APPROVED BY
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TestGene, LLC
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INSTRUCTION FOR USE

"DNA-Fast" Reagent for Collection, Transporting, and Extraction of DNA from Clinical Material

under TS 21.20.23-016-97638376-2019

Version 2 of 24.05.2021

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Introduction

Target analyte. DNA-Fast reagent is used during the phase of sampling, transportation and preparation of samples for the subsequent analysis. The DNA-Fast reagent is not designed for isolation of obtained DNA as a target analyte.

Scientific validity

Collection, transporting and extraction of DNA is an important step in sample preparation. Many methods, such as amplification, detection of accumulation of amplification products by real-time PCR, etc., cannot be performed directly on clinical samples without preliminary preparation of nucleic acids.

DNA extraction is a preliminary stage in performing molecular genetic tests used for scientific and medical purposes, such as diagnosis of hereditary diseases, identification of various molecular genetic markers, risks of developing various hereditary diseases, detection of infectious agents DNAs, etc.

The use area of the reagent is clinical laboratory diagnostics.

Indications and Contraindications for Use

Indications for use: DNA-Fast reagent is recommended for use during preliminary analytical stage when performing tests in clinical laboratory diagnostics. Extracted total human DNA is suitable for tests performed by polymerase chain reaction.

Contraindications for Use: when used by specially trained personnel and taking into account the intended use, contraindications were not identified.

1. Intended Use

Intended Use: DNA-Fast reagent is designed for collection, transporting and extraction of DNA from human clinical material (nasal swabs, oropharynx swabs, vaginal mucosa smears, cervical canal scrapings, urethra scrapings, cellular sediment of urine, saliva, spinal fluid, synovial fluid, prostatic fluid) using the method based on the lysis of cell membranes and organoids with the release of DNA, and sedimentation of proteins and other pollutants for subsequent analysis in clinical laboratory diagnostics by polymerase chain reaction.

Functional purpose: DNA-Fast reagent is designed for the use in preliminary analytical stage of molecular genetic analysis. DNA extracted from human clinical material can be used for subsequent testing in clinical laboratory diagnostics when testing by polymerase chain reaction.

Potential users of the medical device

The reagent is designed for professional use in medical institutions and clinical diagnostic laboratories. Professional level of potential consumers - doctor of clinical laboratory diagnostics, medical laboratory technician.

2. Method Principle

Type of sample to test

Nucleic acids can be extracted from nasal swabs, oropharynx swabs, vaginal mucosa smears, cervical canal scrapings, urethra scrapings, cellular sediment of urine, saliva, spinal fluid, synovial fluid, and prostatic fluid.

Detection Principle

The detection principle used in the reagent is based on the thermal destruction of cells in the presence of lysing components. After thermal lysis and centrifugation of the sample, the supernatant fluid containing the extracted DNA is ready to be added into the reaction mixture for PCR.

Method Limitation

Contamination of clinical material may occur during sample preparation.

Breach of the package integrity during transportation.

Use of an expired reagent or use of a reagent being stored under inappropriate storage conditions.

Violation of storage conditions and transporting conditions of clinical material.

Total time for DNA isolation is 15 minutes. Time for clinical material preparation for extraction is not included.

3. Reagent Composition

The reagent is produced in one design version – DNA-Fast.

The product includes 100 tubes with 500µl solution in each.

It is recommended to deliver the tubes with DNA-Fast reagent to the treatment rooms of clinics, or to the laboratories where samples are prepared. The tubes with DNA-Fast reagent should be used as containers for collecting, storage and transporting clinical material for PCR analysis (see section 8).

Number of Testing Samples

The reagent is designed for DNA extraction from 100 testing samples (including negative control samples).

Reagent Components

Table 1 – DNA-Fast reagent components

No.	Reagent	Description	Quantity
1	DNA-Fast reagent	Transparent colorless liquid	100 tubes, 500 µl in each

The product does not include calibrators or control materials.

The reagent does not contain medicinal products for medical use, substances of human or animal origin.

