Vcheck

eProgesterone

EQUINE PROGESTERONE

For veterinary use only

INTENDED USE

The Vcheck eProgesterone is an *in vitro* diagnostic test kit for the quantitative measurement of progesterone concentration in equine serum and plasma. Progesterone testing is used to predict whether the mare has sufficient progesterone levels to maintain pregnancy. The BIONOTE Vcheck Equine Progesterone is designed to be used only by veterinarians.

PRINCIPLE

The Vcheck eProgesterone Test Kit is based on a competitive immunoassay method for the quantitative measurement of equine progesterone concentration. When the specimen is delivered to the sample hole of the test device, progesterone in the specimen and the colloidal gold-labeled anti-progesterone monoclonal antibody in conjugate pad migrate along the nitrocellulose membrane. They react with progesterone-BSA coated on the membrane. Here, the nonbinding gold-labeled antibody binds to progesterone-BSA on the membrane. The density of the test line is inversely proportional to the progesterone concentration in equine serum or plasma. The BIONOTE Vcheck Analyzer reads the density of the test line and calculates the progesterone concentration from the calibration curve data. The control line is a reference line that indicates the test has been performed correctly.

MATERIALS PROVIDED

Reagent	5 Tests/Kit
① Vcheck eProgesterone Test device	5
② Assay diluent tube	5
③ Disposable pipette tip	10
④ Instructions for use	1

MATERIALS REQUIRED, BUT NOT PROVIDED

1. BIONOTE Vcheck Analyzer
2. 50 µℓ pipette
3. 100 µℓ pipette

STORAGE AND STABILITY

1. Store the test kit at 2~8 °C. **DO NOT FREEZE.**
2. Do not store the test kit in direct sunlight.
3. The test kit is stable until the expiry date that is marked on the package label.

Reagent	Open status	Storage	Stability	Note
Test device	Unopened	2~8 °C, Sealed	12 months	Finished product
	Opened	Do not store	-	Use directly
Assay diluent	Unopened	2~8 °C, Sealed	12 months	Finished product
	Opened	Do not store	-	Use directly

PRECAUTIONS

1. The test kit is for equine use only. Do not use for other animals.
2. This reagent needs to be stored at 2~8 °C. If refrigerated, allow all kit components to reach room temperature (15~30 °C) prior to testing.
3. The test device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the aluminum foil pouch.
4. Do not reuse the test components.
5. Do not touch the membrane in the result window of the test device.
6. Do not use the test kit beyond the stated expiry date marked on the label.
7. Do not use the test kit if the pouch is damaged or the seal is broken.
8. Do not mix components from different lot numbers; the components in this kit have been quality control tested as a standard batch unit.
9. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterwards.
10. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials safely in accordance with national and local regulations.
11. Severely hemolyzed samples with precipitate such as fibrin may give erroneous results.
12. It is recommended to use a plain tube for sample collection. Test results cannot be guaranteed for anything other than the recommended tubes.
13. Although the Vcheck eProgesterone Test Kit offers simple and quick quantitative measurement of progesterone concentration in equine serum or plasma, there may be a difference in the detection performance with other clinical or laboratory methods with more sophisticated principles.
14. Professional veterinarian should make a final diagnosis based on the results of this product, other test results and clinical findings.
15. Strictly follow the test procedure (e.g. adequate sample volume), as failure to do so may adversely affect test performance and/or produce invalid results.
16. BIONOTE Vcheck Analyzer is recommended to use at 15~30 °C.

COLLECTION AND PREPARATION OF SAMPLE

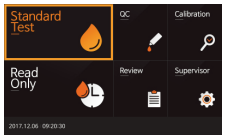
1. Equine serum or plasma should be used with this test. A method for preparing the sample is as follows.
2. **[Serum]** Collect the whole blood into a blood collection tube containing **NO anticoagulant**. Leave to settle for 30 minutes for blood coagulation and then centrifuge to obtain a serum supernatant.
   [Plasma] Collect the whole blood into a blood collection tube containing anticoagulant (**ONLY** heparin). Then centrifuge to obtain plasma supernatant.
3. If serum or plasma samples are not tested immediately, they can be frozen (-20 °C or colder) for a month. Frozen samples should be brought to room temperature (15~30 °C) prior to use.

