



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Thomas R. Frieden, MD, MPH
Commissioner

2009 Veterinary Alert # 4

Advisory Regarding the Rabies RAPID™ Screen from Dyne Immune

- Dyne Immune is marketing a rapid test for rabies labeled, Rabies RAPID™ Screen
- The Rabies RAPID™ Screen is not USDA approved and is NOT recommended for rabies testing; inaccurate results can have serious consequences for animals and humans
- The New York City Department of Health and Mental Hygiene (DOHMH) Health Code Article 11 sections §11.27 (formerly §11.65) requires that testing of animals for rabies be performed at the NYC Public Health Laboratory or another Health Department approved laboratory
- NYS Department of Agriculture and Markets (DAM) has requested the sale of the Rabies RAPID™ Screen in New York State and New York City be limited to the Health Department and Cornell University (see attached letter)
- Please report attempts by this company to market this product to the NYS DAM (see contact information below)
- Healthy dogs, cats and domestic ferrets and livestock that have bitten a person or pet do not need to be tested and can be observed for a 10 day period. Suspect rabid animals should be reported to Veterinary Public Health Services (VPHS) at the Health Department at 212-676-2483 during regular business hours, or the NYC Poison Control Center at 212-POISONS (212-764-7667) after hours, or on weekends and holidays.

Please share with your colleagues in Veterinary Medicine and your staff

March 12, 2009

Dear Veterinary Colleagues,

A company named Dyne Immune LLC is marketing a new product called Rabies RAPID™ Screen, a rapid test for animal rabies. The test is advertised as providing a rapid method to test saliva for the presence of rabies in live animals (see www.dyneimmune.com). The Health Department is advising veterinarians NOT to use this test. In New York City and State, rabies testing should only be conducted by the New York City Public Health Laboratory (PHL) or a laboratory approved by the Health Department using brain tissue. Results from unapproved laboratories or commercial kits cannot be legally recognized and may be unreliable, putting people and other animals at risk. Dyne Immune LLC does not provide data regarding the test's sensitivity or specificity, which is needed to determine the likelihood of false positive or negative test results. A publicity event in New York to promote this test resulted in a kitten being euthanized because it tested positive for rabies according to the Rabies RAPID™ Screen test. Confirmatory testing by the NYS Department of Health revealed the kitten did NOT have rabies. Because of the fatal outcome associated with rabies infection, incorrect test results could lead to unnecessary euthanasia of animals and/or administration of rabies postexposure prophylaxis for humans due to a false positive test result in an uninfected animal. A false negative could result in continued exposure to rabies from an infected animal.

According to §89 of Article 5 of New York State Agriculture and Markets Law, the DAM has the authority to restrict sale of and distribution of biologics used in the detection, prevention, control or eradication of infectious diseases. As such, it recently issued a letter to Dyne Immune (see attached) requesting that the company restrict sale of Rabies RAPID™ Screen to the Health Department and Cornell University for research purposes only. The New York City Health Code, Articles 11, sections §11.27 (formerly §11.65) states that animals suspected of being rabid must be tested at the Public Health Laboratory or a laboratory approved by the Health Department. If Dyne Immune attempts to sell the Rabies RAPID™ Screen test to you or your clinic, please contact DAM (Dr. Dave Chico at 1-800-554-4501).

Healthy dogs, cats, domestic ferrets and livestock that have bitten a person or pet that can be observed for a 10 day period should not be tested for rabies. Veterinarians in NYC should report suspect rabid animals to Veterinary Public Health Services (VPHS) at the Health Department at 212-676-2483 during regular business hours, or the NYC Poison Control Center at 212-POISONS (212-764-7667) after hours, or on weekends and holidays. When rabies testing is indicated, VPHS will facilitate arrangements to have the animal collected, prepared and submitted for rabies testing at PHL. Veterinarians may also contact VPHS at 212-676-2483 for guidance on the management of animal to animal bites.

For inquiries regarding management of persons exposed to rabid or suspect rabid animals, administration of rabies preexposure vaccination or rabies titer testing, contact the Bureau of Communicable Disease at 212-788-9830 during regular business hours, or the NYC Poison Control Center at 212-POISONS (212-764-7667) after regular business hours. For additional information, refer to the Centers for Disease Control and Prevention website at <http://www.cdc.gov/rabies/qanda/rabiesdiagnostics.html>.

As always, we greatly appreciate your partnership and cooperation.

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