

Syphilis Total Ab

1 plate - ▽ 96

REF 72530

5 plates - ▽ 480

REF 72531

KITS FOR THE QUALITATIVE DETECTION OF ANTIBODY TO
TREPONEMA PALLIDUM IN HUMAN SERUM OR PLASMA USING AN
ENZYME IMMUNOASSAY TECHNIQUE



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BIO-RAD

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1. INTENDED USE

These kits are intended for use by appropriately trained and qualified personnel for the qualitative detection of antibodies to *Treponema pallidum* in human serum and plasma. The product may be used for the screening of blood donors, and to aid in the diagnosis of patients where syphilis infection is suspected.

2. SUMMARY AND EXPLANATION OF THE TEST

Syphilis is a chronic infection that progresses through distinct stages of infection: primary, secondary, tertiary, and quaternary. These stages produce diverse clinical symptoms, typically producing initial sores known as chancres then syphilitic rash followed by long periods of dormancy. Untreated infection may eventually result in cardiovascular problems and neurosyphilis.

The infection is caused by the spirochaete *Treponema pallidum*, and is usually acquired by sexual contact, although the disease may be transmitted by transfusion of infected blood. Intra-uterine infection also occurs. The organism has proved virtually impossible to culture in artificial media, and diagnosis of the infection usually depends on the demonstration of antibodies in the blood, which appear soon after initial infection and may persist for many years.

Tests for Syphilis fall into four categories: direct microscopic examination, treponemal antibody tests, non - treponemal antibody tests and direct antigen tests. Because of the long periods of dormancy and the non - specific nature of non - treponemal tests, methods that detect specific anti-treponemal antibodies in blood specimens have become increasingly popular for screening. Syphilis Total Ab is one such test.

3. PRINCIPLES OF THE PROCEDURE

Syphilis Total Ab use three recombinant antigens in a sandwich assay. The antigens will detect *T. pallidum* specific IgG, IgM, and IgA; enabling the test to detect antibodies during all stages of infection.

The wells are coated with a mixture of 15Kd, 17Kd, and 47Kd *T. pallidum* recombinant antigens. Specific antibodies in serum or plasma specimens combine with these antigens and with the same antigens conjugated to horseradish peroxidase when conjugate is added to a well in which the specimen has been incubated. After unreacted material has been removed by washing, the presence of bound enzyme, indicating the presence in the specimen of specific antibodies, is revealed by a colour change in the substrate/chromogen mixture. The intensity of the colour is compared to that in control wells to determine the presence or absence of specific antibodies.

4. REAGENTS

4.1. Description

Identification on label		Description	Presentation/ preparation	
			72530	72531
R1	Microplate	Microplate 12 strips of 8 wells each, coated with <i>T. pallidum</i> recombinant Antigens (rAg) Specific ID number = 97	1 plate Ready to use	5 plates Ready to use
R2	Concentrated washing solution (20X)	Concentrated Washing Solution (20X) Tris NaCl Buffer pH 7.4 Preservative: ProClin™ 300 (0.04%)	1 vial 70 ml To be diluted	1 vial 235 ml To be diluted
R3	Negative control	Negative control Tris Buffer, containing BSA (Bovine Serum Albumin) Preservative: ProClin™ 300 (0.1%)	1 vial 2.1 ml Ready to use	1 vial 2.1 ml Ready to use
R4	Positive control	Positive control (Human) Human serum containing antibodies to <i>T. pallidum</i> negative for HIV1/2, HBs Ag, and HCV diluted in a Tris buffer containing BSA (Bovine Serum Albumin) Preservative: ProClin™ 300 (0.1%)	1 vial 1.6 ml Ready to use	1 vial 1.6 ml Ready to use
R6	Conjugate	Conjugate <i>T. pallidum</i> rAg / Peroxidase Preservative: ProClin™ 300 (0.05%)	1 vial 8 ml Ready to use	1 vial 30 ml Ready to use
R8	Substrate buffer	Substrate buffer Citric acid and Sodium acetate solution pH 4.0 containing H ₂ O ₂ (0.015%) and DMSO (4%)	1 vial 60 ml To be reconstituted	1 vial 60 ml To be reconstituted
R9	Chromogen: TMB solution (11X)	Chromogen: TMB solution (pink) Solution containing 3.3', 5.5' tetramethylbenzidine (TMB)	1 vial 5 ml To be diluted	1 vial 5 ml To be diluted
R10	Stopping solution	Stopping solution Sulphuric acid solution (H ₂ SO ₄ 1N)	1 vial 28 ml Ready to use	1 vial 28 ml Ready to use

4.2. Storage and handling requirements

This kit should be stored at +2-8°C. Each item of the kit preserved at +2-8°C can be used up to the expiry date mentioned on the package (unless otherwise indicated).

