Microgen

Antigen for V.D.R.L. microflocculation reaction (according to W.H.O. regulations)

IVD CE

Instructions for Use (IFU)

ORDERING INFORMATION

Form	Code	Composition
Kit 1000 test	REF CSI087802	n° 2 vials x 2,5 ml n°2 vials x 25 ml

INTENDED USE

In vitro diagnostic medical device for the execution of the nontreponemal flocculation test for qualitative research, and/or semi-quantitative dosage, of luetic reagins in human serum. Test results should always be interpreted in relation to the clinical context. For professional use only.

CLINICAL SIGNIFICANCE

Syphilis is a sexually transmitted disease, chronic infectious and often congenital, caused by Treponema pallidum. Microgen reagent is a stabilized suspension of cholesterol crystals coated with cardiolipin and lecithin, added to adjust sensitivity. The reagent acts as antigen against the antibodies present in sera of syphilis suffering persons. These antibodies are called "luetic reagins". When the luetic reagins are significantly present in the specimen, Microgen V.D.R.L. test gives a positive result with an evident flocculant reaction; if the reagins are absent there is no the flocculant reaction and the test is negative.

PRINCIPLE OF THE METHOD

Microgen reagent is a stabilized suspension of cholesterol crystals with the addition of cardiolipin and lecithin for the correction of sensitivity. The reagent reveals immunoglobulins (luetic reagins) present in sera from syphilis patients. When luetic reagins are present in the sample in significant quantities, the Microgen test (V.D.R.L.) is positive and therefore there is evident flocculation; When these reactions are absent there is no flocculation and therefore the test is negative.

Storage and stability

= Storage temperature 15-25 °C

If stored closed at 15-25 °C, avoiding direct light, the reagent is stable until the expiration date printed on the label. Avoid freezing. Avoid bacterial contamination.
If stored as described the reagent is stable for 36 months

KIT CONTENTS AND COMPOSITION

Microgen V.D.R.L. Antigen			
	Conc.	**U.M.**	
Cardiolipin	0,03	%	
Cholesterol	0,9	%	
Lecithin	0,22	%	* GHS02
Buffer pH 6 (±0.1)			
Formaldehyde Solution	0,5	mL/L	
Disodium phosphate ($Na_2HPO_4 \cdot 12H_2O$)	0,093	g/L	
Monopotassium phosphate (KH_2PO_4)	0,17	g/L	
Sodium Chloride	10	g/L	

Warning*: **Danger

H225 - Highly flammable liquid and vapour
P101 - If medical advice is needed, have product container or label at hand.
P102 - Keep out of reach of children.
P103 - Read carefully and follow all instructions.
P240 - Ground and bond container and receiving equipment.
P241 - Use explosion-proof [electrical/ventilating/lighting] equipment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P403+P235 - Store in a well-ventilated place. Keep cool.
P501 - Dispose of contents/container in accordance with local/ regional/national/international regulations.

PRECAUTIONS AND WARNINGS

1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. In addition to any risk claims relating to active components, reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. All human samples must be handled and disposed as potentially infectious materials.
5. The kit should only be used by qualified and properly trained technical personnel.
6. Diagnoses shall only be carried out by authorised and qualified personnel.
7. It is recommended to handle the reagent according to the rules of good laboratory practice and to use appropriate personal protective equipment.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that comply with current standards.

Reporting of serious incidents

Please inform the manufacturer (through your distributor) and the competent authority of the member state of the European Union in which the user and/or patient is established, of cases of serious incident that has occurred in relation to the device. For other jurisdictions, reports of serious incidents must be made in accordance with the regulatory requirements of the home Member State. By reporting serious incidents, you help provide more information about the safety of your in vitro medical diagnostic device.

PROCEDURE

QUALITY CONTROL

It is recommended to use positive and negative controls in each session to monitor the performances of the procedure and for having a comparative pattern for a better result interpretation.

REAGENT PREPARATION

The reagents are liquid and ready to use. Bring reagents and samples to room temperature before use (test sensitivity may be reduced at low temperatures). After opening, the reagent is stable until its expiration date if maintained under the conditions indicated in "Conservation and stability".

SAMPLE PREPARATION AND STORAGE

Fresh serum obtained by centrifugation and inactivated at 56°C for 30 minutes. Do not use hemolyzed or lipemic serums. Fibrin samples should be centrifuged before use. The sample can be stored 7 days at 2-8°C or for about 3 months at -20°C.

REACTION PROCEDURE

1) Antigenic suspension preparation

In order to obtain the antigen suspension ready for use, with a pipette drop 0.4 mL of buffer into a suitable bottle. Then add, drop by drop, 0.5 mL of V.D.R.L. antigen, turning for 10 seconds; then add quickly 4.1 mL of buffer, turning again for 10 seconds. Stability: 24 hours, in a well closed bottle at 2-8°C.

2) Specimen collection and preservation

Use clear serum, inactivated at 56°C for 30 minutes (if used after 4 hours, repeat the inactivation for 10 minutes).

TECHNIQUE

Qualitative test

Spread the specimen (**0,05 mL**) evenly on the bottom of the cell. Then add one drop **17 µL** (1/60 mL) of antigen suspension (well mixed).
Turn manually or mechanically (but do not shake) for 4 minutes, then carry out the reading on the microscope (8 X).

Quantitative test

This test is performed with the classic procedure of two-fold dilution of specimen (whole, 1:2, 1:4, 1:8, 1:16, 1:32, 1:64), diluting with saline. The titer is indicated from the highest dilution that still determines a positive reaction.

RESULTS

Finely dispersed particles (needles)	Not Reactive
Irregularly distributed particles	Weakly Reactive
Particles collected into heaps of varying size with or without clarification of the liquid	Reactive

NOTE

The V.D.R.L. reaction may also be carried out on active liquor. In this case the antigen, which must be prepared as described in the procedure, must be diluted in a 1:2 ratio with a 10% sodium chloride solution. In addition, after adding the antigen to the sample, the turning motion must be carried out for 5 minutes.
The coline chloride in concentrated solution (Cat. No. CSI053050) for procedure on plasma or active serum (RPR and USR test), and positive control serum (Syphilitic control serum: Cat. No. CSI053060) are available in separate packaging.

ANALYTICAL PERFORMANCES

Specificity

Test carried out with three different lots of reagents on samples of human negative serum have given repeatedly negative results.

Precision

Human normal sera	no flocculation
Human serum tit. 1:16	1:16 (±1 dil)
Human serum tit. 1:64	1: 64 (±1 dil)

Diagnostic Sensibility: 72% (Primary syphilis); 100% (Secondary syphilis)
Diagnostic Specificity: 99%

Comparison

The results obtained with the Microgen reagent (flocculation method) are well matched, for each approved batch, with the results obtained with the reagents for the complement fixation reaction for the determination of lipoid antibodies.

Bibliography

Manual tests for syphilis: U.S. Dept. Health Educ. and Welfare Public. Health Service 1969, page 33.

Symbols used for IFU and Packaging	
IVD In vitro diagnostics medical device	Manufacturer
REF Catalog number	Instruction for Use
LOT Lot Number	Storage Temperature
Expiration Date	Biological Risk

REVISION	DATE	CHANGES
F	12-2022	New issue for IVDR Regulation (EU) 2017/746 compliance

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