. PRI ZAUŽITJU: izprati usta.

NE izzvati bruhanja. PRI STIKU S KOŽO (ali lasmi):

takoj odstraniti/sleči vsa kontaminirana oblačila.

Izprati kožo z vodo/prho. Če nastopi draženje kože

ali se pojavi izpuščaj: poiščite zdravniško pomoč/

oskrbo. Vsebino/vsebnik odstranite v skladu z

lokalnimi/regionalnimi/narodnimi/mednarodnimi

predpisi.

(SK)**Nebezpečnost**

Provoacă arsuri grave ale pielii și lezarea ochilor.

Môže vyvolať alergickú kožnú reakciu.

Noste ochranné rukavice/ochranný odev/ochranné

okuliare/ochranu tváre. PO ZASIAHNUTÍ OČÍ:

Niekoľko minút ich opatrne vyplachujte vodou. Ak

používate kontaktné šošovky a ak je to možné,

odstráňte ich. Pokračujte vo vyplachovaní. PO

POŽITÍ: vypláchnite ústa. Nevyvolávajte zvracanie.

PRI KONTAKTE S POKOŽKOU (alebo vlasmi):

Odstráňte/vyzlečte všetky kontaminované časti

odevu. Pokožku ihneď opláchnite vodou/sprchou.

Ak sa prejaví podráždenie pokožky alebo sa

vytvoria vyrážky: vyhľadajte lekársku pomoc/

starostlivosť. Zneškodnenie obsahu/obalu v súlade

s miestnymi/oblastnými/národnými/medzinárodnými

nariadeniami.

Bio-Rad

3, boulevard Raymond Poincaré
92430 Marnes-la-Coquette France
Tel. : +33 (0) 1 47 95 60 00
Fax.: +33 (0) 1 47 41 91 33
www.bio-rad.com



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