

RapidVet[®]-H IC Feline

Immuno-Chromatographic Test

For Identifying Feline A, B and AB Blood

For *in vitro* use

Description and Intended Use: RapidVet-H IC Feline Blood Typing System is intended for use to classify cats as blood group Type A, Type B or Type AB.

The importance of identifying blood groups in cats has increased in recent years, particularly in transfusion medicine, because only by predetermining the blood type of the transfusion recipient can potentially fatal transfusion mistakes be avoided.

One blood group system consisting of two antigens expressed either alone or in combination has been described in cats: Type A, Type B and Type AB. The antigens are unrelated to human A B O antigens and are defined by feline alloimmune sera. Blood group incidence varies among breeds.

Blood groups in cats are inherited as simple autosomal traits, with Type A being dominant over Type B. Most cats possess the A antigen, and about one-third of those have naturally occurring, low-titered anti-B antibody. Type B cats all have a naturally occurring, high-titered anti-A antibody. A survey in the United States showed that the percentage of cats with the B antigen varied depending on the breed. Type AB cats are rare and such cats have both A and B antigens on the erythrocyte membrane.

Principle and Explanation of the Assay: RapidVet-H IC Feline Blood Typing System, based on advanced immunochromatographic (lateral flow) technology, is the first such system to present the result as a red line on a white background, thus making it very easy to read.

The system consists of a test device containing three membranes, and is dependent upon the use of a microtube containing pre-measured diluent specific for this feline test and a special buffer to facilitate movement of the red cells along the membranes. It uses feline whole blood, or packed red blood cells diluted 1:1 with saline. It is a cell capture assay and, as such, patients exhibiting auto-agglutination or low PCV can be typed with this system.

Each of the membranes contains, in a sharply defined area, a substance that captures red blood cells under only one set of conditions. The membranes intersect under the sample port. Fluids added to the sample port are transported by capillary action along each of the membranes to points distant from the sample port and separate from each other. A viewing window exists over each of three defined areas on the device.

The membrane under the viewing window labeled “Control” contains a substance that captures all cells. This window should display a **horizontal red line** to indicate the test has performed properly.

The second membrane contains a monoclonal antibody for feline Type A red blood cells that will capture red blood cells corresponding to that blood type in a vertical line under the viewing window labeled “Type A.”

The third membrane contains an antibody for feline Type B red blood cells that will capture red blood cells corresponding to that blood type in a vertical line under the viewing window labeled “Type B.”

Reagents and Materials: RapidVet-H IC test kits contain:

IC Test Devices (in sealed, foil pouch)

Red Top Blood Prep Tubes (pre-filled, feline test-specific)

Pipettes (30 µL)

Buffer (feline test-specific) (1 per kit – do not discard)

Blood Group Report Cards

Package Insert

Materials Required But Not Provided: None

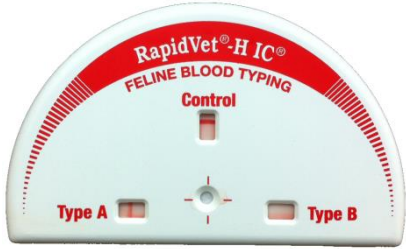
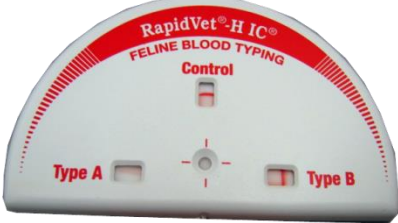

Reagent Preparation: None

Storage and Stability: Stable at room temperature (20-25°C/68-77°F) for 18 months from date of manufacture. Each test is labeled with an expiration date. DO NOT FREEZE.

