

GROUP
ALKOR BIO

BIOTECHNOLOGICAL GROUP:
RESEARCH, DEVELOPMENT, MANUFACTURE



GROUP

ALKOR BIO



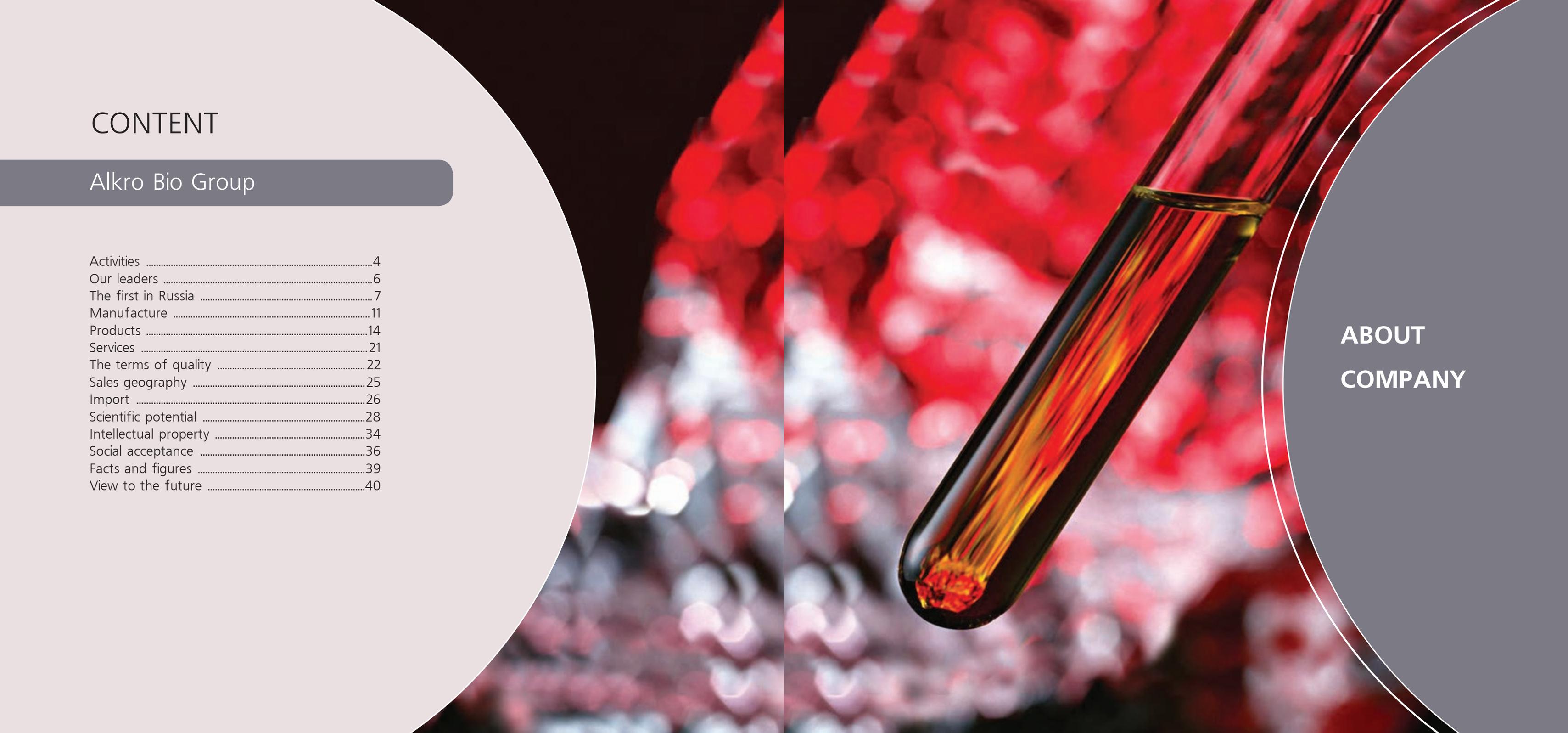
- medical biotechnologies
- high-tech manufacturing
- own developments
- high quality of products
- continuous development

