NEW GENERATION OF GENETICS

AGREED
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CEO

INSTRUCTION
FOR USE OF

Kit of reagents for the qualitative detection of fetal RHD gene in the blood of rhesus-negative pregnant woman based on real-time PCR "Test-RHD-quatre"

	Generic Device Term	Commercial name
1	Kit of reagents	Kit of reagents "Test-RHD-quatre-strip" in strip tubes
2	Kit of reagents	Kit of "Test-RHD-quatre-tube" in separate tubes

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1. INTENDED USE

The kit «Test-RHD-quatre» is intended for qualitative determination of *RHD* gene in the peripheral blood plasma of rhesus-negative pregnant woman by «real-time» polymerase chain reaction (PCR).

Material for PCR – probes of free-circulating DNA isolated from peripheral blood plasma of rhesus-negative pregnant woman.

The method

Qualitative multiplex allele-specific real-time polymerase chain reaction with hybridization-fluorescence detection.

Indication for use: testing of fetal Rh-factor since 10 week of gestation during prenatal screening of pregnancy, prediction of rhesus hemolytic disease risk.

Application area – clinical laboratory diagnostics, prenatal diagnosis.

The kit is intended for use in medical and healthcare institutions including diagnostic and criminalistics laboratory as well as for scientific purpose. Potential users are doctor of clinical diagnostic laboratory and laboratory technicians.

Information about its scientific validation

15% of pregnant women are rhesus-negative therefore development of rhesus incompatibility, one of the most frequent reasons of hemolytic disease of fetus and newborns, is possible in 50% of cases. Hemolytic disease of fetus and newborns is the most frequent reason of intrauterine fetal death and infant mortality. As of today, the single method of fetal rhesus-factor determination is the test of material obtained by invasive way (chorion biopsy or cordocentesis).

Use of diagnostic kits for fetal DNA identification in blood of rhesus-negative pregnant woman allows fetal rhesus-factor gene identifying from 10^{th} "embryologic" week of pregnancy assisting specialist to make conclusion on fetal Rhesus factor.

2. KIT CHARACTERISTICS

Kit composition

Reagents kit «Test-RHD-quatre-strip» **includes:**

No.	Reagent	Marking on the tube cap	Description	Quantity, volume
1	PCR Mix RHD-1	-	Pink-colored transparent liquid in strip paraffin-fixed tubes	12 strips of 8 tubes with alternating PCR mixes (20 µl each)
2	PCR Mix RHD-2	-	Pink-colored transparent liquid in strip paraffin-fixed tubes	
3	Taq-polymerase	**Taq**	Transparent colorless liquid	2 tubes (500 µl each)
4	PC	**К+**	Transparent colorless liquid	1 tube (480 µl)
5	NC	**К-**	Transparent colorless liquid	3 bottles (8 ml each)
6	Mineral oil	-	Colorless viscous liquid	2 tubes (1,0 ml each)
7	Strips caps	-	Colorless polypropylene caps for strip tubes of 8 pc	12 pc

Reagents kit « Test-RHD-quatre-tube » **includes:**

No.	Reagent	Marking on the tube cap	Description	Quantity, volume
1	PCR Mix RHD-1	-	Pink-colored transparent liquid in strip paraffin-fixed tubes with caps	48 tubes (20 µl each)
2	PCR Mix RHD-2	-	Pink-colored transparent liquid in strip paraffin-fixed tubes with caps	48 tubes (20 µl each)
3	Taq-polymerase	**Taq**	Transparent colorless liquid	2 tubes (500 µl each)
4	PC	**К+**	Transparent colorless liquid	1 tube

				(480 µl)
5	NC	**К-**	Transparent colorless liquid	3 bottles (8 ml each)
6	Mineral oil	-	Colorless viscous liquid	2 tubes (1,0 ml each)

3. PRINCIPLE OF PROCEDURE

Detection principle

The process of DNA amplification by PCR (that is the base of test system) is hold in reaction buffer using specific to relevant regions DNA primers and Taq-polymerase. It consists of repeated cycles of temperature DNA denaturation and primers annealing.

PCR-Mix includes fluorescence-labelled oligonucleotide probes that are hybridized with complementary region of amplified DNA-target and destroyed by Taq-polymerase. As a result, fluorescence extinguisher and quencher are separated and fluorescence intensity grows. It allows registering accumulation of specific amplification product by measuring of fluorescence signal intensity in the «real-time» mode.

