**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 Analyzer, if you have questions, contact Abaxis Technical Support at 800-822-2947.

**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:**

<table>
<thead>
<tr>
<th>g/L</th>
<th>mg/dL</th>
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<tbody>
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<td>1.5 - 4.0</td>
<td>150 - 400</td>
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**Dynamic Range:**

<table>
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<tr>
<th>g/L</th>
<th>mg/dL</th>
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<tbody>
<tr>
<td>0 - 20</td>
<td>0 - 2000</td>
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</table>

**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 technique 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 interferences may result in an instrument error or faulty test result.

- Hematocrit: If the plasma is more red than yellow (~1.5% hemolysis), 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 (2.2% or 3.8%)
  - Syringe (21 gauge needle)
  - 100 µL pipette
  - Pipette tip (supplied with each test kit)
  - Centrifuge (min. 7000 g-minutes)
  - VetScan 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.

- **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.

**REFERENCE RANGES**

**Performance**

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<th>Mean</th>
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<td>mg/dL</td>
<td></td>
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<tr>
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<tr>
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<td>0.14</td>
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**Plasma samples were analyzed using the VetScan VSPro Specialty Analyzer and the Beckman Coulter ACL Top Analyzer.**
**Blood collection:** Use 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 clot 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·min. See appendix A for a list of centrifuge 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.

**IMPORTANT:** Use the 100 μL pipette and one of the supplied pipette tips to extract 100 μL of plasma from the collection tube.

**WARNING:** Only use the supplied VetScan VSIpro Fibrinogen pre-filled microtube. The VetScan VSIpro 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 VSIpro Analyzer.

**WARNING:** The VetScan VSIpro Analyzer must be properly calibrated using the VetScan VSIpro Fibrinogen Calibration Kit annually.

**OPERATING PRECAUTIONS**

**DO NOT** use VetScan VSIpro 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 with policies and regulations in practice at the place of operation.

**OPERATING INSTRUCTIONS**

To perform a test, the following is needed:
- VetScan VSIpro Analyzer
- VetScan VSIpro Fibrinogen test cartridge

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

**APPENDIX A**

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