Vcheck

Foal IgG

FOAL IMMUNOGLOBULIN G

For veterinary use only

INTENDED USE

The Vcheck Foal IgG is an *in vitro* diagnostic test kit for the quantitative measurement of immunoglobulin G (IgG) concentration in equine serum, plasma, or whole blood. The measurement of equine IgG concentration serves as a sensitive marker for determining the adequacy of passive immunity transfer. A foal with a low IgG concentration is considered to have experienced a failure in transfer of passive immunity (FTPI), leaving it susceptible to infectious diseases and mortality. Therefore, assessing the equine IgG concentration is a valuable diagnostic tool for determining the presence of sufficient IgG levels. The BIONOTE Vcheck Foal IgG is designed to be used only by veterinarians.

PRINCIPLE

The Vcheck Foal IgG test kit is a fluorescent immunoassay for the quantitative measurement of equine IgG concentration.
The Vcheck Foal IgG test kit uses specific anti-equine IgG antibodies that will blind to equine IgG. When the specimen is delivered to the sample hole of the test device, equine IgG in the specimen and the anti-equine IgG antibody in conjugated pad migrate along the nitrocellulose membrane. They react with the anti-equine IgG antibody coated on the membrane. As a result, the density of the test line reflects the concentration of equine IgG in the sample. The BIONOTE Vcheck Analyzer reads the density of this test line and calculates the equine IgG concentration from the calibration curve data. The control line is a reference line which indicates the test has been performed correctly.

MATERIALS PROVIDED

Reagent	5 Tests/Kit	10 Tests/Kit	20 Tests/Kit
① Vcheck Foal IgG Test device	5	10	20
② Assay diluent bottle	5	10	20
③ Disposable pipette tip	10	20	40
④ Instructions for use	1	1	1

MATERIALS REQUIRED, BUT NOT PROVIDED

1. BIONOTE Vcheck Analyzer
2. 5 µℓ pipette
3. 100 µℓ pipette

STORAGE AND STABILITY

1. Store the test kit at 2~30 °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	2~30 °C, Sealed	12 months	Finished product
	Opened	Do not store	-	Use directly
Assay diluent	Unopened	2~30 °C, Sealed	12 months	Finished product
	Opened	Do not store	-	Use directly

PRECAUTIONS

1. This test kit is for equine use only. Do not use for other animals.
2. The test device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the aluminium foil pouch.
3. Do not reuse the test components.
4. Do not touch the membrane in the result window of the test device.
5. Do not use the test kit beyond the stated expiry date marked on the label.
6. Do not use the test kit if the pouch is damaged or the seal is broken.
7. Do not mix components from different lot numbers; the components in this kit have been quality control tested as a standard batch unit.
8. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterwards.
9. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials safely in accordance with national and local regulations.
10. Do not use samples from equine with severe dehydration or shock conditions, or samples showing severe hyperlipidemia, hyperbilirubinemia, or hemolysis.
11. It is recommended to use a plain tube for sample collection. Test results cannot be guaranteed for anything other than the recommended tubes.
12. Strictly follow the test procedure (e.g. adequate sample volume) including the amount of sample used, as failure to do so may adversely affect test performance and/or produce invalid results.
13. This reagent is designed for quantification of the IgG concentration in equine blood using a simple and quick method, but there may be differences in accuracy compared to other laboratory methods.
14. Final diagnosis must be confirmed by a veterinarian with other clinical data available.
15. BIONOTE Vcheck Analyzer is recommended to use at 15~30 °C.

COLLECTION AND PREPARATION OF SAMPLE

1. Equine serum, plasma and whole blood should be used with this test.
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 (EDTA or heparin). Then centrifuge to obtain plasma supernatant.
   [Whole blood] Collect the whole blood into a blood collection tube containing anticoagulant (EDTA or heparin).
3. **The samples should be tested immediately after collection**. If samples are not tested immediately, they should be refrigerated at 2~8 °C and used within 7 days. For longer storage, serum can be frozen (-20 °C or colder) for 2 months. Frozen samples should be brought to room temperature (15~30 °C) prior to use.

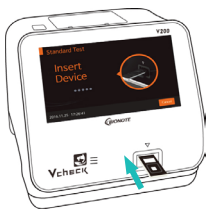
TEST PROCEDURE

* Refrigerated reagents and samples must be at room temperature (15~30 °C) before use.
* Prepare the necessary kit components by referring to the 'MATERIALS PROVIDED' section.

[Coding]

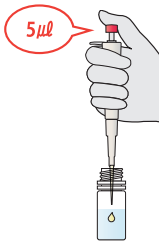
1. Turn on V200 Analyzer and select "Standard Test".

2. Remove the test device from the aluminum foil pouch. Once the "Insert Device" is displayed in the screen, insert the test device.
3. After checking Foal IgG item name and test procedure on the display window, proceed as follows.

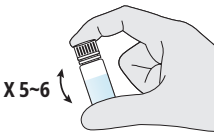


[Dilution of sample & Measurement]

1. Using a 5 µℓ pipette, draw 5 µℓ of serum (plasma) or 10 µℓ of whole blood(5 µℓ x 2) and add the sample into an assay diluent bottle (10 mL).

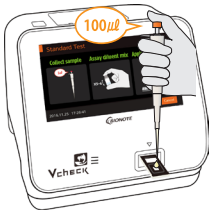


2. Close the bottle cap and shake for 5~6 times to mix the sample and the diluent thoroughly.



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 5 minutes.
5. Remove the test device.

*** Strictly follow the test procedure including the amount of sample (serum or plasma 5 µℓ, whole blood 10 µℓ) used and the test time (5 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 IgG appearing on the display of the BIONOTE Vcheck Analyzer. (100~1,000 mg/dL)
2. If "↓ 100 mg/dL" appears on the display, it means the concentration of equine IgG in the specimen is less than 100 mg/dL.
3. If "↑1,000 mg/dL" appears on the display, it means the concentration of equine IgG in the specimen is greater than 1,000 mg/dL.
4. If the [Invalid] result appears on the screen, a retest shall be carries out.

REFERENCE RANGE

< 400 mg/dL	400 ~ 800 mg/dL	> 800 mg/dL
Failure of passive transfer in foal	Partial failure of passive transfer in foal	Successful passive transfer in foal

* Each laboratory should establish its own reference interval, as reference values may vary depending on the test population.
* The veterinarian in charge must conduct a clinical diagnosis along with the measured results of this reagent, clinical symptoms, and other test results.

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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Manufactured by BIONOTE
BIONOTE, Inc.
22, Samsung 1-ro 4-gil, Hwaseong-si, Gyeonggi-do, 18449, Republic of Korea
TEL: 82-31-211-0516 I FAX : 82-31-8003-0618 I www.bionote.co.kr