After opening and in the absence of contamination, R3, R4, R6, R8, R9 and R10 reagents preserved at +2-8°C can be used up to the expiry date shown on the label.

Identification	Preservation
R1	After opening the vacuum-sealed bag, the microwell strips stored at +2-8°C can be used for 1 month in their carefully resealed original bag.
R2	The diluted washing solution can be stored at +2-30°C for 2 weeks. The concentrated washing solution (R2) can be stored at +2-30°C.
R8 + R9	After reconstitution, the reagents stored in the dark can be used for 6 hours at room temperature (18-30°C).

5. WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. For healthcare professional use.

5.1. Health and Safety precautions:

- This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
- The test kit contains human blood components. Human source materials used in the preparation of the reagents have been tested and found non-reactive for hepatitis B surface antigen (HBs Ag), antibodies against human immunodeficiency viruses (HIV-1 and HIV-2) and antibodies against hepatitis C virus (HCV). No known test method can offer complete assurance that infectious agents are absent. Therefore, all human blood derivatives, reagents and human specimens should be handled as if capable of transmitting infectious disease, following recommended Universal Precautions for blood borne pathogens as defined by local, regional and national regulations.
- Biological spills: Human source material spills should be treated as potentially infectious. Spills not containing acid should be immediately decontaminated, including the spill area, materials and any contaminated surfaces or equipment, with an appropriate chemical disinfectant that is effective for the potential biohazards relative to the samples involved (commonly a 1:10 dilution of household bleach, 70-80% Ethanol or Isopropanol, an iodophor [such as 0.5% Wescodyne™ Plus, etc.], and wiped dry. Spills containing acid should be appropriately absorbed (wiped up) or neutralized, the area flushed with water and wiped dry; materials used to absorb the spill may require biohazardous waste disposal. Then the area should be decontaminated with one of the chemical disinfectants.

NOTE: Do not place solutions containing bleach into the autoclave!

- Dispose of all specimens and material used to perform the test as though they contain an infectious agent. Laboratory, chemical or biohazardous wastes must be handled and discarded in accordance with all local, regional and national regulations.
- 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.

5.2. Precautions related to the procedure

5.2.1. Preparing

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 reagents from different lots within a test run.
- Before use wait for 30 minutes for the reagents to stabilize at room temperature (18-30°C).
- The name of the test, as well as a specific identification number for the test is written on the frame of each microplate. This specific identification number is stated on each strip too.

Syphilis Total Ab: Specific ID number = 97

Verify the specific identification number before use. If the identification number is missing, or different from the stated number corresponding to the assay to be tested, the strip should not be used.

REMARK: For washing solution (R2, label identification: 20X coloured green), peroxidase substrate buffer (R8, label identification: TMB buffer, coloured blue), chromogen (R9, label identification: TMB 11X, coloured purple) and stopping solution (R10, label identification: 1N coloured red), it is possible to use other lots than those contained in the kit, provided the same lot is used within a given test run. These reagents can be used with some other products of our company. Contact our technical service for detailed information.

- Carefully reconstitute the reagents avoiding any contamination.
- Use glassware thoroughly washed and rinsed with deionized water or preferably, disposable material.
- Do not allow the microplate to dry between the end of the washing operation and the reagent distribution.
- The enzyme reaction is very sensitive to metal ions. Consequently, do not allow any metal element to come into contact with the various conjugate or substrate solutions.
- The development solution (substrate buffer + chromogen) must be coloured pink. The modification of this pink colour within a few minutes after reconstitution indicates that the reagent cannot be used and must be replaced.

Preparation of the development solution can be made in a clean disposable single use plastic tray or glass container that has first been pre-washed with 1N HCl and rinsed thoroughly with distilled water and dried. This reagent must be stored in the dark.

- Never use the same container to distribute conjugate and development solution.

