CROATIAN INSTITUTE FOR TOXICOLOGY AND ANTI-DOPING

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INTRODUCTION

















HRVATSKO**NE DOPING**U

he basic goal of the Department for Anti-Doping of Croatian Institute for Toxicology and Anti-Doping (CITA) is permanent work on the protection of athletes' basic rights - to participate in sports without doping and to promote health, fairness and equality for all athletes in that manner.

One of our most important tasks in 2014 was to implement a harmonised, balanced and efficient anti-doping programme. A large portion of activities of the Department was conducted with regards to adopting and implementing the new international legal framework in the field of anti-doping in sports.

Since the new, significantly changed **World Anti-Doping Code** entered into force on 1st January 2015, and the new **International Standards** (International Standard for Testing and Investigations, International Standard for Therapeutic Use Exemptions, International Standard for the Protection of Privacy and Personal Information, International Standard for Laboratories and the List of Prohibited Substances and Methods) were adopted as mandatory documents for all signatories of the UNESCO Convention, our task was to ensure their professional translation, do the reviews of all the abovementioned documents and present the news in the field of anti-doping legislation to all interested parties. CITA had prepared the third draft of the third version of the CITA Anti-Doping Rules in accordance with the Model Rules, which were provided to all signatories of the UNESCO Convention by WADA as guidelines for creating national anti-doping regulations. After WADA confirmed that all relevant provisions of the 2015 Code have been included in the draft of CITA Anti-Doping Rules and approved its entire text, the Governing Council of CITA made the decision on adopting the Rules and its coming into effect on 1st January 2015.

All International Standards, as well as the new Code and the new Anti-Doping Rules have been published on our web site in November 2014 in order to enable athletes and all other participants in sports to inform and acquaint themselves with the new amendments on time.

When it comes to the implementation of doping controls, we have achieved the ideal rate of testing. The national programme encompassed 268 in-competition and 281 out-of-competition tests. The standards set by WADA were achieved in that field of work as well. A total of 798 tests were conducted (at both national and international events). The planned number of tests within the national testing programme was reduced due to budgetary amendments and decreased funding.

All our committees were active - the Hearing Panel of CITA, the Anti-Doping Appeal Panel of CITA and the Therapeutic Use Exemptions Committee. During 2014, six (6) suspensions were imposed on the account of doping-related offences.

In 2014, an encompassing doping prevention programme was conducted, which included a number of activities in order to achieve the best results possible, similarly to the years before. The education programme was based on our own experience, experience of other anti-doping organisations and WADA's recommendations. Around 2,100 athletes and support personnel have been educated through direct communication. As the steroidal module (the module aimed at detecting the androgenic anabolic steroids) is fully functional since the beginning of 2014, we pointed out that information during our lectures, aware that it is also one of the manners in which we can significantly impact the fight against doping. The anti-doping message is constantly being sent through our website and the **NEIDOPINGU** (tr. No to Doping) magazine.

We participated in the graduate study lectures at the University of Zagreb School of Medicine by being involved in the optional classes "Doping and Anti-Doping" for students of the 4th year of medical studies, as well as in the classes of the doctoral study at the Faculty of Kinesiology in Zagreb.

The employees of our Department also participated in various international conferences and projects.

Anti-Doping and Rational Pharmacotherapy Counselling Centre also started its activity.

Within the scope of research of the new immunochemical methods for the detection of peptides and anti-peptide antibodies used as doping in sports, a fast and simple procedure for extraction and analysis of bioactive components of peptide molecules was developed and applied on erythropoietin as a model.

THE REPORT

















IMPLEMENTATION AND IMPROVEMENT OF LEGAL FRAMEWORK

The most important part of activities of the Anti-Doping Department in 2014 was conducted in the field of adoption and implementation of the international legal framework related to anti-doping in sports. At the IV. World Conference on Doping in Sport held in Johannesburg from 12th to 15th November 2014, the fourth version of World Anti-Doping Code (the Code) was adopted. In addition to the new, significantly changed Code (a total of 2,269 amendments in the 4th version of the 2015 Code compared to the 2009 Code), new International Standards were adopted:

- ► International Standard for Therapeutic Use Exemptions
- International Standard for Testing and Investigations
- ▶ International Standard for the Protection of Privacy and Personal Information
- ► International Standard for Laboratories

All the adopted documents had a common date of entering into force - 1st January 2015, which meant that they would have to be applied in practice starting from that date. All of the Standards are mandatory for all signatories of UNESCO Convention. After the abovementioned Conference, WADA published the so-called "Model Rules" - a template for the anti-doping rules of national anti-doping organisations, based on the 4th version of the Code and the International Standards. In 2014, WADA sent the instructions and protocols for implementation of certain activities that had to be implemented starting from 1st January 2015 by all NADOs.

