

RapidVet®-D

Companion Animal

Rapid Test for Veterinary Dermatophytosis

IMPORTANT PRECAUTIONS

Also See "Results"

The following precautions are necessary requisites for obtaining a positive or negative determination within 96 hours:

- Sample must be properly collected from the edge of the lesion where the organism is most active.
- RapidVet-D reaction tubes must be maintained at room temperature (22-25°C/72-77°F) for the duration of the test period.
- Sample must be placed on the surface of the reaction substrate. Results may not be reliable if sample is pressed below the surface of the reaction substrate.
- The tubes must be loosely capped to avoid moisture buildup which can slow the reaction.
- ANY tube retained substantially beyond the 96 hour test period WILL change color. This color change does not indicate dermatophyte presence in the sample.

Intended Use

RapidVet-D is for use as part of the differential diagnosis of dermatological conditions in companion animals: dogs, cats, rabbits, and horses. It is especially designed to provide a statistically significant indication of the involvement, or absence, of dermatophytes as a causal factor of the underlying condition. Since RapidVet-D employs a proprietary formulation designed for the detection of only those fungi that cause clinical complications in the noted animal species, the product should not be used for other animal species or for humans. Likewise, RapidVet-D is not designed to test for the presence of viable but dormant dermatophytes superficially present on the fur of asymptomatic animals. While frequently present, these are not a causal factor in the underlying condition.

Summary and Explanation of the Assay

In the late 1960's and early 1970's, Taplin and colleagues formulated a culture medium for dermatophyte identification and ancillary growth that improved the earlier work of Sabouraud. Specific nutrients in the medium promoted the growth of dermatophytes, while selective antibiotics inhibited the growth of nonpathogenic saprophytic mycetes and bacteria. The alkaline metabolites produced by the *Microsporum*, *Trichophyton* and *Epidermophyton* genera that grow on that medium caused a distinctive and discernible color change in the pH-indicator, Phenol Red, contained in the medium. Tests based on this medium require up to 14 days for completion.

RapidVet-D represents a further improvement of this work that focuses on the specific need of the veterinary practice for a much faster result. It is designed to be used by the clinician to rapidly determine within acceptable statistical limits, rather than with absolute certainty, the likelihood of dermatophyte involvement. This has been accomplished by use of a proprietary formulation for the reaction substrate.

Principle of the Assay

RapidVet-D uses a proprietary differential reaction substrate. It enables the target organisms to metabolize various nutrients and produce alkaline metabolic substances much faster than the Sabouraud or Taplin medium – typically within 4 days. It also more aggressively suppresses the metabolism of other organisms that would normally also cause the pH indicator to change color.

The length of time required for the target organisms to cause the color change is less than the length of time during which the growth of other organisms is suppressed. Thus, a color change, or absence thereof can statistically be considered an indication of the presence or absence of dermatophytes in the sample.

Test Reagents and/or Materials

1. Glass tubes with blue caps containing the differential RapidVet-D reaction substrate.
2. Labels for the tubes to identify patients.

Materials Required but not Provided:

1. Scalpel.
2. Forceps, scissors or nail clipper (optional).

Storage and Stability

In order to meet the needs of the veterinary practice, RapidVet-D remains stable at room temperature (72-77°F/22-25°C), and away from direct sunlight, for 36 months. Product may also be refrigerated (36-46°F/2-8°C), however, if refrigeration is used, the tube(s) must be brought to room temperature before use. Freezing and/or overheating must be avoided.

Specimen Collection and Inoculation

The site of sampling must be inspected to ensure that it has not been treated with medicaments that could affect the result. If necessary, clean the site carefully so as not to destroy the viability of any dermatophytes collected. It is sometimes necessary to clean the site to reduce bacterial and/or saprophytic contamination. If so, cleaning should be limited to gentle use of a gauze pad with 70% isopropyl alcohol.

Collect the specimen, using a scalpel to take scales and/or hair from the border of obvious lesions. In some instances, use of forceps may be more convenient for removal of hair. If a hair sample is utilized, that portion of the hair more than 2 cm (0.8 inch) from the skin should be clipped off and discarded. If the nail area is infected, clippings from the nail edges can be used as the sample.

Place the sample on the surface of the reaction substrate without pushing into it. Partially close the tube, keeping the screw cap loose. Label the tube with the patient's name and date using the labels provided. Maintain the tube at *room temperature* (72-77°F/22-25°C) and away from direct sunlight for the duration of the test period.

Results

Periodically examine the reaction substrate in each tube for up to 96 hours. Any change in color from yellow to red, even in only a small region of the reaction substrate, is interpreted as positive for the presence of dermatophytes. However, the degree of red will normally intensify, and the area of color will normally spread with time.

If the user is confident that all conditions in the box headed "Important Precautions" have been followed and/or maintained, the test can be deemed terminated and the tube discarded in an environmentally correct manner.

Performance Characteristics

When used to test 1681 samples taken from symptomatic dogs and cats and in-field samples from horses, RapidVet-D produced positive results on 510 samples, or 30.3%, of which 494 were confirmed to be positive by reference methodology conducted by a specialist in dermatophyte infections. Thus, the false positive rate can be considered to be 3.1%. The remaining 1171 samples, or 69.7%, produced negative results of which 1150 were confirmed to be negative by reference methodology conducted by a specialist in dermatophyte infections. Thus, the false negative rate can be considered to be 1.8%.

The overall accuracy can be considered to be 97.7% and not materially different by species tested.

Limitations of the Assay

1. RapidVet-D is only for *in vitro* diagnostic use on samples taken from symptomatic dogs, cats, rabbits, and horses.
2. RapidVet-D is intended for use by the clinician who wants to obtain a result that is highly likely to be clinically significant. It is not intended for use by a microbiologist who wants a conclusive result with the capability to identify the organism involved.
3. Colony identification IS NOT the intended use of this product. As such, it is unnecessary, although possible, for a practiced eye to determine the identity of the dermatophyte involved by maintaining the tube for an extended period of time until colony growth is noted, and then examining the colonies with comparison to pictorial representations in standard reference works. In this instance, any color change after 7 days must be ignored.

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