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SUCCEED® EQUINE FECAL BLOOD TEST™

Freedom Health

RAPID DUAL ANTIBODY TEST DETECTS OCCULT EQUINE ALBUMIN AND HEMOGLOBIN IN A FECAL SAMPLE.

- Aids diagnosis of GI tract conditions in horses.
- Helps differentiate foregut and hindgut conditions.

FOR VETERINARY USE ONLY.

DESIGNED FOR STALL-SIDE USE.

Use this product stall-side, in conjunction with history, physical examination and blood work, to support a differential diagnosis of gastrointestinal health conditions in horses, including:

- As an indicator of suspected gastric ulcers, colonic ulcers, protein-losing enteropathies (PLEs) and other GI tract conditions.
- As part of regular check-ups for ongoing assessment of GI health and for early detection of potential pathological issues.

Refer to the instruction sheet inside each individual container for more information.

PRECAUTIONS: For *in vitro* diagnostic use. Do not use after expiration date on back of test cassette. Store in original packaging at temperatures below 27°C (80° F). Keep out of direct sunlight or heat sources. Product may be refrigerated.

USE INSTRUCTIONS AND TECHNICAL INFORMATION

CONTENTS

Contains one complete SUCCEED[®] equine fecal occult blood test, including:

- 1 clear plastic container
- 1 dual test cassette - contains both an albumin test (Test A) and a hemoglobin test (Test H)
- 1 disposable sample pipette
- 1 polyethylene glove
- 1 instruction sheet
- 1 desiccant pouch (for moisture)

INTENDED USE

The SUCCEED[®] Equine Fecal Blood Test[™] (FBT) is a qualitative lateral-flow rapid test that detects horse hemoglobin and albumin in equine fecal specimens. The SUCCEED FBT is for veterinary use only, for use as a diagnostic aid in assessing GI tract conditions in their equine patients.

TEST MECHANISM

The SUCCEED FBT utilizes proprietary antibodies to equine albumin and hemoglobin, and has been calibrated to detect levels consistent with a disease condition. (See Figure 1, page 2 for detection limits.)

Test A detects albumin in feces, which indicates injury equivalent to grade 2 or higher at locations caudal to the common bile duct in the duodenum (or, generally in the hindgut). Test H detects hemoglobin in feces, which indicates injury equivalent to grade 2 or higher anywhere along the GI tract of the horse. Taken together, the two parts of the test may provide a means of distinguishing foregut and hindgut conditions in horses.

PRECAUTIONS

- For veterinary use only.
- For *in vitro* diagnostic use.
- Note: the SUCCEED FBT is a medical device and must be handled with care.
- Do not use after expiration date, which is printed on the back of the test cassette and outside foil pack.
- Keep specimen clear of any potential contaminants. Use only the provided plastic container to collect and mix the fecal sample.
- Keep test cassette in sealed foil pack until use. Exposure to moisture will affect antibodies.
- Product may be safely shipped throughout the year, and safely used in temperatures between 5° C and 30° C (40° F to 85° F).
- Keep product refrigerated when not in use. Keep out of direct sunlight or heat sources.

PATIENT CONSIDERATIONS

1. Check horse for signs of external bleeding where blood may be introduced to the digestive tract, particularly around the mouth.
2. Avoid testing horses within 48 hours of racing, especially those prone to bleeding (i.e., exercise induced pulmonary hemorrhage) where horse may swallow blood.
3. Avoid testing horses within 48 hours of having teeth floated.
4. Avoid testing mares during ovulation or immediately post-partum, where bleeding may be present.
5. Avoid testing horses within five days following anthelmintic treatment.

INSTRUCTIONS

1. Remove all items from the plastic container and set aside. Do not discard container lid.
2. Using provided glove, carefully collect fecal material from a single, fresh, complete bowel movement of subject horse. (Feces should be as fresh as possible, never more than 4 hours old.) Collect about a pinch from multiple locations in a complete fecal specimen. *Do not palpate to obtain sample.*
3. Drop each pinch-sized sample into the plastic container up to the Sample Fill Line (lower line) on the label. *Allow fecal matter to sit loosely in the container - do not pack or compress.*



4. Add clean (potable) tap water to the fecal matter in the container. Fill to the Water Fill Line (top line). Do not use water from dirty containers or from sources that may be contaminated with equine blood. Water should be room temperature.