After WADA confirmed that all relevant provisions of the 2015 Code have been included in the proposal of the new CITA Anti-Doping Rules and approved its entire text, the Governing Council of CITA at its 4th session held on 15th October 2014 reached the decision on adopting the Rules and its coming into effect on 1st January 2015.

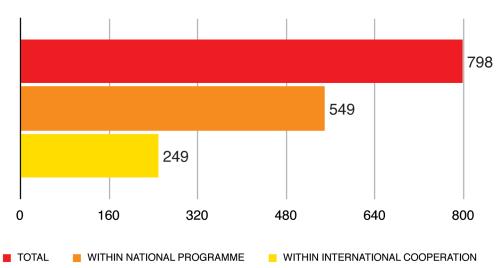
We ensured the professional translation of the new Code, all International Standards and "Model Rules", as well as the new List of Prohibited Substances and Methods as the fifth International Standard that has been continuously changing once a year. We provided support to the translators, did the expert reviews and visual unification of all the documents required for the work of a national anti-doping organisation and published them on our web site www.antidoping-hzta.hr. Besides that, we published the Anti-Doping Rules, the Code, the 2015 List and the Guide for Athletes in the printed form.

One of the steps in the implementation of the new anti-doping regulations was that they had to be presented to all employees of the Department, the Therapeutic Use Exemptions Committee of CITA, the Hearing Panel of CITA, the Anti-Doping Appeal Panel of CITA, all external associates, employees of the Ministry of Health involved in anti-doping activities, employees of the Ministry of Science, Education and Sports involved in anti-doping activities, the Croatian Olympic Committee (COC), the Health Commission of the Croatian Olympic Committee and the representatives of the national sports federations and teams and accepted by them.

CONDUCTING DOPING CONTROLS AND RESULTS MANEGEMENT

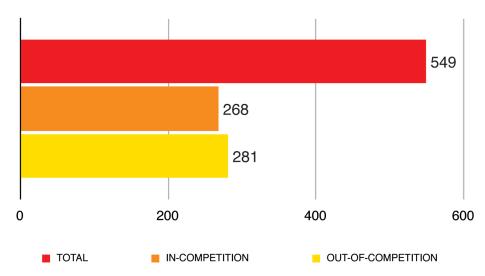
A total of 798 tests were conducted during 2014, 549 of which were done within the scope of the national testing programme and 249 as a part of international cooperation. The plan for 2014 included conducting 600 doping tests, but due to budgetary amendments and decreased funding, we were forced to reduce the number of doping tests.





The goal of the Anti-Doping Department and its Testing Section for was to equalise the number of incompetition and out-of-competition tests as much as possible. The national programme encompassed 268 in-competition and 281 out-of-competition tests. The goal was achieved.

CONTROLS CONDUCTED WITHIN NATIONAL PROGRAMME IN 2014



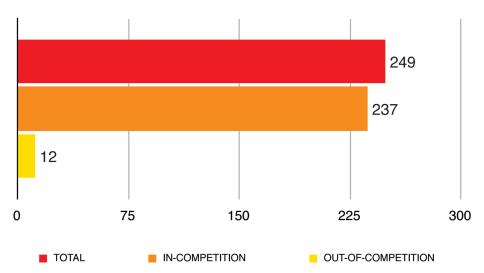
The international cooperation programme covered 237 in-competition tests and 12 out-of-competition tests. In all 12 out-of-competition tests blood was sampled as biological material.

We conducted doping controls at the following international events in the Republic of Croatia:

- ► Junior World Handball Championship
- ► Junior World Freestyle Wrestling Championships
- ► World Archery Field Championships
- Coarse Angling World Championships
- **European Youth Boxing Championships**

- **▶** Judo Grand Prix
- ► Grand Prix of Figure Skating
- Artistic Gymnastics World Cup
- ► Rapier Cup Fencing Tournament
- Water Polo World League
- World University Bridge Championships

CONTROLS CONDUCTED AT INTERNATIONAL COMPETITIONS IN 2014



The participation of our doping controllers in major sports events is a recognition of our work, as well as the contribution to the quality of work of our doping controllers.

