

Rockeby Human Influenza A Antigen Test

The **Rockeby Human Influenza A Antigen** test kit is an in-vitro, rapid immunochromatographic assay for the qualitative detection of Influenza virus antigen type A in human specimens, either direct swab or liquid samples.

The **Rockeby Human Influenza A Antigen** test kit, has been developed for primary diagnosis with ease of use, and quick results. The kit has been coated with a monoclonal antibody against the nucleoprotein of influenza virus type A. This has been found to identify influenza virus with a high degree of accuracy. The kit contains test devices, specimen tubes, assay diluent, sample collection swabs and disposable droppers sufficient to test 10 samples.

Features :

- For in-vitro diagnostic use only
- Rapid test device
- Sandwich principle assay
- Applicable to human specimens, either direct swab or liquid samples
- Results in 10 minutes
- Kits can be stored between 2-30°C
- Tested by WHO Collaborating Centre for Reference and Research on Influenza, Australia.⁷

Avian influenza is caused by the influenza virus, of the Orthomyxoviridae Family. The virus can be divided into three types: A, B and C according to the matrix protein (M) (Swayne and Halvorson, 2003). Only Influenza Virus Type A is communicable and is highly pathogenic (HPAI). The HPAI Type A virus that causes disease in chickens is the H5 and H7.

In Thailand, the first epidemic was reported in February 2004, from a chicken farm. The epidemic covered more than 30 provinces all over the country (www.oie.int). Symptoms may be varied due to virus subtype and kind of infected animal (Perkin and Swayne, 2003). Avian Influenza not only caused great damage to the avian farm industry, but also caused a panic in public health due to humans being susceptible to this avian flu subtype. Infected people have respiratory problems and can be fatal.

Procedures currently used to diagnose influenza Type A infection include serological assay, hemagglutination inhibition, polymerase chain reaction, direct specimen immunofluorescence assay (IFA) and culture isolation with confirmation procedure. The latter is considered the standard method and employs initial viral isolation in cell culture followed by hemadsorption inhibition, immunofluorescence, or neutralization assay to confirm the presence of the Influenza A virus. These methods take more time to get the results, which could be done only in authorized laboratory centers.

Assay Procedure :

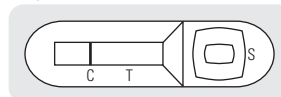
A. Procedure for direct swab sample (nasopharyngeal, throat or nasal).

1. Add the assay diluent provided into the test tube until the marked line (1 ml).
2. Immerse the specimen swab into the test tube containing assay diluent.
3. Mix the swab until the sample has been dissolved into the diluent, remove as much liquid from the swab as possible.
4. Let the test tube stand until the large particles have settled down to the bottom of the tube.
5. Remove the test device from the foil pouch, and place it on a flat and dry surface.
6. Using the disposable dropper provided, dispense **eight drops** of the supernatant from extracted sample into the sample well (S), avoiding adding bubbles.
7. Interpret test results at **10 minutes**.

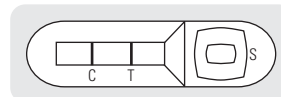
B. Procedure for nasopharyngeal aspirate, nasal wash or allantoic fluid.

1. Dispense **three drops** of specimen sample into the test tube using the disposable dropper.
2. Add **six drops** of the assay diluent from the dropper bottle into the tube containing the specimen, mix well by pipetting up and down using the disposable dropper provided.
3. Dispense **eight drops** of the mixture into the sample well (S) with the same dropper, avoid adding bubbles.
4. Interpret test results at **10 minutes**.

Negative Result:



Positive Result:



Marketed by:

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Table 1: Results of a study showing that the Rockeby Human Influenza A Antigen test kit is able to detect H3N2 and H5N1 infections and performance is similar to other commercial kits.⁷

Assay	Clinical samples		Virus isolation	
	#ID39 (H3N2)	#ID1 (H5N1)	#ID39 (H3N2)	#ID1 (H5N1)
IFA (infected cells)	Pos	Pos	Pos	Pos
Kit "A"	Pos	NA*	Pos	Pos
Kit "B"	NA*	NA*	Pos	Pos
Kit "C"	NA*	NA*	Pos	Pos
Rockeby Human Influenza A	Pos	NA*	Pos	Pos

* Not applicable

Table 2: Results of a specificity study indicating that the Rockeby Human Influenza A Antigen test had no cross reactivity with other viruses found in the respiratory system, which includes parainfluenza virus, adenovirus and measles virus.⁷

Result by IFA and/or culture	No. of test	RT-PCR (H1, H3, H5)	Rockeby Human Influenza A Clinical Samples	
			Negative	Positive
Parainfluenza 1	3	Neg	3	0
Parainfluenza 3	1	Neg	1	0
Adenovirus	2	Neg	2	0
* Mixed infection	3	Neg	3	0
Negative for all viruses	13	Neg	13	0
Overall	22	22	22	0

* Adenovirus/parainfluenza type 2, adenovirus, parainfluenza type 3, parainfluenza virus 1 / measles.

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7. Rockeby biomed confidential data on file.