GENESIS

P231123 CE IVD

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EZER™ CRP/MxA Combo Rapid Test

INTENDED USE

The *EZER*™ CRP/MxA Combo Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of Myxovirus resistance protein A (MxA) and C-reactive protein (CRP) in human whole blood. This test aids in identification of viral and/or bacterial infection in patients with clinical symptoms caused by infection. The assessment of whether a bacterial infection is present should always be based on consideration of all available information, and not based solely on the test results. For *in vitro* diagnostic use only.

BACKGROUND

Acute respiratory infections (ARIs), which includes acute uncomplicated bronchitis, pharyngitis, rhinosinusitis, the common cold and influenza, affect 20% of the population each year. Due to the apparent overlap of ARI symptoms, it is difficult for physicians to differentiate viral and/or bacterial infections based on symptoms, to the detriment of antibiotic therapy[1]. Myxovirus resistance protein A (MxA) is an interferon-induced GTPase, the level of which increases rapidly during acute viral infections. MxA has a low basal concentration of less than 15 ng/mL, a fast induction time of 1-2 hours, and a long half-life of 2.3 days[2]. Therefore, MxA level can be directly taken as a deal marker in response to acute viral infection[3]. CRP is a non-specific acute temporal response protein with extremely low levels in normal health, and CRP levels are significantly elevated within 4-6 hours of bacterial infection and peaks after 36 hours, while viral infections have a weak effect on them, thus CRP can be used as a typical indicator of bacterial infection[4]. CRP/MxA Combo Rapid Test simultaneously detects elevated levels of MxA and CRP to help identify patients suffering from clinically significant ARI as well as differentiate viral from bacterial infection.

PRINCIPLE

The test is ready to use and is based on a membrane technology with colloidal gold nanoparticles. Our kit is aimed to the detection of Myxovirus resistance protein A (MxA) and C-reactive protein (CRP) from whole blood. Each pouch contains one lateral-flow strips for the identification of MxA and CRP.

A nitrocellulose membrane is sensitised with:

(1) a monoclonal antibody directed against MxA (“MxA” line)

(2) a monoclonal antibody directed against CRP (“CRP” line)

(3) a control capture reagent (upper “C” line).

Three different colloidal gold nanoparticles conjugates are dried on a membrane: a conjugate directed against MxA, a conjugate directed against CRP and a control conjugate.

When the whole blood and the buffer comes into contact with the strip, the solubilised conjugates migrate with the sample by passive diffusion, while conjugates and sample material come into contact with the immobilised respective antibodies that are adsorbed onto the nitrocellulose strip. If the MxA of sample exceeds 40 ng/mL and the CRP exceeds 20 µg/mL. the respective complexes made of the conjugates and either MxA or CRP will remain bound to their respective specific lines (MxA: “MxA” line, CRP: “CRP” line). The migration continues by passive diffusion and both conjugates and sample material come into contact with the (upper) line control reagent that binds a control conjugate (“C” line), thereby producing a red line. The result is visible within 15 minutes in the form of red lines on the strip.

CONTENTS

CRP/MxA Combo Rapid Test: 20 PCS
Sample Buffer: 1 Vial
Plastic Dropper: 20 PCS
Package Insert: 1PC

Warnings and Precautions

1. For *in vitro* Diagnostic Use.
2. Use only fresh samples and sample with severe hemolysis must not be used.
3. Wear protective clothing such as laboratory coats and disposable gloves when specimens are collected and evaluated.
4. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
5. Do not use kit components beyond the expiration date.
6. Apply universal precaution when performing the test.
7. The test plate should be used immediately after opening the packaging. When it absorbs moisture, the quality deteriorates and an accurate result cannot be obtained.
8. Please do not touch the sample drop and the judgment part of the test board directly by hand.
9. Do not reuse the device.
10. If the test is invalid, one should consider the possible improper handling, inaccurate operation procedure, or device quality. Repeat the test with a new device

ensuring that the test procedure has been followed accurately.

11. Assessment must be conducted exactly 15 minutes after starting the reaction. Given the nature of the measurement, the reaction and color development may slightly continue and progress even after 15 minutes.
12. The color tone of the line may vary depending on the color tone and the specimen properties. However, the test result is valid as long as a red line is present.
13. This test is a qualitative assay and will not yield any quantitative result. This test should be used as an aid for identify viral and/or bacterial.

