QuickVet® Diagnostic System

Package insert for QuickVet® Feline Blood Typing Test™ Version: January 12, 2017

Introduction

The QuickVet®/RapidVet® Feline Blood Typing Test cartridge is used in conjunction with the QuickVet® Analyzer for in vitro blood group determination testing. The QuickVet®/RapidVet® Feline cartridge is intended for use in performing a rapid blood group determination in cats.

The practice of veterinary transfusion medicine has undergone tremendous growth in recent years, and as a result the understanding of the importance of identifying blood types has increased [1].

The AB system is the major blood group system in domestic cats. The common blood types are A and B. Cats with blood type A have naturally occurring anti-B antibodies at a low titer and cats with blood type B have naturally occurring anti-A antibodies at a high titer. A third rare type AB is also known. Cats with the rare AB type do not have anti-A or anti-B antibodies. There is, however, no null phenotype; and as a consequence, there is no universal donor [2].

The A and B blood groups are genetically determined and blood



type A is the most common among cats but the frequency varies significantly by breed and geographic location. Breeds that do not have the B type are Siamese, Burmese, Oriental Shorthair and Tonkinese. Breeds with high incidence of the B blood type are Abyssinian, Japanese Bobtail, Birman, Persian, Scottish Fold, British Shorthair, Cornish Rex, Exotic Shorthair, Somali, Sphynx, Turkish Van, Turkish Angora and Devon Rex [3].

The inheritance of the rare AB group is not well understood and the incidence of the AB type is reported to be less than 1%. Breeds that have the very rare type AB blood include Birman, British Shorthair, Scottish Fold, Somali, and Sphynx. Somalis are more likely than average to have the rare type AB blood [3].

Blood Transfusion Risks

Cats that are transfused, even once, with an incompatible blood type, are at risk for a transfusion reaction. Cats with type B blood exhibit an immediate and catastrophic systemic anaphylactic reaction and a Hemolytic Transfusion Reaction (HTR) when transfused with type A blood because of their natural high-titered anti-A antibody. As an outcome, death of the patient is extremely likely.

Cats with type A blood exhibit a natural low-titered anti-B antibody response when transfused with type B blood. In this case, the reaction is mild but the transfused cells will have a shortened life span. The recipient will develop moderate titers of anti-B antibody that will result in a serious reaction if a subsequent incompatible transfusion

is administered [2].

Mating Risks

Serious problems can result from accidental or mismatched mating. A mating of a type B queen with a type A or AB tom will result in their type A or AB kittens being at risk for neonatal isoerythrolysis (NI), commonly known as "fading kitten syndrome". The maternal naturally occurring, highly titered anti-A antibody occurs in the colostrum where from it can be absorbed by the newborn kittens. The absorbed antibody attacks the kitten's type A erythrocytes. Although the kittens can seem normal at birth, they develop signs after nursing, fade and die within the first days of life. Determining the blood type of the queen and the tom prior to mating, coupled with appropriate genetic counseling, can minimize the risk of NI. Furthermore, immediate blood type determination of the newborn kittens will alert the client to remove the kittens and to begin surrogate nursing where necessary [2].

The QuickVet®/RapidVet® Feline Blood Typing Test cartridge used with the QuickVet® Analyzer is intended for use to classify cats as A positive, B positive or A and B positive.

Principle and Explanation of the Assay

The QuickVet[®]/RapidVet[®] Feline assay is based on the agglutination reaction that occurs when the sample interacts with the specific

antibody/lectin deposited in the channels. The test cartridge has two fluidic channels. The monoclonal antibody proven specific to Feline A is deposited in one channel and lectin specific to Feline B is deposited on the other channel.

The sample moves through the cartridge by capillary action and the QuickVet® Analyzer reads the status of the blood/antibody and blood/lectin interaction or lack thereof. All A positives react with the reconstituted antibody within the cartridge and all B positives react with the lectin. The agglutination is then automatically examined by the QuickVet® Analyzer.

No visual reading is needed or possible. The QuickVet® Analyzer determines if agglutination has occurred and displays the result.