The use of the APLIKATA programme enabled significant improvement of the quality of work, not only in organisational sense, but in the statistics and the analysis of the work done as well.

The largest number of tests on the national level was conducted in basketball - 93, followed by 91 samples in handball, 71 in football, 42 in volleyball, 33 in water polo, 28 in swimming, 27 in athletics, 18 in boxing, 13 in ice hockey, etc.

The largest overall number of tests was done in handball - 140, basketball 93, wrestling 74, etc.

Registered Testing Pool was revised four times a year. It consisted of 50 to 70 athletes. The athletes included in the Registered Testing Pool were educated and provided with a 24/7 phone call support.

The doping controllers were continuously educated and their work was supervised.

Report on the work of the Hearing Panel and the Anti-Doping Appeal Panel of CITA in 2014

The Hearing Panel of CITA held six (6) sessions in 2014 because of CITA Anti-Doping Rules violations:

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- **1.** Session held on 22nd April 2014, athlete competing in powerlifting and bench press competitions, tested positive for norandrosterone, a nandrolone metabolite, stanozolol and its metabolites and a tamoxifen metabolite (categories S1 Anabolic agents and S4 Hormone and metabolic modulators from the Prohibited List), the disciplinary measure of suspension from competing and participating in all sports competitions and activities was determined in the duration of 3 years and 6 months,
- **2.** Session held on 24th April 2014, athlete competing in powerlifting and bench press competitions, tested positive for 4-androstene-3,6,17 trione (6-oxo), ephedrine and oxilofrine (categories S1 Anabolic agents and S6.b Specified stimulants from the Prohibited List), the disciplinary measure of suspension from competing and participating in all sports competitions and activities was determined in the duration of 2 years and 6 months,
- **3.** Session held on 10th June 2014, athlete competing in wrestling, tested positive for testosterone or prohormones of testosterone (category S1.1.b Anabolic agents from the Prohibited List), the disciplinary measure of suspension from competing and participating in all sports competitions and activities was determined in the duration of 2 years,
- **4.** Session held on 12th June 2014, athlete competing in kickboxing, tested positive for clenbuterol (category S1.2 Anabolic agents from the Prohibited List), the disciplinary measure of suspension from competing and participating in all sports competitions and activities was determined in the duration of 1 year and 6 months,
- **5.** Session held on 9th September 2014, athlete who participated in doping another athlete, kickboxing, according to the regulation 2.1 in relation to the category S1.2 Anabolic agents from the Prohibited List, the disciplinary measure of suspension from competing and participating in all sports competitions and activities was determined in the duration of 4 years,
- **6.** Session held on 10th September 2014, athlete competing in athletics, tested positive for anabolic agent ostarine and its metabolites (category S1.2 Other anabolic agents), the disciplinary measure of suspension from competing and participating in all sports competitions and activities was determined in the duration of 2 years.

Table overview of the Hearing Panel sessions

SESSION Date	SPORTS	VIOLATOR	NAME AND CATEGORY OF THE SUBSTANCE	DISCIPLINARY MEASURE	VIOLATED RULE
22.4.2014	powerlifting and bench press	athlete	norandrosterone, a nandrolone metabolite, stanozolol and its metabolites and a tamoxifen metabolite (categories S1 and S4)	3 years and 6 months	2.1
24.4.2014	powerlifting and bench press	athlete	4-androstene-3,6,17 trione (6-oxo), ephedrine and oxilofrine (categories S1 and S6.b)	2 years and 6 months	2.1
10.6.2014	wrestling	athlete	testosterone or prohormones of testosterone (category S1.1.b)	2 years	2.1
10.6.2014	kickboxing	athlete	clenbuterol (category S1.2)	1 years and 6 months	2.1
09.09.2014	kickboxing	athlete	clenbuterol (category S1.2)	4 years	2.8
10.09.2014	athletics	athlete	ostarine (category S1.2)	2 years	2.1

The Anti-Doping Appeal Panel of CITA held one (1) session in 2014:

1. Session held on 9th June 2014, athlete competing in powerlifting and bench press competitions, tested positive for 4-androstene-3,6,17 trione (6-oxo), ephedrine and oxilofrine (categories S1 - Anabolic agents and S6.b - Specified stimulants from the Prohibited List), the disciplinary measure of suspension from competing and participating in all sports competitions and activities in the duration of 2 years and 6 months was confirmed.

