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Nanotechnologies — Performance evaluation requirements for quantifying biomolecules using fluorescent nanoparticles in immunohistochemistry

National foreword

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Foreword

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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).

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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 229, *Nanotechnologies*.

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.

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Introduction

Fluorescent nanoparticles are expanding their market into bio-technological and research fields as a labelling material to be used for immunohistochemical staining.

Conventionally, various fluorescent dyes, including FITC (fluorescent isothiocyanate), rhodamine-isothiocyanate and sulforhodamine 101 acid chloride, have been used for immunohistochemical staining. They are still powerful tools for identifying localization of target biomolecules, for example, proteins and sugar chains, mainly for qualitative analyses. They are also applied to quantitative analysis in combination with various algorithms for calculating signal intensity related to the quantity of the target biomolecules. The quantification system generally consists of sample preparation, staining, microscopic observation and photography, and image processing for obtaining quantification results as shown in Figure 1. For reliable measurement results of quantification, fluorescent dyes that are brighter and more photostable by exposure to the excitation light are more appropriate.

Large number of fluorescent nanoparticles are available in the market. Generally, they show higher brightness and are more resistant to photobleaching, compared to the conventional fluorescent dyes. The characteristics of fluorescent nanoparticles can be an advantage for the quantification of target biomolecules by immunohistochemical methods also combining with the same algorithm employed for the quantification with conventional fluorescent dyes.[1][2][3][4]

In this context, various staining kits with fluorescent nanoparticles and various quantification systems have been developed and are available in the market.[5] Thus, the needs to realise the compatibility of various systems are expanding in the research and industrial fields.

In this document the minimum requirements for performance evaluation of products and application using fluorescent nanoparticles is addressed. This document provides information ensuring the comparability of the results of relative quantification by using fluorescent nanoparticles.

This document does not provide industry segment specific performance criteria for the workflow of measuring biomolecules. When applicable, users can also additionally consult existing industry specific standards.

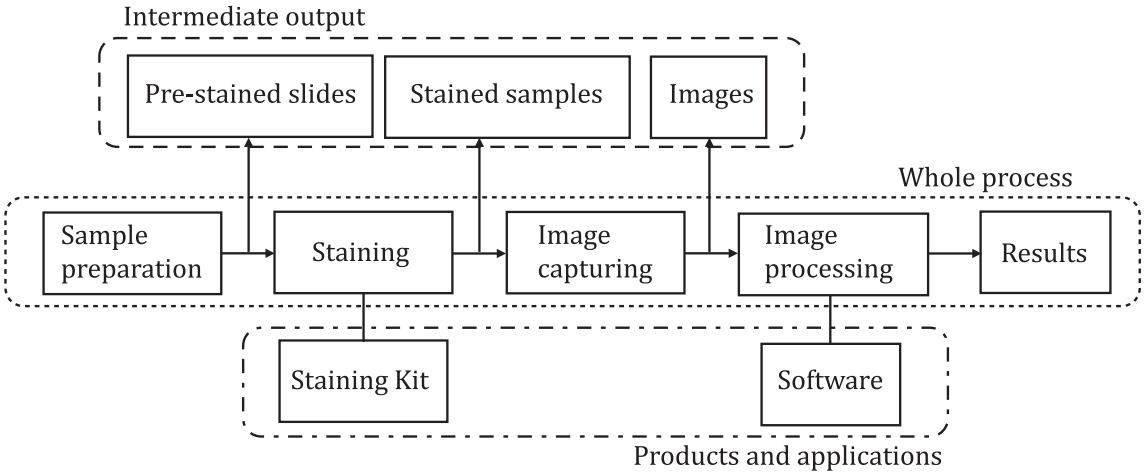


Figure 1 — Target quantification process by using of fluorescent nanoparticles

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Nanotechnologies — Performance evaluation requirements for quantifying biomolecules using fluorescent nanoparticles in immunohistochemistry

1 Scope

This document describes minimum requirements for performance evaluation of applying fluorescent nanoparticles in quantitative immuno-histochemistry.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology 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
fluorescent nanoparticle
nanoparticle emitting fluorescence excited by light of specific wavelength

3.2
cell block array
paraffin block re-embedded with plural cylinders gouged out from paraffin embedded cell suspension for histopathology

3.3
cell block array section
thin slice of cell block array obtained by cutting cell block array using microtome, and mounted onto a glass slide

3.4
agglomerate
collection of weakly or medium strongly bound particles where the resulting external surface area is similar to the sum of the surface areas of the individual components

Note 1 to entry: The forces holding an agglomerate together are weak forces, for example van der Waals forces or simple physical entanglement.

Note 2 to entry: Agglomerates are also termed secondary particles and the original source particles are termed primary particles.

[SOURCE: ISO 26824:2022, 3.1.2]

3.5
agglomeration
process through which agglomerates form

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