AVIAN INFLUENZA VIRUS TYPE A ANTIGEN TEST KIT

FluDETECT™ | Avian — ENGLISH

I. GENERAL INFORMATION

FluDETECT™ Avian is an in vitro, rapid immunochromatographic immunoassay designed to aid in the qualitative detection of Influenza Type A virus in tracheal and cloacal samples from symptomatic birds or flocks. This assay detects all 16 subtypes of Influenza Type A virus. Positive results should be submitted to a reference lab for confirmation and subtype determination. Negative results indicate that no detectable Influenza Type A virus is present.

II. TEST PRINCIPLES

FluDETECT™ Avian is based on Rapid Immuno Migration (RIM™) technology. The test strip uses two antibodies that are specific to the p56 nucleoprotein of Influenza Type A Virus. An anti-Influenza A antibody bound to Influenza A antigen present in the sample forms an antigen-antibody 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.

Development of very faint test lines may be due to non-specific binding and should be investigated further. Positive samples must be submitted to an approved reference laboratory for confirmation and subtype determination. If a Negative Control test is desired, Zoetis recommends using Brain Infusion Broth or alternate viral transport media described in Section III. Follow the procedure described in Section VII.B SAMPLE EXTRACTION.

III. SAMPLE COLLECTION

- Use the provided swabs to collect tracheal, oropharyngeal and/or cloacal samples from avian species. See Section VI. PRECAUTIONS.
- Samples obtained earlier in the course of infection will contain the highest detectable amount of virus.
- Tracheal or oropharyngeal samples should be taken from behind the tongue and into the tracheal or oropharyngeal area (not just from the mouth).
- Cloacal samples should be taken from within the cloacal area avoiding excess solid fecal material or visible blood. Excess fecal material may interfere with the performance of the test. See Section VI. PRECAUTIONS.
- If additional testing is to be performed on the sample, it is possible to collect the sample in a viral transport media. These alternate media are not provided in this test kit. Approved media that may be used, in order of preference are: Brain Heart Infusion Broth - porcine origin (BHI), Tris Buffered Tryptone Broth (TBTB), Nutrient Broth (NB) or Peptone Broth (PB).

IV. SAMPLE STORAGE

Samples should preferably be tested immediately after collection.

If testing is delayed, samples should be kept refrigerated (up to 48 hours at +4 °C).

For long term storage, samples should be kept frozen (-70 °C or colder). Do not store samples at -20 °C. Do not store samples in a self-defrosting freezer. Avoid multiple freeze-thaw cycles.

Swab samples should be kept moist during transport. Transport of dry swabs is not recommended.

V. KIT CONTENTS

- 1 Vial containing 20 test strips and desiccant.
- 1 Extraction Buffer dropper bottle (6.0 mL)
- 20 Swabs
- 20 Test tubes
- 20 Test tube caps
- 1 Test tube rack
- Instructions for use

VI. PRECAUTIONS

- Do not use this kit or any of its components after the expiration date.
- Kit should be stored at +2 °C – 30 °C. **Kit should not be frozen.**
- Do not mix materials from different test kits.
- The vial holding the test strips contains a desiccant and should be kept tightly closed when not in use.
- Use the test strips within 10 minutes after removal from the desiccant vial.
- Test strips should only be handled in the upper, labelled region. Avoid contact with the surface of the test strip.
- The test strip should be placed in the test tube vertically.
- 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.
- Do not centrifuge samples prior to use.
- Swabs containing visible blood may partly obscure a weak positive band due to hemoglobin background.
- Handle all reagents and samples as biohazardous material.
- Sample extractions of cloacal swabs containing an excess of fecal material may interfere with the test. Allow the feces to settle to the bottom of the tube then draw the sample off from the top for testing.
- Extraction buffer is preserved with sodium azide.
- For animal use only.

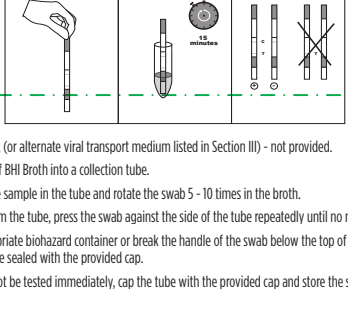
VII. SAMPLE EXTRACTION

Zoetis 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 250 µL) of Extraction Buffer in the test tube provided (Figure 1, Step 1).
- Place the swab containing the sample in the tube and rotate the swab 5 - 10 times in the buffer (Figure 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 (Figure 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 Section IV. SAMPLE STORAGE.

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



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

- Place approximately 0.5 mL of BHI Broth into a collection tube.
- Place the swab containing the sample 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 IV. SAMPLE STORAGE.

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

VIII. TEST PROCEDURE

Allow samples and kit to come to 15 °C – 30 °C before testing.

Testing samples - Use either Method A or B as appropriate.

A. Sample Extracted in Buffer:

- Remove a test strip from the desiccant vial for each sample to be tested. Handle the test strip on the labeled portion of the strip. (Figure 1, Step 4) 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.
- 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. Sample 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 labeled portion of the strip. (Figure 1, Step 4) 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.
- 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.

IX. READING TEST

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

X. RESULTS

Valid 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 (Figure 1, Step 6).

Interpretation of Results

- **POSITIVE** for Influenza A 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 Influenza Type A is present in the sample. **Positive samples can be submitted to an approved reference laboratory for confirmation and subtype determination.**
- **NEGATIVE** for Influenza A 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 Influenza Type A 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 low 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).*

SYMBOL DESCRIPTIONS

	Use by (expiration date)	EC REP	Authorized Representative in the European Community
LOT	Batch code		Consult Instructions for use
SN	Serial number	IVD	*In vitro* diagnostic medical device
	Temperature limitations (storage temperature range)		Manufacturer

zoetis

Zoetis Inc.

Kalamazoo, MI 49007, USA

VLN/PCN 190/5180.52

1-888-963-8471

www.zoetis.com

EC REP

ZOETIS FRANCE

23 Rue Pierre Gilles de Gennes,

69007 Lyon, FRANCE