BoatBIO

CE IVD

EV71 IgM Rapid Test Kit (Colloidal Gold)

PRODUCT NAME
EV71 IgM Rapid Test Kit(Colloidal Gold)

SPECIFICATION
25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE
The EV71 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of IgM-class antibodies to human Enterovirus 71 (EV71) in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with EV71. Any reactive specimen with the EV71 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

NTRODUCTION
Human Enterovirus 71 (EV71), the newest member of Enterovirudae, is notable for its etiological role in epidemics of severe neurological diseases in children. It appears to be emerging as an important virulent neurotropic enterovirus in the upcoming era of poliomyelitis eradication. The illness usually peaks in June or July. EV71 infection may be asymptomatic or may cause diarrhea and rashes. EV71 one of the major causative agents for hand, foot and mouth disease (HFMD), is sometimes associated with severe central nervous system diseases. Direct detection of virus is the mainstay of diagnosis. EV71 can be isolated from throat and stool specimens, as well as from skin vesicle fluid. PCR testing provides generally greater sensitivity than culture for throat and stool specimens, and viral RNA has also been detected in vesicular fluid, blood and urine. EV71 specifc serological assays, including tests specific for IgM antibody, have also been developed to assist for early and easier diagnosis of the disease.

PRINCIPLE
The EV71 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is based on the principle of agglutinating sera on membrane and utilizes the technique of immunochromatography. The sample pad is coated with EV71 antigen. As the test specimen flows through the sample pad assembly of the device, the EV71 antigen complex with the EV71 specific antibodies in the test specimen. When this complex travels on the conjugated pad which is impregnated with mouse anti-EV71 antibody conjugated to colloidal gold, the EV71 colloidal gold react with the complex then travels on the membrane due to capillary action. This complex moves further on the membrane to the test region (T) where it is immobilized by anti human IgM antibody coated on the membrane, leading to formation of a pink/purple coloured band. The absence of this band in the test region (T) indicates a negative result. The test contains an internal control (C band) which is coated with goat anti-mouse IgG should exhibit a burgundy colored band regardless of the color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

MATERIALS
Materials provided

Components	25 tests/kit	5 tests/kit	1 test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution With Dropper	5ml/bottle	1ml/bottle	300ul/tube
Cotton Swab	25 pcs	5 pcs	1 pcs
Package insert	1 pcs	1 pcs	1 pcs

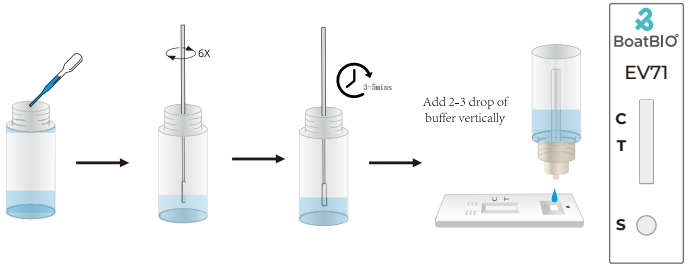
Materials Required but Not Provided
1.Specimen collection containers 2.Lancets (for fingerstick whole blood only)
3.Centrifuge (for plasma only) 4.Timer
5. Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

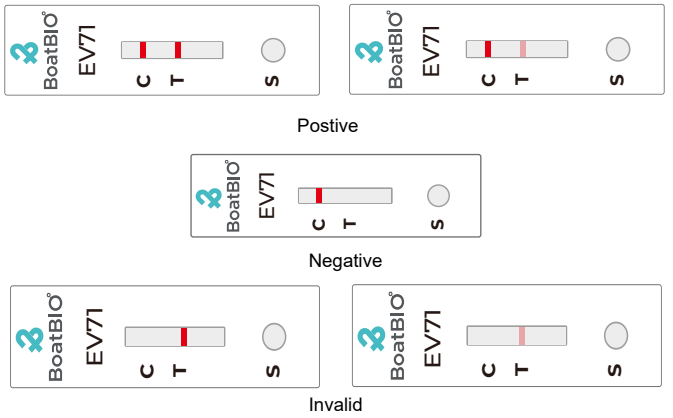
STORAGE AND STABILITY
All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

WARNINGS AND PRECAUTIONS
1.For professional in vitro diagnostic use only.
2.For best results, strict adherence to these instructions is required.
3.All specimens should be handled as being potentially infectious.
4.Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
5. The test device is sensitive to humidity as well as to heat.
6.Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7.Do not use it beyond the expiration date. The shelf-life of the kit is as indicated on the outer package.
8. Do not use the test kit if the pouch is damaged or the seal is broken.
9.The components (test device and assay diluent) in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.
10.The assay diluent contains low concentration of sodium azide as a preservative. Sodium azide is toxic and should be handled carefully to avoid ingestion and skin contact.
11.Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.

SPECIMEN COLLECTION AND PREPARATION
1.Anticoagulated whole blood as well as serum/plasma can be used. Whole blood or plasma specimens containing anticoagulants other than EDTA, Oxalate or Heparin may give incorrect results.
2.Serum/plasma may be stored at 2- 8°C up to 3 days in case of delay in testing. For long-term storage, freeze the specimen at –20°C. Whole blood should be used immediately and should not be frozen.
3.Repeated freezing and thawing of the serum/plasma specimen should be avoided. Maximum of 2 freeze/thaw cycles are allowed.
4.Do not use haemolysed, clotted, contaminated, viscous/turbid specimen.
5.Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
6.Do not heat inactivate the sample before use.

TEST PROCEDURE
1. Dilution of the specimen: Add 30-35 uL serum/plasma sample or 30-35 uL whole blood sample into the sample dilution tube by pipette and mix completely.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3.Be sure to label the device with specimen's ID number.
4. Fill the pipette dropper with the specimen. Holding the dropper vertically, dispense 2-3 drops (about 60-70μL) of the diluted specimen into the sample well making sure that there are no air bubbles,and start the timer.
5. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes





INTERPRETATION OF RESULTS
Positive: If both C and T band are developed, the test indicates for the presence of IgM anti-EV71 in the specimen. The result is positive.
Negative: If only the C band is developed, the test indicates that no detectable IgM anti-EV71 is present in the specimen. The result is negative.
Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL
An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS
1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing. Failure to follow the procedure may give inaccurate results.
2.This test detects the presence of IgM antibodies to EV71 in the specimen and should not be used as the sole criterion for the diagnosis of EV71 infection
3.Negative results do not exclude the possibility of EV71 exposure or infection. Infection through recent exposure (seroconversion) to EV71 may not be detectable. For positive results, line intensity cannot be used to evaluate the EV71 IgM antibody levels. A test giving an invalid result should be repeated.
4.A negative result can occur if the quantity of the anti-EV71 IgM present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5.If, after retesting of the initially reactive samples, the test results are negative, these samples should be considered as non-repeatable (false positive) and interpreted as negative. As with many very sensitive rapid diagnostic tests, false positive results can occur due to the several reasons, most of which are related but not limited to the quality of the sample and exposition of the test to humidity.
6.The product is only suitable for testing individual samples in vitro. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
7.As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS
A total of 185 samples from susceptible subjects were tested by the EV71 IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and by a commercial PCR test. Comparison for all subjects is showed in the following table:

Method		EIA		Total
EV71 IgM Rapid Test	Results	Positive	Negative	Results
	Positive	36	7	43
	Negative	4	138	142
Total Results		40	145	185

Relative sensitivity: 90.0%
Relative specificity: 95.2%
Accuracy: 94.1%

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		

BASIC INFORMATION

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