

Antimicrobial Test Laboratories LLC

●●●●● Disinfectant Development Specialists

Independent Scientific Review of ATS-LABS Study # A01959

Review by Benjamin Tanner, Ph.D, 1/23/08

Reviewer Background:

Benjamin Tanner is the president of Antimicrobial Test Laboratories, a commercial microbiology laboratory. He holds a Ph.D. in Microbiology and Immunology and has worked in the disinfectant industry for several years. Before launching Antimicrobial Test Laboratories, he worked as a microbiologist for the Clorox Company (Oakland, CA), developing disinfectants and other antimicrobial consumer products.

Summary of the Microgen, Inc. Study:

The test report for study #A01959 (Microgen, Inc) reflects guidelines put forth by the United States Environmental Protection Agency for testing of virucides (DIS/TSS-7, Nov. 12, 1981). The study was carried out, briefly, as follows:

- 1) Avian-human reassortant influenza virus H3N2 was cultured, adjusted to contain 98% fetal bovine serum (organic load) and then dried onto a glass surface.
- 2) Two separate lots of D-125 disinfectant were prepared by dilution in 400 ppm hard water, and then the contaminated surfaces were treated with 2.0 mL of product in accordance with normal use instructions.
- 3) After treatment with D-125, liquid on the contaminated surfaces was harvested and then analyzed for the presence of viruses.
- 4) In addition, normal test controls were analyzed, including cytotoxicity, virus titer, and neutralization.

Note: The method of viral enumeration employed for this study was "TCID₅₀." Using this technique, the number of viruses present at a given dilution is roughly calculated by placing 4 aliquots of each of a series of dilutions into 4 separate culture wells containing mammalian host cells. The number of viruses is then determined statistically based on the number of culture wells showing viral presence (cell destruction) at each dilution after incubation. TCID₅₀ produces *estimates* of actual viral titers.

Interpretation of Study Results:

The study performed here is standard for virucide testing in the United States, except that the culture was adjusted to contain an extraordinarily high concentration of "organic soil." It is generally accepted that even low levels of organic soil (*i.e.*, 5%) can make disinfectant tests challenging to pass. Thus, this test, performed at 98% soil load, would be considered by the industry to be a "worst-case" scenario. This is especially important considering that some disinfectants, such as sodium hypochlorite, are inactivated rapidly by high levels of organic matter.

The data tables in the study report indicate that one lot of D-125 achieved a 3.25 log₁₀ reduction, while the other lot achieved a 2.75 log₁₀ reduction. Since the TCID₅₀ test method is subject to statistical variability, and the test itself is subject to some inherent variability (not addressed in the study report), it is fair to say that the D-125 disinfectant achieves, on average, a 3-log₁₀ reduction¹ in avian flu virus under "worst-case" use conditions.

Relevance to Contemporary Infection Control:

The virus tested for this study is a human-avian reassortant influenza virus. This is highly relevant to concerns about pandemic disease, since human-avian reassortant influenza viruses such as influenza H5N1 have recently demonstrated bird-to-human transmission and may soon demonstrate widespread bird-to-human-to-human transmission. Disinfectant studies using the H5N1 strain are not normally performed in the U.S. because of risks to laboratory workers and the general public, but the H3N2 avian-human reassortant virus tested here is as close a strain as is possible to potentially pandemic influenza strains, which are constantly evolving. Since avian influenza virus can be spread from chicken excretions/droppings, which are high in organic matter, this study on an avian-human reassortant influenza virus at 98% organic soil load is timely and epidemiologically relevant.

¹ A 3-log₁₀ reduction corresponds with a "pass" per current EPA testing requirements.