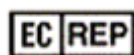




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For professional use only

STOR-M transport medium**INSTRUCTION FOR USE**

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1. INTENDED USE

The **STOR-M transport medium** is intended for transport and storage of human biological samples (scrapes/swabs of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye), including those containing an impurity of mucus, followed by nucleic acids analysis (human and microbial DNA, viral RNA) by polymerase chain reaction and reverse transcription (PCR/RT-PCR) methods.

This medical device is an auxiliary agent in clinical laboratory diagnostics.

The application of the kit does not depend on population and demographic aspects. There are no contradictions for use of the **STOR-M transport medium**.

The **STOR-M transport medium** can be used in clinical and diagnostic laboratories of medical institutions and research practice.

Potential users: personnel qualified in molecular diagnostics methods and working in the clinical and diagnostic laboratory.

It is necessary to apply the kit only as directed in this instruction for use.

2. METHOD

The **STOR-M transport medium** is a ready-to-use water-salt transparent, colorless solution with the addition of a preservative, mucolytic and flavoring agent. The preservative prevents the growth of non-specific microorganisms, and mucolytic acts on disulfide bonds of mucopolysaccharides, thereby diluting mucus.

3. CONTENT

The detailed description of content is represented in Tables 1-2.

Table 1. The **STOR-M transport medium** content, package S, 500 for P-910-1/1EU

| Reagent | Description | Total volume | Amount |
|------------------|------------------------------|------------------------|-----------|
| Transport medium | Colorless transparent liquid | 50 mL (500 µL in each) | 100 tubes |

Table 2. The **STOR-M transport medium** content, package S, 1000 for P-911-1/1EU

| Reagent | Description | Total volume | Amount |
|------------------|------------------------------|-------------------------|-----------|
| Transport medium | Colorless transparent liquid | 100 mL (1.0 mL in each) | 100 tubes |

All components are ready to use and do not require additional preparation for operation.

The kit is intended for single use and designed for 100 tests, including negative controls.

4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

4.1. Specimen collection

- Specimen collection swabs: sterile single use swabs, cytobrushes, cotton swabs e.t.c for sampling of biomaterial.

4.2. Preparation for NA extraction

- Biological safety cabinet class II;
- Vortex mixer;
- Refrigerator;
- NA extraction kit;
- High speed centrifuge (RCF(g) no less than 12,000);
- Tube rack for 1.5 mL tubes;
- Container for used pipette tips, tubes and other consumables;
- Single channel pipettes (dispensers covering 100-1000 µL volume range);
- RNase and DNase free filtered pipette tips (volume 1000 µL);
- Powder-free surgical gloves;
- Disinfectant solution;
- Nucleic acid extraction kit.

5. TRANSPORT AND STORAGE CONDITIONS

Expiry date – 12 months from the date of production.

The **STOR-M transport medium** must be transported in thermoboxes with ice packs by all types of roofed transport at temperatures inside the thermoboxes corresponding to storage conditions of the kit components.

It is allowed to transport the kit in thermoboxes with ice packs by all types of roofed transport at temperatures from 2 °C to 25 °C inside the thermoboxes, but for no longer than 14 days.

The kit transported with violation of temperature conditions must not be used.

All components of the **STOR-M transport medium** must be stored in a refrigerator or a cooling chamber at temperatures from 2 °C to 8 °C over the storage period.

The excessive temperature can be detrimental to product performance.

Shelf-life of the kit following the first opening of the primary container: components of the kit must be stored in a refrigerator or a cooling chamber at temperatures from 2 °C to 8 °C over the storage period.

The kit stored under undue regime must not be used.

An expired **STOR-M transport medium** must not be used.

We strongly recommend to follow the given instructions in order to obtain accurate and reliable results.

The conformity of the **STOR-M transport medium** to the prescribed technical requirements is subject to compliance of storage, transportation and handling conditions recommended by manufacturer.

Contact our official representative in EU by quality issues of the **STOR-M transport medium**.

6. WARNINGS AND PRECAUTIONS

Only personnel trained in the methods of molecular diagnostics and the rules of work in the clinical and diagnostic laboratory are allowed to work with the kit.

Handle and dispose all biological samples, reagents and materials used to carry out the assay as if they were able to transmit infective agents. The samples must be exclusively employed for certain type of analysis. Samples must be handled under a laminar flow hood. Tubes containing different samples must never be opened at the same time. Pipettes used to handle samples must be exclusively employed for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from the DNases and RNases, free from DNA and RNA. The reagents must be handled under a laminar flow hood. The reagents required for amplification must be prepared in such a way that they can be used in a single session. Pipettes used to handle reagents must be exclusively employed for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from the DNases and RNases, free from DNA and RNA. Avoid direct contact with the biological samples reagents and materials used to carry out the assay. Wear powder-free surgical gloves. Wear protective clothing (work clothes and personal protective equipment) working with microorganisms classified as particularly pathogenic. The protective clothing and personal protective equipment must comply with the work to be performed and health and safety requirements. Avoid producing spills or aerosol. Any material being exposed to biological samples must be treated for at least 30 minutes with disinfecting solution or autoclaved for 1 hour at 121 °C before disposal.

