

VetScan VSpro Fibrinogen Test Cartridge

For Veterinary Use Only

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PN: 740-7031 Rev. D

INTRODUCTION

The VetScan VSpro Fibrinogen test cartridge is a quantitative test intended for in vitro testing of the fibrinogen level in equine platelet poor plasma from a citrate stabilized whole blood sample.

This test is intended for equine use only.

This package insert provides you with the necessary information needed to use the Fibrinogen test cartridge with the VetScan VSpro Analyzer. If you have questions, contact Abaxis Technical Support at 800-822-2947.

CARTRIDGE STORAGE AND HANDLING

- Each VetScan VSpro Fibrinogen test cartridge is labeled and individually packaged in a sealed pouch with a desiccant bag. When using VetScan VSpro Fibrinogen test cartridges, remember the following:
- The cartridge must be stored at 2-8 °C (36-46 °F).
 - The cartridge is stable until the expiration date printed on the pouch.
 - The cartridge must not be exposed to direct sunlight and temperatures higher than 30 °C (86 °F).
 - When the pouch has been opened, the cartridge must be used within 10 minutes.
 - Each VetScan VSpro Fibrinogen test cartridge can only be used once.
 - VetScan VSpro Fibrinogen test cartridges can only be used with the VetScan VSpro Analyzer.

TEST CHARACTERISTICS

A VetScan VSpro Fibrinogen test takes less than 15 minutes to perform. The actual time depends on the test environment. Lower and higher ambient temperatures may change the warm up time. The amount of fibrinogen is reported in grams per liter (g/L), grams per deciliter (g/dL), or milligrams per deciliter (mg/dL) of blood plasma. Units may be changed through the **Settings** icon on the home screen.

Reference Range:			Dynamic Range:	
	g/L	mg/dL	g/L	mg/dL
Equine	1.5 - 4.0	150 - 400	0 - 20	0 – 2000

PERFORMANCE

Precision:

	Mean		SD	%CV	N
	g/L	mg/dL			
Control 1	3.73	373	0.16	4	20
Control 2	1.65	165	0.14	8	20

Correlation:

	Correlation Coefficient	Slope	Intercept	N
Equine	0.96	0.94	0.22	173

Plasma samples were analyzed using the VetScan VSpro Specialty Analyzer and the Beckman Coulter ACL Top Analyzer.

LIMITATIONS

IMPORTANT: The accuracy of VetScan VSpro Fibrinogen test results is dependent on:

- Quality of the blood sample which in turn is dependent on the blood sample collection, proper volume of blood/citrate and proper mixing of the citrated blood.
- Process of producing platelet poor plasma from the citrated blood sample.
- Precision of plasma volume mixed with diluents in pre-filled microtube and proper mixing of plasma and diluents in the microtube.
- Proper introduction of the diluted plasma sample into the cartridge well.

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

IMPORTANT: Any test result exhibiting inconsistency with a patient’s status should be repeated and/or supplemented with additional diagnostic tests.

WARNING: Plasma samples with RBC’s, hemolysis, lipemia and other sample interferences that may affect the turbidity of the sample is not recommended for use with the VetScan VSpro Analyzer. Plasma samples affected by such interference may result in an instrument error or faulty test result.

- **Hematocrit:** If the plasma is more red than yellow, it should not be used for testing. The maximum hematocrit permissible is 0.5% where visually the sample is more red in color and cannot be mistaken for plasma. If the plasma sample is contaminated with red blood cells, the test result may be lower than expected.
- **Hemolysis:** If the plasma is more red than yellow (~1.5% hemolysis), it should not be used for testing. If the plasma sample is hemolysed, the test result may be lower than expected.
- **Platelets:** Platelets have an influence on the turbidity of the sample. Therefore, samples that are turbid should not be used for testing.

SAMPLE PREPARATION

Materials needed:

- Citrate tube (3.2% or 3.8%)
- Syringe (≥21 gauge needle)
- 100 µL pipette
- Pipette tip (supplied with each test kit)
- Centrifuge (min. 7000 g•minutes)
- VSpro Fibrinogen microtube pre-filled with diluent (supplied with each test kit)

General Rules:

- **DO NOT** use blood that is over-filled or under-filled in the citrate tube.
- **DO NOT** use blood samples with visible clotting or debris accumulation.
- **DO NOT** use blood that has been stabilized in any other way than in the prescribed citrate tube.
- **DO NOT** use plasma from samples that have been centrifuged at less than 7000 g•minutes. See appendix A.
- **DO NOT** use plasma exhibiting signs of RBC’s, hemolysis, lipemia or other conditions that may affect turbidity.

In relation to hemolysis, lipemia and other conditions that may affect turbidity, a general guideline is the sample should be clear and more yellow than red in color.

Precautions Before Blood Sample Collection:

- The accuracy of the VetScan VSpro Fibrinogen test is dependent on the quality of the blood sample. The way the blood is collected and handled can affect the sample quality.
- 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.

Collecting Blood Sample:

- To avoid mechanical hemolysis, the needle used should be a 21 gauge or larger.
- The vein puncture site should be cleaned with alcohol and allowed to air-dry completely.