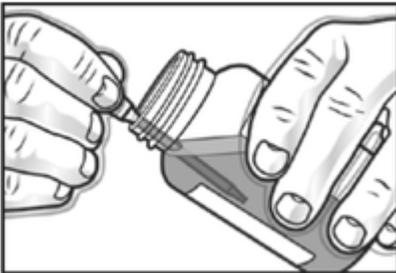


5. Replace cap on container, and *shake vigorously* to mix fecal matter and water. Set container on a flat surface, and remove lid.

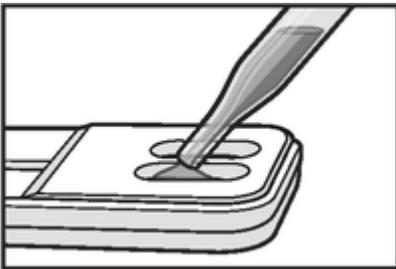


6. Open foil pack and remove test cassette and sample pipette. (Discard empty foil pack and desiccant pouch.)

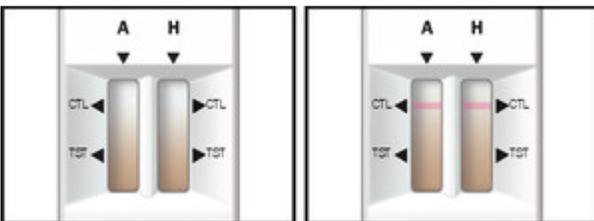
7. Use provided disposable pipette to collect solution from container. Collect liquid only, minimizing particles. For best results: (i) tip jar slightly, (ii) depress pipette bulb before placing in solution, (iii) insert tip of pipette below surface of solution and release bulb **slowly** to draw up solution.



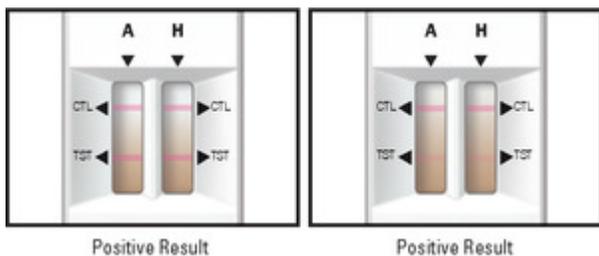
8. Apply 2 drops of solution from pipette to EACH of the two sample wells. Depress pipette bulb slowly to produce large drops.



Watch for liquid to wick up the membrane in the test window: it should wick to above the CTL line in 2-3 minutes. If wicking does not occur, check that well is not clogged with silt, and apply one more drop **ONLY** to non-wicking well. (Excess fluid can flood the test, negating the result.)



9. Read results. A positive result may appear within 5 minutes after solution has clearly wicked up test membrane, but may take longer. **DO NOT** read results after 15 minutes. If a line appears at the TST point on either the Test A or Test H window, that is a positive test. Note that even a faint line reflects a positive test.

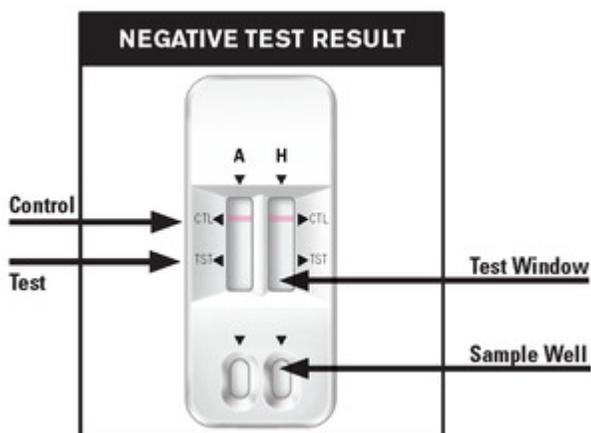


Failure to carefully follow these instructions may lead to incorrect interpretation.

