GeNext Next Genetic Researches

Проекты ULNANOTECH Ulyanovsk Technology Transfer Center

GeNext&TestGene Group

COMPETENCE CENTER IN BIOTECHNOLOGY AND MOLECULAR GENETICS
DEVELOPMENT AND PRODUCTION OF DIAGNOSTIC KITS AND OTHER MOLECULAR GENETIC APPLICATIONS

Companies review

TestGene and GeNext are subsidiary companies of Ulyanovsk nanocenter (Rosnano group)

GeNext develops and **TestGene** produces kits of reagents for molecular genetics and diagnostics.

The products are intended for use in scientific research, molecular biology, practical medicine, forensic, agriculture.

The companies have their own high-technology laboratory satisfied all the essential requirements Situated in Ulyanovsk.

The companies team is highly skilled, young team, half of which has PhDs, all has experience in the science and participation in foreign trainings and collaborations.

GeNext Next Genetic Researches
www.genext.pro

TESTGENE
www.testgen.ru

ULNANOTECH
Ulyanovsk Technology Transfer Center
www.ulnanotech.ru

The Team

Toropovskiy Andrey

CEO, PhD, MD, developer of non-invasive method of gender and RH factor determinatin of a fetus, the prize holder among Russian youth in nanotechnology, participant of exhibitions in Korea and Taiwan.
He graduated From Samara State University of Medicine, with a degree in clinical laboratory diagnostics. In 2013 he completed the presidential programme of management training at the Kazan State Medical University.
He is a member of the European Society of Immunogenetics (EFI) and ASHI (American Society for Histocompatibility and Immunogenetics).

Victorov Denis,

PhD, Senior Researcher,

author of over 100 scientific articles, receiver of 11 grants. Passed internship on molecular biological research methods, including automated synthesis of DNA / RNA, DNA cloning, phage display technology, and others.
The developer of molecular genetic test systems for the detection of bacterial infections; bacteriological methods for the isolation and typing of pathogens; biological products based on bacteriophages; biological products based on bacteria-oil destructors; biological products for recycling and organic waste.

Nikitin Alexey,

Scientific Director of the project, PhD

Head of the Laboratory of Molecular Genetics in the Russian Federal Clinical Research Centre, molecular geneticist, a developer of unique test systems for molecular diagnostics, coauthor of a patent for the invention "A kit of oligonucleotide primers and probes and a method for determining the RhD of fetus using fetal DNA from the blood of Rh-negative pregnant woman", author of more than 40 publications in the field of molecular genetics.

Jmirko Ekaterina

Development Manager

She has more than 12 years of experience in the field of molecular and medical genetics (Institute of Genetics and Experimental Biology, Institute of Biochemistry); 3 years of experience and leadership diagnostic laboratory; took part in 12 government grants for fundamental and applied fields; author of over 20 scientific publications in the field of molecular genetics. She studied at the Department of the Hebrew University (Jerusalem, Israel), and the Institute of Immunology of the Ministry of Health (Moscow, Russia); is the winner of "Best Young Scientist 2010"; member of the project “100 portraits of Innovators 2014”

Toropovskaya Tatiana
Head of the Laboratory

Skorokhodov Lev
Laboratory researcher

Solovieva Ekaterina
Laboratory researcher

Hohlova Yuliyu
Laboratory researcher

Masyaeva Ekaterina
Accountant

Shinkareva Kristina
International department

The Projects of GeNext/TestGene

TestGene and GeNext do research in 4 major areas:

- **NON-INVASIVE PRENATAL TESTING**
- **PERSONAL IDENTIFICATION**
- **LIQUID BIOPSY**
- **SNP AND MUTATION TESTING**

The Companies have 4 operating grants from the Foundation for Assistance to Small Innovative Enterprises (Programme Start1 and Start2), are residents of Skolkovo Innovation Support Fund, members of the nuclear innovative cluster in Dimitrovgrad.

The Companies have 2 Eurasian patents and 2 applications for a patent, and a number of scientific publications.

TestGene has its own registered and successfully commercialized product - the "Diagnostic complex for non-invasive detection of fetal gender and Rhesus factor.

