

AB Results: The test is designed as a 5 minute or less test. However, one of the 42 AB samples tested took longer than 5 minutes to develop.

Performance Characteristics: A prior version of RapidVet-H IC was used to test 115 feline samples in a blind test on routine samples at an independent veterinary medical center site. The samples were also tested on various other methods including a gel tube test that was considered the “gold standard”. On all methods the samples were correctly typed as Type A: 89 (77.39%), Type B: 20 (17.39%) and Type AB: 4(3.48%). Two AB cats tested inconclusive (1.74%). (Please note that the 6 AB samples and 7 additional B samples from other sources were intentionally included in the sample population.) Of the 115 samples typed on RapidVet-H IC, a result was obtained in 10 minutes or less with all samples and in 5 minutes or less with most samples. All samples were tested within 5 days of blood draw.

A subset of 15 samples was tested multiple times on that version of RapidVet-H IC on the same day and on subsequent days without any change in the results. The same subset of 15 samples was also tested by different lab personnel without any change in the results.

A second series of 100 samples was also typed using a slightly different methodology than that set forth in this package insert. There were no differing results on the second series. Of those 100 samples, it took 12 minutes to obtain results with 2 samples; the rest were obtained in 10 minutes or less and 23 in 5 minutes or less.

The current version of RapidVet-H IC was tested with 50 feline samples (20 Type A, 20 Type B and 10 Type AB) a total of 256 times (including same-day and subsequent-day repeatability studies and reproducibility studies by other lab personnel). 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.

HFIC-002

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Rev. 06/01/15 HFIC

RapidVet[®]-H IC Feline

ImmunoChromatographic 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, highly-titered, anti-A antibody. A recent 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 Microtubes (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

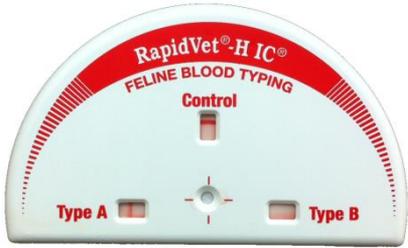
Reagent Preparation: None

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 microtube 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 or whole blood segment sample from previously collected packed RBC's. The collection tube or syringe should be filled to ensure a proper concentration of EDTA. (Packed cells may also be used, but 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 of blood into the pre-filled red top microtube. Replace the cap and gently invert several times to mix.
5. Uncap the red top microtube and use a new pipette to put 3 drops 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 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 microtube (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. Typical laboratory PBS or BBS must not be used.

Incomplete Vertical 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.