STORAGE CONDITIONS

Test devices must be stored at 2~30°C. DO NOT FREEZE. Devices must be at ambient room temperature at time of testing.

SPECIMEN HANDLING AND COLLECTION

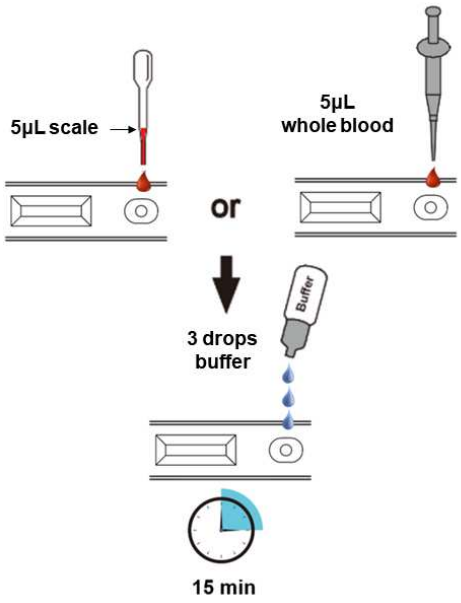
- Applicable samples：Whole Blood
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2~8°C if the test is to be run within 1 days of collection.
- Do not freeze whole blood specimens.
- Bring specimens to room temperature prior to testing.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents. EDTA K_2, Heparin sodium and Citrate sodium can be used as the anticoagulant for collecting the specimen.

PROCEDURE

Allow the *EZER*™ CRP/MxA Combo Rapid Test and collected samples to equilibrate to room temperature (15~30°C) prior to testing. Refer to testing procedures provided in the kit.

1. Bring the specimen and test components to room temperature if refrigerated.
2. Open the foil pouch and take out the reagent plate. Once opened, test immediately. Write down the patient's name or number on the reagent plate. (One patient per reagent plate)
3. To use a dropper: Hold the dropper vertically, draw the specimen to the scale and transfer approx. 5μL of specimen to the sample well. Then add 3 drops of buffer (approximately 90μL) and start the timer.
   To use a pipette: To transfer 5μL of whole blood to the specimen well, then add 3 drops of buffer (approximately 90μL), and start the timer according to the illustration below.
4. Read the results after 15 minutes. If more than 30 minutes, please retest with another test device.

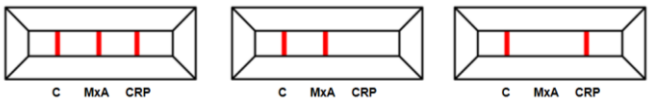
Note: It is suggested not to use the buffer, beyond 1 year after opening the vial.



INTERPRETATION OF RESULTS

Allow the samples to react according to the procedure and read the reddish-purple lines that appear in the reading area.

Positive Result:



Positive

Viral infection and bacterial infection:

The reddish-purple line in the control line region (C) as well as test line regions CRP and MxA appear. The color intensities of the lines do not have to match. This result is positive for MxA and CRP, indicating the presence of elevated MxA and CRP proteins, which means that a mixed viral and bacterial infection has occurred.

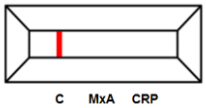
Viral infection：

The reddish-purple line in the control line region (C) appears and a reddish-purple line appears in test line region MxA indicating a positive result for MxA. This may point to the presence of a viral infection.

Bacterial infection:

The reddish-purple line in the control line region (C) appears and a reddish-purple line appears in test line region CRP indicating a positive result for CRP, which means that a bacterial infection is present.

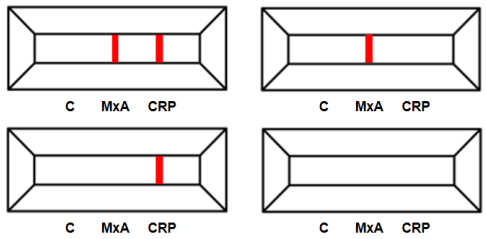
Negative Result:



Negative

The reddish-purple line in the control line region (C) appears. No line appears in test line regions (CRP or MxA).

Invalid Result:



Invalid

Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test Device immediately and contact your local distributor.

