

ISO/DTS 21569-10

ISO/TC 34/SC 16

ISO/CD TS 21569-10(en)

Secretariat: ANSI

Date: 2025-06-25

**Horizontal methods for molecular ~~Molecular~~ biomarker analysis —**  
**Methods of analysis for the detection of genetically modified**  
**organisms and derived products —**

**Part 10:**

**Construct- and event-specific detection methods for genetically**  
**modified salmon expressing CS-GHc2 growth hormone**

iTeh Standards  
https://standards.itih.ai  
Document Preview

ISO/DTS 21569-10

<https://standards.itih.ai/catalog/standards/iso/ce2741b6-2afc-4ff0-b3bf-3399f528a2e9/iso-dts-21569-10>

## ISO/DTS 21569-10:2025(en)

© ISO 2025

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  
E-mail: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

Field Code Changed

# iTeh Standards (<https://standards.iteh.ai>) Document Preview

ISO/DTS 21569-10

<https://standards.iteh.ai/catalog/standards/iso/ce2741b6-2afc-4ff0-b3bf-3399f528a2e9/iso-dts-21569-10>

Contents

Foreword..... iv

1 Scope..... 1

2 Normative references ..... 1

3 Terms and definitions..... 1

4 Principle ..... 2

5 Reagents and materials ..... 2

6 Apparatus..... 3

7 Procedure ..... 3

7.1 Preparation of test samples ..... 3

7.2 DNA extraction ..... 3

7.3 PCR setup ..... 3

7.4 Temperature-time programme ..... 4

8 Accept/reject criteria..... 5

8.1 General..... 5

8.2 Detection ..... 5

9 Validation status and performance criteria..... 5

9.1 Sensitivity ..... 5

9.2 Specificity ..... 6

9.3 Robustness of the two methods ..... 10

9.4 Interlaboratory trial for the construct-specific detection method ..... 10

9.5 Interlaboratory trial for the event-specific detection method ..... 13

9.6 Summary evaluation ..... 15

10 Test report..... 15

Bibliography ..... 16

ISO/DTS 21569-10

<https://standards.itech.ai/catalog/standards/iso/ce2741b6-2afc-4ff0-b3bf-3399f528a2e9/iso-dts-21569-10>

## 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](http://www.iso.org/directives)).

Field Code Changed

~~Attention is drawn to the possibility that some of the elements of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at [www.iso.org/patents](http://www.iso.org/patents). 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 ).~~

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

For an explanation of 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 [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html) the following URL.

This document was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 16, *Horizontal methods for molecular biomarker analysis*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 275, *Food analysis - Horizontal methods*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 21569 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

Field Code Changed