

**For professional use only**



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# Axis-Shield RPR

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## 1 Product details

Manufacturer:	Axis-Shield Diagnostics Ltd. The Technology Park, Dundee DD2 1XA, UK
Intended use:	<i>In vitro</i> diagnostic medical device. Axis-Shield RPR is a slide flocculation test for the qualitative and semi-quantitative determination of antibodies to VDRL Antigen (a presumptive diagnosis for syphilis) in human serum or plasma. Axis-Shield RPR can be used: <ul style="list-style-type: none"><li>• for the screening of donated blood;</li><li>• for the rapid screening of patients suspected of having syphilis;</li><li>• to monitor the immunological response to treatment;</li><li>• for use in programs for the screening of healthy individuals or population groups.</li></ul>
Intended user:	Skilled professionals (within the intended use environment) are intended to use this product in accordance with local legislation.
Use by:	See labels for the expiry date of individual kit components (date = YYYY-MM-DD).
Storage:	Store between +2 and +8°C.
Special precautions:	This kit contains substances of both human and animal origin. All such materials should be handled with caution and treated as being potentially infectious.

For technical assistance or additional product information, contact your local Axis-Shield Diagnostics representative.

## 2 Introduction




Serologic tests are important as an aid in the clinical diagnosis of syphilis. Individuals infected with the spirochete *Treponema pallidum* (*T. pallidum*) produce a number of different antibodies. Syphilitic infection caused by *Treponema pallidum* leads to the appearance of antibodies called reagins. The detection of reagin has been the basis for the development of a reagent utilising extracts of various tissue components namely cardiolipin, lecithin and cholesterol. This is the classic VDRL Antigen. The antigen used in this kit is a modification of VDRL Antigen that contains microparticulate carbon, which enhances the visual difference between a positive and a negative result. When these

antibodies are detected in serum or plasma it is a presumptive diagnosis for syphilis.

### 3 Principle of the procedure

Axis-Shield RPR is a macroscopic non-treponemal flocculation test and it is used to detect reagin. When a drop of positive serum and reagent are mixed on a test slide, black flocculants are formed which are visible macroscopically due to the presence of the carbon particles. When reagin antibody is not present, flocculation does not occur and the appearance is that of an even grey colour.

### 4 Contents of the kit

	Component Description			
5 x 2 mL	<b>AG   SUSP</b>	<b>Antigen Suspension</b> Modified VDRL antigen Preservative: Sodium azide 1 mg/mL. Ready to use as supplied.	Xn 	R22 S23 S29/35 S36/37/39
2 x 1 mL	<b>CONTROL   -</b>	<b>Negative Control</b> Human serum. Preservative: Sodium azide 1 mg/mL. Ready to use as supplied.	Xn 	R22 S23 S29/35 S36/37/39
2 x 1 mL	<b>CONTROL   +</b>	<b>Positive Control</b> Diluted human serum reactive for anti- <i>T.pallidum</i> . Preservatives: Sodium azide 1 mg/mL. Ready to use as supplied.	Xn 	R22 S23 S29/35 S36/37/39
50 x		<b>Disposable test cards</b> Each card contains 10 test circles		
500 x		<b>Disposable plastic pipettes</b>		
2 x		<b>Suction caps</b> for pipettes		
500 x		<b>Disposable plastic spatulas</b>		
1 x		<b>Plastic dispensing bottles</b>		
1 x		<b>Dispensing needles</b>		

### 5 Additional equipment required

Platform mixer, capable of operating at 100 rpm.

### 6 Type of specimens, handling and storage

#### **Specimen collection**

Human serum or plasma may be used. No special preparation or fasting of the patient is necessary. Blood should be collected by normal venipuncture technique and handled with the proper precautions e.g. according to the NCCLS. H3-A5\*, and OSH-A FDA 29CFR 1910.1030\*\*. Care should be taken to allow serum samples to clot completely.

Plasma samples using heparin or EDTA as anticoagulants may be used. The use of other anticoagulants may affect the outcome of the assay.

\* NCCLS. H3-A5, Procedures for the Collection of Diagnostic Blood Specimen by Venipuncture; Approved Standard [ISBN 1-56238-350-7].

\*\* OSH-A FDA 29CFR: Blood borne pathogens. 1910.1030 Occupational Safety and Standards.

#### **Specimen handling and storage**

Fresh specimens may be stored for up to one week at 2 to 8°C if free of microbial contamination. If longer storage is required, specimens should be stored frozen at -20°C or below. Conditions that favor microbial growth should be avoided. The quality of the specimens can be seriously affected by

microbial growth, which may lead to erroneous results.