The kit includes reagents for multiplex detection of four exons of *RHD* gene (4, 5, 7 and 10) and human genomic DNA (sampling control, further as SC): amplification products of exon 4 are registered in tubes with PCR-mix RHD-1 (uneven) by channel conforming FAM fluorophor; exon 5 of *RHD* gene – in tubes with tubes with PCR-mix RHD-1 (uneven) by channel conforming ROX fluorophor; amplification products of exon 7 are registered in tubes with PCR-mix RHD-2 (even) by channel conforming FAM fluorophor, exon 10 of *RHD* gene – in tubes with tubes with PCR-mix RHD-2 (even) by channel conforming ROX fluorophor; exon 10 of *RHD* gene – in tubes with tubes with PCR-mix RHD-2 (even) by channel conforming ROX fluorophor. Amplification products of SC are registered in all tubes by channel conforming HEX fluorophor (table 1).

Table 1 – Detection channels

	FAM	**HEX**	**ROX**

PCR Mix RHD-1	exon 4	SC	exon 5
PCR Mix RHD-2	exon 7	SC	exon 10

SC allows for estimation of DNA isolation efficiency and possible inhibition in the probe that may lead to false-negative results.

The kit is produced in two versions:

1) «Test-RHD-quatre-strip» in strip tubes,
2) «Test-RHD-quatre-tube» in separate tubes.

Number of tested probes

Each kit «Test-RHD-quatre-strip» and «Test-RHD-quatre-tube» includes reagents for 96 tests that conforms to testing of 46 test samples (each in two repeats), negative and positive control samples or 16 single reactions of test samples with negative and positive control samples in each reaction.

Positive control sample (PC) is ready-to-use and consists of the mix of genomic DNA from Jurkat human cell culture with concentration of 200 GE/ µl (genome-equivalent per µl) of *RHD* gene.

Negative control sample (NC) consists of 0,9 % saline solution.

Total time of testing is not less than 2 hours.

4. ANALYTICAL KIT CHARACTERISTICS

Diagnostic Sensitivity	97,5 %
Diagnostic Specificity	97,7 %
Analytical specificity	PCR with detection on relevant fluorescent channels are specific to 4, 5, 7 and 10 exons of *RHD* gene and *COMT* gene region.
Analytical sensitivity	1 copy (<0,1 ng) of *RHD* gene and *COMT* in 1 µl of DNA solution that conforms to 100-130 copies of genomic DNA (summary fetal and maternal DNA) in 1,0 ml of test plasma sample.

5. METHOD LIMITATION

Do not use chylous, hemolyzed or high lipids blood (visual evidence of the sample), multiple pregnancy, because invalid results can be obtained of such samples.

Blood plasma samples that taken into tubes with heparin and sodium citrate as anticoagulant are unsuitable for testing.

Sampling material cannot be used if storage and transportation conditions (temperature, duration, repeated freeze-thawing) are broken.

When working with DNA it is necessary to use only sterile disposable plastic consumables with a special «DNase-free» marking.

Operator errors during sample preparation and in the course of the analysis, the violation of the instructions for use can lead to inaccurate results.

6. PRECAUTIONS DURING WORK WITH THE KIT

Agents of chemical and biological danger are absent in the kit.

The work should be conducted in the laboratory performed molecular-biological (PCR) tests of clinical material. The following requirements should be always met during work:

- Dispose carefully unused reagents carefully in accordance with local regulations.

ATTENTION! *Opening of tubes and content spraying are unacceptable during waste disposal* after amplification as this can lead to contamination of laboratory area, equipment and reagents by PCR products.

- Use the kit strictly for purpose intended in accordance with this instruction.

- Only specially trained staff should work with the kit.

- Do not use the kit after its expiry date.

- Avoid contact with skin, eye, and mucous membrane. Immediately flush the affected area with water and seek medical attention.

- There are no necessary precautions against the effect of magnetic fields, external electrical effects, electrostatic discharge, pressure or pressure differences, overload, thermal ignition sources.

