# Product information

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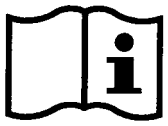

Useŕs Manual

# RF-Absorbent

For the removal of interfering factors prior to an IgM specific Immunoassay

REF IB79001

Σ 20 ml

RUO **For Research Use Only – Not for Use in Diagnostic Procedures**

**Immuno-Biological Laboratories, Inc. (IBL-America)**
8201 Central Ave NE, Suite P, Minneapolis, MN 55432
Toll Free: (888) 523-1246 Fax: (763) 780-2988
www.ibl-america.com / info@ibl-america.com

Version 4a
DMC
Updated 180410

**CONTENTS**





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## 1. INTENDED USE

The RF Absorbent method provides a fast and easy method as a treatment of human serum and plasma for the removal of interfering factors (rheumatoid factor and IgG antibodies) before or after the determination of IgM specific antibodies using an EIA. **For research use only – Not for use in diagnostic procedures.**

## 2. GENERAL INFORMATION

The detection of specific IgM antibodies is one possibility for a fast serological diagnosis. A potential interference may be the presence of rheumatoid factors that react with antigen bound IgG and cause false-positive results. There are further interfering factors as high levels of IgG antibodies (maternal antibodies in newborns). However, these factors hardly play an important role in practice.

## 3. PRINCIPLE OF THE TEST

The RF Absorbent reagent is based on an anti-IgG antibody. By pre-treatment of the sample serum with this reagent IgG antibodies are absorbed, so that they are no longer available for rheumatoid factors, and no immune complex can be built.

## 4. LIMITATIONS, PRECAUTIONS AND GENERAL COMMENTS

- Only for research use! Do not ingest or swallow! The usual laboratory safety precautions as well as the prohibition of eating, drinking and smoking in the lab have to be followed.
- All sera and plasma or buffers based upon, have been tested respective to HBsAg, HIV and HCV with recognized methods and were found negative. Nevertheless precautions like the use of latex gloves have to be taken.
- Serum and reagent spills have to be wiped off with a disinfecting solution (e.g. sodium hypochlorite, 5%) and have to be disposed of properly.
- All reagents have to be brought to room temperature (18 to 25 °C) before performing the test.
- Before pipetting all reagents should be mixed thoroughly by gentle tilting or swinging. Vigorous shaking with formation of foam should be avoided.
- It is important to pipet with constant intervals, so that all the wells of the microtiter plate have the same conditions.
- When removing reagents out of the bottles, care has to be taken that the stoppers are not contaminated. Further a possible mix-up has to be avoided. The content of the bottles is usually sensitive to oxidation, so that they should be opened only for a short time.
- In order to avoid a carry-over or a cross-contamination, separate disposable pipet tips have to be used.
- No reagents from different kit lots have to be used, they should not be mixed among one another.
- All reagents have to be used within the expiry period.
- In accordance with a Good Laboratory Practice (GLP) or following ISO9001 all laboratory devices employed should be regularly checked regarding the accuracy and precision. This refers amongst others to microliter pipets and washing or reading (ELISA-Reader) instrumentation.
- The contact of certain reagents, above all the stopping solution and the substrate with skin, eye and mucosa has to be avoided, because possible irritations and acid burns could arise, and there exists a danger of intoxication.

## 5. REAGENTS PROVIDED

The RF Absorbent reagent is sufficient for the pre-treatment (absorption) of 50 sample sera. The storage has to be at 2-8°C. The expiry date is printed on the label.