Specimens should be equilibrated to room temperature (15 to 30°C) before testing begins.

Storage of specimens in self-defrosting freezers is not recommended.

## 7 Personal safety

**Caution:** Handle Axis-Shield RPR with care; potentially infectious material. This product includes materials prepared from human serum or plasma that has been tested and found to be non reactive for antibody to HIV-1 and HIV-2, HIV-1 RNA or HIV-1 Ag, antibody to hepatitis C virus (HCV) as well as for hepatitis B surface antigen (HBsAg). However, as it is not possible to offer complete assurance that infectious agents are not present, all materials of human origin should be handled as though they might contain potentially infectious agents.

The Antigen suspension and the controls contain sodium azide as a preservative.

**R22:** Harmful if swallowed.

**S23:** Do not breathe fumes.

**S29/35:** Do not empty into drains; this material and its container must be disposed of in a safe way.

**S36/37/39:** Wear suitable protective clothing, gloves and eye/face protection.

Use disposable gloves and handle all materials used in the assay including samples, waste solution, reaction trays and pipettes, cautiously as though capable of transmitting infectious agents e.g. according to NCCLS M29-A3. Consult a physician immediately in the event that contaminated materials are ingested or come in contact with open lacerations, lesions, or other breaks in the skin.

\* NCCLS M29-A3 Protection of Laboratory Workers from Occupationally Acquired infections

(Third edition, approved guideline).

### ***Cleaning & decontamination***

Spills of potentially infectious material should be cleaned up immediately; e.g. with absorbent paper tissue and the contaminated area should be decontaminated with, for example, 0.5% freshly prepared sodium hypochlorite - (1:10) dilution of 5% sodium hypochlorite (household bleach) before work continues.

**Sodium hypochlorite should not be used on acid-containing spill unless the spill-area is first wiped dry.**

Materials used to clean spills, including gloves, should be disposed of as potentially biohazardous waste e.g. in a biohazard waste container.

### ***Disposal & destruction***

Disinfect and/or autoclave the solutions or wastes containing biological samples before disposing of them according to local regulations.

Samples and reagents of human origin, as well as contaminated materials, disposables, neutralized acids and other waste materials must be decontaminated before disposal, either by:

- by immersion in a freshly prepared 0.5% of sodium hypochlorite for 30 minutes (1 volume of 5% sodium hypochlorite for 10 volumes of contaminated fluid or water). **Neutralize (chemically) liquid wastes that contain acid before adding sodium hypochlorite**
- or by autoclaving at 121°C for 60 minutes.

Autoclaving is the best method to inactivate HIV and HBV.

**Do not autoclave materials or solutions containing sodium hypochlorite.**

Chemicals should be handled in accordance with Good Laboratory Practice and disposed of according to local instructions.

## 8 Reagent preparation

Prepare the following reagent before starting the assay procedure. Reagents and samples should be equilibrated to room temperature (15 to 30°C) before beginning the assay and can remain at room temperature during testing. Store reagents at 2 to 8°C when not in use.

### ***Antigen suspension***

The Antigen suspension is ready to use. Ensure that the suspension is allowed to reach room temperature and is shaken well before use. Remove the cap from the plastic dispensing bottle and attach a dispensing needle via the luerlock plug. Then transfer the Antigen Suspension to the dispensing bottle by squeezing the plastic dispensing bottle and inserting the tip of the needle into the Antigen suspension. Allow the plastic bottle to expand. This will then suck up the Antigen suspension. After each day of testing return any unused Antigen suspension into the original glass vial.

Rinse the plastic bottle and needle with distilled water and air dry.

## **9 Storage conditions and stability of reagents**

The kit is stable until the date given on the pack when stored between 2 and 8°C.

Do not freeze the Antigen Suspension.

Do not store the Antigen Suspension in the plastic dispensing bottle, as this will reduce the shelf life of the product.

After opening the test pack, store the test cards at ambient temperature. Do not place in the refrigerator.

Store unopened components at 2 to 8°C.

**Note:** Components, either unopened or opened, may not be used after the expiry date printed on the label of each component.

## **10 Procedural precautions**

Check all packaging before using the kit. Damage to the outer packaging does not prevent the contents of the kit from being used. However, if the packaging is damaged the user must check that components of the kit are intact before using them.

Do not mix different lot numbers.

Alterations in the physical appearance of assay kit materials may indicate instability or deterioration.