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Alkro Bio Group

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ABOUT COMPANY



ACTIVITIES

ALKOR BIO GROUP

Was found
in 1992

IS ONE OF THREE LEADERS

OF RUSSIAN MARKET OF KITS REAGENTS FOR
LABORATORY DIAGNOSTICS

Ranks the FIRST POSITIONS

A MANUFACTURER OF PRODUCTS FOR HORMONAL AND
IN-VITRO ALLEGRO DIAGNOSTICS

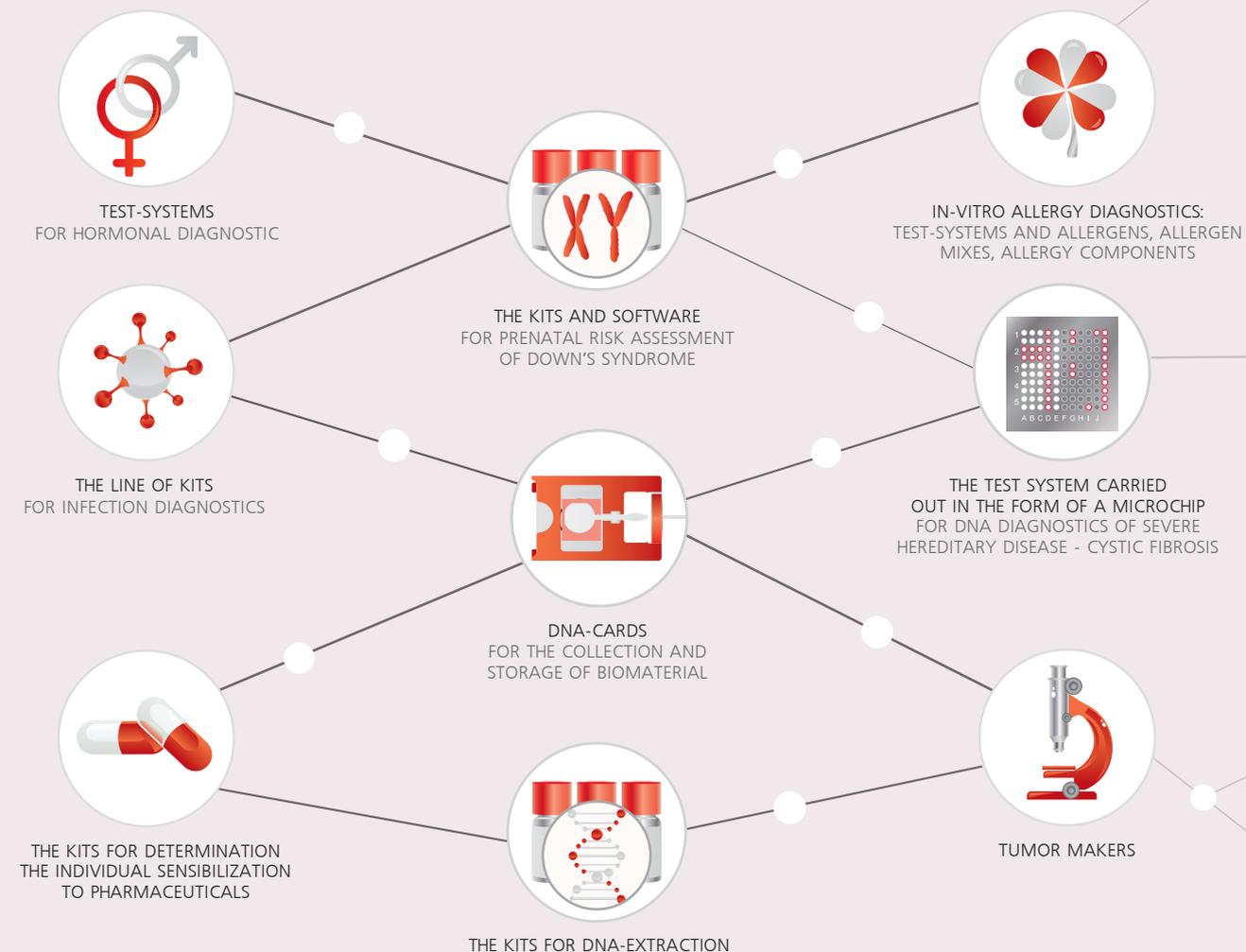
Alkor Bio Group incorporates 10 companies, three of them are engaged innovative developments. One of the companies of Alkor Bio Group is the resident of innovation centre "Skolkovo".

Specialization of Alkor Bio Group is the development, manufacturing and production of kits reagents for laboratory diagnostics with ELISA and PCR methods. One more line of activity is development of cell technologies.

Besides, Alkor Bio Group provides people services in the collection and storage the cord blood stem cells in Stem cell bank "Trans-Technologies" and invests in high-tech projects in the field of biotechnologies.

THE COMPANY'S product catalogue comprises more than 80 names of kits.