5.2.2. Processing

- Do not change the assay procedure.
- Do not carry out the test in the presence of reactive vapors (acid, alkaline, aldehyde vapors) or dust that could alter the enzymatic activity of the conjugate.
- Use a new distribution tip for each sample.
- Well washing is a critical step in this procedure: respect the recommended number of washing cycles and make sure that all wells are completely filled and then completely emptied. Incorrect washing may lead to inaccurate results.
- Carefully follow the washing procedures described to obtain maximum test performance. With some instrument, it could be necessary to optimize the washing procedure (increase of number of cycle of washing step and/or volume of wash buffer for each cycle) to obtain an acceptable level of OD background for the negative sample.
- Contact our company for the adaptations and special procedures.

6. SPECIMENS

Collect a blood sample according to the current practices.

The tests should be performed on undiluted serum or plasma (collected on EDTA, Sodium Citrate, Sodium Heparin or ACD)

Specimens containing aggregates must be clarified by centrifugation before testing. The samples should be stored at +2-8°C if testing is to be carried out within 7 days or stored at -20°C for a longer period. Do not repeat more than 5 freeze/thaw cycles. Samples that have been heat-treated at 56°C for 1/2 hour may be used.

Samples containing up to 120 g/l of albumin, 200 mg/l of bilirubin, 33 g/l of triolein or 2 g/l of haemoglobin do not affect the results. However, it is not recommended to use hyperlipaemic or hyperhaemolysed sera or plasma.

Samples should be thawed and well mixed before testing.

If the specimens are to be shipped, they must be packaged in accordance with the regulations in force regarding the transport of etiological agents and preferably transport frozen.

7. PROCEDURE

7.1. Materials required but not provided

- Distilled water.
- Sodium hypochlorite (household bleach) and sodium bicarbonate.
- Absorbent paper.
- Disposable gloves.
- Safety glasses.
- Disposable tubes.
- Automatic or semi-automatic, adjustable or preset pipettes or multipipettes to measure and dispense 50 µl, 1 ml and 10 ml.
- Graduated cylinders of 100 ml and 1 L capacity.
- Automatic, semi-automatic or manual microplate washer system (*).
- Microplate incubator, thermostatically set at 37°C ±1°C (*).
- Container for biohazardous waste.
- Microplate reader equipped with 450, 490 nm and 620-700 nm filters (*).

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

7.2. Reagents preparation

7.2.1. Ready for use reagents

Reagent 1 (R1): Microplate

Each frame support containing 12 strips is wrapped in a sealed foil bag. Cut the bag using scissors or a scalpel 0.5 to 1 cm above the sealing. Open the bag and take out the frame. Put the unused strips back into the bag. Close the bag carefully and put it back into storage at +2-8°C.

Reagent 3 (R3): Negative control

Reagent 4 (R4): Positive control

Reagent 6 (R6): Conjugate

Homogenize by inverting before use.

Reagent 10 (R10): Stopping solution

7.2.2. Reagents to reconstitute

Reagent 2 (R2): Concentrated washing solution (20X)

Dilute 1:20 in distilled water to obtain the ready-for-use washing solution.

Prepare 800 ml for one plate of 12 strips.

Reagent 8 (R8) + Reagent 9 (R9): Enzyme development solution

Dilute 1:11 the chromogen (R9) in the Substrate Buffer (e.g. 1 ml reagent R9 + 10 ml of R8 reagent) given that 10 ml are necessary and sufficient to treat 12 strips. Homogenize.

7.3. Assay Procedure

Strictly follow the procedure.

Use negative and positive controls sera for each test in order to validate the test quality.

Follow the following Good Laboratory Practice:

- 1) Carefully establish the sample distribution and identification plan.
- 2) Prepare the diluted washing solution R2
- 3) Take out from the protective packing the support frame and the necessary number of strips (R1). Put the unused strips back in their packing. Close the packing and replace it at +2-8°C.
- 4) Distribute in the well in the following order (advisable plate distribution):
 - 50 µl of negative control (R3) in A1, B1, C1
 - 50 µl of positive control (R4) in D1, E1
 - 50 µl of undiluted sample in each well, F1, G1, etc
 - 50 µl of conjugate (R6) in each well

Depending on the used system, it is possible to modify the position of controls or the order of distribution.

Homogenize the reaction mixture with at least 3 aspirations or with a microplate shaker during 5 seconds.

REMARK: The sample and controls distribution can be visually controlled at this step of the manipulation, there is a difference of colouration between empty well and well with sample.

