Version 22-04/24

User's Manual

Human Clonorchis sinensis IgG ELISA Kit

REF **DEIA1089**

Σ **96T**

RUO

This product is for research use only and is not intended for diagnostic use.

For illustrative purposes only. To perform the assay the instructions for use provided with the kit have to be used.

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PRODUCT INFORMATION

Intended Use

Clonorchis sinensis IgG ELISA Kit is a qualitative procedure for the detection of Clonorchis sinensis IgG in human serum or palsma.

General Description

Clonorchis sinensis is a kind of zoonoses transmitted in a food-source way. Because of low sensitivity and labor intensive, the traditional diagnostic method, which is directly looking for the clonorchis sinensis in patient's tissue, is not suitable for routine use. Instead, detecting specifical antibody in an immunological way is a sensitive and rapid test.

Principles of Testing

The assay is a sandwich ELISA.If the sample to be tested contains Clonorchis sinensis IgG, it will specifically bind to Clonorchis sinensis antigen on the pre-coated plate and the enzyme-labeled conjugate of Clonorchis sinensis antigen added in the second step. The color reaction between the enzyme-labeled complex of Clonorchis sinensis antigen indirectly bound on the coated plate and the substrate can reflect whether the sample contains Clonorchis sinensis IgG.

Reagents And Materials Provided

1. Coated microtiter strips, 96T
2. Enzyme conjugate(1), 10 mL
3. Washing solution(2), 6mL
4. Substrate solution A(3), 6mL
5. Substrate solution B(4), 6mL
6. Sample dilution(5), 6mL
7. Stop solution(6), 6mL
8. Positive control, 0.85 mL
9. Negative control, 0.85 mL
10. Sealing Film, 3 pieces

Materials Required But Not Supplied

1. Validated microplate reader.
2. Deionized or distilled water.
3. Validated adjustable micropipettes, single and multi-channel.
4. Automatic microtiter plate washer or manual vacuum aspiration equipment.

5. 37°C incubator.

Storage

Store at 2-8°C for 12 months, avoid freezing and light.

Specimen Collection And Preparation

1. This reagent is only suitable for detecting human serum or plasma;
2. In order to achieve the best experimental results, avoid using samples containing sodium azide, hyperlipidemia, long bacteria and severe hemolysis;
3. If samples are not assayed immediately, they should be stored at 2 - 8°C and assayed within 3 days. For longer storage, -20°C or lower temperatures are recommended. Repeated freezing and thawing of samples should be avoided. Thawed samples must be mixed prior to diluting.

Assay Procedure

1. Add sample dilution: Add 1 drop of sample dilution to each well.
2. Add sample/control: Add 50μL sample to each sample well; Set two blank wells, add 50μL sample dilution; Two wells of negative control, and 50μL negative control substance was added into each well; Two wells of positive control were used, and 50μL positive control substance was added into each well. Cover the plate and incubate 30 min at 37°C in the dark.
3. Discard the liquid of the well, add 1 drop washing solution into each well and fill with distilled water promptly, incubate for 30 seconds, then discard the liquid, continue perform another 4 washing cycles as above, then discard the liquid, flap to dry with the absorbent paper.
4. Add enzyme conjugate solution:Dispense 2 drops enzyme conjugate(1) into wells(except the blank wells),cover the plate and incubate 30 min at 37 °C in dark. Discard the contents of the wells and wash 5 times as described in step 3.
5. Adding substrates: add 1 drop of substrate solution A (3) and 1 drop of substrate solution B(4), mix well, cover the plate and incubate 30 min at 37 °C in dark.
6. Stop: add 1 drop of Stop solution (6), adjust zero with blank control, and read OD value at 450 nm wavelength (630 nm as reference wavelength) by enzyme-labeled instrument.

Quality Control

1. To determine the cut-off(COV) value, calculate the mean of the negative control absorbance values and multiply this value by 2.1(When the OD value of negative control hole is ≤ 0.10, it shall be counted as 0.10).
2. All negative control absorbance values should be ≤ 0.15.
3. The positive control absorbance value should be ≥ 0.50.

Interpretation Of Results

The OD_{sample} ≥COV, clonorchis sinensis IgG positive.

The OD_{sample}

Specificity

Clonorchis sinensis IgG

Precautions

1. The pre-coated plate shall be sealed against moisture. When taken out from the refrigerated environment, it should be balanced to room temperature before opening. Unused strips should be immediately put back in a self-sealing bag with desiccant, sealed at 2 ~ 8 °C.
2. Before dropping reagent, shake and mix the bottle gently and discard the first drop. The bottle should be kept upright when dropping reagent.
3. The cap should be tight after each use, the cap can not be mixed. The reagent components of different batches of kits cannot be mixed.
4. Water bath is recommended for incubation. If there is no water bath, the sealed wet box can be put into a 37 °C incubator for use.
5. The discarded kits and samples should be properly treated according to the pollutants. The termination liquid in the kit is corrosive and should be used carefully

Limitations

For research use only.