（**FOR RESEARCH USE ONLY. DO NOT USE IT IN CLINICAL DIAGNOSIS !**）

Human Adenoviruses Antigen Lateral Flow Assay Kit

Catalog No: E-HD-C093

20T/40T

Version Number:	V1.1.1
Replace version:	V1.1.0
Revision Date:	2022.10.25

This manual must be read attentively and completely before using this product.

If you have any problems, please contact our Technical Service Center for help.

Toll-free: 1-888-852-8623 Tel: 1-832-243-6086 Fax: 1-832-243-6017

Email: techsupport@elabscience.com

Website: www.vetassay-elab.com

Please kindly provide us the lot number (on the outside of the box) of the kit for more efficient service.

Test principle

The Adenoviruses Antigen Test Kit is a lateral flow chromatographic immunoassay. The test strip consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-adenovirus antibody conjugated with colloidal gold (anti-adenovirus conjugates) and 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with anti-adenovirus antibody, and the C line is pre-coated with a control line antibody.

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Adenovirus Ag, if present in the specimen, will bind to the anti-adenovirus conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-adenovirus antibody forming a burgundy colored T line, indicating an adenovirus positive test result.

Absence of the test lines suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of the control antibodies, regardless of color development on any of the test lines. Otherwise, the test result is invalid and the specimen must be retested with another device.

Kit components

Item	Specification
Detection Card	20T/40T
Stool Sampler	20/40 vials
Manual	1 copy

Note: All reagent bottle caps must be tightened to prevent evaporation and microbial pollution.

Notes

1. It is a disposable reagent. Do not reuse it. Please use it within the validity date.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not open the sealed pouch until ready to conduct the assay.
4. Do not use any kit components beyond their stated expiration date.
5. Bring all reagents to room temperature (15-30 ℃) before use.
6. Do not use the components of any other type of test kit as a substitute for the components in this kit.
7. Wear protective clothing and disposable gloves while handling the kit reagents and specimens. Wash hands thoroughly after performing the test.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Users of this test should follow the US CDC Universal Precautions for bio-safety.
11. Do not scoop fecal specimen as this may lead to excess fecal specimen that tends to clot the sample pad and interfere with sample migration.

12. The testing results should be read 15-20 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside of the 15-20 minute window should be considered invalid and must berepeated.
13. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air conditioning.
14. If you have any questions or suggestions during use, please do not hesitate to contact the manufacturer.

Storage and expiry date

Storage: Store at 4-30℃. With cool and dry environment.

Expiry date: expiration date is on the packing box.

Requirements of sample

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

To prepare specimens using solid stool samples follow Procedure A below. To prepare specimens using watery stool samples follow Procedure B below.

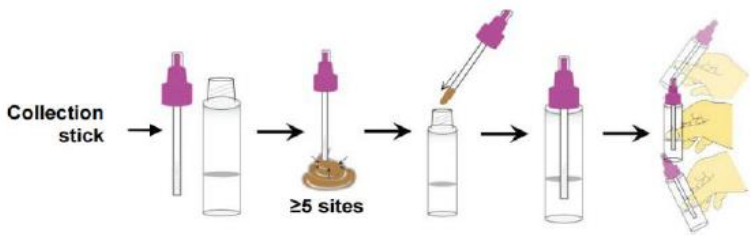
Procedure A: Solid stool samples

Step 1: Collect a random stool sample in a clean, dry receptacle.

Step 2: Label the stool collection device with the specimen's ID number (patient ID sticker). Open the stool collection device by unscrewing the top and use the collection stick to randomly pierce the stool sample in at least five different sites. **Do not scoop stool sample. Ensure that stool specimen is only in the grooves of the collection stick. Excess stool specimen may lead to an invalid test result.**

Step 3: Replace the collection stick and tighten securely to close the stool collection device.

Step 4: Shake the stool collection device vigorously.



Procedure B: Watery stool samples

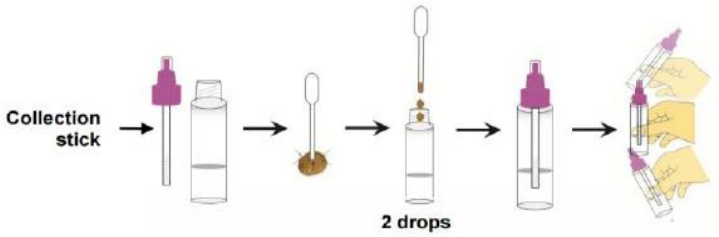
Step 1: Collect a random stool sample in a clean, dry receptacle.