ALKOR BIO GROUP IS LAUNCHING MORE THAN 300 THOUSAND KITS REAGENTS EVERY YEAR. MOST OF THEM ARE INNOVATIVE, UNIQUE FOR THE RUSSIAN MARKET; SOME OF PRODUCTS AND TECHNOLOGIES OF ALKOR BIO GROUP HAS A WORLD NOVELTY.



OUR LEADERS



CLUSTER OF HIGH MEDICAL BIOTECHNOLOGIES

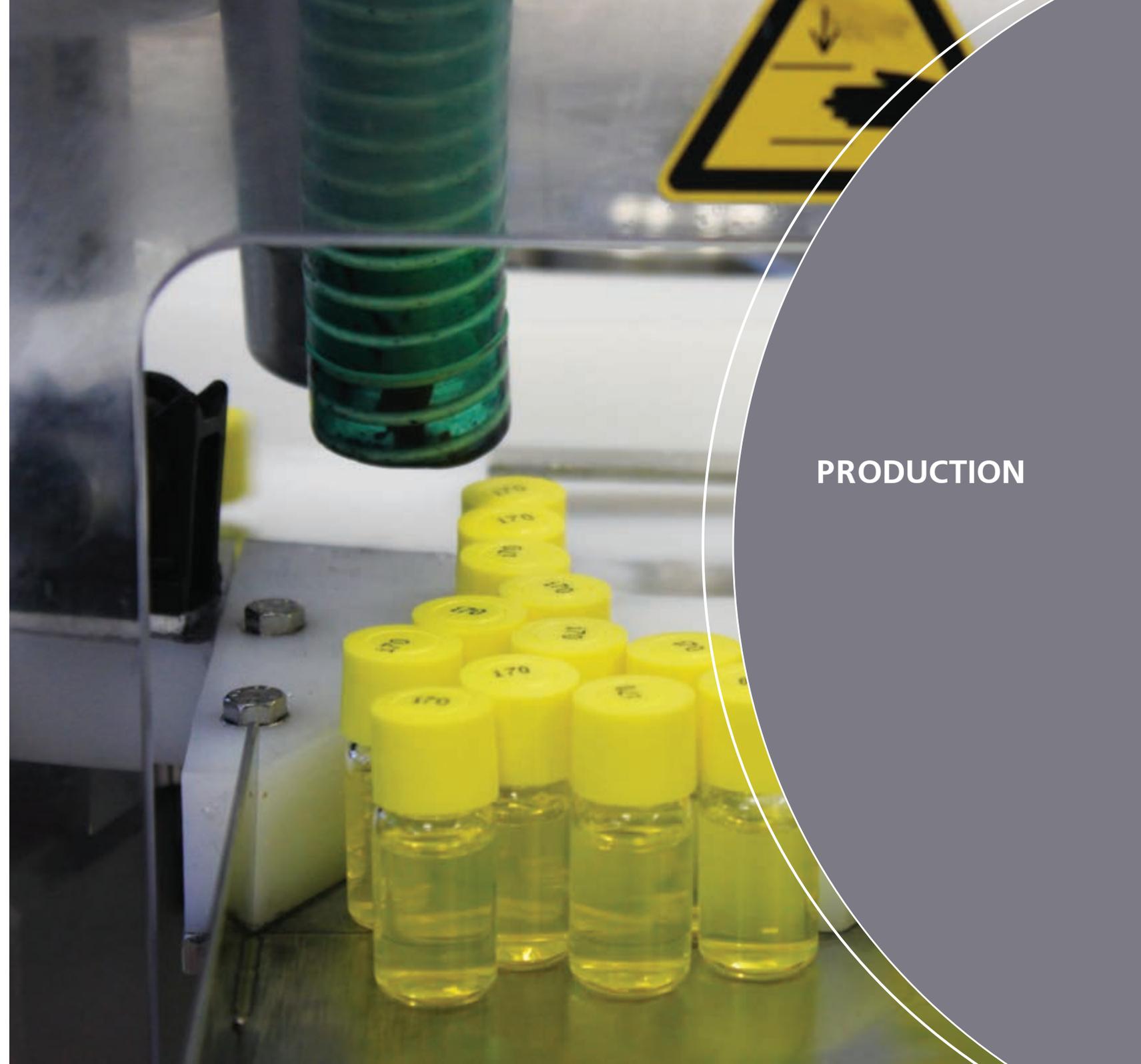
<p>Alkor Bio Company Ltd.</p> <p>Certification, production and realization of kits for ELISA and molecular-genetic analyzes</p>	<p>Vega Ltd.</p> <ul style="list-style-type: none"> • Development reagent kits for laboratory diagnostics of infectious, allergic, endocrine, cancer and hereditary diseases, their verification and implementation in production • Validation of developed commercial products in the experimental groups on clinical bases
<p>Trans-Technologies Ltd.</p> <ul style="list-style-type: none"> • Research of stem cell biology • Pre-clinical research on application of stem cells in different pathologies • Verification methods, patenting and development of protocols for mass application of stem cells in clinical practice • Banking hematopoietic of cord blood stem cells • Development the line of new generation bioactive wound coverings 	<p>Sequoia genetics Ltd.</p> <ul style="list-style-type: none"> • Development kits in multiplex format for diagnostics of infectious diseases and molecular-genetic diagnostic • The resident of innovation centre "Skolkovo" <p>Diagnostic centers Alkor Bio Ltd.</p> <ul style="list-style-type: none"> • Approbation of the kits its own production • Primary screening of blood serum which is used for quality control and certification of the new series kits • Research of clinical material for development the new kits