Table overview of the Anti-Doping Appeal Panel sessions

SESSION Date	SPORTS	VIOLATOR	NAME AND CATEGORY OF THE SUBSTANCE	DISCIPLINARY MEASURE	VIOLATED RULE
9.6.2014	powerlifting and bench press	athlete	4-androstene-3,6,17 trione (6-oxo), ephedrine and oxilofrine (categories S1 and S6.b)	2 years and 6 months	2.1

The annual session of the Hearing Panel and the Anti-Doping Appeal Panel of CITA was held, with the purpose of reviewing the activities of the two Panels with the goal of improving their practice. The members of the Panels used the opportunity to consider the amendments to the Rules that enter into force on 1st January 2015, in line with the new legal framework and related to the functioning of the Panels and the position of the CITA Anti-Doping Department with respect to the implementation of certain provision of the new Rules.

DOPING PREVENTION

In 2014, an encompassing doping prevention programme was conducted, which included a number of activities in order to achieve the best results possible, similarly to the years before. The education programme was based on our own experience, experience of other anti-doping organisations and WADA's recommendations.

The year was marked by preparations for the implementation of the new global anti-doping legislation (the new Code and the appropriate International Standards), thus we adapted our activities to those preparations. With the goal of encompassing as many athletes possible, we placed emphasis on the Athlete Outreach Programme and, combined with the lectures, we reached a number of around 2,100 athletes and support personnel who have been educated through direct communication. About 500 participants acquired their knowledge through 15 lectures and 1,600 participants were educated in six (6) Athlete Outreach events. In addition, there is a large number of athletes, the support personnel and other people connected to sports who received the anti-doping message through other communication channels such as the website, the **NEIDOPINGU** (tr. No to Doping) magazine and the education materials (brochures, flyers, other materials carrying anti-doping message, such as T-shirts, pens, balls). It should be noted that within the meaning of the timely implementation of the anti-doping legislation, the education material was prepared and sent to the Croatian Olympic Committee and the national sports federations, in order to familiarize all participants in sports in Croatia with changes that were about to enter into force on 1st January 2015. All information related to the implementation of the new legislation simultaneously send very strong anti-doping messages that raise awareness of the harmful effect of doping.

By giving lectures, we continued activities on education of athletes, placing special emphasis on the harmful effects of doping, but not neglecting legal and ethical consequences. As steroidal module (the module aimed at detecting androgenic anabolic steroids) is fully functional since the beginning of 2014, we pointed out that information during our lectures, aware that it is also one of the manners in which we can significantly impact the fight against doping. The concept of the education programme implemented in Croatia ensures distribution of timely and expert information regarding doping to all interested

athletes and their organisations. We believe that in that manner we make significant contribution to the fight against doping. Our targeted groups are very different and include the following: members of national teams and A category athletes, registered sports teams, national sports federations, physicians, attorneys, judges, students and elementary and secondary school children. The opportunities and venues we use to conduct education programmes encompass the National Championship of School Sports Associations, various international sports tournaments, training camps, sports teams, national federations, conferences and meetings related to sports, as well as faculties and schools.

During the past year, we also directed a part of our programme at younger age groups. We called their attention to dangers of using doping and placed special emphasis on food supplements that often contain some of the prohibited substances. We demonstrated to them the procedure for conducting doping controls in order to prepare them for what they might encounter should they decide to actively participate in sports. We taught them what to do in case they had health problems. We presented the procedure for regulation of applying prohibited substances for therapeutic use. At some sports competitions, we conducted the Athlete Outreach Programme and additionally educated young athletes through anti-doping quiz. At the information booths of the programme we used an interactive approach towards athletes by answering all of their questions. Those events were photographed and the photos were published on our website and in our anti-doping magazine.



The information regarding doping are regularly published and updated on the website of the CITA Anti-Doping Department. Each separate doping case in Croatia is published on our website and a media release is sent to all Croatian media. Our website had around 500,000 hits in 2014, and 12,000 pages visited. The most visited section of our site is the List of Medicinal Products in the Republic of Croatia that are banned by the List of Prohibited Substances and Methods, as well as the List of Prohibited Substances and Methods itself. Our cooperation with HALMED (tr. Agency for Medicinal Products and Medical Devices) contributed to the overall number of visitors of our website. HALMED and CITA implemented mutual connection through their websites.

In addition to the website, the important medium for sending messages and education is our bimonthly magazine **NEIDOPINGU**, that is continuously published for seven years. It features news related to doping issues, all achievements in the field of fight against doping, the history of doping, as well as some interesting doping cases (with regards to the athlete's name and status or the specificity of the substance detected).

