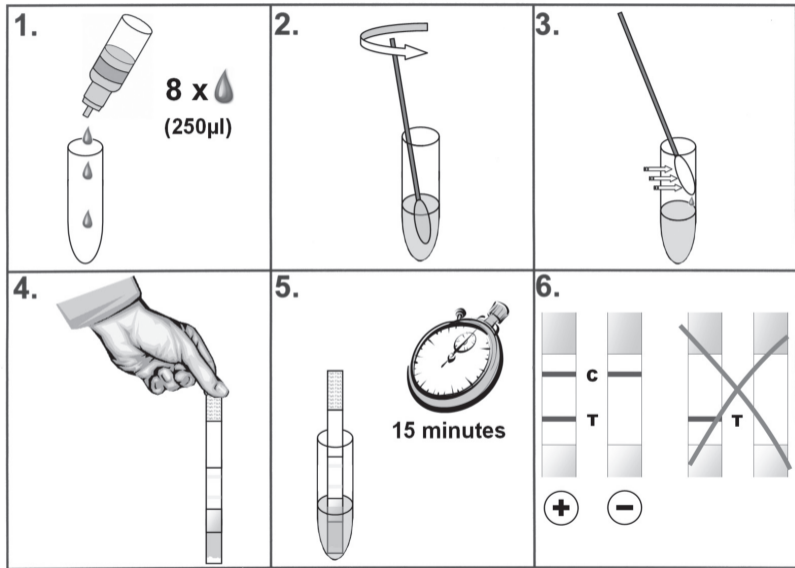


FIGURE 1 - Sample Extraction and Test Procedure - Method "A"



Swine Influenza Virus Type A Antigen Test Kit

Flu **DETECT™ Swine**

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Swine Influenza Virus Type A Antigen Test Kit

I. INTRODUCTION

Influenza Type A viruses can infect swine. Subtypes known to infect swine include H1N1 and H3N2. Swine influenza viruses (SIV) typically cause high morbidity and low mortality. Signs of infection in swine may include fever and respiratory problems.

II. INTENDED USE

Flu **DETECT™ Swine** kit is an in vitro test, designed to aid in the qualitative detection of Swine Influenza Type A virus in nasal samples from porcine. Positive results may be submitted to a reference lab for confirmation and subtype determination. Negative results indicate no detectable SIV is present.

III. TEST PRINCIPLE

Flu **DETECT™ Swine** is based on Rapid Immuno Migration (RIM™) technology. The test strip uses two antibodies that are specific to the p56 nucleoprotein of Influenza Virus Type A. Anti-Influenza A antibody bound to Influenza A antigen if present in the sample forms a complex, which migrates along a strip and is captured on a sensitized reaction line by the second antibody. The accumulation of the complex causes the formation of a clearly visible pink/purple band. The presence of a control band, located above the reaction line, ensures that the test was performed correctly.

IV. SAMPLE COLLECTION

1. Use provided swabs to collect nasal samples from symptomatic swine (see VI. GENERAL PRECAUTIONS).
2. Samples obtained early in the course of infection will contain the highest detectable amount of virus.
3. If additional testing is to be performed on the sample, it is possible to collect the sample in a viral transport medium. These alternate media are not provided in this test kit. Approved media, in order of preference, are: Brain Heart Infusion Broth – porcine origin, Tris Buffered Tryptone Broth (TBTB), Nutrient Broth (NB) or Peptone Broth (PB). **If further testing is planned, follow Sample Extraction Method VII B.**

V. KIT CONTENTS

- A. 1 desiccated vial containing 20 test strips
- B. 1 dropper bottle containing extraction buffer (6.0 mL)
- C. 1 pack of 20 swabs
- D. 1 pack of 20 test tubes
- E. 1 pack of 20 test tube caps
- F. 1 test tube rack (for 5 tubes)
- G. Instructions for Use

VI. GENERAL PRECAUTIONS

- 1. Allow samples and kit to come to room temperature (15° to 30°C; 59°-86°F) before testing.
- 2. Do not use kit components after expiration date.
- 3. Do not mix materials from different test kits.
- 4. The vial holding the test strips contains a desiccant and should be kept tightly closed when not in use.
- 5. Use the test strips within 10 minutes of removing from desiccant vial.
- 6. Test strips should only be handled in the upper, labelled region. Avoid contact with the surface of the test strip.
- 7. The test strip should be placed in the test tube vertically.
- 8. Use a separate swab for each sample. Swabs with wooden handles or containing calcium alginate may interfere with the test and must not be used.
- 9. Do not centrifuge samples prior to use.
- 10. Swabs containing visible blood may partly obscure a weak positive band due to hemoglobin background.
- 11. Consider all specimens potentially infectious and dispose of accordingly.
- 12. For veterinary use only.

