RapidVet[®]-M Companion Animal

Test for Veterinary Malassezia

IMPORTANT PRECAUTIONS Also See "Results"

The following precautions are necessary requisites for obtaining a positive or negative determination within 5 days:

- Sample must be properly collected from the lesion or area where the organism is most active.
- <u>RapidVet-M reaction tubes must be brought to room temperature (22-25°C/72-77°F) one hour</u> prior to use.
- Sample must be streaked onto the surface of the reaction substrate. Results may not be reliable if sample is injected below the surface of the reaction substrate.
- The tubes must be loosely capped to avoid moisture buildup which can slow the reaction.
- The appearance of growth in any tube retained substantially beyond 5 days should be disregarded.
- · Do not use beyond stated expiration date.

Intended Use

RapidVet-M is for use as part of the differential diagnosis of dermatological conditions in companion animals: dogs and cats. It is especially designed to provide an indication of the degree of involvement of *Malassezia pachydermatis* in the underlying skin condition. The RapidVet-M formulation is designed for the detection of fungi that cause clinical complications in the noted animal species and has not been validated for use in other animal species or for humans. While this yeast is normally present in the mucous membranes and skin of dogs and cats, *Malassezia* can become pathogenic under certain conditions, overpopulate and cause otitis and severe itchy dermatitis.

Principle of the Assay

RapidVet-M uses a specific chromogenic substrate in a sterile solidified culture medium for the detection of *Malassezia* yeasts. The chromogenic substrate reacts with specific yeast enzymes and causes rounded and smooth pink, dark pink or violet colonies to form. The *Malassezia* colonies generally begin to grow within 48-72 hours from the inoculation of the sample. The chromogenic staining allows results to be clearly and visually interpreted without the additional laboratory instrumentation in common use (cf. Rostaher, A [2016] Malassezia Dermatitis – How do I manage this? In: 8th World Congress of Veterinary Dermatology, France, 16 May 2016 – 4 June 2016, http://doi.org/10.5167/uzb-126301).

Test Reagents and/or Materials

- 1. Glass tubes with green screw caps containing the differential RapidVet-M reaction substrate.
- 2. Labels for the tubes to identify patients.
- 3. Package insert.

Materials Used but not Provided:

- 1. Cotton swab or scalpel.
- 2. Saline solution (optional).
- 3. Incubator at 32°C (90°F).

Storage and Stability

RapidVet-M has been designed to be stable for 12 months when stored in the dark and under refrigeration (36-46°F/2-8°C). Freezing and/or overheating must be avoided. The expiration date on the box corresponds to refrigerated storage.

Specimen Collection

Proper sample collection is very important. Optimal results will be obtained when the specimen is of ample amount and taken from the area of most involvement. If necessary, clean around the site using 70% isopropyl alcohol to reduce bacterial and/or saprophytic contamination.

Otitis: Samples of wax or aural exudate should be obtained from the horizontal portion of the ear canal using a cotton swab.

A cotton swab can also be used for samples obtained between paws or in deep skin folds.

Dermatitis: Skin scrapings should be obtained using a dry swab or one dipped in saline solution. Sample affected areas of erythema, pruritus, or where lesions are evident.

Test Procedure

Ensure that glass tube has been brought to room temperature before proceeding with test. Sample should be streaked onto substrate medium as soon as possible following sampling. Refrigeration of sample is not recommended.

- Streak or roll sample onto medium to dispense material generously and evenly on surface.
- Gently press material onto surface to ensure good contact with medium.
- Partially close the tube, keeping the screw cap loose.
- Label the tube with patient name and date using the labels provided.
- Incubate at 32°C (90°F) for 5 days, examining daily.

Results

Examine the inoculated tubes daily for growth. In most cases, *Malassezia pachydermatis*, if present, grows within 48-72 hours. Colonies are round and smooth, and pink to violet in color.

Other *Malassezia* species can grow and are identifiable according to their colony color and appearance.

Candida spp. can be present and their growth is characterized by green to light blue colonies.

Result Interpretation

The finding of *Malassezia* colonies in excessive numbers is linked to a concurrent underlying pathology that causes the overgrowth of the organism as a secondary occurrence. Accordingly, the diagnosis and treatment of the underlying primary disorder is essential, in addition to the treatment of *Malassezia* dermatitis or otitis.

The growth of more than ten *M. pachydermatis* colonies with concurrent symptoms is clinically indicative that an infection is in progress. Macroscopic or microscopic examination of colonies can lead to identification of other species of *Malassezia* (Table 1) or *Candida* (Table 2).

Disposal

Discard tubes in an environmentally appropriate manner.

Limitations of the Assay

- 1. RapidVet-M is for veterinary use only for *in vitro* testing on samples taken from symptomatic dogs and cats.
- 2. RapidVet-M is intended for use by the clinician who wants to identify in a symptomatic animal the overpopulation of *M. pachydermatis*, a yeast normally present in small numbers in healthy dogs and cats.
- 3. Follow instructions for use precisely.
- 4. Do not use beyond expiration date.

Table 1: Colony characteristics of Malassezia spp.

Pathogen	Colony appearance and color
Malassezia pachydermatis	Large, smooth, peanut shaped, pink to violet
Malassezia furfur	Large, rough, pale pink
Malassezia globosa	Small, smooth, violet
Malassezia sympodialis	Large, smooth, pale pink
Malassezia obtusa	Medium large, rough, pink
Malassezia restricta	Small, smooth, pink

Table 2: Colony characteristics of Candida spp.

Pathogen	Colony color and appearance
Candida albicans	Pale green
Candida tropicalis	Light blue with violet halo

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> **dms**laboratories, inc. 2 Darts Mill Road Flemington, NJ 08822 (908) 782-3353 / 800-567-4367 Fax (908) 782-0832 Technical Services: 888-VET-TEST www.rapidvet.com

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