Procedure:

1. Remove from the box: 1 sealed foil pouch, 2 pipettes and 1 pre-filled red top Blood Prep tube along with 1 report card. Also remove the dropper bottle which contains enough buffer for all the tests in the box.
2. Open the sealed pouch and remove the device. Write the patient name on the front of the device. Place the device on a flat surface to run the test.
3. Obtain EDTA anticoagulated whole blood sample. The collection tube or syringe should be filled to ensure a proper concentration of EDTA. (If packed cells are used, they must be diluted 1:1 with saline before proceeding to Step 4.)
4. Using the supplied pipette, prepare a blood dilution by pipetting 1 drop (30 µL) of blood into the pre-filled red top Blood Prep tube. Replace the cap and gently invert several times to mix.
5. Uncap the Blood Prep tube and use a new pipette to put 3 drops (90 µL) of the diluted blood into the round sample port. **Wait several seconds to allow for absorption of the sample**, then
6. Uncap the dropper bottle and dispense 3 drops of buffer (120 µL) into the round sample port. (Return dropper bottle to kit box for use with remaining tests.)
7. Allow the device to rest on the flat surface. Result lines will be visible within 5-10 minutes. Record patient results on provided Blood Group Report Card. See Limitations below.

Results: A positive result is represented only by the formation of a **vertical red line on a white background**. The Control window must display a **horizontal red line** to indicate the test has performed properly.

| | |
|---|---|
| <p>Vertical line forms in the “Type A” window, the cat has blood group A</p> |  |
| <p>Vertical line forms in the “Type B” window, the cat has blood group B</p> |  |
| <p>Vertical lines form in both “Type A” and “Type B” windows, the cat has blood group AB.</p> <p>See Limitations below.</p> |  |

Limitations of the Procedure:

If blood sample is not fresh, the background membrane may turn rosy red. This may indicate lysing of the blood cells, but will not affect the test results.

Sample Dilution: It is important that the dilution be properly done; that is, 1 drop from the pipette into the pre-filled red top Blood Prep tube (both supplied with test kit) (Procedure Step 4).

The fluid components provided with this kit must be used and are not interchangeable in tests for use with other species. Laboratory PBS or BBS must not be used.

Incomplete Line(s) in Viewing Windows: Occasionally the line(s) in the viewing windows (A, B and/or Control) may be incomplete within the time period of the test. This still represents a correct result.

AB Results: The test is designed as a 5 minute or less test. However, AB samples may take up to 10 minutes for all lines to develop.

Performance Characteristics: An independent clinical study¹ on blood samples from 89 sick and 16 healthy cats compared an earlier version of RapidVet-H IC with two reference methods: a gel column test considered to be the “gold standard” and a tube agglutination method. The reference methods agreed with each other 100% and determined the samples to be from 85 type A, 17 type B and 3 AB cats. Of the 85 type A samples, 80 were correctly identified by the IC test, four were misidentified as AB and one was rated inconclusive. All B samples were correctly typed. Two of the three AB samples were correctly identified by the IC test and one was rated inconclusive. The agreement of the RapidVet-H IC test with the reference methods was 96.1% and the IC test showed high sensitivity and specificity for A and B antigen detection.

An in-house evaluation using the current version of RapidVet-H IC tested blood samples from 50 healthy felines (20 type A, 20 type B and 10 type AB as determined by a tube agglutination test performed by an outside blood bank) a total of 256 times (including same-day and subsequent-day repeatability studies and reproducibility studies). All results were obtained in less than 10 minutes, and 98% were obtained in 5 minutes or less. The accuracy of the test was 99.2%. [1 type A cat was not identified (no reaction) and 1 type AB cat was misidentified as type A.]

Quality Control: All reagents and materials incorporated into this kit have been quality controlled by standard testing procedures using a routine quality control program during manufacture.

Disposal: Dispose of all biological materials, pipettes and tubes in a biohazard container.

Manufactured for **dms**laboratories,inc. by Agrolabo SpA

RapidVet is a registered trademark of **dms**laboratories, inc.

¹ Hourani, L., Weingart, C., & Kohn, B. (2014). Evaluation of a novel feline AB blood typing device. *Journal of Feline Medicine and Surgery*, Vol. 16(10), 826–831.