



BSI Standards Publication

**Medical laboratories — Concepts and specifications  
for the design, development, implementation,  
and use of laboratory-developed tests**

---

# National foreword

This British Standard is the UK implementation of EN ISO 5649:2024. It is identical to ISO 5649:2024.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its committee manager.

## Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2024  
Published by BSI Standards Limited 2024

ISBN 978 0 539 20664 7

ICS 11.100.10

**Compliance with a British Standard cannot confer immunity from legal obligations.**

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 December 2024.

## Amendments/corrigenda issued since publication

| Date | Text affected |
|------|---------------|
|------|---------------|