Reagents and Materials

Each test is individually packaged in a sealed pouch with a desiccant bag, and contains the following

- 1 QuickVet®/RapidVet® Feline test cartridge.
- 1 plastic tube prefilled with diluent buffer [phosphate buffered saline (PBS) at pH 7.4]. Each bottle contains enough diluent to perform a test for one cartridge.
- Pipette tips.

Required but not provided with the test kit is the QuickVet[®] Analyzer and the 100 μ L fixed volume pipette. The QuickVet[®] Analyzer is designed for use for other hematology determinations in addition to

this assay. Refer to the Operator's Guide for complete information concerning the Analyzer.

Storage and Stability

All components of the test kit are stable at refrigerated temperatures or room temperature (2 °C to 25 °C or 36 °F to 77 °F) for 24 months. It is recommended that storage for more than a week should be at refrigerated temperatures (2 °C to 8 °C or 36 °F to 46 °F). The stability of the test components has been determined through the use of a routine accelerated aging protocol. Kits and components should not be exposed to direct sunlight.

Each QuickVet*/RapidVet* Test Cartridge contains a monoclonal antibody specific to the Feline A blood types and/or lectin specific to the Feline B blood types. Each test cartridge can only be used once. Each cartridge is individually packaged in a sealed pouch containing a desiccant bag to keep moisture out. A torn or otherwise damaged pouch may allow moisture to reach the test cartridge and adversely affect performance. Do not use a test cartridge from a damaged pouch. Open the pouch just prior to use. Once the pouch has been opened, the test cartridge should be used within one day.

The test cartridge is stable for 24 months from the date of manufacture if stored according to the instructions above. The expiration date of each cartridge is printed on the pouch label. Do not use the cartridge after the expiration date. The diluent is also stable for 24 months from the date of manufacture.

Operating Instructions

Before performing any tests, make sure that the analyzer software has been upgraded to a version capable of performing the Quick-Vet®/RapidVet® Feline Blood Typing Test according to the instructions in the QuickVet® Analyzer Operator's Guide.

The time it takes to perform a blood type determination with this system depends on factors such as type of test and test environment. At room temperature it takes about 90 seconds for the instrument to warm up the test cartridge to 37 °C (98.6 °F). Lower and higher room temperatures may change the warm up time. Once the procedure of the assay begins, an answer should be available within 5 minutes.

To complete a blood typing test follow the steps below

- **Step 1** Draw blood from the patient into a syringe or into a tube coated with or containing EDTA as an anticoagulant. The assay requires $100 \,\mu$ L whole blood (in some cases more than $100 \,\mu$ L due to the low hematocrit level of the sample.) but the syringe or tube should be filled to the appropriate line to ensure the correct concentration of EDTA. If the blood type is not to be determined immediately, nutrients such as CPDA should *not* be added.
- **Step 2** Determine the hematocrit of the sample.
- **Step 3** Remove the cartridge from the foil package and the diluent tube from the kit box.
- Step 4 Touch the Analyze button on the Analyzer's main screen

and follow the on-screen instructions.

- Step 5 Insert the test cartridge when the message Please insert new cartridge is displayed on the screen. The insertion of a new cartridge into the slot on the front of the QuickVet® Analyzer will trigger the warming up of the cartridge to 37 °C (98.6 °F).
- **Step 6** When prompted to do so, enter the cartridge code located on the pouch label and touch the Next button.
- **Step 7** When prompted to do so, enter Patient ID and Sample ID (optional) and touch the Next button.
- Step 8 When prompted to do so, enter the hematocrit of the sample. Based on the specified hematocrit the QuickVet® Analyzer will calculate the required amount of blood needed to be added to the diluent tube.
- Step 9 Dilute the sample following the on-screen instructions. Use the 100 μL volume pipette to add blood to the diluent. Ensure proper mixing by aspirating a couple of times using the pipette.
- **Step 10** When the message Add 100 μ L sample and wait is displayed on the screen, use the 100 μ L volume pipette to dispense 100 μ L diluted blood into the sample well on the cartridge. Avoid bubbles. The determination will start automatically once the blood is detected by the Analyzer.
- Step 11 The QuickVet® Analyzer will determine whether or not agglutination has occurred and the test result will be dis-

played on the screen. If a printer is connected, the test result can be printed out by pressing the Print button. To obtain suggested advice about safe transfusion/donation with the tested sample touch the Advice button. To print a blood type certificate touch the Certificate button.

