vmd



Foal IgG Test User Guide

Components



Reader sold separately.

Component	Quantity
Each individually packaged	test contains:
Test Cartridge	1
Dilution Tubes	2
Sampling Devices	2

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1 The basics

1-1 Testing Foal IgG

Measuring IgG levels is a vital component of any exam for both sick and outwardly healthy neonatal foals. Foals are born without circulating antibodies and cannot initially produce their own IgG, leaving them defenseless against many pathogens. The first milk produced by the mare (colostrum) contains high levels of antibodies that the foal must absorb through nursing within the first 12-18 hours of life. If a foal has not ingested enough good quality colostrum during this time, IgG will be low and risk for serious infection will be high.

Point-of-care IgG testing allows appropriate oral and/or intravenous therapy to be instituted in a timely manner to provide antibodies to help the foal fight off infections. The VMRD Foal IgG Test makes this easy for equine veterinarians, offering objective results and room temperature storage.

1-2 Quick test facts



Objective results

No refrigeration required

Reader Calibration

 Standard kit can be used with fresh or EDTA blood

Whole

blood

- Samples are collected directly from syringe or blood tube
- Objective interpretation of results with the VMRD Reader
- Calibration card keeps results consistent and accurate between readers and over time.
- · Results in 10 minutes

2 Running a test

2-1 Reader-timed

standard test

Test temperature should be between running for most

SAMPLES MUST BE DILUTED TWICE BEFORE APPLYING TO CARTRIDGE Capillary sampling devices & dilution tubes are identical to each other either one can be used first.

1. Attach Foal IgG calibration card

Ensure lot-specific Foal IgG calibration card is attached to the reader.



FIRST dilution:

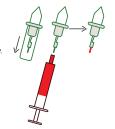
2. Measure blood for FIRST dilution

Remove protective cover from capillary and place tip into blood at an angle. Allow to fill, which measures the blood volume needed (3 µL).

Avoid introducing bubbles.

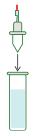
Make sure capillary fills completely.

Wipe excess blood from outside of capillary without touching tip.



3. Puncture foil

Use conical cap to fully puncture foil seal of dilution tube. Do not use capillary tip.

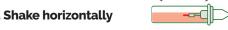


4. Assemble dropper

Firmly insert base of dropper top into mouth of dilution tube. Ensure dropper top is seated tightly in dilution tube.



5. Shake horizontally



Vigorously shake dropper horizontally for 3-5 seconds to thoroughly mix blood with diluent.

SECOND dilution:

6. Prepare diluted sample for SECOND dilution

Unscrew conical cap from dropper

Discard initial drops

Squeeze dropper to suspend a drop from the tip



7. Fill SECOND capillary with diluted sample

Use clean SECOND capillary to collect diluted sample from the suspended drop

Avoid introducing bubbles.

Make sure capillary fills completely.

Wipe excess blood from outside of capillary without touching tip.



8. Puncture foil with conical cap

- 9. Assemble dropper by inserting dropper top into dilution tube
- 10. Shake horizontally and vigorously to mix sample

RUN TEST WITH DOUBLE DILUTED SAMPLE:

11. Prepare reader

Snap reader on top of cartridge
Press button to turn on (shows LR57) result)
Press button again for (RER3Y)



12. Apply DOUBLE DILUTED SAMPLE to cartridge

Unscrew cap from dropper Discard initial drops Add 3 drops to sample well

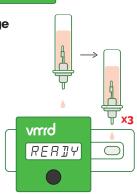
13. Start timed test

Short-press button (<1 sec) for a timed read

Results will be shown in 10 minutes

Do not press button for >1 sec unless performing an instant read (see next page)

Reader will shut off automatically after 50 sec of inactivity



2-2 **User-timed instant read**

- For use ONLY with cartridges that will be run outside of reader and timed by the user.
- Often used so that multiple tests can be run simultaneously and read using the same reader. It is recommended to wait about 30-60 seconds between the start of each test to allow enough time to read at completion.
- Each test must be timed and the result read at 10 minutes.
- Tests should be allowed to reach 60-80°F prior to performing the test.

Running the test

- To prepare samples, follow steps 2 through 10 in section 2-1, completing both first and second sample dilutions.
- Unscrew conical cap from second dropper and discard initial drops.
- Hold dropper vertically and add 3 drops of double-diluted sample to fill sample well.
 - Avoid touching dropper to cartridge or dispensed liquid.
- · Start your timer (10 min) immediately after applying sample.

Reading the test

- When approximately 15 seconds remain on the timer, press button to turn reader on (previous test result will be shown).
- Press button again to move to RERIY screen.
- When 10 minutes has elapsed, fit reader over cartridge test window and **long-press button (>1 sec)** to perform an instant read. The reader will display <u>SERN</u> while reading calibration card, and then show result (mg/dL).

3 Interpretation of results

- o to 400 mg/dL Very low IgG
- 400 to 800 mg/dL Low lgG
- · >800 mg/dL Normal IgG

4 Precautions and limitations

Disclaimer: This product is intended to measure the amount of IgG in equine blood. It does not diagnose any specific disease or injury and should only be used by or under the supervision of a licensed veterinarian as a tool to assess neonatal foals for adequate IgG levels.

- · Sample handling and quality may impact test performance.
- Always check for development of control line if there is concern regarding test performance.
- If run at low temperatures, results will likely be lower than expected. If run at higher temperatures, results may be slightly higher than expected.



