

## Manuals+

[Q & A](#) | [Deep Search](#) | [Upload](#)

manuals.plus /

- › [OSOM](#) /
- › [OSOM Trichomonas Test Instruction Manual](#)

## OSOM 181

# OSOM Trichomonas Test Instruction Manual

Model: 181

## 1. INTRODUCTION

---

The OSOM Trichomonas Test is a rapid, qualitative immunoassay designed for the detection of *Trichomonas vaginalis* antigen from vaginal swab specimens. This test is intended for *in vitro* diagnostic use and provides results in 10 minutes or less, aiding in the timely diagnosis of trichomoniasis.

## 2. INTENDED USE

---

This device is for professional and laboratory use only. It is a CLIA-waived rapid test for the qualitative detection of *Trichomonas vaginalis* antigen.

## 3. KIT COMPONENTS

---

Each OSOM Trichomonas Test kit contains the following components, sufficient for 25 tests:

- **25 Test Sticks:** Individually pouched test devices.
- **25 Sterile Swabs:** For specimen collection.
- **25 Test Tubes:** Reaction tubes for sample processing.
- **1 Sample Buffer Vial:** Reagent for sample dilution.
- **1 Sample Buffer Dropper Top:** For dispensing buffer.
- **1 Positive Control Swab:** For quality control purposes.
- **1 Workstation:** To organize tubes during testing.
- **1 Instructions for Use:** This manual.

*Note: Extra components (swabs, tubes) are provided for convenience.*



**Figure 3.1:** Overview of the OSOM Trichomonas Test kit contents, including the test box, test sticks, sterile swabs, test tubes, and buffer vial.

## 4. WARNINGS AND PRECAUTIONS

---

- For *in vitro* diagnostic use only.
- Do not use components beyond the expiration date printed on the label.
- Handle all specimens and reagents as if capable of transmitting infectious agents.
- Wear appropriate personal protective equipment (PPE), such as gloves and lab coats, when handling specimens.
- Dispose of all used materials in accordance with local, state, and federal regulations for biohazardous waste.
- Do not interchange components from different kit lots.

## 5. STORAGE AND STABILITY

---

Store the OSOM Trichomonas Test kit at room temperature (15-30°C or 59-86°F). Do not freeze. The kit components are stable until the expiration date printed on the outer box when stored properly.

## 6. SPECIMEN COLLECTION AND HANDLING

---

Proper specimen collection is crucial for accurate results.

### 6.1 Vaginal Swab Specimen

1. Collect the vaginal swab specimen using the sterile swab provided in the kit.
2. Insert the swab into the posterior fornix of the vagina and rotate it firmly against the vaginal wall for 10-15 seconds to ensure adequate sample collection.
3. Immediately place the swab into a clean, dry test tube.
4. Specimens should be tested as soon as possible after collection. If immediate testing is not possible, specimens may be stored at 2-8°C for up to 24 hours.

## 7. TEST PROCEDURE

---

Allow all kit components and specimens to reach room temperature (15-30°C) prior to testing.

1. **Prepare the Sample Tube:** Place one clean test tube into the workstation. Add 0.5 mL (approximately 10 drops) of Sample Buffer to the test tube using the dropper top provided.
2. **Add Specimen:** Insert the patient swab into the test tube containing the Sample Buffer. Rotate the swab vigorously against the side of the tube for 10 seconds. Squeeze the sides of the tube as the swab is removed to express as much liquid as possible from the swab. Discard the swab.
3. **Add Test Stick:** Remove one test stick from its foil pouch. Immediately place the test stick into the test tube with the arrows pointing down into the liquid.
4. **Incubate:** Allow the test to develop for 10 minutes. Do not read results after 15 minutes.

## 8. INTERPRETATION OF RESULTS

---

Results are easy-to-read, two-color results.

### 8.1 Positive Result

Two distinct colored lines appear: one in the Control (C) region and one in the Test (T) region. The presence of a line in the Test region, regardless of its intensity, indicates a positive result for *Trichomonas vaginalis* antigen.

### 8.2 Negative Result

Only one colored line appears in the Control (C) region. No line appears in the Test (T) region. This indicates that *Trichomonas vaginalis* antigen was not detected.

### 8.3 Invalid Result

No colored line appears in the Control (C) region, or only a line appears in the Test (T) region. An invalid result indicates that the test procedure was not performed correctly or the test device has deteriorated. Repeat the test with a new test stick and a new specimen if possible. If the problem persists, contact Sekisui Diagnostics Technical Support.

## 9. QUALITY CONTROL

---

Internal procedural controls are included in the test. A colored line appearing in the Control (C) region indicates that sufficient sample volume was added and membrane wicking occurred correctly.

A Positive Control Swab is provided with the kit. It is recommended that a positive control be run with each new lot of kits or as required by local regulations and laboratory accreditation requirements.

## 10. LIMITATIONS

---

- The OSOM *Trichomonas* Test is a qualitative test and does not indicate the quantity of *Trichomonas vaginalis* antigen present.
- A negative result does not rule out the possibility of *Trichomonas vaginalis* infection, as the antigen concentration may be below the detection limit of the test.

- Test results should be interpreted in conjunction with other clinical and laboratory findings.
- The test has a sensitivity of 83% and a specificity of 99% for vaginal swab specimens.

## 11. TROUBLESHOOTING

Problem	Possible Cause	Solution
No Control Line (Invalid Result)	Insufficient sample volume; incorrect procedure; expired or damaged test stick.	Ensure correct sample volume; follow procedure carefully; use a new test stick from a valid lot.
Faint Test Line	Low concentration of antigen; early stage of infection.	Any visible line in the Test region, no matter how faint, indicates a positive result.
Results not appearing within 10 minutes	Incorrect temperature; insufficient sample buffer.	Ensure components are at room temperature; verify correct buffer volume. Do not read after 15 minutes.

## 12. SPECIFICATIONS

- **Product Name:** OSOM Trichomonas Test
- **Model Number:** 181
- **Test Type:** Rapid Immunoassay
- **Sample Type:** Vaginal Swab
- **Results Time:** 10 minutes or less
- **Sensitivity:** 83% (vaginal swab)
- **Specificity:** 99% (vaginal swab)
- **CLIA Status:** Waived
- **CPT Code:** 87808QW
- **Package Dimensions:** 8.39 x 4.84 x 3.78 inches
- **Item Weight:** 7.04 ounces

## 13. MANUFACTURER AND SUPPORT INFORMATION

**Manufacturer:** Sekisui Diagnostics

For technical support or inquiries, please contact Sekisui Diagnostics at:

**Phone:** 1-800-332-1042

Please have the lot number of your kit available when contacting support.