ALKOR BIO GROUP IS THE FIRST RUSSIAN COMPANY, WHICH HAS DEVELOPED AND LAUNCHED TO THE MARKET:

- **The test-system in DNA-biochip form for molecular-genetic diagnostic of cystic fibrosis**

Test-system "Cystic Fibrosis-BioChip" allows you to make a diagnosis in the first days of a child's life quickly and reliably. This test-system based on the principle of microarray analysis. This innovation product can be used both for neonatal screening and cystic fibrosis screening for family planning. The uniqueness of kit "Cystic Fibrosis-BioChip" is that it allows you to analyze 25 mutations of the CFTR-gene most important for Russian population at the same time. Alkor Bio Group has developed a software "Master-Microchip" for automatically interpretation of test results.

- **Extra-DNA-Bio – the kit for DNA extraction from dried blood spots**
It is only one domestic kit for DNA extraction from a specified biomaterial.
- **DNA-cards for the collection and storage of biological material samples**
Application of DNA-cards allows you to collect samples of biological material, blood or saliva, and store them at RT in the compact card files.
- **Allergy components for mass using in clinical practice of in vitro allergy diagnostic**
Allergy components are individual allergenic proteins which can be obtained by extraction from natural sources (natural highly purified allergens) and by molecular-biological methods (recombinant allergens). Component's allergy diagnostic is a modern approach researches the causes of allergic reactions and destination the right treatment.



MANUFACTURE

Alkor Bio Group has own building with a general square 7500 square meters, which includes:

S = 7500 M²

- Manufacture
- Stem cell bank
- Seven research laboratories
- Warehouses of the raw materials, intermediates and finished products
- Administration

Laboratories use modern high-tech equipment. The cleanroom complying with international GMP standards was set up for the stem cell bank. The warehouse is equipped with modern refrigeration units with electronic temperature control system.

The modern automatic line is using for manufacturing immunobiological tablets. It is using for dosing of antibody solution (antigens) for sorption, incubation and washing off the tablets. Each tablet has an individual number and barcode. With the release, all information about the technological operations and modes for each plate is introduced in the installation database.

For entering antibodies the line is equipped with high-precision dosing devices, high accuracy of which is protected by several patents of the manufacturer. The incubation boards is going automatically within the line to ensure the uniformity and reproducibility conditions for each tablet. Drying boards is carried out in a gentle vacuum.



**Bottling speed –
up to 5000 bottles
per hour**

Bottling the reagents is carried out on three lines of automatic filling and capping of bottles. Bottling is carried out in 4, 20, 50 and 100 milliliters bottles and tubes automatically in laminar flow of sterile air. These conditions of the Bottling allow you to achieve high product stability. Productivity of automatic lines – up to 5000 bottles per hour.

Bottling area is equipped with freeze-dryer which is developed specially for Alkor Bio Group in Germany. This freeze dryer is automated and computerized completely. It allows controlling and managing all process parameters in real time. In addition, the unit is equipped with CIP system allowing for an self-cleaning of the working area of the dryer automatically.

**Purifying
deionised water**

Purifying deionised water is used for making all kit's components. The water is produced in a special water conditioning section. The water conditioning process is automated completely: urban water passes through the stages of coarse and fine mechanical cleaning, softening and removing the chlorine from water, osmosis and cleaning on ion-exchange resins. The water with resistivity up to 18 Mhom per sm is used for production. The recipe of the components includes mostly compounds of high purity and quality delivered by known manufacturers of chemical raw materials.