PRECAUTIONS FOR ASSESSMENT

1. Assessment must be conducted exactly 15 minutes after starting the reaction. Given the nature of the measurement (immunochromatography), the reaction and color development may slightly continue and progress even after 15 minutes.
2. The color tone of the line may vary depending on the color tone and specimen properties. However, the test result is valid as long as a red line is present. Occasionally, broken lines may appear due to an uneven sample distribution on the test strip, but the test result is valid as long as a red line is present.
3. If the specimen is dark-colored, it may stain the membrane and affect the assessment.
4. A highly viscous specimen may affect sample migration and/or the reaction, resulting in weak coloration, delayed or no formation of the line, or a nonspecific reaction because of specimen retention.

QUALITY CONTROL

Each *EZER*™ CRP/MxA Combo Rapid Test contains internal/procedural controls. The appearance of a control line at the Control “C” position validates the proper reagent function and assures that the correct test procedure was followed.

PERFORMANCE CHARACTERISTICS

Detection limit

Detection limits determined with purified MxA and CRP proteins were assessed as follows:

Target	Detection limit
MxA	40 ng/mL
CRP	20 μg/mL

Interfering Substances

The following compounds have been tested using the *EZER*™ CRP/MxA Combo Rapid Test and no interference was observed.

Triglyceride: 50 mg/dL
Ascorbic Acid: 20 mg/dL
Hemoglobin: 1000 mg/dL
Bilirubin: 60 mg/dL
Total cholesterol: 6 mmol/L
Ibuprofen: 25 mg/dL
Acetaminophen: 16 mg/dL
HAMA: 1000 ng/mL
Rheumatoid Factor (RF): 50 IU/mL
K_2-EDTA 6 mg/mL
Na-Heparin 12 mg/mL
Li-Heparin 12 mg/mL
Sodium Citrate 32 mg/mL

Clinical Evaluation

The *EZER*™ CRP/MxA Combo Rapid Test was compared with similar competitor products in 320 clinical samples. The results show that *EZER*™ CRP/MxA Combo Rapid Test has a high sensitivity and specificity.

Result for viral infection：

		Comparator product		
		+	−	Total
EZER™ CRP/MxA Combo Rapid Test	+	142	0	142
	−	3	175	178
	Total	145	175	320

Relative Sensitivity: 97.93%
Relative Specificity: 100%
Accuracy: 99.06%

Result for bacterial infection：

		Comparator product		
		+	−	Total
EZER™ CRP/MxA Combo Rapid Testt	+	74	0	74
	−	1	245	246
	Total	75	245	320

Relative Sensitivity: 98.67%
Relative Specificity: 100%
Accuracy: 99.69%

LIMITATIONS OF THE PROCEDURE

1. This device should be used within three days from onset of a fever and less than seven days of new respiratory symptoms.
2. This device is not intended to diagnose any specific bacteria or virus.
3. This device doesn’t detect bacterial colonization or localized infection.
4. Fresh blood must be used on this device. Serum and/or plasma cannot be used.
5. An adequate amount of blood must be taken for the test to be performed correctly. An insufficient blood sample may result in a false negative.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. Patients receiving anti-infective drugs, interferon

therapy and/or live viral immunization maybe affect the results.

8. The results obtained with this test should be interpreted in conjunction with other diagnostic procedures and clinical findings.
9. Negative results do not preclude respiratory infection and should not be used as the sole basis for diagnosis, treatment, or other clinical and patient management decisions.

AVAILABILITY

Product	Cat. No.	Contents
EZER™ CRP/MxA Combo Rapid Test	P231123	20 Tests

REFERENCES

1. Harris AM et al. Appropriate antibiotic use for acute respiratory tract infection in adults: advice for high-value care from the American College of Physicians and the Centers for Disease Control and Prevention. Annals of Internal Medicine. 2016.
2. Nakabayashi M et al. MxA-based recognition of viral illness in febrile children by a whole blood assay. Pediatric Research. 2006.
3. Metz M et al. MxA for differentiating viral and bacterial infections in adults: a prospective, exploratory study. Infection. 2023.
4. Tang MQ et al. Research progress of C-reactive protein analysis. Chinese Journal of Analytical Chemistry. 2020.

Index of Symbols

Attention, see instructions for use	Tests per kit	Authorized Representative
For *in vitro* diagnostic use only	Use by	Do not reuse
Store between 2~30℃	Lot Number	Catalog #

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