Solventum MedTech OEM
Biocompatibility summary
Product Name: Solventum™ Microfluidic Diagnostic Film 9962
Effective: December 2021

Microfluidic Diagnostic Film 9962 has been subjected to the following preclinical biocompatibility evaluations per ISO 10993 standards under FDA GLP Regulations (21 CFR Part 58):

In Vitro Cytotoxicity

The test was to determine the potential for cytotoxicity based on the requirements of International Organization for Standardization (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 24-26 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis. The test article showed no evidence of causing any cell lysis or toxicity and had a grade 0 (no reactivity). The test article met the requirements of the test since the grade was less than or equal to a grade 2 (mild reactivity). EM-05-014334

Cytotoxicity Study Using the ISO Elution Method

An additional *in vitro* study was conducted to evaluate for potential cytotoxic effects using a mammalian cell culture test following the guidelines of International Organization for Standardization 10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium (IX MEM) at 37°C for 24 hours. The negative control, reagent control, and positive control were similarly extracted. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37°C in the presence of 5% CO2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. The test article extract showed no evidence of causing cell lysis or toxicity and had a grade 0 (no reactivity). The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity). EM-05-014334

Hemolysis

This test was conducted to evaluate for the potential to cause hemolysis following the guidelines of ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials and ISO 10993-4, Biological evaluation of medical devices -Part 4: Selection of tests for interactions with blood. Anticoagulated whole rabbit blood was pooled, diluted, and added to polystyrene containers with the test article in calcium and magnesium-free phosphate buffered saline (CMF-PBS) or in polystyrene tubes with a CMF-PBS test article extract. Negative controls, positive controls, and blanks were prepared in a similar manner. Following incubation for at least 3 hours at 37°C, the samples were centrifuged, and each supernatant collected. The supernatant was mixed with Drabkin's reagent and the resulting solution was analyzed using a spectrophotometer at a wavelength of 540 nm. The hemolytic index for the test article in direct contact with blood was 0.0% and the hemolytic index for the test article extract was 0.0%. Both the test article in direct contact with blood and the test article extract were non-hemolytic. EM-05-014334

Microfluidic Diagnostic Film 9962, as part of a different construction, has been subjected to the following preclinical biocompatibility evaluations per ISO 10993 standards under FDA GLP Regulations (21 CFR Part 58):

ISO Skin Irritation Study in Rabbits
The test article, MTDID 51991, was evaluated for primary skin irritation in rabbits. This study was conducted in accordance with the guidelines of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. Two 25 mm x 25 mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for 23 hours and 31 minutes. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single sample application. There was very slight erythema and no edema observed on the skin of the animals treated with the test article. The Primary Irritation Index for the test article was calculated to be 0.0/8.0. The response of the test article was categorized as negligible. EM-05-014248

ISO Guinea Pig Maximization Sensitization Test
The test article, MTDID 51991, was evaluated for the potential to cause delayed dermal contact sensitization in a guinea pig maximization test. This study was conducted based on the requirements of ISO 10993-10, Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization. The test article was extracted in 0.9% sodium chloride USP and sesame oil, NF. Each extract was intradermally injected and occlusively patched to ten test guinea pigs (per extract). The extraction vehicle was similarly injected and occlusively patched to five control guinea pigs (per vehicle). Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract and the vehicle control. All sites were scored for dermal reactions at 24 and 48 hours after patch removal. The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test. EM-05-014248

It is the responsibility of our customers to determine final suitability of our products for their application. Final testing of a converted device made with this material is the responsibility of the customer.

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