OneStep Filariasis IgG/IgM RapiCard™ InstaTest (Whole Blood/Serum/Plasma)

REF 177582

PIC ID177582VV86

IVD See External Label 2°C-30°C 40 Tests

Filariasis IgG/IgM RapiCard™ InstaTest	
Principle	Rapid Chromatographic Immunoassay
Detection	Qualitative
Specificity	IgG: 98.4% IgM: 98.8%
Sensitivity	IgG: 92.5% IgM: 96.9%

PRODUCT FEATURES

- High Sensitivity and Specificity
- Built in Internal Controls
- Simplified Workflow, Non-invasive, and Safe
- Rapid and Faster Results

A rapid test for the qualitative detection of IgG and IgM antibodies to Filariasis parasites (W. Bancrofti and B. Malayi) in human whole blood, serum, or plasma. For professional in vitro diagnostic use only.

INTENDED USE

The OneStep Filariasis IgG/IgM RapiCard™ InstaTest (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to *Filariasis parasites* (*W. Bancrofti and B. Malayi*) in whole blood, serum, or plasma to aid in the diagnosis of Filariasis infection.

SIGNIFICANCE AND SUMMARY

The lymphatic filariasis known as Elephantiasis, mainly caused by W. bancrofti and B. malayi, affects about 120 million people over 80 countries[1,2]. The disease is transmitted to humans by the bites of infected mosquitoes within which the microflariae sucked from an infected human subject develops into third-stage larvae. Generally, repeated and prolonged exposure to infected larvae is required for establishment of human infection.

The definitive parasitologic diagnosis is the demonstration of microflariae in blood samples[3]. However, this gold standard test is restricted by the requirement for nocturnal blood collection and lack of adequate sensitivity. Detection of circulating antigens is commercially available. Its usefulness is limited for W. bancrofti[4]. In addition, microfilaremia and antigenemia develop from months to years after exposure.

Antibody detection provides an early means to detect filarial parasite infection. Presence of IgM to the parasite antigens suggest current infection, whereas, IgG corresponds to late stage of infection or past infection[5]. Furthermore, identification of conserved antigens allows 'pan- filaria' test to be applicable. The utilization of recombinant proteins eliminates cross-reaction with individuals having other parasitic diseases[6]. The Filariasis Rapid Test uses conserved recombinant antigens to simultaneously detect antibody to the W. bancrofti and B. malayi parasites without the restriction on specimen collection.

ASSAY PRINCIPLE

The OneStep Filariasis IgG/IgM RapiCard™ InstaTest (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to Filariasis in whole blood, serum, or plasma. In this test procedure, anti-human IgG is immobilized in the IgG line region of the test, anti-human IgM is immobilized in the IgM line region of the test. After specimen is added to the specimen well of the device, it reacts with Filariasis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-human IgG/ anti-human IgM in respective line. If the specimen contains Filariasis antibodies, colored line will appear indicating a positive result. If the specimen does not contain Filariasis antibodies, a colored line will not appear in IgG/IgM region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains Filariasis antigen coated particles and anti-human IgG/IgM coated on the IgG/IgM region of membrane.

Diagnostic Automation/Cortez Diagnostics, Inc.
21250 Califa St, Suite 102 and 116, Woodland Hills, CA 91367 USA Phone: 818-591-3030, Fax: 818-591-8383
Email: onestep@rapidtest.com Website: www.rapidtest.com

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The OneStep Filariasis IgG/IgM RapiCard™ InstaTest (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- **To collect Fingerstick Whole Blood specimens:**
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using a **capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 40 µL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Add the Fingerstick Whole Blood specimen to the test by using **hanging drops**:
  - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
  - Allow 1 hanging drop of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below 20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS AND COMPONENTS

Materials provided with the test kit

- Test Cassettes
- Droppers
- Buffer
- Package insert

Materials required but not provided

- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
- Centrifuge
- Timer

ASSAY PROCEDURE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the cassette on a clean and level surface.

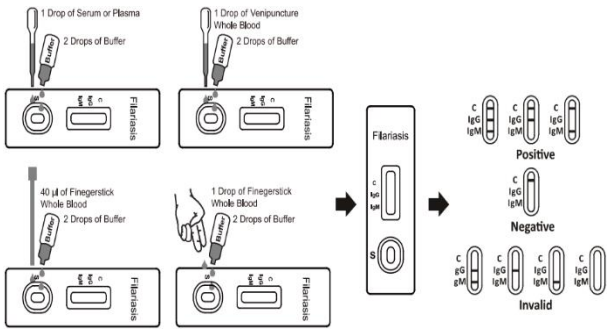
For **Serum or Plasma** specimen: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 40 µL) to the specimen area, then **add 2 drops of buffer** (approximately 80 µL), and start the timer, see illustration below.