4. Reagent Characteristics

4.1. Technical and Functional Characteristics

Table 2 – Technical and Functional Characteristics of DNA-Fast reagent

Parameter Name	Characteristics and Standards
1. Technical Characteristics	
1.1. Visual appearance	
DNA-Fast reagent	Transparent colorless liquid
1.2. Physical and chemical parameters	
Hydrogen ion concentration, pH	
DNA-Fast reagent	9,5-10,5 pH
1.3. Completeness	According to point 1.4 by TS 21.20.23-016-97638376-2019
1.4. Marking	According to point 4 by TS 21.20.23-016-97638376-2019
1.5. Packing	According to point 5 by TS 21.20.23-

	016-97638376-2019
2. Functional Characteristics	
2.1. DNA extraction efficiency, %, not less	20
2.2. No contamination of the reagent by foreign DNA	Negative result with NC in the control PCR
2.3. PCR inhibition	No PCR inhibition

Note: when conducting control PCR, separate tubes with the DNA-Fast reagent are used as a negative control sample (NC). Human cell culture suspension of HCT-8 cell line is used as a control sample.

4.2 Clinical Efficiency Characteristics

According to the clinical trial results, the effectiveness of the medical device was confirmed when used in accordance with its intended purpose. Clinical and laboratory tests were performed using polymerase chain reaction with DNA samples isolated from 119 samples of clinical material (nasal swabs, oropharynx swabs, vaginal mucosa smears, cervical canal scrapings, urethra scrapings, cellular sediment of urine, saliva, spinal fluid, synovial fluid, prostatic fluid) with the use of registered IVD medical devices.

To assess the inter-assay precision, DNA was extracted from clinical samples using the tested medical device in two series of tests.

Thus, the quality, safety and effectiveness of the tested medical device was examined in 238 experiments.

For statistical processing of clinical and laboratory test data, the Clopper and Pearson method was used (Clopper-Pearson Confidence Interval; Clopper, C., & Pearson, E. (1934). The Use of Confidence or Fiducial Limits Illustrated in the Case of the Binomi-al. Biometrika, 26(4), 404-413. doi:10.2307/2331986).

The study results of diagnostic characteristics of the tested medical device are shown in Table 3.

Confidence interval lower level is determined by the Clopper-Pearson method.

Table 3 – Clinical trial results

Test samples	Number of tests	Diagnostic characteristics	**CI** with 95% of confidence probability
Vaginal mucosa smears	18	100%	100% (95% CI:96%-100%)
Cervical canal scrapings	17	100%	100% (95% CI:96%-100%)
Urethra scrapings	15	100%	100% (95% CI:96%-100%)
Spinal fluid	7	100%	100% (95% CI:96%-100%)
Cellular sediment of urine	13	100%	100% (95% CI:96%-100%)
Prostatic fluid	11	100%	100% (95% CI:96%-100%)
Nasal swabs	11	100%	100% (95% CI:96%-100%)
Oropharynx swabs	9	100%	100% (95% CI:96%-100%)
Saliva	10	100%	100% (95% CI:96%-100%)
Synovial fluid	8	100%	100% (95% CI:96%-100%)

5. Risks Associated With the Use of DNA-Fast Reagent

The border risk zone includes the following:

– loss of functional properties of the reagent due to transportation, storage or operation under inappropriate conditions;

– contaminants in DNA that prevent or complicate PCR performance;

– DNA extraction from insufficient quantity of clinical material;

– failure to meet requirements for sample preparation, testing and disposal due to the fact that unqualified personnel work with the reagent;

– use of an unsuitable reagent (use after the expiration date or if the packaging is broken).

In the area of the unacceptable zone, no risks were identified.

Total residual risk of using a medical device "DNA-Fast Reagent for Collecting, Transporting and Extracting DNA From Clinical Material under Technological Specification (TS) 21.20.23-013-97638376-2019)", produced by TestGene, LLC is acceptable; the benefit of its use exceeds the risk.

6. Precautions When Working With the Reagent

Potential risk Class – 2a in accordance with Nomenclature Classification of Medical Devices approved by the Order of the Ministry of Health of the Russian Federation dated June 6, 2012 No.4n.

When using DNA-Fast reagent the work with clinical material should be carried out in compliance with Guidelines "Sampling, Transportation and Storage of Clinical Material for PCR-Diagnostics", developed by the Federal State Budgetary Institution of Science Central Research Institute of Epidemiology of Federal service for surveillance on consumers' rights protection and human well-being (Rospotrebnadzor), Moscow, 2012.

The hazardous components of the reagent in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) are shown in Table 3.

