

# ISO/TS 27878:2023-01 (E)

## Reproducibility of the level of detection (LOD) of binary methods in collaborative and in-house validation studies

---

<b>Contents</b>	<b>Page</b>
<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Symbols</b> .....	<b>2</b>
<b>5 General principles</b> .....	<b>3</b>
5.1 General considerations.....	3
5.2 Considerations for the conventional approach.....	3
5.3 Considerations for the factorial approach.....	3
<b>6 Conventional approach</b> .....	<b>4</b>
6.1 Experimental design.....	4
6.2 Statistical model for methods for continuous measurands.....	4
6.3 Statistical model for methods for discrete measurands.....	7
6.4 Reliability of precision estimates.....	10
<b>7 Factorial approach</b> .....	<b>10</b>
<b>8 In-house validation</b> .....	<b>13</b>
<b>9 Software</b> .....	<b>13</b>
<b>Bibliography</b> .....	<b>15</b>