READING THE TESTS

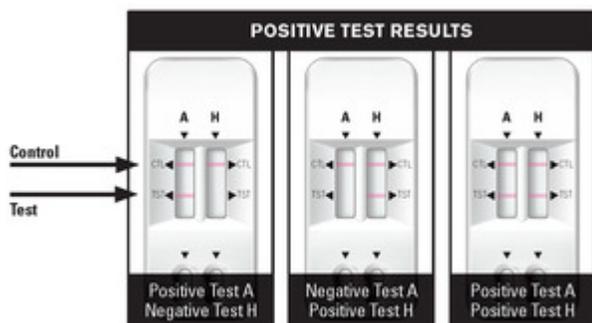
Observe results after applying the solution to each of the two sample wells on the cassette, per instructions.

1. If a Control line does not appear within 15 minutes (at the CTL point on the cassette) that test result is invalid. The test must then be repeated with a new SUCCEED Equine Fecal Blood Test.
2. If only a Control line appears on either strip, that test is **NEGATIVE**. *NOTE: only a complete line is a meaningful result.*



If a solid line appears only at the CTL point (Control line) on either Test A or Test H, this is a **NEGATIVE** result.

3. If both the Control and Test lines appear on either window (Test A or H), this indicates a **POSITIVE** test result. *Even if the test line is faint, the test is POSITIVE.*



If a complete, solid line appears at the TST point (Test line) on either or both Test A and Test H, that is a **POSITIVE** test result. Test A detects equine albumin. Test H detects equine hemoglobin.

Note - even if the test line is faint, the test is **POSITIVE**.

4. Do not read test results after 15 minutes.

If you have questions about reading the SUCCEED Equine Fecal Blood Test, please call: 800-281-6727 from 8AM - 5PM ET Monday through Friday.

INTERPRETING THE RESULTS

The following chart summarizes the meaning of a positive and/or negative test results across SUCCEED FBT tests A and H.

		Test A	
		Albumin	
		Negative	Positive
Test H	Negative	No GI tract issue detected.	GI tract issue detected in hindgut.
Hemoglobin	Positive	GI tract issue detected in foregut.	GI tract issue detected in hindgut. Foregut issue also possible.*

* Note that Test A uses an antibody for albumin, which typically breaks down in digestion, particularly when exposed to digestive enzymes in the proximal portion of the small intestine. Thus a positive Test A will indicate bleeding from a source caudal to the duodenum (e.g. hindgut). Also, because albumin may be present at the site of low-grade injury absent whole blood, you may get a positive Test A in response to a low-grade lesion in the hindgut, such as may occur with heavy parasitism or disseminated grade 1 colonic ulcers.

Test H uses an antibody for hemoglobin, which is more resistant to enzymatic activity. Thus a positive Test H, with negative Test A, will indicate occult blood from a foregut source. You will not obtain a positive result from either Test A or H when a horse has a foregut lesion equivalent to a grade 1 gastric ulcer, where whole blood loss does not occur.

LIMITATIONS OF THE TEST

The SUCCEED FBT is a fecal occult blood test. It is designed to detect blood components in feces that may be indicative of underlying pathologic conditions. This makes the SUCCEED FBT a qualitative test for the presence and location of gastrointestinal injury. It is not a quantitative test.

Albumin may be present at the site of injury absent whole blood. Thus a positive test A reflects injury equivalent to grade 1 or higher ulceration in the hindgut. Hemoglobin is only present with whole blood. Therefore, a positive test H reflects injury equivalent to grade 2 or higher ulceration anywhere in the GI tract.

