

Claims

1. A method for assigning an antibody standard and determining ~~the~~ a minimum detection limit of an antibody detection reagent, specifically comprising the following steps:

S1, determination of a neutralized antigen equivalent of an antibody standard or a ~~sample~~ antibody-containing sample; wherein an antigen with a known purity and concentration is subjected to a gradient dilution using a matrix, to obtain a series of gradient diluents with different concentrations; and an equal amount of ~~an~~ the antibody standard or the antibody-containing sample is added to each of the diluents with different concentrations respectively, and after a neutralization reaction, each mixture is subjected to an antibody detection using a first antibody detection reagent, to determine the neutralized antigen equivalent of the antibody standard or antibody-containing sample, wherein if the mixture of a certain dilution presents a positive reaction in test result, an antigen quantity of the mixture with a higher concentration immediately before the mixture is determined as the neutralized antigen equivalent of the antibody standard or antibody-containing sample, thereby assigning the antibody standard or the antibody-containing sample;

S2, determination of an antibody titer of ~~the sample~~ the antibody standard or the antibody-containing sample; wherein the antibody standard or the antibody-containing sample in the step S1 is subjected to a gradient dilution using ~~a~~ the matrix, to obtain a series of gradient diluents with different dilutions; and the diluent of each dilution is subjected to an antibody detection using a second antibody detection reagent, to determine the antibody titer of the antibody standard or the sample the antibody-containing sample, wherein if the diluent of a certain dilution presents a negative reaction in detection result, the dilution of a diluent with a higher concentration immediately before the present diluent is determined as the antibody titer; and

S3, acquisition of ~~the~~ a minimum detection limit of ~~an~~ the second antibody detection reagent; wherein the neutralized antigen equivalent of the antibody standard or the sample the antibody-containing sample determined in the step S1 is multiplied by the antibody titer of the antibody standard or the sample the antibody-containing sample determined in the step S2, to

5 acquire the minimum detection limit of the second antibody detection reagent;

wherein the first antibody detection reagent used in the step S1 have a higher precision and a lower detection limit than the second antibody detection reagent used in the step S2;

wherein the matrix refers to the serum components in the antigen with a known purity and concentration and the serum components in the antibody standard or the antibody-

10 containing sample.

2. The method for assigning ~~an~~ the antibody standard and determining the minimum detection limit of ~~an~~ the antibody detection reagent according to claim 1, further comprising a step S4, confirmation of the minimum detection limit of ~~an~~ the second antibody detection

15 reagent; wherein at least three antibody-containing samples are treated according to the steps S1-S3, to acquire the minimum detection limit of the second antibody detection reagent; if the acquired minimum detection limit of the antibody-containing samples is consistent with the minimum detection limit acquired in the step S3, the antibody-containing samples are

respectively diluted to a the concentration of the minimum detection limit, and tested

20 repeatedly; and if the positive rates are $\geq 90\%$, the minimum detection limit of the second antibody detection reagent passes the confirmation.

3. The method for assigning ~~an~~ the antibody standard and determining the minimum detection limit of ~~an~~ the antibody detection reagent according to claim 2, further comprising a

25 step S5, verification of the minimum detection limit of ~~an~~ the second antibody detection

reagent: wherein at least three antibody-containing samples are respectively diluted to a concentration of the minimum detection limit, and tested repeatedly; and if the positive rates reach 90-95%, the minimum detection limit of the second antibody detection reagent passes the verification.

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4. The method for assigning ~~an~~ the antibody standard and determining the minimum detection limit of ~~an~~ the antibody detection reagent according to claim 1, wherein the dilutions of the gradient dilution of the antigen in the step S1 are: 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, 1:128 and 1:256 respectively.

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5. The method for assigning ~~an~~ the antibody standard and determining the minimum detection limit of ~~an~~ the antibody detection reagent according to claim 4, wherein in the step S1, an equal amount of ~~an~~ the antibody standard or specific antibody-containing sample is added to each of the antigen diluents with different concentrations respectively, and after ~~a~~ the reaction of 30 min at 37°C, each mixture is tested using ~~a~~ the first antibody detection reagent respectively; and if ~~a~~ the mixture of a certain dilution presents a positive reaction in the test result, ~~an~~ the antigen quantity of a mixture with a higher concentration immediately before the present mixture is determined as the neutralized antigen equivalent of the antibody standard or antibody-containing sample.

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6. The method for assigning ~~an~~ the antibody standard and determining the minimum detection limit of ~~an~~ the antibody detection reagent according to claim 4, wherein the dilutions for diluting the antibody-containing sample in the step S2 are 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 and 1:128 respectively; in the step S2, the diluent of each dilution is subjected to an antibody detection using the second antibody detection reagent; and if a diluent of a certain dilution

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presents a negative reaction in the detection result, the dilution of a diluent with a higher concentration immediately before the present diluent is determined as the antibody titer.

~~7. The method for assigning an antibody standard and determining the minimum detection limit of an antibody detection reagent according to claim 6, wherein in the step S3, the neutralized antigen equivalent of the sample acquired in the step S1 is multiplied by the antibody titer of the sample determined in the step S2, to acquire the minimum detection limit of the second antibody detection reagent.~~

8.7._____The method for assigning ~~an~~ the antibody standard and determining the minimum detection limit of ~~an~~ the antibody detection reagent according to claim 2, wherein in the step S4, if the positive rates are lower than 90% after the repeated tests, the antibody titer in the step S2 is adjusted by selecting a dilution immediately before the currently determined antibody titer as a new antibody titer, and then repeated tests are performed until the positive rates are $\geq 90\%$ and at this time, the confirmed minimum detection limit is recalculated according to the new antibody titer.

9.8._____The method for assigning ~~an~~ the antibody standard and determining the minimum detection limit of ~~an~~ the antibody detection reagent according to claim 4 ~~3~~, further comprising a step S5, verification of the minimum detection limit of ~~an~~ the second antibody detection reagent; wherein at least three antibody-containing samples are respectively diluted to a concentration of the minimum detection limit, and tested 3 times first; if the 3 tests are all positive, the verification is passed; if one of the 3 tests is negative, another 7 tests are performed, and if all of the 7 tests are positive, the verification is passed; if two of the 3 tests

are negative, another 18 tests are performed, and if all of the 18 tests are positive, the verification is passed; and if the 3 tests are all negative, the verification fails.

5 ~~10.9.~~ The method for assigning ~~an~~ the antibody standard and determining the minimum detection limit of ~~an~~ the antibody detection reagent according to claim 3, wherein in the step S4, at least three representative clinical samples containing to-be-detected antibodies from different sources are respectively selected for the confirmation of the minimum detection limit of the second antibody detection reagent; and in the step S5, at least 3 clinical samples with temporal and regional characteristics and different from the samples used for the

10 confirmation of the minimum detection limit of the second antibody detection reagent in the step S4 are selected for the verification of the minimum detection limit of the second antibody detection reagent.

15 ~~11.10.~~ The method for assigning ~~an~~ the antibody standard and determining the minimum detection limit of ~~an~~ the antibody detection reagent according to claim 1, wherein the first antibody detection reagent used in the step S1 have a higher or same precision and a lower or same detection limit than the second antibody detection reagent used in the step S2 ~~wherein the first antibody detection reagent in the step S1 is an antibody detection reagent superior to or the same as the second antibody detection reagent in the step S2.~~