Step 2: Label the stool collection device with the specimen's ID number (patient ID sticker). Open the stool collection device by unscrewing the top.

Step 3: Fill the plastic dropper with the sample; dispense 2 drops (70-85 μL) into the stool collection device.

Step 4: Replace the collection stick and tighten securely to close the stool collection device.

Step 5: Shake the stool collection device vigorously.



The specimen is now ready for testing, transportation or storage.

Note: It is recommended to test the specimen immediately after extraction. If not tested immediately, the extracted specimen may be stored at 2-8 ℃ for up to 3 days. For longer storage, the extracted specimen may be frozen at -20 ℃. Avoid multiple freeze-thaw cycles.

Assay procedure

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

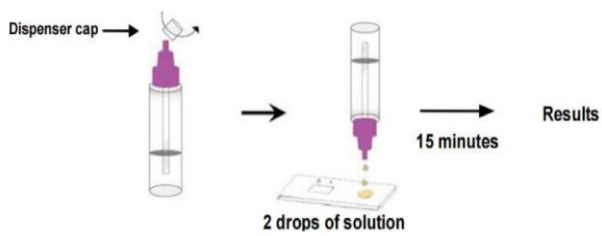
Step 2: When ready to test, open the pouch at the notch and remove the test cassette. Place the test device on a clean, flat surface.

Step 3: Shake the stool collection device vigorously to ensure a homogenous liquid suspension.

Step 4: Hold the stool collection device vertically. Twist off the cap, dispense 2 drops 70- 85 μL) of the solution into the sample well of the test device. Do not overload specimen.

Step 5: Set up the timer.

Step 6: Results can be read at 15 minutes. Positive results can be visible in as short as 1 minute. Negative results must be confirmed at the end of 20 minutes only. Any results interpreted outside of the 15-20 minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.

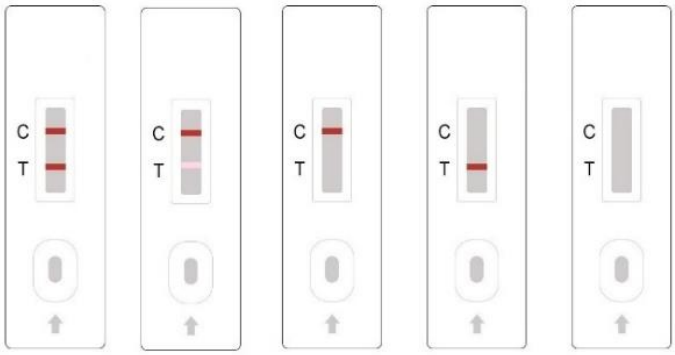


NOTE: This figure is only used as a reference.

Interpretation of results

Positive: If both C and T lines develop, the test indicates the presence of detectable RSV antigen in the specimen. The result is positive or reactive.

1. Negative: If only the C line is developed, the test indicates that no detectable RSV antigen is present in the specimen. The result is negative or non-reactive.
2. Invalid: If no C line develops, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new reagent.



NOTE: This figure is only used as a reference.

Limitations of this test method

1. The Test Procedure and the Interpretation of Results sections must be followed closely when testing for the presence of adenovirus Ag in feces. Failure to follow the procedure may lead to inaccurate results.
2. The Adenoviruses Antigen Test Kit is limited to the qualitative detection of adenovirus antigen in human fecal specimens. The intensity of line does not have a linear correlation with antigen concentration in the specimen.
3. A negative or non-reactive result for an individual subject indicates absence of detectable adenovirus antigen. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with adenovirus.
4. A negative or non-reactive result can occur if the quantity of the adenovirus antigen present in the specimen is below the limits of detection or if the antigens that are detected are not present during the stage of disease in which a sample is collected.
5. Infection may progress rapidly. If the symptoms persist, while the result from Adenoviruses Antigen Test Kit is negative or non-reactive, it is recommended to test with alternative test methods.
6. The use of meconium stools in this assay is not recommended, as their performance characteristics have not been evaluated.
7. The test result of this reagent can only be used as auxiliary tool. The test result should be combined with other data.