REF

AKIT-H5N1-AG-01

assaya

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English

# H5N1 (Avian Influenza) Ag - Instructions For Use (IFU)

For in vitro diagnostic use only.

## Sample Collection Method


## Intended Use

The Rapid Antigen Test for Avian Influenza (H5N1) is a chromatographic immunoassay intended for the visual qualitative detection or machine read quantitative detection of antigens of H5N1 in samples. H5N1 Avian Influenza is a highly contagious viral disease that can affect birds, livestock, cats, dogs, rodents and may also cause serious illness and death in humans. This RDT detects H5N1 Avian Influenza antigens, and is a valuable tool for veterinarians and livestock producers to help identify infected animals and control the spread of the virus. H5N1 is characterized by a range of clinical symptoms in birds including respiratory distress, drop in egg production, swelling of the head, neck, and eyes, and high mortality rates in severe cases. Prevention measures include strict biosecurity measures, quarantine, and vaccination.

This user-friendly and reliable H5N1 Rapid Antigen Test has been designed to assist veterinarians, animal health professionals, and farmers in quickly identifying H5N1-infected birds, allowing for prompt action to limit the spread of the virus and minimize its economic impact.

This test utilizes a lateral flow immunoassay, employing dye-labeled particles that bind to H5N1 antigens in the sample. The appearance of a colored line on the test strip indicates the presence of H5N1 antigens. A nitrocellulose membrane is immobilized with a monoclonal antibody against the Avian influenza antigen. Another anti-Avian influenza Ag monoclonal antibody is conjugated to colloidal gold particles. This conjugate is placed on a polyester pad as a conjugate pad. When the test is in assay buffer containing specimens, the solubilized conjugate migrates with the sample by passive diffusion and both the conjugate and sample come into contact with the anti-Avian influenza antibody that it absorbed onto the nitrocellulose.

Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results should be considered in the context of recent exposures, history and the presence of clinical signs and symptoms. The Rapid Antigen Test for H5N1 is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel.

## Materials

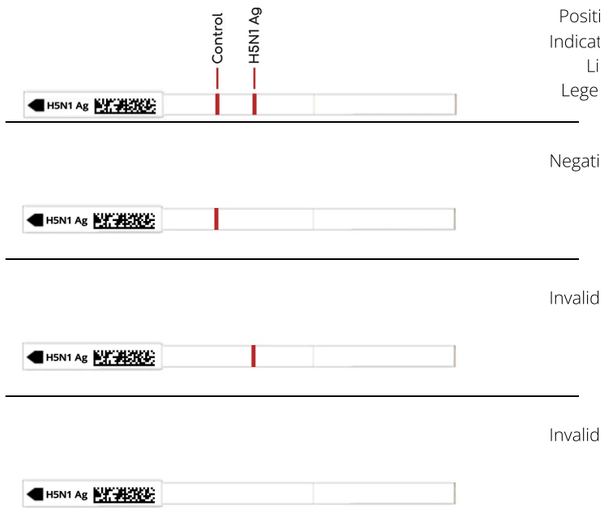
Each box contains 50 test kits. Each test kit contains:

The following materials are provided with the RDT for Avian Influenza:

- LEIQA Test strips with desiccant (50 kits)
- Buffer solution (50 Spackets)
- UTID.ORG DataMatrix label for reading
- 1 SWAC (Sterile Wood Abrasive Collector)

Materials Required but not Provided:

## Result Interpretation




## Positive Results

At 10 minutes, the appearance of the Control Line and  Test Line on the Test Indicator, indicates a positive result for the presence of antigens for H5N1. Positive test results only mean antigens for H5N1 exist in the specimen

- The appearance of a Control Line and Test Line, indicates a positive result for the presence of antigens for H5N1. The intensity of the test line may vary depending on the amount of antigens present in the sample.

## Negative Results

At 10 minutes, the appearance of only Control Line indicates a negative result for the presence of antigens for H5N1.

## Invalid Results

If at 10 minutes, the Control Line does not appear, even if a Test Line appears in the indicator, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new Test Indicator.

## Internal Controls

Two internal procedural controls are needed to confirm correct assay procedure and active kit components. One of two is a line appearing in the “Control Line” area in every run of the test to assess validity of the test. Another one is a clear background serving as an internal negative control. The background color should be white and not interfere with the reading of the test result. If the background color interferes with the reading, it is recommended to repeat the test.





- Timer – you may use a smartphone to read the QR code of the Spacket
- Gloves and Cleaning disinfectant
- Blood collection and transfer devices if using blood sample

## Storage And Disposal

The product should be stored at 2-30°C. Do not freeze or overheat the test kit or kit reagents. Kit contents are stable until the expiration date printed on each test kit. The indicators must be kept in the foil pouch until use. Dispose of used contents in accordance with federal, state, and local requirements.

## Sample Preparation

Before use, check the expiration date of the packaging. If the kit is past its expiration date, do not use. Confirm that all components needed are in the kit.

Various collection methods are available for sampling H5N1, with each approach tailored to specific scenarios. The Sterile Wood Abrasive Collector, known as SWAC, offers versatility in this regard. For live humans and mammals, the SWAC can collect epithelial cells potentially harboring replication-competent virus particles through nostril sampling. In the case of small birds and rodents, the SWAC is inserted into the oropharyngeal region to gather viral particles ensconced in mucus. Cloacal swabs are utilized by inserting a swab into the cloaca, the convergence point of the digestive, urinary, and reproductive tracts, to collect fecal matter. During necropsy, tissue samples can be procured from organs like the lungs, trachea, and intestines. The choice of collection method hinges on the intended purpose and the bird’s condition.

