

# **DNA/RNA Shield<sup>™</sup> swab collection**

Product Insert and Instructions for Use Catalog Number: R1124

Revised on: 02/12/2020





# Label Legend

Collect sample by

Catalog number

Manufacturer

15°C 1/25°C Storage instructions

↑ Consult instructions for use

Lot number

② Do not reuse

#### 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<sup>™</sup> 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

# **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 screen for a wide range of infectious diseases (i.e., viral, bacterial, etc.), so nucleic acids integrity of clinical specimens during transport and storage should be preserved. DNA/RNA Shield™ medium contains prevents viral and microbial proliferation, thus DNA/RNA Shield™ is not intended to be used for culture-based techniques.

#### **Product Description**

- 1 x Copan FLOQSwab™
- 1 x DNA/RNA Shield™ Collection Vial (12 x 80mm)

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 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 is able to capture 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.

#### Storage & Stability

The product should be transported and stored in its original container at 15-25°C until use. DNA/RNA Shield™ and FLOQSwabs® have been tested for product stability during 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.

#### 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.

#### Sample collection

- (1) Peel open the swab package and remove swab.
- (2) Insert the swab in your mouth and touch the area close to your tonsils 5 times.
- (3) Insert swab into the collection tube.
- (4) Break the plastic shaft swab at the break point line.
- (5) Secure the tube cap and invert tube several times.
- (6) 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 room temperature. No cold chain needed.















**Please note:** At-Home COVID-19 collection kit is for specimen collection for detecting the virus that causes COVID-19. The specimen should be sent to the testing lab as instructed by the test provider or ordering physician.

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).

#### Processing specimens for molecular testing in the laboratory.

Specimens received in the laboratory for nucleic acid detection should be processed when received in the laboratory. If there is a delay in processing, specimen in DNA/RNA Shield™ reagent preserves nucleic acids for >30 days at room temperature and can be frozen <-20°C for prolonged periods. Specimens preserved in DNA/RNA Shield™ reagent should be extracted before rRT-PCR amplification. DNA/RNA Shield™ reagent can be adopted to automated platforms from Tecan, Hamilton, Thermo-Fisher, bioMérieux, PerkinElmer, Eppendorf, Promega, etc. and manual methods, columm-based and magnetic beads.

#### General Guidelines

- 1. Wear gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe 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. 100ul-400ul or as per the protocol recommendations) directly into the extraction buffer tube.
- 5. Continue as per extraction and amplification kit procedures.

#### **Warnings and Precautions**

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.

This product is intended for professional use or for use in POC. DO NOT use if the product is visibly damaged.

Avoid mixing the reagent and sodium hypochlorite (bleach) or other strong acids and bases. These mixtures could release noxious gases.

For specifics, consult product Safety Data Sheet (SDS) by contacting Zymo Research Corporation directly.



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

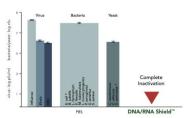
# **Additional Performance Specifications**

#### **Microbial Inactivation**

#### Used by scientists around the world for:

Bacteria	Viruses	Yeast & Eukaryotes			
B. subtilis	Parvovirus	C. albicans			
E. faecalis	Chikungunya Virus	C. neoformans			
E. coli	Dengue Virus	S. cerevisiae			
L. fermentum	Ebolavirus	P. malariae			
L. monocytogenes	Herpes Simplex Virus-1				
M. tuberculosis	Herpes Simplex Virus-2				
P. aeruginosa	Influenza A				
S. enterica	Rhinovirus				
S. aureus	MERS-coronavirus				
S. pneumoniae	West Nile Virus				
X. fastidiosa					

#### Microbial and viral inactivation

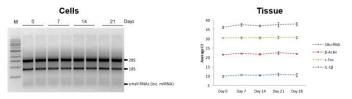


Samples containing the infectious agent (virus, bacteria, yeast) were treated for S minutes witt DNA/RNA Shield\* or mock (PBS). Titer (PFU) was subsequently determined by plaque assay.

# **Nucleic Acid Stability**



Nucleic acids from blood, saliva and stool are effectively stabilized in DNA/RNA Shield\* at ambient temperature. Graphs show: cellular RNA from human whole blood and spike-in DNA and RNA controls from saliva and stool purified at the indicated time points and analyzed by (RT)gPCR. Controls: HSV-1 and HIV (AcroMetrix, Life Technologies).



RNA from cells and tissue is effectively stabilized in DNA/RNA Shield\*\* at ambient temperature. Data show RNA from human cells and tissue purified at the indicated time points and visualized on agarose gel (HCT 116) or analyzed by (RT)qPCR (muscle tissue).

# **Notes**


# **Notes**



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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.

This product is for research use only and should only be used by trained professionals. It is not for use in diagnostic procedures. 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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