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Table 3 – Hazardous components of the reagent

Reagent	Hazardous component	Quantity	GHS hazard pictogram	Hazard phrases	Prevention precautionary statements
DNA-Fast Reagent	Sodium hydroxideCAS 1310-73-2	less than 5%		H314	P260, P280, P303+P361+P353, P305+P351+P338, P501
	Sodium azide CAS 26628-22-8	less than 0,1 %		H300, H400, H410	P273, P391, P501

Hazard phrases

H300	Fatal if swallowed
H 314	Causes severe skin burns and eye damage
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long-lasting effects

Prevention precautionary statements

P 260	Do not breathe dust/fumes/gas/mist/vapors/spray
P273	Avoid release to the environment
P 280	Wear protective gloves/protective clothing/eye protection/face protection
P303+P361+P353	If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P391	Collect spillage
P501	Dispose of contents/container at the industrial combustion plant.

The symbol located on the label shows that there is additional safety information in the relevant paragraph on the Instruction for Use.

The components listed above are considered hazardous, but they are present in quantities less than the registered limits and are safe for the end user.

When used for its intended purpose and observing precautionary measures, contact with the human body is excluded.

In case of emergencies, the following is possible: irritation of the skin and mucous membrane of the eyes in sensitive persons, an allergic reaction. Avoid contact with the skin and mucous membranes. Rinse the affected areas with plenty of water. In case of contact with the eyes or gastrointestinal tract, seek medical attention immediately.

Sodium azide can react with lead and copper, from which sewer pipes are made, to form potentially explosive metal azides. When disposing of such reagents, be sure to wash them off with a large amount of water to avoid the accumulation of azides.

The work should be carried out in a laboratory that performs molecular biological (PCR) studies of clinical material in compliance with Health Regulations 1.3.2322-08 “Safety of work with microorganisms of pathogenicity group III–IV (hazard) and parasites”, SanPiN 2.1.3684-21 “Sanitary and epidemiological requirements for maintenance of territories of urban and rural settlements, for water bodies, drinking water and drinking water supply, atmospheric air, soils, residential premises, operation of industrial and public premises, organization and conduct of sanitary and anti-epidemic (preventive) measures” and Methodology Guidelines 1.3.2569-091.3.2569-09 “Work of laboratories that use methods of nucleic acid amplification when working with material containing microorganisms of pathogenicity group I-IV”.

When working it is required:

– to handle test samples as infectious and dangerous, organize work and storage in compliance with Health Regulations 1.3.2322-08 “Safety of work with microorganisms of pathogenicity

group III–IV (hazard) and parasites" or in compliance with Health Regulations 1.3.3118-13 "Safety of work with microorganisms of pathogenicity group I–II (hazard)" depending on the analysis being performed;

– remove and disinfect spilled samples or reagents, using disinfectants in accordance with Health Regulations 1.3.2322-08 "Safety of work with microorganisms of pathogenicity group III–IV (hazard) and parasites";

– testing process in a laboratory should be unidirectional. The analysis is performed in separate rooms (zones). Work should start in the Extraction Zone and continue in the Amplification and Detection Zone. Do not return samples, equipment, or reagents to the area where the previous stage of the process is performed;

– unused reagents, expired reagents, and used reagents should be disposed in accordance with the requirements of SanPiN 2.1.3684-21 "Sanitary and epidemiological requirements for maintenance of territories of urban and rural settlements, for water bodies, drinking water and drinking water supply, atmospheric air, soils, residential premises, operation of industrial and public premises, organization and conduct of sanitary and anti-epidemic (preventive) measures";

– it is permitted to use only disposable filter tips for automatic dispensers. Change tips for each operation. Disposable plastic dishes must be removed into a special container containing a disinfectant that can be used for decontamination of medical waste;

– table surfaces, as well as the rooms where PCR is performed, must be exposed to UV-radiation as provided for by accepted standards;

– use the reagent strictly for its intended purpose, according to this instruction;

– only specially trained personnel is allowed to work with the reagent;

– not to use the reagent after the expiration date;

– not to use the reagent if the internal packaging is broken or the appearance of the reagent does not match the description;

– use disposable gloves, lab coats, and eye protection when handling samples and reagents. Wash hands thoroughly after work;

– all reagent components are non-toxic to humans in the concentrations used. In case of contact with the skin or mucous membranes, the contact area must be washed with plenty of water.

Necessary precautions against influence of magnetic fields, external electrical influence, electrostatic discharges, pressure or pressure drops, overload, or sources of thermal ignition are not recommended.

The reagent contains no substances of human or animal origin that have a potential infectious nature, so precautions against any special, unusual risks when using or selling the product are not provided.

