Hydatidosis Rapid Test

Cat. No.:DTS742
Pkg.Size:25 Tests

Intended use

Immunochromatographic test for the qualitative detection of total antibodies against Echinococcus granulosus in serum/plasma samples.

Kit Features

It is recommended to read carefully the “Precautions” section. The test is accomplished in minutes with the help of a micropipette and a timer and can be read visually.

General Description

Echinococcus granulosus is the causal agent of human hydatidosis. The adult phase parasites the small intestine of cannids (definitive hosts), while the larva affects sheep and cattle (intermediate hosts) and, in a secondary or accidental way, other animals included humans. When the larval phase infects internediate host, hydatidic cysts develop in their internal organs, most often located in the liver (mainly in the right lobule), followed by the lung and other organs, such as the brain and bones.
The intensity of the immune response depends on the location and integrity of the cyst. Cysts in liver and bone are more reactive than those in lung, brain or spleen. Serologic assays, together with imaging techniques, are most frequently used for the diagnosis of hydatidosis. Cross-reactions may appear in patients infected by other helminths (mainly with cysticercosis) and in oncological processes.
A HPLC-purified E. granulosus 5/B enriched antigen is used in CD HYDATIDOSIS to improve the specificity of the assay while keeping a high sensitivity.

Principle Of The Test

When the sample is added into the well of the cassette, the colloidal gold is solubilized and the first immunological reaction between the specific antibodies of the serum/plasma and the protein coupled to the gold particles takes place. These complexes move along the membrane to the reaction line (test line), and a colored band will appear if the analyte to be detected is present in the sample. Each strip contains a control line for the validation of the assay. This line has to appear always even if the sample is negative.

Reagents And Materials Provided

1. CD HYDATIDOSIS CASSETTE: 25 cassettes for the qualitative detection of total antibodies against Echinococcus granulosus.
2. CD HYDATIDOSIS DEVELOPER SOLUTION: 3 ml of buffered solution, containing sodium azide.

Materials Required But Not Supplied

Automatic micropipette and the corresponding tips Chronometer

Storage

Store at room temperature or refrigerated, 2-30ºC. **DO NOT FREEZE.** Do not use the kit reagents beyond the expiry date. This will be valid only if reagents are capped and stored at 2-30ºC.

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com

Specimen Collection And Preparation

Blood should be collected aseptically using venipuncture techniques by qualified personnel. Use of sterile or aseptic techniques will preserve the integrity of the specimen. Serum samples are to be refrigerated (2-8ºC) upon collection or frozen (-20ºC) if the test cannot be performed within 7 days. Samples should not be repeatedly frozen and thawed. Do not use hyperlipemic, hemolyzed or contaminated sera. Samples containing particles should be clarified by centrifugation.

Reagent Preparation

All reagents supplied are ready to use.

Reagent Stability

1. CD CASSETTE: Once opened, use in the next hour.
2. Rest of the components: Store at 2-30ºC and use until expiration date.
3. The kit is stable until the expiration date at 2-30ºC.
4. Handle reagents in aseptic conditions to avoid microbial contaminations.
5. CD, S.L. does not accept responsibility for the mishandling of the reagents included in the kit.

Assay Procedure

1. Bring all reagents to room temperature before use (approximately 1 hour), without removing the cassettes from the pouches.
2. Open the pouch and put the cassette **1** on a flat surface.
3. Add 30 µl of sample into each well with an automatic micropipette. Let the drop be absorbed.
4. Add 2 drops of developer solution **2** onto each well.
5. The result must be read after 30 minutes.

Discard any reading made after 45 minutes.

Quality Control

Each batch is subjected to internal quality control testing before releasing, complying with highly strict specifications. Final quality control results for each particular lot are available.

Interpretation of Results

In order to perform the reading of the test and to determine the positivity of the samples, the intensity card included in the kit should be used. 4 levels of colour intensity ranging from 0.5 to 3 can be read. When the intensity is lower than 0.5, the result is considered negative. When the intensity is higher than or equal to 0.5, the result is considered positive.
If the sample contains antibodies against E. granulosus, a coloured line will appears in the corresponding place. The control line must be always positive and legible if the test has been performed correctly. If this line does not appear, the test must be considered invalid.

Sensitivity and Specificity

282 samples were assayed against a commercial available hemoagglutination and ELISA kit. The results were as follows:
Sensitivity (%): 94,74%.
Specificity (%): 99.5%.

Precision

INTRA-ASSAY PRECISION:
2 samples (one positive close to the detection limit and one negative) were tested 5 times in a single assay performed by the

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com

same operator in essentially unchanged conditions. The same results were observed in all the assays.

