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## **In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice**

*Dispositifs médicaux de diagnostic in vitro — Études des  
performances cliniques utilisant des prélèvements de sujets humains  
— Bonnes pratiques d'étude*



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## 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)).

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](http://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](http://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*.

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).

## Introduction

In vitro diagnostic (IVD) medical devices are used to conduct tests outside of the human body to provide valuable information regarding a person's health or physiological status. They include tests and related devices, such as test strips and reagents, using specimens such as blood, tissue or urine, to carry out screening, diagnosis, prognosis, predictive testing, and monitoring of conditions. IVD medical devices are fundamentally different from other medical devices because they perform their function outside of the body on specimens taken from the human body. Human subjects are typically not exposed to risks with the performance testing of IVD medical devices, except for the risk associated with specimen collection procedures or when the obtained information is used for patient management. The specimens are obtained via normal body functions (e.g. urine) or through the use of invasive medical devices to allow for the specimen to be obtained (e.g. biopsy). The specimens are never reintroduced into the human body. These differences make the performance and risk characteristics of IVD medical devices different and unique from other medical devices.

Most of the studies for IVD medical devices are performed using samples resulting from the remnants of specimens taken for purposes of standard of care (leftover or archived). In these studies, there is no risk for the subjects arising from either the information provided by the IVD medical device or from the collection procedure of the specimen. However, when leftover specimens are not used, additional requirements should be considered

- when the specimens are collected specifically for the study and the specimen collection procedures present additional risk of direct harm for the subject (e.g. lumbar puncture or tissue biopsy, blood collection from neonates or critically ill patients), and/or
- when the information obtained from the IVD medical devices during the study is used to make patient management decision (i.e. interventional studies), presenting a risk of indirect harm for the subject (e.g. false negative or false positive result leading to inappropriate patient management decisions).

For the majority of IVD clinical performance studies, issues related to the use of vulnerable subjects might not arise but should be considered on a case by case basis.

Considering the reliance on specimens taken from the body and the absence of direct contact of the IVD with the patient, issues related to procedures for obtaining informed consent for IVD clinical performance studies differ from those associated with other medical devices, especially for studies with leftover or archived specimens. This document will provide guidance on the requirements for the various situations described above for IVD medical devices.

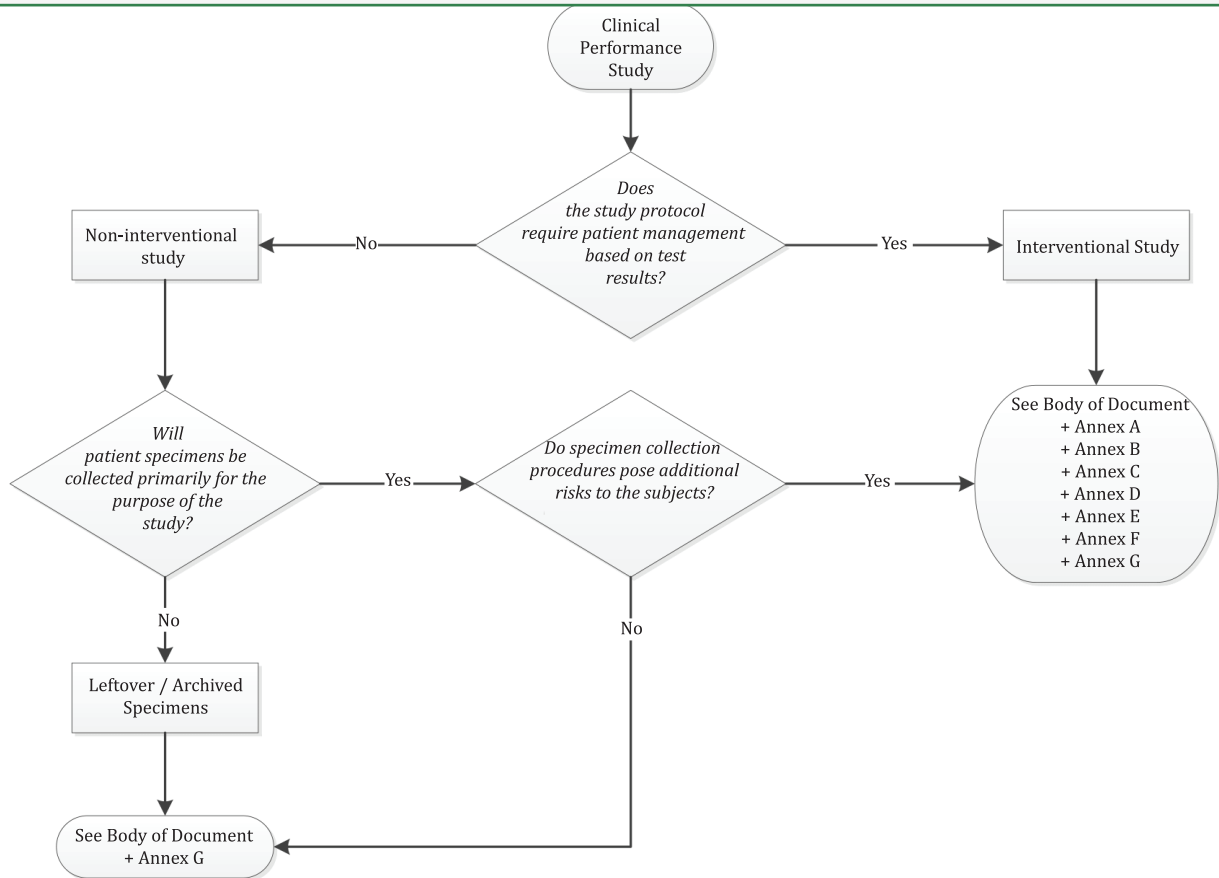
This document is intended for clinical performance studies as these studies involve specimens taken from the human body. When specimens other than leftover or archived specimens are used, there might be additional collection risks for the subject. Also in interventional studies, there might be a risk for the subject coming from the information provided by the result of the IVD under investigation.

This document is specific for IVD medical devices and therefore uses definitions and concepts that are appropriate for IVD medical devices. It is a stand-alone standard for clinical performance studies for IVD medical devices. In the situation for which there is an IVD medical device and a medical device used in an integrated system (e.g. a lancet, an IVD test strip and a glucose meter), the respective jurisdiction's regulation will define it as either an IVD medical device or a medical device and subsequently, aspects of both this document and ISO 14155 might need to be considered.

Except for these situations, this document should not be read in conjunction with ISO 14155, which excludes IVD medical devices from its scope.

The flowchart represented in [Figure 1](#) provides guidance on how to use this document.

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**Figure 1 — Clinical performance study flow chart**

The main body of the document, in addition to [Annex G](#), includes minimum requirements for all studies. No additional requirements apply for studies using leftover/archived specimens or studies with specimen collection procedures that pose no additional risks to the subject.

However, additional requirements for interventional studies, and those studies in which the specimen collection procedures pose a risk to subjects primarily recruited for the study, are found in [Annexes A to E](#). The nature of these studies warrants an increased level of stringency in the requirements for conduct of the study. The flowchart indicates the annexes which describe the additional requirements for each type of more complex studies. When necessary, the annexes describe differences in the requirements for the different types of study. Additionally, informative annexes are included to provide information on good study practice documentation (see [Annex H](#)) and auditing (see [Annex I](#)).