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

Nanotechnologies — Exigences d'évaluation des performances pour la quantification de biomolécules en immunohistochimie à l'aide de nanoparticules fluorescentes

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~~*A model manuscript of a draft International Standard (known as "The Rice Model") is available at https://www.iso.org/iso/model_document-rice_model.pdf*~~

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Contents

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This document was prepared by Technical Committee ISO/TC 229, *Nanotechnologies*.

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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.

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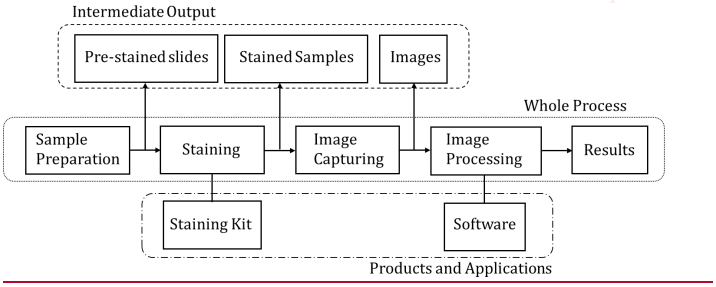

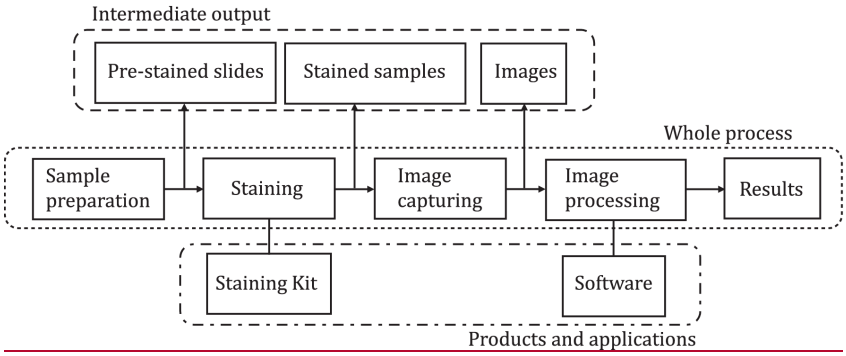

Figure 1 — Target quantification process by using of fluorescent nanoparticles

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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

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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/

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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.

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

[SOURCE: ISO 26824:~~2013,~~ 2022, 3.1.2]

3.5
agglomeration
process through which agglomerates form

3.6
aggregate
particle comprising strongly bonded or fused particles where the resulting external surface area is significantly smaller than the sum of surface areas of the individual components

Note 1 to entry: The forces holding an aggregate together are strong forces, for example, covalent or ionic bonds, or those resulting from sintering or complex physical entanglement.

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

[SOURCE: ISO 26824:~~2013,~~ 2022, 3.1.3, modified — Note 1 to entry has been adapted.]

3.7
aggregation
process through which aggregates form

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3.8
quantum yield
number of quanta emitted per quantum absorbed

[SOURCE: ISO 22493:2014, 6.6.9]

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3.9
molar extinction coefficient
~~**molar absorption coefficient**~~
optical density of ~~1M~~1 M fluorescent substance per 1- cm of optical path of absorption cell

3.10
photobleaching
destruction of fluorescing properties of molecules by light, resulting in reduced fluorescence of the sample

[SOURCE: ISO 10934:2020, 3.2.31]

4 Principle

Immunofluorescence methods are based on staining of thin tissue sections with specific antibodies recognizing intended molecules, e.g. proteins and sugars. The specific antibodies are prepared by immunizing animals, e.g. goat, rabbit, or mouse with target molecules. While monoclonal and polyclonal antibodies are used for immunofluorescence methods, antibodies need to be labelled with fluorescent substances, e.g. dyes or nanoparticles. For investigating localization and quantity of the