Equine albumin and hemoglobin in feces may arise from a variety of conditions, including but not limited to:

- Bleeding ulcers (gastric or colonic)
- Excessive parasitic activity
- Protein-losing enteropathy (PLE)
- Lesions caused by hard particles of feed or other ingested material

- Petechiation, hyperemias or lypomas

Equine GI lesions - including petechiation and parasite pits - may bleed lightly or intermittently, so a test result may be negative even when disease is present. And because blood components may be non-uniformly distributed in a fecal dropping, negative readings may occasionally be obtained from a fecal sample of an unhealthy horse. As with any fecal blood test, SUCCEED FBT is not a conclusive diagnostic for occult gastrointestinal bleeding or pathology; it should be employed only as an aid to diagnosis.

Additionally, a positive test result (especially Test H), can arise from extraneous sources, such as:

- Dentistry or exercise-induced pulmonary hemorrhage
- Mare ovulation
- Post-surgery bleeding

As with any diagnostic, a definitive diagnosis should not be based on the result of a single test. The test is designed to be complementary to blood tests and physical examination. NOTE: Practitioners experiencing a positive Test A without a positive Test H, should include a protein-losing enteropathy as one differential diagnosis, especially in the presence of hypoproteinemia/hypoalbuminemia on a CBC/chem profile. A negative test result in conjunction with hypoproteinemia/hypoalbuminemia may reflect a protein-losing nephropathy.

APPLICATIONS

Because symptoms are an unreliable indicator of GI health, practitioners should test horses periodically. Given the ease and affordability of the FBT, testing all horses on a regular schedule is a practical option for early detection.

Consistent testing is especially important for performance horses, or wherever the care, feeding and general husbandry can affect digestive health, including intermittent feeding, high-grain diets, stall confinement, etc. Because it is possible that GI health may be a root cause of many performance or behavioral problems, horses with such issues may be prime candidates for testing.

The SUCCEED FBT may also be a valuable part of a pre-purchase exam.

PERFORMANCE CHARACTERISTICS

The performance of the SUCCEED FBT was assessed with multiple *in vitro* and *in vivo* tests, with the results as detailed below.

ANALYTICAL SENSITIVITY

The antibodies used in the two parts of the SUCCEED FBT - Test A and Test H - were evaluated by introducing equine blood at varying concentrations into a solution of water and rabbit fecal matter. The detection limits of the FBT antibodies, at a 95% confidence level, are provided here.

Fig 1: Detection limits of FBT antibodies

	Test A (Albumin)	Test H (Hemoglobin)
Lower	.8 ppm	.8 ppm

Upper	10,000+ ppm	10,000+ ppm
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DIAGNOSTIC RELIABILITY

Figure 2 indicates the statistical accuracy of the SUCCEED FBT results as a reflection of actual pathological conditions in horses, as determined by comparing FBT results on fecal samples from equine subjects with observed GI tract injury in those same subjects post-necropsy.

The SUCCEED FBT has been calibrated to detect blood components at levels reflecting true pathologies and to ignore subclinical or baseline bleeding.

Fig 2: Analysis of tests A & H as indicators of ulceration

N=178	Test A (Colon)	Test H (Full GI Tract)
True Positives	166	154
True Negatives	3	11
False Positives	8	5
False Negatives	1	8
Sensitivity	99.4%	95.1%
Specificity	27.3%	68.8%
Positive Predictive Value	95.4%	96.9%
Negative Predictive Value	75.0%	57.9%
P-value	.045	.028

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SUCCEED® Digestive Conditioning Program® holds U.S. Patent Nos. 7,658,964; 7,824,706 and 7,988,989. Further patents pending.

SUCCEED® Equine Fecal Blood Test™ holds U.S. Patent No. 7,629,180.

Contact Information:

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Toll-free service line: 877-734-6558 24 hours a day

For more information, visit our website at www.SucceedFBT.com

Also available from Freedom Health:

SUCCEED® Digestive Conditioning Program® Veterinary Formula.

I501 Rev H 04/12

CONTENTS:		
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10 complete test kits. Each kit contains 1 dual test cassette, 1 sample pipette and 1 polyethylene glove, in plastic specimen jar with instruction sheet. (Desiccant pouch included to absorb moisture.)	50110	P510 Rev C 10/11
40 pack case		P540 11/11

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