Dispense conjugate within 5 minutes after the sample distribution. There is a clear difference of colouration between an empty well and a well containing the red conjugate solution (R6) (Refer to § 7.7).

- 5) When possible, cover the plate with new adhesive film.
- 6) Incubate the microplate for 30 to 35 minutes at 37°C ± 1°C.
- 7) If necessary, remove the adhesive film. Aspirate the contents of all wells into a liquid waste container and add a minimum of 370 µl of washing solution into each well. Aspirate again and repeat the washing a minimum of 4 times (Total of 5 washing cycles). The residual volume must be lower than 10 µl (if necessary, dry the strips by turning them upside down on absorbent paper).

If you have an automatic washer, follow the same operating cycle.

REMARK: Proceed to washing step within 20 minutes.

- 8) Prepare development solution (reagent R8 + R9).
- 9) Quickly dispense into each well 50 µl of prepared development solution (R8+R9), freshly prepared before use. Allow the reaction develop in the dark for 25 to 35 minutes at room temperature (18-30°C). Do not use adhesive film during this incubation.

REMARK: The distribution of the development solution, which is pink, can be visually controlled at this step of the manipulation. There is a clear difference of colouration between an empty well and a well containing the pink substrate solution. (Refer to § 7.7).

- 10) Add 50 µl stopping solution (R10) by using the same sequence and rate of distribution as for the substrate solution. Homogenize the reaction mixture.

REMARK: Distribution of the colourless stopping solution can be visually controlled at this handling stage. The substrate colour, pink (for negative samples) or blue (for positive samples), fades from the wells, which become colourless (for negative samples) or yellow (for positive samples) after adding stopping solution.

- 11) Carefully wipe each plate bottom. Wait at least 4 minutes after stopping solution addition and within 30 minutes after stopping the reaction, read the optical density at 450/620-690 nm using a plate reader.
- 12) Check for agreement between the spectrophotometric and visual readings and against the plate and sample distribution and identification plan.

7.4. Quality Control

Use the negative (R3) and positive (R4) controls for each run to validate the tests results. (Refer to §7.5).

7.5. Test Validation criteria

This test is validated if the conditions below are respected:

- 1) For the negative control R3:

$$OD R3 \leq 0.080$$

If one control value is above this value, disregard it and carry out the calculation with the two remaining negative control values.

- 2) For the positive control R4:

$$OD R4 \geq 0.700$$

7.6. Calculation / Interpretation of the results

The Cut-Off is determined with the negative control R3:

Calculate the mean measured absorbance value for negative control R3 and calculate the Cut-Off Value (COV) as follow:

$$COV = \text{Mean OD R3} + 0.100$$

Samples with OD less than the COV are considered negative by Syphilis Total Ab.

Results just below the cut-off value ($COV - 10\% < OD < COV$) should however, be interpreted with caution. It is advisable to retest the corresponding samples in duplicate when the systems and laboratory procedures permit.

Samples with OD greater than or equal to the COV are considered positive by Syphilis Total Ab and should be re-tested in duplicate before final interpretation.

Re-tested samples that are above the COV in at least one duplicate are considered positive and should be investigated further. Samples that are below the Cut-Off in both duplicates are considered to be negative.

In case of very low optical density for tested samples (negative OD) and when the presence of samples as well as of reagent is controlled, the results can be interpreted as negative.

It is recommended to confirm the positive samples following the current national recommendations and algorithms.

7.7. Spectrophotometric verification of sample and conjugate pipetting (optional)

Samples and controls

The presence of samples and controls into the well can be verified by automatic reading at 450/620 nm.

A well with sample added will have an OD between 0.050 and 1.100.

Conjugate

The conjugate is coloured red.

The presence of conjugate into the wells can be controlled by automatic reading at 450/620 nm. A well with sample and conjugate will have an OD ≥ 1.200 .

Development solution pipetting verification

It is possible to verify the presence of pink development solution into the well by automatic reading at 492 nm.

A well with development solution must have an optical density >0.100 (a lower OD indicates a poor dispensing of the development solution).

8. TEST LIMITATION

As with all serological tests for syphilis, interpretation of results obtained with Syphilis Total Ab EIA assay must be used in conjunction with the patient's clinical symptoms, medical history and other laboratory findings to produce an overall clinical diagnosis.

No single test or definitive reference standard is available for every stage of the disease. Thus, syphilis diagnosis relies predominantly on serological testing, requiring results from both nontreponemal and treponemal methods.

