Ministry of Education and Science of the Republic of Kazakhstan
Science committee

RGE "Research institute for biological safety problems"

Senior researcher,
Lab «Collection microorganisms»
Kairat TABYNOV
Main activities and institute structure

- performance of research works on tasks of Republican scientific and technical and international programs
- carrying out researches in the field of scientific and technical ensuring biological safety of the Republic of Kazakhstan
- basic researches in molecular biology and genetic engineering of microorganisms
- replenishment and maintenance of a collection of strains of microorganisms - causative agents of especially dangerous diseases
- development and improvement of manufacturing techniques of diagnostic and preventive preparations
- production and realization of biological preparations
- examination of a pathological material on diagnosis statement

In structure of institute there are 11 scientific divisions, and also production and auxiliary departments in which 278 people work. More than 100 people have the higher education, among which 3 doctors and 27 candidates of science.

Middle age of the research associate makes 35 years.
Scientific and technical programs and the projects realized at institute

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<td>1</td>
<td>STP O.0535 &quot;Monitoring, learning, development of diagnostic tools, prevention and treatment of flu &quot;influenza A/H1N1&quot; in 2009-2012</td>
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<td>STP O.0534 &quot;Equine influenza epizootological monitoring, development of specific prevention and diagnosis,&quot; 2010-2012</td>
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<td>STP O.0566 &quot;Developing a vaccine against tuberculosis for the Health of the Republic of Kazakhstan&quot; for 2011-2014</td>
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<td>4</td>
<td>STP &quot;Epizootological monitoring the circulation of infectious diseases in the population of saiga antelopes living on the territory of the Republic of Kazakhstan and the development of methods of prevention&quot; for 2012-2014</td>
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<td>STP &quot;Brucellosis in cattle: the monitoring of the epizootic situation, the development of diagnostics and prevention&quot; for 2012-2014</td>
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The institute is the winner of 7 projects (trivalent seasonal vaccine against flu, PRRSV inactivated vaccine, Bluetongue associated vaccine and others) in competition on grant financing for 2012-2014.
The highly pathogenic avian influenza A/H5N1 for the first time in Kazakhstan was registered in July 2005 in such oblasts as Pavlodar, Akmola, North-Kazakhstan and Karaganda. For the purpose of elimination and reduction the epizootic process in the infection nidus were slaughtered and killed more than 13 thousand heads of different species of domestic birds.

In 2009, in Kazakhstan were recorded 15 confirmed cases of A/H1N1 influenza among people. All of them got sick after foreign trips and suffered a mild form of the disease without complications.
For the first time in RK “Refluvac” manufacturing techniques - vaccines against A/H1N1 flu from a recombinant strain of NIBRG-121xp (NIBSC, reverse genetic), against pandemic flu of A/H1N1 are developed for country health care. Are carried successfully out preclinical and clinical (the I-II phase) tests of a vaccine of “Refluvac”.

The veterinary vaccine "Kazakhstan-15" an inactivated emulgated vaccine against a high-pathogenic avian flu is developed. Realization of this vaccine provided stability on an epizootical and epidemiological situation on bird flu in the Republic of Kazakhstan.

For the first time in Republic of Kazakhstan “Kazfluvac” manufacturing techniques - vaccines against high-pathogenic flu of A/H5N1 from a recombinant strain of A/AstanaRG/6:2/2009 (reverse genetic) are developed for health care. Preclinical and clinical tests (the I-II phase) “Kazfluvac” vaccines are carried successfully out.
Manufacturing scheme of Kazfluvac и Refluvac vaccines

Kazfluvac
productive virus – recombinant strain A/AstanaRG/6:2/2009 (H5N1), obtained with the method of reverse genetics at RIBSP

Preparation of the vaccine strain of influenza virus in 10-11 daily chicken embryos, harvesting of suspension and clarification

Inactivation of virus containing allantoic fluid with formaldehyde

Chromatographic purification and concentration of inactivated viral biomass with the help of sequential technological procedures of microfiltration, diafiltration and gelfiltration

Sterilizing filtration with the use of membrane technology

Sorption of pre-diluted sterile semi-finished product up to the required parameters on weight content of the hemagglutinin with aluminium hydroxide

Prepacking, packing

Refluvac
productive virus – recombinant strain NIBRG-121 xp (H1N1), obtained with the method of reverse genetics at NIBSC
Pre-clinical and clinical (phase I and II) trials of Kazfluvac и Refluvac vaccines

Pre-clinical and clinical trials of inactivated vaccines Kazfluvac и Refluvac were carried out on bases:

- "National center of examination of medicines, products of medical appointment and medical technology" MH Kazakhstan
- "Flu research institute", St. Petersburg, Russia
- "Toxicology institute" St. Petersburg, Russia
- "State research institute of standardization and control of medical biological preparations of a name L.A. Tarasevich", Moscow, Russia
- "State chemical and pharmaceutical academy", St. Petersburg, Russia
Volunteer’s Vaccination
Innovation Project

GMP CREATION – PRODUCTION ON RELEASE OF BIOLOGICS AT RIBSP

Aim: Establishment of universal production complex for biologics and diagnostical test-system with GMP requirements

Realization period: for 2012 - 2014

Total financing: - 3400,0 mln. KZT

Including:
- 2012 - 1100,0 mln. KZT
- 2013 - 1300,0 mln. KZT
- 2014 - 1000,0 mln. KZT
PROJECT PRODUCTION CAPACITY

- Realization of 9 of vaccine preparations and 10 of diagnostic test systems on the first stage will be organized.
- At a total of the planned volumes of production of live vaccine and diagnostic preparations will make 150 million doses per year.
- Technological line of production of the inactivated vaccines will allow to produce 21 million doses per year.
International cooperation

1. Cooperation with World Health Organization (WHO):
World Health Organization (WHO) is allocated the grant for development of seasonal influenza vaccine for 2011-2014 and the positive decision for co-financing of factory buildings on release of the preventive preparations (the Agreement № IER/SPHQ11-LOA-241 dated 11.24.2011) is received. The first part of the project directed on researches on development of technology is at present realized, plant construction on release of vaccines on the GMP standards further is planned.

2. Cooperation with the International scientific and technical center (ISTC):
Two projects with collaborator of the USA and Europe are carried out. Projects K-1925 and K-1704r.

- KZ-27 and KZ-30 projects are carried out.
- The Zone diagnostic laboratory (ZDL) is constructed and started.
- At a completion stage BSL-3 Laboratory construction.
- The offer on studying of Congo - the Crimean hemorrhagic fever together with the Texas University.

4. Cooperation with University of Vienna, Austria:
The project on receiving recombinant strains – candidates of a vaccine against tuberculosis and a brucellosis.

5. Cooperation with scientific centers of Russia:
Research institutes of Moscow and St. Petersburg on large-scale clinical tests of vaccines.
Thank you for attention!