Do not eat, drink, or smoke while using this product.



Avoid running at temperatures outside the designated range of 60-80°F.

5 Reader technical information

Calibration card

- If you use your VMRD reader for more than one type of test, make sure you are using the correct card for the type of test you are currently running.
- Each batch of tests is assigned a lot number during manufacturing. The
 associated calibration card is embedded with the optimal settings for
 that specific lot number and type of test. This eliminates variability to
 maximize accuracy across lots, providing you with consistent results
 over time.
- The calibration card provides the programming needed to run the test which is transmitted to the reader via RFID technology. Therefore, the calibration card must be attached to the reader for use.
- The calibration card should be changed every time a new box of tests is opened. The new calibration card can be found in the lid of the green test box. Alternatively, you can compare the lot number of the new box with the lot number printed on the current card. If they match, the card does not need to be changed.

Reader operation & screen text

- When the button is **first** pressed, the last test result will be displayed,
 LR57 and value in µg/mL.
- Pressing the button a **second** time will bring you to the RERIY screen, at which time the reader is ready for the diluted sample to be applied if running a standard test.
- After applying sample, the button must be pressed a **third** time to start the test. The reader will display 5CRN as it scans for the calibration card.
- When reading the result, the reader will display RUN.
- The reader will **turn off automatically after 50 seconds of inactivity**. There is no manual "off" function.

Batteries & maintenance

- · Avoid exposure to water.
- · Clean reading window by wiping with water or alcohol if smudged or dirty
- AUSB charging cable is included with the VMRD* reader. It is recommended to fully charge the reader before using.

- Charge the reader when the battery icon is displayed. The light will show red when the reader is charging.
- · The light will flash blue when the reader is on.
- The reader can be used while charging; the light will flash red and purple.

If your reader has batteries:

- Takes 3 CR 2032 batteries. Use batteries equivalent to Energizer or Duracell
 if available, or VARTA if outside of the U.S. Purchased battery quality may
 vary.
- · Typical battery life is 100+ tests.
- The battery compartment is located on the side of the reader and can be opened using a flat object such as a coin.
- Battery performance may be affected by low temperatures or continuous testing. Battery life will gradually restore once the reader is warmed or left unused for a period of time.
- · Change the batteries if the battery icon diplays thorugh multiple tests.
- Batteries can drain over time when left in the reader during periods of disuse.

Stored data

- Result of previous test will be stored and viewable on the reader screen until a new test is started. These results will then be transferred to long-term storage.
- Up to 100 results will be stored on the reader and can be downloaded to a
 computer via USB cable. Data can then be transferred into Excel in tab
 delimited (tsv) format. If you are interested in this feature, please contact
 VMRD to obtain the USB cable and DataReader software.

Error messages

- @#@4 Sensor exposed to direct light at start-up: Let the reader turn off (automatic after 50 sec. of inactivity) then turn it on again, ensuring underside of reader is protected from bright light.
- [B* 11] Battery too low to complete test: Change batteries, or, if due to low ambient temperature, allow reader to warm up which should restore battery life.
- The reader flashes <u>SERN</u> and <u>TEST</u> then shows <u>ERR</u> after pressing the button to start the test: This indicates the calibration card is not properly attached. See Section 6 Troubleshooting, "My reader won't progress past the <u>RERIY</u> screen."
- For any other errors, please contact VMRD Technical Support at support@vmrd.com.

6 Troubleshooting

I ran your test and a different IgG test at the same time and got different results. Which one is right?

- Slightly different results are expected when using two different types of tests and cannot be directly compared.
- The VMRD IgG test is calibrated against the reference standard RID test and is kept up-to-date through use of our lot-specific calibration cards, which ensure the most accurate and consistent results.

The following situations may affect results to varying degrees:

- Running the test outside of the designated temperature range (see page 5).
- · Extra blood on the outside of the sampling device.
- · Inadequate filling or bubble in the capillary tube.
- · Inadequate mixing of sample with diluent.
- · Too many drops in the sample well.
- If <3 drops are applied, the test and control lines may not develop appropriately
 it is better to have too much of the diluted sample applied than not enough.

I used the wrong calibration card. How will this affect my results?

- If the card is not labeled "Foal IgG Test" (i.e. is intended for use with a
 different test), the results are not valid.
- Use of the proper lot-specific calibration card (matching lot numbers between test and card) ensures maximal accuracy, as there is always some variation between batches/lots for any test.
- If the lot number of the test you ran is the same as the lot number on the card, there will be no effect on the results.
- If the calibration card is from a different lot of Foal IgG, the result may be incorrect.

My reader won't progress past the READY screen, and flashes SCAN if I try to run a test. What is going on?

- Check to make sure the calibration card is properly attached to the reader (velcroed firmly, with top of card flush with top of reader).
- In rare circumstances, the calibration card may have been compromised.
 Please contact VMRD if you continue to encounter this issue despite proper attachment of the calibration card.

I'm trying to run a timed test and the reader gives me a value when I press the button at the "READY" screen. What is going on?

- Make sure you are pressing the button for the appropriate duration of time.
- A **short press (<1 sec)** at the RERIY screen will start the 10-minute timed option for the test, with the test read occurring after 10 minutes have elapsed.
- If the button is pressed for more than 1 second at this point, the reader will
 read the cartridge immediately and give a value. This is designed to be
 used on a test that has already been run and independently timed by the
 user for 10 minutes prior to reading (see page 4).

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