CE IVD

RDE (II) "SEIKEN"

(for use in the serodiagnosis test of influenza virus)

INTENDED USE

Elimination of the inhibitors in human serum during a serodiagnosis test (Hemagglutination Inhibition test: HI test) of the influenza virus.

SUMMARY AND EXPLANATION

RDE (II) "SEIKEN" is used in the HI test for the influenza virus in order to eliminate nonspecific hemagglutination inhibitors existing in a serum specimen by using an RDE (Receptor Destroying Enzyme) produced from *Vibrio cholerae serovar Ogawa strain 558*.

CONTENT

RDE (II) "SEIKEN" (lyophilized product), 20 mL x 5 vials

Filter-sterilized and lyophilized culture supernatant containing RDE, which is produced through pure culture of *Vibrio cholerae serovar Ogawa strain 558* in a liquid medium.

Each vial contains 2mg of kanamycin sulfate as a preservative.

PRECAUTIONS

1. General precautions

1) For *in vitro* diagnosis purpose only.
2) Final diagnosis should be made based on clinical symptoms, and the results of other assays.
3) Do not use human serum with RDE (II) "SEIKEN" for serodiagnosis of the mumps or parainfluenza viruses since it may result in destruction of some of the antibodies contained in the serum.
4) RDE (II) "SEIKEN" should not be used for purposes other than the intended use described above.

2. Handling precautions

1) The RDE should be used immediately after it has been dissolved in the physiological saline. If the dissolved solution has to be used at a latter date, store by freezing at –20°C or lower. NOTE: the freeze/thaw procedure should only be performed once.
2) All samples should be treated as potentially infectious, and should be handled with care, with all necessary precautions taken.
3) Used containers should not be used for any other purpose.
4) Use a water bath in the heating process described in "TEST PROCEDURES", and keep at a constant temperature of 56°C.
5) When handling the product ALWAYS wear gloves, eye protection, and a mask.
6) Avoid ingestion of the reagents. If the reagent comes into contact with the skin, or eyes flush with copious amounts of water. If in any doubt consult a physician.

3. Disposal precautions

All specimens, used containers, and equipment used for the analysis should be treated according to either methods (1) or (2) described below, and then disposed of according to the appropriate waste handling regulations.

(1) Soak in 0.5 w/v% sodium hypochlorite (effective chloride: 5,000 ppm) for a minimum of 1 hour.
(2) Autoclave at 121°C for a minimum of 20 minutes.

TEST PROCEDURE

1. Materials necessary for the test but not provided

1) Graduated pipette 10 mL
2) Micropipette 100 µL
3) Constant temperature water bath
4) Sterile physiological saline

2. Specimen

Human serum

3. Preparation of RDE solution

Completely dissolve the product in 20 mL of sterile physiological saline. This solution should be used immediately.

4. Treatment of the serum with RDE, and serodiagnosis test

1) Under sterile conditions, add specimen serum to the RDE solution in the ratio of 1:3, and mix thoroughly.
2) Heat the mixture at 37°C for 18 to 20 hours for the reaction to occur.
3) Then heat at 56°C for 30 to 60 minutes to deactivate the RDE.
4) Use the treated serum (as stated in steps 1, 2, and 3) in the serodiagnosis test (HI test) for the influenza virus.

PERFORMANCE VERIFICATION

The performance of RDE(II) can be verified by using the method detailed below.

1. Use human serum without the HI antibody to influenza as the serum specimen. The seasonally selected influenza A and B virus antigens should be used for the HI test.

2. Mix the serum specimen and RDE in a 1:3 ratio, and leave the mixture to stand at 37°C for 18 to 20 hours to complete the reaction, and then stop the RDE reaction by heating at 56°C for 30 to 60 minutes. Next remove the nonspecific hemagglutinin substances to chicken red blood cells by absorption.

3. The HI test for influenza virus should be performed using the virus antigen described in clause 1 above. Confirm that every serum specimen has no hemagglutination inhibition activity.

STORAGE / SHELF LIFE

Store at 2°C to 10°C protected from light.

Do not use this product beyond the stated expiry date

PACKAGE

RDE (II) "SEIKEN": 20 mL x 5 vials

REFERENCE

1) Lennette, E. H. & Schmidt, N. J.,: Hemagglitination-inhibition test, Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections, 5th ed. Am. Pub. Hlth. Assn. 603 (1979).

Symbols

LOT	Batch code
	Use by
IVD	In Vitro Diagnostic Medical Device
	Temperature limitation (Store at)
REF	Catalogue number
	Consult Instruction for use
	Manufacturer
EC REP	Authorized representative in the European Community
	Keep away from sunlight

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