

# ISO/TS 23366:2023-05 (E)

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

---

<b>Contents</b>		<b>Page</b>
Foreword .....		v
Introduction .....		vi
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	1
4	Principle .....	2
5	Selection of fluorescent nanoparticles .....	3
5.1	General .....	3
5.2	Characteristics of nanoparticle .....	3
6	Quantification system .....	4
6.1	Overall design .....	4
6.2	Antibody .....	5
6.2.1	General .....	5
6.2.2	Antibody type .....	5
6.2.3	Target antigen .....	5
6.2.4	Applicability of antibody to method .....	6
6.2.5	Animal species .....	6
6.2.6	Immunoglobulin class .....	6
6.2.7	Titre .....	6
6.2.8	Specificity .....	7
6.3	Staining procedure .....	7
6.3.1	Staining conditions .....	7
6.3.2	Robustness of staining procedure .....	7
6.4	Image processing .....	8
6.4.1	Image quality and relevant factors .....	8
6.4.2	Selection of image processing software .....	8
7	Comparability of results .....	9
7.1	Light source adjustment .....	9
7.2	Reference material .....	9
8	Performance characteristics .....	9
8.1	Background .....	9
8.1.1	General .....	9
8.1.2	Autofluorescence .....	10
8.1.3	Nonspecific absorption of nanoparticles .....	10
8.1.4	Nonspecific absorption of antibodies .....	10
8.1.5	Loss of intensity and interferences .....	10
8.2	Reference material dependent indices .....	11
8.2.1	General .....	11
8.2.2	Limit of detection (LOD) .....	11
8.2.3	Limit of quantification (LOQ) .....	11
8.2.4	Linearity and dynamic range .....	11
8.3	Robustness .....	12

<b>9</b>	<b>Validation and verification .....</b>	<b>12</b>
<b>9.1</b>	<b>General .....</b>	<b>12</b>
<b>9.2</b>	<b>Single lab precision .....</b>	<b>12</b>
<b>9.3</b>	<b>Reproducibility .....</b>	<b>13</b>
<b>10</b>	<b>Reporting .....</b>	<b>13</b>
	<b>Annex A (informative) Example of the reference material .....</b>	<b>14</b>
	<b>Annex B (informative) Example of the nanoparticle aggregation/agglomeration evaluation method .....</b>	<b>16</b>
	<b>Bibliography .....</b>	<b>18</b>