

DNA/RNA Shield™

Collection Tube w/ Swab - Dx


Product Insert and Instructions for Use (CE edition)

Catalog Numbers or

| |
|-----|
| REF |
|-----|

- R1107-E DNA/RNA Shield™ Collection Tube w/ Swab
(1 ml fill), 50 pack
- R1109-E DNA/RNA Shield™ Collection Tube w/ Swab
(2 ml fill), 50 pack



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Product Contents

| DNA/RNA Shield™ Collection Tube w/ Swab - Dx | R1107-E (50 pack) | R1109-E (50 pack) |
|---|----------------------|----------------------|
| Flocked Swab (sterile) | 50 | 50 |
| DNA/RNA Shield™ Collection Tube, 1 ml fill | 50 | - |
| DNA/RNA Shield™ Collection Tube, 2 ml fill | - | 50 |
| Instructions For Use | 1 | 1 |

Specifications

- **Product Description**

1 x flocked swab (sterile)

1 x DNA/RNA Shield™ Collection Tube (12 x 80 mm)

- **Storage and Stability**

The product should be transported and stored in its original container at 5-30°C until use. DNA/RNA Shield™ and sterile flocked swabs have been tested for product stability of a maximum of 24 months after the manufacturing date as its shelf life.

- **Product Deterioration**

DNA/RNA Shield™ should not be used if (1) there is evidence of damage or contamination to the product, (2) there is evidence of leakage, (3) the expiration date has passed or (4) there are other signs of deterioration.

- **Materials Required, But Not Supplied (for downstream analysis)**

Appropriate materials for molecular testing according to recommended protocols.

General Laboratory Warnings/Precautions

This assay is for *in vitro* diagnostic use. Nucleic acid extraction kits are designed for procedures of molecular diagnostic and can only be handled by personnel trained in molecular biology methods.

- ✓ This product is intended for professional use or for use in POC. DO NOT use if the product is visibly damaged.
- ✓ Wear gloves when handling specimens or reagents.
- ✓ Do NOT pipette by mouth.
- ✓ DO NOT insert swab into the reagent before collecting a sample.
- ✓ DO NOT drink, touch or remove the reagent from the vial.
- ✓ The DNA/RNA Shield™ reagent can be harmful if ingested and may cause irritation if exposed to the skin and eyes.
- ✓ If the contents of the vial contact your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush eyes with water. Notify your health-care provider if irritation develops. If the contents of the vial are spilled, use a new collection kit.
- ✓ Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
- ✓ Clean and disinfect spills of specimens by including the use of soap and water (i.e., 20% aqueous solution of Sodium Dodecyl Sulfate disinfectant (SDS)).
- ✓ Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the relevant regulatory authority in which the user and/or the patient is established.
- ✓ Decontaminate and dispose of all potentially infectious materials in accordance with local, state, and European regulations.

Important information regarding the safe handling, transport, and disposal of this product is contained in the Safety Data Sheet. Safety Data Sheets are available from Zymo Research Corp. Inquire directly.

Intended Use

The DNA/RNA Shield™ swab collection is intended for the collection and transport of clinical specimens to be analyzed by nucleic acid-based assays.

DNA/RNA Shield™ reagent is pre-filled into vials which ensures sample stability during transport/storage at ambient temperatures without refrigeration or specialized equipment. Specimen collected can be frozen (-20/-80°C) for prolonged periods. The reagent is compatible with commercially available nucleic acid extraction kits and automated workflows. Specimens collected and stored in a DNA/RNA Shield™ collection tube are suitable for use with legally marketed molecular diagnostic devices.

Explanation

Clinical specimens stored and transported in DNA/RNA Shield™ reagent can be processed, using standard clinical laboratory operating procedures, for the detection of nucleic acids with molecular amplification assays. The primary purpose of nucleic acid amplification techniques is to aid in the diagnosis of infectious diseases, so nucleic acids integrity of clinical specimens during transport and storage should be preserved. DNA/RNA Shield™ medium inactivates and prevents viral infectivity, thus DNA/RNA Shield™ is not intended to be used for culture-based techniques.

Each unit consists of a package containing two components:

- A. a pre-labeled polypropylene screw-cap tube with a skirted conical tube filled with 1mL or 2mL of DNA/RNA Shield™ reagent and
- B. a specimen collection swab which tip is a regular size flocked nylon swab applicator intended for the collection of samples from the nose, throat, mouth.

The swab applicators provided have a molded breakpoint in the shaft of the applicator. After the sample is collected from the patient, the molded breakpoint facilitates easy breakage of the swab applicator into the DNA/RNA Shield™ reagent tube. The tube caps have an internal molded design that captures the swab shaft when broken off into the tube and the cap is closed. The action of screwing the cap onto the tube moves the end of the broken swab shaft into a funnel shaped molded docking receptacle in the cap. This molded funnel shape effectively captures the end of the broken applicator shaft and secures it firmly in the dock via friction. In the testing laboratory when the swab cap is unscrewed and removed, the swab applicator is attached to the cap. This feature allows the operator to conveniently remove the swab from the transport tube.

Instructions For Use

Proper specimen collection is extremely critical for the successful identification of infectious organisms. For specific guidance regarding specimen collection procedures, consult published standard collection manuals.

General Specimen Collection

1. Initial and date the reagent tube.
2. Peel open the swab package and remove swab.
3. Swab the area of interest. (For recommendations based on sample type, see page 5).

Note: Ensure you do not touch or lay the swab tip down to avoid contamination.

4. Insert swab into the collection tube.
5. Break the plastic shaft swab at the break point line.
6. Secure the tube cap and invert tube several times.
7. The specimen should be sent to the testing lab as instructed by the test provider or ordering physician.

