RealLine Transportation Solution

Instructions for Use

RealLine Transportation Solution

SOLUTION FOR TRANSPORTATION AND STORAGE OF CLINICAL SPECIMEN

In vitro diagnostics

CE

RealLine Transportation Solution	**VBC8894**	**100 Tests**
valid from	**September 2019**	

BIORON Diagnostics GmbH
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RealLine Transportation Solution

Explanation of symbols used in labeling

IVD	*In vitro* diagnostic medical device
LOT	Batch code
REF	Catalogue number
	Contains sufficient for <n> tests
	Use-by-date
	Temperature limit
	Consult instructions for use
	Keep away from sunlight
	Manufacturer

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In vitro Diagnostics

1. INTENDED USE

Transportation Solution is intended for transportation and storage of clinical specimens from biopsies and epithelial cells swabs for subsequent detection of infectious agents by polymerase chain reaction (PCR) with fluorescent detection of PCR products.

The kit is intended for transportation and storage of 100 specimen.

2. PRINCIPLE OF THE METHOD

The Transportation Solution represents an isotonic aqueous saline buffer solution with preservative intended for preservation of biological samples: biopsies and epithelial cells from mucosa of cervical canal, urethra, vagina, posterior laryneal wall, etc.

3. KIT COMPONENTS

Transportation Solution -	100 tubes 300 µl each

4. SPECIFICATIONS

Performance evaluation:
Stability of the clinical specimens during storage in transport solution is 100% (within the range 98.9% - 100% with confidence level of 90%), as determined on 280 clinical specimens.

5. WARNINGS AND SAFETY PRECAUTIONS

- For in vitro use only.
- The kits must be used by skilled personnel only.
- Transport solution contains sodium azide (0.05%). Avoid direct skin or mucosal membranes contact with kit components. In case of contact, immediately wash skin with large volume of water.
- Wear protective disposable gloves, laboratory coats and eye protection when handling specimens and kit reagents.
- Never use the same tips for different samples.
- When handling the kit, follow the national safety requirements for working with pathogens.
- Dispose unused reagents and waste in accordance with country, federal, state and local regulations.
- Do not use the solution after the expiration date at the side label of the kit.

6. ADDITIONAL MATERIALS AND DEVICES REQUIRED BUT NOT SUPPLIED

- Refrigerator;
- Half-automatic variable-volume single-channel pipettes;);
- Disposable gloves, powder-free;
- Disposable pipette tips with aerosol filter;
- 1.5 ml microtube racks;
- Eppendorf-type micro-centrifuge;
- Biohazard waste container;
- Disposable sterile probes (tampons, cervix brushes) intended for collecting specimens from cervix, vagina, urethra, oropharyngeal surface, rectum, as well as erosive-ulcerative lesions of skin and mucosa

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7. PREPARATION OF SPECIMENS

7.1 Prior to the opening, collect any drops from the tube lid and inside walls.

7.2 Transfer the analysed specimens into the tube with transport solution using the disposable sterile probe. Mix thoroughly, collect residual liquid from the probe by pressing on tubes walls, remove the probe to the waste container and close the tube tightly.

Transportation and storage of specimens:

- At (18 - 25) °C – for no more than 48 hours;
- At (2 - 8) °C – for no more than 2 weeks;
- At minus (18 - 60) °C – for no more than 2 months.

Do not freeze – thaw specimens repeatedly!

Specimens should be delivered to the laboratory within 3 – 4 hours in the thermal containers with refrigerant or ice.

8. PROCEDURE

8.1 Prior to the DNA/RNA extraction, spin the tubes briefly to collect all transport solution containing the test material from the walls of the tubes. Gently resuspend cell pellet formed by centrifugation.

8.2 For extraction procedure take 100 µl of each specimen using disposable tips with aerosol barrier.

9. STORAGE AND TRANSPORTATION

- Store the Transportation Solution at (2 - 8) °C in the manufacturer's packing.
- Transport at (2 -8)°C; transportation up to 25 °C for 10 days is allowed.
- Do not freeze the solution!
- Shelf life is up to 24 months after production, please note the expiry date at the side label of the carton.
- To obtain reliable results, strictly follow the Instruction manual provided with the kit.
- Do not use kits with damaged inner packages and get in contact with BIORON Diagnostics GmbH.

Requests to: techsupport@bioron.de

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