SLOVENSKI STANDARD
SIST EN ISO 15216-1:2017/oprA1:2020

01-november-2020

Mikrobiologija v prehranski verigi - Horizontalna metoda za ugotavljanje virusa hepatitisa A in norovirusov z RT-PCR v realnem času - 1. del: Metoda za kvantifikacijo - Dopolnilo A1 (ISO 15216-1:2017/DAM 1:2020)

Microbiology of the food chain - Horizontal method for determination of hepatitis A virus and norovirus using real-time RT-PCR - Part 1: Method for quantification - Amendment 1 (ISO 15216-1:2017/DAM 1:2020)

Mikrobiologie der Lebensmittelkette - Horizontales Verfahren zur Bestimmung von Hepatitis-A-Virus und Norovirus mittels Real-time-RT-PCR - Teil 1: Verfahren zur Quantifizierung - Änderung 1 (ISO 15216-1:2017/DAM 1:2020)

Microbiologie de la chaîne alimentaire - Méthode horizontale pour la recherche des virus de l'hépatite A et norovirus par la technique RT-PCR en temps réel - Partie 1: Méthode de quantification - Amendement 1 (ISO 15216-1:2017/DAM 1:2020)

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07.100.30 Mikrobiologija živil Food microbiology

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DRAFT AMENDMENT
ISO 15216-1:2017/DAM 1

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Secretariat: **AFNOR**

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Microbiology of the food chain — Horizontal method for determination of hepatitis A virus and norovirus using real-time RT-PCR —

Part 1:
Method for quantification

AMENDMENT 1

Microbiologie de la chaîne alimentaire — Méthode horizontale pour la recherche des virus de l'hépatite A et norovirus par la technique RT-PCR en temps réel —

Partie 1: Méthode de quantification

AMENDEMENT 1

ICS: 07.100.30

This document is circulated as received from the committee secretariat.

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Foreword

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This document was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 463, *Microbiology of the food chain*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This corrected version of ISO 15216-1:2017/Amd.1:2020 incorporates the following corrections:

— Use of EDTA disodium dihydrate (not EDTA) in recipe for EDTA buffer;

— Requirement to store chloroform/butanol in a dark glass bottle;

— Addition of new CECT reference for mengo virus vMC0;

— Change to Annex F (RNA extraction using Nuclisens equipment) to use simple equipment instead of the miniMAG/easyMAG.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Microbiology of the food chain — Horizontal method for determination of hepatitis A virus and norovirus using real-time RT-PCR —

Part 1:
Method for quantification

AMENDMENT 1

5.2.16

Replace the text with the following:

Ethylenediaminetetraacetic acid (EDTA) **disodium dihydrate.**

8.2.5, first paragraph

Replace the paragraph with the following:

This document is appropriate for water bottles with volumes up to 2 l. The entire contents of the bottle should be tested. For each sample, record the volume tested.

B.2.2

Replace the text with the following:

Mix the components together.

Store at room temperature in a dark glass bottle for a maximum of 12 months.

B.7.1

Replace the text with the following:

Ethylenediaminetetraacetic acid (EDTA) disodium dihydrate	(18,6 ± 0,2) g
Water (5.2.1)	as required

B.7.2

Replace the first sentence with the following:

Dissolve the EDTA disodium dihydrate in (90 ± 1) ml water.

E.1

Replace the second sentence with the following:

Mengo virus strain MC_0 (CECT 10 000)[2] is a recombinant (deletant) virus which lacks the poly(C) tract in comparison to the wild-type mengo virus, with identical growth properties to those of the wild-type virus but with an avirulent phenotype.

Footnote 2

Replace the first sentence with the following:

CECT 10 000 and ATCC® CCL-2™ are trademarks of products supplied by the Spanish Type Culture Collection and American Type Culture Collection respectively.

F.2

Replace the text with the following:

F.2.1 **Magnetic rack for** 1,5 ml tubes.

F.2.2 **Thermoshaker** or equivalent apparatus for shaking 1,5 ml tubes at (60 ± 2) °C and approximately 1 400 oscillations min^{-1}.

F.3

Replace the text with the following:

Add (2 ± 0,1) ml of NucliSens® lysis buffer to a tube. Add (500 ± 10) µl of sample (BMS) or entire sample (other matrices) and mix by vortexing briefly.

Incubate for (10 ± 1) min at room temperature.

Add (50 ± 2,5) µl of well-mixed magnetic silica solution to the tube and mix by vortexing briefly.

Incubate for (10 ± 1) min at room temperature.

Centrifuge for (120 ± 10) s at 1 500*g* or allow silica to sediment using a magnetic rack then carefully discard supernatant by, for example, aspiration.

Add (400 ± 10) µl wash buffer 1 and resuspend the pellet by pipetting or vortexing, taking care to avoid foaming.

Transfer suspension to a clean 1,5 ml tube. Cap tube and wash silica for (30 ± 2) s by vortexing. After washing, allow silica to sediment using the magnetic rack. Discard supernatant by, for example, aspiration.

Add (400 ± 10) µl wash buffer 1. Cap tube and wash silica for (30 ± 2) s by vortexing, allow silica to sediment using magnetic rack then discard supernatant.

Add (500 ± 10) µl wash buffer 2. Cap tube and wash silica for (30 ± 2) s by vortexing, allow silica to sediment using magnetic rack then discard supernatant. Repeat.

Add (500 ± 10) µl wash buffer 3 (samples shall not be left in wash buffer 3 for more time than necessary). Cap tube and wash silica for (15 ± 1) s, allow silica to sediment using magnetic rack then discard supernatant.

Add (100 ± 5) µl elution buffer. Cap tube and transfer to thermoshaker or equivalent and incubate for (5,0 ± 0,5) min at 60 °C with shaking at approximately 1 400 oscillations min^{-1}.

