



BSI Standards Publication

Molecular biomarker analysis — Requirements for microarray detection of specific nucleic acid sequences

National foreword

This British Standard is the UK implementation of [ISO 16578:2022](#). It supersedes [BS ISO 16578:2013](#), which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee AW/275, Food analysis - Horizontal methods.

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

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Molecular biomarker analysis — Requirements for microarray detection of specific nucleic acid sequences

*Analyse moléculaire des biomarqueurs — Exigences relatives
à la détection sur microréseaux de séquences d'acides
nucléiques spécifiques*



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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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.

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This document was prepared by Technical Committee ISO/TC 34 *Food products*, Subcommittee SC 16, *Horizontal methods for molecular biomarker analysis*.

This second edition cancels and replaces the first edition (ISO 16578:2013), which has been technically revised.

The main changes are as follows:

- [Annex A](#) has been added to provide the practical determination of limit of detection for microarray platform (LODP).

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.

Introduction

Available methods for nucleic acid sequence discovery using nucleic acid containing samples are based on three technologies: the polymerase chain reaction (PCR), deoxyribonucleic acid (DNA) sequencing and oligonucleotide microarrays.^[1]

DNA microarrays are used in biomarker identification and the measurement of gene expression. International harmonization efforts of experimental methods for microarray experiments began with the “Minimum Information about a Microarray Experiment (MIAME)—toward standards for microarray data”^[2] and the US Food and Drug Administration’s critical path project the Microarray Quality Control project (MAQC),^{[3][4]} which began in 2005 and focused on technical aspects of gene expression measurements, robust technology platforms and the development of accurate and reproducible multivariate gene expression-based prediction models.

DNA microarrays are made either by chemically synthesizing DNA probes on a solid surface or by attaching pre-made DNA probes to a solid surface, e.g. a microplate or coated bead. Microarray assays can be designed to detect multiple single nucleotide polymorphisms (SNPs) simultaneously. High density oligonucleotide microarrays synthesized *in situ* using techniques such as photolithography, ink-jet deposition and robotic arraying of PCR products and pre-synthesized oligonucleotides are manufactured for detecting specific sequences over a wide range of variability.^[5] This technology continues to develop along with PCR and next generation sequencing (NGS).

DNA microarrays are typically used to probe a solution of mixed labelled nucleic acids: hybridization of the labelled targets to the fixed probes on the array is detected, and their relative concentration to the remaining nucleic acid species in solution is measured. By generalizing to a very large number of spots of DNA, an array can be used to quantify an arbitrarily large number of different nucleic acid sequences in solution.^[6]

Microarray technologies are used in food analysis for detection and identification of genetically modified organisms (GMO) analysis and other biomarkers.^{[7][8][9][10][11][12]} The focus of this document is DNA microarray-based methodologies for food products and products of agriculture.

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