7. EQUIPMENT AND MATERIALS

1. PCR-box (e.g., BAV-PCR-Laminar-S, Laminar Systems, Russia).
2. Vortex (e.g., TETA-2, Biocom, Russia).
3. Kit of electronic or automatic variable volume dispensers (e.g., Eppendorf, Germany).
4. Refrigerator with a temperature from 2 °C to 8 °C with a freezing chamber (max minus 16 °C).
5. Cycler of rotary type, e.g., Rotor-Gene 3000 or 6000 (Corbett Research, Australia), or cycler of plate type, e.g. Real-Time CFX96 Touch (e.g., BioRad, USA), or equivalent ones.
6. Racks for 0.2 ml tubes or for 0.2 ml strip tubes (e.g., InterLabService, Russia).

Materials and reagents not included in the kit:

ATTENTION! When working with DNA it is necessary to use only sterile disposable plastic consumables with a special marking «DNase-free».

1. Disposable tips with an aerosol barrier of up to 1000 µl, up to 200 µl, up to 20 and 10 µl (e.g., Axygen, USA).
2. An individual coat and disposable gloves.
3. Container with a cover for disinfecting solution.

8. TEST SAMPLES

Drawing of whole peripheral human blood

For plasma production blood (not less than 4-5 ml) is collected in the tube with added CPDA or EPDA as anticoagulant. Turn the tube 2-3 times after blood collection to mix blood with anticoagulant.

ATTENTION! Do not use heparin and sodium citrate as anticoagulant.

Transportation and storage conditions of initial clinical material:

When using tubes with CPDA as anticoagulant it is allowed to transport whole blood during 2 days at temperature 4-8 °C. Plasma must be separated during 48 hours since blood drawing.

When using EDTA tubes, blood must be delivered at the laboratory during 1 hour. Plasma must be separated during 2-3 hours since blood drawing.

ATTENTION! It is important to exclude freezing and warming above 25 °C of tube with blood.

Do not use chylous and hemolyzed blood because invalid results may be obtained.

Blood plasma separation procedure

For plasma production centrifuge the tube with blood during 10-15 min at 2000-3000 g at room temperature (18-25 °C).

Mark necessary amount of 1.5-2.0 ml Eppendorf tubes.

Carefully select all top layer of plasma by automatic dispenser without touching cell fraction and transfer 1100 µl into separate consumable marked tubes of 1.5-2.0 ml. It is strongly prohibited to contact selected material with leukocytes clots and layers with red blood cells.

Centrifuge obtained tubes with plasma the second time during 15 min at 13 000 g or 10 min at 16 000 g. Select 1000 µl of plasma by automatic dispenser without affecting the sediment at the tube bottom and transfer it to new marked tubes of 1.5-2.0 ml.

Isolate DNA from not less than 1 ml of plasma (2-3 ml are recommended) and elute 60-80 µl.

Storage conditions of blood plasma:

Store obtained plasma after double centrifugation:

- At temperature not above 4-8 °C – not more than 5 days;
- At temperature not above minus 20 °C – within 1 month;
- At temperature minus 70 °C – a long time.

Defrost one tube of each sample at room temperature before isolation procedure.

DNA isolation from test samples

For DNA isolation the following reagent kits are recommended:

- Kit for DNA isolation from blood plasma (DNA-Plasma-M) by TS 9398-002-97638376-2015 in the versions: 1) “DNA-Plasma-M-50” for 50 preparations, 2) “DNA-Plasma-M-100” for 100 preparations (TestGene, Russia)

- Kit for free circulating DNA isolation from blood plasma (DNA-Plasma-M-RT) (TestGene, Russia)

- NucleoSpin® Blood (MACHEREY-NAGEL, Germany)

- QIAamp Circulating Nucleic Acid Kit, QIAamp UltraSens Virus Kit (QIAamp, Germany)

or equivalents intended to isolation of circulated nucleic acids from biological fluids.

ATTENTION! Together with DNA isolation from test samples of blood plasma, it is necessary to prepare NC included in the «Test-RHD-quatre» composition. Volume of NC should be similar to volume of plasma samples specified in IFU of the kit for DNA isolation.

Storage conditions of DNA test samples

Fetal DNA sample is stored at temperature from +2 to +8 ^{0}C during 12 hours before testing, at temperature minus 20 °C – no more than 3 months or at temperature minus 70 °C – no more than 1 year.

Interfering substances

Interfering substances may get into DNA samples in traces from blood plasma and if DNA isolation procedure is violated.

- Plasma taken into tubes with heparin or sodium citrate as anticoagulant;
- At hemolysis and chylous blood.

However, these substances can interfere only at concentrations exceeding permissible concentrations (table 2).

Table 2 – Concentrations which exceeding may cause PCR inhibition.

