



## Genotoxicity Salmonella typhimurium Reverse Mutation Assay - Ames Test

### Application field and interests

For medical devices which are in contact with mucosal membrane or breached or compromised surface (permanent contact) or external communicating devices (prolonged or permanent contact) or implant devices (prolonged or permanent contact, also for limited contact with blood).

### Principle of the test

The bacterial reverse mutation test uses amino-acid requiring strains of Salmonella typhimurium and/or Escherichia coli to detect point mutations, which involve substitution, addition or deletion of one or a few DNA base pairs. The principle of this bacterial reverse mutation test is that it detects mutations which revert mutations present in the test strains and restore the functional capability of the bacteria to synthesize an essential amino acid. The revertant bacteria are detected by their ability to grow in the absence of the amino acid required by the parent test strain.

### Test procedure

Genotoxicity test is performed on five mutant strains of Salmonella typhimurium

- TA1535
- TA1537
- TA98
- TA100
- TA102



The mutagenic activity of the medical device under test is compared with a positive and a negative control with and without metabolic activation (S9 mix).

### Normative references

- EN ISO 10993-3:2003
- OECD 471:1997
- EN ISO 10993-12:2007

### Exclusion from test

Genotoxicity testing is not necessary for medical devices, and components thereof, made only from materials known to show no genotoxicity.

### Turn around time

4 weeks.

### Number of products/Quantity necessary to the analysis

At least, 2 samples of 4 grams for devices with irregular shape or 2 samples of 120 cm<sup>2</sup> for each extract (2 extract are recommended: polar and non-polar).

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