embodiment of the present invention, FIG. 1(B) is a plan view of test pieces, and FIG. 1(C) is a cross-sectional side view of the test pieces.

FIG. 2 is a schematic view illustrating the principles of test by immunochromatography.

FIG. 3 is a flowchart illustrating an example of a test method according to the present embodiment.

FIG. 4 is a schematic view illustrating an example of the test method according to the present embodiment.

FIG. 5 is a schematic view illustrating an example of a test kit according to the present embodiment.

FIG. 6 is a schematic view illustrating an example of the test kit according to the present embodiment.

Description of Embodiments

[0024]

Hereinafter, an embodiment of the present invention will be described with reference to the drawings. FIG. 1 to FIG. 4 are views illustrating examples of the present embodiment of the present invention. Portions assigned with the same reference numeral in the drawings indicate the same member. It is noted that in the drawings, some of the structures are appropriately omitted for the simplification of the drawings. The size, shape, thickness, and the like of members are appropriately exaggerated.

[0025]

CLAIMS

1. A test device by immunochromatography comprising a case including a dropping window on which a specimen is dropped and a detection window, and test pieces accommodated in the case, wherein:

the test pieces include

a first test piece and a second test piece,

a first detection portion of the first test piece,

a second detection portion of the second test piece, and

a dropping area common to the first detection portion and the second detection portion;

the test device is configured so that, when the specimen is dropped on the dropping area through the dropping window, the specimen is caused to migrate downstream and the same specimen is allowed to reach both the first detection portion and the second detection portion;

the first detection portion can trap a complex of a first labeled body and a first antibody contained in the specimen;

the second detection portion can trap a complex of a second labeled body and a second antibody contained in the specimen;

the first antibody is an antibody produced by vaccination or infection with a predetermined virus;

the second antibody is an antibody produced by infection with the virus; and

the test device is configured so that a test result from the first detection portion and a test result from the second detection portion, both visually observed through the detection window, can be determined in parallel and at the same time.

2. The test device according to claim 1, wherein a number of the dropping window is one.

3. The test device according to claim 1 or 2, wherein the first antibody and the second antibody are antibodies that are derived from human and same type of immunoglobulin and trap different antigens.

4. The test device according to any one of claim 1 to 3, comprising a first labelled body-containing portion containing the first labeled body, and a second labeled body-containing portion containing the second labeled body.

5. The test device according to any one of claims 1 to 4, wherein:

the first labeled body includes, as an antigen, a part of a spike protein of the virus; and

the second labeled body includes, as an antigen, a nucleocapsid protein of the virus.

6. The test device according to any one of claims 1 to 5, wherein the first detection portion and the second detection portion are disposed in parallel.

7. The test device according to any one of claims 1 to 6, wherein the virus is a SARS-CoV-2 virus.

8. A test kit comprising:

the test device according to any one of claims 1 to 7; and

a determination guide that allows for determining a state of the specimen including a possibility that an antibody is produced by the vaccination on a basis of a test result from the first detection portion and a test result from the second detection portion.

9. A test method using the test device according to any one of claims 1 to 7, the method comprising:

a step of dropping the specimen on the dropping area to cause the specimen to migrate within the test pieces so that the same specimen is allowed to reach both the first detection portion and the second detection portion;

a step of detecting presence or absence of the first antibody in the specimen and detecting presence or absence of the second antibody in the specimen; and

a step of combining detection results from the first antibody and the second antibody to determine a state of the specimen, wherein

a determination is derived from a plurality of determination candidates including a determination on a possibility that antibodies are produced by the vaccination, as a state of the specimen.

10. The test method according to claim 9, wherein when the detection result of the first antibody is positive and the detection result of the second antibody is negative, it is determined that the first antibody may have been produced in the specimen by the vaccination.

11. A test method for determining presence or absence of a first antibody and a second antibody in a specimen by immunochromatography, where the first antibody is an antibody produced by vaccination or infection with a predetermined virus, and the second antibody is an antibody produced by infection with the virus,

the method comprising:

a step of dropping the specimen on a dropping area of

test pieces including a first test piece and a second test piece, a first detection portion of the first test piece, a second detection portion of the second test piece, and the dropping area common to the first detection portion and the second detection portion, so that the specimen is caused to migrate within the test pieces and the same specimen is allowed to reach both the first detection portion and the second detection portion;

a step of determining presence or absence of the first antibody in the specimen by the first detection portion and determining presence or absence of the second antibody in the specimen by the second detection portion; and

a step of combining detection results of the first antibody and the second antibody to derive a determination from determination candidates including a possibility that the first antibody is produced by the vaccination in the specimen.

12. The test method according to claim 11, wherein when a detection result of the first antibody is positive and a detection result of the second antibody is negative, it is determined that the first antibody may have been produced in the specimen by vaccination.

13. The test method according to claim 11 or 12, wherein the virus is a SARS-CoV-2 virus.