

QuickVet®

Diagnostic System

Package insert for

QuickVet® Fibrinogen Calibration Kit™

Version: January 12, 2017

Introduction

The QuickVet® Fibrinogen Calibration Kit is used to calibrate the QuickVet® Analyzer in order for it to perform a test on the QuickVet® Fibrinogen test cartridge correctly.

It is recommended to calibrate the QuickVet® Analyzer minimum every 12 months. The software will automatically remind the user that it is time to calibrate the instrument. This reminder can be switched off via the calibration page.

The calibration kit can only be used one time.

The calibration procedure takes approximately 1 hour.

This package insert provides you with the necessary information needed to perform the calibration. 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.

Materials Provided

The kit contains the following items

- 3 QuickVet® Fibrinogen calibration cartridges.
- 1 bottle with freeze dried QuickVet® Fibrinogen Calibrator.
- 1 bottle with QuickVet® Fibrinogen Buffer.
- 1 Fixed-volume 100 µL pipette.
- 3 Pipette tips for the 100 µL pipette (included in cartridge pouch).

To perform the calibration the following materials are needed but not provided with the Calibration Kit

- QuickVet® Analyzer instrument.
- Software version on QuickVet® Analyzer instrument capable of performing a QuickVet® Fibrinogen test.

Important

- The calibration kit must be stored at 2 °C to 8 °C/36 °F to 46 °F and must be allowed to reach room temperature before use.
- The calibration kit is functional until the expiration date printed on the cartridge pouch and box label.
- The test kit must not be exposed to direct sunlight and temperatures higher than 30 °C/86 °F.

- When the pouches have been opened the QuickVet® calibration cartridges must be used within 30 minutes.
- Each QuickVet® calibration cartridge can only be used once.
- The QuickVet® calibration cartridge can only be used with the QuickVet® Analyzer.
- The QuickVet® calibration cartridge can only be used to calibrate the QuickVet® Analyzer for the Fibrinogen test cartridge.

Operating Precautions

Do not use QuickVet® calibration cartridges that are damaged, past their expiration date, or have been improperly stored.

Warning The calibrator is based on human fibrinogen and it is recommended to use gloves when working with the calibrator fluid.

Warning All biohazard safety guidelines pertaining to the handling and disposal of samples containing human blood fraction products should be strictly adhered to when working with the calibrator fluid.

QuickVet® Fibrinogen Calibrator Fluid Preparation

Materials needed

- Bottle with freeze dried QuickVet® Fibrinogen Calibrator.
- Bottle with QuickVet® Fibrinogen Buffer.

Preparation of Calibrator Fluid

- Ensure that no liquid is caught in the cap of the pre-filled bottle with calibration buffer by tapping the cap. Then remove the cap from the bottle with QuickVet® Fibrinogen Buffer.
- Remove the cap from the bottle with freeze dried QuickVet® Fibrinogen Calibrator.
- Pour the QuickVet® Fibrinogen Buffer into the bottle with freeze dried QuickVet® Fibrinogen Calibrator. Ensure that no buffer remains in the tube.
- Replace the cap on the bottle with freeze dried QuickVet® Fibrinogen Calibrator and ensure that the cap is securely fastened.
- Gently swivel the bottle 1 minute until the freeze dried calibrator is completely dissolved. Do not invert the bottle.
- Let the calibrator fluid settle for 2–3 minutes before continuing.

Warning All of the liquid from the QuickVet® Fibrinogen Buffer bottle must be transferred to the bottle with freeze dried QuickVet® Fibrinogen Calibrator. If liquid remains in the bottle or is spilled the calibration will not be correct.

Calibration procedure

Important Before performing the calibration make sure that the QuickVet® Analyzer software has been upgraded according to the instructions in the QuickVet® Analyzer Operator's Guide.

Important Make sure that the calibrator fluid has been prepared according to guidelines in this package insert.

- Step 1** Let the cartridge reach room temperature 15 °C to 30 °C/59 °F to 86 °F.
- Step 2** Touch the Setup button in QuickVet® Analyzer's main menu and then the Calibration button in the setup menu.
- Step 3** In the calibration menu touch the Calibrate button and the *Confirm calibration fluid screen* is displayed. Touch the Confirm button if the fluid has been prepared according to instructions. Otherwise cancel the calibration.
- Step 4** Use the on-screen keyboard to enter the 11-digit calibration code and then touch the Done button. The 11-digit calibration code can be found on the Bottle with freeze dried QuickVet® When the *Please insert cartridge 1 of 3* is shown

on the screen open the first pouch and insert calibration cartridge in the cartridge slot. The instrument automatically starts the calibration with heating the cartridge.

- Step 5** Gently swivel the bottle with calibrator fluid to obtain a uniform mixture. When the message *Add sample and wait* is displayed on the screen use the pipette with the supplied pipette tip to add 100 μL of calibrator fluid to the sample well. Avoid bubbles. Discard the pipette tip after use.
- Step 6** Part one of the calibration takes 12 minutes. When part one is finished you will be asked to remove the cartridge. Discard cartridge.
- Step 7** When the *Please insert cartridge 2 of 3* is shown on the screen open the second pouch and insert the new calibration cartridge in the cartridge slot. The instrument automatically starts the calibration with heating the cartridge.
- Step 8** Fix the new pipette tip from the pouch to the pipette. When the message *Add sample and wait* is displayed on the screen use the pipette to add 100 μL of calibrator fluid to the sample well. Avoid bubbles. Discard pipette tip after use.
- Step 9** Part two of the calibration takes 12 minutes. When part two is finished you will be asked to remove the cartridge. Discard cartridge.
- Step 10** When the *Please insert cartridge 3 of 3* is shown on the screen open the third pouch and insert the new calibration

cartridge in the cartridge slot. The instrument automatically starts the calibration with heating the cartridge.

- Step 11** Fix the new pipette tip from the pouch to the pipette. When the message *Add sample and wait* is displayed on the screen use the pipette with the supplied pipette tip to add 100 μ L of calibrator fluid to the sample well. Avoid bubbles. Discard pipette tip after use.
- Step 12** Part two of the calibration takes 12 minutes. When part two is finished the screen will display that the calibration has been successfully completed and you will be asked to remove the cartridge. Discard the cartridge.
- Step 13** If the calibration has been successfully completed the instrument is now ready to perform a QuickVet® Fibrinogen test. If the calibration failed please contact customer support. Customer support for your country can be found on www.quickvet.net.

QuickVet® Analyzers and QuickVet® cartridges are manufactured by

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