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ФОНД СОДЕЙСТВИЯ РАЗВИТИЮ малых форм предприятий в научно-технической сфере

Sk Сколково

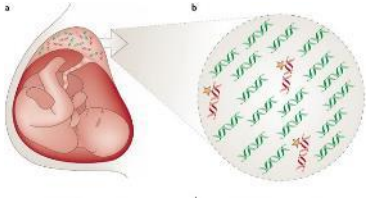
Noninvasive prenatal testing of fetal gender and RHD status

Market– **method allows to adjust the hemolytic disease of fetus and newborn prophylaxis (HDFN), and also to detect exactly gender of fetus starting from 8th week of pregnancy.** 15% of pregnant women are RhD-negative, but only a half of them carry RhD-positive fetus. Only this category of pregnant women requires the HDFN prophylaxis. The market capacity is estimated at 3 000 000 tests per a year for RHD, and at 1 000 000 tests per a year fetus gender.

Product – RT PCR test system for non-invasive prenatal diagnostic of fetus gender and RhD.

Current condition – the product was developed in 2011, the Eurasian Patent was received in 2014 and the registration certificate in 2015. The product is successfully delivered in more than 60 clinics in the regions of Russia and CIS (Kazakhstan, Armenia, Ukraine, etc.). The current turnover on sales of the test system was 10 million rubles in 2015.

The product is a winner in innovative competitions in Russia, Korea and Taiwan. Prize-Winner of Business Success-2014.



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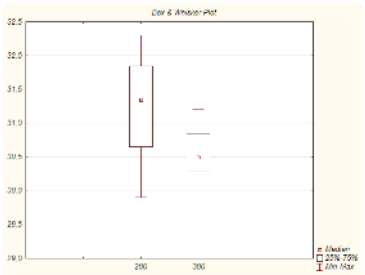
Nonivasive prenatal testing of Down's syndrome and other common fetal aneuploidies using digital PCR

Market – **prenatal non-invasive testing of Down syndrome and other aneuploidies. The morbidity rate is 1:700, the risk increases dramatically with age of pregnant woman. The potential market capacity is 2 000 000 tests per year in Russia, and 35 billion dollars in the world.**

Product – test system for non-invasive prenatal testing of Down syndrome and other common aneuploidies. Revealing feature of the test system is a focus on the digital PCR method, which provides the high diagnostic performance and makes it available for almost every laboratory.

Current condition – We have a prototype kit for the Down's Syndrome detection in the fetus using a pregnant mother's blood since 9 weeks. The project is supported by the Foundation for Assistance to Small Innovative Enterprises in the form of Start1 and Start2 programs, and also is supported by the Scolkovo Fund and is its resident.

	Wilcoxon Matched Pairs Test (Spreadsheet1) Marked tests are significant at p <,05000			
Pair of Variables	Valid N	T	Z	p-value
200 & 300	11	0,00	2,934058	0,003346



Personal identification and paternity testing

Market - **there are nearly 5% of men bringing up non-relative child without knowing about it in the world. There are about 10% of parents which are not sure in raising their native child.**
The tests are very expensive and only focused on the sequencing (expensive and complex in implementation technology).

Product - There is a diagnostic solution for personal identification based on the real-time PCR technology which is generally available and inexpensive.
It can be used both in the "family medicine" (paternity, maternity and other family relationships), as well as in forensics and disaster medicine (identification of the criminals).

Current condition - We have a prototype kit, project underway, supported by the Ulnanotech. The project is implemented in partnership with FMBA.
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Noninvasive prostate cancer diagnostics using PCA3 marker

Market – prostate cancer is the third of the most common oncopathologies, **there are about 400 000 new cases of prostate cancer in the world each year, and 15 000 in Russia. On the average, there are 214 incidence cases per 100 000 men in the world. The group of risk consists of the men older than 40 years.** The group of people pertain to screen for prostate cancer is estimated at 29 million people in Russia, more than 1.5 billion people in the world.

Product – A test system for the diagnostics of prostate cancer by the urine of the patient. Advantages – it has specificity towards cancer process in the prostate gland; it is non-invasive and can be conducted in any PCR-standard equipped laboratory.