No diagnostic test provides absolute assurance that a sample does not contain low levels of antibodies to *T. pallidum*, such as those present at a very early stage of infection. Therefore, a negative result at any time does not preclude the possibility of exposure to infection with syphilis.

Any ELISA technique may produce false positive reactions. It is recommended to check the specificity of the reaction of any sample found to be a repeatable positive, according to the interpretation criteria of the Syphilis Total Ab kit, using a suitable method: *Treponema pallidum* Hemagglutination assay.

All treponemal test results tend to remain reactive following treponemal infection therefore they should not be used to evaluate response to therapy. Because of the persistence of reactivity, generally for the life of the patient, the treponemal tests are of no value in determining relapse or re-infection in a patient who had a reactive result. In this case, it is recommended to use other assays: Syphilis IgM EIA, RPR and TPHA.

The spectrophotometric method for verifying the sample, conjugate, development solution deposition does not allow to verify the accuracy of the dispensed volume of samples and conjugate. This method shows only the presence of sample and conjugate. The error rate with this method is closely linked to the accuracy of the utilized system (a cumulated coefficient of variation of over 10% for dispensing and reading will significantly decrease the quality of this step).

9. PERFORMANCES CHARACTERISTICS

9.1. Precision Measurement

The repeatability and intermediate precision have been determined using samples with different concentrations of Syphilis antibodies. The samples were tested 30 times during the same series of tests to determine the repeatability.

The samples were also tested in duplicate during 20 days at a rate of 2 tests a day.

The ratio means, standard deviations and Coefficients of Variation (CV) were calculated.

9.1.1. Repeatability:

Samples	N	Mean of ratios	Standard deviation	CV %
Low Negative	30	0.14	0.014	9.5%
High Negative	30	0.68	0.051	7.5%
Low positive Syphilis ab	30	1.90	0.070	3.7%
Positive Syphilis ab	30	3.76	0.130	3.5%

The CVs obtained on the positive samples are less than 10%.

9.1.2. Intermediate Precision

Samples	N	Mean of ratio	Intra assay		Inter assay / operator		Inter day		Total reproducibility	
			SD	CV %	SD	CV %	SD	CV %	SD	CV %
Low Negative	80	0.15	0.035	22.5%	0.023	14.7%	0.017	10.9%	0.045	29.0%
High Negative	80	0.74	0.038	5.1%	0.074	10.0%	0.006	0.8%	0.084	11.2%
Low positive Syphilis ab	80	2.30	0.112	4.9%	0.312	13.5%	0.099	4.3%	0.346	15.0%
Positive Syphilis ab	80	4.13	0.180	4.3%	0.543	13.1%	0.195	4.7%	0.604	14.6%

The CVs obtained on the positive samples are less or equal to 15%.

9.2. Clinical Performance

The clinical performance of the Syphilis Total Ab assay has been determined by testing samples from prospective and retrospective studies:

Prospective study:

- 5195 samples from random blood donors;
- 460 samples from patients for whom Syphilis was suspected

Retrospective study:

- 350 positive from STD patients.

The studies were carried out at 2 blood donor sites, at a STD center (Sexually Transmitted Disease) and at the Bio-Rad site.

9.2.1. Diagnostic Specificity

The study was carried out on serum and EDTA plasma samples collected at 2 blood banks on random donors in France.

A specificity study was also carried out on samples from patients.

All the results were compared to those obtained with other CE mark Syphilis tests.

Table 1: Specificity Test (IR = Initial Reactive; RR= Repeat Reactive)

Population	Site	Sample type	Total number specimens	Initial Reactive (IR)	Repeat Reactive (RR)	RR Specificity (%)	95% CI (%)
Blood donors	#1 + #2	Serum SST	3127	2	2*	3125/3125	99.93% - 100%
		Plasma EDTA K2	2068	2	2*	2066/2066	
		Total	5195	4	4*	100% 5191/5191	
Patients	#3	Serum	351	1	1	99.72% 350/351	98.42 - 100%

* Repeat Reactive samples found positive with other CE mark EIA Syphilis assay were excluded from the diagnostic specificity calculation.

9.2.2. Diagnostic Sensitivity

Retrospective study:

The study was done on 350 frozen samples of which 2 samples were declared negative and 348 confirmed positive with the CE mark Syphilis assays.