Molecular biology procedures, such as nucleic acids extraction, reverse transcription, PCR-amplification and detection require qualified staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or sample contamination by amplification products.

All the liquid solutions are designed for single use and can not be used more than once. Plastic tubes do not contain phthalates. Do not breathe gas/fumes/vapor/spray produced by the components of the kit. Do not eat/drink components of the kit. Avoid contact with eyes. Only use the reagents provided in the kit and those recommended by manufacturer. Do not mix reagents from different batches. Do not use reagents from third party manufacturers' kits. All laboratory equipment, including dispensers, test tube racks, laboratory glassware, lab coats, bouffant caps, etc., as well as reagents should be strictly stationary. It is not allowed to move them from one room to another. Waste materials are disposed of in accordance with local and national standards. All surfaces in the laboratory (work tables, test tube racks, equipment, etc.) must be treated daily with disinfecting solution.

Emergency actions

Eye Contact: If any component of this kit enters the eyes, wash eyes gently under potable running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

Skin Contact: If any component of this kit contacts the skin and causes discomfort, remove any contaminated clothing. Wash affected area with plenty of soap and water. If pain or irritation occurs, obtain medical attention.

Ingestion: If any component of this kit is ingested, wash mouth out with water. If irritation or discomfort occurs, obtain medical attention.

Do not use the kit:

- When the transportation and storage conditions are breached;
- When the reagents' appearance does not respond to the kit passport;
- When the kit components packaging is breached;
- After the expiry date provided.

Significant health effects are **NOT** anticipated from routine use of this kit when adhering to the instructions listed in the current manual.

7. SAMPLES

The **STOR-M transport medium** is designed to transport and storage the scrapes/swabs of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye.

General requirements

Remove free separable mucus with a sterile cotton prior to sampling. In case of sampling from several locations, repeat the procedure several times, each time taking a new swab into new different tube.

To prevent contamination, open the tube, add sample, then close the tube before proceeding to the next sample.

Scrapes/swabs of epithelial cells sampling

Method limitations: local use of medications, vaginal ultrasound less than 24 hours before the test.

WARNING!

1. The use of cytobrushes for urogenital swabs/scrapes is contraindicated in pregnancy.
2. To prevent contamination only open the tube you are working with and close the cap before proceeding to the next tube.

Order of taking:

1. Scrape epithelial cells from the corresponding biotope (i.e. urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye) with a sterile swab, transfer it to a 1.5 mL plastic tube with STOR-M transport medium and wash it thoroughly for 10-15 seconds. Avoid splashing.
2. Remove swab from solution, press it to the wall of the tube above the solution level and squeeze the rest of the liquid with a rotating liquid. Remove the swab from the tube and dispose of it.
3. Close the tube tightly and mark it.

Transportation and storage of the samples

Transport and store samples in **STOR-M transport medium** for subsequent analysis of human and microbial DNA at temperatures from 2 °C to 8 °C for no longer than 3 months.

Transport and store samples in **STOR-M transport medium** for subsequent analysis of viral RNA at temperatures from 2 °C to 8 °C for no longer than 28 days.

Transport and store samples in **STOR-M transport medium** for subsequent analysis of human and microbial DNA at temperatures from 18 °C to 25 °C is acceptable for no longer than 28 days.

Transport and store samples in **STOR-M transport medium** for subsequent analysis of viral RNA at temperatures from 18 °C to 25 °C is acceptable for no longer than 7 days.

8. PROCEDURE

8.1. General recommendations

1. Use only disposable RNase and DNase free filtered pipette tips.
2. When adding the solution into sample, do not touch the walls of the tubes with the tip. If the tip has touched the wall of the tube, change the tip. Tip should be changed each time when you take out solution from the tube with sample.
3. To prevent contamination, open the tube, add sample/reagent, then close the tube before proceeding to the next sample/reagent.

8.2. Preparation for NA extraction (package S, 500; package S, 1000)

8.2.1 Centrifuge samples in transport medium at RCF(g) 12,000 for 10 minutes.

8.2.2 Remove the supernatant, leaving the approximately 100 µL (precipitate+liquid fraction) in the tube.

WARNING! If for sample pretreatment centrifugation is not needed, p.8.2.1 and 8.2.2 are not performed.