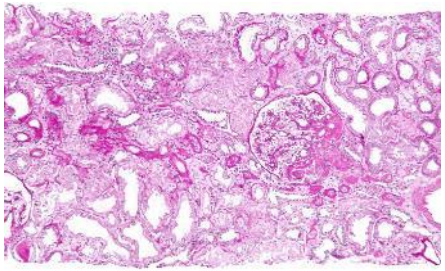
Current condition - We have developed product based on the PCA3 gene expression. The product is at the stage of registration, passed through extensive clinical trials, has an application for Eurasian patent and a number of scientific publications. The new development of the second generation of the product is started. It will include an analysis of the chimeric gene **TMPRSS2-ERG**. The project is implemented in the partnership with the Kazan Cancer Center.

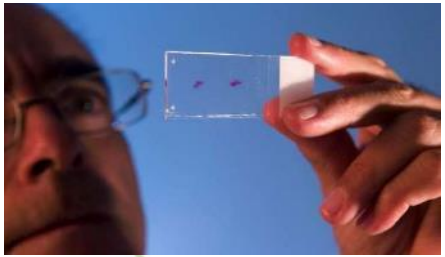
A kit of reagents for the epigenetic determination of prostate cancer

Market – **the complexity of the analysis based on prostate biopsy, the absence of hardware-based tests.** The market capacity - more than 50 thousand biopsies per year in Russia.

Product – A new test system is developing to minimize the disadvantages of prostate cancer diagnostics based on biopsy – **the use of the epigenetic methylation analysis, the accuracy of which is more than 90%.** Advantages: applying epigenetic approach to estimate the level of gene methylation for the prostate cancer diagnosis allows determine clearly the presence or absence of a malignant tumor.
The results of this analysis allow to get a precise diagnosis (with accuracy more than 90%). The level of methylation fluctuates before the changes become visible by the microscope. So it becomes possible to establish earlier and accurate diagnosis.

Current condition –The project is on the stage of approval and is implemented in the partnership with the Kazan Cancer Center.





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Early diagnosis of cervical cancer

Market – **one of the most common cancer pathology of women.**
There are more than 500 000 cases in the world and more than 12 000 cases of cervical cancer in Russia, 12: 100 000. The incidence peak occurs in age of 35-55 years, it is a socially significant pathology. Key of successful recovery is in the early detection of disease. There are a very few of reliable screening tests.

Product – molecular genetic test system for the early detection of cervical cancer, based on the methylation of promoter suppressor gene DAPK1 analysis. It has no direct analogues; the sensitivity and specificity of the methodic are more than 95%; non-invasive analysis – it is based on the cervical swab study. The test can be conducted in any PCR-standard equipped laboratory.
The test cost is estimated at 1 500 rubles.

Current condition - project underway is supported by the Foundation for Assistance to Small Innovative Enterprises, is implemented in partnership with the "Consilium" clinic

Test system for diagnosis of mutations in 21-hydroxylase gene

Market – **The morbidity rate is 1:1 000 among women,** mutations in the 21-hydroxylase gene lead to the congenital adrenal hyperplasia, are the common cause of infertility.
There are no reliable test system in the market.

Product - a new diagnostic panel is able to determine the **11 major mutations leading to deficiency of 21-hydroxylase.** Technology: the multilocus allele-specific PCR amplification. The advantages: the ability to reliably identify mutations, their form of inheritance (homo-heterozygous), and accordingly, cause of Congenital Adrenal hyperplasia, infertility and prevent complications in children. Available for any clinical laboratory.

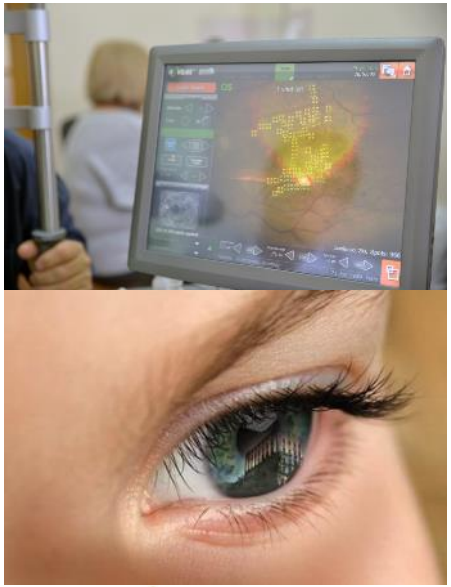
Current condition - project underway is implemented in partnership with the “IDK" clinic.