**The resistivity
of water:
> 18 Mohm per-sm**

Storage of the raw materials, intermediates and finished products is carried out at the company's warehouses, which have all the necessary storage modes.

A unified temperature control system is used for all warehouses. In case of any deviations from the norm in conditions of storage It can alert engineering services about it.

Each product has the own barcode. It is necessary to order's assembly and shipping of products. The application of such automated system eliminates the possibility to mix the kits by their names, series and quantity.

Packaging area has two automatic labeling lines, where the labeling of kit's components is (bottles of reagents).



PRODUCTS



Alkor Bio Group produces a full range of test systems for hormonal diagnostics:

- adrenal function
- reproductive function
- thyroid function
- iron-deficiency anemia



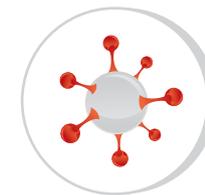
The kits and software for prenatal screening for Down's syndrome

- kits for the determination of biochemical markers on 1st and 2nd trimesters of pregnancy
- Prenatal Risk Assessment Software Isida™. This software allows to calculate risk of Down's syndrome, Edwards's syndrome, neural tube defects, and fetal growth retardation. Three variants of screening protocols are possible: only for the 1st pregnancy trimester, for the 2nd pregnancy trimester, and also by results of both trimesters estimation. Protocols of risk assessments support not only biochemical and ultrasound markers data but also woman's age, her weight, type 1 diabetes mellitus incidence. For the first time chromosomal abnormalities during previous pregnancy and woman's ethnicity are considered in risk calculation.



Tumor makers

- Tumor markers are complete protein substances which are produced by the body in response to cancer growth or by the cancer tissue itself. Some tumor markers are specific, while others are seen in several cancer types. Tumor markers can be used to examine clinically relevant questions:
- revealing groups which are under high risk of cancer development
- localization of a tumor before more detailed investigation
- prediction of the diseases remission after the termination of treatment
- estimation of operative treatment effectiveness
- control of the treatment process



Infection diagnostics

- HIV diagnostics
- Diagnostics of Viral Hepatitis (B & C)
- ToRCH-infections
- Sexually Transmitted Infections



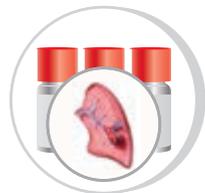
In-vitro allergy diagnostics.

- the kit for the quantitative determination of total immunoglobulin E (Total IgE) in human serum
- the kit for quantitative determination of specific immunoglobulin E (Spec IgE) in human serum
- the main groups of allergens: foods, drugs, epithelia, mites, moulds, dusts, insects-venoms, grasses, weeds, trees, occupational, parasites and etc.
- allergens mixes
- allergens components (recombinant and native)

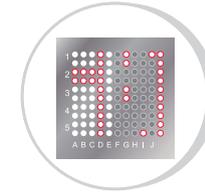


The DNA cards for the collection and storage of biological material samples

- DNA Card is a porous material impregnated with reagent complex that lyses cells, denatures proteins and helps DNA storage, preventing its destruction and killing pathogens. The DNA card allows collecting the biological material samples, blood or saliva and storage it in compact card files at room temperature

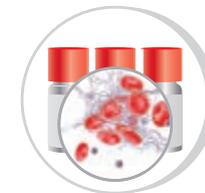


The kit of reagents for the detection of hereditary thrombophilia and the risk assessment of deep vein thrombosis and pulmonary thromboembolism



Microchip for DNA diagnostics of cystic fibrosis and software for automatic interpretation of the results

- the kit "Cystic Fibrosis-BioChip" is unique because it allows detecting 25 mutations at the same time that are found at high frequency in European populations (including Slavic populations) and cause severe disease phenotype. Only 1 ng per ml is a sufficient concentration of DNA for assay. The source of the genomic DNA could be venous blood, buccal epithelium or dried blood spots. The "Cystic Fibrosis-BioChip" kit allows detecting cystic fibrosis patients in 95% of cases
- the program "EIA-Master" is software for automatic interpretation of the results. This program analyzes the image from scanner and determines whether there are clinically important mutations of CFTR gene, as well as homo- or heterozygous mutations for the patient. This software allows you to save the results on the computer, add the information about patient and institution, which conducted the research



The kits of reagents for the determination of individual sensitivity to indirect anticoagulant (warfarin)