Interfering substances	Concentrations that inhibit PCR
Heparin (anticoagulant)	>0,15 u/ml
Sodium citrate (anticoagulant)	>1 mmol/l
Hemoglobin (hemolysis)	>1 mg/ml
Triglycerides (chylous blood)	>0,5 mmol/l

Limitations for testing material use:

Testing material is not suitable for use:

- if storage and transportation conditions are violated (temperature, duration, multiple freezing and thawing).
- if plasma is contaminated with leucocytes and erythrocyte pellets;
- if samples are contaminated with outside biological material are not allowed for use.

9. SAMPLING PROCEDURE

Installation, configuration and calibration of medical device are not required for putting into operation.

ATTENTION! At work with DNA it's necessary to use only disposable sterile plastic materials with special labeling "DNase-free". Use only special tip with aerosol barrier for each component.

ATTENTION! Mix components of reaction mixture in PCR-tubes before testing according to table 3.

Preparation of the components for testing

1. Mix thoroughly contents of tubes with isolated DNA, NC, Taq-polymerase and PC, turn over each tube 10 times or vortex at low speed during 3-5 sec, precipitate drops by short centrifugation.

2. Choose necessary amount of strips or tubes included in the kit contents for amplification of tested and control DNA samples (table 3).

Before PCR it is necessary to do wet cleaning of PCR box, equipment and materials by disinfectants suitable for PCR-laboratory, turn on the UV lamp for 20-30 minutes.

Total test volume – 40 µl.

ATTENTION! Test volume should not be changed. Method sensitivity is strongly decreased at volume change!

For testing of 1 sample (both test sample, PC and NC) it is necessary:

1) 1 reaction tube with **PCR-mix RHD-1** under paraffin;

2) 1 reaction tube with **PCR-mix RHD-2** under paraffin;

3) 2 portions of Taq-polymerase, 5 µl each;

4) 2 samples (test sample, PC or NC), 15 µl each.

ATTENTION! Testing of each DNA sample should be carried out two times because fetal DNA is in minimal amount in the pregnant woman blood.

Prepare reaction tubes according to table 3 in the following order:

1. In couples mark tubes with PCR-mixes RHD-1 and RHD-2 for each test sample, PC and NC in conjunction with DNA isolation (table 3).

Table 3 – Example of tubes placement and components adding for PCR procedure

Component	Sample 1		Sample 2		Control			
					PC		NC	
PCR-mix RHD, µl	20	20	20	20	20	20	20	20
Taq-polymerase, µl	5	5	5	5	5	5	5	5
DNA sample, µl	15	15	15	15	-	-	-	-
PC, µl	-	-	-	-	15	15	-	-
NC, µl	-	-	-	-	-	-	15	15

2. Add 5 µl of Taq-polymerase into each tube without damaging the paraffin.

3. Add one drop of mineral oil (20 µl) into each tube. Close tubes caps.

4. Add 15 µl of isolated DNA into relevant tubes for test samples (1 tube for each sample with PCR mix RHD-1 and 1 tube with PCR mix RHD-2). DNA is not added into tubes for PC and NC.

5. Add 15 µl of PC into relevant tubes without damaging the paraffin.

6. Add 15 µl of NC in conjunction with DNA isolation into relevant tubes without damaging the paraffin.

7. Centrifuge tubes during 1-3 sec on the vortex for drops precipitation.

8. Place tubes into reaction module of device for real-time PCR. It is recommended to set tubes in the center of thermal block for evenly clamp the tubes with a heating cap.

9. Start relevant software of used cycler.

10. Program the cycler for amplification program according to table 4, following the instruction for used device.

Table 4 – Amplification program

Stage	**Temperature, ˚C**	**Time, min:sec**	**Detection channels**	**Total cycles**
1	95	02:00		1
2	95	00:10		10
	66	00:05	Without plate read!	
3	95	00:05		40
	64	00:05	FAM, HEX, ROX	

11. Indicate amount and samples identifications, notice tubes placement on the thermal block matrix in accordance with its installation.

12. Prove that detection channels FAM, HEX and ROX are involved in the parameters of optical measurements in the amplification program.

13. Start PCR with detection of the fluorescent signal.

14. Start the results analysis at the end of the program.

10. REGISTRATION AND INTERPRETATION OF RESULTS

Results are registered automatically during amplification using software of used device.

