

TECHNICAL REPORT

ISO/TR
10993-33

First edition
2015-03-01

Biological evaluation of medical devices —

Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3

Évaluation biologique des dispositifs médicaux —

*Partie 33: Directives sur les essais pour évaluer la génotoxicité —
Supplément à l'ISO 10993-3*



Reference number
ISO/TR 10993-33:2015(E)

© ISO 2015



COPYRIGHT PROTECTED DOCUMENT

© ISO 2015

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

| | Page |
|---|-------------|
| Foreword | vi |
| Introduction | viii |
| 1 Scope | 1 |
| 2 Selection of tests | 1 |
| 3 Recommended tests | 1 |
| 4 Use of <i>in vitro</i> tests to detect genotoxicity | 2 |
| 5 Use of <i>in vivo</i> tests to detect genotoxicity | 2 |
| 6 Bacterial reverse mutation assay | 3 |
| 6.1 General | 3 |
| 6.2 Preparations | 3 |
| 6.2.1 Bacteria | 3 |
| 6.2.2 Medium | 4 |
| 6.2.3 Metabolic activation | 4 |
| 6.2.4 Test sample preparation | 4 |
| 6.3 Test conditions | 4 |
| 6.3.1 Solvents | 4 |
| 6.3.2 Exposure concentrations | 5 |
| 6.3.3 Controls | 6 |
| 6.4 Procedure | 7 |
| 6.4.1 Treatment with test sample | 7 |
| 6.4.2 Incubation | 7 |
| 6.4.3 Data collection | 7 |
| 6.5 Data and reporting | 8 |
| 6.5.1 Treatment of results | 8 |
| 6.5.2 Evaluation and interpretation of results | 8 |
| 6.5.3 Criteria for a valid test | 8 |
| 6.5.4 Test report | 9 |
| 7 <i>In vitro</i> mammalian chromosome aberration test | 11 |
| 7.1 General | 11 |
| 7.2 Preparations | 11 |
| 7.2.1 Cells | 11 |
| 7.2.2 Media and culture conditions | 11 |
| 7.2.3 Preparation of cultures | 11 |
| 7.2.4 Metabolic activation | 11 |
| 7.2.5 Test sample preparation | 12 |
| 7.3 Test conditions | 12 |
| 7.3.1 Solvents | 12 |
| 7.3.2 Exposure concentrations | 12 |
| 7.3.3 Controls | 13 |
| 7.4 Procedure | 14 |
| 7.4.1 Treatment with test sample or extract and harvest time | 14 |
| 7.4.2 Chromosome preparation | 14 |
| 7.4.3 Analysis | 14 |
| 7.5 Data and reporting | 15 |
| 7.5.1 Treatment of results | 15 |
| 7.5.2 Evaluation and interpretation of results | 15 |
| 7.5.3 Test report | 15 |