QuickVet®
Diagnostic System

Package insert for
QuickVet® Equine Fibrinogen Test™
Version: January 12, 2017

Introduction

The QuickVet® Equine Fibrinogen Test is a quantitative test intended for measuring the fibrinogen concentration in platelet poor plasma prepared from a citrate-stabilized whole blood sample.

The test is intended for veterinary use only and should not be used for human diagnostics.

This package insert provides you with the necessary information needed to use the QuickVet® Equine Fibrinogen Test cartridge with the QuickVet® Analyzer. If you have any further questions, you are welcome to contact Customer Support. Contact information for your particular country can be found at www.quickvet.net.

Once the procedure of the assay begins, the test result should be available within approximately 10 minutes. The actual time depends on the test environment. At room temperature it takes about 5 minutes for the instrument to warm up the test cartridge to 37 °C/99 °F. Lower and higher ambient temperatures may change the warm up time.

Test results obtained under normal operating conditions have a precision of 0.3 g/L or better. By default, the fibrinogen concentration is reported in grams per liter of blood plasma (g/L) but the unit can be changed in the Analyzer's Settings menu.

The normal range for fibrinogen concentration in plasma is shown in Table 1.

Table 1: Normal range.

Species	Fibrinogen [g/L]
Equine	1.5 to 4.0

Materials

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

- One QuickVet® Equine Fibrinogen Test cartridge.
- One disposable plastic pipette tip.

Provided separately in the kit for use with the test packages are the following items:

- One tube pre-filled with diluent for sample preparation.

Required but not provided with the test kit are the following items:

- QuickVet® Analyzer. The QuickVet® Analyzer is designed for use for other hematology determinations in addition to this assay. Refer

to the Operator's Manual for complete information concerning the Analyzer.

- A 100 µL fixed volume pipette.
- A tabletop centrifuge (see centrifugation requirements at the end of the package insert).
- Sample tube containing 3.2 % or 3.8 % citrate as an anticoagulant.
- A syringe with a 21-gauge needle or larger.

Storage and Stability

All components of the test kit are stable at 2 °C to 8 °C/36 °F to 46 °F for 12 months from the date of manufacture. The cartridges can be stored at room temperature (15 °C to 30 °C/59 °F to 86 °F) for up to one week prior to opening the pouch. 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 test cartridge can only be used once. Each cartridge is individually packaged with a plastic pipette tip in a sealed foil 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 24 hours.

The test cartridge is stable for 12 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 cartridges that are damaged, past their expiration date, or have been improperly stored.

The diluent is stable for 12 months from the date of manufacture. One pre-filled tube with diluent should be used with each test. Dispose of the diluent tube after running a test.

Operating Instructions

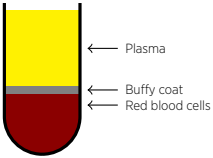
Before performing any tests, make sure that the Analyzer software has been upgraded to a version capable of performing the QuickVet® Equine Fibrinogen Test according to the instructions in the QuickVet® Analyzer Operator's Manual and that the Analyzer has been properly calibrated using the QuickVet® Fibrinogen Calibration Kit.

To complete a Equine Fibrinogen Test follow the steps below:

Step 1 Let the cartridge reach room temperature 15 °C to 30 °C/59 °F to 86 °F. The cartridges can be removed from the refrigerator up to one week prior to testing.

Step 2 Draw blood from the patient into a syringe or into a tube containing citrate as an anticoagulant. The assay requires only 100 µL plasma but the syringe or tube should be full to ensure the correct concentration of the anticoagulant. Gently invert the blood filled citrate tube 8–10 times to enhance the mixing of blood and citrate in the tube.

Step 3 Fractionate the whole blood by centrifuging the blood sample in the collection tube into platelet poor plasma. To achieve sufficient platelet poor plasma, the blood sample must be centrifuged at minimum 7000 g × minutes. See the table near the end of this package insert for a list of required centrifugation times.



The plasma should be extracted as soon as possible after collecting the blood sample. The whole blood sample can be kept for maximum 12 hours provided that the temperature does not exceed 30 °C/86 °F. It is recommended to store the sample at room temperature until testing. Do not expose to direct sunlight.

Step 4 Remove the cartridge and pipette tip from the pouch and the pre-filled tube with diluent from the kit box.

Step 5 Insert the test cartridge into the slot on the front of the QuickVet® Analyzer. The insertion of a new cartridge into the slot on the front of the Analyzer will trigger the warming up of the cartridge to 37 °C/99 °F.

Step 6 When prompted to do so, enter the cartridge code located on the pouch label and touch the Next button.

