

# ISO 21474-2:2022-05 (E)

## In vitro diagnostic medical devices - Multiplex molecular testing for nucleic acids - Part 2: Validation and verification

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	1
4	General requirements .....	2
4.1	General .....	2
4.2	Laboratory requirements .....	2
4.3	Reagents requirements .....	3
4.4	Apparatus and equipment .....	3
4.5	Reference and control materials .....	3
4.5.1	General .....	3
4.5.2	Endogenous nucleic acid .....	4
4.5.3	Nongenomic reference materials (RMs) .....	4
4.6	Calibration of the analysis .....	4
4.7	Input range .....	4
5	Evaluation of performance characteristics .....	5
5.1	General .....	5
5.2	Analytical specificity .....	5
5.2.1	Analytical reactivity .....	5
5.2.2	Limit of blank .....	6
5.2.3	Cross-reactivity .....	6
5.2.4	Exclusivity .....	7
5.2.5	Interfering substances and carryover .....	7
5.3	Range of reliable signal, reportable range and reference range .....	7
5.4	Limit of detection of multiplex molecular test platform (LODP) .....	7
5.5	Measurement precision and uncertainty .....	8
5.6	Accuracy and method comparison studies .....	8
Annex A (informative)	Certified reference materials (CRMs) .....	10
Annex B (informative)	Example of human genome reference materials (RMs) .....	12
Bibliography .....		15