The kits for DNA extraction

- rapid-DNA-Bio. The kit for rapid DNA extraction based on thermic lysis, consisting of additional component – coprecipitant of inhibitors, which increases quality of the sample purification during the centrifugation.
- the kit based on Ethanol precipitation is suitable for genomic DNA extraction from dried blood spots, using broadly during newborn screening
- the kit for extraction of nucleic acids by magnetically controlled adsorption on silica gel method. Coated with silica gel magnetic particles are used as sorbent. Due to this centrifuge is not necessary to wash the precipitate. All you need is a magnetic tripod. This method allows you to work without expensive equipment. Therefore, you need much less time for the extraction of nucleic acids than using other techniques. Possibility of automating the process is the important magnetically controlled extraction



Specific components of test systems for

- conjugates
- antibodies
- oligonucleotides
- reagents for PCR



SERVICES



SERVICES

FOR BUSINESS

- The development and production of test systems for molecular-genetic researches based on PCR method with detection of amplification products in real time
- The synthesis of simple and modifying oligonucleotides
- The synthesis of conjugates
- Freeze drying. Productivity of the drying chamber is 50 kg per day. In addition to freeze-drying Alkor Bio Group offers the following services (related to the solution, dried in bottles): solution preparation, bottling solutions, sealing bottles of dried solutions, marking/labeling

FOR PEOPLE

- Collection, separation and storage of cord blood stem cells in the Stem cell bank "Trans-Technologies"

THE TERMS OF QUALITY

All kits for laboratory diagnostics have a Registration Certificate and CE-mark



Alkor Bio Group quality management system is certified in accordance with the requirements of international standards ISO 9001 and ISO 13485 by British auditing company Lloyd's Register.

All diagnostic kits producing by Alkor Bio Group are registered in the Federal Service for Surveillance in Healthcare (Roszdravnadzor) and have a CE-mark. It allows Alkor Bio Group to export their products to EU market.

A cleanroom complying with the international GMP standards

Quality control is performed at all stages of production, from raw materials to finished products.

Laboratories use modern high-tech equipment. The cleanroom complying with the international GMP standards. It means that the private storage of hematopoietic stem cells of human umbilical cord blood is carried out according to European standards in the field of cellular technologies.

All laboratory staff has a higher biological or biotechnological education and high qualification. Some of them have a successful experience in the best foreign R&D centers and biotechnology companies.

Alkor Bio Group renders a range of services: technical support, training, on-time delivery and consulting support.





SALES GEOGRAPHY

Alkor Bio Group sells the products throughout the Russia. A dealer network consists with more than 40 companies in every Russian region: from Vladivostok to Kaliningrad. We have two representative office in Moscow and Roston-on-Don.

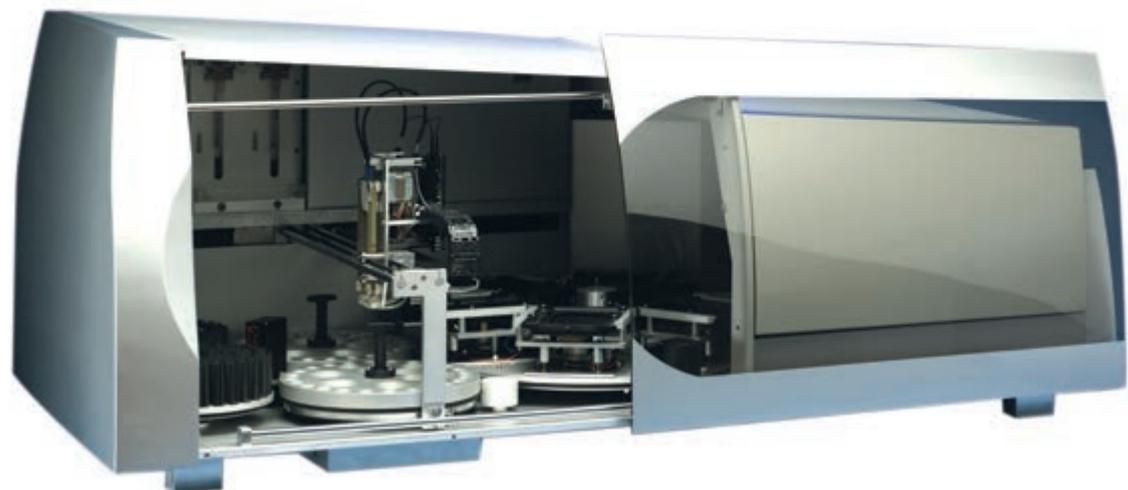
Alkor Bio Group exports products to the following countries:

- | | |
|--|---|
|  Belorussia |  Italy |
|  Georgia |  Croatia |
|  Kazakhstan |  Brazil |
|  Kyrgyzstan |  Argentina |
|  Ukraine |  Turkey |
|  Latvia |  India |
|  Lithuania |  Iran |
|  Germany | |

IMPORT

Alkor Bio Group is exclusive dealer of Automated EIA-analyzer "Alisei Q.S." on Russian and CIS market. The developer of this analyzer is SEAC Company (Italy). This high-speed analyzer could significantly improve work efficiency of diagnostic laboratory. At present time Alkor Bio Group is finishing the transfer of "Alisei Q.S." production in Saint-Petersburg.