7. Required Equipment and Materials

Equipment:

1. Sterile laminar box of biological (microbiological) safety, Class II;
2. Thermostat for Eppendorf type tubes from 25°C to 100 °C;
3. Vortex-microcentrifuge for 1.5/2ml type Eppendorf type tubes;
4. Variable volume dispensers for taking 20-200 ml, 200-1000 ml volumes of liquid;
5. Centrifuge 12100g with a rotor for 1.5/2 ml tubes;
6. Refrigerator for +2°C to +8°C;
7. Freezer for -2°C to -40°C.

Materials and reagents not included in the product:

1. Racks for 1.5-2.0 ml tubes and tips;

2. Disposable pipette tips for variable 100 µl, 1,000 µl volume dispensers with an aerosol barrier, DNA/RNA and DNase/RNase free;

3. Isolation or disposable gown coat and disposable gloves (powder free, talk free);

4. Container with disinfectant for removal of used tips, tubes and other consumables;

5. Sterile saline solution (0.9% NaCl).

Materials required for collection and pre-processing of clinical material

When doing cervical canal scraping: cervical brash with max 7 mm diameter of the working part

When doing urethral scraping: gynecological universal polymer probe, fleecy with max 7 mm diameter of the working part

When collecting vaginal smears: gynecological universal polymer probe, fleecy with max 7 mm diameter of the working part or a swab with max 7mm diameter of the working part

Nasal and oropharynx swabs: a swab with max 7mm diameter of the working part

When urine collecting:

1. Dry sterile bottle or 60 ml sterile container for collecting biomaterials;

2. Disposable polypropylene microcentrifuge 1.5 ml tubes with screw-on or tightly closed lids.

When collecting prostatic fluid, saliva, spinal fluid, synovial fluid: disposable polypropylene microcentrifuge 1.5 ml tubes with screw-on or tightly closed lids.

Use of other materials and reagents that are not part of the product is not provided.

Measuring equipment is not required when using the reagent.

8. Test Samples

Before the work, it is required to study Guidelines "Sampling, Transportation and Storage of Clinical Material for PCR-Diagnostics", developed by the Federal State Budgetary Institution of Science Central Research Institute of Epidemiology of Federal service for surveillance on consumers' rights protection and human well-being (Rospotrebnadzor), Moscow, 2012.

Preparation of clinical material for nucleic acids extraction

All stages of preparation are carried out at room temperature (from +18°C to +25°C).

8.1. Epithelial cells swabs (nasal swabs, oropharynx swabs, vaginal swabs, cervical canal scraping, urethra scraping)

Before collecting scrapings from the cervical canal, it is required to remove the mucus with a sterile cotton swab.

8.1.1. Using sterile probe transfer epithelial cells scraping to the test tube with DNA-Fast reagent, mix.

8.1.2. Remove the probe by pressing it against the test tube wall and squeezing out the excess liquid. Close the test tube tightly. Label the test tube.

8.2. Urine

8.2.1. A portion of urine (approximately 50 ml) should be collected in a sterile container and tightly closed with a lid.

8.2.2. Leave the urine for 1 hour, mix it by pipetting.

8.2.3. Transfer 1.0 ml of the material to 1.5 ml plastic test tube.

8.2.4. Centrifuge the test tube at 13,000 g for 10 min.

8.2.5. Drain the supernatant, leaving approximately 50 μl in the test tube (sediment and liquid fraction).

8.2.6. Add 500 μl of sterile saline solution to the sediment.

8.2.7. Centrifuge the test tube at 13,000 g for 10 min.

8.2.8. Drain the supernatant leaving approximately 50 μl in the test tube (sediment and liquid fraction).

8.2.9. Add 500 μl of sterile saline solution to the sediment.

8.2.10. Centrifuge the test tube at 13,000 g for 10 min.

8.2.11. Drain the supernatant leaving approximately 50 μl in the test tube (sediment and liquid fraction).

8.2.12. Add 500 µl of DNA-Fast reagent to the sediment (the volume of the reagent from one test tube), mix intensively by pipetting. Transfer the received solution back to the test tube with the reagent. Close the test tube tightly. Label the test tube.