Inadequate or inappropriate sample collection, storage, and transport may yield false test results. The training in specimen collection is highly recommended because of the importance of specimen quality.

| 1. | 2. |
| --- | --- |
| Obtain the sterile SWAC. Make sure the SWAC head does not touch anything until sample collection. | Insert the SWAC into the mouth of the animal being tested. Keep the SWAC near the cheek in the mouth. Rotate the SWAC 5 times to collect saliva. |

## Assay Procedure

| 1. | 2. |
| --- | --- |
| Stand up the Spacket, and tear it open. Be careful not to spill the liquid reagent inside. | Put the SWAC into the Spacket. Roll the swab 5 times. Leave the SWAC in the Spacket for 1 minute |

## Result Interpretation with the iaX-2101

Please refer to the full iaX-2101 Instructions for Use for complete instructions on how to operate the IaX.

Place the test indicator into the iaX-2101, with the barcode pointing in.

- A Green ( – ) indicates a negative result for the presences of antigens for H5N1, or that the antigen level is below the detection limit.
- A Yellow ( ! ) indicates that the test is invalid and a new test must be performed with a freshly collected specimen sample.
- A Red ( + ) indicates a positive result for the presence of antigens for H5N1.

GREEN – (NEGATIVE)

YELLOW ! (INVALID)

RED + (POSITIVE)

before inserting the test indicator.

3.

4.

10 Minutes

While the SWAC remains in the Spacket, place the test indicator into the Spacket with the sample pad going down. Leave the test indicator in the Spacket for 10 minutes. Use the assaya timerDx to keep track of the test time.

Take out the test indicator and read the result at 10 minutes. Do not read the result after 20 minutes. The test indicator may also be read by the intelligent analyzer eXpress (iaX-2101) after 10 minutes.

## Warnings & Precautions

1. For in vitro diagnostic use only.
2. This test has been authorized for the detection of antigens for H5N1 only.
3. To obtain accurate results, you must follow the Package Insert.
4. Check if the device package is complete; test indicator must be sealed in foil pouch and the expiration date of the device must be shown. Do not use if any of the test materials is broken or beyond the labelled expiration date.
5. Do not interchange or mix different lots of assaya Rapid Antigen Test for H5N1.
6. Do not reuse kit components.
7. Use of protective tools is recommended when collecting, handling, storing, and disposing of the components within process.
8. Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
9. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
10. Disregard test results beyond the specified time (20 min).
11. Test results must be interpreted together with other clinical information available to the physician.
12. Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to skin. When contacted acidic substances, it may produce highly toxic gases. In case of accidental contact with the skin, please wash immediately with plenty of water.

## Product Limitations

1. The contents of this kit are to be used for the qualitative detection of antigens for H5N1. For quantitative detection of the assay, use the iaX-2101. Please refer to the iaX-2101 IFU for full instructions on using the iaX-2101.
2. The amounts of antigens in the specimen may decrease or increase as the duration of illness increases.
3. Test result must be combined with clinical observations, clinical history, and epidemiology to make an overall judgment.
4. Positive test results only mean antigens for H5N1 exist in the specimen. Negative test result may occur if the level of antigens in a specimen is below the detection limit of the test.

## Clinical Performance



## References

1. “How to Protect Yourself & Others”. Centers for Disease Control and Prevention (CDC). 8 April 2020. Archived from the original on 26 February 2020. Retrieved 9 April 2020.
2. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, DC (2007).
3. Henretig F.M. MD, King C. MD, Textbook of Pediatric Procedures, Chapter 123 – Obtaining Biologic Specimens Williams and Williams (April 1997).

## Technical Support

Email: support@assaya.com (mailto:support@assaya.com)

## Adverse Events Reporting

Use this link to report any adverse events: assaya.com/ae (https://assaya.com/ae)

## Ordering Information

Catalog Number (REF): AKIT-H5N1-AG-01
50 pcs per box (Carton of 50 test kits)

## Symbol Legend



The RDT for H5N1 has been evaluated for sensitivity and specificity using a panel of known H5N1-positive and H5N1-negative chicken samples. The test was found to have a sensitivity of 99% and a specificity of 98%.

| | | |
|---|---|---|
| Catalog Number | Consult Package Insert | Do not reuse |
| Batch Code | Manufacturer | Contains sufficient for <50> tests |
| In Vitro Diagnostic Medical Device | Temperature Limit | Humidity Limit |
| No Direct Sunlight | Expiration Date | Do not use if package is damaged |
| Do not expose to water | Warning | CE Marking |

## Manufacturers

### IVD

**Assaya Pvt. Ltd. Singapore**
160 Robinson Road, #14-04 Singapore Business Federation Centre, Singapore 068914
Web: assaya.com/ (https://assaya.com/)

### Spacket

**Taiwan Swabs Technology Company Inc.**
No.329-1, Sucuo, Anding Dist.,
Tainan City 745, Taiwan
Web: yt-swabs.com.tw/eng (http://www.yt-swabs.com.tw/eng)

## Distributor

**NordicDx**
Måltidets hus,
Richard Johnsens Gate 4
4021 Stavanger, Norway
Web: n (https://assaya.com/)ordicdx.no