SPECTRUM
MEDICAL DIAGNOSTICS

# IGE Rapid Test

QUICK REFERENCE INSTRUCTIONS

Please refer to the Package Insert for complete instructions. Read the complete test procedure before performing the test.

## Before Running The Test

- Before running the test, please ensure that you have read all the information in this package insert.
- The IGE Rapid Test Cassette (Nasopharyngeal Swab/Nasal Aspirate) is intended for professional in vitro diagnostic use only.
- Follow the specimen collection and preparation instructions carefully, and make sure all materials are at room temperature before testing.

## Intended Use

- The IgE Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of human IgE antibodies in whole blood, serum, or plasma to aid in the diagnosis of allergy.
- It is specifically designed for professional in vitro diagnostic use.
- Immunoglobulin E (IgE) is a specific antibody found in mammals and plays a crucial role in immune responses to parasites and allergic diseases. The IgE Rapid Test Cassette detects IgE antibodies through a lateral flow chromatographic immunoassay.

## Warnings & Precautions

1. **For in vitro diagnostic use only:** The IgE Rapid Test Cassette is intended for professional in vitro diagnostic use only. It should not be used for any other purpose.
2. **Do not use after the expiration date:** Ensure that the test cassette is used before the expiration date printed on the sealed pouch. Using expired tests may result in inaccurate results.
3. Avoid smoking, drinking, or eating in areas where specimens or kit reagents are handled: To prevent contamination of specimens or kit reagents, refrain from smoking, drinking, or eating in the testing area.
4. **Wear protective clothing:** When handling specimens during testing, wear appropriate protective clothing, including laboratory coats, disposable gloves, and eye protection. This helps to ensure the safety of the operator and prevent cross-contamination.
5. **Humidity and temperature can adversely affect results:** Be aware that both humidity and temperature can affect the performance and accuracy of the test. Store and handle the test cassette according to the storage instructions provided.
6. **Proper disposal of used tests:** After completing the test, discard used tests and components according to the local regulations for biohazardous waste disposal. Follow appropriate procedures to prevent potential contamination and ensure the safety of others.

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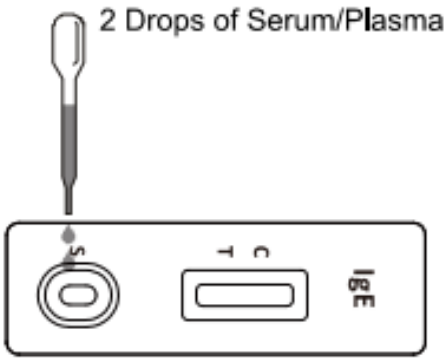
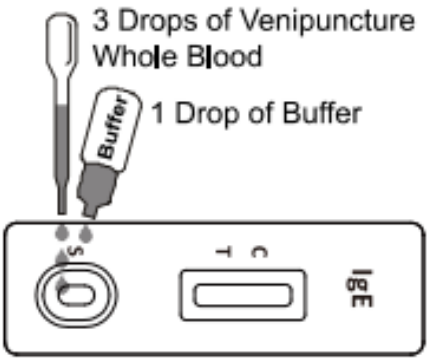
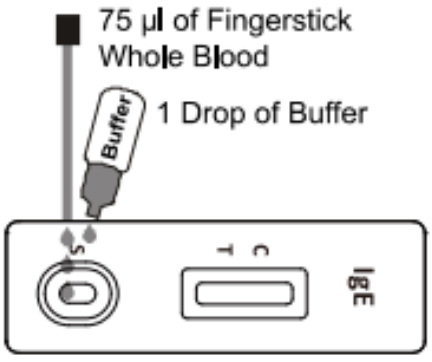
## Test Procedure

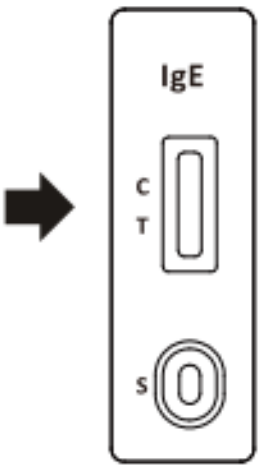
1. Bring the sealed pouch containing the test cassette to room temperature. Open the pouch within 1 hour of removal. Place the test cassette on a clean and level surface.
2. **For Fingerstick Whole Blood Specimen:**