8.3. Saliva, spinal fluid, synovial fluid

8.3.1. Collect saliva, spinal fluid or synovial fluid (approximately 500 µl) into sterile container.

8.3.2. Transfer 500 µl of the material to 1.5 ml plastic test tube.

8.3.3. Centrifuge the test tube at 13, 000 g for 10 min.

8.3.4. Drain the supernatant, leaving approximately 50 µl (sediment + liquid fraction) in the test tube.

8.3.5. Add 500 µl of sterile saline solution to the sediment.

8.3.6. Centrifuge the test tube at 13, 000 g for 10 min.

8.3.7. Drain the supernatant, leaving approximately 50 µl (sediment + liquid fraction) in the test tube.

8.3.8. Add 500 µl of DNA-Fast reagent to the sediment (the volume of the reagent from one test tube), mix intensively by pipetting. Transfer the received solution back to the test tube with the reagent. Close the test tube tightly. Label the test tube.

8.4. Prostatic fluid

8.4.1. Prepare plastic 1.5 ml test tube with 500 µl of sterile saline solution.

8.4.2. Place 20-30 µl of the material into the test tube.

8.4.3 Centrifuge the test tube at 13, 000 g for 10 min.

8.4.4. Drain the supernatant, leaving approximately 50 µl (sediment + liquid fraction) in the test tube.

8.4.5. Add 500 µl of DNA-Fast reagent to the sediment (the volume of the reagent from one test tube), mix intensively by pipetting. Transfer the received solution back to the test tube with the reagent. Close the test tube tightly. Label the test tube.

Transportation and Storage of Tested Material

Transport and store tubes with the specimens and DNA-Fast reagent ahead the test at a temperature of +2°C to +8 °C max for 24 hours, at a temperature of -18 °C to -22 °C – max for 2 weeks.

Interfering substances

The effect of potentially interfering substances on the function of DNA-Fast reagent was tested for potentially interfering substances that may occur during clinical material sampling and during DNA isolation.

According to Risk analysis and R&D, PCR inhibitors that may occur during DNA extraction from clinical material are the following: sodium hydroxide -50 mM and sodium chloride-5 mM, which are part of the DNA-Fast reagent.

According to the results of a series of PCR reactions, these substances in concentrations used in the DNA-Fast reagent do not have an interfering effect on the amplification of the laboratory control sample.

Potentially interfering substances that can occur during the procedure of sampling clinical material include:

Interfering substances	Maximum concentration
Endogenous interfering substances and anticoagulants	
Haemoglobin	0,35 mg/ml
Mucin	5%
Exogenous interfering substances	
Anti-inflammatory drugs	
Acetaminophen	200 mcM
Acetylsalicylic acid	3,7 mM
Ibuprofen	2,5 mM
Antibiotics	
Erythromycin	81,6 mcM
Ciprofloxacin	31 mcM
Tobramycin	5 mg/ml
Nasal spray and drops	
Phenylephrine	10%
Oxymetazoline	10%
Saline nasal spray	10%
Drugs administrated orally	
Ambrobene (ambroxol hydrochloride)	0,003 mg/ml
Bromhexine (bromhexine)	0,016 mg/ml

Kaletra (lopinavir, ritonavir)	0,02 mg/ml
Interferon (interferon alfa)	0,2 U/ml
Theraflu (paracetamol, pheniramine, phenylephrine)	0,071 mg/ml
Vaginal medications	
Polygynax (neomycin, nystatin, polymyxin B)	34 IU/ml
Gynalgin (metronidazole, chlorquinaldol)	0,07 mg/ml
Ciclopirox (Cyclopiroxum)	0,02 mg/ml
Clotrimazole (Clotrimazole)	0,02 mg/ml
Fluomisin (dequalinium chloride)	0,002 mg/ml
Elzhina (ornidazole, neomycin, prednisolone, econazole)	0,12 mg/ml
Topical Application	
Lubricant	10%
Talk	10%

Based on the results of the study, these substances do not interfere with the operation of the reagent (DNA isolation) and do not lead to inhibition of PCR at concentrations not exceeding the permissible ones.

To reduce the number of PCR inhibitors, it is necessary to follow the rules for collecting clinical material.

Restrictions on the use of the tested material:

- testing material is not subject to use in case of violation of storage and transportation conditions (temperature, duration, repeated freezing and thawing);
- use of samples contaminated with foreign biological material is not allowed.

9. Preparation of the Components for Testing

It is not required to install, assemble, adjust, or calibrate a medical device before operation. The reagent is a ready-to-use reagent DNA-Fast for collecting, transporting clinical material and isolating DNA, packaged in separate plastic tubes.

1) Separation of layers or sedimentation do not affect the quality of the reagent.

2) Before operation tubes with the reagent should be thoroughly mixed.

10. Testing Procedure

Only specially trained personnel with PCR analysis skills are allowed to work with the kit.

