
**Molecular in vitro diagnostic
examinations — Specifications for
pre-examination processes for saliva
— Isolated human DNA**

*Analyse de diagnostic moléculaire in vitro — Spécifications relatives
aux processus préanalytiques pour la salive — ADN humain extrait*

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

ISO 4307:2021

<https://standards.iteh.ai/catalog/standards/iso/c2e61f58-2c9e-4c43-b6f3-6f21b39dabf5/iso-4307-2021>



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

ISO 4307:2021

<https://standards.itih.ai/catalog/standards/iso/c2e61f58-2c9e-4c43-b6f3-6f21b39dabf5/iso-4307-2021>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

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
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General considerations	4
5 Activities outside the laboratory	5
5.1 Specimen collection	5
5.1.1 Information about the specimen donor/patient.....	5
5.1.2 Selection of the saliva collection device by the laboratory	5
5.1.3 Saliva specimen collection from the donor/patient and stabilization procedures.....	6
5.1.4 Information on the specimen and storage requirements at saliva collection facility/site.....	7
5.2 Transport requirements	8
5.2.1 General	8
5.2.2 Using saliva collection devices with DNA stabilizers	8
5.2.3 Using saliva collection devices without DNA stabilizers.....	8
6 Activities inside the laboratory	9
6.1 Specimen reception.....	9
6.2 Storage requirements.....	9
6.3 Isolation of the saliva DNA.....	9
6.3.1 General.....	9
6.3.2 Using a commercial kit.....	10
6.3.3 Using the laboratory's own protocol.....	10
6.4 Quantity and quality assessment of isolated DNA.....	10
6.5 Storage of isolated saliva DNA.....	11
6.5.1 General.....	11
6.5.2 Saliva DNA isolated with commercially available kits	11
6.5.3 Saliva DNA isolated with the laboratory's own protocols.....	11
Bibliography	12

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 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.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *in vitro diagnostic medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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.