Among these 348 positive samples, 7 samples were from patients at early stage of the infection.

All the 348 samples were found positive with Bio-Rad Syphilis Total Ab assay.

Prospective study:

A total of 460 fresh samples was evaluated with Bio-Rad Syphilis Total Ab assay and compared to CE mark Syphilis tests.

348 were found negative with both Bio-Rad and reference tests (*with two samples qualified as false positive with reference EIA test*)

109 were found positive with both assay tests.

3 samples were showing discrepant results (after retest with Bio-Rad assay):

- 1 sample positive with the Bio-Rad Assay and high negative with the reference tests. This sample with low syphilis rate was at the limit cut-off value for both EIA tests;
- 1 sample positive with the reference tests, negative with the Bio-Rad assay (from 1 patient without sign)
- 1 sample positive with the reference tests, negative IR and positive in re-test with Bio-Rad assay,

Retrospective and Prospective studies:

The global diagnostic sensitivity is equal to 99.56% (457/459) with a confidence interval at 95% of [98.44% - 99.95%].

Clinical sensitivity:

The clinical sensitivity was also studied on 3 commercial panels and 1 seroconversion panel. The Bio-Rad Syphilis Total Ab assay was compared to a CE-marked syphilis assay. The detection of each specimen of the panels is equivalent between Bio-Rad assay and the syphilis reference assay.

9.3. Analytical Sensitivity

The analytical sensitivity has been evaluated on 2 NIBSC Standards, and calculated at the cut-off value using a regression:

1. The limit of detection for IgG / IgM was evaluated on 3 lots of Syphilis Total Ab assay and estimated at **0.53 mIU/ml** with CI 95% [0.10 mIU/ml – 1.30 mIU/ml] using the WHO Standard IgM/IgG (NIBSC code: 05/132).
2. The limit of detection for IgG was evaluated on 1 lot of Syphilis Total Ab Assay and estimated at **0.11 mIU/ml** with CI 95% [0.02 mIU/ml – 0.27 mIU/ml] using the WHO Standard IgG (NIBSC code: 05/122).

9.4. Analytical Specificity/Cross Reactivity Study

A total of 125 potentially interfering samples containing antibodies against pathogens that could lead to infectious illnesses (Lyme, Toxoplasmosis, EBV, Leptospirosis, SLE (lupus), Hepatitis A Antibody, Hepatitis B Antibody, Hepatitis C Antibody, HTLV I/II, and HIV), samples from patients at-risk group (pregnant women, and multiparous women) or samples from patients with immune system disorders (rheumatoid factors) was tested with the Syphilis Total Ab assay.

Among the 125 samples tested, 1 specimen was found positive repeatable with Syphilis Total Ab assay; this sample was verified true positive with other CE Syphilis EIA and confirmatory assays.

The specificity observed on this target population is equal to 100% (124/124) with a 95% confidence interval of [97.1% - 100.0%].

9.5. Hook Effect

The existence of a possible hook effect was studied by testing 6 Syphilis positive samples with high titers at different dilutions. The equivalence of results observed among non-diluted and diluted samples indicates the absence of the hook effect on the samples tested.

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- (NO)** • Dette produktet inneholder humane eller animalske komponenter. Håndteres med forsiktighet.
- (PL)** • Niniejszy produkt zawiera składniki pochodzenia ludzkiego lub zwierzęcego. Należy obchodzić się z nim ostrożnie.
- (PT)** • Este medicamento contém componentes de origem humana ou animal. Manuseie com cuidado.
- (RO)** • Acest produs conține materiale de origine umană sau animală. Manevați-l cu grijă.
- (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: Промийте 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 замърсено 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/ ochranné oční čočky štít. PŘI ZASAŽENÍ OČÍ: Několik minut opatrně vyplachujte vodou. Vyměňte kontaktní čočky, jsou-li nasazeny a pokud je lze vymout snadno. Pokračujte ve vyplachování. PŘI POŽITÍ: Vypláchněte ústa. NEVYVOLÁVEJTE zvracení. PŘI STYKU S KŮŽÍ (nebo s vlasy): Veškeré kontaminované části oděvu okamžitě svlékněte. Opláchněte kůži vodou/ osprchuje. Při podráždění kůže nebo vyrážce: Vyhleďte 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/øjenskyttelse/ 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):

Tilsmudset 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)

Ettevaatus

Põhjustab rasket nahasöövitust 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 korra. 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: pöörduda arsti poole. Sisu/konteineri käitlets vastavuses kohalike/regionaalsete/rahvuslike/rahvasvaheliste 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.