Extraction of DNA from clinical material

Before extraction, preheat the thermostat to +98 °

10.1. Vortex the pre-prepared sample (see paragraph 8) in DNA-Fast test tube during 10 seconds.

10.2. Incubate the test tube at +98 °C for 10 minutes. The tubes should be tightly closed. Possible spontaneous opening of the lids should be avoided.

10.3. Centrifuge the test tube at 13, 000 g for 3 min at room temperature. Sedimentation is possible.

Supernatant fluid contains DNA and is ready to be added into the reaction PCR mix.

The extracted DNA can be stored at a temperature of +2°C to +8°C for no more than 7 days or at a temperature of -18°C to -22°C for up to 6 months. The stored DNA should re-centrifuged at 13,000 g for 3 minutes before PCR reaction at a room temperature

11. Possible Problems and Solutions

1. Low yield of DNA, cause and possible solution:

– state of the sample (the sample contains an insufficient quantity of DNA; the sample was stored for a long time, or improperly stored, or repeatedly frozen and thawed) – possible solutions: take more of the source material, repeat collection of the material;

– incomplete lysis – suspend the sample as thoroughly as possible (step 10.1);

2. Possible degradation of DNA, cause and possible solution:

1. an old sample, or the sample was subjected to freezing-thawing – it is necessary to collect the material again. Avoid freezing the sample during transport and storage. To prevent DNA

degradation it is required to use DNase decontamination material to treat work surfaces of laboratory equipment and PCR consumables. Working surfaces and rooms where DNA is extracted, should be exposed to ultraviolet radiation of bactericidal lamps according to the regulatory documentation of the laboratory.

3. PCR Inhibition (no fluorescence signal of a specific product), possible solution:

– Repeat DNA extraction. To do this, transfer 100 ml of the supernatant liquid (step 10.3) containing extracted DNA into a 1.5 ml plastic test tube and repeat extraction of DNA.

12. Storage, Transportation and Usage Conditions

Storage. DNA-Fast reagent in the package of manufacturer should be stored at a temperature from +2 °C to +8 °C.

A reagent stored in violation of storage conditions cannot be used.

Transporting. DNA-Fast reagent can be transported by all types of covered vehicles in accordance with the transport rules applicable to this type of transport. It is allowed to transport the reagent at temperatures from +2°C to +8°C, and relative humidity up to 90%. It is allowed to transport at temperatures of +18 °C to +25 °C maximum 5 days. Atmospheric pressure is not controlled, because it does not affect the quality of the product.

A reagent transported in violation of temperature conditions cannot be used.

Shelf Life. Shelf life for DNA-Fast is 12 months from the date of acceptance by the manufacturer's Quality Control Department, provided that all conditions of transportation, storage and operation are observed. A reagent with expired shelf life cannot be used.

Shelf Life after Opening of the Reagent Package

DNA-Fast reagent is intended for single use, therefore, the stability when used after the first opening of the primary packaging of the reagent has not been assessed.

13. Disposal

When the reagent is used in a clinical and diagnostic laboratory it generates waste of Class A and B, that is classified and disposed of in compliance with requirements of SanPiN 2.1.3684-21 “Sanitary and epidemiological requirements for maintenance of territories of urban and rural settlements, for water bodies, drinking water and drinking water supply, atmospheric air, soils, residential premises, operation of industrial and public premises, organization and conduct of sanitary and anti-epidemic (preventive) measures”.

The reagents that have become unusable, including shelf life expiration and unused reagents belong to Class B and are subject to disposal in accordance with requirements of SanPiN 2.1.3684-21 and Methodology Guidelines 1.3.2569-09.

The reagent contains sodium azide as a preservative. Sodium azide can react with lead and copper pipes, forming explosive metal azides. When disposing of reagents, be sure to wash them off with plenty of water to avoid accumulation of azides.

After the use the consumer packaging (box) of the reagent belongs to waste of Class A and is disposed of with household wastes.

Personnel disposing reagent kits must comply with the safety rules for conducting a particular method of disposal.

14. Warranty Obligations, Contacts

The manufacturer guarantees that DNA-Fast reagent meets quality and safety requirements during its shelf-life until its expiration date subject to compliance with established requirements for transportation, storage and use.

In case of complaints about the product quality, undesirable events or incidents, submit information to:

Limited Liability Company “TestGene”
(TestGene, LLC),
9 44th Inzhenerny Proezd, office 13, Ulyanovsk 432072
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www.testgen.ru

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