

Design Output

SYPHILIS RPR TEST

CONTENTS

1	Product Design	2
1.1	Area of Applicability.....	2
1.2	Test Format.....	2
1.3	Physical and Chemical Properties.....	3
1.4	Storage.....	3
1.5	Stability.....	3
2	Product and Quality Specifications	3
2.1	Description of Test Methods.....	3
2.2	QC Specifications / COA.....	4

1 Product Design

1.1 Area of Applicability

SYPHILIS RPR TEST (RPR = Rapid Plasma Reagin) has been designed as a flocculation test for the detection of reagin antibodies which serve as a presumptive diagnosis of syphilis. Results are obtained by comparison with a negative and a positive control.

1.2 Test Format

SYPHILIS RPR TEST consists of 3 components, including a cardiolipin suspension which also contains enhancing microparticulate charcoal, a positive control serum and a negative control serum as well as accessories for convenient handling. Test formats correspond with the respective customer needs. For OEM customers the reagents may also be delivered in bulk and neutral unlabeled vials

REF	RPR Antigen Suspension	Positive Control	Negative Control	Accessories
50001	1 x 2.0 ml, filled into transparent plastic vial, closed with white screw cap, labelled	1 x 0.5 ml, filled into transparent plastic dropper vial with red cap, labelled	1 x 1.0 ml, filled into transparent plastic dropper vial with green cap, labelled	10 test cards with 10 cells, 100 disposable dispenser, 1 dispensing needle
50002	5 x 2.0 ml, filled into transparent plastic vial, closed with white screw cap, labelled	1 x 1.0 ml, filled into transparent plastic dropper vial with red cap, labelled	1 x 1.0 ml, filled into transparent plastic dropper vial with green cap, labelled	50 test cards with 10 cells, 500 disposable dispenser, 1 dispensing needle
50016	5 x 2.0 ml, filled into transparent plastic vial, closed with white screw cap, labelled	1 x 1.0 ml, filled into transparent plastic dropper vial with red cap, labelled	1 x 1.0 ml, filled into transparent plastic dropper vial with green cap, labelled	10 test cards with 10 cells, 1 dispensing needle
50001N	1 x 2.0 ml, filled into transparent plastic vial, closed with white screw cap, unlabelled	1 x 0.5 ml, filled into transparent plastic dropper vial with red cap, unlabelled	1 x 1.0 ml, filled into transparent plastic dropper vial with green cap, unlabelled	10 test cards with 10 cells, 100 disposable dispenser, 1 dispensing needle
50002N	5 x 2.0 ml, filled into transparent plastic vial, closed with white screw cap, unlabelled	1 x 1.0 ml, filled into transparent plastic dropper vial with red cap, unlabelled	1 x 1.0 ml, filled into transparent plastic dropper vial with green cap, unlabelled	50 test cards with 10 cells, 500 disposable dispenser, 1 dispensing needle
50016N	5 x 2.0 ml, filled into transparent plastic vial, closed with white screw cap, unlabelled	1 x 1.0 ml, filled into transparent plastic dropper vial with red cap, unlabelled	1 x 1.0 ml, filled into transparent plastic dropper vial with green cap, unlabelled	10 test cards with 10 cells, 1 dispensing needle
50001B/1	Bulk delivery, filled into appropriate plastic container, closed with screw cap			
50001B/2		Bulk delivery, filled into appropriate plastic container, closed with screw cap		
50001B/3			Bulk delivery, filled into appropriate plastic container, closed with screw cap	

1.3 Physical and Chemical Properties

1.3.1 RPR Antigen Suspension

Aggregate state	liquid
Density	Approx. 1 g/ml
Appearance	Black particle suspension in clear liquid
Smell	May have fish odour
pH	6.8-7.3
Particle size	4µm
Chemical constituents	Carbon particles 0.375g/L, Cardiolipin 0.003%, Lecithin 0.02%, Cholesterol 0.09% working strength, Sodium azide 0.095%.

1.3.2 Control serum positive

Aggregate state	liquid
Density	similar to water
Appearance	slightly yellowish
Smell	none
pH	neutral, approx. pH 7.2
Chemical constituents	human serum, adjusted to produce positive results with the test, 0.95g/l sodium azide, 2.00g/l Proclin950

1.3.3 Control serum negative

Aggregate state	liquid
Density	similar to water
Appearance	slightly yellowish
Smell	none
pH	neutral, pH 7.2
Chemical constituents	serum matrix, non-reactive with RPR Antigen Suspension, 0.95g/l sodium azide

1.3.4 Classification und Dangerous Goods Aspects

All materials of human origin have been tested at the source and found non-reactive for HBsAg, HCV- and HIV-antibodies using approved methods. However, originating from human blood the standard should be treated as potentially infectious material.

