
**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**

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*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

PROOF / ÉPREUVE



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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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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).

A list of all parts in the ISO 15216 series can be found on the ISO website.

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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 text 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, first paragraph

Replace the second sentence with the following:

Mengo virus strain MC₀ (CECT 100 000)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.

E.1, Footnote 2

Replace the first sentence with the following:

CECT 100 000 and ATCC® CCL-2™ are trademarks of products supplied by the Spanish Type Culture Collection and American Type Culture Collection respectively.

F.1.2, Footnote 3

Replace the text with the following:

BioMerieux NucliSens® is the trade name of a product supplied by bioMerieux. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products can be used if they can be shown to lead to the same results.

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F.2

<https://standards.iteh.ai/catalog/standards/sist/085be174-e2d6-4664-8360-44ed82b3dada/iso-15216-1-2017-prf-amd-1>

Replace the four subclauses with the following subclauses:

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 $(2 \pm 0,1)$ 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 $(50 \pm 2,5)$ 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 500g 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) μ l 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) μ l 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) μ l 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) μ l elution buffer. Cap tube and transfer to thermoshaker or equivalent and incubate for $(5,0 \pm 0,5)$ min at 60°C with shaking at approximately $1\ 400$ oscillations min^{-1} .

Place tube in magnetic rack and allow silica to sediment, then transfer eluate to a clean tube.

Vortex adapters that enable multiple tubes to be processed simultaneously may be used for vortexing steps.

Automated platforms for RNA extraction using the NucliSens[®] magnetic extraction reagents may also be used.

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