



# FINAL DRAFT International Standard

## ISO/FDIS 20397-3

### Biotechnology — Massively parallel sequencing —

#### Part 3: General requirements and guidance for metagenomics

ISO/TC 276/SC 1

Secretariat: **ANSI**

Voting begins on:  
**2025-04-30**

Voting terminates on:  
**2025-06-25**

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

ISO/FDIS 20397-3

<https://standards.iteh.ai/catalog/standards/iso/a844fabb-445b-4040-ad5a-b4bc91ff2156/iso-fdis-20397-3>

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

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

ISO/FDIS 20397-3

<https://standards.itih.ai/catalog/standards/iso/a844fabb-445b-4040-ad5a-b4bc91ff2156/iso-fdis-20397-3>



**COPYRIGHT PROTECTED DOCUMENT**

© 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  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

|                                                                                                     |           |
|-----------------------------------------------------------------------------------------------------|-----------|
| <b>Foreword</b>                                                                                     | <b>iv</b> |
| <b>Introduction</b>                                                                                 | <b>v</b>  |
| <b>1 Scope</b>                                                                                      | <b>1</b>  |
| <b>2 Normative references</b>                                                                       | <b>1</b>  |
| <b>3 Terms and definitions</b>                                                                      | <b>1</b>  |
| <b>4 Principle</b>                                                                                  | <b>4</b>  |
| 4.1 General                                                                                         | 4         |
| <b>5 Sampling strategy</b>                                                                          | <b>5</b>  |
| 5.1 General                                                                                         | 5         |
| 5.2 Primary sample type                                                                             | 6         |
| 5.3 Primary sample stabilization and storage                                                        | 6         |
| 5.4 Primary sample transportation                                                                   | 6         |
| 5.5 DNA/RNA isolation                                                                               | 7         |
| 5.6 DNA/RNA sample quality                                                                          | 7         |
| <b>6 Nucleic acid library preparation</b>                                                           | <b>7</b>  |
| <b>7 Design and review process including sequencing strategy and assessment</b>                     | <b>7</b>  |
| 7.1 General                                                                                         | 7         |
| 7.2 Short read                                                                                      | 7         |
| 7.3 Long read                                                                                       | 8         |
| 7.4 Hybrid assembly                                                                                 | 8         |
| 7.5 Sample preparation and library construction                                                     | 8         |
| 7.6 Assessment                                                                                      | 8         |
| <b>8 Database construction</b>                                                                      | <b>9</b>  |
| 8.1 General                                                                                         | 9         |
| 8.2 Public database                                                                                 | 9         |
| 8.3 Self-built database                                                                             | 9         |
| <b>9 Bioinformatics analysis</b>                                                                    | <b>10</b> |
| 9.1 General                                                                                         | 10        |
| 9.2 Identification list of microorganisms                                                           | 11        |
| <b>10 Validation and verification</b>                                                               | <b>11</b> |
| 10.1 General                                                                                        | 11        |
| 10.2 In silico sequence control for bioinformatics pipeline evaluation                              | 11        |
| 10.3 Real sample control for pipeline evaluation                                                    | 11        |
| <b>11 Evaluation</b>                                                                                | <b>12</b> |
| <b>12 Test report</b>                                                                               | <b>12</b> |
| 12.1 General                                                                                        | 12        |
| 12.2 Test report content                                                                            | 12        |
| <b>Annex A (informative) Checklist for NA sample quality assessment before library construction</b> | <b>13</b> |
| <b>Annex B (informative) Methods for sample stabilization and storage</b>                           | <b>14</b> |
| <b>Annex C (informative) Bioinformatics pipeline</b>                                                | <b>15</b> |
| <b>Bibliography</b>                                                                                 | <b>17</b> |

## 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 document 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)).

ISO draws attention to the possibility that the implementation 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.

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 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 [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 276 *Biotechnology*, Subcommittee SC 1, *Analytical methods*.

A list of all parts in the ISO 20397 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).

<https://standards.iteh.ai/catalog/standards/iso/a844fabb-445b-4040-ad5a-b4bc91ff2156/iso-fdis-20397-3>