Calculations and interpretations of results are performed based on Cp values of SC (HEX channel) and dCp on FAM and ROX channels for two PCR mixtures for each sample. Obtained results for PCR mixes RHD-1 and RHD-2 are equal.

Cp and dCp values are shown in tables 5-9. Firstly, PCR procedure and Cp values are evaluated on the control samples. Interpretation of results in the test DNA samples must be started after procedures with PC and NC.

Interpretation of results in control samples

For negative and positive control samples in tubes with PCR-mixes RHD-1 and RHD-2 the following results should be obtained:

Table 5 – Testing results for negative and positive control samples

Added material	Selected fluorophor		
	FAM (*RHD*, exon 7)	HEX (SC)	ROX (*RHD*, exon 10)
NC	Cp is not identified or >31	Cp is not identified or >29	Cp is not identified or >31
PC	Cp ≤22	Cp ≤22	Cp ≤22

If values obtained for NC differ from results indicated in the table 5, all results of production series are considered to be invalid. In this case, it is necessary to carry out special measures for avoiding contamination.

If values obtained for PC differ from results indicated in the table 5, it is required repeated amplification of all samples batch.

Interpretation of results in the test samples

Interpretation of results is shown in the table 6 for cycler «Rotor-Gene» and table 7 for cycler «CFX96» and performed in the following order:

1. Determine the quality of isolated DNA for testing based on Cp for HEX channel not above 25.

2. Evaluate results under channels FAM and ROX in the tubes with PCR mixes RHD-1 and RHD-2.

3. Evaluate difference (dCp) between Cp on channels FAM and/or ROX and Cp on channel HEX provided there is amplification graphs.

Interpretation of results should be made as follows:

Fetal Rh factor is genotypically «-», if Cp value on channel HEX is not above 25, Cp values on two channels (FAM and ROX) are not identified or more than 31.

Fetal Rh factor is genotypically «+», if Cp value on channel HEX is not above 25, Cp value is not above 31 on at least one channel (FAM or ROX), and difference (dCp) between Cp value on this channel and Cp value on channel HEX is not less than 0,2 for **«Rotor-Gene»** or not less than -1 for **«CFX96»**.

Rh factor of pregnant woman is genotypically «+», fetal Rh factor is impossible to determine using this method, if Cp value on channel HEX is not above 25, Cp value is not above 31 on at least one channel (FAM or ROX) but difference (dCp) between Cp value on this channel and Cp value on channel HEX is less than 0,0 for **«Rotor-Gene»** or less than -2 for **«CFX96»**.

Table 6 – Interpretation of PCR results for cycler **«Rotor-Gene»**

Result on channel FAM (FAM Ct)	Result on channel HEX (HEX Ct)	Result on channel ROX (ROX Ct)	dCt ((FAM Ct) minus (HEX Ct))	dCt ((ROX Ct) minus (HEX Ct))	Interpretation of results
Ct is not identified or >31	Ct≤25	Ct is not identified or >31	-	-	Fetal Rh factor: genotypically «-»
Ct≤31		Ct≤31	Less than 0,2	Not less than 0,2	

Ct is not identified or >31		Ct≤31	-	Not less than 0,2	Fetal Rh factor: genotypically «+»
Ct≤31		Ct is not identified or >31	Not less than 0,2	-	
Ct≤31		Ct is not identified or >31	Less than 0,0	-	Rh factor of pregnant woman: genotypically «+», determination of fetal Rh factor is impossible using this method
Ct is not identified or >31		Ct≤31	-	Less than 0,0	
Ct≤31		Ct≤31	Less than 0,0	Less than 0,0	

Table 7– Interpretation of PCR results for cycler **«CFX96»**

Result on channel FAM (FAM Cq)	Result on channel HEX (HEX Cq)	Result on channel ROX (ROX Cq)	dCq ((FAM Cq) minus (HEX Cq))	dCq ((ROX Cq) minus (HEX Cq))	Interpretation of results
Cq is not identified or >31	Cq≤25	Cq is not identified or >31	-	-	Fetal Rh factor: genotypically «-»
Cq≤31		Cq≤31	Not less than -1	Not less than -1	Fetal Rh factor: genotypically «+»
Cq is not identified or >31		Cq≤31	-	Not less than -1	
Cq≤31		Cq is not identified or >31	Not less than -1	-	
Cq≤31		Cq is not identified or >31	Less than -2	-	Rh factor of pregnant woman: genotypically «+», determination of fetal Rh factor is impossible using this method
Cq is not identified or >31		Cq≤31	-	Less than -2	
Cq≤31		Cq≤31	Less than -2	Less than -2	

Result for samples with insufficient for testing DNA amount (Cp>25,0 on detection channel HEX), incorrect values dCp or mismatching of results in doubles are considered to be doubtful or invalid (table 8 for cyclers «Rotor-Gene», table 9 for cycler «CFX96»).