Step 7 Confirm that the blood sample has been obtained in a cit-

rate test tube and that it has been spun to platelet poor plasma at minimum 7000 g × minutes. Extract 100 µL platelet poor plasma from the collection tube using the 100 µL fixed volume pipette and the supplied pipette tip. Dilute the platelet poor plasma by aspirating into the supplied diluent tube and ensure proper mixing by aspirating a minimum of 5 times.

Touch the Confirm button to acknowledge proper sample preparation.

Step 8 When prompted to do so, enter Patient ID and Sample ID (optional) and touch the Next button.

Step 9 When the message *Add 100 µL sample and wait* is displayed on the screen, use the pipette to dispense 100 µL diluted plasma into the sample well on the cartridge. Avoid bubbles. The determination will start automatically once the sample is detected by the analyzer.

Step 10 The test result will appear after approximately 10 minutes. When the test is finished the test result is displayed on the screen. If a printer is connected to the instrument the test result can be printed by touching the Print button.

Step 11 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.

Precautions and Limitations

The accuracy of the test results is dependent on the quality of the plasma sample. The quality of the blood sample is dependent upon the blood sample collection, the proper blood to citrate 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.

Please observe the following when obtaining and handling the blood sample

- Contamination from thromboplastin, alcohol and intravenous solutions will interfere with the fibrinogen assay. Hemolysis and foaming of the blood sample are potential sources of erroneous test results.
- Do not use blood that has been stabilized in any other way than using 3.2 % or 3.8 % citrate collection tubes.
- Do not use blood from over-filled or under-filled citrate tubes.
- Do not use plasma from samples that have been centrifuged at less than 7000 g × minutes. See table with centrifugation times near the end of this package insert.
- Do not use blood samples with visible clotting or debris accumulation.

- Do not use plasma exhibiting signs of hemolysis, lipemia or other conditions that may affect turbidity. A general guideline is that the sample should be clear and more yellow than red in color.
- To avoid mechanical hemolysis, the needle used should have a 21-gauge or larger.
- The vein puncture site should be cleaned with alcohol and allowed to air-dry completely.
- When diluting the platelet poor plasma, ensure that no diluent is caught in the top of the pre-filled micro tube by tapping the tube prior to piercing the lid.
- Use only the supplied QuickVet® Equine Fibrinogen pre-filled micro tube. The QuickVet® Equine Fibrinogen Test will not work correctly if other diluents are used.
- To avoid contaminating the plasma with red and white blood cells, please extract the required volume from the upper half of the plasma.
- Do not touch the part of the pipette tip that will come in contact with the plasma when removing the pipette tip from the pouch.
- Test results may be impaired if the whole blood sample is older than 12 hours or the extracted plasma is older than 3 hours.

Please observe all precautions cited in this package insert and use good blood sampling and laboratory techniques at all times.

Important The veterinarian is always the final arbiter of test result interpretation and impact on diagnosis. Therefore, it is highly recommended that QuickVet® Equine Fibrinogen test results should be scrutinized in the light of a specific patient's condition and medical history, as well as current or potential therapy. Any test result exhibiting inconsistency with a patient's status should be repeated and/or supplemented with additional diagnostic tests.

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

Used test cartridges, pipettes and collection tubes are considered potentially infectious. Dispose of them properly in a biohazard container in accordance to policies and regulations practiced at the place of operation.

All biohazard safety guidelines pertaining to the handling and disposal of animal blood samples should be strictly adhered to when collecting and handling blood samples and when operating the QuickVet® Analyzer.

Manufacturer Information

QuickVet® is a registered trademark of Zoetis Denmark. The QuickVet® Analyzer and QuickVet® Test cartridges are manufactured by Zoetis Denmark.

Centrifugation Time

Radius [cm]	RPM [1/min]	Acc. [g]	Time [min]	Radius [cm]	RPM [1/min]	Acc. [g]	Time [min]
2.5	5000	698	11	7.5	7000	4104	2
2.5	6000	1005	7	7.5	8000	5360	2
2.5	7000	1368	6	7.5	9000	6784	2
2.5	8000	1787	4	7.5	10 000	8375	1
2.5	9000	2261	4	10.0	2000	447	16
2.5	10 000	2792	3	10.0	3000	1005	7
5.0	5000	1396	6	10.0	4000	1787	4
5.0	6000	2010	4	10.0	5000	2792	3
5.0	7000	2736	3	10.0	6000	4020	2
5.0	8000	3574	2	10.0	7000	5472	2
5.0	9000	4523	2	10.0	8000	7147	1
5.0	10 000	5584	2	10.0	9000	9045	1
7.5	5000	2094	4	10.0	10 000	11 167	1
7.5	6000	3015	3				

Note: Centrifuge radius is measured from center to middle of the tube holder.

QuickVet® Analyzers and QuickVet® cartridges are manufactured by

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