INTER-ASSAY PRECISION:

2 samples (one positive close to the detection limit and one negative) were individually tested on 3 consecutive days by 2 different operators. The same results were observed in all the assays.

Cross-Reactivity and Interferences

8 samples known to be positive for other specimens of the taxonomic group (Leishmania infantum, Taenia solium, Trichinella spiralis, Toxoplasma gondii), were assayed.

The negative results of the test demonstrated the specific reaction of the kit with no cross-reaction or interferences with the referred specimens. Cross-reactions may appear in patients infected by other helminths (mainly with cysticercosis) and in oncological processes.

Precautions

1. For professional use only.
2. Use kit components only. Do not exchange CD CASSETTES and CD DEVELOPER SOLUTION between lots and kits.
3. Specimens should be handled as in the case of infectious samples using safety laboratory procedures.
4. Wear protective disposable gloves, laboratory coats and eye protection when handling specimens. Wash hands thoroughly after manipulating samples.
5. Do not use the kit after expiration date.
6. Dispose of unused reagents and waste in accordance with all applicable regulations.
7. Reagents in this kit could include substances of animal and/or human origin. Although that material is not infectious, it should be handled as potentially infectious. The cassettes contain inactivated E. granulosus antigen. Nevertheless, they should be considered potentially infectious and handled with care. All materials should be handled and disposed as potentially infectious. Observe the local regulations for clinical waste disposal.
8. The developer solution contains sodium azide. Sodium azide may react with metal plumbing, forming explosive components. Upon disposal, flush with plenty of water.
9. If the kit or its components (cassettes or developer solution) are stored in the refrigerator, please bring them at room temperature before use.
10. The cassettes are stable in their closed pouch until the expiry date indicated in the label. Do not open until you are ready to perform a test.
11. Several tests can be performed at the same time.
12. Do not let the tip of the developer solution bottle touch the sample well in order to prevent contaminations.
13. A good performance of the test depends on the correct size of the drops of developer solution. For this purpose, push the dropper smoothly, allowing the air to pass through into the bottle between each two samples.
14. Avoid the use of samples subjected to repeated freezing-thawing cycles as well as hemolyzed samples. Both can produce erroneous results (signal decrease) or reading failures (lack of visibility).

Limitations

1. This kit is intended to be used with human plasma/serum.
2. The user of this kit is advised to carefully read and understand the package insert. Strict adherence to the protocol is necessary to obtain reliable test results.
3. This test will not indicate the site of infection. It is not intended to replace isolation.
4. As with any diagnostic test, results must be interpreted with consideration of all clinical and laboratory findings. The kit results may be used in conjunction with clinical evaluation and other diagnostic procedures.
5. The test provides qualitative results. No correlation can be drawn between the magnitude of a positive result and the titer of antibodies in the sample.

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com

6. This test has been verified to be used with human plasma/serum. This test has not been verified with other kinds of samples.
7. Reliable results are dependent on adequate specimen collection, transport, storage and processing procedures.
8. A negative result does not exclude the possibility of infection.
9. A positive test does not rule out the possibility that other pathogens may be implicated in the disease.
10. The kit has not been evaluated to follow up the disease after a treatment.

REFERENCES

1. Grimm, F., F. E. Maly, J. Lu, and R. Llano. 1998. Analysis of specific immunoglobulin G subclass antibodies for serological diagnosis of Echinococcosis by a standard enzyme-linked immunosorbent assay. Clin Diagn Lab Immunol 5:613-6.
2. Guisantes, J. A., L. A. Yarzabal, V. M. Varela-Diaz, M. I. Ricardes, and E. A. Coltorti. 1975. Standardziation of the immunolectrophoresis test with whole and purified hydatid cyst fluid antigens for the diagnosis of human hydatidosis. Rev Inst Med Trop Sao Paulo 17:69-74.
3. J. Eckert, M.A. Gemmell, F. X., Meslin and Z. S. Pawlowski 2002 WHO/OIE Manual on Echinococcosis in Humans and Animals: A Public Health Problem of Global Concern.
4. Oriol, R., J. F. Williams, M. V. Perez Esandi, and C. Oriol. 1971. Purification of lipoprotein antigens of Echinococcus granulosus from sheep hydatid fluid. Am J Trop Med Hyg 20:569-74.
5. Ravinder, P. T., S. C. Parija, and K. S. Rao. 2000. Urinary hydatid antigen detection by coagglutination, a cost-effective and rapid test for diagnosis of cystic echinococcosis in a rural or field setting. J Clin Microbiol 38:2972-4.

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com