Diabetic retinopathy

Market – There are **366 million of patients with diabetes in the world, over 50%** of them have diabetic retinopathy (DRP). DRP is a **leading cause of vision loss** in working-age population in the most countries of the world (Uemura A..2013; Liu L, 2011, Zheng Y, 2012). According to WHO **timely laser coagulation of the retina allows to prevent deterioration and development of diabetic macular edema (DME) in 70% of cases.**

Product - a new diagnostic panel is able to determine the genetic risk of diabetic retinitis. Early treatment and prevention of DRP are possible in the case of affordable and mass screening of predisposition to DRP among diabetic patients. Using the system of assessing the state of specific genes may determine the risk of DRP reliably, and thus determine the indications for laser photocoagulation to prevent DRP. The analysis will be available for any clinical laboratory

Current condition - project underway is implemented in partnership with the Samara clinical ophthalmologic T.I. Eroshevsky hospital.



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Congenital deafness testing

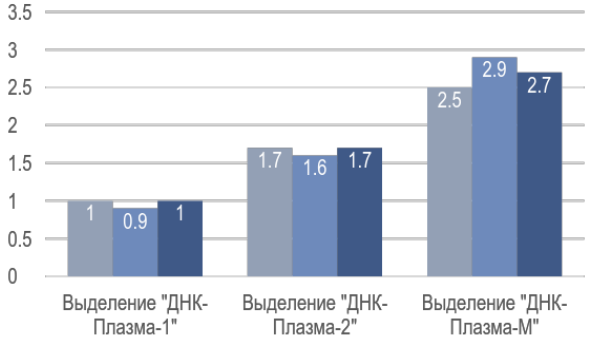
Market – There are **360 million people suffer from disabling hearing disease in the world (5% of the population)**. **1 of 500 newborns has a hearing disorder. There are 13 million people with hearing disorders In Russia**. Hearing disorder can be intrinsic (genetically determined) or acquired. Industry problems: lack of commercial reagents for genetic diagnosis of hearing disorders. For the subsequent successful treatment (including cochlear implantation) it is necessary to identify true cause of hearing disorders.

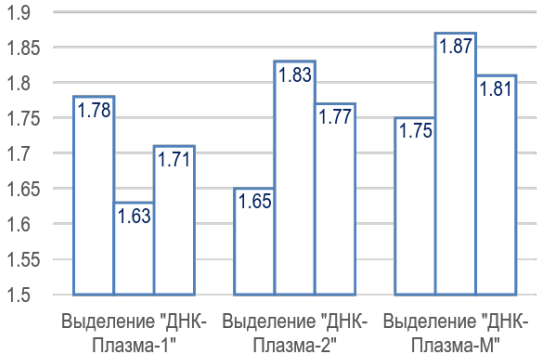
Product - molecular genetic test system for early detection and updating of indications for surgery and aftertreatment for of examinees with Nonsyndromic Hearing Loss and Deafness, DFNB1. There are no direct analogues in the world.
Based on the mutations in 35delG GJB2 gene detection by Real-Time PCR. The sensitivity and specificity of the method are more than 95%. The method is able to be used in the first days of life. The analysis time does not exceed one working day.

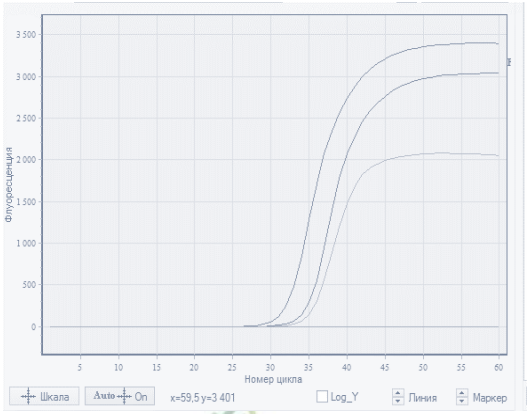
Current condition - project underway is supported by the Foundation for Assistance to Small Innovative Enterprises.

Kits for nucleic acid extraction

- We also developed and produced our own kits for the nucleic acids extraction.
- Kits based on the principle of sorption on silica-based columns for isolation of DNA / RNA from whole blood and plasma kits based on the principle of separation the nucleic acids on the surface of the micro-sized magnetic beads.







