

This is a preview of "ISO 19040-3:2018". [Click here to purchase the full version from the ANSI store.](#)

First edition
2018-08

Water quality — Determination of the estrogenic potential of water and waste water —

Part 3: In vitro human cell-based reporter gene assay

*Qualité de l'eau — Détermination du potentiel oestrogène de l'eau et
des eaux résiduaires —*

Partie 3: Essai in vitro sur cellules humaines avec gène rapporteur



Reference number
ISO 19040-3:2018(E)

© ISO 2018

This is a preview of "ISO 19040-3:2018". [Click here to purchase the full version from the ANSI store.](#)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, 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
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

This is a preview of "ISO 19040-3:2018". Click here to purchase the full version from the ANSI store.

Contents

	Page
Foreword	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Interferences	4
5 Principle	4
6 Apparatus and materials	4
7 Reagents, cells and media	5
8 Sampling and samples	9
8.1 General.....	9
8.2 Bottles and material for sampling.....	9
8.3 Bottles and material pre-cleaning.....	9
8.4 Sampling procedure.....	9
8.5 Transport of samples.....	9
8.6 Pretreatment of sample.....	10
8.7 Storage of samples.....	10
9 Procedure	10
9.1 Cell culture maintenance.....	10
9.1.1 Freezing cells.....	10
9.1.2 Starting a new cell culture.....	10
9.1.3 Culturing cells.....	11
9.2 Human cell reporter gene assay test procedure.....	11
9.2.1 Seeding the cells (day 1).....	11
9.2.2 Preparation of the E2-reference (day 2).....	11
9.2.3 Preparation of the sample dilutions (day 2).....	12
9.2.4 Field blank.....	12
9.2.5 Exposing the cells (day 2).....	12
9.2.6 Harvesting the cells (day 3).....	13
9.2.7 Measurement of luminescence (day 3).....	13
9.3 Data analysis.....	13
9.3.1 Calculation of the reporter gene induction.....	13
9.3.2 Calculation of the percentage of maximum response.....	14
9.3.3 Calculation of the dose-response curve.....	14
10 Validity criteria	14
10.1 Validity criteria for the assay.....	14
10.2 Validity criteria for samples.....	15
11 Assessment criteria	15
12 Test report	15
Annex A (informative) Settings of the luminometer	16
Annex B (informative) Plate setup	17
Annex C (informative) Bioassay characteristics and details	18
Annex D (informative) Test set up for chemicals and extracts	20
Annex E (informative) Preparation of dilution series	22
Annex F (informative) Performance data	23
Annex G (informative) Statistical assessment	33
Annex H (informative) Calculation of 17β-estradiol equivalents	34

This is a preview of "ISO 19040-3:2018". [Click here to purchase the full version from the ANSI store.](#)

Annex I (informative) Measurement of the lowest ineffective dilution (LID) of waste water — A simplified evaluation for testing of waste water	36
Bibliography	39

This is a preview of "ISO 19040-3:2018". [Click here to purchase the full version from the ANSI store.](#)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 147, *Water quality*, Subcommittee SC 5, *Biological methods*.

A list of all parts in the ISO 19040 series can be found on the ISO website.