

UNIVERSITY OF TEXAS AT ARLINGTON

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

LD 50 TESTING SOP

The LD 50 test evaluates acute lethality from exposure to a substance or product. An LD 50 value is the dose at which 50 percent of the test animals can be expected to die. The test is used to classify substances or products for regulatory purposes, including safe transporting and labeling; provide information for treatment of acute intoxications; standardize certain biological products; set dose levels for subsequent toxicity studies; provide comparative information on the chemical's dose response curve; and provide data for evaluation and validation of alternative test methods. The LD 50 tests have become controversial among toxicologists, animal welfare organizations, legislators, and the public primarily due to ethics of using a large number of animals and evaluating only mortality.

The University of Texas at Arlington IACUC has established the following policy: (The Interagency Research Animal Committee (IRAC) studied this issue in depth and made the identical recommendation, as published in ILAR Volume 35, Numbers 3 – 4, Summer-Fall 1993).

A. Definitions:

1. The Classical LD 50 test is used to determine the lethal dose (LD) of a substance that will kill 50 percent of test animals. Typically, this method can use 100 or more animals. The test material is administered in increasing doses, usually five or more, to groups of 10 male and 10 female animals. Mortalities are recorded within a given period, and the LD 50 is determined with the aid of statistical calculations.
2. The Limit Test is used to determine if the toxicity of a test substance is above or below a specified dose. Five to 10 animals of each sex or 10 animals of the susceptible sex are administered a dose specified by regulations. Toxic responses occurring within a given period are recorded. Based on the results, additional testing may be authorized by the IACUC.

B. IACUC Policy

1. The Classical LD 50 test should only be conducted when specifically justified for reasons of scientific necessity and approved by the Institutional Animal Care and Use Committee (IACUC).
2. Toxicity testing procedures based on the principles of reduction and refinement (such as the Limit Test) should be used until alternative test methods become validated.