In this case, conclusion cannot be issued, it is necessary to draw blood once more and test the sample again.

The reason of doubtful result may be inhibitors on DNA sample obtained from clinical material; incorrect performance of test report; noncompliance of temperature amplification conditions, etc.

Table 8 – Determination methods of doubtful and invalid results for cycler **«Rotor-Gene»**

Testing characteristics	Variants of results		
	1	2	3
Result on channel FAM (FAM Ct)	Ct≤31	Not considered	Not considered
Result on channel HEX (HEX Ct)	Ct≤25	Ct>25	Ct≤25
Result on channel ROX (ROX Ct)	Ct≤31	Not considered	Not considered
dCt ((FAM Ct) minus (HEX Ct))	0,0-0,2	Not considered	Not considered
dCt ((ROX Ct) minus (HEX Ct))	0,0-0,2	Not considered	Not considered
Interpretation of results	Doubtful result	Invalid result	Invalid results

Table 9 – Determination methods of doubtful and invalid results for cycler **«CFX96»**

Testing characteristics	Variants of results		
	1	2	1
Result on channel FAM (FAM Cq)	Cq≤31	Not considered	Not considered
Result on channel HEX (HEX Cq)	Cq≤25	Cq>25	Cq≤25
Result on channel ROX (ROX Cq)	Cq≤31	Not considered	Not considered
dCq ((FAM Ct) minus (HEX Cq))	-2…-1	Not considered	Not considered
dCq ((ROX Cq) minus (HEX Cq))	-2…-1	Not considered	Not considered
Interpretation of results	Doubtful result	Invalid results	Invalid results

11. KIT STORAGE CONDITIONS AND HANDLING

Storage

«Test-RHD-quatre» kit must be stored at 2 °C to 8 °C in the manufacturer packing during all shelf life.

After packing opening kit components should be stored under the following conditions:

- Kit components must be stored at 2 °C to 8 °C during all shelf life;
- PCR mix must be stored in a light-proof place during all shelf life.

Kit stored with violation of storage conditions are not to be applied.

Transportation

«Test-RHD-quatre» kit must be transported by all kinds of transport at the covered vehicles in accordance with rules of transportation acting on the transport of this type.

Kit must be transported at temperature from 2 °C to 8 °C during all shelf life. Transportation at room temperature (15–25°C) is acceptable but no longer than 5 days.

Atmosphere pressure is not controlled because it does not influence the sample quality.

For ensuring of transportation conditions during all transportation period the kit is placed into reusable polyurethane-foam thermal container with ice pack for temporary storage and transportation. Type, volume, ice pack amount at transported kits and thermal container volume are selected depending on duration and transportation conditions.

Kits transported with violations of temperature conditions are not to be used.

Shelf life. Shelf life of the kit «Test-RHD-quatre» is 12 months. The kit shall not be used after the expiry date.

Shelf life of opened kit components. 12 months if stored at 2 °C to 8 °C.

Shelf life of kit components ready for operation. 1 hour if stored in an ice bath and complied with conditions that prevent components drying and contamination by outside biological material.

12. UTILIZATION

Kits of reagents which have come in unsuitability, including after the expiration date must be disposed of in accordance with the requirements and regulations of territorial authorities.

It is allowed to use the kit components (while maintaining their operational properties) if the kit is recognized unfit for use, within their shelf life.

Liquid components (reagents) are destroyed in the sink drains with predilution of the reagent with tap water 1: 100 and export packages as an industrial or household waste.

Consumer packaging of kit «Test-RHD-quatre» is subject to mechanical failure with removal of residues as an industrial or household waste.

Staff carrying out the destruction of reagents, must comply with the safety rules of disposal.

13. WARRANTY OBLIGATIONS, CONTACTS

The manufacturer guarantees the conformity of kits to technical requirements under transportation, storage and operation conditions established by technical specification.

If there are any complaints regarding the quality, undesired events that may cause adverse event (incident), send the information to the address:

Limited liability company «TestGene»
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