Besides the abovementioned educational anti-doping activities in 2014, we also participated in the graduate study lectures at the University of Zagreb, School of Medicine by being involved in the optional classes "Doping and Anti-Doping" for students of the 4th year of medical studies, as well as in the classes of the doctoral study at the Faculty of Kinesiology in Zagreb. The cooperation with eSTUDENT association was arranged, and a lecture on doping was held at the Faculty of Pharmacy and Biochemistry in Zagreb. We also held a lecture in our premises on the activities of the Anti-Doping Department to the sanitary engineering students from the Faculty of Health Sciences in Mostar.

During 2014, we began cooperating with WADA regarding the education programme WADA ALPHA, which is planned to be held in Croatian language in the future.

In cooperation with the Slovenian anti-doping agency SLOADO, we prepared for participation in the ERASMUS PLUS programme in relation to the education programme offering a specific way of spreading the anti-doping message.

INTERNATIONAL COOPERATION

During 2014, the representatives of CITA participated in the following meetings held within the international cooperation framework:

- ▶ 10th WADA's annual symposium for anti-doping organisations: "A New Era for the Fight Against Doping", Lausanne, Switzerland, 25-26 March 2014. WADA's symposium encompassed implementation of the new Code and Athlete Biological Passport and the issues of education of athletes and the support personnel.
- ▶ 29th meeting of the Ad Hoc European Committee for the World Anti-Doping Agency (CA-HAMA) and 40th meeting of the Monitoring Group of the Anti-Doping Convention, Strasbourg, 5th 7th May 2014. Relevant topics from the meetings encompassed the prevention and education, annual reports of all ADOs regarding their operation, new platform for anti-doping questionnaire, adoption and implementation of the new Code, cooperation with external partners European Commission, UNESCO, WADA, iNADO and a series of other questions.
- ▶ 30th meeting of the Ad Hoc European Committee for the World Anti-Doping Agency (CA-HAMA), Paris, France, 11th September 2014. The meeting covered a series of issues, one of which was the future financing of the World Anti-Doping Agency (WADA). WADA demanded its budget to be increased by 3% in 2015 in order to conduct the new activities in line with the new Code, which came into effect on 1st January 2015. They demanded support of the Council of Europe and clear elaboration of activities with the projections for 2015 based on both 0% and 3% increase in budget was presented in Lausanne on 20th September 2014 at the meeting of WADA's Executive Committee. Furthermore, it was decided that during 2015, WADA will assess compliance regarding implementation of the Code in 2015 in individual countries. In that sense, WADA will publish the lists of countries that have and that have not implemented the new Code on its website.
- ▶ TUE symposium (WADA Therapeutic Use Exemption Symposium), Paris, France, 22nd 25th October 2014. The symposium covered various expert topics in the area of approving the therapeutic use exemptions. An overview of significant differences between the International Standard for Therapeutic Use Exemptions that entered into force on 1st January 2015 and the Standard valid until that date was given. One of the most important changes in the Standard is related to the procedures of mutual acceptance of TUEs among the individual organisations involved in anti-doping activities.
- ▶ the Anniversary of UNESCO International Convention against Doping in Sport, Ad Hoc European Committee for the World Anti-Doping Agency (CAHAMA) and T-DO, Strasbourg, France, 4th 6th November 2014.

- ▶ Anti-Doping Workshop related to anti-doping in sports: "The Prohibited List", Seibersdorf Laboratories, Seibersdorf, Austria, 23rd 24th November 2014. The meeting covered the topics related to the Prohibited List in sports and CITA also contributed to the workshop programme by holding the invited lecture with the topic of beta-2 agonists and corticosteroids.
- ▶ 31st meeting of the Ad Hoc European Committee for the World Anti-Doping Agency (CA-HAMA) and 41st meeting of the Monitoring Group of the Anti-Doping Convention, Strasbourg. The meeting covered various issues, one of which was implementation and application of the Technical Document for Sport Specific Analysis. The application of this Technical Document is mandatory for all national anti-doping organisations.
- ► Council of Europe's Anti-Doping Convention, 4th 7th November 2014, to mark the 25th anniversary of fight against doping, review of its past work and the strategy for future.

