

IDEXX Water Internal Control

Internal Control for the
IDEXX Water SARS-CoV-2 RT-PCR Test

IDEXX Water Internal Control

Name and Intended Use

The IDEXX Water Internal Control is for use with the IDEXX Water SARS-CoV-2 RT-PCR test. It serves as a control for nucleic acid purification and PCR amplification. This product is added to the reagents during nucleic acid purification, which can be performed using the IDEXX Water DNA/RNA Magnetic Bead kit, or an equivalent product. This product has been validated with the IDEXX Water DNA/RNA Magnetic Bead Kit.

General Information

The IDEXX Water Internal Control is a synthetic DNA sequence, which is spiked into the extraction lysis solution and co-purified with the sample. The product enables users to verify successful purification of nucleic acids for each sample, and to evaluate whether PCR amplification in the IDEXX Water SARS-CoV-2 RT-PCR Test has been inhibited by substances in that sample.

Materials and Storage

Identification/General Information	Cap color	Quantity	Storage		Freeze/Thaw cycles
			At receipt	After reconstitution	
IDEXX Water Internal Control, dried [REF] 61-57010-00 Reconstitute to 500 μ L in PCR Grade Water. Allow to sit at 18 to 26°C for at least 10 minutes; mix and microcentrifuge briefly prior to use. Aliquot as appropriate and store the solutions frozen. The expiration date on the vial is valid for either the dry or reconstituted form.	white	0.5 mL	-25 to 8°C	-25 to -15°C	<6
PCR Grade Water [REF] 61-56624-00 PCR Grade Water has been qualified for reverse transcription-PCR (RT-PCR) use. It is used for the reconstitution of the Internal Control.	clear	1.0 mL	-25 to 8°C		N/A

Note: See table at the end of the insert for a description of symbols used on the insert and labels.

Materials Not Provided

- Pipettes (adjustable volume)
- Sterile, nuclease-free, aerosol-resistant pipette tips
- Sterile, nuclease-free microcentrifuge tubes
- Microcentrifuge for 2 mL microtubes capable of reaching 1500 – 3000 x g
- Commercial DNA/RNA extraction kit as recommended in the IDEXX Water SARS-CoV-2 RT-PCR Test product insert (**Note:** this product has been validated with the IDEXX Water DNA/RNA Magnetic Bead Kit).
- IDEXX Water SARS-CoV-2 RT-PCR Test
(see the IDEXX Water SARS-CoV-2 RT-PCR Test product insert for instructions)

Warnings and Precautions

General

- Follow all local regulatory and safety guidelines for the handling of wastewater samples. In addition, follow local health authorities' recommended procedures for handling and processing of wastewater samples associated with SARS-CoV-2. One source of information is the U.S. Centers for Disease Control & Prevention (CDC) Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19). (<https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>).
- Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious samples.
- Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human samples are handled.
- Dispose of waste in compliance with the local, state, and federal regulations.

Extraction and PCR

- Reagents must be stored and handled as specified in these instructions for use. Do not use reagents past expiration date.
- The entire procedure must be performed under nuclease-free conditions.
- Wear powder-free gloves when working with the reagents and nucleic acids.
- Always use pipette tips with aerosol barriers. Tips that are used must be sterile and free from DNases and RNases.
- Keep reagents and tubes capped or covered as much as possible.
- To avoid cross-contamination, use nuclease-free, aerosol-resistant pipette tips for all pipetting, and physically separate the workplaces for nucleic acid extraction/handling, PCR setup and PCR.
- Work surfaces, pipettes, and centrifuges should be cleaned and decontaminated with cleaning products such as 10% bleach, "DNAZap™" or "RNase AWAY®" to minimize risk of nucleic acid contamination. Residual bleach should be removed using 70% ethanol.

Procedure for use with IDEXX Water DNA/RNA Magnetic Bead kit

Add the Internal Control to extraction lysis solution

1. Reconstitute Internal Control according to the instructions in the "Materials and Storage" section of this insert.
2. Thaw at 18 to 26°C for approximately 15 to 30 minutes, mix gently and then microcentrifuge briefly (~1,500 – 3,000 × RCF).
3. This product is added to the reagents during nucleic acid purification (extraction). Follow the procedure detailed in the [IDEXX Water DNA/RNA Magnetic Bead kit product insert](#)
4. Interpret results according to instructions in the [IDEXX Water SARS-CoV-2 RT-PCR product insert](#).

Procedure for use with other extraction kits

Add the Internal Control to extraction lysis solution

1. Reconstitute Internal Control according to the instructions in the "Materials and Storage" section of this insert.
2. Thaw at 18 to 26°C for approximately 15 to 30 minutes, mix gently and then microcentrifuge briefly ($\sim 1,500 - 3,000 \times \text{RCF}$).
3. Determine the amount of Internal Control needed based on the final elution volume. Add 1 μL of Internal Control per 50 μL of final elution volume.
4. Add the amount of Internal Control calculated in the previous step to the extraction lysis solution prior to adding wastewater sample. If a bulk solution is prepared to process multiple samples, the Internal Control should be added when preparing that solution.
5. Gently vortex to ensure the extraction lysis solution and Internal Control are mixed well.

Perform extraction and PCR

1. Purify nucleic acids from the sample according to the manufacturer's instructions.
2. Perform the PCR test and interpret results according to instructions in the [IDEXX Water SARS-CoV-2 RT-PCR product insert product insert](#).

NOTE: The Internal Control is not compatible with other PCR test kits, and is used only with the IDEXX Water SARS-CoV-2 RT-PCR Test

For technical assistance:

North / South America: 1 207 556 4496 / 1 800 321 0207

Europe: 00800 4339 9111

UK: +44 (0) 1638 676800

China: +86 21 61279528

Japan: 03 5301 6800

Australia: 1300 443 399

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06-57010-00

Symbol Descriptions

LOT

Batch Code (Lot)

SN

Serial Number

REF

Catalog Number



Use by date



Date of manufacture



Manufacturer



Temperature limitation



Consult instructions for use

Manufactured in France for
IDEXX Laboratories, Inc., One IDEXX Drive, Westbrook, Maine 04092 USA
Tel: 1 800 321 0207