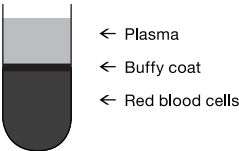
- Blood is collected using a test tube containing sodium citrate (3.2% or 3.8%). It is very important to collect the right amount of blood in the test tube as indicated on the tube. If there is no indication, contact the manufacturer for information.
- Gently invert the blood filled citrate tube five times to thoroughly mix the blood and citrate in the tube.

Handling of Blood Sample:

- The blood sample is good up to 24 hours at room temperature as whole blood and 2 hours at room temperature once spun to plasma. Temperature should not exceed 30 °C (86°F).
- Blood samples should be spun down to plasma as soon as possible after collecting the blood sample.
- It is recommended to store the sample at room temperature until testing.

Preparation of Test Sample:

- Fractionate the whole blood by centrifuging the blood sample in the collection tube into platelet poor plasma.



IMPORTANT: To achieve platelet poor plasma, the blood sample must be centrifuged at minimum 7000 g•minutes. See appendix A for a list of required centrifugation times.

IMPORTANT: Examine the plasma to ascertain there is no RBC’s, hemolysis, lipemia and other conditions that may affect turbidity. A general guideline is that the sample should be clear and more yellow than red in color.

- Use the 100 uL pipette and one of the supplied pipette tips to extract 100 uL of plasma from the collection tube.

- Deposit the 100 uL of plasma into the pre-filled diluent tube by piercing the foil lid with the pipette tip. Mix the diluent and sample by extracting and depositing the mixture using the pipette.

WARNING: Use only the supplied VetScan VS*pro* Fibrinogen pre-filled microtube. The VetScan VS*pro* Fibrinogen test will not work correctly if other diluents are used.

IMPORTANT: To avoid contaminating the plasma with red and white blood cells, extract the required volume from the upper half of the plasma.

IMPORTANT: The plasma and diluent solution must be mixed gently. Do not use a vortex mixer. Do not shake the sample.

IMPORTANT: Test results may be impaired if plasma sample is older than two hours.

WARNING: 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 VetScan VS*pro* Analyzer.

WARNING: The VetScan VS*pro* Analyzer must be properly calibrated using the VetScan VS*pro* Fibrinogen Calibration Kit anually.

OPERATING PRECAUTIONS

DO NOT use VetScan VS*pro* cartridges that are damaged, past their expiration date or have been improperly stored.

WARNING: Used Fibrinogen test cartridges, pipettes and collection tubes are considered potentially infectious. Dispose them properly in accordance to policies and regulations in practice at the place of operation.

OPERATING INSTRUCTIONS

To perform a test, the following is needed:

- VetScan VS*pro* Analyzer
- VetScan VS*pro* Fibrinogen test cartridge

- VetScan VS*pro* Fibrinogen pre-filled microtube with diluent
- Test sample (prepared according to guidelines)
- 100 µL precision pipette

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

To perform a test, the following is needed:

Step 1: Let the cartridge reach room temperature (15 - 30 °C (59 - 86 °F)).

Step 2: Touch the “Analyze” button in VetScan VS*pro* Analyzer’s main menu.

Step 3: When the “Please insert new cartridge” is shown on the screen, insert a new VetScan VS*pro* test cartridge in the cartridge slot.

Step 4: Use the on-screen keyboard to enter the 7- 9 digit cartridge code. Cartridge code can be found on the cartridge pouch label.

Step 5: Touch the “Confirm” button to acknowledge that the blood sample has been obtained in a citrate test tube.

Step 6: Touch the “Patient ID” button and enter Patient ID (Optional).

Step 7: Touch the “Patient Name” button and enter Patient Name (Optional).

Step 8: Start the test by touching the “Next” button on the analyzer screen. To abort the test, touch the “Cancel” button.

Step 9: Mix the diluent and sample in the diluent tube by extracting and depositing the mixture using the pipette. Be sure to obtain a uniform mixture of plasma and diluent. When the message “Add 100 µL sample and wait” is displayed on the screen, use the pipette with the supplied pipette tip to add 100 µL of sample to the sample well. Avoid bubbles.

Step 10: The test takes approximately 15 minutes. When the test has finished, the test result is displayed on the screen. If a printer is connected to the analyzer, the test result can be printed by touching the “Print” button.

Step 11: Return to the main menu by touching the “Done” button and remove the used test cartridge and dispose of it properly.

APPENDIX A

Centrifuge radius [cm]	RPM [1/min]	g [g]	Time [min]	Centrifuge radius [cm]	RPM [1/min]	g [g]	Time [min]
2.5	5000	698	10	7.5	8000	5360	1
2.5	6000	1005	7	7.5	9000	6784	1
2.5	7000	1368	5	7.5	10000	8375	1
2.5	8000	1787	4	10	2000	447	16
2.5	9000	2261	3	10	3000	1005	7
2.5	10000	2792	3	10	4000	1787	4
5	5000	1396	5	10	5000	2792	3
5	6000	2010	3	10	6000	4020	2
5	7000	2736	3	10	7000	5472	1
5	8000	3574	2	10	8000	7147	1
5	9000	4523	2	10	9000	9045	1
5	10000	5584	1	10	10000	11167	1
7.5	5000	2094	3				
7.5	6000	3015	2				
7.5	7000	4104	2				

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

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