The classifications as hazardous substances are shown in the Safety Data Sheet of the respective article in Chapter 2. The requirements for transport as dangerous goods are mentioned in the Safety Data Sheet of the respective article in Chapter 14.

1.4 Storage

All kit components have to be stored at 2-8°C. Freezing must be avoided.

1.5 Stability

The Syphilis RPR kits are stable up to the expiration date when sealed and stored properly. All components are stable for up to 24 months from the date of manufacture if stored at 2-8°C.

2 Product and Quality Specifications

2.1 Description of Test Methods

2.1.1 General remarks

Tests are performed by the quality control department according to written procedures. Testing equipment is checked in advance and calibrated at suitable intervals.

2.1.2 Function test

RPR antigen suspension, samples and controls are brought to room temperature. 50 µl sample or control are pipetted in the middle of separate areas of the test card. The RPR antigen suspension is thoroughly and carefully mixed, and by holding the dispensing bottle in a vertical position, 1 drop of RPR antigen suspension is dispensed onto each drop sample/control. The test card is rotated at low speed (approx. 100 rpm) for 8 minutes. After this incubation time the agglutination pattern is read under bright artificial light. The agglutination pattern is interpreted in the following way:

- a reactive result is indicated by large aggregates in the centre or the periphery of the test area;
- a weak reactive result is indicated by small aggregates, preferably occurring around the edge of the test area;
- a non-reactive (negative) result is indicated by a smooth, even appearance of the RPR antigen suspension.

2.2 QC Specifications / COA

QC specifications for product release are summarised in attached Certificate of Analysis.

CERTIFICATE OF ANALYSIS

SYPHILIS RPR TEST

Quicktest for the Qualitative and Quantitative
Determination of Reagin Antibodies in Serum or
Plasma

REF	50001
Pack. LOT	LOTNUMMER
Prod./Inv. Date:	PRODDATUM
Expiry Date:	EXPDATUM

QUALITY SPECIFICATIONS		
1. Filling Volumes: Antigen Suspension: AGS Positive Control: PC Negative Control: NC	2.0 ml 0.5 ml 1.0 ml	passed passed passed
2. Function test Function positive controls: Function negative controls:	agglutination after 2 minute no agglutination after 2 minute	passed passed

This product passed the quality control release criteria and has been released by the responsible Quality Control Department of HUMAN Gesellschaft für Biochemica und Diagnostica mbH.

Following release of the product, this certificate of analysis is electronically regenerated and valid without signature.

Date of print: 29.09.2023

CERTIFICATE OF ANALYSIS

SYPHILIS RPR TEST

Quicktest for the Qualitative and Quantitative
Determination of Reagin Antibodies in Serum or
Plasma

REF	50002
Pack. LOT	LOTNUMMER
Prod./Inv. Date:	PRODDATUM
Expiry Date:	EXPDATUM

QUALITY SPECIFICATIONS		
1. Filling Volumes: Antigen Suspension: AGS Positive Control: PC Negative Control: NC	5 x 2.0 ml 1.0 ml 1.0 ml	passed passed passed
2. Function test Function positive controls: Function negative controls:	agglutination after 2 minute no agglutination after 2 minute	passed passed

This product passed the quality control release criteria and has been released by the responsible Quality Control Department of HUMAN Gesellschaft für Biochemica und Diagnostica mbH.

Following release of the product, this certificate of analysis is electronically regenerated and valid without signature.

Date of print: 29.09.2023

CERTIFICATE OF ANALYSIS

SYPHILIS RPR TEST

Quicktest for the Qualitative and Quantitative
Determination of Reagin Antibodies in Serum or
Plasma

REF	50016
Pack. LOT	LOTNUMMER
Prod./Inv. Date:	PRODDATUM
Expiry Date:	EXPDATUM

QUALITY SPECIFICATIONS		
1. Filling Volumes: Antigen Suspension: AGS Positive Control: PC Negative Control: NC	5 x 2.0 ml 1.0 ml 1.0 ml	passed passed passed
2. Function test Function positive controls: Function negative controls:	agglutination after 2 minute no agglutination after 2 minute	passed passed

This product passed the quality control release criteria and has been released by the responsible Quality Control Department of HUMAN Gesellschaft für Biochemica und Diagnostica mbH.

Following release of the product, this certificate of analysis is electronically regenerated and valid without signature.

Date of print: 29.09.2023