THERAPEUTIC USE EXEMPTIONS

During 2014, a total of six (6) sessions of the Therapeutic Use Exemptions Committee were held. The CITA Anti-Doping Department had received a total of eight (8) applications for TUE approval. Out of the total number of applications, two (2) applications were unsubstantiated, i.e. the 25% (2/8). All applications considered at individual sessions of the Committee were granted the TUE approval. Three (3) retroactive (RA) and three (3) prospective therapeutic use exemptions (A) were granted at the Committee's sessions in 2014. The table below gives their overview according to the active substance, diagnosis and type of TUE. None of the valid applications for TUE were rejected.

ACTIVE SUBSTANCE	DIAGNOSIS	TUE TYPE
insulin aspart; insulin detemir	Diabetes mellitus typ l	A
hydrocortisone	Hyperplasia gl. suprarenalis congenita	А
insulin detemir	Diabetes mellitus typ l	А
dexamethasone	Syndroma lumbosacrale	RA
methylprednisolone	Reactio allergica	RA
methylprednisolone	Urticaria	RA

At the annual session of the TUE Committee held on 4th December 2014 in the CITA premises, in addition to the review of the activities of the TUE Committee in 2013 and 2014, all members of the Committee were acquainted with the changes in work that enter into force on 1st January 2015, in line with the new legislation (The 2015 Code and the appropriate International Standards, especially the International Standard for Therapeutic Use Exemptions (TUE) and the International Standard for the Protection of Privacy and Personal Information). Among the most significant changes, it should be mentioned that the national anti-doping organisations were given jurisdiction over approving the therapeutic use exemptions for athletes competing at national level. In case an athlete competes at an international level, he/she is under the jurisdiction of international federations. But, there is a possibility of mutual acceptance of the approved therapeutic use exemptions. In addition, there is an option of revising the already approved therapeutic use exemptions, approved by other anti-doping organisations or international federations, which would be a case similar to examples when an athlete submits the standard TUE application. Such cases will be solved, if possible, through the procedure of automatic acceptance, but in certain cases the need might arise to convene the Committee session.

Based on the International Standard for Protection of Privacy and Personal Information and TUE Guidelines, members of the TUE Committee are required to sign a statement on protecting sensitive personal information. Due to this reason, a form named "Conflict of interest and confidentiality declaration" was prepared. Starting from 1st January 2015, each decision of the Therapeutic Use Exemptions Committee must contain a statement that the decision of the TUE Committee is valid only for athletes competing at a national level.

The deadline for the TUE Committee to reach the decision in any individual athlete's case has been shortened to 21 days, starting with the date of receiving complete documentation (instead of the previously valid deadline of 30 days).

As in the previous year, all decisions of the TUE Committee will be entered into the ADAMS online database, with the purpose of maintaining transparency of the data and availability of information to the relevant organisations within the framework of implementation of a successful anti-doping programme.

MEDICINE AND SCIENCE

The Anti-Doping and Rational Pharmacotherapy in Sports Counselling Centre also started working. Its purpose is to provide services to athletes in professional and recreational sports, medical staff employed in federations and sports teams, specialists in occupational and sports medicine, physicians of other specialties involved in treating athletes, sport workers and other persons related to the problems of doping and rational use of medications in sports. In order to conduct planned activities in an appropriate manner, we hired one employee as the Head of Medicine and Science Section, in line with the existing organisational scheme.

Within the scope of research of the new immunochemical methods for the detection of peptides and anti-peptide antibodies used as doping in sports, in cooperation with experts from Ruđer Bošković Institute, a fast and simple procedure for extraction and analysis of bioactive components of peptide molecules was developed and applied on erythropoietin as a model. The procedure consists of three steps: 1. determining the bioactive region of the protein, 2. design of the antisense peptide that binds to the bioactive region using the molecular recognition theory and 3. verification of the binding of the antisense peptide to the bioactive region of the molecule using fluorescence spectroscopy and thermophoresis. An antisense ligand targeting receptor-binding site of the erythropoietin (152-166 aa) was also designed. The obtained results were published in the form of a paper: Štambuk N, Manojlović Z, Turčić P, Martinić R, Konjevoda P, Weitner T, Wardega P, Gabričević M. A Simple Three-Step Method for Design and Affinity Testing of New Antisense Peptides: An Example of Erythropoietin. International Journal of Molecular Sciences. 2014; 15(6):9209-9223. The Journal is a part of the Current Contents database (IF = 2.339). Based on the obtained data, the possibility of developing tests for detection of erythropoietin (ELISA, MPEIA) based on the technology described above is under research.

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