For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer 1 drop of whole blood** (approximately 40 µL) to the specimen area, then **add 2 drops of buffer** (approximately 80 µL), and start the timer. See illustration below.

For **Fingerstick Whole Blood** specimen:

- To use a capillary tube: Fill the capillary tube and **transfer approximately 40 µL of fingerstick whole blood specimen** to the specimen area of test cassette, then **add 2 drops of buffer** (approximately 80 µL) and start the timer. See illustration below.
- To use hanging drops: Allow **1 hanging drop of fingerstick whole blood specimen** (approximately 40 µL) to fall into the specimen area of test cassette, then **add 2 drops of buffer** (approximately 80 µL) and start the timer. See the illustration below.

3. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.



RESULTS

(Please refer to the illustration above)

POSITIVE:* Two or three lines appear. One colored line should always appear in the control line region (C) and another one or two apparent colored line(s) should be in the test line region(s) (IgM and/or IgG).

IgM Positive: A colored line appears in control region (C), another colored line appears in IgM region. It indicates a IgM positive test result for antibodies to Filariasis.

IgG Positive: A colored line appears in control region (C), another colored line appears in IgG region. It indicates a IgG positive test result for antibodies to Filariasis.

***NOTE**: The intensity of the color in the test line regions (IgM and IgG) may vary depending on the concentration of Filariasis antibodies present in the specimen. Therefore, any shade of color in the test line region (IgM and/or IgG) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insuffcient 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. If the problem persists, discontinue using the test immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal 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 Assay Procedure and the Results must be followed closely when testing the presence of antibodies to filarial parasites in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Filariasis Rapid Test is limited to the qualitative detection of antibodies to *W. bancrofti and B. malayi* in human serum, plasma or whole blood. The intensity of the test band does not have a linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates the absence of detectable *W. bancrofti and B. malayi* antibodies. However, a negative test result does not preclude the possibility of exposure to *W. bancrofti and B. malayi*.
4. A negative result can occur if the quantity of *W. bancrofti and B. malayi* antibodies present in the specimen is below the detection limits of the assay, or if the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy
IgG Results

40 samples from patients with chronic lymphatic filariasis and 251 samples collected from a non-filariasis region were

tested by the OneStep Filariasis IgG/IgM RapiCard™ InstaTest. Comparison for all subjects is showed in the following table:

Method		ELISA		Total Results
Filariasis IgG/IgM RapiCard™ InstaTest	Results	Positive	Negative	
	Positive	37	4	41
	Negative	3	247	250
Total Results		40	251	291

Relative Sensitivity: 92.5% (95%CI*: 79.6%-98.4%)
Relatively Specificity: 98.4% (95%CI*: 96.0%-99.6%)
Accuracy: 97.6% (95%CI*: 95.1%-99.0%)
*Confidence Interval

IgM Results

32 samples from patients with chronic lymphatic filariasis and 251 samples collected from a non-filariasis region were tested by the IneStep Filariasis IgG/IgM RapiCard™ InstaTest. Comparison for all subjects is showed in the following table:

Method		ELISA		Total Results
Filariasis IgG/IgM RapiCard™ InstaTest	Results	Positive	Negative	
	Positive	31	3	34
	Negative	1	248	249
Total Results		32	251	283

Relative Sensitivity: 96.9% (95%CI*: 83.8%-99.9%)
Relatively Specificity: 98.8% (95%CI*: 96.5%-99.8%)
Accuracy: 98.6% (95%CI*: 96.4%-99.6%)
*Confidence Interval

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the OneStep Filariasis IgG/IgM RapiCard™ InstaTest (Whole Blood/Serum/Plasma) have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

Sera containing known amounts of antibodies to *Filariasis* have been tested with Hepatitis A, B, C, E, HIV and Syphilis. No cross-reactivity was observed, indicating that the OneStep Filariasis IgG/IgM RapiCard™ InstaTest (Whole Blood/Serum/Plasma) has a high degree of specificity for antibodies to Filariasis.

Interfering Substances

The OneStep Filariasis IgG/IgM RapiCard™ InstaTest (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum specimens containing high bilirubin levels. In addition, no interference was observed in specimens containing up to 1,000 mg/dL hemoglobin; up to 1,000 mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin

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MANUFACTURER AND BRAND DETAILS

ISO 13485:2016

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

Diagnostic Automation/Cortez Diagnostics, Inc.
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Woodland Hills, California 91367 USA

Date Adopted	**2025-03-25**
Brand Name	**AccuDiag™**
REF 177582	**CORTEZ – OneStep Filariasis IgG/IgM RapiCard ™ InstaTest (Whole Blood, Serum, Plasma)**
PIC	**ID177582VV86**
Revision Date: 2025-03-25	