TEST PROCEDURE

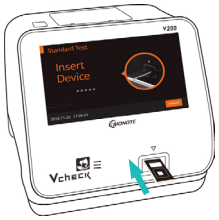
* Allow all kit components and sample to reach room temperature (15~30 °C) prior to testing.
* Prepare the necessary kit components by referring to the 'MATERIALS PROVIDED' section.

[Coding]

1. Turn on V200 Analyzer and select “Standard Test".

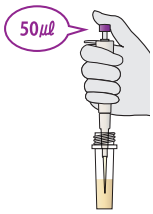


2. Remove the test device from the aluminum foil pouch. Once the “Insert Device” is displayed in the screen, insert the test device.

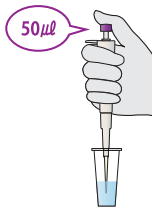


[Dilution of sample & Measurement]

1. Use a 50 µℓ pipette to draw 50 µℓ of the sample and add to the assay diluent tube (100 µℓ).

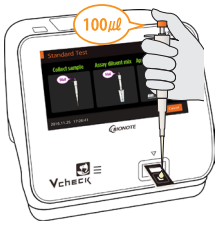


2. Use a 50 µℓ pipette to mix the sample with diluent by pipetting for 5~6 times.



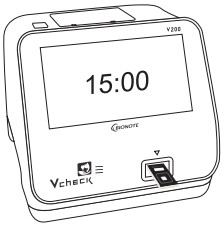
3. Add the mixed sample (100 µℓ) into the sample hole of the test device using a 100 µℓ pipette and press the [START] to initiate testing.

*** Caution: If the time to press [START] button is delayed, it may affect the test result.**



4. The V200 Analyzer will display the test result on the screen after 15 minutes.

5. Remove the test device.



*** Strictly follow the test procedure including the amount of sample (50 µℓ) used and the test time (15 min), as failure to do so may adversely affect test performance and/or produce invalid results.**

INTERPRETATION OF THE RESULT

1. Read the concentration value of equine progesterone appearing on the display of the BIONOTE Vcheck Analyzer. (1~30 ng/mL)
2. If "↓1 ng/mL" appears on the display, it means the concentration of equine progesterone in the specimen is less than 1 ng/mL.
3. If "↑30 ng/mL" appears on the display, it means the concentration of equine progesterone in the specimen is greater than 30 ng/mL.
   * 1 ng/mL is equal to 3.18 nmol/L.
4. If the [Invalid] result appears on the screen, a retest shall be carried out.

REFERENCE RANGE

> 2.0 ng/mL (> 6.36 nmol/L)	≤ 2.0 ng/mL (≤ 6.36 nmol/L)
High (Gestation)	Low

* It is recommended that each laboratory establishes its own reference ranges.

SCREEN MESSAGES AND TROUBLE SHOOTING

[V200]

Error message	Error description
Contaminated Device	The test device is damaged or inserted improperly. **Solution:** Discard the test device and retest with a new test device and a new specimen.
Insufficient Sample	An insufficient amount of blood has been applied. **Solution:** Retest with a new test device with enough specimen, ensuring that blood is placed in to the narrow channel in the top edge of the test device.
Expired Device	The test devices are expired. **Solution:** Retest with a new test device that is not expired.
Temperature Error	The environmental temperature is above or below the operating range of the analyzer. **Solution:** Move to an area in the acceptable temperature range for the analyzer and perform the test. Do not heat or cool the analyzer artificially.
Printer Connection Fail	The communication between analyzer and barcode or printer has failed. **Solution:** Reconnect the analyzer and external device. If the error continues after turning ON/OFF the analyzer, please contact BIONOTE, Inc.
Barcode Error	
Extremely High Total Hemoglobin	The measured total hemoglobin is out of the range of 7 to 23 g/dL. **Solution:** This error occurs when a specimen has a total hemoglobin in the abnormal range. If the error continues after turning ON/OFF the analyzer, please contact BIONOTE, Inc.
Result: Invalid	The test is invalid. **Solution:** Retest with a new test device and a new patient specimen. If the error continues after turning ON/OFF the analyzer, please contact BIONOTE, Inc.
Calibration Overdue	The calibration is overdue. **Solution:** If the error continues after turning ON/OFF the analyzer, please contact BIONOTE, Inc.
Not Supported Device	A test device that is not supported by the analyzer has been loaded. **Solution:** Check whether the test device is manufactured by BIONOTE, Inc.
EEE	Internal error has occurred. **Solution:** If the error continues after turning ON/OFF the analyzer, please contact BIONOTE, Inc.

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