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The automatic nucleic acids extraction.

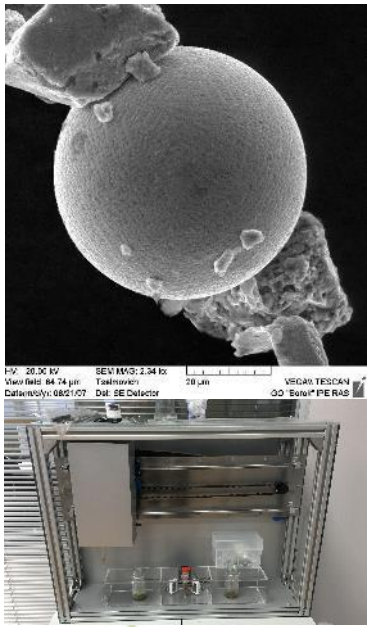
Market – **PCR laboratories**

Product - Desktop device that makes automated sample preparation available to any laboratory. This device simplifies and harmonises the procedure of isolating and purifying nucleic acids and proteins by the complete automation of the standard procedures. The Innovative device uses high technologies of operating with the magnetic microspheres.

The innovative device will:

- **Save working time by automation manual operations;**
- **Use proven kits**;
- **Conduct the isolation and purification of DNA, RNA or proteins from 1-24 samples per a single run;**
- **Standardize results;**
- **Increase efficiency and productivity.**

Current condition - project underway is supported by the Foundation for Assistance to Small Innovative Enterprises.

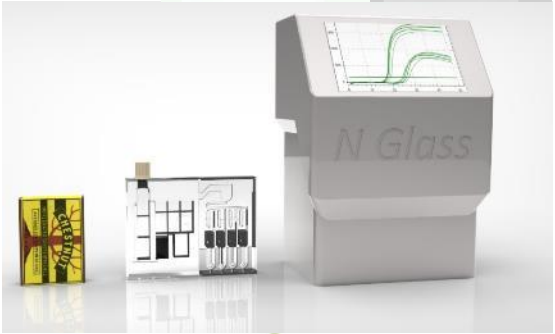


Automated system for molecular diagnostics

The target audience – the main users of the complex are the **medical facilities (hospitals), the laboratory and the clinic**, experts biological laboratories tasked with the rapid molecular diagnosis on the spot taking biomaterial. **For home use** – this device can be used to test food at home, in the field, veterinary and agriculture.

Intended use - automated system for molecular diagnostics is designed for the molecular analysis of biological material to be examined both in the field and in the laboratory, and the device produces DNA extraction and PCR diagnostics implements automated. For analysis, it is only necessary to manually using a pipette, add biomaterial cartridge analyzed for DNA extraction and PCR, and the remaining operations and analysis device will itself automatically.

Product - Desktop device that makes automated sample preparation available to any laboratory. This device simplifies and harmonises the procedure of isolating and purifying nucleic acids and proteins by the complete automation of the standard procedures. The Innovative device uses high technologies of operating with the magnetic microspheres. This device is applicable not only in the laboratory, but is also suitable for non-professional use. Its scope is not limited to medicine, **it is possible used to test the food at home, in veterinary medicine and agriculture.**



Automated complex molecular diagnostics consists of:

- **Cartridge for DNA extraction and PCR**
- **Base station**
- **Cloud service**

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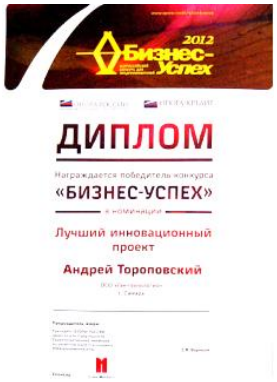
The team’s rewards



- ✓ Start-1 AF MP NTS - 4 projects
- ✓ Start-2 MP PT NTS
- ✓ Skolkovo residency
- ✓ Gold medal in Seoul
- ✓ Gold medal from Taiwan
- ✓ The winner of the "Business Success 2012"
- ✓ The winner of the regional competition "Young Entrepreneur 2012
- ✓ Best Innovative Product 2014
- ✓ The winner in the Innovation Competition «U-Novus 2015"


ДИПЛОМ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