"Alisei Q.S." – is the analyzer for all types of immunoassay with 6 tablets



SCIENTIFIC
POTENTIAL

SCIENTIFIC POTENTIAL

The first research laboratory was found in 1992 with purpose in order to develop own diagnostic kits and launch them to the market.

VEGA

Laboratory of ELISA test-systems development

Specialization of this laboratory is the development of test systems for hormonal, infectious and oncological diagnostics. At the present time laboratory is developing an ELISA test-system for quantitative and qualitative determination of different analytes in serum and plasma of human blood. Use of own certified reagents allows to laboratory staff to create an ELISA test-systems with high quality and affordable price.

Biochemical laboratory

Biochemical laboratory ensures the production of biologically active components used in the production of diagnostic test systems. Laboratory staff repurifies the monoclonal antibodies, recombinant and native proteins, and control the quality of all purchased albuminous preparations used in the production of test systems. Synthesis of antibody conjugates with enzymes, biotinylation of antibodies and allergens, obtaining conjugates of steroid hormones and thyroid peroxidase horseradish: all of this are accomplished in biochemical laboratories. Modern equipment and thorough quality control allow obtaining reproducible test systems components from the lot to lot, and it ensures the high quality of products produced by Alkor Bio Group.

The hybridoma laboratory

The main task of this laboratory is development and production antibodies and antigens for the launching kits, and creating new hybridomas and recombinant proteins. The laboratory work is aimed at development of own antibodies and recombinant proteins for creating test-systems because it allows to decline expenditures.

Reagents
of own
production

Laboratory of Allergology

The aim of Laboratory of Allergology is development and launching allergens, mixes of allergens, allergy components for an Alkor Bio "Allergy ELISA human specific IgE" diagnostic kit for detecting allergen-specific immunoglobulin E in blood. The main task of laboratory research work is development of other diagnostic tools for the detection of different types of allergen reactions.

Laboratory of Molecular Diagnostics

The aim of this Laboratory is developing novel (for the company and the Russian market) diagnostic technologies. The innovations include DNA and protein microarrays, immunoblotting and immunochromatography tests which are required for development of such fields as human genetic diagnostics, allergologic and infection diagnostics. Another field of the laboratory research is development of up-to-date test systems in real time PCR format for detection of wide spectrum of bacterial and virus pathogens. Laboratory of molecular diagnostics includes an oligo synthesis group, which synthesizes primers, fluorescent probes for real-time PCR and other oligonucleotides necessary for the development and manufacture of diagnostic systems.

Creating a
panels of
modern test
systems



SEQUIOA GENETICS

The Laboratory of "Sequoia genetics" company

The Laboratory of Sequoia genetics company develops kits in multiplex format for diagnostics of infectious diseases and molecular genetic diagnostics. Sequoia Genetics creates a new platform for development of diagnostic tests based on real-time PCR that allows at least a 3-fold increase the degree of multiplexing in comparison with classical methods. The high level of multiplexing makes it possible to reduce the cost per analysis by reducing instrumentation time, reagent consumption and reduce the amount of manipulation.

TRANS-TECHNOLOGIES

The laboratory of "Trans-technologies" company

The laboratory is developing and introducing in clinical practice the technologies of treatment using stem cells. Since 2004, "Trans-Technologies" company took part in limited clinical developments on the application of autologous (own) mesenchymal stem cells of human bone marrow to treat several diseases in cardiology, neurology, oncology and hematology, traumatology, angiology and dentistry. As a result the patients on methods of treatment using stem cells have been obtained.



In 2005 “Trans-Technologies” company has opened the first in Saint-Petersburg Stem cell bank and starts rendering a full range of services on long-term storage of cord blood stem cell’s concentrate.

The laboratory staff has developed a new generation of biologically active wound covers. They are intended for the restoration skin damaged by thermal and radiation injuries, after correction of cosmetic defects and the venous ulcers healing.

