TECHNICAL REPORT

ISO/TR 27877

First edition
2021-10

This document is a preview generated by EVS

Statistical analysis for evaluating the precision of binary measurement methods and their results

Analyse statistique pour l'évaluation de la fidélité des méthodes de mesure binaire et de leurs résultats

Reference number
ISO/TR 27877:2021(E)

© ISO 2021

This document is a preview generated by EVS

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

© ISO 2021 – All rights reserved

Contents

Page

Foreword ..... **v**
Introduction ..... **vi**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions, and symbols **1**
3.1 Terms and definitions 1
3.2 Symbols 3
4 Overview **4**
5 Examples used in this document **6**
5.1 Case 1: Listeria monocytogenes 6
5.2 Case 2: Human cell line activation test (h-CLAT)-1 6
5.3 Case 3: Intratracheal administration testing 7
5.4 Case 4: Histopathological classification of lung carcinoma 8
5.5 Case 5: Human cell line activation test (h-CLAT)-2 8
5.6 Case 6: Statistical model for predicting chemical toxicity 8
6 Statistical analysis for evaluating the precision of binary measurement methods and their results **9**
6.1 ISO 5725-based method 9
6.1.1 Overview 9
6.1.2 Case 1 12
6.1.3 Case 2(a) 12
6.1.4 Case 2(b) 13
6.1.5 Case 3(a) 13
6.1.6 Case 3(b) 13
6.2 Accordance and concordance 13
6.2.1 Overview 13
6.2.2 Case 1 15
6.2.3 Case 2(a) 15
6.2.4 Case 2(b) 16
6.2.5 Case 3(a) 16
6.2.6 Case 3(b) 16
6.3 ORDANOVA 16
6.3.1 Overview 16
6.3.2 Case 1 18
6.3.3 Case 2(a) 18
6.3.4 Case 2(b) 19
6.3.5 Case 3(a) 19
6.3.6 Case 3(b) 19
6.4 CM-accuracy, sensitivity and specificity 19
6.4.1 Overview 19
6.4.2 Case 4 20
6.4.3 Case 5 20
6.4.4 Case 6 20
6.5 Kappa coefficient 21
6.5.1 Overview 21
6.5.2 Case 4 21
6.5.3 Case 5 21
6.5.4 Case 6 22
7 Remarks on the methods introduced in this document **22**
7.1 Comparison between the mathematical expressions of the precision estimates 22
7.2 Comparison between the numerical examples of the precision estimates 23

This document is a preview generated by EVS

© ISO 2021 – All rights reserved

Bibliography **25**

This document is a preview generated by EVS

© ISO 2021 – All rights reserved

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 69, *Application of statistical methods*, Subcommittee SC 6, *Measurement methods and results*.

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.

This document is a preview generated by EVS

© ISO 2021 – All rights reserved

Introduction

The documents in the ISO 5725 series define the precision of quantitative measurement methods and their results, and assume that the errors follow normal distributions in their basic models. Also, they provide how to run experiments to evaluate precision measures, such as repeatability and reproducibility. Nowadays, there is also a demand for dealing with qualitative measurement methods and their results, which output binary data, categorical data, etc. However, the ISO 5725 series is not suitable mathematically for analyzing such data.

Several existing studies propose statistical methods for dealing with binary and/or categorical data, but no guidance documents are available so far. Hence, this document summaries various methods to evaluate the precision of binary measurement methods and their results, which are the most essential and frequently used methods for qualitative data.

This document is a preview generated by EVS

© ISO 2021 – All rights reserved

Statistical analysis for evaluating the precision of binary measurement methods and their results

This document is a preview generated by EVS

1 Scope

This document introduces five statistical methods for evaluating the precision of binary measurement methods and their results. The five methods can be divided into two types. Both types are based on measured values provided by each laboratory participating in a collaborative study. In the first type, each laboratory repeatedly measures a single sample. The samples measured by the laboratories are nominally identical. The second type is an extension of the first type, where there are several levels of samples.

For each statistical method, this document briefly summarizes its theory and explains how to estimate the proposed precision measures. Some real cases are illustrated to help the readers understand the evaluation procedures involved. For the first and second types of methods, five and three cases are presented, respectively.

Finally, this document compares the five statistical methods.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3534-1, *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

3 Terms and definitions, and symbols

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534-1 and ISO 5725-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1.1
accordance
probability that two binary measured values be identical when they are taken from the same laboratory

Note 1 to entry: The concept corresponds to the definition of “repeatability” in ISO 5725 and was originally proposed by Reference [3].

© ISO 2021 – All rights reserved