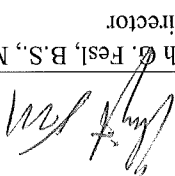


Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

Approved by:


Elizabeth G. Fesi, B.S., M.S., L.A.T.G.
Study Director

Date Completed
6-12-12

Supervisory Personnel:

Lisa A. Severhof, B.A.
Assistant Manager, Toxicology
Austin M. Zdawczyk, B.S., M.B.A., ALAT
Supervisor, In Vitro

The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than or equal to a grade 2 (mild reactivity).

The test article, NANYA TT fabric, was evaluated to determine the potential for cytotoxicity based on the requirements of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity. Triplicate wells were dosed with a 1 cm x 1 cm portion of the test article. Triplicate wells were dosed with a 1 cm length portion of high density polyethylene as a negative control. Triplicate wells were dosed with a 1 cm x 1 cm portion of latex as a positive control. Each was placed on an agarose surface directly overlaying a subconfluent monolayer of L-929 mouse fibroblast cells. After incubating at 37°C in the presence of 5% CO₂ for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis.

Summary