**Instructions for use BIOSAVE® ANTIBODY Assay** CE

Detection of ANTIBODIES by LATEX AGGLUTINATION

Total assay time: 2 to max. 10 min

**INTENDED USE**
The Biosave® Antibody assay is a latex agglutination test for the rapid, qualitative up to semi-quantitative determination of antibodies in human or animal serum. The Biosave® Antibody assay is determined for in vitro diagnostic use only.

**PRINCIPLE OF THE ASSAY**
The test is based on the method of latex agglutination (indirect agglutination). The latex particles, which have been coated with antigen, are provided as a stabilized suspension. Patient serum and latex reagent are placed within the application sites on the agglutination plate. Both liquids are mixed gently. Any agglutinating antibodies to antigens on the latex particles present in the sample will bind and cause visible agglutination reactions after 2 up max. 10 minutes. If there are no antibodies to antigens on the latex particles present in the investigated patient specimen, no agglutination can be observed and the reaction mixture remains turbid.

**LIMITATIONS OF THE PROCEDURE**
Biosave® Latex Agglutination Assays are tests for the qualitative detection of agglutinating antibodies to the respective antigen. Differentiation of antibody classes (e.g. IgG) is impossible with this method. For additional class-specific or quantitative determinations the Bios® assays of the product lines Biognost® (IFA) and Biolisa® (ELISA) are suitable.
Clinical interpretations should not only be based on the results of one assay. In any case, results should always be interpreted in the context of the general clinical picture, the timing of specimen collection and other laboratory findings. To confirm negative and equivocal test results or to detect seroconversion, it may be recommended to repeat the assay within 10-14 days using a fresh serum specimen.

**BIOSAVE® REAGENTS**
Biosave® Assays are available as test kit or test set.
Test kits contain latex reagent, positive control, negative control, 1 agglutination plate, plastic applicator sticks and Biosave® instruction for use. Test sets contain the same reagents as test kits except the agglutination plate. All reagents are also available separately.
Latex reagent: stabilized suspension of latex particles coated with antigen, ready to use, in a dropper vial.
Positive control: stabilized human serum containing agglutinating antibodies to the respective antigen, ready to use.
Negative control: stabilized human serum negative for agglutinating antibodies, ready to use.
Agglutination plate: 12 application sites (reusable after cleaning, therefore the cheaper sets can be offered).

**MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED**
Pipettes to deliver serum samples and controls
Mechanical plate shaker (optional)
Timer
High intensity incandescent lamp (optional)

**STORAGE AND STABILITY**
Store Biosave® latex reagent and Biosave® controls at the temperature specified on the label. The **unopened** reagents are stable up to the expiry date indicated on the label if the recommendations are strictly followed. Do not use any of these reagents after they have expired. After first use the reagents have to be well closed and stored at the temperature specified on the label. These reagents must be consumed as soon as possible. Stability on reuse does not necessarily correlate with expiry date.
Caution: Do not freeze the latex reagent, otherwise irreversible clotting of the latex particles will occur!
The agglutination plate and the plastic applicator sticks may also be stored indefinitely at room temperature. These items are nevertheless issued with an expiry date that appears on the product label. It serves no other purpose but to allow easy stock control.

**SAFETY PRECAUTIONS**
1. All kits and assay reagents are for in vitro diagnostic use only.
2. All human sera used in the manufacture of the preparations from human sera (controls) must be considered potentially infectious and handled with appropriate care.
3. Controls and latex reagent contain 0.09% sodium azide as preservative. Sodium azide is poisonous. Don't swallow and avoid any contact with skin and mucous membranes. Azide containing reagents must not be brought into contact with any copper or lead containing objects, for example certain drain pipes, as this could lead to formation of explosive metal azides.
4. The safety regulations of trade associations and of the respective institute (laboratory) should be strictly followed (see notices, laboratory guidlines, safety instructions etc.).
5. Actual Good Laboratory Practice rules (GLP guide lines) should always be followed.
6. Materials and reagents used in the test must be disposed off in compliance with the applicable legal regulations and the workplace has to be disinfected.

**MATERIAL FOR TESTING**
Serum and plasma from humans or animals are both suitable for testing. Serum and plasma samples are stable for about 1 week if held at 5-10°C. If storage or repeated testing of samples is required for longer periods, samples should be subdivided into small portions (50 µl), snap-frozen in liquid nitrogen and stored at or below -20°C. Larger volumes of serum or plasma should not be exposed to repeated freeze-thaw cycles because this can cause aggregation of proteins and degradation of some serum and plasma components. Serum and plasma samples also may be stabilized with 0.09% azide provided this does not interfere with the assay (azide would interfere e.g. with peroxidase-based ELISAs). Such samples can be stored for prolonged periods (up to 1 year) at 5-10°C without loss of analyte.

**QUALITY CONTROL AND TROUBLE SHOOTING**
Both a positive and a negative control should be included with each run. Each control must demonstrate expected reactions in order to validate the test. Do not use clumped latex reagent (expired, freezed). Reused agglutination plates have to be without residues and fluffs.

**ASSAY PROCEDURE**
Before starting the assay, allow the Biosave® Latex reagent and Biosave® controls to equilibrate to room temperature. This takes about 5 minutes. Please protect all reagents from sunlight and keep away from heaters. The reagents and sera are used undiluted. Agitate the latex reagent gently before use.
1. Apply 25 µl of the positive, the negative control and of each undiluted patient serum to separate application sites of the test plate.
2. Add one drop of latex reagent to each well and immediately
3. thoroughly mix the contents in each well, using a separate applicator stick for each application site.
4. Agitate the test plate gently at room temperature (either by hand or using a mechanical plate shaker).


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5. Evaluate the test after about 2 minutes. It is recommended to observe the test wells for agglutination using a high intensity incandescent lamp. A positive reaction mostly can be observed within 2 minutes. Depending on room temperature agglutination can last longer. Reading has to be done within 10 minutes, otherwise incorrect results may occur due to drying
6. Restore the latex reagent and the positive and negative control at 5-10° C immediately after use.
7. Cleaning of the agglutination plate before reuse: First, disinfect and clean the agglutination plate by means of an appropriate disinfectant combined with a cleaning agent (Follow the directions for use of the manufacturer!). Then, rinse thoroughly with tap water and after that, either polish the plate with a lint-free tissue or rinse with distilled or deionized water and air-dry.

**EVALUATION AND INTERPRETATION OF RESULTS**

**Positive**:

If agglutination (clumping) of the latex particles can be observed within about 2-3 min, in Ausnahmefällen 10 min, the specimen is considered positive for antibodies to the antigen on the latex particles.

**Negative**:

A homogeneous and milky suspension with no visible clumping after 2 min of incubation is considered as negative result.

**REFERENCES**

Singer J.M., Plotz C.M.: The Latex Fixation Test. I. Application to the Serologic Diagnosis of Rheumatoid Arthritis. Am. J. Med. 21, 1956, 888-892



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