Note: *Prior to use, test and control bands appear yellow. The bands are dyed yellow for quality control purposes. The dye does not interfere with the test results and will wash away while the test is developing.*

VII. SAMPLE EXTRACTION

Synbiotics recommends two methods of sample extraction. If the sample will be tested using this test kit only, follow METHOD A. If further testing is to be performed on the sample, follow METHOD B.

A. Extraction Buffer – Provided in kit box

- Place 8 drops (approximately 0.25 mL) of Extraction Buffer in the test tube provided (Figure 1, Step 1).
- Place the swab containing the specimen in the tube and rotate the swab 5 – 10 times in the buffer (Fig. 1, Step 2).
- When removing the swab from the tube, press the swab against the side of the tube repeatedly until no more liquid comes from the swab (Fig 1, Step 3).
- Discard the swab in an appropriate biohazard container.
- If the extracted samples will not be tested immediately, cap the tube with the provided cap and store the sample according to VIII. STORAGE.

B. Brain-Heart Infusion (BHI) Broth, (or alternate viral transport medium listed in Section IV) – not provided.

- Place approximately 0.5 mL of BHI Broth into a collection tube.
- Place the swab containing the specimen in the tube and rotate the swab 5 – 10 times in the broth.
- When removing the swab from the tube, press the swab against the side of the tube repeatedly until no more liquid comes from the swab.
- Discard the swab in an appropriate biohazard container or break the handle of the swab below the top of the tube such that the tube containing the swab tip can be sealed with the provided cap.
- If the extracted sample will not be tested immediately, cap the tube with the provided cap and store the sample according to VIII. STORAGE.

Note: *0.2 mL of extracted sample is required for each test; remaining volume can be used in alternate test method.*

VIII. STORAGE

- If samples will not be tested immediately they should be stored at 4°C (ice chest, cooler or refrigerator) for up to 48 hours. For prolonged storage, samples should be kept frozen (-70°C). Do not store samples at -20°C. Do not store samples in a self-defrosting freezer. Avoid multiple freeze-thaw cycles.
- Test kits should be stored between 2° and 30°C (35° to 86°F). **DO NOT FREEZE Test Kits.**

IX. PROCEDURE

1. Testing Samples – Use either Method A or B as appropriate

A. Extracted in Buffer:

- Remove a test strip from the desiccant vial for each sample to be tested. Handle the test strip on the labelled portion of the strip. (Fig. 1, Step 4).
- Place the test strip directly into the test tube containing the sample. Place test strip so that the pink pad is submerged in the extracted sample. Incubate the test strip in the sample for 15 minutes. (Figure 1, Step 5).
- Remove the test strip from the test tube to read.

B. Extracted in Viral Transport Media:

- Place 0.2 mL of the viral transport media into the test tube provided.
- Add 3 drops of Extraction buffer to tube; tap side of tube to mix.
- Remove a test strip from the desiccant vial for each sample to be tested. Handle the test strip on the labelled portion of the strip. (Fig. 1, Step 4).
- Place the test strip directly into the test tube containing the sample. Place test strip so that the pink pad is submerged in the extracted sample. Incubate the test strip in the sample for 15 minutes. (Fig. 1, Step 5).
- Remove the test strip from the test tube to read.

2. Reading Results

- After 15 minutes, observe the presence or absence of pink/purple bands in the center of the test strip between the two absorption pads (Fig.1, Step 6).

- The control band appears in the upper end of the test strip (closest to the handle), while the sample test results are read in the lower part of the test strip.
- Discard the test strip in an appropriate biohazard container.

3. Interpretation of Results

- The test is **VALID** if the Control Line (pink/purple band) develops in the upper part of the test strip. The absence of the Control Line indicates that the test is invalid and must be repeated (Fig. 1, Step 6).
- **POSITIVE** for Swine Influenza Virus: Two pink/purple bands (Control Line and Test Line) are clearly visible on the test strip (C & T). A **POSITIVE** result indicates that a detectable level of SIV is present in the sample. Positive samples can be submitted to an approved reference laboratory for confirmation and subtype determination.
- **NEGATIVE** for Swine Influenza Virus: A single pink/purple band (Control Line) is present in the upper part of the test strip (C). A **NEGATIVE** result indicates that no detectable SIV is present in the sample.
- Very faint lines may be due to non-specific binding and should be further investigated.

Note: *The Control Line on the upper part of the test strip may appear earlier. This does not mean that the test is complete. The test strip must incubate for a full 15 minutes before a sample is interpreted as Negative. The test can be considered to be complete if the Test Line on the lower part of the stick appears before the 15 minute incubation period is over. This sample is interpreted as Positive. If the test strip remains in the test tube for more than 20 minutes a false positive ghost band could appear in place of the reaction band (T).*

X. TECHNICAL SERVICE

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