WARNING! For scrape/swab from oropharynx and nasopharynx for subsequent analysis of viral RNA preliminary centrifugation is not required.

8.2.3 Add the lysis buffer in the volume recommended by the NA extraction kit used into the tube with precipitate.

8.2.4 Perform NA extraction according to NA extraction kit user manual.

8.2.5 To make a negative control sample perform p. 8.2.1 and 8.2.2 for tube with **STOR-M transport medium** which does not contain sample, or add 100 µL of STOR-M not containing biomaterial into lysis solution from the NA extraction kit.

The recommended kits for nucleic acids extraction:

- **PREP-RAPID DNA Extraction Kit** ("DNA-Technology Research & Production", LLC, "DNA-Technology TS", LLC, Russia);
- **PREP-GS and PREP-GS PLUS DNA Extraction Kits** ("DNA-Technology Research & Production", LLC, "DNA-Technology TS", LLC, Russia);
- **PREP-NA and PREP-NA PLUS DNA/RNA Extraction Kits** ("DNA-Technology Research & Production", LLC, "DNA-Technology TS", LLC, Russia);
- **PREP-MB RAPID DNA Extraction Kit** ("DNA-Technology Research & Production", LLC, Russia);
- **PREP-NA-S DNA/RNA Extraction Kit** ("DNA-Technology TS", LLC, Russia).

9. SPECIFICATIONS

The preservation of DNA in biomaterial samples taken into STOR-M (package S, 500) at different storage conditions

| Biomaterial | Preservation of DNA (%) | |
|---|---|--|
| | 28 days under temperatures from 18 °C to 25 °C | 3 months under temperatures from 2 °C to 8 °C |
| scrapes/swabs of epithelial cells from urogenital tract | 76.7 | 67.5 |
| scrapes/swabs of epithelial cells from oropharynx | 79.6 | 68.6 |
| scrapes/swabs of epithelial cells from nasopharynx | 64.9 | 67.6 |
| scrapes/swabs of epithelial cells from conjunctiva of the eye | 64.3 | 51.6 |
| scrapes/swabs of epithelial cells from rectum | 86.4 | 93.1 |
| scrapes/swabs of epithelial cells from skin | 83.6 | 67.1 |
| Total (average, 95% CI) | 75.9 (67.8-85.2) n=50 | 69.2 (57.8-79.4) n=50 |

The preservation of DNA in biomaterial samples taken into STOR-M (package S, 1000) at different storage conditions

| Biomaterial | Preservation of DNA (%) | |
|---|--|---|
| | 28 days under temperatures from 18 °C to 25 °C | 3 months under temperatures from 2 °C to 8 °C |
| scrapes/swabs of epithelial cells from urogenital tract | No losses. The sample is suitable for PCR | No losses. The sample is suitable for PCR |
| Total (average, 95% CI) | n=25 | n=25 |

The preservation of viral RNA in biomaterial samples taken into STOR-M at different storage conditions

| Biomaterial | Preservation of RNA (%) | |
|--|---|--|
| | 7 days under temperatures from 18 °C to 25 °C | 28 days under temperatures from 2 °C to 8 °C |
| scrapes/swabs of epithelial cells from oropharynx (SARS-CoV-2) | No losses. The sample is suitable for RT-PCR | No losses. The sample is suitable for RT-PCR |
| scrapes/swabs of epithelial cells from nasopharynx (HRV) | No losses. The sample is suitable for RT-PCR | No losses. The sample is suitable for RT-PCR |
| Total (package S, 500) | n=7 | n=9 |
| Total (package S, 1000) | n=7 | n=9 |

10. QUALITY CONTROL

“DNA-Technology Research&Production”, LLC declares that the abovementioned products meet the provision of the Regulation (EU) 2017/746 of the European parliament and of the Council of 5 April 2017. The quality control procedures performed in accordance with ISO 9001:2015 and ISO 13485:2016:

- observation of quality management in manufacturing of IVDR products;
- creation of values for customers;
- maintenance of the best service quality and customer management.

Contact our official representative in EU by quality issues of **STOR-M transport medium**.

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11. KEY TO SYMBOLS

| | | | |
|---|---|--|------------------------------|
|  | <i>In vitro</i> diagnostic medical device |  | Date of manufacture |
|  | Temperature limit |  | Consult instructions for use |
|  | Contains sufficient for <n> tests |  | Catalogue number |
|  | Use-by date |  | Manufacturer |
|  | Batch code |  | Version |
|  | Authorized representative in the European Community |  | Non-sterile |
|  | Do not re-use | | |



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