VZV-FA "SEIKEN"

Varicella-zoster virus detection kit

Anti-VZV monoclonal antibody labeled with FITC

CE IVD

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2004.3

Symbols

LOT	Batch code
	Use by
Σ	Contains sufficient for <n> tests
IVD	In Vitro Diagnostic Medical Device
	Temperature limitation (Store at)
REF	Catalogue number
CONT	Contents of kit
	Consult Instructions for Use-

VZV-FA "SEIKEN"

Varicella-zoster virus detection kit

Anti-VZV monoclonal antibody labeled with FITC

30 tests

INTENDED USE

Detection of varicella-zoster virus (VZV) in epithelial cells

SUMMARY AND EXPLANATION

Infection with VZVs occur mainly during the pediatric period and causes chickenpox (varicella). Reactivation of the latent virus can result in secondary infection in the sensory nervous system. Reactivation occurs in patients with suppressed immune systems, and can lead to the onset of shingles (herpes zoster).

The significance of the early detection of varicella or herpes zoster has been highlighted in a recent tendency for complications arising from severe symptoms of varicella or herpes zoster in pediatric patients with leukemia and adult patients with cancer.

VZV-FA "SEIKEN" contains highly specific monoclonal antibodies conjugated to fluorescent dyes (fluorescein isothiocyanate: FITC) to directly detect VZV in clinical specimens.

PRINCIPLE

The reaction between anti-VZV monoclonal antibody labeled with FITC and varicella-zoster viruses is evaluated on the basis of the specific fluorescence detected with a fluorescence microscope.

Anti-VZVmonoclonal antibody labeled with FITC.

VZV

PRODUCT PROFILE

For the rapid, specific, and direct detection of viruses using anti-VZV monoclonal antibody labeled with FITC.

CONTENTS

VZV-FA "SEIKEN": One box for 30 tests, including:

1. **Anti-VZV monoclonal antibody labeled with FITC(Lyophilized)** :
   1 x 1 mL vial of reconstitution solution
   Lyophilized FITC-labeled anti-VZV mouse monoclonal antibodies (66 to 84 μg/mL) containing

bovine serum albumin (BSA) as a stabilizer.

2. **Reconstitution solution**: 1 x 1.5 mL vial
Purified water containing Evans blue at a concentration of 0.01 w/v% and sodium azide at 0.09 w/v%.

3. **Inclusion Liquid**: 1 x 1 mL vial
Mixture of glycerin and phosphate buffer solution in the ratio of 9:1.

PRECAUTIONS

1. General precautions

1) For *in vitro* diagnosis purposes only.

2) Final diagnosis should be made based on clinical symptoms, and the results of other assays.

3) When performing this test a known infected cell specimen is recommended to be used as a control.

2. Handling precautions

1) Allow the reagent and specimens to return to room temperature before use. Prior to use gently stir the antibody solution to ensure homogeneity of the solution.

2) Before mounting, confirm that the specimen has sufficiently dried. Insufficient drying of the specimen may create a hazy background.

3) The reagents in this kit contain sodium azide as a preservative. As sodium azide may react with lead and copper to generate explosive heavy metal azides, dispose of the kit reagents with copious amounts of water to avoid azide build up.

4) Avoid ingestion of the reagents. If reagent comes into contact with the skin, or eyes flush with copious amounts of water. If in any doubt consult a physician.

5) Be sure to keep the anti-VZV monoclonal antibody labeled with FITC and the prepared antibody solution away from strong light.

6) Micropipette tips should be changed for each specimen.

7) Specimens processed using trypsin may result in a remarkable reaction decline.

8) Used containers should not be used for any other purpose.

9) Do not mix reagents from different bottles.

10) The test should be carried out according to the procedures detailed in this insert, otherwise DENKA SEIKEN does not warrant the reliability of obtained data.

