

ISO/TS 5798:2022-04 (E)

In vitro diagnostic test systems - Requirements and recommendations for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV -2) by nucleic acid amplification methods

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Overview	7
4.1	SARS-CoV-2	7
4.1.1	General	7
4.1.2	Pre-examination	9
4.1.3	Examination -- Overview	9
4.1.4	Post-examination	11
4.2	Nucleic acid amplification methods	11
4.2.1	Reverse transcription qPCR (RT-qPCR)	11
4.2.2	Reverse transcription digital PCR (RT-dPCR)	12
4.2.3	Isothermal amplification methods	12
5	Laboratory requirements	12
5.1	General	12
5.2	Biosafety requirements	13
5.2.1	Laboratory area	13
5.2.2	Risk control	13
5.2.3	Personal protective equipment (PPE)	13
5.3	General laboratory set-up	13
5.4	Instrumentation	14
5.5	Laboratory personnel	14
6	Design and development	14
6.1	Customer, patient and stakeholder needs	14
6.2	Intended use of analytical test	14
6.3	Institutional guideline strategy	15
6.3.1	Laboratory developed tests (LDTs) versus in vitro diagnostic medical devices (IVD medical devices)	15
6.3.2	Emergency use authorization	15
6.4	Clinical strategy	15
6.5	Design and development planning	16
6.5.1	Pre-examination of respiratory specimens for SARS-CoV-2 testing	16
6.5.2	Examination design specifications (analytical test specifications)	22
6.5.3	Design risk management	27
6.6	Optimization of reagents and methods	28
6.6.1	Selection of SARS-CoV-2 target sequences	28
6.6.2	Potential impact of variants of concern (VOCs) on the quality of NAAT diagnostic methods for detecting SARS-CoV-2	28
6.6.3	Selection of amplification methods	28
6.6.4	Design and selection of primers	28

6.6.5	Optimization of the reaction system	29
6.6.6	Determination of cut-off values	29
6.6.7	Verification and validation of test design	29
7	Verification for patient care	31
7.1	General	31
7.2	Confirmation of analytical performance characteristics	31
7.2.1	Accuracy	31
7.2.2	Limit of detection (LOD)	31
7.2.3	Inclusivity	32
7.2.4	Specificity	32
7.2.5	Robustness	32
7.3	Clinical evidence	33
8	Validation for patient care	33
8.1	General consideration	33
8.2	Clarification of the intended use	33
8.3	Performance with clinical specimens or samples	34
9	Design transfer to production	34
10	Implementation and use in the laboratory and reporting of results	34
10.1	Implementation and use in the laboratory	34
10.2	Reporting and interpretation of results	35
11	Quality assurance	36
11.1	Performance monitoring	36
11.2	Design change including optimization of analytical test	36
11.3	Interlaboratory comparison	37
	Annex A (informative) Nucleic acid amplification techniques	38
	Bibliography	41