There are 2 large projects in company at the present time:

- Preclinical evaluation of therapeutic drug efficacy of human Multipotential Mesenchymal Stromal Cells of Bone Marrow (MMSCBM) in the experimental ischemic stroke in rats. This research was carried in a strictly controlled environment with clean laboratory animals, vital activity of which corresponds to the highest standards. The result of the research should be a quantification of therapeutic effect. It should allow carrying out further clinical development of the drug.
- Research of the gene expression in the brain tissues bordering the lesion of rats with experimental stroke: both untreated and after MMSCBM-treatment. In the future it will make possible to detect entry points MMSCBM (so called “target”) in brain tissue and clarify the mechanisms of cell’s therapeutic effect.

Projects are carried out in cooperation with the Institute of Experimental Medicine RAMS, St. Petersburg, Russia, and the Institute of Neurosciences of the Newcastle University, Newcastle, UK.

INTELLECTUAL PROPERTY

Alkor Bio Group has twelve patents in allergy diagnostics, diagnostics of hepatitis C virus, biologically active wound covering, on the biochip for the diagnostics of cystic fibrosis, on treatment methods using stem cells: severe fractures, periodontitis, and mental retardation.

Patents:

Patentee "VEGA" Ltd

№ 2007142478/15

issued 08.11.2007 Soft form of food allergens for skin testing and patch applicator for skin application

№ 134171

issued 27.12.2012 Hybridization chamber

№ 2529717

issued 06.08.2014 Biochip test-system, primers and targets for identification of mutations in the human CFTR gene

Patentee "Trans-Technologies" Ltd

№ 2296328

issued 27.03.2007 Method of determining susceptibility to cancer and a diagnostic kit for its implementation

№ 2303632

issued 27.07.2007 Method of obtaining mesenchymal stem cells from bone marrow of mammals and the population of mesenchymal stem cells obtained in this way

№ 2303631

issued 27.07.2007 The medium for cryopreservation of mesenchymal stem cells and biotransplantat with its use

№ 2303462

issued 27.07.2007 Biotransplantat and method of treatment of mental retardation

№ 2309756

issued 10.11.2007 Method of treatment of false joints by transplantation of autologous mesenchymal stem cells. Biotransplantat for its application

№ 2370227

issued 20.10.2009 Method of treatment of multisplintered and multiple fractured of long tubular bones

№ 2368338

issued 20.10.2009 Method of reconstruction of periodontal tissues

№ 2430743

issued 10.10.2011 Biologically active wound dressing

Patentee "Diagnostic Center Alkor Bio" Ltd

№ 2370776

issued 20.10.2009 The set of antigens for the separate detection of antibodies to structural and nonstructural proteins of hepatitis C virus



SOCIAL ACCEPTANCE

Alkor Bio Group is:

- A winner of the Ministry of Education and Science of the Russian Federation competition about selection of organizations for the right to receive subsidies for the implementation of integrated projects for high-tech manufacturing;
- A finalist of the nationwide ranking of fast-growing innovative companies "technical success";
- A three-time winner of the competition for the prize of the Government of St. Petersburg for the best innovative project implemented within the cluster;
- A two-time winner of the "Best Exporter of St. Petersburg" competition;
- A two-time winner of the competition for the best innovative projects in the field of science and higher education of St. Petersburg;
- A member of the national program "Oncology";
- A winner of the award of the grant Skolkovo for the best project among residents within the cluster of biomedical technologies;
- A six-time winner of the award of the grant of State Organization "Fund for Assistance to Small Innovative Enterprises in the scientific and technical field" for the implementation of an innovative project.

The president of Akor Bio Group Dmitry H. Polyntsev is a two-time laureate of an independent Business award "Chief of the Year" in nomination "Chief – Innovation - Manufacturer".



FACTS
AND FEATURES



FACTS AND FEATURES

Alkor Bio Group:

The market launch in **1992**

10 companies, **3** of them are engaged in innovative developments

More than **40** distributors in Russia

Production over **300** thousand kits of reagents for more than **80** titles, over **600** allergens and allergy components

The CIS market launch in **2002**

7500 sq.m. of the manufacturing areas

7 research laboratories

Over **17%** of the ELISA allergy diagnostic market in Russia

The middle age of the staff is **35** years

300 employees, **16** MSc, **1** PhD

12 patents

Over **40%** of hormonal diagnostics market in Russia

Export to **15** countries

VIEW TO THE FUTURE

In spite of the strong leadership, Alkor Bio Group continues to increase manufacture rates, developing new types of products complying with international standards, introduces modern technologies.

High quality of products, regular expansion of assortment, and attention to customer needs - just these principles of Alkor Bio Group allowed to succeed in the high biotechnology field.

Alkor Bio Group

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