- Fill the capillary tube provided with approximately 75µL of fingerstick whole blood.
- Transfer the collected blood from the capillary tube to the specimen well on the test cassette.
- Add 1 drop of buffer (approximately 40µL) to the specimen well.
- Start the timer immediately after adding the buffer.
- Once the specimen and buffer have been added, start the timer and wait for 5 minutes. Do not interpret the results after 10 minutes.
- After 5 minutes, observe the appearance of coloured lines in the test line and control line regions of the test cassette




## QUALITY CONTROL

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

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## Positive Result:

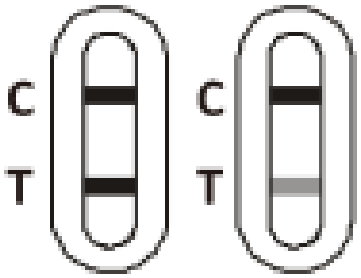
- If two coloured lines appear—one in the control line region (C) and another in the test line region—it indicates a positive result for the presence of IgE antibodies.
- The intensity of the colour in the test line region may vary depending on the concentration of IgE antibodies present in the specimen. Any shade of colour should be considered positive.

## Negative Result:

- Negative Result: If only one coloured line appears in the control line region (C) and no line appears in the test line region, it indicates a negative result, suggesting the absence of IgE antibodies in the specimen.

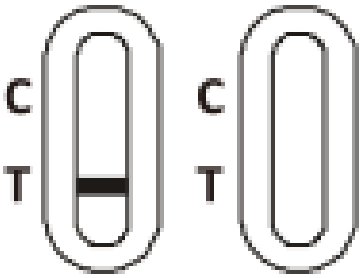
## Invalid Result:

- An invalid result is indicated **when the control line fails to appear.**
- This can be due to insufficient specimen volume or incorrect procedural techniques.
- It is advised to review the procedure, repeat the test with a new kit, and ensure proper specimen volume.
- If the problem persists, discontinue using the test kit and contact us at (866) 287-2425 or info@spectrummdx.com




Positive


Negative




Invalid

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# IGE Rapid Test Training Quiz

**What is the intended use of the IgE Rapid Test Cassette?**
a) Detection of human IgE antibodies in whole blood, serum, or plasma for allergy diagnosis.
b) Detection of human IgA antibodies in urine for viral infection diagnosis.
c) Detection of human IgM antibodies in saliva for bacterial infection diagnosis.

**What is the principle behind the IgE Rapid Test Cassette?**
a) It detects the presence of mouse anti-human IgE antibodies in the specimen.
b) It detects the presence of human IgE antibodies in the specimen through a lateral flow immunoassay.
c) It detects the presence of human IgG antibodies in the specimen through a fluorescence

**What is the overall accuracy of the IgE Rapid Test Cassette compared to other IgE Rapid tests?**
a) 80%
b) 95%
c) 98.6%

**What precautions should be taken during the testing process?**
a) Avoid smoking, drinking, or eating in the testing area.
b) Wear protective clothing such as laboratory coats, disposable gloves, and eye protection.
c) Both a and b.

**How should Fingerstick Whole Blood specimens be collected?**
a) Clean the patient's hand, puncture the skin with a sterile lancet, and transfer the blood using a capillary tube.
b) Collect the blood directly from the patient's vein using a syringe.
c) Collect the blood using a cotton swab and squeeze it onto the test cassette.

**What is the interpretation of a positive result in the IgE Rapid Test Cassette?**
a) One coloured line appears in the test line region.
b) Two coloured lines appear—one in the control line region and another in the test line region.
c) No coloured lines appear in either the control line region or the test line region.

**How long should the test be read for interpreting the results?**
a) 5 minutes.
b) 15 minutes.
c) 30 minutes.