3. Disposal precautions

1) The reconstitution solution contains sodium azide at a concentration of 0.09 w/v%. As sodium azide may react with lead and copper piping to generate explosive heavy metal azides, dispose with copious amounts of water to avoid azide build up.

2) All specimens, used containers, and tools used for the analysis should be treated by one of the following methods 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

- Incident-light fluorescence microscope
- Non-fluorescent glass slide
- Micropipette

2. Specimen preparation

Epithelial cells infected with the VZV are used as specimens.

1) If the upper skin of a bulla is used, peel the epithelium off the lesion, and press the back directly against a glass slide.

If the basal membrane inside a bulla is used, wipe the whole surface of the basal part of the lesion with a swab moistened using physiological saline, and smear the specimen on to a glass slide.

2) After air-drying, fix the specimen by soaking in acetone for 5 to 10 minutes.

3. Preparation of the reagents

Material provided	Resolving method	Storage after resolving
Anti-VZV monoclonal antibody labeled with FITC(Lyophilized)	1 mL of the reconstitution solution is poured into a vial containing FITC-labeled anti-VZV monoclonal antibody to resolve.	The reconstituted antibody should be stored at 2 to 10℃, protected from light, and used within 6 months of preparation
Reconstitution solution	Use as supplied	2℃ to 10℃
Inclusion liquid	Use as supplied	2℃ to 10℃

4. Test procedure

1) Put 30 μL of anti-VZVmonoclonal antibody labeled with FITC solution over the specimen that was smeared on the glass slide, and place the slide in a moisture chamber at 37℃ for 15 minutes to facilitate the reaction. During preparation, prevent the reagent from drying out since dried reagent may induce nonspecific reactions.

2) After the reaction, wash off any excess reagent on the glass slide using a wash bottle and purified water. Do not pour water directly on the specimen-smeared portion of the glass slide.

3) After air-drying, mount the slide with the inclusion liquid and observe with a fluorescence microscope (×200 to ×500). If the prepared slides can not be observed immediately, the glass slides can be stored protected from light at 2 to 10°C; however, slides should be observed within 24 hours of preparation.

RESULT INTERPETATION

Cells infected with VZV will be observed with a green specific fluorescence and other cells not infected with VZV will be stained red.

Final diagnosis should be taken based not only on the test results of this product, but also in conjunction with other test results and clinical symptoms.

PERFORMANCE CHARACTERISTICS

1. Sensitivity

When anti-VZV monoclonal antibody labeled with FITC was serially diluted using the diluent and the test was performed using a control VZV-infected cell-fixed smear slide as the sample, specific fluorescence was observed up to a 1:4 dilution.

2. Specificity

1) When the test was performed using a control VZV-infected cell-fixed smear slide as the sample, specific fluorescence was observed.

2) When the test was performed using the control slide smeared with viruses belonging to the same herpes virus group, as listed below, cross reactivity (specific fluorescence) was not observed.

Herpes simplex virus (HSV), type 1
Herpes simplex virus (HSV), type 2
Cytomegalovirus (CMV)

3. Reproducibility

When five tests were performed simultaneously using a control VZV-infected cell-fixed smear slide as the sample, specific fluorescence was observed for all slides.

4. Correlation

Fifty specimens were compared with VZV-FA "SEIKEN" and a competitor's reagent using the same principle as Denka's. Results were identical, as shown below.

		Reagent developed by another company	
		+	−
VZV-FA "SEIKEN"	+	12	0
	−	0	38

(+)Specific fluorescence was observed.

(−) Specific fluorescence was not observed.

STORAGE / SHELF LIFE

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

Do not use this product beyond the stated expiry date indicated on the packaging.

PACKAGE

VZV-FA " SEIKEN" One box for 30 tests

REFERENCE

1) Schirm, J., *et al*: Rapid detection of varicella-zoster virus in clinical specimens using monoclonal antibodies on shell vials and smears. J. Med. Virol, 28, 1 (1989).