

# ISO 16578:2022-09 (E)

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

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	1
4	Principle .....	3
4.1	DNA microarray platform assay .....	3
4.2	Microarray design and manufacture .....	3
4.2.1	General .....	3
4.2.2	Control probe sequences and targeted probes .....	3
4.2.3	Analytical power of microarray assay .....	4
4.3	Validation of hybridization specificity .....	4
4.3.1	Theoretical assessment of specificity .....	4
4.3.2	Experimental assessment of specificity .....	4
4.3.3	Experimental assessment of cross-hybridization .....	4
4.4	Interlaboratory validation of qualitative methods .....	5
4.4.1	General .....	5
4.4.2	Detection limit .....	5
4.4.3	Probability of detection .....	6
4.4.4	Limit of detection for microarray platform .....	6
4.4.5	Range of reliable signal .....	6
4.4.6	Test sample .....	6
4.4.7	Measuring system .....	6
4.4.8	Estimation of measurement uncertainty .....	7
4.4.9	Microarray reagents .....	7
5	Expression of results .....	7
5.1	General .....	7
5.2	Expression of a negative result .....	7
5.3	Expression of a positive result .....	7
5.4	Expression of inconclusive or ambiguous results .....	8
6	Test report .....	8
Annex A (informative) Practical determination of limit of detection for microarray platform (LODP) ...		9
Bibliography .....		13