

ISO 16578:2022-09 (E)

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

Contents		Page
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