

## Required Testing of Cell lines Prior to introduction into Rodents

An important potential source of virus outbreaks in the animal facility is contaminated biological materials that are injected into animals. To protect the health status of NCI mice, all cell lines, stem cells, and biological products originating outside of NCI animal facilities, including tissues from the ATTC (American Type Tissue Collection) and all rodent serum products must be screened for contamination with rodent pathogens. Documentation of this screening is a component of the ASP. Results from more than ten years ago are acceptable only if the cells or materials have been routinely re-passaged in rodents in clean NCI animal facilities where no viral outbreaks have occurred.

If there is a possibility of cell lines or biological products being passaged through mice during a disease outbreak or being exposed to rodent serum, they should be tested or retested. If cells were passaged in animals from another animal facility, they should be retested before being used in any NCI animal facility, unless an exception is officially reviewed and approved by the facility veterinarian. The following are recognized exemptions to the testing policy:

- Fresh or frozen human tissue (tissues must be from documented HIV and Hepatitis B negative patients).
- Human cell lines grown *in-vitro* at NIH that have never been passaged through rodents or exposed to rodent serum.
- Cells and tumors that have originated in a specific facility that will only be used at the same facility. If the facility has an outbreak, testing will be required before these materials may be re-introduced.
- Biological products from a commercial manufacturer who certifies with testing or screening that the materials are not contaminated with excluded rodent viral pathogens, specifically including LDH-elevating virus.
- Cell lines that will be used only in the laboratory, which have no chance of being injected or implanted into laboratory animals residing in an NIH animal facility.

In many cases, the history of passaging and potential contamination is not known, so in those cases, testing is still required. Cross contamination of clean cells or media can also occur in the laboratory. If uncertainties remain, a risk assessment and decision should be made by consultation with the Animal Program Director, the Head of Lab Animal Medicine, or the Director of the [AHDL](#).

In addition to the panel of viruses screened, (described at <http://www.ncifcrf.gov/rtp/lasp/intra/ahdl/>) contamination by Mycoplasma is also evaluated. Some PCR tests for mycoplasma do not distinguish murine mycoplasmosis from human-origin mycoplasma. Mycoplasma-contaminated products should not be injected into experimental animals,

but instead should be disinfected or replaced with documentation of mycoplasma-free status by follow-up testing.

The [AHD](#) has instructions for packaging and submitting mouse, rat, hybridoma and human cells for screening by PCR. Investigators are responsible for the cost of this testing.