All reagents must be mixed well before use.

Avoid microbial or any other contamination of reagents.

## **11 Assay procedure**

### ***Qualitative test***

- 1 Use a new pipette for each sample. It is important to maintain the pipette in a vertical position to ensure an accurate drop is dispensed.
- 2 With an assembled pipette and suction cap, take up sufficient sample and transfer one free-falling drop onto a circle on the test card.
- 3 Using a spatula spread the sample over the entire area of the test circle.
- 4 Ensure that the Antigen Suspension is homogeneous by gently shaking the plastic dispensing bottle (+ needle) containing the Antigen Solution.
- 5 Hold the bottle in a vertical position and dispense one free-falling drop to the same test circle. **Do not stir.**
- 6 Immediately place the card on a platform mixer and rotate the card at 100 rpm.
- 7 Read results after 8 minutes.

### ***Semi-quantitative test***

To perform a semi-quantitative test, prepare a serial dilution of the sample in physiological saline and test each dilution as described for the qualitative test.

### ***Quality Control (optional)***

Negative Control and Positive Control reagents can be used for quality control purposes. Use controls (instead of samples) and follow the procedure described above for the qualitative test.

## 12 Results

### **Qualitative test**

Read the results immediately after the 8 minutes rotation. Read with the naked eye, preferably in good daylight.

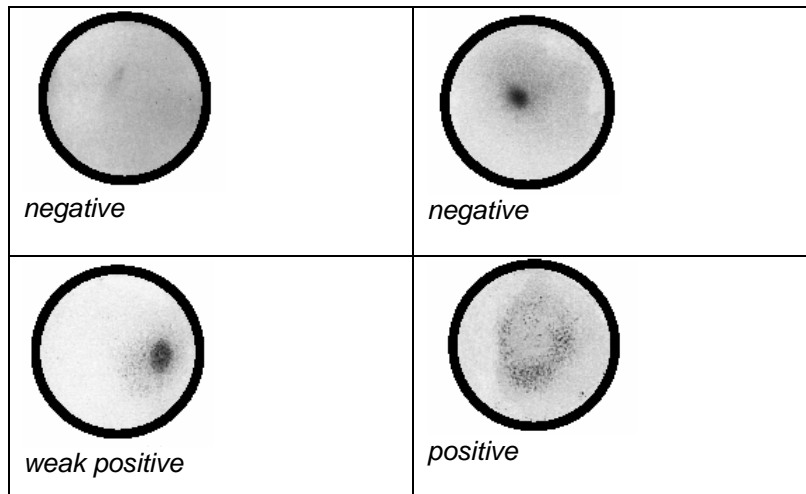
A **negative** reaction will appear as a concentration of smooth carbon in the center of the circle or as a smooth, even gray suspension throughout the test circle.

A **weak positive** reaction is characterized by a concentration of fine black aggregates surrounded by a diffuse area of fine black aggregates.

A **positive** reaction is the production of black aggregates most commonly observed throughout the test circle.

### **Semi-quantitative test**

The last circle in the dilution series that contains any black aggregates gives the titre of the sample.



### **Interpretation of results**

A nonreactive result indicates that the sample tested either does not contain antibodies against VDRL antigen or that it contains antibodies against VDRL antigen at concentrations below the detectable limits of Axis-Shield RPR.

A reactive result indicates that the sample tested either contains anti-VDRL or contains a nonspecifically reacting factor. Specimens that initially show a reactive result may be retested. If the specimen is reactive after retest, a specimen is considered positive for anti-VDRL, which is a presumptive diagnosis for syphilis.

## 13 Limitations of the assay

Occasionally biologically false positive reactions (BFP's) can occur with Axis-Shield RPR, as with all other reagin tests. These results can be caused by a variety of diseases including infectious mononucleosis, leprosy, lupus erythematosus, malaria, vaccinia and viral pneumonia.

For confirmation a treponemal test such as Trepanostika TP recombinant, FTA-ABS or TPHA, should be performed on all positive reagin tests.

Cases of zone phenomena have been observed. Consequently, a negative qualitative test for a patient strongly suspected of having syphilis must be confirmed by a quantitative test, in order to eliminate the possibility of a zone phenomenon.



*In Vitro* Diagnostic Medical



Catalogue number



Lot



500 tests



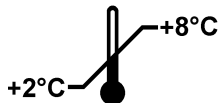
Caution



See instructions for use



Use



Store at 2-8°C



Positive Control



Negative Control



Antigen Suspension



Manufactured by



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