ICS 11.100.01 PREDBEŽNÁ SLOVENSKÁ TECHNICKÁ NORMA Február 2023

STN P	**Diagnostické skúšobné systémy *in vitro* Požiadavky a odporúčania na detekciu závažného akútneho respiračného syndrómu koronavírusu 2 (SARS-CoV-2) metódami amplifikácie nukleovej kyseliny (ISO/TS 5798: 2022)**	**STN P CEN ISO/TS 5798** 85 1035

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 (ISO/TS 5798:2022)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/23

Táto predbežná slovenská technická norma je určená na overenie. Prípadné pripomienky pošlite do novembra 2024 Úradu pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky.

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English Version

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 (ISO/TS 5798:2022)

Systèmes d'essai pour diagnostic in vitro - Exigences et recommandations pour la détection du coronavirus 2 associé au syndrome respiratoire aigu sévère (SARS-CoV-2) par des méthodes d'amplification des acides nucléiques (ISO/TS 5798:2022)

In-vitro-Diagnostika-Systeme - Anforderungen und Empfehlungen für Qualitätsverfahren für den Nachweis des Coronavirus 2 des Schweren Akuten Respiratorischen Syndroms (SARS-CoV-2) mittels Nukleinsäureamplifikation (ISO/TS 5798:2022)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

The text of ISO/TS 5798:2022 has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" of the International Organization for Standardization (ISO) and has been taken over as CEN ISO/TS 5798:2022 by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices" the secretariat of which is held by DIN.

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Endorsement notice

The text of ISO/TS 5798:2022 has been approved by CEN as CEN ISO/TS 5798:2022 without any modification.

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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

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*, in collaboration with Technical Committee ISO/TC 276, *Biotechnology*.

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Introduction

Coronaviruses are enveloped RNA viruses that are broadly distributed in the animal kingdom. They have been identified in humans, other mammals, and birds. Coronaviruses were named because the spike proteins known to facilitate viral attachment and cell entry appear like a halo on the virus surface when viewed under an electron microscope. Coronaviruses are roughly spherical with a diameter ranging from 118 nm to 136 nm. The coronavirus genome, which ranges from 26 kb to 32 kb, is the largest among all RNA viruses, including RNA viruses that have segmented genomes. Until 2019, six coronaviruses have been associated with human diseases:

— severe acute respiratory syndrome-related coronavirus (SARS-CoV),

— Middle East respiratory syndrome coronavirus (MERS-CoV),

— human coronavirus 229E (HCoV-229E),

— human coronavirus OC43 (HCoV-OC43),

— human coronavirus NL63 (HCoV-NL63), and

— human coronavirus HKU1 (HCoV-HKU1)[1].

In 2019, a cluster of patients presenting with a respiratory disease were shown, by sequencing, to be infected with a novel coronavirus[2]. The coronavirus associated with this cluster was subsequently named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by the International Committee on Taxonomy of Viruses[3]. SARS-CoV-2 is the seventh coronavirus known to infect humans. The disease caused by SARS-CoV-2 was designated as coronavirus infectious disease 2019 (COVID-19) by the World Health Organization (WHO)[4].

The host range for SARS-CoV-2 is not yet fully defined. SARS-CoV-2 is a beta-coronavirus. The receptor for SARS-CoV-2 is the angiotensin-converting enzyme 2 (ACE2). ACE2 is a cell-surface, zinc-binding carboxypeptidase involved in regulation of cardiac function and blood pressure. It is expressed in epithelial cells of the lung and the small intestine, which are the primary targets of SARS-CoV-2, as well as the heart, kidney, and other tissues.

SARS-CoV-2 replicates in the upper and lower respiratory tracts and is transmitted by droplets and aerosols and most likely other contact with asymptomatic and symptomatic infected persons. The basic reproduction number (R_0) of the original variant is between 2 and 3, but significantly more contagious variants have developed. The median incubation period is 5,7 (range 2 to 14) days[5]. Similarly to SARS and MERS, superspreading events have been reported, with a dispersion parameter (kappa) estimated at 0,1. Most infections are uncomplicated, and 5 % to 10 % of patients are hospitalized mainly due to pneumonia with severe inflammation. However, complications include respiratory and multiorgan failures. Risk factors for the complicated disease increase with age and include hypertension, diabetes, chronic cardiovascular and chronic pulmonary diseases, and immunodeficiency.

Clinical management of COVID-19 and control of infections and spread of SARS-CoV-2 require effective and efficient in vitro diagnostics. There are a number of tests and kits in use for the detection of SARS-CoV-2 and the number of methods will continue to increase. Acceptable design, development and establishment of quality SARS-CoV-2 diagnostics based on nucleic acid detection methods is critical to ensure COVID-19 infection control. Establishing indices for conducting comprehensive quality evaluation of these methods and kits both during development and in routine application will ensure the accuracy of the test results and support epidemic prevention and control. This document provides requirements and recommendations to consider for the quality practice of SARS-CoV-2 nucleic acid amplification methods.

TECHNICAL SPECIFICATION ISO/TS 5798:2022(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

1 Scope

This document provides requirements and recommendations for the design, development, verification, validation and implementation of analytical tests for detecting the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) using nucleic acid amplification. It addresses pre-examination, examination and post-examination process steps for human specimens.

This document is applicable to medical laboratories. It is also intended to be used by in vitro diagnostic developers and manufacturers, as well as by institutions and organizations supporting SARS-CoV-2 research and diagnostics.

This document does not apply to environmental samples.

2 Normative references

There are no normative references in this document.