Step 12 Return to the Analyzer's main screen by touching the Done button and, when the message *Please remove cartridge* is displayed on the screen, remove the used test cartridge and dispose of it properly in accordance to policies and regulations in practice at the place of operation.

Important Make sure that the test sample has been collected and prepared according to the guidelines in this package insert.

Limitations of the Procedure

- The accuracy of the test results is dependent on the quality of the blood sample. The quality of the blood sample is dependent upon the blood sample collection, the proper blood to EDTA ratio, and the proper introduction of the diluted sample into the sample well. Please observe all precautions cited in the QuickVet[®] Analyzer Operator's manual and use good blood sample collection techniques at all times.
- Blood samples with a hematocrit of less than 4 % or greater than 60 % are not recommended for use with the QuickVet[®] Analyzer.

Blood samples outside this range may result in an instrument error or inaccurate test result.

Quality Control

All materials incorporated into the test package have been quality controlled by standard testing procedures using a routine quality control program during manufacture.

Disposal

Dispose of all biological materials, pipettes and cartridges in a biohazard container.

Performance Characteristics

A total of 100 different feline samples (43 A cats, 42 B cats and 15 AB cats) has been tested on QuickVet® cartridges with 5 repetitions per sample. All samples were also run in parallel on a reference system. All samples from cats with A blood type have been detected flawlessly. Four samples of B blood type were detected as Type AB. Twenty-five AB samples were detected as B positive. Overall, the accuracy of the QuickVet® Feline Blood Typing Test[™] was 94 % in this study.

The samples used in the study were not representative of the general cat population and they have been selected to test the product performance on the three different blood types. Out of the general population of cats, approximately 80% are A positive, about 19% are B positive and only 1% are type AB. Correcting for the distribution of blood types, the expected accuracy for QuickVet® is 99.31%.

Trouble Shooting Guide

In most circumstances the instrument will interrupt the test and report an advisory message if a problem occurs during the sample analysis. If this happens, make a note of the advisory number and follow the instructions given in the advisory message. In most cases the problem can be resolved by obtaining a fresh blood sample and repeating the test. Make sure to follow the operating instructions given on-screen and in this package insert. Contact customer support if the problem persists and include the advisory number from the original advisory message in your inquiry. Special attention should be paid to the potential issues with the collected blood samples listed in Table 1. Table 1: Potential sample quality issues and suggested corrective actions.

Problem	Corrective action
Aggluti- nates in the sample tube	Only use fresh blood properly collected in an EDTA tube. If a non-agglutinating sample cannot be ob- tained the blood should not be used for transfusion.
Hemolysis	Only use fresh blood properly collected in an EDTA tube. The degree of hemolysis can be estimated by visual inspection of the blood plasma when measur- ing the hematocrit of the sample. If the plasma is clear and more yellow than red the sample is suitable for use with the QuickVet®/RapidVet® Feline Blood Typing Test [™] .

References

- A. Kristensen and B. Feldman, The veterinary clinics of North America (USA); Small animal practice (1995).
- [2] N. Mamak and I. Aytekin, Blood Cell An Overview of Studies in Hematology (InTech, 2012).
- [3] Silvestre-Ferreira, A. C., and P. Josep, Veterinary Medicine International (2010).

Manufacturer Information

The monoclonal antibody is licensed from Kansas State University.

The QuickVet®/RapidVet® Feline Blood Typing Test[™] is a joint development of **dms**laboratories, inc. and Scandinavian Micro Biodevices ApS and is manufactured by Scandinavian Micro Biodevices ApS.

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