Llevar 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): Quitar 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: Huuhto huolellisesti vedellä usean minuutin ajan. Poista piilolinssit, _edical voi tehdä helposti. Jatka huuhtomista. JOS KEMIKAALIA ON NIELTY: Huuhto suu. Ei saa oksennuttaa. JOS KEMIKAALIA JOUTUU IHOLLE (tai hiuksiin): Riisu saastunut vaatetus välittömästi. Huuhto/suihkuta iho vedellä. Jos ilmenee ihoärsytystä 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/récipient 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 ξεπλύνετε. 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/στο ντους. Εάν παρατηρηθεί ερεθισμός του δέρματος ή εμφανιστεί εξάνθημα: Συμβουλευθείτε/Επισκεφθείτε/επιγράψτε. Απορρίψτε τα περιεχόμενα/δοχεία σύμφωνα με τους τοπικούς/εθνικούς/διεθνείς κανονισμούς.

(HR)

Ppasnost

Uzrokuje teške opекline kože i ozljede oka. Može izazvati alergijsku reakciju na koži.

Nositi zaštitne rukavice/zaštitnu odijelo/zaštitu za oči/zaštitu za lice. U SLUČAJU DODIRA S OČIMA: oprezno ispirati vodom nekoliko minuta. Ukloniti kontaktne leće ukoliko ih nosite i ako se one lako uklanjaju. Nastaviti ispiranje. AKO SE PROGUTA: ispirati usta. NE izazivati povraćanje. U SLUČAJU DODIRA S KOŽOM (ili kosom): odmah ukloniti/skinuti svu zaganenu odjeću. Ispirati kožu vodom/tuširanjem. U slučaju nadražaja ili ospa na koži: zatražiti savjet/pomoć liječnika. Odložite sadržaje /spremnike u skladu s lokalnim/regionalnim/nacionalni/ međunarodnim odredbama.

(HU)

Veszély

Smárkiai nudegina odą ir pažeidžia akis. Allergiás bõrreakcióit válthat ki.

Védõkesztyû/védõruha/szemvédõ/arcvédõ használatra kötelezõ. SZEMBE KERÛLÉS esetén: Több percig tartó óvatos öblítés vízzel. Adott esetben a kontaktlencsék eltávolítása, ha könnyen megoldható. Az öblítés folytatása. LENYELÉS ESETÉN: a szájat ki kell öblíteni. TILOS hánytatni. HA BÕRRE (vagy hajra) KERÛL: Az összes 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. Smaltire il prodotto/recipiente in conformità con le disposizioni locali / regionali / nazionali / internazionali.

(LT)

Pavojinga

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

Mûvėti apsauginis pirštines/dėvėti apsauginius drabužius/ naudoti akių (veido) apsaugos priemones. PATEKUS Į AKIS: Kelias minutes atargiai 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 plauku): Nedelsiant nuvilkti/pašalinti visus užterštus drabužius. Odą nuplauti vandeniu/čiurkšle. Jeigu sudirginama oda arba ja išberia: kreiptis į gydytoją. Turinį/talpą išpilti (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/gelatsbescherming 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 ØYNENE: 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 tilsolte 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:
Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki
kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
W PRZYPADKU PÓLKNIĘCIA: 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:
Zasiegnąć porady/zgłosić się pod opiekę lekarza. Zawartość
/ pojemnik usuwać 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 vómito. 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/îmbrăcămintele 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 îmbrăcămintea 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
munnan. 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 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 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 s lokalnimi/regionalnimi/narodnimi/mednarodnimi
predpisi.

(SK)

Nebezpečnostvo

Provocáa arsuri grave ale pielii și lezarea ochilor. Může vyvolat
alergickú kožnú reakciu.
Noste ochranné rukavice/ochranný odev/ochranné okuliare/
ochranu tváre. PO POŽITÍ: vypláchnite ústa. Nevyvolávejte
zvracanie. PO POŽITÍ: vypláchnite ústa. Nevyvolávejte
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 vytvorí vyrážky: vyhľadajte
lekársku pomoc/starostlivosť. Zneškodnenie obsahu/obalu v
súlade s miestnymi/oblastnými/ národnými/medzinárodnými
nariadeniami.

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