Samples preserved in the DNA/RNA Shield™ reagent are stable and can be transported and stored at 5-30°C. No cold chain needed.



Warnings: DO NOT drink, touch the solution. The solution can be harmful if ingested and may cause irritation if exposed to the skin and eyes. For specifics, consult product Safety Data Sheet (SDS).

Recommendations for Throat Swab Specimen Collection

1. Carefully insert the swab into the mouth and gently swab both sides of the tonsil and throat areas. Pull out swab from mouth.
2. Proceed to Step 4 of General Specimen Collection (page 4).

Recommendations for Vaginal Swab Specimen Collection

1. Hold the swab in the middle of the swab shaft.
2. Carefully insert the swab into the vagina approximately 2 inches (5 cm) deep and gently rotate the swab for 15 seconds. Ensure the swab brushes the vaginal walls and then pull out the swab after sampling.
3. Proceed to Step 4 of General Specimen Collection (page 4).

Recommendations for Wound Specimen Collection

1. If needed, expose the base of the wound to access fluid from area to be swabbed.
2. Gently swab the wound to absorb fluid for 15 seconds, being careful not to draw blood or irritate the area.
3. Proceed to Step 4 of General Specimen Collection (page 4).

Recommendations for Rectal Swab Specimen Collection

1. Hold the swab in the middle of the swab shaft. Carefully insert the swab into the rectum approximately 2 inches (5 cm) deep and gently rotate the swab for 15 seconds. Pull out the swab from rectum.
2. Proceed to Step 4 of General Specimen Collection (page 4).

Appendices

Processing Specimens for Molecular Testing in the Laboratory

Specimens received in the laboratory for nucleic acid detection should be processed when received. If there is a delay in processing, specimen in DNA/RNA Shield™ collection tube preserves nucleic acids for ≤ 28 days at room temperature. Specimens preserved in DNA/RNA Shield™ reagent should be processed using validated methods before rRT-PCR amplification. DNA/RNA Shield™ collection tube can be adopted to automated or manual methods.

General Guidelines

1. Wear gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe Center for Disease Control (CDC) Biosafety Level recommendations.
2. When working with NAAT assays, care should be taken to prevent carry over contamination. Spatial separation of working areas and unidirectional workflow are essential to prevent amplicon carry-over.
3. Vortex specimen tube for 10 seconds or until sample is homogenous.
4. Unscrew the cap and transfer the appropriate amount of sample (e.g. 100 μ l-400 μ l or as per the protocol recommendations) directly into the extraction buffer tube.
5. Continue as per processing method and amplification kit procedures.

Limitations

1. **Avoid mixing the reagent and sodium hypochlorite (bleach) or other strong acids and bases. These mixtures could release noxious gases.**
2. The user is responsible for validating DNA/RNA Shield™ with all diagnostic assays.
3. The user is responsible for establishing appropriate system performance characteristics for all specimen types.
4. The DNA/RNA Shield™ system is a collection, preservation, transport, and storage system for biological specimen. Extraction and purification of nucleic acids have been validated on the *Quick-RNA™* Viral MagBead kit using the KingFisher Flex Purification System. The user is responsible for validating additional extraction and purification kits.



H302: Harmful if swallowed
H315: Causes skin irritation
H319: Causes eye irritation

Quality Control

Physical Properties

Physical properties of DNA/RNA Shield™ are routinely assessed for batch-to-batch consistency.

Nucleic Acid Preservation

Accelerated performance testing of DNA/RNA Shield™ is routinely conducted using contrived samples to ensure functionality of the reagent.

Nucleic Acid Contamination

Each batch of DNA/RNA Shield™ reagent is assessed for both Human and Microbial DNA contamination

Technical Support

For technical support, call Zymo Research Technical Support at 1-949-679-1190 ext. 3 or email at: tech@zymoresearch.com

Label Legend



Authorized representative in the European community/European Union



Swiss authorized representative



CE IVD vertical



CE IVD horizontal



Do not-reuse



Warning



In vitro diagnostic medical device



Lot number



Manufacturer



Reference **or** Catalogue number



Consult instructions for use



Storage instructions



Unique device identifier



Use-by-date

Troubleshooting Guide

| Problem | Possible Causes and Suggested Solutions |
|---------------------|---|
| DNA/RNA degradation | To prevent DNA/RNA degradation: Immediately collect and lyse fresh sample into a stabilization reagent (i.e., DNA/RNA Shield™) to ensure nucleic acid stability. Homogenized samples in DNA/RNA Shield™ can be stored frozen for later processing. |

For technical assistance, please contact 1-888-882-9682 or email tech@zymoresearch.com

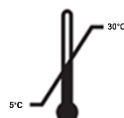
Ordering Information

| Product Description | Catalog No. | Size |
|---|-------------|---------|
| DNA/RNA Shield™ Collection Tube w/ Swab - Dx (1 ml fill) | R1107-E | 50 pack |
| DNA/RNA Shield™ Collection Tube w/ Swab - Dx (2 ml fill) | R1109-E | 50 pack |

Authorized representative:

EC REP

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Notes

This image shows a blank sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



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or your money back.**

Zymo Research is committed to simplifying your research with quality products and services. If you are dissatisfied with this product for any reason, please call 1(888) 882-9682.

Integrity of kit components is guaranteed for up to one year from date of purchase.
Reagents are routinely tested on a lot-to-lot basis to ensure they provide the highest performance and reliability.

Some reagents included with this kit are irritants. Wear protective gloves and eye protection. Follow the safety guidelines and rules enacted by your research institution or facility.

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DNA/RNA ShieldTM product technologies are subject to U.S. and foreign patents or are patent pending. Other trademarks: KingFisher Flex (Thermo ScientificTM).

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