### 5.1. RF Absorbent Reagent

**IgG-RF** **SORB** 20 mL, anti-IgG (goat). Addition of < 0.1 % sodium azide for preservation, ready-to-use.

## 6. MATERIALS REQUIRED BUT NOT PROVIDED

- 20 µL- and 100 µL micropipets
- Test tubes for the pretreatment

## 7. SAMPLE COLLECTION AND HANDLING

Principally serum or plasma (EDTA, heparin) can be used for the determination. Serum is separated from the blood, which is aseptically drawn by venipuncture, after clotting and centrifugation. The serum or plasma samples can be stored refrigerated (2-8°C) for up to 48 hours, for a longer storage they should be kept at -20 °C. The samples should not be frozen and thawed repeatedly. Lipemic, hemolytic or bacterially contaminated samples can cause false positive or false negative results.
For the performance of the test the samples (not the standards) have to be diluted 1:101 with ready-to-use sample diluent (e.g. 5 µL serum + 500 µL sample diluent).

## 8. ASSAY PROCEDURE

### 8.1. Preparation of Reagents

**RF Absorbent:** Bring to room temperature and mix thoroughly prior to use.

### 8.2. Assay Steps

1. Add 20 µL RF Absorbent to 400 µL of the 1:100 diluted serum or plasma sample and mix thoroughly.
2. Incubate for at least 5 minutes (<15 minutes) at room temperature. A turbidity may form, which has no influence on the test result.
3. Pipet the prepared sample in the IgM test according to the test instruction.

## 9. EVALUATION

As outlined in the test instruction of the ELISA test kit.

## 10. CHARACTERISTICS

**Intra-Assay Variation:**
The mean intra-assay coefficient of variation of samples treated with RF Absorbent was determined for four different infectious diseases test kits by a 20fold measurement to 9.4%

**Inter-Lot Variation:**
The mean inter-lot coefficient of variation of samples treated with RF Absorbent was determined for four different kit lots of four different infectious diseases test kits to 9.5%

**Performance:**
The determination of 5 RF positive samples had a negative result in four different infectious diseases test kits after treatment with RF Absorbent.

**Interferences:**
No interferences to bilirubin up to 0.3 mg/mL, haemoglobin up to 8.0 mg/mL and triglycerides up to 5.0 mg/mL.

**Stability:**
Real-time stability tests showed an efficient performance of the RF Absorbent after more than 12 months.

**Manufactured for:**
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## SYMBOLS USED WITH IBL-AMERICA ASSAYS

| Symbol | English | Deutsch | Francais | Espanol | Italiano |
|---|---|---|---|---|---|
| CE | European Conformity | CE-Konfirmitäts-kennzeichnung | Conforme aux normes européennes | Conformidad europea | Conformità europea |
|  | Consult instructions for use | Gebrauchsanweisung beachten | Consulter les instructions d'utilisation | Consulte las Instrucciones | Consultare le istruzioni per l'uso |
| IVD | In vitro diagnostic device | In-vitro-Diagnostikum | Ussage Diagnostic in vitro | Diagnóstico in vitro | Per uso Diagnostica in vitro |
| RUO | For research use only | Nur für Forschungszwecke | Seulement dans le cadre de recherches | Sólo para uso en investigación | Solo a scopo di ricerca |
| REF | Catalogue number | Katalog-Nr. | Référence | Número de catálogo | No. di Cat. |
| LOT | Lot. No. / Batch code | Chargen-Nr. | No. de lot | Número de lote | Lotto no |
|  | Contains sufficient for <n> tests/ | Ausreichend für "n" Ansätze | Contenu suffisant pour "n" tests | Contenido suficiente para <n> ensayos | Contenuto sufficiente per "n" saggi |
|  | Note warnings and precautions | Warnhinweise und Vorsichtsmaßnahmen beachten | Avertissements et mesures de précaution font attention | Tiene en cuenta advertencias y precauciones | Annoti avvisi e le precauzioni |
|  | Storage Temperature | Lagerungstemperatur | Temperature de conservation | Temperatura de conservacion | Temperatura di conservazione |
|  | Expiration Date | Mindesthaltbarkeits-datum | Date limite d'utilisation | Fecha de caducidad | Data di scadenza |
|  | Legal Manufacturer | Hersteller | Fabricant | Fabricante | Fabbricante |
| *Distributed by* | Distributor | Vertreiber | Distributeur | Distribuidor | Distributtore |